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The effect of PORON® and Plastazote® insoles on forefoot plantar pressures

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ABSTRACT

Background. Tissue destruction and ulceration is often attributed to increases in plantar pressures commonly observed in systemic diseases such as diabetes mellitus and rheumatoid arthritis. Insoles frequently form part of the management plan to reduce the risk of complications by reducing plantar pressures.

Method. Nine subjects were recruited to use PORON® insoles and combined PORON® and Plastazote® insoles for 50,000 steps. The peak pressure and the force-time integral under the forefoot were measured using the F-Scan in-shoe measurement system. Measurements were taken before and after the subjects had completed 50,000 steps wearing the insoles.

Results. The study revealed a significant difference in peak pressure between no insole and both the PORON® and PORON®/Plastazote® insoles. Peak pressures were found to be significantly lower when wearing either of the insoles both before 50,000 steps ($P<0.05$, $P<0.05$) and after 50,000 steps ($P<0.05$, $P<0.05$) than when no insoles were worn. Peak pressures were found to be higher when wearing the PORON® insole after 50,000 steps were completed than before ($P<0.05$). No significant difference ($P=0.68$) in the force-time integral was found when wearing either of the insoles after 50,000 steps compared with no insole.

Conclusion. Both the PORON® insoles and the PORON®/Plastazote® insoles were effective at reducing peak pressure under the forefoot initially. Nevertheless, the PORON®/Plastazote® insoles were more effective at reducing peak pressure and the force-time integral under the forefoot after 50,000 steps had been completed.

INTRODUCTION

Clear links between peripheral neuropathy and increased plantar pressures in the development of foot ulceration have been observed in conditions such as diabetes mellitus and Hansen's disease.[1-3] However, Mason[4] found that in individuals with diabetes there were increased plantar pressures, but a lower incidence of plantar ulceration, than in individuals with peripheral neuropathy. Previous work[5] has also suggested the duration of plantar pressures may also be of importance when considering tissue damage. It therefore seems that elevated plantar pressures alone do not cause ulceration in the absence of sensory neuropathy.[1] This finding has been attributed to an intact sensory system, allowing the individual to change foot position in response to painful stimuli[1], highlighting the complex and multifactorial aetiology of plantar ulceration.[1]

One of the major management strategies to reduce elevated plantar pressures in chronic disease is the use of insoles and orthoses.[3] In order to be successful the insole must be able to reduce the elevated plantar pressure to below a threshold level for ulceration. However, the magnitude of this threshold is currently unknown.[1,3] Studies have shown that soft insole materials reduce plantar pressures by conforming to the shape of the foot, thus increasing the contact area of the foot with the ground.[6] The clinical objective is the reduction of plantar pressures, and the mechanical strategy used is the redistribution of load from one region of the foot to another.[3]

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Two soft materials, both commonly used in podiatric practice, were used in this study.[2,7] The first was a single density material, PORON®, and the second, a multidensity combination material comprised of PORON® and Plastazote®. There is currently little research available regarding the effectiveness of multidensity materials in comparison with single density materials.

With the development of in-shoe measurement systems, it is now possible to determine the distribution of pressure under the foot when wearing insoles. The significance of this lies in obtaining an objective measure in order to determine the sustainability and effectiveness of management strategies for pressure reduction.[1] The purpose of this study was to establish whether or not there is a difference in both the peak pressure and the force-time integral (FTI) under the forefoot, when using either a PORON® insole or a combined PORON® and Plastazote® insole. In addition, the durability of the insoles was also investigated over a period of 50,000 steps.

METHODS

Subjects

Fourteen subjects were recruited to participate in this study (male = 3, female = 11). Subjects were included if they were able to give informed consent, available to attend each session and had shoe sizes 4, 6, 8 and 10 (UK) due to limitation of resources for the Tekscan sensors. Potential subjects were excluded if there was a motor or gait disorder, a history of trauma to foot or less within one year of starting the study, gross cutaneous, soft-tissue or osseous abnormality to the foot or leg, foot symptoms or a body mass index of more than 25. The simple test of kicking a football was used to identify the subject's dominant foot.

Materials

In terms of the characteristics of the materials used in this study, the PORON® (Polyurethane open-celled foam) insole was 6.4mm thick and orientated shiney side up to allow foot to slide into the shoe. The combination insole consisted of a 3.2 mm Plastazote® (Polyethylene closed-cell foam) top-layer and a 3.2mm PORON® bottom-layer. All materials were supplied by Algeos Ltd, Liverpool U; Subjects were provided with a pair of PORON® insoles and a pair of PORON® and Plastazote® combination insoles.

Equipment

Data was collected using the F-Scan in-shoe pressure measurement system (Software v3.1 Tekscan Inc). The system consists of a 0.18mm thick sensor (with 960 pressure-sensing locations) interfaced with a laptop. The F-Scan insoles were trimmed to the correct size as recommended by the manufacture's guidelines. The same four F-Scan insoles were used throughout the data collection process. Prior to data collection the F-scan was calibrated as per manufacturer's recommendations.

Data collection

The F-Scan insole was inserted into the shoe of the subject's dominant foot. Measurements were taken from the subject's dominant foot as it was asserted that the increased workload imposed on the dominant foot would exacerbate the effects of repeated load on the insoles. The subject then replaced their shoes. Baseline data were collected first by asking the subject to walk along the 3-metre long walkway. In order to collect data more representative of the subject's normal walking pattern, measurements were taken from the third, fourth and fifth step, thus avoiding the confounding effects of acceleration and deceleration.

The process was then repeated, placing the PORON® insoles in the subject's shoes for the second data collection and the PORON®/Plastazote® combination insoles for the third data collection. When the subjects had the insoles in their shoes, the F-Scan insole was placed on top of the insole in order to measure the interface between the insole and the plantar surface of the foot. Once the three sets of data had been collected, the subjects were given both PORON® and the PORON®/Plastazote® insoles. They were then asked to wear each of the insoles for a total of 50,000 steps. Each subject was issued with a pedometer and a chart to record to record the number of steps completed. Pedometers are currently the best low-cost tool for monitoring activity.[8] Once 50,000 steps had been completed for both the pairs of insoles, the subjects were asked to return and the follow-up data was collected using the F-Scan. The test conditions are displayed in Table 1. Subjects wore the same pair of their own training shoes for both the initial and the follow-up data collections.

No insole
PORON® insole before 50,000 steps
PORON® insole after 50,000 steps
PORON®/Plastazote® insole before 50,000 steps
PORON®/Plastazote® insole after 50,000 steps

Table 1. Test conditions.

RESULTS

Demographic data

Nine participants completed the study over a mean of 57 days (male, n=2, (two right feet); female, n=7, (two left feet, five right feet)). Five participants dropped out of the study as they were unable to complete the data collection. The mean age of the participants was 25, mean weight 70.3kg and mean height 1. 73cm.

Statistical analysis

Two-tailed paired *t*-tests were utilised to analyse the data using Microsoft Excel. This was because the study was testing for differences within the data without stating direction,[9] and because the Z scores for skewness and kurtosis, lay between ± 2, indicating that data were normally distributed and appropriate for parametric testing.[9] Differences were considered significant when $P<0.05$.

The forefoot region was defined as the area between the base of the hallux and lesser toes to the beginning of the medial arch. Peak pressure (kPa) under the forefoot was defined as the maximum pressure recorded by any sensor under the forefoot region during the stance phase of gait.[3] Systeme International units were used so that the data collected could be compared with data from similar studies.[10]

Peak pressure

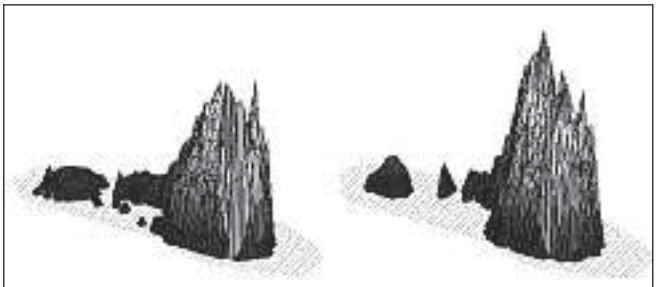
The mean, standard deviation and range of peak pressure for each experimental condition are displayed in Table 2. Peak pressure was significantly lower when using the PORON® insole and PORON®/Plastazote® insole compared with no insole, both before 50,000 steps ($P<0.05$), and after 50,000 steps ($P<0.05$). Peak pressure was significantly increased ($P<0.05$) for the PORON® insole after 50,000 steps when compared with before, as illustrated in Figure 1. There was, however, no significant difference in peak pressure between before and after 50,000 steps for the PORON®/Plastazote® insole ($P=0.48$). Likewise, there was no significant difference in peak pressure between the PORON® insole and the PORON®/Plastazote® insole, both before ($P=0.18$) and after 50,000 steps ($P=0.68$).

Force-time integral (FTI)

Table 3 displays the mean, standard deviation and the range of the FTI for each experimental condition. No significant differences were found in the FTI between no insole and the PORON®

Condition	*Mean*	*Range*	*SD*
No insole	186.39	126.51-240.60	34.70
PORON® insole before 50,000 steps	130.70	78.14-175.23	25.29
PORON® insole after 50,000 steps	152.36	87.38-240.99	40.60
PORON®/Plastazote® insole before 50,000 steps	134.20	71.71-214.81	30.07
PORON®/Plastazote® insole after 50,000 steps	139.19	106.28-174.13	20.62

Table 2. Table to show the means, ranges and standard deviation of the forefoot PP in kPa (2dp) for each experimental condition.



(a) Before 50,000 steps (b) After 50,000 steps

Figure 1. F-Scan diagram to represent a typical increase in PP under the forefoot between before and after 50,000 steps whilst wearing the PORON® insoles.

insole, either before or after 50,000 steps (P=0.64, P=0.14). Similarly, no significant difference was found in the FTI between no insole and the PORON®/Plastazote® insole before 50,000 steps (P=0.42). However, a small difference was found in the FTI between no insole and the PORON®/Plastazote® insole after 50,000 steps, but this did not reach statistical significance (P<0.1) as illustrated in Figure 2. There were no significant differences in the FTI between before and after 50,000 steps for either the PORON® or the PORON®/Plastazote® insole (P=0.49, P=0.15). Finally there were no significant differences between the PORON® insole and the PORON®/Plastazote® insole, either before or after 50,000 steps (P=0.67, P=0.49).

DISCUSSION

The purpose of this study was to evaluate plantar pressures under the forefoot when wearing no insoles compared with PORON® insoles and PORON®/Plastazote® insoles. Both peak pressure and force-time integral under the forefoot were measured before and after 50,000 steps.

Peak pressure

The peak pressure reduction found between the PORON® insole and no insole initially (mean = 130.70kPa) was possibly achieved by distributing plantar forces over a larger area of the ground, by increasing the surface contact area of the foot (force/area = pressure) as agreed by Foto[2] and Sanfilippo.[6] A study completed by Bus[3] found reductions in peak pressure using PPT (an open cell polyurethane foam similar to PORON®) under various regions of the forefoot, including the first metatarsal phalangeal head (mean = 302kPa) and lateral metatarsal phalangeal heads (mean = 145kPa). The peak pressure reductions were not as great as those observed in this study, however the subjects participating in the Bus[3] study displayed neuropathy and foot deformity, which may account for peak pressure reductions not being as great as in this study. PORON® also exhibits good elastic memory properties by resisting deformation from repeated compression,[11-13] suggesting that PORON® insoles would continue to maintain peak pressure reduction over a period of time.

This corresponds with the findings from this study, in which the PORON® insole continued to reduce peak pressure compared with no insole, even after the insoles had been worn (mean =152.36kPa). However, after the insoles had been worn there was a significant increase in peak pressure recorded with the PORON® insoles (before mean = 130.70kPa; after mean = 152.36kPa). As formerly discussed, previous studies[12-13] supported the maintenance of peak pressure reduction using the PORON® insoles, and no further studies could be found to support this increase in peak pressure. Although no visible compression was observed in the PORON® insoles after they had been worn, it is feasible that micro-architectural damage or changes may have occurred. Additionally, environmental changes may have influenced the properties of PORON®. For example, the first sets of data were recorded early in the year (February) and the second sets of data were recorded later in the year (April); thus, there may have been an increase in ambient temperature. Micro-architectural and environmental changes would require further research in a material testing laboratory.

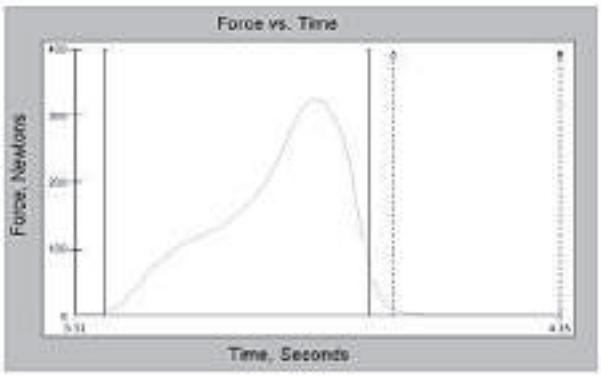
The PORON®/Plastazote® insole also provided peak pressure reduction under the forefoot initially (mean =134.20kPa) and after the insoles had been worn (mean = 139.19kPa) compared with no insole. No previous research could be found regarding peak pressure when using the PORON®/Plastazote® insole. Nevertheless, it is recognised that Plastazote® readily moulds to the shape of the foot.[12] Thus, like PORON®, Plastazote® is a useful material for redistributing plantar force over a wider area, accounting for the pressure reduction observed initially. However, on its own, Plastazote® has poor elastic memory properties and is unable to return to its original thickness, eventually 'bottoming out'.[12] This 'bottoming out' causes force redistribution to become poorer with time, indicating a limited life span in the peak pressure reduction effectiveness of this material.[12]

Leber[14] postulated that combining different materials may create a multidensity material, demonstrating properties of both materials concerned. Correspondingly, a study by Foto15 showed that the synergistic relationship between PORON® and Plastazote® slowed the 'bottoming out' effect found in Plastazote® alone. This study concurs with previous research[14-15] as a continued reduction in peak pressure was observed under the forefoot after the PORON®/Plastazote® insoles had been worn, compared with no insole.

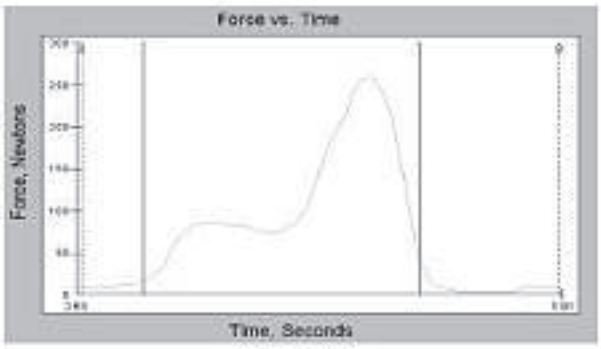
No significant difference was found for the PORON®/Plastazote® insole between the initial peak pressure (mean = 134.20kPa) and the peak pressure after the insoles had been worn (mean = 139.19kPa), further indicating the ability of the insole to produce a sustained reduce peak pressure reduction. Furthermore, the peak pressure data collected using the PORON®/Plastazote® insole after 50,000 steps exhibited a smaller standard deviation than the other experimental conditions, indicating less spread amongst the data.[9] However, there were ultimately no significant differences between the reduction in peak pressure achieved with either the PORON® insole or the PORON®/Plastazote® insole compared with no insole.

Condition	*Mean*	*Range*	*SD*
No insole	129.35	88.26-205.94	37.36
PORON® insole before 50,000 steps	124.94	68.65-176.52	29.62
PORON® insole after 50,000 steps	112.98	29.42-205.94	42.56
PORON®/Plastazote® insole before 50,000 steps	120.92	58.84-196.13	38.34
PORON®/Plastazote® insole after 50,000 steps	104.93	39.23-176.53	42.46

Table 3. Table to show the means, ranges and standard deviation of the FTI under the forefoot in N.s (2dp) for each experimental condition.



(a) no insole



(b) PORON®/Plastazote® insole after 50,000 steps

Figure 2. F-Scan diagram to show the typical reduction in the FTI when wearing the PORON®/Plasatzote® insole after 50,000 steps.

Research has been unable to identify a threshold of pressure above which ulceration will occur.[1] Consequently, it is uncertain whether the increase in peak pressure observed from the PORON® insole in this study has clinically significance, or indeed whether any reductions observed in peak pressure are clinically significant in terms of reducing/preventing pathology. Both insoles appeared effective at reducing peak pressure initially, with the PORON®/Plastazote® insole more effective than the PORON® insole in reducing peak pressure under the forefoot after a period of 50,000 steps. The degree to which the PORON®/Plastazote® insole can reduce peak pressure more than the PORON® insole may be beneficial in preventing ulceration in individuals with insensate neuropathy, where elevated plantar pressures are considered the primary cause of plantar ulceration.[2-3]

Force-time integral

FTI reduction was observed for the experimental condition comparing no insole (mean = 129.35Ns) with the PORON®/Plastazote® insole after 50,000 steps (mean =104.93Ns). One possible explanation for this outcome is that the PORON®/Plastazote® insoles visibly moulded to the shape of the subject's feet as they were worn. Curryer[7] recognised that moulding to the foot may be beneficial because a portion of the load is redistributed through the compression of the material, rather than through the breaking down of plantar skin, as when using flat insoles. Although it is recognised that the PORON®/Plastazote® insoles are not custom-made insoles, previous research[3] has shown that the FTI was significantly reduced at the first metatarsal head region for custom-made insoles compared with flat insoles (mean = 82.7Ns).[3]

Although the FTI was not significantly different between any of the experimental conditions, the mean FTI did decrease when wearing both the PORON® and the PORON®/Plastazote® insoles, initially and after they had been worn, compared with no insole. As in the case of peak pressure, it remains to be shown what reductions in the FTI are sufficient to minimise the risk of tissue damage.[3] Consequently, the findings from this study may be clinically important in the management of individuals whose pathology increases the FTI under the forefoot, however further work is recommended in this area.

CONCLUSIONS

Whilst both insoles were equally effective at reducing the initial peak pressure, the PORON®/Plastazote® insoles were more effective than the PORON® insoles in reducing peak pressure and FTI under the forefoot after 50,000 steps. Future studies would benefit from increasing the testing time of the insoles to more than 50,000 steps and include subjects with at-risk conditions such as diabetes and rheumatoid arthritis. This would allow the longevity of the insoles effectiveness to be assessed. Studies with larger subject numbers would also allow the power of the study to be improved.[9]

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