An exploration of the effects of prefabricated and customized insoles on lower limb kinetics and kinematics during walking, stepping up and down tasks: A time series analysis

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ABSTRACT

Background**:** Prefabricated and customized insoles are used in clinical practice to reduce foot pronation. Although data exist on the effects at key points within the stance phase, exploring the impact of different insoles using time series analysis may reveal more detail about their efficacy.

Research question: What are the effects revealed by a time series analysis of arch-supported prefabricated insoles (PREFABRICATED) *versus* arch-supported prefabricated insoles customized with a 6º medial wedge (CUSTOMIZED) on the lower limb biomechanics during walking, stepping up and down tasks in individuals with pronated feet?

Methods: Nineteen individuals with excessive foot pronation performed walking, stepping up and down tasks using three insoles: CONTROL (flat insole), CUSTOMIZED, and PREFABRICATED. Angles and moments of ankle and knee coronal and hip transverse planes were compared between conditions using statistical parametric mapping (SPM).

Results: For walking, CUSTOMIZED reduced ankle eversion moment compared to CONTROL during midstance and PREFABRICATED during propulsion. CUSTOMIZED decreased KAM during midstance and propulsion compared to PREFABRICATED. Compared to CONTROL, CUSTOMIZED and PREFABRICATED reduced hip internal rotation during propulsion and loading response, respectively. CUSTOMIZED decreased eversion movement during midstance and propulsion for the stepping up task. PREFABRICATED reduced eversion movement during midstance in comparison to CONTROL. For the stepping down task, CUSTOMIZED increased eversion movement during propulsion compared to PREFABRICATED. CUSTOMIZED reduced hip internal rotation angle for stepping up task during propulsion, decreased medial rotation movement during midstance compared to CONTROL, and reduced medial rotation during midstance compared to PREFABRICATED. CUSTOMIZED increased KAM for stepping up and down tasks during propulsion.

Significance: These findings suggest that both CUSTOMIZED and PREFABRICATED reduce foot pronation. However, non-local effects, such as changes in KAM and hip internal rotation, were seen only in the CUSTOMIZED. Therefore, CUSTOMIZED may be preferable if the objective is to modify the knee and hip mechanics.

Keywords: walking; stepping up and down tasks; foot orthoses; kinematics; kinetics; SPM.

1. Introduction

Different insoles are described in the literature to reduce foot pronation. Some authors employ low-cost prefabricated insoles which only consider foot size [1, 2]. In contrast, others consider customizing prefabricated insoles by adding medial or lateral wedges [3, 4], and custom-made insoles manufactured through foot casting aim to position the subtalar joint in neutral [5, 6]. There are many prescriptions for insoles with different purposes that have been researched and used clinically. An example of this is the prescription of insoles with a focus on reducing foot pronation and reducing the amount of pronation in the stance phase along with increases in the duration of stance time [1, 2].

The effects on the proximal joints of the lower limb (i.e., non-local effects) have also been described with customized insoles. Recent studies have reported a reduction of the range of motion in the transverse plane at the knee and hip joints and adduction at the hip during running [3, 7] and walking [7, 8]. However, little is known about the effects of customized insoles on the lower-limb mechanics during other activities of daily living. Despite being a routine functional task, stepping up and down tasks are challenging activities related to patellofemoral pain (PFP) [9, 10] and knee osteoarthritis (OA) [11]. In turn, some studies indicate that excessive foot pronation may be a risk factor for the development of these conditions [11-13], as well as of other conditions like plantar fasciitis [14], calcaneal tendinopathy [15, 16], and medial tibial stress syndrome [17, 18].

Most research using three-dimensional kinetic and kinematic analyses is limited to the analysis of discrete variables. Reducing an entire time series to discrete points of interest during a functional task may determine the efficacy of interventions [19, 20]. Conversely, continuous analysis using techniques such as Statistical Parametric Mapping (SPM) allows the identification of the differences between the signals over the whole time series [19-22].

Therefore, the present study aimed to compare the effects of prefabricated insoles with arch support (PREFABRICATED), prefabricated insole with arch support and a 6º medial wedge (CUSTOMIZED), and flat insole (CONTROL) on the lower limbs' angles and moments of individuals with pronated feet during walking and stepping up and down tasks using the SPM. The hypotheses were that both intervention insoles would reduce the calcaneal eversion, increase the external knee adduction moment

(KAM), and reduce the hip internal rotation over time. The non-local effects of the CUSTOMIZED insoles would be more evident than the PREFABRICATED insoles.

2. Methods

2.1. Participants

Inclusion criteria were; aged between 18 and 45 years, body mass index (BMI) < 28 kg/m², Foot Posture Index (FPI) ≥ 6 [23], and no history of lower limb injuries on the lower limb and pelvis in the last year. Participants were excluded if they presented discomfort or pain when using the insoles. The sample size was determined using G*Power version 3.1 [24] using a repeated-measures analysis of variance (ANOVA), statistical power of 0.7, moderate effect size (0.6), and significance level of 0.05, which resulted in a sample size of 16 being required. Participants were recruited by convenience through verbal and virtual invitations (email/social media). All participants signed an Informed Consent Form before data collection, and the study was approved by the Institutional Research Ethics Committee (nº 2.622.183).

2.2. Experimental conditions

Three insole conditions were tested: CONTROL, PREFABRICATED, and CUSTOMIZED. All insoles were made from ethylene-vinyl acetate (EVA) shore 40. CONTROL was a 2mm thick flat insole (Fig. 1a), PREFABRICATED insoles were manufactured by Dilepé Orthopedic Products, Brazil, with medial longitudinal arch support and no posting under the rearfoot (Fig. 1b). CUSTOMIZED were the prefabricated insole with the addition of a 6º medial wedge under the rearfoot (Fig. 1c). This wedge was custom made on a CNC (Computer Numerical Control) milling machine also 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. A previous study showed that wedges inclined at 6º could promote significant changes in the kinetics and kinematics of the lower limbs during walking and running [25].

2.3. Instruments

The kinematic data were recorded using a 9-camera Oqus 3+ system at 200 Hz (Qualisys Medical AB, Sweden). The kinetic data were recorded using three synchronized force plates (FP 4060-08, Bertec, USA) at 1000Hz.

2.4. Procedures

On the day of data collection mass, height, BMI, and FPI were measured by the same experienced examiner [23]. The order of tasks was randomized using an opaque envelope and a code written on a piece of paper for each experimental situation. Passive retro-reflective markers were placed on the volunteers. A static trial was performed with the participants using standardized footwear (New Fit, Bout's, Brazil) with the control insole. The three insole conditions were recorded in a randomized order with walking trials performed on a 12-meter walkway and stepping up and stepping down tasks were performed from the ground level to a 20cm step and from a 20cm step to the ground level, respectively. All tasks were performed at self-selected speed and participants had a 5-minute wash-out period between wearing each pair of insoles. The steps were placed over the force plates to record the kinetics, and their weight were removed before data collection. More information about data collection is presented in the Supplementary Materials.

2.5. Data processing

Kinematic and kinetic data were processed using Visual 3D (version 6, C-motion, USA). Marker trajectories and force data were low-pass filtered using a 4th-order Butterworth filter at 6Hz and 25Hz, respectively [26]. All body segments were modeled using the Calibrated Anatomical System Technique [27]. 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. External joint moments were calculated using three-dimensional inverse dynamics normalized to body mass. The analysis focused on the ankle coronal plane, knee coronal plane, and hip transverse planes, as these have previously been related to foot pronation [23,24]. The time series were normalized to 100% of the stance phase, and the average of five trials was used for analysis. More information about data processing is presented in the Supplementary Materials.

2.6. Data analysis

A time series analysis was performed using the SPM [19, 28]. Before any inferential procedures, the data distribution was examined and found to be normally distributed 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 (CONTROL vs. CUSTOMIZED, CONTROL vs. PREFABRICATED, and CUSTOMIZED vs. PREFABRICATED) were performed using SPM post-hoc paired t-tests when the ANOVA main effect was significant. A Bonferroni correction was applied for multiple comparisons ($p<0.0167$). 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). The technical details on the SPM methods used have been previously reported [19, 26, 28], and all analyses were implemented using the open source spm1d code (www.spm1d.org) for Matlab (2021a, The MathWorks, Inc., USA).

3. Results

In total, ten women and nine men completed the study. Table 1 shows the characteristics of the participants. The SPM results are presented below.

3.1. Walking

The 1RM-ANOVA revealed significant main effects for ankle eversion angle and moment. For kinematic results, both CUSTOMIZED and PREFABRICATED reduced the ankle eversion at the beginning of midstance compared to CONTROL. Regarding kinetic results, CUSTOMIZED decreased the ankle eversion moment during midstance and at the beginning of the propulsion phase. In turn, PREFABRICATED increased the ankle eversion moment during the loading response phase and reduced the eversion moment during midstance and at the beginning of the propulsion phase compared to CONTROL. Additionally, CUSTOMIZED reduced the ankle eversion moment at the end of the midstance and the beginning of the propulsion phase compared to PREFABRICATED (Figure 2 and Table 2).

The 1RM-ANOVA also revealed significant main effects for the knee adduction moment (KAM) and hip rotation movement and moments. CUSTOMIZED reduced the

KAM during midstance and at the beginning of the propulsion phase compared to PREFABRICATED (Figure 3 and Table 2). For the hip angles, CUSTOMIZED increased the external rotation movement at the end of the propulsion phase, and PREFABRICATED increased the external rotation movement during the loading response phase compared to CONTROL. For the hip moments, CUSTOMIZED increased the lateral rotation at the beginning of midstance and PREFABRICATED increased the lateral rotation moment at the beginning of midstance compared to CONTROL (Figure 4 and Table 2).

3.2. Stepping up task

The 1RM-ANOVA revealed significant main effects for ankle eversion angle. CUSTOMIZED reduced the eversion movement in the midstance and the beginning of the propulsion phase. PREFABRICATED reduced the eversion movement at the beginning of midstance compared to CONTROL (Figure 2 and Table 2).

There were also significant main effects for KAM. CUSTOMIZED increased KAM at the beginning of the propulsion phase, and PREFABRICATED increased KAM at the beginning of the propulsion phase compared to CONTROL. Additionally, comparing CUSTOMIZED to PREFABRICATED, CUSTOMIZED increased KAM at the beginning of the propulsion phase, and PREFABRICATED increased KAM at the end of the propulsion phase (Figure 3 and Table 2). For the hip, compared to CONTROL, CUSTOMIZED reduced medial rotation at the beginning of the propulsion phase (Figure 4 and Table 2).

3.3. Stepping down task

The 1RM-ANOVA revealed significant main effects for ankle eversion angle. CUSTOMIZED reduced the eversion movement at the beginning of midstance and increased the eversion in the propulsion phase. PREFABRICATED reduced the eversion movement at the beginning of midstance compared to CONTROL. Moreover, CUSTOMIZED increased the eversion movement in the propulsion phase compared to PREFABRICATED (Figure 2 and Table 2).

There were significant main effects for knee adduction angle, KAM, and hip rotation. PREFABRICATED reduced the knee adduction angle during the propulsion phase and midstance phase when compared to CONTROL and CUSTOMIZED. CUSTOMIZED increased KAM at the beginning of midstance and propulsion phases compared to CONTROL (Figure 3 and Table 2). For the hip, CUSTOMIZED reduced the medial rotation movement at the beginning of midstance compared to CONTROL, and CUSTOMIZED decreased the medial rotation movement of the midstance compared to PREFABRICATED (Figure 4 and Table 2).

4. Discussion

This study used the SPM to explore the effects of CUSTOMIZED and PREFABRICATED over time on the lower limb biomechanics during walking and stepping up and down tasks. Confirming our hypotheses, there were several differences in the kinetic and kinematic variables between the different insoles. The SPM revealed that CUSTOMIZED and PREFABRICATED reduced the angle of eversion of the rearfoot during all tasks compared to the CONTROL. CUSTOMIZED decreased the eversion moment compared to the CONT and PREFABRICATED during walking. CUSTOMIZED increased KAM while stepping up and down tasks. PREFABRICATED increased KAM during stepping up task and reduced the adduction angle compared to CONTROL and CUSTOMIZED. CUSTOMIZED and PREFABRICATED reduced the medial rotation of the hip during walking compared to CONTROL. Finally, CUSTOMIZED reduced the hip medial rotation angle during the stepping down task and hip medial rotation moment during the stepping down task. Each finding will be discussed below.

4.1. Walking

CUSTOMIZED and PREFABRICATED reduced the rearfoot eversion angle compared to the CONTROL (*p*<0.001). Corroborating with other studies, which also observed a reduction in the rearfoot eversion [29, 30]. People with excessive foot pronation do not have an arch to cushion the ground pressure due to an arch collapse problem caused by several congenital factors or other acquired predisposing factors [31]. Abnormal pressure leads to discomfort in flat feet, which, if left untreated, will produce pain and disability [32]. For kinetics, our study showed that CUSTOMIZED reduced the ankle eversion moment during midstance and at the beginning of the propulsion phase. However, other studies found no significant kinetics differences [30, 33, 34]. This inconsistency may be explained by the difference in data analysis since the previous studies focused on discrete variables.

CUSTOMIZED increased the KAM when compared to PREFABRICATED (*p*<0.001). This is supported by Chen, Lou, Huang and Su [35] who examined walking under the conditions of shoes with and without insoles to control foot pronation and showed an increased peak adductor moment at the knee. Kosonen, Kulmala, Müller and

Avela [7] reported significant differences in the application of medially wedged insoles in knee kinetics during walking in men aged between 18 and 30 years with pronated feet during running. Furthermore, a longitudinal study carried out by Jafarnezhadgero, Shad and Majlesi [36] considered children and adolescents with flat feet and showed that the use of insoles with medial longitudinal arch support resulted in a decrease in the medial rotation angle of the knee and the knee abduction angle in the short and long term.

For the hip, CUSTOMIZED and PREFABRICATED reduced the medial rotation of the hip angle and moments compared to CONTROL ($p<0.001$; $p=0.014$); however, other studies have shown no significant differences in the kinematics and kinetics of the hip when using shoes with insoles to control pronation [7, 35]. Jafarnezhadgero, Alavi-Mehr and Granacher [37] reported lower hip abductor torques and lateral rotation in male children with prefabricated medially posted insoles compared to shod with no orthoses in the long-term. These inconsistencies may be due to methodological differences between the aforementioned studies, such as the applied tests, preferred speed versus walking speed, and children versus adults or men versus female or mixed participants, and only included discrete point analysis compared to the time series analysis conducted in this current study.

4.2. Stepping up and down tasks

CUSTOMIZED and PREFABRICATED reduced the rearfoot eversion compared to the CONTROL during the stepping up task ($p<0.001$; $p=0.01$) and stepping down task ($p<0.001$; $p=0.002$), respectively. CUSTOMIZED increased the eversion concerning PREFABRICATED ($p=0.009$). McKenzie, Galea, Wessel and Pierrynowski [10] showed that female PFP participants descended the step with the most adducted hips and more significant internal rotation than asymptomatic individuals. Evidence supports the relationship between excessive rearfoot eversion and PFP [38, 39]. From a theoretical point of view, excessive rearfoot eversion causes greater tibia internal rotation, consequently creating more significant hip internal rotation and adduction. Hip adduction and internal rotation are reported to increase knee dynamic valgus and lateral patella tracking, leading to a reduction in the patella’s contact area, then growing the patellofemoral stress. This mechanism has been associated with PFP [40].

CUSTOMIZED and PREFABRICATED increased the KAM during the stepping up ($p<0.001$; $p=0.003$) and down tasks ($p<0.001$) when compared to CONTROL. When compared CUSTOMIZED and PREFABRICATED in the stepping up task, CUSTOMIZED increased KAM during the beginning of the propulsion phase (*p*=0.007) and PREFABRICATED increased KAM during the end of the propulsion phase (*p*<0.001). PREFABRICATED reduced the adduction angle during the stepping down task compared to CONTROL and CUSTOMIZED (*p*<0.001). Previous studies have shown that the dynamic valgus of the knee may affect pain and joint stability during stepping up and down tasks and can predispose lesions in the lower limbs. Studies show that biomechanical changes are considered an essential factor affecting the loss of cartilage and the progression of knee OA [11, 38, 39, 41, 42].

CUSTOMIZED increased the lateral rotator moment of the hip during the stepping up task compared to the CONTROL (*p*<0.001). Also, it decreased the angle of medial hip rotation during the stepping down task compared to CONTROL and PREFABRICATED (*p*=0.008; *p*>0.001;). Bonifácio, Richards, Selfe, Curran and Trede [43] found that insoles significantly decreased medial hip rotation and knee adduction compared to the control insole during the stepping down task, which could benefit individuals with PFP. Moreover, the orthoses provided greater stability and less work performed by the abductor halluces and tibialis anterior muscles, arguably through the mechanical changes in the joints of the foot and lower limbs from the orthoses [43].

4.3. Clinical Implications

During closed chain activities, motions and moments of different joints are interdependent. Foot pronation is often coupled with shank, thigh, and medial hip rotation since the talus transfers the rearfoot motions to the lower limb [31, 44]. Our study showed that reducing foot pronation with the CUSTOMIZED insole reduced also hip transverse plane angle and moment, which is in accordance with the theory. Also, it has been proposed that calcaneal eversion is coupled with knee abduction [45]. Our study showed that reducing foot pronation with the CUSTOMIZED insole did not change knee angle but increased knee moment. The proximal effects on the hip and knee occurred with the CUSTOMIZED insole and not with the PREFABRICATED insole. Perhaps, the greater the local effect on the ankle, the higher its proximal effects. When prescribing insoles, clinicians must be aware of their proximal effects.

As excessive foot pronation has been associated with some musculoskeletal injuries [7, 14-18], the reduced foot eversion, increased KAM and decreased medial rotation of the hip can contribute to a reduction in pain and improvement in function in some musculoskeletal conditions. Based on the results of our study, we could show the effects of the insoles on the kinematic and kinetics of the ankle, knee, and hip, providing clinicians with evidence to guide therapeutic interventions. Likewise, providing further confirmation that a simple modification such as the medial wedge can promote more non-local changes in the kinetics and kinematics. However, clinicians must be aware that not all prefabricated insoles have the same effect; perhaps modifying an insole may be necessary depending on the desired clinical objective. Besides, the dosage of the wedge inclination must also be taken into consideration. The same insole dynamically interferes with the joints differently between tasks. Perhaps, when choosing the insole, it is necessary to focus on the task with the greatest demand or the one in which the patient reports pain. Finally, we encourage the execution of future studies that analyze this data in the long term and different tasks. Future Randomized Clinical Trials may be a great alternative to assess the effectiveness of the intervention in different outcomes, tasks and populations.

4.4. Limitations

The use of markers on shoes may not perfectly reflect the movements of the foot segments. However, it is necessary to keep the integrity of the shoe structure to better anchor the insole. The use of prefabricated insoles did not allow an individualized correction for each participant. Nevertheless, the standardized longitudinal arch support and medial wedge prevented variation in the intervention by ensuring that the insoles were the same for the different volunteers.

5. Conclusion

This study revealed through the SPM that CUSTOMIZED reduces the ankle eversion moment compared to CONTROL and PREFABRICATED in the midstance and the beginning of propulsion phase during walking, respectively. CUSTOMIZED increases KAM during stepping up and down tasks at the beginning of the propulsion phase. In addition, CUSTOMIZED decreases the medial hip rotation at the beginning of the propulsion phase during the stepping down task. Therefore, if the objective is to reduce foot pronation, considering only local effects, CUSTOMIZED and PREFABRICATED should be considered; however, for non-local effects, such as changes in the KAM and medial rotation of the hip, CUSTOMIZED should be considered.

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Figures:

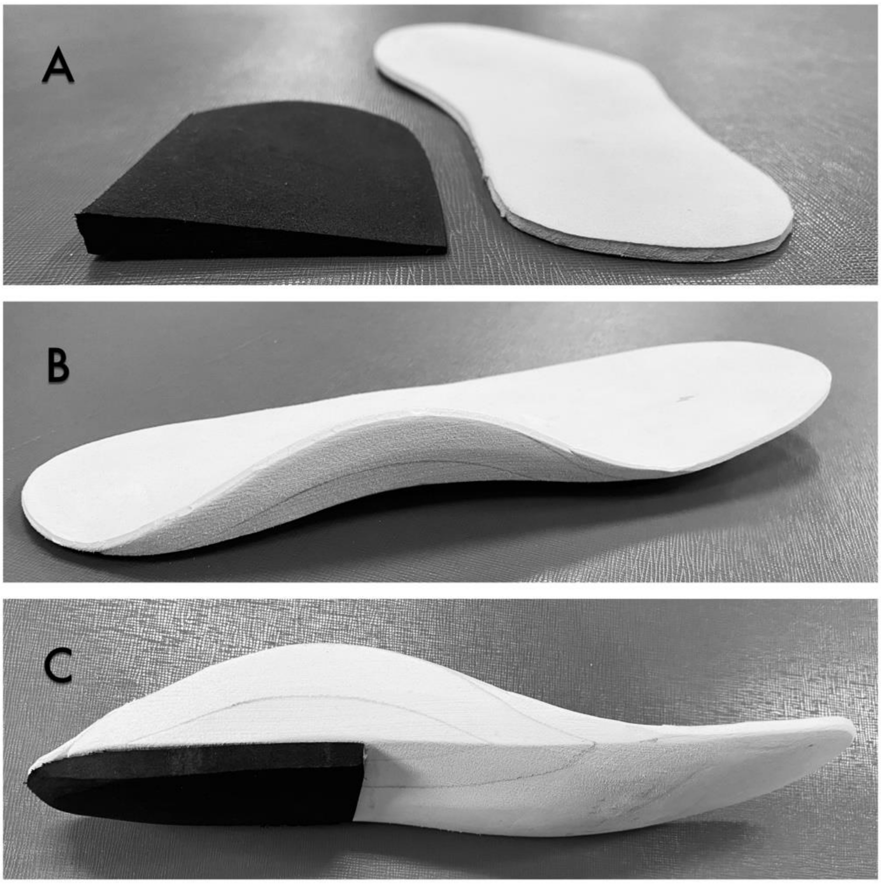

Figure 1. A: Posterior view of the control insole (right) and anterior view of the 6º medial wedge (left). **B**: Posterior-medial view of the prefabricated insole with the medial longitudinal arch support. **C**: Medial view of the customized insole: medial longitudinal arch support and medial wedge inclined at 6º.

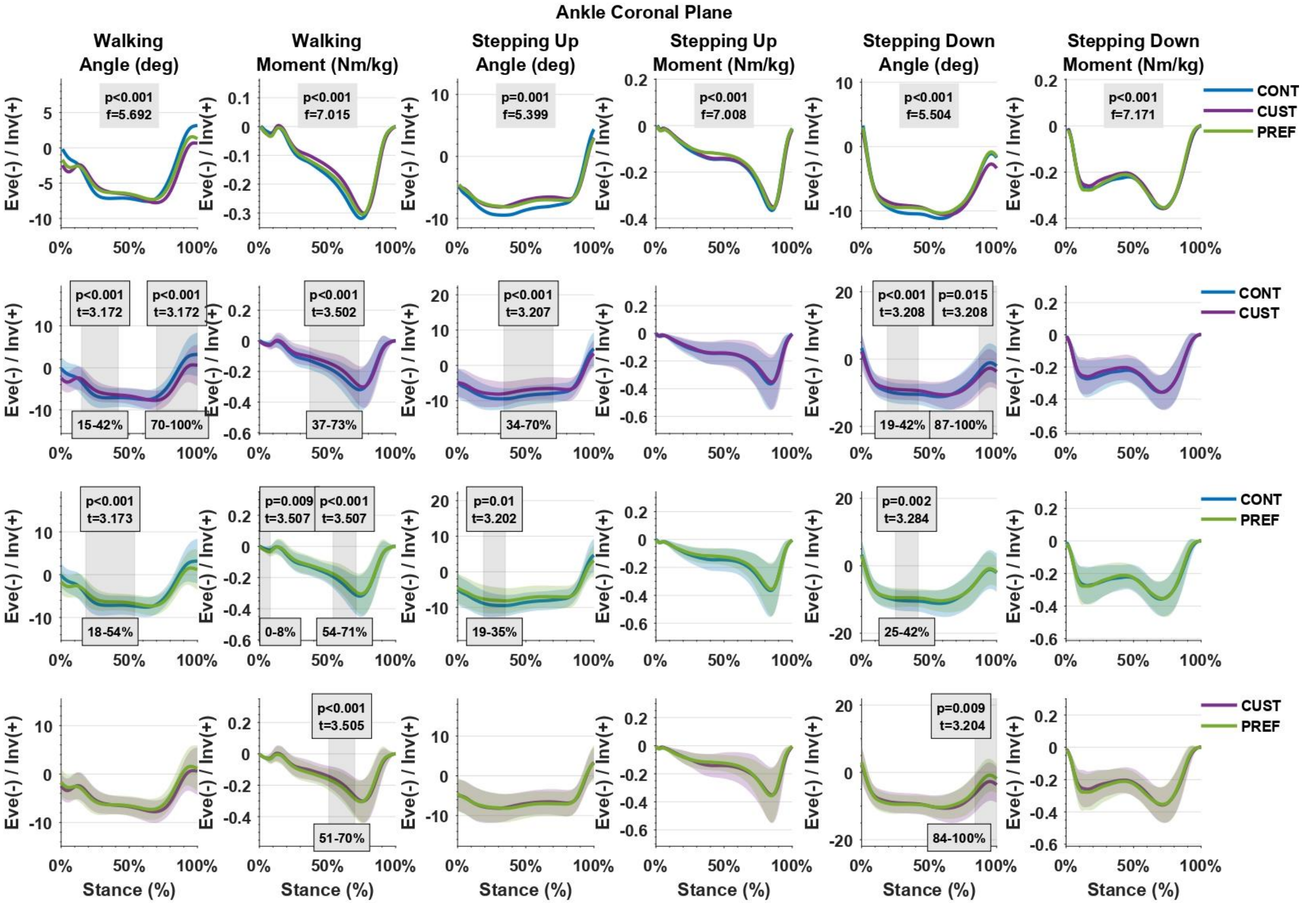

Figure 2: Ankle coronal plane during walking, and stair ascent and descent. First row corresponds to ANOVA-1RM. Second to fourth rows correspond to the comparison between groups. CONT: control insole. CUST: customized insole. PREF: prefabricated insole. Eve: eversion. Inv: inversion. Deg: degrees. Nm: Newton meter. Kg: kilogram.

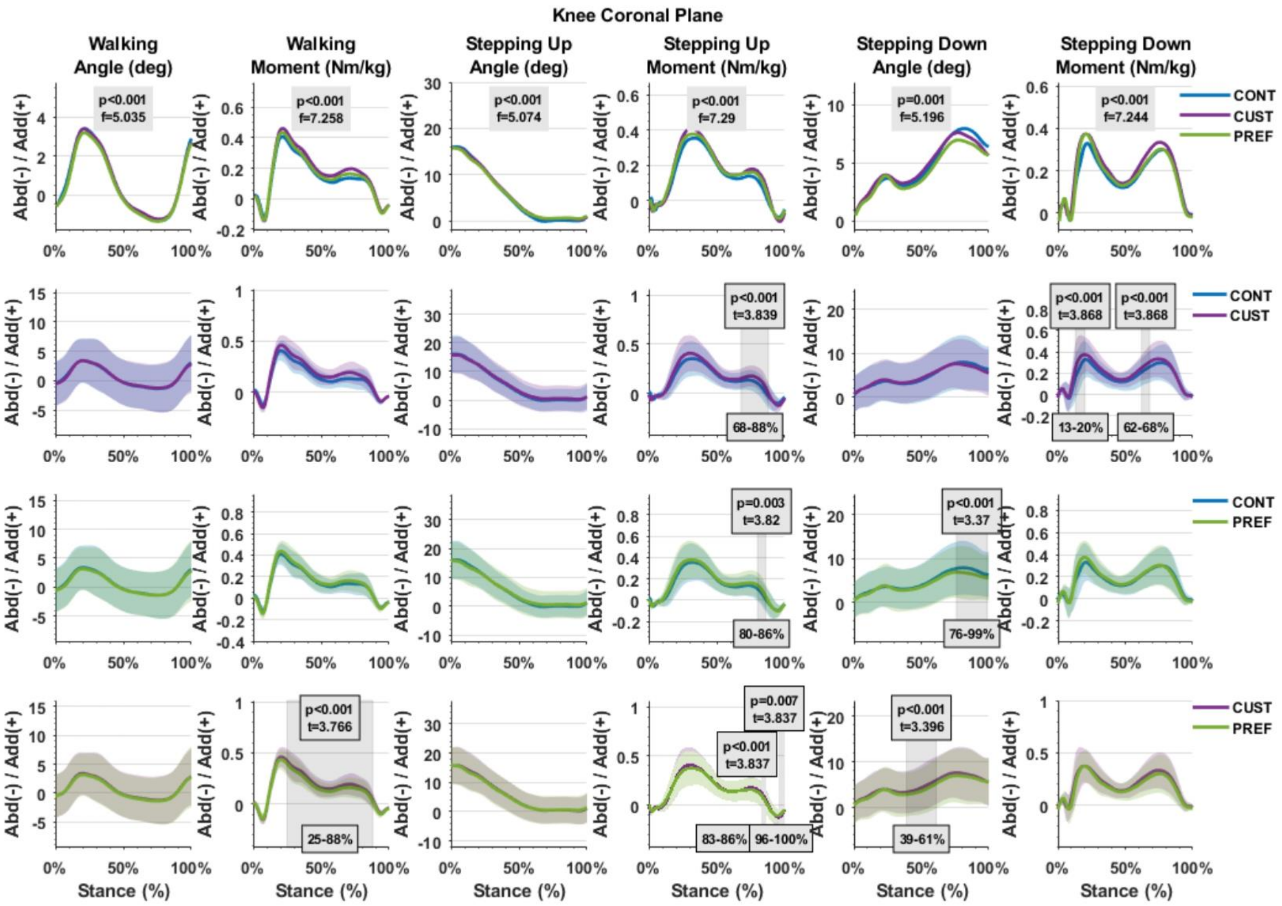

Figure 3: Knee coronal plane during walking, and stair ascent and descent. First row corresponds to ANOVA-1RM. Second to fourth rows correspond to the comparison between groups. CONT: control insole. CUST: customized insole. PREF: prefabricated insole. Abd: abduction. Add: adduction. Deg: degrees. Nm: Newton meter. Kg: kilogram.

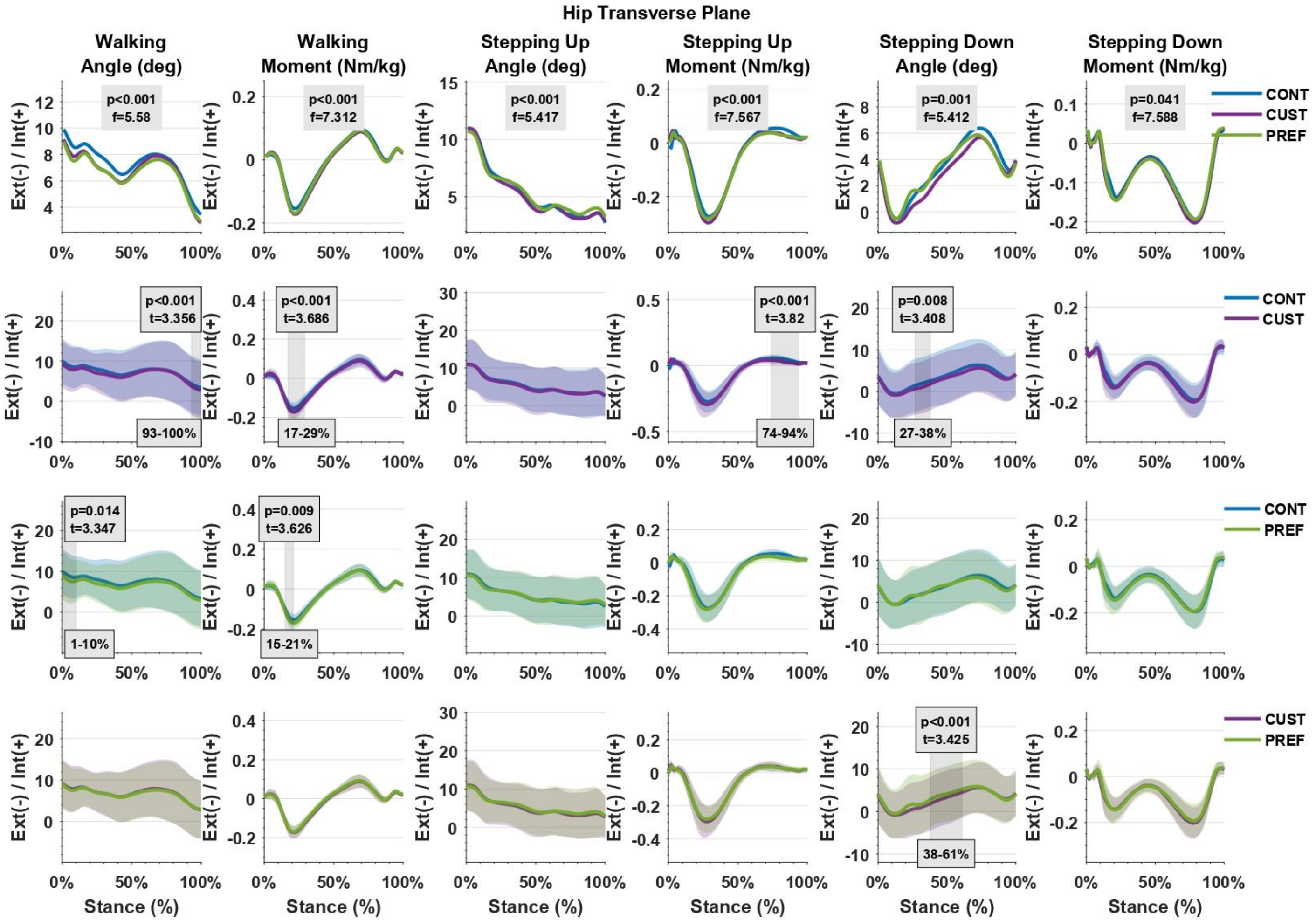

Figure 4: Hip transverse plane during walking, and stair ascent and descent. First row corresponds to ANOVA-1RM. Second to fourth rows correspond to the comparison between groups. CONT: control insole. CUST: customized insole. PREF: prefabricated insole. Ext: external rotation; Int: internal rotation. Deg: degrees. Nm: Newton meter. Kg: kilogram

Tables:

Table 1 - Characteristics of the participants.

Variables	Participants Group (mean ± SD)	IC 95%	Minimum	Maximum
Age (years)	27.0 ± 8.07	24.05- 31.05	19	45
Body mass (kg)	65.43 ± 11.36	60.73 – 70.68	49.60	87.00
Height (cm)	173.7 ± 7.32	170 - 177	165	188
BMI (kg/m^2)	21.60 ± 2.93	20.31 – 22.94	16.88	26.89
FPI	9.84 ± 1.46	9.21 – 10.42	+7	+12

Abbreviations: BMI = Body Mass Index; FPI = Foot posture index; IC = Confidence Interval; SD = Standard deviation.

Table 2 - Comparative table for the ankle, knee, and hip during walking, stepping up and stepping down tasks.

Joint	Variable	Task	CUST vs CONT	PREF vs CONT	CUST vs PREF
Ankle coronal plane	**Angle**	**Walking**	t=3.17 (p<0.001) ΔTD=59%	t=3.17 (p<0.001) ΔTD=37%	-
		Stepping up	t=3.20 (p<0.001) ΔTD=37%	t=3.20 (p=0.01) ΔTD=17%	-
		Stepping down	t=3.20 (p<0.001) ΔTD=38%	t=3.28 (p=0.002) ΔTD=18%	t=3.20 (p=0.009) ΔTD=17%
	Moment	**Walking**	t=3.50 (p<0.001) ΔTD=37%	t=3.50 (p<0.001) ΔTD=27%	t=3.50 (p<0.001) ΔTD=20%
		Stepping up	-	-	-
		Stepping down	-	-	-
Knee coronal plane	**Angle**	**Walking**	-	-	-
		Stepping up	-	-	-
		Stepping down	-	t=3.37 (p<0.001) ΔTD=24%	t=3.39 (p<0.001) ΔTD=23%
	Moment	**Walking**	t=3.75 (p=0.001) ΔTD=71%	t=3.73 (p<0.001) ΔTD=22%	t=3.76 (p<0.001) ΔTD=64%
		Stepping up	t=3.83 (p<0.001) ΔTD=21%	t=3.82 (p=0.003) ΔTD=7%	t=3.83 (p<0.001) ΔTD=9%
		Stepping down	t=3.86 (p<0.001) ΔTD=15%	-	-
Hip transverse plane	**Angle**	**Walking**	t=3.35 (p<0.001) ΔTD=21%	t=3.34 (p=0.014) ΔTD=19%	-
		Stepping up	-	-	-
		Stepping down	t=3.40 (p=0.008) ΔTD=12%	-	t=3.42 (p<0.001) ΔTD=24%
	Moment	**Walking**	t=3.68 (p<0.001) ΔTD=13%	t=3.62 (p=0.009) ΔTD=7%	-
		Stepping up	t=3.82 (p<0.001) ΔTD=21%	-	-
		Stepping down	-	-	-

Summed values from all regions in which there were significant differences for each comparison. Abbreviations: CONTROL: control insole; CUSTOM: customized insole; PREFABRICATED: prefabricated Insole; t: critical value of Student's t distribution; p: p-value; ΔTD: time difference (in percentage) reported by subtracting between the end and the onset of significant differences in the support phase. (-): No significant differences.