An investigation into the variable biomechanical responses to antipronation foot orthoses

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"Like everything, the end is just the start"
(Mark Pollock, 2014)

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Abstract

Antipronation foot orthosis are commonly used by health care professionals to treat a variety of lower limb conditions thought to be caused by excessive foot pronation. However, despite their widespread use, laboratory based research indicates that antipronation foot orthosis cause variable joint moment/motion biomechanical responses. If a specific biomechanical response is required to treat a specific clinical condition, it follows that practitioners cannot tailor foot orthosis confidently to alleviate symptoms thought to be associated with excessive pronation. A conceptual framework representing a biomechanical system of foot function was proposed to explain how external forces, foot structure, and neuromuscular factors cause these variable joint moment/motion responses to foot orthosis. Two studies (study 1 & study 2) sought to understand how external forces influenced joint moment/motion responses. Study 1 examined if systematic changes in external forces created by varying APFO geometry correlate to changes in joint moment/motion responses. To answer this research question a pilot study (n = 11) developed suitable increments in anti-pronation orthotic geometry that could systematically alter external forces under the plantar foot. The main study (n = 20) demonstrated that varying orthotic arch geometry and medial heel wedge geometry could systematically alter external forces (measured as peak pressure and centre of pressure) and joint moment/motion responses in foot structures. However, study 1 showed that changes in external forces created by varying APFO geometry are generally not strongly correlated (r < 0.6) to changes in joint moment/motion responses thus indicating that other factors (e.g. structural/neuromuscular) influence biomechanical responses to foot orthoses.

On the basis that forces applied to the sole of the foot pass through plantar soft tissues prior to being applied to bones of a joint to affect moments and kinematics, study 2 characterised how soft tissue respond to change in external forces due to change in orthotic geometry. A pilot study (n = 10) developed a reliable method that could be used to quantify soft tissue thickness between the surface of an orthosis and bones overlying the medial arch. The results for the main study (n = 27) found that antipronation orthosis systematically compressed soft tissue structures under the plantar foot.

The studies reported in this thesis show that antipronation orthosis can be tailored to systematically alter tissue compression, external forces and joint moment/motion responses. However, systematically altering external forces under the plantar foot with antipronation foot orthosis is not strongly correlated with changes in joint moment/motion responses. This suggests moment/motion responses are strongly influenced by structural features and/or neuromuscular action in combination with external forces. The work presented in this thesis offers a foundation for future studies seeking to understand how foot orthoses alters foot biomechanics.

Chapter 1 Introduction

Foot orthoses are defined as orthopaedic devices designed to promote the structural integrity of the joints of the foot and lower limb. They do this by altering the ground reaction forces that cause skeletal motion to occur during the stance phase of gait, motion which is often assumed to be abnormal and the cause of lower limb problems (Anthony, 1991). The key function of orthoses is to alter the forces to reduce the amount or timing at which foot pronation occurs, so that there is less heel eversion and less lowering of the medial arch, and this is often known as the 'anti pronation' function of the orthosis.

Studies show unequivocal evidence supporting the use of foot orthosis for a number of systemic disorders affecting the foot. In diabetes for example, custom made foot orthosis significantly reduce plantar pressures under the foot compared to sham orthosis (Burns et al., 2009), and cause a 26 % greater reduction in peak pressure under the calcaneus compared to prefabricated orthosis (Hellstrand Tang et al., 2014). A systematic review of the literature concludes foot orthoses have the potential to prophylactically prevent the development of ulceration in the diabetic neuropathic foot (Paton et al., 2011). Both National Health Service, UK (NHS 2010) and Health Service Executive, Ireland (HSE 2011) best practice clinical guidelines recommend foot orthosis to treat and prevent foot lesion development for individuals with diabetes. Foot orthosis have proven beneficial for individuals whom suffer from foot pain secondary to arthritic disorders. For example, rheumatoid arthritis (RA) studies showed foot orthosis reduce pain under the metatarsal heads (Mejjad et al., 2004), and reduce pain in individuals with mobile rearfoot deformities (Woodburn et al., 2002). Also, foot orthosis significantly reduce pain in children with idiopathic juvenile arthritis, where custom made orthosis have shown to be more effective in reducing pain than prefabricated orthosis (Powell et al., 2005). The National Institute for Health Care and Excellence (NICE) guidelines recommends the use of foot orthosis for individuals with foot pathology caused by RA (NICE 2009). It follows that practitioners who tailor foot orthosis for individuals with diabetes, RA and a number of musculoskeletal conditions alter orthosis geometry to redistribute plantar loading and reduce foot motion (stabilise foot structures). In diabetes for example, practitioners tailor orthotic arch geometry to be in total contact with the plantar surface of the medial arch to decrease load under the heel and forefoot (Burns et al., 2009; Bus et al., 2004). In RA orthotic arch geometry

and medial rearfoot wedges are tailored to decrease foot motion associated with excessive foot pronation (Woodburn et al., 2002; Woodburn et al., 2003). It follows practitioners tailor antipronation orthotic design features in conditions to directly decrease excessive foot pronation, but also use the same design features to treat conditions not necessarily linked to excessive foot pronation (e.g. load redistribution in diabetes).

Practitioners tailor foot orthosis by changing the orthosis shape or changing the material from which various parts of the orthosis are made. These decisions and change in orthotic design alter joint moments and motion responses in the foot joints and are assumed to decrease stress in symptomatic structures (e.g. an inflamed tibialis posterior tendon), and thereafter clinical benefit is derived. However, laboratory based research characterising the biomechanical effects of foot orthoses demonstrate joint moment and motion responses are variable between individuals (Liu et al., 2012; MacLean et al., 2006; Mündermann et al., 2003; Stacoff et al., 2007; Williams et al., 2004). If foot orthoses cause variable moment/motion responses then changing foot orthosis design to elicit a specific change in joint moment/motion, and in turn cause a specific clinical response, would appear to be a very challenging part of the clinical decision making process. Previous work in the literature has focussed exclusively on the general effect of foot orthoses on foot biomechanics, no previous work has attempted to characterise the factors that might explain variation in joint moment/motion responses between individuals.

The focus of this PhD is to investigate factors that can explain the variation between people in their biomechanical response to anti-pronation foot orthoses.

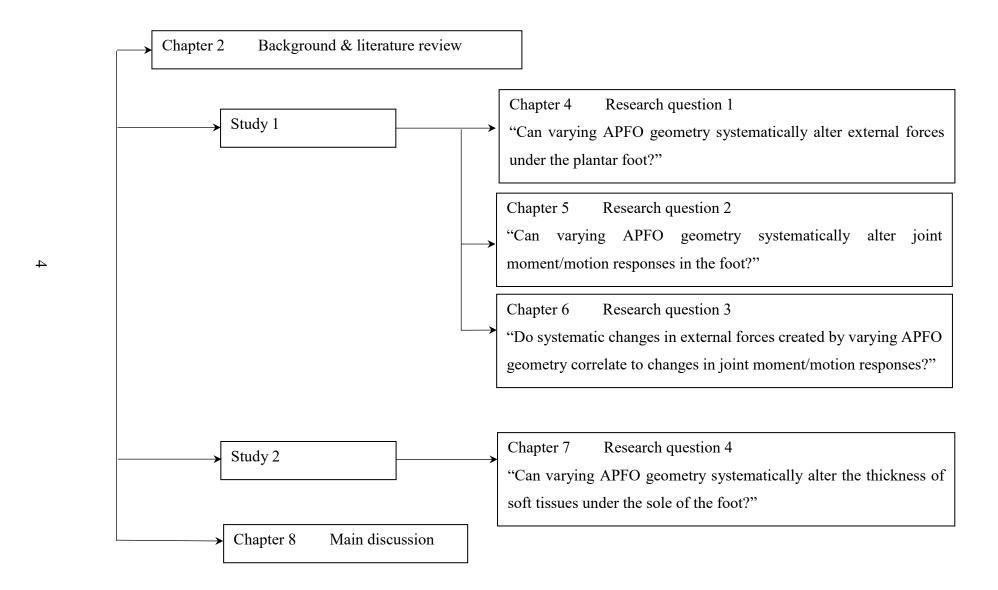
Chapter 2 critically reviews foot pronation and paradigms of foot function that promote the use of foot orthoses and proposes a conceptual model that explains how foot orthoses affect foot biomechanics. A key feature of this model relates to the potential role of external forces, and changes in these forces, in determining the kinematic response to a foot orthosis. Chapter 2 examines how a foot orthosis alters external forces under the sole of the foot and proposes how systematic changes in external forces causes systematic joint moment/motion responses in foot structures. The focus on the role of external forces in determining kinematic response to a foot orthosis provides the basis for two studies presented in this thesis.

Study 1 investigates three research questions to understand if systematic changes in external forces applied to the foot (changes created by varying foot orthotic design) correlate to changes in joint moment/motion responses. Chapter 3 outlines the methodology involved in the collection of pressure, kinetic and kinematic data in a range of different orthotic conditions, and data analysis. Based on this data, Chapter 4 investigates if APFO can systematically alter external forces under the sole of the foot (research question 1) and chapter 5 examines if APFO can systematically alter joint moment/motion responses (research question 2). Chapter 6 subsequently uses statistical approaches to investigate the relationship between changes in external forces applied to the foot and changes in joint moment/motion responses and determines if systematic changes in external forces correlate to changes to joint moment/motion responses (research question 3).

Study 2 is presented in Chapter 7, as is work already published in the literature. This investigates the effect of changes in APFO geometry on soft tissue compression under the sole of the foot. This is important because soft tissues transfer load to bones thus may also influence joint moment/motion responses. This study develops a reliable method of quantifying soft tissue thickness under the sole of the foot using ultrasound, whilst participants stood on an APFO. This data allows us to investigate whether changes in the geometry in the medial arch and heel area of an APFO can systematically alter the thickness of soft tissue under the sole of the foot (research question 4).

Finally, Chapter 8 provides an overview the work completed and contribution to the field, discussing the implications of this research for future studies and for clinical practice. The structure of the thesis is overviewed in section 1.1.

1.1 Overview of thesis framework



Chapter 2 Background/Literature Review

The aim of this review is to examine theories and evidence for foot orthosis use, with specific reference to biomechanical effects of orthoses, and to investigate factors that influence these effects. The purpose of doing so is to identify whether individual variation in response to foot orthoses can be explained, and if not to identify how to approach this research question. This would then lead onto design of suitable studies to add substantially to the literature and knowledge base. Whilst the review and general focus of this PhD is on laboratory based biomechanics the author wishes to keep this work clinically grounded.

2.1 Literature review

The strategy developed to identify appropriate literature for the literature review was structured on elements of the Population Intervention Comparison Outcome (PICO) framework, a recommended strategy when performing a review of medical literature (Sayers, 2008). This provided a framework but allowed for flexibility given that technical, laboratory and anatomical studies (e.g. cadaver studies) were expected in addition to intervention (i.e. orthoses) related literature. The following describes criteria used to filter studies identified in the literature.

Participants

Only studies involving adults over 18 years of age were accepted, independent of whether they were symptomatic/asymptomatic.

Interventions

Only studies involving foot orthosis with anti-pronation design features were accepted. This included both prefabricated and custom made foot orthosis that possessed orthotic arch geometry and/or medial rearfoot wedge geometry, or where the stated aim of the orthotic was to reduce excessive foot pronation or components of pronation (e.g. rearfoot eversion).

Comparisons

All randomised trials, clinical trials and laboratory trials were included. Case studies or papers that were opinion pieces were excluded unless they were deemed necessary in supporting topics

fundamental to clinical practice, or presenting/appraising theories that underpin practice. Studies were included if the effects of anti-pronation foot orthoses were compared to a control condition that consisted of a no orthotic condition and/or a different anti-pronation foot orthoses design.

Outcome measures

Outcome measures included any quantitative measurement of lower limb biomechanics in walking or running gait, and the effect of foot orthoses on gait. Specifically, outcome measures included changes in lower limb kinematics, joint moments, plantar pressure, muscle function and plantar soft tissue structures. Quantitative pain scales were accepted since they can characterise the effect of APFO on clinical outcomes.

Limits

Only papers written in English were included in the literature review. There were no restrictions in publication periods because paradigms of foot orthotic practise are based on literature published in the 1950's and 60's, thus relevant to the literature review.

Sources

OVID-Medline, Pubmed, Science Direct and Google Scholar were searched. The initial search was performed in September 2009 and updated in September 2012, and again in January 2016. Furthermore, the references listed in papers selected electronically were manually searched and included if deemed relevant.

Key words

The search terms used, both individually and in combinations, included; foot orthosis(es), insole, medial wedge, arch support, foot biomechanics, medial longitudinal arch, foot structure, antipronation, pronation, kinematics, kinetics, moment, pressure, muscle, proprioception.

2.2 Traditional views of foot kinematics in gait

Historically there have been various 'schools' of thought (theories) to describe foot movement during gait and these have developed as a means of supporting clinical reasoning and orthotic practice, but they have also shaped research designs. Clinicians and researchers alike

characterise the functional role of the foot complex as a shock absorber and rigid lever. They attribute key triplanar movements between leg and foot to joints of the rearfoot and assume that these are the primary functional roles of the foot. Foot pronation, defined as combined dorsiflexion, abduction and eversion motion is thought to enable the foot to fulfil its role as a shock absorber when the foot first hits the ground. Foot supination, defined as combined plantarflexion, adduction and inversion, is however thought to allow the foot to become a rigid lever (Valmassy, 1996). It is reported that the foot absorbs shock and pronates from loading response through to midstance (0-30% of gait cycle), whilst it becomes rigid through supination that occurs during terminal stance (30-50% of gait cycle) (Perry, 1992). In addition to allowing the foot to act as a shock absorber, pronation is considered an integral component of facilitating the body's forward advancement over the foot, since dorsiflexion is a component of pronation.

Traditionally, it is thought that the primary articulations involved in closed chain (weightbearing) foot pronation and supination movements occur at the subtalar and midtarsal joints. It was proposed that these two joints are synergistic in nature and possess axes of rotation that move in sequence during different periods of stance phase enabling the foot to be flexible to facilitate the transfer of load between loading response and midstance, and become rigid for efficient propulsion at terminal stance.

The axis of the subtalar joint extends from a posterior, plantar and lateral position to an anterior dorsal and medial position. It is reported that the angulation of the axis has a 42 ° inclination towards the sagittal plane from the transverse plane and a 16 ° medial deviation from the sagittal plane (Figure 2.1) (Valmassy, 1996). The midtarsal joint is formed by the combined articulations of the talonavicular and calcaneocuboid joints and is traditionally described as having two axes of rotation consisting of a longitudinal axis and an oblique axis (Figure 2.2), the orientation of both have described by Valmassy (1996). The longitudinal axis extends from a proximal plantar and lateral direction to a distal dorsal and medial direction, and the angulation of the axis is 15 ° from the transverse plane and 9 ° from the sagittal plane. The oblique axis is positioned from a proximal plantar and lateral direction to a distal dorsal and medial direction but its axis is aligned more obliquely relative to the longitudinal midtarsal joint axis, being angulated by 52 ° from the transverse plane and 57 ° from the sagittal plane.

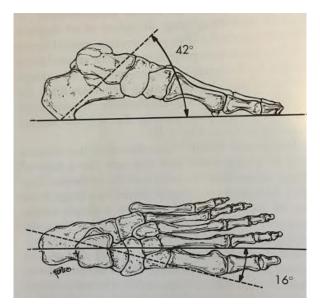


Figure 2.1 Illustration showing axis of rotation of the subtalar joint (Valmassy, 1996).

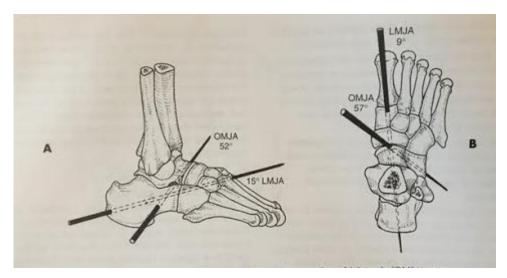


Figure 2.2 Illustration showing the oblique and longitudinal axes of the midtarsal joint (Valmassy, 1996).

2.2.1 Synergistic function

The motion at the subtalar and midtarsal joints continue to be compared to the function of a mitred hinge (Dawe et al., 2011). If a vertical segment is connected to a horizontal segment with a hinge then a 'torque converter' is created whereby rotation at the vertical segment will cause rotation of the horizontal segment (Figure 2.3; A). An additional segment (Figure 2.3; B) can be added to the horizontal segment distally to represent the action of the midtarsal joint.

This arrangement would allow rotations of the shank and rearfoot to occur whilst maintaining forefoot contact (otherwise the forefoot would leave the ground).

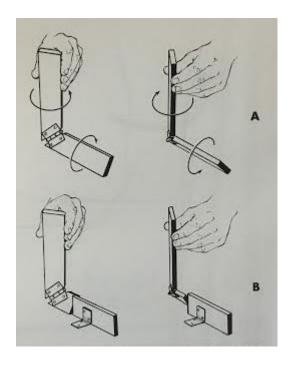




Figure 2.3 Action of subtalar joint is similar to that a mitred hinge. Internal tibial rotation causes subtalar joint pronation and external tibial rotation caused subtalar joint supination (Dawe et al., 2011; Valmassy, 1996).

Mann et al. (1964) and Elftman (1960) were first to describe these concepts and ascribe specific roles to the subtalar and midtarsal joints in gait. Based on their largely observational cadaver studies they outlined that from heel strike through to midstance internal tibial rotation is facilitated by subtalar joint pronation, whereby the talus inverts, adducts and plantarflexes relative to the calcaneus. During midstance the midtarsal joint was described as pronating around its oblique axis and supinating at its longitudinal axis. The oblique axis subsequently becomes parallel to the transverse plane and the axis of rotation within the calcaneocuboid joint and talonavicular joint become parallel to each other (Figure 2.4). Being parallel their axis of rotation becomes similar which enables a greater increase in oblique midtarsal joint motion thus increases sagittal plane motion. It follows the midtarsal joint is also referred to as a secondary ankle joint, and is purported to unlock with reference to the calcaneus. Pronation of the subtalar joint combined with supination of the midtarsal joint about its longitudinal axis and pronation about its oblique axis, enable the foot to act as a shock absorber from loading response to midstance phases of gait. Conversely, supination of the subtalar joint axis causes the midtarsal joint axes to obliquely align relative to one another, therefore on the basis the

axes of rotation have different orientations, a restriction in midtarsal joint motion is purported to occur therefore enabling to the foot to act as a rigid lever thought necessary for propulsion.

The traditional ideas described by Mann et al. (1964) and Elftman (1960) surrounding the simultaneous axes of rotation at the midtarsal joint have been challenged as they are however not consistent with the principles of kinematics. Conflicting motions cannot occur in a single joint, thus simultaneous midtarsal joint pronation at the oblique axis and supination at the longitudinal axis is questionable. The midtarsal joint will either pronate or supinate about its axes relative to the calcaneus but not do both (Nester et al., 2001).

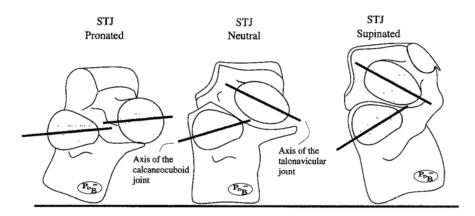


Figure 2.4 Subtalar joint pronation causes the axes of the talonavicular and calcaneocuboid joints to become parallel with one another (Nester, 1997).

2.3 Structures that regulate foot pronation

As previously outlined, the interdependent action of the articular facets forming the subtalar and midtarsal joints can influence foot motion. In addition to articular facet geometry, there are a number of soft tissue structures that act to passively and actively constrain foot pronation and the motion at these joints. For example, tension within the deltoid ligaments, extending from the anterior colliculus of the medial malleolus and inserting into the talus and sustenaculum tali, limits pronation of the rearfoot from loading response to midstance (Lever et al., 2016). The interosseous ligament, extending from the plantar aspect of the talus to the upper surface of the calcaneus, isometrically strains to limit pronation within the subtalar joints articulating surface, and pronation of the subtalar joint and supination of the midtarsal joint

about its longitudinal axis causes the short and long plantar ligaments extending under the midtarsal joint to strain (Valmassy, 1996). Other structures that passively constrain foot pronation include the plantar fascia which extends under the medial longitudinal arch. Formed by complex attachments at the calcaneus, talus, navicular, cuneiforms, and 1-3 metatarsals, it is the primary passive soft tissue structure the inhibits excessive foot pronation (or medial longitudinal arch collapse) and its mode of operation is widely compared to that of a truss model (Figure 2.5 a), (Hicks, 1954).

Distally the plantarfascia extends beyond the metatarsophalangeal joint and inserts into the proximal phalanges. Through its distal attachment, extension of the metatarsophalangeal joint causes the plantarfascia to be pulled and wound around the metatarsal heads akin to a cable being wound on a windlass. Hicks described this as the windlass effect (Hicks, 1954). During propulsion, the windlass effect is initiated by metatarsophalangeal joint extension which causes the medial longitudinal arch to increase in height (foot supination) thus enabling the foot to become a rigid lever at push off (Figure 2.5 b). There has been variability in the reported measurements of 1st metatarsophalangeal joint extension with values ranging between 42 ° to 65 ° (Hopson et al., 1995; Nawoczenski et al., 1999; Perry, 1992). Considering the action of the Hicks windlass mechanism, is seems likely that variability in 1st metatarsophalangeal joint extension coincides with variability in an increase in medial longitudinal arch height during propulsion.

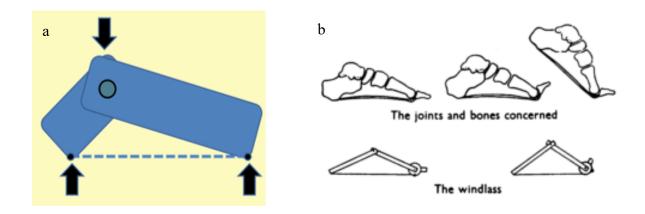


Figure 2.5 (a) Illustration of truss model providing medial longitudinal arch support. Tautness within the plantar fascia prevents the ends of the arch from moving apart under load applied by body weight (Dawe 2011); (b) Hicks Windlass effect where MTPJ extension causes an increase in medial arch height (Hicks, 1954).

Extrinsic and intrinsic foot muscles actively constrain pronation and their phasic activity and ranking of importance have previously been described (Perry, 1992). The tendons of the extrinsic muscles pass medial to the subtalar joint axis and include; tibialis posterior, tibialis anterior, flexor digitorum longus, flexor hallucis longus and soleus. The primary rearfoot inverters are the tibialis posterior and tibialis anterior muscles. It has been shown that the inversion moment arm in the tibialis posterior is much greater than the tibialis anterior muscle (Klein et al., 1996). It has also been reported the tibialis posterior muscle accounts for a large proportion of the physiological cross sectional area of the deep posterior muscles of the shank, with values ranging from 53.5 % to 66.7 % of total cross sectional area (Friederich et al., 1990; Fukunaga et al., 1992; Wickiewicz et al., 1983). On the basis physiological cross sectional area reflects the muscles ability to generate force, the tibialis posterior muscle has the largest capacity to generate force output relative to other synergists, thus highlights its importance in constraining foot pronation in gait. The peaks in EMG amplitude for both the tibialis anterior and tibialis posterior muscles arise between 0-20 % of the gait cycle, periods during loading response whereby these muscles eccentrically contract to resist foot pronation (Murley et al., 2009a; Murley et al., 2014a). Between 40-60 % of the gait cycle a second peak in EMG amplitude occurs in the tibialis posterior muscle that corresponds to concentric contraction to supinate the foot during propulsion (Murley et al., 2009a; Murley et al., 2014a). It has been shown that the peaks in amplitude of these muscles increase with a corresponding increase in walking speed (Murley et al., 2014a). Furthermore, foot posture has been shown to influence the magnitude of EMG intensity of extrinsic foot muscles where Murley et al. (2009b) reported the EMG intensity in the tibialis posterior muscle in individuals with excessively pronated feet was 26.5 % (p < 0.05) greater compared to individuals with neutrally aligned feet.

Five intrinsic muscles located under the plantar surface of the foot act to resist foot pronation and maintain the integrity of the medial longitudinal arch. The abductor digiti minimi and flexor hallucis brevis are active during midstance, whilst the abductor hallucis, flexor digitorum brevis and interossei are active during terminal stance (Mann et al., 1964). It has been reported that in excessively pronated feet the abductor hallucis, flexor digitorum brevis and flexor hallucis brevis muscles are active up to 50 % earlier in stance phase compared with individuals with neutrally aligned feet (Mann et al., 1964) and fatigue of the plantar intrinsic muscles increases navicular drop (Headlee et al., 2008). The cross sectional area and thickness of the intrinsic foot muscles has shown to differ in different foot postures. Angin et al. (2014) reported intrinsic foot muscles in individuals with excessively pronated feet were significantly

smaller compared to individuals with neutrally aligned feet. The same study also found that flexor digitorum longus and flexor hallucis longus muscles (extrinsic foot muscles) were significantly larger in individuals with excessively pronated feet. Furthermore, the geometry of intrinsic foot muscles can be influenced by disease and may also differ in individuals with toe deformities. Bus et al. (2002) reported the cross sectional area in distal intrinsic foot muscles in individuals with neuropathic diabetes decreased by 73 % compared with non-affected control subjects, and Mickle et al. (2016) reported that individuals with toe deformities have smaller intrinsic foot muscles compared to individuals without toe deformities.

2.4 Contemporary views on foot/ankle kinematics in gait

As previously outlined, motion at the subtalar and midtarsal joints are thought to be primarily involved in facilitating foot pronation from loading response to midstance periods of the gait cycle. The characterisation of how these structures function stems from the dissection of cadaveric specimens undertaken by Manter and others in the 1960s. Quantifying in-vivo kinematics within these articulations is problematic as their structures are not readily accessible, however contemporary research has questioned the validity underpinning some of the assumptions surrounding subtalar and midtarsal joint function. For example, invasive bone studies directly measuring motion at the calcaneus and talus showed that in some individuals that frontal plane rearfoot motion occurs primarily at talocrural joint and not at the subtalar joint (Arndt et al., 2007; Lundgren et al., 2008). Also, the concept of the two joint axis of the midtarsal joint that "unlocks" and "locks" during midstance and terminal stance periods has been questioned. It is suggested that motion thought to occur about the oblique and longitudinal midtarsal joint axes may better be described as having, for any instant in time, a single instantaneous axis of rotation, which varies in position and orientation (Keenan et al., 1996; Nester et al., 2001).

Laboratory based studies tend to model the talus and calcaneus as a single rigid rearfoot segment and quantify motion of this segment with reference to the shank. Similarly for the midfoot, studies quantify motion at the navicular bone relative the calcaneus to characterise kinematics within the medial longitudinal arch. Studies using large sample sizes have quantified the typical foot kinematics involving asymptomatic individuals. Cornwall et al. (2006) measured frontal plane rearfoot eversion motion in 279 subjects and identified four distinct eversion patterns (Figure 2.6) with mean peak rearfoot eversion angles measuring

between $1.6\,^{\circ}$ to $3.1\,^{\circ}$ dependant on the grouping. In a previous study involving 153 subjects he reported a mean peak eversion angle measuring $2.2\,^{\circ}$ and a mean peak midfoot dorsiflexion angle (navicular vrs calcaneus) measuring $3.2\,^{\circ}$ (Cornwall et al., 2002). In 100 subjects Nester et al. (2014) reported mean peak eversion values of $3.9\,^{\circ}$ and mean peak midfoot dorsiflexion angle (navicular/cuboid vrs calcaneus) measuring $3.2\,^{\circ}$. Studies on smaller cohorts (n = 18 - 22) reported peak rearfoot eversion ranging from $1.9\,^{\circ}$ to $4.5\,^{\circ}$ (Hunt et al., 2001; Legault-Moore et al., 2012). The peak rearfoot eversion and peak midfoot dorsiflexion values reported by these studies are kinematic measures of rearfoot/midfoot foot structures representing foot pronation. The data illustrates normative values of what constitutes typical peaks in rearfoot eversion and midfoot dorsiflexion, however these studies did not characterise foot posture.

It is suggested that a relationship exists between foot posture and foot function in gait, whereby an excessively pronated foot posture will cause increased foot pronation in gait, measured as increased peak rearfoot eversion angle and/or increased peak midfoot dorsiflexion angle. Chuter (2010) reported that an increase in peak rearfoot eversion angle was strongly correlated with an increase in a pronated static foot position (Figure 2.7). Furthermore, it is suggested that excessive foot pronation is a precursor to development of adverse symptoms in structures that are designed to resist excessive foot pronation. Huang et al. (2004) suggested that 10 to 25 % of the adult population exhibit an excessively pronated foot type.

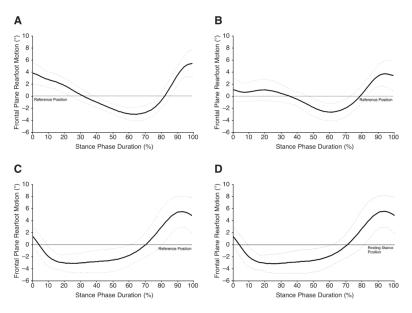


Figure 2.6 Four different frontal plane motion patterns as described by Cornwall (2006). Pattern A = typical eversion, pattern B = prolonged eversion, pattern C = delayed eversion, and pattern D = early eversion.

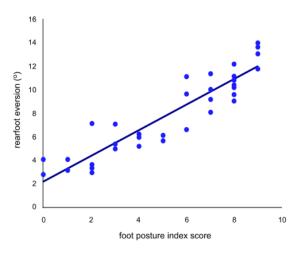


Figure 2.7 As outlined by Chuter (2010); Scatterplot of maximum rearfoot eversion vrs total FPI scores (r = 0.92, p < 0.05)

2.5 Clinical methods of classifying foot posture

Clinical methods of identifying foot postures that are likely to pronate more than others is thought to be of benefit to clinicians. This is based on the assumption that excessive pronation is a problem worth identifying. Methods clinicians use to characterise foot posture are based on foot morphology, and as described in the literature typically involve; radiographic evaluation (Lamm et al., 2016; Thomas et al., 2006), quantification of foot prints (Buldt et al., 2015a; Menz et al., 2016), anthropometric measurement (Banwell et al., 2015; Levinger et al., 2004), and visual non-quantitative inspection (Nielsen et al., 2014; Redmond et al., 2006). Resulting classifications generally characterise the position of a single segment, usually the rearfoot and/or midfoot, which by itself is a composite measure of foot position (e.g. increased rearfoot eversion is a composite measure of an excessively pronated foot posture).

Radiographic measurements

Radiographic angular measurements quantifying foot structures are often used by foot and ankle surgeons to help guide surgical procedures (Lamm et al., 2016). Some of the typical radiographic measurements include; calcaneal inclination angle (via lateral radiograph), formed by angle located between supporting surface and the calcaneal inclination axis, and talar metatarsal angle (via anterior-posterior radiograph), formed by the angle created between a bisection of the first metatarsal and a line perpendicular to a bisection of the talar head. Figure 2.8 shows a number of the radiographic measurements typically used. Thomas et al. (2006)

outlined typical radiographic values of the adult foot in a standardized population, and Younger et al. (2005) characterised differences in these measurements between normal feet and symptomatic flat feet. Younger et al. (2005) found that patients with the flat feet had a 5.4° (p < 0.01) and 9.8° (p < 0.01) greater increase in calcaneal inclination angle and talar metatarsal angle compared to the controls. Using radiographic measures to quantify the alignment of foot structures has been shown to have excellent intra-rater and inter-rater reliability (Saltzman et al., 1994). Studies have used radiographic measurements to classify normal and excessively pronated foot structures. For example, Murley et al. (2009b) used radiographic measurements to investigate the effect of excessive foot pronation on lower limb muscle activity in gait, and Menz et al. (2016) investigated the effect of excessive pronation on foot pain. Radiography is not however routinely used by practitioners who prescribe foot orthosis in clinical practice due to availability of other tests that are quicker and easier to perform and do not expose the patient to radiation (e.g. Foot Posture Index, Rearfoot Angle).

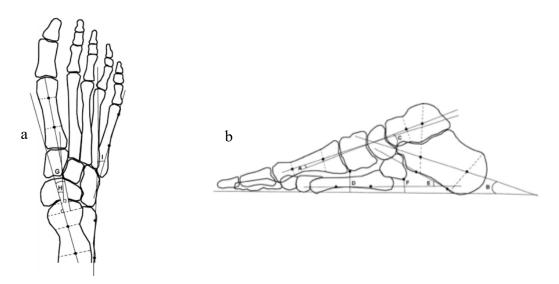


Figure 2.8 (a) anteroposterior radiograph showing methods to calculate; talar-first metatarsal angle (G), talonavicular uncoverage angle (H), and calcaneal fifth metatarsal angle (I). (b) lateral radiograph showing methods to calculate talar first metatarsal angle (A), calcaneal pitch (B), talocalcaneal angle (C), medial column height (D), calcaneal fifth metatarsal height (E), and lateral column height (F) (Younger et al., 2005).

Foot Prints Indices

A foot imprint is a method of characterising the geometry of the area of the plantar surface of the foot that contacts the ground and has been used as a means of foot type classification. A static or dynamic imprint of the foot, provided by an ink pad, is thought to reflect orientation and alignment of the foot. The arch index (AI) was first described by (Cavanagh et al., 1987a) and is the ratio between three areas of contact under the foot. A foot axis line is drawn from

the centre of the heel to the second toe and another line perpendicular to the axis is then drawn at the vicinity of the metatarsal heads. The bisector between these lines is identified and the foot axis is divided into 3 equal parts. The total area of the footprint (A+B+C) and the area of the midfoot (B) are calculated and the arch index is then found by dividing the midfoot value by the sum of the total area of the footprint (Figure 2.9). Cavanagh et al. (1987a) described a high arch as having a small AI and a low arch (pronated foot) as having a high arch index. Menz et al. (2016) used the arch index to categorise foot posture when investigating the association of planus foot posture and pronated foot function with foot pain, and Buldt et al. (2015a) used the arch index to categorise normal, planus and cavus foot postures when examining the effect of foot posture on kinematics. Wong et al. (2012) reported that foot classification based on the arch index had excellent reliability, however it may it has also been found to be a poor predictor of dynamic foot function in gait (Hamill et al., 1989). Razeghi et al. (2002) described the arch angle, footprint index, arch-length index and Brucken index as other means of quantifying foot prints to characterise foot posture. It follows that many different foot print parameters can be used to categorise foot posture.

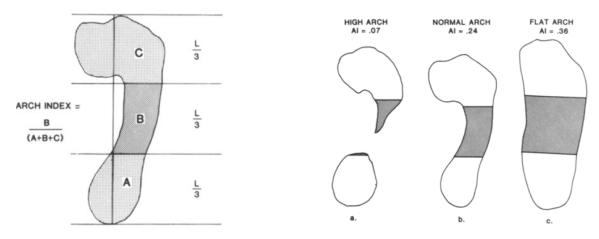


Figure 2.9 Illustration showing calculation of Arch Index (AI). Arch index values for (A) high arch, (B) normal arch and (C) flat arch (Cavanagh et al., 1987a).

Navicular Drop & Drift

Navicular drop represents the sagittal plane movement of the navicular bone and is a means of characterising medial longitudinal arch deformation when loaded with body weight. Measuring navicular drop involves positioning the foot in the subtalar joint neutral position (talar head is fully congruent) and recording the height from the navicular tuberosity to the floor. With the subject stood in a relaxed position, the navicular height is then re-recorded.

Navicular drop is measured as the difference between these two measurements (Figure 2.10). Navicular drop measurement is considered a reliable composite measurement of foot pronation (Mueller et al., 1993), however it is flawed because it is not standardised according to foot length or gender (Nielsen et al., 2009). Nielsen et al. (2009) reported for every 10 mm increase in foot length, the navicular drop increased by 0.40 mm in males and 0.31 mm in females.

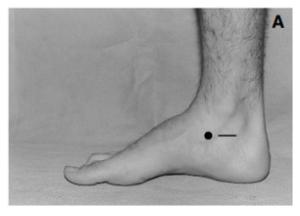
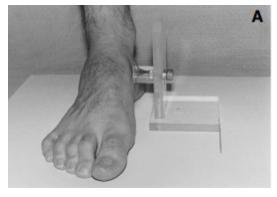




Figure 2.10 Method to calculate navicular drop; the height of the navicular tuberosity is measured in neutral (A) and (B) resting stance position (Menz, 1998). Navicular drop is the difference between these two measurements, and was first described by Brody (1982).

The navicular drift measurement was first described by Menz (1998) and is a means of characterising movement of the medial longitudinal arch in the frontal and transverse planes. Similar to the navicular drop measurement, this technique involves measuring the position of the navicular when the talar head is congruent, and the again in the relaxed standing. The frontal plane displacement between these two positions is described as navicular drift (Figure 2.11). This technique is used to characterise the prominent talonavicular bulging often present in the excessively pronated foot type. However, it is considered only a moderately reliable means of characterising foot posture (Vinicombe et al., 2001) and lacks data from large samples to indicate normative values.



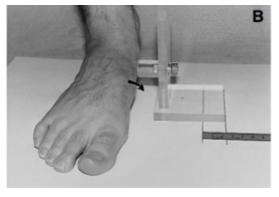


Figure 2.11 Navicular drift measurement. The position of the navicular tuberosity is recorded in neutral (A) and in resting standing position (B). Navicular drift is the difference between these two measurements (Menz, 1998).

Rearfoot angle

The rearfoot angle is formed by line bisecting the distal one-third of the lower leg and a line bisecting the calcaneus (Figure 2.12). This angle is purported to provide information regarding the position and movements of the subtalar joint during the midstance phase of gait (McPoil et al., 1996a). Cornwall et al. (2004) used the rearfoot angle to categorise foot posture as being inverted or everted when characterising the effect of static foot posture on rearfoot kinematics in gait. Levinger et al. (2004) used the rearfoot angle to examine foot posture in individuals with patellofemoral pain syndrome. Under the Rootian paradigm of foot function, it is suggested during midstance that the subtalar joint is in its neutral position before it supinates to allow the foot to become a rigid lever required for propulsion (Root et al., 1977). The subtalar joint neutral position is reported to be represented by a single perpendicular line bisecting both the calcaneus and distal leg (0 ° rearfoot angle) and any eversion deviation of the rearfoot angle at midstance is indicative of excessive foot pronation (Root et al., 1977). However, the validity of using the rearfoot angle to characterise normal and abnormal foot position under the Rootian paradigm of foot function has been questioned. Studies on asymptomatic individuals showed that during midstance the rearfoot angle is typically positioned in eversion (classified as excessively pronated according to Root) (McPoil et al., 1996a; McPoil et al., 1996c; Pierrynowski et al., 1996). McPoil et al. (1996a) reported a static rearfoot angle measured in single leg standing is a potential indicator of the degree of maximum rearfoot eversion present during gait, however others have questioned the validity and reliability of using static hindfoot measurements to characterise foot function (Menz, 1995).

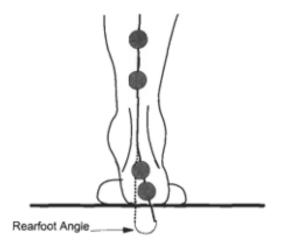


Figure 2.12 Bisections of calcaneus and distal calf forming the rearfoot angle (McPoil 1996).

Foot Posture Index

The foot posture index (FPI) is a tool developed to provide an easy and reliable method for measuring foot position (Redmond et al., 2006). It consists of six validated criterion based observations of foot posture at the rearfoot and forefoot of a subject standing in a relaxed position. Rearfoot assessment involves palpation of the talar head, observation of the curvature above and below the lateral malleoli and the position of the calcaneus. For the midfoot and forefoot, assessment involves assessing the bulge at the talonavicular joint, the shape of the medial longitudinal arch and the level of abduction/adduction of the forefoot relative to the rearfoot (Redmond et al., 2006).

An advantage of the FPI over other methods of assessing foot position is that the FPI characterises multiple structures within the foot and not just a single structures as is the case with the rearfoot angle (calcaneus vrs shank). Furthermore, the FPI also characterises foot position involving using information from the sagittal, frontal and transverse planes, unlike other techniques that quantify position in a single plane (e.g. sagittal in navicular drop measurements).

The FPI classifies foot posture by using a 5 point Likert-type scale (-2 to +2) and total scores characterise foot posture as being normal (0 to +5), pronated (+6 to +9), highly pronated (10+), supinated (-1 to -4) and highly supinated (-5 to -12) (Figure 2.13). The FPI has demonstrated good validity (Keenan et al., 2007) but studies have reported differences in reliability. Evans et al. (2003) deemed the original 8 item FPI as having inadequate reliability, however Barton et al. (2010) suggested the newer 6 item FPI possessed high intra and inter-rater reliability. However, as is the case with other methods of statically characterising foot posture, FPI measures explain only a small variation in foot kinematics (Buldt et al., 2015b). Both Menz et al. (2013) and Nielsen et al. (2014) used the FPI to differentiate foot posture and investigate the association between excessive foot pronation with foot pain.

Foot Posture Index (6-item) Datasheet

ID number

Patient name

COMPONENT	PLANE	DateComment		DateComment		DateComment	<u>-</u>
		Left (-2 to +2)	Right (-2 to +2)	Left (-2 to +2)	Right (-2 to +2)	Left (-2 to +2)	Right (-2 to +2)
Talar head palpation	Transverse						
Curves above and below lateral malleoli.	Frontal/ trans						
Inversion/eversion of the calcaneus	Frontal						
Bulge in the region of the TNJ	Transverse						
Congruence of the medial longitudinal arch	Sagittal						
Abduction/adduction of the forefoot on the rear foot (too-many-toes).	Transverse						
TOTAL							

Figure 2.13 Foot Posture Index (FPI) scorecard (Redmond 2006).

2.6 The association between excessive pronation and the development lower limb pain

As previously outlined, the tibialis posterior muscle and the plantar aponeurosis are principle active and passive soft tissue structures within the foot that function to resist excessive foot pronation. Studies have described the association between the development of trauma within these soft tissue structures and excessive foot pronation.

Rabbito et al. (2011) suggested that excessive foot pronation, measured as increased peak rearfoot eversion, is a biomechanical risk factor associated with the development of tibialis posterior tendon dysfunction. This study investigated if arch height, ankle inverter muscle strength and kinematic factors differed in runners with tibialis posterior dysfunction and age and gender matched healthy controls. Arch height index and maximum voluntary isometric testing of the tibialis posterior muscle were used to characterise the foot posture and inverter muscle strength, whilst three-dimensional movement analysis characterised stance phase kinematics at the rearfoot (calcaneus vrs shank) and at the midfoot between the calcaneus, navicular and 1st metatarsophalangeal joint (Figure 2.14 a) when walking.

The study reported that non-weightbearing (unloaded) arch index was significantly lower in the symptomatic group compared to the control, however no significant differences in weightbearing (loaded) arch index and ankle inverter muscle strength were found between the two groups. For between group differences in kinematics, the symptomatic group demonstrated significantly greater peak rearfoot eversion compared to the control (Figure 2.14 b), however no significant differences were found for midfoot sagittal plane motion.

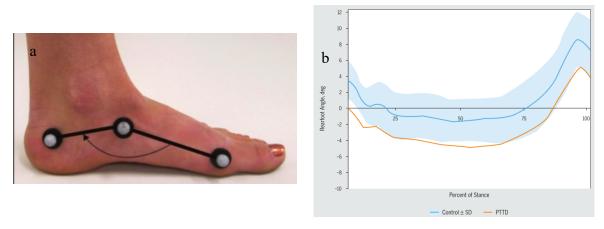


Figure 2.14 (a) Landmarks to calculate medial longitudinal arch angle. (b) Rearfoot eversion angular displacement curves for control group and tibialis posterior dysfunction (PTTD) group during the stance phase of gait (+ve = inversion, -ve = eversion) (Rabitto 2011).

Rabbito et al. (2011) concluded that runners with tibialis posterior tendon dysfunction possess normal inversion muscle strength and normal foot posture, but may have significantly greater levels of rearfoot pronation compared to healthy controls. Interestingly the results of this study infer that there is no relationship between midfoot static foot posture and kinematic function, however this study failed to characterise rearfoot static foot posture, thus it is unclear whether there is some association between an excessively pronated rearfoot foot posture measured statically and excessive rearfoot pronation measured dynamically.

Zhang et al. (2013) reported that the frontal plane position of joints within the rearfoot were significantly excessively pronated in subjects with tibialis posterior dysfunction compared to healthy feet. CT scans of the rearfoot in both groups were taken (n=30), and a custom build loading device was used to simulate normal full body weightbearing during image capture. CT images were taken under non loaded and fully loaded conditions and 2D image data obtained from the scans were used to construct 3D image models of the foot (Figure 2.15). A reverse engineering software programme quantified rotation of the calcaneus relative to the talus, the navicular relative to the calcaneus and the cuboid relative the calcaneus.

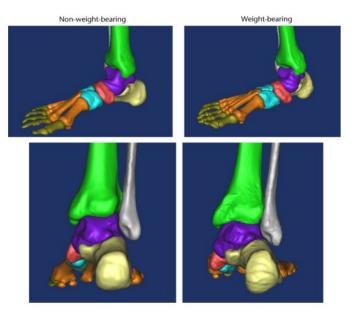


Figure 2.15 Medial and posterior views of CT images of right foot with posterior tibial tendon dysfunction under non weightbearing and full weightbearing (Zhang, 2013).

The results of the study showed that in the tibialis posterior subject group the calcaneus was significantly more everted compared to the talus (1.4°) and the navicular was significantly more everted compared with the calcaneus (3°) . No significant differences were found between the groups for calcaneocuboid joint motion. It follows that this study showed some association between tibialis posterior dysfunction and an excessively pronated static foot posture.

These results were similar to those reported by Dyal et al. (1997) who found a strong correlation between excessively pronated foot structures characterised by radiographs and symptomatic tibialis posterior tendon insufficiency. Interestingly this study did not use symptomatic subjects as a control but instead involved subjects with unilateral foot symptoms and therefore used the non-symptomatic side as the control. The study also found a strong correlation between the degree of excessive pronated foot position (described as flat foot deformity) between the asymptomatic and symptomatic feet. The authors suggested that this inferred that individuals with posterior tibial tendon insufficiency often have a pre-existing flat foot deformity. However, the fact that the control side had a similar foot posture as the affected side, both characterised as being excessively pronated, but yet the control side was asymptomatic, suggests the link between an excessively pronated foot posture and the development of foot pain secondary to tibialis posterior dysfunction is complex and multifactorial.

A number of studies have outlined the importance of the plantar fascia in maintaining arch height. For example, Kitaoka et al. (1994) reported that high tensile loads were required to cause the plantar aponeurosis to rupture (1189N) when the medial arch of cadaver specimens were loaded. Furthermore, Huang et al. (1993) reported that the plantar aponeurosis is the primary structure involved in medial longitudinal arch stability where its resection in cadaveric feet decreased arch stiffness by 25 %.

Excessive foot pronation is thought to be a contributing in the development of plantarfasciitis, whereby increased tensile loading of the plantar aponeurosis causes inflammation at its origin in the vicinity of the calcaneal tuberosity. Werner et al. (2010) reported that excessive foot pronation was a risk factor in the development of plantarfasciitis among assembly plant workers. This study quantified how baseline demographics, medical history, ergonomic exposures, psychological factors, discomfort ratings, shoe characteristics and foot biomechanics contributed to the prevalence of plantarfasciitis in an assembly plant. 407 subjects recruited for the study underwent a physical examination and completed a symptom questionnaire. The subjects also had their footwear and ergonomic posture assessed (time spent in specific postures) whilst performing their regular job routines. The biomechanical assessment involved capturing dynamic foot pressure, whilst static foot posture and dynamic foot movement was visually assessed. A pes planus (excessively pronated) foot posture was defined as present if the inferior surface of the navicular bone was palpated and was less than 2cm from the floor when standing. Excessive foot pronation (described as abnormal forefoot pronation in the study) was deemed to occur if the examiner saw excessive pronation during gait compared with standing. For the study, if a subject reported moderate or severe foot pain lasting longer than a week or occurring at least 3 times within the previous 12 months, and the pain was localised to the insertion of the plantarfascia at the calcaneus, the subjects were deemed to have the diagnosis of plantarfasciitis.

The results showed that 8 % of the subjects recruited were diagnosed as having plantar fasciitis. Significant risk factors were prolonged periods of walking and standing on hard surfaces, midrange tenure working at the plant (4-7 years), and increased number of times getting in and out of a vehicle (truck/forklift drivers). However, subjects with excessive foot pronation were 4 times more likely to development plantarfasciitis whilst subjects with increased metatarsal head pressure were 2.7 times more likely to develop plantar fasciitis. Interestingly, an excessively pronated foot posture (characterised by static measurement of navicular height to floor) was not significantly associated with plantarfasciitis. This questions the relationship

between static foot position in standing and dynamic foot function when walking because excessive foot pronation in gait was associated with an increased risk of developing plantarfasciitis, but an excessively pronated foot posture (measured when standing) was not deemed a risk factor. However, this study did not outline specific criteria used to define excessive foot pronation in gait and relied on a subjective visual assessment, thus it is difficult to extrapolate what features of excessive pronation were quantified (e.g. frontal plane eversion or transverse plane abduction).

Taunton et al. (2002) reported a significant association between excessive foot pronation and plantarfasciitis. This study quantified the relationship between anthropometric, training and biomechanical variables associated with plantarfasciitis in 268 patients who partook in a variety of different sporting activities. Anthropometric measurements included assessing leg length discrepancy, knee valgus/varus position, Q angle, hallux valgus and Morton's toe (hallux). Foot posture was characterised by medial longitudinal arch position and was categorised as being low, normal or high. The study described that gait analysis involved observation of the subjects, and classifications were over-pronation, normal and oversupination.

The results showed that subjects with an altered knee position had plantarfasciitis (e.g. 20.2 % of subjects with genu varum), however the largest association involved subjects who were categorised as having excessive pronation that accounted for 54.7 % of study population. 7.5 % of the subjects deemed to have a pronated foot posture had plantarfasciitis. Therefore, compared with subjects with a pronated foot posture, the relationship between excessive foot pronation characterised dynamically and plantarfasciitis in subjects was much greater. This larger association between dynamic foot excessive pronation and plantarfasciitis is similar to the results described by Werner et al. (2010), but also presents with similar study design difficulties in that an excessively pronated foot posture and excessive foot pronation was not objectively measured but categorised by visual interpretation. Furthermore, Taunton et al. (2002) used descriptive statistics to analyse the relationships between the different variables. Inferential statistics would provide greater confidence in the relationships between plantarfasciitis and the anthropometric and biomechanical variables measured in the study.

There are however inconsistencies between studies characterising the relationship between excessive foot pronation and lower limb pain. In addition to the studies described in the

preceding text, a number of other studies show a link between excessive foot pronation and lower limb pain. For example, Riskowski et al. (2013) reported that a planus foot posture is associated with a greater incidence of knee and ankle pain in a study involving 1856 participants over 50 years of age. Buist et al. (2010) reported that increased navicular drop (composite measure of excessive foot pronation) was a significant predictor of injury risk in female runners and Kaufman et al. (1999) reported that dynamic pes planus was shown to increase the risk of developing overuse injuries in Navy Seals. Finally, Willems et al. (2006) reported individuals with exercise related lower limb pain had significantly increased levels of foot pronation compared to asymptomatic controls. However, the results reported by these studies contrast the findings of Burns et al. (2005b) who showed an excessively pronated foot type was not associated with a greater increase in the incidence of injury in a cohort of triathletes. Furthermore, Nielsen et al. (2014) reported that excessive foot pronation was not associated with an increased risk of injury in runners. They reported the occurrence of running related injuries at 50, 100, 250, 500 and 1000km distances in 927 novice runners over a 12 month period. The results of the study showed there were no significant differences in distance to first running related injury between highly supinated, supinated, pronated and highly pronated feet compared with neutral feet. Moreover, this study showed pronated feet sustained significantly fewer injuries per 1000km of running than neutral feet.

These contrasting results question the notion that excessive foot pronation is synonymous with the development of lower limb pain. Healthy individuals with foot structures that excessively pronate may possess appropriate adaptive changes in soft tissue and bony structures to keep them free of tissue damage and therefore symptoms. This is evidenced by an ultrasonography study showing individuals with excessively pronated feet have smaller intrinsic foot muscles, but larger extrinsic supinator foot muscles compared to individuals with normally aligned feet (Angin et al., 2014). The study also showed that in excessively pronated feet the peroneal muscles were smaller thus it is hypothesised that the larger supinatory extrinsic muscles could account for the smaller intrinsic foot muscles, but at the same time the smaller peroneal muscles would provide minimal pronatory resistance to the extrinsic muscles responsible for supination. Angin et al. (2014) cited a study by Murley et al. (2009b) that reported decreased peroneal muscle activity in individuals with flat feet thus further supporting the notion that muscle structures have the potential to change their behaviour thus benefitting foot/ankle complex as a whole. The same principles apply for bony remodelling in individuals with excessively pronated foot structures, where according to Wolfs law, bones forming articular facets may

remodel thus enabling an excessively pronated foot posture to adequately function whilst maintaining an asymptomatic status.

2.7 Foot orthotic practice

2.7.1 Clinical and biomechanical background to antipronation orthosis use

Excessive foot pronation, which involves increased rearfoot eversion and midfoot dorsiflexion/abduction, is cited as causing numerous foot conditions such as plantarfasciitis (Huerta et al., 2008; Taunton et al., 2002; Werner et al., 2010), achilles tendinitis (Clement et al., 1984; Ryan et al., 2009) and tibialis posterior tendinitis (Rabbito et al., 2011; Williams 111 et al., 2001). These conditions typically involve symptoms arising in excessively stressed soft tissue structures that act to passively or actively resist pronation. For this reason anti-pronation foot orthoses (APFO) are recommended to treat symptoms affecting the lower limb that are thought to be associated with excessive pronation (Bowring et al., 2010; Shih et al., 2011; Valmassy, 1996; Zammit et al., 2007).

Practitioners use antipronation foot orthosis to provide clinical benefits by tailoring the design of specific parts of an orthosis (e.g. heel, arch, forefoot) to increase external supination moments and decrease excessive foot pronation. These biomechanical changes are thought to reduce symptoms by decreasing tensile strain in painful soft tissue structures (e.g. tibialis posterior tendon, plantarfascia) that are otherwise responsible for resisting excessive foot pronation. Orthoses with the anti-pronation design are commonly used to benefit individuals whom have complaints not directly related to excessive foot pronation. For example, practitioners tailor the design of the medial arch in an antipronation orthosis to assist in redistribution of plantar foot loading in individuals with diabetes and arthritis. Also, medial arch components are added to laterally wedged orthoses designed to reduce knee adduction moments for individuals with medial knee osteoarthritis (Jones et al., 2013).

Anti-pronation foot orthoses are purported to alleviate a variety of lower limb complaints, however evidence for their clinical benefit is inconsistent between studies. For example, Franklin-Miller showed foot orthoses significantly reduced the occurrence of overuse injuries in military recruits (Franklyn-Miller et al., 2011), whereas Esterman showed foot orthosis caused only small and non-significant clinical effects (Esterman et al., 2005). Roos and Drake

showed that foot orthosis are beneficial for the treatment of plantarfasciitis (Drake et al., 2011; Roos et al., 2006), which contrasted the findings of Landorf who showed minimal long term clinical affects (Landorf et al., 2006). Rodriguez and Collins showed foot orthosis are effective in treating knee pain caused by a variety of knee pathologies (Collins et al., 2008; Rodrigues et al., 2008). However a systematic Cochrane review showed no clear advantages in using foot orthosis over other interventions for the treatment of knee pain (Hossain et al., 2011). Furthermore, a systematic Cochrane review into the clinical efficacy of certain types of APFO has led Hawke to conclude that "there is limited evidence on which to base clinical decisions regarding the prescription of custom-made foot orthoses for the treatment of foot pain" (Hawke et al., 2008). Differences in APFO design is a factor that potentially explains the variable clinical responses reported between studies. Furthermore, in almost all cases the actual orthoses tested have been very poorly described and the geometric and mechanical properties are in effect unknown.

2.7.2 Theories underpinning the prescription of APFO

Published studies characterising the clinical and biomechanical effects of APFO usually employ the Root theory (or derivatives) of foot function. The Root model focuses the design of orthoses to position the foot in the subtalar joint neutral (STJN) position during the midstance phase of gait (Root 1977). This is arguably the foundation for foot orthoses practice globally. Other theories of foot function are used by practitioners but less frequently seen in studies quantifying biomechanical/clinical affects. They are also almost always extensions of the Root model, seeking to enhance it. These include:

- the Subtalar Joint Axis Location and Rotational Equilibrium Theory (SALRE) that designs orthosis to alter moments at the STJ axis (Kirby, 1989),
- the Sagittal Place Facilitation Theory (SPF) that designs orthosis to allow fluid sagittal plane progression (Dananberg, 2000), and
- the Preferred Movement Pathway Theory (PRM) that recommends tailoring orthoses to reduce muscular activity (Nigg, 2001)

Thus, to be comprehensive theories of foot function commonly used in research and clinical practice warrant review.

2.7.2.1 Rootian Theory

Clinicians prescribe foot orthosis based largely upon principles developed by Merton Root and co-workers (Root et al., 1977). Their philosophy involves designing foot orthoses to align foot structures to fulfil what they term *biophysical criteria for normalcy*. This criteria states that in a normal foot, when standing, the heel and tibia will be vertical in the frontal plane, the subtalar joint should be in a position of maximum congruency (i.e. its neutral positon) and the forefoot and rearfoot parallel to each other. Root classifies feet, and thereby the rearfoot and forefoot structures that do not meet this criteria as "abnormal" and in need of correction using a foot orthosis. The location (rearfoot/forefoot) and nature (varus/valgus) of the deviation from the criteria links directly to the design of the foot orthosis required.

The Rootian biomechanics places great emphasis on the position of the subtalar joint (STJ) during stance in gait. The STJ should be in its neutral position, which Root defines as being neither pronated nor supinated, during the midstance phase of gait (Root 1977). Osseous foot deformities involving the rearfoot and forefoot are characterised relative to this subtalar joint neutral position. When designing foot orthosis, Root recommends taking a non-weight-bearing model (cast) of a patient's foot held in its STJ neutral position whilst also capturing any osseous foot deformities present (e.g. varus/inversion of the heel relative to the leg). An orthotic shell is subsequently moulded over the foot model/cast where internal/external posting corrects and/or accommodates the osseous deformities. There is thus a clear relationship between the static shape of the foot in subtalar neutral and the shape of the orthotic upper surface. Root suggests that for patients whom possess abnormal foot mechanics, designing foot orthosis in this manner will reposition the subtalar joint to its neutral position during the stance phase of gait, thus enabling a patient's foot mechanics to function more normally.

The principles underpinning Roots definition of what constitutes a mechanically ideal foot have been questioned. Particularly, that to have normal foot mechanics individuals must have a STJ that is in its neutral position at midstance, and foot structures without this osseous alignment are classified as abnormal, even in the absence of symptoms. However, laboratory based studies have shown that it is rare for asymptomatic feet to pass through the STJN position in gait (Cornwall et al., 1999; Pierrynowski et al., 1996) and this undermines the notion it is an important position for normal foot function. In response to this McPoil suggests the neutral position is better described as being relaxed calcaneal stance position (McPoil et al., 1994),

since this is a position that most feet appear to function around. Furthermore, there is wide variation in foot kinematics reported by laboratory based studies (Cornwall et al., 1999; Nester et al., 2014), which is now regarded as normal variation (Nester, 2009). As a result, the concept of a normal foot based on its structure and movement is being challenged, with the suggestion that a normal foot is one without symptoms, irrespective of its shape or biomechanical function. Importantly, this questions the rationale of using foot orthoses to position an individual's foot in the subtalar joint neutral position, as recommended by Root theory. Foot orthosis design should be based on an individual patients requirements and their symptoms, and not attempt to align the feet of all patients to a single common structural position (e.g. STJ neutral).

Root recommends practitioners should characterise abnormal foot structures by using static weightbearing measurements involving the rearfoot. According to Root, quantifying relaxed calcaneal stance position and neutral calcaneal stance position assists clinicians in diagnosing pathological motion arising at the subtalar joint during the gait cycle. Resting calcaneal stance position (RCSP) is calculated from the angle formed between longitudinal bisection of the back of the calcaneus and the supporting surface when standing. The neutral calcaneal stance position (NCSP) is also calculated using the angle formed between the back of the calcaneus and supporting surface but measured with the subtalar joint held in its neutral position. Both RCSP and NCSP measurements are important features of the Root model that assist clinicians in characterising foot structures and designing foot orthosis. However, they present practitioners with a number of difficulties. Firstly, both Menz (1997) and Jarvis (2012) showed RCSP and NCSP measurements are unreliable thus question the validity of employing these measures to characterise subtalar joint position and foot function. Secondly, Cornwall (2004) showed the rearfoot angle, representing a static measurement formed between the calcaneus and lower leg, does not relate to dynamic rearfoot motion. This finding questions the validity of using static measurements to characterise dynamic foot function. It is worth noting that many of the structural foot deformities defined by Root, rearfoot and forefoot varus for example, are themselves all defined via a static assessment. They are thought to produce distinct compensations during the gait cycle, but this seems unlikely if static assessment, from which they are defined, do not relate strongly to dynamic foot motion during gait. Thus, the approach the Root model employs to characterise foot structures using static weightbearing measurements is questionable.

2.7.2.2 Subtalar Joint Axis Location Rotational Theory

Kirby developed the subtalar joint axis location rotational equilibrium theory (SALRE) as a method of designing foot orthosis by altering foot/ankle kinetics (Kirby, 1989). This is achieved by tailoring the design of the heel part of the orthosis to alter external inversion forces and thus the rotational equilibrium at the subtalar joint axis throughout gait. This is thought to reduce pathological forces applied through symptomatic soft tissue and bony structures (Kirby, 2001). This contrasts the Rootian approach that seeks to reposition foot structures to the STJN position, i.e. focusing on kinematic rather than kinetics (Root et al., 1977).

Kirby pays particular attention to the location of the subtalar joint axis and applying load using an orthosis medial to the axis, thus resisting foot excessive pronation. He suggests characterising its spatial orientation so orthotic design can be adjusted to reflect differences between individuals, a focus clearly derived from the preceding Root theories concerning STJ axis location. In normal feet, during relaxed calcaneal stance position, Kirby indicates that the STJ axis passes through the posterior-lateral aspect of the calcaneus posteriorly and passes over the first metatarsal head anteriorly (Kirby, 2000). A deviated axis is present if the STJ axis translates in a medial or lateral position relative to the normal STJ axis position (Figure 2.16).

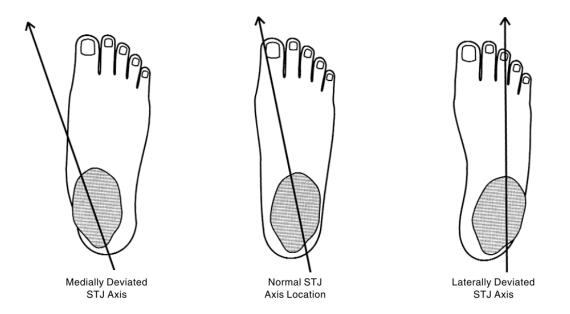


Figure 2.16 Illustration showing normal STJ axis location (centre), medially deviated STJ axis location (left) and laterally deviated STJ axis (Kirby, 2000).

GRF's that act to the medial and lateral of the STJ axis cause supination or pronation moments respectively. Kirby recommends that practitioners tailor orthosis to reduce pathological forces present in symptomatic structures by altering moments at the STJ axis. This is achieved by increasing orthotic geometry on one side of the axis to alter moments, thus knowing the location of the axis is important. Also, the axis position is thought to affect the contact area under the plantar foot where pronation/supination moments can be created by a GRF, since a medially deviated STJ axis significantly decreases the contact area under the medial calcaneus to which forces can be directed by an orthosis (Figure 2.17).

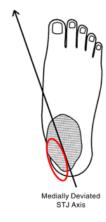


Figure 2.17 Medially deviated STJ axis and limited contact area under the medial calcaneus an orthosis can influence to increase external supination moments

For example, he suggests that the design of foot orthosis incorporates features that decrease pronation moments in a STJ axis that is medially deviated. He described the medial heel skive technique (Kirby, 1992) and promotes this design feature as a means of decreasing pronation moments at the STJ axis. This involves adding additional material inside the medial part of the heel area cup i.e. underneath the heel, to increase pressures under the medial aspect of the heel. Conversely, he proposes the lateral heel skive modification to decrease supination moments caused by excessive supination, including peroneal tendinitis.

The SALRE paradigm of foot biomechanics models the foot as a single rigid body and thus what occurs at the STJ has an explicit influence on the biomechanics of the rest of the foot. Kirby defends this assumption referencing theories proposed by Husan (2000), and a study by Cornwall and McPoil (1999), which all indicate that strong kinematic coupling exists between tarsal bones. Kirby cites his own clinical experience in assessing thousands of feet as evidence that the STJ axis is the most important axis of rotation in the foot (Kirby, 2001). However, invasive bone pin studies, which are devoid of skin movement artefact error, show how the

ankle as well as the subtalar joint contributes to frontal, transverse and sagittal plane rearfoot kinematics, and thus joints other than the STJ are important contributors to foot function. For example, Lundgren reports that the total range of transverse ankle joint motion was greater than transverse STJ motion in 3 of 4 subjects when walking (Lundgren et al., 2008), whilst Arndt reports that frontal plane ankle motion was greater than frontal STJ motion in 2 of 3 subjects when running (Arndt et al., 2007). Thus, data shows that ankle joint is not just a simple hinge facilitating sagittal plane dorsiflexion/plantarflexion, it also contributes to frontal and transverse plane motions, previously assumed to only occur in the subtalar joint. Furthermore, Lundgren showed that motion measured at the talonavicular joint and calcaneocuboid joint is greater than motion measured at the subtalar joint, thus highlight the important contributions midfoot articulations make to foot kinematics (Lundgren et al., 2008). Although these bone pin studies have small sample sizes due to the invasive methods employed, the data presented is similar to those reported in in vivo studies (Hunt et al., 2001; Hyslop et al.; Nester et al., 2014) thus trends can potentially be applied to the general population.

The single rigid body model underpinning SALRE theory of foot function neglects the important contributions other foot articulations make to foot/ankle kinematics, such as those that have been shown to occur at the talonavicular, calcaneocuboid and naviculocuniform joints (Arndt et al., 2007; Lundgren et al., 2008). It follows, that many articulations present in the foot are capable of compensating for changes in STJ axis position and therefore its true influence on overall foot function remains unknown.

2.7.2.3 Sagittal Plane Facilitation Theory

The sagittal plane facilitation theory (SPFT) was first described by clinician Howard Dannenberg (Dananberg, 1986). The premise underpinning the theory is that in gait the body's centre of mass (COM) transitions efficiently in a forward direction from the initial loading phases in gait (when it is behind the foot), through midstance to propulsion (when it is in front of the foot). Foot/ankle structures pivot in the sagittal plane to facilitate the forward progression on the COM with gait dysfunction occurring if its anterior progression is restricted in any way by joints in the foot. Dannenberg purports the SPFT model is superior to other models of biomechanical function because 500% more movement occurs in the sagittal plane compared to frontal and transverse plane based models that typically quantify rearfoot/midfoot

biomechanics. He proposes orthotic interventions that are designed to reduce restrictions of sagittal plane foot motion during the three stance phase rockers, as described in Perry (1992).

The SPFT describes a variety of abnormalities thought to cause gait dysfunction. These abnormalities are described as "sagittal plane blockages", i.e. limitations in the sagittal plane motion available in the foot, caused by reduced ankle dorsiflexion, forefoot equinus, and reduced metatarsophalangeal joint (MTPJ) dorsiflexion. Dannenberg coined the pathology "functional hallux limitus" (FHL) as a MTPJ sagittal plane blocker. In theory, when the foot is at the propulsive phase of gait, the first MTPJ dorsiflexes and activates the windlass mechanism by increasing tension in the plantar fascia. This action is thought to stabilise the foot by compressing foot joints and resisting dorsiflexion of the foot in response to external ground reaction force. In cases of functional hallux limitus, normal MTPJ range of dorsiflexion is present in non-weightbearing but is restricted in gait. The lack of hallux dorsiflexion is thought to limit the effectiveness of the windlass mechanism and lead to a more unstable foot. As a result of this instability and assumed increased predisposition to excessive foot pronation and thereby injury, FHL is cited as a causative factor for low-back pain, which Dannenberg suggests responds well to foot orthosis (Dananberg et al., 1999).

The SPFT proposes a number of orthotic approaches to assist individuals in overcoming the supposed blockages in the required sagittal plane motion. These techniques, involving manual manipulation and foot orthosis, are outlined in company promotional literature (Vasyli Medical TM). Firstly, manipulations are recommended to improve motion in joints with restrictions. For example, Dannenberg suggests dorsiflexion of the ankle joint causes translation of the fibula superiorly and laterally which if impeded will restrict ankle dorsiflexion and subsequently cause equinus and FHL (Dananberg, 2004). To improve fibular translation Dannenberg describes a technique that involves firstly manipulating the proximal fibula and then applying distal traction to the calcaneus. By improving fibular translation this technique is purported to increase ankle dorsiflexion range. Dannenberg also reports a manipulation method to reduce restrictions at the calcaneocuboid joint. Secondly, foot orthoses with specific design features are recommended to assist individuals with foot/ankle sagittal blockages. For example, in individuals with functional hallux limitus Dananberg recommends using orthosis with a first MTPJ "cut-out", namely removing material under the first metatarsal head, and thereby allowing the metatarsal to plantarflex to a greater degree. This design feature is reported to reduce load under the 1st MTPJ thus reducing resistance to hallux dorsiflexion. Facilitating hallux dorsiflexion is thought to enable the Hicks windlass mechanism to engage to stabilise the foot during propulsion. Also, Dannenberg suggests using a heel raise in the presence of restricted ankle dorsiflexion. This design feature is thought to facilitate sagittal plane progression of the tibia anteriorly over the foot in gait. Practitioners can use in-shoe pressure measurement systems to guide orthosis modifications designed to improve sagittal plane progression (Harradine et al., 2009).

Although used in clinical practice, the SPFT presents foot health practitioner with a number of difficulties. Firstly, there is only a single study that demonstrates positive outcomes when using the SPFT approach for the treatment of low back pain (Dananberg et al., 1999), and no laboratory studies are available to quantify the biomechanical effect of orthoses using the SPFT. Thus the biomechanical principles underpinning the SPFT's framework have not been robustly examined. Furthermore, this study (Dananberg et al., 1999), presents with a number of research design and quality issues. All participants in the study received an orthosis thus it is not possible to contrast clinical effects with a control group. Also, this study provides mean pain score data from subjects over two time periods, however no data is offered to characterise the effects of the orthosis on plantar pressure variables, thus it is not possible to understand how changes in plantar pressure and thereby foot biomechanics relates to clinical responses. This is surprising considering that the premise underpinning the SPFT involves tailoring orthosis to alter COP position and force vrs time curves. Yet, a practitioner reviewing this paper is offered no insight into how to alter these biomechanical variables. Therefore limited information is available to guide practitioners regarding prescription guidelines. Also, the SPFT recommends the use of in-shoe pressure analysis to guide the design of orthosis. Due to its expense, this technology is not readily available for clinicians to use in clinical practice. Finally, one can argue the SPFT uses an overly generic approach, using a single approach (adding heel raises and 1st MTPJ cutouts) to cure all pathologies, which only holds true if these pathologies all have a common aetiology.

2.7.2.4 Preferred movement pathway theory

The preferred movement pathway theory was first described by (Nigg et al., 1999). The theory is based on the premise that foot orthosis elicit their beneficial effects by altering muscle function and not by altering kinematics or impact forces as traditionally proposed (although these things might happen too, they are not considered critical to the clinical orthotic effect).

Nigg cites a number of studies that supports his assumptions. Firstly, to refute claims that foot orthosis function by altering skeletal alignment he describes studies that show foot orthosis alter rearfoot eversion by relatively small amounts (2-3 degrees) (Eng et al., 1994; McCulloch et al., 1993). Nigg also cites a study showing that foot/ankle alignment is not a predictor of injury development in marathon runners (Wen et al., 1997) thus questions the relevance in using foot orthosis to alter skeletal alignment (Nigg et al., 1999). Secondly, Nigg references studies which counter claims that foot orthosis derive their benefits by altering impact forces in gait. He cites a study showing impact forces at heel strike, similar in magnitude to those occurring in running, cause minimal effect on peak forces in common injury sites seen in runners (Scott et al., 1990) and also that that running on hard or soft surfaces, which causes variable impact forces, does not affect the incidence of running injuries (van Mechelen, 1992). Nigg proposes that foot orthosis derive beneficial affects by minimising muscle activity by altering an individual's established foot/ankle movement pathway (Nigg et al., 1999).

Two features involving neuromuscular action underpin the concepts involved in the preferred movement pathway theory. The first concept relates to *muscle tuning*. The impact force at heel strike causes an impact signal that is characterised by amplitude and frequency. This impact signal produces bone and soft tissue vibrations. Nigg proposes that neuromuscular action dampens these vibrations by way of a tuning strategy but implies that foot orthosis offer the potential to alter impact signals at initial heel contact. In the second concept Nigg suggests the neuromuscular system regulates skeletal movement patterns, but is also hard wired to avoid deviations from these movement patterns. Thus, external factors influencing the movement path cause a muscular response. It follows that a foot orthosis designed to resist the preferred movement pathway causes muscular activity to increase, conversely foot orthosis supporting the movement pathway causes muscular activity to decrease. Nigg suggests an optimally designed orthosis reduces muscular activity by supporting the preferred movement pathway.

Nigg has also integrated the issue of comfort into his explanation of how foot orthoses have their effect. He describes comfort as a subjective indicator of muscle activity and illustrates this relationship by characterising comfort in footwear. If comfort indicates muscle activity, wearing comfortable footwear requires lower oxygen consumption compared with wearing uncomfortable footwear. Nigg describes a pilot study (not published) he conducted supporting his assumption regarding the relationship between comfort and oxygen consumption. Oxygen consumption measurements in 10 subjects running in most and least comfortable footwear

showed significantly more oxygen was required for the least comfortable running shoe. Nigg proposes that foot orthosis influences both muscle tuning and muscle activity thus affects fatigue, comfort, work and performance (Nigg, 2001).

The preferred movement pathway theory presents with a number of difficulties. Firstly, it is very much a theoretical explanation for foot/ankle function in gait, and for how orthosis derive their beneficial effects. Nigg himself states that the preferred movement pathway is a paradigm for foot orthosis function that needs more evidence to support or reject it (Nigg, 2001). Secondly, and related to the first difficulty, practitioners cannot as yet knowingly tailor the design of foot orthosis to influence muscle tuning and support the preferred movement pathway since neither a measureable. Nigg suggests that foot orthoses described as comfortable are more likely to support the preferred movement pathway. Practitioners should endeavour to design orthosis that are comfortable, but comfort is subjective and specific to the individual and thus prescribing orthosis using comfort as a guide to orthotic design does sit easily with the aspiration for more evidence based practice.

2.7.3 Features of antipronation foot orthoses

A number of design features in an APFO influence joint moment/motion responses. The geometry/shape of its surface contacting the skin, and the mechanical properties of the material in which an APFO is constructed from, both affect how external forces are applied from the footwear sole to the foot sole. This in turn influences the location and magnitude of the forces applied to the foot and thereafter joint moments and motion responses in foot structures.

Key geometric features of an APFO include medial heel wedges (tilting the orthosis up on the medial side) and orthotic medial arch profile (increasing/decreasing height of the orthotic in the arch area) (Figure 2.18, Figure 2.19, Figure 2.20, Figure 2.21). Practitioners routinely tailor these features either for individual patients or for groups of patients according to foot type or clinical problem. These modifications are focussed on creating an anti-pronation biomechanical response, that is a reduction in the range, speed or timing of excessive foot pronation. Laboratory based studies have shown that orthosis with anti-pronation components increase medial plantar foot peak pressure and displace the centre of pressure medially (Bonanno et al., 2012; McCormick et al., 2013; Paton et al., 2006; Van Gheluwe et al., 2004) and decrease both peak rearfoot eversion (Branthwaite et al., 2004; Fong et al., 2008;

Majumdar et al., 2013; Mündermann et al., 2003; Stacoff et al., 2007; Telfer et al., 2013c) and internal inversion moments at the rearfoot (Hsu et al., 2014; Huerta et al., 2008; Nigg et al., 2003; Stacoff et al., 2007; Telfer et al., 2013c).

Similarly, practitioners can use materials with different properties to influence biomechanical responses. Studies have shown that the hardness of the material an orthosis is constructed from influences how load is transferred to the foot. To increase load under the medial foot, and to resist foot excessive foot excessive pronation, it is recommended that antipronation foot orthoses be constructed from materials with high compressive stiffness (Paton et al., 2007). Constructing APFO medial wedge and arch geometry from soft materials, with low compressive stiffness, will not adequately increase load under the plantar foot required to decrease rearfoot eversion and dorsiflexion of joints forming the medial longitudinal arch.

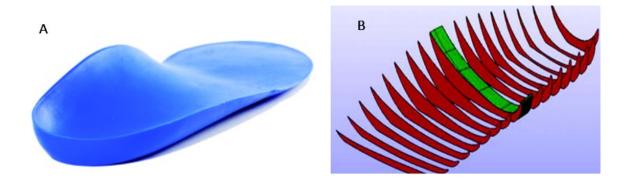


Figure 2.18 A; prefabricated orthosis showing orthotic arch geometry (for right foot) and B; same orthosis but showing geometry of rearfoot and midfoot frontal plane sections (for left foot). Illustrations taken from Majumdar et al., (2013).

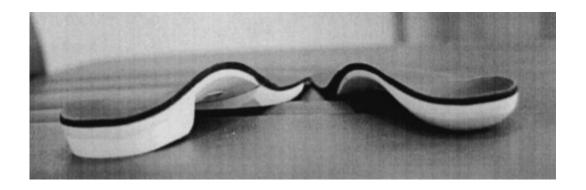


Figure 2.19 Custom moulded orthoses with extrinsic posting (left) and without posting (right), taken from Mundermann et al., (2003).

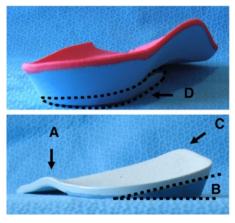


Figure 2.20 Prefabricated (top) and custom made (bottom) foot orthosis showing extrinsic medial wedge designs. For custom made orthosis; A – cuboid notch; B – 20 ° extrinsic medial wedge; C = medial arch geometry. For prefabricated orthosis; D – extrinsic medial heel wedge. Taken from Murley et al, (2010).

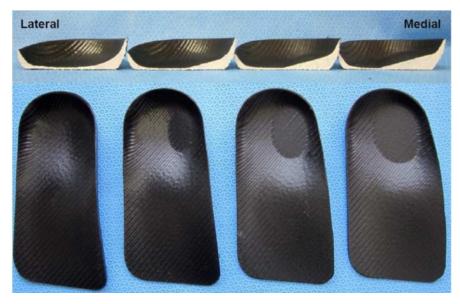


Figure 2.21 Custom made orthosis showing cross-sectional (top) and superior (bottom) view of orthoses with intrinsic medial wedge designs. Left to right: (1) orthosis with no intrinsic wedge, (2) orthoses with a 2mm intrinsic wedge; (3) orthoses with a 4mm intrinsic wedge; and (4) orthosis with a 6mm intrinsic wedge. Taken from Bonnano et al., (2012).

Practitioners tailor these APFO design features in foot orthoses to create a biomechanical responses most suited for a given clinical condition. Individuals with tibialis posterior tendon dysfunction for example, typically possess foot/ankle structures that excessively pronate (Rabbito et al., 2011). Thus, for this condition the desired biomechanical response is to reduce strain in the tibialis posterior tendon by increasing external supination moments and decreasing excessive foot pronation. As described, these biomechanical objectives can be achieved by constructing anti-pronation orthosis from materials with high compressive stiffness with heel and arch geometry tailored to increase external forces under the medial calcaneus and medial

arch of the foot (Kirby, 2000; Paton et al., 2007). Constructing orthosis from materials with low compressive stiffness, with anti-pronation arch geometry has been shown to decrease plantar pressures values under the heel and forefoot (Chen et al., 2003; Lord et al., 1994; Paton et al., 2007), thus will cause an appropriate biomechanical response for individuals with diabetes or RA where high plantar pressures have been shown to increase the risk of ulceration (Payne et al., 2002) and are also associated with foot pain (Hodge et al., 1999).

2.7.4 Classification of APFO used in previous research studies

Studies exploring the clinical and biomechanical effects of APFO typically classify orthoses as custom made or prefabricated, thus classify orthoses according to their method of manufacture rather than their properties. In clinical studies for example, Landorf et al. (2006) describes the effects of prefabricated and custom made orthosis in reducing pain in plantar fasciitis, whilst Finestone et al. (2004) compares the effects between prefabricated and custom made orthosis in the occurrence of foot pain in military recruits. Similarly for laboratory based studies, Tsung et al. (2004) compares the effects of prefabricated and custom made orthoses on plantar pressure in individuals with diabetes. Nawoczenski et al. (1995), Mundermann et al. (2003) and Williams et al. (2003) characterise the effect of custom made orthosis on lower kinematics/kinetics in runners. Liu et al. (2012) and Rodrigues et al. (2013) characterise the effect of prefabricated orthoses on lower limb kinematics in individuals when walking and running respectively.

Characterising foot orthoses based on their method of manufacture (custom made vrs prefabricated), however, assumes that this difference leads to specific differences in orthotic properties and thereafter biomechanical effects. It is argued that custom made orthosis are better at causing a specific biomechanical response for an individual because their geometry is bespoke to an individual's plantar foot. Thus to the fit to the sole of the foot and ability to manipulate where loads are applied should be better. However, the geometry of custom made APFO is based on static foot shape, whereas the foot is a dynamic structure and possesses many different shapes throughout gait. This questions the assumed superiority in using custom made orthosis tailored from a single static foot shape. Also, custom made and prefabricated orthoses may have similar material properties and geometry that alters external forces under the foot in similar ways. Thus, two apparently contrasting orthoses, characterised only by the method of manufacture, may elicit similar biomechanical responses. It is not the method of manufacture

that determines the biomechanical response, nor the technique used in obtaining a model of an individual's foot structures prior to fabricating orthoses (cast, foam, of 3D scan), but how geometry and material properties alter external forces under the sole of the foot.

Furthermore, studies often omit details regarding orthosis design features, thus it is not possible to characterise what features in the orthosis is responsible for the biomechanical response observed. For custom made orthosis, studies describe the materials used to form the plastic shells that are the main body of the device, but do not outline its thickness (Mundermann et al., 2003; Williams et al., 2003). Studies that provide detail relating to material thickness (Nawoczenski et al., 1995; Rao et al., 2009) fail to acknowledge how arch geometry contributes to the ability of an orthoses to resist deformation under vertical load caused by body weight. A vertical load causes greater deflection in orthoses with lower arch heights compared to orthosis with higher arch heights, even when manufactured from identical materials with the same thickness. Thus, for studies using custom made orthoses, there are potentially many different arch heights (even in feet classified as having similar foot shapes) that deform differently when placed under vertical load.

Similarly, geometry in prefabricated orthoses are uniform and often fitted to subjects in studies according to shoe size. However, in contrast to custom orthosis, it is unclear when using orthoses with uniform geometry where the apex in orthoses arch geometry resides with reference to an individual's medial longitudinal arch. Thus, even for subjects with similar shoe sizes, the apex in arch geometry might reside under different parts of the medial arch therefore influence the various joints forming the medial arch in different ways. Two subjects with similar foot sizes will be issued with the same size prefabricated orthosis, and the external forces under the talonavicular joint may be affected differently. In one subject the peak of the arch may occur under the talonavicular, whilst for another subject the arch curvature may be positioned more anteriorly relative to their joint, and thus influence external forces under the navicular-cuneiform joint instead.

To date researchers have placed an emphasis in classifying foot orthoses as either prefabricated or custom made and fail to characterise and control design features that influences biomechanical responses. It is thus rarely clear precisely what orthosis has been tested and what feature of the orthosis tested is responsible for the data reported. There is also limited opportunity to repeat the research design.

2.8 Effect of foot orthoses

2.8.1 Evidence of variable clinical effect of foot orthoses

Although widely used by foot health practitioners clinical based studies show APFO have variable beneficial effects. For example, APFO have been shown to be beneficial in the treatment of overuse injuries (Franklyn-Miller et al., 2011), plantar fasciitis (Drake et al., 2011; Roos et al., 2006) and knee pain (Collins et al., 2008; Rodrigues et al., 2008). However these contrast with the results found by other studies to treat the same conditions (Esterman et al., 2005; Hossain et al., 2011; Landorf et al., 2006). Studies normally characterise the clinical response to APFO across a group and thus individual clinical responses are less clear. For example, Roos (2006) showed foot and ankle outcome pain scores (0 – 100; worst-best scale) decreased in subjects using foot orthosis from baseline (mean 56, SD 12), at 12 weeks (mean 76, SD 26) and 52 weeks (mean 89, SD 16). However, the mean and standard deviation values clearly illustrate some variation in clinical response exists.

2.8.2 Factors explaining variable clinical effects

A number of factors may explain why APFO cause variable clinical responses. Firstly, in some clinical cases changing the biomechanical parameters foot orthosis alter may be beneficial, but in other clinical cases, the changes foot orthosis create may be less important in terms of reduction in symptoms. Clinical evidence supporting the use of foot orthosis with medial arch anti-pronation geometry to redistribute plantar foot loading for individuals with diabetes and RA is substantive, however the relationship in how orthosis alters plantar pressure, and how changes in plantar pressure influence moment/motion changes purported to be beneficial for a number of musculoskeletal complains (e.g. inflamed achilles or tibialis posterior tendons) is less clear. Changing plantar pressure may be more explicitly linked to reduction in symptoms (forefoot pain), whereas moment/motion changes might be less closely associated with symptoms (muscle/tendon pain). Therefore if all biomechanical parameters are affected in an equal way, the resultant change in symptoms across different clinical conditions could still be variable. Perhaps APFO cause their greatest effect in redistributing load under the foot but their effects on altering lower limb, joint moments and muscles/tendons are secondary or less consistent. Secondly, many of the musculoskeletal conditions for which foot orthosis are prescribed have complex and multifactorial actiologies (e.g. tissue changes associated with age, Verdijk et al., (2010) and foot biomechanics may only play a minor role in the creation of

symptoms. Thereafter, changes in foot biomechanics might only offer minor contribution to alleviating symptoms.

Perhaps the most obvious reason for variation in the outcome of clinical studies is variation in the underlying biomechanical response to foot orthoses. Laboratory based research demonstrates variation between individuals in how moments and motion changes in response to APFO use. The biomechanical responses caused by APFO (plantar pressure, joint moments, joint kinematics, muscle/tendon/soft tissue stresses) are influenced by many factors which are specific to each person, for example, articular facet geometry and neuromuscular response to the change in external forces. However, how these factors influence the biomechanical response to APFO have not been explored to date. Without understanding the reasons for the inconsistencies in biomechanical responses to APFO, the prescription of APFO is fraught with difficulty. The practitioner is not able to predict with confidence how the foot biomechanics of an individual patient will respond to an APFO intervention they provide. Likewise, they are unable to tailor the APFO prescription knowing confidently that biomechanical changes they make will enhance the clinical effect.

2.8.3 Evidence of subject specific variation in the biomechanical effect of APFO

Several laboratory based research studies shows APFO cause subject specific changes to lower limb joint moment and motion. These variable responses are subject specific in terms of the direction and the magnitude.

APFO are typically tailored to decrease peak rearfoot eversion/eversion range and internal tibial rotation (Banwell et al., 2014b; Collins et al., 2007; Valmassy, 1996) yet running studies report that subjects experience opposite responses (Figure 2.22). For example, Williams (2003) reported APFO increased peak rearfoot eversion and eversion range in 8 of 11 subjects and 3 of 11 subjects respectively, and likewise that an APFO with an inverted design increased peak rearfoot eversion and eversion range in 5 of 11 and 6 of 11 subjects respectively. Maclean et al., (2006) and Mündermann et al., (2003) reported APFO increased peak rearfoot eversion in 4 of 11 subjects and 13 of 21 subjects respectively. An invasive bone pin study quantified the effect of APFO on rearfoot kinematics and showed that two designs of orthosis increased peak eversion in 1 of 4 subjects (Stacoff et al., 2000). Although bone pin studies usual employ fewer subjects, the data is high quality because it is the only true means of quantifying bone

kinematics beneath the skins surface (void of errors associated with skin movement artefact). Studies have also shown similar contrasting responses for tibial rotation. For example one study showed that for runners classified as having high arched foot postures, APFO increased tibial rotation in 4 of 10 subjects. In the same work for runners with low arch foot postures APFO increased tibial rotation in 3 of 11 subjects (Nawoczenski et al., 1995). Similarly, a different study showed APFO increased tibial rotation in 3 runners but decreased rotation in 7 (Nigg et al., 1998).

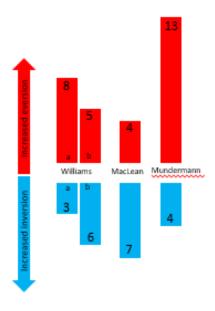


Figure 2.22 Studies showing number of subjects with contrasting changes in peak rearfoot eversion. Both McLean (2006) and Mündermann et al., (2003) characterised the effect of custom made APFO. Williams et al., (2004) characterised the effect of custom APFO using standard design (a) and inverted design (b).

The effects of AFPO on joint moment responses in runners are more systematic and fewer subjects experience a response that contrasts the mean response. For example, Maclean and Mundermann showed AFPO increased internal inversion moment at the ankle joint in 1 of 11 subjects and 3 of 21 subjects respectively (MacLean et al., 2006; Mündermann et al., 2003). It follows that joint moment responses reported by studies are more systematic compared with kinematic responses. This is because the kinematic response is the net biomechanical response to an orthosis resulting from changes in external joint moment and internal factors, such as neuromuscular action and soft tissue stiffness that may increase the likelihood of variability in the final kinematic response. However, the moment responses are still variable and subject specific (Figure 2.23).

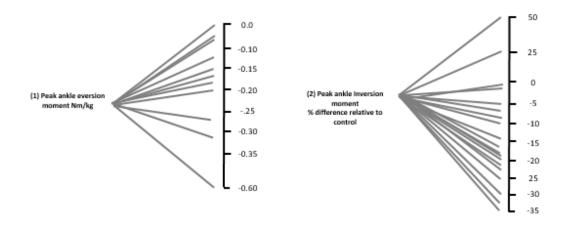


Figure 2.23 Range of subject specific joint moment responses, as described by (1) Williams (2003) and (2) Mundermann (2003).

Compared with running studies, studies characterising the effect of AFPO in individuals in walking report more systematic changes in joint moment and motion responses between individuals. A possible explanation for this is running places a greater demand on the neuromuscular system compared with walking. Thus this greater demand creates greater opportunity for variability in biomechanical responses. Nonetheless, studies also show that joint moment/motion responses in walking are subject specific. For example, an invasive bone pin study reported APFO decreased STJ eversion in individuals ranging from 0.1 ° to 3.8 ° (Liu et al., 2012). The same study described how a prefabricated AFPO caused non-systematic subject specific coupling effects involving the subtalar and ankle joints. Liu et al. (2012) described how one subject experienced a 1.6 ° decrease in peak STJ eversion coupled with a 1.5° increase in peak ankle joint inversion, whereas another subject experienced a 2.3° increase in peak STJ eversion coupled with a 1.4° increase in peak ankle joint inversion. Furthermore, two subjects showed frontal plane changes occurred primarily at the ankle joint while the remaining 3 showed changes occurred at both ankle and subtalar joints. The results of this study demonstrate considerable variability in the magnitude of kinematic responses, but also in how the two rearfoot joints can respond differently, even among a small cohort of testing subjects (Figure 2.24). As previously described data from bone pin studies is of high quality as it is void of skin movement artefact error associated with skin mounted markers (Nester et al., 2007).

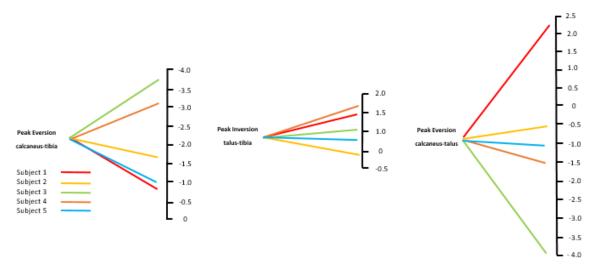


Figure 2.24 Range of subject specific kinematic responses. Plots showing change in the initial peak eversion of the calcaneus relative to the tibia (°), change in initial peak inversion of the talus relative to the tibia (°), and change in the initial peak eversion of the calcaneus relative to the talus (°) (Liu et al., 2012).

Variability in joint moment/motion responses was also shown by a study that characterised the dose response effect of custom made APFO in individuals with asymptomatic neutrally aligned feet (control) and individuals with symptomatic pronated feet (Telfer et al., 2013c). This study showed that incrementally altering the angle of medial wedging systematically altered rearfoot joint moments and rearfoot motion responses in both groups. However, the magnitudes of the responses were variable in both cases. In both pronated and control groups, the total range of ranges decreased peak eversion by 1.8 ° in some subjects and in excess of 3.6 ° in others (Figure 2.25). Similar variability in response was found for changes in external ankle joint moments (Telfer et al., 2013c). In contrast to prior literature, covered above, changes in peak eversion were more systematic than changes in the eversion moment. All subjects in both groups reported decreases in eversion whilst two subjects in the pronated group and one subject in the control group reported decreases in eversion moment. This suggests the relationship between joint moments and motion is not linear and supports the conjecture that other factors influence the final kinematic response.

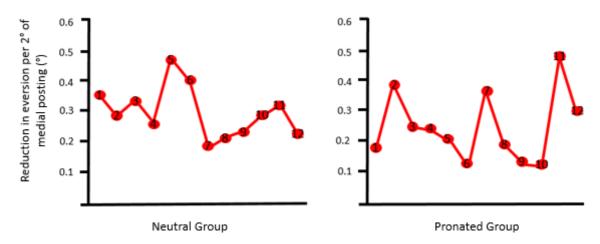


Figure 2.25 Range of kinematic responses in 12 participants with neutral and 12 individuals with pronated feet. Changes created by altering medial posting in individuals with neutral and pronated foot posture (Telfer et al., 2013c).

It follows, APFO cause subject specific joint moment and motion responses, both in terms of the magnitude and direction of the response. These subject specific responses occur regardless of foot alignment, with/without the presence of musculoskeletal pain and are independent of APFO geometry. Practitioners seek to derive clinical benefits by prescribing APFO to deliver a specific biomechanical response. However, laboratory studies show this is a difficult task and question the principles upon which AFPO are commonly prescribed. It follows that orthosis prescribed on questionable biomechanical principles will cause variable biomechanical responses reported by studies.

2.8.4 Factors affecting the biomechanical effect of foot orthoses

During functional movement the human foot and ankle exhibits specific kinematic patterns that result from (1) external forces applied to the sole of the foot, (2) foot structures that experience those external forces and (3) neuromuscular action that generates dynamic internal forces. Kinematic responses elicited by individuals result from the interaction between these three factors, which are complex and person and likely task specific. For example, a neurological response may involve some degree of adaptation (learning), as might changes in muscle or other soft tissues, as loads in tissues vary over extended time periods in response to the orthoses.

Thus, effects may not be immediate. Furthermore, these factors change with age, activity levels and disease processes and are thus not necessarily static even within one individual. This concept is represented in Figure 2.26 and provides a framework for the concepts explored in this PhD.

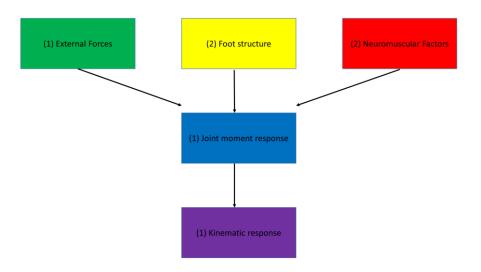


Figure 2.26 Conceptual framework representing biomechanical system of foot function

2.8.5 External Forces

External forces applied to the sole of the foot influences foot kinematics. GRF transfers load through the sole of the foot affecting moments acting in joint centres of rotation in foot/ankle articulations. During dynamic foot motion the vertical force component and horizontal shearing components of the GRF continuously change. During contact and propulsion phases the peaks in vertical force measure 1.2 times body weight, and elevation of the COM during midstance reduces this to 0.7 times body weight. Contact and propulsion phases involve peaks in anterior and posterior shearing forces respectively, both measuring 0.2 times body weight. Contact phase also involves a laterally directed shearing force (0.05 to 0.1 times body weight) which changes to move medially then laterally in direction with forward progression through stance. The magnitude and orientation of the vertical and shearing components of the GRF will depend upon the movement task being undertaken and also on the supporting surface, and footwear too. The vertical GRF can increase from 1.2 times body weight in walking to 2.5 times body weight in running (Keller et al., 1996). Running on a cross slope was shown to significantly change medial-lateral shearing forces (Damavandi et al., 2012) whilst running

with different foot strike patterns was shown to significantly affect both vertical and shearing forces (Lohman Iii et al., 2011).

Studies using pressure measurement systems have characterised the distribution of force under the sole of the foot. In barefoot standing, pressure values have been shown to be greatest under the rearfoot (Cavanagh et al., 1987b) whereas in walking pressure values are greatest under the forefoot (Butterworth et al., 2015; Martínez-Nova et al., 2007). Foot morphology has been shown to influence pressure values, where compared with normal feet, cavus feet demonstrate higher pressure values under the rearfoot (Burns et al., 2005a) and forefoot (Fernández-Seguín et al., 2014). However, the pressure measurement systems these studies use only quantifies the vertical component of the GRF, and not the anterior-posterior and medial-lateral shearing forces.

Using an APFO will strongly influence how external forces are applied to the sole of the foot. Arch geometry has been shown to significantly increase peak pressure under the midfoot and decrease peak pressure under the rearfoot and forefoot (Bonanno et al., 2012; Burns et al., 2006; Bus et al., 2004; Lin et al., 2013; Tang et al., 2015). Similarly for extrinsic and intrinsic medial wedges (under and inside the heel cup respectively) have been shown to increase pressure values under the medial rearfoot (Bonanno et al., 2012; Telfer et al., 2013a) and increase the medial displacement of the COP under the plantar foot (Paton et al., 2006; Van Gheluwe et al., 2004). Footwear and sole design influence the orientation and magnitude of load under the plantar foot (Brown et al., 2004) and hosiery has been shown to affect plantar shear properties at the skins surface (Dai et al., 2006). It follows that these features will influence how APFO applies load to the sole of the foot.

2.8.6 Foot Structure

A number of structural features of the foot and lower limb affect foot kinematics. Internal features relating to articular facet geometry and congruency, and the constraining action of soft tissue structures surrounding joints, all affect foot kinematics. Joints formed by articulating surfaces that possess different levels of congruency, or variations in congruency depending upon where in their total range of motion they are at, will have different motion patterns. MRI (Shahabpour et al., 2011) and osteometry (Barbaix et al., 2000) based studies show distinct

variations between people in the shape of the articulating surfaces between the talus and calcaneus. This includes absent anterior articulating facets and fused anterior middle articulating facets. Absent anterior articulating facets has been cited as a causative factor on the development of flat feet in children (Kothari et al., 2015). Variations in talocalcaneal geometry causes variations in pronation/supination movement at the subtalar joint (Imhauser et al., 2008). Soft tissue structures surrounding joints constrain motion thus also influence kinematics. Cadaveric studies show lateral and deltoid ligaments act to stabilise the ankle (Watanabe et al., 2012). The calcaneofibular and tibiocalcaneal ligaments experience variable levels of tensile forces during plantarflexion/dorsiflexion therefore help guide movement of the talus relative to the tibia (Leardini et al., 1999), thus helping to determine not just limit motion.

Structural features, including articular facet geometry and the constraining action of ligaments, will influence joint centres of rotation and the moment arms around which external and internal forces act. This must inevitably affect the resulting path of joint movement. The relationship between the centres of rotation at a joint also influence neuromuscular response. Muscles whose tendons are located in close proximity to a joint axis of rotation will require more effort to elicit kinematic motion than muscles located further away due to shorter moment arms (Richards, 2008). It follows that structural characteristics relating to foot structure can vary greatly in individuals (Matricali et al., 2009).

There is some evidence that static foot posture is associated with different foot postures. Static foot posture is not specifically a structural feature but more a response of foot structures to loads applied in standing (or whatever other assessment protocol is used). Compared to neutral and planus foot postures, for example, the cavus foot possesses altered frontal and transverse plane kinematics at the rearfoot and less midfoot motion during stance (Buldt et al., 2015a). Compared to cavus and neutral postures, the planus foot demonstrates reduced frontal plane motion during pre-swing. It is reported that individuals with planus foot postures that are mobile have decreased midfoot abduction excursions during midstance and increased inversion excursions at pre-swing compared to individuals with normal foot postures (Cobb et al., 2009).

2.8.7 **Neuromuscular action**

The central nervous system regulates neuromuscular responses that influence foot kinematics. These responses are affected by the action of afferent neural impulses transmitted from sensory receptors to the CNS where neuromuscular action modulates the contraction of skeletal muscle via efferent neural impulses. It follows that the action of afferent and efferent neural impulses strongly influences kinematic response. If orthoses affect these afferent inputs then they too must affect the afferent signals and the subsequent muscle action.

To facilitate movement and balance the CNS assimilates afferent neural impulses prior to deriving an appropriate neuromuscular response that is relevant to the movement task being performed. Afferent neural impulses result from stimulation of the somatosensory system and are reliant on vestibular, visual and somatosensory information (Horak, 2006; Jeka et al., 1998; McKeon et al., 2007). The somatosensory system plays a particularly important role in maintaining balance and stability in gait and is formed by tactile and proprioceptive systems (Hijmans et al., 2007; McKeon et al., 2007). The tactile system processes sensations of touch, pressure and vibration to the CNS and consists of several cutaneous mechanoreceptors positioned under the sole of the foot, including; Meissner's, Pacinian, and Ruffini corpuscles, and Merkel discs.

Mechanoreceptors are purported to play an important role in controlling upright stance (Kavounoudias et al., 2001). Studies show cooling or anesthetizing cutaneous mechanoreceptors under the sole of the foot decreases postural stability (McKeon et al., 2007; Meyer et al., 2004). The proprioceptive system processes movement sensations to the CNS and is formed by receptors in muscle spindles, joint afferents and Golgi tendon organs (van Deursen et al., 1999). Research suggests automatic balance correcting responses requires lower limb proprioceptive feedback (Rao et al., 2006; Simon et al., 2006). When tactile and proprioceptive mechanisms are disrupted, as with peripheral neuropathy caused by diabetes for example, a decrease in the control of balance may occur which is associated with an increased risk of falls (Rao et al., 2006). Altering the sensory input under the plantar foot causes significant changes in plantar pressure distribution (Chen et al., 1995), thus sensory feedback is potentially an integral component involved in foot kinematics (Nigg et al., 1999).

Following sensory afferent feedback, the CNS elicits a neuromuscular response. Efferent neural impulses cause muscle fibres residing in intrinsic and extrinsic foot muscles to contract thus acting in conjunction with external forces and moments to alter joint rotations. Muscle force is generated within sarcomeres and is transferred to bone through tendons. Extrinsic foot muscles including, tibialis anterior and posterior, gastrocnemius, and soleus, collectively

eccentrically contact to resist excessive foot pronation (O'Connor et al., 2004) and intrinsic foot muscles, including; abductor halluces, flexor halluces brevis, flexor digitorum brevis, abductor digiti minimi and dorsal interossei muscles act to maintain arch height (Headlee et al., 2008), thus also function to resist excessive foot pronation. Intrinsic and extrinsic foot muscles are therefore responsible for modulating motion in 33 separate articular facets in the human foot, and since all muscles are multi joint there is considerable duplication of action and redundancy in the system. Considering the complexity in the morphology of the foot, resulting neuromuscular responses can be highly specific to each individual person since the redundancy allows for many different solutions to the application of a specific force. For example, Murley and co-workers found 50 % of subjects showed co-contraction between tibialis posterior and peroneus longus, where the other 50 % relied only on tibialis posterior (Murley et al., 2009a). Clearly, the extent to which a foot orthosis reduces the force in a specific muscle or tendon will be sensitive to the forces in that structure initially.

It follows that if such a complex system is able to provide a wide range of solutions to applying forces across many foot joints, that changing the distribution of the GRF, as orthoses do, will likely lead to altered patterns of muscle control and different muscle forces acting on joints. The consequence of this could be different changes in joint kinematics between individuals. However, clearly, these muscle forces are also dependent upon the foot structures across which forces are applied (e.g. passive stiffness of joints due to ligament tension, and moment arm length due to articular fact geometry), and thus neuromuscular influences interact with external GRF and foot structure factors to influence foot kinematics.

2.8.8 Relationship between APFO effects and clinical biomechanical models of foot function

APFO are purported to influence joint moments and motion by altering the magnitude and distribution of force under the sole of the foot. As discussed above, internal factors, including foot structure and neuromuscular action, and external forces affect the final kinematic response to the externally applied forces.

Practitioners usually design APFO to alter joint motion (Root theory) or alter joint moments (e.g. Kirby theory). The effect of AFPO on joint motion is widely reported, especially for

rearfoot eversion movement, which is typically the primary rearfoot characteristic being targeted. Meta-analysis of the literature shows APFO generally reduce maximum eversion by 2.1 ° (95 % CI 0.72 to 3.53) (Mills et al., 2010) to 2.2 ° (95 % CI = 1.42 to 3.07) (Cheung et al., 2011), however the confidence internal values demonstrate variation between people. Also, as previously described studies show changes are often non-systematic, reporting that AFPO increase eversion in certain individuals (Figure 2.27).

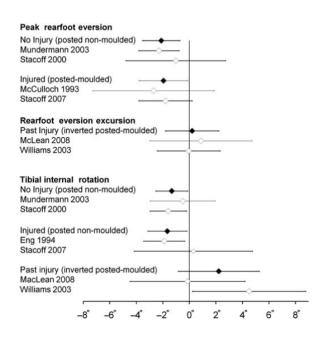


Figure 2.27 Forest plot of data pooling for rearfoot eversion and tibial internal rotation as described by meta-analysis of literature characterising biomechanical effect of foot orthosis (Mills et al., 2010).

It follows that practitioners using these models to design orthosis in clinical practice have difficulty prescribing APFO to elicit specific kinematic responses. Given a specific kinematic response is often assumed to be required to treat pathology, an inability to design orthoses to produce specific responses for an individual patient is not a sound basis for clinical practice. This differs from most forms of medical intervention where specific guidelines and rationale must be followed to elicit a known response (kinematics) from a known dose of an intervention (e.g. 2 degrees of medial wedge). Thus, an alternative explanation is required that includes all relevant features of the biomechanical model of foot function, including neuromuscular response, foot structure and external forces, and how these three interact when one (i.e. external forces) is affected by a foot orthosis.

The conceptual framework representing the biomechanical model of foot function (Figure 2.26) explains how APFO may cause variable biomechanical responses. Specifically, the manner by which APFO alter external forces under the foot, and how internal factors influence how these external forces alter external joint moments, muscle forces and internal joint moments, and eventually motions in foot joints. For example, as illustrated in Figure 2.28, the same APFO design may cause 3 different input forces in three individuals. Individual differences in internal factors, including joint geometry, passive internal factors and neuromuscular response, may cause three different kinematic responses despite all having the same APFO. Also, different APFO designs may cause the same input force in 3 individuals, however individual differences in internal factors may also cause three different kinematic responses.

It follows that internal factors may strongly influence kinematic responses, however little is known about the relationship between how APFO alters external forces under the foot, and how these changes in external force relate to changes in external and internal joint moments and thereafter kinematic responses. Characterising the relationship between these factors may help explain why APFO cause variable kinematic responses and thus further our understanding of the mechanism by which foot orthoses affect foot function. An improved understanding would allow for a more scientifically based approach to orthotic design and prescription, targeting more predictable biomechanical outcomes. It is assumed that this would thereafter link to more predictable clinical responses to APFO.

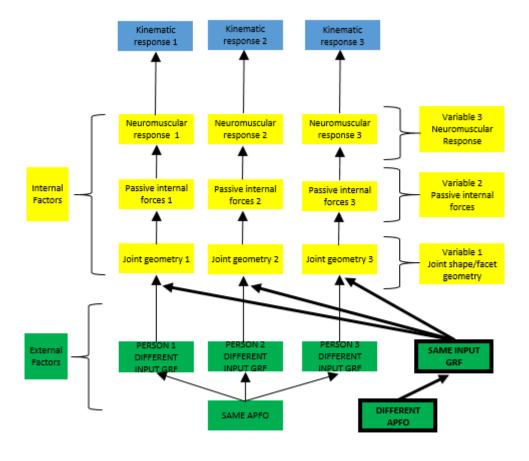


Figure 2.28 Theoretical basis for how factors interact to produce foot kinematics.

2.8.9 Mechanical System of APFO effect

A potential explanation of how APFO affect foot function is to compare its function to that of a mechanical system. A mechanical system has actuators that generate input force, a system of gears/levers that derive output forces to perform specific applications, and a control system that regulates both the input and output forces. Changes to the output force can be made by 1) altering the movement of the gears/levers while keeping that actuator input force constant, 2) altering the input force whilst keeping the gears/levers constant and 3) altering both actuator input force and the system of gears/levers. Systematically altering the actuator input force will cause proportional response changes to the output force because the relationship between input and output can be characterised.

We can apply similar principles to the proposed biomechanical model of foot function. The action of GRF under the plantar foot performs a similar function to that of the actuator in a mechanical system. As previously described, the magnitude and spatial orientation of the GRF

will vary with movement tasks and terrain, and APFO will strongly influence how the GRF is transferred to the plantar foot. The geometry of articular facets and constraining action of capsular soft tissues structures are akin to a system of gearwheels present in a mechanical system. However, unlike the geometry present in gears/levers that possess single centres of rotation, the geometry of articular facets in foot bones are non-uniform and have complex shapes thus possess multiple centres of rotation. Furthermore, external forces cause changes in the congruency of articulating surfaces thus alter joint centres of rotation. It follows that the central nervous system, with its associated neuromuscular action, acts in a similar manner to the control system found in the mechanical system where risk of undesired perturbations in biomechanical responses are adjusted via neuromuscular action. The primary features influencing kinematic output in a mechanical model are 1) the system of gearwheels formed by articular facets and other passive tissues and 2) force input to the gearwheels (caused by APFO), 3) response of the control system (neuromuscular response).

APFO affect forces at a number of different articular facets forming systems of gearwheels present in the foot. Medial wedge components apply load under the calcaneus and by altering external moments seek to alter osseous position of articulations forming the talocalcaneal joint, representing the rearfoot's system of gearwheels (Figure 2.29). The geometry forming the articular facets between the calcaneus and talus enables rotation and translation movements. Thus, applying a load medially increases external inversion moments at the rearfoot, inverts the calcaneus and causes the talus to evert thereby decreasing rearfoot eversion, which is similar to the output response in a mechanical system. However studies show inversion/eversion rotations can also occur at the talotibial joint (Arndt et al., 2007; Lundgren et al., 2008; Nester et al., 2007). Therefore, output responses (decrease in rearfoot eversion) may occur as a result of rotations from the talocalcaneal joint or talotibial joint, or through contributions from both joints.

The arch section in an APFO applies load through the midfoot system of gearwheels represented by the talonavicular and calcaneocuboid joints. The midfoot system of gearwheels primarily permit sagittal plane dorsiflexion/plantarflexion gliding rotations where an APFO seeks to resist dorsiflexion motion. The location of the apex present in the orthosis arch section will determine which gearwheel will be mostly affected.

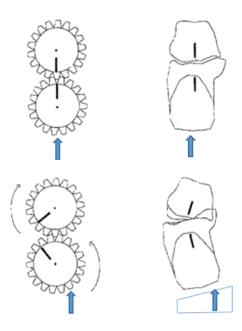


Figure 2.29 The system of gearwheels shown at the rearfoot forming the talocalcaneal joint. A medal (varus) wedge increases load under the medial calcaneus and thus causes calcaneal inversion and talar eversion, or ant-clockwise rotation for the lower gearwheel and clockwise rotation for the upper gearwheel, illustration taken from Nester (1998).

The rotations acting at the rearfoot and midfoot gearwheels are interdependent because the joints share the same bones. Motion at the talocalcaneal joint influences motion at the talonavicular joint and conversely talonavicular motion influences talocalcaneal motion. Consequently rotations between these gearwheels can be affected by fusing one of these joints (Huson, 2000). This has been considered a kinetic chain, and the function of the various joints are interdependent, since so many structures cross multiple foot joints simultaneously. Thus no joint or structure can move without affecting the loading and function of adjacent joints in some way. The associated coupling formed between joints within the foot can be characterised as similar to a system of gearwheels, although in reality the mechanical coupling between adjacent segments may not strictly be on a 1 to 1 ratio. For example, Dubbeldam (2012) investigated coupling relationships in foot and ankle structures in subjects during stance phase of gait and reported changes in rearfoot eversion/inversion motion explained 50 % the variance in forefoot abduction/adduction motion. This study also reported that changes in internal/external shank rotation explained 50 % the variance in midfoot dorsiflexion/plantarflexion. Duddledam (2012) demonstrated that coupling exists in foot/ankle segments, however the fact that motion in one segment could explain only 50 % motion in another, implies relationships are not on a 1 to 1 ratio. Pohl (2007) also reported low coupling between rearfoot frontal plane motion and shank transverse plane motion, although suggested the strength of coupling increased in running compared with walking. Joint coupling may also be different in different motion planes. Wolf (2008b) investigated kinematic coupling within bones forming the tarsus. They reported bones in the proximal medial longitudinal arch had similar frontal plane and transverse plane rotations, but differing sagittal plane rotations. Nonetheless in the context of mechanical coupling, an orthotic arch profile applying load under the midfoot gearwheel has the potential to influence the rearfoot gearwheel and likewise a medial wedged orthotic applying load under the rearfoot gearwheel has the potential to influence the midfoot gearwheel.

In addition to the curvature of articular facets, the action of ligaments influence rotations in both rearfoot and midfoot gearwheels. Ligaments modulate multiaxial movements and limit range of motion in foot joints. They possess two different strain behaviours that act to perform different roles. Firstly, a ligament can increase or decrease its length during a particular joint rotation, for example the tibiocalcaneal ligament increases in length with rearfoot eversion, thus its role can be described to limit motion (Luo et al., 1997). Secondly, a ligament can be isometrically strained. For example the anterior talofibular ligament isometrically strains with rearfoot inversion/eversion (Luo et al., 1997). Thus, in addition to the curvature of articular facets, the tension in surrounding ligaments influences a foot orthosis ability to alter the rearfoot and midfoot system of gearwheels.

In a purely mechanical system, systematically altering the input force should cause systematic and proportional changes to the kinematic outputs and the relationship between input and output is fixed. If the same principles apply to the action of APFO, then systematically increasing the external force (i.e. inputs) through the rearfoot gearwheels should cause systematic and proportional decreases in rearfoot eversion motion (i.e. outputs). If the mechanism is the same in different individuals (i.e. no variation in structures involved in the mechanism) then the same input forces should lead to the same output kinematics in all people. As we have seen, evidence from the literature suggests that this is not the case, implying that the structures involved in the mechanism, or the control of the structures, is not the same in all cases.

2.8.10 Using APFO to adjust input forces

APFO compress a variety of soft tissue structures situated on top of its surface. Medial wedging will compress soft tissues underneath the calcaneus. These tissues form the heel pad,

containing fat filled chambers and the mechanical properties of the heel pad will affect how GRF is transferred to the calcaneus. Ageing and diseases such as diabetes and rheumatoid arthritis will influence the capacity of the heel pad to absorb load (Hsu et al., 1998; Rome, 1998). The arch profile of an APFO will compress the network of muscles, ligaments and tendons forming the medial arch of the foot. For example, the abductor halluces muscle and flexor halluces longus tendon are located underneath the talo-navicular joint. The quadratus plantae muscle and plantar aponeurosis are located underneath the navicular-cuneiform joints. These soft tissue structures are designed either to passively constrain joint movement or to actively alter joint position following neuromuscular action. Soft tissue structures underneath the arch of the foot are not designed to be compressed and yet research indicates that APFO transfer load to these areas (Bus et al., 2004; Redmond et al., 2000). The mechanical properties of these soft tissues will influence how APFO applies load (alters input force) to the mechanical system thus affects joint moment and motion responses. Furthermore, differences in soft tissue compression may be a factor in explaining variability in the transfer of load measured at the skin surface of the orthosis to the underlying bones. However, quantifying soft tissue thickness through an APFO has not been previously attempted.

To improve the clinical prescription of APFO it is necessary to understand the effect of external forces on the mechanical system, and to understand factors that influences how these forces are transmitted to the foot's system of gearwheels thus affecting joint motion. If changes in external force input (plantar pressure), associated with systematic alteration of APFO design features, are measured, then it may be possible to quantify whether the same force input can elicit similar moment and motion responses across different individuals. Studies employing in-shoe pressure measurement confirm that medial wedging and arch profile affect input forces (Bonanno et al., 2012; Stolwijk et al., 2011; Telfer et al., 2013a; Van Gheluwe et al., 2004), however it is less clear to the extent in which changes in input forces caused by APFO are variable among individuals or indeed whether the force input can be systematically altered. If external force input causes systematic moment and motion responses within an individual then characterising the effect of APFO on foot structures using a mechanical based model proves correct. However, if there is no systematic relationship between changes in external force input and changes in moment and motion responses within an individual then the model is not truly mechanical and which would suggest it is influenced by other factors (neuromuscular). To examine the relationship between the kinematic response elicited following use of APFO, the force applied to the sole of the foot needs to be systematically altered while the resulting

kinematic patterns are measured. The relationship between these two for each individual person can then be compared. If, at the same time, joint moments are measured, then the role of moments in determining the kinematic response can be considered. Any variation between people in the kinematic response to an APFO not accounted for by changes in external load and joint moments (due to the APFO), would most likely reflect the neuromuscular contribution to determining foot kinematics.

2.9 Formulation of research strategy

Characterising how systematic adjustment of APFO geometry can alter the force input to the sole of the foot is a prerequisite for testing the concept of the mechanical model outlined above. If the external forces input can be characterised then it may be possible to characterise its relationship with moment and motion responses. Since the structural link between the external forces and joint moments/motion is the soft tissues through which the external forces must pass before reaching the joints, understanding how these respond to changes in APFO geometry is also relevant.

This PhD will therefore examine the relationship between changes in input forces applied to the sole of the foot due to APFO and changes in soft tissue behaviour and moment/motion responses in the foot.

2.9.1 Approach

Two studies are proposed to complete the PhD. Study 1 poses 3 research questions.

- 1) Can varying APFO geometry systematically alter external forces under the plantar foot?
- 2) Can varying APFO geometry systematically alter joint moment/motion responses in the foot?
- 3) Do systematic changes in external forces created by varying APFO geometry correlate to changes in joint moment/motion responses?

Table 2.1 outlines the research questions and corresponding hypotheses for study 1.

In addition, to explore the role of soft tissues in the relationship between external forces input to the foot and joint moments and motions, a second study addresses a further research question:

4) Can varying APFO geometry (in the heel and arch) systematically alter the thickness of soft tissues under the sole of the foot?

Table 2.2 outlines the research questions and corresponding hypothesis for study 2.

If external forces can be systematically altered with APFO, and a systematic relationship is present between changes in external force input and changes in joint moment/motion responses, then using a mechanical based model to describe the effects of APFO on moment and motion responses would be appropriate. However, if this proves not to be the case, and weak or no relationship exists between changes in external force input and joint moment/motion responses, then other factors are likely wholly or partly responsible for the changes in joint moment/motion responses (i.e. neuromuscular or structural features).

It is hoped that the work to be completed for this PhD will increase the understanding of how APFO change foot biomechanics. This PhD seeks to direct future studies that will explore the biomechanical effects of APFO thus assisting clinicians to tailor orthosis specifically to meet an individual's needs with respect to altering foot kinetics and kinematics.

Table 2.1 Research questions and corresponding hypotheses for study $1\,$

Research	Can varying APFO geometry systematically alter external forces under the plantar
Question 1	foot?
Hypothesis 1	Increases in orthotic arch geometry height will systematically increase peak pressure under the medial midfoot and systematically decrease peak pressure under the rearfoot.
Hypothesis 2	Increases in orthotic arch geometry height will systematically increase the medial displacement of the centre of pressure.
Hypothesis 3	Increases in medial heel wedge geometry will systematically increase peak pressure under the medial rearfoot.
Hypothesis 4	Increases in medial heel wedge geometry will systematically increase the medial displacement of the centre of pressure.

Research	Can varying APFO geometry systematically alter joint moment/motion responses?	
Question 2		
Hypothesis 1	Increases in orthotic arch height geometry will systematically decrease internal ankle	
	inversion moments/increase internal ankle eversion moment, systematically decrease	
	peak and range of rearfoot eversion and systematically decrease minimum midfoot	
	dorsiflexion.	
Hypothesis 2	Increases in medial heel wedge geometry will systematically decrease internal ankle	
	inversion moments/increase internal ankle eversion moment, systematically decrease	
	peak and range of rearfoot eversion and systematically decrease minimum midfoot	
	dorsiflexion.	

Research	Do systematic changes in external forces created by varying APFO geometry
Question 3	correlate to changes in joint moment/motion responses?
Hypothesis 1	Changes in medial rearfoot peak plantar pressure are strongly correlated with changes in frontal plane moments at the ankle joint
Hypothesis 2	Changes in medial midfoot peak plantar pressure are strongly correlated with changes in minimum midfoot dorsiflexion
Hypothesis 3	Changes in medial rearfoot peak plantar pressure are strongly correlated with changes in peak rearfoot eversion and peak rearfoot eversion range
Hypothesis 4	Changes in the medial displacement of the COP are strongly correlated with changes in frontal plane moments at the ankle joint
Hypothesis 5	Changes in the medial displacement of the COP are strongly correlated changes in peak rearfoot eversion and peak rearfoot eversion range

Table 2.2 Research question and corresponding hypotheses for study 2 $\,$

Research	Can varying APFO geometry systematically alter the thickness of soft tissues
Question 4	under the sole of the foot?
Hypothesis 1	Increases in arch geometry height will systematically decrease the tissue thickness of soft
Trypomesis 1	tissues under the medial arch
Hypothesis 2	Increases in medial heel wedge geometry will systematically decrease the thickness of
riypomesis 2	soft tissues under the calcaneus

Chapter 3 Method

This PhD involves two related studies. In Chapter 3 the methods relate to study 1. The aim of study 1 is to characterise the effect of altering APFO geometry on 1) external forces under the plantar foot, and on 2) joint moment/motion responses in foot structures. Finally, study 1 examines if changes in external forces created by systematically varying APFO geometry correlate to changes in joint moment/motion responses. It follows that plantar pressure data, kinematic data and joint moment data are required to be collected under various conditions whereby orthotic geometry is modified in specific ways.

3.1 Participants

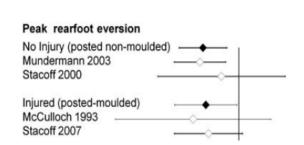
Prior to commencing data collection ethical approval was sought and granted from the University of Salford's Ethics Committee (HSCR12/57). Details of this application for ethical approval are shown in the appendices (1-4). 20 participants were recruited; mean age 33.7 years (SD 4.8 years), mean weight 71.6 (SD 12.4 kg) and height 1.71 m (SD 0.07 m). All participants were over 18yrs and self-reported no recent history of lower limb pathology or surgery.

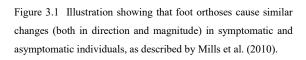
All participants recruited for this study were asymptomatic at the time of testing, meaning they had no low back pain or lower limb pain over the previous 6 months which caused them to seek medical intervention or modify their activity levels. It is hypothesised that individuals presenting with pain or systematic disorders have different gait patterns, and thus may respond differently to APFO. It follows that perhaps use of a symptom free population is not an appropriate basis for studying the effects of APFO. It is true that disease processes associated with diabetes, rheumatoid arthritis and others change foot tissues structure and function (Chao et al., 2011; Chatzistergos et al., 2014; Louwerens et al., 2013; Turner et al., 2006). However, some of these groups are unlikely to be targeted for use of antipronation devices, since the objective is accommodation of foot shape and pressure relief. Some sub groups would be a target for antipronation foot orthosis therapy, such as early rheumatoid arthritis, where preservation of foot shape and posture could be an objective. However, there is little compelling evidence that those who experience symptoms have feet that are fundamentally different from those who are asymptomatic. There is evidence of small differences in peak eversion or knee angles between those with and without musculoskeletal symptoms (Barton et

al., 2011; Chang et al., 2014), but the general direction and timing of the movement is very similar. Such is the similarity, it seems unlikely that the response to orthosis would be so dramatically different that the direction of changes in pressure, moments and kinematics observed in this thesis are incorrect.

Furthermore, meta-analysis of data from the literature characterising orthotic effect on foot kinematics showed that symptomatic and asymptomatic individuals experienced similar changes in foot kinematics (Mills et al., 2010) (Figure 3.1).

Participants were not selected based on their foot type and this too has been hypothesised to be associated with APFO effects. For example, it has been shown that compared to feet with normal alignment, in planus feet the cross sectional area in intrinsic foot muscles are smaller and the cross sectional area in extrinsic foot muscles are larger (Angin et al., 2014). Also, it has been reported that whilst the general pattern of movement is the same, cavus feet possess some aspects of foot kinematics that differ from normal and planus feet (Buldt et al., 2015). However, as is the case in the symptomatic vrs asymptomatic debate, it seems unlikely that differences in foot posture will cause dramatically different, or opposing, changes in pressure, moment and kinematic responses with APFO. Indeed this is supported by studies that reported increasing medial heel wedging in individuals with pronated and neutral foot types experienced similar direction of changes in pressure (Telfer et al., 2013a) and joint moments and motion responses (Telfer et al., 2013c) (Figure 3.2).





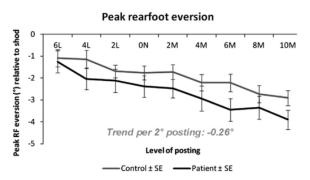


Figure 3.2 Illustration showing that incrementally altering the angle of extrinsic rearfoot wedging causes similar changes in peak rearfoot eversion in asymptomatic individuals with normally aligned foot types and in symptomatic individuals with pronated foot types, as described by (Telfer et al., 2013c).

3.2 Orthoses

A suitable APFO was required and prior research had proven an orthotic developed within the Salford research team to have anti pronation effects, namely reducing rearfoot eversion (Majumdar et al., 2013). However, this PhD required that the orthosis changed plantar pressure in systematic ways so that the effects of these systematic changes on soft tissue and moments and motion could be related to each other. A pilot study was therefore undertaken (n=11) to determine whether systematic changes to the geometry of the Salfordinsole® (Salfordinsole Health Care Ltd, UK) led to systematic changes in plantar pressure under the foot. The orthotic was also available in digital form and therefore changes in geometry could be made with high accuracy and repeatable across all foot sizes.

The Salfordinsole is a full length insole and a pre-fabricated version constructed from Shore A 75 material was chosen as the base APFO to be used in the pilot study (Figure 3.3). Orthoses of Shore A 75 are considered to be towards the hard end of the range used in clinical practice and therefore most likely to lead to changes in pressure under the foot. To characterise the effect of systematically changing orthosis geometry, 4° and 8° medial wedges were added beneath the heel (also made from shore A 75) and a 3mm arch pad was added to the medial arch section (shore A 65). Sizes 6-9 UK orthoses with these anti-pronation adaptions were constructed for both feet for participants in the pilot study. A total of 6 conditions were therefore tested including 3 heel conditions; flat inlay (baseline condition), 4° and 8° medial wedges, and 3 arch conditions; flat inlay (baseline), standard arch (i.e. unmodified Salfordinsole), and the Salfordinsole +3mm arch height added.

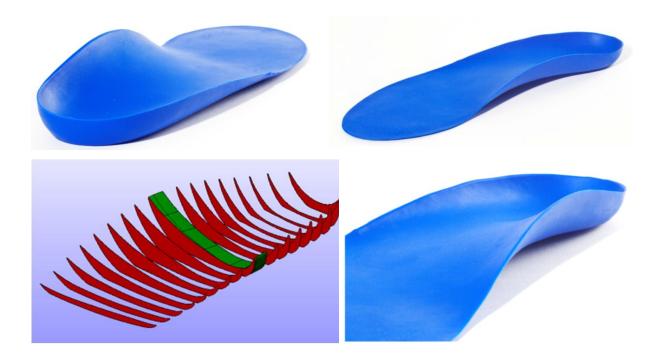


Figure 3.3 Illustration showing geometry of the Salfordinsole

Participants for the pilot study were instructed to wear trainers with standard designs (heel heights, depths etc.) that would accommodate the orthotic conditions. In-shoe pressure measurement (Medilogic® T&T Medilogic, Berlin, Germany) quantified the effect of the orthotic conditions on plantar pressure (sampled at 60 Hz) whilst subjects walked at controlled but self-selected speeds. Pressure data were collected for twenty continuous steps for each condition, and to avoid order effects, the sequence of the testing conditions was randomised.

Pressure data were analysed using a programme written in Matlab® (Mathworks, Massachusetts, USA) which masked the foot into medial heel and arch segments, since these were the areas where orthotic geometry had changed. This was similar to the mask developed by Cavanagh et al. (1994) (section 3.4.1). Peak pressure was chosen as the outcome measure because it has been extensively used to characterise how foot orthoses alters load under the foot (Bonanno et al., 2011; Bus et al., 2004; McCormick et al., 2013).

Repeated measures ANOVA testing (SPSS v.10) (repeated measures factors and levels shown in Figure 3.4) confirmed that medial wedges significantly altered peak pressure under the medial heel (F $_{(2,20)}$ = 45.2, p < 0.001) and the arch heights significantly altered peak pressure under the medial midfoot (F $_{(1.2,11.6)}$ * = 166.5, p < 0.001); *Mauchlys' test of sphericity

indicated that the assumption of sphericity had been violated for the medial midfoot pressure data, $x^2(2) = 11.7$, p = .007, therefore the degrees of freedom were adjusted with a Greenhouse-Geisser correction. Bonferroni post hoc testing showed the 4 ° and 8 ° wedges significantly decreased peak pressure by 15 % and 12.8 % (p < 0.05) respectively compared to the flat inlay, and the standard and +3mm arch heights significantly increased peak pressure by 43.8 % and 51.4 % (p < 0.05) respectively compared to flat inlay.

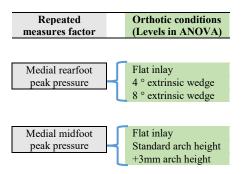


Figure 3.4 Illustration showing the repeated measures factors associated with each of the ANOVA's undertaken for the pilot study

The pilot showed 4° and 8° extrinsic medial wedges significantly altered external forces under the medial rearfoot relative to the baseline condition. This is evidence that external forces and the distribution of these forces under the foot, can be manipulated by changing orthotic geometry. It follows that this is a suitable basis for investigating how these changes in pressure may relate to changes in joint moments and motions. These increments in medial wedges were therefore selected for the main study.

Whilst not tested in the pilot study, in the main study, these extrinsic wedges were compared to intrinsic medial wedges (or Kirby skive). This is an orthosis modification used by the SALRE model of foot function (Kirby, 1992), used previous studies (Bonanno et al., 2012), and used in clinical practice. To maintain the clinical relevance of the orthotic designs tested, 4mm and 8mm intrinsic medial wedges were therefore also used. Thus, in the main study, 5 heel orthotic conditions were used to characterise the effect of altering the geometry of the medial heel in an APFO on the external forces and subsequent moment and motion responses of the foot. These conditions were; a standard orthotic with neutral wedge (i.e. 0°), 4° and 8° extrinsic wedges, and 4mm and 8mm intrinsic wedges.

The pilot study showed that the standard and +3mm arch heights significantly increased plantar pressure under the medial longitudinal arch relative to the baseline condition. To increase the

range in arch heights, the standard arch, and arch heights that were 6mm less and 6mm greater than the standard arch height were chosen for the main study.

Orthoses were fabricated from high density EVA (Shore 65) with the aid of CADCAM to accurately define the orthosis geometry (Figure 3.5). A flat inlay (3mm insole made from a very compliant material, PPT) which had no heel or arch geometry, formed a baseline condition. This occupied approximately the same volume of space in the shoe as the other orthoses under the forefoot area. This approach sought to isolate the heel and arch geometries as the independent variables investigated. All other orthoses conditions were compared to this baseline. Thus, a total of 8 conditions were used for the main study.

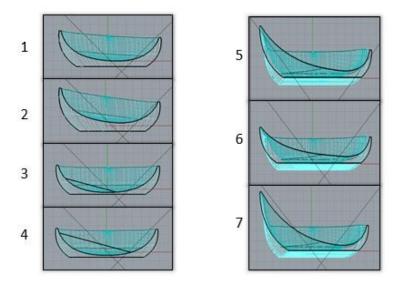


Figure 3.5 Orthotic conditions. 1-2 are 4° and 8° extrinsic medial wedges (wedges under the orthosis), 3-4 are 4mm and 8mm intrinsic medial wedges (wedges inside the heel cup). 5 is standard arch profile, 6 is -6mm arch height, and condition 7 is +6mm arch height. A 3mm PPT flat inlay condition formed the baseline.

3.3 Protocol

3.3.1 Plantar pressure data collection

For the main study Novel Pedar-X system was used to collect in-shoe plantar pressure. Other studies have used the Pedar system when quantifying the effects of orthoses on plantar pressure (Bonanno et al., 2012; Bus et al., 2004; Redmond et al., 2009) and it has been proven to be repeatable and reliable (Ramanathan et al., 2010). As per the manufacturer's recommendation, the pressure measuring insoles were calibrated prior to data collection for the study, which improves the accuracy of the pressure measurement system (Hsiao et al., 2002). The Pedar system quantified the effect of the orthotic conditions while subjects walked. Data were collected from the right foot.

3.3.2 Motion analysis

A twelve infra-red OQUS system (Qualysis system, Qualsys, Gothenburg, Sweden) with passive reflective markers was used to collect three dimensional foot/ankle kinematic data from each participants right foot. Qualisys Track Manager (QTM) software was used for data collection and digitisation. The primary phases involved when conducting three dimensional motion analysis are; 1) camera configuration & setup, 2) data collection, and 3) data analysis (Richards 2008).

3.3.3 Camera configuration & setup

The gait laboratory used to conduct the data collection is purpose built in design. Motion analysis cameras are permanently wall mounted thus allow quick set up and calibration (vrs time required to manually set up and calibrate non-permanent cameras). During data collection the orientation of the cameras were checked to ensure all reflective markers could be viewed over the force plates. Four AMTI force plates each measuring 400mm x 600mm were positioned in the centre of laboratory. For this study two force plates captured two consecutive stance phase events for each subject's right foot. The cameras were orientated to ensure all self-reflective markers were viewed over the capture space. Figure 3.6 shows the orientation of cameras and position of force plates.

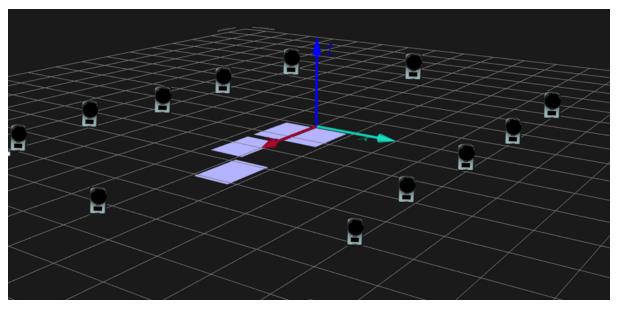


Figure 3.6 Illustration showing gait analysis laboratory setup with orientation of force platforms and position of motion capture cameras.

3.3.4 Calibrating the image capture space

To derive three-dimensional coordinates from the two-dimensional coordinates provided by each camera, a global or laboratory reference system must first be created. This involves calibrating the motion capture system to the position and orientation a known plane of reference. An "L" shaped calibration frame with four retro-reflective markers attached was positioned at the border of the force plate. The calibration frame was orientated so the apex of the frame was positioned at the corner of the force plate thus defining the origin of the global coordinate system (0, 0, 0 for X, Y and Z axis). A "T" shaped wand with retro-reflective markers was moved for a 30 second period within the measurement capture space (a process referred to as dynamic calibration). The distance between the two reflective markers on the wand is derived and compared to the known distance between the markers through a procedure known as bundle adjustment (Richards, 2008). The manner by which the cameras estimate the coordinates for each marker is associated with residual error. Following this dynamic calibration the Qualysis system calculated the mean residual error, which is the mean error from all cameras. To be deemed successful, the manufacturer recommends that residual error should be less than 2mm, however for the current study the mean residuals for all calibrations were less than 1mm. A QTM programme reconstructed two dimensional images from retroreflective makers captured by each camera into 3 dimensional coordinates. To create 3D coordinates a minimum of two cameras must provide a set of 2D coordinates for a single marker. This process happens for each time frame following which the trajectory of the marker is defined. The trajectories for the markers can subsequently be used for kinematic analysis.

3.3.5 Force plates

To quantify joint moments, and also to determine the timing of gait events (initial contact & toe off), two AMTI force plates (Type: BP400600, dimensions: 600mm x 400mm) were used to record GRF data throughout this study. These force plates generate data from piezoelectric crystals positioned in pylons at each corner, that when loaded produce 8 channels of voltage output. To eliminate signal drift, a problem associated with piezoelectric force platforms, the platforms were reset before each trial. The voltage output is used to calculate force data (N).

3.3.6 Marker placement and kinematic foot model

This study quantified motion in foot structures using the Calibrated Anatomical System Technique (CAST) developed by Cappozzo et al., (1995). CAST creates an anatomically relevant reference frame for limb segments by placing reflective markers on externally identifiable anatomical landmarks that provide an external reference for the orientation of the internal bones. These anatomical markers are also used either sides of joints to allow the centre of articulating joints to be defined. The joint centres and external landmarks markers can be used to derive a co-ordinate reference frame that is well aligned to the three body planes of the limb segment. CAST also uses tracking markers, which unlike the anatomical markers, remain in place during the movement being studied. These markers track the movement of the rigid segments of interest but the co-ordinate frames defined from tracking markers have little anatomical relevance. Therefore, the motion captured by the tracking markers has to be projected into the anatomical planes defined by the anatomical markers. This generates data describing joint angular motion in cardinal body planes that are aligned to the proximal segment of the joint being studied (e.g. of the femur and thigh for knee angles).

Kinematic data were required for the leg, heel and midfoot whilst participants wore shoes. Anatomical markers to allow definition of an anatomically relevant shank co-ordinate reference frame were positioned at the medial and lateral knee condyles and malleoli. Anatomical markers for the foot were attached to the shoe at locations relative to the posterior heel, 1st and 5th metatarsal heads, and second toe. Dynamic tracking markers attached to rigid plates were positioned at the shank, calcaneus and midfoot. The tracking marker for the shank had four retroreflective markers attached to a rigid plate positioned laterally on the leg, whilst the tracking marker for the midfoot had three retroreflective markers attached to a rigid plate positioned over the midtarsal joint. The tracking marker for the rearfoot consisted of a triad of

retroreflective markers attached to a small spherical plate positioned at the lateral aspect of the calcaneus. This plastic plate allowed the triad at the heel to be removed and reapplied between the different conditions and ensured the alignment of the markers was kept consistent throughout the testing. The footwear used throughout the testing had an aperture positioned in the lateral heel counter for the tracking of the dynamic rearfoot marker. Figure 3.7 shows the marker placement used throughout the testing.







Figure 3.7 Location of anatomical markers; posterior heel, 1st & 5th metatarsal heads, 2nd toe, medial and lateral knee condyles and malleoli, and tracking markers; shank, calcaneus and midfoot.

Rigid plates were chosen to define foot segments of interest because previous research has shown they provide a truer reflection of underlying kinematics compared to using individual markers attached to the skin surface (Nester et al., 2007). This is especially true when characterising segments incorporating multiple articulations. A rigid segment containing two articulations may violate the rigid segment assumption if using skin mounted markers because the markers may move relative to one another (relative error), which means the segment is technically not rigid. Furthermore, rigid plates have been shown to decrease soft tissue

artefacts, which are cited as the primary cause of error when measuring kinematics with skin mounted retro-reflective markers (Leardini et al., 2005; Reinschmidt et al., 1997).

Studies quantifying foot kinematics use different rigid segments or "foot models". Some basic models model the foot as a single rigid segment (rearfoot) (Branthwaite et al., 2004; Pascual Huerta et al., 2009), others studies model the foot as two (rearfoot & forefoot) (Hunt et al., 2001; Rattanaprasert et al., 1999) or three (rearfoot, midfoot & forefoot) (Leardini et al., 2007) rigid segments. MacWilliams et al. (2003) used an 8 rigid segment foot model (hallux, medial/lateral toes, medial/lateral forefoot, calcaneus, cuboid, & talus/navicular/cuneiform). It is obvious that the foot should not be modelled as a single segment because there are many articulating joints within the foot and this contravenes the rigid body assumption. However, not every foot joint can be represented in a model, not least because it would involve too many markers on the foot, which would be difficult to track during complex movements such as walking. Also, it is not clear that even if the motion was tracked the data would truly represent the movement of the underlying bones. Instead, as a compromise, the foot is partitioned into different functional units and the kinematics of these units used to represent the most important articulations in the foot. This allows articulations that make considerable contribution to foot kinematics to be represented, especially those present at the midfoot and forefoot (Lundgren et al., 2008; Nester et al., 2006), but makes data collection practical in terms of the number of markers required. Furthermore, several bones move broadly in unison and might be considered to be close to "rigid". Talonavicular and calcaneocuboid joint kinematics are closely correlated for example (Vogler et al., 2000; Wolf et al., 2008). To a lesser extent talocalcaneal and talotibial joint kinematics have also been described as correlated since they share a common bone (Wolf et al., 2008). It follows articulations with similar kinematic pathways residing in close proximity could be modelled as a rigid segments. Or, at least, if for practical reasons (e.g. avoiding too many markers on the foot), the number of segments has to be limited, it seems logical that these could be reasonably combined into single segments. For this study, and since participants would wear shoes and therefore cover many logical marker locations, a two segment model was used to characterise the effect of APFO on rearfoot and midfoot kinematics. This two segment foot model was based on a four segment foot model previously reported by Nester et al. (2007) and has been used in studies characterising foot/ankle kinematics (Buldt et al., 2015a; Buldt et al., 2015b; Nester et al., 2014). It has been validated in terms of being an effective means of fulfilling the rigid body assumptions compared with other foot models (Nester et al., 2010). Although the repeatability of this specific model has

not been established, other models involving more complex segments and the same or similar landmarks for marker location have shown to be repeatable (between trial, day and assessor) (Caravaggi et al., 2011; Deschamps et al., 2011; Leardini et al., 2007; Seo et al., 2014; Stebbins et al., 2006). It follows that the 2 segment foot model used by the current study should offer similar and acceptable repeatability.

3.3.7 **Data collection protocol**

During data collection participants were shorts to facilitate marker placement. To prevent the markers from moving or falling off during testing a medical adhesive spray was applied to the skins surface, following which the markers were subsequently secured to the skins surface with double sided sticky tape. Kinesiotherapy tape applied over the rigid plates further secured the dynamic markers. All retro-reflective markers measured 9mm in diameter.

With all markers in place a static calibration trial was collected for each subject for the shoe only & flat inlay condition. During this trial subjects were asked to stand in relaxed calcaneal standing position (RCSP) on the force plate, and this was used later to define 0 ° of rotation for the shod with flat inlay condition. Before dynamic data collection (i.e. walking) subjects were afforded a 2-4 minute period to become accustomed to walking in each of the orthotic conditions, the order of which was randomised.

A Brower TC (Utah, USA) timing system ensured participants walked within \pm 5 % of predetermined self-selected speeds within a 10m walkway and trials outside these limits were rejected. Furthermore, trials where participants visibly targeted the force plate were also rejected. The force plates are orientated within the walkway in such a way as to enable two consecutive stance phase contacts of the right foot to be recorded. A total of 10 walking trials for each condition were recorded during which in-shoe pressure measurement simultaneously captured 40-50 steps. Kinematic, GRF and pressure data were therefore all collected simultaneously and at 100Hz, 3000Hz and 50 Hz respectively.

3.4 Data Analysis

3.4.1 Pressure

A bespoke Matlab programme was used to process the plantar pressure data. This programme was provided by the University of Salford and is specifically tailored to processing plantar pressure data. It has been used in studies characterising plantar pressure (Chapman et al., 2013; Melvin et al., 2014). Pressure data collected from Pedar was exported in ascii file format and then processed with the assistance of the Matlab programme. The programme plots mean pressure over the entire insole and defines heel strike and toe off gait events using a threshold setting. These defined gait events are converted to a matfile where the regions of interest under the foot can be masked to calculate required pressure parameters for each region.

To quantify the effect of the orthotic conditions on plantar pressure under the foot, the pressure measurement insole was masked into 4 regions of interest; medial/lateral rearfoot, and medial/lateral midfoot (Figure 3.8). These correspond to the areas of the orthosis that were varied. The rearfoot and midfoot boundaries were defined by 73 % and 45 % of the foot length from the toes to the heel respectively. The medial and lateral rearfoot and midfoot sections were then divided by a longitudinal foot axis extending from the centre of the heel to the centre of the forefoot. The mask employed was similar to the mask described by Cavanagh and Ulbrecht (1994). Peak plantar pressure is the parameter most commonly reported by studies quantifying the effect of orthoses on plantar pressure (Bonanno et al., 2011; Bus et al., 2004; McCormick et al., 2013). It is also strongly correlated with mean and impulse plantar pressure parameters (Che et al., 1994; Keijsers et al., 2010), thus the effect of AFPO geometry on peak plantar pressure under both the medial/lateral rearfoot and midfoot were selected as the outcome measures. Mean peak plantar pressure data for each of the 4 regions of interest under the foot were calculated by averaging the peak plantar pressure data for each region across the 20 steps recorded. This was done for every orthotic condition, to produce 1 peak pressure value for each of the 4 regions of interest in each of the 8 orthotic conditions, i.e. 32 data values for each participant.



Figure 3.8 Mask used throughout the testing.

The centre of pressure (COP) position is defined by the average location of all the forces acting between the plantar surface of the foot and the shoe during stance phase (Richards, 2008). Anti-pronation foot orthoses are purported to shift the position of the COP medially to the subtalar joint axis thus increases net external supination moments (Fuller, 1999). Increasing net external supination moments is thought to decrease stress experienced in internal structures that apply supination moments. These could be soft tissues (e.g. tibialis posterior tendon) and bony structures (e.g. sinus tarsi) that act to resist foot excessive foot pronation. For this reason the effect of APFO geometry on COP displacement was also chosen as an outcome measure.

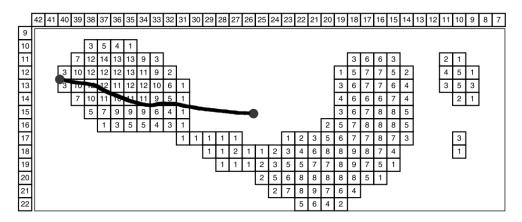


Figure 3.9 Schematic showing the position of the centre of pressure at midstance phase of gait (Fuller 1999).

The COP under the plantar foot was calculated using data from Pedar in-shoe pressure measurement system. A coordinate system for each size of Pedar insoles was formed by defining the most medial and posterior sensors as the origin (0, 0) of an X-Y coordinate system (Figure 3.10). All X and Y coordinates were normalised to the maximum width and length of

the insole respectively. Each location of pressure (for each sensor) is assigned an (X, Y) coordinate. The pressure is multiplied by its X direction coordinate and Y direction coordinate to create pressure times distance values. These values are then added and the result is divided by the sum of the pressure values to yield an X-Y COP coordinate, Figure 3.11 shows a worked example.

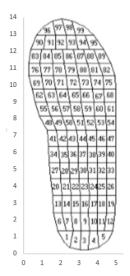


Figure 3.10 Coordinate system for pedar insole (right side) used to calculate the position of the centre of pressure.

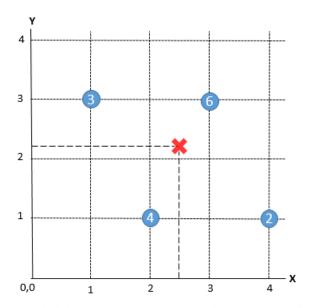


Figure 3.11 Illustration showing COP calculation. Sensors measure pressure values in 4 X-Y coordinates; 3kPa at (1,3), 4kPa at (2,1), 6kPa at (3,3) and 2kPa at (4,1). Adding the pressure values for the four points gives 15kPa. For each location of pressure, the pressure value is multiplied by its X direction coordinates and the result is then summed; [(3x1) + (4x2) + (3x6) + 4x2)] = 37, and similar computation is undertaken for the Y direction coordinates; [(3x3) + (4x1) + (6x3) + (2x1)] = 33, thus creating a pressure times distance X and Y value. These values are then divided by the sum of the pressure values (15kPa) to offer the location (X-Y coordinate) of the COP. In the illustration above the coordinates of the COP are (2.5, 2.2).

Mean COP values were calculated by averaging COP at each percentage during stance over 20 steps. The COP data were subsequently divided into 3 phases including; loading response (0-10 %), midstance (10-30 %), and terminal stance (30-50 %) (Figure 3.12). Mean COP values for each of the three periods in stance were derived for each orthotic condition for each subject. The loading response, midstance and terminal stance phases in gait are periods during stance defined by Ranchos Los Amigos Gait Analysis Committee (Perry, 1992) and represent periods in stance when antipronation medial wedge and arch components contacts the plantar surface of the foot thus influences the COP.

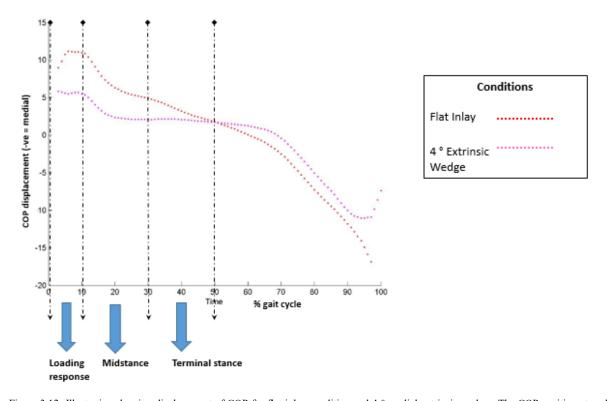


Figure 3.12 Illustration showing displacement of COP for flat inlay condition and 4 ° medial extrinsic wedge. The COP position at each percentage in stance phase was recorded and used to form a mean COP value for periods during loading response (0-10%) midstance (10-30%) and terminal stance (30-50%).

3.5 Kinematic & kinetic data analysis

Kinematic data digitisation assigns 3D co-ordinates to the markers observed in the camera system for each frame of data and allows creation of continuous kinematic data for each tracking marker. Kinematic modelling allows the individual tracking marker data to be used with anatomical marker data to define local co-ordinate frames for the shank, heel and midfoot segments, and then derive angular rotations between the segments.

3.5.1 Digitisation of kinematic data

Qualisys Track Manager (QTM) was used to digitise the kinematic data. The length of each walking trial was reduced to a minimum of 10 frames before the first heel contact at the force plate and ten frames after the second heel strike. Trials where the foot did not properly contact the force plate, or where markers were missing were discarded. From the 10 walking trials recorded for each condition, a minimum of 5 were digitised. To digitise the data an Automatic Identification of Markers model (AIM model) was applied to each walking trial for the same subject. This automated process is an efficient technique for labelling markers used for large data sets compared to manually labelling markers. All trials were inspected to ensure the makers were correctly labelled. In the event of any missing marker data QTM gap filled using spline interpolation technique thus estimating the position of the marker up to a maximum of 10 frames, a recommended default value set by Qualisys (QTM user manual 2011). For the trials selected for analysis, the markers were rarely lost and if so for a period that did not exceed 5-6 frames.

All digitised static and dynamic trials were subsequently exported as C3D files from QTM for model building.

3.5.2 Kinematic and kinetic model

Visual 3D (C-Motion, Rochelle, USA) was used to calculate the three dimensional joint moment and motion data. This software is commonly used in studies quantifying the biomechanical effects of foot orthosis (Hsu et al., 2014; Liu et al., 2012; Majumdar et al., 2013; Telfer et al., 2013c). The C3D files exported by QTM were imported into Visual 3D for processing, which involves: 1) creation of a model and segment definition, 2) signal processing, 3) definition of gait events, 4) Creation of inter-segmental angles and 5) exportation of data from Visual 3D.

3.5.2.1 Creation of a model and segment definition

The modelling used for this study followed the principles outlined by the CAST technique. CAST assumes that segments defined are rigid and have six degrees of freedom including; medio-lateral, anterior-posterior and vertical translations, and sagittal, coronal and transverse rotations. A three segment six degrees of freedom model quantified the effects of APFO on

rearfoot (heel versus shank) and midfoot (midfoot versus heel) kinematics. Changes in rearfoot kinematics were characterised relative to the local coordinate system defined for the shank. The reference frame for the heel, onto which midfoot kinematics were calculated, was set relative to the coordinate system defined for the shank. The vertical (z) axis of the local shank frame was defined using the knee and ankle centres formed by midpoints between femoral condyles and malleoli respectively. The anterior-posterior (y) shank axis was perpendicular to a plane defined by the femoral condyle and malleoli markers. The medio-lateral (x) axis was perpendicular to the other y and z shank axes. The z axis was the axis around which transverse plane motion was calculated. The y axis represented the axis around which frontal plane motion occurred and the x axis represented sagittal plane motion. Tracking markers attached to a rigid plate quantified motion at the shank during walking trials. The triad of tracking markers attached to the calcaneus, and the tracking markers attached to the rigid midfoot plate quantified kinematics at the rearfoot and midfoot respectively. The tracking markers at the shank, heel and midfoot defined the local coordinate frames for each rigid segment such that in relaxed standing trial the x (anterior/posterior), y (medial/lateral), and z (transverse) were parallel to those of the global reference plane. The local coordinate system for the foot and the tracking markers at the heel were used to characterise the effect of APFO on internal moments at the ankle joint.

3.5.2.2 Definition of zero (0°) reference system

In visual 3D, a static calibration file was created for each subject from the shod with flat inlay condition. This determined the zero reference position of the model. Movement at the rearfoot/midfoot segments were described relative to this position. Static calibration files for each subject were assigned to walking trials across all conditions so that 0 ° always represented the position of the joint in relaxed standing.

3.5.2.3 Signal processing

Bi-directional Butterworth Lowpass filters with a cut off frequencies of 6Hz and 25 Hz was used to smooth kinematic and force plate data respectively. Lowpass filters allow low frequency data through but not high frequency therefore reduces noise associated with skin movement artefact (Richards, 2008).

3.5.2.4 Definition of gait events in Visual 3D

The force plates were used to determine stance phase gait events. The timing of heel strike and toe off was set at a threshold of 10N.

3.5.2.5 Calculation of inter-segmental angles and joint moments

Two intersegmental joint angles were chosen to quantify the effect of APFO on motion in foot structures. Firstly, the angle formed between the calcaneus and shank was chosen to characterise the effects of AFPO on combined subtalar joint and talocrural joint (rearfoot motion). Secondly the angle formed between the midfoot and calcaneus was chosen to characterise the effects of APFO on midtarsal joint motion. Both the shank and calcaneus can be described as reference segments for rearfoot and midfoot motions respectively.

The reference segment used to calculate the ankle joint moment was formed by the local coordinate system defined for the foot and internal joint moments were calculated about the ankle joint centre (midpoint between both malleoli, defined by anatomical markers). Joint moment data were normalised to body mass (Nm/kg). A cardan sequence of x-y-z was chosen to describe the orientation of rotation for this study where x, y and z reference sagittal (flexion/extension), frontal (inversion/eversion) and transverse (internal/external) plane joint moments/motions. Intersegmental angles characterising motion of the midfoot relative to rearfoot, and rearfoot relative to the shank were described with positive angles signifying dorsiflexion, inversion and abduction, and negative angles signify plantarflexion, eversion and adduction. Figure 3.13 shows the group mean stance phase sagittal plane angular displacement of the midfoot relative to the calcaneus for the baseline condition and the different orthotic arch height conditions. Figure 3.14 shows the group mean stance phase frontal plane angular displacement of the calcaneus relative to the shank for the baseline condition and the different rearfoot orthotic conditions.

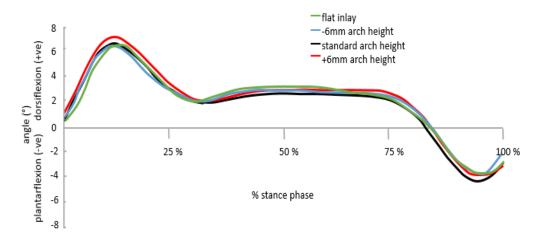


Figure 3.13 Group mean sagittal plane angular displacement of the midfoot relative to the rearfoot for the baseline and orthotic arch height conditions.

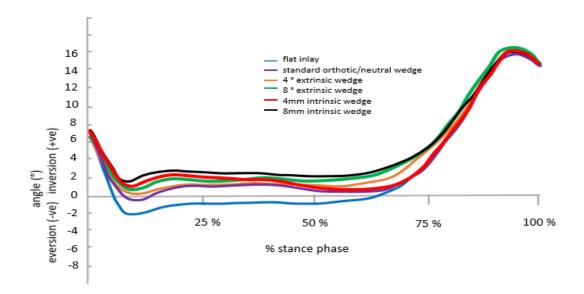


Figure 3.14 Group mean frontal plane angular displacement of the calcaneus relative to the shank for the baseline and orthotic rearfoot conditions.

A number of variables of interest were chosen to characterise the effect of APFO on foot kinematics and kinetics (Table 3.1). The kinematic variables included; peak rearfoot eversion, peak rearfoot eversion range, and minimum midfoot dorsiflexion (Figure 3.15 & Figure 3.16). The kinetic variables included; 1st and 2nd peak maximum ankle inversion moments and minimum ankle inversion moment (Figure 3.17). The kinematic and kinetic variables were chosen to answer the proposed hypotheses. Laboratory based studies report APFO significantly affect these moment (Stacoff et al., 2007; Telfer et al., 2013c), motion

(Branthwaite et al., 2004; Majumdar et al., 2013) and range (Novick et al., 1990; Zifchock et al., 2008) variables of interest. From the 5 trials used for each condition, for each of these trials the variables of interest relating to the hypotheses (shown in Figures 3.15 to 3.17) were extracted. A mean value for each variable was derived as the mean of the variables from across the 5 trials. This process was repeated for all orthotic conditions for each subject. A Matlab R2009b (Mathworks) programme was used to extract the variables of interest from Visual 3D. Parameters stored in Matfiles were exported to Microsoft Excel for subsequent data analysis and presentation.

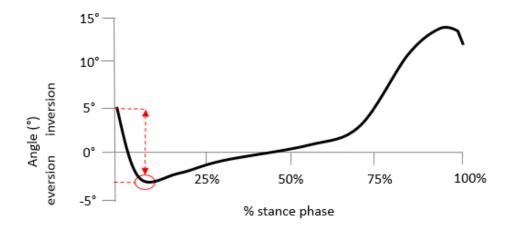


Figure 3.15 Frontal plane motion of the rearfoot relative to the shank during stance phase. The graph shows two variables of interest: the red circle shows peak eversion, the red arrow shows peak eversion range (range of motion between initial contact and peak eversion).

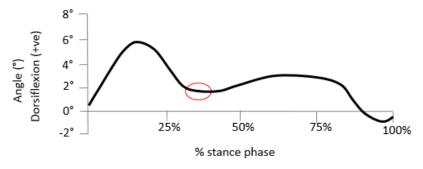


Figure 3.16 Sagittal plane motion of the midfoot relative to the rearfoot during stance phase. The red circle identifies the point of minimum midfoot dorsiflexion during midstance.

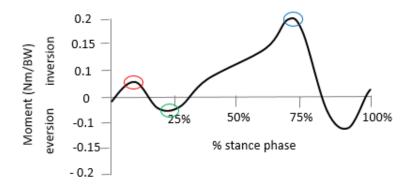


Figure 3.17 Internal inversion/eversion moment at the ankle joint during stance phase. The red and blue circles show 1^{st} and 2^{nd} peak of maximum inversion moment. The green circle identifies the trough showing the point of maximum ankle eversion moment.

Table 3.1 Variables of interest for study 1

Internal joint moment	
MaxAnkINm	Maximum ankle inversion moment (1st peak)
Max2AnkINm	Maximum ankle inversion moment (2 nd peak)
MaxAnkEVm	Maximum ankle eversion moment
Kinematics	
PRE	Peak rearfoot eversion
PRER	Peak rearfoot eversion range
MMP	Minimum midfoot dorsiflexion
Pressure	
MMPP	Medial midfoot peak pressure
LMPP	Lateral midfoot peak pressure
MRPP	Medial rearfoot peak pressure
LRPP	Lateral rearfoot peak pressure
Centre of pressure	
COPLR	Centre of pressure - loading response
COPMS	Centre of pressure - midstance
COPTS	Centre of pressure - terminal stance

3.6 Statistical analysis

All statistical analysis was performed using SPSS version 20. Prior to the statistical analysis, a Shapiro-Wilk's test (p >.05) (Shapiro & Wilk, 1965; Razali & Wah 2011) and a visual inspection of their histograms, normal Q-Q plots and box plots, showed the data were normally distributed across all conditions. This confirms the suitability of parametric analysis. All statistical calculations were completed using SPSS version 20 (SPSS Inc Chicago Illinois, USA).

A number of statistical approaches were used to answer the research questions. In all cases, effects were described as statistically significant if p < 0.05 with Bonferroni correction applied to examine significant main pairwise effects. A Bonferroni correction is used to reduce the chances of obtaining false positive results (type 1 error) and is made by dividing the p value by the number of comparisons being made.

Firstly, to answer research question 1, a repeated measures ANOVA quantified the main effects of altering APFO geometry on peak pressure under the different regions of the foot and on COP during the three defined stance phases in gait. Secondly, and for research question 2, a separate repeated measures ANOVA quantified the main effects of altering APFO geometry on internal ankle inversion/eversion joint moments, peak rearfoot eversion/eversion range, and minimum midfoot dorsiflexion. Finally, for research question 3, Pearson product moment correlation coefficients were used to characterise any relationship between changes in external force under the plantar foot (plantar pressure data) and changes in foot kinematics and kinetics. Under the premise that systematic changes to external forces under the medial aspect of the plantar foot systematically alter joint moments and kinematics, the extrinsic/intrinsic medial heel wedges that caused significant changes to external forces under the medial rearfoot, and orthotic arch heights that causes significant changes to external forces under the medial midfoot, were the primary conditions of interest used in the correlation analysis, since significant effects are a prerequisite for a corresponding change in the other data. However, it is also plausible that non-significant changes in external forces under the medial foot may systematically alter joint moments and kinematics. Thus to be comprehensive, non-significant changes in external forces under the medial rearfoot and midfoot, caused by the medial wedges and orthotic arch heights respectively, were also included in the correlation analysis.

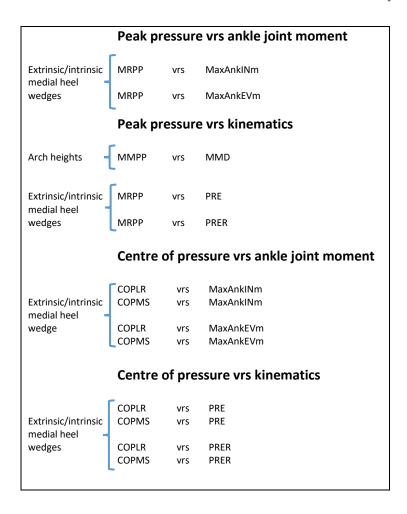
The correlation analysis involved orthotic conditions that were anatomically aligned in terms of the location of pressure/COP changes and temporally aligned in terms of joint moment/motion responses. For example, plantar pressure changes under the *midfoot*, caused by the orthotic *arch* heights, were correlated with *midfoot* kinematics whilst plantar pressure changes under the *rearfoot*, caused by the extrinsic/intrinsic *heel* medial wedges, were correlated with *rearfoot* moments and kinematics. COP changes occurring during loading response and midstance, caused by the extrinsic/intrinsic medial heel wedges, were correlated with rearfoot moments and kinematics.

For the correlation analysis, the pressure data and moment/motion data were derived from participant average data because using individual trial data (pressure and moment/motion data) from the same steps would provide too few pressure data. Furthermore, absolute values for pressure, motion and moment data were converted into relative change between orthotic conditions for each subject. Values for the arch conditions (-6mm, standard, +6mm) and wedge condition (4°, 8°, 4mm, 8mm) were subtracted from the values for the flat inlay condition. To characterise the effects of the different wedge geometry (whilst keeping arch height constant), data for the wedge conditions were subtracted from the standard orthotic (with neutral wedge) condition. Thus, the correlation analysis was of the change in pressure versus change in joint moments, and change in pressure versus change in kinematics. Direct measures of absolute values were not used in the correlation analysis because the hypotheses proposed by the research question sought to characterise the relationships between changes in external forces and changes in biomechanical responses.

Table 3.2 shows the variables of interest used in the correlation analysis. These variables were selected because they most closely match the hypothesised effect of the orthotic condition on load under the plantar foot (measured as pressure and COP) with corresponding change in joint moment/motion response. Incorporating other data into the correlation analysis may increase the likelihood of a type 1 error (false positive).

Correlations from 0.0 to 0.3 were considered weak, between 0.3 and 0.6 were considered moderate, between 0.6 and 0.8 were considered strong and above 0.8 was considered very strong. These correlation coefficients have been used previously in studies involving lower limb biomechanics (Billis et al., 2007; Chuter, 2010).

Table 3.2 Variables of interest and associated orthotic conditions used in correlation analysis



Chapter 4 Research Question 1: Can varying APFO geometry systematically alter external forces under the plantar foot?

4.1 Hypotheses

A number of hypotheses outlined in Chapter 2 were proposed to answer research question 1.

4.2 Hypotheses – antipronation orthosis arch geometry

It is proposed that relative to the baseline orthotic condition (flat inlay), increases in arch geometry height will systematically increase peak pressure under the medial midfoot and systematically decrease peak pressure under the rearfoot (hypothesis 1). For the effects of orthoses arch geometry on centre of pressure, it is proposed that relative to the baseline orthotic condition, increases in arch geometry height will systematically displace the centre of pressure medially during loading response, midstance and terminal stance phases of gait (hypothesis 2).

4.3 Hypotheses – antipronation orthoses heel geometry

It is proposed that relative to the baseline orthotic condition (flat inlay), increases in medial wedge geometry will systematically increase peak pressure under the medial rearfoot (hypothesis 3). For the effects of orthoses wedge geometry on centre of pressure, it is proposed that relative to the baseline condition, increases in medial wedge geometry will systematically displace the centre of pressure medially during loading response, midstance and terminal stance phases of gait (hypothesis 4).

4.4 Summary of statistical analysis

As described in section 3.6, repeated measures ANOVA quantified the effects of altering APFO geometry on peak pressure under the different regions of the plantar foot and on centre of pressure during the three phases of gait. Figure 4.1 shows the repeated measures factors and the levels associated with the repeated measures analysis of variance used in Chapter 4.

4.5 Results

Figure 4.2 (A, B, C) and Figure 4.3 (A, B, C) show the effect of orthotic arch geometry and medial heel wedge geometry on peak pressure and centre of pressure displacement.

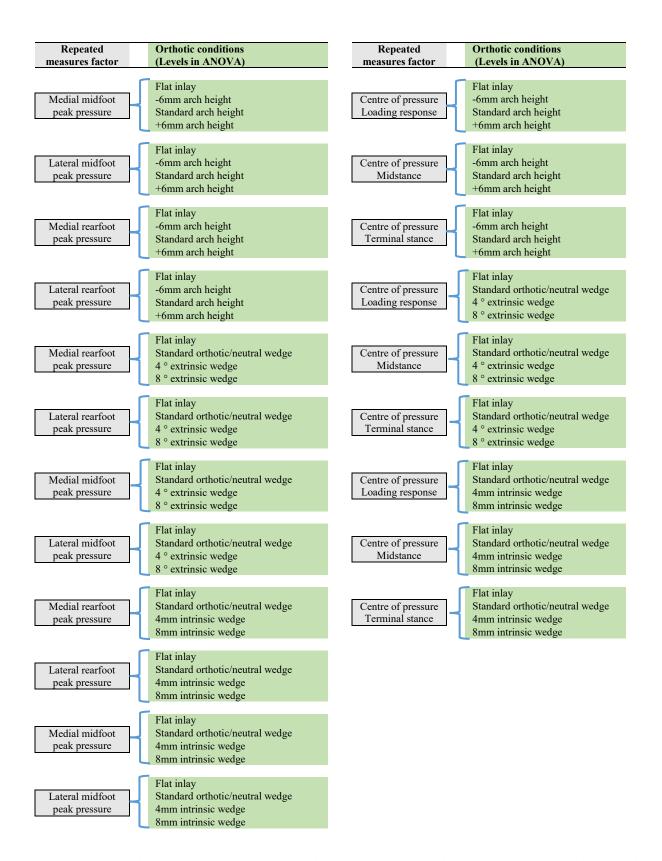


Figure 4.1 Illustration showing the repeated measures factors and levels for the peak pressure data and the centre of pressure data associated with each of the ANOVA's undertaken for Chapter 4.

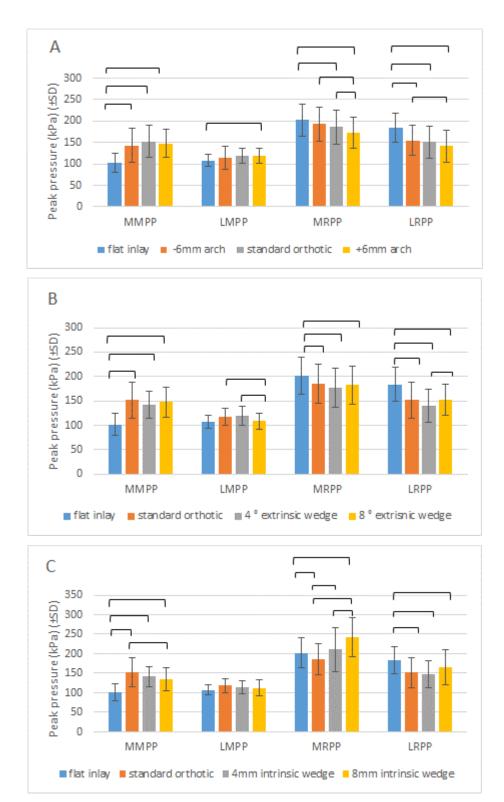
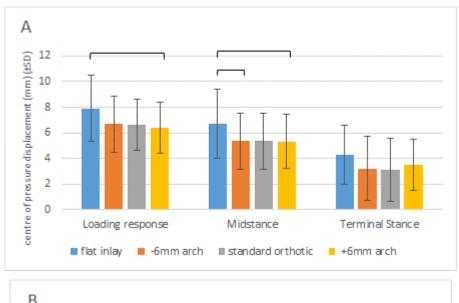
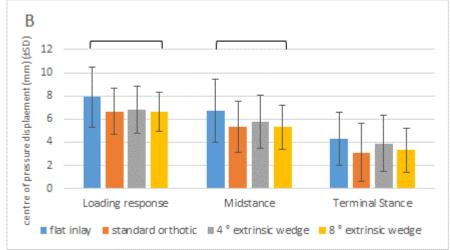


Figure 4.2 (A, B, C) The effect of the orthotic conditions on medial midfoot peak pressure (MMPP), lateral midfoot peak pressure (LMPP), medial rearfoot peak pressure (MRPP) and lateral rearfoot peak pressure (LRPP). The horizontal lines indicate significant differences between the orthotic conditions (Bonferroni corrections applied).





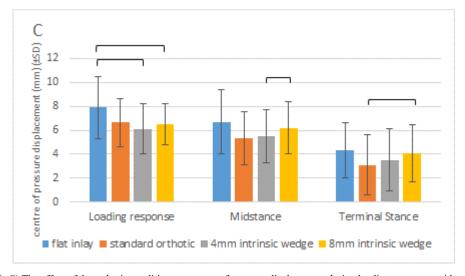


Figure 4.3 (A, B, C) The effect of the orthotic conditions on centre of pressure displacement during loading response, midstance and terminal stance. Values shown represent medial displacement of the COP (mm). The horizontal lines indicate significant differences between the orthotic conditions (Bonferroni corrections applied).

4.5.1 Orthotic arch geometry – effect on peak pressure

Increases in arch geometry height significantly increased MMPP (medial midfoot peak pressure) (F $_{(1.9,\ 36.8)}=28.4$, p < 0.001)*, and significantly decreased both MRPP (medial rearfoot peak pressure) (F $_{(2,\ 39.6)}=17.3$, p = 0.001)* and LRPP (lateral rearfoot peak pressure) (F $_{(3,\ 57)}=52.7$, p < 0.001). Increases in arch geometry height caused no significant changes to LMPP (lateral midfoot peak pressure) (F $_{(2.1,\ 39.1)}=2.8$, p = 0.071)*. Post hoc testing revealed a number of significant differences between the different arch heights and the flat inlay condition under each masked region of the plantar foot (see Table 4.1). Compared to the flat inlay condition, the -6mm, standard and +6mm arch heights increased MMPP by 41.1 % (p < 0.001), 49.5 % (p < 0.001) and 44.8 % (p < 0.001) respectively. Compared to the flat inlay condition, the standard and +6mm arch heights decreased MRPP by 8.2 % (p < 0.05) and 14.8 % (p < 0.001) respectively. Compared to the flat inlay condition, the -6mm, standard and +6mm arch heights decreased LRPP by 15.8 % (p < 0.001), 17.8 % (p < 0.001) and 23.4 % (p < 0.001). Compared to the -6mm arch height, the +6mm arch height decreases LRPP by 9 % (p = 0.001).

4.5.2 Orthotic arch geometry – COP displacement

Increases in arch geometry height significantly increased the medial position of the COP during loading response (F $_{(3,57)} = 5.8$, p = 0.002), and midstance (F $_{(3,57)} = 6.5$, p = 0.001), however no significant changes were found during terminal stance (F $_{(2.1,39.2)} = 2.8$, p = 0.071)*. Post hoc testing revealed a number of significant differences between the different arch heights and the flat inlay condition during the different stance phases in gait (see Table 4.2). Compared to the flat inlay condition, the +6mm arch height increased the medial COP displacement 18.9 % (p < 0.05) during loading response and increased the medial COP displacement by 20.9 % during midstance (p < 0.05). Compared to the flat inlay condition the -6mm arch height increased the medial COP displacement by 20 % (p < 0.05) during midstance.

^{*} Mauchlys' test of sphericity indicated that the assumption of sphericity had been violated therefore the degrees of freedom were adjusted with a Greenhouse-Geisser correction.

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Table 4.1 Effect of the arch conditions on mean peak pressure values (kPa). Differences shown are all relative to the flat inlay condition.

	Medial M	lidfoot			Lateral N	Iidfoot			Medial l	Rearfoot			Lateral R	learfoot		
C III	Mean	inter	onfidence val for erence	a	Mean	95 % cor interv differ	al for	a	Mean	inter	onfidence val for rence	a	Mean	95 % cor interva differ	al for	a
Condition	(SD)	Lower bound	Upper bound	p-value"	(SD)	Lower bound	Upper bound	p-value	(SD)	Lower bound	Upper bound	p-value	(SD)	Lower bound	Upper bound	p-value"
Flat Inlay	101.6 (22.4)	na	na	na	107.6 (13.7)	na	na	na	202.1 (38)	na	na	na	184.1 (34.6)	na	na	na
-6mm arch height	143.4 (39.6)	65.9	-17.6	<.001	114.3 (27.3)	-24.9	11.3	1.0	193 (40.1)	-6.3	24.7	.577	155 (35.5)	20.1	38	<.001
Standard arch height	151.9 (37.3)	-67.1	-33.5	<.001	118.4 (17.5)	-22.7	.9	.082	185.6 (40.4)	3.1	30	.011	151.3 (37.5)	21.7	43.8	<.001
+6mm arch height	147. 2 (32.7)	-62.8	-28.2	<.001	119.2 (18.1)	-23.3	1	.047	172.2 (36.3)	14.5	45.4	<.001 ^{b c}	141.1 (38.1)	30.7	55.3	<.001 b

^a Adjustments for multiple comparisons: Bonferroni

b Mean difference significant at the 0.05 level (Bonferroni adjusted) compared to the -6mm arch height

^c Mean difference significant at the 0.05 level (Bonferroni adjusted) compared to the standard arch height

Table 4.2 Effect of the arch heights on centre of pressure displacement (mm) during the different stance phase periods in gait. Decreases (mm) relative to the flat inlay condition signify medial displacement of the centre of pressure. Differences shown are all relative to the flat inlay condition.

	Loading R	Response			Midstanc	e						
	Mean	95 % confidence interval for difference		_ a	Mean	interv	nfidence val for rence	_ a	Mean	interv	onfidence val for rence	_ a
Condition	(SD)	Lower bound	Upper bound	p-value	(SD)	Lower bound	Upper bound	p-value "	(SD)	Lower bound	Upper bound	p-value"
Flat Inlay	7.9 (2.6)	na	na	na	6.7 (2.7)	na	na	na	4.3 (2.3)	na	na	na
- 6mm arch height	6.7 (2.2)	04	2.4	.060	5.36 (2.2)	.03	2.6	.043	3.2 (2.5)	6	2.8	.443
Standard arch height	6.65 (2.0)	2	2.7	.123	5.35 (2.2)	03	2.7	.059	3.1 (2.5)	4	2.7	.271
+6mm arch height	6.4 (2.0)	.26	2.9	.013	5.33 (2.1)	.36	2.4	.005	3.5 (2.0)	3	1.9	.247

^a Adjustments for multiple comparisons: Bonferroni

4.5.3 Extrinsic wedges – effect on peak pressure

Increases in extrinsic medial wedge geometry significantly decreased both MRPP (F $_{(2.2,\,41.4)}$ = 13.2, p < .001)*, and LRPP (F $_{(2.2,\,41)}$ = 49, p < 0.001)*, and significantly increased both MMPP (F $_{(3,\,57)}$ = 29, p < 0.001) and LMPP (F $_{(3,\,57)}$ = 6, p = 0.001). Post hoc testing revealed a number of significant differences between the different extrinsic wedges compared to the flat inlay (see Table 4.3). Compared to the flat inlay condition, the standard orthotic (with neural wedge), 4 ° and 8 ° extrinsic wedges decreased MRPP by 8.2 % (p < 0.05), 12.76 % (p < 0.05) and 9.7 % (p = 0.001) respectively, and decreased LRPP by 17.8 % (P < 0.001), 24.1 % (p < 0.001) and 17.1 % (p < 0.001) respectively. Compared to the flat inlay, the standard orthotic, 4 ° and 8 ° extrinsic wedges increased MMPP by 49.5 % (p < 0.001), 39.6 % (p < 0.001) and 45 % (p < 0.001). Compared to the 4 ° extrinsic wedge, the 8 ° wedge increased LRPP by 9.2 % (p < 0.05) and decreased LRPP by 8.7 % (p < 0.05). Compared to the standard orthotic, the 8 ° wedge decreased LRPP by 8.7 % (p < 0.05).

4.5.4 Extrinsic wedges – COP displacement

Increases in extrinsic wedge angle significantly increased the medial position of the COP during loading response (F $_{(3, 57)} = 4.2$, p = 0.010), midstance (F $_{(3, 57)} = 6.0$, p = 0.001) and terminal stance (F $_{(2, 38.8)} = 3.6$, p = 0.035)*. Post hoc testing revealed that compared to the flat inlay condition, the 8 ° extrinsic wedge increased the medial COP displacement by 16.5 % (p < 0.05) during loading response and by 20.9 % (p < 0.05) during midstance (see Table 4.4).

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^{*} Mauchlys' test of sphericity indicated that the assumption of sphericity had been violated therefore the degrees of freedom were adjusted with a Greenhouse-Geisser correction.

Table 4.3 Effect of the extrinsic wedges on mean peak pressure values (kPa) for the masked regions of the foot. Differences shown are all relative to the flat inlay condition.

	Medial I	Rearfoot			Lateral R	earfoot			Medial I	Midfoot			Lateral Mi	dfoot		
Condition	Mean	inter	onfidence val for erence	_ a	Mean	95 % cor interv differ	al for	_ a	Mean	inter	nfidence val for rence	<u>,</u> a	Mean	95 % co interv diffe		_ a
Condition	(SD)	Lower bound	Upper bound	p-value	(SD)	Lower bound	Upper bound	p-value"	(SD)	Lower bound	Upper bound	p-value"	(SD)	Lower bound	Upper bound	p-value"
Flat Inlay	202.1 (38)	na	na	na	184.1 (34.6)	na	na	na	101.6 (22.4)	na	na	na	107.6 (13.7)	na	na	na
Standard Insole (SI)	185.6 (40.4)	3.1	30	.011	151.3 (37.5)	21.7	43.8	<.001	152 (37.3)	-67.1	-33.5	<.001	118.4 (17.5)	-22.7	.9	.082
4°extrinsic wedge	176.3 (39.8)	8.8	42.7	.002	139.8 (33.1)	36.5	52.1	<.001	141.8 (28.4)	-57.9	-22.5	<.001	118.9 (19.5)	-22.9	.3	.058
8° extrinsic wedge	182.5 (39.2)	7.6	31.7	.001	152.6 (31.9)	17.8	45.1	<.001 b	147.4 (31.2)	-67.1	-24.4	<.001	108.6 (16.6)	-13	10.9	1.0 ^{b c}

Adjustments for multiple comparisons: Bonferroni Mean difference significant at the 0.05 level (Bonferroni adjusted) compared to the 4 $^{\circ}$ extrinsic wedge

^c Mean difference significant at the 0.05 level (Bonferroni adjusted) compared to the neutral wedge

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Table 4.4 Effect of extrinsic wedges on centre of pressure displacement (mm) during different stance phase periods in gait. Decreases (mm) relative to the flat inlay condition signify medial displacement of the centre of pressure. Differences shown are all relative to the flat inlay condition.

	Loadin	g Response			Midstan	ce						
C IV	95 % confidence interval for Mean difference		val for	_ a	Mean	95 % cor interv differ	al for	_ a	Mean	95 % cor interv differ	al for	_ a
Condition	(SD)	Lower bound	Upper bound	p-value "	(SD)	Lower bound	Upper bound	p-value"	(SD)	Lower bound	Upper bound	p-value ^a
Flat Inlay	7.9 (2.6)	na	na	na	6.7 (2.7)	na	na	na	4.3 (2.3)	na	na	na
Neutral wedge	6.7 (2.0)	2	2.7	.123	5.4 (2.2)	04	2.7	.059	3.1 (2.5)	4	2.7	.271
4° extrinsic wedge	6.8 (2.0)	4	2.6	.258	5.8 (2.3)	3	2.1	.211	3.9 (2.4)	7	1.4	1.0
8 °extrinsic wedge	6.6 (1.7)	.02	2.7	.044	5.3 (1.9)	.061	2.7	.037	3.3 (1.9)	3	2.1	.210

^a Adjustments for multiple comparisons: Bonferroni

4.5.5 Intrinsic wedges – effect on peak pressure

Increases in medial wedge thickness significantly increased both MRPP (F $_{(3, 57)} = 23.9$, p < 0.001) and MMPP (F $_{(3, 57)} = 31.4$, p < 0.001) and significantly decreased both LRPP (F $_{(2, 38.9)} = 20.6$, p < 0.001)* and LMPP (F $_{(3, 57)} = 3.2$, p = 0.030). Post hoc testing revealed a number of significant differences between the different intrinsic wedges compared to the flat inlay condition (see Table 4.5). Compared to the flat inlay condition the 8mm intrinsic wedge increased MRPP by 19.9 % (p < 0.001). Compared to the flat inlay, the 4mm and 8mm wedges decreased LRPP by 19.7 % (p < 0.001) and 10.1 % (p < 0.05) respectively. Compared to the flat inlay, the 4mm and 8mm wedges increased MMPP by 38.9 % (p < 0.001) and 33.3 % (p < 0.001) respectively. Compared to the 4mm wedge, the 8mm wedge increased MRPP by 15.1 % (p < 0.05) Compared to the standard orthotic condition, the 8mm wedge decreased MMPP by 11.2 % (p < 0.05).

4.5.6 Intrinsic wedges – COP displacement

Increases in intrinsic wedge thickness significantly increased the medial position of the COP during loading response (F $_{(3,57)} = 6.3$, p = 0.001), midstance (F $_{(2.3,43)} = 5.4$, p = 0.006)* and terminal stance (F $_{(1.9,35.8)} = 3.6$, p = 0.040)*. Post hoc testing revealed that compared to the flat inlay condition, the 4mm and 8mm intrinsic wedges increased the medial COP displacement during loading response by 22.8 % (p < 0.05) and by 17.7 % (p < 0.05) respectively (see Table 4.6). Compared to the 8mm wedge the 4mm wedge increased the medial COP displacement during midstance by 11.3 % (p < 0.05). Compared to the 8mm intrinsic wedge, the standard orthotic (neutral wedge) increased the medial COP displacement during terminal stance by 24.4 % (p < 0.05).

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^{*} Mauchlys' test of sphericity indicated that the assumption of sphericity had been violated therefore the degrees of freedom were adjusted with a Greenhouse-Geisser correction.

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Table 4.5 Effect of the intrinsic wedges on mean peak pressure values (kPa). Differences shown are all relative to the flat inlay condition.

	Medial Rea	rfoot			Lateral R	earfoot			Medial !	Midfoot			Lateral Mi	dfoot		
	Mean	inter	onfidence val for erence	_ a	Mean	inter	onfidence val for erence	_ a	Mean	inter	onfidence val for rence	_ a	Mean	interv	nfidence /al for rence	_ a
Condition	(SD)	Lower bound	Upper bound	p-value"	(SD)	Lower bound	Upper bound	p-value [*]	(SD)	Lower bound	Upper bound	p-value"	(SD)	Lower bound	Upper bound	p-value [*]
Flat Inlay	202.1 (38)	na	na	na	184.1 (34.6)	na	na	na	101.6 (22.4)	`na	na	na	107.6 (13.7)	na	na	na
Neutral wedge	185.6 (40.4)	3.1	30	.011	151.3 (37.5)	21.7	43.8	<.001	152 (37.3)	-67.1	-33.5	<.001	118.4 (17.5)	-22.7	.9	.082
4 mm intrinsic wedge	210.6 (56)	-29.4	12.4	1.0 b	147.8 (34.8)	26.3	46.3	<.001	141.1 (25.7)	-57.1	-21.9	<.001	114.1 (17.7)	-17.7	4.5	.58
8 mm intrinsic wedge	242.4 (50.3)	-58.2	-22.3	<.001 bc	165.4 (45.2)	2.3	35	.020	135.4 (29.5)	-50.4	-17.1	<.001 b	112.6 (20.8)	-18.2	8.2	1.0

^a Adjustments for multiple comparisons: Bonferroni

b Mean difference significant at the 0.05 level (Bonferroni adjusted) compared to the neutral wedge

c Mean difference significant at the 0.05 level (Bonferroni adjusted) compared to the 4mm intrinsic wedge

Table 4.6 Effect of intrinsic wedges on centre of pressure displacement (mm) during different stance phase periods in gait. Decreases (mm) relative to the flat inlay condition signify medial displacement of the centre of pressure. Differences shown are all relative to the flat inlay condition.

	Loading Response				Midstanc	e		Terminal stance				
G 11.1	Mean			a	Mean	interv	nfidence val for rence	a	Mean	inter	onfidence val for erence	a
Condition	(SD)	Lower bound	Upper bound	p-value	(SD)	bound bound		p-value"	(SD)	Lower bound	Upper bound	p-value a
Flat Inlay	7.9 (2.6)	na	na	na	6.7 (2.7)	na	na	na	4.2 (2.3)	na	na	na
Neutral wedge	6.7 (2.0)	2	2.7	.123	5.4 (2.2)	03	2.7	.059	3.1 (2.5)	4	2.7	.271
4 mm intrinsic wedge	6.1 (2.1)	.5	3	.003	5.5 (2.2)	01	2.3	.053	3.5 (2.6)	5	2.1	.582
8 mm intrinsic wedge	6.5 (1.7)	.002	2.7	.049	6.2 (2.2)	8	1.7	1.0 b	4.1 (2.4)	-1.2	1.5	1.0°

Adjustments for multiple comparisons: Bonferroni
 Mean difference significant at the 0.05 level (Bonferroni adjusted) compared to the 4mm intrinsic wedge

^c Mean difference significant at the 0.05 level (Bonferroni adjusted) compared to the neutral wedge

4.6 Discussion

4.6.1 The effect of increasing orthoses arch geometry height on external forces under the foot

To characterise the effect of changes in arch geometry on external forces under the foot this study quantified how different arch heights altered peak pressures and COP under the foot. Two hypotheses were proposed to describe the effects of arch geometry relative to a baseline condition. Hypothesis 1 proposed that increasing arch geometry height would systematically increase peak pressure under the midfoot and systematically decrease peak pressure under the rearfoot. Hypothesis 2 proposed that increasing arch geometry height would systematically displace the centre of pressure medially during loading response, midstance and terminal stance phases of gait.

Hypothesis 1 can be partially accepted for the effects of the arch heights on peak pressure. The three arch heights systematically increased medial midfoot peak pressure (MMPP) and systematically decreased lateral rearfoot peak pressure (LRPP). The standard and +6mm arch heights systematically decreased medial rearfoot peak pressure (MRPP), whilst the -6mm arch caused no systematic changes to MRPP.

Hypothesis 2 can be partially accepted for the effects of the arch heights on COP displacement. The +6mm arch height systematically displaced the COP medially during loading response, whilst the -6mm and +6mm arch height systematically displaced the COP medially during midstance. None of the arch heights systematically displaced the COP during terminal stance. The -6mm and standard arch heights caused non-systematic changes in COP during loading response whilst the standard arch height caused non-systematic changes in COP displacement during midstance.

The results of this study showed increasing arch height geometry caused a number of main effects on peak plantar pressures at the midfoot and rearfoot. Firstly, and as expected, compared to the flat inlay condition increasing arch height geometry caused large increases in medial midfoot peak pressure and small increases in lateral midfoot peak pressure (up to 50 % increase in MMPP and 10 % increase in LMPP for standard arch height). This is expected

because the orthotic arch geometry is higher under the medial midfoot relative to the lateral midfoot. As no previous study quantified the effect of systematically altering arch geometry it is not possible to contrast the results of this study with others, however a number of studies described the effects of an arch profile (i.e. a single arch height) on peak pressure under the medial and lateral midfoot. For example, Bus et al. (2004) reported custom made insoles increased peak pressure under the medial midfoot by 31.1 % (p < 0.05) and increased lateral midfoot pressure by 7 % (p > 0.05) relative to a flat insole condition. These changes in peak pressure are closest to the effects caused by the -6mm arch height for the current study which caused a 10 % greater increase in medial midfoot pressure and a 0.7 % greater decrease in lateral midfoot pressure. A number of studies reported orthotic arch geometry caused changes in midfoot peak pressure that contrast to some degree with the results of the current study. For example, compared with the standard arch height used for the current study, Aminian et al. (2013) reported a prefabricated insole caused a 25.5 % greater increase MMPP and a 22.9 greater % increase LMPP, whilst McCormick et al. (2013) reported customised foot orthosis caused a 34.5 % greater decrease in MMPP and a 4.9 % greater increase in LMPP. The variable changes in midfoot peak pressures across studies is expected since each study uses an orthosis with different design features, midfoot masks to extract pressure data, and subjects with different foot postures (e.g. pronated/neutral).

Secondly, and unexpectedly, the greatest increase in MMPP arose not from the highest arch height (+6mm), but from the standard arch height. A pain avoidance strategy is a potential reason for this finding. The +6 mm arch height may cause excessive soft tissue compression in tissues residing between the arch profile and bones forming the medial longitudinal arch. This seems plausible since the orthoses tested were made from stiff EVA (shore 65 value) and compared to many orthoses the standard arch height is already interpreted by clinicians as quite high. To avoid discomfort arising from possible excessive tissue compression a neuromuscular response might cause the foot to supinate, or to pronate less, thus decreasing load measured at the +6mm arch height's interface compared to the standard arch height. No other study describes a similar response and it is likely that the systematic design used in this investigated (testing arch height in distinct increments) has allowed identification of this effect for the first time. The changes in MMPP caused by the different arch heights for the current study contrast with the results observed by the pilot study, whereby the highest arch height in the current study is 3mm greater than the highest arch height used for the pilot, thus it is plausible that the

3mm additional arch height may be sufficient to cause a neuromuscular response to avoid tissue damage. This suggests there may be a ceiling in terms of orthotic arch height, above which further arch height does not lead to further increases in pressure. Based on the difference between pilot and main study, this may be circa 3-4mm higher than the standard arch height.

Thirdly, the different arch heights significantly alter peak pressure relative to the baseline condition of a flat insole, but result in very little change in pressure relative to one another. For example, an 8.4 % increase in peak pressure was recorded between the arch height causing the lowest (-6 mm) and highest (standard) change in peak pressure under the medial midfoot. This contrasts the 41.1 % increase in peak pressure associated with the first increment in arch height (-6mm) relative to the baseline conditions. On the basis that soft tissue compression influences peak pressure measured at the surface of the orthosis, the results support the conjecture that the arch geometry in an APFO compresses soft tissue under the medial midfoot to a maximum value, and that further increases in arch height do not lead to further soft tissue compression, or else pressure should have risen proportionally with increases in arch height. Increasing arch geometry beyond this value causes minimal changes in peak pressure as the tissues under the midfoot are likely already maximally compressed, and further compression would threaten tissue damage. As described above, this may illicit a pain avoidance strategy to reduce excessive load applied at the surface of the orthosis, with reduced pronation or even foot supination. It follows that variations of this neuromuscular response may also explain why the different arch heights caused small changes in midfoot peak pressure relative to one another. If true, this strongly suggests that the response of the foot to presence of a foot orthotic is not purely a mechanical response, but rather a neuro-muscular-mechanical response.

Finally, this study showed that increasing arch geometry height decreased rearfoot peak pressures, however the decreases between MRPP and LRPP differed. Increasing arch geometry height caused greater decreases in LRPP compared to decreases found for MRPP, though pressure increases in the arch were greater for MMPP compared to LMPP. For example, the +6mm arch height decreased LRPP by 23.4 % and decreased MRPP by 14.8 %. These results are similar to those reported by Bus et al. (2004) who showed orthosis with custom made arch geometry decreased MRPP by 20.9 % and LRPP by 23 %. These results are closest to the +6 mm arch height for the current study which had a 6.1 % greater decrease in MRPP and a 0.4 % greater increase LRPP. A potential explanation as to why orthosis arch geometry caused different changes in peak pressure under the medial rearfoot compared to the

lateral rearfoot relates to differences in soft tissue thickness situated at the medial and lateral heel pad. The medial calcaneal tuberosity is located under the medial calcaneus and is assumed to be the primary weightbearing surface at the rearfoot. This region is located in the medial rearfoot mask of the pressure data, which displayed the highest peak pressure value of all the foot masks for the flat inlay condition. It follows that soft tissues under the lateral calcaneus are thicker than soft tissues under the medial calcaneus because thicker tissues are associated with lower peak pressures (Morag et al., 1997). Furthermore, the heel pad is thicker under the lateral calcaneus because it is placed under less vertical load and the surface of the lateral calcaneus extends more proximally compared to the surface of the medial calcaneal tuberosity (Figure 4.4). It follows that a thicker portion of the heel pad, as found under the lateral calcaneus, has the potential to have greater thickness when unloaded, thus a greater decrease in LRPP when compared to MRPP.

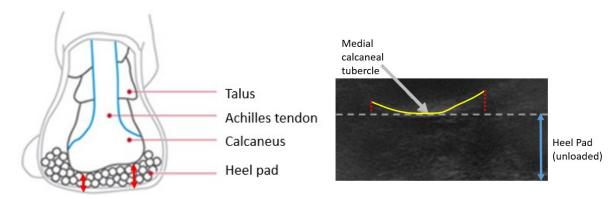


Figure 4.4 Illustrations showing heel pad thickness under calcaneus. Ultrasound image (right) shows plantar contour of calcaneus (yellow line) with its lateral surface extending more proximally compared to the medial surface (red lines).

For the effect of increasing arch geometry height on COP displacement, and similar to the effects of arch geometry on peak plantar pressures, the results of this study support the conjecture that individuals demonstrate a threshold above/below which arch height geometry influences the displacement of COP differently. Only the +6 mm arch height significantly displaced the COP medially in loading response and midstance relative to the baseline condition. Relative to one another the different arch heights caused small changes in COP displacement during the 3 periods in stance (p > 0.5). In loading response for example, the standard arch height displaced the COP medially by 0.05mm (0.7 % change) relative to the -6 mm arch height. A 12 mm range in arch height (between -6 mm and +6 mm) displaced the COP medially by 0.5mm (4.5 % change). These results are similar to effects of the arch

geometry on loading under the midfoot where the different arch heights decrease peak pressure by small amounts relative to one another. However, the threshold at which arch geometry alters both peak pressure and COP displacement differs. The lowest arch height significantly increased peak pressure under the medial midfoot but changes to COP displacement were not significant. Only the highest arch profile (+6mm) significantly altered the COP displacement. These contrasting responses imply arch geometry alters peak pressure at lower thresholds whereas higher thresholds are required to displace the COP. However, the COP is a general measure of all forces applied to the pressure measurement insole (through 99 sensors), whereas the peak pressure values are derived from 12 sensors positioned in the medial midfoot mask. For this reason changes in loading under the midfoot mask will be more sensitive to changes compared to changes in COP displacement measured from all sensors in the pressure measurement insole.

This is the first study to characterise the effect of arch geometry on COP displacement between the foot/orthosis interface in gait thus it is not possible to directly contrast findings with other studies. Other studies characterised the effect orthoses on the overall displacement of the COP during stance phase in gait. Using force plates, these studies showed increases in arch geometry decreased the total mediolateral COP displacement (at the floor/shoe interface) relative to barefoot conditions when walking (Aboutorabi et al., 2013; McPoil et al., 1989). The current study did not quantify the overall mediolateral COP displacement but did show that different orthotic arch heights displaced COP in a more medial direction during loading response and midstance phases in gait compared to the flat inlay condition. By shifting the COP more medially, these results imply the orthotic arch heights may have also caused a decrease in total COP mediolateral displacement, thus are similar to the trends previously reported (Aboutorabi et al., 2013; McPoil et al., 1989).

4.6.2 The effect of increasing medial wedge geometry on external forces under the foot

To characterise the effect of changes in medial wedge geometry on external forces under the foot this study quantified how different designs of medial wedge altered plantar peak pressures and COP. Two hypotheses were proposed to describe the effects of medial wedge geometry relative to a baseline condition (flat inlay). Hypothesis 3 proposed that increasing medial wedge geometry would systematically increase medial rearfoot peak pressure. Hypothesis 4

proposed that increasing medial wedge geometry will systematically displace the centre of pressure medially during loading response, midstance and terminal stance phases of gait. Hypothesis 3 can be partially accepted for the effects of the *extrinsic wedges* on peak pressure. None of the extrinsic wedges systematically increased medial rearfoot peak pressure (MRPP) relative to the flat inlay condition. However, all of the extrinsic wedges systematically decreased MRPP. Thus, there was a relationship between wedge geometry and changes in pressure, but in the opposite direction to that anticipated. This can warrant that the hypothesis is partially accepted because the concept underlying the hypothesis is evident (systematic change).

Hypothesis 4 can be partially accepted for the effects of the *extrinsic wedges* on COP displacement. The 8 ° extrinsic wedge systematically displaced the COP medially during loading response and midstance. The standard orthotic (with neutral wedge) and 4 ° extrinsic wedge causes no systematic changes to the COP during loading response or during midstance. None of the extrinsic wedges systematically altered to the COP during terminal stance.

Hypothesis 3 can be partially accepted for the effects of the *intrinsic wedges* on peak pressure. The 8mm intrinsic wedge systematically increased MRPP compared the baseline condition, however the 4mm intrinsic wedge causes no systematic changes to MRPP. Hypothesis 4 can be partially accepted for the effects of the *intrinsic wedges* on COP displacement. Both the 4mm and 8mm intrinsic wedges systematically displaced the COP medially during loading response. However, none of the intrinsic wedges caused systematic changes to the COP during midstance or terminal stance.

An important finding is that the effects of the extrinsic wedges contrasted those of the intrinsic wedges. Firstly, relative to the baseline condition, intrinsic wedges increased MRPP whereas the extrinsic wedges decreased MRPP. The 4mm and 8mm intrinsic wedges increased MRPP by 4 % and 19.9 % respectively, whilst the 4 ° and 8 ° wedges decreased MRPP by 12.8 % and 9.7 % respectively. Similar contrasting effects were also evident compared to the standard orthotic condition, where the 4mm and 8mm intrinsic wedges increased MRPP by 13.5 % and 30.6 % respectively, whereas the 4 ° and 8 ° extrinsic wedges decreased MRPP by 5 % and 1.7 % respectively. The buttressing action of the medial and lateral walls of the heel cup in the orthotic may explain these different effects. Studies show the heel counter in footwear and the heel cup in orthoses geometry increases soft tissue thickness at the heel pad, which purportedly

decreases pressure values measured under the calcaneus (Perhamre et al., 2010). The walls of the heel cup prevent soft tissues under the heel pad from displacing laterally when the heel is loaded. This "buttress effect" is greater in the extrinsic wedges compared to the intrinsic wedges and could affect plantar tissue compression and stiffness and thus plantar pressures. The geometry of the intrinsic wedge elevates the calcaneus within the heel cup and thus reduces the buttressing effect, whereas the extrinsic wedge is positioned exterior to the heel cup and the heel cup is tilted but the walls remain adjacent to the soft tissue under the heel. The buttress therefore remains in place. This explains why, compared to the standard orthotic condition, the extrinsic wedges caused small changes in MRPP whereas the intrinsic wedges caused larger changes in MRPP. The loss of this buttressing effect, may cause soft tissues under the calcaneus to compress more thus increase pressure under the calcaneus. The effect of altering APFO geometry on soft tissues under the foot will be further examined in study 2.

The effects of the extrinsic wedges also contrasted those of the intrinsic wedges in terms of their effects on MMPP. Compared to the standard orthotic condition, the 8mm intrinsic wedge significantly decreased MMPP by 11 % whereas neither extrinsic wedge caused significant changes in MMPP (8° extrinsic wedge decreasing MMPP by 4.6 %; p > 0.05). These noneffect of extrinsic wedges on MMPP can be explained by comparing the detailed geometry of both wedge designs. The heel section of the intrinsic wedge is thicker compared to the extrinsic wedge. Thus, the intrinsic wedges elevate the heel with respect to the forefoot more than the extrinsic wedges, and therefore also elevate the medial midfoot relative to the orthoses arch profile. This would result in the observed decrease in medial midfoot pressure with intrinsic wedges but not extrinsic wedges.

This is the first study to compare the effects of intrinsic and extrinsic medial wedges on plantar loading and this result could have important implications for orthotic practice and design. This is particularly true since the choice of extrinsic/intrinsic wedge has thus far been largely down to clinician preference rather than research data. Practitioners tailor the design of an anti-pronation orthosis to increase load under the medial calcaneus and therefore increase internal inversion rearfoot moments and decrease peak rearfoot eversion movement. For the extrinsic medial wedge however, the results of this study show the combined action of the arch profile and buttressing effect of the heel cup *decreases load under the medial calcaneus*. Thus, orthoses possessing arch geometry and extrinsic medial wedges potentially have a minimal anti-pronation effect at the rearfoot because these design features decrease load under the

medial rearfoot. This is surprising as practitioners routinely combine the action of extrinsic medial wedges and arch geometry in APFO to resist excessive foot pronation. On the basis increasing load under the medial calcaneus decreases calcaneal eversion and inversion moments at the rearfoot, the intrinsic wedges may possess a greater anti-pronation effect as the results of this study show intrinsic wedges significantly increase peak pressure under the medial calcaneus. It is plausible that wedges causing differing effects on pressure under the foot may cause different joint moment/motion responses. This relationship will be explored in more detail by research question 3 (Chapter 6).

4.6.3 Individual variation in external forces due to changes in arch geometry height

The results of this study showed that altering APFO geometry systematically altered peak pressure and COP under the sole of the foot. However, the results showed individual variation in terms of both the direction and the magnitude of the response. For example, at group level, the +6mm arch systematically increased MMPP, systematically decreased MRPP and systematically displaced the COPLR. This orthotic condition decreased MMPP in 1 subject, increased MRPP in 2 subjects and laterally displaced the COPLR in 3 subjects. Similarly for the group effects of the intrinsic wedges, when compared to the flat inlay condition the 8mm wedge systematically increased MRPP, systematically decreased MRPP (compared to standard orthotic) and systematically medially displaced the COPLR. However, the same wedge decreased MRPP in 2 subjects, increased MMPP in 4 subjects, and laterally displaced the COPLR in 4 subjects. In addition to causing contrasting responses, altering APFO geometry caused varying changes in magnitudes of response between subjects. Relative to the flat inlay condition, increasing APFO geometry had little effect in some subjects whilst others experienced large changes in peak pressure/COP displacement. For example, the +6mm arch height decreased MRPP by 2.3 % in one subject and decreased it by 30.5 % in another. The same condition increased medial COPLR in one subject by 0.6 % and 52 % in another. Similar individual differences in the magnitude of responses are also found for the extrinsic and intrinsic medial heel wedges (Figure 4.5, Figure 4.6 and Figure 4.7). A potential explanation for these individual variations in pressure response relates to the influence of the neuromuscular system. Anti-pronation foot orthosis are designed to apply a load under the medial foot to decrease foot pronation, however in some individuals possessing compliant foot structures the AFPO may cause supination instability. A neuromuscular response (increase in peroneal muscle force) will moderate this supination instability and stabilise the foot/ankle. It follows

that by altering foot kinematics, this neuromuscular response will also alter pressure under the foot. Therefore, individuals with different neuromuscular responses, that cause differing kinematic responses, may also cause different pressure responses measured under the sole of the foot.

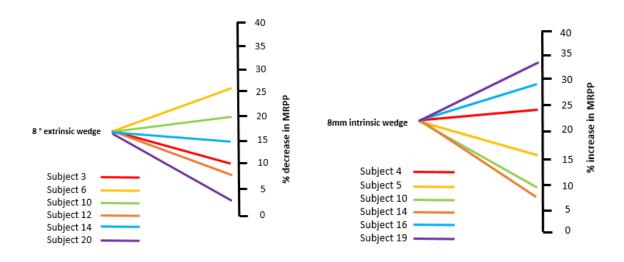


Figure 4.5 Range of subject specific changes in medial rearfoot peak pressure (MRPP) caused by the 8 ° extrinsic and the 8mm intrinsic wedge. % decreases/increases in MRPP are described relative to the flat inlay condition.

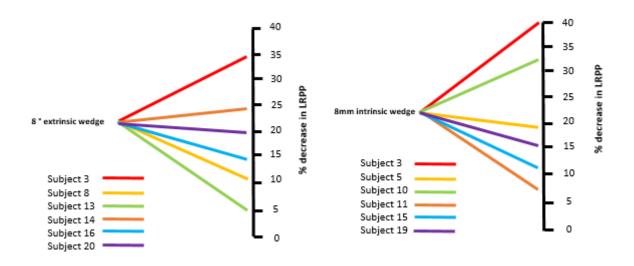


Figure 4.6 Range of subject specific changes in lateral rearfoot peak pressure (LRPP) caused by the 8 ° extrinsic and the 8mm intrinsic wedge. % decreases/increases in LRPP are described relative to the flat inlay condition.

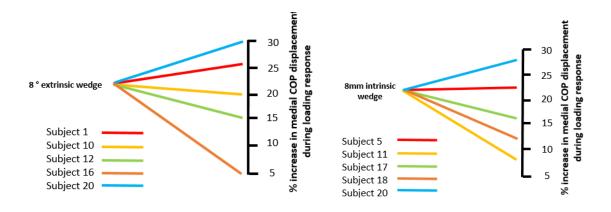


Figure 4.7 Range of subject specific changes in the medial COP displacement caused by the 8 ° extrinsic wedge and the 8mm intrinsic wedge. % increases in COP displacement are described relative to the flat inlay condition.

4.6.4 Limitations

There are a number of limitation to the current study. Firstly, studies imply the curved geometry of an APFO causes complex shearing forces (Orlin et al., 2000; Rao et al., 2006; Spooner et al., 2010). However, in-shoe pressure measurement systems cannot quantify these shearing forces as they can only quantify vertical forces acting under the foot, normal to the sensor surface. Furthermore, the sensors may not behave electrically in a linear manner when used over a curved rather than a flat surface. Thus sensor performance may differ between the experimental conditions used here and different levels of measurement error could be present in the data. Strictly speaking, the errors could be different between each orthotic condition, since each involves an orthotic (and therefore measurement insole) of different curvature. For the current study, to minimise this limitation, the sensors situated at the radius forming the heel cup (the most curved surface and therefore most likely to be affected by errors) were excluded. Despite their limitations, in-shoe pressure measurement systems are commonly used by studies quantifying the effect of orthoses on loading under the sole of the foot (Bonanno et al., 2012; Bonanno et al., 2011; Van Gheluwe et al., 2004). A recent study has shown the Pedar system used here is preferable to at least 2 other system (Price et al., 2016).

The second limitation is that a relatively large number of conditions were tested (8 in total). Time constraints meant subjects were afforded only small periods to acclimatise to each condition between testing. Other studies allow participants longer periods to acclimatise (e.g 2 weeks) (Bonanno et al., 2012; Telfer et al., 2013c), however, a recent study shows peak pressures stabilises quickly in a range of different shoe conditions (Melvin et al., 2014) after

around 166 steps. Effects may of course change over longer time periods, such as days, weeks or even months. However, orthotic material and geometry also change over such periods. Finally, the study has identified that even small changes in orthotic shape can affect plantar pressure. Whilst not strictly a limitation of the research design, it follows that the results reported apply largely only to the orthoses tested or close derivatives of them. Effects could vary if orthotic geometry and materials were substantially different.

4.6.5 Conclusion

This study showed that compared to the flat inlay condition, APFO with a medial wedge and arch geometry can be tailored to systematically alter external forces (measured as peak pressure and centre of pressure) under the foot. Increasing arch geometry height systematically increased medial midfoot peak pressure and systematically decreased rearfoot peak pressure. Increasing arch geometry height systematically increased the medial COP displacement during loading response and midstance. For the effects of the medial wedges, increasing *extrinsic wedge* geometry systematically decreased medial rearfoot peak pressure and systematically increased the medial COP displacement during loading response and midstance. Increasing *intrinsic wedge* geometry systematically increased medial rearfoot peak pressure and systematically increased the medial COP displacement during loading response and midstance.

The results found for research question 1 demonstrated that external forces applied to the foot can be systematically altered by changing foot orthotic geometry, but also that changes in peak pressure are variable between subjects. Systematic changes in peak pressure occurred in areas under the medial rearfoot and medial midfoot (tested by the hypotheses), but also occurred under the lateral rearfoot and midfoot. These results reinforce the importance of the investigations to be undertaken to answer research questions 2 and 3 (Chapters 5 and 6), and study 2 (Chapter 7).

Chapter 5 Research Question 2: Can APFO geometry systematically alter joint moment/motion responses?

5.1 Hypotheses

A number of hypotheses outlined in chapter 2 were proposed to answer research question 2.

5.2 Hypothesis – antipronation orthosis arch geometry

It is proposed that relative to the baseline orthotic condition, increases in arch geometry height will systematically decrease internal ankle inversion moments/increase internal ankle eversion moment, systematically decrease peak and range of rearfoot eversion, and systematically decrease minimum midfoot dorsiflexion (hypothesis 1).

5.3 Hypothesis – antipronation orthosis medial wedge geometry

It is proposed that relative to the baseline condition increases in medial heel wedge geometry will systematically decrease internal ankle inversion moments/increase internal ankle eversion moment, systematically decrease peak and range of eversion and systematically decrease minimum midfoot dorsiflexion (hypothesis 2).

5.4 Summary of statistical analysis

As described in section 3.6, repeated measures ANOVA quantified the effects of altering APFO geometry on joint kinetics and kinematics. Figure 5.1 shows the repeated measures factors and levels associated with the repeated measures analysis of variance used in Chapter 5.

5.5 Results

Figure 5.2 (A, B, C) and Figure 5.3 (A, B, C) shows the effect of orthotic arch geometry and medial heel wedge geometry on internal frontal plane ankle moments, peak rearfoot eversion and eversion range, and minimum midfoot dorsiflexion.

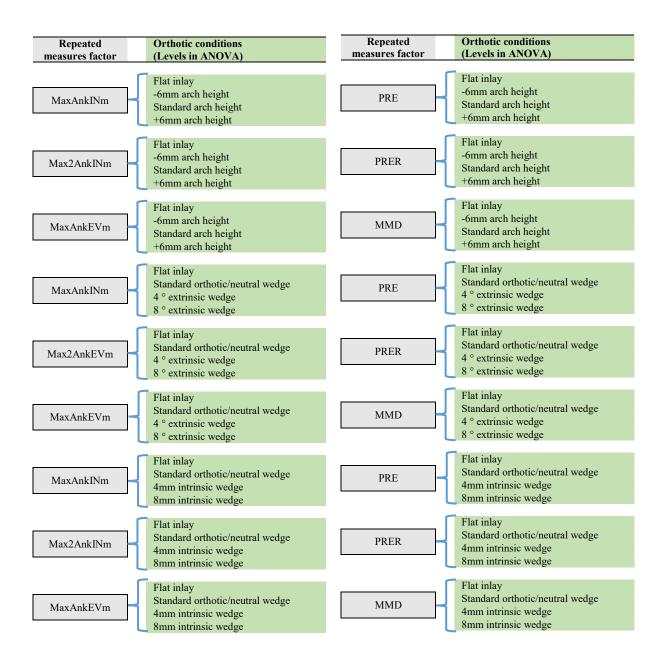


Figure 5.1 Illustration showing the repeated measures factors and levels associated with each of the ANOVA's undertaken for Chapter 5. MaxAnkINm = 1st peak internal ankle inversion moment; Max2AnkINm = 2nd peak internal ankle inversion moment; MaxAnkEVm = peak internal ankle eversion moment;; PRE = peak rearfoot eversion; PRER = peak rearfoot eversion range; MMD = minimum midfoot dorsiflexion.

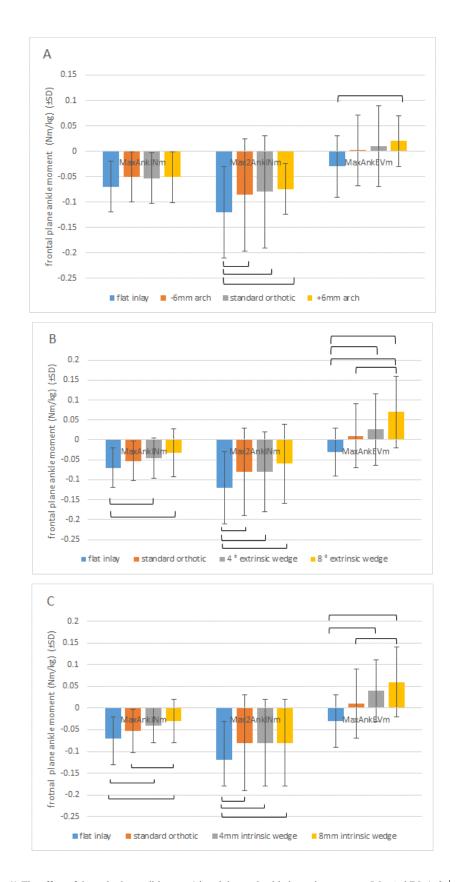


Figure 5.2 (A, B, C) The effect of the orthotic conditions on 1st peak internal ankle inversion moment (MaxAnkINm), 2nd peak internal ankle inversion moment (MaxAnkINm) and peak internal ankle eversion moment (MaxAnkEVm). The horizontal lines indicate significant differences between the orthotic conditions (Bonferroni corrections applied).

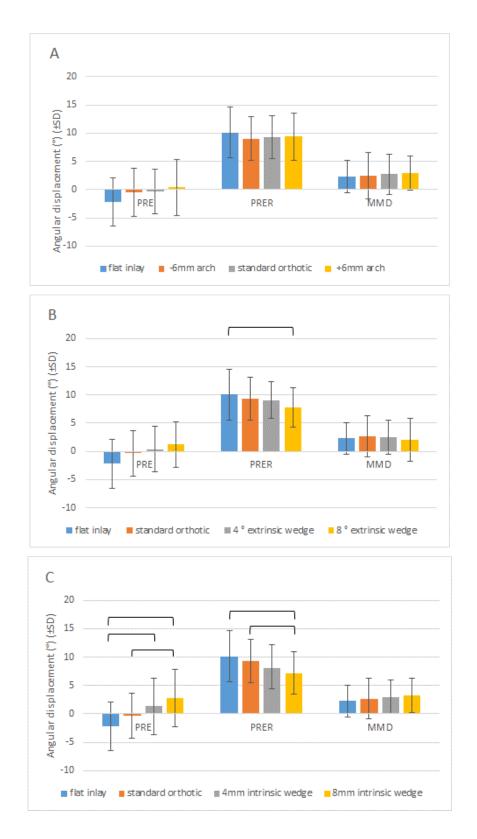


Figure 5.3 (A, B, C) The effect of the orthotic conditions on peak rearfoot eversion (PRE), peak rearfoot eversion range (PRER) and minimum midfoot dorsiflexion (MMD). The horizontal lines indicate significant differences between the orthotic conditions (Bonferroni corrections applied).

5.5.1 Arch geometry – effect on ankle kinetics

Increases in orthotic arch height significantly decreased MaxAnkINm (1st peak internal maximum ankle inversion moment) (F $_{(3,57)}$ = 2.83, p = 0.046), Max2AnkINm (2nd peak internal maximum ankle inversion moment) (F $_{(2.1,39.6)}$ = 5.208; p = 0.009)* and significantly increased MaxAnkEVm (maximum ankle eversion moment) (F $_{(3,57)}$ = 6.816; p = 0.001). Post hoc testing revealed a number of significant differences between the different orthotic arch heights and the flat inlay condition for Max2AnkINm and MaxAnkEVm, but not for MaxAnkINm (see Table 5.1). Compared to the flat inlay condition, the +6mm, standard and -6mm arch heights decreased Max2AnkINm .044Nm/kg (p = 0.021), .038Nm/kg (p = 0.012) and .032 Nm/kg (p = 0.042) respectively, and the +6mm arch height increased MaxAnkEVm by .055Nm/kg (p = 0.007).

5.5.2 Arch geometry – effect on kinematics

Increases in orthotic arch height significantly reduced PRE (peak rearfoot eversion) (F $_{(2.1, 39.2)}$ = 3.5, p = 0.04)* but caused no significant changes to PRER (peak rearfoot eversion range) (F $_{(3, 57)}$ = 1.2, p = 0.3) or MMD (minimum midfoot dorsiflexion) (F $_{(3, 57)}$ = .45, p = 0.72). Despite the significant ANOVA test, post hoc testing revealed no statistically significant differences between any specific orthotic condition and the flat inlay condition for PRE & PRER (see Table 5.2) nor MMD (see Table 5.3).

^{*} Mauchlys' test of sphericity indicated that the assumption of sphericity had been violated therefore the degrees of freedom were adjusted with a Greenhouse-Geisser correction.

Table 5.1 Effect of orthotic arch height on internal inversion moments at the ankle joint. Differences shown are relative to the flat inlay condition.

	MaxAnkl	Nm (Nm/kg	<u>(</u>)		Max2AnkII	Nm (Nm/kg)			MaxAnkE	Vm (Nm/kg)		
G 11.1	Mean	95% con interv differ	al for	a	Mean	95% cont interva differe	ıl for	p-value ^a	Mean	95% conf interval for o		p-value ^a
Condition	(SD)	Lower bound	Upper bound	p-value	(SD)	Lower bound	Upper bound	F	(SD)	Lower bound	Upper bound	P
	0.07				0.12				0.03			
Flat Inlay	(0.05)	na	na	na	(0.09)	na	na	na	(0.06)	na	na	na
	0.05	006	.049	.217	0.086	.001	.064	042	-0.002	012	077	.276
-6mm arch height	(0.049)	000	.049	.217	(0.11)	.001	.004	.042	(0.07)	012	.077	.270
Standard arch	0.053	012	040	529	0.08	007	068	012	-0.01	007	000	121
height	(0.05)	012	.049	.528	(0.11)	.007	.068	.012	(0.08)	007	.088	.121
+6mm arch	0.051	000	009 .05 .313	212	0.074	005	002	021	-0.02	012	007	007
height	(0.06)	009		.313	(0.11)	.005	.083	.021	(0.08)	.013	.097	.007

^a Adjustments for multiple comparisons: Bonferroni

Table 5.2 Effect of orthotic arch height on peak eversion and peak eversion range. Differences shown are all relative to the flat inlay condition.

	Peak Eve	rsion (°)			Peak Ev	ersion Range	(°)	
	M		nfidence r difference		M	95% confide for diff		
Condition	Mean (SD)	(SD) Lower Upper p-value (SD) bound bound		Lower bound	Upper bound	p-value ^a		
Flat inlay	-2.2 (4.3)	na	na	na	10.1 (4.5)	na	na	na
- 6mm arch height	-0.47 (4.3)	-4.217	.849	.391	9 (3.9)	879	3.106	.689
Standard arch height	-0.34 (4.0)	-4.88	1.252	.587	9.3 (3.8)	-1.370	3.067	1.0
+6mm arch height	0.4 (5.2)	1.009	.121	.121	9.4 (4.2)	-1.6	3.1	1.0

^a Adjustments for multiple comparisons: Bonferroni

Table 5.3 Effect of orthotic arch height on minimum midfoot dorsiflexion. Differences shown are relative to the flat inlay condition.

	Mean	inter	onfidence val for erence	
	(SD)	Lower bound	Upper bound	p-value
Flat Inlay	2.3 (2.8)	na	na	na
- 6mm arch height	2.5 (4.1)	-1.542	2.038	1.0
Standard Insole (SI)	2.7 (3.6)	-1.315	2.298	1.0
+6mm arch height	2.9 (3)	-1.233	2.546	1.0

5.5.3 Extrinsic medial wedge geometry – effect on kinetics

Increases in extrinsic wedge angle significantly decreased MaxAnkINm (F $_{(2.3, 43.3)}$ = 7.6, p < 0.001)*, Max2AnkINm (F $_{(3, 57)}$ = 10, p < 0.001), and increased MaxAnkEVm (F $_{(3, 57)}$ = 15.62, p < 0.001). Post hoc testing revealed a number of significant pairwise comparisons relative to the flat inlay condition (see Table 5.4). The 4 ° and 8 ° wedges decreased MaxAnkINm by .026 Nm/kg (p = 0.023) and .039 Nm/kg (p = 0.005) respectively. The neutral, 4 ° and 8 ° wedges decreased Max2AnkINm by .038 Nm (p = 0.012), .038 Nm (p = 0.036), and .054 Nm/kg (p = 0.001) respectively. The 4 ° and 8 ° wedges increased MaxAnkEVm by .056 Nm/kg (p = 0.002) and .1 Nm/kg (p < 0.001). Furthermore, the 8 ° wedge significantly increased MaxAnkEVm by 0.6 Nm/kg (p = 0.004) compared to the neutral wedge condition.

5.5.4 Extrinsic medial wedge geometry – effect on kinematics

Increases in extrinsic wedge angle significantly decreased PRE (F $_{(1.5,29.4)}$ = 6.1, p = 0.01)* and PRER (F $_{(3,57)}$ = 4.5, p = 0.007), but caused no significant changes to MMD (F $_{(3,57)}$ = .37, p = 0.77). Post hoc testing showed trends towards statistical significance for PRE, where the 8 ° wedge caused a 3.4 ° decrease (p = 0.053) compared to the flat inlay condition. The 8 ° wedge decreased PRER by 2.1 ° (p = 0.025) compared to the flat inlay condition, and by 1.3 ° (p = 0.058) compared to the 4 ° extrinsic wedge. Table 5.5 & Table 5.6 shows pairwise comparisons outlining the effect of the extrinsic wedges on PRE, PRER, and MMD respectively.

^{*} Mauchlys' test of sphericity indicated that the assumption of sphericity had been violated therefore the degrees of freedom were adjusted with a Greenhouse-Geisser correction.

Table 5.4 Effect of extrinsic wedges on internal inversion moments at the ankle joint. Differences shown are relative to the flat inlay condition.

	MaxAnkl	Nm (Nm/kg))		Max2Anl	dNm (Nm/l	kg)		MaxAnkEVm	n (Nm/kg)		
C. Pri	Mean	95% con interv differ	al for	a	Mean	95% cor interv differ	al for	p-value ^a	Mean	inter	onfidence val for erence	p-value ^a
Condition	(SD)	Lower bound	Upper bound	p-value	(SD)	Lower bound	Upper bound	· •	(SD)	Lower bound	Upper bound	.
Flat inlay	0.07 (0.05)	na	na	na	0.12 (0.09)	na	na	na	0.03 (.06)	na	na	na
Neutral wedge	0.053 (0.05)	012	.049	.528	0.08 (0.11)	.007	.068	.012	-0.01 (0.08)	007	.088	.121
4 ° extrinsic wedge	0.046 (0.052)	.003	.049	.023	0.08 (0.11)	.002	.075	.036	-0.026 (0.09)	.019	.095	.002
8 ° extrinsic wedge	0.032 (0.06)	.010	.069	.005	0.06 (0.12)	.021	.086	.001	-0.07 (0.09)	.050	.151	<.001 ^b

^a Adjustments for multiple comparisons: Bonferroni

b Mean difference significant at the 0.05 level (Bonferroni adjusted) compared to neutral wedge

Table 5.5 Effect of extrinsic wedges on peak eversion and peak eversion range. Differences shown are relative to the flat inlay condition

	Peak E	version (°)			Peak Eve	rsion Range (°)	
			confidence for difference				onfidence or difference	_ a
Condition	Mean (SD)	Lower bound	Upper bound	p-value ^a	Mean (SD)	Lower bound	Upper bound	p-value
Flat inlay	-2.2 (4.3)	na	na	na	10.1 (4.5)	na	na	na
neutral wedge	-0.34 (4)	4880	1.252	.587	9.3 (3.8)	-1.370	3.067	1.0
4° extrinsic wedge	0.39 (4.1)	-5.413	.329	.104	9.1 (3.3)	936	3.033	.818
8° extrinsic wedge	1.2 (4.3)	-6.832	.028	.053	7.8 (3.5)	.204	4.099	.025

^a Adjustments for multiple comparisons: Bonferroni

Table 5.6 Effect of extrinsic wedges on minimum midfoot dorsiflexion. Differences shown are relative to the flat inlay condition.

	Mean	95% con interva differ	al for	p-value
	(SD)	Lower bound	Upper bound	
Flat Inlay	2.3 (2.8)	na	na	na
Neutral wedge	2.7 (3.6)	-1.315	2.298	1.0
4 ° extrinsic wedge	2.5 (3.3)	-1.520	1.985	1.0
8 ° extrinsic wedge	2.1 (3.8)	-2.179	1.939	1.0

^a Adjustments for multiple comparisons: Bonferroni

5.5.5 Intrinsic medial wedge geometry – effect on kinetics

The intrinsic wedges significantly decreased MaxAnkINm (F $_{(3, 57)} = 8.7$, p < 0.001), Max2AnkINm (F $_{(3, 57)} = 8.9$, p < 0.001), and significantly increased MaxAnkEVm (F $_{(3, 57)} = 15.2$, p < 0.001). Post hoc testing showed a number of significant pairwise comparisons relative to the flat inlay condition (see Table 5.7). The 4mm and 8mm intrinsic wedges decreased MaxAnkINm by .034 Nm/kg (p = 0.005) and .04 Nm/kg (p = 0.002) respectively. The neutral, 4mm and 8mm wedges decreased Max2AnkINm by .038 Nm/kg (p = 0.012), .034 Nm/kg (p = 0.003) and .043 Nm/kg (p = 0.013) respectively compared to the flat inlay. The 4mm and 8mm wedges significantly increased MaxAnkEVm by .071 Nm/kg (p < 0.001) and .086 Nm/kg (p < 0.001) respectively. Furthermore, post hoc testing showed a number of significant differences between the intrinsic wedge conditions (see Table 5.7). Compared to the neutral wedge, the 8mm wedge significantly decreased MaxAnkINm (.021 Nm/kg; p = 0.044) and significantly increased MaxAnkEVm (.045 Nm/kg; p = 0.001).

5.5.6 Intrinsic medial wedge geometry – effect on kinematics

Increases in intrinsic medial wedge geometry significantly reduced both PRE (F $_{(3,57)}$ = 12.2, p < 0.001) and PRER (F $_{(2.2,41.2)}$ = 8.1, p < 0.001)* but caused no significant changes to MMD (F $_{(3,57)}$ = 1, p < 0.39). Post hoc testing revealed a number of significant pairwise comparisons. Compared to the flat inlay condition, 4mm and 8mm intrinsic wedges decreased PRE by 3.6 ° (p = 0.023) and 5 ° (p < 0.001) respectively. The 8mm intrinsic wedge decreased PRE by 1.8 ° (p < 0.001) compared to the neutral wedge condition. The 8mm intrinsic wedge decreased PRER by 2.9 ° (p < 0.001) and 2.1 ° (p = 0.001) compared to the flat inlay and the neutral wedge conditions respectively. Table 5.8 and Table 5.9 show pairwise comparisons for the effects of the intrinsic wedges on PRE, PRER and MMD respectively.

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^{*} Mauchlys' test of sphericity indicated that the assumption of sphericity had been violated therefore the degrees of freedom were adjusted with a Greenhouse-Geisser correction.

Table 5.7 Effect of intrinsic wedges on internal inversion moments at the ankle joint. Differences shown are relative to the flat inlay condition.

MaxAnkINm (Nm/kg)				Max2AnkINm (Nm/kg)				MaxAnkEVm (Nm/kg)				
		95% confidence interval for difference				95% confidence interval for difference				95% confidence interval for difference		
Condition	Mean (SD)	Lower bound	Upper bound	p-value ^a	Mean (SD)	Lower bound	Upper bound	p-value ^a	Mean (SD)	Lower bound	Upper bound	p-value
Flat inlay	0.07 (0.05)	na	na	na	0.12 (0.09)	na	na	na	0.03 (0.06)	na	na	na
Neutral wedge	0.05 (.05)	102	.049	.528	0.08 (0.1)	.007	.068	.012	-0.01 (0.08)	007	.088	.121
4mm intrinsic wedge	0.04 (0.04)	.009	.059	.005	0.08 (0.1)	.011	.058	.003	-0.04 (0.07)	.030	.112	<.001
8mm intrinsic wedge	0.03 (0.05)	.013	.067	.002 ^b	0.08 (0.1)	.007	.078	.013	-0.06 (0.08)	.038	.133	<.001 ^b

^a Adjustments for multiple comparisons: Bonferroni

^b Mean difference significant at the 0.05 level (Bonferroni adjusted) compared to neutral wedge

Table 5.8 Effect of intrinsic wedges on peak eversion and peak eversion range. Differences shown are relative to the flat inlay condition.

	M	95% confidence interval for difference			M	95% confidence interval for difference		_ a
Condition	Mean (SD)	Lower bound	Upper bound	p-value ^a	Mean - (SD)	Lower bound	Upper bound	p-value
Flat inlay	-2.2 (4.3)	na	na	na	10.1 (4.5)	na	na	na
Standard orthotic	-0.34 (4)	-4.880	1.252	.587	9.3 (3.8)	-1.37	3.07	1.0
4mm intrinsic wedge	1.4 (4.9)	-6.774	382	.023	8.1 (4.1)	238	4.185	.09
8mm intrinsic wedge	2.8 (5)	-7.833	-2.055	<.001 ^b	7.2 (3.7)	.716	5.094	.006 ^b

Table 5.9 Effect of intrinsic wedges on minimum midfoot dorsiflexion. Differences shown are relative to the flat inlay condition.

Minimum Midfoot Dorsiflexion (°)							
	Mean	95% confide for diffe	p-value ^a				
	(SD)	Lower Upper bound bound		F variate			
Flat Inlay	2.3 (2.8)	na	na	na			
Neutral wedge	2.7 (3.6)	-1.315	2.298	1.0			
4mm intrinsic wedge	3 (3.3)	566	2.063	.66			
8mm intrinsic wedge	3.2 (3.4)	670	2.495	.67			

^a Adjustments for multiple comparisons: Bonferroni

^a Adjustments for multiple comparisons: Bonferroni
^b Mean difference significant at the 0.01 level (Bonferroni adjusted) compared to the standard orthotic condition

5.6 Discussion

5.6.1 The effect of orthosis arch geometry on joint moment/motion responses

To characterise the effect of changes in arch geometry on biomechanical responses in foot structures this study quantified how different orthotic arch heights altered kinematic responses, including; peak rearfoot eversion, peak rearfoot eversion range and minimum midfoot dorsiflexion, and kinetic responses, including; internal inversion/eversion moments at the ankle joint. It was proposed that increasing orthotic arch height geometry would systematically decrease internal ankle inversion moments/increase internal ankle eversion moment, systematically decrease peak and range of rearfoot eversion and systematically decrease minimum midfoot dorsiflexion (hypothesis 1)

Hypothesis 1 can be partially accepted for the effects of the arch heights on kinetics. The three arch height geometries systematically decreased Max2AnkINm and the +6mm arch height systematically increased MaxAnkEVm. However, none of the arch height geometries systematically altered MaxAnkINm and the -6mm and standard arch heights caused no systematic changes to MaxAnkEVm. Hypotheses 1 can be rejected for the effects of the orthotic arch heights on kinematics because no orthotic systematically altered peak rearfoot eversion, peak rearfoot eversion range nor minimum midfoot dorsiflexion.

Increasing orthotic arch height geometry caused only minimal changes to midfoot kinematics. A 12mm range in arch height (-6mm arch height to +6mm arch height) decreased minimum midfoot dorsiflexion by 0.4°. This suggests that load applied by the orthosis to bones forming the medial longitudinal arch is absorbed by soft tissue structures situated at its surface (e.g. abductor hallucis muscles, flexor hallucis longus tendon) thus will only influence midfoot kinematics to a small extent. No previous study has quantified the effect of arch geometry on midfoot kinematics, although one prior study quantified the effects of arch geometry on medial longitudinal arch angle. This study reported similar findings to the current study, showing orthotic arch geometry caused non-significant changes to midfoot kinematics (Ferber et al., 2011).

Compared to kinematic changes, the effects of orthotic arch profile on kinetics were far greater. For example, the standard orthotic arch height caused a 33 % decrease in Max2AnkINm compared to the flat inlay condition. Thus, although no apparent changes in foot alignment may be evident, the orthotic arch geometry can derive beneficial affects by other means. The 33 % decrease in Max2AnkINm caused by the standard arch height will decrease the muscular demand placed on the foot inverters throughout stance phase. Similar contrasting effects between kinematic and kinetic changes have been previously reported. As described, Ferber et al. (2011) showed orthotic arch geometry caused non-significant changes to midfoot kinematics but suggested it caused a 38 % decrease in plantar fascia strain.

5.6.2 The effect of medial heel wedge geometry on joint moment/motion responses

It was proposed that increasing medial heel wedge geometry would systematically decrease internal ankle inversion moments/increase internal ankle eversion moment, systematically decrease peak and range of rearfoot eversion and systematically decrease minimum midfoot dorsiflexion (hypothesis 2).

Hypothesis 2 can be partially accepted for the effects of the extrinsic wedges on kinetics. The 4 ° and 8 ° extrinsic wedges systematically decreased MaxAnkINm and systematically increased MaxAnkEVm. The standard orthotic (with neutral wedge), 4 ° and 8 ° wedges systematically decreased Max2AnkINm. The standard orthotic condition caused no systematic changes to MaxAnkINm nor MaxAnkEVm.

Hypothesis 2 can be partially accepted for the effects of the extrinsic wedges on kinematics. The 8 ° extrinsic wedge systematically decreased PRE and PRER, however the standard orthotic (neutral wedge) and 4 ° extrinsic wedge caused no systematic changes. None of the extrinsic wedge conditions caused systematic changes to MMD.

Hypothesis 2 can be partially accepted for the effects of the intrinsic wedges on kinetics. The 4mm and 8mm intrinsic wedges systematically decreased MaxAnkINM and systematically increased MaxAnkEVm. The standard orthotic, 4mm and 8mm intrinsic wedges systematically decreased Max2AnkEVm. The standard orthotic caused no systematic changes to MaxAnkINm nor MaxAnkEVm.

Hypothesis 2 can be partially accepted for the effects of the intrinsic wedges on kinematics. The 4mm and 8mm intrinsic wedges systematically decreases PRE and PRER, however the

standard orthotic caused no systematic changes. None of the intrinsic wedges conditions caused systematic changes to MMD.

The effects of the intrinsic wedges rather than the extrinsic wedges caused the greatest decrease in peak rearfoot eversion, and the effect of orthotic arch heights was least of all. Furthermore, relative to the flat inlay condition only the intrinsic wedges caused statistically significant decreases in peak rearfoot eversion. The reduction in peak eversion found for 4 ° extrinsic wedge $(2.6 \,^{\circ} \, \text{decrease})$ and $+ \, 6 \, \text{mm}$ arch $(2.6 \,^{\circ} \, \text{decrease})$ is marginally greater than the decreases reported by meta-analysis of the literature (2.1 ° (Mills) and 2.2 ° (Cheung). The reductions in peak rearfoot eversion range found in the current study are greater than those reported in the literature by Stacoff et al., (2007) and Zifchock et al., (2008) that both reported decreases ≤ 1 ° (vrs 1.86° decrease for neutral wedge condition for current study). These differences can be explained by differences in AFPO geometry and material properties used between the current study and the other studies. Further evidence of the importance of material properties and comparing like for like orthoses is apparent. A previous study reported much greater reductions in peak eversion using an orthoses with the same shape as the standard (no wedge, standard arch height) orthotic used in the current study (3.8 ° decrease vrs 1.9 ° decrease) (Majumdar et al., 2013), although the orthoses used by both studies had identical geometries they had differing hardness properties. The orthoses used for the current study were constructed from a shore value of 65 whilst the orthosis used by the previously study were constructed from a harder shore value of 85. It follows, the harder shore value explains why the previous study reported a greater decrease in peak rearfoot eversion.

As expected the APFO used in the current study generally decreased internal ankle inversion moment. The effects of the extrinsic/intrinsic wedges on ankle inversion moment were greater than the effects arising from the arch conditions (e.g. 8° extrinsic wedge caused a 25 % greater decrease in MaxAnkINm compared to the +6mm arch height. The 8mm intrinsic wedge caused the greatest decrease in the 1st peak of internal inversion moment at the ankle joint (MaxAnkINm), whilst the 8° extrinsic wedge caused the greatest decrease in the 2nd peak of inversion moment (Max2AnkINm). It follows that the 8mm intrinsic wedge and 8° extrinsic wedge elicit their greatest effects during loading response and terminal stance respectively. A possible explanation for this is that the intrinsic wedges affect contact under the calcaneus whilst the extrinsic wedges extend to the proximal portion of the orthotic arch geometry thus the designs of wedges will influence kinetics during different periods of stance phase. The results of this study suggest that practitioners seeking to alter moments during loading response

should employ an intrinsic wedge, whilst practitioners wanting to alter moments during terminal stance should use the extrinsic wedge design. This could indicate some potentially useful time based effect of each design and allow clinicians to target changes in function at both periods of stance.

Other studies have reported similar findings to the results shown by the current study (MacLean et al., 2008; Mündermann et al., 2003; Pascual Huerta et al., 2009; Stacoff et al., 2007). Hsu et al., (2014) and Stacoff et al. (2007) found AFPO decreased peak ankle inversion moment by 36 % and 21 % respectively. These values are closest to the effects of the neutral wedge condition for the current study, which relative to the flat inlay condition caused a 33 % decrease in inversion moment (MaxAnkINm). The 12 % greater decrease found for the APFO in the current study compared to the APFO used by Stacoff et al. (2007) can be explained by the differences in APFO design, with the standard orthotic (neutral wedge) condition for the current study eliciting a greater antipronation effect that the orthosis used by Stacoff et al. (2007).

5.6.3 Individual variation in response to changes in orthotic design

The results of the study generally showed APFO caused systematic changes in joint moment and motion responses, however the results also showed individual variation in response to changes in orthotic design. A number of subjects displayed contrasting directions in response. For the effects of APFO geometry on kinematics for example, the 8° extrinsic wedge increased PRE in 3 subjects and increased PRER in 5 subjects. The 8mm intrinsic wedge increased PRE in 4 subjects and increased PRER in 5 subjects. Similar contrasting directions in response can be found for the effect of APFO geometry on kinetics. The -6mm, standard and +6mm arch heights increased MaxAnkINm in 4 subjects. The 4 ° extrinsic and 4 mm intrinsic wedges increased MaxAnkINm in 5 subjects and 3 subjects respectively. In addition to causing contrasting responses, altering APFO geometry caused varying changes in magnitudes of response between subjects. Relative to the flat inlay condition, increasing APFO geometry had little effect in some subjects whilst other subjects experienced much larger changes in kinetic/kinematic responses. In kinematic responses for example, the 4 ° and 8 ° wedges decreased PRE in one subject by 1 ° and 1.9 ° respectively, whilst the same wedges decreased PRE in another subject by 5.3 ° and 5.8 ° respectively. Variability in the magnitude of responses can also be observed for kinetic changes. The -6mm, standard and +6mm arch

heights decreased Max2AnkINm in one subject by 3.5 %, 8.6 % and 6.6 % respectively, whilst the same arch heights decreased Max2AnkINm in another subject by 30 %, 62.6 % and 41.9 % respectively. As described in chapter 2 the variability in the direction and the magnitude of the joint moment/motion responses to APFO can be explained by the action of the neuromuscular system or by the action of external forces, both of which are illustrated by the conceptual model shown in (Figure 2.26). Referencing the mechanical system of APFO effect (section 2.8.9), it is proposed that systematic changes in external force causes systematic changes to biomechanical responses.

5.6.4 Limitations

There are a number of limitations to the current study. Firstly, this study did not characterise the effect of APFO on transverse and sagittal plane kinematics at the rearfoot or frontal and transverse plane kinematics at the midfoot. A study on a large sample of asymptomatic individuals showed that these planes of rotation contribute to kinematic pathways (Nester et al., 2014), however they are not rotations that practitioners typically target when using an APFO. Furthermore, studies typically characterise the effect of APFO on joint moments at the rearfoot (Hsu et al., 2014; Stacoff et al., 2007; Telfer et al., 2013c) because characterising joint moments at the midfoot is complex, specifically in terms of identifying centres of rotation in articulations forming joints at the midfoot.

Secondly, a study shows that biomechanical responses derived by orthosis in individuals will change over time (Turpin et al., 2012). Ideally a study should characterise the effect of AFPO over a longer period to enable a participant's biomechanical response to become better established. It is plausible that foot musculature may adapt over time to APFO. Furthermore, a study has shown that measures of comfort when wearing foot orthoses improves significantly over time following a habituation period (Murley et al., 2010). It follows that comfort may be a feature of an individual's adaptive response to wearing an orthosis which may also influence kinematic responses. However, as the current study is exploratory, and considering the volume of conditions tested, characterising the short term biomechanical responses is deemed an acceptable limitation. Over time the biomechanical effects might get smaller or larger but should not differ in direction between each of the conditions, thus all conditions should be equally affected.

Finally, a further limitation relates to measurement error arising from multi-segment foot models. Soft tissue artefacts have been cited as a source of measurement error (Richards, 2008) and occur when movement of a skin mounted marker mounted at the surface of the skin does not replicate the movement of the underlying bone it represent (absolute error), or if markers move relative to one another (relative error). To reduce the error associated with soft tissue artefacts the current study used rigid plates to define segments of interest which have been shown to provide a truer reflection of underlying kinematics compared with using individual markers attached to the skins surface (Nester et al., 2007). Also, the effects of soft tissue artefacts are likely to be systematic whereby both the direction and size of the effect are expected to be consistent with the underlying bone kinematics.

5.6.5 Implications for orthotic practice

The findings of this study have a number of implications for practitioners prescribing AFPO. Firstly, the results show the intrinsic wedges have a greater effect on rearfoot kinematics than the extrinsic wedges. If decreasing peak rearfoot eversion/eversion range is the objective of treatment, it follows that the AFPO with an intrinsic wedge geometry is most suited for this purpose. Secondly, the results suggest that the different wedge designs affect internal inversion moments during different periods in stance. Practitioners should consider using the intrinsic wedge design if they wish to alter internal inversion moments during loading response and the extrinsic wedge design if they seek to alter inversion moments at terminal stance. Finally, practitioners should be mindful that altering midfoot kinematics using orthosis arch geometry is challenging. A 12mm range in arch height (-6mm to +6mm) caused only small changes in midfoot kinematics and none were statistically significant. This finding questions the rationale in using orthotic arch geometry in APFO if this design feature cannot cause significant changes in midfoot kinematics. However, the resulting kinetic changes were substantial where of the arch heights significantly decreased Max2AnkINm. These findings validate the use of orthotic arch geometry in APFO design. However, the effects of the orthotic arch geometry were not as pronounced as the effects of the medial heel wedges on kinetics. For example, the 8 $^{\circ}$ extrinsic wedge caused a 47 % greater decrease in MaxAnkINm compared to the +6mm orthotic arch height. Thus, although the orthotic arch heights significantly affected kinetics, they caused much smaller changes in joint moments compared with both designs of medial heel wedges.

5.6.6 Conclusion

This study showed APFO can be tailored to systematically alter foot kinetics and kinematics. For 4 out of 9 conditions, increasing orthotic arch height geometry systematically decreased internal inversion ankle joint moments and systematically increased internal eversion ankle joint moments. For 19 out of 27 conditions, increasing medial heel wedge geometry systematically decreased peak rearfoot eversion and eversion range, systematically decreased internal inversion ankle joint moments, and systematically increased internal eversion ankle joint moments. Increasing orthotic arch height geometry did not cause systematic changes to minimum midfoot dorsiflexion or peak rearfoot eversion/eversion range. Neither design of medial heel wedge systematically altered minimum midfoot dorsiflexion and the extrinsic wedges causes no systematic changes to peak rearfoot eversion.

Chapter 6 Research Question 3: Do systematic changes in external forces created by varying APFO geometry correlate to changes in joint moment/motion biomechanical responses?

Chapter 3 investigated if APFO could systematically alter external forces under the foot, and chapter 4 investigated if APFO could systematically alter kinetics and kinematics. Both chapters proved that APFO geometry could be tailored to systematically alter external forces and kinetic/kinematic responses. The traditional model of foot biomechanics and orthotic practices assumes changes in external force and joint kinematics are part of a mechanical system (as outlined by background/literature review in chapter 2), and thus should be closely correlated. This is the assumption that underpins changes in orthotic design that are made in clinical practice. Chapter 6 is therefore concerned with the relationship between systematic changes in external forces and join moment and motion responses.

6.1 Hypotheses

For the effects of external force (measured as peak pressure) on joint moment and motion responses it is proposed that; changes in medial rearfoot peak pressure are strongly correlated with changes in frontal plane moments at the ankle joint (hypothesis 1), changes in medial midfoot peak pressure are strongly correlated with changes in minimum midfoot dorsiflexion (hypothesis 2) and changes in medial rearfoot peak pressure are strongly correlated with changes in peak rearfoot eversion and peak rearfoot eversion range (hypothesis 3).

For the effects of external forces (measured as centre of pressure displacement) on joint moment and motion responses it is proposed that; changes in the medial displacement of the COP are strongly correlated with changes in frontal plane moments at the ankle joint (hypothesis 4), changes in medial displacement of COP are strongly correlated with changes in peak rearfoot eversion and peak rearfoot eversion range (hypothesis 5).

To resist foot pronation, anti-pronation foot orthosis are typically tailored to alter external forces under the medial aspect of the plantar foot. For this reason, changes in medial rearfoot and medial midfoot peak pressure values were chosen as the primary outcome measures used by the correlation analysis to test the hypotheses.

As described in section 3.6, orthotic conditions that caused systematic changes in external forces (peak pressure/centre of pressure) were to be used in the correlation analysis because a systematic change in loading under the sole of the foot is a pre-requisite for causing a corresponding change in joint moment and motion data. However, it is plausible that relationships exist between non-systematic changes in external forces and subsequent joint moment/motion responses, thus orthotic conditions that caused non-systematic changes to peak plantar pressure and centre of pressure displacement were also used in the correlation analysis.

6.2 Results

Of the 36 correlations recorded characterising changes in peak plantar pressures with changes in joint moment and motion responses 4 were significant. The highest correlation recorded was r = -0.562 between medial rearfoot peak pressure and peak rearfoot eversion range when geometry changed from the flat inlay condition to the standard orthotic/neutral wedge (see Table 6.3 and Figure 6.4). Three statistically significant correlations ranged from 0.4 to 0.5 (all p < 0.05).

Of the 72 correlations recorded characterising changes in COP displacement with changes in joint moment and motion responses, 12 were significant. The highest correlation recorded was r = -0.700 between COPMS and MaxAnkINm when geometry changed from the standard orthotic/neutral wedge condition to the 4mm intrinsic wedge (see Table 6.4 and Figure 6.12). 1 statistically significant correlation ranged from 0.4 to 0.5 (p < 0.05), 8 ranged from 0.5 to 0.6 (p < 0.05 & 0.01) and 2 ranged between 0.6 and 0.7 (p < 0.01).

6.3 Peak pressure and internal frontal plane ankle joint moments

Relative to the flat inlay condition, changes in orthotic geometry revealed two significant correlations between medial rearfoot peak pressure and internal frontal plane moments at the ankle joint (see Table 6.1). There was a significant negative correlation between MRPP and

MaxAnkINm when geometry changed from the flat inlay condition to the 4mm intrinsic wedge (r = -.470, p < 0.05); MRPP increased as MaxAnkINm decreased (see Figure 6.1). There was a significant negative correlation between MRPP and MaxAnkEVm when geometry changed from the flat inlay condition to the standard orthotic/neutral wedge (r -.485, p < 0.05); MRPP decreased as MaxAnkEVm increased (see Figure 6.2).

Table 6.1 Correlation coefficients between changes in medial rearfoot peak plantar pressure and changes in 1st peak maximum ankle inversion moment and maximum ankle eversion moment. Changes in peak pressure and ankle moments are described relative to the flat inlay and standard orthotic conditions. Values within brackets show conditions that caused significant changes in peak pressure. Values without brackets identify conditions that caused non-significant changed in peak pressure.

Medial heel wedges		MRPP vrs MaxAnkINm	MRPP vrs MaxAnkEVm
	neutral	333	485*
	4 °	157	095
Difference from	8 °	364	434
flat inlay	4mm	(470*)	(176)
	8mm	355	291
	4 °	(.173)	(.051)
Difference from standard orthotic/ neutral wedge	8 °	(282)	(431)
	4mm	232	191
	8mm	034	071
MRPP MaxAnkINm MaxAnkEVm *	Medial rearfoot peak pressure 1 st peak maximum ankle inversion moment Maximum ankle eversion moment Correlation significant at the .05 level (2-tailed)		

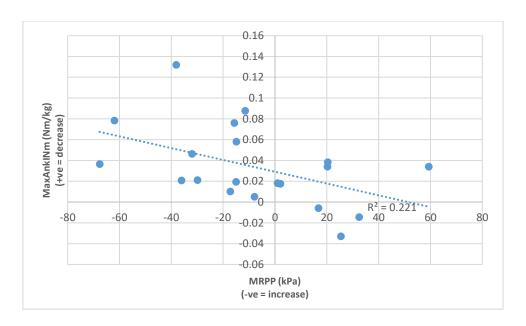


Figure 6.1 Scatterplot showing the relationship between MRPP and MaxAnkINm when geometry is changed from the flat inlay to the 4mm intrinsic wedge condition (r = -0.470). X axis shows change in peak pressure (kPa) and Y axis shows change in ankle inversion moment (Nm/kg).

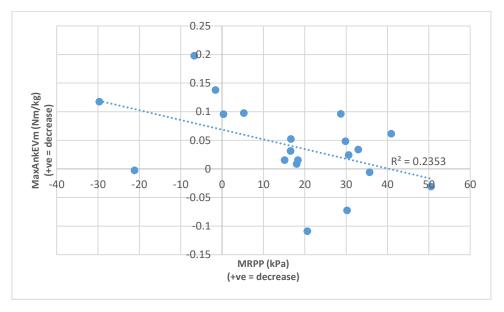


Figure 6.2 Scatterplot showing the relationship between MRPP and MaxAnkEVm when geometry is changed from the flat inlay to the standard orthotic (neutral wedge) condition (r = -0.485). X axis shows change in peak pressure (kPa) and Y axis shows change in ankle eversion moment (Nm/kg).

6.4 Peak pressure and kinematics

Relative to the flat inlay condition, changing orthotic geometry to the -6mm arch height revealed a single significant negative correlation between MMPP and MMD (r = -.494, p < 0.05); MMPP increased as MMD decreased (see Table 6.2 & Figure 6.3).

Table 6.2 Correlation coefficients between changes in medial midfoot peak plantar pressure and changes in minimum midfoot dorsiflexion, both described as changes relative to the flat inlay condition. Values within brackets show conditions that caused significant changes in peak pressure. Values without brackets identify conditions that caused non-significant changed in peak pressure.

Arch conditions		MMPP vrs MMD	
Difference	-6mm	494*	
from flat	Standard	399	
inlay	+6mm	.005	

MMPP Medial midfoot peak pressure
MMD Minimum midfoot dorsiflexion
* Correlation significant at the .05 level (2-tailed)

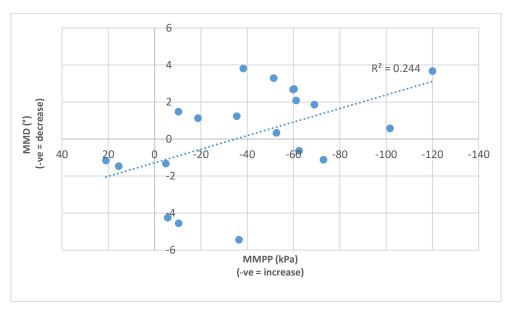


Figure 6.3 Scatterplot showing the relationship between MMPP and MMD when geometry is changes from the flat inlay condition to the -6mm arch height (r = -0.494). X axis shows change in peak pressure (kPa) and Y axis shows change in minimum midfoot dorsiflexion ($^{\circ}$).

Changing orthotic geometry from the flat inlay condition to the standard orthotic/neutral wedge revealed a significant negative correlation between MRPP and PRER (r = -.562, p < 0.01); MRPP decreased as PRER increased (see Table 6.3 & Figure 6.4). Changing orthotic geometry from the standard orthotic/neutral wedge revealed a significant negative correlation between MRPP and PRE (r = -.447, p < 0.05); MRPP increased as PRE decreased (see Table 6.3 & Figure 6.5).

Table 6.3 Correlation coefficients between changes in medial rearfoot peak pressure and changes in peak rearfoot eversion/peak rearfoot eversion range. Changes in peak pressure and rearfoot kinematics are described relative to the flat inlay and standard orthotic/neutral wedge conditions. Values within brackets show conditions that caused significant changes in peak pressure. Values without brackets identify conditions that caused non-significant changed in peak pressure.

Medial wedge conditions			MRPP vrs PRE	MRPP vrs PRER
		neutral	.334	562**
Difference from flat inlay		4 °	.002	037
	m	8°	.261	165
nat imay		4mm	(.283)	308
		8mm	.407	246
Difference from standard		4 °	(214)	(089)
		8°	(251)	(283)
orthotic/neutral wedge	al	4mm	447*	395
weage		8mm	047	.118
PRE I PRER I PRER	Medial rearfoot peak pressure Peak rearfoot eversion Peak rearfoot eversion range Correlation significant at the .05 level (2-tailed) Correlations significant at the .01 level (2-tailed)			

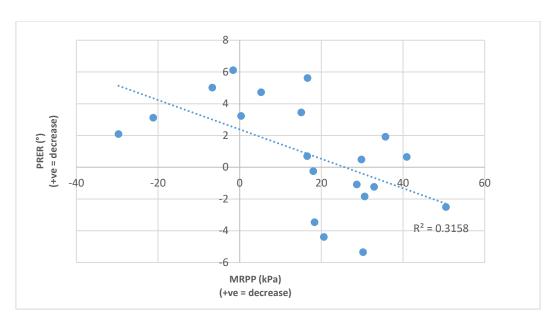


Figure 6.4 Scatterplot showing the relationship between MRPP and PRER when geometry is changed from the flat inlay condition to the standard orthotic (neutral wedge) (r = -0.562). X axis shows change in peak pressure (kPa) and Y axis shows change in peak rearfoot eversion range ($^{\circ}$).

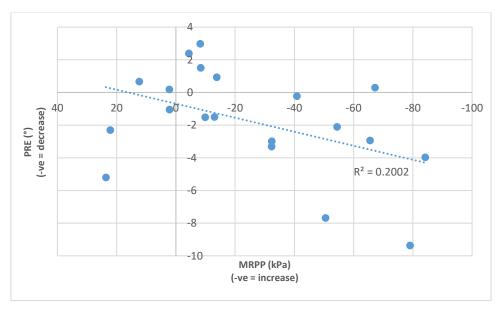


Figure 6.5 Scatterplot showing the relationship between MRPP and PRE when geometry is changed from the standard orthotic condition (neutral wedge) to the 4mm intrinsic wedge (r = -0.447). X axis shows changes in peak pressure (kPa) and Y axis shows change in peak rearfoot eversion ($^{\circ}$).

6.5 Centre of pressure and frontal plane ankle joint moments

Relative to the flat inlay and standard orthotic/neutral wedge conditions changes in orthotic geometry revealed 8 significant correlations between changes in COP displacement and changes in frontal plane moments at the ankle joint (see Table 6.4).

There were 4 significant negative correlations when geometry was changed from the flat inlay condition to the 8 ° extrinsic wedge. These were between, (1) COPLR and MaxAnkINm (r = -.511, p < 0.05); COPLR medial displacement was associated with MaxAnkINm decrease (see Figure 6.6), (2) COPLR and MaxAnkEVm (r = -.448, p < 0.05); COPLR medial displacement was associated with MaxAnkEVm increase (see Figure 6.7), (3) COPMS and MaxAnkINm (r = -.568, p < 0.01); COPMS medial displacement was associated with MaxAnkINm decrease (see Figure 6.8), and (4) COPMS and MaxAnkEVm (r = -.568, p < 0.01); COPMS medial displacement was associates with MaxAnkEVm increase (see Figure 6.9).

There were 4 significant negative correlations when geometry was changed from the standard orthotic/neutral wedge condition to the 4mm intrinsic wedge. These were between, (1) COPLR and MaxAnkINm (r = -.577, p < 0.01); COPLR medial displacement was associated with MaxAnkINm decrease (see Figure 6.10), (2) COPLR and MaxAnkEVm (r = -.548, p < 0.01); COPLR medial displacement was associates with MaxAnkEVm decrease (see Figure 6.11), (3) COPMS and MaxAnkINm (r = -.700, p < 0.01), COPMS medial displacement was associated with MaxAnkINm decrease (see Figure 6.12), and (4) COPMS and MaxAnkEVm (r = -.583, p < 0.01); COPMS medial displacement was associated with MaxAnkEVm decrease (see Figure 6.13).

Table 6.4 Correlation coefficients between changes in centre of pressure displacement (loading response and midstance) and changes 1st peak maximum ankle inversion moment and maximum ankle eversion moment. Changes in centre of pressure displacement and ankle moments are described relative to the flat inlay condition and standard orthotic/neutral wedge condition. Values within brackets show conditions that caused significant changes in peak pressure. Values without brackets identify conditions that caused non-significant changed in peak pressure.

Medial wedge conditions		COPLR vrs MaxAnkINm	COPLR vrs MaxAnkEVm	COPMS vrs MaxAnkINm	COPMS vrs MaxAnkEVm
	neutral	(346)	(236)	259	254
	4 °	(355)	(343)	273	352
Difference from flat inlay	8°	511*	(448*)	568**	568**
Hom hat may	4mm	266	(369)	372	394
	8mm	230	(189)	197	205
Difference from standard orthotic/ neutral wedge	4°	(143)	(.239)	(267)	(.026)
	8°	(105)	(.028)	(086)	(.069)
	4mm	(577**)	(548*)	(700**)	(583**)
nearar weage	8mm	(148)	(.072)	(372)	(266)
COPLR COPMS MaxAnkINm MaxAnkEVm *	Maximum ankle ev Correlation signific	- midstance ankle inversion mon	2-tailed)		

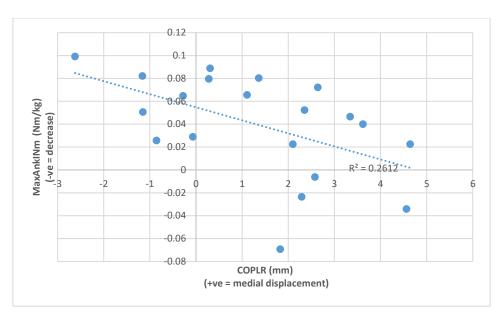


Figure 6.6 Scatterplot showing the relationship between centre of pressure (loading response) and MaxAnkINm when geometry is changed from the flat inlay condition to the 8° extrinsic wedge (r = -0.511). X axis shows centre of pressure displacement (mm) and Y axis shows ankle inversion moment (Nm/kg).

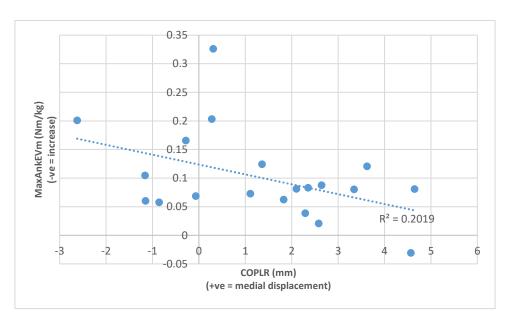


Figure 6.7 Scatterplot showing the relationship between centre of pressure (loading response) and MaxAnkEVm when geometry is changed from the flat inlay condition to the 8° extrinsic wedge (r = -0.448). X axis shows centre of pressure displacement (mm) and Y axis shows ankle eversion moment (Nm/kg).

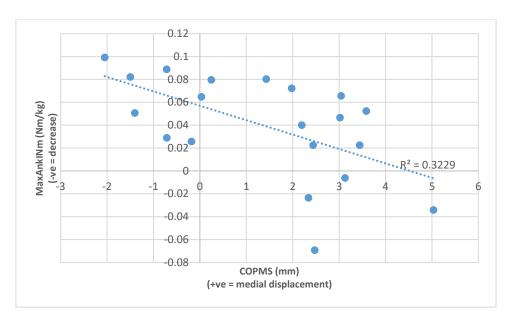


Figure 6.8 Scatterplot showing the relationship between centre of pressure (midstance) and MaxAnkINm when geometry is changed from the flat inlay condition to the 8 $^{\circ}$ extrinsic wedge (r = -0.568). X axis shows centre of pressure displacement (mm) and Y axis shows ankle inversion moment (Nm/kg).

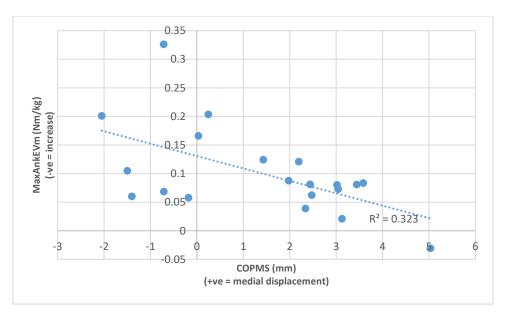


Figure 6.9 Scatterplot showing the relationship between centre of pressure (midstance) and MaxAnkEVm when geometry is changed from the flat inlay condition to the 8° extrinsic wedge (r = -0.568). X axis shows centre of pressure displacement and Y axis shows ankle eversion moment (Nm/kg).

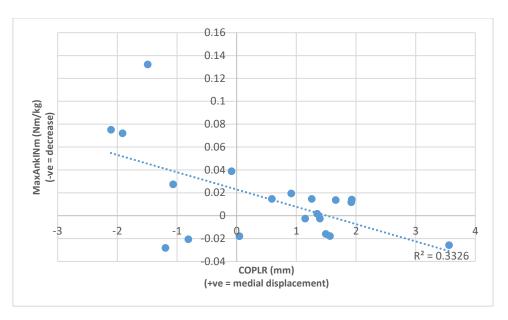


Figure 6.10 Scatterplot showing the relationship between centre of pressure (loading response) and MaxAnkINm when geometry is changed from the standard orthotic condition to the 4mm intrinsic wedge (r = -0.577). X axis shows centre of pressure displacement and Y axis shows ankle inversion moment (Nm/kg).

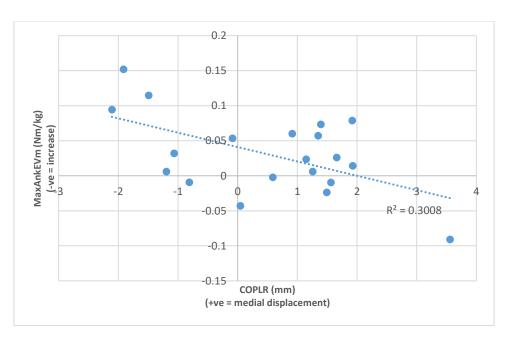


Figure 6.11 Scatterplot showing the relationship between centre of pressure (loading response) and MaxAnkEVm when geometry is changed from the standard orthotic condition to the 4mm intrinsic wedge (r = -0.548). X axis shows centre of pressure displacement and Y axis shows ankle eversion moment (Nm/kg).

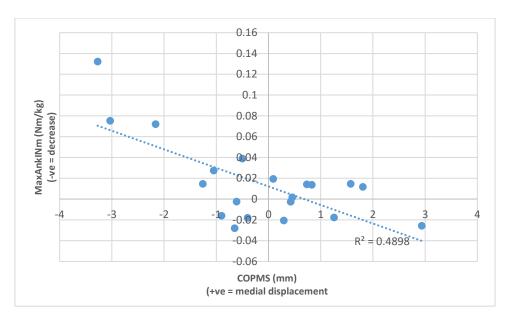


Figure 6.12 Scatterplot showing the relationship between centre of pressure (midstance) and MaxAnkINm when geometry is changed from the standard orthotic condition to the 4mm intrinsic wedge (r = -0.700). X axis shows centre of pressure displacement and Y axis shows ankle inversion moment (Nm/kg).

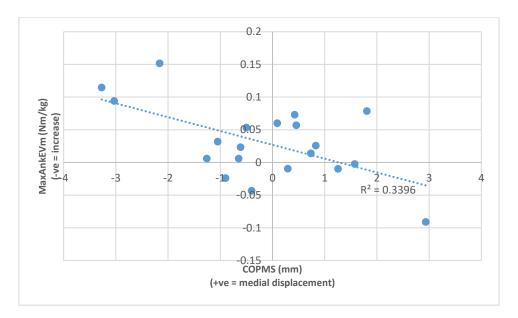


Figure 6.13 Scatterplot showing the relationship between centre of pressure (midstance) and MaxAnkEVm when geometry is changed from the standard orthotic condition to the 4mm intrinsic wedge (r = -0.583). X axis shows centre of pressure displacement and Y axis shows ankle eversion moment (Nm/kg).

6.6 Centre of pressure and kinematics

Relative to the standard orthotic/neutral wedge condition changing orthotic geometry to the 4mm intrinsic wedge revealed 4 significant correlations between changes in COP displacement and changes in peak rearfoot eversion/peak rearfoot eversion range (see Table 6.5). There were two significant positive correlations between COPLR and PRE (r = .575, p < 0.01) and COPMS and PRE (r = .690, p < 0.01); COPLR and COPMS medial displacement was associated with decreases in peak rearfoot eversion (see Figure 6.14 & Figure 6.15). There were two significant negative correlations between COPLR and PRER (r = .544, p < 0.01) and COPMS and PRER (r = .656, p < 0.01); COPLR and COPMS medial displacement was associated with increases in peak rearfoot eversion range (see Figure 6.16 & Figure 6.17).

Table 6.5 Correlation coefficients between changes in centre of pressure displacement (loading response and midstance) and changes in peak rearfoot eversion and peak rearfoot eversion range. Changes in centre of pressure displacement and peak eversion/peak eversion range are described relative to the flat inlay condition and standard orthotic/neutral wedge condition. Values within brackets show conditions that caused significant changes in peak pressure. Values without brackets identify conditions that caused non-significant changed in peak pressure.

Medial wedg	ge		COPLR vrs PRE	COPMS vrs PRE	COPLR vrs PRER	COPMS vrs PRER
		neutral	(.229)	.217	(.056)	028
		4 °	(.365)	(.192)	(297)	(223)
Difference fr flat inlay	om	8°	.192	.191	.027	067
Hat illiay	•	4mm	157	.276	042	109
	•	8mm	.157	.175	.073	.005
		4 °	(.035)	(.200)	(.184)	(073)
Difference fr standard	om	8°	(030)	(021)	(.025)	(173)
orthotic/neut wedge	ral	4mm	(.575**)	(.690**)	(544**)	(656**)
weage	•	8mm	(210)	(.089)	(.059)	(.204)
COPMS OPER IN THE INTERPOLATION OF THE INTERPOLATIO	Centre o Peak rea Peak rea	of pressure – load of pressure – mids arfoot eversion arfoot eversion ran iions significant a	stance	led)		

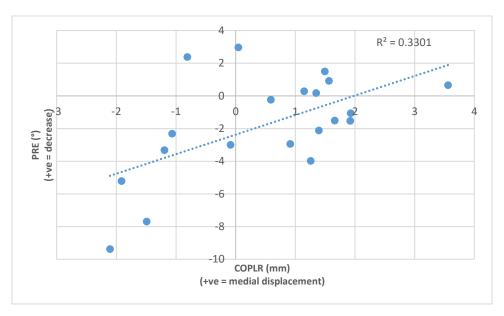


Figure 6.14 Scatterplot showing the relationship between centre of pressure (loading response) and PRE when geometry is changed from the standard orthotic to the 4mm intrinsic wedge (r = .575). X axis shows change centre of pressure displacement (mm) and Y axis shows change in peak rearfoot eversion (°).

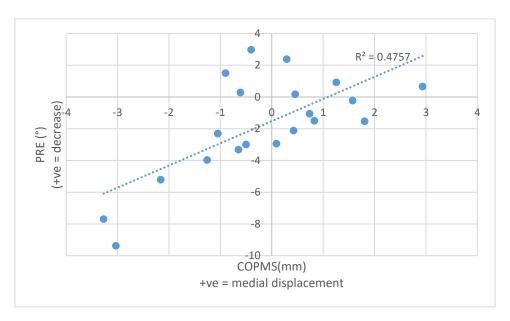


Figure 6.15 Scatterplot showing the relationship between centre of pressure (midstance) and PRE when geometry is changed from the standard orthotic to the 4mm intrinsic wedge (r = .690). X axis shows change centre of pressure displacement (mm) and Y axis shows change in peak rearfoot eversion ($^{\circ}$).

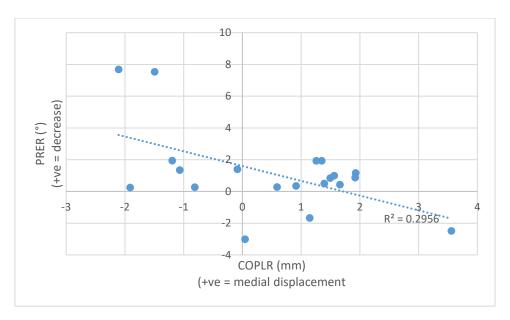


Figure 6.16 Scatterplot showing the relationship between change in centre of pressure displacement (loading response) and change in peak rearfoot eversion range when geometry is changed from the standard orthotic to the 4mm intrinsic wedge condition (r = -.544). X axis shows centre of pressure displacement (mm) and Y axis shows peak rearfoot eversion range ($^{\circ}$).

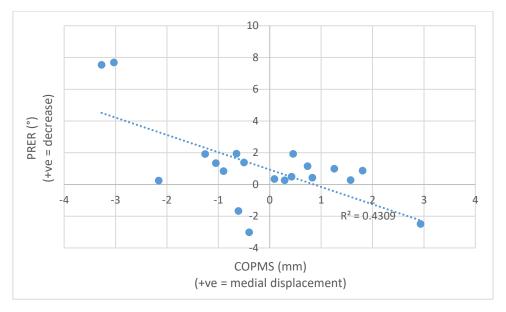


Figure 6.17 Scatterplot showing the relationship between change in centre of pressure displacement (midstance) and change in peak rearfoot eversion range when geometry is changed from the standard orthotic to the 4mm intrinsic wedge condition (r = -.656). X axis shows centre of pressure displacement (mm) and Y axis shows peak rearfoot eversion range ($^{\circ}$).

6.7 Discussion

6.7.1 Hypotheses

This study characterised the relationships between changes in external forces (measured as peak pressure and COP displacement) and joint moments and motion in foot structures due to different orthotic geometries.

When characterising external forces as changes in peak pressure, it was proposed that changes in medial rearfoot peak plantar pressure are strongly correlated with changes in frontal plane moments at the ankle joint (hypothesis 1), changes in medial midfoot peak pressure are strongly correlated with changes in medial midfoot dorsiflexion (hypothesis 2) and changes in medial rearfoot peak pressure are strongly correlated with changes in peak rearfoot eversion and peak rearfoot eversion range (hypothesis 3). None of the orthotic conditions revealed a strong correlation between changes in peak pressure and changes in frontal plane moments at the ankle joint, changes in minimum midfoot dorsiflexion nor changes in peak rearfoot eversion/peak rearfoot eversion range. Thus hypothesis 1, 2 and 3 were rejected.

When characterising external forces as changes in COP displacement, it was proposed that changes in the medial displacement of the COP is strongly correlated with changes in frontal plane moments at the ankle joint (hypothesis 4) and changes in medial displacement of the COP are strongly correlated with changes in peak rearfoot eversion and peak rearfoot eversion range (hypothesis 5). Relative to the standard orthotic/neutral wedge condition the 4mm intrinsic wedge caused a strong correlation between changes in medial displacement of the centre of pressure during midstance and MaxAnkEVm (r = -.700, p < 0.01). It follows hypothesis 4 was accepted for this condition but rejected for all other orthotic conditions. Relative to the standard orthotic/neutral wedge condition the 4mm intrinsic wedge caused a strong correlation between changes in medial displacement of the centre of pressure during midstance and changes in peak rearfoot eversion (r = .690, p < 0.01) and changes in peak rearfoot eversion range (r = -.656, p < 0.01). It follows that hypothesis 5 was accepted for this condition but rejected for all other orthotic conditions.

The results of the study broadly showed that targeting orthotic design to achieve specific changes in external force (peak pressure and COP displacement) under the medial rearfoot and medial midfoot will not enable a practitioner to create specific changes in rearfoot and midfoot kinematics, or changes in rearfoot kinetics.

6.7.2 Is there any evidence of a relationship between changes in pressure, kinematics and kinetics due to foot orthoses?

The hypotheses for this study proposed that a strong relationship (r > 0.6) exists between changes in external forces (measured as plantar pressure, centre of pressure displacement) and changes in biomechanical responses (measured as joint moments and motion). requirement for a strong relationship was based on the strength of belief in the relationship within clinical practice models whereby specific moment/motion responses are dependent in how APFO geometry alters external forces under the sole of the foot (e.g. Root Model, SALRE model described in Chapter 2). Although the proposed hypotheses were largely rejected based on the r value, the results generally showed evidence of moderate rather than strong relationships between changes in external forces and changes kinetic/kinematic responses. For example, relative to the flat inlay condition the effects of the standard orthotic/neutral wedge caused moderate correlations between changes in medial rearfoot peak pressure and changes in both ankle eversion moment (r = -.485), and peak rearfoot eversion range (r = -.562). It follows that changes in peak pressure caused by this condition explained 24 % of change in ankle eversion moment ($r^2 = 0.221$; Figure 6.1) and 32 % change in peak rearfoot eversion range ($r^2 = -.3158$; Figure 6.4). Relative to the standard orthotic/neutral wedge condition, the effects of the 4mm intrinsic wedge caused moderate correlations between changes in COP displacement during loading response and changes in both 1st peak ankle inversion moment (r = -.577) and peak rearfoot eversion (r = .575). Changes in COP displacement caused by this condition explained 33 % of change in 1st peak ankle inversion moment ($r^2 = 0.332$; Figure 6.10) and 33 % change in peak rearfoot eversion ($r^2 = 0.33$; Figure 6.14).

The strongest correlations occurred when characterising changes in external forces using centre of pressure displacement. This was especially true for the effects of the 8° extrinsic wedge on ankle joint moments relative to the flat inlay condition and the effects of the 4mm intrinsic wedge relative to the standard orthotic/neutral wedge condition (Table 6.4). The 4mm intrinsic wedge caused the strongest correlations between changes in COP displacement and changes in both ankle joint moments and kinematics relative to the standard orthotic condition (Table 6.4 & Table 6.5). This condition explained 49 % of the variance between COPMS medial displacement and 1^{st} peak ankle inversion moment decrease ($r^2 = 0.4898$; Figure 6.12) and 48% of the variance between COPMS and peak rearfoot eversion decrease ($r^2 = 0.4757$; Figure 6.15).

An explanation as to why the 4mm intrinsic wedge caused stronger correlations between COP displacement and moment/motion responses relative to the standard orthotic/neutral wedge compared to other conditions may relate to the small perturbations this condition caused in modifying COP displacement. Chapter 3 showed the 4mm intrinsic wedge caused non-significant changes in COP displacement during midstance relative to the standard orthotic /neutral wedge condition (Table 4.6). Yet, this non-significant or systematic change in external force input was associated with the strongest correlation in moment (r = -0.700) and motion (r = 0.690) responses. Perhaps small perturbations in COP displacement may give rise to more systematic joint moment/motion responses and larger COP changes may cause a greater neuromuscular response to control a moment/motion pathway, which may in turn give rise to increased variability in the response thus explain the weaker correlations between the other conditions.

The majority of significant correlations found in the current study were moderate and explained approximately 25-35 % change in peak eversion, peak eversion range and internal frontal plane moments at the ankle joint. It follows that paradigms and practitioners alike should re-evaluate their expectations as to the extent to which external forces influence joint moment/motion responses considering the remaining ~ 75 % is caused by other factors (e.g. neuromuscular).

Previous studies have characterised the effect of AFPO on external forces (Bonanno et al., 2012; Redmond et al., 2009; Tang et al., 2015), moment responses (Hsu et al., 2014; Pascual Huerta et al., 2009; Stacoff et al., 2007) and motion responses (Branthwaite et al., 2004; Majumdar et al., 2013; Stacoff et al., 2007), however no study has attempted to characterise the relationship between how AFPO alters external forces and how these changes in external forces influence moment/motion responses. Studies have sought to understand whether structural alignment in the foot/ankle can predict patterns of loading under different regions of the plantar foot. These studies reported poor relationships between medial rearfoot peak pressure and arch index, navicular drop, navicular drift (Jonely et al., 2011) and between rearfoot peak pressure and frontal plane rearfoot motion (Giacomozzi et al., 2014). It has been shown that foot posture measures explains only a small amount of variation (5 to 22 %) in foot kinematics (Buldt et al., 2015a). There is thus no strong evidence for a relationship between static/dynamic measure of foot structure and dynamic behaviour of the foot. This current work has shown there is also no strong evidence for a relationship between different data even when collected during the same dynamic task thus further reduces the likelihood of a link between static and dynamic measures of foot biomechanics. Furthermore a study characterising the

relationship between COP displacement and rearfoot kinematics in runners found a low correlation between peak rearfoot eversion, eversion range and COP lateral to medial displacement (Dixon, 2006). Although these studies characterise plantar pressure/COP as a response variable (i.e. an effect) rather than an input variable (i.e. a cause) of foot kinematics as in this study, findings from both suggest changes in pressure/COP are not related to foot posture or foot kinematics. Therefore, the relationship between measures that reflect external forces and measures of foot kinematics should be reconsidered, as there are other factors involved in determining kinematics. As discussed and proposed in Chapter 2, this points strongly to the response to a foot orthosis not being a purely mechanical response, and this is a key outcome of this thesis. Rather, in light of this evidence, it is pertinent to revisit the question of what, if not exclusively external forces, might explain the kinematic response to foot orthoses? This question is addressed in the subsequent discussion chapter drawing upon the work contained in all of the experiments presented in this thesis (see chapter 8).

6.7.3 Limitations

There are a number of limitations to the current study. Firstly, the foot mask did not take into account pressure changes that occurred at the forefoot thus were not added to the correlation analysis. Studies characterising the relationships between external forces under the foot and foot posture/kinematics reported the correlations involving forefoot pressure values were stronger when compared to correlations involving rearfoot pressure values (Giacomozzi et al., 2014; Jonely et al., 2011). However, medial wedge and arch geometry in APFO are purported to function by altering biomechanical responses at the rearfoot and midfoot (Ferber et al., 2011; Kirby, 1992), thus this study sought understand the relationship between how changes in loading influences changes in moment/motion responses for these regions. Indeed, when peak forefoot pressure occurs the heel and midfoot are off the ground, and peak rearfoot pressures, moments and kinematic changes occur much earlier than changes in forefoot pressure due to orthoses. Also related to pressure, in-shoe pressure measurement systems quantify the effect of the vertical component of the GRF, but do not measure anterior-posterior and medial-lateral shearing forces. Thus, for the correlation analysis between peak pressure and joint moment/motion responses only the vertical force component was used. It follows that the influence of shearing forces may potentially increase the strength of the correlations between external forces and joint moment/motion responses above the 25 -35 % reported by the current study.

Secondly, this study did not characterise the effect of APFO on kinematics in individuals with different foot types, which has been shown to have some general association with foot kinematic patterns, though foot type is not strongly predictive of dynamic foot kinematics (Buldt et al., 2015). It is plausible that changes in external forces caused by AFPO in individuals with different foot types may result in differing biomechanical responses. For example, cavus and planus foot types, measured by either static or dynamic means, might be expected to occupy different space within the shoe. However, the current study is exploratory in nature and sought to understand whether changes in external forces influence biomechanical responses in a group of asymptomatic individuals. It follows that future studies could consider foot type to a greater degree. Furthermore, future studies could characterise how altering geometry of custom made APFO influences pressure and joint moments and motion. For example, the standard orthotic in a future study could be a custom made version, with other conditions possessing -6mm and +6mm increments in arch height from the standard.

In conclusion, with reference to the research question proposed, changes in external forces applied to the plantar surface with different AFPO were generally not strongly correlated with changes in foot kinetics/kinematics as the hypotheses assumed. There was evidence of strong correlations in some specific cases, but the overall majority of significant correlations found were weak to moderate. It is therefore possible to conclude that the moment and kinematic response to a foot orthosis cannot be explained as a purely mechanical system as suggested in section 2.8.9 and by the hypotheses proposed in section 2.9.1

Chapter 7 Research Question 4: Can APFO geometry systematically alter the thickness of soft tissues under the sole of the foot?

In Chapters 4, 5 and 6 the belief that external forces predict moment responses, or are strongly related to kinematics responses, has been challenged. It follows that factors other than external forces are related to the moment and motion responses of the foot to the FO. The forces applied to the plantar surface pass through plantar soft tissues prior to being applied to bones of the joint and affect moments or kinematics. As highlighted in Chapter 2 (section 2.8.10) it would be valuable to understand how soft tissues respond to change in external forces due to change in orthotic geometry, as this infers whether and how this factor might influence the response of the foot to a foot orthosis. This chapter is comprised of research published during the course of the PhD (Sweeney et al., 2015).

The principal design features in an APFO are the geometry of the heel and arch sections. In addition to orthotic material stiffness (Healy et al., 2012), these features will alter loads between the plantar aspect of the foot and orthotic surface (Che et al., 1994; Hinz et al., 2008; Redmond et al., 2009). Increases in peak pressure in the arch (Bus et al., 2004; Chen et al., 2003) and reductions in pressure in the heel (Ashry et al., 1997; Bus et al., 2004; Chen et al., 2003; El-Hilaly et al.) have been well documented for total contact orthosis used in patients with diabetes. Similarly, both extrinsic (Telfer et al., 2013a; Van Gheluwe et al., 2004) and intrinsic (Bonanno et al., 2012) heel wedges have been shown to increase pressure values in the medial heel. The results in Chapters 4, 5 and 6 provide further evidence of this effect, though it falls short of fully explaining the response of the foot to an orthosis and change in geometry of that orthosis. It is less clear how changes in load at the skin surface affect loads transferred to bone nor how this is 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 (Luo et al., 2011). 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 (Perhamre et al., 2012). However, the

orthoses used in previous studies did not incorporate a medial wedge. This design feature has been associated with an antipronation effect (Bonanno et al., 2012; Telfer et al., 2013b; Van Gheluwe et al., 2004) and there are also two different designs (inside and outside the heel cup) with proposed different effects (Kirby, 1992). Thus, it is unclear how an antipronation orthosis will affect plantar soft tissues characteristics under either the calcaneus or medial arch.

Chapter 7 outlines an approach using ultrasound to quantify soft tissue structures under the plantar heel and arch through an antipronation foot orthosis.

7.1 Ultrasound

Diagnostic ultrasound (or sonography) is an imaging modality that uses high frequency sound waves to produce images of structures within the body. Typical audible sound sensed by the human ear ranges between 20 Hz to 20 kHz, however ultrasound has a frequency greater than 20 kHz. Ultrasound is becoming an increasingly popular diagnostic tool as compared with other imaging modalities it is non-invasive, portable and less expensive. Furthermore, being a real time method of imaging structures, ultrasound enables the practitioner to move a body segment and interact with a patient thus directing imaging towards the symptomatic structure of interest. Other imaging modalities (X-ray, MRI) do not permit dynamic image analysis in this way. Table 7.1 compares ultrasound with a number of imaging modalities and Figure 7.1 shows the growth in use of ultrasound. Unlike other imaging modalities, the image quality and quantification of imaged structures is dependent on the proficiency of the operator, thus this is considered the principle limitation of ultrasound (Crofts et al., 2014).

Table 7.1 Comparison of imaging modalities, from Szabo (2013)

Modality	Ultrasound	X-ray	ст	MRI
What is imaged	Longitudinal, shear, mechanical properties	Mean X-ray tissue absorption	Local tissue X- ray absorption	Biochemistry (71 and 72)
Access	Small windows adequate	2 sides needed	Circumferential around body	Circumferential around body
Spatial resolution	Frequency and axially dependent 0.2 - 3 mm	~1 mm	~1 mm	~ 1 mm
Penetration	Frequency dependent, 3-25 cm	Excellent	Excellent	Excellent
Safety	Excellent for > 50 years	Ionizing radiation	lonizing radiation	Very good
Speed	> 100 frames/sec	Minutes	20 minutes	Typical: 45 minutes; fastest-10 frames/sec
Cost	\$_>\$-	\$	\$\$	\$\$\$
Portability	Excellent	Good	Poor	Poor
Volume Coverage	Real-time 3D volumes, improving	2D	Large 3D volume	Large 3D volume
Contrast	Increasing (shear)	Limited	Limited	Slightly flexible
Intervention	Real-time 3D increasing	No, Fluoroscopy limited	No	Yes, limited
Functional	Functional ultrasound	No	No	fMRI

Global imaging modality use 2000/2011

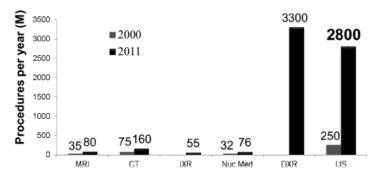


Figure 7.1 Comparison of estimated number of imaging exams given worldwide for the years 2000 and 2011. CT, computated tomography; DXR, digital W-ray; iXR, interventional X-ray; MRI, magnetic resonance imaging; Nuc Med, nuclear medicine; PET, positron emission tomography; US, diagnostic ultrasound, from (Szabo, 2013).

In medical diagnostics ultrasound waves are produced by a piezoelectric transducer. Electrical pulses generate oscillations of crystals forming the transducer that creates sound waves. These soundwaves transmit through tissue and are subsequently reflected and returned as echoes back to the transducer. These echoes are converted by the crystals into electrical signals and are processed to form an image. When forming an image the ultrasound machine needs to determine the direction and strength of the echo and the time taken between when the signal was sent to when it was received. When a sound wave encounters tissues with different acoustic impedances, part of the sound wave is reflected back to the transducer and detected as

an echo. The intensity of the echo is proportional to the differences in acoustic impedances between the different mediums. Tissues with similar acoustic impedances will generate low intensity echoes and conversely tissues with differing acoustic impedances will generate high intensity echoes. Table 7.2 shows the acoustic impedances associated with different tissues within the body.

The time taken for the echo to be transmitted to the transducer is used to calculate the depth of the tissue causing the echo. Larger differences between acoustic impedances are associated with the larger echoes. Echogenicity of the tissue is used to describe its ability to reflect or transmit US waves with reference to adjacent tissues where structures can be imaged as hyperechoic (white), hypoechoic (gray) and anechoic (black) (Ihnatsenka et al., 2010). The boundaries of bone appear hyperechoic, however as US cannot penetrate bone beyond its boundary thus bone appears anechoic. Fascia and connective tissues appear hyperechoic whilst muscle appears hypoechoic.

Probes with higher frequencies (shorter wave lengths) are recommended when characterising superficial structures, however the attenuation of the sound wave increases with higher frequencies therefore to better penetrate deeper structures probes with lower frequencies (longer wavelengths) are indicated. In addition to frequency, transducer probes can be characterised according their shape and footprint size. Straight or linear array probes create a straight US beam and image whereas curvilinear probes generate a wedge-based US beam with a broader image (Figure 7.2). The footprint size is used to characterise the dimensions of the scanning surface of the probe. Smaller footprint sizes are beneficial when scanning over small body segments thus ensuring the entire probe remains in contact with the skin, however probes with larger footprint sizes offer a larger image.

Table 7.2 Acoustic impedances of different tissues within the body. Adapted from Narouze (2011).

Body tissue	Acoustic impedance (10 ⁶ Rayls)
Air	0.0004
Lung	0.18
Fat	1.34
Liver	1.65
Blood	1.65
Kidney	1.63
Muscle	1.71
Bone	7.8

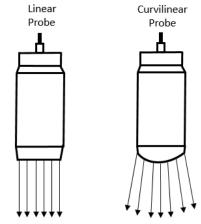


Figure 7.2 Illustration showing linear probe and curvilinear probe.

An operator may obtain an optimum image by altering the orientation of the US probe when scanning (rotating or tilting). Furthermore, an operator may improve image quality by altering the gain setting which changes the overall brightness of the image, and the depth settings whereby increasing the depth allows deeper structures to be viewed, although this decreases the image resolution. An operator must ensure that US images produced are not influenced by artefacts such as; attenuation, where tissues absorb sound; reverberations, where sound waves reflecting back and forth between the surface of the probe and reflect at the surface of the image area; and refraction, where sound waves are refracted it is passes from one medium to another (Sites et al., 2010).

Ultrasound is becoming increasingly popular for quantifying soft tissue characteristics (Cameron et al., 2008; Mickle et al., 2013). As well as being non-invasive it is portable so, unlike MRI (Wolf et al., 2007), can be used to quantify tissue characteristics in a weight bearing prone position. Ultrasound has been used to measure foot muscles (McCreesh et al., 2011), skin and plantar aponeurosis (Duffin et al., 2002). Furthermore, it demonstrates good intra and inter observer reliability with foot structures (Mickle et al., 2013). 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 (Telfer et al., 2014).

The aim of the study within chapter 7 was to use ultrasound to characterise static barefoot plantar tissue responses to different APFO geometries.

7.2 Hypotheses

Research question 4 examined if altering APFO geometry (in the heel and arch) caused systematic changes in soft tissue compression. A number of hypotheses were proposed to answer this research question. Hypothesis 1 proposed that increases in orthotic arch geometry height will systematically decrease the thickness of soft tissues under the medial arch. Hypothesis 2 proposed that increases in medial heel wedge geometry will systematically decrease the thickness of soft tissues under the calcaneus.

7.3 Method

7.3.1 Participants

Ethical approval was granted from the institutional Ethics Committee (HSCR12/57). Details of this application for ethical approval are shown in appendices (1-4). Ten participants were recruited for a pilot study; (50 % male), mean age of 28.1 years (SD 4.9 years), mean weight 68.2 kg (SD 7.47 kg), and height 1.71 m (SD 0.07m). For the main study 27 participants were recruited; (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). Data were collected from the right foot. Participants reported no recent history of lower limb pathology or surgery and all gave informed written consent to participate.

7.3.2 **Pilot study**

A pilot study sought to determine a reliable method of quantifying soft tissue thickness between the surface of an APFO and bones overlying the medial longitudinal arch (related to the effects of orthotic arch height). The pilot did not examine the reliability of quantifying soft tissue thickness under the calcaneus, because with its superficially location, shape and surrounding tissue properties, it is easily identifiable and has demonstrated good reliability (Rome, 1998; Telfer et al., 2014).

7.3.2.1 *Orthosis*

The Salfordinsole™ (Salfordinsole Health Care Ltd, UK) was chosen as an example APFO (Majumdar et al., 2013) but like most orthotic products it is impenetrable to ultrasound signals due to the presence of air in its materials. 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 a milled EVA version of the Salfordinsole™. A 3 mm Northplex sheet was subsequently heat moulded and vacuum formed over the Salfordinsole™ positive model. 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 (Figure 7.3).



Figure 7.3 Photo of Northplex® orthotic used during the plot study testing

7.3.2.2 Ultrasound and Scanning Platform

A MyLab 70 Xvision ultrasound machine and 13MHz linear array transducer (Type, LA523, 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. 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 7.4).

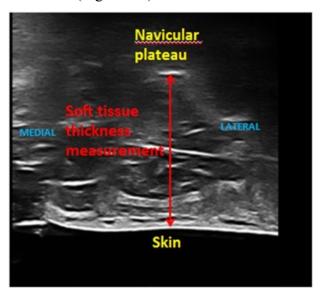


Figure 7.4 Ultrasound image showing landmarks used to record tissue thickness measurement under the medial longitudinal arch.

This landmark was imaged in the frontal plane and lateral to the navicular tuberosity by 1/3 of the navicular width. Frontal plane images of transverse tissue thickness, between the bony reference landmark and skin were recorded through the Northplex® insole with the subject stood on top. A platform incorporating a 50 mm x 120 mm opening (Figure 7.5) was used to position the ultrasound transducer under the orthotic/foot at the and arch scanning site.

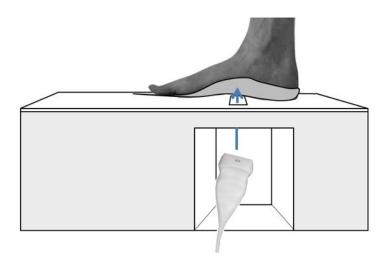


Figure 7.5 Scanning platform used to enable US imaging of the plantar soft tissues under the arch through the Northplex® insole.

7.3.2.3 *Ultrasound scanning protocol*

As outlined, a 4 – 13 MHz linear array probe was used to scan the navicular plateau through the Northplex insole. This probe was selected because its frequency enabled sufficient resolution of the navicular plateau at depths ranging between 25-40mm through the Northplex orthosis. A higher frequency transducer would provide greater resolution of soft tissue structures situated between skin and bone, however for this study the goal was to achieve the most detailed visualisation of the hyperechoic rim in bone forming the plantar surface of the navicular plateau, which was achieved by the selected probe. Furthermore, this probe was selected because its footprint area (50mm x 8mm) was sufficient to visualise the anatomy under the midfoot but also because the dimensions of the probe enabled ease of use whilst scanning through the scanning platform.

To ensure the probe appropriately contacted the plantar surface of the orthotic a standoff pad was used. This has also been shown to decrease the generation of intense echoes in superficial regions positioned in close proximity to a probe (Biller 1998), thus is particularly applicable

when scanning through the Northplex orthotic therefore assisting in visualisation of the navicular plateau. The acoustic impedance (Z) of Northplex is not known however, it is thought to be similar to that of polypropylene, a comparable thermoplastic material that has an acoustic impedance of 2.36 (10⁶ Rayls) (Selfridge, 1985).

Before data were collected, a grid was drawn on the subject's medial midfoot. This grid consisted of perpendicular lines positioned 5mm apart. Once the grid was drawn, a freehand scan was performed on each participant. This enabled identification of the scanning site for the navicular plateau, which was subsequently marked on the skin with reference to the grid. Northplex® is transparent, thus markings at the skins surface could be viewed from the underside of the orthotic whilst the subject stood on top thus facilitated placement of the ultrasound probe when scanning.

During scanning the probe was positioned at the scanning site (transversely) under the orthotic and the target area (navicular plateau) was positioned on the top/centre of the screen. As described previously, for this study the primary interest was characterising tissue thickness between the navicular plateau and skin, and not the specific architecture of the soft tissue structures. A higher frequency probe may have enabled more detailed analysis of these structures however a higher frequency with shorter wavelengths would decrease the depth of the view due to higher attenuation of ultrasound waves within the tissues. The depth settings were adjusted by approximately 10mm deeper than the target region of interest. The gain of the ultrasound machine was also adjusted to alter the grey scale imaging of the navicular plateau with a view to improving the clarity of the hyperechoic rim in bone forming the plantar surface of the navicular plateau. The depth and gain settings were consistent for the same subject across all conditions. During data collection the probe was held in a perpendicular position relative to the target region with the assistance of a spirit level.

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 (Richards, 2008). The same examiner (the PhD candidate) recorded three images

of tissue thickness for each subject and the probe was removed between each scan. To quantify intra-rater reliability the same examiner took all scans on two separate occasions twenty four hours apart.

7.3.2.4 Pilot study data analysis

Image J software was used to quantify tissue thickness through the Northplex® orthosis with the assessor blinded to image and day of scan. This software has excellent inter-rater reliability when measuring soft tissues from ultrasound images (McCreesh et al., 2011). Day 1 and day 2 mean values of tissue thickness were derived from the three images taken for each subject. Intraclass correlation coefficients (ICC; 3,1) were calculated using SPSS (Version 19, SPSS Inc., Chicago, IL) to assess day-to-day reliability of the measurements. Excellent reliability was defined as an ICC > 0.75 (Fleiss, 1999).

7.3.2.5 Pilot study results

The intra-rater reliability for quantifying tissue thickness between the skin and navicular plateau through a Northplex® orthosis was excellent, with an ICC _{3,1} of 0.980, 95% CI [0.92 0.99]. Day 1 and day 2 individual measurements of tissue thickness are shown in Figure 7.6. A mean (SD) value of 27.7 mm (SD 4.2 mm) was recorded for day 1 testing and a mean of 27.3 mm (SD 3.8 mm) was found for day 2.

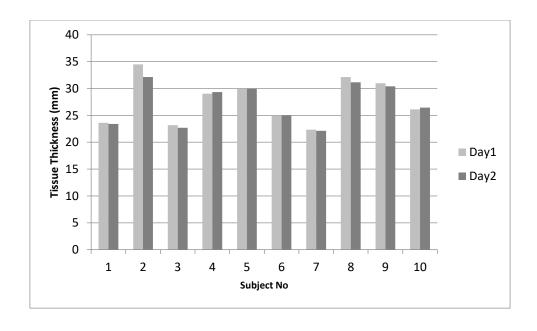


Figure 7.6 Day 1 and day 2 values of arch tissue thickness (mm) measured through the Northplex® insole.

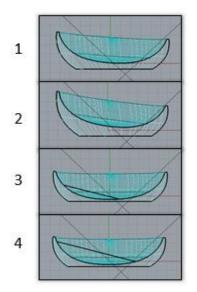
The results of the pilot showed that using ultrasound to quantify tissue thickness in the arch of the foot through a Northplex® orthosis has excellent intra-rater reliability.

7.3.3 Main study

7.3.3.1 *Orthoses*

As in the pilot study, the Salfordinsole[™] (Salfordinsole Health Care Ltd, UK) was chosen as the APFO base design to manufacture a number of orthosis with different heel and arch geometries from Northplex®. Three Northplex® insoles were produced to investigate the effect of varying arch geometry 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.

For the main study it was decided to investigate the effect of varying the size of the medial wedge using two different approaches, both used in clinical practice: an intrinsic wedge (inside the heel cup) measured in millimetres, and an extrinsic wedge measured in degrees (under the heel cup). The 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 (Kirby, 1992). Two Northplex® designs were produced for each approach: a 4 ° and 8 ° extrinsic wedge and a 4mm and 8mm intrinsic wedge. All orthotic designs were created and modified using CAD/CAM to strictly control changes in orthotic geometry (Salfordinsole iCUSTOM software). Figure 7.7 shows the design of the different heel and arch geometries.



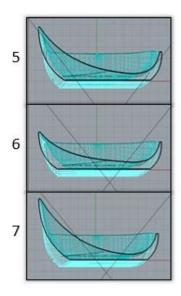


Figure 7.7 1-2 are 4° and 8° extrinsic medial wedges, 3-4 are 4mm and 8mm intrinsic medial wedges. 6 is the standard arch profile, 7 is -6mm arch height and 8 is +6mm arch height.

7.3.3.2 *Method*

For the main study, 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 plateau on the plantar surface of the navicular was used as the internal bony reference for measures of arch tissue thickness which the pilot study 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. As previously described, due to its superficial location, shape and tissue properties, it is easily identified and has demonstrated high reliability (Rome, 1998; Telfer et al., 2014). The same ultrasound protocol outlined in 7.3.2.3, was used to visualise the hyperechoic border of the calcaneal tuberosity. Each participant stood with their right foot on the orthotic which was secured over the platform aperture. As described by the pilot, participants stood on one leg and used hand rails to prevent sway and a weighted vest was used to improve the extent to which this static assessment might replicate soft tissue compression in walking.

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).

7.3.3.3 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. Image J software quantified soft tissue thickness from each of the 3 images captured which were then subsequently used to form a mean tissue thickness value for each condition. This process was repeated for all conditions for each subject. 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 ($\alpha = 0.05$).

Figure 7.8 shows the repeated measures factors and levels associated with the repeated measures analysis of variance used in Chapter 7. Bonferroni post hoc testing was used to examine significant main effects.

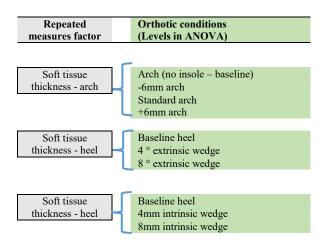


Figure 7.8 Illustration showing the repeated measures factors and levels associated with each of the ANOVA's undertaken for Chapter 7.

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.

7.3.3.4 *Results*

Arch soft tissue thickness at baseline was 29.9mm (SD 3.6mm). Varying the arch height had a significant effect on soft tissue thickness $(F_{1.6,39}) = 70.6$, p < 0.001)*. Post hoc testing showed that the three arch heights significantly reduced tissue thickness compared to the baseline condition (see Figure 7.9). The +6mm 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 -6mm arch height (9.1 %; p < 0.001). There was a 2.37 % decrease in tissue thickness between the -6mm and standard arch height ranges (0.4 % decrease per mm increase in arch height). A 2.26 % decrease was found between the standard and +6mm arch height ranges (0.38 % decrease per mm increase in arch height).

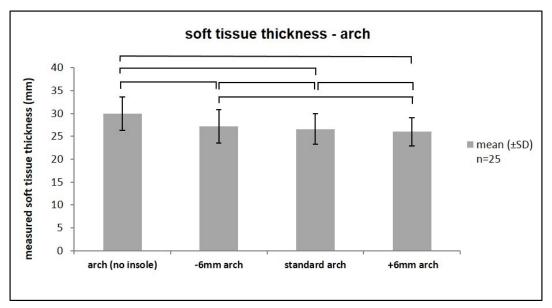
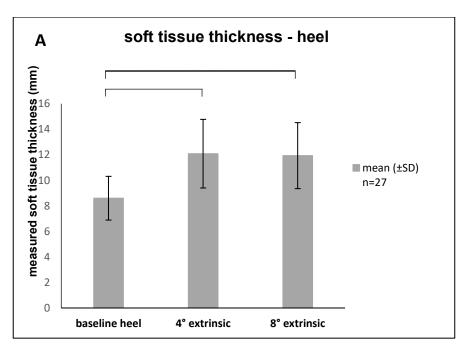


Figure 7.9 Measured soft tissue thickness for arch baseline, -6mm, standard and +6mm arch heights. The horizontal lines indicate significant differences between insole conditions. Pairwise comparisons are as follows (with Bonferroni corrections); arch (no insoles) to -6mm arch (p < 0.001, 95 % CI 0.167 - 0.378), arch to standard arch (p < 0.001, 95 % CI 0.231 - 0.434), arch to +6mm arch (p < 0.001, 95 % CI 0.053 - 0.185), standard to +6mm arch (p < 0.004, 95 % CI 0.016 - 0.104).

Heel soft tissue thickness at baseline was 8.6mm (SD 1.7mm). The extrinsic wedge conditions had a significant effect on soft tissue thickness ($F_{2, 52}$) = 116.6, p<0.001). Post hoc testing showed that both extrinsic wedges significantly increased tissue thickness compared to the baseline (see Figure 7.10 A). The 4° extrinsic increased tissue thickness by 28.3% (p<0.001)

^{*} Mauchlys' test of sphericity indicated that the assumption of sphericity had been violated therefore the degrees of freedom were adjusted with a Greenhouse-Geisser correction.

whilst the 8 ° 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). Post hoc testing showed that both intrinsic wedges significantly increased tissue thickness compared to the baseline (see Figure 7.10 B). The 4mm intrinsic wedge increased tissue thickness by 23 % (p < 0.001) whilst the 8mm 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 8mm wedge (8.3 % increase; p < 0.001). A 4.1 % reduction in tissue thickness was found between the 4 ° and 8 ° 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).



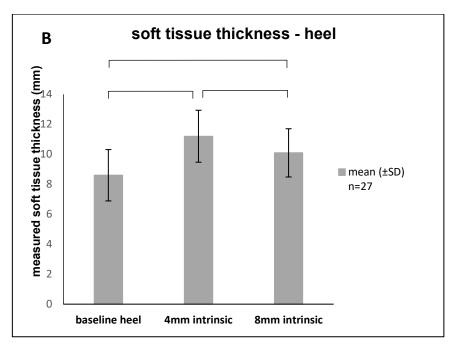


Figure 7.10 Measured soft tissue thickness for (A) extrinsic wedges and (B) intrinsic wedges. The horizontal lines indicate significant differences between insole conditions. Pairwise comparisons are as follows (with Bonferroni corrections); baseline heel to 4 ° extrinsic wedge (p < 0.001, 95 % CI 0.273 – 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 4mm intrinsic wedge (p < 0.001, 95 % CI 0.094 – 0.215), 4mm intrinsic wedge to 8 mm intrinsic wedge (p < 0.001, 95 % CI 0.064 – 0.15).

7.4 Discussion

To characterise the effect of changes in arch geometry on soft tissue structures under the foot this study quantified how different arch heights altered tissue thickness under the medial arch and also quantified how different medial wedge geometry affected tissue thickness under the calcaneus. Two hypotheses were proposed to characterise the effects of APFO on tissue compression relative to a baseline condition. Hypothesis 1 proposed that increasing arch geometry height would systematically decrease tissue thickness under the medial arch. Hypothesis 2 proposed that increasing medial heel wedge geometry (angle and thickness) would systematically decrease tissue thickness under the calcaneus.

Hypothesis 1 was accepted for the effects of the arch heights on tissue thickness under the medial arch because the three arch heights systematically decreased tissue thickness under the medial arch compared to the baseline condition. The effect between the different arch heights on tissue compression however was small. The -6 mm and standard arch heights caused a 2.7mm and 3.3mm decrease in tissue thickness respectively, and the +6mm arch height resulted in a 3.9mm decrease in tissue thickness. This 1.2mm difference in tissue compression between -6mm and +6mm 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 (Sarrafian, 1987). 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 the observation that soft tissue does not significantly compress further with large changes in orthotic geometry. However, changes in foot position were not measured to test this idea and considering the foot was not constrained in a shoe, adjusting foot position whilst weightbearing on orthotic could be different whilst wearing footwear.

Hypothesis 2 was partially accepted for the effects of both the extrinsic wedges and intrinsic wedges. Both designs of wedges did not systematically decrease tissue thickness under the calcaneus, but they did however systematically increase tissue thickness. Thus, although changes in tissue thickness were opposite in direction that was expected (increased), the changes were nonetheless systematic, therefore the hypothesis was partially accepted.

The increases in soft tissue thickness under the calcaneus was most likely due to the heel cup present in both designs of wedges which prevented lateral tissue displacement in the orthotic but not baseline condition. This buttressing effect has previously been observed. A 3.57mm 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 (Perhamre et al., 2012). Similarly, a 3.3mm increase in heel pad thickness due to a heel cup was measured using in-shoe ultrasound measures while walking on a treadmill (Telfer et al., 2014). These values are close to those reported in the present study (3.49mm and 3.3mm 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 8mm intrinsic wedge resulted in a significantly reduced tissue thickness compared to the 4mm wedge. The extrinsic wedges, due to the buttressing 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 8mm than with the 4mm wedge.

7.4.1 Individual variation in tissue thicknesses due to changes in orthotic geometry

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 4mm) compared to the baseline measurement, while others had greater change (decrease in thickness) with the second increment in wedging (8 ° or 8mm). 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.

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 (Liu et al., 2012; Stacoff et al., 2007).

7.4.2 Limitations

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 since muscles were not contracted, or not at least to the same degree as they might be during gait. Whilst one approach to measuring heel pad compression during walking has been reported (Telfer et al., 2014) no approach is available for arch tissues. Also, the heel pad measures in this static study are very close to those from dynamic studies (Perhamre et al., 2012; Telfer et al., 2014). Secondly, 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, this study 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.

Whilst not a limitation as such, it is worth noting that tissue compression was measured from a point that is lateral to the navicular tuberosity. The 6mm changes in arch height occurred at the most medial aspect of the orthosis and tapered to 0mm at the lateral border under the cuboid. Thus, at the location where arch tissue thickness was measured, there is less than a 6mm 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. This is not a limitation because it was not supposed that, for example, 6mm change in the arch would lead to 6mm change in soft tissues, but this does highlight that the actual difference between arch conditions (in mm) at the measurement location is not known.

7.4.3 Conclusion

This is the first study to quantify how altering orthotic 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 (4mm and 8mm). 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.

Chapter 8 Main discussion

8.1 Review of thesis aims

This thesis sought to understand factors that explain the individual variation in the way that joint moments and joint kinematics change due to an APFO. A conceptual framework relating to the effect of AFPO on foot biomechanics was proposed based on a critical appraisal of the literature (see Figure 2.26). This framework described how various factors interact to influence how joint kinematics are changed by an APFO. This thesis presents experimental data to explore the relationships between one of these factors (external forces) and changes in joint moments and motion due to an APFO. Two studies formed the basis of the research for this PhD. The main study explored the effects of AFPO by answering three research questions; 1) can APFO systematically alter external forces applied to the plantar surface of the foot 2) can APFO systematically alter rearfoot moments and foot kinematics, and 3) do systematic changes in external forces relate to the changes in foot kinematics and rearfoot joint moments. A second study characterised the effect of AFPO on soft tissue structures under the plantar heel and medial arch, because tissue compression has been shown to influence the transfer of load to foot bones (Perhamre et al., 2010).

The following points represent the key findings presented in the thesis and forms the basis of the discussion of findings presented in section 8.2.

- Changes in external forces caused by foot orthoses are not strongly related to changes in joint moment/motion responses
- Orthotic arch height geometry had a much greater effect on altering rearfoot joint moments compared with midfoot and rearfoot joint kinematics
- Orthotic arch height geometry had a threshold effect on loading foot structures in the medial arch
- The intrinsic medial heel wedges caused greater systematic changes in peak pressure, joint moments and kinematics compared to the extrinsic medial heel wedges
- The extrinsic medial heel wedges caused a greater increase in soft tissue thickness under the calcaneus by way of a buttressing effect compared to the intrinsic medial heel wedges

8.2 Discussion of findings

8.2.1 Changes in external forces are not strongly related to changes in joint moment/motion responses

Data presented in this thesis verified that APFO components can be tailored to systematically alter external forces (see Chapter 4; Tables 4.1 - 4.6), and can also systematically alter joint moments (see Chapter 5; Tables 5.1, 5.4 and 5.7) and joint kinematics (see Chapter 5; Tables 5.5 and 5.8). These results are in line with prior research (Bonanno et al., 2012; Telfer et al., 2013c; Williams et al., 2003). However, the results obtained in Chapter 6 generally indicate there is no, weak or at best a moderate relationships between the changes plantar loading, moments and kinematics (see Chapter 6; Tables 6.1 and 6.5). Only the 4mm intrinsic wedge condition caused a strong correlation between changes in external force (measured as COP displacement) and changes in ankle inversion moment (r = -0.7, p < 0.01) (see Chapter 6; Table 6.4 and Figure 6.12) and peak rearfoot eversion (r = 0.69, p <0.01)/peak eversion range (r = -0.656, p < 0.01) (see Chapter 6; Table 6.5 & Figures 6.15 and 6.17), however this condition was the exception. Changes in external forces did not strongly correlate to joint moment/motion responses as the traditional orthotic paradigm assumes. Thus, for clinical practice, this finding implies that it is not possible to create a specific kinematic response from a known pressure change. Furthermore, orthotic geometry may change pressure in a specific direction, but may not lead to the change in moments nor motion that is expected.

With reference to the conceptual framework proposed at the beginning of this thesis (Figure 2.26), this acknowledges the contributions of structural and neuromuscular factors as well as external forces on joint moments and joint kinematics.

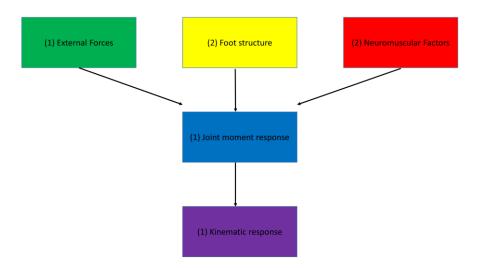


Figure 2.26 Conceptual model representing biomechanical system of foot function

A key outcome of this thesis therefore, is that the data confirm that factors other than changes in external forces (measured as plantar pressure) influence joint moment and kinematic outcomes. Thus, it is not appropriate to compare how foot orthoses alter moment/motion responses to that of a purely mechanical system as described in Chapter 2 in section 2.8.9. Structural features are in many respects mechanical factors (i.e. bone shape, ligament arrangement) and all passive forces. However, the overall system may better be described as neuromechanical, reflecting the importance of muscle forces and changes in these in response to the external forces, internal passive forces, and sensory input to control of muscle forces. A move from a mechanical to a neuromechanical model of foot orthotic effect would be something of a paradigm shift in how the effects of foot orthoses are understood, practiced and researched in the future.

The balance of the various contributions to any observed kinetic or kinematic effect of an APFO was not explicitly investigated in this thesis. However, by way of an example, 20 % of the decrease in peak rearfoot eversion was explained by an increase in medial rearfoot peak pressure when orthotic geometry changed from the standard orthotic condition to the 4mm intrinsic wedge (see Chapter 6; Figure 6.5). Also, 32 % of the internal ankle inversion moment (1st peak) was explained by an increase in the medial displacement of the COP during midstance when geometry changed from the flat inlay to the 8 ° extrinsic wedge (see Chapter 6; Figure 6.8). Therefore, 80 % of the decrease in peak rearfoot eversion, and 68 % the decrease in internal ankle inversion moment were caused by other factors other than changes in external forces under the sole of the foot. Future research would need to measure all relevant structural

or neuromuscular factors to indicate their contributions and perhaps allow some weighting of these factors within the conceptual framework. This might also need to consider the variation in these contributions between individuals, tasks, and reasons for this.

8.2.2 The effect of orthotic arch height on foot biomechanics

A number of key observations relating to the effect orthotic arch height on foot biomechanics are now possible. Firstly, increasing arch height geometry had a significant effect on foot kinetics but had little effect on foot kinematics. Relative to the baseline orthotic condition, a number of the arch heights significantly altered internal frontal plane ankle moments (see Chapter 5; Table 5.1). However, none of the arch heights significantly altered peak midfoot dorsiflexion, peak rearfoot eversion or peak rearfoot eversion range (see Chapter 5; Tables 5.2 and 5.3). These results indicate that orthotic arch geometry has limited effect on midfoot and rearfoot kinematics and this questions the use of arch geometry if the intention is to alter foot kinematics. It would, however, validate any approach to orthotic practice that focused on changes joint kinetics rather than kinematics. Other studies have also questioned the approach of using foot orthoses to alter foot kinematics (Nigg, 2001; Pascual Huerta et al., 2009; Wu et al., 1995), mainly because effects are only small kinematic changes, although assumptions underpinning their prescription are also questioned. As outlined in Chapter 2, Rootian biomechanics recommend tailoring orthoses to position the STJ in its neutral position in midstance (Root et al., 1977), yet research shows asymptomatic feet rarely adopt this position during stance (Cornwall et al., 1999; Pierrynsowski et al., 1996). It has been suggested that practitioners prioritise their design of foot orthosis to alter kinetics (Kirby, 1989; Pascual Huerta et al., 2009; Zammit et al., 2007), however a counterarguments for this relates to the accumulative effect of small changes in kinematics at multiple foot joints, and the assumed relationship between changes in kinematics and changes in kinetics. The data presented here challenge this assumption. Invasive bone pin studies have shown that the combined motion between articulations present in the midfoot are considerable. For example, Lundgren reported the combined motion between the joints forming the medial arch (from 1st metatarsal to talus) was 17.6°, 9.6° and 14.7° in the sagittal, frontal and transverse planes respectively (Lundgren et al., 2008). Lundgren also reported that motion between the navicular and cuboid is similar to motion at the subtalar joint (Lundgren et al., 2008). It follows that although studies report that orthoses cause small changes in rearfoot kinematics e.g. (Branthwaite et al., 2004; Majumdar et al., 2013), it is likely the effect of orthoses when kinematic changes across all

foot joints are combined would be much greater. This accumulative effect could have corresponding effects on the soft tissues that often cross multiple foot joints. However the effects on midfoot articulations are difficult to quantify due to muscle and soft tissue coverage overlying these joints

The second key observation relates to a threshold effect of arch height geometry. As reported in other studies (Aminian et al., 2013; Bus et al., 2004; McCormick et al., 2013), using an orthosis with an arch geometry decreases peak pressure under the rearfoot. This is due to load previously borne by the rearfoot being transferred to the medial arch area, which would previously have been non-weight bearing. However, whilst having an arch geometry compared to flay inlay had a large effect, large changes in orthotic arch geometry (i.e. 12mm) caused relatively minimal changes in peak pressure under the medial arch (see Chapter 4; Table 4.1). Similar effects of large changes in arch geometry on arch tissue thickness were observed in Chapter 7 (see Figure 7.9). Here data demonstrated a large effect on arch soft tissue thickness of an arch geometry compared to a flat insole, but relatively little effect of varying arch geometry height by 12mm. This is quite contrary to general assumptions made in orthotic practice, especially those underpinning the use of customised orthoses to modify foot kinematics. One explanation is that there is a 'threshold' like effect of arch height on loading of foot structures in the medial arch. At a certain threshold of arch height load is applied to the arch by the orthotic, but above this threshold changes in arch height do not lead to proportional changes in loading, soft tissue compression, and thereafter kinematic responses. This questions the benefit in tailoring arch geometry to closely contour to the plantar surface of the medial arch, since perhaps only the threshold height need be achieved. This 'threshold' like response was also observed between the different arch heights for the displacement of COP (see Chapter 4; Table 4.2). Of course the threshold height might be different for feet of different shapes or movement profiles. However, this still does not necessitate a custom orthosis since for many feet, such as those close to a mean foot shape, the threshold is likely met with an orthosis of a shape close to that of the mean foot shape, if made in a suitably stiff material. Since the effect of -6mm arch height in this study was close to that of the standard orthotic, it seems likely that the -6mm arch height was already at or above any threshold. Above this height, +6 and then a further +6mm (i.e. 12mm in total) had no significant effect. This points towards further work that might seek out an arch height that, at a group or person specific level, might be the threshold, or minimum arch height required. However, this also questions what is defined as "achieved", but this would most likely be specific change in joint moments. The above could

be quite sensitive to the correct characterisation of the mean foot shape, but if differences in orthotic arch height of 12mm have little effect on kinematics then the 12mm is in effect a "tolerance" for getting the geometry 'wrong'. This may even explain why, for all the variation in foot shape that is known to occur when different practitioners capture foot shape on the same patient, patients all tend to get better regardless of the clinician they see.

8.2.3 The effect of heel wedges on foot biomechanics

A number of key findings were observed for the effects of the heel wedges on foot biomechanics. Firstly, the effects of the intrinsic wedges contrasted those of the extrinsic wedges because the intrinsic wedges caused greater systematic affects in a number of biomechanical parameters. For example, compared to the standard orthotic condition, neither the 4 ° nor 8 ° extrinsic wedge significantly altered medial rearfoot peak pressure (see Chapter 4; Table 4.3), peak rearfoot eversion and peak rearfoot eversion range (see Chapter 5; Table 5.5). In contrast, compared to the standard orthotic condition, the 4mm and 8mm intrinsic wedges significantly increased medial rearfoot peak pressure (See Chapter 4; Table 4.5), and the 8mm wedge significantly decreased peak rearfoot eversion and peak rearfoot eversion range (see Chapter 5; Table 5.8). Also, for the effects on ankle joint moment, compared to the standard orthotic condition, both the 8° and 8mm wedges significantly increased internal ankle eversion moment (see Chapter 5; Tables 5.4 and 5.7), but only the 8mm wedge significantly decreased internal ankle inversion moment (see Table 5.7). These contrasting effects between intrinsic and extrinsic heel wedges has not been previously reported, and they concur with the contrasting responses of heel pad tissue to intrinsic and extrinsic heel wedges (see Chapter 7; Figure 7.10 A & B) (Sweeney et al., 2015). On the basis that an increase in load under the medial calcaneus is a desirable clinical biomechanical objective, then the results shown by this thesis advocate use of intrinsic rather than extrinsic wedges. This design both offers an improved ability to control the increases in medial heel pressure and to increase pressures in order to alter joint moments, and decreases calcaneal eversion, implying the intrinsic wedge design may cause a greater kinematic response.

The second key finding relates to how both designs of medial wedges constrain the soft tissues that form the heel pad. Compared to the baseline orthotic condition, both medial wedge designs increased tissue thickness under the calcaneus. This increase in tissue thickness is likely caused by the buttressing affect provided by the heel cup section in an APFO that prevents lateral

tissue displacement. No significant changes in tissue thickness were observed between the 4 ° and 8 ° extrinsic wedges, however, the 8mm wedge significantly decreased tissue thickness compared to the 4mm wedge (see Chapter 7; Figure 7.10 A & B). These contrasting effects on tissue thickness likely occur because the intrinsic wedges elevate the heel within the heel cup thus the containment effect of the heel cup is lost. Furthermore as described in Chapter 7, this buttressing effect may explain why intrinsic wedge geometry caused greater increases in medial rearfoot peak pressure compared with extrinsic wedge geometry, because containment of heel pad tissues has been shown to decrease pressure under the calcaneus (Perhamre et al., 2010).

It follows that this containment effect poses a number of questions regarding medial wedge design and use in practice. For example, would increasing the height of walls forming the heel cup when using an intrinsic wedge design, thus restoring the containment effect at the heel pad, decrease pressure under the calcaneus? Or conversely, would decreasing the heel cup height in the extrinsic wedge design, thus decreasing the containment effect at the heel pad, increase pressure under the calcaneus? If this is the case then tailoring orthosis by using extrinsic/intrinsic medial wedges with absence of a heel cup, thus eliminating the heel pad containment effect, potentially may prove more effective in eliciting an anti-pronatory biomechanical responses by causing greater increases in load under the medial calcaneus. Modification of heel cup wall height is not routinely part of orthotic prescriptions concerning anti-pronation effects.

8.3 Novelty

The work presented within this PhD is novel. This thesis presents for the first time a study that reports foot pressure, moments and kinematics under circumstances when orthotic geometry is systematically changed. Many studies have characterised the effect of a single orthosis or different designs of orthoses on plantar pressure (Bonanno et al., 2012; Bonanno et al., 2011; Bus et al., 2004; Redmond et al., 2009; Van Gheluwe et al., 2004), and joint moments and kinematics (Hsu et al., 2014; MacLean et al., 2008; Majumdar et al., 2013; Mündermann et al., 2003; Stacoff et al., 2007; Williams et al., 2003), however these studies typically quantify the mean group effect of the orthosis on foot biomechanics and fail to explore factors explaining individual variability in biomechanical responses. Laboratory based studies that examine the group effect of orthotic design are important because they validate the use of certain orthotic

designs tailored for specific patient populations (e.g. total contact orthosis for diabetes) and thus enable practitioners to follow evidence based best practice. However, understanding factors explaining individual variability in biomechanical responses is also a priority because this enables the practitioner to tailor an orthosis to cause a specific biomechanical response most suited for an individual, and thus increase the likelihood of a specific clinical outcome. The approach adopted by studies in this PhD sought to quantify the relationship between changes in plantar loading (measured as peak pressure and centre of pressure) and changes in joint moments and kinematics in foot structures through systematic adjustment of heel and arch features of the APFO design. This is the first study to do this in such a systematic way. This allowed the investigation of whether changes in plantar loading explained subsequent changes in kinetics and kinematics in specific individuals. A number of studies characterising the biomechanical effect of orthosis make reference to the fact that individual variability in changes in joint moments and kinematics exist, and cite foot structural, neuromuscular, proprioceptive factors as potential causes (Nigg et al., 2002; Stacoff et al., 2007). However, these studies do not explicitly investigate these factors.

Two studies have used an approach that is similar to the methods used by this PhD. Bonanno et al. (2012) quantified the effect of systematically increasing medial heel skive thickness in orthoses on plantar loading under the foot. They reported that increases in medial skive increased medial rearfoot peak pressure, which is in line with the data in this thesis. However, this study characterised the effect of a single design of medial wedge geometry (intrinsic not extrinsic wedges) and did not explore how each condition affected joint moments or kinematics.

The methodology employed by Telfer et al. (2013c) was closest to the current study. This study quantified the effect of systematically altering an extrinsic heel wedge on joint moments and kinematics. They reported that systematically altering extrinsic wedge geometry significantly decreased external eversion ankle moments and significantly decreased peak rearfoot eversion. This study also reported that systematically altering extrinsic wedge geometry caused linear joint moment and motion changes and that for every 2 ° of wedge as 1.1 % and 0.26 ° change in moments/motion occurred. These results are broadly similar to the results found in this thesis which showed altering heel wedges could systematically alter joint moments and kinematics at a group level (see Chapter 5; Tables 5.4, 5.7 and 5.8). However, Telfer et al. (2013c) did not characterise the effect of altering orthotic design on plantar loading

thus attributed changes to foot biomechanics based solely on the design of the orthosis. They therefore had to assume the changes in plantar loading and how changes in plantar loading influence moment and motion responses. Thus, for the first time with the unique data set in this PhD, it is possible to understand the extent by which external forces, manipulated via APFO systematic adjustment, influences foot biomechanics.

Furthermore, this is the first study to quantify the effect of an APFO on soft tissue thickness under the medial arch. A previous study quantified the effect of a heel cup insert on heel pad behaviour and reported results similar to the findings in the current thesis, where heel cupping decreased heel pad compression (Telfer et al., 2014). However, Telfer et al. (2014) did not quantify the effects of different medial wedge designs (extrinsic or intrinsic) commonly used in clinical practice, nor any effect on the medial arch. This thesis is therefore the first to characterise how these design features influence soft tissues under the calcaneus, and is the first to characterise how orthotic arch geometry affects soft tissues in the medial arch.

8.4 Limitations

8.4.1 Plantar pressure measurement

A limitation arises from the incomplete description of plantar pressure that current measurement systems offer. The study in this thesis used in-shoe pressure measurement to quantify how APFO alters load under the plantar foot. However, as described in Chapter 3, in-shoe pressure measurement does not quantify medial/lateral and anterior/posterior shearing pressures and this may be particularly important if measurements are taken between the sole of the foot and curved surface of orthosis geometry. Data always relate to the force applied perpendicular to the sensor surface and when this surface is inclined because of the orthotic geometry the forces measured are in a different reference frame than when measured in the flat inlay condition. They are also in a different reference than sensors located elsewhere on the orthotic. Furthermore, this study employed masks to subsample peak pressure data under the medial and lateral rearfoot and midfoot. However, subsampling has been shown to decrease spatial information and cause regional conflation between masks (e.g., medial and lateral rearfoot mask) (Pataky et al., 2008a; Pataky et al., 2008b). Pedobarographic statistical parametric mapping (PSPM) is a technique proposed to overcome these difficulties (Pataky et

al., 2008b) and is a method that can be used for future work to characterise the effect of orthosis on plantar foot loading.

8.4.2 Generalisability of outcomes

A second limitation relating to the results is that they only apply to the orthosis-footwear combination used throughout data collection thus may not be transferrable to other studies/clinical situations. The footwear used was a commercially available trainer of a relatively standard design (from Fila®). All subjects wore this trainer throughout the data collection because using footwear with different design features will influence foot biomechanics in differing ways, thus the effects of footwear must be controlled if the foot orthotic is to be the independent variable. Considering sole construction for example, studies show heel height influences both peak internal knee adduction moments and peak internal ankle eversion moments (Barkema et al., 2012). Also, the geometry of the outer sole has been shown to influence plantar pressure and kinematics. Increased outer sole curvature increases midfoot pressures, alters sagittal plane ankle moments and kinematics, and does so during midstance and propulsive phases in gait (Forghany et al., 2013). Features relating to upper construction also influence foot biomechanics. Research shows that altering footwear volume or the compliance of materials used for the upper affect plantar pressures (Branthwaite et al., 2013; Melvin et al., 2014; Onodera et al., 2015).

Because upper and outer sole design features vary greatly between footwear sold in high street retailers, they will cause differing biomechanical responses compared to the footwear used in this thesis. This may therefore influence the extent by which the results reported by this thesis are transferrable in clinical situations. Furthermore, and similar to the effects of footwear design, the results reported in this thesis will only apply to anti-pronation foot orthosis with similar geometries and material properties to the orthoses tested. Orthosis with different design features will influence changes in foot biomechanics differently. For example, and as outlined in Chapter 2, the durometer in the material an orthosis is constructed from influences the transfer of load to the plantar foot (Hinz et al., 2008; Tong et al., 2010; Windle et al., 1999). Thus orthoses made from materials with different stiffness will transfer load to the foot differently. Inevitably, the same is true for APFO medial wedge and arch geometry design, whereby differences in geometrical features will influence foot biomechanics differently. However, the work presented here sought to investigate and report general patterns in the

responses to the APFO, and it is largely expected that the trends in the observed effect are transferable to similar orthotic devices, albeit the exact size of effects would differ,

8.4.3 Lack of moment data for joints within the foot

The final limitation relates to the segment definition used to quantify joint moments. This study characterised the effect of APFO on internal inversion moment at the ankle joint. However, when designing foot orthosis to alter joint moments practitioners tailor the orthosis to alter moments at the subtalar joint axis (Banwell et al., 2014a; Kirby, 1992). The approach used by the current study therefore did not strictly measure the effect of orthosis on moments at the subtalar joint. However, bone pin studies showed in some individuals that the ankle joint contributes to the majority of frontal plane rearfoot motion (Lundgren et al., 2008; Nester et al., 2007). This challenges the assumption that the subtalar joint must change for an orthosis to be biomechanically effective. On the basis both talocalcaneal and talotibial articulations contribute to frontal plane joint moments/motion, quantifying the net contribution of these joints in the rearfoot is more clinically meaningful.

Furthermore, characterising moments at the ankle joint can be undertaken with relative ease. The medial and lateral malleoli and the calcaneus, rigid segments that quantify ankle joint moments/motion, are readily accessible. It not possible to use surface mounted markers to define rigid segments that will quantify talocalcaneal joint moment/motion. It is likewise currently very challenging to consider measuring, or rather calculating, moments acting around midfoot joints. Identifying centres of rotation in articulations forming the midfoot is challenging, unlike ankle and knee joint moments, derived using joint centres that are relatively easy to define (Hsu et al., 2014; Jones et al., 2013; Levinger et al., 2013; Williams et al., 2003).

8.5 Future Research

This study shown that changes in external forces do not strongly correlate with changes in joint moments and joint kinematics, which goes some way to explain the variability in response to an APFO. However, it has also highlighted the fact that the response to an APFO might be more fully explained by considering other features in the biomechanical model of foot function. Future research should therefore be directed towards understanding how foot structure and neuromuscular action influence joint moment/motion responses caused by foot orthosis.

A systematic review of the literature showed that foot posture, a classification of external foot structure when standing, is somewhat related to the motion of the foot during gait (Buldt et al., 2013). Cavus, normal and planus foot postures demonstrate some distinct differences in kinematics (Buldt et al., 2015a) and foot posture has been shown to strongly correlate (r = 0.92) with frontal plane rearfoot motion (Chuter, 2010). However, a recent study showed foot posture measures explain only small variations in kinematics between people and cited a potential relationship between foot mobility and muscle structure as a cause of variability (Buldt et al., 2015b). Buldt et al. (2015b) suggested greater foot mobility may require increased force generated by muscles to counteract external forces applied to the foot, and supported their hypothesis by showing different foot postures possess different muscle structural and functional properties (Murley et al., 2009b; Murley et al., 2014b). It follows that individual differences in foot mobility and muscle properties are structural features, although the latter is also a neuromuscular feature, that may explain variability in kinematic responses to foot orthosis.

A potential experimental approach to characterise these features would be to firstly determine if variability in foot mobility and muscle properties are present in individuals with the same foot posture. Methods that are reliable and can quantify variability in these features include; the foot mobility magnitude to quantify midfoot mobility (McPoil et al., 2009) and ultrasound to quantify thickness of muscles in the foot (Cameron et al., 2008). On the basis variability in foot mobility and muscle structure exists, changes in joint moment/motion responses caused by foot orthosis could be recorded in a sample of people with similar foot postures but with different foot mobility and muscle thicknesses. This approach would allow us to understand how these structural features influence the individual response to the APFO in terms of joint moments and joint kinematics. For example, a foot orthosis may cause a greater change in foot motion in an individual with greater foot mobility compared to an individual with less foot mobility. On the assumption that foot mobility reflects the stiffness of passive structures that constrain joint motion (articular facet geometry, tension in ligaments etc.), it follows that these passive structures will offer less resistance to how an orthosis alters joint alignment compared to an individual with stiffer structures associated with less foot mobility. However, the opposite may also be true where an orthosis may cause a smaller change in foot motion in an individual with greater foot mobility. This is because the changes in motion caused by the orthosis may elicit a greater muscular response for an individual with increased foot mobility to resist the motion change and regulate the joints normal kinematic pathway.

This response has been described previously (Mündermann et al., 2003) and follows the preferred movement pathway theory proposed by Nigg (2001). Mündermann (with Nigg) reported that posted orthosis caused significantly greater EMG intensities in peroneus longus and gastrocnemius muscles compared to posted and moulded orthosis (Mündermann et al., 2006). Results of a previous study using the same subjects and conditions showed the posted orthosis significantly decreased peak rearfoot eversion whereas the posted and moulded orthosis caused minimal changes (Mündermann et al., 2003). Mündermann speculated that a joint has a preferred movement pathway, which if supported by an orthosis will decrease EMG activity, but if orthosis resists the pathway EMG activity will increase. Furthermore, following this approach, characterising foot flexibility and muscle features, may offer insight into the contribution of the neuromuscular system to the proposed biomechanical system of foot function. If an individual with increased foot flexibility exhibits large kinematic changes as a result of an orthosis, but these changes are independent of muscle structure (e.g. thickness) and function (e.g. EMG), then this would suggest the neuromuscular system does not influence changes in foot moments/motion. However, the opposite may also be true and small kinematic changes accompanying large muscle thicknesses/EMG responses to foot orthosis would indicate that the neuromuscular system strongly contributes to moment/motion responses.

The central nervous system regulates neuromuscular responses that influence changes in foot kinematics/kinetics. Afferent neural impulses transmitted from proprioceptive sensory receptors in the CNS regulates the contraction of skeletal muscle via efferent neutral impulses. Mazzaro et al. (2005) suggested these afferent neutral impulses continuously contribute to the automation of muscular responses in gait. Studies have also reported proprioception under the plantar foot can be highly variable in people (Kekoni et al., 1989; Nurse et al., 1999) and changes with age (Mold et al., 2004). It is plausible individual variations in proprioception may explain variable joint moments and joint kinematics. Orthoses specifically designed to alter afferent input have been shown to both influence proprioception and joint moments and Altering orthotic geometry under the metatarsal heads affected joint kinematics. mechanosensitivity in the forefoot (Vie et al., 2015). Textured insoles decreased muscle activity in tibialis anterior and soleus muscles (Nurse et al., 1999) and improved ankle inversion movement discrimination (Steinberg et al., 2014). On the basis orthoses alter afferent signals (proprioception), which are variable in people, and changes in proprioception influences joint moments and joint kinematics, it follows that attempting to characterise variability in proprioception may also explain variability in joint moment and motion responses caused by foot orthosis.

A potential experimental approach that characterises the relationship between proprioception and joint moment/motion responses would be to quantify the effect of incrementally increasing proprioceptive input whilst measuring changes in joint moment/motion. Proprioceptive orthosis used by other studies are typically made from a flat inlay with small spherical domes positioned on the surface (see Figure 8.1). These domes are purported to alter efferent neutral impulses. For the design of the orthosis to be used in the proposed experiment, clusters of spherical domes could be situated on the medial aspect of the orthosis to elicit an anti-pronation neural input effect. A range of these orthosis could be manufactured, varying only by the depth of the spherical domes (ranging from low to high), whilst other design features remain constant (location of domes, material properties etc.). Thus the study could explore the relationship between how increasing afferent neutral input influences joint moment/motion responses in foot structures where mechanosensitivity has been characterised. Individuals with low mechanosensitivity may elicit small joint moment/motion responses compared with individuals with high mechanosensitivity. If foot orthosis influence mechanosensitivity, and on the basis that mechanosensitivity influences afferent neural impulses to the CNS, which in turn influences kinematic responses, then variability in mechanosensitivity may be a feature that explains variability in joint moment/motion responses to foot orthosis.

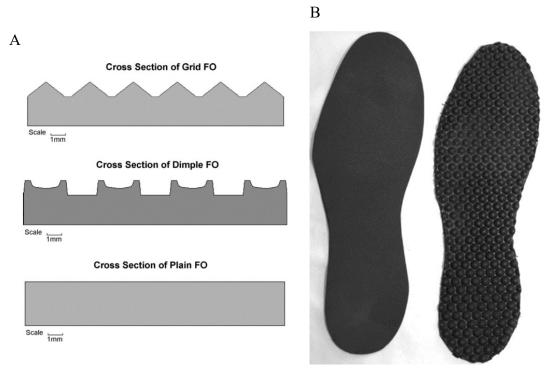


Figure 8.1 A & B showing different designs of proprioceptive orthoses used in by studies (Nurse et al., 2005; Wilson et al., 2008).

Future research should also consider the effect of foot orthoses on foot placement position at initial contact during loading response. The effect of foot orthosis on frontal plane peak rearfoot eversion has been widely reported (Branthwaite et al., 2004; Majumdar et al., 2013; Telfer et al., 2013c), as too has the frontal plane position of the calcaneus relative to the shank at initial contact (Novick et al., 1990; Stacoff et al., 2007). However the effect of foot orthoses on foot placement position has not been explicitly investigated. It seems plausible that foot placement position at initial contact may influence other kinematic parameters such as peak rearfoot eversion for example. An individual may place the foot in a position of greater abduction relative to the centre of the base of support during loading response to counter an unwanted or unexpected inversion perturbation caused by a foot orthosis. By increasing the base of support to decrease inversion instability, this abducted foot position may also act to decrease peak rearfoot eversion, thus in this situation the reduction in peak rearfoot eversion is not directly caused by the foot orthosis as is traditionally described. It follows that this process may occur as an automatic involuntary neuromuscular response and follow the preferred movement pathway as described by Nigg (2001).

8.6 Implications for practice

Paradigms of foot function promote the use of foot orthosis using different approaches. When prescribing an orthosis to alleviate a musculoskeletal complaint, the practitioner should tailor the orthosis with reference to the validated biomechanical affects, that is to change the orthoses in ways that leads to the expected, and predictable, changes in pressure, or joint kinetics or motion. The results reported by this thesis show changes in external forces under the plantar foot are not strongly related to kinematic or joint moment responses. At the same time, however, the results show that anti-pronation foot orthosis will significantly affect plantar loading characteristics, plantar soft tissue structures, kinematics and joint moment responses in foot/ankle structures. Therefore, joint kinetics and kinematics are likely influenced by factors exerting an influence alongside external forces.

The results presented in this thesis question the merit in using orthotic arch geometry, a feature traditionally used in anti-pronation foot orthosis, to alter foot kinematics. Compared with the flat inlay condition, none of the orthotic arch geometries significantly altered midfoot or rearfoot kinematics (see Chapter 5; Tables 5.2 and 5.3). Furthermore, this questions the rationale in choosing custom made orthoses with bespoke orthotic arch height geometry over less expensive prefabricated orthosis, as it seems likely that both orthotic arch geometries will cause minimal changes to foot kinematics. However, the results of this study showed that arch geometry had a much greater influence on plantar pressures under the midfoot and heel (see Chapter 4; Table 4.1) and on internal inversion moments at the ankle joint (see Chapter 5; Table 5.1). Thus, if a practitioner is seeking to decrease muscle inverter contractile force to decrease the load applied through an inflamed tendon (e.g. tibialis posterior tendon), or alter plantar foot loading (e.g. in diabetes), then orthotic arch height geometry will fulfil these biomechanical objectives.

This thesis shows, for the first time, the different biomechanical effects caused by extrinsic and intrinsic medial heel wedges. If a practitioner wishes to decrease load under the calcaneus and increase heel pad tissue thickness then the extrinsic wedge design is most suited to cause this effect (see Chapter 4; Figure 4.2 B & C). This design feature may therefore be beneficial in clinical situations that warrant load reduction under the calcaneus (e.g. Severs disease, plantar fat pad atrophy). Both designs of wedges have been shown to decrease internal inversion moments at the ankle joint, however the results imply that intrinsic wedge geometry causes its

greatest effect during loading response (see Chapter 5; Table 5.7) whilst the extrinsic wedge geometry causes its greatest effect during late midstance (see Chapter 5; Table 5.4). This indicates a potentially useful time based effect that may allow practitioners to tailor changes in function during either period of stance. Perhaps if used in combination both periods could be affected by the same orthosis. In terms of the medial wedge geometry that alters kinematics the most, the intrinsic medial heel wedges were shown to cause the greatest decrease in peak rearfoot eversion and eversion range (see Chapter 5; Table 5.8). Thus, if a practitioner wishes to tailor an orthosis to alter kinematics, the results presented in this thesis imply intrinsic wedge geometry is most suited to achieving this effect.

Practitioners use both custom made and prefabricated orthoses in clinical practise. Custom made orthoses are recognised as the "gold standard" because an orthosis that is bespoke to the individual is thought to influence foot biomechanics to a greater extent compared to a prefabricated orthosis. However, the results of this thesis suggest there is a threshold beyond which changes in the orthosis do not influence foot biomechanics, which questions whether custom made orthosis are superior to prefabricated orthosis if the threshold can be met without customisation. This thesis showed that relative to the baseline conditions, changes in orthotic geometry created large changes in plantar pressure (see Chapter 4; Figure 4.2), plantar soft tissue thickness (see Chapter 7; Figures 7.9 and 7.10), internal joint moments (see Chapter 5; Figure 5.2), and kinematics (except orthotic arch geometry) (see Chapter 5; Figure 5.3). However, the changes in these biomechanical variables that occurred between the different increments in orthotic geometry were often small and rarely significant. This was especially true for the effect of the different orthotic arch heights on peak pressure (see Chapter 4; Table 4.1) and tissue compression under the medial longitudinal arch (see Chapter 7; Figure 7.9). On the basis that large changes occur relative to the 1st increment in orthotic geometry (baseline versus lowest arch orthotic, -6mm), and small changes occur thereafter, this implies there may be a threshold for how changes in orthotic geometry influence foot biomechanics. If this is the case, then this questions the benefit in tailoring orthotic geometry to closely contour to the sole of the foot, as conceivably only a threshold in geometry need be achieved (e.g. arch height).

Practitioners should acknowledge subject specific differences in foot structure, alignment and neuromuscular response and tailor the design of orthoses to influence biomechanical changes based on an individual's unique kinematic/kinetic pathway. Acknowledging the limitations of the Rootian model of foot biomechanics, McPoil et al. (1995) proposed the tissue stress model

as a basis for examining and managing foot disorders. They suggest that tissue damage associated with overuse injuries can be avoided by maintaining the level of stress in the affected structure within an elastic region. If a magnitude of load applied to a tissue increases, then the tissue may deform beyond a micro failure zone into a plastic range thus causing an overuse injury (McPoil et al., 1996b). The tissue stress model proposes that foot orthosis should be tailored to treat foot disorders by decreasing tissue stress in an affected structure to a tolerable level.

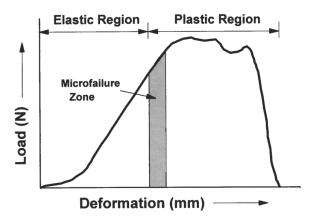


Figure 8.2 Illustration taken from McPoil et al. (1995) showing the load-deformation curve.

This approach places no emphasis on a altering the function in a single foot structure or altering a single biomechanical response, as is the case with the Rootian, SALRE and SPF theories (Dananberg et al., 2000; Kirby, 1989; Root et al., 1977) but focuses the design of an orthosis to alteration of foot biomechanics that is specific to the individual. This thesis shows that APFO geometry can be altered to substantially change joint moments to thus decrease abnormal stresses being applied through both soft and bone tissue structures. However, the relationship between these two (geometry and effect) is complex and thus **orthotic geometry alone is not a strong basis for orthotic practice**.

8.7 Conclusion

This PhD has shown that systematically altering external forces under the plantar foot with APFO is not strongly correlated with changes in joint moment/motion responses. This finding suggests moment/motion responses are strongly influenced by structural features and/or neuromuscular action in combination with external forces. Nonetheless, this PhD shows antipronation foot orthosis can be tailored to systematically alter tissue compression, plantar loading, joint moments and joint motion in foot structures and provides an evidence base supporting their use in clinic practice.

Chapter 9 Appendices

Appendix 1: Ethical approval for subject testing



Appendix 2: Recruitment poster

Would you like to participate in a research study?



Volunteers Required

We are looking to recruit subjects to take part in a research study. We are investigating how special insoles (anti-pronatory foot orthoses) affect (1) distribution of force under the sole of the foot, (2) compression of soft tissues in the heel and foot arch areas. We hope the outcome of this research, in conjunction with other research, will assist clinicians to prescribe insoles more effectively.

What would be involved?

You will be asked to stand and walk on special insoles while we use various gait laboratory equipment to record changes in both foot pressure and foot/leg movement. The testing will take place in the Podiatry Gait Lab and will last for about 90 minutes.

Who can participate?

We are looking to recruit participants who are in good health and have no recent history of lower limb pain or foot problems. You must be aged 18 years or older, be between UK6 – UK9 shoe size and be available to for testing between 17-28 February 2014

Interested in participating?

If you think you would like to participate in this research and would like a participant information sheet please contact Jonathan Chapman (PhD Researcher) by email sweeney.declan@gmail.com

Appendix 3: Participant information sheet

Study Title "An investigation into how special insoles (anti-pronatory foot orthoses) affect (1) distribution of force under the sole of the foot, (2) compression of soft tissues in heel and foot arch areas".

You are being invited to take part in a research study. Before you decide whether to participate it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Please ask if there is anything that is not clear or if you would like more information.

Background to the study

Special insoles (anti-pronatory foot orthoses (APFO), are commonly used by practitioners to treat a variety of lower limb conditions that are thought to be caused by excessive amounts of foot movement (the rolling in and lowering of your foot arches). Special insoles are reported to reduce symptoms by altering the alignment of the foot/ankle complex whilst you walk. Clinical and laboratory based research has however demonstrated an inconsistent response to these special insoles. We are interested in explaining why people respond differently to these special insoles.

The study will examine how APFO affects the distribution of pressure under your feet and how they compress the soft tissues under your feet, and investigate whether these factors explain why some people respond differently to these insoles.

It is anticipated that the outcome of this research, in conjunction with other research, will assist clinicians to prescribe APFO more effectively.

Do you have to take part?

No. It is up to you to decide whether or not to take part. You are under no obligation.

What will happen to me if I take part?

To participate you will have no health problems or musculoskeletal problems that affect your foot, ankle or lower limbs. In addition we will:

- test whether you can feel light touch and vibration in your feet this checks the sensation in your feet
- Check the pulses in your feet.

- Ask you to complete a "Foot Health Status Questionnaire". This is a simple questionnaire which will investigate how you perceive your foot health.

Your GP will be notified should any health or musculoskeletal problems be identified following the assessment. The investigation will be carried out in a gait laboratory. This is a room that contains a walkway and equipment that is used to analyse how you walk.

The testing will then involve:

- Measurement of soft tissue compression while standing on an insole

We will measure soft tissue compression in your heel and arch area while standing on a variety of insoles. The insoles will be made from a clear plastic. Ultrasound imaging will be used to scan through the insole and take a picture of the underside of your foot.

- Measurement of foot pressure & lower limb motion whilst you are walking:

You will be asked to walk while wearing various types of foot orthoses in a standard shoe that we will provide. While walking we will use a special insole that measures the pressure under your feet as you walk. We will also measure how your foot and leg move when you walk. To do this we will place small spherical markers on the side of your leg and on your heel area. The markers will be attached to your skin with double sided cellotape (which can be easily removed after the testing). Special cameras will track these markers when you walk.

All of the above will be explained during the experiment and please ask questions if you are unsure about anything. The entire testing will take approximately 100-120 minutes. You will be required to wear insoles and walk short distances for a period of approximately 45 minutes. During this part of the data collection you will be given multiple breaks. For the remaining period of the data collection you will be standing on the insoles or be in the seated position. If you chose to participate in the study you will be required to wear shorts during the testing. If you feel tired, unwell or do not wish to complete the study you can stop at any time.

What are the possible disadvantages and risks of taking part?

This study is very low risk. The study will be performed with equipment that is widely used in the study of biomechanics. The insoles being tested are used widely in the NHS.

What are the possible benefits of taking part?

The study will provide useful insight into how the orthoses we are testing can affect the behaviour of your feet. It is possible you will feel more comfortable walking in some of the insoles. The main benefit is that we hope to learn how to design better insoles, or how to better select which insoles to use for which patients.

What if there is a problem?

If you have concern about any aspect of the study the researcher (Declan Sweeney) will do his best to answer any problems. Please contact him on <u>D.Sweeney@pgr.salford.ac.uk</u>,

What will happen if I do not want to participate in this study?

You can withdraw from the study at any time without giving a reason. Any data which has been collected data will be deleted.

Will my taking part in the study be kept confidential?

Yes. Any information obtained in connection with this study will be treated as privileged and confidential. All information will be kept anonymous. The data and information collected will be stored in a locked filing cabinet. Electronic copies of the data will be stored in a password protected hard drive. Only the researcher (Declan Sweeney) will access the data. The data will be stored for a period of seven years.

What will happen to the results of the study?

The results of the study will be published in the scientific and clinical journals, conferences and the principle investigator's research thesis. They will also be fed back to health care professionals.

What do you do now?

If you wish to take part or if you have any questions or would like more information please do not hesitate to contact Declan Sweeney (sweeney.declan@gmail.com)

SALFORD RESEARCH CONSENT FORM

Title of Project:

"An investigation into how anti-pronatory foot orthosis effect (1) distribution of force under the sole of the foot, (2) compression of soft tissues in heel and arch areas, and whether resulting changes explain individual kinematic responses in a group of healthy subjects"

Name of Researcher: Declan Sweeney Please initial box 1. I confirm that I have read and understand the information sheet dated..... (Version 2) for the above study and have had the opportunity to ask questions. 2. I understand that my participation is voluntary and that I am free to withdraw at an time, without giving any reason, without my medical care or legal rights bein affected. 3. I understand that members of the University of Salford research staff/student who are working on the project will only look at plantar pressures, heel & foot arch tissue compression, lower limb 3D movement while walking. I give permission for these individuals to have access to this data. 4. I understand that my information and data arising from the research will be used anonymously in future research and publications 5. I understand that my GP will be contacted in the event of any health problems being identified during the research study 6. I agree to take part in the above study. Name of subject Date Signature Name of Person taking consent Date Signature Researcher Date Signature

Chapter 10 References

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