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1<sup>st</sup> metatarsophalangeal joint  
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# Effect of Interpod and Custom Orthoses on Plantar Loading of the 1<sup>st</sup> Metatarsophalangeal Joint During Gait

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## Abstract

This study employed a blind randomised crossover design on 8 asymptomatic participants comparing Interpod prefabricated orthotics, custom orthotics and a shoe only control state using the Pedar in-shoe system during gait. No statistical difference was found between the Interpod and custom orthotics under the 1<sup>st</sup> MTPJ for maximum force, maximum mean pressure, or peak pressure. However it was found that the custom orthotic was able to significantly delay instant of peak pressure and significantly increased contact time, whereas the Interpods didn't. No significant correlations were made between the foot posture and parameters which were significantly affected between experimental states. Further research is needed to determine if these changes are mirrored in larger symptomatic samples.

## Introduction

Many different types of orthoses are used to treat lower extremity biomechanical dysfunction<sup>1</sup> and in the NHS approximately £11.4 million is spent on foot orthotics (FO) each year.<sup>2</sup> These range from simple over-the-counter accommodative devices to custom made functional FO.<sup>3</sup>

However a lack of clear evidence-based guidelines exists to their use<sup>1</sup> and decisions are normally based on personal experience, cost, and availability of materials.<sup>3</sup> With an ever increasing range of materials available these decisions are not likely to become easier.<sup>2</sup> This may explain the high failure rate of 51%<sup>4</sup> which is equivalent of £5.8 million of scarce NHS resources wasted each year.

Based on this it would seem that it is important that patients are provided with the most effective orthotic so that time and money are not wasted and to this extent there has been considerable research comparing prefabricated and custom FO.<sup>5-</sup>

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Previous investigators have examined a wide variety of prefabricated FO from simple medial heel wedges and arch fillers<sup>13</sup> and silicone heel cups<sup>12</sup> to rigid contoured FO.<sup>1,5,13</sup> Much of this research has shown prefabricated FO to perform comparably to custom FO<sup>5-9</sup> and some has shown prefabricated FO to be more effective than custom FO.<sup>10</sup> There is also a large variation in effectiveness depending on the type of prefabricated FO used.<sup>10,12</sup>

Interestingly no research was found indicating custom FO performed better unless they were further adapted with the addition of metatarsal domes and bars.<sup>10</sup>

The relevance of a variety of parameters has been reported in the literature with regards to foot function. One study reported that the temporal parameters of plantar pressure, rather than those of magnitude, are markedly affected in rheumatoid arthritis.<sup>14</sup> Conversely, in patients with diabetes, higher plantar pressures have been noted.<sup>15,16</sup>

Similarly, previous research has shown a variety of parameters are effected by orthotic intervention.<sup>10,15,17-21</sup> Loading of the medial forefoot has been shown to occur significantly earlier with a rigid custom FO than in the shoe only control state.<sup>18</sup> Several Authors<sup>10,15,19-21</sup> have investigated changes in plantar pressure and it has been reported that there is a trend toward a reduction in maximum force and peak pressure in the region of the first metatarsophalangeal joint (1<sup>st</sup> MTPJ).<sup>15,19</sup> Conversely, it has also been reported that rearfoot wedges have no significant effect on forefoot pressure.<sup>21</sup>

In one study<sup>1</sup> the biomechanical effectiveness of FO was measured in single limb static stance so results may not represent dynamic function. This highlights the need for dynamic study of the effectiveness of the FO.

At present there is limited evidence comparing the ability of prefabricated and custom FO to alter maximum force, maximum mean pressure, peak pressure, contact time, and instant of peak pressure, under the 1<sup>st</sup> MTPJ during gait.

This study intended to focus on the measurable consequences of altering foot function during gait and investigated; maximum force, maximum mean pressure, peak pressure, contact time, and instant of peak pressure at the interface of the foot and footwear. The following hypotheses were tested;

*Hypothesis:* There will be a difference in the effect of the two types of FO on the measured parameters under the 1<sup>st</sup> MTPJ during gait.

*Null Hypothesis:* There will be no difference in the effect of the two types of FO on the measured parameters under the 1<sup>st</sup> MTPJ during gait.

## **Method**

### **Sample**

A convenience sample of 15 asymptomatic participants with a rearfoot varus were recruited from the staff and undergraduate student population of The University of Southampton who met the inclusion criteria of;

1. Volunteers who are within the ages of 18-60 years old.
2. Volunteers without a neuromuscular condition which may interfere with normal foot function and plantar pressure loading.
3. Volunteers without a limb leg difference greater than 1cm.
4. Volunteers who have not recently suffered acute lower extremity trauma.
5. Those without previous lower extremity operations such as prosthesis in hip, knee, ankle, or foot.
6. Volunteers who do not have any problems of cooperation, including eye, ear or cognitive disorders.
7. Volunteers must be able to walk unaided without the use of walking aids such as sticks

Written informed consent was obtained from each suitable participant and ethical approval was received from The School of Health Professions and Rehabilitation Sciences Ethics Committee.

## **Analysis Equipment**

The Novel Pedar™ system (Novel GmbH, Munich, Germany) in-shoe measurement system, with a sampling rate of 50 Hz was used. This system has been shown to have greater accuracy, reliability, and repeatability in comparison with other in-shoe devices such as the F-scan system.<sup>22,23</sup>

In order to determine the posture of the foot, the Foot Posture Index – 8 (FPI-8) was used. This uses 8 observations of the foot and assigns a score of -2 (supinated) to +2 (pronated) to each observation and results in a numerical value describing the posture and position of the foot. This tool has been shown to be a reliable and valid tool for assessing and quantifying foot posture.<sup>1,24-26</sup> Intra-rater reliability was increased with repetitive testing on a single participant until consecutive results reached concordance.

## **Footwear and Foot Orthoses**

In order to control for the effects of footwear type on plantar pressure<sup>27</sup> all participants wore trainers and it was ensured that participants did not change footwear between trials.

Interpod Flex  $\frac{3}{4}$  length with heel cup prefabricated orthotics (supplied by A. Algeos Ltd, Liverpool, UK) were used, with the correct size being used for each participant. The Interpod orthotics consisted of a contoured polypropylene shell with plantar fascial groove and 6° rearfoot wedge. The optional self adhesive cover was not used.

Custom orthotics consisted of a 3mm homopolymer polypropylene shell with an extrinsic high density EVA rearfoot post (materials supplied by A. Algeos Ltd). Again no top sheet was used, which in conjunction with identical shell material, was done in order to limit the possibility of any observed effect being due to variation in material properties. The custom orthotics were constructed from a neutral suspension cast with the help of Strides in Healthcare (Southampton, UK).

### **Procedure**

At the initial meeting, all potential participants were screened for a rearfoot varus and those that fitted the study criteria were asked to return for a second visit. At the second meeting, 15 participant's FPI-8 scores were determined and all demographic data collected. Rearfoot varus angles were measured and non-weight bearing neutral casts were made of both the participant's feet.

Prior to the final data collection a pilot study was carried out on 2 subjects, as a result of which no alterations were made to the method.

At the third meeting a blind randomised crossover design was employed. All participants were initially allowed a 2 minute period to walk along the 10m platform in order to acclimatise to the laboratory environment and walking in front of an audience. The Pedar insoles were then inserted to the participant's trainers and participants walked up and down the walkway 5 times at their own comfortable pace to collect data for the shoe only control state.

The order of the two experimental states (custom and Interpod orthotics) was randomly assigned using a random number generator<sup>28</sup> to produce a 15 digit sequence consisting only of 1 and 2. Participants who were assigned to group 1 were tested with the Interpod first and those assigned to group 2 were tested with the Custom FO first. This was done to reduce any possible effects of series.<sup>29</sup> All orthoses were inserted and removed behind a screen to ensure participants remained blind.

Subjects were given a maximum acclimatisation period between test states of 2 minutes and were not allowed to walk more than 20m in order to reduce the possible effects of fatigue.

### **Data Analysis**

Data were prepared and manipulated using the Novel win 09.8 data analysis software (Novel GmbH, Munich, Germany) with only data from the third steps of each walk being used in order to reduce the effects of acceleration and deceleration.<sup>30</sup>

Individual masks were made for each participant corresponding to the area of the 1<sup>st</sup> MTPJ with mean values being calculated from the third step of the five walks in each experimental state.

Statistical analysis of data were conducted using SPSS for Windows, version 14.0 (Chicago Inc). After assessing for normality, Paired t-tests were used to identify differences between experimental states. Pearson's correlation coefficients were

used to determine the association of the FPI-8 with changes in any parameter that was found to have changed between the experimental states (e.g. Contact time with no orthotic – contact time with custom orthotic). This was done because previous work has raised the possibility of a correlation between foot posture and efficacy of prefabricated orthoses.<sup>13</sup>

## Results

A total of 7 females and 1 male attended the final data collection session. The mean age was 26.3 (+/- 10) years and the mean BMI was 21.2 (+/- 2.4). The mean FPI-8 for the left foot was 4.9 (+/- 3.5) (range: 0 to +11) and 4.8 (+/- 3.4) (range: -1 to +10) for the right.

The data were assessed for normality using the Kolmogorov-Smirnov statistic and histograms which enabled outliers to be identified.

Statistically significant differences between experimental states were only achieved in the right foot for contact time ( $p=0.05$ ) and instant of peak pressure ( $p=0.023$ ). Thus custom orthoses had a significantly longer contact time and delayed instant of peak pressure than the Interpods (see table 1). Therefore the hypothesis was accepted and the null hypothesis rejected for the parameters of contact time and instant of peak pressure.

No statistically significant difference was detected between the shoe only control state and either orthotic in maximum force, maximum mean pressure, or peak pressure.

Paired States		State 1 Mean	State 2 Mean	p Value	Statistically Significant
State 1	State 2				
Conttime C L	Conttime I L	510	488.5	0.461	NO
Conttime C L	Conttime N L	510	489	0.402	NO
Conttime N L	Conttime I L	489	488.5	0.99	NO
Conttime C R	Conttime I R	515	462.5	0.05	YES
Conttime C R	Conttime N R	515	479.5	0.035	YES
Conttime N R	Conttime I R	479.5	462.5	0.476	NO
InstpeakP C L	InstpeakP I L	532	488	0.053	NO
InstpeakP C L	InstpeakP N L	532	498	0.158	NO
InstpeakP N L	InstpeakP I L	498	488	0.656	NO
InstpeakP C R	InstpeakP I R	509	475	0.023	YES
InstpeakP C R	InstpeakP N R	509	483.5	0.03	YES
InstpeakP N R	InstpeakP I R	475	483.5	0.651	NO

Table 1. Results of t-tests showing statistically significant differences between experimental states. Where Conttime = Contact time (ms), InstpeakP = Instant of Peak Pressure (ms), C = Custom Orthotic, I = Interpod Orthotic, N = No Orthotic, L = Left Foot, R = Right Foot.

Pearson's correlation tests were carried out between FPI-8 and changes in instant of peak pressure, and contact time (see table 2) as these were the only variables shown to have been changed significantly by either orthotic (see table 1).

There appeared to be mainly weak negative correlations of varying strengths in both experimental states, and a weak positive correlation between FPI-8 and change in contact time with the Interpod orthotic in the right foot. However all of these correlations failed to reach statistical significance ( $p \leq 0.05$ ).

	Foot Posture Index and Changes in Instant of Peak Pressure For Each Orthotic Type	Foot Posture Index and Changes in Contact Time For Each Orthotic Type
Custom Left	-0.698 (p = 0.054)	-0.425 (p = 0.294)
Custom Right	-0.047 (p = 0.930)	-0.149 (p = 0.725)
Interpod Left	-0.61 (p = 0.108)	-0.34 (p = 0.409)
Interpod Right	-0.041 (p = 0.924)	+0.65 (p = 0.878)

Table 2. Correlation Between FPI-8 and Change in Variables That Were Significant

## Discussion

This study investigated the effect of custom and Interpod FO on maximum force, maximum mean pressure, peak pressure, contact time, and instant of peak pressure at the interface of the foot and footwear during gait in 8 asymptomatic volunteers. Of the high number of participants who withdrew from the study (7), 2 withdrew due to changes in health, and 2 withdrew due to family bereavement, with the other 3 giving no reason.

The results have shown that there were no significant differences between Interpod and custom FO in maximum force, maximum mean pressure, or peak pressure. This is in agreement with a previous study which found no statistical difference between custom and Interpod FO when in shoe pressure and force variables were compared relative to a shoe only control state during gait.<sup>5</sup> The same study<sup>5</sup> found that pressure and force variables were significantly reduced in the forefoot region with both types of FO. This is in contrast to the current study which found neither FO made significant changes in maximum force, maximum mean pressure, or peak pressure under the 1<sup>st</sup> MTPJ from the control state.

Redman et al<sup>5</sup> also reported that load was shifted from the forefoot and rearfoot towards the midfoot region, although this was not investigated in the current study.

The lack of any significant change in maximum force, maximum mean pressure, or peak pressure at the 1<sup>st</sup> MTPJ may have several explanations. The addition of the FO may have raised the height of the rearfoot relative to the forefoot. Raising the rearfoot has been shown to significantly increase forefoot pressure and move the area of peak pressure medially towards the 1<sup>st</sup> metatarsal and hallux.<sup>30</sup>

Furthermore it may be possible that the FO improved the alignment of the foot but this was cancelled out by the increased mechanical advantage of peroneus longus which may have dorsiflexed the first metatarsal.

It was found that the custom FO significantly delayed the instant of peak pressure and increased the contact time in the area of the 1<sup>st</sup> MTPJ on the right foot, when compared with the Interpod FO. This has not been previously reported in the literature although prolonged loading in the midfoot region has been described with the addition of orthoses due to the contour of the FO acting as an extra fulcrum.<sup>5</sup> However, no one has compared functional FO and custom FO in this way.

The FPI-8 is a reliable tool<sup>1,24-26</sup> that was used to describe participants' foot posture. However statistical analysis failed to find significant correlations between FPI-8 score and changes in parameters that were affected by orthotic intervention and this is in contrast to previous research.<sup>13</sup>

Attempts were made in this study to reduce the 'Hawthorne effect'<sup>29</sup> by allowing participants to acclimatise to the laboratory environment prior to data collection. Furthermore, this study was designed to reduce the possibility of participant bias affecting gait by ensuring participants remained blind to which orthotics they were testing. To the authors knowledge this has not been previously reported in the literature.

Statistical analysis in this project was conducted in way that avoided pooling data, as left and right feet were analysed separately. Whilst this approach decreases the risk of Type I errors, it also decreases the statistical power, further increasing the likelihood of Type II error<sup>32</sup> in an already diminished sample size. Never the less, the statistical methods used in this study have been advocated in the literature.

<sup>32,33</sup> Direct comparison of results with studies that have pooled data however may be difficult.<sup>32</sup>

The results of this study have to be interpreted in the context of a number of limitations. The sample consisted of asymptomatic young volunteers which may not be representative of a pathological population, although the range in FPI-8 scores (-1, 'normal' to +11, 'highly pronated') would suggest a wide range of foot types in the study.

The work was conducted as part of the author's undergraduate degree and as such was conducted by a novice researcher. The researcher's inexperience may have also resulted in errors during the manufacture of the negative casts and custom orthotics, with the result that custom orthotics manufactured by more experienced clinicians may be more effective than those used in this study.

Further work is needed to investigate whether statistical significance in all parameters for both feet may be reached with a larger sample. It would also be interesting to investigate whether custom orthotics made by a more experienced practitioner show differences. Work should also be conducted to investigate whether the life time of Interpod FO is comparable to that of the custom FO.

## **Conclusion**

This study has shown no significant difference between custom and Interpod Flex with heel cup orthotics in maximum force, maximum mean pressure, or peak pressure during gait. Significant differences between the orthotics in their ability to alter contact time and instant of peak pressure in the right foot were observed although no statistical significance for the same parameters was found in the left foot.

Although the results of this study have no impact on current clinical practice and practitioners should continue their normal practice when prescribing foot orthoses, the study does however provide suggestions for further research.

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