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Dose–response effects of customised foot orthoses on lower limb muscle activity and plantar pressures in pronated foot type

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ABSTRACT

Customised foot orthoses (FOs) featuring extrinsic rearfoot posting are commonly prescribed for individuals with a symptomatic pronated foot type. By altering the angle of the posting it is purported that a controlled dose–response effect during the stance phase of gait can be achieved, however these biomechanical changes have yet to be characterised. Customised FOs were administered to participant groups with symptomatic pronated foot types and asymptomatic normal foot types. The electromyographic (EMG) and plantar pressure effects of varying the dose were measured. Dose was varied by changing the angle of posting from 6° lateral to 10° medial in 2° steps on customised devices produced using computer aided orthoses design software. No effects due to posting level were found for EMG variables. Significant group effects were seen with customised FOs reducing above knee muscle activity in pronated foot types compared to normal foot types (biceps femoris $p = 0.022$; vastus lateralis $p < 0.001$; vastus medialis $p = 0.001$). Interaction effects were seen for gastrocnemius medialis and soleus. Significant linear effects of posting level were seen for plantar pressure at the lateral rearfoot ($p = 0.001$), midfoot ($p < 0.001$) and lateral forefoot ($p = 0.002$). A group effect was also seen for plantar pressure at the medial heel ($p = 0.009$). This study provides evidence that a customised FOs can provide a dose response effect for selected plantar pressure variables, but no such effect could be identified for muscle activity. Foot type may play an important role in the effect of customised orthoses on activity of muscles above the knee.

1. Introduction

Customised foot orthoses (FOs) are regularly prescribed for the treatment of symptomatic pronated foot type, with proposed modes of action including reduced calcaneal eversion [1] and muscle tuning [2]. A variety of FOs are available, and these vary primarily in terms of level of customisation to the individual patient. While the evidence base suggests that in general this type of intervention does provide at least some benefit for a number of conditions, the level of customisation required to optimise outcomes for different foot conditions and how to achieve this remains a matter of some debate [3].

To achieve the desired biomechanical effect there are a number of FO design features which can be added or modified [4]. In this article we focus on investigating the dose response effect of one key variable in the prescription of FOs: the extrinsic rearfoot post, which is intended to help control the movement of the rearfoot in the stance phase of gait [5]. The post can be angled medially or laterally, and by varying this angle it is purported that a range of biomechanical effects can be achieved, however these have yet to be fully characterised.

Previous research using surface electromyography (EMG) has provided some evidence that FOs can alter muscle activity during gait [6]. Limited evidence exists for alterations in activity of the peroneus longus [7,8] and tibialis posterior muscles [7–10] however the consistency of the effects is unclear. Contradictory findings have also been reported for a range of other leg muscles [7,9]. There are a number of factors such as foot type and type of device used which may potentially confound these measurements, and a recent review of the literature emphasised the need for research of higher methodological quality in this area [6].

Similarly, plantar pressure distribution may also be affected by the use and dose of FOs [11]. Material choice [12] and modifications such as medial heel skives [13] have been demonstrated to have an effect on pressures and some steps have been taken towards integrating plantar pressure measurements into the FO and footwear design process [14,15]. Again however, the literature is limited in terms of quantifying the dose response effects of FOs on these parameters and in describing how foot type influences the response to the intervention.

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This study aims to investigate the dose response effect of customised FOs on EMG activity of selected lower limb muscles and on in-shoe plantar pressures in participants with normal and pronated foot types. The study exploits the latest CAD–CAM technologies to test a range of FOs with varying levels of extrinsic rearfoot posting. Our primary hypothesis is that by progressively altering the angle of the rearfoot post on a personalised FO design, there will be a significant and linear effect on the EMG activity and plantar pressures during stance phase. In addition, we hypothesise that there will be significant differences between symptomatic pronated foot types and asymptomatic normal foot types.

2. Methods and materials

2.1. Participants

The study protocol was reviewed and ethical approval granted by the local National Health Service Ethics Committee (reference: 10/S0703/73). The study was conducted in accordance with the Declaration of Helsinki. Twelve participants were enrolled in the patient group along with 12 age and gender matched controls. The exploratory nature of this study combined with the complexity of the protocol meant that the sample size was limited to this number of participants. Participants were equally split in terms of gender, and had a mean age of 29.9 years (SD 8.7), weight 71.6 kg (SD 10.7), height 1.71 m (SD 0.08). All participants provided informed, written consent upon enrolment into the study.

Potential participants for the patient group were recruited from local podiatry centres. Inclusion criteria were: pronated foot type as defined by the foot posture index (FPI) [16]; relaxed calcaneal stance position (RCSP) $>4^\circ$ everted; a current history of self-reported foot and ankle pain; and a foot or ankle condition which indicated custom FO treatment. Control participants were recruited from the staff and student bodies at Glasgow Caledonian University and were eligible for inclusion if they had: a normal foot type as defined by the FPI; a RCSP $\leq 4^\circ$ everted; and no current or significant past-history of lower limb pain or dysfunction deemed by a UK Health and Care Professions Council registered podiatrist (MA) as likely to affect gait.

2.2. Foot orthoses

FOs for this study were ¾ length semi rigid devices which were designed using OrthoModel software (Delcam, Birmingham, UK) from a three dimensional (3D) surface scan of the foot. The protocol used to design these devices has previously been described [17], and additional information has been provided in the supplementary materials. FOs were fabricated using a 3D printing system (RapMan; Bits from Bytes, Clevedon, UK) in polylactide (PLA).

2.3. Protocol

Weight-bearing 3D surface scans of the participant's feet were taken with the foot held in subtalar joint neutral position. One pair of participant-specific FOs, henceforth "acclimatisation FOs", were designed and manufactured as described above. These devices were checked for fit and, if satisfactory, were taken away with the participant along with instructions on how to standardise device accommodation and use over a 14-day period.

After successful fitting of the acclimatisation FOs, nine variations on the design for one foot per participant – either the symptomatic side or randomly chosen for those with bilateral pain and controls – were produced and manufactured. The level of the external rearfoot posting was modified in these nine designs from 6° lateral to 10° medial in 2° increments using the CAD software. This range was chosen as it encompasses the majority of posting levels routinely prescribed in clinic.

Approximately two weeks after fitting and having successfully introduced the acclimatisation FOs into daily wear, the participant attended the motion analysis laboratory at Glasgow Caledonian University for the main evaluation where the nine posting variations were tested. Footwear was standardised for the testing, with all participants wearing a modified pair of neutrally posted training shoes (see supplementary materials).

EMG data were recorded from biceps femoris (BF), lateral gastrocnemius (GL), medial gastrocnemius (GM), peroneus longus (PL), soleus (S) tibialis anterior (TA), vastus lateralis (VL), and vastus medialis (VM) muscles during gait. A wireless surface EMG system was used to collect data (Trigno; Delsys Inc., Boston, USA), with skin preparation and electrode positioning carried out in accordance with SENIAM guidelines [18]. Electrodes were 99% sliver contact material in single differential configuration, inter-electrode distance 10 mm, 4-bar formation, and bandwidth 20–450 Hz. Data were recorded at 2.4 kHz using Qualisys Track Manager (Qualisys AB, Gothenburg, Sweden) simultaneously with kinetic data from a force plate embedded in the walkway (9286B; Kistler Winterthur, Switzerland) to facilitate event identification and allow stance phase to be defined. In-shoe plantar pressures were measured using the Pedar-X® system (Novel GmbH, Munich, Germany) recording at 50 Hz.

Walking trials were carried out for shod only and the nine FO conditions. A randomised test order was used to avoid order effects, and participants were blinded to the posting level of the FO during testing. Researchers were also blinded to the FO test condition during both testing and data processing.

After being given a few moments to acclimatise to each new condition, participants were asked to walk along the motion capture walkway until at least seven clean strikes on the force plate with the foot of interest were recorded. Walking trials exceeding $\pm$ 5% of the participant's predetermined self selected speed were rejected. A rest period of approximately 2 min was given after testing of each condition to reduce potential fatigue effects.

2.4. Analysis

A core set of EMG and plantar pressures variables (summarised in Table 1) were identified from the literature and our pilot work for this study as those which are clinically meaningful and may form mechanical therapeutic targets for FO interventions, and the analysis was limited to these variables.

Processing of EMG data was carried out using Visual 3D software (C-Motion Inc.; Rockville, MD, USA). Data were high pass filtered with a cut off frequency of 20 Hz and a 25 ms root mean squared (RMS) moving average applied. Stance was divided into three periods: total stance, and first and second half of stance as identified by the anterior/posterior sheer force changing polarity. For each individual, EMG data for the FO conditions were normalised to peak activity in the muscle during the shod condition.

For the plantar pressure data, Automask software (Novel GmbH, Munich, Germany) was used to divide the foot into five regions: medial rearfoot, lateral rearfoot, midfoot, 1st ray, and lateral forefoot (see Supplementary materials for further description). Twelve steps were processed for each condition and the mean of these used for the statistical analysis. Results were normalised to the shod condition for all variables.

For all test variables, two-way mixed effect ANOVAs were carried out to determine if the effects of posting level and foot type were significant ($\alpha = 0.05$). Linear, quadratic and cubic contrasts were tested when significant effects of posting level were found.

3. Results

The results for all tested EMG variables are presented in Table 2. Interaction effects were found for GM peak ($p = 0.034$) and S peak ($p = 0.015$). No significant main effects were seen for posting level for any of the EMG variables. Significant group effects were found for above knee muscle groups (BF mean $p = 0.022$; VL peak

Table 1
Measurement variables.

Measurement type	Variable
EMG	BF peak (100%)
	BF mean (1st 50%)
	GL peak (100%)
	GL mean (2nd 50%)
	GM peak (100%)
	GM mean (2nd 50%)
	PL peak (100%)
	PL mean (1st 50%)
	PL mean (2nd 50%)
	S peak (100%)
	S mean (2nd 50%)
	TA peak (100%)
	TA mean (1st 50%)
	VL peak (100%)
	VL mean (1st 50%)
	VM peak (100%)
	VM mean (1st 50%)
Plantar pressure	MRF peak
	MRF mean
	LRF peak
	LRF mean
	MF peak
	MF mean
	1st ray peak
	1st ray mean
	LFF peak
	LFF mean

Percentages refer to stance phase. BF: bicep femoris; GL: gastrocnemius lateralis; GM: gastronemius medialis; PL: peroneus longus; S: soleus; TA: tibialis anterior; VL: vastus lateralis; VM: vastus medialis; MRF: medial rearfoot; LRF: rearfoot; MF: midfoot; LFF: lateral forefoot.

Table 2
Two way mixed effects ANOVA for EMG variables.

	Wilks' lambda	*F*	*p*-Value	Partial eta squared
BF peak (100%)				
Posting	0.734	0.802	0.54	0.4
Group	–	1.713	0.206	0.083
Posting × group	0.496	4.496	0.699	0.35
BF mean (1st 50%)				
Posting	0.672	1.168	0.331	0.058
Group	–	6.239	0.022[a]	0.247
Posting × group	0.565	1.490	0.223	0.073
GL peak (100%)				
Posting	0.654	1.337	0.26	0.057
Group	–	0.052	0.822	0.002
Posting × group	0.424	1.587	0.18	0.067
GL mean (2nd 50%)				
Posting	0.609	1.08	0.375	0.047
Group	–	1.534	0.229	0.065
Posting × group	0.747	1.03	0.321	0.45
GM peak (100%)				
Posting	0.381	1.201	3.16	0.052
Group	–	0.003	0.958	>0.001
Posting × group	0.503	2.672	0.034[a]	0.108
GM mean (2nd 50%)				
Posting	0.443	1.431	0.23	0.061
Group	–	0.272	0.607	0.012
Posting × group	0.528	1.865	0.123	0.078
PL peak (100%)				
Posting	0.732	1.288	0.269	0.055
Group	–	0.045	0.834	0.002
Posting × group	0.685	0.962	0.451	0.042
PL mean (1st 50%)				
Posting	0.647	0.719	0.625	0.032
Group	–	0.301	0.589	0.013
Posting × group	0.475	0.632	0.692	0.028
PL mean (2nd 50%)				
Posting	0.58	0.777	0.563	0.034
Group	–	0.334	0.569	0.015
Posting × group	0.61	1.125	0.351	0.049
S peak (100%)				
Posting	0.417	1.134	0.347	0.051
Group	–	1.565	0.225	0.069
Posting × group	0.508	3.101	0.015[a]	0.129
S mean (2nd 50%)				
Posting	0.705	0.864	0.51	0.04
Group	–	0.011	0.917	0.001
Posting × group	0.514	2.24	0.54	0.096
TA peak (100%)				
Posting	0.726	0.567	0.681	0.025
Group	–	1.904	0.181	0.08
Posting × group	0.621	1.257	0.294	0.054
TA mean (1st 50%)				
Posting	0.76	0.534	0.693	0.024
Group	–	0.376	0.546	0.017
Posting × group	0.567	1.129	0.347	0.049
VL peak (100%)				
Posting	0.839	0.459	0.787	0.02
Group	–	7.284	0.013[a]	0.249
Posting × group	0.725	0.777	0.556	0.034
VL mean (1st 50%)				
Posting	0.749	0.604	0.671	0.027
Group	–	17.266	<0.001[a]	0.44
Posting × group	0.56	1.779	0.136	0.075
VM peak (100%)				
Posting	0.673	0.844	0.531	0.039
Group	–	8.165	0.009[a]	0.28
Posting × group	0.582	2.057	0.068	0.089
VM mean (1st 50%)				
Posting	0.832	0.741	0.592	0.034
Group	–	13.594	0.001[a]	0.393
Posting × group	0.383	2.255	0.055	0.097

[a] Statistically significant.

$p = 0.001$; VL mean $p < 0.001$; VM peak $p = 0.009$; VM peak $p = 0.001$) with the patient group showing reductions in activity relative to the shod condition in all cases when compared to the controls (Fig. 1).

Technical problems with the plantar pressure measurements for one participant from the patient group led to this dataset being removed from the plantar pressure analysis. The results for all tested plantar pressure variables are presented in Table 3 and significant results presented graphically in Fig. 2. No interaction effects were found. Significant ($p = 0.002$) linear effects ($p = 0.001$) for posting level were seen for LRF mean (Fig. 2), with a mean reduction in pressure of 0.58% per 2° of posting in the medial direction. At the midfoot, both variables showed a significant linear effect (MF peak ($p < 0.001$), MF mean ($p < 0.001$)), with reductions of 2.48% and 1.59% per 2° of medial posting, respectively. Quadratic contrasts were also significant for these variables at $p = 0.002$ for MF peak and $p = 0.008$ for MF mean. Significant main effects were seen for LFF peak and LFF mean ($p = 0.042$ and $p = 0.002$, respectively) with results showing an increase of 0.74% and 0.71% per 2° of medial posting, respectively. A significant group effect was also found for the MRF mean ($p = 0.009$), with the control group showing consistently higher pressures at this region.

Graphical results for all variables tested are provided in the supplementary materials.

4. Discussion

This study aimed to determine the dose response effects of customised FOs on the EMG activity of selected lower limb muscles and in-shoe plantar pressures, and the effect of foot type on these variables. For EMG activity, the results showed no clear effect of posting level; however a significant group effect was seen for muscles above the knee. Both soleus and gastrocnemius medialis showed interaction effects. For plantar pressures, our findings demonstrate that when the level of rearfoot posting is altered there is a linear response in terms of plantar pressures at the lateral forefoot, midfoot and rearfoot. These effects appear not to be dependent on foot type. These results increase our understanding of the mechanical effects of FOs for both pronated and normal foot types.

Our results support previous findings from Murley and Bird [8] who did not find any significant effects on muscle activity by varying the level of wedging in inverted custom made FOs. They did find significant differences between barefoot walking and FO conditions in asymptomatic participants with a pronated foot type, but no differences between different types of FO. As with our study, responses between conditions for FO conditions were highly variable. A muscle that was not tested in this study and may be affected by posting level is tibialis posterior. This muscle acts as a stabiliser of the rearfoot and is particularly affected in the pronated foot type [19], however it is deep lying and cannot be assessed using surface EMG. Murley et al. previously used intramuscular electrodes to determine that this muscle is affected by the use of both customised and prefabricated FOs [20]. Future studies of FO posting which include intramuscular EMG measurement of this muscle may further elucidate the frontal plane biomechanical effects of FOs.

This study has demonstrated that foot type played a significant role in the muscle activity of biceps femoris, vastus lateralis and vastus medialis. A marked change in muscle activity was found within the pronated foot type when comparing shod to FO conditions, a change which is not visible in asymptomatic foot type. This was consistent for all proximal muscles tested and appears to be independent of the posting level of the device. The mechanism for this reduction in activity is unclear. However, as the muscles affected included flexors and extensors, and act both medially and laterally to the knee centre, it suggests that correcting the position of the pronated foot may have an effect on the active stabilisation and neuromuscular control of the knee joint through

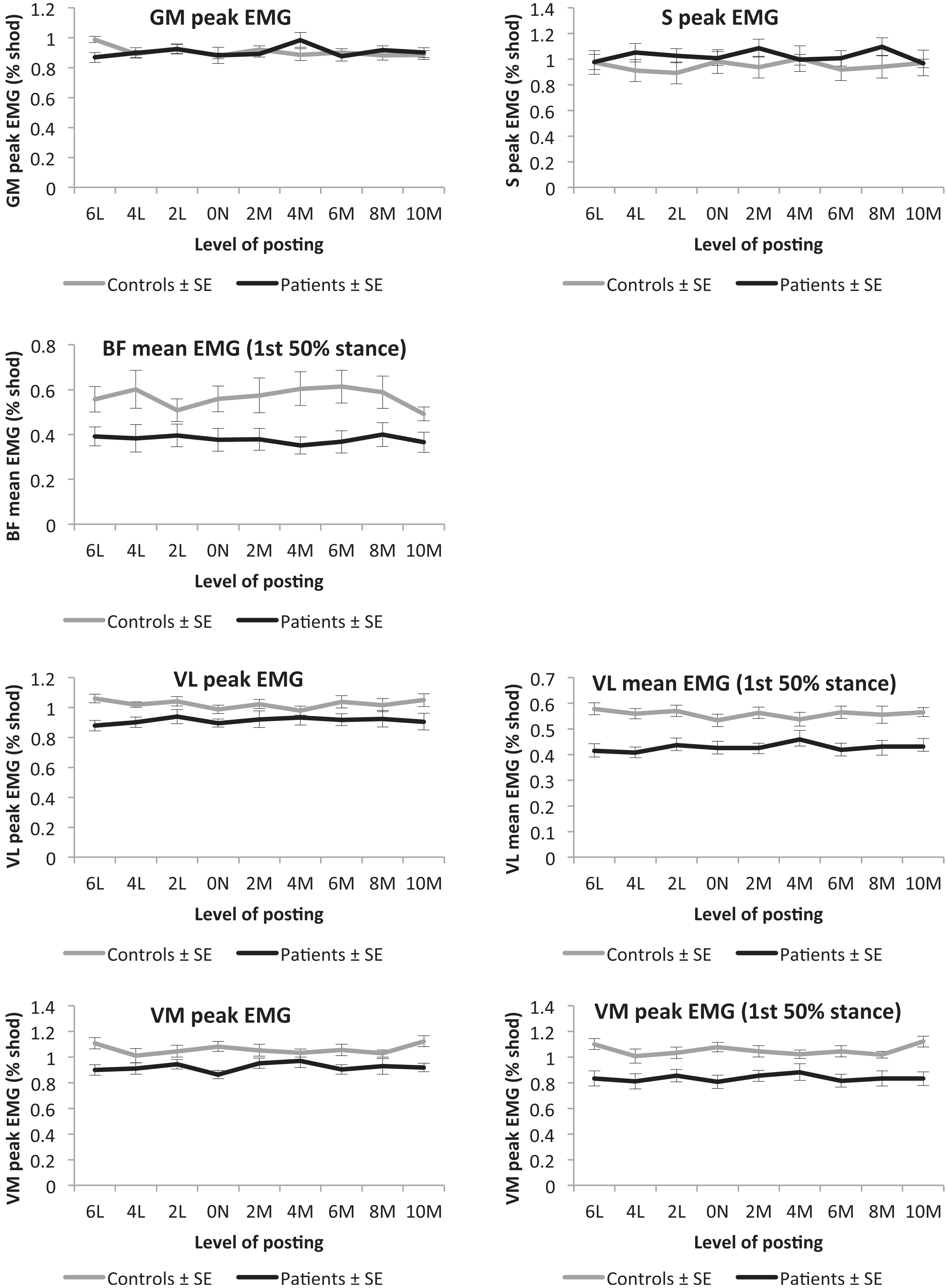

Fig. 1. Electromyography results. BF: biceps femoris; GM: gastroc medialis; S: soleus; VL: vastus lateralis; VM: vastus medialis; SE: standard error; nL: degrees laterally posted; 0N: neutrally posted; nM: degrees medially posted.

agonist/antagonist co-activation. Potentially this may be the result of the previously demonstrated proprioceptive effects of FOs [21], however further research is required to fully determine the mode-of-action of this finding.

A range of EMG effects have previously been reported in the literature for both FOs and different types of footwear [6]. However, few of these effects appear to be consistent or have been independently replicated. Difficulties in extrapolating a proportional

Table 3
Two way mixed effects ANOVA for plantar pressure variables.

	Wilks' lambda	F	p-Value	Partial eta squared	Best contrast	Trend per 2° posting lateral to medial
Peak medial RF						
Posting	0.584	1.393	0.231	0.062		
Group	–	1.757	0.199	0.077		
Posting × group	0.558	1.387	0.233	0.062		
Mean medial RF						
Posting	0.556	1.204	0.313	0.054		
Group	–	8.157	0.009[a]	0.28		
Posting × group	0.626	0.835	0.522	0.038		
Peak lateral RF						
Posting	0.488	1.836	0.179	0.07		
Group	–	0.746	0.397	0.034		
Posting × group	0.540	1.493	0.345	0.051		
Mean lateral RF						
Posting	0.29	4.038	0.002[a]	0.161	Linear ($p = 0.001$)	−0.58%
Group	–	1.973	0.175	0.086		
Posting × group	0.385	1.355	0.245	0.061		
Peak midfoot						
Posting	0.287	7.517	<0.001[a]	0.264	Linear ($p < 0.001$)	−2.48%
Group	–	0.011	0.918	0.001		
Posting × group	0.521	1.612	0.164	0.071		
Mean midfoot						
Posting	0.361	5.471	<0.001[a]	0.207	Linear ($p < 0.001$)	−1.59%
Group	–	0.799	0.382	0.037		
Posting × group	0.536	1.241	0.296	0.056		
Peak 1st ray						
Posting	0.768	0.519	0.796	0.024		
Group	–	0.041	0.842	0.002		
Posting × group	0.57	1.211	0.304	0.055		
Mean 1st ray						
Posting	0.517	1.152	0.337	0.052		
Group	–	1.217	0.283	0.055		
Posting × group	0.636	0.782	0.58	0.036		
Peak lateral FF						
Posting	0.448	2.413	0.042[a]	0.103	Linear ($p < 0.001$)	0.74%
Group	–	2.593	0.122	0.11		
Posting × group	0.632	0.833	0.527	0.038		
Mean lateral FF						
Posting	0.256	3.83	0.002[a]	0.154	Linear ($p < 0.001$)	0.71%
Group	–	0.001	0.975	0.001		
Posting × group	0.619	0.834	0.537	0.038		

[a] Statistically significant.

relationship from EMG data to muscle force generation are widely acknowledged [22], and more advanced techniques such as wavelet analysis have been proposed for investigating FO effects on muscle activity [7]. Future work should investigate these methods when measuring dose response effects of FOs on muscle activity.

Customised FOs have been shown to affect pressure distribution in a number of patient groups and foot types [13,23,24]. Bonanno et al. [13] recently demonstrated that altering the depth of a medial heel skive resulted in increased peak pressures at the medial rearfoot, with increases in skive magnitude resulting in increases in pressure, however no changes were seen at the more distal portions of the foot. Our results found significant effects at the lateral rearfoot as well as additional effects at the midfoot and the forefoot, suggesting that the extrinsic post used in our study may have a greater effect on full foot biomechanics than the medial skive. The changes in pressure, particularly at the forefoot were relatively small (<1% per 2° of posting relative to shod) however it is beyond the scope of the current study to determine if these changes are clinically relevant.

At the midfoot, although linear contrasts proved to be the most significant, there is an indication that a more complex relationship exists in terms of the dose response to the devices, with medial posting beyond 4° not seeming to produce any further decrease in peak or mean pressure. This potentially suggests that there may be a threshold as to how far the centre of pressure can be shifted laterally, however further research is required to test this hypothesis.

Plantar pressure measurement systems have several limitations which are relevant to FO research [25]. Most relevant to this study is the fact that the sensors embedded in the insole only measure forces acting perpendicularly to them, and this combined with the geometrically complex shape of an FO means that potentially relevant non-perpendicular components of the forces applied will not be quantified. Despite this limitation, when taken in context with our existing knowledge of the effects of FOs we believe the plantar pressure results described here to be an accurate representation of the changes occurring.

The use of 3D printing to manufacture FOs is a relatively new approach [26], and long term testing of the performance of the devices used here is required, in particular to understand safety and tolerance. However this study has demonstrated that low cost 3D printing of FOs is feasible and a useful research tool for short-term FO studies. These technological advances give the opportunity to understand more fully the mechanical response to smaller incremental changes in functional design features and enable robust parametric CAD design rules to be developed.

A number of limitations should be noted for this study. Standard clinical measures were used to define foot type and these may represent a source of error. In addition, although the individuals were acclimatised to wearing FOs it is possible that the variations tested may have had different effects given a longer period of wear, thus only the acute biomechanical effects of varying the dose of the FOs were measured. A wide range of FOs are available, varying in

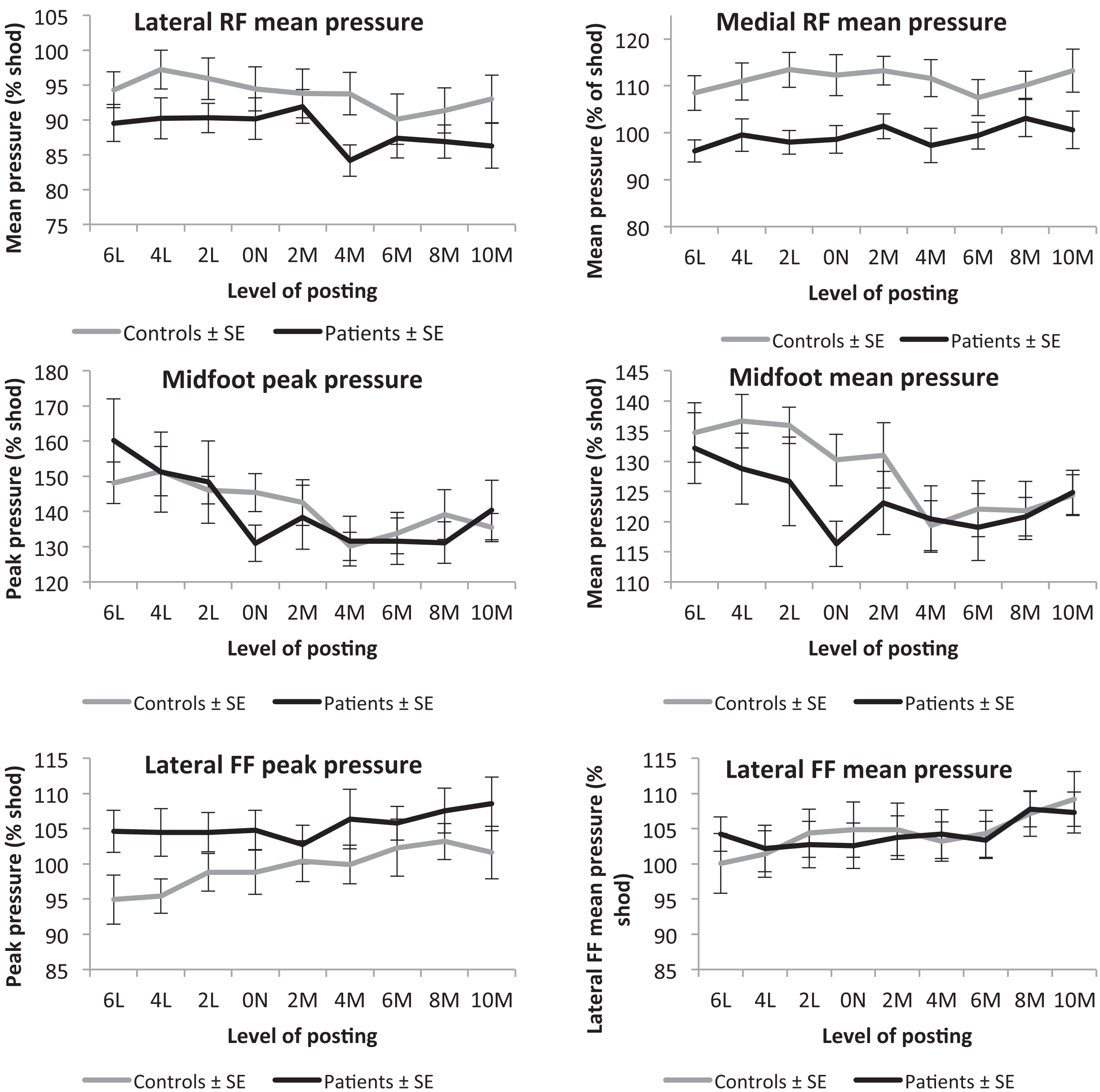

Fig. 2. Plantar pressure results. RF: rearfoot; FF: forefoot; SE: standard error; nL: degrees laterally posted; 0N: neutrally posted; nM: degrees medially posted.

materials, features and level of customisation. The devices used in this study were ¾ length semi rigid FOs produced using CAD software, and care is advised if extrapolating these results to other types of FO. The type of footwear worn may play a large role in the effect of the FO, and standardised footwear was used in this study to allow the effects of the posting to be determined without this potentially confounding variable. Again the authors advise caution in extrapolating these results across all types of footwear.

A number of statistical comparisons were carried out for this study and it is possible that some significant findings may have been down to chance. The authors feel the exploratory nature of the study justifies this type of analysis. This is supported by the majority of effects found being consistent with each other and/or with our existing knowledge of FO effects.

In conclusion, this study provides evidence that there is a significant and linear dose response effect of FOs on plantar pressure variables at the rearfoot, midfoot and forefoot. Foot type appears to play a significant role in the effect of FOs on above-knee muscle activity, with the devices producing a reduction in activity in pronated foot type.

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Conflict of interest statement

The authors declare that they have no conflict of interest relating to the material presented in this article.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.gaitpost.2013.01.012.

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