



Over-the-Counter Customised Insoles for Offloading Foot Focal Pressure

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Abstract

Purpose Over-the-counter prefabricated offloading relief insoles with removable modular cells for customisation have not been extensively studied in literature, and no studies have examined designs specifically intended for calluses and corns. This study examined the immediate effects of such insole prototype on the users.

Methods Foot pressure distribution was measured by in-shoe F-Scan system during normal walking cycles under four conditions: walking with normal footwear (C1), with prototype insoles inside the footwear (C2), with a cavity under the second metatarsal-phalangeal joint on the left or right side of the prototype insole (C3), and with cavities on both sides on the prototype insoles (C4). Subjective data were also collected in terms of insole fitting, comfort rating and balance feeling.

Results Overall, the prototype insoles designed to offload focal pressure via removing modular cells showed significant immediate effects (all $P \leq 0.002$). Averaged across both sides, average peak pressure (PP) of C2, C3 and C4 reduced from C1 by 19%, 25% and 28%, respectively; maximum PP of C2, C3 and C4 was reduced from C1 by 16%, 18% and 19%, respectively. With bilateral cavities, average PP at the second cavity side significantly decreased by a further 11% (C4 vs. C2, $P = 0.003$). These findings suggest that creating cavities alters the loading response during the gait cycle, as the metatarsal and heel peak pressures decreased. No imbalance was observed for C3 and C4. Participants reported satisfactory comfort and provided insights for future design development.

Conclusion This over-the-counter prototype shows potential for individuals to customise cavities in their insoles to manage excessive focal pressure.

Keywords Modular insole · Offloading · Plantar pressure · Callus · Walking

Introduction

Foot pressure is a key in the management of the lesions and/or pain, such as calluses and hard corns, which can cause pain and discomfort and negatively affect people's quality of life [1]. Not only older adults are at the risk of high focal foot pressure [2], athletes such as cyclists also experience this risk [3]. Around 85% of terrestrial sport athletes have foot callus [4]. In a podiatry clinic setting, callus formation was the most common complaint (53.6%) among patients

presenting with foot pain [5]. Chronic pressure or friction can lead to calluses and hard corns – essentially forms of mechanical hyperkeratosis – which can be managed conservatively in most cases through appropriate footwear and orthoses [6, 7]. If left untreated, these conditions carry risk of ulceration [8]. For management, the National Health Service (NHS, United Kingdom) recommends treatment such as removal of hard skin, skin softening, wearing soft in-shoe insoles and pads, cushioned socks and comfortable footwear [9]. Moreover, a podiatrist may provide treatment that includes 'specially made soft pads or insoles to take pressure of the painful area', in combination with sharp debridement [9].

Offloading technologies have been widely applied in the treatment and prevention of plantar ulcers, particularly in individuals with diabetes. These include total contact casts, and prefabricated pneumatic walking braces [10] that provide partial or total non-weight bearing benefits, as well

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as therapeutic shoes and milled orthoses [11] designed to redistribute the plantar pressure away from the wound site. Additionally, adding felt padding to the foot or orthoses to create a “window” around the wound area can substantially reduce peak pressure beneath the wound when wearing therapeutic shoes or cast walkers [12, 13]. Some studies have implemented local material deformation to achieve offloading, such as using softer material in small plugs beneath the top layer [14], or employing smart systems capable of sensing plantar pressure and deforming the high-pressure cells through magnetic-field-controlled valves embedded in the insoles [15] or soft hydraulic actuators [16].

Another offloading concept has been adopted in customised insoles for diabetic foot care, allowing users to create regional offloading areas by removing pixels or modular cells. Several studies have demonstrated effective pressure relief using such plug- or pixel- removal offloading orthotics designed for the diabetic foot [17–19]. Penny et al. conducted a comparative analysis of two pixel-based plug removal systems – the PegAssist insole system (Darco International, USA) and the FORS-15 offloading insoles (Saluber, Italy) – to evaluate their effectiveness in reducing localised plantar pressure [18]. Similarly, Lin et al. reported that selectively removing plugs beneath areas of elevated plantar pressure, in combination with incorporating arch support within a foam-based insole, could effectively reduce peak plantar pressure in individuals with diabetic peripheral neuropathy [17]. Reduced peak pressure was also observed in the study by Raspovic et al. which evaluated the DH Offloading Post-op Shoe™ (Ossur, Canada) with removable plugs compared to patients’ own footwear [19].

Although these systems employ removable plugs or pixels to offload regions of high plantar pressure, their primary clinical application has focused on promoting plantar wound healing rather than on the prevention or management of plantar callus formation. Furthermore, such systems typically require specialised footwear (e.g., the PegAssist by Darco or the Kerraped shoe). Another limitation of these designs is the formation of abrupt, cliff-like edges around the offloaded zones, which can induce a “mushrooming” effect – whereby plantar soft tissue is displaced into the cavity during weight-bearing – potentially leading to stress concentration at the cavity edges [20]. In contrast, the prototype insoles evaluated in this study incorporated a transitional design in which the surrounding edges are hollowed out to reduce high pressure zones forming. Double-adhered fabrics were also used for the top cover to reduce peak pressure and mitigate against potential localised edge loading.

Therefore, this study investigates the plantar pressure changes during walking using prototype insoles with removable modular cells designed for calluses, corns and other painful pressure-induced foot lesions in individuals without

peripheral neuropathy or active foot wounds. The prototype insoles allow users to trim the insoles to fit and, critically, to create cavities by manually removing the modular cells beneath areas of excessive or painful pressure area. If effective, this approach may benefit a broad population, as described above.

In this study, we focus on plantar pressure in the region of the second metatarsal-phalangeal (MTP) joint, which is defined as the target zone. The second MTP joint is known to experience high pressure during walking [21–23] and is a common site for callus formation [24]. We also examine temporal changes in plantar pressure across different foot regions.

Materials and methods

Participants

Fifteen healthy participants (7 men and 8 women, age: 43.0 ± 10.3 years, height: 172.5 ± 10.1 cm, weight: 79.4 ± 18.3 kg, body mass index: 26.5 ± 4.9 kg/m²) performed the walking tests and provided their user feedback. They were without: (1) pain or discomfort during walking; (2) injury history of lower limbs within six months; (3) diagnosis of neurological disorders. The study was approved by the University of Wales Trinity Saint David's Research Ethics Committee (ethical approval number EC1051), and all participants had given their written consent forms.

Materials and Apparatus

The prototype insoles (ZeroSole, Kaydiar Ltd., United Kingdom) were ranged from UK size 4 to 11 (7 pairs of UK size 4–7, 8 pairs of UK size 8–11), trimmed to fit in the participant's shoes. They were made of solid silicone with a shore hardness of A40. The original insoles of the participants' footwear were mainly trainer insoles with an EVA base. When inserting the prototype insoles into the shoes, the original insoles of the footwear were removed if possible. When the participant in a standing position was performing a heel-to-toe roll-over movement on the prototype insole, a transferable sticker from the skin of the second MTP joint could transfer onto the insole, thus defining where to create a cavity on the insole for this foot. Then three cells in a triangle shape were removed from the prototype insole to create the cavity (Fig. 1A). The ultra-thin F-Scan insoles (TekScan, Inc., Boston, United States, Fig. 1B) were placed on the top of the other insoles (original footwear insoles or prototype insoles) in the shoes, directly

Fig. 1 Experiment setup of (A) bottom view of the prototype insoles with a triangle cavity on each side at the second MTP joint, (B) F-Scan insoles for measuring plantar pressure



under the foot surface for pressure mapping at 200 Hz. A 9-m walkway was marked on the floor with a starting line and a finishing line.

Procedures

Participants walked normally at their comfortable pace, in an order of four conditions: walking with their normal footwear (C1), with prototype insoles inside the footwear (C2), with a cavity under the second MTP joint on randomised left or right side of the prototype insole (C3), and with cavities on both sides on the prototype insoles (C4). Each condition was repeated three times before starting the next condition. After the walking tests, questions around user experience were asked: (1) How does the prototype insole fit inside your shoe? (2) How do you rate its comfort from 1 to 5 (1 being very uncomfortable, 5 being very comfortable)? (3)

Does wearing the insoles cause you to feel any imbalance when you are walking?

Data Analysis

Three gait cycles (98% trials) or two cycles (2% trials only had two valid cycles) in the middle were analysed. Analysed gait parameters were stance time, swing time, gait cycle, as well as Symmetry Index (%) (Eq. 1), the mostly used Robinson index [25], using the difference between the two legs to divide by their mean.

$$\text{Symmetry Index} = \frac{2 \times (X_u - X_a)}{(X_u + X_a)} \times 100\% \quad (1)$$

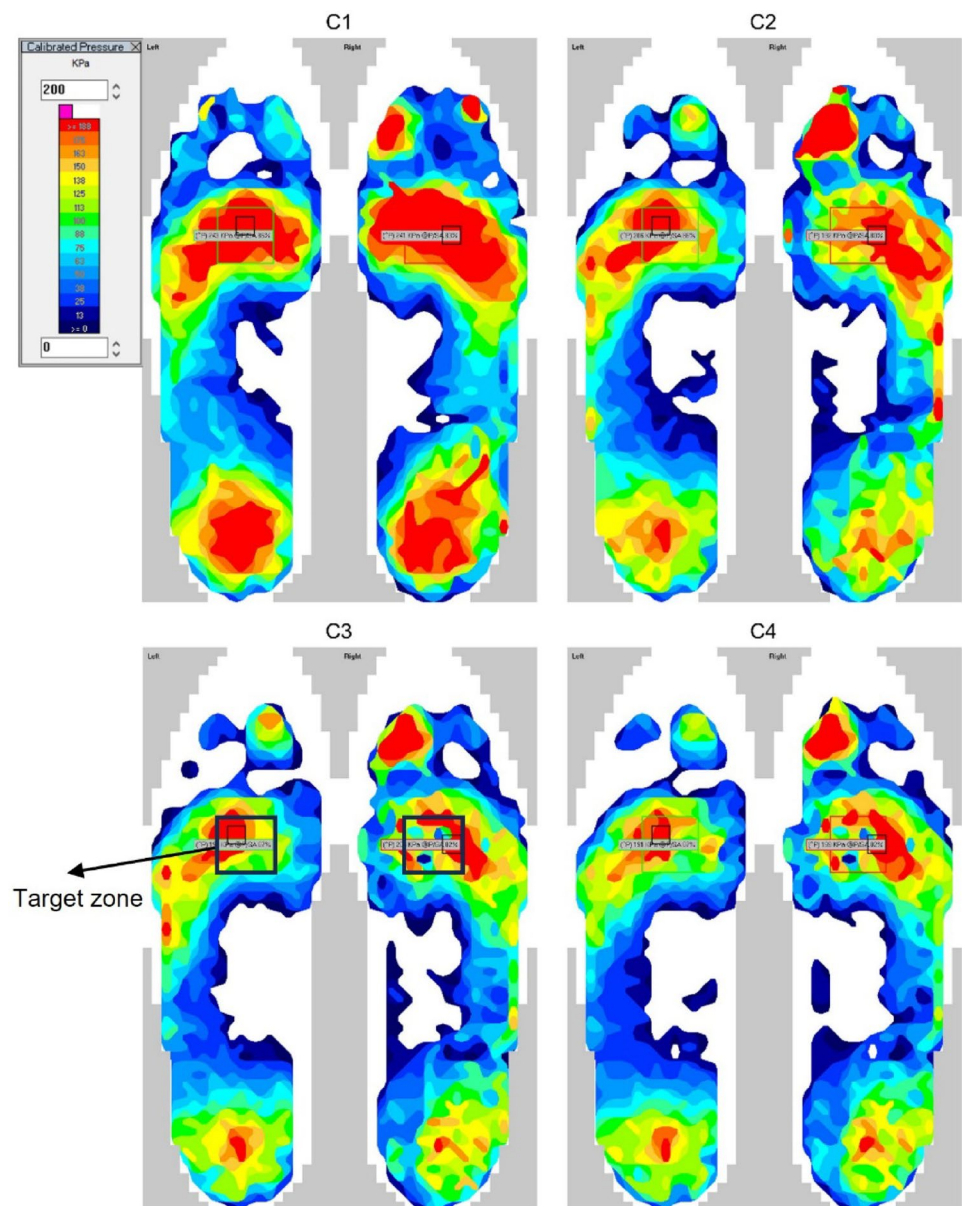
Where X_a represented the stance time of the first cavity side and X_u represented the stance time of the other side. The target zone (3.048 cm × 3.048 cm) corresponded to a

square area of 6 sensels $\times$ 6 sensels on the F-Scan sensing insole, covering the triangle cavity.

To locate the target zone at the same position relative to the feet across the four conditions, C4 was processed first as it might suggest the actual cavity positions from the image of the pressure distribution (Fig. 2). The target zone on F-Scan was double-checked and aligned with the photo of cavity on the prototype insole. For comparison across various conditions, the participants' data of C3's cavity side were grouped (7 left side and 8 right side) as the 'first cavity side', referring to the same side as the first cavity was created, and the other side was grouped as the 'second cavity side'. If the first cavity was created on the right, then the first cavity side of C1 was also right.

Peak stance in F-Scan consist of the maximum pressure during the stance period of each sensel, and averaged stance in heatmaps represented the averaged results from all selected stances (Fig. 2). Average peak pressure (average PP) was calculated from the averaged pressure of the target zone, while maximum peak pressure (maximum PP) represented the averaged pressure of 2 sensels $\times$ 2 sensels (1.016 cm $\times$ 1.016 cm) within the target zone. The moment when peak pressure occurred during the stance time, i.e., Peak at Stance (%), was also reported. In MATLAB (MathWorks, USA) with customised coding, force was calculated as the integral of pressure and area for all the sensels, then normalised by each individual's body weight and stance duration. Peak pressure (PP) over time was plotted as well for toe, metatarsal, midfoot and heel regions. Statistical

Fig. 2 Heatmaps under each condition of a participant's walking trial. Target zones of the left and right plantar areas are highlighted by black boxes



Parametric Mapping (SPM) was applied to PP throughout the stance phase to compare differences between conditions, using MATLAB codes (nonparametric equivalent to repeated measures ANOVA) downloaded from spm1d.org. This method has been applied in the biomechanical field for continuous walking data comparison over time [26]. To correct for multiple post-hoc comparisons, a Bonferroni correction was applied with adjusted significance level at $\alpha = 0.008$.

For some pressure data and gait parameters that were not normally distributed, non-parametric Friedman tests were performed in SPSS 28 (IBM SPSS Statistics, USA), with post-hoc Wilcoxon signed-rank tests to compare across different conditions; otherwise, repeated-measures ANOVA was performed for normally distributed data that met its assumptions. Significance level was set at $\alpha = 0.05$, except a Bonferroni correction applied to the Wilcoxon signed-rank tests, resulting in a significance level set at $\alpha = 0.008$.

Results

Average and maximum PP of the target zone indicated a significantly decreasing trend from C1 to C4 for both sides (Table 1). Significant decreases of average PP around the second MTP joint were shown when wearing the prototype insoles (C2, C3 and C4) compared to without wearing (C1) for both sides (all $P < 0.001$). Compared to the normal footwear walking condition (C1), C3 significantly decreased average PP in the target zone by 28% for the cavity side and 22% for the other side, and both insoles with cavities (C4) decreased 29% and 27%, respectively. Averaged across both sides, average PP of C2, C3 and C4 reduced from C1 by 19%, 25% and 28%, respectively. Compared to wearing zero-cavity prototype insoles (C2), with one-cavity (C3) average PP of the first cavity side decreased by 8% ($P = 0.011$), close to the adjusted significance level 0.008) and the other side decreased by 6% ($P = 0.019$). When bilateral cavities were created (C4), average PP of the second cavity side significantly decreased about 11% ($P = 0.003$) comparing to wearing the prototype insoles with no cavity (C2), and the first

cavity side also decreased by 11% ($P = 0.009$, close to the significance level 0.008).

Averaged across both sides, maximum PP of C2, C3 and C4 reduced from C1 by 16%, 18% and 19%, respectively. The second cavity side also showed a significant reduction when wearing the prototype insoles (C2, C3 and C4) compared to without (all $P = 0.002$). For the first cavity side, the P values were close to the adjusted significance level but not significant (C2 vs. C1, $P = 0.011$; C3 vs. C1, $P = 0.009$; C4 vs. C1, $P = 0.020$). Additionally, Peak at Stance (when maximum PP occurred) did not differ between conditions (Table 1).

For the entire foot during the stance phase, two periods generated large PP (Fig. 3). The first period was around 10%–23% of the stance phase, when heel strike was nearly over and transferring to loading response, so the peaks were mostly contributed by the heel and formed plateaus of the curves. The second period was around 82%–86% of the stance phase, during which PP reached 505 kPa, 502 kPa, 440 kPa and 422 kPa from C1 to C4 (Fig. 3A), mainly contributed by the toe and metatarsal regions. PP decreased for both metatarsal region (by 16%–17%) and heel region (by 21%–27%) when wearing the prototype insoles (C2, C3, C4 vs. C1, Fig. 3A). After normalising the plantar force to individual's body weight, a clear decreasing trend from C1 to C4 was found in the entire foot, metatarsal, midfoot and heel regions (Fig. 3B). The maximum forces in the metatarsal region of C2, C3 and C4 were reduced by 16%, 23% and 25% of body weight, respectively, compared to C1. In the heel region, they were reduced by 19%, 28% and 30%, respectively.

Interestingly, PP in the toe region increased under C2 but decreased under C4 (Fig. 3A). To better compare the changes occurred between conditions over time, Figs. 4, 5, 6 and 7 show the SPM analysis for sub-regional PP during the stance phase and the pairwise comparison between conditions. Though C2 shows a slightly higher toe PP than C1 after mid-stance (negative in C1 vs. C2 of Fig. 4), it is not significant. Comparing to C1 and C2, C3 and C4 significantly show PP decreases in the toe region (Fig. 4).

Table 1 Pressure related parameters (mean $\pm$ standard deviation) for the first cavity side (defined by C3) and the second cavity side, regardless of left and right

Variable	Side	C1	C2	C3	C4	P
Average PP (kPa)	First cavity	269 $\pm$ 149	213 $\pm$ 128	195 $\pm$ 124	190 $\pm$ 131	<0.001*
	Second cavity	250 $\pm$ 111	206 $\pm$ 98	194 $\pm$ 95	183 $\pm$ 86	<0.001*
Maximum PP (kPa)	First cavity	395 $\pm$ 249	341 $\pm$ 274	325 $\pm$ 233	339 $\pm$ 279	0.002*
	Second cavity	393 $\pm$ 218	324 $\pm$ 181	323 $\pm$ 173	303 $\pm$ 145	0.001*
Peak at stance (%)	First cavity	81.6 $\pm$ 2.6	80.9 $\pm$ 2.7	81.5 $\pm$ 2.6	81.7 $\pm$ 2.7	0.231
	Second cavity	81.6 $\pm$ 2.4	81.5 $\pm$ 3.0	82.1 $\pm$ 2.7	82.4 $\pm$ 2.9	0.323

Average PP average peak pressure of the target zone (9.29 cm²), *maximum PP* maximum peak pressure within the target zone (1.06 cm²), *peak at stance* percentage in stance time when maximum PP occurred. P significance of Friedman test, except for peak at stance first cavity which used repeated measures ANOVA

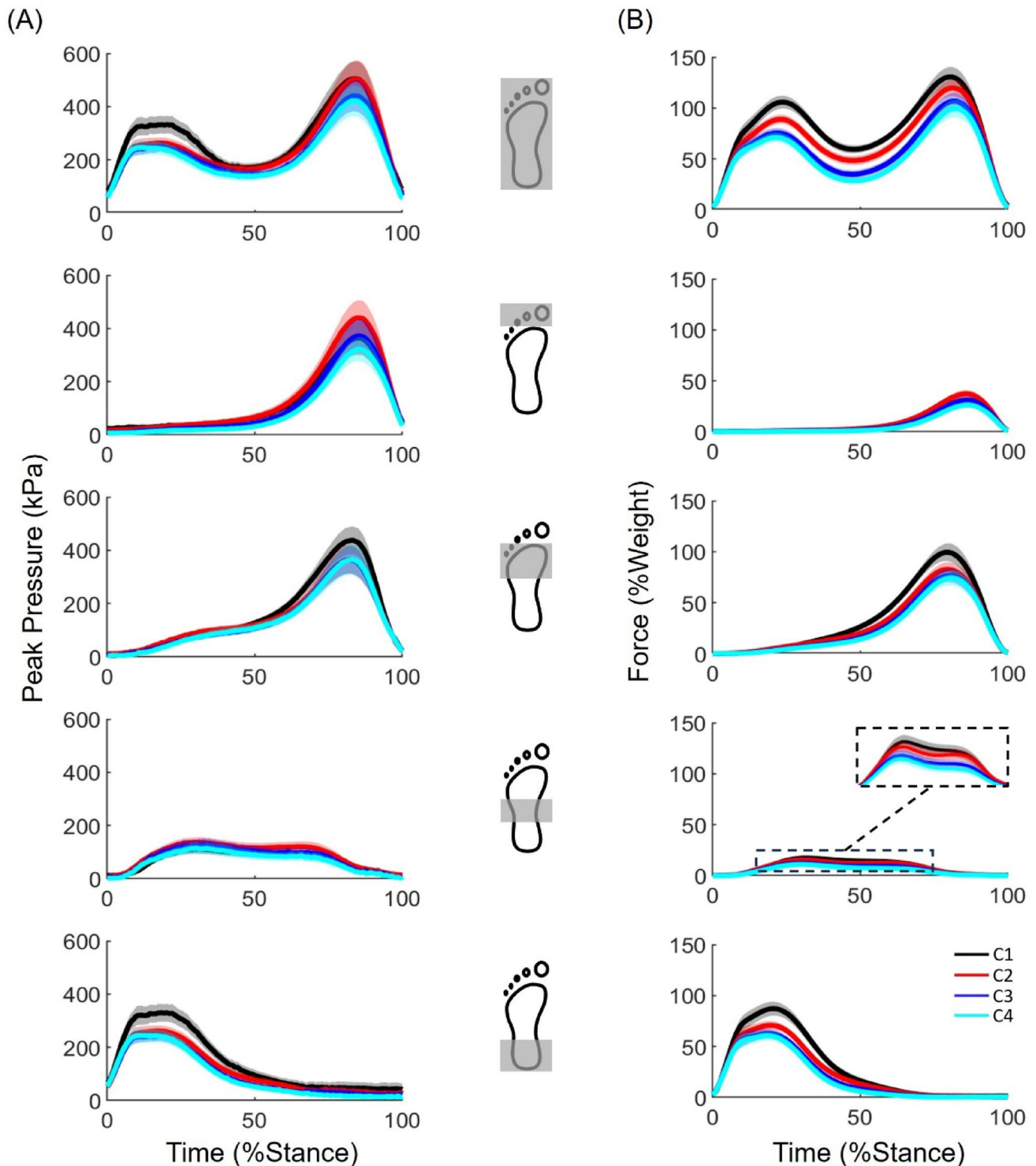


Fig. 3 (A) Peak pressure and (B) normalised force of different foot regions (the entire foot, toe, metatarsal, midfoot and heel) under four conditions (C1–C4) among all participants. Shaded area represents standard error across 15 participants

In the metatarsal region, PP reduced significantly for C2, C3 and C4 comparing to C1 (Fig. 5). C3 and C4 also show significant reductions than C2 between 10% and 25% of the stance phase. In Fig. 6, the midfoot region significantly

increased PP during the stance phase comparing C2 to C4, as well as C2 to C3. Comparing to C1, the midfoot PP of C2 and C3 were non-significantly larger during 3%–97% and 6%–83% of the stance phase, respectively. In the heel

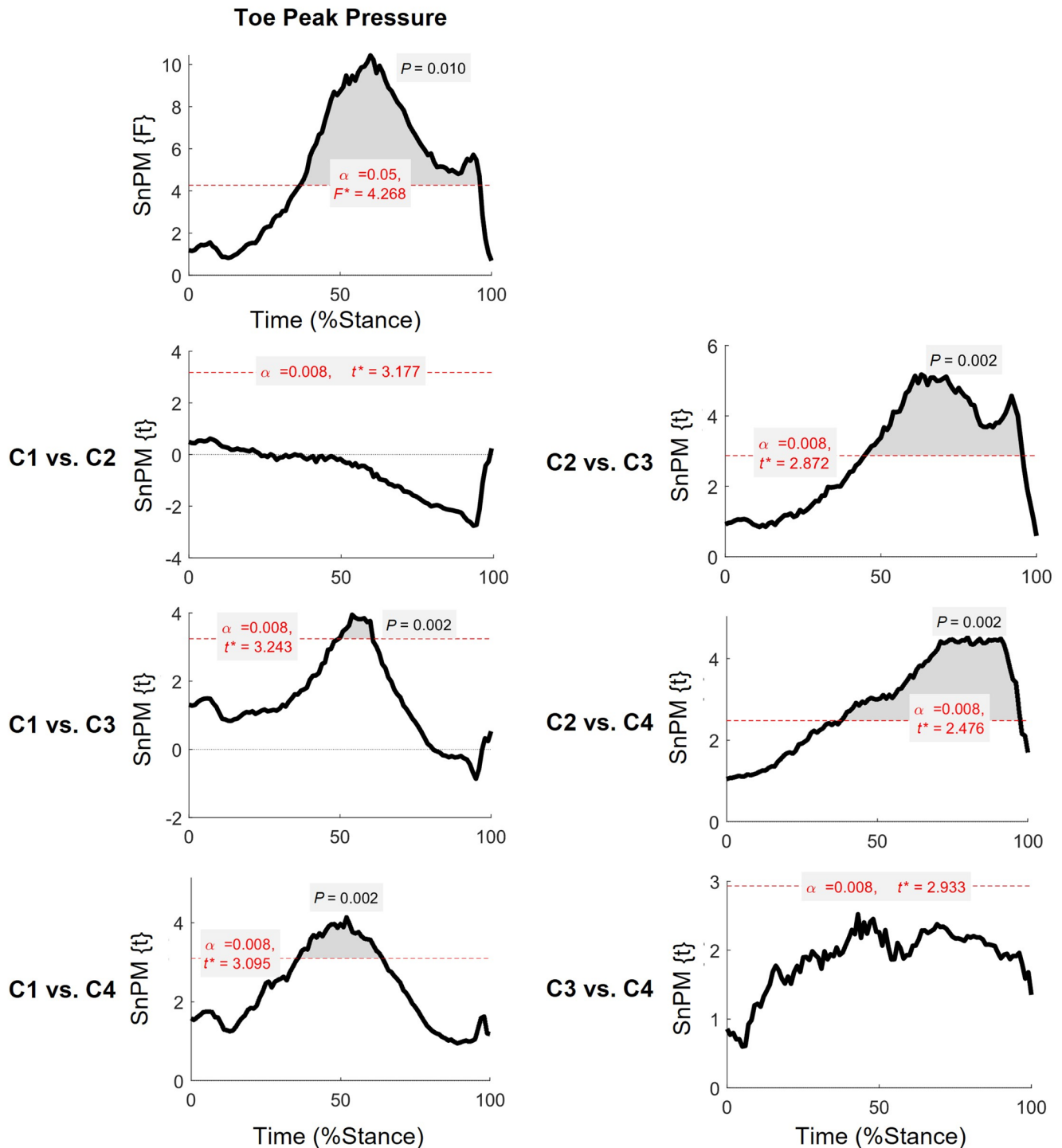


Fig. 4 SPM analysis of toe peak pressure during the stance phase

region, C3 and C4 reduced PP significantly than C2 during 14%–65%, 20%–43% of the stance phase, respectively (Fig. 7). C2, C3 and C4 also reduced heel PP significantly than C1 during 5%–35%, 5%–54%, 5%–67% of the stance phase, respectively (Fig. 7).

Gait parameters among different conditions are reported in Table 2. No significant difference was observed for gait cycle or Symmetry Index. Interestingly, the stance time for both sides decreased significantly from C1 to C4. Pairwise comparisons of the first cavity side showed significance in C1 vs. C4 ($P=0.002$), C2 vs. C3 ($P=0.020$) and C2 vs. C4

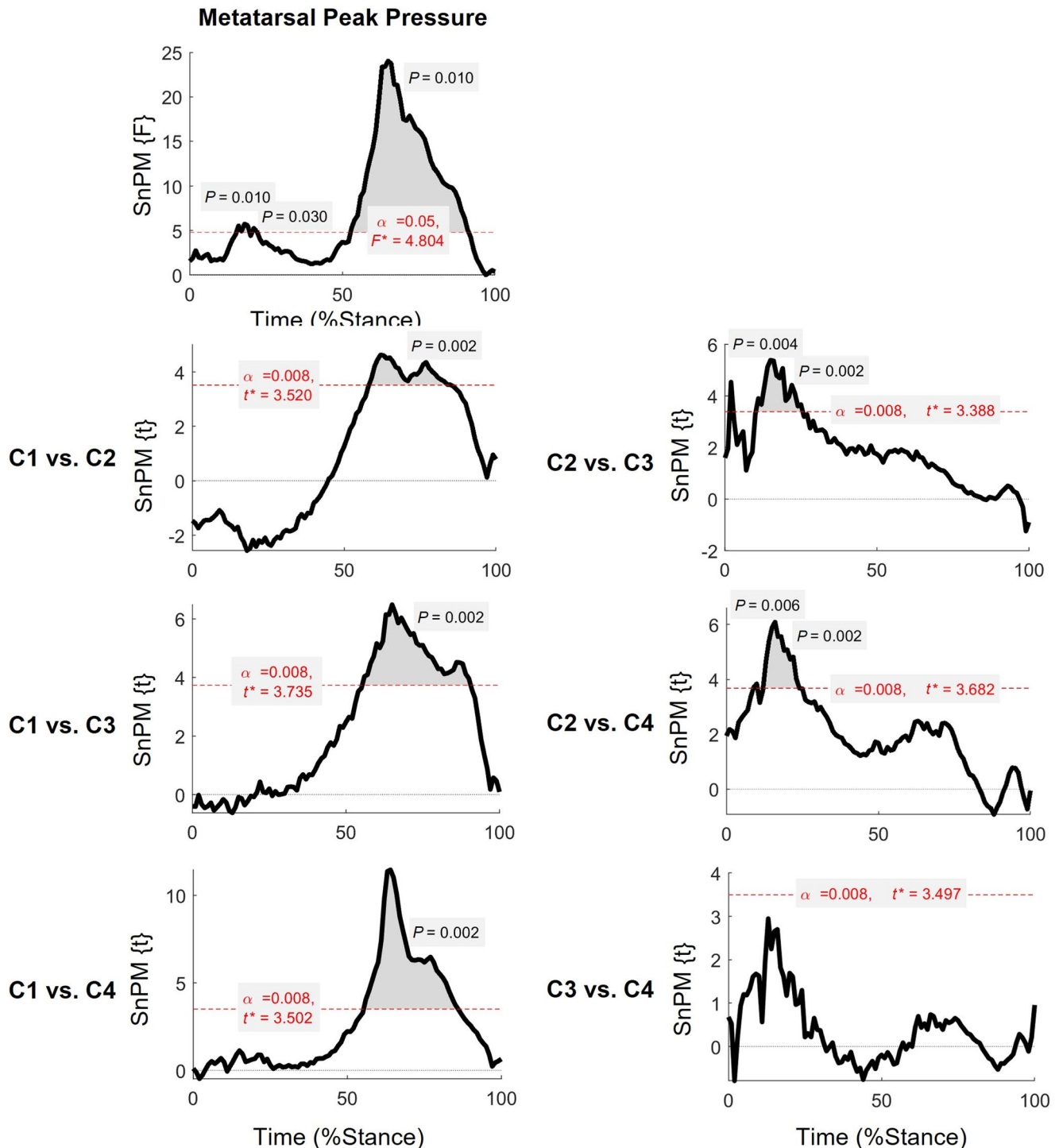


Fig. 5 SPM analysis of metatarsal peak pressure during the stance phase

($P=0.007$). The second cavity side also showed significant reduction in C1 vs. C3 ($P=0.005$), C1 vs. C4 ($P=0.001$) and C2 vs. C4 ($P=0.002$). For swing time, only the first cavity side showed significant difference between C2 and C3 ($P=0.006$), no significance was observed for the other side. Walking speed significantly differed between conditions

($P<0.001$) and post-hoc comparison showed the only significant difference between C1 and C4 ($P=0.007$).

The participants indicated no imbalance feeling (15/15 participants). They also indicated a high score in comfort 4.5 ± 0.5 wearing the prototype insoles, with only a few comments on slight tightness in the footwear (2/15), friction

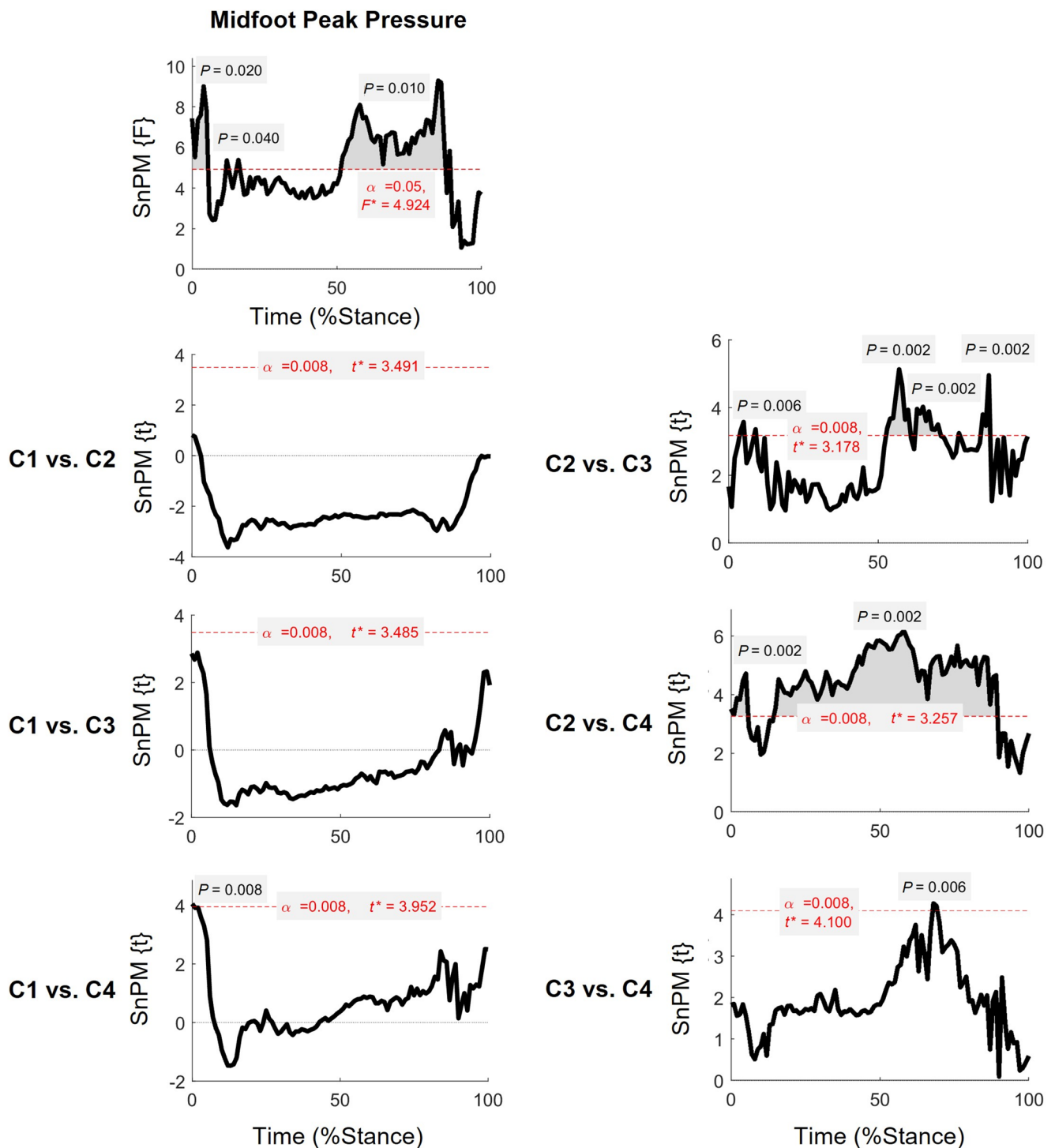


Fig. 6 SPM analysis of midfoot peak pressure during the stance phase

at the front (2/15), lift-up feeling (2/15), and more arch support (1/15).

Discussion

This study examined the offloading technology incorporated into an insole prototype designed for people with corns, calluses, and other painful foot lesions without peripheral neuropathy or active wounds. The focus was on pressure

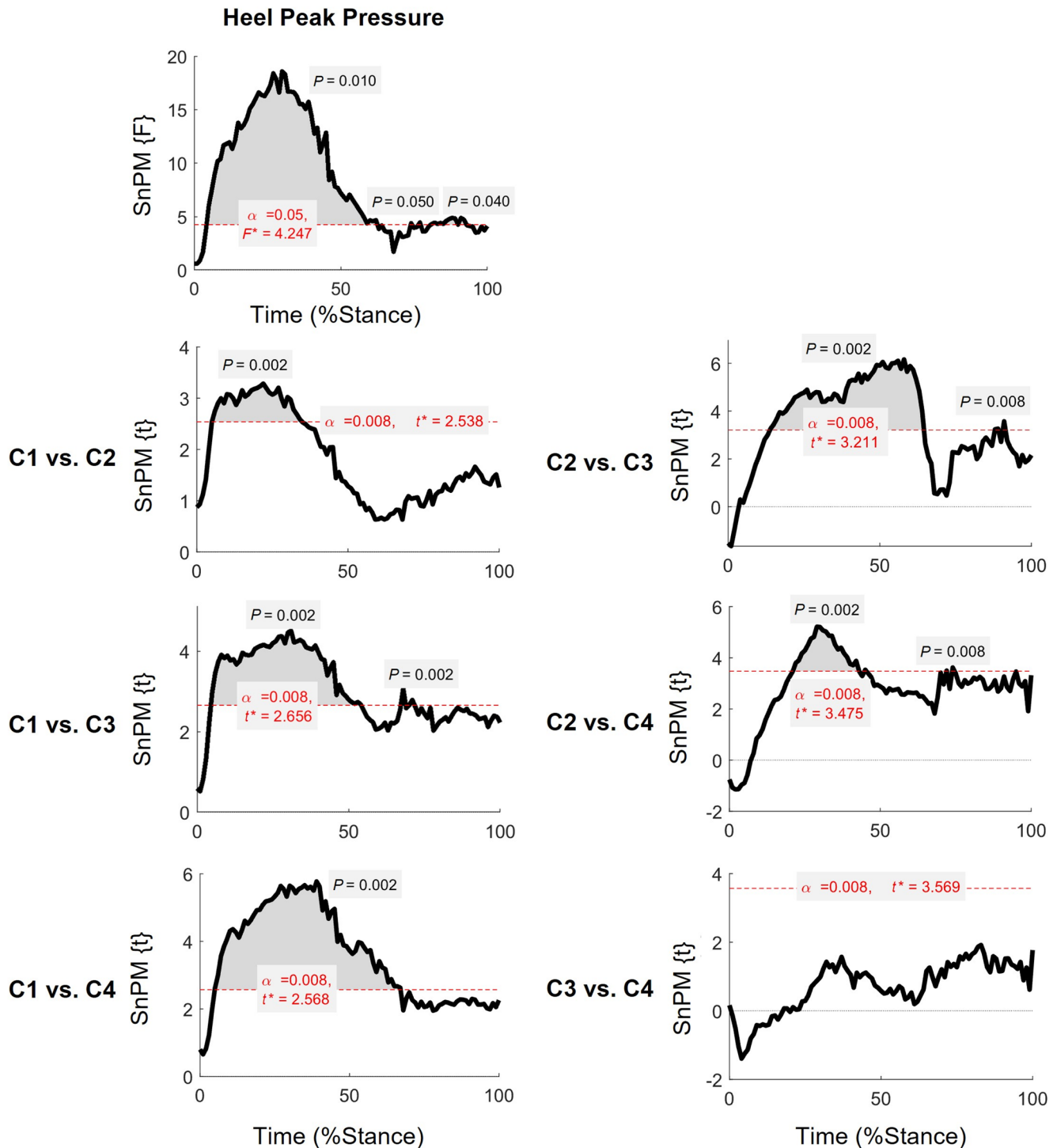


Fig. 7 SPM analysis of heel peak pressure during the stance phase

changes in the target zone as well as across various foot regions. To our knowledge, this is the first study to evaluate pressure offloading in insoles specifically designed for hard corns and calluses.

PP Changes

Overall, most pressure relief was provided by the cushioning effect of the complete prototype insoles, evidenced by an 18%–21% reduction in average PP in the target zone (C2 vs. C1). Creating cavities provided an additional reduction

Table 2 Gait parameters (mean±standard deviation) under all conditions. *p*: significance of repeated measures ANOVA for stance on the first cavity side and gait cycle; significance of Friedman test for the other parameters. Huynh-Feldt correction was used if Mauchly's test of sphericity was significant

Variable	Side	C1	C2	C3	C4	<i>P</i>
Stance (s)	First cavity	0.686±0.072	0.674±0.081	0.663±0.083	0.657±0.072	<0.001*
	Second cavity	0.695±0.099	0.672±0.083	0.662±0.085	0.655±0.076	<0.001*
Swing (s)	First cavity	0.444±0.103	0.417±0.039	0.427±0.038	0.429±0.032	0.014*
	Second cavity	0.447±0.108	0.421±0.034	0.431±0.034	0.430±0.023	0.069
Gait cycle (s)		1.140±0.156	1.092±0.109	1.092±0.113	1.086±0.094	0.113
Symmetry Index (%)		0.946±5.705	−0.253±2.954	−0.216±3.004	−0.444±3.754	0.998
Walking speed (m/s)		1.140±0.142	1.188±0.143	1.200±0.167	1.216±0.144	<0.001*

of approximately 8%–11% (C3 and C4). In total, average PP beneath the second MTP joint was reduced about 28% (C3, C4 vs. C1). This reduction is smaller than that reported in studies evaluating orthotics with removable plugs designed for the diabetic foot. For example, one study reported a significant 32% reduction in average peak pressure after removing the modular plugs [17]. Another study comparing two pressure-relief insoles with removable pixels designed for the diabetic foot reported pressure reduction of approximately 43%–47% under the first MTP joint compared with normal insoles [18], which is larger than our findings. This difference may be partly due to the use of an additional pad beneath the first MTP joint to simulate excessive focal pressure, leading to higher baseline pressure than in our study. Another possible reason is that those offloading devices were designed for neuropathic or diabetic feet, whereas the prototype insoles in the present study were designed for hard corns and calluses; therefore, different materials, thickness, and structural design may have influenced the outcomes.

In the target zone, average PP significantly decreased when cavities were created, but maximum PP showed non-significant decreases, compared with wearing non-cavity prototype insoles. This may be attributed to differences in the shapes of the target zone and the cavity. In this study, the target zone was defined as a square area that encompassed the triangular cavity. Consequently, maximum PP within the target zone may reflect limited edge effects, with some pressure decreases but not to a statistically significant extent. In the broader metatarsal region, maximum PP decreased significantly when wearing prototype insoles and decreased non-significantly with cavities, suggesting that higher pressure was not transferred to adjacent areas surrounding the cavity. This outcome was likely mitigated by the edge design and top layer construction of the prototype insoles, as described in the Introduction section. Although edge effects have been reported as a potential risk to the wound sites [20, 27–29], they are not observed universally. Such edge effects can be minimised through insole design strategies, including the use of soft localised plugs beneath high plantar pressure regions to allow partial tissue penetration without sharp edges [14], as well as graded material stiffness [30].

In the comparative study of two pixelated insole systems by Penny et al., edge effects were observed in the PegAssist system but not in the FORS-15 system [18]. Another study involving healthy participants employed valves to control deformable modular cells and demonstrated a maximum peak pressure reduction of 18%–24% over the target area and 6%–10% around the area with peak pressure 273–607 kPa [15], while avoiding edge effects.

PP changes in the metatarsal region were further examined across the entire stance phase. Notably, in this region, PP reduced significantly with cavities than without between 10% and 25% of the stance phase (Fig. 5), corresponding to foot-flat through mid-stance in gait [31]. This indicates that creating cavities reduced PP across a larger metatarsal region from middle of loading response through the end of mid-stance, occurring earlier than push-off phase during which the maximum PP typically occurs.

Not all participants were able to remove the original insoles from their footwear; therefore, the added thickness of the prototype insoles may have affected the toe-box space and pressure. Increased PP was observed in the toe region when a full pair of prototype insoles were inserted, which may be attributed to increased toe-box tightness. This was also reflected in participant feedback, with two participants reporting friction at the forefoot. However, both C3 and C4 showed significant reductions in toe PP compared with C1 and C2 (Fig. 4), suggesting that the cavities created in the metatarsal region may have allowed the foot to 'sink' into the insole and thereby relieved pressure in the region. Additionally, PP tended to redistribute toward the midfoot in C2 and C3 compared to C1, although these increases were non-significant and substantially smaller than those reported for offloading devices designed for diabetic foot care, which typically produce large increases in midfoot pressure [11]. Interestingly, midfoot PP decreased significantly when cavities were created on both sides. A similar decrease was observed in midfoot force, which may be partly attributable to drift effects associated with the F-Scan system, as total force can decrease over time [32].

Previous studies have demonstrated that plantar pressure increases with body weight [33, 34]. Accordingly, plantar

force during stance phase was normalised to participants' body weight (Fig. 3B), confirming that the observed offloading effects were not due to difference in body weight. Visual inspection of Fig. 3B shows a reduction in the area under the curve from C1 to C4, suggesting mechanical offloading benefits associated with the prototype insoles. Kinematic analysis by Shuang et al. suggested that higher heel strike and toe off velocity contributed to lower pressure time integral [29]. Therefore, the gradual increase in walking speed from C1 to C4 could contribute to the decreasing area under the curve. We also observed that heel PP was significantly reduced after cavities were created. This finding contrasts with Shuang et al. who reported that metatarsal cavities could lead to increased heel peak pressure [29]. One possible explanation is that hollowing out material locally reduces structural stiffness, allowing greater energy absorption during the loading response and consequently reducing the peak pressure.

New Findings

A key novelty of this study is the analysis of PP changes throughout the entire stance phase across multiple foot regions under different plantar surface conditions (with and without prototype insoles, with zero, one or two cavities). The results illustrate how the highest PP transfers from heel to the forefoot over time and demonstrate that significant reductions in metatarsal PP occurred earlier in stance, prior to the timing of maximum PPs. These findings suggest that creating cavities alters the loading response during the gait cycle, contributing to reductions in both metatarsal and heel peak pressures.

This study also evaluated the conditions in which only one cavity was created (C3) and compared it with condition involving two cavities (C4), an approach rarely reported in the literature. Shuang et al. compared unilateral and bilateral heel cavities, and found that bilateral cavities reduced the step width asymmetry measured using treadmill force plates [29]. In contrast, the present study did not find that a single cavity affected gait symmetry, as assessed by the temporal Symmetry Index. Neither the plantar pressure nor subjective perception differed significantly between one- or two-cavity conditions, suggesting that C3 did not induce imbalance in the participants. The pressure differences between sides were also comparable to those reported for healthy control group in another study [35], providing further reassurance that imbalance did not occur. The discrepancy between studies may be due to the location and size; in particular, a large heel cavity may have a greater influence on balance. Furthermore, it is not clear if spatial parameters

are more sensitive than temporal parameters for detecting asymmetry induced by unilateral cavity.

The walking tests combined with user feedback indicated generally positive perceptions of the prototype insoles. Participant responses also provided valuable insights for future design development, such as reducing insole thickness to increase toe-box space. Other crucial aspects for footwear design include materials [36–38] and in-shoe friction and shear forces [39, 40], which should also be considered for the future design.

Limitations

Due to limited resources, standardised footwear could not be provided, so the differences in participants' own footwear may have influenced the results in conditions. The order of the experiment was not randomised, as doing so would have substantially increased the number of prototype insoles required. The fixed order may have contributed to increased walking speed and reduced stance time from C1 to C4, as participants became more familiar with the experimental setup, potentially increase the pressure in the heel and metatarsal regions. In addition, long-term effects were not evaluated in individuals with calluses. Future research should investigate the relationship between cavity area and pressure distribution, as well as the long-term effectiveness of the insoles designed for hard corns and calluses.

Conclusion

The prototype insoles designed for calluses and corns demonstrated immediate effects in offloading focal planar pressure through removal of modular cells showed. This over-the-counter prototype shows promise as a user-customisable solution for managing excessive focal plantar pressure.

Author Contributions YZ designed the study, collected and analysed data, YZ and JL wrote and edited the manuscript. Both authors reviewed and approved the final manuscript.

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Data Availability The data will be made available upon reasonable request.

Declarations

Competing Interests The authors declare no conflict of interest.

Ethical Approval The study was approved by the University of Wales

Trinity Saint David's Research Ethics Committee (ethical approval number EC1051), and all participants had given their written consent forms.

Consent To Publish All participants provided written consent for their data to be used anonymously in scientific publications.

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