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The biomechanical effects of 3D printed and traditionally made foot orthoses in individuals with unilateral plantar fasciopathy and flat feet

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ABSTRACT

Background: Foot orthoses (FOs) are used to manage foot pathologies such as plantar fasciopathy. 3D printed custom-made FOs are increasingly being manufactured. Although these 3D-printed FOs look like traditionally heat-moulded FOs, there are few studies comparing FOs made using these two different manufacturing processes.
Research question: How effective are 3D-printed FOs (3D-Print) compared to traditionally-made (Traditional) or no FOs (Control), in changing biomechanical parameters of flat-footed individuals with unilateral plantar fasciopathy?
Methods: Thirteen participants with unilateral plantar fasciopathy walked with shoes under three conditions: Control, 3D-print, and Traditional. 2 × 3 repeated measures analysis of variance (ANOVAs) with Bonferroni post-hoc tests were used to compare discrete kinematic and kinetic variables between limbs and conditions. Waveform analyses were also conducted using statistical parametric mapping (SPM).
Results: There was a significant condition main effect for arch height drop ($p = 0.01$; $\eta p^2 = 0.54$). There was 0.87 mm (95% CI [−1.84, −0.20]) less arch height drop in 3D-print compared to Traditional. The SPM analyses revealed condition main effects on ankle moment ($p < 0.001$) and ankle power ($p < 0.001$). There were significant differences between control condition and both 3D-print and Traditional conditions. For ankle moment and power, there were no differences between 3D-print and Traditional conditions.
Significance: 3D-printed FOs are more effective in reducing arch height drop, whist both FOs lowered ankle plantarflexion moment and power compared to no FOs. The results support the use of 3D-printed FOs as being equally effective as traditionally-made FOs in changing lower limb biomechanics for a population of flat-footed individuals with unilateral plantar fasciopathy.

1. Introduction

Individuals with flat-feet present with greater rearfoot eversion and arch flattening [1]. However, the association of these biomechanical changes to higher risks of foot injuries is inconclusive [2–4]. Foot orthoses (FOs) are still regularly used to support the foot arch for individuals with flat-feet [5] and change lower limb biomechanics during walking, running and jumping tasks [6–8]. Although the effects of FOs on re-aligning the foot and leg seem small [9,10], the efficacy of FOs in reducing painful symptoms is well supported [11,12]. Therefore, FOs are still used by clinicians to treat painful musculo-skeletal foot injuries. FOs can be custom-made specifically to the wearer and customised prescription is common [13]. 12.5% of clinicians surveyed felt that new technology such as 3D printing of FOs can be incorporated into clinical practice [14]. Many orthotic laboratories have started to 3D print custom-made FOs to reduce the time, dependence on manual labour and long-term cost of orthotic manufacture [15–17]. There is a trend of using 3D-printing for the commercial manufacture of custom-made FOs, but a paucity of evidence supporting their biomechanical effectiveness.

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Table 1
Physical and clinical characteristics of 13 participants (5 males, 8 females) with unilateral plantar fasciopathy and flat-feet.

Variable	Mean (SD)
Age, years	45.8 (9.1)
BMI, kg·m^{-2}	28.6 (6.0)
FPI of painful foot, − 12 to + 12	7.0 (1.4)
FPI of non-painful foot, - 12 to + 12	7.2 (1.4)
Duration of painful symptoms, months	26.4 (25.4)
NRS level of pain in painful foot, 0–10	4.9 (2.9)

Note: BMI – Body Mass Index, FPI – Foot Posture Index, NRS – Numeric Rating Scale.

To date, very few studies have compared biomechanical outcomes between 3D-printed and traditionally-made FOs [18–20]. In healthy, pain-free participants, compared to traditionally-made FOs, 3D-printed FOs lowered plantar pressure under the heel and reduced the sagittal range of motion, dorsiflexion at heel strike, and maximum eversion of the ankle during walking [18]. 3D-printed FOs were also as effective as traditionally-made FOs in supporting the arch as indicated by a similar arch height drop [19]. However, another study reported no differences in peak rearfoot eversion angle and velocities, or loading rates during running between 3D-printed and traditionally-made FOs [20]. These results may not be clinically useful as it is unlikely that custom-made FOs will be prescribed for pain-free individuals where FOs use is not clinically indicated.

Plantar fasciopathy is a common cause of heel pain and is associated with degenerative changes in the plantar fascia [21]. Individuals with flat-feet [13] and plantar fasciopathy [11] are commonly treated with custom-made FOs. Therefore, it is clinically relevant to investigate the efficacy of 3D-printed FOs in individuals with these conditions. Among individuals with plantar fasciopathy, 3D-printed FOs moved the centre of pressure trajectory laterally during walking [22]. This has been postulated to be advantageous in off-loading the plantar fascia to aid recovery and reducing painful symptoms in the heel [23]. Currently, no studies have examined the effects of 3D-printed FOs in individuals with plantar fasciopathy and flat-feet. Furthermore, when an individual has unilateral plantar fasciopathy and requires FOs, the devices are worn bilaterally. The effect of FOs on the asymptomatic foot is unknown. Thus, the aims of this study were to examine the effects of 3D-printed and traditionally-made FOs on foot biomechanics during walking in individuals with unilateral plantar fasciopathy and flat-feet. We hypothesise that (1) 3D-printed and traditionally-made FOs will cause the same biomechanical effects and (2) these effects will be the same in the feet with and without plantar fasciopathy.

2. Method

This study employed a within-subject single-blinded randomised crossover design under three conditions: (1) control, (2) 3D-printed FOs, and (3) traditionally-made FOs. Institutional Human Research Ethics Committee (HREC) approval was obtained (Approval number: 21471). Registration was lodged and approved with the Australian New Zealand Clinical Trials Registry (ANZCTR) (Registration number: ACTRN12620000960954). Participants were recruited from the university health clinic and provided written informed consent.

2.1. Participants

An a-priori estimation of sample size (an alpha of 0.05, and a power of 0.80, and effect size of 0.4 for interaction effect) predicted that at least 12 participants were required for this study [24]. The effect size of 0.4 was from previous published work which reported an effect size of 0.387 for comfort perception of arch support of foot orthoses [25]. Thirteen participants (5 males, 8 females) were included in the study (Table 1). This sample size is consistent with similar studies [10,20]. Participants were first screened by two Australian registered podiatrists. Participants were included if they were ≥ 18 years of age, had unilateral heel pain for more than three months, a Body Mass Index (BMI) < 36 kg·m^{-2}, and a Foot Posture Index (FPI) score≥ +6, indicating a pronated foot [26]. Exclusion criteria were pain at other lower limb sites, existing medical conditions affecting gait (e.g., arthritis, Parkinson's disease), current analgesia and FOs use.

2.2. Orthotic fabrication process

Digital scans and plaster of Paris casts were taken of the participant's feet by the same assessing podiatrist according to clinical practice previously reported [26]. Both 3D-printed and traditionally-made FOs (Fig. 1) were made to the same prescriptions by one commercial orthotic manufacturer (Orthotech Laboratory Pty Ltd, VIC, Australia). FOs were assigned unique identifier numbers so the manufacturer was blinded to the participant identity. All 3D-printed and traditionally-made FOs shells were made using 3 mm 3D printed material and polypropylene respectively and covered with 1.5 mm poron and black leather full-length top covers (Fig. 1). Dimensions of the two types of FOs were previously reported [25].

2.3. Data collection

3D motion analysis data was collected under three conditions: (1) shoe without FOs (Control), (2) shoe with 3D-printed FOs (3D-Print), and (3) shoe with traditionally-made FOs (Traditional). The orders of conditions were randomised. Prior to collecting motion data, participants' preferred walking time along a 5-m walkway was determined using electronic timing gates (Smartspeed Pro, Fusion Sport, Colorado, USA). To control for walking speed in the experiment, a trial was accepted if participants walked within 5% of their preferred time.

Forty-two 14 mm retro-reflective markers were placed on each participant according to the Vicon Nexus Plug-in Gait Lower Limb and Oxford Foot Models [27] (Fig. 2). Holes about the size of 25 mm [28] were cut into the standard issued shoes. Between each condition, participants were given a five-minute rest period, during which time, the markers and shoes were removed and FOs changed. To ensure that all removed markers were replaced in the exact same location, each marker base was outlined with a black marker prior to removal to facilitate accurate replacement [29].

Kinematic data were collected at 120 Hz using an eight-camera motion capture system (Vicon Nexus, Vicon Motion Systems Ltd, Oxford, UK) and kinetic data was collected at 2000 Hz using a force plate (AMTI, Advanced Mechanical Technology Inc., MA, USA) embedded within the walkway. Five trials with clean force plate strike were collected for each condition and limb. Vicon Nexus software (version 2.9.3, Vicon Motion Systems, Oxford, UK) was used to collect and process data. For each trial, 3D marker trajectories were reconstructed, missing frames (gaps < 10 frames) were manually reviewed and filled using a pattern gap-fill function. Data was smoothed with a Woltring filter (mean square error =20) [30] and modelled according to the Vicon Nexus Plug-in gait Lower Limb and the Oxford Foot Model [27]. The joint angles were computed according to the Cardan sequence: sagittal, transverse and frontal. Gait events were identified as previously reported [31] and joint kinematic and kinetic data during contact phase of gait was time normalised to 101 data points and exported using a custom-written MATLAB code. (MATLAB R2019B, The Mathworks, Inc, USA).

2.4. Biomechanical variables

FOs alter joint biomechanics in the foot, with minimal effect on more proximal joints such as the knee and hip [6]. Thus, the variables

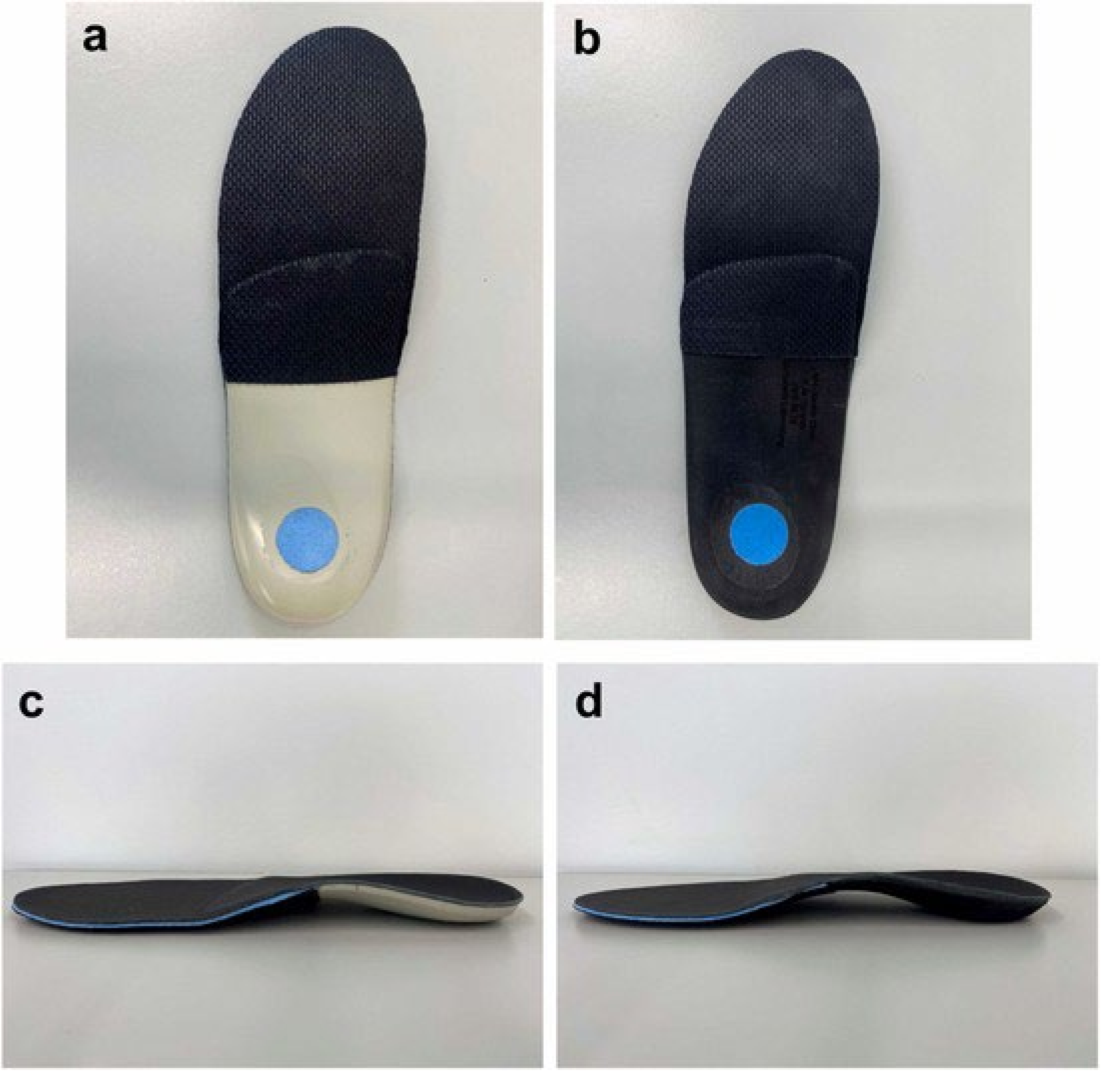

Fig. 1. a) Plantar view of traditionally-made foot orthoses b) Plantar view of 3D-printed foot orthoses c) medial view of traditionally-made foot orthoses d) medial view of 3D-printed foot orthoses.

analysed were focused on the foot and ankle. Kinematic variables selected for analysis included total range of rearfoot eversion [6], and total arch height drop during the stance phase [19]. Kinetic variables selected included vGRF, ankle moment, and ankle joint power.

2.5. *Statistical analysis*

2 × 3 analysis of variance (ANOVAs) with Bonferroni *post-hoc* tests were used to compare total range of rearfoot eversion and arch height drop between limbs (pain and no pain limbs) and conditions (Control, 3D Print, Traditional). Effect size (partial eta-squared, ηp^2) was reported as small ($\eta p^2 \leq 0.01$), medium ($0.01 < \eta p^2 \leq 0.06$), large ($0.06 < \eta p^2 \leq 0.14$) and very large ($\eta p^2 < 0.14$) [32]. Data were analysed using SPSS V25 (IBM Corp., Armonk, NY, USA) and level of statistical significance was set at $\alpha = 0.05$.

For all other biomechanical variables, waveform analyses over time were conducted using statistical parametric mapping (SPM) 2 × 3 ANOVAs to provide additional dynamic information that may be missed when reporting discrete variables [33]. These analyses were conducted within MATLAB R2019B (The Mathworks, Inc, USA) using the open-source SPM1D package (v.0.4.8) [34]. If statistical significance was reached, post-hoc paired sample t-tests were performed with a Bonferroni correct alpha level to account for multiple comparisons.

3. Results

3.1. *Kinematic analysis*

There was no significant condition main effect or limb x condition interaction for the total range of motion of rearfoot eversion, which was consistent with the SPM analyses (Fig. 3a-f). There was a significant condition main effect ($p = 0.01$; $\eta p^2 = 0.54$) in arch height drop (Table 2). Post- hoc tests identified significantly less arch height drop of 0.87 mm (95% CI [−1.84, −0.20]) for 3D-Print compared to Traditional. The SPM analyses for arch height revealed no significant limb or condition main effect or limb x condition interaction (Fig. 3g-l).

3.2. *Kinetic analysis*

For vGRF, the SPM analysis noted a condition main effect (Fig. 4b and e) and limb x condition interaction (Fig. 4c and f). Post-hoc analyses of the condition main effect revealed significantly lower vGRF during the Traditional and 3D-Printed compared to the Control between ~0.5% and 7% of stance (vs. both FO conditions, $p < 0.001$), as well as between 61% and 69% of stance (vs. Traditional, $p < 0.001$) and 61–67% of stance (vs. 3D-Printed, $p < 0.001$). Post-hoc analysis of the interaction noted lower vGRF in the no-pain limb between 63% and

Fig. 2. Clockwise from left: Lateral aspect, medial aspect, anterior aspect and posterior aspect of the foot with shoes and markers in place.

66% of stance phase with the Traditional compared to the Control ($p = 0.001$). There were no differences between conditions for the painful limb.

For ankle moment, the SPM analysis also revealed a condition main effect ($p < 0.001$; Fig. 4h and k) with post- hoc tests noting greater ankle plantarflexion moment during Control condition (vs. Traditional 54–72% stance, $p < 0.001$; vs. 3D-Print 53–71% stance, $p < 0.001$) There was no difference between 3D-Print and Traditional conditions.

For ankle power, the SPM analysis noted a condition main effect ($p < 0.001$; Fig. 4n and q) with post-hoc tests revealing greater power absorption during Control compared to Traditional (4–5% of stance, $p = 0.016$) and compared to 3D-print (48–55% of stance, $p = 0.001$). There was no difference between 3D-Print and Traditional.

4. Discussion

3D-printed and traditionally-made FOs changed some biomechanical variables of the flat-foot during walking compared to Control (no FOs).

4.1. *Effect of foot orthoses*

Contrary to previous studies findings [10,35], there were no difference in rearfoot range of motion between conditions, implying that the FOs did not reduce rearfoot eversion. This lack of apparent effect could be due to the high between-person variance of the immediate response to the FOs, as suggested by the high standard deviation in the results.

Also, all walking trials were conducted in canvas footwear with minimal support, which were chosen to ensure that any changes in biomechanics were because of FOs only. However, in normal practice, clinicians would usually advise participants to wear their FOs in shoes with supportive properties. It could be possible that any effects from FOs may only be seen if worn in conjunction with appropriately supportive footwear. A study examining the effect of FO on rearfoot motion with participants wearing similar canvas shoes also found that FOs did not affect rearfoot motion [36]. Furthermore, due to the number of markers required to be placed on the foot, multiple holes had to be cut from the canvas shoe. Initially, the minimum hole size was cut but progressively enlarged to allow the markers to be detected by the optical cameras. Finally, each hole was about 25 mm in diameter, which was still within acceptable limits [28]. However, this may have further reduced the integrity of the shoe. Future studies investigating participants wearing supportive footwear may be warranted to mimic real-life practice.

4.2. *Effect of 3D-printed and traditionally-made FOs*

3D-print FOs were more effective in supporting the arch (less arch height drop) compared to Traditional FOs. This was contrary to the finding of a similar $n = 1$ study which found that both FOs supported the arch equally [19]. Our current study consisted of a larger sample size producing more valid and robust results.

The difference in arch height drop was between the 3D-print and Traditional. The difference was less than 1 mm and whilst statistically significant, may not be clinically significant. There was no significant difference between either FOs or Control, where the arch height drop was expected to be the largest. The intrinsic foot muscles and extrinsic muscles such as tibialis anterior, have been theorised to play a vital role in maintaining arch height during weight bearing activities [37]. In this study, the arch height was measured during a short duration of weight bearing activity, and could infer that without FOs, the arch height may be maintained by increased conscious muscle activation. However, when using FOs, the individual may rely on FOs to support the arch. Unfortunately, the recording of electromyographic activity of intrinsic foot muscles was beyond the scope of this study. Studying the effect on arch height under the three conditions, with participants walking for

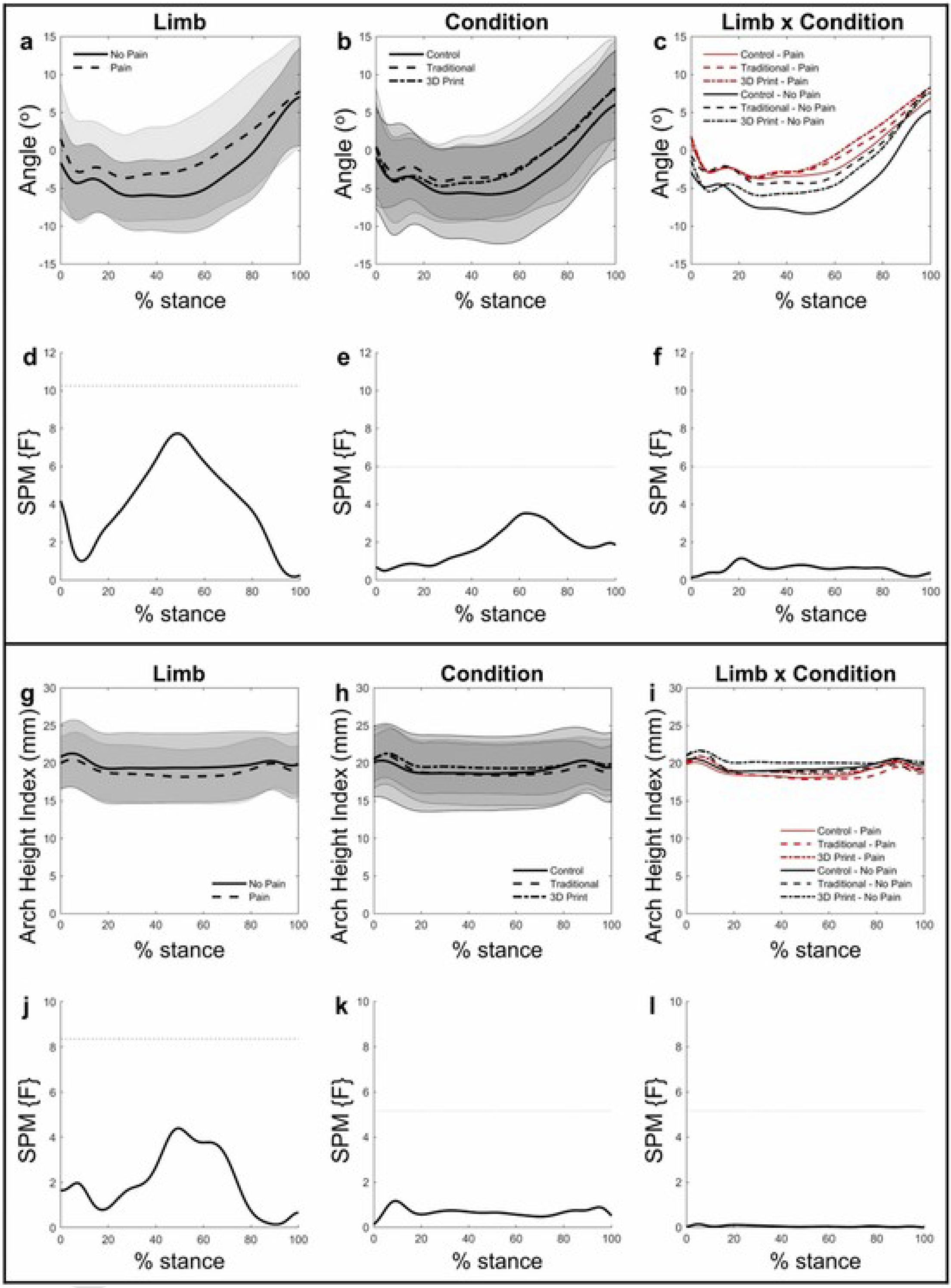

Fig. 3. a-c) Ensemble average rearfoot inversion/eversion graphs with SD (shaded); d-f) corresponding SPM analyses with horizontal dashed line denoting the critical threshold for significance ($p < 0.05$). g-i) Ensemble average arch height with SD (shaded); j-l) corresponding SPM analyses with horizontal dashed line denoting the critical threshold for significance.

longer periods, may result in muscle fatigue in the control condition, allowing the analysis of arch height over time.

During walking, when the heel lifts from the ground, there is an ankle plantarflexion moment created as the ankle plantarflexor muscles are activated to plantarflex the foot for propulsion [37]. With the use of both FOs, there was a lower plantarflexion moment which could infer less plantarflexor muscle activation during the propulsion phase. For individuals with plantar fasciopathy, this may be advantageous as lower contractile activation of the ankle plantarflexors may result in lower tensile strain in the plantar fascia given their common attachment to the calcaneus.

Ankle power absorption was higher in the Traditional and 3D print compared to the Control condition. It is currently not conclusive how ankle joint power reflects muscle activation in humans and whether changes may be beneficial or clinically significant [38–40]. Further in-

Table 2
Kinematic variables during the stance phase of walking.

Biomechanical variable	Condition	Painful limb	No-pain limb	Limb main effect		Condition main effect		Limb x condition interaction	
				F	p (ηp^2)	F	p (ηp^2)	F	p (ηp^2)
Total range of rearfoot eversion [°]	Control	12.9 (7.3)	14.9 (6.3)	0.551	0.47	0.529	0.60	0.674	0.53
	3D Print	13.6 (5.1)	15.9 (7.6)		(0.04)		(0.09)		(0.11)
	Trad	14.1 (5.1)	14.6 (5.2)						
Arch height drop during stance [mm]	Control	3.7 (1.1)	3.7 (1.5)	0.131	0.73	6.530	**0.01**[*]	0.112	0.90
	3D Print	3.3 (1.1)	3.5 (1.6)		(0.01)		**(0.54)**		(0.02)
	Trad	4.1 (1.7)	4.4 (1.9)						

3D Print = 3D-printed orthoses, Trad = traditionally-made orthoses.
[*] indicates significant difference.

vestigation into the effects of 3D-printed and traditionally-made FOs on muscle activity is warranted.

4.3. Limitations

There were several methodological considerations that require attention when interpreting our data. First, this study examined the immediate effects of FOs. Future studies measuring the long-term effect of 3D-printed and traditionally-made orthoses may be more clinically relevant.

No previous studies have reported the minimal detectable difference for arch height drop in low arched individuals during walking. From our data taken from the five walking trials of the non-painful limb during the control (no FOs) condition, we calculated the minimal detectable difference of arch height drop at 2.7 mm. Our measurements for arch height drop are larger than 2.7 mm for all FOs conditions (Table 2) meaning that the results represent real change in arch height drop for all three FOs conditions. However, we cannot conclude that a difference in 0.87 mm in arch height drop between 3D- and traditionally-made FOs translates to a clinical difference. Our study may be underpowered as we used a large effect size in the a-prior power analysis. With a relatively small sample size of 13 participants, future longitudinal studies with a larger sample size are warranted to confirm our initial findings.

5. Conclusion

3D-printed FOs are more effective in reducing arch height drop compared to traditionally-made FOs. SPM analyses showed that both FOs lowered ankle plantarflexion moment and power compared to no FOs. Overall, the results of this study support the use of 3D-printed FOs as being equally effective as traditionally-made FOs for a population of flatfooted individuals with unilateral heel pain.

CRediT authorship contribution statement

Malia Ho: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Funding acquisition, Writing – original draft. **Julie Nguyen:** Conceptualization, Data curation, Investigation, Methodology, Funding acquisition, Writing – review & editing. **Luke Heales:** Conceptualization, Methodology, Funding acquisition, Writing – review & editing. **Robert Stanton:** Conceptualization, Methodology, Funding acquisition, Supervision, Writing – review & editing. **Pui W. Kong:** Conceptualization, Methodology, Funding acquisition, Writing – review & editing. **Crystal Kean:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Writing – review & editing.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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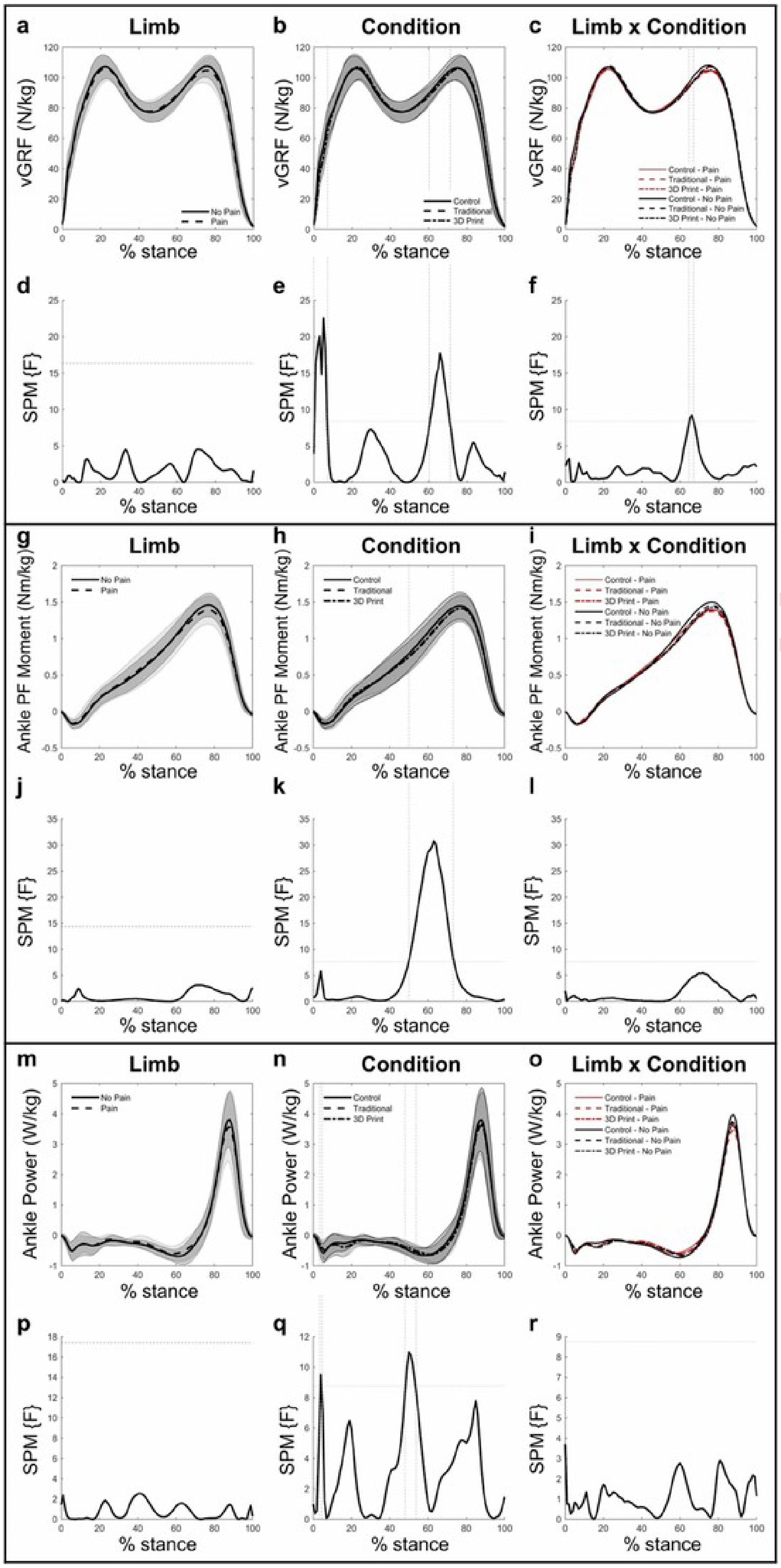

Fig. 4. a-c) Ensemble average vGRF with SD (shaded); d-f) corresponding SPM 2 × 3 ANOVA results. Vertical dashed lines denote areas of significance that exceed the critical threshold (dashed horizontal line) ($p < 0.05$). g-i) Ensemble average ankle plantarflexion (PF) moment with SD (shaded); j-l) corresponding SPM 2 × 3 ANOVA results. Vertical dashed lines denote areas of significance that exceed the critical threshold (dashed horizontal line) ($p < 0.05$). m-o) Ensemble average ankle power with SD (shaded); p-r) corresponding SPM 2 × 3 ANOVA results. Vertical dashed lines denote an area of significance that exceed the critical threshold (dashed horizontal line) ($p < 0.05$).

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