Title: Effect of 3D printed foot orthoses stiffness and design on foot kinematics and plantar pressures in healthy people

Abstract

Background: Foot orthoses (FOs) have been widely prescribed to alter various lower limb disorders. FOs' geometrical design and material properties have been shown to influence their impact on foot biomechanics. New technologies such as 3D printing provide the potential to produce custom shapes and add functionalities to FOs by adding extra-components.

Research question: The purpose of this study was to determine the effect of 3D printed FOs stiffness and newly design postings on foot kinematics and plantar pressures in healthy people.

Methods: Two pairs of ¾ length prefabricated 3D printed FOs were administered to 15 healthy participants with normal foot posture. FOs were of different stiffness and were designed so that extra-components, innovative flat postings, could be inserted at the rearfoot. In-shoe multi-segment foot kinematics as well as plantar pressures were recorded while participants walked on a treadmill. One-way ANOVAs using statistical non-parametric mapping were performed to estimate the effect of FOs stiffness and then the addition of postings during the stance phase of walking.

Results: Increasing FOs stiffness altered frontal and transverse plane foot kinematics, especially by further reducing rearfoot eversion and increasing the rearfoot abduction. Postings had notable effect on rearfoot frontal plane kinematics, by enhancing FOs effect. Looking at plantar pressures, wearing FOs was associated with a shift of the loads from the rearfoot to the midfoot region. Higher peak pressures under the rearfoot and midfoot (up to +31.7%) were also observed when increasing the stiffness of the FOs.

Significance: 3D printing techniques offer a wide range of possibilities in terms of material properties and design, providing clinicians the opportunity to administer FOs that could be modulated according to pathologies as well as during the treatment by adding extra-components. Further studies including people presenting musculoskeletal disorders are required.

Keywords: Foot orthoses; 3D printing; Foot kinematics; Plantar pressures; Gait

1. Introduction

Foot orthoses (FOs) have been widely used as an intervening device to prevent and/or manage various foot and lower limb disorders [1,2]. Acting as an interface between the footwear and the foot, FOs help to improve feet and lower limb function. In healthy subjects, FOs have been shown to act on various biomechanical lower limb variables such as kinematics, kinetics, muscle activity or plantar pressures [3-5]. For people suffering from lower limb musculoskeletal disorders, changes induced by wearing a FO can result in positive outcomes and symptom relief [2,6,7]. As each pathology induces different and specific needs, a variety of designs and materials have been used in the fabrication of FOs.

Geometrical modifications, such as posting or arch support, are common in FOs design to address different musculoskeletal disorders. A recent systematic review and meta-analysis focusing on healthy individuals [8] showed that despite the heterogeneity between studies, gait features are altered in a different way based on FOs geometrical design. Moreover, the degree of modification induces different changes in lower limb kinematics and kinetics. Indeed, Telfer et al. [3] reported that a dose-response effect exists between the level of posting and the ankle and knee joint biomechanics. Thus, a higher medially posted device was associated with a lower rearfoot eversion and a greater knee adduction moment in both control and flatfeet subjects. Similarly, a dose-response effect to plantar pressures has been found when altering the degree of posting inclination [9]. Besides the geometrical design, various materials, with different mechanical properties, have been used for the construction of FOs through traditional techniques. Material density has been shown to affect plantar pressures, a softer material resulting in reduced peak pressures and increased contact areas [10]. Yet, only little effects have been reported on lower limb kinematics [11]. Furthermore, custom-made FOs may be more effective than prefabricated ones in the correction of foot posture [12]. Although not the subject of this study, clinical outcomes between custom and prefabricated FOs might not differ [13]. In addition, customize FOs is a time consuming and expensive process that can make clinicians choose prefabricated over customized FOs [14].

New technologies like 3D printing have facilitated the production of innovative custom shapes and geometries in accordance with patient-specific needs, which was hardly feasible using traditional fabrication techniques. Further, 3D printing aims at reducing the costs and production time, and increasing the mass customization. In addition, it becomes possible to add functionalities to FOs by inserting extra-components that provide new features or by modifying the internal geometry of some areas in order to change the intrinsic properties of the device [15,16]. Although 3D printed FOs have been shown to alter lower limb biomechanics [3,17], little is known on the influence of their stiffness and of the addition of extra-components.

The aim of this study was to evaluate the effect of the stiffness and the addition of innovative extra-components in 3D printed FOs on foot kinematics and plantar pressures during gait in participants with normal foot posture.

2. Methods

2.1. Participants

Fifteen males with normal foot posture (age: 24.9±4.9 years, height: 176.4±4.2 cm, body mass: 75.5±7.4 kg, shoe size: 9.5-10 US) gave their written informed consent to participate in the study. Participants were free from any limb injury at the time of testing and had no known history of foot pathologies or structural abnormalities. All testing procedures were approved by the institution ethics committee (17-145-CERES-D).

2.2. Foot orthoses

Two pairs of standardized contoured ¾ length FOs, named flexible and rigid for the purpose of this study, were designed using SpecifX (Shapeshift3D, CA) based on a 3D surface scan of a size 10 US foot shape representing an average of 2,000 European male feet. The FOs had a countered medial arch, heel and lateral arch, and consisted of a 1.5 mm thick plate superimposed to honeycombs (Fig. 1). Two different stiffness were reached by changing the height of the honeycomb cells, the rigid FOs having higher honeycombs and being stiffer, *i.e.* less deformable (see Fig. S1 in Supplementary Material). In addition, FOs were designed so that two extra-components (*i.e.*, posting), named medial and mediolateral, could be inserted under FOs heel (Fig. 1). Contrary to commonly used postings, designed to incline the orthotic, ours were flat and 4 mm thick. Hence, adding a posting to the FOs induced an elevation of 2 mm at the heel. Both FOs and postings were 3D printed in Nylon 12 using Selective Laser Sintering technology. Participants were presented a total of five conditions: (i) shoe only, referred as the control, (ii) flexible FOs, (iii) flexible FOs with medial posting, (iv) flexible FOs with mediolateral posting, and (v) rigid FOs.

2.3. Experimental procedures

Prior to data collection, a static trial was acquired to locate joint centres and personalize a multibody kinematic model. Participants were first asked to walk 5-min on a treadmill at a comfortable speed for acclimation and establish the speed for the following measurements. Then, each participant walked for 3-min at his predetermined speed under each condition. To avoid fatigue effects, a rest period of approximately 5-min was given between the conditions. Participants were blinded to the conditions being tested and the order was randomized.

2.4. Data collection

An 18-camera motion capture system (VICON, UK) at 100 Hz was used to record the participants' dominant foot kinematics during gait. For this purpose, a multi-segment foot model, according to the marker placement protocol of the Instituto Ortopedico Rizzoli, was used to track shank, rearfoot, midfoot and forefoot motion [18]. All participants wore neutral running shoes (860 v8, New Balance, USA) in which ⌀2.5-cm circular holes [19] were made to allow reflective markers to be directly placed on the feet. Pen marks were made on the skin to ensure accurate marker reapplication each time FOs were changed. In-shoe plantar pressures were measured using the Medilogic Flex-Sohle plantar pressure system (T&T Medilogic Medizintechnik GmbH, Germany) at 400 Hz. Plantar pressure insoles were placed between the foot and FOs. Foot kinematics was recorded for all five conditions, while plantar pressures were only recorded during the conditions without postings. Kinematic and plantar pressure data were recorded during the last 30-s of each trial to allow participants familiarize to each condition.

2.5. Data processing and statistical analysis

All data analyses were performed using Matlab software (R2018a, The Mathworks, USA). Inter-segment joint angles were computed according to the Rizzoli foot model [18]. Motion of the rearfoot with respect to the shank, the midfoot with respect to the rearfoot and the forefoot with respect to the midfoot were calculated. Joint centre of rotations were defined based on body landmarks: Shank-Rearfoot (midpoint between malleoli), Rearfoot-Midfoot (midpoint between the cuboid and the navicular bone) and Midfoot-Forefoot (base of the second metatarsal). Generalized joint coordinates were estimated using an extended Kalman filter algorithm [20]. Kinematic data were normalized from 0 to 100% of the stance phase (heel strike to toe-off) using the foot velocity algorithm [21].

Plantar pressure was analyzed by dividing the contact area of the foot into seven regions corresponding to anatomically relevant areas of the foot, namely the medial and lateral rearfoot, medial and lateral midfoot, and medial, central and lateral forefoot (see Fig. S2 in Supplementary Material). Data were normalized from 0 to 100% of the stance phase using a force detection algorithm with a 10% force threshold [22]. Peak pressure (N/cm^2), mean pressure (N/cm^2) and contact area (cm^2) were reported for each region during the stance phase.

Curve analyses were conducted using one-dimensional Statistical non-Parametric Mapping (SnPM) code (www.spm1d.org) [23]., Non-parametric tests were used as the d'Agostino-Pearson K2 test revealed that the data were not normally distributed. SnPM one-way ANOVAs, with a significance level set at $\alpha=0.05$, were performed to test the effect of FOs stiffness on foot kinematics and plantar pressures. SnPM one-way ANOVAs were also performed to estimate the effect of the addition of rearfoot postings on foot kinematics. SnPM *post-hoc* *t*-tests with Bonferroni correction (0.05/3=0.0167) were used for multiple comparisons. Cohen's d effect sizes (ES) were computed over the entire stance phase per *post-hoc* comparison.

3. Results

ANOVAs and *post-hoc* analyses (Fig. 2) relative to foot kinematics indicated differences in rotation in the frontal, sagittal and transverse planes for the rearfoot, midfoot and forefoot during the stance phase of walking. Only *post-hoc* tests comparing flexible to rigid FOs, as well as flexible FOs with and without postings that yielded $p<0.001$ are described below. For ES see Fig. S3 in Supplementary Material, only mean ES>0.4 are reported below.

At rearfoot, and compared to flexible FOs, rigid FOs were shown to further decrease rearfoot eversion between 8-100% of stance with a mean difference (MD) of 0.83°, and to increase rearfoot abduction between 14-100% of stance (MD=1.02). Both posting enhanced the effect of the flexible FOs in the frontal plane (MD=2.43° ES=0.85 and MD=1.15° ES=0.47, for medial and mediolateral postings respectively) and significantly increased rearfoot plantarflexion (MD=1.58° ES=0.55 and MD=1.10° ES=0.41, for medial and mediolateral postings respectively) throughout the stance phase.

At midfoot, rigid FOs induced a greater increase in eversion between 10-78% of stance (MD=0.48°) compared to flexible FOs. Again, both postings reinforced flexible FOs' effect on the frontal plane throughout the stance phase (MD=1.38° ES=0.65 and MD=0.69°, for medial and mediolateral postings respectively). In the sagittal plane, rigid FOs were shown to decrease dorsiflexion between 2-48% and 49-78% of stance (MD=0.69° and MD=0.77° respectively), while the use of medial postings increased significantly midfoot dorsiflexion between 0-80% of stance (MD=1.36° ES=0.41). In the transverse plane, rigid FOs decreased midfoot abduction throughout the stance phase (MD=0.52°) whereas the addition of a medial posting increased it between 0-44% of stance (MD=0.49°).

At forefoot, and compared to flexible FOs, rigid FOs were shown to increase forefoot eversion between 68-100% (MD=0.55°).

Regarding peak pressures, mean pressures and contact area, ANOVAs revealed significant differences for the seven foot regions during the stance phase of walking. *Post-hoc* analysis results are presented in Fig. 3-5 for the rearfoot, the midfoot and the forefoot respectively. Only *post-hoc* tests comparing flexible to rigid FOs that yielded $p<0.001$ are described below. For ES see Fig. S4-6 in Supplementary Material, only mean ES>0.4 are reported below.

Compared to flexible FOs, rigid FOs were shown to further increase peak pressures in both medial and lateral rearfoot, between 33-100% (MD=+31.7% ES=0.41) and 8-82% of stance (MD=+23.1% ES=0.46) respectively. Also, average pressure was increased between 68-80% of stance (MD=+25.3%), while contact area was decreased between 28-43% of stance (MD=-3.6%) in medial rearfoot using rigid FOs compare to flexible FOs.

At midfoot, rigid FOs induced greater peak pressures than flexible FOs in both medial and lateral part, between 17-100% (MD=+22.5% MES=0.47) and 68-100% of stance (MD=+21.6%) respectively. They were also shown to increase mean pressures between 51-97% (MD=+27.5%) and 68-100% of stance (MD=+30.6%), in medial and lateral midfoot respectively, compared to flexible FOs. Contact area was decreased between 15-41% (MD=-11.4%) and 18-45% (MD=-4.6%) in medial and lateral midfoot respectively, and was then increased between 73-80% (MD=+12.2%) and 76-95% (MD=+16.6%) in medial and lateral midfoot respectively using rigid FOs.

At forefoot, and compared to flexible FOs, rigid FOs were shown to decrease both peak and mean pressures in the lateral part, between 9-65% (MD=-14.7%) and 10-69% (MD=-17.1%) respectively. Looking at contact area, using rigid FOs induced an increase between 85-94% of stance (MD=3.19%) in the central part, and a decrease between 11-28% of stance (MD=10.9%) in the lateral part, compared to flexible FOs.

4. Discussion

The aim of this study was to assess the effect of 3D printed FOs stiffness and extra-components on foot kinematics and plantar pressures during gait. Significant differences were found in frontal and transverse plane foot kinematics when increasing FOs stiffness. Increased stiffness was also associated with higher peak pressures. In addition, our innovative extra-components were shown to enhance FOs effect on foot kinematics.

In contrast to a previous study reporting little effects of various insole materials on lower limb kinematics [11], our results suggest that changing the stiffness of 3D printed FOs have a significant effect on foot kinematics, and especially on the rearfoot. Thus, increasing the overall stiffness of the FOs was associated with a less everted and more abducted position of the rearfoot relative to the shank, from the loading response to heel-off. Since rearfoot and midfoot motion are coupled [24], an increase of eversion and a decrease of abduction were observed at midfoot during the same phase of stance using the rigid FOs. Significant results in the present study could be explained by the statistical analysis of the whole stance phase, whereas Healy et al. [11] investigated the change in joint angles only during the early stance (from heel strike to 6% of the gait cycle). Further, and in line with Telfer et al. [3], our neutrally posted 3D printed FOs were shown to alter rearfoot frontal plane kinematics, suggesting that contoured FOs are effective to support the foot and prevent the deformation of the medial longitudinal arch. Given rigid FOs provided a greater control of rearfoot motion, and especially on variables contributing to flatten the arch [25], i.e. rearfoot eversion and adduction, they could represent a beneficial intervention when clinicians are attempting to reduce excessive rearfoot pronation. However, the reported mean angle differences were relatively small (1.17-1.40°) and, in the case of individuals with musculoskeletal disorders, one might wonder if clinical benefits could be associated with these kinematic changes.

The use of denser material for the fabrication of FOs through traditional techniques has been associated with greater peak pressures [11]. Similar findings emerge from the present study as peak pressures were increased under the rearfoot and the midfoot (up to +31.7%) when using the rigid FOs, suggesting to favor flexible FOs, especially for patients with a need to offload pressure to avoid foot pain and/or ulcers. On the other hand, contrary to previous studies reporting a reduction in mean pressures and a better pressure distribution with the use of a softer material [10], no notable changes due to stiffness were observed in the present study. Our results might be explained by the way we increased the stiffness of our FOs, which was not by changing the material or its properties, but by increasing the height of the honeycomb cells. However, focusing on the effect of FOs compared to the control condition, a decrease in mean pressure at the medial rearfoot and an increase in mean pressure at the medial midfoot were observed. These changes were associated with an increase in contact area under the medial midfoot region. Hence, in accordance with a previous study [4], a shift of the loads from the rearfoot toward the midfoot exists when wearing FOs. Yet, and contrary to this previous study [4], no notable shift was observed from the forefoot to the midfoot, which could certainly be explained by the use of ¾ length FOs in the present study. Given that the stiffness of 3D printed FOs has the potential to alter kinematics but also influence plantar pressures, further studies should be carried in order to find the amount of stiffness that will have an impact on foot kinematics while avoiding excessive increase in peak pressures.

FOs designed with insert can alter foot kinematics and have various effects depending on their design and/or location [3,9]. Regarding the impact of postings, our results are in line with these previous studies. However, contrary to commonly used inserts, ours were not designed to tilt and try to correct the foot posture, but intended to affect the function by stabilizing and controlling the deformation of the FOs supporting the foot, especially at rearfoot and under the medial arch. Yet, besides enhancing the impact of the FOs on the frontal plane, especially by further reducing rearfoot eversion, our postings were shown to increase rearfoot plantarflexion. These changes in the sagittal plane with the use of postings may be attributed to the foot being lifted inside the shoe due to the extra depth (2 mm) induced when using these extra-components [26]. This heel raise might be beneficial in subject with limited ankle dorsiflexion [26], but could have an adverse effect in individuals with flatfoot in which rearfoot plantarflexion is already increased [27]. In addition to the benefits from saving space in the shoe, the design of a thinner insert might be beneficial for flatfeet. Yet, results from the present study revealed that rearfoot motion, especially in the frontal plane, can also be controlled using postings that do not necessarily tilt the shell of the orthotic.

Some limitations should be taken into consideration for this study. Even if the body has previously been shown to adjust quickly to FOs [28], only the immediate effect of FOs and their design modifications was investigated. In addition, although markings were made on the skin where the markers were to be placed to ensure correct reapplication, error could have been introduced in the computation of kinematics results. According to a study based on palpation and target marker location on the foot [29], the error in our case could be about 1.4±0.2 mm. Another limitation to this study is that investigations were done on healthy individuals while further studies including people presenting musculoskeletal disorders are required to fully appreciate the impact of stiffness and our innovative postings. Similarly, our results hold for prefabricated 3D printed FOs made from Nylon 12 while FOs made from 3D printing techniques are usually customized and a wide range of material can be used to produce them. Finally, mechanical effects of these FOs with and without inserts on overlying joints should be investigated as it has previously been reported that a further decrease in rearfoot eversion could have adverse effects on the knee joint [3].

5. Conclusion

Our findings suggest that non-customized contoured 3D printed FOs could be effective to alter foot kinematics with a potential to optimize and individualize their effect by changing their stiffness. Further, a multitude of new kinds of 3D printed inserts, interchangeable/removable, can be developed, giving clinicians the possibility to modulate FOs all along the treatment.

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Figure captions

Fig. 1: Bottom view of a right FO with medial (A) and mediolateral (B) posting; Medial view of a right FO with posting (C).

Fig. 2: Rearfoot, midfoot and forefoot kinematics.

Top graph shows the mean kinematics of each condition with 95% confidence interval cloud (control condition). Bars indicate significant periods for which the SnPM{t} statistic exceeded the supra-critical threshold ($p<0.02$). Panels (a) show results of the effect of FOs; panels (b) show results of the addition of rearfoot postings. Grey bar indicates a p-value <0.02 and black bar a p-value <0.001. CO: control, F: flexible FOs, MP: flexible FOs with medial posting, MLP: flexible FOs with mediolateral posting, R: rigid FOs.

Fig. 3: Rearfoot peak (A) and mean pressure (B), as well as contact area (C) of the medial and lateral parts.

Top graph shows the mean of each condition with 95% confidence interval cloud (control condition). Bars indicate significant periods for which the SnPM{t} statistic exceeded the supra-critical threshold ($p<0.02$). Grey bar indicates a p-value <0.02 and black bar a p-value <0.001. CO: control, F: flexible FOs, R: rigid FOs.

Fig. 4: Midfoot peak (A) and mean pressure (B), as well as contact area (C) of the medial and lateral parts.

Top graph shows the mean of each condition with 95% confidence interval cloud (control condition). Bars indicate significant periods for which the SnPM{t} statistic exceeded the supra-critical threshold ($p<0.02$). Grey bar indicates a p-value <0.02 and black bar a p-value <0.001. CO: control, F: flexible FOs, R: rigid FOs.

Fig. 5: Forefoot peak (A) and mean pressure (B), as well as contact area (C) of the medial and lateral parts.

Top graph shows the mean of each condition with 95% confidence interval cloud (control condition). Bars indicate significant periods for which the SnPM{t} statistic exceeded the supra-critical threshold ($p<0.02$). Grey bar indicates a p-value <0.02 and black bar a p-value <0.001. CO: control, F: flexible FOs, R: rigid FOs.

Figures

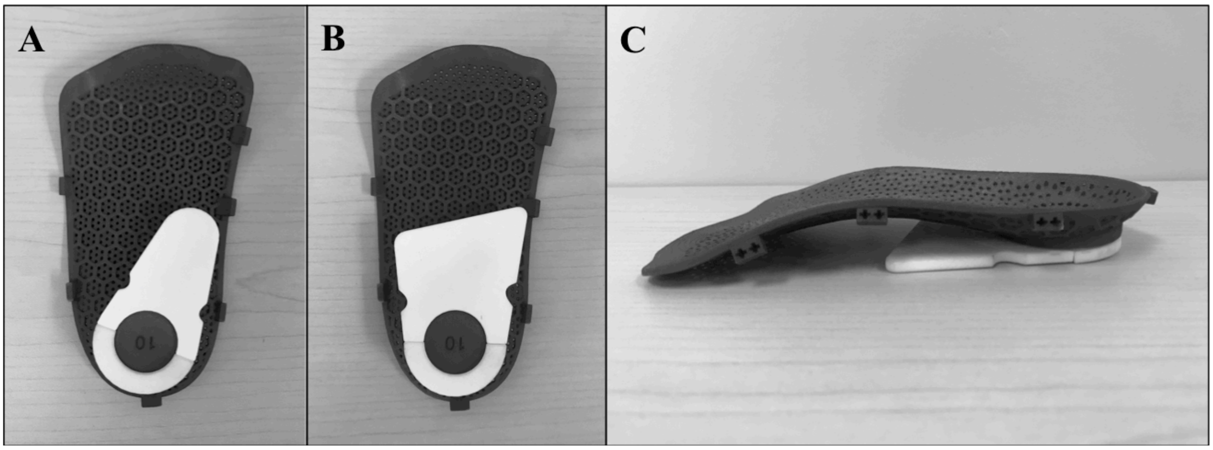


Fig. 1

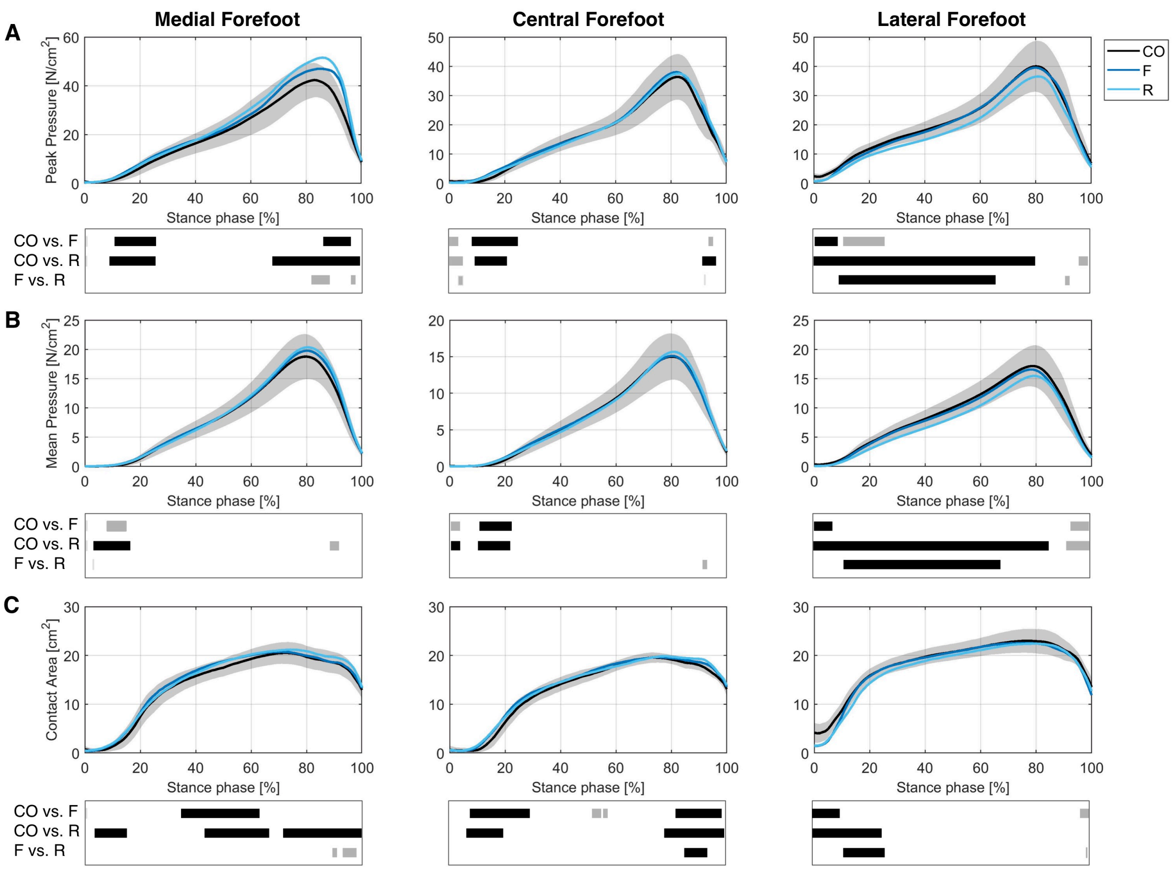
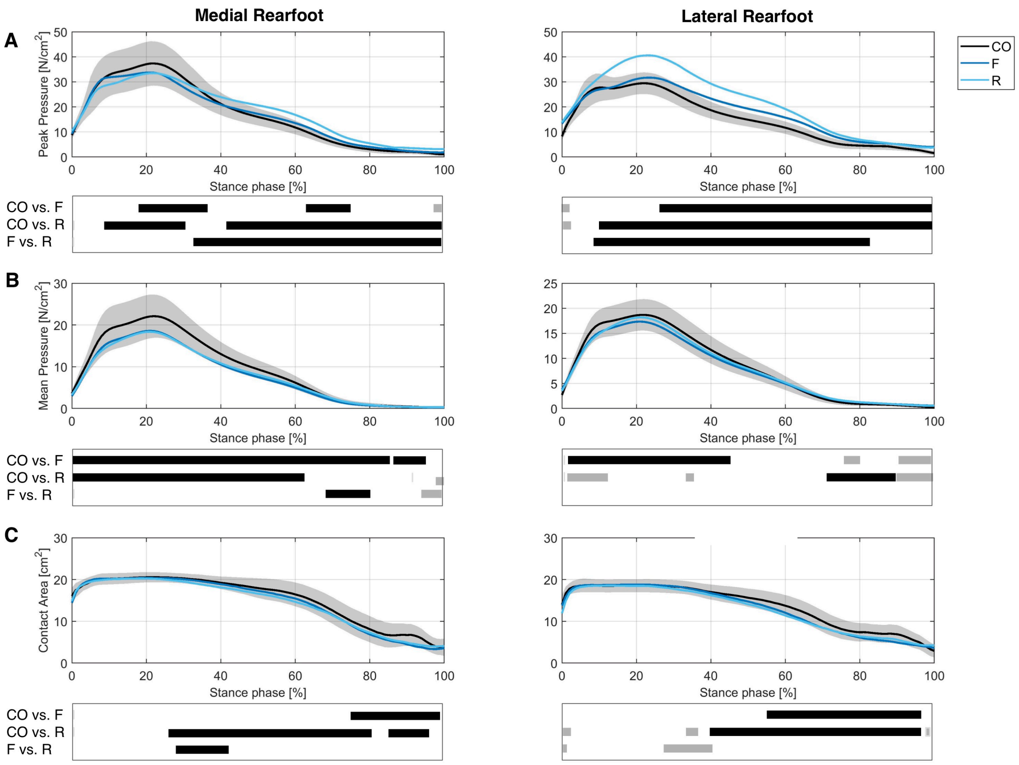
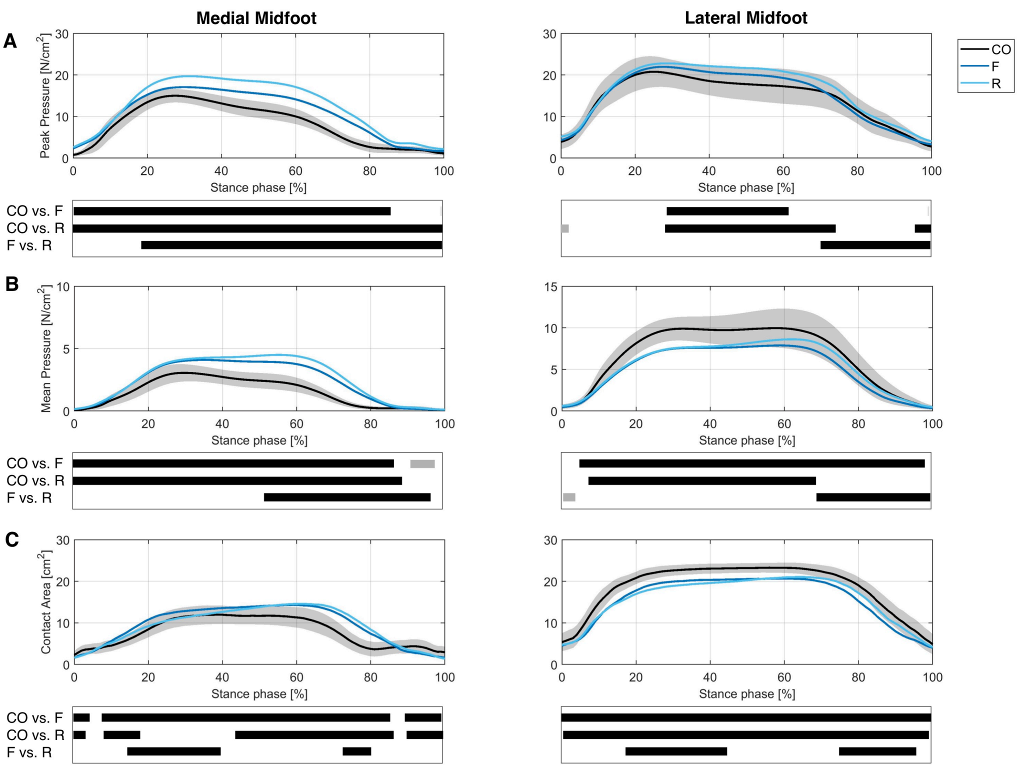


Fig. 2



Medial Rearfoot
Lateral Rearfoot
A
B
C
Peak Pressure [N/cm²]
Mean Pressure [N/cm²]
Contact Area [cm²]
Stance phase [%]
CO vs. F
CO vs. R
F vs. R
CO
F
R

Fig. 3



Medial Midfoot
Lateral Midfoot
A
B
C
Peak Pressure [N/cm²]
Mean Pressure [N/cm²]
Contact Area [cm²]
Stance phase [%]
CO vs. F
CO vs. R
F vs. R
CO
F
R

Fig. 4

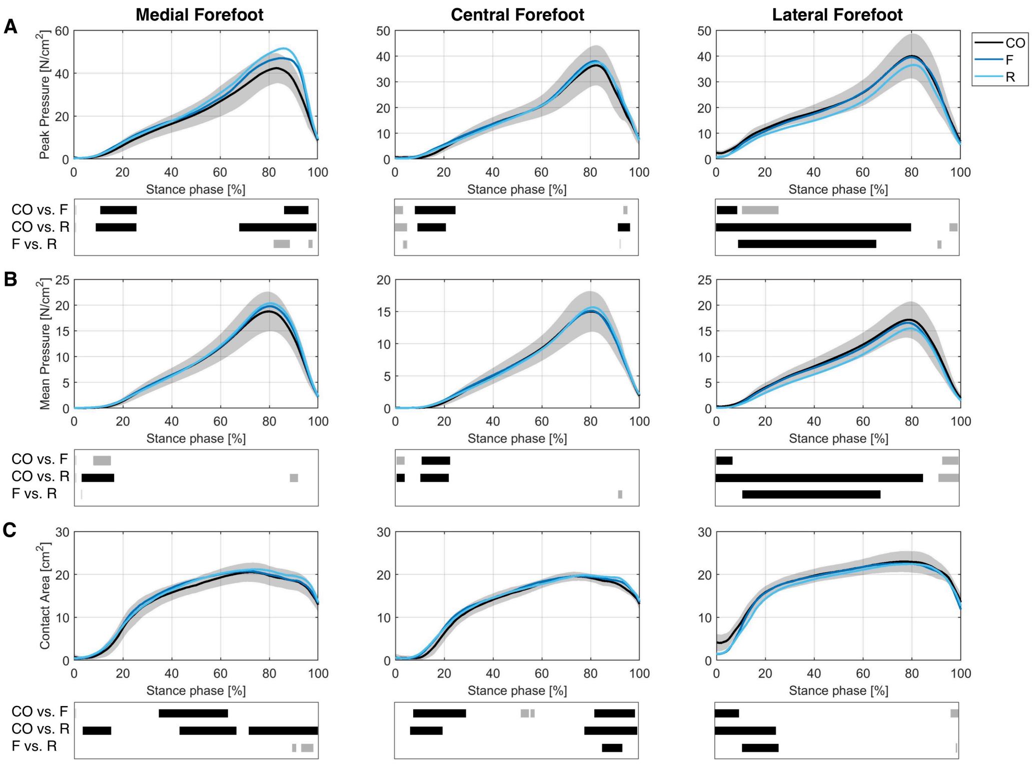

A
B
C
Medial Forefoot
Central Forefoot
Lateral Forefoot
CO
F
R
Peak Pressure [N/cm²]
Mean Pressure [N/cm²]
Contact Area [cm²]
Stance phase [%]
CO vs. F
CO vs. R
F vs. R

Fig. 5

Supplementary materials

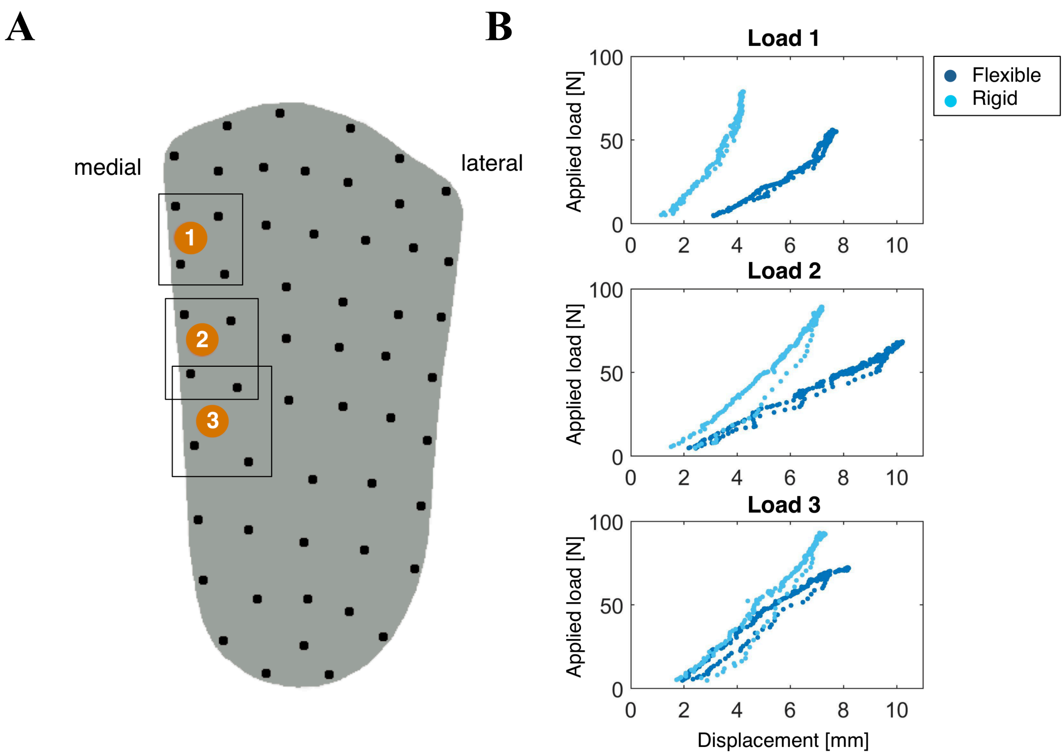


Fig. S1 : Foot orthoses stiffness

(A) Schematic representation of a foot orthosis with reflective markers (black dots) taped on its plantar surface. Orange circles represent the application point of three different loads applied using a stick instrumented with a load cell. Black squares contain the markers from which the vertical displacement has been estimated. (B) Graphs corresponding to the average vertical displacement of the markers depending on the applied load (1, 2 or 3).

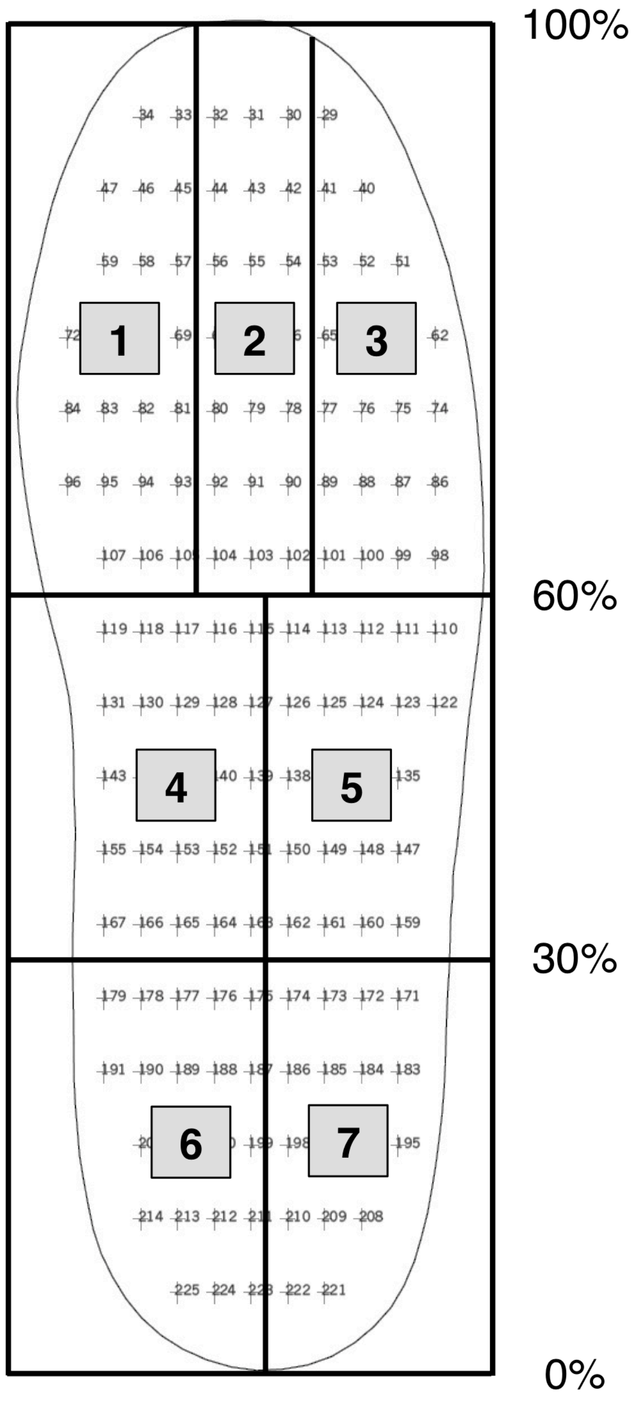


Fig. S2: Plantar pressure insole masks.
(1) Medial forefoot, (2) central forefoot, (3) lateral forefoot, (4) medial midfoot, (5) lateral midfoot, (6) medial rearfoot, (7) lateral rearfoot.
Each sensor is a 0.75 x 1.5 cm rectangle (1.125 cm^2) with a pressure range from 0.6 to 64 N/cm^2.

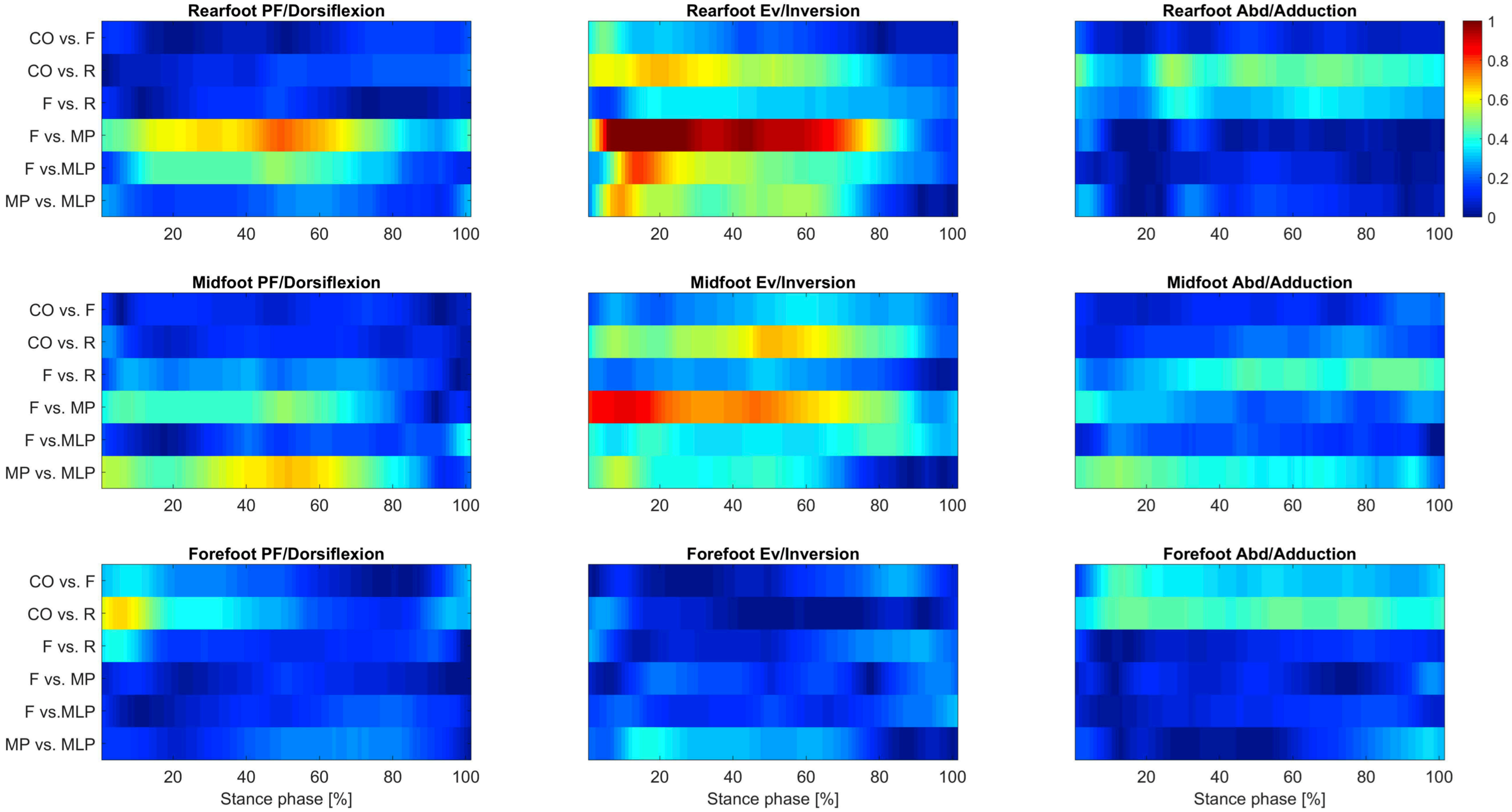


Fig. S3: Effect Sizes of the post-hoc comparison relative to the foot joint angles.
The color blue represents no/minimal effect and dark red represents large/maximum effect.

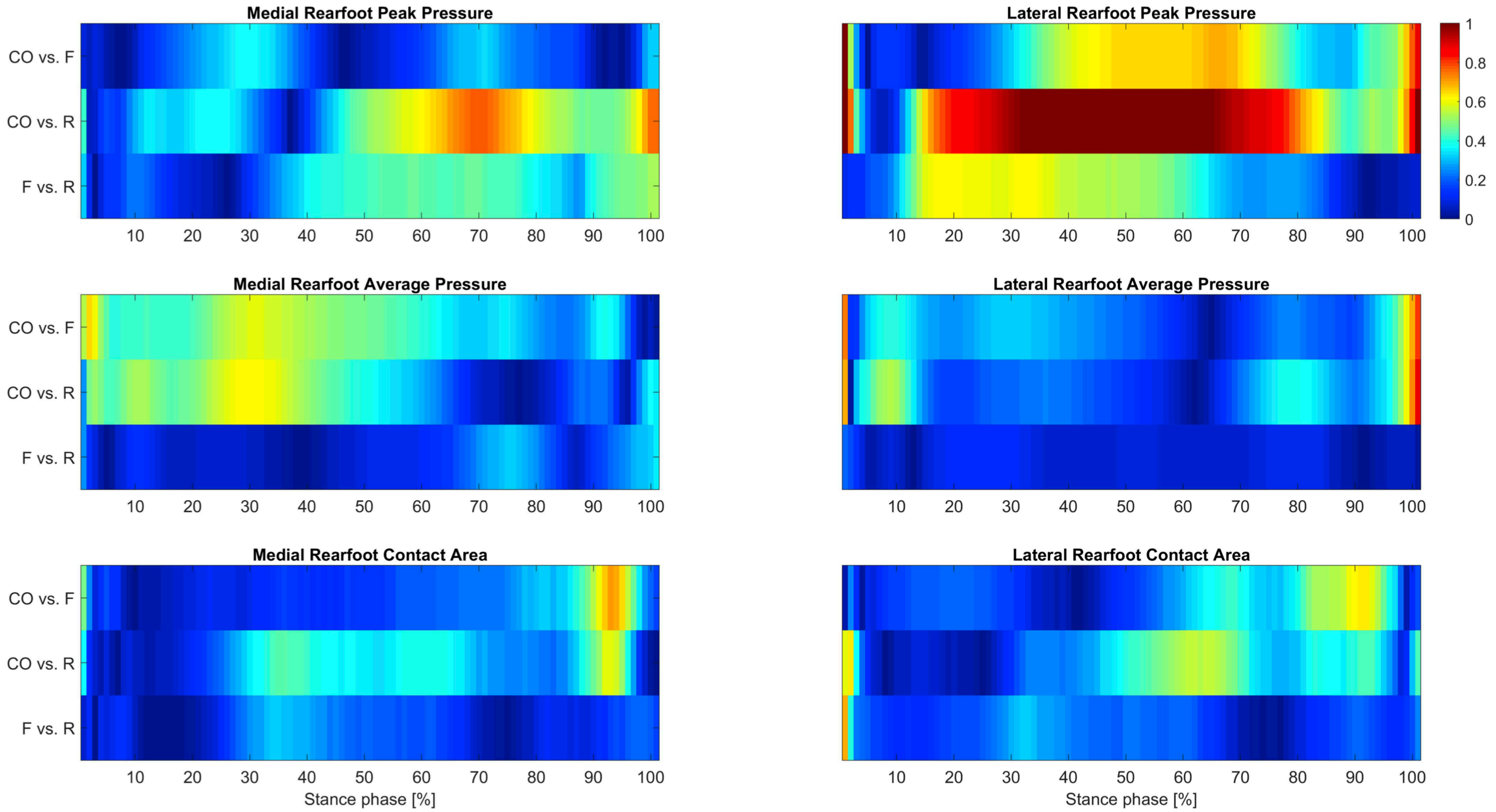


Fig. S4: Effect Sizes of the post-hoc comparison relative to the rearfoot plantar pressure variables.
The color blue represents no/minimal effect and dark red represents large/maximum effect.

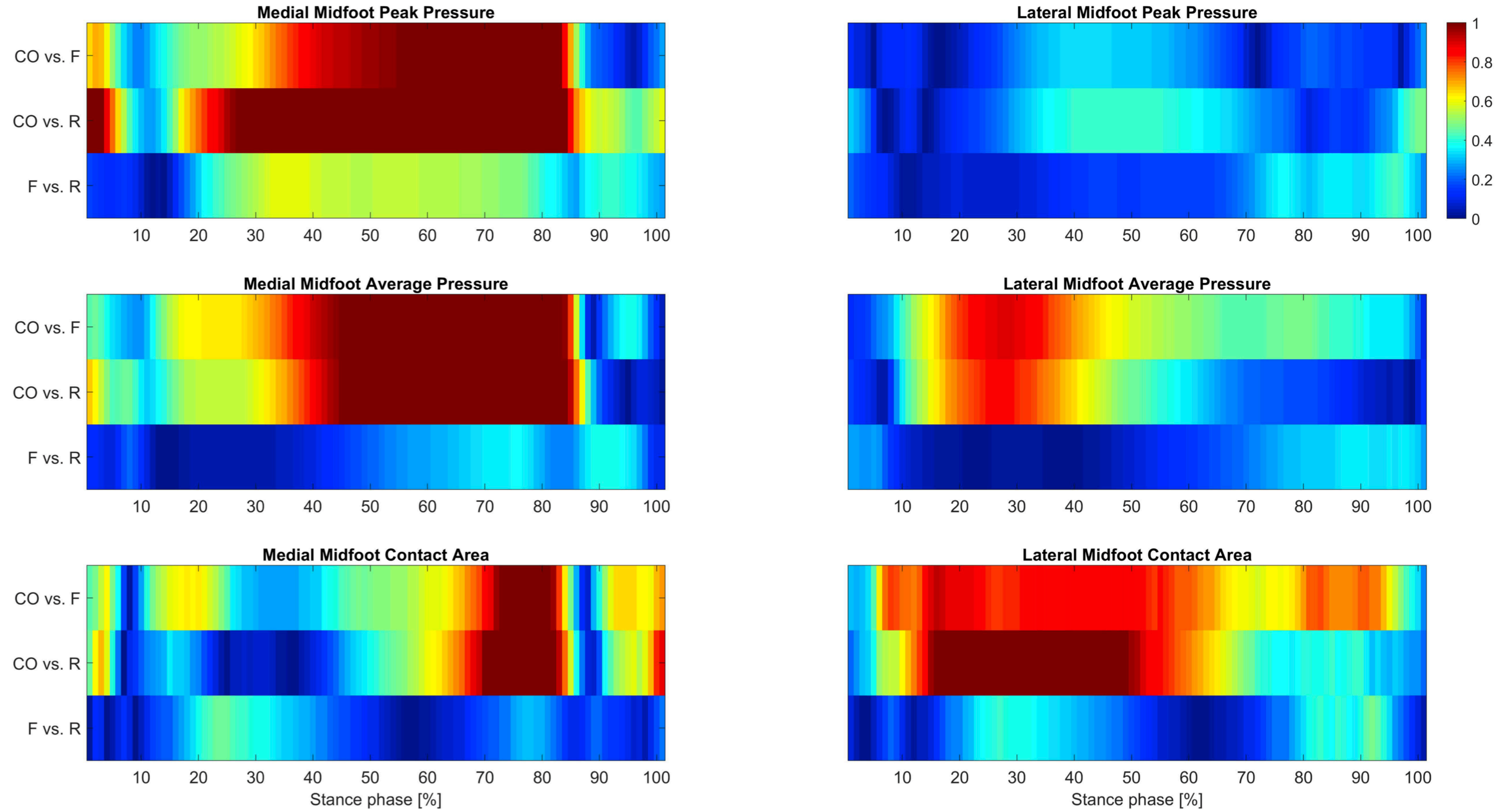


Fig. S5: Effect Sizes of the post-hoc comparison relative to the midfoot plantar pressure variables.
The color blue represents no/minimal effect and dark red represents large/maximum effect.

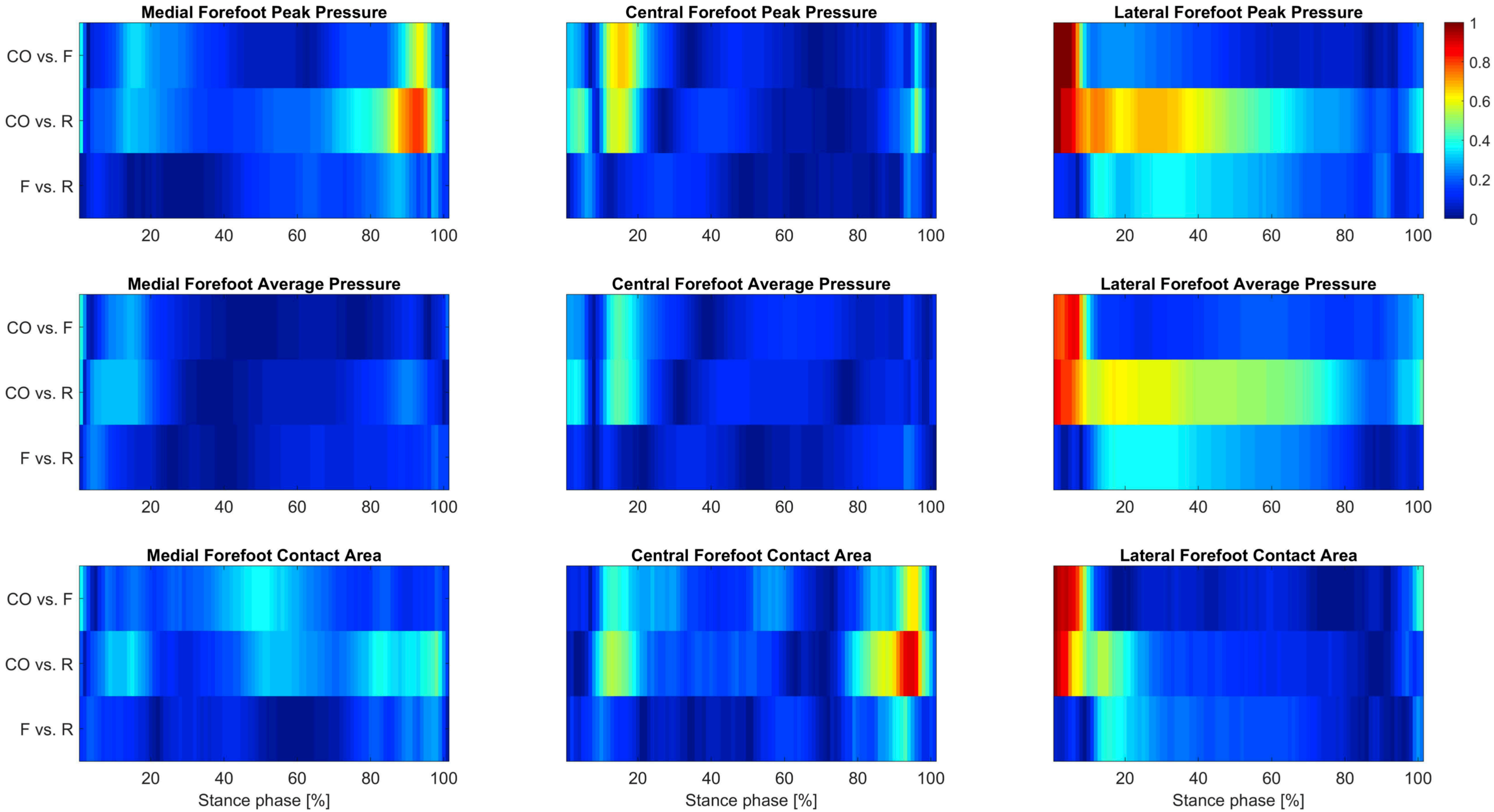


Fig. S6: Effect Sizes of the post-hoc comparison relative to the forefoot plantar pressure variables.
The color blue represents no/minimal effect and dark red represents large/maximum effect.