Analysis of Insole Geometry and Deformity by using 3D Image Processing Technique: A Preliminary Study

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ABSTRACT

Background: Accurate representation of the insole geometry is crucial for the development and performance evaluation of foot orthoses that are designed with the aim to redistribute plantar pressure, especially for diabetic patients.

Methods: Taking into consideration that there are limitations in the type of equipment and space available in clinical practices, this study has adopted a simple portable 3D desktop scanner to evaluate the 3D geometry of an orthotic insole and the corresponding deformities after the insole has been worn. The shape of the insole structure along the horizontal cross sections is defined with the use of 3D scanning and image processing. Accompanied with an in-shoe pressure measurement system, the plantar pressure distribution in four foot regions, the hallux, metatarsal heads, midfoot and heel, is analyzed, and evaluated for insole deformity.

Results: The insole deformities are quantified across the four foot regions. The hallux region tends to show the greatest changes in shape geometry ranging from 17% to 50% compared to the other foot regions after 2 months of insole wear. As a result of the insole deformities, the plantar peak pressures considerably change amongst the subjects (-4.3 to +69.5%) during the course of the treatment.

Conclusion: The changes in shape geometry of the insoles could be objectively quantified by using 3D scanning technique and image processing. The investigation finds that in general, the design of orthotic insoles may not be adequate for diabetic subjects with similar foot problems. The drastic changes in the shape geometry of the insole and its cross-sectional areas during the orthotic treatment may reduce insole fit and conformity. An inadequate insole design may also affect the performance of plantar pressure reduction. The approach proposed in this study therefore allows for the objective quantification of the shape geometry of insoles which thus results in effective and optimal orthotic treatment.

Clinical Relevance: The 3D scanning approach facilitates the evaluation of insole geometry during the course of treatment. This allows practitioners to objectively decide and choose the most appropriate insole materials for patients with different needs and support requirements, thus optimizing the efficacy of the orthotic treatment and avoiding costly trials and errors.

Keywords: Shape quantization, Image analysis, Insole structural shape

INTRODUCTION

Custom-molded insoles are known to be more effective than flat insoles for pressure relief and ulceration prevention in diabetic patients [1, 2]. The foot morphology of each individual patient is taken into consideration in the fabrication of custom-made orthotic insoles, which offer adequate support to reduce the magnitude of pressure and redistribute the forces and weight on the plantar area through total contact with the plantar surface, thus reducing the development of diabetic foot ulcers [3]. The insole design includes both structural (shape) and material factors [4]. Consequently, a large number of studies have focused on evaluating the effectiveness of different combinations of insole materials to address the effects of plantar pressure [5, 6, 7, 8]. However, studies on the evaluation of the insole structure (shape) are somewhat lacking.

The insole shape is crucial for the fabrication of total-contact insoles because the success and effectiveness of their pressure-relieving properties in locations that cause pain or are at risk of ulceration are highly dependent on the degree of conformity and fit between the contact surface of the insoles and the contours of the foot [9, 10]. In addition to the interface shape of insoles, their deformation characteristics also have implications on the comfort of the wearer [11]. A mismatching or poorly fitting insole design can result in undue pressure on the foot, thus causing discomfort [12, 13].

The use of three-dimensional (3D) scanning has been growing in popularity in recent years because the technology allows various applications to capture the human anatomy in a fast, reproducible and noninvasive way for surface registration and analysis [14, 15]. Three-dimensional scanning has been widely used to obtain a complete picture of the foot and measure pathologic abnormalities, which is key to evaluating the diabetic foot. The technique may also help to monitor changes in the feet and evaluate the effects of treatment [16, 17]. Many studies have also shown that the foot parameters obtained from 3D scanning do not significantly differ from clinical measurements [16, 17, 18, 19, 20, 21]. Despite the widespread availability of 3D foot scanning methods, and their ability to deliver comprehensive and reproducible information on the foot morphology and process a significant number of patients in an economically feasible and effective way, [16, 22, 23], there is a paucity of studies on 3D insole image analysis that quantify insole deformation during the course of treatment. The quantitative analysis and description of orthotic insoles enable the acquisition of a diverse range of information for use in insole fabrication and clinical assessment so as to improve orthotic treatment. Hence, the objective of this study is to propose a novel method that is easy to use to continuously monitor the insole geometry which will enhance the development of orthotic insoles and the quality of orthotic treatment. As the use of 3D scanning to capture images for evaluation the change in insole, it is used in conjunction with an in-shoe pressure measurement system to ascertain the peak pressure locations on the foot, thereby supporting the assessment of practitioners during insole design and prescription [24]. It is hypothesized that 1) the magnitude of insole deformities varies across the plantar, and 2) the overall plantar pressure could be redistributed/ reduced during the course of treatment.

METHODS

Participants

One male and three female diabetic patients volunteered for the study, and provided eight foot images respectively. They range in age from 44 to 67 years old (mean: 54.5, SD: 9.54), and their body mass index (BMI) ranges from 23 to 25 (mean: 24.3, SD: 0.90) kg/m^2. All of the patients have Type 2 diabetes with a history of 3 to 20 years. None had plantar ulcers at the time of the evaluation. Only the male patient was diagnosed with reduced tactile sensitivity on both feet by not recognizing a 10 g monofilament. The subjects were required to undergo scanning of their feet and insoles (as a record) and take part in pressure measurements during three separate sessions: the initial visit and visits after one- and two-months had passed. The same procedure was followed for each session. Before data were collected at the initial visit, the subjects were fitted with custom-made multilayer insoles made with the same combination of materials, which they were asked to wear for at least 40 hours per week. Written consent was obtained from all of the subjects prior to study commencement. All of the study procedures were approved by the Human Subjects Ethics Sub-committee of the Hong Kong Polytechnic University, and the study conformed to all policies with regard to the use of human participants.

Development of Custom-fabricated Orthotic Insoles

Orthosis fabrication began with plaster casting to capture the contours of the foot in a subtalar neutral position with the subject lying prone. The resulting cast could then be altered by either removing or adding plaster, followed by carrying out standardized insole construction procedures. The same fabrication method was used in constructing the three-layer insoles for each subject. The top, middle and bottom layers of each full-length insole were constructed from 3-mm Nora® Lunairflex (perforated), 3-mm Nora® Lunalastike and 8-mm Nora® Lunalight A, respectively (Table 1). To reduce inter- and intra-clinician variability, one practitioner evaluated all of the plaster casts and subjects.

Table 1 Summary of orthotic insole specifications

Brand	Thickness (mm)	Density (g/cm^3)	Hardness (Shore A)	Insole position of material	Description
Nora® Lunairflex	3	0.12	22	Top layer	Closed-cell ethyl vinyl acetate foam (Perforated)
Nora® Lunalastike	3	0.23	25	Middle layer	Closed-cell ethyl vinyl acetate foam
Nora® Lunalight A	8	0.36	58	Bottom layer	Closed-cell ethyl vinyl acetate foam

3D Shape Quantification of Insole Geometry

Taking into consideration that there are limitations in the type of equipment and space available in hospitals, a portable 3D laser scanner with an accuracy of 0.005 inches (Next Engine Inc., Santa Monica, CA, U.S.) was used to capture 3D images of the insoles of the subjects. The 3D images can be displayed at any angle on a computer screen, and the data can be transformed and exported to different types of files. In this study, the orthotic insoles of each subject were affixed to an auto-positioner connected to the 3D scanner which was located 0.43 meters away. The auto-positioner was rotated after each image capture, which required about two minutes. The 3D insoles were thus obtained through the auto-alignment function of the software from the scanning system after five captures from different angles of view (Figures 1 and 2). Normal homogeneous office lighting conditions were used during the scanning. The initial insole images with small holes were mended by using a reverse engineering software, Rapidform 2006 (INUS Technology Inc., Seoul, Korea), for curvature smoothing. Irregular triangular faces from cloud points when generating the surface were also rectified so as to generate a complete insole image.

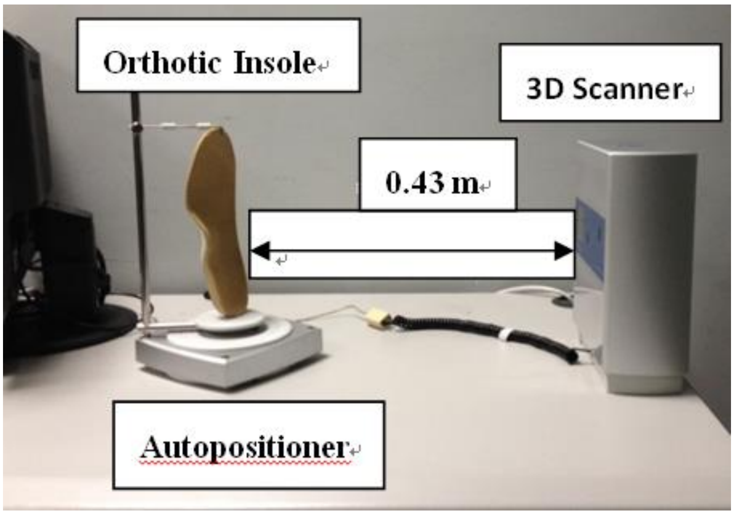


Figure 1 Equipment setup for foot scanning from five different angles

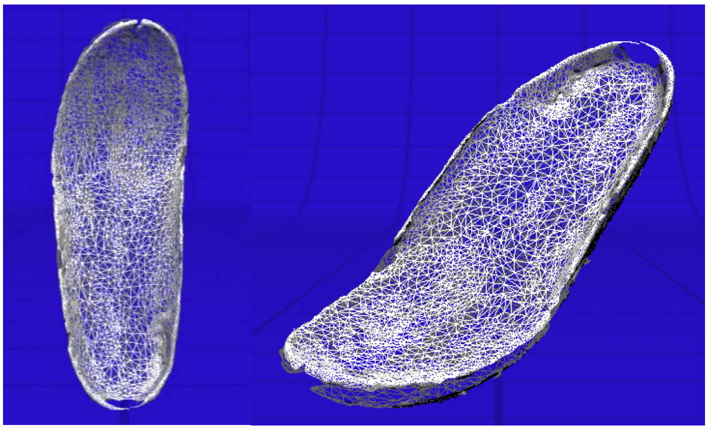


Figure 2 Different views of 3D images of insole after scanning

Analysis of Insole Geometry and Deformity

To evaluate the insole deformity during the course of the orthotic treatment, the shape geometry of the insoles was measured by cutting cross-sectional lines that passed through four predefined regions: the hallux, metatarsal head (MTH) regions, midfoot and heel from the 3D insole images taken during each visit. Any changes in the shape geometry at each corresponding foot region over the course of the three visits were then calculated by using Equation 1 and through data extraction, see Figure 3. An example is shown in Figure 4. A reduction in the total cross-sectional area represents an increase in insole deformity.

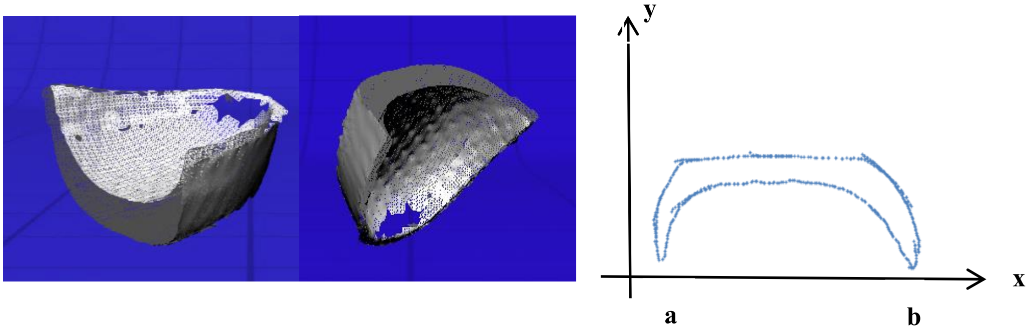
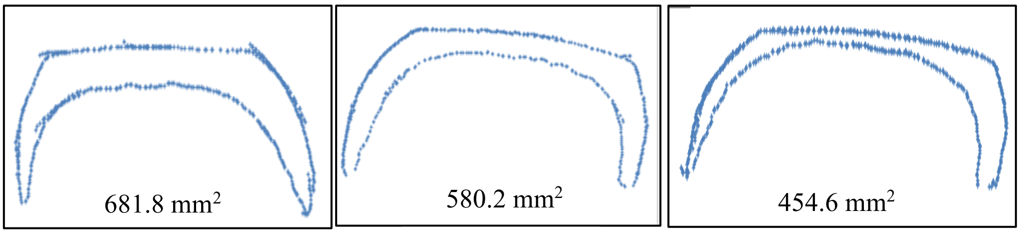


Figure 3 Data extraction of heel cross section for insole deformity analysis

$$Area\ of\ corresponding\ foot\ region = \int_a^b y\ upper\ dx - \int_a^b y\ lower\ dx$$

Equation 1



Initial visit | After 1 month | After 2 months

Figure 4 Heel cross sections of insole at each visit

Plantar pressure evaluation

The F-Scan® in-shoe system (Tekscan, Inc., South Boston, MA, U.S.) with 960 sensors and a spatial resolution of 4 sensels/cm^2 was used to measure the pressure on the plantar surface of the foot inside the shoe, both with and without the custom-made orthosis. The study participants wore their own sport shoes, and were fitted with new F-Scan® disposable insole sensors trimmed down to their shoe size. They were then asked to walk at their own self-desired pace. During each visit, they underwent two practice trials 10 minutes before data recording was carried out to familiarize themselves with the sensors and ensure equilibration in the temperature of the insoles. The participants then walked a distance of 8 meters, and two steps in the middle – those at 4 meters – were chosen and averaged for analysis. The peak pressure at the hallux, MTH regions, midfoot and heel was calculated.

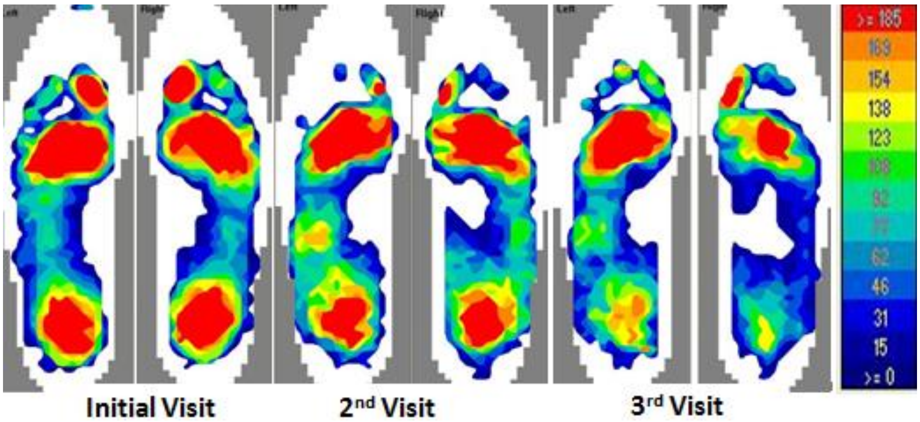


Figure 5 Example of mean peak pressure distribution on foot-insole interface from each visit

RESULTS

Insole deformity

The results in Figure 6 show that the cross-sectional areas of various regions are progressively reduced after repeated wearing. The degree of deformity is increased in the hallux, MTHs and heel with the wear duration. The hallux tends to show more notable changes (deformity of 17-50%) compared to the other foot regions after wearing the insoles for 2 months. The changes in deformation patterns vary amongst the subjects, even though they have a similar BMI. It is obvious that the insole deformity changes after the insoles are worn for the second month (2nd months – 1st month) tend to be greater than those after the insoles are worn for the first month (1st month - initial visit).

Plantar pressure distribution

Figure 7 presents the percentage change in plantar pressure of various regions of the foot in which the orthotic insoles were used after 1 and 2 months. The peak pressure profile and pattern are somewhat varied (ranged from -4.3 to +69.5%) amongst the subjects. In terms of Subjects 1 and 2, the pressure reduction ranges from 6.6% to 34.6% (except for the hallux and heel of Subject 1, and MTHs of Subject 2) in the left foot after the course of the treatment. However, the plantar pressure experienced by Subject 1 is found to have increased in the MTHs, midfoot and heel of the right foot while the plantar pressure experienced by Subject 2 is found to have only increased in the MTHs of the right foot after wearing the insoles for 2 months. For Subject 3, most of the peak pressure (except in the MTHs of left foot, midfoot of both feet) across the plantar tends to increase in both feet after wearing the custom-made insoles. The peak pressure of both feet is increased in Subject 4 (>12%) in the MTHs and midfoot after wearing the insoles for 1 month. It can be observed that the peak pressure further increases in the midfoot (>14%) of the left foot while in the MTHs, there is an increase of 12%. However, pressure reduction could be found in the hallux of both feet after wearing the insoles for 1 month.

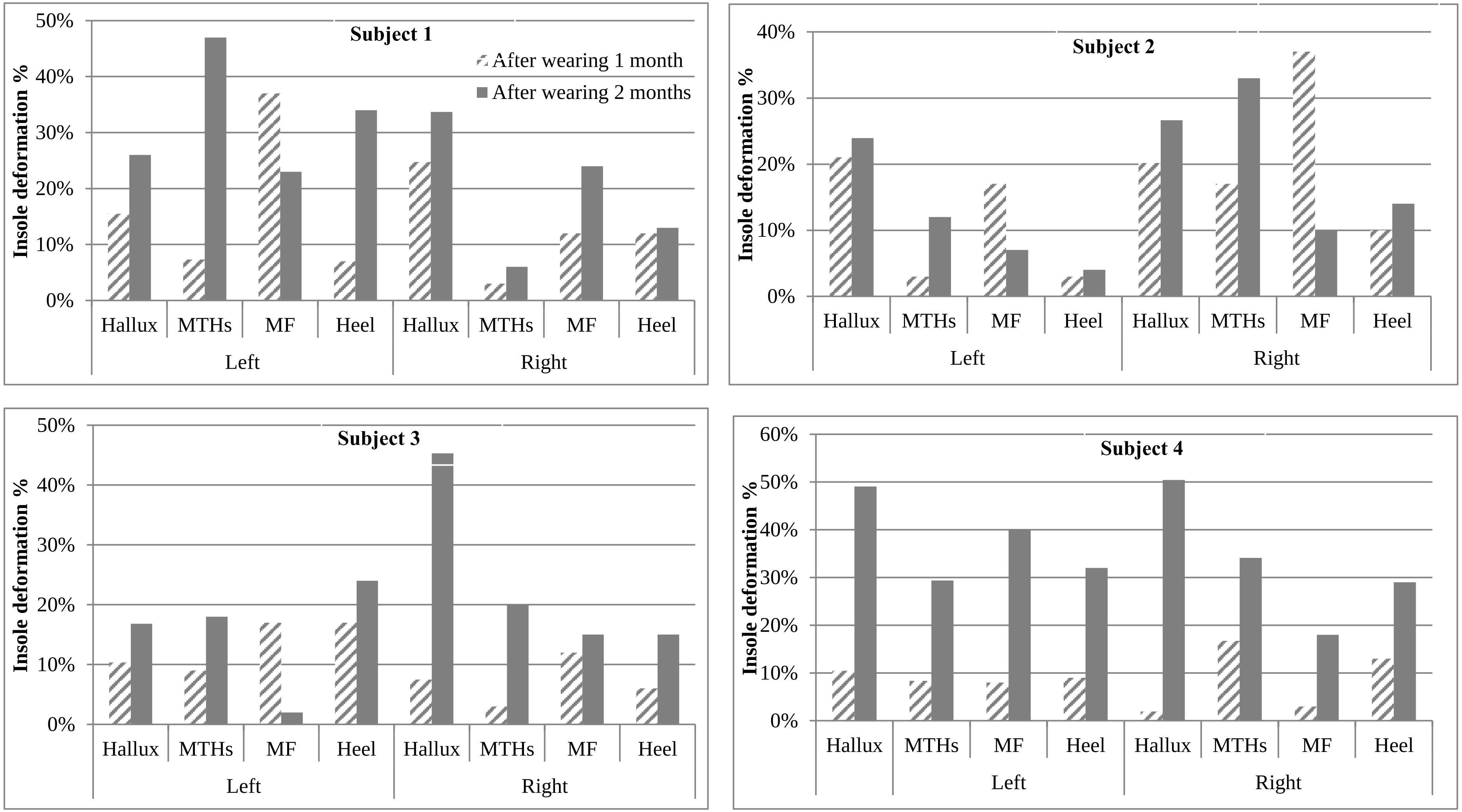


Figure 6 % changes in insole deformation for both feet of each subject. All differences in changes are calculated as difference between 1 month of wear and initial visit, and difference between 2 months and 1 month of wear

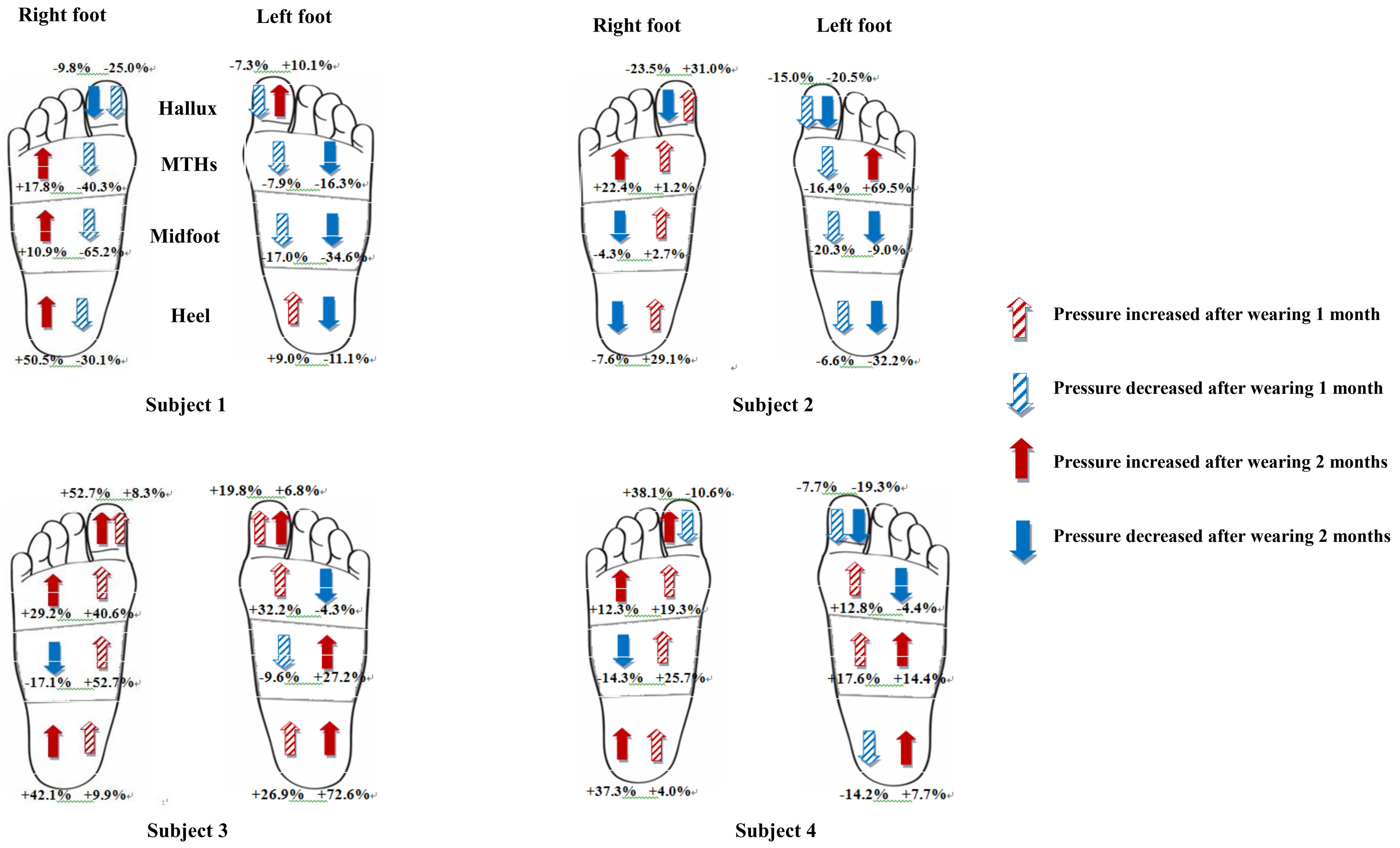


Figure 7 % changes in peak pressure in various regions of both feet of each subject. All differences in changes are calculated as difference between 1 month of wear and initial visit, and difference between 2 months and 1 month of wear

DISCUSSION

To obtain a better understanding of the changes in the insole structure (shape) in clinical practices, this study has adopted 3D scanning and image processing to quantify the shape and performance of custom-fabricated insoles during the course of the orthotic treatment. The results support the hypothesis that the degree of changes or deformation in the orthotic insoles vary along the plantar. However, wearing orthotic insoles may increase the peak pressure at various regions of the foot during the course of the treatment.

This study has identified several potential improvements in insole fabrication. It is obvious that the magnitude of deformation in the insole cross-sectional areas varies among the foot samples from the same subject or between subjects. Although the insole shape is tailored to the foot of each subject, their needs or foot conditions may be treated in a similar manner. In this study, diabetic subjects are fitted with insoles made with the same combination of materials. This combination of materials may not have performed equally well for both feet and all of the subjects, as each have different foot conditions. The selection of an appropriate insole should be based on the background of the patient, medical history, BMI and foot conditions, among other factors. The optimization of insole configurations may require frequent reviews, replacements and further adjustments to achieve the best overall performance in accordance with the foot structure and requirements of each individual patient [13, 25]. Besides, by scanning the insoles, the insole shape along the transverse and horizontal cross sections could be objectively quantified. With the large variability in insole design among foot practitioners, this quantification approach could help to develop evidence based insole design guidelines which could provide uniformity in treatment amongst foot experts.

Previous studies have debated whether it is better to adjust the orthotic insoles and then determine whether sustainable pressure relief has been realized, or wait to see whether the materials used therein have deteriorated after two months of wear, as neither method is optimal [29]. The present study has demonstrated that the insole cross-sectional areas of the forefoot (hallux and MTHs) show progressive changes in each subject after the course of treatment (2 months of wear). This may be due to the excessive load and repeated force exerted, thus eventually leading to compression of the corresponding cross-sectional areas. This could possibly explain why ulceration often occurs in those locations. Furthermore, the cross-sectional area of the hallux region demonstrated notable changes in the foot samples, which is a result of the custom-made insole that is thin and has low recovery in the front-end, thus causing the material to easily flatten.

The changes in the peak pressure patterns are also noticeably different amongst the subjects. The peak pressure is moderately reduced in the left foot of two subjects after using the orthotic insoles. However, the changes in the peak pressure somewhat fluctuate during the course of the treatment, with the mean peak pressure initially decreasing and then increasing or vice versa amongst the foot samples, possibly because the inappropriate design and deformed shape of the insoles affect the performance of pressure reduction. Therefore, a orthotic insoles with a general design may not be an adequate solution for diabetic subjects with similar foot problems.

In conclusion, the performance and deformity of insoles are often somewhat uncertain in clinical practices, which affect the quality and efficacy of orthotic treatment. A high degree of insole deformity may limit the effectiveness of the insoles. This study therefore proposes a practical yet efficient approach for both practitioners and patients which may facilitate the continuous monitoring and evaluation process of insole performance. The 3D scanning technique herein allows for the capture of the insole geometry to carry out the evaluation and quantification of insole deformity. This approach also allows practitioners to objectively decide and select the most appropriate insole materials for patients with different needs and support requirements, thus optimizing the efficacy of the orthotic treatment and avoiding costly trials and errors. It should be noted that the generalizability of the results presented herein is compromised by the relatively small sample size. Nonetheless, the study provides preliminary evidence that supports the use of 3D scanning technology, thereby providing the foundation for future research, especially in terms of a prediction model for deformity and pressure monitoring. Therefore, optimal pressure relieving conditions could be easily identified by understanding the effects of insole deformity and pressure distribution.

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DECLARATION OF CONFLICTING INTERESTS

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