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Effects of foot orthoses: How important is the practitioner?

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ABSTRACT

Foot orthoses (FO) are commonly used in the treatment of numerous lower limb problems, pains and injuries. Whilst many studies report their positive effects, and most practitioners would confirm those findings, the available information appears to be anecdotal. As such, the exact mechanisms in which FO work are not fully understood. Therefore, a need exists to study the influence of the inter-practitioner variability in the assessment of orthoses performance. This investigation is central to the understanding of the performance variations in custom-made foot orthoses (CFO). Eleven practitioners took part in the study. Each practitioner completed a clinical assessment of one subject, after which a pair of foot orthoses was manufactured based on casts of the subject's feet using a neutral non-weight bearing plaster cast. Ten trials per condition were recorded during which kinematic and kinetic data were collected. CFO did not have any systematic significant effects ($p < 0.05$) on any kinetic except for the right-leg peak active force. In addition, systematic kinematic effects could be observed mainly for the sagittal plane for forefoot-to-hindfoot and hindfoot-to-tibia peak angles. The results from this study demonstrate that inter-practitioner variability is a major factor in orthotic intervention in treating a single patient and for a specific pathology. It is therefore strongly recommended to use caution when drawing general conclusions from research studies using custommade foot orthoses. The results suggest that CFO effects can differ between limbs. More importantly, their effects are also practitioner-dependant. Great caution should be used when comparing studies on CFO with different practitioners as conclusions could vastly differ.

1. Introduction

Foot orthoses (FO) are generally used by clinical practitioners to treat a number of musculoskeletal pathologies. Previous researchers have attempted to study different orthotic devices to understand their effects on gait kinematics and kinetics. Understanding these differences would improve the chances of achieving the desired treatment or outcome. Nevertheless, the exact mechanisms by which FO work are yet to be fully understood. In fact, a number of studies have reported contradicting or unsystematic results [1–5]. Yet, certain main themes can be extracted from these studies. Recent literature surveys [6,7] concluded that FO generally have an attenuating effect on the peak impact vertical force and loading rate. Commonly reported kinematic effects normally relate to ankle joint sagittal plane movements, rearfoot frontal plane and tibial transverse plane movements [8]. Specifically, many studies reported that FO increased plantarflexion of the foot, decreased rearfoot eversion and internal tibial rotation [5,9–17]. However, kinetic or kinematic effects do not appear to be consistent through all studies [1,2,13,14,18,19]. Hence, controversies still persist with regards to whether or not FO induce generic effects on subjects.

Furthermore, the lack of standardisation of the terminology surrounding FO only adds to the ambiguity of their effects [8]. Throughout the literature, the term "foot orthoses" is used as an umbrella term to describe a broad range of devices including custom-made foot orthoses (CFO), prefabricated foot orthoses, heel-lifts, lateral/medial wedges and even flat insoles. Whilst the inherent differences in design and purpose of each device may appear simple, all are defined as foot orthoses despite their different effects. It is therefore crucial that more precise descriptions are provided in order to allow clear and easy classification of devices. Therefore, the terminology used in the current paper will specify which type of foot orthoses is discussed in an attempt to avoid any confusion.

Heiderscheit et al. [20] suggested plausible explanations for the contradicting conclusions on the effects of orthoses. Variation in orthoses fitting methods was amongst the suggested explanations. Although it has been reported that CFO can yield good results for the treatment of lower-limb disorders and injuries [1,15,21], construction methods and casting techniques are seldom described in great detail. Based on previous studies [1,2,22], it is possible to assume that the prescription and casting method could

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differ between studies depending on the practitioner involved. This could, in part, explain the conflicting results. Consequently, the exact method used to produce these orthoses remains unclear and almost impossible to replicate.

However, other external factors may also influence the results. As each study focussing on custom-made foot orthoses (CFO) will use a specific practitioner to assess, prescribe and cast each subject included within a study, it is difficult to rule out the importance of the practitioner on the final outcome measure. For example, whilst Stacoff et al. [15] observed significantly different effects between three types of orthoses, three different podiatrists were involved in the process, each one in charge of making one type of orthoses. It cannot be dismissed that the observed changes could be attributed to the change in practitioner or techniques used instead of the orthoses themselves as reported.

As the process of fabricating a CFO involves many variables, the influence of each variable is currently unknown. Due to the nature of the CFO, specifically designed for each subject, assessing their effects and effectiveness is a complex task that has not been completed. Consequently, the aim of the present study was to assess the influence of one of those variables, the inter-practitioner variability of CFO and their different kinematic and kinetic effects during normal gait.

2. Methodology

A total of 11 practitioners (six podiatrists and five orthotists) with years of clinical experience ranging from 2 to 20 years (mean 11.5 years, ±7.0) took part in the study. A broad spectrum of experience and two different professions were included in the study with a view to better represent the current services and choices available to patients suffering from musculoskeletal pathologies. The practitioners taking part in the study were considered as subjects in order to assess the inter-practitioner variability. Whilst they all worked in different geographical areas, all practitioners were trained in the United Kingdom. Musculoskeletal cases and prescribed FO and CFO were their primary focus as part of their normal clinical practice. The practitioners evaluated a single subject (female, 29 years old, 62.5 kg, 156.0 cm) in order to minimise external variables and compare the kinematic and kinetic effects of each pair of CFO. Ethical approval was sought and granted by the University's Ethics Committee. Informed consent was provided by all practitioners as well as the subject prior to the beginning of the study.

This subject had been suffering of medial knee pain of the right leg for at least a six month period prior to this study. Pain prevented the patient from participating in prolonged physical activity such as jogging or taking part in her normal training regimen as an elite rower. No other lower-limb musculoskeletal problems were reported. All practitioners completed a clinical assessment of the subject, during which the same information was provided to each practitioner. Additional questions from practitioners were answered when appropriate, ensuring that no advantage was given to any one practitioner. Each practitioner casted the subject's feet using a neutral non-weight bearing plaster cast method. Orthoses were then manufactured based on the individual practitioner's diagnosis and prescription. All orthoses were manufactured by the same manufacturer (Salts TechStep, Birmingham, UK) to standardise the manufacturing process. A standardised manufacturing protocol was utilized and supervised by an experienced, clinically trained technician. All casts were digitised using a three-dimensional photogrammetric scanner. To accommodate for skin and fat pad movements within the footwear, the same standardised minimal dressing was then applied to each scan. Once the processing was completed, each orthosis was milled using a CAD-CAM machine. The materials used for the shell and cover (if required) of the orthoses were chosen according to each practitioner's prescription.

2.1. Data collection

Kinematic and kinetic data were collected simultaneously for each baseline and experimental condition. Kinematic data was capture using a optoelectronic motion capture system (Vicon MX, OMG, UK) at 200 Hz, using a clinically validated [23,24] multi-segment marker set (Oxford Foot Model). The chosen marker set allowed for calculation of tibia–femur movements and a detailed analysis of foot movements. Two AMTI-OR6 force platforms (Advanced Mechanical Technology, Inc., MA, USA) set in a 12-m walkway were used to collect the kinetic data at 1000 Hz. A pair of modified plimsolls was used as standardised neutral shoes to minimise the effect of footwear. Small holes were cut out in the shoe upper to accommodate for the skin-mounted reflective markers. After a 10-min adaptation period, the patient completed 10 acceptable trials whilst walking in each pair of CFO, following an elliptical pattern drawn on the laboratory floor. A trial was deemed acceptable if the subject's feet made contact within the confines of the force platforms. To eliminate the possibility of targeting, the force platforms were located within the floor, hidden by the floor cover. In order to ensure impartiality from both the researcher and the patient, conditions were double-blinded and randomized insofar as the identity of the practitioner behind each CFO was unknown. The patient was also tested barefoot and wearing only the plimsolls at the beginning and the end of the session. A 10-min rest period was allocated between each pairs to minimise muscle fatigue.

2.2. Data reduction

Upon completion of data collection, each trial was processed using proprietary software (Nexus, Vicon – OMG, UK), during which gait cycle events (heel-strike and foot off) were identified. The ten trials within each condition were averaged through a temporal normalisation of the gait cycle – from heel-strike (0%) and its subsequent one (100%) – using the Polygon Authoring Tool software (Vicon – OMG, UK). The average angle curves were then exported into MS Excel where the research variables were subsequently extracted. The force platform data from each trial were converted into ASCII and saved as a comma separated value (.csv) file format. The data were then processed using a custom-made Matlab Software (The MathWorks, Inc., MA, USA). From each trial, the following variables (Table 1) were calculated, and then averaged per condition using ten trials. Confidence intervals were calculated using a *p*-value of 0.05. For the purpose of this paper, a similar effect shared by six or more CFO will be defined as a systematic effect.

3. Results

3.1. Kinematic variables

Tables 1 and 2 present a summary of the kinematic results for the knee, hindfoot-to-tibia and forefoot-to-hindfoot. For the calculated kinematic variables, there were a number of significant systematic changes recorded. On the left lower limb, peak knee flexion, peak knee internal rotation and sagittal knee angle at heel strikes were reduced by a mean of 3.28° (±1.25°), 5.88° (±3.67°) and 1.87° (±0.60°) respectively. For the left foot, a decrease in peak forefoot plantarflexion, forefoot peak pronation and an increase in sagittal plane forefoot angle at heel strike by a mean of 10.85° (±5.38°), 2.91° (±1.23°) and 9.78° (±6.01°) respectively. A decrease of 3.57° (±2.50°), 4.06° (±2.28°) and an increase 2.88° (±1.62°) was observed for the right hindfoot-to-tibia peak dorsiflexion, sagittal angle at heel strike and peak eversion respectively. Right forefoot-to-hindfoot plantarflexion was decrease by 5.20° (±2.99°) on average, and the sagittal forefoot-to-hindfoot angle at heel strike was increase by a mean of 4.72° (±2.53°).

3.2. Kinetic variables

Table 3 presents a summary of the kinetic results. For the kinetic variables of interest, CFO only had systematic effects on the active peak for the right leg, where a reduction of 1.84% (±0.73%) was observed. No other systematic effects could be observed for the kinetic variables. CFO did yield other significant effects. However, those effects were sporadic insofar as the direction of the effect, relative increase or decrease compared to the plimsoll condition, was not systematic between devices and therefore could not be generalized.

4. Discussion

4.1. Variability and consistency

The current results suggest that high variability exists between the effects generated by the 11 different CFO used in the study. Only a third (22/64) of the calculated variables caused systematic changes. For most variables, effects appeared to be sporadic, with many CFO producing opposite effects when compared to other CFO. The standard protocol to study FO, as reported in the literature, is to use multiple subjects with a single pair of orthoses. The observed results from each condition are then usually assumed to be the general effects that any CFO has on a specific patient. Whilst patient specific responses to CFO may explain the above-mentioned unsystematic and contradicting findings regarding FO effects, it