Effect of antipronation foot orthosis geometry on compression of heel and arch soft tissues

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**Recommended Citation**  
Sweeney, Declan; Nester, Christopher J.; Preece, Stephen; and Mickle, Karen J., "Effect of antipronation foot orthosis geometry on compression of heel and arch soft tissues" (2015). *Faculty of Science, Medicine and Health - Papers: part A*. 3210.  

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Abstract
2015, Rehabilitation Research and Development Service. All rights reserved. This study aimed to understand how systematic changes in arch height and two designs of heel wedging affect soft tissues under the foot. Soft tissue thickness under the heel and navicular was measured using ultrasound. Heel pad thickness was measured while subjects were standing on a flat surface and also while they were standing on an orthosis with 4 and 8 degree extrinsic wedges and 4 and 8 mm intrinsic wedges (n = 27). Arch soft tissue thickness was measured when subjects were standing and when standing on an orthosis with -6 mm, standard, and +6 mm increments in arch height (n = 25). Extrinsic and intrinsic heel wedges significantly increased soft tissue thickness under the heel compared with no orthosis. The 4 and 8 degree extrinsic wedges increased tissue thickness by 28.3% and 27.6%, respectively, while the 4 and 8 mm intrinsic wedges increased thickness by 23.0% and 14.6%, respectively. Orthotic arch height significantly affected arch soft tissue thickness. Compared with the no orthosis condition, the -6 mm, standard, and +6 mm arch heights decreased arch tissue thickness by 9.1%, 10.2%, and 11.8%, respectively. This study demonstrates that change in orthotic geometry creates different plantar soft tissue responses that we expect to affect transmission of force to underlying foot bones.

Disciplines
Medicine and Health Sciences | Social and Behavioral Sciences

Publication Details

This journal article is available at Research Online: https://ro.uow.edu.au/smhpapers/3210
Antipronation orthosis

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Abstract

This study aimed to understand how systematic changes in arch height and two designs of heel wedging affect soft tissues under the foot. Soft tissue thickness under the heel and navicular was measured using ultrasound. Heel pad thickness was measured when standing on a flat surface and standing on an orthosis with 4° and 8° extrinsic wedges, and 4 mm and 8 mm intrinsic wedges (n=27). Arch soft tissue thickness was measured when standing, and when standing on an orthosis with -6 mm, standard, and +6 mm increments in arch height (n=25). Extrinsic and intrinsic heel wedges significantly increased soft tissue thickness under the heel compared to the no orthosis condition. The 4° and 8° extrinsic wedges increased tissue thickness by 28% and 27.6% respectively, whilst the 4 mm and 8 mm intrinsic wedges increased thickness by 23% and 14.6%. Orthotic arch height significantly affected arch soft tissue thickness. Compared to the no orthosis condition, the -6 mm, standard and +6 mm arch heights decreased arch tissue thickness by 9%, 10% and 11.8% respectively. This study demonstrates that change in orthotic geometry create different plantar soft tissue responses which we expect to affect transmission of force to underlying foot bones.

Key Words: antipronation, arch profile, extrinsic wedge, foot orthosis, heel pad, intrinsic wedge, plantar foot, pronation, tissue compression, ultrasound

Abbreviations: APFO = antipronation foot orthoses, CAD = computer aided design, CI = confidence interval, EVA = ethylene vinyl acetate, SD = standard deviation
1 Introduction

Antipronation foot orthoses (APFO) are commonly used by healthcare professionals to treat a variety of lower limb pathologies that are thought to be caused by excessive pronation [1, 2]. APFO are purported to function by applying an inversion moment at the rearfoot, reducing calcaneal eversion, and by reducing dorsiflexion of the joints forming the medial longitudinal arch of the foot [3]. To achieve this, the orthosis must first alter the load being applied through the sole of the foot.

The principal design features in an APFO are the geometry of the heel and arch sections. In addition to material stiffness [4], these features will alter loads between the plantar aspect of the foot and orthotic surface [5-7]. Increases in peak pressure in the arch [8, 9] and reductions in pressure in the heel [8-11] have been well documented for total contact orthosis used in patients with diabetes. Similarly, both extrinsic [12, 13] and intrinsic [14] heel wedges have been shown to increase pressure values in the medial heel. However, it is less clear how changes in load at the skin surface affect loads transferred to bone. This will be influenced by mechanical properties of soft tissues residing between the foot-orthosis interface.

The effect of foot orthoses on plantar tissue structures has been quantified previously. MRI modelling has been used to examine how cushioning materials of different densities and contours affect tissues under the calcaneus [15]. Similarly, lateral radiographs have been used to show that a heel cup that constrains soft tissue displacement increases plantar heel pad thickness compared to use of no heel cup [16]. However, the orthoses used in previous studies did not incorporate a medial wedge. This design feature has been associated with an antipronation [12, 14, 17] effect and there are also two different designs (inside and outside the heel cup) with
proposed different effects [18]. Thus, it is unclear how an antipronation orthosis will affect plantar soft tissues characteristics under either the calcaneus or medial arch.

Ultrasound is becoming increasingly popular for quantifying soft tissue characteristics [19, 20]. As well as being non-invasive it is portable, so, unlike MRI [21], can be used to quantify tissue characteristics in a weight bearing prone position. Ultrasound has been used to measure foot muscles [22], skin and plantar aponeurosis [23]. Furthermore, it demonstrates good intra and inter observer reliability with foot structures [20]. However, to date, only one study has used ultrasound to study the effect of orthotic designs, focusing on the heel and did not use an APFO [24].

The aim of this paper was to use ultrasound to characterise static barefoot plantar tissue responses to different APFO geometries. Specifically, we examined the effect of incrementally increasing a medial heel wedge and arch height on plantar soft tissues. We hypothesised that incrementally increasing wedge and arch height would compress soft tissues in a systematic manner.

2 Method

2.1 Participants

Ethical approval was granted from the institutional Ethics Committee (HSCR12/57). Twenty-seven participants (14 male/13 female), mean age of 29.9 years (SD 6.7 years), mean weight 70.7 kg (SD 9.3 kg) and mean height 1.71 m (SD 0.08 m), volunteered. Data were collected from the right foot. Participants reported no recent history of lower limb pathology or surgery and had a neutral foot alignment as defined by the Foot Posture Index [25]. All gave informed written consent to participate.
2.2 Orthoses

The Salfordinsole™ (Salfordinsole Health Care Ltd, UK) was chosen as an example APFO [26] but like most orthotic products it is impenetrable to ultrasound signals. To study its effect on foot tissues an exact copy of the APFO was made in a rigid plastic sonographic material (Northplex®). To create these copies, positive plaster of paris moulds of the orthotic were created from milled EVA versions of the Salfordinsole™ based on CAD designs. 3 mm Northplex sheets were subsequently heat moulded and vacuum formed over the Salfordinsole™ positive models. Northplex® allows ultrasound signals to pass through its structure and is almost incompressible in sheet form. It remains very rigid when moulded into an APFO shape, being similar to a polypropylene style foot orthotic. We chose to investigate the effect varying the size of the medial wedge using two different approaches, both used in practice: an intrinsic wedge (inside the heel cup) measured in millimetres, and an extrinsic wedge measured in degrees (under the heel cup). Our rationale for this choice was that the extrinsic wedge alters only the geometry underneath the orthotic (i.e. the surface in contact with the shoe), but tilts the upper surface and heel cup that is in contact with the heel laterally. In contrast the intrinsic wedge alters the internal geometry of the heel cup that directly contacts the heel skin [18]. Two Northplex® designs were produced for each approach: a 4° and 8° extrinsic wedge and a 4 mm and 8 mm intrinsic wedge.

A further three Northplex® insoles were produced to investigate the effect of varying arch height. The first of these had the standard Salfordinsole™ arch height. The other two had arch heights that were 6 mm less and 6 mm greater that the standard. All orthotic designs were created and modified using CAD/CAM to strictly control
changes in orthotic geometry (Salfordinsole iCUSTOM software). Figure 1 shows the
design of the different heel and arch geometries.

![Figure 1](image)

**Figure 1.** 1-2 are 4° and 8° extrinsic medial wedges. 3-4 are 4mm and 8 mm intrinsic
medial wedges. 6 is standard arch profile. 7 is -6 mm arch height. 8 is +6 mm arch
height.

### 2.3 Ultrasound and Scanning Platform

A MyLab 70 Xvision ultrasound machine and 13MHz linear array transducer (Esoate
Europe, United Kingdom) was used to image plantar soft tissues on top of the
orthotic. Measures of soft tissue thickness were obtained in the arch (3x arch heights)
and heel area (4x heel wedges). For the arch, the navicular was assumed to represent
the peak in the medial arch height and correspond to peak orthotic arch height. A
plateau on the plantar surface of the navicular was used as an internal bony reference
for measures of arch tissue thickness (Figure 2). This landmark was imaged in the
frontal plane and lateral to the navicular tuberosity by 1/3 of the navicular width.
Pilot work (n=10) showed high intra-rater reliability (ICC 0.980, 95% CI=0.922–
0.995) of this measure whilst standing on the standard APFO orthotic. For the heel area, the calcaneal tuberosity was selected as the reference anatomical landmark, viewed in the frontal plane. Due to its superficial location, shape and tissue properties, it is easily identified and has demonstrated high reliability [20].

Figure 2. Ultrasound image showing landmarks used to record tissue thickness measurement for baseline arch condition.

A platform incorporating a 50 mm x 120 mm opening (Figure 3) was used to position the ultrasound transducer under the orthotic/foot at the heel and arch sites. Baseline measurements of arch and heel soft tissue thickness (i.e. with no orthotic) were obtained when standing on the platform. For the heel baseline measurement, tissue was imaged through a flat sheet of Northplex®.
Each participant stood with their right foot on the orthotic which was secured over the platform aperture. Participants stood on one leg and used hand rails to prevent sway. To improve the extent to which this static assessment might replicate soft tissue compression in walking, each subject was fitted with a vest weighted by 5% of their own body weight. This weight was a compromise between what was tolerable during testing and trying to increase loading to the equivalent of body weight, since forces passing through the foot exceed body weight twice during stance [27]. The sequence of testing the seven orthotic conditions was randomised (using customised Matlab program) and three scans were taken for each condition by a single operator. The probe was removed between each scan for the orthotic conditions (21 times) and the heel and arch baseline conditions (6 times).
2.4 Analysis

Image J software (National Institute for Health, Bethesda, MD, USA) was used to measure the perpendicular distance between the navicular/calcaneus landmarks and skin surface. All images were coded to blind the observer to the orthotic condition, however, as baseline images differed considerably they were often recognisable. A single operator carried out all measurements.

Repeated measures ANOVA (SPSS v.19) was used to examine the effect of (1) arch height, (2) extrinsic and (3) intrinsic wedges, using absolute measures (mm) of tissue thickness ($\alpha =0.05$). Bonferroni post hoc testing was used to examine significant main effects.

To quantify the effect of varying orthotic arch height and the heel wedges, differences in tissue thickness between the baseline measurement (no insole) and each orthotic design were described as percentage change in tissue thickness.

3 Results

Arch soft tissue thickness at baseline was 29.9 mm (SD 3.6 mm). Varying the arch height had a significant effect on soft tissue thickness ($F_{1,6, 39} = 70.6$, $p<0.001$) (Figure 4). Post hoc testing showed that the three arch heights significantly reduced tissue thickness compared to the baseline condition. The +6 mm arch height resulted in the greatest reduction of tissue thickness (11.8%; $p<0.001$). This was followed by the standard arch height (10.2%; $p<0.001$) and the -6 mm arch height (9.1%; $p<0.001$). There was a 2.37% decrease in tissue thickness between the -6 mm and standard arch height ranges (0.4% decrease per mm increase in arch height). A 2.26% decrease was found between the standard and +6 mm arch height ranges (0.38% decrease per mm increase in arch height).
Heel soft tissue thickness at baseline was 8.6 mm (SD 1.7 mm). The extrinsic wedge conditions had a significant effect on soft tissue thickness ($F_{2, 52} = 116.6$, $p<0.001$) (Figure 5A). Post hoc testing showed that both extrinsic wedges significantly increased tissue thickness compared to the baseline. The $4^\circ$ extrinsic increased tissue thickness by 28.3% ($p<0.001$) whilst the $8^\circ$ extrinsic wedge increased tissue thickness by 27.6% ($p<0.001$). Similarly, the intrinsic wedge conditions had a significant effect on tissue thickness ($F_{2, 52} = 60.4$, $p<0.001$) (Figure 5B). Post hoc testing showed that both intrinsic wedges significantly increased tissue thickness compared to the baseline. The $4$ mm intrinsic wedge increased tissue thickness by 23% ($p<0.001$) whilst the $8$ mm intrinsic wedge increased tissue thickness by 14.6% ($p<0.001$). The $4$ mm wedge caused a significantly greater increase in tissue thickness compared to the $8$ mm wedge (8.3% increase; $p<0.001$). A 4.1% reduction in tissue thickness was found between the $4^\circ$ and $8^\circ$ extrinsic wedge ranges (1.02% decrease per degree increase in extrinsic wedge). An 8.83% decrease was found between the intrinsic wedge ranges (2.21% decrease per mm increase in intrinsic wedge).

4 Discussion

The purpose of this study was to characterise how soft tissue structures in the plantar foot respond to different APFO designs. Specifically, we sought to characterise how increasing both heel wedging (extrinsic and intrinsic) and arch height compresses soft tissue. As hypothesised, incremental increases in arch height and heel wedging (extrinsic and intrinsic) caused soft tissues to compress in systematic manner (Figures 4 & 5).
Figure 4. Measured soft tissue thickness for arch baseline, 6 mm, standard, and +6 mm arch heights. Horizontal lines indicate significant differences between insole conditions. Pairwise comparisons are as follows (with Bonferroni correction): arch (no insole) to -6 mm arch ($p < 0.001$, 95% confidence interval [CI] 0.167–0.378), arch to standard arch ($p < 0.001$, 95% CI 0.231–0.434), arch to +6 mm arch ($p < 0.001$, 95% CI 0.278–0.505), -6 mm arch to standard arch ($p < 0.002$, 95% CI 0.019–0.101), -6 mm arch to +6 mm arch ($p < 0.001$, 95% CI 0.053–0.185), and standard to +6 mm arch ($p < 0.004$, 95% CI 0.016–0.104). SD = standard deviation.

The effect between the different arch heights on tissue compression was however small. The -6 mm and standard arch heights caused a 2.7 mm and 3.3 mm decrease in tissue thickness respectively, and the +6 mm arch height resulted in a 3.9 mm decrease in tissue thickness. This 1.2 mm difference in tissue compression between -6 mm and +6 mm orthotic arch heights suggests that large differences in orthotic arch heights can have similar effects on arch tissue compression. A number of factors may explain this. Firstly, when the foot is load bearing the plantar foot structures bear tensile forces and become stiff to resist external loads applied [28]. If soft tissues are already very stiff in the direction of vertical compression then the orthotic arch profile may only have a small compressive effect, regardless of its geometry. Thus, stiff plantar tissues transfer load directly to bone. Secondly, the orthotic arch profile may
have caused a neuromuscular response to avoid excessive soft tissue compression and pain in the plantar muscles and skin in the arch. This response might be considered an ‘avoidance tactic’ under the threat of excessive muscle tissue compression in the arch due to the orthotic geometry. This neuromuscular response would adjust foot position with each increase in orthotic arch height ensuring that further compression of tissues does not occur, thus reflecting our observations that soft tissue does not significantly compress further with large changes in orthotic geometry.
Figure 5. Measured soft tissue thickness for (a) extrinsic and (b) intrinsic wedges. Horizontal lines indicate significant differences between insole conditions. Pairwise comparisons are as follows (with Bonferroni correction): baseline heel to 4° extrinsic wedge ($p < 0.001$, 95% confidence interval [CI] 0.273–0.425), baseline heel to 8° extrinsic wedge ($p < 0.001$, 95% CI 0.260–0.406), 4° extrinsic wedge to 8° extrinsic wedge ($p < 1.0$, 95% CI 0.029–0.060), baseline heel to 4 mm intrinsic wedge ($p < 0.001$, 95% CI 0.193–0.328), baseline heel to 8 mm intrinsic wedge ($p < 0.001$, 95% CI 0.084–0.215), and 4 mm intrinsic wedge to 8 mm intrinsic wedge ($p < 0.001$, 95% CI 0.064–0.158). SD = standard deviation.

The heel wedges (both extrinsic and intrinsic) significantly increased soft tissue thickness under the calcaneus compared to the baseline. This increase was most likely due to the heel cup of the APFO which prevented lateral tissue displacement in the orthotic but not baseline condition. This buttressing effect has previously been observed. A 3.57 mm increase in heel pad thickness was reported in a study using lateral radiographs to quantify the effect of a heel cup with subjects in a standing position [16]. Similarly, a 3.3 mm increase in heel pad thickness due to a heel cup was measured using in-shoe ultrasound measures while walking on a treadmill [24]. These values are close to those reported in the present study (3.49 mm and 3.3 mm increase in tissue thickness for the 4° and 8° extrinsic wedges respectively).

No significant difference in tissue thickness under the heel was observed between the 4° and 8° extrinsic wedges. In contrast the 8 mm intrinsic wedge resulted in a significantly reduced tissue thickness compared to the 4 mm wedge. The extrinsic wedges, due to the confining action of the heel cup, may make the soft tissues stiffer and therefore more difficult to compress even when further wedging is applied. The observation of no further reduction in tissue thickness between the 4° and 8° extrinsic wedges might suggest the heel pad is close to maximum compression and stiffness. Such a scenario may be beneficial for transmission of force from an orthosis designed to influence joint moments. In contrast, the intrinsic wedge elevates the heel within
the heel cup which will reduce the buttressing effect and this would be greater with the 8 mm than with the 4 mm wedge.

Inevitably the effect of APFO arch and heel geometry on soft tissue compression was variable between subjects. Increasing the arch height had little effect on some subjects while others reported larger reductions in tissue thickness between the arch height ranges. For example, one subject had a 0.14 % and 1.58 % decrease in tissue thickness between the -6mm to standard, and standard to +6mm arch heights respectively, whilst another had a 4.6 % and 8 % decrease between the -6mm to standard, and standard to +6mm arch heights. Likewise, the same was true for both the extrinsic and intrinsic heel wedges. Some subjects experienced the greatest change in thickness (increase in thickness) with the first wedging increment (4° or 4 mm) compared to the baseline measurement, while others had greater change (decrease in thickness) with the second increment in wedging (8° or 8 mm). In the extrinsic wedges for example, one subject had a 36.7 % and 32.9 % increase in tissue thickness for the 4° and 8° wedges respectively. In contrast another subject had a 31.4 % increase for the 4° wedge and 36.3 % increase for the 8° wedge.

The manner in how heel and arch soft tissues compress viscoelastically under load will influence how the AFPO transfers load from its surface to bones thus affecting joint moments. If the heel or arch tissues are very stiff, then the loads at the skin surface will be directly transferred to the bones. Alternatively, greater soft tissue compliance could result in loads being dissipated across internal soft tissue structures, such as the columns of collagen and fat in the heel pad and muscle in the arch. Given the difference in tissue type between the heel and the arch, it is likely that the effect of tissue compliance would be different and this may lead to differing responses at these
sites. Variability in how APFO compress soft tissues may in part explain inter-subject variability in the effect of AFPO on rearfoot kinematics [29, 30]

There are some limitations to this study. Firstly, static measurements of tissue thickness may not reflect how tissues behave dynamically. This is especially relevant in the context of suggested neuromuscular responses. Whilst one approach to measuring heel pad compression during walking has been reported [24] no approach is available for arch tissues. Also, the heel pad measures in this static study are very close to those from dynamic studies [16, 24]. Secondly, tissue compression is measured from a point that is lateral to the navicular tuberosity. The 6 mm changes in arch height occurred at the most medial aspect of the orthosis and tapered to 0 mm at the lateral border under the cuboid. Thus, at the location where arch tissue thickness was measured, there is less than a 6 mm difference between each change in arch profile. Likewise for the heel, incremental increases in wedging (extrinsic and intrinsic) are located at a point on the orthosis that does not correspond to the point at which tissue thickness is measured. However, these measurement limitations would not affect the overall patterns observed in this study. Arguably the feet could have been tested on an orthosis with a heel cup but no heel wedging. Whilst this would explain how heel cups without wedging affect heel tissue, our question was focussed on how changes in wedge geometry affect tissues. Finally, participants did not wear footwear. This would have prevented use of our ultrasound probe but it means that constraints applied by a shoe upper on the response of the foot to the different orthotic designs was not included.
5 Conclusion

This is the first study to quantify how systematic changes in arch height and the two designs of heel wedging affect soft tissues under the plantar foot. The arch geometry had a significant effect on compression of soft tissues in the arch; however compression between the ranges in arch height were small. Likewise for soft tissues under the heel, significant increases in thickness were found with the wedges (extrinsic and intrinsic), however only the intrinsic wedges resulted in a significant difference between the two ranges (4 mm and 8 mm). The effect of altering APFO arch and heel geometry on tissue compression under the plantar foot is variable between individuals. Tissue properties under the plantar foot affect the transfer of load from the orthosis surface to bone and thus influence how joint moments are altered by APFO. Further work is required to understand the relationship between how foot orthosis compress soft tissues and alter foot kinetics/kinematics.
Acknowledgements:

Funding/Support: Declan Sweeney received financial assistance to undertake this research from his employer (St Gabriel’s Centre, Limerick). Dr Karen Mickle holds an Australian National Health and Medical Research Council Post-doctoral Fellowship (Overseas Clinical Training Fellowship, ID 1016521).

Institutional Review: Ethical approval for the study was obtained from the institutional ethical review board. Participants gave informed consent to partake in the study.

Participant Follow-Up: The authors do not plan to inform participants of the publication of this study because contact information is unavailable. However, all participants were made aware at the time of data collection that data obtained would be used for publication.
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