Analysis of Insole Geometry and Deformity by Using a Three-Dimensional Image Processing Technique: A Preliminary Study

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

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

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

Conclusions: Changes in shape geometry of the insoles could be objectively quantified with 3-D scanning techniques and image processing. This investigation finds that, in general, the design of orthotic insoles may not be adequate for diabetic individuals with similar foot problems. The drastic changes in the insole shape geometry and cross-sectional areas during orthotic treatment may reduce insole fit and conformity. An inadequate insole design may also affect plantar pressure reduction. The approach proposed herein, therefore, allows for objective quantification of insole shape geometry, which results in effective and optimal orthotic treatment. (J Am Podiatr Med Assoc 109(2): 98-107, 2019)

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Custom-molded insoles are known to be more effective than flat insoles for pressure relief and ulcer prevention in diabetic patients.[1,2] The foot morphology of each individual patient is considered 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 structural (shape) and material factors.[4]

Consequently, many studies have focused on evaluating the effectiveness of different combinations of insole materials to address the effects of plantar pressure.[5-8] 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 for 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 (3-D) 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 monitor changes in the feet and evaluate the effects of treatment.[16,17] Many studies have also shown that the foot parameters obtained from 3-D scanning do not significantly differ from clinical measurements.[16-21] Despite the widespread availability of 3-D foot scanning methods, and their ability to deliver comprehensive and reproducible information on foot morphology and to process a large number of patients in an economically feasible and effective way,[16,22,23] there is a paucity of studies on 3-D 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 was to propose a novel method that is easy to use to continuously monitor insole geometry to enhance the development of orthotic insoles and the quality of orthotic treatment. As the use of 3-D scanning to capture images for the evaluation of insole changes increases, 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 surface and 2) overall plantar pressure can 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. These patients range in age from 44 to 67 years (mean ± SD: 54.5 ± 9.54 years), and their body mass index (BMI; calculated as weight in kilograms divided by height in meters squared) ranges from 23 to 25 (mean ± SD 24.3 ± 0.90). All of the patients have type 2 diabetes, with a duration of 3 to 20 years. None had plantar ulcers at the time of the evaluation. Only the male patient was diagnosed as having reduced tactile sensitivity on both feet by not recognizing a 10-g monofilament. The participants were required to undergo scanning of their feet and insoles (as a record) and to take part in pressure measurements during three separate sessions: the initial visit and visits after 1 and 2 months had passed. The same procedure was followed for each session. Before data were collected at the initial visit, the participants 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 participants before study commencement. All of the study procedures were approved by the human subjects ethics subcommittee of The Hong Kong Polytechnic University (Hong Kong), and the study conformed to all of the policies regarding 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 patient lying prone. The resulting cast could then be altered by either removing or adding plaster, followed by performing standardized insole construction procedures. The same fabrication method was used in constructing the three-layer insoles for each participant. The top, middle, and bottom layers of each full-length insole were constructed from 3-mm Nora Lunairflex (perforated), 3-mm Nora Lunalastik, and 8-mm Nora Lunalight A, respectively (Nora Systems GmbH, Weinheim, Germany) (Table 1). To reduce interclinician and intraclinician variability, one practitioner

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

(C.F.C.) evaluated all of the plaster casts and participants.

3-D Shape Quantification of Insole Geometry

Taking into consideration that there are limitations in the type of equipment and space available in hospitals, a portable 3-D laser scanner with accuracy of 0.005 inches (NextEngine Inc, Santa Monica, California) was used to capture 3-D images of the insoles of the patients. The 3-D 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 patient were affixed to an auto-positioner connected to the 3-D scanner, which was located 0.43 m away. The auto-positioner was rotated after each image capture, which required approximately 2 min. The 3-D images of the insoles were, thus, obtained through the auto-alignment function of the software from the scanning system after five captures from different angles of view (Figs. 1 and 2). Normal homogeneous office lighting conditions were used during the scanning. The initial insole images with small holes were mended with 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.

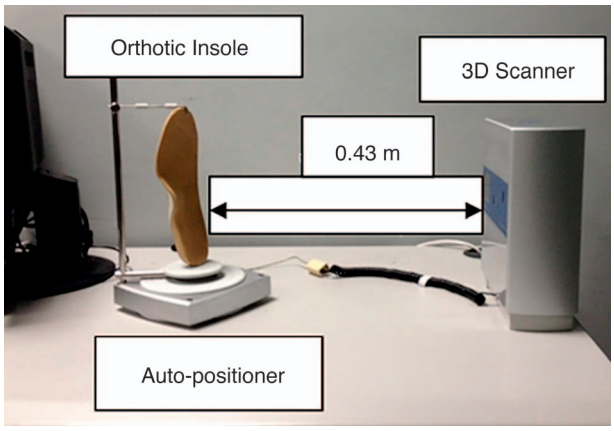


Figure 1. Equipment setup for foot scanning from five different angles.

Analysis of Insole Geometry and Deformity

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

$$\textit{Area of corresponding foot region} = \int_a^b y\ \textit{upper}\ dx - \int_a^b y\ \textit{lower}\ dx \qquad (1)$$

Plantar Pressure Evaluation

The F-Scan in-shoe system (Tekscan Inc, South Boston, Massachusetts), with 960 sensors and spatial resolution of 4 sensels/cm^2, was used to

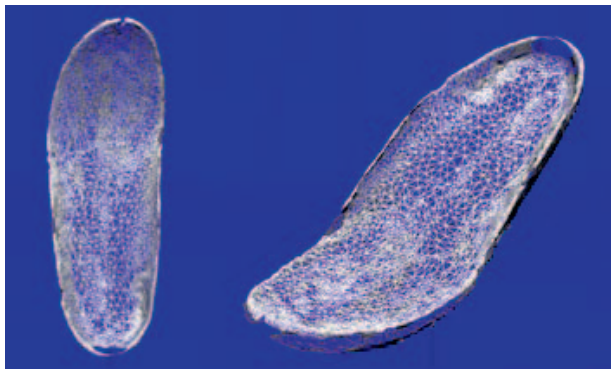


Figure 2. Different views of three-dimensional images of the insole after scanning.

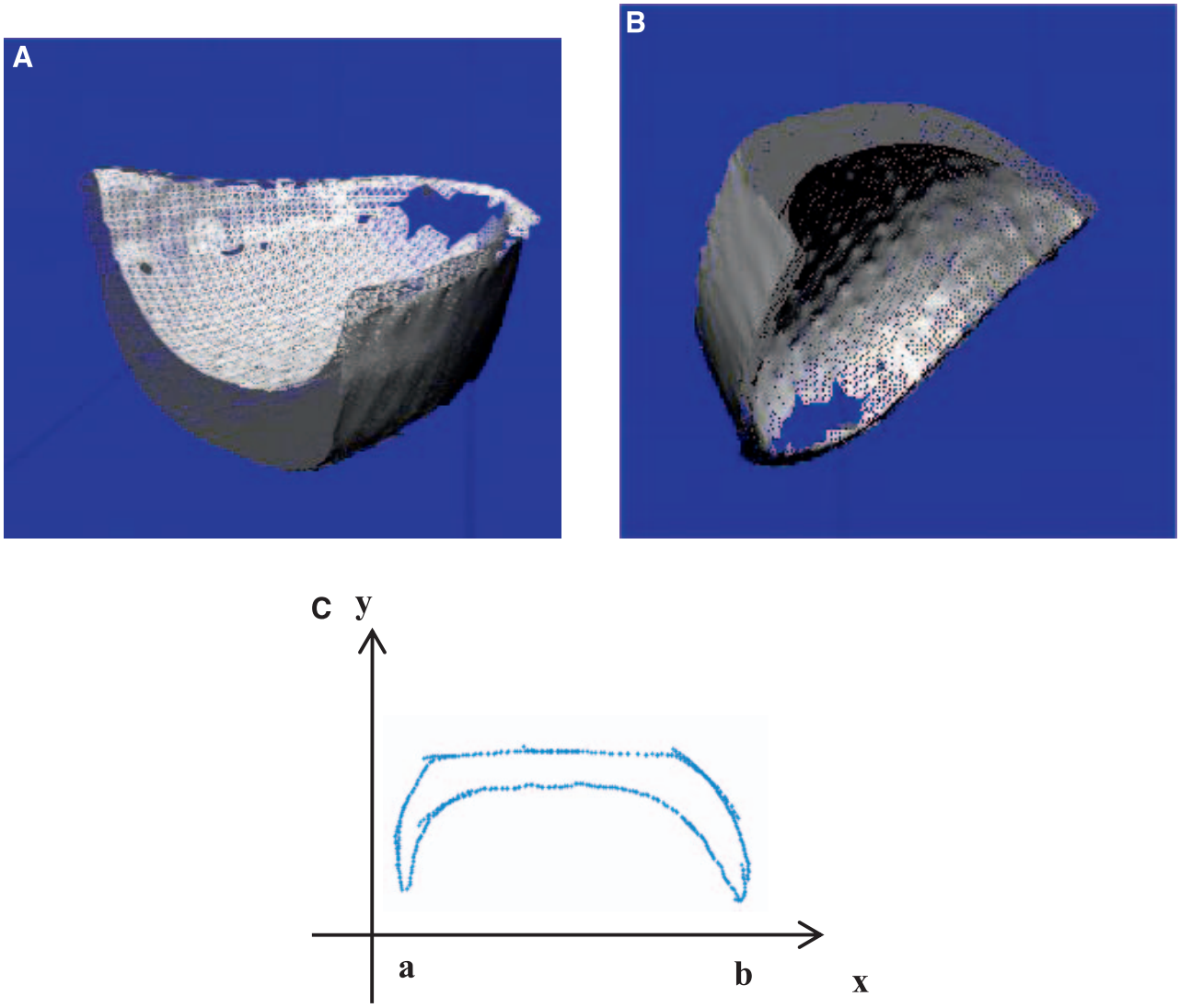


Figure 3. Data extraction of a heel cross section for insole deformity analysis.**[Q3]**

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 min before data recording was performed to familiarize themselves with the sensors and ensure equilibration in the temperature of the insoles. The participants then walked a distance of 8 m, and two steps in the middle—those at 4 m—were chosen and averaged for analysis. Peak pressures at the hallux, MTHs, midfoot, and heel were calculated (Fig. 5).

Results

Insole Deformity

The results in Figure 6 show that the cross-sectional areas of various regions were progressively reduced after repeated wearing. The degree of deformity was increased in the hallux, MTHs, and heel with wear duration. The hallux tended to show more notable changes (deformity of 17%–50%) compared with the other foot regions after wearing the insoles for 2 months. The changes in deformation patterns varied among the participants, even though they had similar BMIs. It is obvious that the changes in insole deformity after the insoles were worn for the second month (second month – first month) tended

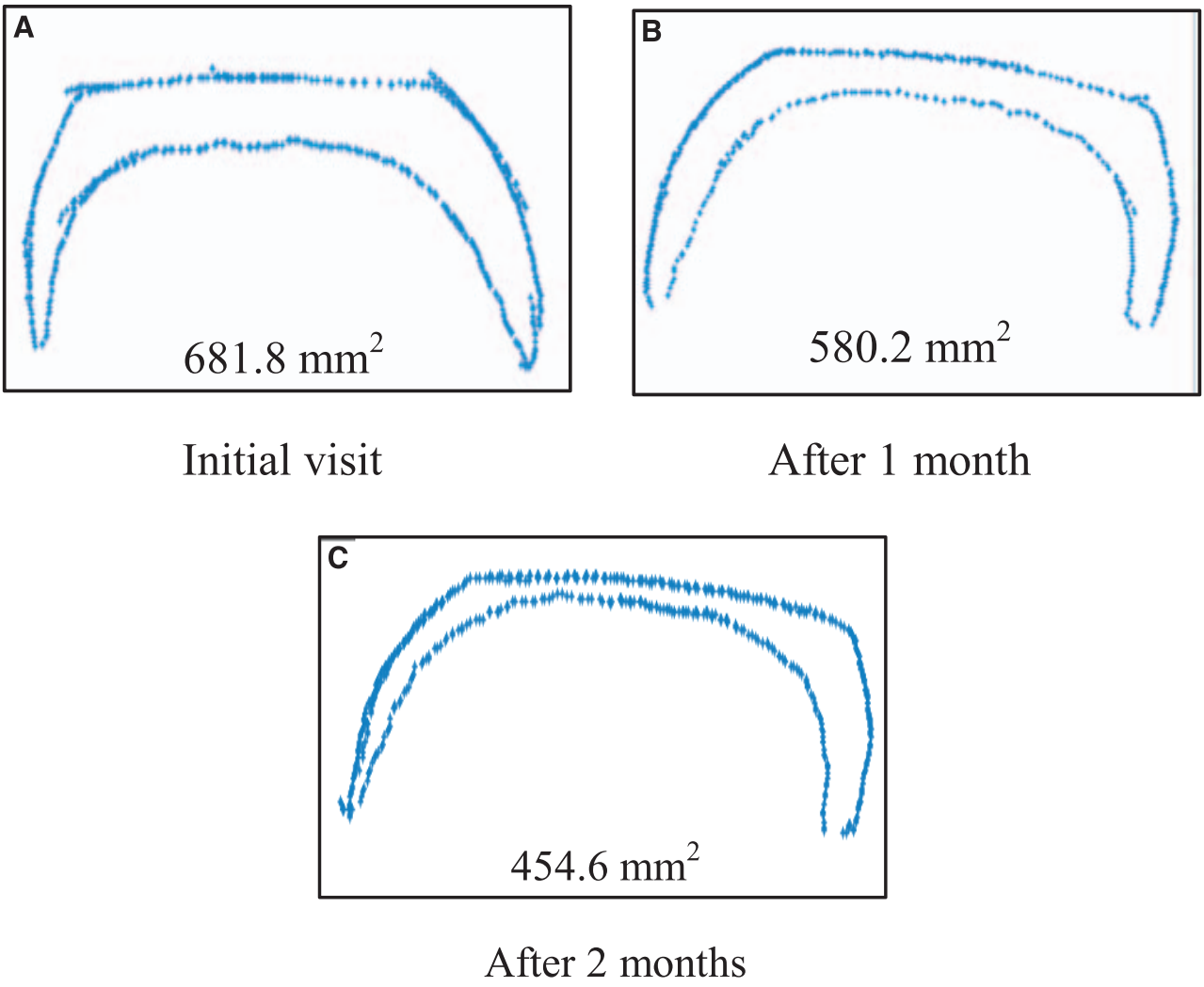


Figure 4. Heel cross sections of the insole at each visit.

to be greater than those after the insoles were worn for the first month (first 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 were somewhat varied (range, –4.3% to +69.5%) among the participants. In patients 1 and 2, the pressure reduction ranged from 6.6% to 34.6% (except for the hallux and heel of patient 1 and the MTHs of patient 2) in the left foot after the course of treatment. However, the plantar pressure experienced by patient 1 was found to have increased in the MTHs, midfoot, and heel of the right foot, whereas the plantar pressure experienced by patient 2 was found to have increased only in the MTHs of the right foot after wearing the insoles for 2 months. For patient 3, most of the peak pressure (except in the MTHs of left foot and the midfoot of both feet) across the plantar surface tended to increase in both feet after wearing the custom-made insoles. The peak pressure of both feet was increased in patient 4 (>12%) in the MTHs and midfoot after wearing the insoles for 1 month. It can be observed that the peak pressure further increased in the midfoot (>14%) of the left foot, and in the MTHs there was an increase of 12%. However, pressure reduction could be found in the hallux of both feet after wearing the insoles for 1 month.

Discussion

To obtain a better understanding of the changes in the insole structure (shape) in clinical practices,

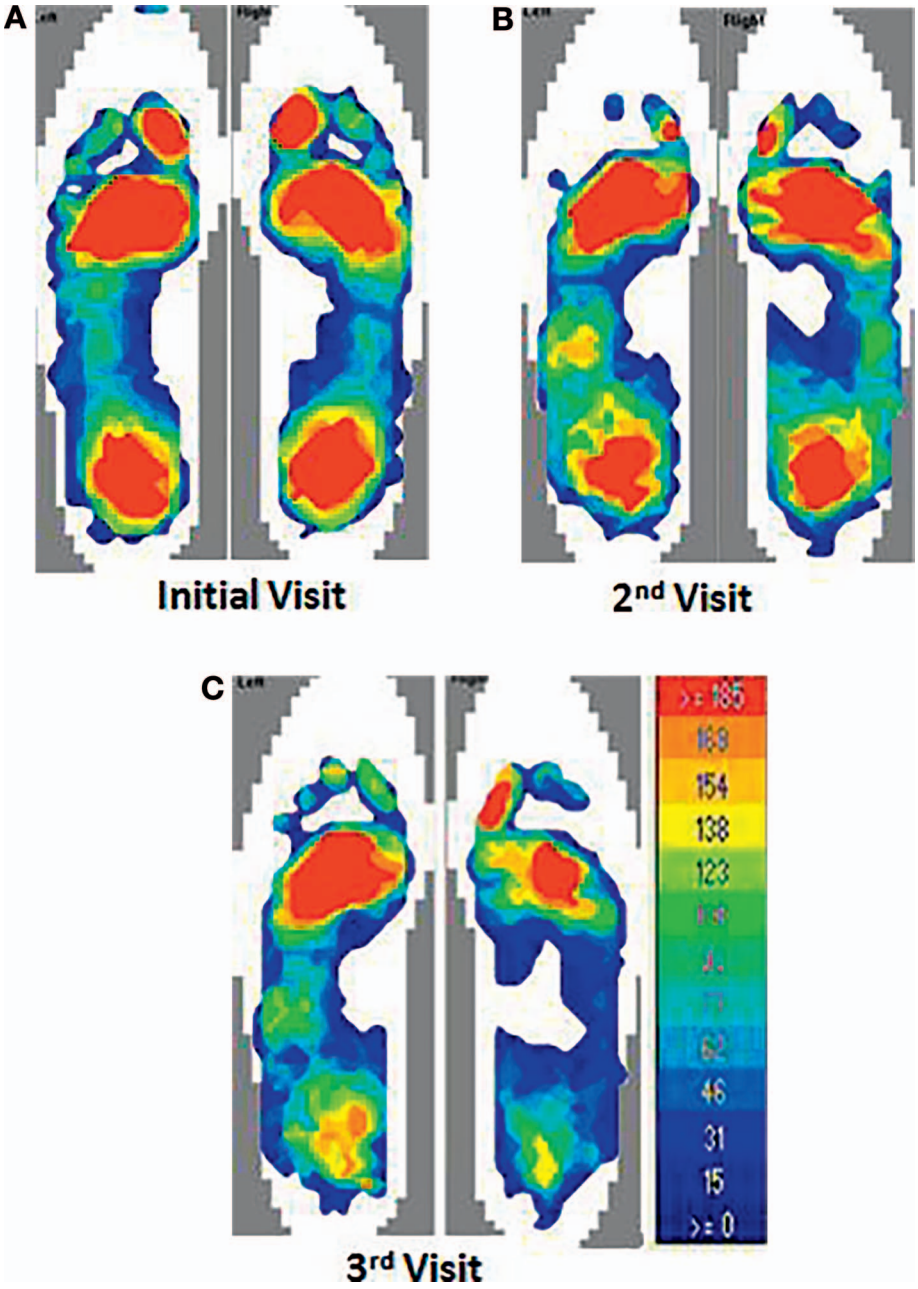


Figure 5. Examples of mean peak pressure distribution on the foot-insole interface from each visit.

this study adopted 3-D scanning and image processing to quantify the shape and performance of custom-fabricated insoles during the course of orthotic treatment. The results support the hypothesis that the degree of change or deformation in the orthotic insoles varies along the plantar surface. However, wearing orthotic insoles may increase the peak pressure at various regions of the foot during the course of treatment.

This study 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 patient or between patients. Although the insole shape is tailored to the foot of each patient, their needs or foot conditions may be treated in a similar manner. In this study, patients with diabetes 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 participants, as each have different foot conditions. The selection of an

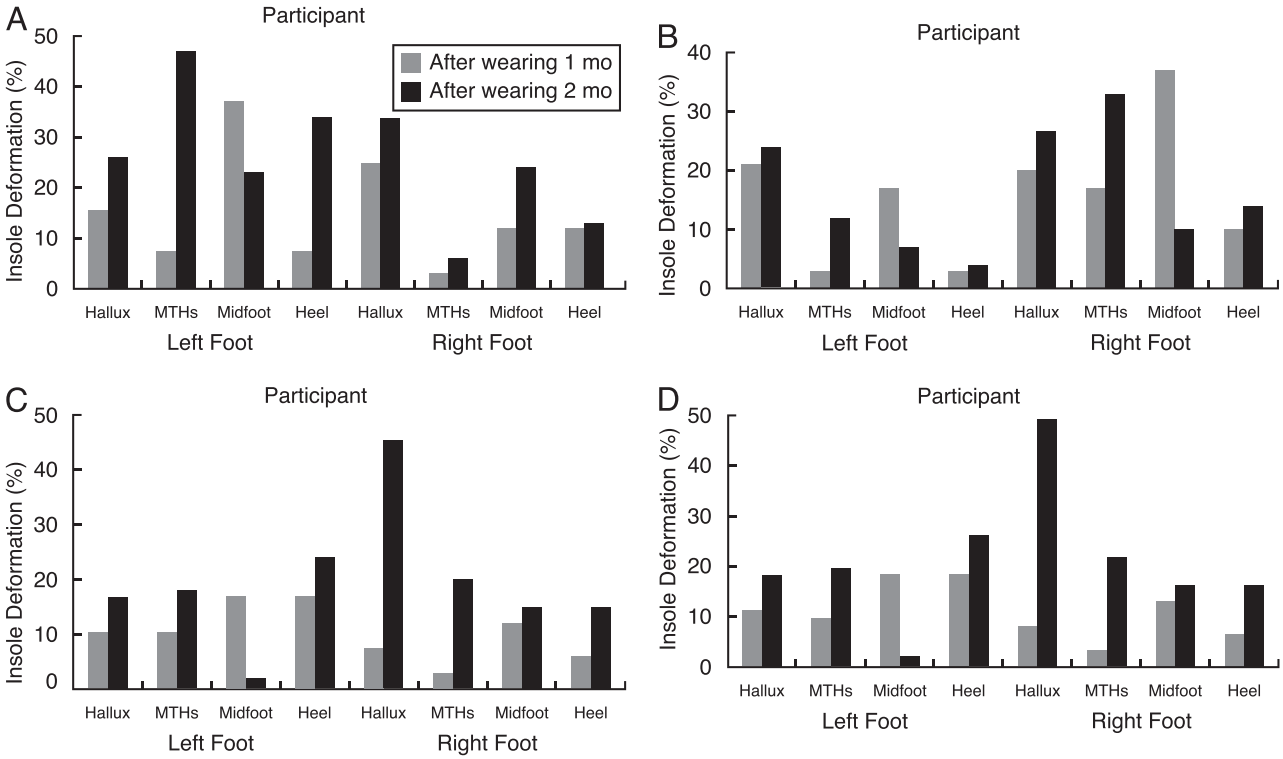


Figure 6. Percentage changes in insole deformation for both feet of each participant. All of the changes are calculated as the difference between 1 month of wear and the initial visit and between 2 months and 1 month of wear. MTH, metatarsal head.

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 among 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 to wait to see whether the materials used therein have deteriorated after 2 months of wear, because neither method is optimal.[26] The present study demonstrates that the insole cross-sectional areas of the forefoot (the hallux and MTHs) showed progressive changes in each participant 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 were also noticeably different among the participants. The peak pressure was moderately reduced in the left foot of two participants after using the orthotic insoles. However, the changes in the peak pressure somewhat fluctuated during the course of treatment, with the mean peak pressure initially decreasing and then increasing or vice versa among the foot samples, possibly because the inappropriate design and deformed shape of the insoles affect the performance of pressure reduction. Therefore, orthotic insoles with a general design may not be an adequate solution for diabetic patients with similar foot problems.

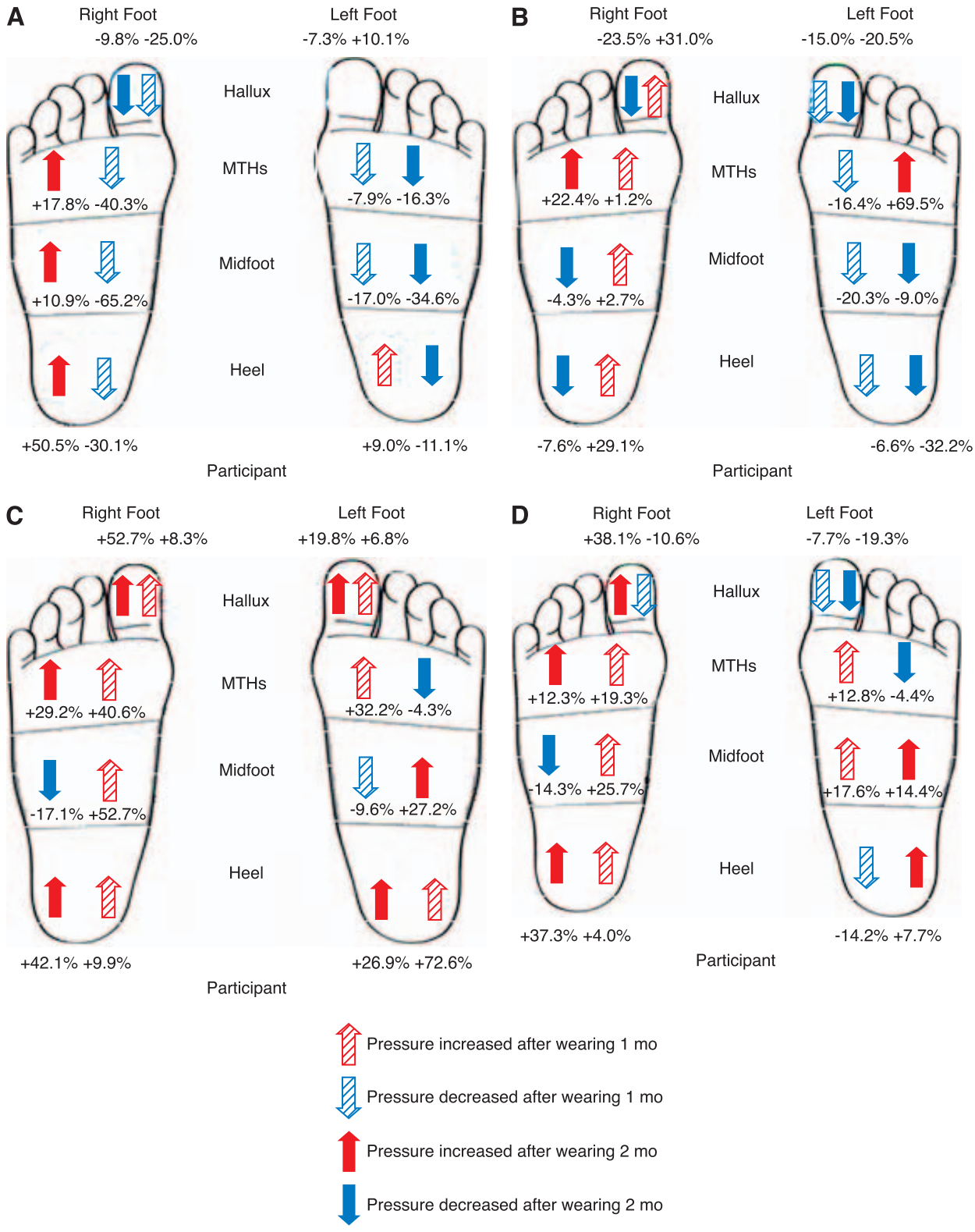


Figure 7. Percentage changes in peak pressure in various regions of both feet of each participant. All of the changes are calculated as the difference between 1 month of wear and the initial visit and between 2 months and 1 month of wear. MTH, metatarsal head.

Conclusions

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 that may facilitate the continuous monitoring and evaluation process of insole performance. The 3-D scanning technique used herein allows for capture of the insole geometry to perform the evaluation and quantification of insole deformity. This approach also allows practitioners to objectively 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. Note 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 3-D 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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Conflict of Interest: None reported.

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