Research study

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Management

Kinematic comparison of functional foot orthoses produced to three different manufacturing protocols: An exploratory study

L Short[1*], N Chockalingam[2]

Abstract

Introduction

In clinical practice, it is common for casted and non-casted foot orthoses to be prescribed. Since there are differences between these orthoses in terms of manufacturing protocols a subject with the same prescription, could end up with radically different looking insoles dependent on the technique used. The main objective of this exploratory study was to compare the kinematic effect of three 3 different methods of orthotic production using the same prescription for the same individual.

Materials and methods

2 male and 7 female participants aged 19–38 years (mean 26 years) volunteered to participate in this study. The individuals attended for orthoses prescription and returned 5 weeks later for fitting and kinematic analysis. Kinematic data on tibial rotation and heel eversion was compared for 3 different orthoses (a CAD/CAM laboratory device, a traditional plaster cast protocol device and a chair-side pre-moulded shell insole adapted in clinic) which were made using the same prescription. The degree of rear foot motion and tibial rotation during treadmill walking was recorded for three test devices against a control shoe using an electromagnetic tracking device.

Results

For heel eversion (Y axis) significant differences were noted across groups from the control (P=0.05), but there was no significant difference between computer aided design orthoses (CAD) and traditional lab cast orthoses (TRAD). There were no significant differences across groups for dynamic tibial rotation (Z axis). Based on the data gathered in this study, modified chair-side orthoses (MCSO) produced the largest difference in heel eversion within the group of participants in this study.

Conclusion

MCSO produced the largest change in heel eversion. The results suggest that CAD and TRAD insoles produced by using the same negative cast have a similar effect.

Introduction

Functional foot orthoses (FFO's) have been widely used to successfully treat a range of pathologies related to biomechanical dysfunction of the lower limbs[1]. The main aim of the intervention by the health professional often is to resist excessive pronation of the foot[2,3,4,5]. FFO's can be split into 2 broad categories, either casted or non-casted orthoses depending on whether a negative mould of the foot is necessary prior to production[6]. Normally, casted orthoses are reported as being the gold standard[7]. However more recent studies and reviews had questioned this superiority and suggest comparable effects from none casted prefabricated orthoses[2,7,12]. The cost of production between gold standard devices and prefabricated orthoses varies considerably depending on the type used.

Although kinematic comparisons of different types of orthoses have widely been investigated, majority of this research has focused on changes in position/movement of the arch of the foot, the rear foot and the tibia. Furthermore, the variables that have been normally evaluated are the two dimensional changes in sagittal plane arch or navicular height and frontal plane calcaneal position or tibial transverse plane rotation[3,9,10,11,12,13]. Most previous research have not attempted to compare prescriptions designed to produce the same clinical outcome using different manufacturing techniques. Since some of the recent studies suggest a combination of arch moulding and posting is important to enhance the function of the FFO[10,13] or that moulded or contoured FFO's may possess a similar mechanical effect regardless of other prescription variables[8], further structured studies are warranted to examine the differences in manufacturing techniques.

Traditional laboratory manufactured FFO's are expensive and time consuming to produce as the construction of the device involves several manufacturing stages to provide the full prescription[8,9,14,15]. Whilst the necessity of these devices is questioned[6], a cost effective alternative device to laboratory cast devices, are customisable pre-arch-contoured or arch mouldable chairside orthoses. These devices, which are commercially available, consist of a mouldable polypropylene shell with clip in rear foot posts. The device can be balanced to the rear foot by gently heat-moulding the device. Such devices have been shown to have a greater effect on lower limb kinematics to that of an identically posted, off the shelf device made of Ethyl Vinyl Acetate (EVA)[16]. However, there has been little research into these types of devices. This paucity of structured information led to this pilot investigation which aims to test the kinematic effects of a chairside customisable arch contoured and posted device against two lab cast devices taken from the same cast of the foot but manufactured to local laboratory protocols.

*Corresponding author
Email: leeshort210@btinternte.com

[1] Ministry Of Defence Primary Health Care
[2] Faculty of Health, Staffordshire University.

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Materials and methods

This work conforms to the values laid down in the Declaration of Helsinki (1964). The protocol of this study has been approved by the relevant ethical committee related to our institution in which it was performed. All subjects gave full informed consent to participate in this study.

Participants

After receiving full ethical approval from the University ethics committee, nine participants (2 males, 7 females); 19–38 years (mean 26 years) were recruited to participate in this study. Each participant provided written informed consent prior to any testing. Whilst, all participants had signs of excess pronation as defined by a foot posture index of 8 or more[17], they were all generally active healthy individuals with no current or recent history of musculoskeletal complaints. Participants were excluded if FFO's were currently or had previously been used.

Casting and Orthoses prescription

Subtalar joint neutral casts (Plaster of Paris) were taken for each subject and sent for manufacture of appropriate custom FFO's. The same casts of each subject was used to produce a laboratory manufactured Computer Aided Designed and Manufactured device (CAD/ CAM). Once the cast was scanned (or digitised), it was then sent for manufacture of a traditional laboratory device as outline by Anthony[18]. Both traditional laboratory and CAD/CAM direct mill devices were requested in 3mm polypropylene shell. The posting to the CAD/CAM devices was an integral polypropylene post and traditional laboratory device had been supplied with a high density EVA post with polypropylene post cap. The differences in posting techniques were unavoidable, as they formed part of the individual laboratory protocols for orthoses manufacture. A third FFO was produced for each subject using a customisable polypropylene char-side device by using a Vectorthotic (Healthy Step Sensograph, UK). All participants were deemed to have a low subtalar axis outlined by Green and Carol[23] and hence all orthoses were prescribed with a 6° post corrected to allow 6° of motion also outlined by Green and Carol[19].

To formulate the full prescription, static stance subtalar neutral position was located using the technique as described by Sell et al.[20] This position was then compared to resting calcaneal stance position using a weight bearing angle finder[21]. The measurement of the degree of static heel eversion from a position of subtalar neutral to resting calcaneal stance position were recorded for both feet and repeated several times[22].

Kinematic Testing

Prior to commencement of the study, a pilot study was completed to assess the repeatability of the researcher's goniometric measurements, casting method and calibration of an electromagnetic tracking device to enable its use on a treadmill. Metal interference of the treadmill was found to be less than 0.5 degrees in the x axis and less than 0.7 degrees in the Z axis. This degree of error was found acceptable and with normal limits of 1mm translation and 1 degree of rotation outlined in previous studies[24,25,26].

An electromagnetic tracking system (EMT) (6DRESEARCH Skill Technologies Inc, Phoenix, Arizona, USA) was used to measure 3D joint motion. This system employs Fastrak® sensors (Polhemus Inc, Colchester, Vermont, USA). The system tracks the position and orientation of the sensors with 6 degrees-of-freedom. Sensors were attached on the skin overlying the medial tibial surface between the midline of the knee and ankle joints and the posterior surface of the calcaneus in a modified windowed shoe[24]. A video camera (PAL 50Hz) was used to collect video data. The video was compressed to 50 frames per second Quintic video analysis software (Quintic Consultancey Ltd, UK) and used for analysis. Video analysis software was synchronised to EMT data using a technique to identify heel strike and toe off as previously described by Stell and Buckley[15]. Each participant was randomly allocated one intervention device and was blinded to the type.

Before any data collection trial, a "bore-sighting" or neutral orientation alignment procedure was undertaken to rotate and align the axis reference frames for the transmitter source and sensors. This was conducted with the patient standing upright, with the foot and leg forming a 90º angle and the foot wedged on the plantar aspect to hold, following manual palpation and positioning[24,27] (The researchers margin of error was tested in a metal less field with EMT software and was shown to be less than 0.3 degrees when tested in the preliminary study).

All participants were given 20 minutes in the control test shoes to allow a period of familiarisation and to establish a preferred walking speed. The subjects preferred walking speed was recorded and maintained throughout the remainder of the trial. Before testing each participant was given the same 20 minute to become accustomed to each

Table 1: Mean time to maximum heel eversion (Y axis), time to maximal tibial rotation (Z axis) and the angular difference from baseline (Y and Z axis). The mean angular difference is displayed as the mean degree of change from maximum eversion and tibial rotation from a baseline of 11.8 degrees (yaxis) and 0.56 degrees (baseline).

	Mean max Y angular difference	Timing of mean max Y difference	Mean max Z angular difference	Timing of mean max Z difference
Int 1	3.15 (5.17)	0.03 (0.07)	1.52 (4.00)	0.00 (0.13)
Int 2	9.83 (3.95)	-0.75(1.03)	0.96 (3.97)	0.24 (0.36)
Int 3	3.3 (7.59)	0.50 (0.15)	0.62 (3.36)	0.05 (0.13)

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FFO, and a comfort score was recorded. This was done as the comfort of the subject has been shown to be an important factor in orthoses outcomes[23].

Footwear and Data Collection

All Participants were issued with a standardised test shoe. This shoe (Hotter, UK) was modified in accordance with a protocol described by Woodburn et al.[20] The purpose of the modified shoe was to allow free movement of the EMT heel sensor (Figure 1).

After obtaining a preferred speed and allowing at least 3 minutes for the subject to become accustomed both to the lab environment and also for treadmill walking, 5 consecutive 10-second trails were recorded both from EMT software and simultaneous video.

The maximum degree of calcaneal eversion and tibial rotation were obtained from EMT data between heel strike and heel lift. From each trial, the middle three recordings were obtained giving a total of 9 trials for each experimental condition. These included: (1) Just shoe (control); (2) Intervention 1 (Traditional lab cast orthoses); (3) Intervention 2 (Modified chair-side orthoses) and (4) Intervention 3 (Computer Aided Design orthoses). A two way ANOVA, with post hoc Tukey tests were conducted to find significant differences, if any.

Results

Table 1 indicates the mean time to maximum heel eversion (Y axis), the time to maximal tibial rotation (Z axis) and the angular difference from baseline (Y and Z axis). The mean angular difference is displayed as the mean degree of change from maximum eversion and tibial rotation from a baseline of 11.8 degrees (Y axis) and 0.56 degrees (baseline).

The box plots in figure 2 represent the graphical differences between the control and orthoses groups, for tibial rotation which indicates that the largest difference from the control is intervention 2 (Modified chair-side orthotic).

The box plots in figure 3 represent the graphical differences between the control (control and orthoses groups) for heel eversion. Initially it can be seen that the largest difference from the control is intervention 2 (Modified chair-side orthotic).

The box plots in figure 2, demonstrate that there were no significant differences across groups for dynamic tibial rotation (Z axis). The Box plots in figure 3, demonstrate that there were significant differences across groups for heel eversion (Y axis), significant differences were noticed across groups from the control (P=0.5). There was no significant difference between the interventions of Traditional lab cast orthoses and Computer Aided Design orthoses. Based on this data the Intervention 2 (Modified chair-side orthoses) produced the largest difference within this group of participants, followed by the orthotic interventions 1 and 3 (Traditional lab cast orthoses and Computer Aided Design orthoses respectively).

Figure 1A: Footwear and placement of EMT sensors.

Figure 1B: Footwear and placement of EMT sensors.

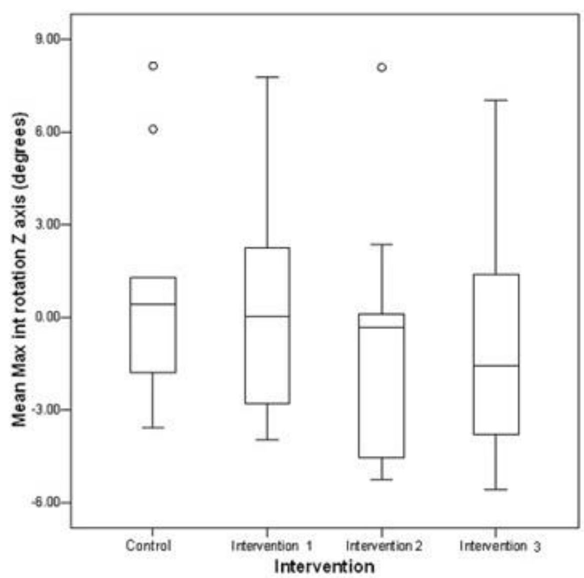

Figure 2: The box plots in figure 2 represent the graphical differences between the control and orthoses groups, for tibial rotation which indicates that the largest difference from the control is intervention 2 (Modified chair-side orthotic).

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The F-test in one-way analysis of was used to assess for significant differences between groups. A further test of Tukey Highest significant difference was chosen in conjunction with the F Test to evaluate the significant differences between means. This was repeated for data sets from both Z and Y Axes. The mean confidence intervals for upper and lower bound values are presented in table 2.
At the 5% level the F-test and Tukey Least significant difference and Tukey highest significant difference demonstrated significant differences only in the Y axis. All differences excluding 2 and 4 were significant at least to the 5% level. Based on these findings, there was no significant difference between interventions 2 and 4 suggesting similarities between groups. Intervention 3 produces the smallest results, Interventions 2 and 4 controls produced the largest results demonstrating largest effect change from intervention 3.

Discussion

The purpose of this study was to establish the kinematic effect of three different commonly used approaches to providing contoured functional foot orthoses on heel eversion and tibial rotation during treadmill walking. Many authors have attempted to compare cast and non-cast orthoses[8,9,28,29]. Only one has attempted to compare like for like prescriptions with similar material properties[4]. If similar effects can be achieved with less costly and less time consuming devices, then there is potential for cost savings both to the provider and patient without a compromise in care. The devices used in this study had intentionally similar profiles and material properties (3mm poly propylene), to ensure that differences incurred were from the manufacturing process and the prescription and not from the prescription protocol.
This study has demonstrated that chair-side orthoses have a similar capacity for controlling rear foot motion as casted laboratory produced devices. All devices utilised in this study offered a significant degree of rear foot motion angular change comparatively to the control condition. Interestingly, the chair side customisable device produced the largest reduction in the peak eversion excursion. Therefore, if the objective of prescription orthoses is to influence rear foot motion, the results of this study would suggest that a customisable modifiable chair-side device may be considered a more cost effective and time efficient alternative to casted laboratory manufactured devices outlined in this study. In addition to this, the time to produce the devices in terms of man-hours was considerably less for the chair-side orthoses. The chair-side device could also be fitted immediately without the need for follow-up fitting consultations. However, this study did not consider the longevity of each type of device. This along with the recommendations on cost effectiveness would require further longitudinal studies.
The fact that no significant recouping of tibial rotation was found is consistent with the findings of Woodburn et al.[30] who reported that this coupling effect was delayed up to 12 months in a pathological group. The findings are also consistent with Ferber et al.[11] who found no difference in coupling effects with orthoses in runners when compared to a control.

Table 2: 95 % Confidence interval for mean angular difference between groups (Z and Y axes).

Z Axis	Intervention	95 % Confidence interval for mean angular difference	
		Lower bound	**Upper bound**
	Control	-2.17	3.96
	Intervention 1	-2.51,	3.06
	Intervention2	-3.78	2.61
	Intervention 3	-3.81	2.34
Y Axis	Control	7.25	16.74
	Intervention 1	1.64	13.24
	Intervention2	0.18	4.74
	Intervention 3	2.67	11.63

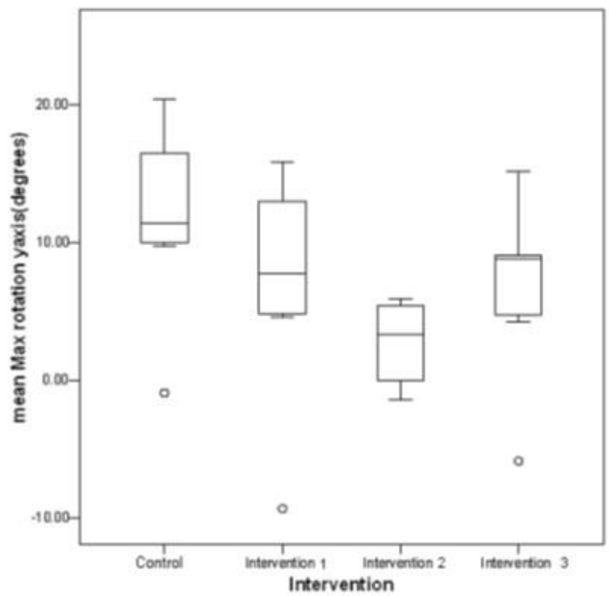

Figure 3: The box plots in figure 3 represent the graphical differences between the control (control and orthoses groups) for heel eversion. Initially it can be seen that the largest difference from the control is intervention 2 (Modified chair-side orthotic).

Limitations

The study was limited by a small sample size. It must also be noted that both laboratories used in the study were aware of the study and not blinded to the request of orthoses. When using the EMT software in this study, we were restricted to a fixed position EMT receiver. This meant that all data had to be recorded on a treadmill to obtain optimum speed and repeated measures. If this study were to be repeated then a protocol for data collection outlined by Black et al.[31] may be adopted. In this case, a foot switch or instrumented walkway and dynamic EMT

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motion capture system could be deployed, thus limiting treadmill bias.

Recommendations

A future recommendation would be to repeat the study prospectively on a sample size with greater statistical power. The recoupling affect, cited as an effect of foot orthoses[1,9,32], was not confirmed in this or other shorter term studies[9]. A prospective study of foot orthoses and their recoupling effects on heel eversion and tibial rotation in symptomatic groups outside those reported in rheumatoid arthritis[30] may be required. It may also be appropriate to study the mechanical changes in timing and pressure distribution as outlined by Redmond et al.[8].

Conclusion

This study compared the same prescription per participant using clinical discretion as to the degree of rear foot control; varying from 4° to 6°. This preliminary study showed that the largest change of heel eversion occurred when wearing the chair-side orthoses. In comparison, both lab manufactured devices produced the same change of rear foot eversion using CAD and TRAD laboratory methods from the same negative cast and measurement data. This study demonstrated that if orthoses are provided for the purpose of controlling rear foot motion then a more proficient and prudent intervention would be the chair side device described in this study.

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