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# Effects of Shoe-Stiffening Inserts on Lower Limb Kinematics in Individuals with First Metatarsophalangeal Joint Osteoarthritis

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## **ABSTRACT**

### **Objective**

To examine the effects of shoe-stiffening inserts on lower limb kinematics in individuals with first metatarsophalangeal (MTP) joint osteoarthritis (OA).

### **Methods**

Forty-eight individuals with radiographically confirmed first MTP joint OA (24 males and 24 females; mean age 57.8 years, standard deviation 10.5) were randomized to receive either shoe-stiffening inserts or sham inserts, and underwent gait analysis during level walking using a 10-camera infrared Vicon motion analysis system. Sagittal plane kinematics of the first MTP, ankle, knee, and hip joints were compared between the shoe only (control) and insert conditions in both groups (within-groups) and between both insert conditions (between-groups).

### **Results**

Compared to the shoe only condition, the sham insert reduced knee flexion and total excursion, and the shoe-stiffening insert reduced first MTP joint maximum dorsiflexion and ankle joint maximum plantarflexion, and increased maximum knee flexion and total excursion. Between-group comparisons indicated that the shoe-stiffening inserts significantly decreased first MTP joint maximum dorsiflexion, ankle joint maximum plantarflexion and total excursion, and increased knee joint maximum flexion and total excursion compared to the sham inserts.

### **Conclusion**

Carbon fibre shoe-stiffening inserts significantly alter sagittal plane lower limb joint kinematics during walking, particularly first MTP joint maximum dorsiflexion. These findings provide insights into the mechanisms that may be responsible for their clinical effectiveness in the treatment of first MTP joint OA, and potentially explain changes in symptoms in other lower limb joints.

*Key words:* osteoarthritis; foot; biomechanics, orthoses

### **Significance and Innovations**

- Shoe-stiffening inserts significantly influence kinematics of the lower limb during walking
- Sham inserts have negligible biomechanical effects
- Reduced first MTP joint dorsiflexion with shoe-stiffening inserts may explain their apparent clinical effectiveness in reducing pain associated with first MTP joint OA
- Kinematic changes in the ankle and knee joints were generally small but may reflect compensations to aid propulsion and facilitate shock attenuation

Osteoarthritis (OA) of the first metatarsophalangeal (MTP) joint is a common and disabling condition affecting 8% of individuals aged over 50 years (1). The condition is characterized by pain, stiffness and reduced range of motion in the first MTP joint (2), which leads to difficulty walking and a subsequent reduction in foot-specific and general health-related quality of life (3). Person-level risk factors for first MTP joint OA include increased age, female sex, and lower socio-economic status (1), while at the foot level, increased length and width of the first metatarsal, proximal phalanx and sesamoid bones may also play a role (4). First MTPJ OA is considered to be a progressive disorder, as radiographic severity increases over time (5) and appears to have a cumulative effect on foot symptoms and function (2).

A range of non-surgical interventions are commonly used in the management of first MTP joint OA, including exercise, taping, foot orthoses, rocker-sole footwear and shoe-stiffening inserts (6, 7). Shoe-stiffening inserts are thin, semi-rigid insoles placed inside the shoe with the objective of decreasing dorsal compression within the first MTP joint by reducing the magnitude of dorsiflexion during the propulsive phase of gait (8). Investigation of the biomechanical effects of shoe-stiffening inserts, however, is limited to studies of healthy individuals (9-13) or individuals with midfoot OA (14, 15), and has not been undertaken in those with first MTP joint OA. Furthermore, few studies have examined the effects of shoe-stiffening inserts on the function of proximal joints (10, 12-14), which is an important consideration given that altered gait patterns may be responsible for adverse effects such as knee pain (16).

Therefore, as part of a larger randomized trial that evaluated the effectiveness of shoe-stiffening inserts for the treatment of first MTP joint OA (17, 18), we conducted a nested biomechanical study to examine the effects of shoe-stiffening inserts and sham inserts on sagittal plane kinematics of the first MTP, ankle, knee and hip joints.

## **METHODS**

### **Participants**

Participants for this study were drawn from a randomized trial that evaluated the effectiveness of shoe-stiffening inserts for first MTP joint OA, the details of which have been published previously (17, 18). The relevant elements of the protocol are briefly summarized below. To be included in the study, participants needed to be aged 18 years of age or older, have pain in the first MTP joint

on most days for at least 12 weeks, rated at least 30 mm on a 100 mm visual analogue scale, have pain upon palpation of the dorsal aspect of the first MTP joint, have restricted first MTP joint dorsiflexion (less than 64° of dorsiflexion range of motion) and be able to walk household distances without the use of a walking aid. Participants were excluded if they had previous first MTP joint surgery, were currently pregnant, had hallux valgus, a systemic inflammatory condition, or cognitive impairment. The La Trobe University Human Ethics Committee provided ethical approval (number HEC15-128) and written informed consent was obtained from all participants.

### **Clinical and Radiographic Assessment**

Clinical features associated with first MTP joint OA (pain on palpation, dorsal exostosis, joint effusion, pain on motion, hard-end feel and crepitus) and passive, non-weightbearing first MTP joint dorsiflexion range of motion were documented using established techniques (19). The presence of radiographic first MTP joint OA was determined using the La Trobe University radiographic atlas, which incorporates weightbearing dorso-plantar and lateral radiographs to document the presence of OA based on observations of osteophytes and joint space narrowing (20).

### **Biomechanical Assessment**

Biomechanical assessment was performed to evaluate kinematics of the first MTP, ankle, knee and hip joints during level walking at self-selected speed. We limited our analysis to the sagittal plane, as (i) decreasing first MTP joint dorsiflexion is the proposed mechanism of action of shoe-stiffening inserts, (ii) it is unlikely that movements in coronal and transverse planes would be large enough to surpass error related to skin movement, and (iii) to minimize the likelihood of false positive findings. A 10-camera infrared motion analysis system (Vicon Motion Systems Ltd, UK) collected trajectory data from 38 passive reflective markers attached to the lower limb and foot based on the Salford foot model (21), the Helen Hayes marker set (22, 23), and a customized model to allow for segmental definition and functional joint calibration (24). Participants were equipped with standardized footwear customized with cut-outs in order to allow visualisation of the foot markers and avoid any alteration in marker placement between testing conditions. Marker trajectories were collected at a frequency of 100 Hz, and for the purposes of this study all lower

limb joint kinematics were calculated using the Conventional Gait Model (24) and Salford Foot Model (21), based on Euler angles and described in terms of movement of the distal segment relative to the proximal segment. It was necessary to modify the Salford Foot Model as it was originally designed for barefoot analysis and in our study, participants needed to be shod to accommodate the shoe-stiffening inserts. To achieve this, we removed the lateral forefoot and midfoot markers, which precluded any measurement of midfoot motion. The minimum and maximum angles throughout the stance phase of gait were averaged from the middle stride of six 10-metre walking trials. The total excursion of each joint was calculated by subtracting the minimum angle from the maximum angle. Temporospatial parameters (velocity, stride length and cadence) were also calculated.

### **Interventions**

Participants were randomly allocated to receive either shoe-stiffening inserts or sham inserts (a single insert if symptoms were unilateral, or a pair of inserts if symptoms were bilateral). The shoe-stiffening inserts (Carbon Fibre Spring Plate, Paris Orthotics Ltd, Vancouver, BC, Canada) weighed 32 to 48 grams across the size range, were 1.5 mm thick, and covered with 3.2 mm foam (PPT<sup>®</sup> 2 809 Blue with an Ultralux top layer, Langer Biomechanics, USA). A full-length piece of nylon woven textile covering (Cambrelle<sup>®</sup>, Camtex Fabrics Ltd, UK) was applied to the underside of the insert to make its appearance similar to the sham insert. The sham inserts were designed to not affect first MTP joint dorsiflexion. To achieve this, the distal portion was removed so that the anterior edge finished at the anterior margin of the heel. As with the inserts provided to the intervention group, the sham inserts were covered with a full-length layer of the same 3.2 mm foam, and a full-length piece of the same nylon woven textile covering was applied to the underside of the insert. See Figure 1. Mechanical testing of the sham insert confirmed that it had a negligible effect on shoe bending stiffness (17). Participants were tested under two conditions: the shoe only (control) condition and their allocated insert condition (i.e. either sham or shoe-stiffening insert).

### **Statistical Analysis**

Statistical analysis was undertaken using IBM SPSS Statistics version 26.0 (IBM Corp, NY, USA). All data were explored for normality and none required transformation. To evaluate the

effects of the interventions (i.e. sham inserts and shoe-stiffening inserts) compared to the shoe only (control) condition, a series of within-group paired *t*-tests were conducted. To directly compare the effects of shoe-stiffening inserts and sham inserts, between-group analyses of covariance were conducted with the intervention group and shoe only condition scores entered as independent variables (25). The effect size for within-group comparisons was calculated using Cohen's *d*, and the following interpretation of effect size was used: negligible (< 0.15), small (0.15 to 0.40), medium (>0.40 to 0.75), large (>0.75 to 1.10) and very large (>1.10) (26). Adjusted mean differences and 95% confidence intervals (CIs) were calculated for between-group comparisons.

## **RESULTS**

### **Participants**

One hundred participants (45 men and 55 women, age 24 to 82 years, mean 57.5 [SD 10.3]) were recruited for the randomized trial (18). Of these, 54 participants consented to biomechanical analysis, and complete data were available for 48 participants (24 males and 24 females).

Characteristics of these participants are reported in Table 1.

### **Effects of Inserts on Lower Limb Kinematics**

Lower limb kinematic data for the sham insert and shoe stiffening insert groups are shown in Figures 2 and 3. Within- and between-group effects of sham inserts and shoe-stiffening inserts on temporospatial parameters (velocity, stride length and cadence) and lower limb kinematics are shown in Table 2. There were no within- or between-group differences for the temporospatial parameters. Compared to the shoe only condition, the sham inserts had no effect on first MTP, ankle or hip joint kinematics, but resulted in a significant decrease in knee joint maximum flexion (mean difference 1.2 degrees,  $d=0.16$ ; small effect) and total excursion (1.0 degree,  $d=0.04$ ; negligible effect). In contrast, the shoe-stiffening inserts led to a significant decrease in first MTP maximum dorsiflexion (3.8 degrees,  $d=0.57$ ; medium effect), ankle joint maximum plantarflexion (2.4 degrees,  $d=0.46$ ; medium effect), ankle joint total excursion (2.8 degrees,  $d=0.68$ ; medium effect) and an increase in knee joint maximum flexion (2.0 degrees,  $d=0.37$ ; small effect) and knee joint total excursion (2.8 degrees,  $d=0.29$ ; small effect). Between-group comparisons indicated that after adjusting for the shoe only condition, the shoe-stiffening inserts significantly decreased first MTP joint maximum dorsiflexion (3.2 degrees), ankle joint maximum plantarflexion (1.8



degrees) and total excursion (2.1 degrees), and increased knee joint maximum flexion (3.2 degrees) and total excursion (3.2 degrees) compared to the sham insert group.

## **DISCUSSION**

The objective of this study was to examine the effects of shoe-stiffening inserts on the sagittal plane kinematics of the first MTP, ankle, knee and hip joints during walking in individuals with first MTP joint OA. We found that the shoe-stiffening inserts significantly decreased first MTP joint maximum dorsiflexion, ankle joint maximum plantarflexion and total excursion, and increased knee joint maximum flexion and total excursion compared to the sham inserts. These findings provide evidence to support the proposed mechanism by which shoe-stiffening inserts are thought to be effective at reducing symptoms in individuals with first MTP joint OA and provide insights into how the inserts may influence the function of joints proximal to the foot when walking.

A key methodological feature of the randomized trial from which this study was derived was the use of a sham insert in the control group. The use of sham inserts in clinical trials of footwear interventions is necessary to account for contextual effects and to minimize performance bias and resentful demoralisation (27). However, it is important that the sham device be as biomechanically 'inert' as possible (28). To achieve this, we designed the sham insert so the carbon fibre component did not extend beyond the heel to avoid any influence on the first MTP joint, and previous bench tests indicated that it had no effect on shoe bending stiffness (17). The results reported here further support the lack of effect of the sham insert and demonstrate that it had no significant effect on first MTP, ankle or hip joint kinematics. At the knee, the sham insert resulted in a decrease in maximum flexion and total excursion, although the magnitude of these effects was very small (1.0 and 1.2 degrees, respectively) and unlikely to be functionally significant.

In contrast, the shoe-stiffening insert resulted in significant reductions in first MTP joint maximum dorsiflexion, ankle joint maximum plantarflexion and total excursion, and increased knee joint maximum flexion and total excursion compared to the sham insert group. The effect size of these changes was medium for the first MTP and ankle joints, and small for the knee. The observed effect of the shoe-stiffening insert on first MTP kinematics is similar to Rao et al (15), who reported a 3 degree reduction in first MTP range of motion with the use of a full-length carbon

fibre insert in individuals with midfoot OA, and Lin et al (9), who reported that the addition of a carbon fibre insert to standard footwear resulted in a 4 degree reduction in maximum first MTP joint dorsiflexion in healthy individuals.

The reduction in first MTP joint dorsiflexion while wearing the shoe-stiffening inserts provides a plausible explanation for their clinical effectiveness (18). First MTP joint OA is characterized by localized pain and stiffness that is most commonly experienced during walking, and on clinical examination, there is typically a hard end-feel when the joint is fully dorsiflexed (19). Osteophyte formation most commonly occurs on the dorsal aspect of the first metatarsal and proximal phalanx, which is thought to result from increased compression during propulsion (29). By limiting maximum first MTP joint dorsiflexion, shoe-stiffening inserts may reduce compressive forces within the joint, thereby alleviating symptoms.

In addition to evaluating the effect of shoe-stiffening inserts on the first MTP joint, we also examined the effects on the ankle, knee and hip joints. The effects of shoe-stiffening inserts on proximal joints may represent compensations to enable bodyweight to progress over the foot during propulsion in the presence of limited first MTP joint dorsiflexion. From heel lift until toe-off, the first MTP joint dorsiflexes as the ankle joint plantarflexes, and this synergistic pattern of movement allows the body to progress forwards over the stationary foot (21). Our observation of decreased ankle joint plantarflexion during propulsion when the shoe-stiffening insert was worn is similar to the findings of Hall and Nester (10), Zhang et al (12) and Takahashi et al (13) who noted that the ankle joint was less plantarflexed during propulsion when healthy participants wore stiff insoles designed to limit first MTP joint motion.

At the knee, we found that maximum flexion in stance phase increased when the shoe-stiffening inserts were worn. Hall and Nester (10), Zhang et al (12) and Takahashi et al (13) made similar observations in healthy participants, with Hall and Nester (10) suggesting that increased knee flexion may be a consequence of increased tension in the gastrocnemius muscle caused by increased ankle joint dorsiflexion. However, as we did not observe any increase in ankle joint dorsiflexion during midstance – the point in the gait cycle at which maximum knee flexion occurs – this suggestion cannot explain our findings. It is possible that the increased knee flexion acts to facilitate shock attenuation, as previous studies have shown that ground reaction forces are higher when wearing shoes with harder soles (30), and increasing knee flexion results in greater impact

attenuation (31). Whether this increase in knee flexion is detrimental is difficult to determine, although it is worth noting that several studies have shown that knee symptoms can be influenced by biomechanical changes induced by footwear interventions (32, 33) and that knee pain is one of the most common adverse effects of shoe-stiffening inserts (16).

We did not observe any effects of the shoe-stiffening inserts on hip joint kinematics. Reduced hip extension while wearing shoe-stiffening inserts has been observed in two previous studies of healthy, young, asymptomatic participants (10, 12). Our trial included relatively older participants (mean age 57.5 years) with symptomatic radiographic first MTP joint OA, so it is likely that variation in responses to the shoe-stiffening inserts can be at least partly attributed to these differences in study populations.

This study has several methodological strengths, including radiographic confirmation of first MTP joint OA, a relatively large sample size for this type of study, and the use of a sham insert as the comparator. However, the results of the study should be interpreted with respect to four key limitations. Firstly, as participants needed to be tested while shod, we used a simplified version of the Salford Foot Model (21), which precluded any analysis of the motion of the midfoot and rearfoot, and we limited our kinematic analysis to the sagittal plane. Secondly, the Conventional Gait Model relies on marker placement to define the joint centres, however, to minimize this error, all marker placements were completed by a single assessor experienced in motion analysis of clinical populations, and markers were not removed between conditions. Thirdly, we only assessed the immediate effects of the inserts, and although participants were allowed a brief familiarisation period, it is possible that their response to wearing the inserts may change over time. Finally, it is unclear as to whether the observed biomechanical changes are clinically meaningful.

In conclusion, this study has demonstrated that carbon fibre shoe-stiffening inserts significantly alter sagittal plane kinematics of the first MTP and knee joints during walking. These findings provide insights into the underlying mechanisms that may be responsible for the reported clinical effectiveness of this treatment in individuals with first MTP joint OA, although further evaluation of the main randomized trial from which this study was derived will provide additional insights into the relationship between these biomechanical changes and clinical outcomes. These findings may also partly explain reported changes in symptoms at more proximal lower limb joints when carbon fibre shoe-stiffening inserts are prescribed.

## **COMPETING INTERESTS**

None of the authors has a competing interest to declare.

## **AUTHOR CONTRIBUTIONS**

All authors were involved in drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be submitted for publication.

*Study conception and design:* McClelland, Menz, Munteanu, Landorf, Cicuttini, Roddy.

*Acquisition of data:* McClelland, Allan, Auhl, Buldt.

*Analysis and interpretation of data:* McClelland, Menz, Allan, Buldt, Munteanu.

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## FIGURE CAPTIONS

**Figure 1.** Sham inserts and carbon-fibre shoe-stiffening inserts used in the study. In the bottom images, thin dark lines represent textile covering, thick blue bar represents foam top cover, and thick dark bar represents semi-rigid carbon fibre plate.

**Figure 2.** Sagittal plane kinematics of the first MTP, ankle, knee and hip joints in the sham insert group (mean  $\pm$  standard deviation). Blue lines indicate shoe-only condition, dashed red lines indicate insert condition.

**Figure 3.** Sagittal plane kinematics of the first MTP, ankle, knee and hip joints in the shoe-stiffening insert group (mean  $\pm$  standard deviation). Blue lines indicate shoe-only condition, dashed red lines indicate insert condition.

**Table 1.** Participant characteristics. Values are mean (SD) unless otherwise noted.

	Sham insert group (n=23)	Shoe-stiffening insert group (n=25)
Demographics and anthropometrics		
Age – years	57.2 (11.4)	58.4 (9.8)
Female – n (%)	13 (56.5)	11 (44.0)
Height – cm	169.19 (9.0)	167.1 (7.7)
Weight – kg	79.6 (12.1)	80.4 (16.2)
Body mass index – kg/m <sup>2</sup>	27.9 (3.9)	28.8 (5.2)
Clinical features		
Passive NWB first MTP joint maximum dorsiflexion – degrees	45.0 (11.1)	45.2 (10.7)
Pain on palpation – n (%)	23 (100)	25 (100)
Palpable dorsal exostosis – n (%)	23 (100)	25 (100)
Pain on motion of first MTP joint – n (%)	18 (78.3)	17 (68.0)
Hard-end feel when dorsiflexed – n (%)	21 (91.3)	23 (92.0)
Crepitus – n (%)	6 (26.1)	10 (40.0)
Radiographic features – n (%)*		
Dorsal osteophytes	20 (95.2)	24 (96.0)
Dorsal joint space narrowing	20 (95.2)	23 (92.0)
Lateral osteophytes	20 (95.2)	24 (96.0)
Lateral joint space narrowing	19 (90.5)	23 (92.0)
Radiographic first MTP joint OA†	19 (90.5)	23 (92.0)

NWB: non-weightbearing

MTP: metatarsophalangeal

\* score >0 using La Trobe Radiographic Atlas (20)

† at least one score of 2 for osteophytes or joint space narrowing from either view, using case definition from La Trobe Radiographic Atlas (20)

**Table 2.** Effects of sham inserts and shoe-stiffening inserts on lower limb kinematics. Values are mean (SD) unless otherwise noted.

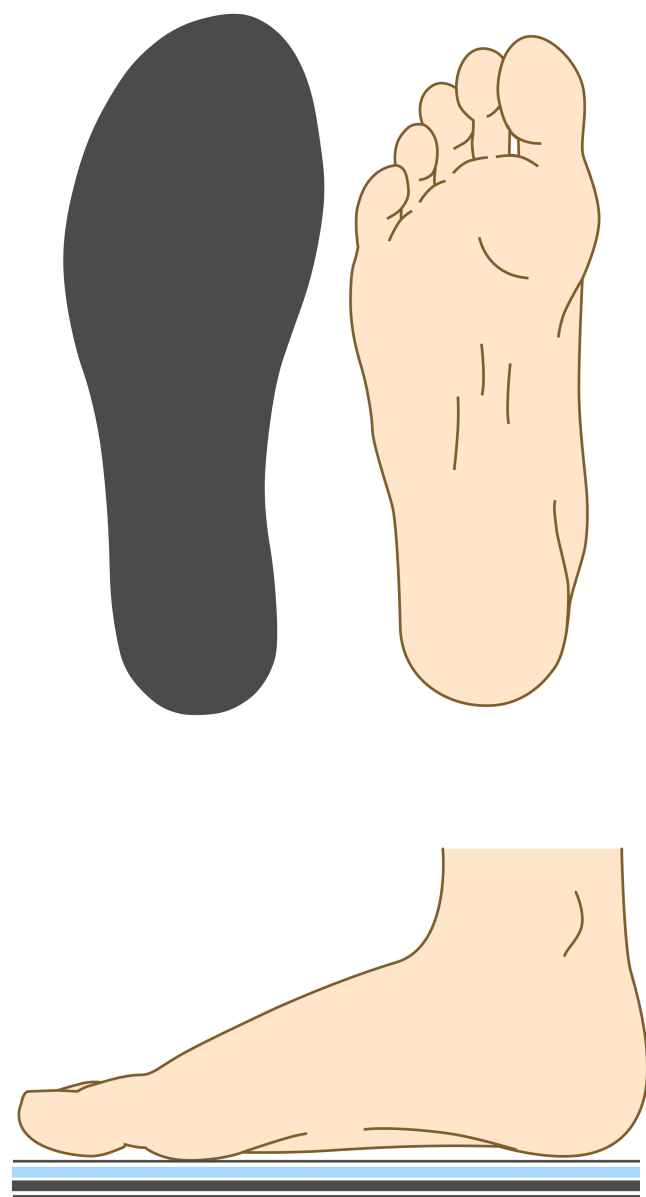
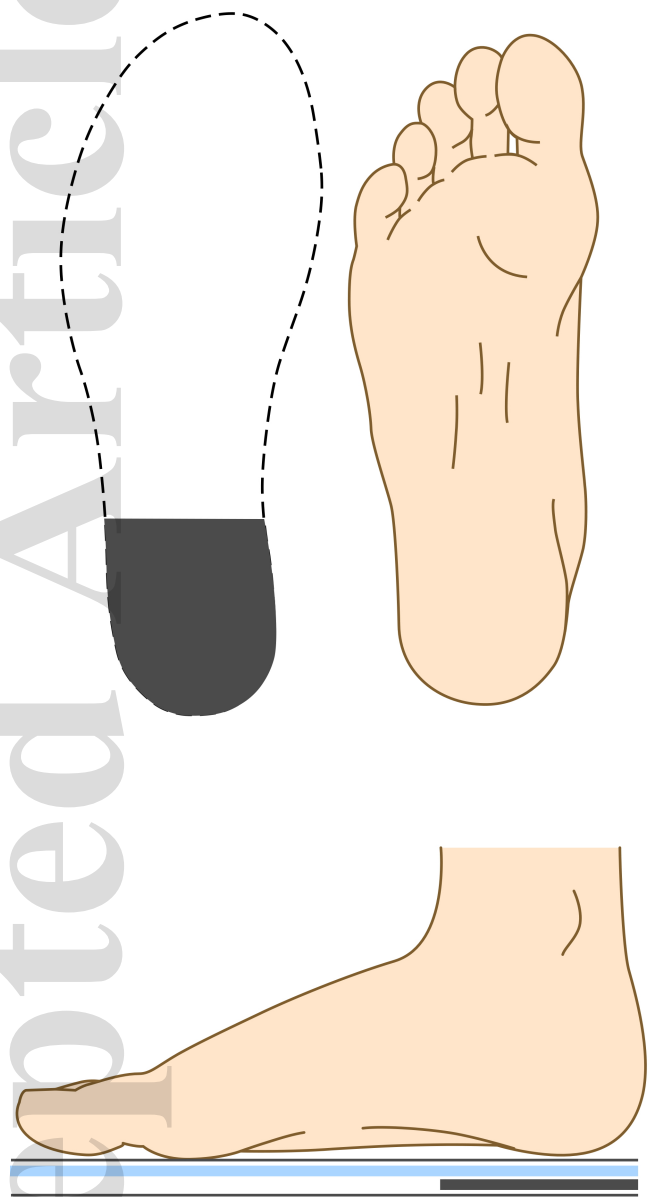
	Within-group comparisons								Between-group comparisons	
	Sham insert group (n=23)				Shoe-stiffening insert group (n=25)					
	Shoe only	Shoe + insert	<i>p</i>	<i>d</i>	Shoe only	Shoe + insert	<i>p</i>	<i>d</i>	MD (95% CI)	<i>p</i>
Temporospatial parameters										
Velocity (m/s)	1.33 (0.16)	1.28 (0.15)	0.112	0.33	1.35 (0.23)	1.36 (0.22)	0.658	0.05	0.06 (0.00, 0.13)	0.056
Stride length (m)	1.40 (0.13)	1.36 (0.17)	0.242	0.27	1.38 (0.19)	1.40 (0.18)	0.273	0.11	0.06 (-0.02, 0.14)	0.132
Cadence (steps/min)	113.2 (7.4)	111.1 (9.2)	0.316	0.27	115.1 (8.8)	114.3 (8.4)	0.443	0.10	2.02 (-2.28, 6.33)	0.348
Kinematics (degrees)										
First MTP joint										
Maximum dorsiflexion	25.12 (6.27)	24.62 (5.90)	0.238	0.08	25.65 (7.21)	21.89 (6.11)	<0.001	0.57	-3.15 (-4.84, 1.46)	<0.001
Ankle joint										
Maximum plantarflexion	-6.79 (4.91)	-6.30 (4.94)	0.135	0.10	-7.70 (5.78)	-5.27 (4.87)	<0.001	0.46	1.79 (0.63, 2.96)	0.003
Maximum dorsiflexion	15.61 (3.98)	15.49 (3.90)	0.495	0.03	15.58 (3.09)	15.13 (3.16)	0.052	0.15	-0.32 (-0.89, 0.26)	0.271
Total excursion	22.36 (3.96)	21.81 (3.88)	0.063	0.14	23.19 (4.87)	20.39 (3.47)	<0.001	0.68	-2.05 (-2.95, -1.15)	<0.001
Knee joint										
Maximum extension	-0.36 (5.39)	-0.47 (5.05)	0.570	0.02	-1.06 (5.69)	-1.06 (5.34)	0.995	0.00	0.06 (-0.56, 0.68)	0.845
Maximum flexion	35.61 (7.48)	34.46 (7.37)	0.001	0.16	35.69 (5.62)	37.73 (5.54)	<0.001	0.37	3.20 (2.03, 4.37)	<0.001
Total excursion	35.88 (5.50)	34.84 (5.04)	0.006	0.04	36.71 (7.21)	38.74 (7.05)	<0.001	0.29	3.15 (2.02, 4.27)	<0.001
Hip joint										
Maximum extension	-13.22 (7.39)	-13.04 (7.08)	0.394	0.03	-	-	0.437	0.02	-0.32 (-0.82, 0.19)	0.213
					13.50 (7.34)	13.63 (7.22)				
Maximum flexion	34.50 (7.54)	34.40 (7.08)	0.749	0.01	33.91 (6.76)	33.83 (6.62)	0.632	0.01	-0.02 (-0.69, 0.64)	0.949
Total excursion	47.69 (4.73)	47.39 (4.32)	0.194	0.07	47.41 (5.76)	47.42 (5.58)	0.927	0.00	0.30 (-0.26, 0.86)	0.292

*d*: Effect size (Cohen's *d*)

MD: mean difference between groups, adjusted for shoe only (control) condition

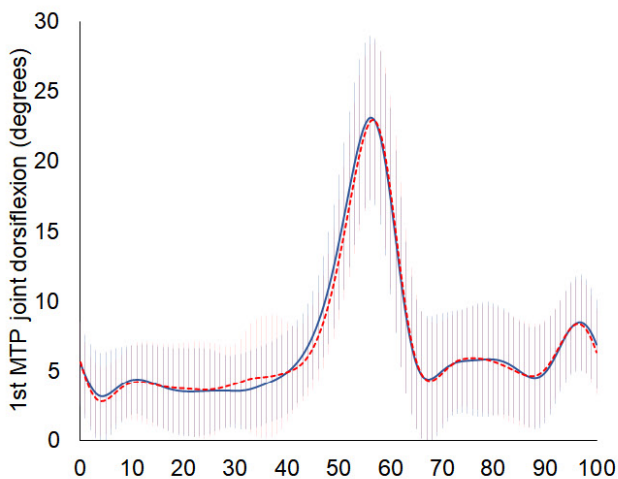
sham insert

shoe-stiffening insert

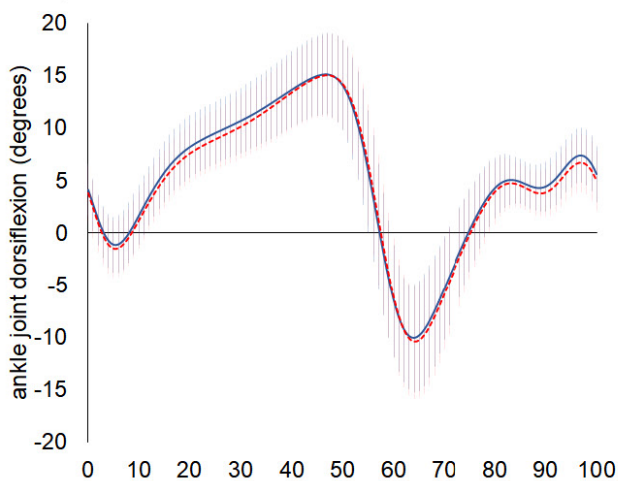


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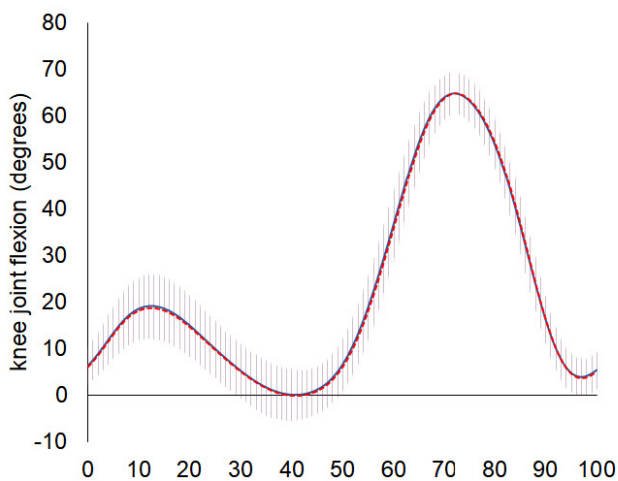
First MTP joint



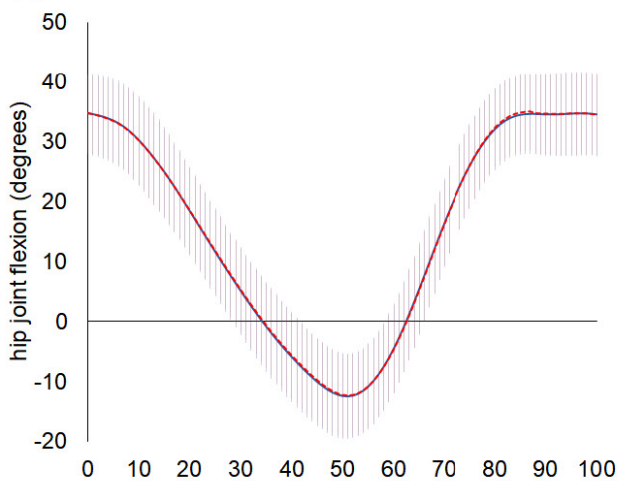
Ankle joint



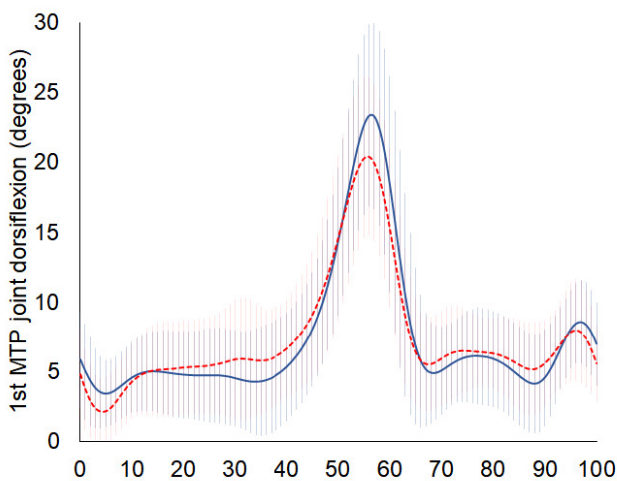
Knee joint



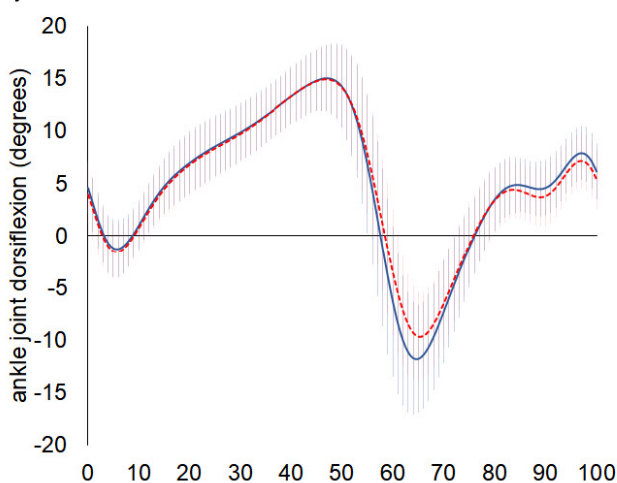
Hip joint



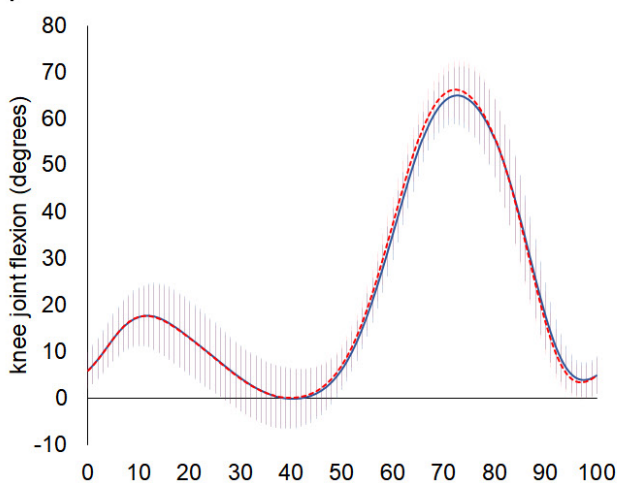
First MTP joint



Ankle joint



Knee joint



Hip joint

