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

Scott Telfer *, Mandy Abbott, Martijn Steultjens, Daniel Rafferty, James Woodburn

Institute for Applied Health Research, Glasgow Caledonian University, UK

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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.

* Corresponding author at: Institute for Applied Health Research, Glasgow Caledonian University, Cowcaddens Road, Glasgow G4 0BA, UK.
Tel.: +44 0 141 331 8475.
E-mail addresses: scott.telfer@gcu.ac.uk, scott.telfer@gmail.com (S. Telfer).

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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 ± 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.