Is there a dose-response of medial wedge insoles on lower limb biomechanics in people with pronated feet during walking and running?

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Abstract

Background: Although the effects of medial wedge insoles on lower limb biomechanics have been investigated, information about the effects of different magnitudes of medial posting is still lacking.

Research question: What are the dose-response effects of medial wedge insoles with postings varying between 0°, 3°, 6°, and 9° of inclination on the lower limb biomechanics during walking and running in individuals with pronated feet?

Methods: Sixteen participants with an FPI ≥ 6 were recruited. Four arch-supported insole conditions with varying degrees of medial heel wedge were tested (0°, 3°, 6°, and 9°). A 3D motion analysis system with force plates was used to obtain the kinetics and kinematics of walking and running at self-selected speeds. To compare the ankle, knee, and hip angles and moments among conditions, a time series analysis was performed using Statistical Parametric Mapping (SPM).

Results: A reduction in ankle eversion angle was observed during walking for all insoles. For running, the 6º and 9º insoles decreased the ankle eversion angle during early stance and increased this angle during the propulsive phase. A decrease in ankle eversion moment was observed in walking and running for 6º and 9º insoles. An increase in knee adduction moment occurred in walking and running for all insoles. For hip, the 6º and 9º insoles showed, during walking, a decrease in hip adduction angle and an increase in hip adduction and external rotation moments. For most variables, statistical differences were found for a greater period across the stance phase as the medial wedge increased, except for ankle eversion moment and hip external rotation moment during walking.

Significance: The biomechanical effects over the time series for many of the parameters increased with the addition of insole inclination, showing a dose-response effect of medial wedge insoles on the lower limb biomechanics during walking and running in adults with excessive foot pronation.

Keywords: Medial wedge insole, Pronation, Gait, Biomechanics, Statistical Parametric Mapping

1 Introduction

Excessive foot pronation has been associated with the development of plantar fasciitis [1], medial tibial stress syndrome [2, 3] and calcaneal tendinopathy [4]. Several studies have evaluated the effect of pronation-control insoles on walking and running biomechanics [5] [6]. Medial wedge insoles are the most common type of orthoses used to decrease foot pronation and change lower limb biomechanics in subjects with pronated feet [7-9]. Posting under the rearfoot facilitates the use of insoles as forefoot posting is difficult to fit inside the shoe and may cause some discomfort [10]. The use of arch supports in combination with rearfoot wedges may improve pronation control and comfort [11] Therefore, the use of medial wedge insoles has been recommended for individuals presenting excessive foot pronation [10, 12].

Although there is evidence of the kinematic and kinetic effects of medial wedge insoles on walking, there is little information on the effects of different angulations of the medial wedge. To our knowledge, only one study has evaluated the dose-response of different levels of medial wedge on the kinetics and kinematics of walking in individuals with excessive pronation [11]. In this study, the authors found a linear relationship between the increasing inclination of posting and reductions in peak and mean rearfoot eversion and external moments of ankle eversion and knee adduction. However, there is a lack of information on such effects on the ankle, knee, and hip kinematics and kinetics over the whole stance phase. Furthermore, as insoles are devices often prescribed for runners, it is necessary to know whether the effects observed during walking can be transferred to running. Knowing the dose-response effect of the amount of posting of medial wedge insoles may help to select the correct prescription for runners presenting excessive foot pronation. Finally, most studies present discrete data reported through peaks at specific points in the walking or running cycle. In this study, continuous data were reported allowing the visualization of the effect of the insoles during the whole gait cycle.

Therefore, this study aimed to investigate the dose-response effects of medial wedge insoles on lower limb joint biomechanics during the stance phases of walking and running using medial posted orthoses with 0°, 3°, 6°, and 9° of posting in individuals with pronated feet identified by a foot posture index ≥ 6. This experiment hypothesized that as we increase the inclination of the medial wedges, we would notice a progressive increase in the external knee adduction moment and a reduction in the eversion of the calcaneus. However, the effect of the same medial wedge inclination on the kinetics and kinematics of walking and running will not be similar, since the foot position would be different, and the joint torques in the running task would be higher and would require a greater inclination of the medial wedge to control the movement of the joints.

2 Methods

2.1 Participants

Nine women and seven men aged 26.63 years (SD 7.94), body mass of 64.11 Kg (SD 10.61), and height of 1.74 m (SD 0.08) agreed to participate. Inclusion criteria were aged between 18 and 40 years, BMI lower than 30kg/m², a Foot Posture Index (FPI) ≥ 6, run at least twice a week, no history of fractures and surgical interventions in the lower limbs or pelvis in the last year, and no history of decompensated cardiovascular diseases. Participants who reported pain or discomfort during the walking or running tasks were excluded. A sample size of 16 participants was calculated for the repeated measures ANOVA, with an effect size of 0.8, statistical power of 70%, four groups, and significance level of 0.05 using the software G*Power (version 3.1). The participants signed an Informed Consent Form before data collection, and the study was approved by the Institutional Research Ethics Committee (nº 2.800.255).

2.2 Experimental conditions

Four arch-supported insole conditions with varying degrees of medial heel wedge were tested (0º, 3º, 6º, and 9º). The arch-supported insoles were made of ethylene-vinyl acetate (EVA, shore 40) with the medial longitudinal arch support height standardized and proportional to the footwear's size. The medial wedges with 3º, 6º, and 9º were made on a CNC (Computer Numerical Control) milling machine using EVA (shore 40) and were fixed within the shoe using double-sided tape underneath the insoles from the calcaneus to the end of the medial longitudinal arch support (Figure 1). The progressive increments of 3º degrees in the inclination of the medial wedges were chosen to allow better visualization of the difference between the interventions since increments of 2º have been shown to only produce small differences in the kinetics and kinematics during walking [11, 13]. The maximum posting of 9º was chosen as medial posting with an inclination greater than 10º has been reported to promote discomfort during walking [13].

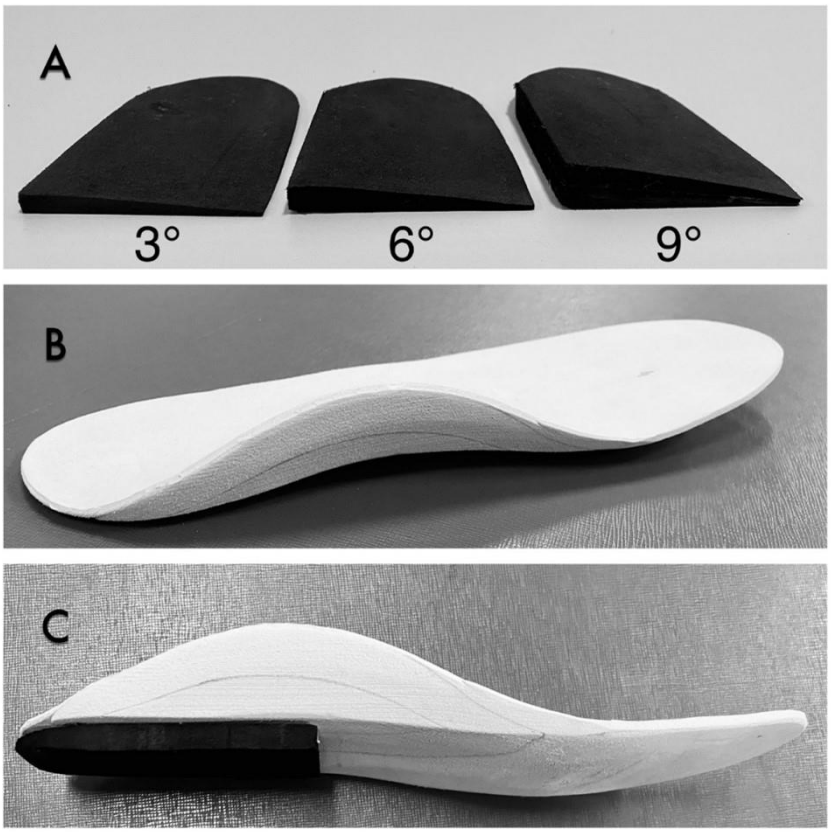

Figure 1. A**)** 3º, 6º, and 9º medial wedges; B) Prefabricated control insole with medial longitudinal arch support and calcaneal region without inclination; C) Medial wedge adhered to the control insole by double-sided tape below the rearfoot. The medial wedge end at the apex region of the arch support.

2.3 Instruments

Kinematic data during walking and running were recorded using a 9-camera Oqus 3+ system at 200 Hz (Qualisys Medical AB, Sweden), and kinetic data were recorded using three synchronized FP 4060-08 force plates (Bertec, USA) at a sampling frequency of 1000Hz.

2.4 Procedures

The body mass, height, and Foot Posture Index (FPI) were assessed by the same experienced examiner [14]. Fourteen-millimeter passive retro-reflective markers were placed on the pelvis, thigh, shank, and foot on the right lower limb. Specifically, anatomical markers were placed on the anterosuperior iliac spines, posterosuperior iliac spines, greater trochanter of femur, medial and lateral epicondyles of the femur, medial and lateral malleolus. For the foot, markers were attached to standardized footwear (New Fit, Bout's, Brazil) over the posterior region of the calcaneus, the 5th metatarsal base, and the 1st and 5th metatarsal heads. In addition, clusters of four non-collinear markers

were attached to the thigh and shank. All segments were modeled using the Calibrated Anatomical System Technique [15]. A full description of the marker model is provided in the Supplementary Materials.

Initially, a static trial was taken with the participants using the control insole. Then, walking and running trials were recorded in a laboratory at a self-selected speed on a 12-meter walkway under the four orthoses conditions. All data collection was performed on the same day in the laboratory and the order of the experimental conditions was randomized. Before data collection, all participants received a pair of 6º medial wedge insoles to use for 30 days to ensure familiarization. They were then requested to not use any insoles for a further 30 days to ensure an adequate washout period removing the effects of the 6º posted insoles.

2.5 Data Processing

Kinematic and kinetic data were processed using Visual 3D software (version 6, C-motion, USA). Marker trajectories and force data were low pass filtered using a 4^{th} order Butterworth filter at 6Hz and 25Hz, respectively [16]. Stance phases were automatically detected between heel-strike and toe-off from the vertical component of the ground reaction force using a threshold of 20N. Mean values of five trials for each participant were considered for analysis and all variables were time-normalized to 100% of the stance phase. External joint moments were calculated using three-dimensional inverse dynamics and were normalized to body mass. The analysis focused on the ankle coronal plane, knee coronal plane, and hip coronal and transverse planes as these have previously been related to foot pronation [16, 17].

2.6 Data Analysis

To compare the experimental conditions, a time series analysis was performed using Statistical Parametric Mapping (SPM) [18]. Before any inferential procedures, the normal distribution of all data was confirmed using the function “spm1d.stats.normality.anova1rm”, therefore parametric tests were used for the analyses. In sequence, One-Way Repeated Measures Analyses of Variance (1RM-ANOVA) over the normalized time-series was used to establish the presence of any significant differences between the conditions. Three pre-planned contrasts (0º vs 3º; 0º vs 6º and 0º vs 9º) were performed using SPM post-hoc paired t-tests when the ANOVA main effect was significant. The time duration of the differences over the stance phase was computed as the subtraction between the end and beginning of the significant differences, which were reported as a percentage of the stance phase (ΔTD). In this way, the dose-response effect was rather based on the time (x-axis) than the magnitudes (y-

axis). The level of significance was 0.05 for all analyses. The technical details on the SPM methods used have been previously reported [18, 19], and all analyses were implemented using the open-source spm1d code (www.spm1d.org) for Matlab (2020a, The MathWorks, Inc., USA).

3 Results

The mean and standard deviation (SD) for FPI measurements for all participants were 9.94 (SD 1.57) with an Intraclass Correlation Coefficient (ICC) of 0.99 ($CI_{95\%}$ 0.96 to 0.99). The SPM results are presented below (topics 3.1 and 3.2), and additional results can be found in the Supplementary Materials.

3.1 Walking

For the ankle, decreases in eversion angle were seen for the following comparisons: 0º vs 3º (ΔTD=7%), 0º vs 6º (ΔTD=31%), and 0º vs 9º (ΔTD=31%). For the ankle moment data, decreases in eversion moments were seen between 0º vs 6º (ΔTD=15%), and 0º vs 9º (ΔTD=2%), Figure 2. No differences were observed for the knee angle data. For knee moments, increases in knee adduction moment were seen between 0º vs 3º (ΔTD=11%), 0º vs 6º (ΔTD=12%), and 0º vs 9º (ΔTD=22%), Figure 3. For the hip angles, a decrease in hip adduction was observed between 0º vs 6º (ΔTD=7%) and 0º vs 9º (ΔTD=6%). For the hip moments in the coronal plane, differences were also seen between 0º vs 3º (ΔTD=12%), 0º vs 6º (ΔTD=17%), and 0º vs 9º (ΔTD=19%), with the hip adduction moment showing an increase in early stance and a decrease in midstance with the medial wedge insoles, Figure 4. Lastly, the hip angles in the transverse plane showed no differences. However, for the moments, an increase in external rotator moment was observed between 0º vs 6º (ΔTD=20%) and 0º vs 9º (ΔTD=6%), Figure 5.

3.2 Running

For the ankle angle, differences were seen in the coronal plane between 0º vs 6º (ΔTD=42%) and 0º vs 9º (ΔTD=49%), with the ankle eversion angle decreasing in early stance and increasing during late stance. For the ankle moment data, a decrease in ankle eversion moment was seen between 0º vs 6º (ΔTD=33%) and 0º vs 9º (ΔTD=43%), Figure 2. No differences were seen for the knee angles, however, the knee adduction moment increased between 0º vs 3º (ΔTD=8%), 0º vs 6º (ΔTD=21%), and 0º vs 9º (ΔTD=49%), Figure 3. For the hip, differences in the adduction angle were only seen

between 0º vs 9º (ΔTD=9%). For the hip moments, a decrease in hip adduction moment was seen between 0º vs 6º (ΔTD=3%), and 0º vs 9º (ΔTD=6%), Figure 4. For the hip in the transverse plane, no differences were observed for joint angles or moments, Figure 5.

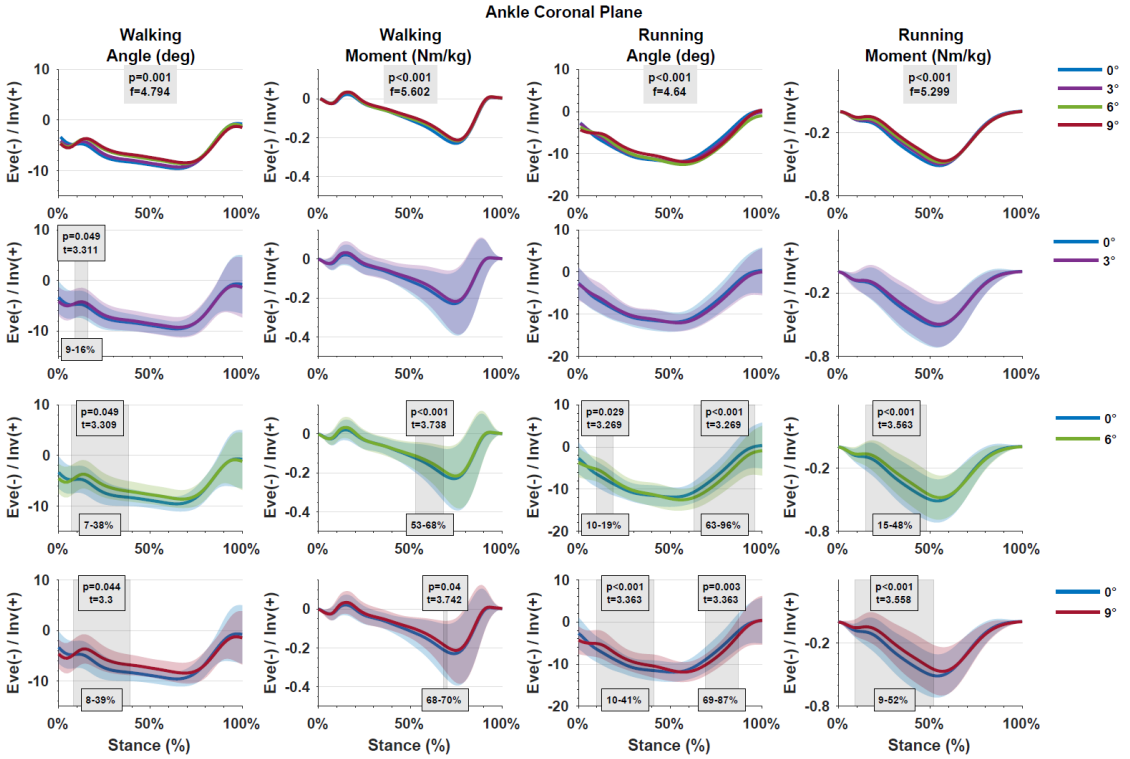

Figure 2. Joint angles and moments during the stance phase of walking and running for the ankle coronal plane. First row: mean curves of all four experimental conditions with the f and p values from the 1RM-ANOVA analysis. Second to fourth rows presents the mean curves and standard deviation bands with the t and p values of the pairwise comparison between the conditions control (in blue) and 3º (in purple), control (in blue) and 6º (in green), and control (in blue) and 9º (in red). Deg: degrees. Nm/kg: newton-meters per kilograms. Eve: eversion. Inv: inversion.

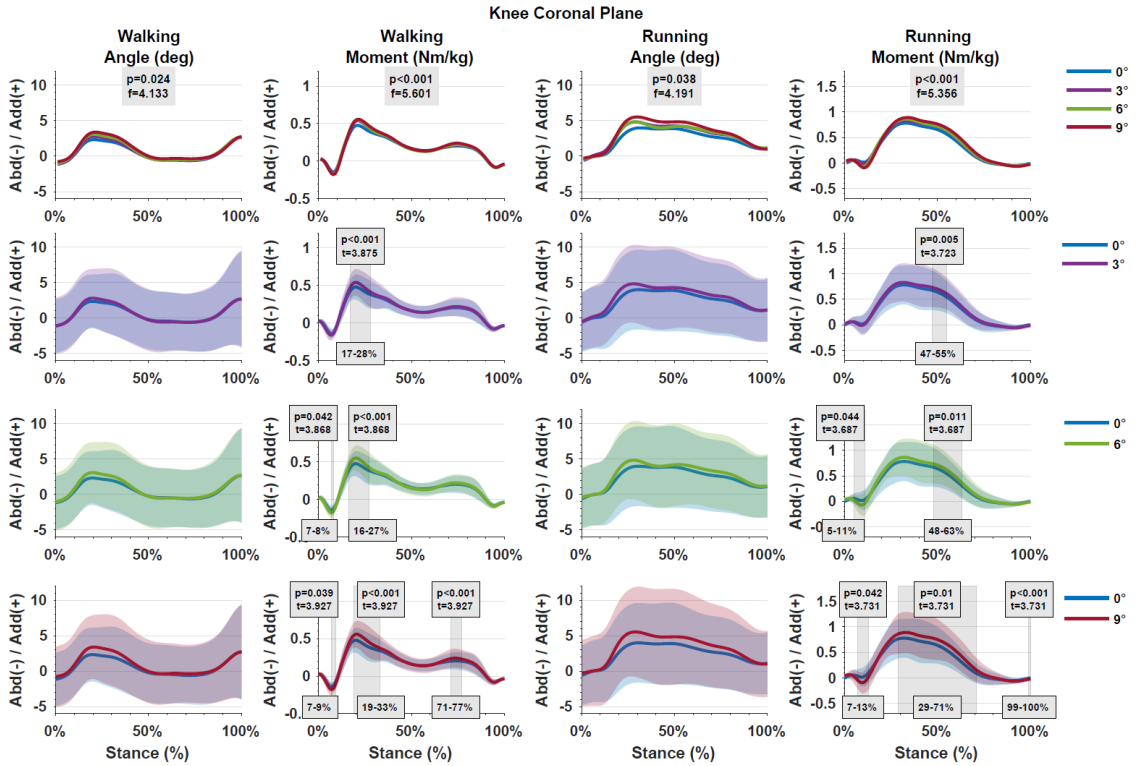

Figure 3. Joint angles and moments during the stance phase of walking and running for the knee coronal plane. First row: mean curves of all four experimental conditions with the f and p values from the 1RM-ANOVA analysis. Second to fourth rows presents the mean curves and standard deviation bands with the t and p values of the pairwise comparison between the conditions control (in blue) and 3º (in purple), control (in blue) and 6º (in green), and control (in blue) and 9º (in red). Deg: degrees. Nm/kg: newton-meters per kilograms. Abd: abduction. Add: adduction.

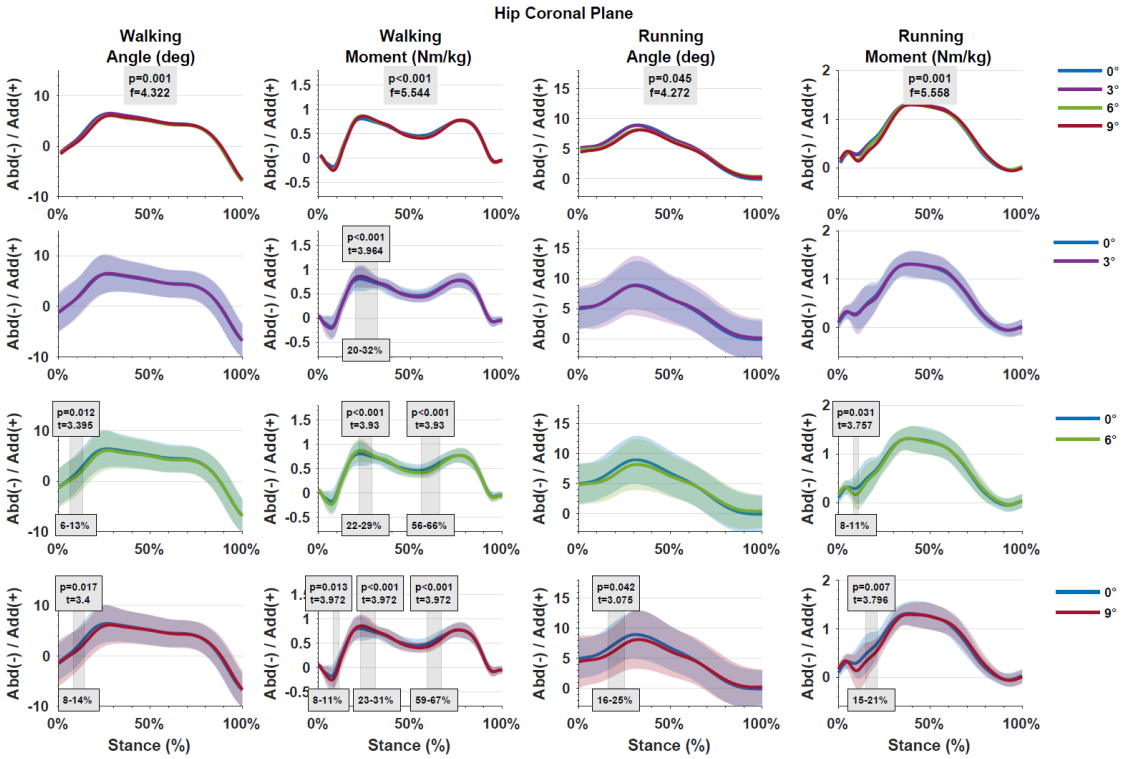

Figure 4. Joint angles and moments during the stance phase of walking and running for the hip coronal plane. First row: mean curves of all four experimental conditions with the f and p values from the 1RM-ANOVA analysis. Second to fourth rows presents the mean curves and standard deviation bands with the t and p values of the pairwise comparison between the conditions control (in blue) and 3º (in purple), control (in blue) and 6º (in green), and control (in blue) and 9º (in red). Deg: degrees. Nm/kg: newton-meters per kilograms. Abd: abduction. Add: adduction.

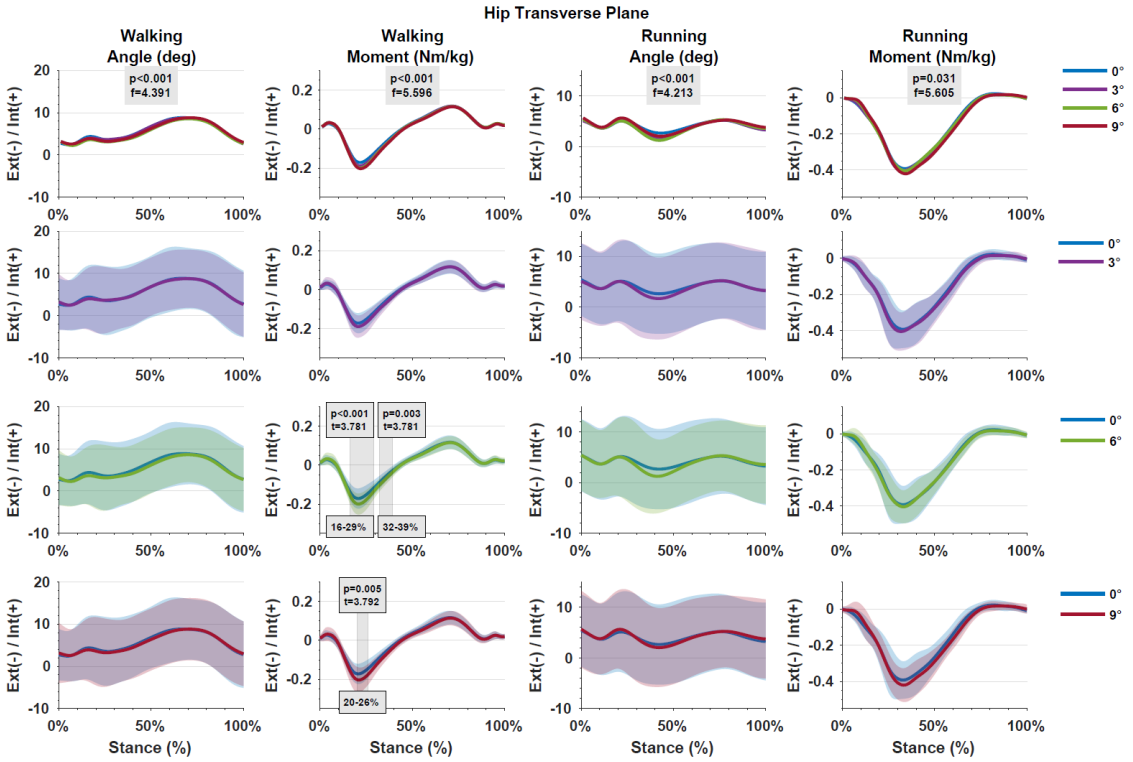

Figure 5. Joint angles and moments during the stance phase of walking and running for the hip transverse plane. First row: mean curves of all four experimental conditions with the f and p values from the 1RM-ANOVA analysis. Second to fourth rows presents the mean curves and standard deviation bands with the t and p values of the pairwise comparison between the conditions control (in blue) and 3º (in purple), control (in blue) and 6º (in green), and control (in blue) and 9º (in red). Deg: degrees. Nm/kg: newton-meters per kilograms. Ext: external rotation. Int: internal rotation.

4 Discussion

This study aimed to investigate the effects of medial wedge insoles with incremental increases in the medial posting on lower limb biomechanics during walking and running in adults with excessive foot pronation. As hypothesized, for most of the variables considered, statistical differences were found for a greater period as the medial posting increased, except ankle eversion moment and hip external rotation moment during walking. For these two variables, the 9º insole showed an effect over a smaller period than the 6º insole. These results, in general, support the hypothesis of dose-response effects of medial wedge insoles on the lower limb biomechanics during walking and running.

Regarding the results from the ankle in the coronal plane, the medial wedge insoles reduced ankle eversion mainly in the loading response and early midstance

phases during walking, with the 6º and 9º insoles showing these effects over a longer duration over stance phase (31% of the stance phase) when compared to the 3º insole (7% of the stance phase). This result agrees with Telfer, et al. [11], who also demonstrated a dose-response effect for rearfoot eversion kinematics, suggesting a potential way to optimize insoles outcomes based on dose-response information. Furthermore, the 6º and 9º insoles reduced the ankle external eversion moment in late midstance, with the 9º insole showing these effects over a short duration (2% of the stance phase) when compared to the 6º insole (15% of the stance phase), which was contrary to our hypotheses and previous research [11]. It is unclear why the dose-response effect seen in rearfoot kinematics was not mirrored by similar trends for kinetics in walking. In running, as hypothesized, a greater inclination of the medial wedge was necessary to control rearfoot kinematics when compared to walking since the 3º insole did not significantly change the kinematics or kinetics, and only the 6º and 9º insoles produced significant effects in running. However, in the second half of the stance phase, the insoles did not affect the kinetics and, in opposition to our hypothesis, the insoles allowed an increase in ankle eversion compared to the control condition. Since the medial wedge used in the present study did not extend under the forefoot, it was expected that the wedge would not influence the ankle during the propulsive phase during running. These results are supported by Braga, et al. [7] and Hsu, et al. [20], but both used medial wedges that extended under the forefoot, and showed a reduction of the ankle eversion angle and invertor moment during the propulsive phase. This indicates that for running, the use of a medial wedge along the entire foot may ensure effects on the ankle during more of the stance phase. Therefore, the decrease in eversion angle and eversion moment showed by the 6º and 9º insoles may be considered as a beneficial effect for excessive pronators during walking and running, reinforcing previous research concluding that modifying rearfoot biomechanics in the frontal plane is an achievable effect that depends on the type of activity and insole inclination [5, 11]. For running, however, there was an unexpected effect on the ankle eversion during the late stance phase that needs further investigation. Although it is important to note that the foot tracking markers were adhered to the footwear, so the results of the ankle kinematics should be considered with caution.

Considering the knee, the use of 3º, 6º, and 9º medial wedge insoles increased the adduction moment mostly during the early stance phase during walking, and in the midstance for walking and running. This effect occurred for a longer duration over the stance phase with the 9º medial wedge insoles than with the 6º and 3º. Other studies [11, 20-22] also found that medial wedges increased the adduction external moment at the knee. Fukuchi, et al. [22] found this difference only when higher degrees of lateral

wedges (6º and 9º) were compared with higher medial wedge conditions (6º and 9º), but when the medial wedge was compared to the neutral condition only a trend was observed and, possibly, the sample size was not big enough to detect this change. Moreover, it should be consider that Schmalz, et al. [21] used a 14º medial wedge, significantly greater than those used in this current study. Increases in knee adduction moments have been interpreted as a clinically negative effect as it may increase compressive stresses in the medial compartment of the knee [23]. Therefore, given the effects seen on the knee in the coronal plane, the medial wedge insoles increased the adduction moment and a dose-response effect was observed.

For the hip in the frontal plane, both 6º and 9º medial wedge insoles showed decreases in adduction angle in the early stance phase of walking. But, for running, only the 9º medial wedge insoles showed decreases in adduction angle. There were also increases in the hip external adduction moments during the early stance phase of walking. These findings suggest that the larger hip external adduction moments are linked to the observed decrease in adduction angle. However, another study [20] found that both hip adduction angle and adduction moment were reduced, and future studies should be conducted to explain these controversial results for the hip moment. Furthermore, it should be noted that during running a decrease in adduction moment was observed in the early stance phase with decreases in hip adduction angle with the 9º insole, indicating the 9º insole may be reducing the stress demands on the hip abductor muscles. Therefore, the 6º and 9º medial wedge insoles reduced hip adduction angle, but its effects on the moment were controversial and need further investigation.

For the hip transverse plane, the 6º and 9º medial wedge insoles increased the external rotation moment during the early stance phase of walking, which is in contrast with the results of other studies that found no difference [7] or a decrease in the hip moment [20]. Moreover, contrary to our hypotheses, the 9º insole showed these effects over a short duration (6% of the stance phase) when compared to the 6º insole (20% of the stance phase). As previous studies did not evaluate the hip joint when investigating the dose-response effect, we cannot compare our results with the literature. Therefore, further investigation on the effects of medial wedge insoles on the hip transverse plane is necessary to better understand which changes may occur and if there is a dose-response effect.

Previous studies have indicated that a dose-response effect exists for the ankle joint kinematics and kinetics during walking for orthoses with a medial wedge [11, 22]. For the knee joint, Telfer, et al. [11] also reported a dose-response effect, while Fukuchi, et al. [22] showed no such effect. It should be noted that these previous studies did not evaluate running biomechanics and did not consider the hip joint. Moreover, these

studies only analyzed discrete variables and did not investigate the effect of the medial wedge insoles over the entire stance phase. Whereas the present study considered the entire time series throughout the stance phase and, also, considered the biomechanical effects at the ankle, knee, and hip joints during walking and running.

It should be noted that the present study considered a standardized intervention, regardless of the individual potential causes for excessive pronation. The literature indicates that foot pronation and related lower limb movements, in weight-bearing tasks, have a multicausal and individual nature [24]. The presence of excessive foot pronation may be due to a combination of different biomechanical features, such as foot-ankle bone alignment [25, 26], midfoot and hip passive stiffness and mobility [25, 27, 28], and hip strength [29], which will vary depending on an individual's presentation. Therefore, the standardized intervention used may be considered a limitation of the present study. Likewise, the insoles used in the present study combined a medial wedge with arch support. The arch support alone may have the potential to reduce foot pronation, although this effect is still controversial in the literature [6, 12, 30]. However, as all orthosis used in the present study have the same medial arch support, the differences observed were due rather to the medial wedging. Future studies should differentiate the medial wedge posting from arch support effects. Additionally, another limitation of the present study is the lack of adjustment on the p-values, which may have increased the Type I error in some comparisons. Although this is a common practice in discrete analyses, there is no explicit indication that it should be done for only three comparisons when using SPM. Finally, the kinematic results obtained for the ankle joint must be considered with caution since the markers were not fixed directly to the feet through cutouts in the shoes to guarantee the structural integrity of the shoes, which, together with the insole, promotes stabilization of the rearfoot.

Conclusion

The medial wedge insoles affected lower limb biomechanics during walking and running in individuals with excessive foot pronation. For most of the biomechanical variables, differences were found for a greater period as the medial posting increased, except ankle eversion moment and hip external rotation moment during walking. The different amounts of posting influenced the presence, timing, and duration of the effects over the stance phase. Further research is necessary to investigate the recurrence of these results in a higher sample size as well as in other symptomatic clinical populations.

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