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Plantar Pressure With and Without Custom Insoles in Patients With Common Foot Complaints

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ABSTRACT

Background: **Although many patients with foot complaints receive customized insoles, the choice for an insole design can vary largely among foot experts. To investigate the variety of insole designs used in daily practice, the insole design and its effect on plantar pressure distribution were investigated in a large group of patients.** ***Materials and Methods:*** **Mean, peak, and pressure-time-integral per sensor for 204 subjects with common foot complaints for walking with and without insoles was measured with the footscan® insole system (RSscan International). Each insole was scanned twice (precision3D), after which the insole height along the longitudinal and transversal cross section was calculated. Subjects were assigned to subgroups based on complaint and medial arch height. Data were analyzed for the total group and for the separate subgroups (forefoot or heel pain group and flat, normal or high medial arch group).** ***Results:*** **The mean pressure significantly decreased under the metatarsal heads II-V and the calcaneus and significantly increased under the metatarsal bones and the lateral foot ($p < 0.0045$) due to the insoles. However, similar redistribution patterns were found for the different foot complaints and arch heights. There was a slight difference in insole design between the subgroups; the heel cup was significantly higher and the midfoot support lower for the heel pain group compared to the forefoot pain group. The midfoot support was lowest in the flat arch group compared to the high and normal arch group ($p < 0.05$).** ***Conclusion:*** **Although the insole shape was specific for the kind of foot complaint and arch height, the differences in shape were very small and the plantar pressure redistribution was similar for all groups.** ***Clinical Relevance:*** **This study indicates that it might be sufficient to create basic insoles for particular patient groups.**

Key Words: Plantar Pressure; Insoles; Foot Pain; Foot Type

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INTRODUCTION

Non-traumatic disorders of the foot, such as metatarsalgia, plantar fasciitis, or hallux rigidus are common in the elderly. Previous studies have reported a prevalence of self-reported foot problems in 10% of a random community sample,[11,12] increasing with age to approximately 24% in individuals 65 years and older.[23] Foot disorders, especially in the elderly, hamper mobility and may result in functional disability, reducing the perceived well-being, and increasing the risk of falling.[12,27,32]

It is assumed that foot pain can be successfully relieved by changing foot posture and/or redistributing the (peak) plantar pressure under the painful areas of the foot by properly fitting insoles.[3,4,19,31,33] As a high plantar pressure under the metatarsal heads (MTH(s)) is associated with foot pain in patients with rheumatoid arthritis and cavus foot deformities, one of the treatment goals is to decrease pressure under those parts of the foot which cause pain. The question remains however, whether such pressure reduction requires a specific type of insole. Hodge and co-workers[19] investigated the effect of four different insoles on plantar pressure in subjects with rheumatoid arthritis and forefoot pain. They found that all (custom molded and prefabricated) insoles significantly decreased the plantar pressure beneath the first and second MTH.[19]

Another goal of the treatment with insoles is to realign the foot so that stress forces are minimized. There are many different theories as to how one can achieve an optimal foot alignment with insoles. Harradine and Bevan[16] classified the existing paradigms in three main categories according to the basis of the treatment (the Foot Morphology Theory, Sagittal

Plane Facilitation Theory, and the Tissue Stress Theory). They showed that these theories differ substantially from each other with respect to the criteria for normal alignment, casting methods, and treatment goal.

Hence, the manufacturing process of insoles is a subjective one, as was also demonstrated by two studies by Guldemond and colleagues.[13,15] They showed that there was almost no agreement between 30 foot experts on the location of high pressure zones in three patients with metatarsalgia, not even between experts of the same discipline.[13] Furthermore, they showed that the design of the insoles made by 31 foot experts for three patients with similar forefoot complaints varied greatly.[15]

Since many patients are satisfied with their insoles, it follows that the precise details of the design might be unimportant. If so, this has important consequences since producing differentiated insoles requires a lot of time and effort, while it might be sufficient to use stereotyped insoles for particular patient groups.

The present study was undertaken in order to investigate insole design and effect of insoles on plantar pressure in a large population of patients with common foot complaints. The differences in insole design as well as the plantar pressure redistribution were compared between patients with forefoot pain and heel pain and among patients with a flat, normal or high medial arch. We addressed three questions: 1) What is the general effect of insoles on the plantar pressure distribution in a large heterogeneous group of patients? 2) Is there any difference in the insole shape between patients with different foot complaints and how these insoles redistribute the plantar pressure? 3) Is there any difference between the insole shape for subjects with a high, normal, and low medial arch height and how these insoles affect the plantar pressure distribution?

MATERIALS AND METHODS

Subjects

This study was conducted at the Sint Maartenskliniek Department of Research Development and Education, Nijmegen, the Netherlands. A total of 223 subjects were included. All subjects were 18 years or older and wore custom made insoles obtained from a podiatrist, a pedorthist or an orthotist because of foot complaints. All were satisfied with their insoles, as the VAS pain score was decreased substantially by insoles (on average 3.3 points). Subjects suffering from rheumatoid arthritis, diabetic mellitus or a neuromuscular disorder or other special systemic disorders associated with foot complaints were excluded as were subjects who wore insoles for treatment of back or knee pain. Signed informed consent was obtained from all subjects, and the local ethical board approved the study. Main group characteristics are specified in Table 1.

Plantar pressure

Plantar pressure distribution was measured during walking at preferred speed on a walkway of approximately 20 meters. All subjects wore seamless socks and standardized shoes (Xsensibles®, Nimco Orthopaedics, Nijmegen, the Netherlands) to ensure that neither socks nor shoe type influenced plantar pressure distribution. Plantar pressure was measured when walking with and without insoles. For the "without insole" measurement, the standard insole of the shoe was removed, so that subjects walked on a flat base. For the "with insole" measurement, the subjects used their own insoles to which they were fully accustomed. Subjects walked twice without insoles and subsequently twice with insoles at their own comfortable speed. Data were collected during 8 seconds, starting from the third step of a walking sequence.

The plantar pressure was measured using the RSscan inshoe pressure-measurement system (RSscan International®, Olen, Belgium). The RSscan system consisted of a footscan datalogger, 4 pairs of insoles (sizes 3, 6, 8 and 10) and a 4 Mb memory card. The insoles were 0.7 mm thick and consisted of 324 matrix-configured sensors. The datalogger was attached at the back of the subject. Data was sampled at a rate of 500 Hz.

Insole shape

To determine the insole shape, the insoles were scanned using a 3D plantar scanner (Precision 3D Limited, UK), which consisted of two firewire high resolution digital cameras which measured the insole shape with an accuracy of 0.5 mm. For the measurement, the bottoms of the insoles were attached to a white hardboard plate with double-sided tape. This plate was placed on top of the scanner, with the insoles downwards, facing the scanner. Each insole was scanned twice and the mean values of the two measurements were taken for further analysis.

Table 1: Group Characteristics

	Age (years)	Length (cm)	Weight (kg)	Shoe size*	Female/male
Total group ($n = 408$)	54.9 (13.7)	171.2 (9.0)	76.5 (14.1)	40.2 (2.6)	193/73

*, European shoe size.

Foot complaints and foot shape

Foot complaints were registered by a physiotherapist. Although subjects suffered from various complaints, forefoot pain and heel pain were the most common. Therefore, 2 subgroups were made: a forefoot pain and a heel pain group.

Finally, to specify foot type, the Arch Index (AI) was calculated for each person when walking barefoot over the Rsscan pressure plate. The pressure plate had a sensor density of 2.6/cm^2 and was placed on top of a force plate (Kistler Instruments, Switzerland). A total of 5 trials per foot per subject were measured. Subjects walked at preferred speed and walked over the pressure plate according to the 3-step-protocol described by Bus et al.[5] Using the normalization method of Keijser et al,[22] the mean plantar pressure of the 5 steps per foot per person was calculated. Based on this mean plantar pressure pattern, the Arch Index (AI) was determined using the equation described in detail by Cavanagh and Rodgers.[7] Three groups were derived: a group consisting of subjects with an AI less than 0.21 (the high arch group), a second with an AI between 0.21 and 0.26 (the normal arch group) and the third one with an AI greater than 0.26 (the flat arch group). Separate analyses were made for the total group, the two foot complaint groups and the three AI groups.

Analysis and statistics

Plantar pressure

Data were analyzed using custom made MATLAB 7.3 software (MATLAB®, The MathWorks Inc, Natick, MA). The effect of insoles on plantar pressure was evaluated by comparing the mean plantar pressure per sensor, the peak plantar pressure per sensor and the pressure time integral per sensor between walking with and without insoles. These parameters were first calculated per sensor for a step. A step was determined as the period between heel strike and toe off. Heel strike was defined as the instant that the ground reaction force exceeded 50 N and toe off when the ground reaction force was below 50 N. After calculating the pressure parameters for a step, the parameters were averaged over the number of qualifying steps for walking with and without insoles. To determine the number of qualifying steps, the ground reaction force (GRF) pattern of each step was inspected. Steps that demonstrated apparent erratic GRF patterns at the end of the walking sequence due to premature slowing down were excluded from further analysis. On average, subjects had 12 (range, 6 to 16) qualifying steps with insoles and 12 steps (range, 7 to 16) without insoles per foot. Per sensor per step, the mean plantar pressure (MP) was calculated by dividing the pressure for all samples by the number of samples per step. Peak pressure (PP) was calculated by taking the maximum pressure of each sensor during one step cycle. The pressure time integral (PTI) equaled the area under the pressure-time curve for each sensor. Furthermore, contact time was calculated as the time between heel strike and toe off, to indicate walking speed.

To indicate if insoles similarly affected MP, PP and PTI, the Pearson correlation coefficient was calculated between these parameters for each sensor for walking without insoles and for the difference between walking with and without insoles. Subsequently the mean correlation coefficient over all pressure sensors was computed.

A paired t-test with adjusted p value was used to determine whether there was an effect of insoles on MP, PP, and the PTI for each sensor. As the analysis of plantar pressure per sensor has only recently been developed, there is not yet any consensus about the best way to treat the large number of sensors in statistical analysis. Therefore, a procedure derived from the analysis techniques used in neuroscience to analyze EEG signals[29] was used as both fields analyze data consisting of a large number of pixels. The technique involves a nonparametric procedure, based on grouping all adjacent sensors that exhibit similar difference in sign (an increase or decrease in MP).[28] First, each pressure sensor was categorized as being a “decreased” or “increased” sensor. Secondly, all neighboring sensors with the same difference in sign (the increase or decrease) were grouped. For each foot, a total of 11 groups were found. For the analysis, we adopted the strategy of adjusting the p value for the number of sensors by using a general Bonferroni correction (α/N), in which the N represents the number of groups for sensors (11). Therefore, the level of significance, used for this analysis, was set at 0.0045.

The difference in MP, PP, or PTI between the heel pain and forefoot pain group was determined with a Student t-test for independent samples with correction for unequal group sizes. For the two groups of complaints, the p value was also set at 0.0045. The difference in MP, PP, or PTI between the three AI groups was also analyzed with a Student t-test for independent samples, but with a p value also adjusted for the number of comparisons. For that analysis, the N represented the product of the number of sensor groups (11) and comparisons (3). Therefore the level of significance, used for that analysis, was 0.0015.

Insole shape

In order to compare the insole shape between different groups of subjects, the 3D insole shape data were first normalized for foot size based on the RSscan pressure plate data using Matlab 7.3 software (MATLAB®, The MathWorks Inc, Natick, MA) software. This normalization method was similar to the normalization method for plantar pressure data developed by Keijsers et al.[22] but now used the 3D data derived from the scanner. In addition, the height of the longitudinal and transverse cross section of the insoles was determined to describe the insole shape more specifically. Both cross sections were calculated using the matrix characteristics obtained from the normalization process, which was a 101 (width) x 231 (length) matrix (shown in Figure 1, upper part). Due to the normalization process, the length and the position in the matrix was similar for all insoles. The

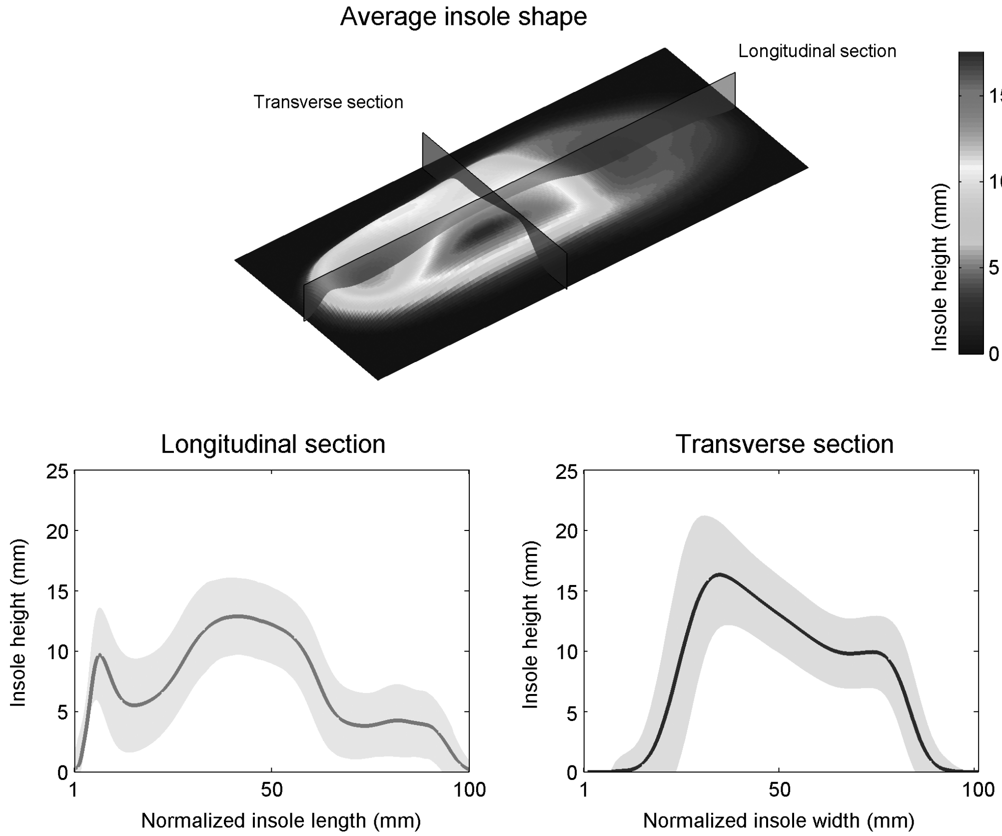

Fig. 1: 3D shape and average insole height (with SD) along the longitudinal and transverse cross section of the average insole.

longitudinal cross section was defined as the perpendicular line through the most proximal point of the heel, which was equivalent to the 51st vertical line of the matrix. The transverse line was defined as the horizontal line at 44% of the total insole length starting from the most posterior point of the heel, the 101st horizontal line of the matrix.

First, the average insole shape and cross sections of the insole for each person was calculated. Secondly, we determined the average insole shape/cross section for the total group and the subgroups: the heel pain and forefoot pain subgroups, and the three AI subgroups. The difference in insole shape between the heel and forefoot group was calculated for each point along the transverse and longitudinal section and was analyzed using a Student t-test for independent samples. The difference in insole shape between the three AI groups was determined with an ANOVA with factor group (3).

RESULTS

Valid data were obtained for 204 subjects, yielding a total of 408 feet. Based on the foot complaints, 170 feet were classified into the metatarsalgia group and 38 feet into the heel pain group. Forty-eight feet did not suffer from any complaint as the subject suffered from pain in only one foot. However, these subjects had received insoles for both feet. The remaining feet ($n = 152$) suffered from various foot complaints other than metatarsalgia or heel pain, for example, pain along the medial longitudinal arch, ankle joint pain, or minor toe deformities.

General characteristics of insole shape and plantar pressure redistribution

The average insole shape for the total group is displayed in Figure 1. As shown, the insole was highest at 10% (start of heel cup) and 40% (midfoot support) of the normalized insole length (longitudinal section). The maximum insole height at the heel cup was 10 (SD 3.6) mm and 13 (SD 3.7) mm at the midfoot support. The transverse cross section data showed that the medial side of the average insole was 6 mm higher compared to the lateral side as the maximum height was 16 (SD 4.3) mm at the medial side and 10 (SD 3.0) mm at the lateral side.

Contact time increased significantly by only 0.003 seconds when walking with insoles compared to walking without insoles (mean contact time with insoles = 0.641 sec (SD 0.06), without insoles = 0.638 sec (SD 0.06), $p = 0.001$). However, since these 2 ms represent only 0.37% of the mean step cycle, it is not to be expected that this small difference in contact time would cause a change in the plantar pressure distribution. As shown in Figure 2, the average plantar pressure distribution pattern for walking without insoles for the total group was markedly different from

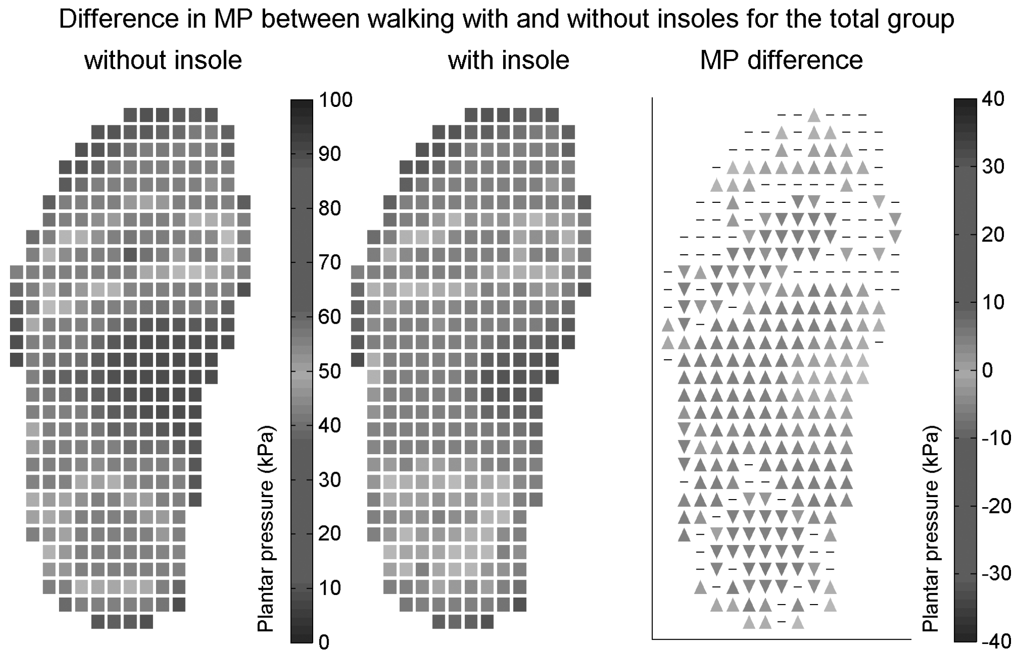

Fig. 2: MP per sensor for walking with and without insoles. The right part of the Figure gives the significant differences in MP between walking with and without insoles (MP difference). Those sensors which are represented as tinted triangles are sensors with a significant difference in MP ($p < 0.0045$). Upward triangles represent a positive difference and downward triangles represent a negative difference. Non-significant differences in MP were found for the sensors which are represented by the black small lines. (A color version of this figure is included in the online version of this article, available at www.datatrace.com/medical/FAI_body.htm.)

the distribution pattern for walking with insoles; there was clearly a much more even distribution in the case of insoles. Nevertheless the total pattern remained similar. The highest plantar pressure was located at the MTHs (mostly around the second MTH) and the calcaneus, while low plantar pressures were located at the midfoot and the toes. Insoles significantly decreased the MP under the MTH II-V and the calcaneus, and significantly increased the MP proximal from the MTHs ($p < 0.0045$). The latter differences can best be evaluated from the differences scores shown in Figure 2 (right side).

The distribution pattern for the other parameters (PP and PTI) was similar to the distribution pattern for the MP. The mean correlation coefficient between the MP and the PP for all sensors and for walking without insoles was 0.94 (SD 0.03) ($p < 0.05$). An even stronger correlation was found between the MP and the PTI ($r = 0.99$ (SD 0.004) $p < 0.05$). The difference in MP between walking with and without insole correlated highly with the difference found for the PP ($r = 0.90$ (SD 0.04) $p < 0.05$) and the PTI ($r = 0.99$ (SD 0.002) $p < 0.05$). This indicates that insoles affected the distribution pattern of all three parameters in a similar way. Therefore, the results of the MP will be presented as being representative for all three parameters in the following sections.

Pressure differences and insole shape for two populations of foot complaints

The difference in the MP between walking with and without insoles per sensor for the two subgroups is displayed in Figure 3A. In both groups, insoles significantly decreased the MP of the sensors located at the MTH (MTH) II-V and the calcaneus ($p < 0.0045$). In addition, the MP under the midfoot was significantly increased, particularly under the area proximal to the MTHs (the base of the metatarsals), the lateral midfoot, and medio-distally of the calcaneus. There was no significant difference between the change in the MP of the forefoot group and the heel group for any sensor ($p > 0.07$).

However, there were significant differences in the insole shape between both groups. The heel cup was significantly higher (max, 3.3 mm) for the heel pain group compared to the forefoot pain group. The slope of the midfoot support was markedly different between both groups, as the midfoot support was significantly lower (from 46.5% to 61% of the total insole length) in the heel group compared to the forefoot group (max difference, 2.2 mm). In the transverse direction, the insole was significantly lower for the heel pain group compared to the forefoot pain group at the first part of the medial slope (at 3% to 6%, 16% to 17% and 21% to 27% of the insole width) and at the lateral part of the insole (57% to 74%, maximum difference: 1.3 mm).

Pressure differences and insole shape for three populations of arch height

In all three arch groups, plantar pressure was redistributed in a similar manner, as all insoles significantly decreased the MP under the MTH (MTH) II-V and the calcaneus ($p < 0.0015$) and increased the MP under the midfoot

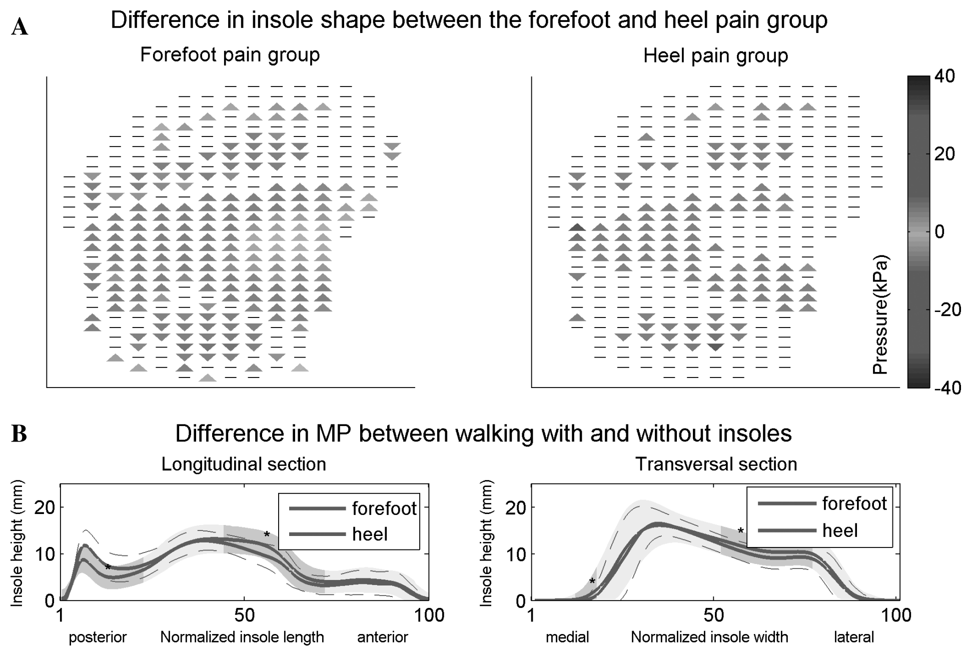

Fig. 3: **A**, Significant change in MP under the entire foot between walking with and without insoles (with - without insoles) for the forefoot pain group and the heel pain group. The colored triangles indicate those sensors with significantly different changes in plantar pressure compared to walking without insoles ($p < 0.0045$). Upward triangles represent a positive difference and downward triangles represent a negative difference. The small black lines indicate those sensors without a significantly different change in plantar pressure. **B**, Mean insole height along the longitudinal and transverse cross section for the forefoot pain (dark grey, blue) and heel pain (light grey, red) group. The light grey (blue) area and the black (red) dotted lines indicate the SD for the forefoot and the heel pain group, respectively. The dark grey parts of the light grey SD area (specified with a *) indicates a significant difference in insole height between both groups ($p < 0.05$). (A color version of this figure is included in the online version of this article, available at www.datatrace.com/medical/FAI_body.htm.)

(Figure 4, Top). With exception of the plantar pressure under the medial midfoot there was no significant difference in plantar pressure redistribution between the 3 groups. Under the medial midfoot there was a significantly higher increase of plantar pressure in the flat arch group compared to the normal and high arch group.

In contrast to the relatively small differences in plantar pressure the variations in the insole shapes were much more pronounced. There was a main effect of insole height from 36% to 52% of the insole length, indicating a significant lower insole for the flat arch group compared to the high arch group ($p < 0.05$). For 36% to 45% of the insole length, the insole height of the flat arch group was significantly lower compared to the normal arch group as well (Figure 4). A main effect for insole height in the transverse section was found for 19% to 24% and 37% to 68% of the insole width. Post hoc analysis revealed a significantly higher insole for the flat arch group at 19% to 24% of the insole width compared to the high arch group. Furthermore, the insole of the flat arch group was significantly lower compared to the high arch group and the normal arch group at 37% to 68% and 39% to 52% of the insole width, respectively ($p < 0.05$).

DISCUSSION

To get a better understanding of the insole designs used in daily practice and its effect on plantar pressure distribution, the present study investigated the insole design and plantar pressure redistribution in a large population of patients with common foot complaints. Although insoles are frequently used to reduce the plantar pressure under painful areas of the foot, there is still no consensus about the best way to treat foot complaints with insoles.[2,4,6,9,19,25,26,31] For example, it is still unclear whether it is important to redistribute the plantar pressure in general or to strive for specific pressure relief under the painful areas of the foot.

The present study identified several major changes in plantar pressure due to insoles. There was a proximal shift of pressure from the MTHs towards the metatarsal bones while the plantar pressure under the heel was reduced significantly. These results showed that insoles distributed the plantar pressure more equally over the foot. Most of these findings agree with previous work on plantar pressure in patients with foot complaints.[1,4,19,21,26,31] These studies indicated that insoles significantly decreased peak pressure under the lateral part,[19,31] the central part[19,21,31] or the medial part[1,19] of the forefoot. However, none of these studies mentioned a decrease under MTHs II-IV. The proximal shift of pressure from the MTHs towards the metatarsal bones has only been described by Postema and colleagues.[31]

The discrepancy between the present study and several previous ones may be related to the coarser methods used in those earlier studies. The present method, based on the analysis of a large number of sensors, is able to

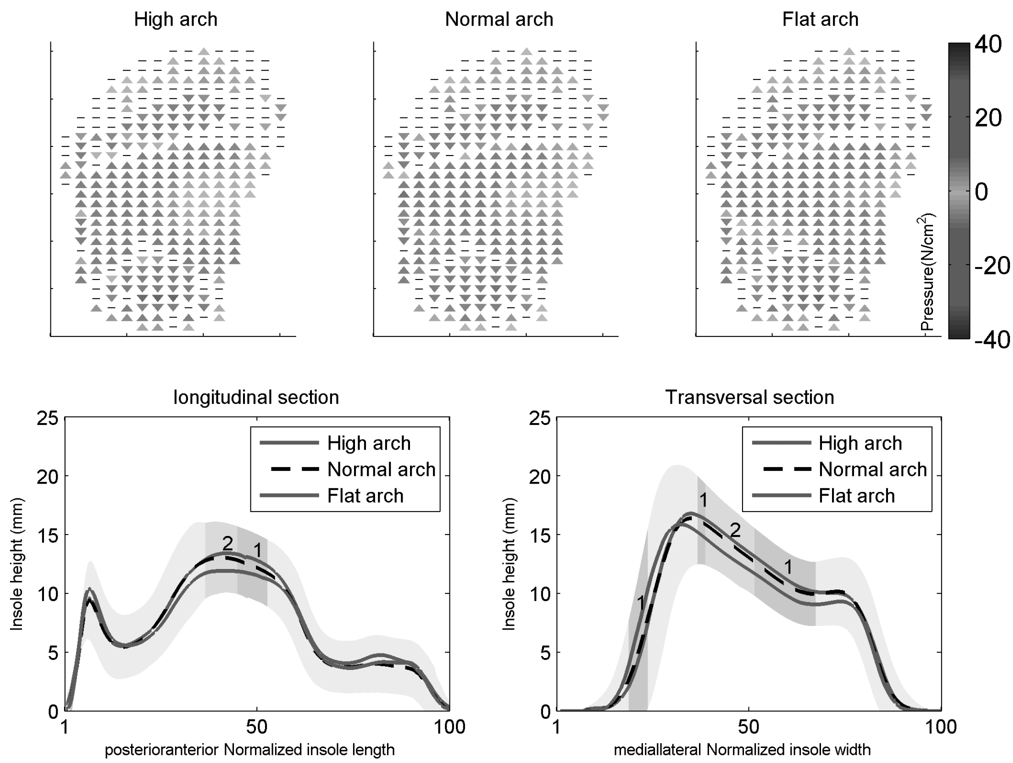

Fig. 4: Upper part, Significant change in MP under the entire foot between walking with and without insoles (with - without insoles) for the three AI groups. The colored triangles indicate those sensors with significantly different changes in plantar pressure compared to walking without insoles for each group ($p < 0.0015$). Upward triangles represent a positive difference and downward triangles represent a negative difference. The small black lines indicate those sensors without a significantly different change in plantar pressure. **Lower part**, The longitudinal and transverse cross section for the high arch (AI $\geq$ 0.21 (dark grey, blue)), normal arch (0.21 < AI > 0.26 (black dotted)) and flat arch (AI $\geq$ 0.26 (light grey, red)) group. The light grey (blue) area indicates the SD of the normal arch group with darker parts indicating a significant difference in insole height between the three AI groups ($p < 0.05$): One, between the high and flat arch group. Two, between the high and flat arch & flat and normal arch groups. Three, between the high arch and normal arch group. (A color version of this figure is included in the online version of this article, available at www.datatrace.com/medical/FAI_body.htm.)

optimally capture all the characteristics of the redistribution of pressure.[22,30] For example, consider the shift of plantar pressure from the MTHs towards the metatarsal bones. Except for some studies on diabetics,[6,33] only Postema and colleagues,[31] have demonstrated that custom molded insoles caused a shift of peak plantar pressure in patients with foot complaints from the central distal forefoot towards the central proximal forefoot.[31] Postema divided the area of the MTHs and bones into four smaller areas, which is in contrast to most studies in which the plantar pressure under the metatarsal bones was measured much more crudely (the midfoot was divided into only one or two areas).[3,4,19,20,34] In such studies, small, but important, increases might be unnoticeable.

Furthermore, the population of this study was deliberately chosen to be more diverse compared to other studies. Most studies investigated one particular patient group,[1,4,8,10,14,20] while we measured a large heterogeneous group of patients to have an adequate sample of patients with various foot complaints. Therefore, the general insole design, as represented in our study, might differ from the designs studied in other studies. However, we demonstrated that the effect of insoles on plantar pressure in the two groups of patients (heel and forefoot pain) was identical, while the design of the insoles was significantly different. In addition, there was a significant difference between the three AI groups regarding the medial support height of the insoles. However, with the exception of a small area under the medial side of the midfoot, the plantar pressure redistribution was similar in the three groups. These findings signify that although there were differences in insole designs within the group, the overall effect on plantar pressure was mostly similar. The decrease of plantar pressure can be the result of absorption of pressure by the material of the insoles and/or the redistribution of plantar pressure. Hinz and colleagues[18] showed that soft neoprene insoles were significantly better in reducing peak pressure under the forefoot than conventional insoles. As only peak pressure will be sensitive to the absorption of pressure by the materials, decrease of both the MP and the PTI point towards the redistribution of pressure. We demonstrated that insoles were effective in reducing peak pressure as well as average pressure. Therefore, it is likely that these effects are a result of the redistribution of pressure rather than of absorption by the insole material.

Another important finding was the difference in insole design among the different groups of patients. Although the differences were only small (2 to 3 mm difference in height), they were statistically significant differences between the groups. This indicates that foot experts take foot structure and foot complaint into consideration when defining the insole design. Furthermore, as the insole shape was specific for the different groups of patients, it seems that foot experts treat foot complaints in a similar manner. This finding is somewhat in contrast with the results found by Guldemond and colleagues,[15] who investigated the variability in insole design among foot experts in patients with forefoot pain;[15] they found that there was a high variability in insole design between foot experts. They however used different outcome parameters. By scanning the insoles, we were able to objectively quantify the insole shape along the transversal and horizontal cross section. Guldemond[15] described the insole configuration based on the materials used, number of corrected and supportive adaptations, the total insole length and the achieved plantar pressure reduction. Hence, in view of the efforts taken to develop evidence based design guidelines,[16,17,24] these results indicate that there is some uniformity in treatment approach among the experts.

It is remarkable however, that the differences in insole design do not result in a greater difference in plantar pressure redistribution. This might be due to the fact that the differences in insole height were quite small. Furthermore, all insoles showed basic similarities since they all provided a distinct midfoot support. This support generally causes a transfer of plantar pressure from the heel and forefoot towards the midfoot area, resulting in a similar redistribution pattern.

It follows that the present data indicate that foot experts use a general insole design, which is adapted slightly depending on the kind of foot complaint or arch height. These adjustments have a similar, equalizing, effect on plantar pressure. Hence, it might be unnecessary to focus on small detailed adjustments. Instead it might be sufficient to create a few general insole designs for some of the basic categories of subjects with common foot complaints.

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