Copyright Statement

THE EFFECTS OF PROLONGED RUNNING ON THE BIOMECHANICS AND FUNCTION OF THE FOOT AND ANKLE

by

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able to contribute to a body of knowledge in a field I couldn't shake interest in for many years. Would I do it again…? Probably ($P<0.05$).

Author's declaration

At no time during the registration for the degree of Doctor of Philosophy has the author been registered for any other University award without prior agreement of the Doctoral College Quality Sub-Committee.

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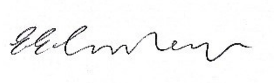
Date:  6 September 2019

Abstract

The effects of prolonged running on the biomechanics and function of the foot and ankle

Emma Eugénie Cowley

Running injuries have been linked to morphology and lower limb function, and changes in foot and ankle biomechanics and function within a run may contribute to the predisposition to injury. This thesis investigates the effects of prolonged running on the foot and ankle, and potential mechanisms underlying changes in foot posture.

Methods: A series of studies were undertaken from field to laboratory, measuring foot posture changes after prolonged running of different durations. Further measures of ankle invertor strength and medial ankle stiffness were taken in the laboratory studies as well as kinematic and plantar pressure data captured every ten minutes to enable repeated measures analysis of pedal movement to be conducted. Reliability across the foot posture, strength and stiffness measures was also determined.

The latter studies involved the development and mechanical testing of a novel foot orthosis component which was compared to a standard open cell orthotic foam. A double blind randomised controlled trial then compared how the novel and standard foam components affected foot posture, ankle invertor strength and medial and plantar soft tissue stiffness after a 30-minute run.

Results: A mean drop in NH and increase in FPI-6 following the half marathon, hour long and 30-minute treadmill runs was seen, with changes decreasing as running duration reduced. Ankle invertor strength and medial ankle stiffness reduced but did not correlate to the change in foot posture. Changes in foot and ankle kinematics were seen within 30 minutes of running.

Mechanical testing of the novel orthotic component and standard foam revealed characteristic differences in response to loading, and changes in foot posture measures after 30 minutes of running in the randomised controlled trial were almost identical across both conditions. Further comparison of invertor strength and medial foot and ankle stiffness revealed no significant differences, but a large difference between exertion measures was seen.

Conclusion: There was an overall effect of duration of running on changes in foot posture in this thesis, and the foot posture change was moderated by two different foot orthosis conditions although the mechanism remains unclear.

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Abbreviations

Abbreviation	Term
3DKFM	3D Kinematic foot models
3DMA	3D Motion analysis
AI	Arch Index
DAI	Dynamic Arch Index
EIF	Exercise-induced fatigue
EMG	Electromyography
FO	Foot orthoses
FPI-6	Foot Posture Index 6 factor score
NH	Navicular height
RRIs	Running related injuries
SD	Standard deviation
SE	Standard error of the mean
sEMG	Surface electromyography
vGRF	Vertical ground reaction force

Glossary

Amateur runner	A person who participates in the sport of running either on an ad hoc 'non-committed' or 'committed' basis such as by regularly running with a club and sometimes competing. Amateur runners do not earn money from running but can be both elite and novice with varying personal interest in their running performance.
Bout of running	An isolated period of running from a state of rest to a state of physical exertion in running to a state of rest again.
Coupling	Torque transmission between one segment and another adjacent and connected segment. Often results in movement couples.
Dynamic Arch Index	The Arch Index tool applied to footprints or plantar pressure maps, acquired during walking.
Eversion / inversion	Frontal (coronal) plane rotation of the heel at the rearfoot complex (talocrural and subtalar joints). Eversion rotates the plantar surface away from the midline, inversion rotates the plantar surface towards the midline.
Exercise(-induced) fatigue	A sense of exhaustion during involving central and peripheral drive changes in the central nervous system and muscles. Reversed after rest.
Foot function	The neuromusculoskeletal operation of the foot involved in the adaption to terrains, and creation of postural stability and propulsion in weightbearing activities.
Foot Posture	The position and shape of the foot in weightbearing.

Foot Posture Index	Tool used to quantify foot posture.
Forefoot striker	A person who achieves initial contact in running gait with the forefoot.
Heel striker	A person who achieves initial contact in running gait with the heel.
In-phase / out-phase	Movement of two adjacent body segments in the direction (in-phase) or opposite directions (out-phase).
Kinematics	Measurement of segmental motion (in the foot and leg in this thesis) without reference to the forces causing the motion.
Kinetics	(In this thesis) Measurement of forces generated at the plantar surface during running
Long-distance / prolonged / endurance running	Running distances over 5 km. In this thesis the minimum run distance is 5.75 km and the maximum distance is 21.1 km.
Material fatigue	In materials science, fatigue is the weakening of a material caused by repeatedly applied loads. It is the progressive and localized structural damage that occurs when a material is subjected to cyclic loading.
Maximalist footwear	Footwear designs aiming to alter the forces and / or movement of the foot during wear. Usually designs aiming to reduce pronation of the foot. These shoes score low on the Minimalist Index.
Midsole	The shoe-part between the insole and outsole.
Minimalist footwear	Footwear designs which aim to allow the foot to function as if shoeless. These shoes score high on the Minimalist Index and are sometimes referred to as barefoot shoes.

Movement	Change in location or position of an object relative to a fixed point in space.
Motion	Change of location or position of an object relative to time.
Muscle fatigue (in exercise)	Exercise-induced decrease in the ability of a muscle to produce force
Muscle function	The operation of muscle to produce power and contraction to elicit or resist movement.
Neutral footwear	Footwear with moderate intrinsic stability and structural componentry to create a stable but not movement- or moment-influencing function on the foot. These shoes score in the middle of the Minimalist Index.
Pedobarography / pedobarometry	The study of pressure fields acting between the plantar surface of the foot and a supporting surface.
Poron 4000™	An open cell foam applied clinically in podiatry in orthotic therapy for pressure and force attenuation.
Prehabilitation	Targeted conditioning of tissues and preparation of the individual to reduce the risk of injury and increase rate of recovery and return to function following injury or surgery.
Pronation (and supination)	Pronation in weightbearing is a change in foot posture involving variable triaxial, segmental contributions. Pronation is usually characterised clinically by a lowering of the medial longitudinal arch, widening of the forefoot and often heel eversion and other parameters captured in the Foot Posture Index. Supination is the opposite of pronation frequently characterised by raising of the

	medial longitudinal arch, narrowing of the forefoot and inversion of the heel, among other characteristics captured in the Foot Posture Index.
Psychometric property	Mostly concerned with reliability and validity of instruments / tests.
Running related injury	Musculoskeletal injuries acquired during running: including acute injuries or overuse conditions.
Surface electromyography	Recording of the electrical activity of muscle using electrodes adhered to the overlying skin, with representation in a visual display.
Smallest detectable difference	Also known as the minimal detectable difference. The smallest change that a test must detect before it can be concluded that a variable was not changed by chance.
Stereophotogrammetry	Motion analysis technique where estimation of 3D co-ordinates of points on an object is achieved by measuring the points in two or more planes and triangulating emitted rays from the points with a camera of known location.

Chapter 1 : Introduction

1.1 Overview and structure of thesis

This thesis investigates the effects of prolonged running on foot posture, the potential mechanisms underlying change in foot posture, and the potential to address foot posture changes using novel foot orthosis technology. The aim was to understand how and why foot posture changes during running, and how this could be minimised. Implicit in this work was the assumption that foot motion and posture is important for the function of running and, where changes result in high tissue stress, it is a potential determinant of running-related injury, especially that related to the medial column of the foot such as stage 1 tibialis posterior tendon dysfunction.

The studies herein investigated exercise induced changes in foot function and biomechanics during and after different durations of prolonged running, as well as how foot orthoses could affect changes in foot posture, strength and stiffness in the medial foot and ankle soft tissues and plantar fascia. Reliability of the measures used in the running studies in this thesis was established in chapter 2, and an initial study then investigated the changes in static foot posture of runners before and after a half marathon running event (chapter 3) using these measures. Changes in foot posture were further assessed, alongside additional measures of ankle invertor strength and medial foot and ankle soft tissue stiffness, in controlled laboratory conditions, before and after a prolonged treadmill run (chapter 5) to begin to identify the mechanism for change in foot posture with prolonged running. To understand the effect of duration of running the laboratory study run duration was half that of the mean half marathon race time. To determine when changes in the biomechanics and function of the foot and ankle occurred during prolonged running it was necessary to measure kinematics of the shank and foot during running which presents challenges with the foot obscured in footwear. To overcome this challenge, proxy measures of in-shoe foot and ankle kinematics were developed (chapter 4) using plantar pressure and 3D motion analysis technology. These were taken forward into chapter 5 to investigate the timing of kinematic changes during prolonged running, and to determine if any relationship existed between the changes in the proxy measures for foot and ankle kinematics and the changes in foot posture, ankle invertor strength and medial foot and ankle stiffness. The proxy measures were validated using walking gait with speeds up to that where participants wanted to transition to a running gait. At a moderate speed of walking the measures were most reliable and since the running speed was determined by the participants in chapter 5, it was anticipated that with a comfortable running gait speed that measures would also be reliable although this was not tested. If the proxy measures in chapter 5 showed a significant change in foot and ankle kinematics at one of the intervals tested, this would be used to determine the duration of the final run time in chapter 7 trials.

With changes in foot posture shown in chapters 3 and 5, alongside changes in invertor strength and medial foot and ankle soft tissue stiffness, the aim of chapter 7 was to investigate how foot orthoses could minimise foot posture changes by moderating the changes in invertor strength and medial foot and ankle soft tissue stiffness. Foot orthoses are frequently applied in clinical practice to help manage or prevent running related overuse injuries in the lower limb and foot, with the aim being to modify kinetics, and subsequently, tissue stress in the medial and plantar foot and ankle structures (Landorf and Keenan, 2000; Payne, 2005; Mills *et al.*, 2010; Kirby *et al.*, 2012; Banwell, Mackintosh and Thewlis, 2014). Orthoses are used for early stage adult-acquired flat-foot to reduce tissue stress on the structures maintaining the medial longitudinal arch (Alvarez *et al.*, 2006; Nielsen *et al.*, 2011). It is not known how effective orthoses are at reducing changes in foot posture. Currently the arch area of semi-rigid shells are often lined with Poron 4000™ for comfort and to reduce the severity of deceleration as the foot loads onto the orthotic shell. In this thesis the development and evaluation of a novel component was undertaken to be used in conjunction with foot orthotic shells in the same way as the Poron 4000™ lining (chapter 6). This component was compared in-vivo to Poron 4000™ (chapter 7) in a double-blind randomised controlled trial to investigate the effect on change in foot posture (primary outcome) and medial foot and ankle and plantar soft tissue stiffness and ankle invertor strength . Finally, the discussion and conclusions chapters (8 and 9) address the considerations in interpreting the results of the studies conducted throughout the thesis as well as highlighting areas for future research and drawing together the overall conclusions.

1.2 Thesis aims and objectives

This thesis aims to:

- define changes in foot posture with prolonged running
- investigate potential changes in ankle invertor muscle strength and medial foot and ankle soft tissue stiffness with prolonged running that could lead to changes in foot posture
- investigate the impact of a novel foot orthotic component on changes in foot posture and biomechanical properties with prolonged running compared to a Poron 4000™ insert

The objectives of the thesis required to fulfil the aims are to:

- determine the reliability of the primary and secondary outcome measures used (chapter 2)
- determine changes in foot posture following a half marathon (chapter 3)
- determine the validity of proxy measures of in-shoe foot kinematics while running (chapter 4)
- determine changes in foot posture and associated biomechanical parameters, and changes in ankle invertor muscle strength and medial

foot and ankle soft tissue stiffness with prolonged treadmill running in a laboratory-based environment (chapter 5)

- develop a novel orthotic component that aims to reduce changes in foot posture while running (chapter 6)
- evaluate the effectiveness of the novel foot orthotic component compared to Poron 4000™ in a randomised controlled trial (chapter 7)

1.3 Background

Chapter 1 herein provides a background to the thesis ahead. Societal participation of running will first be covered, along with prevalence and incidence of running-related injuries (RRIs), creating the drive for research into mechanisms of RRIs.

The concept, definitions and measurement of foot posture will then be discussed, followed by knowledge about change and recovery of foot posture to date, and understanding of medial longitudinal arch (MLA) function in running and possible mechanisms leading to changes in foot posture.

The anatomy of the foot and ankle in the context of foot posture and function will continue from there, with exploration of soft tissue mechanical properties during loading cycles, and consideration of experimental variables relating to the thesis.

Finally, considerations of factors which can affect the variables being measured in this thesis are discussed. These include the use of treadmills in running, techniques in motion analysis of the foot and ankle, segmental motion coupling in running, the influence of footwear and running technique, conditioning and running tolerance, and the role of footwear in altering the variables of running. Finally, the chapter will close with methods used to minimise changes in foot posture and function in clinical settings, with particular emphasis on foot orthotic therapy.

1.4 Running: participation and running-related injuries

1.4.1 Participation in running

Amateur running is an increasingly popular activity in the UK with survey responses revealing that approximately ten and a half million people are participating with an average of one to two runs per week (SMS Inc, 2014). Around 800,000 people (about 10 % of the UK adult running population) participated in long distance events in the UK in 2014 in marathon, half marathon and triathlon events, with 10 km running events attracting many more runners (SMS Inc, 2014). A number of recreational running projects have emerged in recent years including ParkRun UK (ParkRun, 2017) and RunTogether (England Athletics, 2017). These community-based projects have attracted non-committed and committed amateur runners alike, and ParkRun

UK has reported the average number of participants per weekly five kilometre event as 195.5 across its 553 locations (ParkRun, 2017). The free to access, community-based models offer a non-club context and a gateway to running, also seen in the uptake of 'couch to 5k' mobile phone applications and indicate that the actual numbers of people participating in running may be much higher than surveys suggest.

1.4.2 Definitions of distance running

The definitions of long, endurance and prolonged running vary. In anthropology endurance running is cited as continuous running of more than 5 km distance (Lieberman and Bramble, 2007) whilst in athletics the threshold between middle and long-distance events is not easily differentiated. The International Association of Athletics Federations cites events in the 'middle and long distance' category as ranging from 800 m to 3000 m (steeplechase) (IAAF, 2019) whilst the Olympic distance events extend to marathon distance (26.2 miles or 42.2 km) (The Tokyo Organising Committee of the Olympic and Paralympic Games, 2019). In this thesis the term 'prolonged running' is used to encompass running durations from 30 minutes (used in chapter 7) to 2 hours (mean half marathon time). The term 'long distance runner or running' is used to denote running distances longer than 30 minutes' duration up to marathon, and in some cases where explicitly indicated, ultramarathon distances.

1.4.3 Running-related injury in long distance runners

Long distance runners frequently acquire overuse running-related injuries (RRIs), which can curtail the ongoing ability to run (Lopes *et al.*, 2012; Videbaek *et al.*, 2015). Rates of RRIs remain at between 19.8 % and 79.1 % incidence (van der Worp *et al.*, 2015) and the individual and socioeconomic impact can be significant with 2.3% of those affected by RRIs taking time off work as a result of injury with a total economic burden estimated to be €172.22 per injury, and with an estimated 10.7 injuries being sustained per 1000 hours of running (€1849.49 per thousand hours of running) (Hespanhol, van Mechelen and Verhagen, 2016).

The cause of many overuse RRIs remains unclear and is likely to be multi-factorial in most cases, involving environmental effects (e.g the running surface and terrain), types of footwear used, the conditioning of the runner and changes in musculoskeletal function associated with exercise induced fatigue. These factors will be explored in more detail in the following sections and will be used to inform the methods used in the subsequent experimental chapters.

1.5 Foot posture and biomechanics & function in running

1.5.1 Foot posture: definitions and considerations for clinical interpretation

Posture is defined in the Merriam-Webster dictionary as:

> "The position or bearing of the body whether characteristic or assumed for a special purpose" (*Definition of Posture*, 2017).

In the foot, this might relate to the position of the structures of the foot (and thus its shape on observation externally) in relaxed standing. Whilst a useful monitoring tool where change results from changes in the structures of the foot e.g. in pathology or injury, foot posture is merely the nearest reproducible static representation of the mid-midstance part of the gait cycle, although without the accompanying ground reaction forces generated in walking or running (McPoil and Hunt, 1995). It thus limits the description of foot posture, at best, to representing a specific point in time during the gait cycle without the effect of the forces that vary with different gait speeds nor the response of the intrinsic muscles during strain of the MLA. Foot posture may change before and after this point with different forces being applied to the tissues which renders the inference of static foot posture to dynamic function inaccurate. Similarly, the compressive forces across the arch can reach multiples of body weight during locomotion with faster gaits (Komi, Fukashiro and Järvinen, 1992) creating greater ground reaction forces and these conditions are also not recreated in bipedal static foot posture measurements and so should be interpreted with caution as indicators of dynamic foot posture. The FPI-6 tool has, however, been shown to predict up to 41% of the dynamic variation in midstance foot position during walking (Redmond, Crosbie and Ouvrier, 2006).

Measuring arch height and other variables of foot posture can be of interest to a clinician since a low arch may indicate deformity from loss of integrity of a structure normally maintaining the height and shape of the arch (Tryfonidis *et* *al.*, 2008). It may be, however, that the foot is simply low arched but perfectly congruent with no deformity from osseous subluxation during loadbearing despite a low arch profile. To differentiate between the foot that has deformed into a low arch posture and one that is congruent, the clinician takes a history but also may attribute certain characteristics of foot posture across multiple segments of the foot using clinical tests as monitoring tools – the Foot Posture Index (six factor tool) includes many of the signs typically referred to by clinicians.

There are numerous clinical measures of foot posture cited in the literature (Menz, 1998; Evans *et al.*, 2003; McPoil and Cornwall, 2005; Menz *et al.*, 2012; Langley, Cramp and Morrison, 2016) and some have been widely adopted in clinical practice as monitoring tools or aids to orthotic prescription writing (Anthony, 1992; Redmond, Crosbie and Ouvrier, 2006). The Foot Posture Index (FPI-6) introduced above, is one such tool and measures foot posture across forefoot and rearfoot segments in all three cardinal body planes (Redmond, Crosbie and Ouvrier, 2006).

A study comparing various static foot posture measures with kinematics in walking (Buldt *et al.*, 2015) did find the Foot Posture Index to be a significant predictor of foot kinematics and in particular, peak angles, but static tests overall including the Foot Posture Index, truncated normalised navicular height and the Foot Mobility Magnitude test, are not strong predictors of foot kinematics and should not be used to infer kinematics in practice which is common clinical practice (Franettovich *et al.*, 2007).

A further issue with many clinical measures of static foot posture is that they often measure a single plane variable such as arch height, heel eversion or malleolar torsion (Root, Orien and Weed, 1971; Valmassy and Stanton, 1989; Rathleff, Nielsen and Kersting, 2012) when in reality the foot functions in six degrees of freedom across all segments (Nester *et al.*, 2007). Notwithstanding these considerations, a further issue is the definition of foot posture as a concept.

The FPI-6 tool was first introduced in the peer reviewed literature in 2006 (Redmond, Crosbie and Ouvrier, 2006) although the manual is dated earlier to 1998 (Redmond, 1998). Terms such as pronation and supination were deemed by most clinicians and researchers in that era to be adequate in the description of the perceived stereotypical movement of the foot in response to weightbearing as evidenced by the frequency of the terms in the literature from that era (Root, Orien and Weed, 1971; Dananberg, 1993b; Kirby, 2001; Franettovich *et al.*, 2007; Sanner, 2007). A recent narrative paper aimed to better define the terms for clinical use (Horwood and Chockalingam, 2017) and this provides a further guide to referencing the term pronation in a clinical context. The definition of pronation proposed by Horwood and Chockalingam is:

> "Motion of the foot articulations that allow the foot to become more prone to the support surface thereby increasing the ground contact surface area of the foot." (Horwood and Chockalingam, 2017)

Since three dimensional foot kinematic modelling has developed in the years since the FPI-6 was introduced, it is now inadequate in research contexts to describe the response of all feet to weightbearing simply as 'pronation' or 'supination' since there is no definition that encompasses all the variations of foot kinematics measured in studies of normal walking (Nester *et al.*, 2007; Lundgren *et al.*, 2008; Nester, 2009). Broad clinical definitions (Root, Orien and Weed, 1977; Horwood and Chockalingam, 2017) however, are still useful in clinical communications when describing changes in foot posture in clinical and research settings.

The terms pronation and supination will be used in this thesis to describe static foot posture but without inference to the segmental contributions that lead to each position via 'pronation and supination'. The six factors of the FPI-6 tool and NH combined capture information about static foot posture with reference to osseous and soft tissue variables (Redmond, 1998; Snook, 2001; Langley, Cramp and Morrison, 2016) which could be helpful in understanding the changes in foot posture after prolonged running.

1.5.1.1 Measurement of foot posture

There are numerous reliable tools for measuring foot posture including the Arch Index (Cavanagh and Rodgers, 1987; Menz *et al.*, 2012), longitudinal arch angle (McPoil and Cornwall, 2005), Rose's Valgus Index (Menz, 1998), navicular height (NH) (Brody, 1982; Vinicombe, Raspovic and Menz, 2001) and the Foot Posture

Index (FPI-6) (Redmond, Crosbie and Ouvrier, 2006). Of these, the most frequently used test in a clinical setting, from a social media poll in 2018 of 2500 podiatrists in MSK:UK (College of Podiatry Special Advisory Group), is the FPI-6, whilst NH is used more variably by clinicians but has merits when compared to the FPI-6 focusing on skeletal foot posture more than the foot as a whole including the contours of the soft tissues.

Reasons for the popularity of these tests were cited in the poll as ease of use and interpretation, and being quick to perform in a clinical setting, requiring minimal calculations of numbers in the process. These are desired attributes in clinical outcome measures where quick to perform, inexpensive, easy to undertake and highly portable tests score mostly highly on the Clinical Utility Score (Tyson and Connell, 2009; Tyson, 2010). NH is also required by some commercial foot orthotic laboratories to aid accurate representation of the foot during the orthosis manufacturing process (Firefly Orthoses Ltd, 2017).

The Arch Index (Cavanagh and Rodgers, 1987), from which the Dynamic Arch Index is directly derived, is not so widely used in clinical practice but offers an indirect measure of arch height in walking or running. The Arch Index has been shown to be valid (McCrory *et al.*, 1997) when correlated to radiographic arch height measurement ($R=0.67$, $P<0.05$) and also achieves a high Clinical Utility Score although the Dynamic Arch Index requires pressure analysis equipment and so scores lower for clinical utility. Adaptation of the Arch Index to a simplified visual interpretation tool has also been shown to be reliable (Menz *et* *al.*, 2012) and may find greater popularity with clinicians over time if clinical pressure analysis technology becomes more commonplace. The Arch Index may, however, have limitations of use in obese populations, as adipose tissue in the foot can lead to infilling of the arch and the impression of a print from a flatter foot (Wearing *et al.*, 2004).

The measures of foot posture selected for use in this thesis are the Foot Posture Index six factor tool (FPI-6) and the navicular height measure (NH). These each incorporate elements of foot posture not reflected in the other directly (Menz, 2005). The NH measure reflects only sagittal plane position of the navicular in weightbearing while the 'congruence of the medial longitudinal arch' factor of the FPI-6 is estimated using soft tissue contours. It is possible to have differences in the measures of these variables as muscle bulk in the medial longitudinal arch (MLA) may be large giving the impression of a lower MLA than the NH suggests. Indeed, a recent study (Langley, Cramp and Morrison, 2016) showed no correlation between the two measures of foot posture indicating that they measure different variables of foot posture that may be independent of each other. Further discussion of the validity and reliability of the NH and FPI-6 will be undertaken in chapter 2.

1.5.2 Background to foot posture, biomechanics & function in running

The musculoskeletal factors previously reported as a risk factor for RRIs include foot posture although with some ambiguity (Neal *et al.*, 2014; Nielsen *et al.*, 2014). To date, however, the conclusions about foot posture as a risk factor for RRIs have been based on non-fatigued, baseline measurements of foot posture and more work is needed to ascertain if the risk lies rather in the change in foot posture during prolonged running than the baseline, non-fatigued measurement. Indeed highly arched feet have greater potential for medial longitudinal arch (MLA) deformation than flat feet and have been shown to have a higher risk of RRI incidence than lower arched feet (Nielsen *et al.*, 2014). It is the change in foot posture, therefore, that this thesis focuses on

and an understanding of what is known about changes in the MLA and associated anatomical function and integrity is explored below.

1.5.2.1 Foot posture changes in running

Changes in foot posture have been investigated over various running durations. Changes in foot posture have been reported to occur consistently in running durations of 60 minutes or over (Escamilla-Martínez *et al.*, 2013; Fukano and Iso, 2016; Fukano *et al.*, 2018) although variably at 45 minutes (Boyer, Ward and Derrick, 2014; Bravo-Aguilar *et al.*, 2016). The changes reported at various running distances are shown in table 1.1.

Run time	Change reported	Context and controls in place	Study
~ 4h (3hr 57m)	NH reduced by -4.1 mm	Road running Uncontrolled run velocity Runners' own shoes – type, condition and fit not controlled	(Fukano *et al.*, 2018)
~2h (1hr 56m)	NH reduced by -1.5 mm	Road running Uncontrolled run velocity Runners' own shoes – type, condition and fit not controlled	(Fukano and Iso, 2016)
60m	FPI-6 increased by + 2 points*	Over ground running (soft, flat terrain) Controlled run velocity (3.3 m/s or 12 km/h) Laboratory shoes: new, correct size, Mizuno Wave Rider	(Escamilla-Martínez *et al.*, 2013)
45m	No significant difference in NH	Treadmill running Controlled run velocity (3.4 – 2.88 m/s or 10.34 - 12.24 km/h @ 70 % velocity of maximal effort run) Runners' own shoes – type, condition and fit not controlled	(Boyer, Ward and Derrick, 2014)
45m	FPI-6 increased by +1.3 points*	Running circuit Controlled run velocity (12 km/h) Runners' own shoes – type, condition and fit not controlled	(Bravo-Aguilar *et al.*, 2016)

*FPI-6 scores reflect raw scores not Rasch converted scores

Table 1.1 Foot posture changes using the NH and FPI-6 tools with various durations of prolonged running

Changes in foot posture occur in different segments of the foot with 76.2 % feet reportedly changing shape in the lateral column and 47.6 % changing shape in the medial column after a 35 km run (Fukano and Iso, 2016). Other general shape changes have also been noted after 10 km and 20 km distances such as an increase in the measurement across and around the metatarsal heads (Mei *et al.*, 2018). There may be an effect of resting foot posture on the overall change with running as a study of 104 runners showed that those with high arches initially lowered more than one standard deviation than the non-highly arched feet after 200 m of running (Williams, Tierney and Butler, 2014) although this could be explained by a larger strain toe region (de-crumpling) associated with slack passive soft tissues under constantly repeated strain (Davis's Law (Nutt, 1913), or collagen conditioning (Maganaris, 2003; Hawkins *et al.*, 2009), and may plateau early into a prolonged run. Clinical measurement of medial longitudinal arch height alone, therefore, may not be adequate to capture foot posture changes and multifactorial tools such as the Foot Posture Index (FPI-6) (Redmond, Crosbie and Ouvrier, 2006) may be better suited to detect changes across both medial and lateral segments of the foot as well as the rearfoot.

While other gait parameters have been identified to change during prolonged running, a clear mechanism for the changes in foot posture has yet to be reported. Changes in overall foot volume during prolonged running have not been observed (Boni, Takacs and Wilson, 2012; Chlíbková *et al.*, 2014) whilst changes in lower limb strength and stiffness have, although not linked to foot posture changes to date. Some of the possible mechanisms, as well as the methods used to measure foot posture, are discussed in the sections below.

1.5.2.2 Recovery of foot posture and clinical relevance of foot posture change

Recovery of foot posture changes after running a full marathon have been reported to take more than eight days (Fukano *et al.*, 2018) although recovery of muscle strength has been reported to be recovered to 80 % of baseline strength after two minutes in the tibialis posterior following a fatiguing protocol (Pohl, Rabbito and Ferber, 2010).

Changes in foot posture following prolonged running could then have implications for training and activity in the days following although the extent of clinically important changes have not yet been determined. The drop in navicular height (NH) in the study by Fukano and Iso (2016) had an effect size of 0.62 which is described by Cohen (Cohen, 1988; Sullivan and Feinn, 2012) as moderate. This could be considered potentially harmful given that other skeletal measures of the medial longitudinal arch have been reported to change in the same direction in people with symptomatic adult acquired flatfoot defined as showing a clinically flat arch and being severe enough to consider surgery or with tears in the tendon of tibialis posterior (Younger, Sawatzky and Dryden, 2005; Lin *et al.*, 2015). The effect size of the difference in talar-first metatarsal angle was 1.1 (very large) in people with and without adult acquired flatfoot (Younger, Sawatzky and Dryden, 2005) although inference of one foot posture measure with another should be undertaken with extreme caution without correlation being demonstrated given the lack of agreement shown between commonly used foot posture measures including the NH, FPI-6 and longitudinal arch angle (Langley, Cramp and Morrison, 2016).

Since the minimal clinically important difference for foot posture change as a risk factor for RRIs in running is not known, a non-trivial effect size is desirable (trivial being defined as -0.2–+0.2 (Page, 2014)) that is easily detected with regular clinical equipment and simple training (Tyson and Connell, 2009).

1.5.3 The function of the medial longitudinal arch of the foot

The human foot is characterised among the great apes by its medial longitudinal arch (MLA) (figure 1.1), as well as other adaptations suited to bipedal locomotion (Holowka and Lieberman, 2018).

Figure 1.1 Differences between the human and typical close primate foot (Adapted from Holowka and Lieberman, 2018)

Dorsiflexion at the human midfoot is limited by musculoskeletal architecture to allow for enough stiffness to function as a lever whilst creating sufficient compliance to allow the foot to achieve a spring-like mechanism in running. The spring action is, in part, the function of collagenous structures spanning the plantar aspect of the MLA which return elastic energy to the foot to aid propulsion in running (Blickhan, 1989; Morin *et al.*, 2005).

The spring effect of the of the MLA and lower limb was described originally as a true spring-mass model (Ker *et al.*, 1987; Blickhan, 1989) and more recently, in the foot, is considered to be a function of the intrinsic muscles which also span the MLA and / or insert into the plantar fascia (Wong, 2007; Angin *et al.*, 2014; Kelly, Lichtwark and Cresswell, 2015). Given the energy cost in prolonged running, it is possible that there may be an effect of exercise-induced fatigue and loss of muscle strength later in a prolonged run. Changes in loading patterns across the foot during prolonged running, measured with plantar pressure analysis, have been reported after 15.5 miles (just over half marathon distance), 26.2 miles (marathon distance) and 152.8 miles (ultramarathon distance) (Nagel *et al.*, 2008; Karagounis *et al.*, 2009; Rosenbaum, Engl and Nagel, 2016) although it is not known when these changes occur prior to the 15.5 mile point; changes in muscle fatigue and foot posture have been identified at shorter distances (Rahnama, Lees and Reilly, 2006; Peltonen *et al.*, 2012; Boyer, Ward and Derrick, 2014; Fukano and Iso, 2016). In the foot the changes in loading may be associated with an increase in load on the plantar fascia, with associated reduction in strain stiffness, as well as muscular fatigue, and ultimately a reduction in the resistance to MLA compression. Material fatigue has been demonstrated in cyclic loading of mammalian tendon (Wang and Ker, 1995; Ker, Wang and Pike, 2000) where microtears appear. In living tissue this is followed by a cellular response aiming to repair and reinforce the tissue for further loading (Cook *et al.*, 2016). The relationship between mechanical overload within a run and the onset of tissue damage and repair may not be constant among foot and ankle anatomy since the forces withstood by any one structure are also subject to the shape and function of its synergist structures. In the case where prolonged running produces fatigue (material, exercise-induced and muscular) foot posture, along with other biomechanical and functional parameters, may change to the extent that load-bearing structures are exposed to damaging levels of tissue stress and strain within the middle or latter part of a run. Most clinical assessments of foot posture and function are undertaken in the unfatigued individual (and foot). Research into the changes in foot posture during and immediately after a prolonged run may be useful to clinicians in understanding the aetiology of RRIs.

1.5.4 An overview of anatomy maintaining the architecture of the ankle and medial longitudinal arch of the foot

The soft tissues acting to preserve the height of the medial longitudinal arch of the foot in running and walking are both contractile (muscles) and non-contractile; primarily tendons, ligaments, and fascia (Kitaoka *et al.*, 1997; Headlee *et al.*, 2008; Jennings and Christensen, 2008) . The muscles and passive soft tissues can be further divided into intrinsic and extrinsic structures with the extrinsic structures extending both into the leg and the foot and the intrinsic structures lying in the foot alone.

1.5.4.1 Structures extrinsic to the foot

Both intrinsic and extrinsic structures contribute to the stiffness and movement of the foot in walking and running. The arch compresses and recoils during the loading and unloading phases of the gait cycle as the axial compression of bodyweight (a product of mass and acceleration) is transmitted through the foot. The Achilles tendon creates a bending (flattening) moment across the arch as the triceps surae contract during the propulsion phase of the gait cycle (Kirtley, 2006). The tibialis posterior muscle-tendon unit acts to stabilise the arch during midstance to terminal stance in heel-toe patterns of walking (Thordarson *et al.*, 1995; Pohl, Rabbito and Ferber, 2010; Maharaj, Cresswell and Lichtwark, 2016) and more fibres are recruited with faster gaits (Murley, Menz and Landorf, 2014). After fatiguing the tibialis posterior muscle in twenty nine participants using an exercise designed to isolate the muscle, (Pohl, Rabbito and Ferber, 2010) kinematic changes were measured in walking using an eight camera 3DMA system, and compared to a control group of people with unfatigued muscles. The study found that rearfoot kinematic differences between the fatigued and unfatigued groups were within one degree of movement which is of questionable clinical significance when considering the role of the tendon in arch height maintenance. Rather, this reinforces the global stabiliser role of the muscle which has a pennate fibre structure capable of producing high forces over a small range of shortening. The tibialis posterior tendon insertion is continuous with the inferior calcaneonavicular (spring) ligament and talonavicular joint capsule (Taniguchi *et al.*, 2003; Mengiardi *et al.*, 2005; Jennings and Christensen, 2008) and highlights how the passive and active structures of the foot cannot be considered in isolation when discussing function. Changes in foot posture with prolonged running could be caused in part by alterations in soft tissue compliance (stiffness) and reductions in the ability of the ankle invertors to muscles to generate adequate force. The invertors act eccentrically in heel-toe gait at the beginning of stance phase to control the loading response of the foot and ankle with bursts in the tibialis posterior firstly at 5 % of the gait cycle and again at 35 % of the gait cycle (Murley, Buldt, *et al.*, 2009) and tibialis anterior in the first 10 % and secondly in swing phase and preswing at 50 % to 100 % (Hof *et al.*, 2002).

The lateral peri-malleolar muscles comprise the fibularis (peroneus) brevis and fibularis (peroneus) longus. The peroneus longus inserts medially at the base of the first ray and has a more nuanced role possibly acting to both assist the peroneus brevis with eversion and ankle plantarflexion in open kinetic chain (foot away from the ground) conditions, but also in stabilisation of the first ray in closed kinetic chain (foot in contact with the ground) conditions, creating stability of the medial longitudinal arch. Gefen (2002) showed that the peroneus longus and pretibial muscles all fatigue during intensive marching.

The peronei activate during the propulsion phase (Willem *et al.*, 1995) along with tibialis posterior and are both recruited to a greater extent in faster gaits (Mohammadi and Phadke, 2017) as inversion forces increase secondary to the action of the windlass mechanism of the plantar fascia (Aquino and Payne, 2001), co-contraction of the tibialis posterior, and external rotation moment from the swing limb via the pelvis and ipsilateral hip.

Together the peri-malleolar muscles medial and lateral to the ankle balance the frontal or coronal plane forces across the ankle and subtalar joints and aid skeletal alignment thought to be critical to the function of the foot's autosupport mechanisms such as the 'windlass mechanism' of the plantar fascia, and locking of the calcaneocuboid joint (Dananberg, 1993a).

1.5.4.2 Structures intrinsic to the foot

The intrinsic muscles of the foot have been shown to be a significant factor in the maintenance of arch height with the abductor hallucis being the most frequently studied muscle due to its superficial location and anatomy spanning the full length of the medial longitudinal arch of the foot. Fascial binding prevents full bowstringing of the abductor hallucis muscle belly, but the effect is especially noticeable in highly arched feet which may alter its line of pull and function. Headlee *et al*. (2008) used a fatigue protocol on the abductor hallucis muscle in twenty one healthy individuals and measured a ten per cent navicular drop on average after the fatigue exercise. Notably, this study did not include a control group, but other studies have concurred with the findings of this study. One such study (Kelly *et al.*, 2014) investigated the response of the intrinsic muscles of the foot to increased postural demand in standing. In nine healthy males an increasing load of additional twenty-five per cent bodyweight increments was added to the participant, and the movement of the arch as well as intrinsic muscle activation and ground reaction force were measured. The study found that only after an increase of fifty per cent bodyweight did muscle activity increase in the three largest intrinsic foot muscles (abductor hallucis, flexor digitorum brevis and quadratus plantae). Furthermore, with a hundred per cent bodyweight added, the medial longitudinal arches lowered but with electrical stimulation of the three intrinsic muscles a reduction of length and increase in height of the arch was restored to that measured with just an additional fifty per cent bodyweight. This finding concurred with a larger study (Johns and Fuglevand, 2011) of forty healthy individuals using electromyography to determine the activity of the abductor hallucis muscle in both neutral and resting calcaneal stance position before and after local anaesthesia of the tibial nerve. This study showed that the activity of the abductor hallucis is a good predictor of the extent of navicular drop in single limb stance, a finding that may be useful in understanding the role of the muscle in walking and running. These studies indicate that the intrinsic muscles, and in particular the abductor hallucis, have a dynamic stabilising capacity although it is not known if this is reproduced to the same extent in running as it is in walking. To date, a literature search for studies investigating the abductor hallucis in shod walking or running returns very few results likely due to the pragmatic issues associated with the use of electromyography in the shod foot in running due to movement artefact with wired systems. Kelly *et al*. (2015), however, investigated the phasic activity of the intrinsic muscles of the foot in barefoot walking in nine healthy individuals who walked and ran whilst electromyographic data were collected from the abductor hallucis, flexor digitorum brevis and quadratus plantae muscles. Muscle tendon unit length was also estimated, and the muscles were shown to modulate peak rearfoot eversion which had not previously been demonstrated as the extrinsic muscles were more commonly assumed to be primarily acting to achieve this. Of note, the intrinsic muscles of the foot, and especially and abductor hallucis were reported by Kelly et al. (2012) to be resistant to fatigue and so may possibly only present strength deficits after prolonged or exhaustive running.

The role of passive structures intrinsic to the foot and ankle have been demonstrated in cadaver studies to have the most significant role in the maintenance of the arch of the foot. Studies involving nineteen fresh-frozen cadaver feet under 445 N of axial load showed the extent of arch deformation when load-bearing structures were sectioned in series (Kitaoka *et al.*, 1997). The deltoid ligament, spring ligament and interosseous talocalcaneal ligaments yielded the greatest change in arch height when sectioned, and the plantar fascia led to only very slight loss of arch height. Of interest, a study applying a biomechanical computerised model found that baseline arch height made a difference to the contribution of the plantar fascia to the change in arch height (Arangio, Chen and Salathé, 1998). With an initial arch height modelled at 20 mm high (a low arch) the arch elongated by 8.6 mm when 683 N of axial load was applied and dropped by 11.8 mm. By contrast the highly arched foot (60 mm high) showed 8.4 mm arch lengthening with loading and 5.5 mm lowering of the arch simultaneously. The mid-range arch height of 40 mm showed 8.7 mm arch elongation with an arch drop of 8.0 mm under loading.

A further study of navicular displacement in forty runners before and after a forty-five minute treadmill run (Boyer, Ward and Derrick, 2014) did not show any significant differences in either men or women ($P<0.05$). The mean vertical navicular displacement was 5.6 mm throughout the running trials. Arch lengthening was also measured in the pre- post-run trials and was 2.2 % greater in running than standing but did not increase across the 45-minute run. The findings of this study are consistent with another study investigating the creep of the plantar fascia during running in fifty feet from twenty-five people using ultra-sound imaging of cross-sectional thickness. Again, no change in thickness was measured after thirty minutes of running (Welk *et al.*, 2015) although the hypothesis assumed that Poisson's ratio, the transverse contraction to longitudinal strain ratio, would be a dominant characteristic of strain deformation observed in the plantar fascia but not the stress relaxation that may not be associated with observable contraction. Poisson's ratio has been estimated in the plantar fascia to be 0.49 using finite element modelling (Chu, Reddy and Padovan, 1995) but has not to date been reported in-vivo or in-vitro. Cutting the plantar fascia in cadavers has highlighted its primary contribution to medial longitudinal arch stability in static stance (Huang *et al.*, 1993), whilst recent work has also demonstrated the importance of the plantar fascia as a dynamic stabiliser of the foot (Wager and Challis, 2016; Angin, Mickle and Nester, 2018). Biomechanical models of the foot have also been used to highlight how the plantar fascia affects arch height (Arangio, Chen and Salathé, 1998; Tak *et al.*, 2004).

In chapter 7 a novel indirect measure of plantar fascia stiffness is presented. The role of the plantar fascia in stiffening the foot was recently questioned, however. Welte *et al.* (2018) applied loading to nine feet with and without the hallux dorsiflexed on the first metatarsal with the aim of determining the effect of the plantar fascia on stiffness of the foot. Contrary to long-held thoughts (Hicks, 1954) the feet became less stiff and elongated more when under load with the hallux dorsiflexed by 30°. The rationale given by the authors was that in applying load to the relaxed, static foot, with plantar fascia pretensioned and being effective at shortening the unloaded foot, that the other plantar structures were thus unloaded and slack. In this state the bulk stiffness of the arch before the load was applied was reduced and the plantar fascia took more strain that it might in walking when the intrinsic muscles are active and adding to the stiffness of the arch.

The complex functional anatomy of the foot and ankle is still not fully understood but the load sharing of the structures during different weightbearing postures and tasks is evident. Any one structure compromised by injury could lead to another structure becoming overloaded and prone to further injury. Understanding how the structures of the foot and ankle respond to prolonged running may, therefore, contribute to the knowledge about factors leading to running related injuries. The material behaviour of the soft tissues of the MLA and ankle during prolonged running are explored in the next section.

1.6 Behaviour of soft tissues and muscle during prolonged running

Soft tissues aid the skeleton of the foot in maintaining the geometry and function of the medial longitudinal arch. The structures are both active and passive and include muscle, tendon, ligament and fascia. Muscles and tendons act in series in running (Blickhan, 1989) to aid force transmission in the production of movement from kinetic muscle energy and elastic energy from tendon recoil (McNeill Alexander, 2002). Lower limb muscles have been shown to reduce power with exercise induced fatigue (Rahnama, Lees and Reilly, 2006; Skof and Strojnik, 2006) with associated increase in amplitude in electromyographic signals (Wu *et al.*, 2007), decrease in torque and EMG integrals (Nicol, Komi and Marconnet, 1991; Kent-Braun, 1999) and alteration of footstrike pattern in running (Jewell, 2014; Hazzaa Walaa Eldin and Mattes, 2018). Exercise induced fatigue has been defined as:

> “A loss in the capacity for developing force and / or velocity of a muscle, resulting from muscle activity under load and which is reversible by rest.” (‘Respiratory Muscle Fatigue: Report of the Respiratory Muscle Fatigue Workshop Group’, 1990)

It is likely that a combination of central and peripheral fatigue combine in the reduction of muscle power (Gandevia, 2001; Saldanha, Nordlund Ekblom and Thorstensson, 2008) placing increased load on the associated tendon (Ker, 2007). Tendon overuse injuries are associated with running where a damaging mechanical fatigue mechanism takes place at a faster rate than the repair process (Ker, 2007). Tendon fatigue has been shown in-vitro to begin with micro-tears which are accommodated in the early stages by shear load transmission which spreads the load across the tendon but ultimately will be overwhelmed and lead to whole tendon rupture (Ker, 2007). Further research has also shown that this process of fatigue damage can happen when a tendon is stressed to 75 % of its maximal life-stress load in just 300 cycles (Shepherd and Screen, 2013) and a typical half marathon would involve around 11000 steps per limb with possibly less than 75 % maximal life stress for most steps but no doubt increasing as fatigue leads to poorer muscle power and increased reliance on load-bearing tendons. At 1200 cycles at 75 % maximal life stress tendon has been shown to exhibit serious damage in-vitro which would likely elicit a nociceptive response in-vivo, highlighting the protective nature of pain. As runners frequently take more than 1200 steps in training it is possible that they modulate stress in their tendons to reduce this rate of fatigue damage, for example, by altering running style. Repetitive loading and stretching may also result in tissue creep and changes in stiffness of the collagenous structures supporting the medial longitudinal arch of the foot. This may be compounded by temperature changes which would increase the compliance of collagen and thixotropic properties of muscle (Campbell and Moss, 2000). If a similar effect occurred in the invertor tendons and surrounding soft tissues the continued bout of running would suspend re-stiffening which would then be detectable after the run. Where tendon damage does happen it is likely then, that rest days help to reduce the net damage in a runner's limbs (Cook and Purdam, 2008).

Muscle fatigue and tendon fatigue occur together during exercise and in the invertors has been shown to reduce foot and ankle coupling where tibialis posterior is affected (Ferber and Pohl, 2011). The change in bone movements may be directly related to the degeneration in the posterior tibial tendon. Indeed fatigue in the peroneal muscles (also peri-malleolar) has been shown in a study powered a priori to detect a 2˚ ±4˚ (alpha 0.05, power 0.8) difference to not significantly affect proprioception of inversion and eversion at the ankle (South and George, 2007). These results do not relate to the transverse and sagittal planes, but Stacoff and colleagues (2000) reported greater ranges of decoupling in running between the calcaneus and tibia in the frontal plane ranging from 6˚-11˚, whilst only 3˚–6˚ in the transverse plane using cortical bones mounted in five participants. Of interest, out of the five participants, one

(20 %) showed no decoupling at the trial running speed of 2.5-3.0 m/s. The authors of the study of the peronei concluded that other structures may be more involved in ankle proprioception in the frontal plane (South and George, 2007).

Whilst muscle and tendon fatigue are of ultimate interest in the development of running related injuries, the changes in soft tissue characteristics prior to clinically detectable damage are of interest to help understand the pre-clinical stages in overuse injuries. The load bearing tendon with the highest maximal life stress in the human body (67 MPa) is the Achilles tendon with others tolerating less down to 13 MPa in smaller non-primary loadbearing tendons (Shepherd and Screen, 2013). The Achilles tendon has been shown to not significantly change in stiffness after a marathon run (Peltonen *et al.*, 2012) in a study of twelve runners. The study used ultrasound imaging of the tendon during a sub-maximal voluntary isometric contraction to record the change. The change measured was 197±62 Nmm^{-1} to a post-race value of 206±59 Nmm^{-1} (4.3 %). The study did not report a power calculation, however, and animal studies of patellar tendons under increasing cycles of non-damaging loading have demonstrated an increase in stiffness of 18.3 ±10.6 % after 2232 ±768 cycles of non-damaging strain (Fung *et al.*, 2010).

1.6.1 Soft tissue loading behaviour in the ankle and foot

Tendon has been shown to demonstrate strain rate dependent behaviour (Yamamoto *et al.*, 1992; Danto and Woo, 1993; Johnson *et al.*, 1994), with an increase in stiffness with fast loading and a decrease with slower loading (Wren *et al.*, 2001). Additionally, an increase in failure stress and failure strain at higher rates of strain has been demonstrated, and this may predispose the structure to injury in propulsive sports activities (Wren *et al.*, 2001). Tendon fatiguing studies have also shown an increase in strain with continued cycles of strain (Ker, 2007; Shepherd and Screen, 2013) which when applied to the foot could infer that the plantar fascia strains over time leading to a drop in MLA height. Strain recovery time has been shown in-vitro to be fifteen minutes after a period of cyclic loading as long as the tendon is strained within its elastic tolerance (Shepherd and Screen, 2013; Thorpe *et al.*, 2014) so this effect in the foot would be absent in the non-fatigued foot in clinical assessment. Foot orthoses remain in-shoe regardless of the variation of forces acting on them from the foot and this may be an area for future exploration in refining the effect of foot orthoses.

This section has explored the structure and function of the foot and ankle in prolonged running to provide a background to the experimental chapters further on in this thesis. In chapters 3, 5 and 7 foot posture, strength and stiffness will be measured during prolonged running and consideration will now be given to the factors that could influence these to inform and help refine the methodologies used.

1.7 Factors to consider when investigating running

1.7.1 Effects of running over-ground versus on a treadmill

The results of a survey of UK runners reported that 55 % of runners undertake at least a third of their running on the road and the remainder, up to two thirds, indoors on either a treadmill or track (SMS Inc, 2014). An important consideration for research on running, therefore, is the terrain or platform most used versus the experimental conditions a sample is tested in. Treadmill running in scientific experiments is controversial since early studies showed a statistically significant difference in kinematics between over-ground and treadmill running (Nigg, Boer and Fisher, 1995). In a study of twenty-two participants (11 runners with treadmill experience and 11 non-runners with no treadmill experience), for example, significant mean differences in ankle kinematics were seen at speeds up to a fast paced 6 m/s running velocity. There was no effect of treadmill belt length or width across three treadmill models (60 cm x 200 cm, 51 cm x 165 cm and 40 cm x 130 cm) but there was an effect for shoe type, as the trials were undertaken at random in both the laboratory shoes and runners' own shoes (see section 1.7.4 for more detailed discussion on shoe type effects). A limitation of this study, noted by the authors, was the small sample size and the anecdotal finding that runners frequently changed foot strike strategy at different running speeds. No power calculation was reported to detect a specific effect size of change and furthermore, the technology used to measure joint angles was by two-dimensional film analysis which would not account for movement outside of the sagittal plane and is prone to parallax error. As technology to measure kinematic parameters has improved since this study, so too has evaluation of the differences between treadmill and over-ground running. A further study revisited the measurement of kinematics and kinetics in treadmill and over-ground running, but with a sophisticated three dimensional motion analysis system and an instrumented treadmill capable of measuring ground reaction forces for comparison to a floor fitted force plate (Riley *et al.*, 2008). Twenty healthy runners were included in the study and ran at self-selected speeds. All kinetic and kinematic parameters, with the exception of peak knee flexion angle, were within one standard deviation of each other leading the authors to conclude that, treadmills could be substituted for over-ground running for research purposes. Adding to this picture with respect to midfoot motion, which is difficult to access using traditional kinematic measurement techniques, a study was undertaken (Barton *et al.*, 2015) to measure navicular movement during treadmill and over-ground running. A strain gauge was fitted to the skin over the navicular of twenty-six healthy runners and the magnitude of navicular movement was measured to be 16 % greater in treadmill running than over-ground running which equates to an increase in peak drop of 1.3 mm. This is very similar to the change in static navicular height after a long distance run reported in the literature (Fukano and Iso, 2016) despite muscle activity acting on the arch more during running than in quiet standing.

The above studies were primarily concerned with kinetics and kinematics as measures of running but another study of ten recreational runners explored muscle activity, another frequently measured parameter in clinical and performance-based gait analysis. This study focused on the activity of eight large muscles in the thigh and leg using surface electromyography (sEMG) and found no significant difference between over-ground and treadmill running in all eight muscles after five minutes of running (Waldhelm and Fisher, 2016). The findings of this study concurs with the findings of an older study also measuring lower limb muscle activity and kinematics during over-ground and treadmill running (Wank, Frick and Schmidtbleicher, 1998). Here, significant differences in lower limb joint kinematics were identified in contrast to Riley et al. (Riley *et al.*, 2008) but no differences in muscle function were measured alongside. Both the studies using sEMG had small sample sizes with no power calculation reported but the findings are consistent and in agreement adding weight to the findings.

To explore further running related changes with the use of treadmills a final consideration is familiarisation of the running experience prior to measuring gait parameters. A study of seventeen (8 male, 9 female) unimpaired adult runners with no experience of treadmill use measured kinematic changes across the whole lower limb during ten minutes of treadmill running (Lavcanska, Taylor and Schache, 2005). With runners self-selecting their speed, kinematic data were collected at two-minute intervals and found to be significantly different up to the six-minute time point after which there was no further change. The study showed differences in peak to peak angle of pelvic tilt, mean angle of pelvic tilt, peak hip extension, peak stance and swing phase knee flexion angles and ankle dorsiflexion at initial contact; there is, however, no description of foot strike strategy. The largest changes occurred in the first two minutes with ankle dorsiflexion peaking at two minutes at about 10.5 degrees and reducing to a minimum angle at six minutes at about 8.5 degrees. A similar reduction in ankle joint dorsiflexion at initial contact was reported in a study analysing stance phase treadmill running vs over-ground kinematics in twenty runners (Fellin, Manal and Davis, 2010). This study compared the entire kinematic curves across the stance phase in the hip, knee and ankle in twenty runners using the means of five trials. Reliability of the visual evaluation of the curves was confirmed by trend symmetry analysis, which showed the mean trend symmetry across all curves was excellent with correlation of 0.94. The differences lay in the transverse plane at the hip, knee and rearfoot, and also the frontal plane in the knee. The sagittal curves across the whole stance phase in all joints were not significantly different and the frontal plane in the hip and rearfoot were also not significantly different. The magnitude of variation between over-ground and treadmill trials was nearly always less than 1.5 degrees leading the authors to the conclusion that using treadmills in research was generally reflective of over-ground running although there may be individuals for whom treadmills distort the stance phase kinematics and researchers should heed this caution.

Perception of self-selected running speed in nine male young adult experienced runners was also measured in a study of running over-ground and on a treadmill with the belt speed concealed. Participants first determined their self-selected over-ground pace and then aimed to repeat it on the treadmill and ten barefoot 20 m running trials were calculated. The comparison of means revealed that the perceived over-ground speed on the treadmill was up to 1.49 m/s (or 5.4 km/h) slower than over-ground running and that this pattern was consistent among all participants (Kong, Candelaria and Tomaka, 2009). This discrepancy in perception of speed was reproduced in a study by the same group but using a longer duration of run in each condition and averaging the speed across the time. In the twenty-one runners tested the effect of the treadmill once more became apparent as the runners ran three trials in succession: over-ground, treadmill and over-ground again. The average speed of the over-ground runs was not significantly different but the average of the treadmill speed vs the over-ground speeds was significantly slower in all cases. The difference between the first over-ground run and the treadmill run was 1.26 m/s and the difference between the second over-ground run and the treadmill run was 1.07 m/s. These speeds equate to 4.5 km/h (and 3.9 km/h) which could be significant for most runners over a long distance with respect to fatigue.

When asking runners to self-select speed on a treadmill during research trials, these studies show that it is important to factor in the perceived difference. Researchers should either inform the runner that the same over-ground speed on a treadmill will feel faster than over-ground or that when a speed is selected to simulate over-ground running that they will likely be running between 1.07 and 1.49 km/h slower.

Further consideration of the effects of treadmill running will be undertaken in chapter five with respect to plantar pressures.

In summary, conducting research on treadmills may not entirely reflect over-ground running but the kinetic, kinematic and muscle function parameters are comparable to over-ground running. Since up to half of a UK runner's miles are run indoors most likely on a treadmill, it is reasonable to reflect treadmill study findings without need for translation to over-ground running being necessary.

1.7.2 Techniques in pedal motion analysis

1.7.2.1 Stereophotogrammetry

When the foot is shod its movement becomes obscured to the observer, so it is necessary in experimental studies to either measure foot kinematics in the barefoot condition, in footwear that enables positioning external markers, or use a validated proxy measure. The gold standard for measuring foot movement in research settings is 3D stereophotogrammetric motion analysis (3DMA) with intra-cortical bone pins fitted with markers externally (Nester *et al.*, 2007; Deschamps *et al.*, 2011). This method is not feasible for most laboratory based research but skin mounted markers have been demonstrated to be good substitutes for bone pins across the foot (Nester *et al.*, 2007).

The 3D stereophotogrammetric motion analysis system used in this thesis is Codamotion™ (Rothley, Leics, UK). The Codamotion™ system has been reported to have excellent intra- and inter-rater reliability and validity in cervical and lumbar spine movement analysis (O'Sullivan, Clifford and Hughes, 2010; Song *et al.*, 2018) and claims to be accurate to 0.002° in angular resolution and 0.05 mm lateral position resolution at 3 m distance (Charnwood Dynamics, 2004). The Codamotion™ system has been used extensively in walking and running studies and has excellent intra- and inter-rater reliability and validity in the analysis of limb and trunk movements (O'Sullivan, Clifford and Hughes, 2010; Song *et al.*, 2018). The system has also been applied in walking and running studies previously although a search of the literature revealed no reports of use of the system for foot kinematics in running (Charalambous *et al.*, 2012; Exell *et al.*, 2012; McLaughlin *et al.*, 2013). Codamotion™ has been used for both barefoot (O'Sullivan *et al.*, 2008; Birch and Deschamps, 2014) and shod walking studies (Menant *et al.*, 2009; Roberts, Birch and Otter, 2011) with no reported issues when measuring foot kinematics.

1.7.2.2 3D Kinematic foot models

The twenty six bones of the foot move independently to a greater or lesser extent during weightbearing activities (Oosterwaal, 2016) but the size of each bone prohibits the measurement of each one individually with many existing 3D kinematic foot model (3DKFM) systems. The contributions of some joints to general foot movement are greater for some than others (Lundgren *et al.*, 2008) and are captured alongside the contributions of minor joint contributions in models where the foot is divided into fewer segments . To date, at least sixteen 3DKFMs have been reported in the literature (Deschamps *et al.*, 2011; Oosterwaal, 2016) ranging from modelling the foot as a single segment (Reischl *et al.*, 1999), to multi-segment models including a very recent full, twenty six segment model (Leardini *et al.*, 2007; Wright *et al.*, 2011; Oosterwaal, 2016). The tool in this study and in the study in chapter 5 will measure changes in foot movement in the weightbearing phases of the gait cycle (Leardini *et al.*, 2007; Oosterwaal, 2016). The multi-segment foot models aims to reflect as far as possible the movements of multiple segments of the foot although to capture data from twenty six segments may be un-necessary. Similarly, having too few markers / segments has been demonstrated to be problematic since, when the foot is represented as a single unit, movement data contradicts the movement measured by a multi-segment foot model at the ankle (Pothrat *et al.*, 2015). 3DKFMs that have gained popularity offer clinical and research utility, adequate reliability and validity, and sufficient data to inform accurate clinical or research decisions (MacWilliams, Cowley and Nicholson, 2003; Saraswat, Andersen and MacWilliams, 2010).

The use of multi-segment foot models is important, to reflect as far as possible the movements of multiple segments of the foot. There are twenty six bones in the foot but until 2016 there was no twenty six segment model and more commonly three, four and five segments have been used to demonstrate functional segments in the foot rather than individual bones (Oosterwaal, 2016).

Several models such as the Milwaukee, Heidelberg (Kidder *et al.*, 1996; Myers *et al.*, 2004; Simon *et al.*, 2006; Long *et al.*, 2010) and the more recent Oxford Foot Model, 3D foot, Kinfoot and the Leardini foot models have all been shown to have good repeatability, accuracy and reliability despite increasing complexity with larger numbers of markers (Leardini *et al.*, 2007; Curtis *et al.*, 2009; Long *et al.*, 2010; Wright *et al.*, 2011; Powell, Williams and Butler, 2013; Milner and Brindle, 2016). Both the multi-segment Oxford (Curtis *et al.*, 2009) and Leardini (2007) 3DKFMs were candidates for use in this thesis having been applied successfully in other similar studies (Levinger *et al.*, 2010; Giacomozzi, Leardini and Caravaggi, 2014). The Leardini model has been shown to reliable in the measurement of adult feet, even where minor deformities were present (Deschamps *et al.*, 2011), and slightly better than the Oxford Foot Model at detecting frontal plane midfoot movement in feet with different foot postures (Powell, Williams and Butler, 2013). In addition, a study exploring the relationship between pedobarographic data and kinematic data found a moderate to good correlation (sagittal: $R^2 = 0.59 \pm 0.16$, frontal: $R^{2\,=}\ 0.42 \pm 0.2$, and transverse: $R^2 = 0.53 \pm 0.17$) with the movement at the calcaneus-midfoot segment (Giacomozzi, Leardini and Caravaggi, 2014). This is relevant to the study in chapter 5 in which the primary outcome measures focus on NH

(Vinicombe, Raspovic and Menz, 2001) and the FPI-6 (Redmond, Crosbie and Ouvrier, 2006; Keenan *et al.*, 2007), each including the midfoot segment.

1.7.2.3 Pedobarography

Pedobarography is the method that measures pressure between the foot and the floor during dynamic loading (Giacomozzi *et al.*, 2012). The pedobarography system available for the studies in this thesis is the F-Scan™ in-shoe system (Biosense Medical, Chelmsford, UK). The F-Scan™ has been used extensively both clinically and in research, especially in research on foot ulceration associated with diabetes (Yu *et al.*, 2011; Amemiya *et al.*, 2014; Ledoux *et al.*, 2015) due the good reliability of the more modern systems (Ahroni, Boyko and Forsberg, 1998). The technology has developed since a study conducted on the early models where accuracy and repeatability were found to be poor (Woodburn and Helliwell, 1996) with sensors demonstrating up to 23 % variability during the period of warming up the sensor to ambient temperature in-shoe – a variability was reduced to 15 % with warming preparation of the sensor (Koch, 1993).

The F-Scan™ has been shown to be a valid tool for measuring vertical ground reaction forces during walking when compared to force plate data with good to excellent correlation to force plate data (Chen and Bates, 2000; Price, Parker and Nester, 2014). An unpublished study (Eklund *et al.*, 2002), however, showed that F-Scan under-reported vertical ground reaction force when compared to a force plate, by 30 %. The accuracy error of the F-Scan™ has been reported as between 1.3 – 5.8 % when measured in the range of the calibration (Hsiao, Guan and Weatherly, 2002) whilst another study (Price, Parker and Nester, 2016) has shown accuracy in pressure measurement to be variable from 1.3 – 33.9 % when applying pressures from 33 to 500 kPa. Mean pressures have been shown to be prone to high levels of error in low pressure ranges (50 – 200 kPa) during a 30 s pressure test across the range from 50 – 600 kPa with an increase of 14.7 % over a thirty second application of force across the sensor. Repeatability of mean pressures across the whole sensor, however, is high (ICC = 0.797) and higher still for peak pressures (0.859 – 0.965) (Price, Parker and Nester, 2016). The error in the F-Scan was suspected to be due to a phenomenon of drift where the pressure increases due to capacitive changes in the sensors when compressed over time. Peak pressures, however, do not appear to be affected by the period of application of pressure with over-estimation of pressure by 195.3 % to 667.3 %. When determining area of contact from the F-Scan™, the error is reported as being between -50 % and -92 % under low pressure conditions (50 kPa) (Price, Parker and Nester, 2016). A further factor affecting the performance of F-Scan sensors is the build-up of temperature over time of wear. A study (Herbert-Copley *et al.*, 2013) of total force over a period of 140 minutes of walking with data taken at 10 minute intervals, showed an increase in sensor temperature during the first hour of wear after which it plateaued. As sensor temperature rose, total force during walking at constant speed reduced to 63.6 % of the original force. Of interest, the standing trials at each 10-minute measurement did not show a reduction in force over time. The authors suggested that caution be exercised when using total force as an outcome measure and recommended repeated calibration where testing was conducted over a long period of time. In a trial of prolonged running this would involve several minutes interruption and possible recovery which may skew other outcome measures.

With acclimatisation to ambient temperatures the FScan™ is an accurate, valid and reliable tool to detect the high forces generated in running although caution should be exercised when interpreting findings when used over long durations.

1.7.2.4 Relationship between plantar pressure and foot kinematics

Plantar pressures have been shown to have a weak to moderate correlation with segmental foot kinematics and large motions of the foot joints with low plantar pressure in almost all regions (Giacomozzi, Leardini and Caravaggi, 2014). The method should, therefore, be used with caution as a proxy measure of foot kinematics (Catalfamo *et al.*, 2008) in research or clinical settings.

Pedobarographic maps can be used to overlay masks to define segments of interest. As such the Dynamic Arch Index (DAI) (Wearing *et al.*, 2004; Faria *et al.*, 2010) can be used with pedobarography. First described in static form from a single foot print (Cavanagh and Rodgers, 1987) the static Arch Index (AI) has been shown to demonstrate excellent intra-rater reliability (Menz, 2005) on ninety three older adults (ICC = 0.99, P=0.01). The study validated the static AI, NH and FPI-6 against a measure of arch height on plain radiographs and found excellent correlation for the static AI and NH (ICC = 0.99) and moderate correlation for the FPI-6 (0.61) with the radiograph-based measure. A previous study (McCrory *et al.*, 1997) also found a good to excellent correlation between radiographic NH and the static AI measure, with normalisation of the NH to foot length improving the correlation (r=0.67 and 0.71 respectively). The medial longitudinal arch has residual adipose tissue from childhood and the DAI was found to be influenced by body composition in a study using bioelectrical impedance analysis on people with normal fat mass and those with obesity and increased fat mass (Wearing *et al.*, 2004). The authors noted that the DAI should be used with complimentary measures of foot posture rather than in isolation in obese individuals.

The AI measure has been reported in static stance as discussed above however in-shoe footprints gathered using pedobarography enable calculation of a mean 'Dynamic' Arch Index measure. This technique has been documented (Wearing *et al.*, 2004; Faria *et al.*, 2010; Hollander *et al.*, 2018) although further studies are required to validate the DAI against foot 3D kinematic data in adults. A study investigating the relationship between running kinematics and DAI in children aged 11-14 found correlations between a low foot arch and an increase in foot progression angle but no relationship with sagittal plane joint kinematics at ground contact, maximal joint moments or ground reaction forces (Hollander *et al.*, 2018).

A potential concern with donning the FScan™ equipment during running is that the extra weight and bulk could alter running gait (Kong and De Heer, 2008). A study using the FScan™ model with waist-worn a data logger unit (1.8 kg extra weight in total) showed that there was no effect of speed at any of the three conditions tested (3.5, 4.5 and 5.4 km/h). In measured gait parameters there was no difference in stance time, but it did lead to an increase in stride frequency and a decrease in stride length. In this study the FScan™ system was wired with no data logger attached to the person and the weight of the leads was taken by securing them draped over the front console of the treadmill with the aim to minimise any disruption to gait. Additional pilot sessions revealed that participants preferred to have only one limb fitted with equipment (both the FScan™ and Codamotion™ markers and drive boxes) to ensure they maintained their natural gait.

1.7.3 Coupling of the leg to foot in running

Indirect kinematic data such as that from the leg, if correlated to foot marker movement, could also be used as a proxy measure for in-shoe foot movement. For the purposes of the study in Chapter 5 the correlation would have to factor in the coupling of the foot and leg throughout the whole stance phase of gait and any changes associated with exercise induced fatigue.

The movement couple between rotation of the tibia and eversion / inversion of the foot has been well described (Eslami *et al.*, 2007) where kinematic data was collected from sixteen healthy individuals (Eslami *et al.*, 2007) with the tibial internal rotation to rearfoot eversion ratio in barefoot running being 1.80. For every 1° of rearfoot eversion, 0.55° of internal rotation of the tibia occurred (Eslami *et al.*, 2007). The study noted that peak heel eversion and tibial internal rotation movements occurred during early to midstance phases of gait and defined the maximum eversion excursion as the maximum eversion measured during the first 50 % of stance phase minus the rearfoot position measured at heel strike. The decision to use a ratio rather than cross correlation of measures was made to avoid the assumption of linearity between tibial and rearfoot movements due to decoupling and in-phase and out-phase periods during the stance phase. By selecting a ratio instead, they were able to report an overall movement coupling, albeit without the detail of when the movements occurred in the stance phase of gait, up to the point of maximum rearfoot eversion. Indeed a further search of the literature revealed a study demonstrating agreement between the timing of the peaks of tibial internal rotation and rearfoot eversion during walking (DeLeo *et al.*, 2004).

To date, one study has investigated the relationship between foot posture and the tibial / rearfoot movement couple in running challenging the assumption that the subtalar joint axis which frequently relates to arch height anecdotally may alter the couple in running. Nigg, Cole and Nachbauer (1993) tested thirty healthy runners using high speed video and found that arch height did not affect the tibial-rearfoot couple. Two-dimensional high-speed video used in this study is less accurate than using 3DMA (stereophotogrammetry) and further kinematic studies would help confirm or refute this.

In running, kinematic coupling between the leg and foot can vary and a review of the literature up to 2004 (DeLeo *et al.*, 2004) reported considerable variation across kinematic studies that had reported coupling data between the tibia and foot. Ratios are frequently used to describe the amount of tibial internal rotation to rearfoot eversion and values of 1.72 eversion: total internal rotation have been reported (Stacoff, Nigg, Reinschmidt, Bogert, *et al.*, 2000) alongside 1.42 (Mcclay and Manall, 1998). It is possible that the mechanism for minor decoupling of movement in the ankle could relate to changes in soft tissue stiffness in the peri-malleolar structures or loss of strength in the peri-malleolar muscles. Ratios are frequently used to describe the amount of tibial internal rotation to rearfoot eversion and values of 2.24-1.42 eversion: total internal rotation have been reported (Stacoff, Nigg, Reinschmidt *et al*., 2000). Peak heel eversion and tibial internal rotation movements occur during early to midstance phases of gait, so the use of a ratio allows the reporting of overall movement coupling, albeit without the detail of when the movements occurred in the stance phase of gait.

Minor decoupling of movement between the foot and tibia while running compared to walking could relate to changes in soft tissue stiffness in the peri-malleolar structures or loss of strength in the peri-malleolar muscles (South and George, 2007). Factors such as foot posture and footwear may also affect coupling. As discussed above, Nigg, Cole and Nachbauer(1993) tested thirty healthy runners using high speed video and found that arch height did not affect the tibial-rearfoot couple. Footwear may also affect eversion:tibial internal rotation coupling. Kinematic data collected from sixteen healthy individuals in both barefoot and in-shoe conditions during running (Eslami *et al.*, 2007) found that the tibial internal rotation to rearfoot eversion ratio in running was 1.80 to 2.24 respectively, with no statistically significant difference between the two conditions ($P>0.05$). The authors showed that for every 1° of rearfoot eversion, 0.55° of internal rotation of the tibia occurred whilst barefoot and 0.44° tibial rotation occurred in shod conditions.

The effect of footwear on the tibial-rearfoot motion couple was also investigated (Stacoff, Nigg, Reinschmidt, *et al.*, 2000) in a study investigating varying footwear and orthotic conditions for short running trials. Intra-cortical bone pins were fitted to five healthy male volunteers and they were asked to run at self-selected speeds on a treadmill. Of the six footwear conditions tested, four were of note for this present study: barefoot, dual density 'anti-pronatory' midsole running shoe without adaptation (except for a port cut out to accommodate the calcaneal bone pin which was present for each shod condition), the same running shoe adapted with a single density foam midsole with neutral flare and the same running shoe adapted with a single density foam with a rounded sole flare.

They elected to use a ratio to describe the coupling between the tibial and rearfoot since the coupling is dependent on loading, ankle position and ligamentous integrity and is likely to be unrepresentative of a true mechanical gear where simultaneous movement always occurs. The results showed consistent coupling between the tibia and rearfoot in both the barefoot versus shod dual-density test shoe with 1 % variation between the five trials undertaken for these conditions (Stacoff, Nigg, Reinschmidt *et al.*, 2000).

Modifications to the shoe and orthoses can further affect coupling. A posterior arch support orthotic condition showed a reduction in coupling ratio in all but one of the five participants (Stacoff, Nigg, Reinschmidt, Bogert, *et al.*, 2000). Further shoe modifications such as a lateral flare alter the coupling and kinematics significantly. The modifications to the shoe altered the heel strike to a more inverted angle in two of the participants. The modification of kinematics with the lateral flare was deemed ‘extreme’ in contrast to barefoot vs shod conditions where there were only subtle kinematic alterations with the largest variability being between individual participants rather than between shod conditions.

These findings will help inform the protocol of thesis which standardised footwear to avoid entering volunteers into the study if they wore shoes with ‘extreme’ design characteristics such as large lateral flares.

1.7.4 The Influence of footwear on prolonged running

The oldest shoe, a one-piece laced leather moccasin, has been found in date to the times of Neolithic man and is around 5.5k years old (Hollemeyer *et al.*, 2008). Whilst Western footwear used in the twenty-first century is analogous to a moccasin, significantly more sophistication is designed into running shoes in the twenty-first century. This has led to questions about the impact this may have on foot function (Lieberman *et al.*, 2010).

Since the 1970s running footwear has evolved and trends come and gone (Langer, 2012) but injury rates remain high among long distance runners (van Mechelen, 1992; van Gent *et al.*, 2007; Videbaek *et al.*, 2015). At first glance it might be considered that running footwear has very little impact on foot function and kinetics, or that the change in footwear is introducing a new injurious environment as it does appear to impact these parameters.

Since around 2009 a notable trend in design changes in running footwear has been documented (Langer, 2012) and provoked research investigating the impact of the minimalist footwear designs on foot function and incidence and prevalence of running related injuries. Minimalist footwear is the antithesis of heavy, bulky maximalist shoes popular in the 1990s and can be defined as scoring high on the Minimalist Index (Esculier *et al.*, 2015) with low weight, low heel stack height, low heel to toe drop, few / no stability and motion control technologies and high torsional and longitudinal flexibility. The minimalist design ethos aimed to create an environment for the foot that was akin to the barefoot condition but with the added protection against skin erosion and penetration underfoot. Much of the heavy bulk of the midsole was reduced in the new designs with associated loss of heel to forefoot height differential, or 'drop', and uppers lacked reinforcement in the way previous footwear designs had, possibly resulting in less mechanical influence of the upper on midfoot joint movement. The design claims (Curran and Tozer, 2010) and appearance of the footwear indicated that it may be a big enough difference to elicit a measurable influence of footwear on runners' feet.

A study of how vertical ground reaction force (vGRF) and kinematic parameters changed with varying drops compared over-ground and treadmill running in twelve healthy male participants at 0 mm, 4 mm and 8 mm drops as well as a barefoot condition (Chambon *et al.*, 2015). At foot strike the ankle plantarflexion and knee flexion angles were higher in the treadmill in all shod conditions compared to over-ground running. The difference was consistent across all drop conditions between treadmill and over-ground running with an approximately 11° increase in ankle plantarflexion angle and approximately 3° increase in knee flexion on the treadmill, across all drop conditions. The data was collected on highly accurate motion analysis and force plate systems and shoe mass was calculated and reported as negligible by the authors. The data were collected after the warm-up period (seven minutes at steady self-selected speed) was complete and data from twenty steps was recorded for analysis. Whether the differences between the shoe drop conditions varied with longer distances is not known and long-distance runners will run for longer than seven minutes in normal daily running.

The weight of a heavy shoe acts to alter the centre of mass of the leg and this may reasonably lead to alterations in muscle activity as the limb swings from toe off to initial contact. This principle was tested in a study of nineteen runners with a BMI of 74.2 kg (*SD* 10 kg male) and 56.2 (*SD* 6 kg female), with two different masses (0.05 kg and 0.1 kg) sewn into pockets on the lateral aspect of their footwear (Bahlsen and Nigg, 1987). Kinetic and kinematic parameters were measured in five in short running trials at 3.3 m/s (female) and 3.9 m/s (male) following a period of habituation. Neither vertical force peak nor rearfoot angle at heel strike were affected by these added weights but the time to reach peak vertical force decreased with the first addition of weight in the shoe but increased with the second. Knee flexion angle at initial contact was increased too although the study went on the add masses higher up the leg and thigh and this then reduced the knee flexion angle as reported in the abstract. These findings might lead to the assumption that muscle activity was affected by having to control movement of a heavier limb with heavier masses attached and certainly a systematic review of the influence of footwear on electromyographic activity suggests this effect in muscles from the leg to the spine (Murley, Menz and Landorf, 2009).

One characteristic of footwear that could affect muscle activity, and possibly the onset of exercise-induced fatigue during running, is the elasticity or stiffness of the shoe midsole. A study of twenty proficient runners, however, compared the effect of different midsole elasticity characteristics on oxygen consumption as an indicator of metabolic cost, and sEMG signals as an indicator of neuromuscular response during running. The first group of ten runners used a more elastic midsole whilst the second group ran in a more viscous midsole and the results showed insignificant group mean oxygen uptake differences and sEMG patterns. Midsole hardness was explored further alongside sex and age variables to determine if a more nuanced effect of the midsole was present in ninety three male and female runners of different age groups (Nigg *et al.*, 2012). Using principle component analysis three different midsole hardness conditions were compared against age and sex across kinematic and kinetic parameters during running. An effect of midsole stiffness was present with less hip and knee flexion and more range of ankle dorsiflexion with the soft midsole as compared to the hard midsole. There may be an effect of age, however, as an increased range of motion for knee flexion and ankle dorsiflexion and greater vertical displacement of the pelvis was measured in the younger groups compared to the older groups whereas collapsing the ages together produced a group mean effect of decreased knee flexion and increased ankle dorsiflexion with harder midsoles. The authors concluded that there may be implications for recommendations of midsole characteristics for runners of different ages, but a further consideration is the change in hardness that occurs in open cell foams used in running footwear as the shoe endures increasing running mileage.

A study of twenty-four runners who volunteered to run 200 miles in three different styles of footwear measured kinetic and kinematic parameters before and after the running period. The shoes used in the study had midsoles comprising an air-filled chamber (Nike Pegasus 2005), visco-elastic gel (ASICS GT-2100) and mechanical springs (Spira Volare II) and no differences in baseline kinetic or kinematic running characteristics were present between the runners at the zero-mile point. The measure of stance time in running was used as a proxy indicator of shoe degradation and found to be longer in all of the shoe conditions but with no significant differences between each model after 200 miles of running. Kinematic parameters also changed across all shoes with a reduction in maximum dorsiflexion and an increase in plantar flexion at toe-off. Of note, despite the change in kinematic parameters, ground reaction force variables did not alter for any of the shoe conditions indicating that the body had adapted to the altered shoe condition. This is a theory supported by the muscle tuning paradigm (Nigg, 2010) which proposed that anticipation of the stiffness of the terrain leads an athlete to recruit varying amounts of muscle fibres to create optimal tone in the muscle and achieve a controlled landing, reducing injurious vibrations from impact forces. This study is of interest for research concerned with kinetics, kinematics and muscle function in long distance running as the internal adaptations to fatiguing footwear may lead to increased runner fatigue if the adaptions to more 'fatigued' shoes are less metabolically economical than muscle activity in new shoes.

A further characteristic of the midsole hypothesised to influence running is bending stiffness. A study of thirteen runners which was over–powered due to a small initial sample size calculation (Roy and Stefanyshyn, 2006) measured oxygen uptake (VO_2) as the runners undertook sub-maximal running trials in three different shoe conditions: control (18 N-mm), stiff (38 N-mm) and stiffest (45 N-mm). There was a significant reduction in VO_2 in the stiffest shoe compared to the control shoes possibly due to the leaf-spring-like return of elastic energy to the foot as the midsole was strained. The runners then undertook an exhaustive run where VO_{2max} was measured and both the stiff and stiffest shoes demonstrated improved running economy in this measure compared to the control shoe. This study has importance when considering the effects of long distance running in research since a lack of standardisation of footwear stiffness could influence experimental results. Minimalist footwear designs have emerged and been widely adopted since this study was published and are notably less stiff than 'neutral' styles as well as the less popular maximalist motion control styles.

As discussed earlier, extremes of foot posture may be a risk factor for athletic injuries (Cowan, Jones and Robinson, 1993; Burns, Keenan and Redmond, 2005; Cain *et al.*, 2007). The interaction of foot posture variation with footwear, however, has not been noted in either the studies of injury rates, or the studies of footwear on running parameters. A study of arch height interaction with two types of running shoe (cushioned and motion control) during a 25 m over-ground run (Butler, Davis and Hamill, 2006) showed a lower instantaneous loading rate in highly arched feet in the cushioned shoe condition versus a higher rate in lower arched feet. There were no other differences between foot type in each shoe condition, but the motion control shoe reduced peak eversion and eversion excursion more than the cushioned shoe. Values equating to a reduction of 11 % peak eversion and eversion excursion in the motion control shoe and 6 % in the cushioned shoe were reported. The measurement of foot kinematics was achieved by cutting into the heel counter of each shoe which may have affected its performance, however, and whilst clearly a pragmatic option for an over-ground motion analysis study, running 25 m will not reflect the shoe foot interaction during a longer distance run.

Whilst the above studies on the influence of shoe midsoles are of interest, a review of systematic reviews and surrounding controlled trial studies concluded that no original research met stringent criteria to inform clinical recommendations for footwear made by health professionals and footwear prescription was not, therefore, evidence based (Richards *et al.*, 2008). The implications for this thesis of the effects of footwear lie in the potential effects of the footwear worn by runners in the half marathon study (not controlled) and the need for controlling footwear conditions in the laboratory studies. From the literature reviewed here the level of control deemed necessary was to ensure footwear was comfortable, not worn for more than 500 miles of running or less if overt signs of fatigue were observable and the design to not be extreme (minimalist or maximalist) but rather of a neutral design akin to the default laboratory footwear had it been selected by any of the runners to be used to run in for a running trial.

1.7.5 Effects of running technique and running shoe trends on long distance runners

Running injuries have been discussed in the literature for many years (McPhee and Franklin, 1946; Bearzy, 1947; Marti *et al.*, 1988; Hespanhol, van Mechelen and Verhagen, 2016) and the investment of runners in trying to adopt optimal running styles to avoid injury remains buoyant as indicated by the sales of popular literature such as 'The Running Revolution' (Romanov and Brungardt, 2014) and 'Born to Run'(McDougall, 2011). Foot-strike strategy is a frequently occurring theme in both popular and scientific literature and research has focused on its importance with respect to the parameters of running gait as discussed below.

A study of 341 male military recruits with pre-diagnosed running related musculoskeletal injures revealed that 87 % were natural heel strikers and 13 % forefoot strikers. There was no statistical difference in injury prevalence between the two groups. Nonetheless, runners frequently attempt to change from a rearfoot to forefoot striking technique with the perceived aim of reducing the risk of running related injury. A possible reason for the prevailing willingness of amateur runners to attempt to change their strike pattern may relate to the paradigms constructed in the scientific and literature informing mass media, that the human foot did not evolve to run in footwear (Bramble and Lieberman, 2004; Daoud *et al.*, 2012).

A barefoot and minimalist running shoe trend increased (Langer, 2012) following a high profile publication of a study comparing foot-strike strategies and kinetic parameters in habitual shoe-wearing and non-shoe-wearing populations (Lieberman *et al.*, 2010). The study reported the foot-strike strategies in each group with the habitually shod participants (n=8) showing 83 % rearfoot strikers and 17 % midfoot strikers; and in the habitually barefoot participants (n=8) 25 % were rearfoot strikers, and 75 % were forefoot strikers. Whilst this study had a small sample size the foot-strike strategies have been reflected in a larger study (Warr *et al.*, 2015) (n=341) of habitually shoe-wearing soldiers which reported 87 % participants having a natural heel strike pattern and 13 % having a forefoot strike pattern.

The study by Lieberman et al.(2010) reported the differences in vertical ground reaction force and heel strike transient noting that the time to peak loading was longer in barefoot running with a forefoot strike, and the heel strike transient on force time curves was, of course, absent with no additional forefoot strike transient replacing it. The authors summarised the study with a note that quickly caused the popular press and running communities to take note:

"Evidence that barefoot and minimally shod runners avoid RFS [rearfoot strike] with high-impact collisions may have public health implications. The average runner strikes the ground 600 times per kilometre, making runners prone to repetitive stress injuries."(Lieberman *et al.*, 2010)

Many committed amateur runners took on the public health message and immediately changed their running technique to adopt a forefoot strike pattern and a trend in minimalist footwear emerged alongside with a drop in maximalist running shoe styles becoming available in retail outlets and an increase in neutral and minimalist styles (Groner, 2014). As such, asking a runner to 'self-select' their running technique, frequently applied in running research, may not yield the individual's natural running technique. A caveat to this is a finding from a study of twenty three college cross country and twenty three recreational runners found that the self-reported strike pattern was only accurate 56.5 % and 43.5 % of the time respectively (Bade, Aaron and McPoil, 2016). The time to successfully adapt to a new running technique without incurring injury related to transition has not been defined, but a study of thirty eight recreational runners half of whom habitually (for longer than six months) had worn either minimalist or neutral running shoes were revealed to have soft tissue differences accordingly (Zhang *et al.*, 2017). The group in minimalist footwear were shown to have stiffer medial longitudinal arches, and larger cross-sectional area of the abductor hallucis muscle and Achilles tendons. This group also had thinner plantar fasciae than the neutral footwear runners. The authors cautioned against sudden transition into different categories of footwear based on these morphological differences to allow time for adaptation of the soft tissues to the new condition.

This caution is borne out in the findings of a survey of 509 runners (Hryvniak, Dicharry and Wilder, 2014), accessed in a convenience sample from online platforms, revealed that 93 % of participants incorporated barefoot / minimalist shoe-wearing running (17 % and 83 % of the time respectively) into a part of their weekly mileage. Among the respondents 36 % reported new running related injuries since starting barefoot / minimalist running and 64 % reported no new running related injuries whilst 47 % said they had Achilles tendon or foot pain prior to transitioning to barefoot / minimalist running and it resolved after transitioning. A further 8 % reported existing Achilles tendon or foot pain worsening after transitioning and 45 % said their pain resolved after transitioning. Naturally there is no cause and effect relationship established in this survey, but the incidence and prevalence of injury appears consistent with injury rates in habitually shod runners (van Gent *et al.*, 2007). The responses are of interest, however, with respect to the new injury incidence rate of 36 %, since 31 % of these were in the foot and ankle consistent with a systematic review of injury incidence (van Gent *et al.*, 2007) which reported a rate of 5.7 % to 39.3 %. With respect to other sites of injury in the lower limb, though, the survey reported an incidence of new injuries of just 3 % in the knee, and 1 % in the hip compared to 7.2 %-50 % and 3.3 %-11.5 % in shod / heel striking runners (van Gent *et al.*, 2007). Only 6 % of the survey respondents had transitioned within the month of being questioned whilst 86 % had run barefoot / minimalist footwear for between 2 and 12 months. It is unclear from this study when the new injuries occurred after transition but hypertrophy changes in tendon are likely to take place between three and six months based on studies of thickening and stiffening of the Achilles tendon (Fletcher, Esau and MacIntosh, 2010; Milgrom *et al.*, 2014). A further survey-based study sourced valid responses from 211 runners in an online group called the 'Barefoot Runners Society' who had transitioned to minimalist or barefoot running and spanned across ages 15 to 71 years. This survey did explore when injuries occurred in the process of transitioning from being a shod runner to a barefoot / minimalist runner. The rate of injury in the first month of the transition phase was almost three times higher than in shod running and six times higher than the fully transitioned and adapted barefoot / minimalist phase (Daumer *et al.*, 2014).

To summarise, in the consideration of running technique for future study methodologies, it may be prudent to include runners who have not changed running technique within the previous six months to avoid inducing injury under experimental conditions and to capture the most authentic running gait to individual research participants. As discussed in the next section running technique may affect the degree and distribution of tissue strain but also affect the efficiency of running and thus lead to earlier fatigue and alterations in running style and tissue stress.

1.7.6 Effects of conditioning on exercise tolerance

The factors that lead to a running related injury are myriad but a recent review (Gabbett, 2016) highlighted the importance, in particular, of building system resilience as a 'vaccine' to injury. This concept draws on existing principles of prehabilitation and an understanding of tissue stress theory commonly applied in musculoskeletal rehabilitation (McPoil and Hunt, 1995; Mueller and Maluf, 2002; Ross, 2002). By applying a force that creates strain beyond the capacity of a tissue, the structure will yield with either degeneration or complete failure (rupture) (Maganaris and Paul, 1999, 2002). Strengthening and conditioning of bone and soft tissue lead to increased system tolerance, with a graded increase in normal applied forces from specific activities (Mueller and Maluf, 2002; Magnusson *et al.*, 2008; Mascaró *et al.*, 2018). This helps protect tissues from frequently enduring forces beyond elastic limits in weight-bearing exercise (Davenport *et al.*, 2005). Any increase in the application of normal forces to a specific tissue will potentially create stress that could lead to injury, whether overuse or acute (Ker, Wang and Pike, 2000; Abate *et al.*, 2009). This would occur with sudden changes in activity levels such as training for a marathon, or altering running technique where stress is increased in one tissue as it reduces in another on a step by step basis. Further consideration of the mechanical properties and conditions for adaptation of soft tissues will be undertaken in chapter 5.

A change in running technique has been shown above to alter several parameters associated with kinematics, kinetics and running economy as discussed below. Changes in these parameters could potentially affect the findings of a study where participants had not yet adapted to the new technique. Arguably, changing foot-strike is not in the interests of the runner at all given that many of the reasons runners cite for changing remain equivocal in the literature (Hamill and Gruber, 2017). Since many amateur runners have done so, however, it is of interest to explore their rationale and the evidence informing the opinion that to change is of benefit to running.

In a questionnaire with 226 respondents (Daumer *et al.*, 2014), the reasons for change given were linked to the perception that shod running and heel-toe strike strategies increased the risk of injury (Daumer *et al.*, 2014), improved performance and running economy (metabolic cost) which would improve stamina and decrease exercise induced fatigue. The Pose Method™ cited in the book ‘The Running Revolution’ advocates adopting a toe-strike strategy in running for the same reasons. A study of sixteen recreational heel-toe runners with no experience of Pose Method™ running were divided into two groups. The Pose Method™ group were trained in the technique by a trained coach (Fletcher, Romanov and Bartlett, 2008) and no significant differences were found in mean heart rate and oxygen consumption (as measures of running economy) between the groups after an hour of over-ground running. In contrast to the above study, another study of sixteen sub-elite adult runners

(Dallam *et al.*, 2005) found an increase in running economy as measured by increased oxygen uptake after a twelve week introduction to Pose Method™ running compared to the control group who did not alter their running technique. This study used a small number of participants with eight in each group and did not specify the baseline running technique of either group leaving the assumption is that all were heel strikers at baseline. The study did show similar findings to the other studies above, however, with a significant reduction in stride length and vertical oscillation of the centre of mass in the Pose Method™ group, versus no change in the control group.

Oxygen uptake in long distance running is one of many attributes of exercise induced fatigue and subsequent exercise limitation (Ament and Verkerke, 2009). Whilst widely acknowledged that exercise induced fatigue (EIF) involves complex, multi-organ physiology (Mckenna and Hargreaves, 2008), the phenomenon, which is common to all runners, can potentially impact running parameters. With respect to running kinetics, a study of seventeen competitive and recreational adult long distance runners' ground reaction force vectors in 20 m laboratory trials showed that that at 4.5 m/s speed, the vertical ground reaction force was 3 times body weight, the antero-posterior vector 1 times bodyweight, and the mediolateral vector 0.3 times bodyweight (Cavanagh and Lafortune, 1980). This offers insight into the early minutes of a long distance run since the runners were not fatigued and only ran as many trials as were needed to capture five good steps on a floor fitted force plate. To date the kinematic changes during and following prolonged running and the effects of prolonged running on muscle fatigue and tissue properties such as tendon, joint and soft tissue stiffness have not been investigated in detail and will be a focus of this thesis (chapters 3 and 5).

1.7.6.1 Exercise induced fatigue in long distance running of the lower limb

Despite having long compliant tendons and short fibre high force generating muscles, human running efficiency remains similar to animals with longer muscle fibres and shorter tendons (Holt, Roberts and Askew, 2014) and both central and peripheral fatigue ultimately change running gait (Mizrahi *et al.*, 2000; Gerlach *et al.*, 2005; Rosenbaum, Engl and Nagel, 2016). This thesis focused on the strength of the ankle invertors as antagonists to foot pronation, but the tibialis posterior is a synergist muscle rather than a mobiliser with its action creating stability at the ankle, subtalar joint and mid-tarsus (Semple *et al.*, 2009) as opposed to tibialis anterior which has longer muscle fibres, and is a primary dorsiflexor as well as acting to stabilise the foot on the leg in loading response phase of the gait cycle (Willem *et al.*, 1995; Murley, Menz and Landorf, 2014). Inducing isolated fatigue of the tibialis posterior muscle has been shown to correlate to increased decoupling at the ankle (Pohl, Rabbito and Ferber, 2010; Ferber and Pohl, 2011) which may account for the variability of coupling in running. It is likely that the tibialis posterior fatigues in running as other muscles that are more amenable to sEMG methods have been shown to do so

(Lepers *et al.*, 2000; Wu *et al.*, 2007). A two hour run has been shown to reduce quadriceps eccentric strength by 18-21 % (Lepers *et al.*, 2000) and isometric plantarflexor strength by 17 % ±16 % (Saldanha, Nordlund Ekblom and Thorstensson, 2008). The tibialis anterior has been shown to increase signs of exercise induced fatigue with a drop in EMG median frequency at 30 minutes of running at 8 km/h. By 75 minutes this had reached a drop of 12.94 Hz or 17.3 % (although did not reach significance) (Cheung and Ng, 2010). Runners were in neutral shoes akin to those accepted into the studies in this thesis for running trials. By contrast, EMG studies of the gastrocnemius and quadriceps muscles during 30 minutes of running at anaerobic threshold showed no significant reduction in median frequency with significant fatigue and thus no correlation with fatigue (determined by end tidal CO_2 pressure) (Mizrahi, Russek and Verbitsky, 1997). The same group repeated the study in 2000 (Mizrahi, Verbitsky and Isakov, 2000) and found that after 30 minutes of running at 12. 71 km/h (*SD* 0.68) that gastrocnemius integrated EMG did not change significantly but tibialis anterior significantly decreased from 20 minutes onwards demonstrating a potential strength imbalance at the ankle during runs longer than 20 minutes in duration (normalised iEMG = 1.0 to 0.5, p=0.046).

Fatigue related weakness of the quadriceps, however may be a reasonable explanation for changes distally, including fatigue of the ankle invertors. Indeed vastus medialis and lateralis have been shown to reduce strength during a two hour run (Lepers *et al.*, 2000).

In the leg, the tibialis posterior remains of interest as a dynamic arch stabiliser muscle. Fatigue of this muscle alone has been shown to affect coupling of the ankle but the muscle is unlikely to be fatigued in isolation in running. As the tibialis posterior muscle is deep it is not possible to record directly from it using surface EMG. This prevents the use of some measures of muscle fatigue namely measurement of median frequency of the EMG power spectrum. The EMG power spectrum represents the summated signals from motor unit firing. This includes the transmission of motor end plate potentials down the muscle fibres. With fatigue the conduction velocity slows and this is seen as a reduction in the median frequency of the power spectrum. Future work could look at proxy measures (e.g the tibialis anterior) and /or fine wire recordings of the tibialis posterior muscle. However, it may be difficult to achieve stable fine wire recordings while running.

The peroneus longus is a small muscle that has been shown to be to prone to significant loss of strength with prolonged running (Gefen, 2002) and this would not be detected with resisted inversion testing. The peroneus acts on the first ray to stabilise the declination angle and reduce dorsiflexion of the first ray in weightbearing. Hence loss of strength in this muscle may indeed be of interest in future studies.

In summary, exercise induced fatigue affects function of the lower limb and, in order for runners to be able to endure a prolonged running distance they cannot not run a 100 % capacity such as in a sprint race. Other studies have tested prolonged running at 70 % of maximum speed and used the Borg Score or heart rate to help runners determine the rate of perceived exertion needed to achieve this and ensure a relatively consistent level of exertion and exercise-induced fatigue. As discussed earlier in this chapter, economy of running is related to MLA function and foot orthoses have been shown to affect this. The Borg Score will be discussed further in chapter 5 as it is used to help runners self-select their running pace but is employed again in chapter 7 to determine any secondary effects of the orthoses on running economy. The design of the foot orthoses used in chapter aimed to optimise foot function, and running economy, by reflecting contemporary understanding of foot orthotic therapy as discussed below.

1.8 Foot orthotic therapy as a method used to minimise changes in foot posture

1.8 Current foot orthosis practices

With few clear and definitive prescription guidelines the aims and designs of foot orthoses can vary between clinicians aiming to manage any particular condition (Chevalier and Chockalingam, 2012). Practice habits in foot orthotic (FO) prescription have recently been evaluated (Nester *et al.*, 2017, 2018) and after pain relief, functional control was cited in survey respondents as being the primary goal of employing foot orthotic therapy. The selection of materials for shells applying the force to the foot included medium density ethylene vinyl acetate, rigid plastics and high density in the top three, and carbon fibre in fifth place after low density ethylene vinyl acetate (Nester *et al.*, 2017). The most common reason for using foot orthotic therapy across podiatrists, physiotherapists and orthotists is for musculoskeletal conditions (92.2 %, 95.7 % and 67.3 % respectively). The choice of orthotic therapy as a key part of a therapeutic care plan may reflect sensitivity of practitioners to guidelines such as NICE Clinical Guideline 177 which cites with some room for interpretation:

> "People with osteoarthritis who have biomechanical joint pain or instability should be considered for assessment for bracing/joint supports/insoles as an adjunct to their core treatments." (National Institute of Health and Care Excellence, 2014)

Reduction of tissue stress is widely purported to be the primary aim of foot orthoses (Collins *et al.*, 2018) although the lag between publication and changes to policy (and then implementation into practice) has been cited as being seventeen years (Morris, Wooding and Grant, 2011) so the practice habits identified in an earlier survey of podiatrists (Landorf, Keenan and Rushworth, 2001) may be somewhat reflective of the paradigms being employed currently in designs of foot orthoses such as the outmoded Root method (Nester *et al.*, 2018).

1.8.1 Mechanisms of action of foot orthoses

In clinical practice, the aim is often to modify pronation movements or moments across the rearfoot complex as described by broadly adopted traditional models of FO prescription in podiatry (Landorf, Keenan and Rushworth, 2001; Jarvis *et al.*, 2017). Recent evidence from kinematic studies

(Arndt *et al.*, 2007; Nester *et al.*, 2007; Nester, 2009), however, reveals a much more prominent role of the midtarsal complex, than the rearfoot complex traditionally the focus of orthosis designs, in the weightbearing response of the foot. Focus has shifted in the contemporary FO literature towards midfoot movement control or force modulation with shell geometry being reported to be increasingly important in achieving the orthosis reaction force to target the joints which yield most in weightbearing (Harradine *et al.*, 2011; Sweeney *et al.*, 2015). Orthoses have been shown to modify foot kinematics (Nester, van der Linden and Bowker, 2003) with effects at the midfoot (Nester, van der Linden and Bowker, 2003) and rearfoot (Nester and Bowker, 2001) although this is not a consistent finding (Stacoff, Reinschmidt, *et al.*, 2000; Williams, Davis and Baitch, 2003). Other parameters have more recently been shown to change with custom foot orthoses including energetics. Maharaj and colleagues (2018) used intramuscular (fine wire) EMG to demonstrate a reduction in tibialis posterior activation during stance phase with an associated reduction in supination moment at the subtalar joint (3 - 21 %) and energy absorption (5 – 12 %) although it had no effect on joint displacement. This finding is contrary to a study of the effect of orthoses on tibialis posterior activity (Murley, Landorf and Menz, 2010) in normal and low arched feet that found that prefabricated orthoses only achieved a change in EMG patterns in low arched feet. The custom foot orthoses in this study were less able to produce a consistent effect. Both studies used similar asymptomatic participants and were powered to detect significant changes in EMG patterns.

Prefabricated orthoses are highly adopted in contemporary clinical practice (Nester *et al.*, 2017, 2018) ranging from ‘fit and forget’ designs to those designed for modification. This can include changes in the orthoses dispensed that improve shell contour for better fit and comfort, and the addition of orthosis components such as wedges to the inferior aspect of the heel of the shell, or ‘fillers’ in the medial longitudinal arch region of the superior aspect of the shell. Bone pin studies have demonstrated how individual feet achieve the arch lowering and other signs of clinical pronation in weightbearing (Redmond, 1998), with variable contributions from rearfoot and midfoot joints (Nester, 2009).

Compression or deformation of the MLA has been described above to create strain and stress in the plantar fascia and other intrinsic foot structures. This is a plausible mechanism of injury where tissue stress exceeds tolerance and causes damage (Cook *et al.*, 2016). The consensus among clinicians is that FOs can reduce tissue stress creating more optimal conditions for healing from injury or preventing tissue damage from further loading (Bowring and Chockalingam, 2009; Collins *et al.*, 2018) reflecting the Physical Stress Theory (Mueller and Maluf, 2002; Ross, 2002). A study (Stearne *et al.*, 2016) investigating the effects of MLA compression in running, however, revealed that the spring mechanism of the plantar fascia led to better metabolic economy than when this mechanism was impeded by rigid MLA supporting foot orthoses. Restricting MLA compression by 80 % with orthoses during flat, moderate-speed running revealed an increase in metabolic cost of 6 %. The study highlights the importance of the spring effect of the MLA but only in asymptomatic people with normal foot posture; all the participants in the study had normal foot posture (1-1.4 ±2.8 on the Foot Posture Index). The spring effect may vary in feet with different foot postures, and feet with adult-acquired flatfoot: a progressive condition which occurs frequently in runners and is typically managed with foot orthoses. A further study (McDonald *et al.*, 2016) of people with normal foot posture repeated the restriction of MLA compression by 70 % with foot orthoses and measured the effect on plantar fascia strain. There was a reduction in plantar fascia strain compared to resting length with 1.8 % strain in the 'shod' group vs 0.6 % strain in the 'shod with orthoses' group. Participants ran for five minutes in each condition after a five-minute warm up run so it is not known if the effect would have been greater or plateaued with a greater running duration. The above studies highlight the importance of foot function in running economy as well as highlighting considerations for clinicians using foot orthoses to manage conditions of the load-bearing medial and plantar structures of the foot. The potential for varying plantar fascia stiffness, with resultant lowering of the MLA could affect the function of the MLA in prolonged running and it is not known if foot orthoses affect plantar fascia stiffness during running.

Semi-rigid FOs aim to create an orthosis reaction force during the midstance phase of the gait cycle when both heel and forefoot are in contact with the ground. The forces generated in the foot vary with activity and with diurnal changes in gait in a typical day (Bessot *et al.*, 2015) but FOs are not designed to be responsive to this.

Strain of the plantar fascia has been discussed above as part of the process of MLA compression in weightbearing. A further potential mechanism of changing strain and stress in the plantar fascia is with extension of the 1st metatarsophalangeal joint which initiates the windlass mechanism in walking and running (Hicks, 1954; Lucas and Cornwall, 2017). A study of the contribution of each mechanism (Stearne *et al.*, 2016) revealed that MLA compression contributed to plantar fascia strain more than 1st metatarsophalangeal joint extension in shod and shod with FO conditions during running. Unpublished work (Payne and Dawes, 2002) showed that accommodating the plantar fascia as it spans into the arch under strain led to less extension force being required to initiate movement of the hallux into dorsiflexion than in a FO without a groove and it is not clear if the FOs used in Stearne et al.'s study had this feature or not. The addition of a fascial groove should not affect MLA compression as the shell extends either side of the groove, but it may facilitate pre-tensioning of the plantar fascia with small amounts of MLA compression before the shell halts it, which could help stiffen the foot for propulsion (Angin, Mickle and Nester, 2018). A further study of orthoses with fascial accommodation demonstrated an increase in hallux dorsiflexion compared to no orthoses (Scherer *et al.*, 2006). There was no alternative orthosis or control condition to compare the orthoses with fascial accommodation to but anecdotally the author has found improved reports of comfort in patients wearing foot orthosis with plantar fascial accommodation.

In summary, current models in FO therapy aim to either offer an orthosis reaction force to the foot (usually in the region of the MLA), or facilitation of the autosupport mechanisms of the foot, such as timely initiation of the windlass mechanism of the plantar fascia. Common to the majority of all FO types to date is a semi-rigid plastic shell which may be moulded and bespoke to an individual's foot, semi-modifiable, or a generic moulded 'over-the-counter' shell. The orthosis shell is often modified with the addition orthosis components such as arch fillers but the relationship between orthosis stiffness and foot function has not been well defined in the literature although geometric tessellation of the complex curves of the foot with the orthosis shell is key to targeting the orthosis reaction force against the structures of the midfoot (Sweeney *et al.*, 2015) so this is a key element to the fitting process.

1.9 Conclusion

Running is a popular activity but is associated with a high incidence of chronic injuries often affecting the foot and ankle. Running injury rates can be influenced by many factors such as the training environment, footwear type, running style. Temporary changes in some parameters within a run may have an important role to play in the onset of RRIs, such as changes in muscle strength, tendon and fascia stiffness, and resultant changes in foot function. When measuring running it is important to control for independent variables that could influence the dependent variables under investigation.

1.10 Summary

This chapter introduces the narrative themes for the thesis ahead and draws on considerations for the methods used in the experimental chapters. Running is a participation with broad population uptake but also a highly prevalent associated injury rate. Numerous factors have been associated with the incidence of RRIs including resting unfatigued foot posture. Foot posture change has been reported in prolonged running but to date not associated with changes in strength and stiffness of the ankle invertors and medial foot and ankle soft tissues which directly stabilise and maintain the integrity and height of the medial longitudinal arch and overall foot posture.

The following chapters investigate changes in foot posture with prolonged running as well as the mechanisms in the ankle invertors and medial foot and ankle soft tissues. In order to undertake this work reliability of the primary outcome measures used in chapters 3, 5 and 7 must be determined and will be carried out in chapter 2. Further evaluation of reliability of the novel secondary outcome measures (used in chapter 5) is undertaken in chapter 4.

Chapter 2 : Measurement of foot and ankle posture, strength and stiffness: methods and reliability

2.1 Introduction

To measure changes in foot posture and related parameters during a bout of prolonged running it is important to clearly outline methods and reliability of measures to be used. Proposed mechanisms that might lead to a change in foot posture include alterations in strength and stiffness of muscles and soft tissue structures in the foot and ankle which contribute to maintenance of medial longitudinal arch height (Nam, Kwon and Kwon, 2012; Maharaj, Cresswell and Lichtwark, 2016; Angin, Mickle and Nester, 2018). The rationale for choosing the measures of foot posture, ankle invertor strength and medial foot and ankle soft tissue stiffness, as primary and secondary outcome measures, are outlined in chapter 1, and reliability, validity and methods of these tests for the studies in this thesis will now be further explored in this chapter.

Reliability is an essential psychometric property that helps describe the authenticity of a test (Altman and Bland, 1994; Chien *et al.*, 2001; Roach, 2006; Lalkhen and McCluskey, 2008; Sullivan, 2011). The intraclass correlation coefficient (ICC) is recommended as a tool for measuring reliability alongside Bland Altman plots that allow a visual assessment of systematic bias across measures or raters (Bland and Altman, 1986). Reliability defined using the ICC can be graded according to Cicchetti *et al*.(1994) where < 0.4=poor; 0.4-0.59=fair; 0.60-0.74=good; and 0.75-1.00=excellent.

2.1.1 Aims

The aims of this chapter are to describe the methodologies of the measures used in this thesis and establish their reliability for the testers collecting the data in each study. This will be compared to reported levels in the literature (Weir, 2005) to demonstrate external validity.

2.2 Reliability of measures used throughout the thesis

2.2.1 Reliability of foot posture measures

The Foot Posture Index (FPI-6) and navicular height (NH) tests were selected for studies in this thesis in part due to their ease of use, requirement of minimal equipment, speed of execution and the fact that they had real world relevance as they are commonly used in clinical practice. Importantly, however, they have been reported to be valid and reliable (Menz *et al.*, 2003; Menz, 2005) although interrater reliability for the FPI-6 has been reported to vary from moderate to excellent (ICC=0.63 (Cornwall *et al.*, 2008), ICC=066 (Aquino *et al.*, 2018), ICC=>0.9 Cornwall et al. 2008). The explanation given by Cornwall et al. (2008) for the variance between the intra- and interrater reliability between the raters was the limitations of FPI-6 manual (Redmond, 1998), a finding that McLaughlin et al. (2016) noted. In this study two inexperienced raters were trained in the use of the FPI-6 tool and interpretation of the manual and interrater reliability was reported as ICC=0.86. Joint training was also given to raters in Morrison and Ferrari's study of reliability of the FPI-6 in the evaluation of foot posture in children (2009) where interrater reliability was reported as Kw=0.86.

Agreement among raters in the interpretation and methods of the FPI-6 manual prior to data collection may help improve interrater reliability of the FPI-6 and would be a recommendation for both research and clinical practice, where more than one person is repeating the FPI-6.

The Arch Index is also used in an adapted format and discussed in chapter 1 and later in this chapter.

During the half marathon study, the number of runners finishing the race peaked at around the 2 - 2 hour 30 minute mark, and more than one post-race data collector was required to undertake timely FPI-6 and NH measurements before recovery from exercise induced fatigue (Pohl, Rabbito and Ferber, 2010). A podiatry undergraduate volunteered to take foot posture measurements, where several participants were coming off the finish line in close time and more than one data collector was needed. Previous work has shown there is an effect of practice with the FPI-6, with test-retest reliability significantly improving after undertaking twenty FPI-6 full measures (Cornwall *et al.*, 2008). A training protocol was therefore adopted for the student and test-re-rest reliability was assessed between both data collectors.

The NH test, by contrast, has been shown to be highly reliable in numerous studies to date (Weiner-Ogilvie and Rome, 1998; Evans *et al.*, 2003; Menz *et al.*, 2003) and appears to have little dependence on experience of the test in the hands of qualified allied health professionals working with the foot. There is no reliability data available, however, for the NH test described by Brody (Brody, 1982; Rathleff, Nielsen and Kersting, 2012) undertaken by undergraduate podiatrist users and this was therefore also determined prior to using the test in the half marathon study (chapter 3). The FPI-6 and NH were measured by the same experienced podiatrist in the remaining studies with >5 years specific experience of using these tests. The standard protocol described in section 2.3.1 of this chapter was used in all cases.

2.2.2 Reliability of muscle strength measures

There are several possible ways of measuring muscle strength. Hand-held dynamometry can show excellent reliability (ICC>0.75) for ankle muscles in children and younger and older adults including the ankle invertors and evertors (Rose, Burns and North, 2009; Spink, Fotoohabadi and Menz, 2010; Hébert *et al.*, 2011; Mentiplay *et al.*, 2015). This technique, however, generally only allows the assessment of isometric force rather than strength through range reflective of walking and running.

Isokinetic (non-handheld) dynamometry allows the assessment of isokinetic strength and is of particular interest to functional testing of the ankle invertors eccentric muscle strength. Isokinetic dynamometry does, however, have the disadvantage of high cost and reduced portability which limits its use, in general, to laboratory-based studies. Overall, the reliability of measuring isometric and isokinetic strength at the ankle using a dynamometer is good to excellent (Power *et al.*, 2011).

The majority of studies have assessed the reliability of ankle dorsi- and plantar-flexors rather than the invertors. The reliability of maximal velocity and peak power during an ankle dorsiflexor eccentric contraction assessed using the isotonic mode in the Biodex™ dynamometer, for example, is excellent for both measures (ICC=0.93 and 0.98) (Power *et al.*, 2011). The reliability of isotonic; isokinetic and isometric modes of testing ankle plantar- and dorsi-flexor strength has further been found to be excellent in older people (mean age ~70 yrs).

In this thesis eccentric strength of the ankle invertors from mid-range to outer range (the range used in the loading response through to early terminal stance phases of the gait cycle) was measured before and after prolonged running using a Biodex system 3 dynamometer (IPRS, USA). The reliability of isometric ankle eversion and inversion has been tested in a device similar to that used in the current study (Biodex system 4 pro) (Tankevicius, Lankaite and Krisciunas, 2013). The ankle was placed in 3 different inversion positions (0, 7, 14 ^{o}) and reliability was excellent for isometric ankle inversion in all three positions (ICC=0.87-0.96).

In people with functional ankle instability isokinetic ankle invertor and evertor strength (measured between 60-180°/s was reliable (ICC=0.92-0.98) (Sekir *et al.*, 2008). Here the ankle was placed in a neutral position between ankle dorsi- and plantarflexion which places the talocrural joint in a closed packed position which limits movement in the transverse and coronal planes. Moller *et al.,* (2005), tested eccentric strength of ankle dorsi- and plantar-flexor muscles and found in ten healthy participants ICCs varying from 0-0.96 and 0.37-0.95 respectively. The reliability of eccentric contractions of the ankle invertors has not been reported on to date and will be reported in this thesis.

To aid reliability, biofeedback of the force produced was provided. Using a specially constructed rig Hagen *et al*. (2015) found that the reliability of what was termed isometric 'pronator and supinator' strength could be increased by using force biofeedback. This reduced limits of agreement to 18–26 % (ICCs were not reported). Learning effects were also eliminated using force biofeedback (Hagen *et al.*, 2015). Therefore, in the current thesis, eccentric invertor muscle strength was assessed with biofeedback of the applied torque provided to the participants in this thesis as outlined in the methods section.

Although the rearfoot complex is truly triaxial and triplanar (with both roll and glide movements) a dynamometer motor such as the Biodex™ is uniaxial. Hagen *et al*. (2015) defined the muscles as pronators or supinators according to position medial or lateral to the subtalar joint axis. In the current studies a similar definition is applied to describe invertor or evertor muscles. It was the purpose of the current study to measure force close to the frontal (coronal) plane only to mirror the protocol of the Hagen *et al*. (2015).

2.2.3 Reliability of ankle stiffness measures

Stiffness (or the inverse, compliance) in soft tissue structures supporting the medial longitudinal arch of the foot and controlling the load-bearing response of the foot, may also change with prolonged running. Ankle stiffness can be measured using clinical tests or following a perturbation, or with the application of a known force / torque. The latter can be manually applied or delivered via motors. In addition, surface electromyography is commonly used to ensure that the muscles are relaxed if the passive stiffness of the joint is under investigation (Salsich and Mueller, 2011). Customised motor rigs have been developed usually with the aim of measuring stiffness at smaller joints (e.g. 1st MTPJ) or at several joints at once (e.g. 1st MTPJ and ankle). Both commercially available dynamometers (e.g. Cybex and Biodex ICC=0.75 - 0.98) (Breno de Araujo Ribeiro Alvares *et al.*, 2015) and custom made motors / rigs (ICC=0.76-0.96) (Sung, Baek and Hyuk Kim, 2010; Sloot *et al.*, 2015; Zhang *et al.*, 2015; An and Won, 2016) are reliable. In addition, combined measures of applied force and movement using strain gauges and electro-goniometers produce reliable estimates of ankle stiffness into dorsi- / plantarflexion (ICC=0.63-0.97) (Kobayashi *et al.*, 2011; Lorentzen *et al.*, 2012).

Ankle inversion / eversion stiffness, which is relevant to the control of the weight bearing response of the foot, has rarely been assessed. In a novel method, Zinder *et al*. (2007) had people stand on a customised cradle capable of rotating, with an axis aligned with the subtalar joint (rearfoot complex) axis (see figure 2.11). Springs were attached either side of the cradle and the motion of the system measured using a potentiometer as the person stood on the platform with and without known weights being attached. The natural frequency of oscillation of the spring system (ω n) was determined by separately applying a vertical displacement. The natural frequency of a compound pendulum (ω n) pivoting about an axis depends on its moment of inertia (I_P).

$$\omega \text{ n} = \sqrt{\frac{mgr}{Ip}}$$

(where ω n=natural frequency; Ip=moment of inertia; g=acceleration due to gravity; r=distance from the pivot to the centre of mass of the object; m=mass of the object).

Rearranging and adding the stiffness due to the ankle (k)

$$I_P = \frac{k+mgr}{\omega\, n2}$$

The addition of weights to the system in the experiment altered the inertia of the system. The total inertia (I_P) with the weights is a combination of the internal inertia (the combination of the cradle and the ankle) (Io) and external inertia (Iext).

Thus Iext = $\frac{(k+mgr)}{\omega\ n2} + Io$

The pendulum behaviour (mgr) had less than 1 % effect on ankle stiffness and was therefore ignored.

As the external inertia is known, the stiffness (k) could be measured as the slope of the regression line when the external inertia is plotted against the natural frequency as different loads are added. This method showed excellent reliability (ICC=0.96) and produced estimates of ankle stiffness of 35.7±9.45 Nm/rad. Participants were asked not to interfere with the oscillation when standing the device. The occurrence of volitional muscle contraction, however, cannot be ruled out. This system would therefore measure *overall* ankle stiffness, that is the combination of volitional muscle contraction; reflexive muscle contraction (eg due to stretch reflex activation or reactive postural adjustments) as well as passive stiffness (Zinder *et al.*, 2007). It is possible to mathematically break up these components using a system identification approach (Kearney, Weiss and Morier, 1990; Mirbagheri, Barbeau and Kearney, 2000) but this was not performed by Zinder *et al*. (2007).

The aim in the current work was to assess whether passive stiffness of the ankle invertors changed with running. An isokinetic dynamometer was used to apply stereotyped ankle perturbations, and to measure the resultant resistive torque. As described in the methods, care was taken to align the motor axis with the subtalar (rearfoot complex) axis as far as possible to ensure the participant was relaxed with no signal on surface EMG, and to mathematically take into account any resistance to movement imposed by the manipulandum in which the ankle was resting. Recently, Jain *et al*. (2016) have used a similar method to measure inversion / eversion ankle stiffness before and after balance training in people with chronic ankle instability. Stiffness was measured as 0.69 (± 0.37) Nm/deg which is equivalent to 39.5 (±21.2) Nm/rad and thus comparable to Zinder *et al*. (2007) (35.7 ±9.45 Nm/rad). Reliability was, however, not tested (Jain, Wauneka and Liu, 2016).

Compared to measuring stiffness (and strength) of ankle dorsi- / plantarflexion, the measurement of ankle inversion / eversion stiffness may be more unreliable. This is because defining the subtalar (rearfoot complex) axis can be difficult and may result in malalignment of the motor. Furthermore, there are different methods of clinically defining the rearfoot complex / subtalar joint axis (Hagen *et al.*, 2015) e.g. those suggested by Inman vs Kirby (Lewis, Kirby and Piazza, 2007; Nicola Krähenbühl *et al.*, 2017). The current studies used Lewis's modified Kirby method (Lewis, Kirby and Piazza, 2007) to define the subtalar (rearfoot) axis. When testers of differing levels of experience were asked to define the subtalar joint axis using Kirby's method (see methods section), intrarater reliability was high (R=0.78-0.99) (Alsenoy, D 'Aoû, *et al.*, 2014; Alsenoy, De Schepper, *et al.*, 2014). This method was also used to determine (in three raters) the subtalar joint axis on 52 individuals (Schepper *et al.*, 2012). Here, reliability was also found to be good – excellent (ICC=0.72-0.93). Thus, the determination of subtalar (rearfoot complex) axis location may be reliable although the reliability of measuring medial foot and ankle soft tissue stiffness in healthy participants has not been determined to date.

2.2.4 Reliability of plantar fascia stiffness measures

The use of the dynamometer to measure stiffness did not include the plantar fascia. Therefore, in chapter 7, a measurement of plantar fascia stiffness was also assessed.

Plantar fascia stiffness has been assessed using a number of methods. Sonoelastography uses ultrasound to measure tissue strain. Here the tissue is mechanically deformed using either a non-standard deformation (e.g pushing with the fingers) or a standard deformation (e.g using a stereotyped mechanical or sound-wave perturbation). The subsequent tissue strain is measured by tracking the tissue movement using ultrasound in two dimensions or by using Doppler techniques to measure motion. The strain can be colour coded to allow easy visualisation of tissue stiffness. Sonoelastography has been used in recent years to measure muscle and tendon stiffness (Brandenburg *et al.*, 2015; Le Sant *et al.*, 2015; Siu *et al.*, 2016; Saeki *et al.*, 2017) and measurement of the plantar fascia with this method has shown that it becomes more compliant with age and when people have plantar fasciitis (Wu *et al.*, 2011). Its reliability in measuring plantar fascia elasticity was not reported.

Estimates of plantar fascia stiffness during motion have used recordings of foot posture via video tracking techniques (Kitaoka *et al.*, 1994), or combined recording of skeletal motion using a radiographic fluoroscopy system and plantar pressure using an optical system. The latter method allowed an estimate of changes in strain as the plantar fascia elongated during walking (Gefen, 2003). These techniques are costly and time consuming thus prohibiting their use when trying to record changes in stiffness quickly after running. In this thesis a more direct measure of plantar fascia stiffness was used based on the direct measurement of the response to a standardised tissue perturbation based on previous work by Garcia *et al*. (2008).

Garcia *et al*. (2008) used a customised palpation probe to estimate plantar fascia stiffness. The probe could measure the resisting force and degree of indentation and from this stiffness was calculated. As the resistance to movement increases in a non-linear manner with greater displacement, the stiffness (slope of the force–displacement graph) was measured in the initial 'toe' region and over the final 'steep' region. As the probe was manually applied there was variation in the applied force (2-9 N), and the rate of force application (20-30 N/s). This is a potential drawback of the technique that was addressed in the current thesis by using a myotonometer to produce a stereotyped perturbation. Due to the distal insertion of the plantar fascia to the proximal phalanges via the plantar plates, it will stiffen with hallux extension (Welte *et al.*, 2018). Differences in plantar fascia stiffness can therefore be assessed with and without metatarsophalangeal joint (MTPJ) extension to end range. Garcia *et al*. (2008) found that there was a 81.4-87.5 % increase in stiffness with MTP joint extension; this was most marked when stiffness was measured proximal to the 1^{st} MTPJ (Garcia *et al.*, 2008). However, as end range was used the degree of extension was not standardised (or the criteria for defining end range) and could potentially vary between participants.

The method described by Garcia *et al*. (2008) was, therefore, adapted by fixing the ankle in a standardised position and testing stiffness proximal to the 1^{st} MTPJ with and without a standardised amount of hallux extension (30^{o}). The viscoelastic properties were measured using a myotonometer: the MyotonPRO™ (Myoton AS, Estonia): figure 2.1.

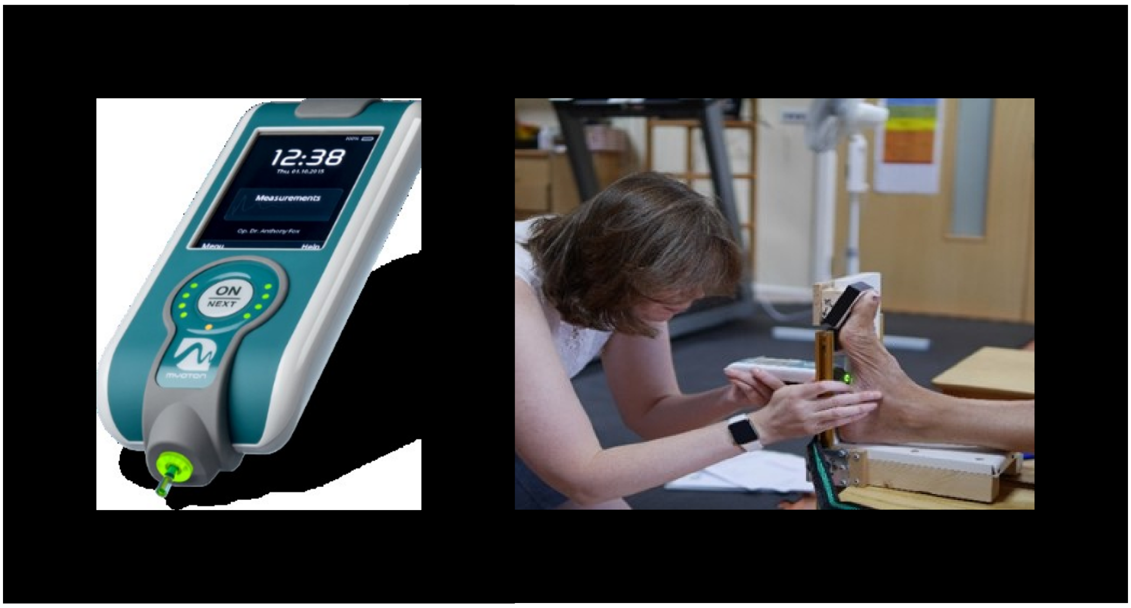


Figure 2.1 MyotonPRO™ Myoton AS, Estonia) with application to the plantar fascia

The MyotonPRO™ works by applying a standardised perturbation (0.6 N tap; 15ms duration) and measuring the subsequent oscillation using an accelerometer from which measures of tissue stiffness and oscillation frequency are measured (see methods). It shows excellent intra- and inter-rater reliability (ICC>0.82) when assessing stiffness in thenar muscles and perineal muscles (ICC>0.8) in people with / without thenar or pelvic floor dysfunction (Davidson *et al.*, 2017) and in hamstring muscles (ICC=0.69), biceps and gastrocnemius (r>0.75) in healthy participants (Leonard *et al.*, 2003a). It is also reliable (ICC>0.70) when arm muscles are assessed in people with a hemiplegia following a stroke (Chuang *et al.*, 2012, 2013; Chuang, Wu and Lin, 2012)

2.3 Methods of measuring reliability for measures in the running studies

2.3.1 Foot posture measures reliability testing

This study was conducted under the ethical approval for study 1 (chapter 3) and participants took part with informed written consent. The participants were undergraduate podiatry students recruited from the University of Plymouth. Rater 1 was an experienced podiatrist with over five years' experience of using the FPI-6 tool. Rater 2 was an inexperienced podiatry undergraduate and was trained by rater 1 according to the standard Foot Posture Index protocol by Redmond (1998). Rater 2 undertook 20 assessments prior to testing intrarater and interrater reliability. Tests were performed on a convenience sample of 10 healthy volunteers (age 18-46 years, 5 female) on two days, two weeks apart to mimic the maximum time frame between measures in study 1 (see chapter 3 for further details on recruitment). A power analysis based on a military study of

NH showed that to detect a 20 % difference in NH with an effect size of 1.12 (given a priori NH data in normally arched feet (Swedler *et al.*, 2010) of 40.4 mm ±7.2, $\alpha = 0.05$, $1\text{-}\beta = 0.85$) the study would need 10 participants. Intrarater reliability was established prior to proceeding to interrater reliability testing using the data gathered at the sessions. The sessions were scheduled for the same time of day and were observed by the rest of the student cohort whose feedback helped ensure that the protocol was followed closely by each data collector. One FPI-6 and NH test was conducted per participant on each occasion as this would reflect the data collected on the day of the half marathon and also because repeated marking and erasing of ink for the NH test would cause an inflammatory flare thus creating bias in the method. Two trials were undertaken as the time of day and conditions of the testing was standardised to any effect of collagen deconditioning which could affect foot posture during the first few steps of weightbearing. Similarly, participants were entered to the reliability study under the same inclusion and exclusion criteria as the participants in the half marathon and laboratory studies thereafter.

2.3.2 Foot Posture Index six factor tool and NH method

2.3.2.1 FPI-6

The Foot Posture Index six factor tool (FPI-6) data was gathered in a standardised way following the order of factors in the datasheet (figure 2.2). On each occasion the testers used new data collection sheets and the order of the participants was randomized by codes being pulled ‘out of a hat’ by one of the students in the cohort.

	FACTOR	PLANE	SCORE 1 Date________ Comment________		SCORE 2 Date________ Comment________		SCORE 3 Date________ Comment________	
			Left -2 to +2	**Right** -2 to +2	**Left** -2 to +2	**Right** -2 to +2	**Left** -2 to +2	**Right** -2 to +2
Rearfoot	Talar head palpation	*Transverse*						
	Curves above and below the lateral malleolus	*Frontal/ transverse*						
	Inversion/eversion of the calcaneus	*Frontal*						
Forefoot	Prominence in the region of the TNJ	*Transverse*						
	Congruence of the medial longitudinal arch	*Sagittal*						
	Abd/adduction forefoot on rearfoot	*Transverse*						
	TOTAL							

Reference values
Normal = 0 to +5
Pronated = +6 to +9, Highly pronated 10+
Supinated = -1 to –4, Highly supinated –5 to -12

Figure 2.2 FPI-6 data sheet completed according to protocol described in Redmond (1998)

The participant was positioned in relaxed standing with each foot on a digital scale and an intermalleolar gap of approximately 10 cm. The examiner ensured the participant was comfortable, facing ahead and evenly balanced before commencing and then positioned themselves in kneeling behind the foot being scored (figure 2.3).

Figure 2.3 Participant positioning for the FPI-6 and NH measurement

The first factor scored was the talar head palpation where the examiner palpated the talar head at the crook of the ankle either side of the extensor tendons. According to the criteria set by Redmond (1998), a score from -2 to +2 was recorded according to whether the bone was more palpable medially or laterally, and to a greater or lesser extent. The scoring guidelines (Redmond, 1998) suggest that an ambiguous finding be scored conservatively to the lower number e.g. if between +1 and 0, a score of 0 is given.

The remaining factors were scored based on visual inspection starting with the evaluation of curves above and below the lateral malleolus. The skin is slackened or pulled taught in eversion and inversion (pronation and supination) respectively and so the curves become deeper and more convex or flatter and more shallow / straight in each position. Once more a score from -2 to +2 was recorded according to the guidance in the manual.

Next the inversion / eversion angle of the heel (calcaneus) was observed and a straight edge (such as a pen held against the rear wall of the scale) was used to offer a vertical reference and aid estimation of the number of degrees of inversion or eversion. A goniometer was not used due to the manual not specifying its use. This aided in the fast execution of the tool where runners were de-fatiguing following their prolonged runs. Scoring was undertaken according to the manual using the same Likert scale as before and continued to build the data set for calculation of the aggregate score once the test was complete.

Moving into the 'forefoot factors' the next observation was of the prominence in the region of the TNJ (talonavicular joint). This is the area viewed from the posterior aspect of the foot again, just distal and inferior to the medial malleolus. A vertical medial aspect of the foot here scored 0 whilst concavity was awarded a -1 or -2 according to severity and convexity (bulge) was awarded a +1 or +2 likewise.

The congruence of the medial longitudinal arch was viewed as the examiner moved to the contralateral side to view the sagittal plane. The medial longitudinal arch was considered both in height and shape and a highly arched, sharp calcaneal inclination was consistent with supination scores: -1 and -2, whilst a low arch with a flattened mid-portion was scored with a +1 and, where the midportion contacted the floor, a +2 was scored. Arches scoring 0 were concentrically curved (neither distorted nor skewed) and had the appearance of a normal height for the size of foot (reported in the literature as the infra-navicular space = 40.4 mm ± 7.2 (Swedler *et al.*, 2010)).

Lastly the abd / adduction of the forefoot on the rearfoot was evaluated. Clinically this is commonly referred to as the 'too many toes sign' as from the posterior aspect of the foot, the hallux and fifth toe are normally visible either side of the heel but in adduction of the forefoot the lateral toe visibility diminishes, and the medial toes become more visible eg the first and second.

The reverse is found with abduction of the forefoot on the rearfoot with more lateral toes becoming visible and the hallux disappearing from view. Adduction of the forefoot is associated with supination and scores of -1 and -2 were recorded in this instance whilst +1 and +2 were scored for abduction of the forefoot associated with pronation.

With all six factors scored the aggregate 'grand total' was calculated and recorded in the data sheet for use in calculation of measures of central tendency during analysis. Keenan *et al*.(2007) analysed the FPI factors using the Rasch method and published Rasch logit conversation values for each grand total score for the FPI-6 (table 2.1). Rasch logits convert raw scores from ordinal to interval data enabling use of parametric inferential statistics. Results can then be converted back to raw scores for clinical audiences to interpret. This method is used in the analysis of FPI-6 data in this thesis and both Rasch and raw converted results are noted as such when reported throughout.

Supinated values													
FPI-6 value	-12	-11	-10	-9	-8	-7	-6	-5	-4	-3	-2	-1	0
Rasch FPI-6 value	-10.47	-7.96	-6.45	-5.54	-4.84	-4.25	-3.71	-3.20	-2.67	-2.12	-1.54	-0.91	-0.21
Pronated values													
FPI-6 value	12	11	10	9	8	7	6	5	4	3	2	1	0
Rasch FPI-6 value	8.65	7.77	7.01	6.36	5.68	4.83	3.81	2.98	2.33	1.75	1.16	0.50	-0.21

Table 2.1 Rasch logit values for the six factor foot posture index (FPI-6) (Keenan *et al.*, 2007)

When reporting the FPI-6 scores the classifications given by Redmond et al. (2006) differ in terminology from those used in Redmond et al. (2008) (Table 2.2).

FPI-6 Score	Descriptor in Redmond et al. 2006	Descriptor in Redmond et al, 2008
0 - +4	Normal	Slightly pronated
+5	Normal	No descriptor used
+6 - +9	Pronated	No descriptor used

Table 2.2 Foot Posture Index descriptors (Redmond, Crosbie and Ouvrier, 2006; Redmond, Crane and Menz, 2008)

To avoid confusion when interpreting the changes in FPI-6 in this thesis, numerical scores will be used herein with clear indication of these being raw scores or converted Rasch logit scores and reference made to the foot posture classifications (eg supinated, highly pronated) (Table 2.2) when relating to other work using these descriptors with the FPI-6 tool or to help interpret findings for clinical practice.

2.3.2.2 Navicular height

Brody described the method used in the present studies and Vinicombe, Raspovic and Menz (2001) went on to demonstrate the technique frequently used in clinical practice for orthotic prescription purposes (Firefly Orthoses Ltd, 2017) clearly thereafter. To follow this method, the participant remained positioned in relaxed stance on the weighing scales with one foot on each scale as for the FPI-6 (figure 2.3). With the participant equally balanced and facing forward the examiner knelt behind and to the side of the foot to view and enable palpation of the navicular tuberosity. In rare cases where the tuberosity was not immediately palpable the participant was asked to 'roll to the outside border and back to the inside border' to enable palpation of the talonavicular joint margin and facilitate navigation of the centro-medial aspect of the navicular from this landmark. A semi-permanent 0.2 mm tipped pen was used to apply a single 0.2 mm diameter dot on the skin of the tuberosity of the navicular at its most medially prominent point. A piece of stiff rectangular card was then placed with its edge to the skin adjacent to the dot and a dot of equivalent height matched onto the card. The height of the dot on the card from the inferior edge was measured later as a blinding measure (figure 2.4).

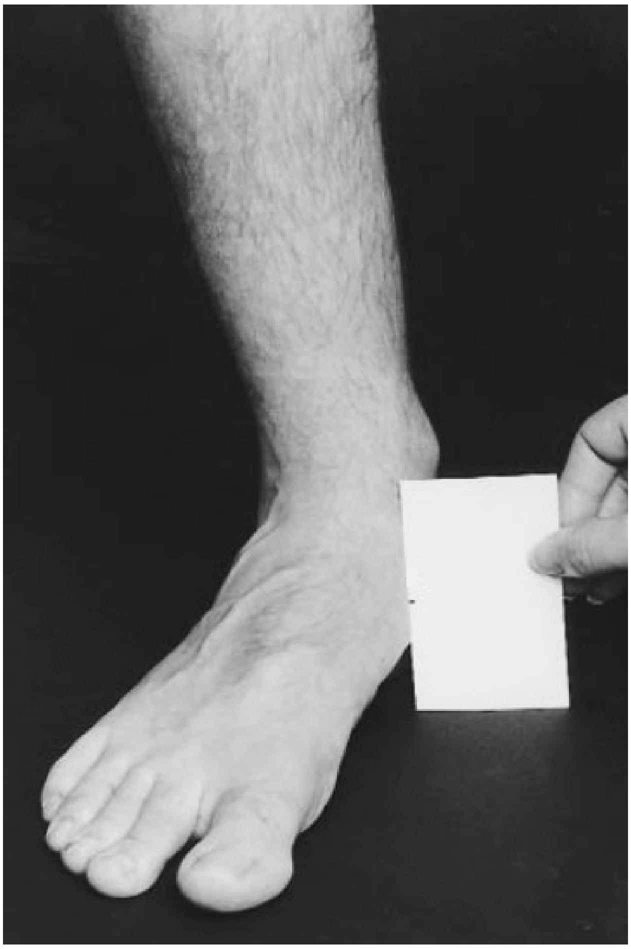


Figure 2.4 The technique used to measure navicular height (modified from Vinicombe et al., 2001)

The scores were not shown to the participants or any person other than the data collector and the participants were allocated a unique code.

2.3.3 Ankle strength and stiffness reliability testing

The reliability of ankle strength and stiffness measures were assessed as part of the study reported in chapter 7 (see chapter 7 for further details on recruitment). In total 17 healthy people (age=38.7 (±11.7), male=7, female=10) were assessed on 2 occasions separated by at least 1 day. One experienced podiatrist rater collected all the strength and stiffness data.

Ankle invertor strength and stiffness was undertaken serially with participants seated in a Biodex™ dynamometer apparatus (Biodex, System 3).

2.3.3.1 Medial ankle stiffness method

Stiffness measures were taken prior to strength measures to avoid any stretch-shortening conditioning effect on the tendons imposed by a maximal muscle contraction (Maganaris, 2003). The foot was secured at 10 degrees plantarflexed at the ankle using a series of adjustable padded clamps and supports. Six passive eversion stretches were conducted at 5 deg/s. The foot moved from a neutral position (as defined by palpation of the talar head being equally palpable medially and laterally and palpable talonavicular joint congruence) through a 15° range of eversion. Surface EMG recording (MT8, MIE, UK) of the tibialis anterior and peroneus longus muscles were used to ensure that the participant was completely relaxed. Torque, position and velocity analogue signals were recorded via the Biodex™ analogue output port and sampled with the EMG signals at 1000 Hz via an analogue-to-digital converter (1401, CED, UK) and collected using spike2 version 6 (CED UK). Participants were provided with a motor safety cut off switch and they were tested to ensure they could safely achieve the required range of movement.

Signals were exported from Spike 2 as Matlab® (.mat) files that were then uploaded into Matlab®. A customised programme identified the start of each stretch and determined the torque and position at the start and immediate end of the stretch over a 250ms window.

Data was initially assessed to ensure that participants are relaxed during the stretch. Records where the EMG values exceeded a level defined over the baseline period (250 prior to stretch onset) were discarded. The level was defined as:

mean baseline + 4 standard deviations of the baseline period.

The onset of the six stretches was aligned and the grand average response determined. Torque invertor and position was measured over a 250ms period immediately before and after the onset of the stretch.

Stiffness was defined as:

Stiffness (Nm/rad) = change in torque / change in position

The torque due to stretching the medial ankle soft tissues (torque medial ST) was calculated as:

$$Torque\ medial\ ST\ = Total\ torque\ - (Torque\ manipulandum)$$

Where Torque total = mean torque measured while the participant is stretched into eversion. The torque associated with moving the manipulandum ($Torque_{manipulandum}$) in exactly the same way without the participant attached was separately measured and determined as negligible. Stiffness was normalised by the person's body mass.

2.3.3.2 Invertor muscle strength: isokinetic MVC method

The Biodex™ dynamometer was used to test maximal voluntary eccentric isokinetic contraction force (MVC). With the participant in mid-range participants were asked to invert their foot, against resistance imposed by the motor, through their full range of eversion ("resist the motor from moving your foot"). Motor speed was 20 deg/s and participants pushed against the foot plate with as much force as they could to resist the movement imposed by the motor. They then rested momentarily and returned to the start position against minimal resistance. Three eccentric contractions were assessed. Visual feedback of the applied torque was supplied in all cases.

Torque, position and velocity analogue signals were recorded via the Biodex™ analogue output port and sampled with the EMG signals at 1000 Hz via an analogue-to-digital converter (1401, CED, UK) and collected using spike2 version 6 (CED, UK) (see figure 2.5). Signals were exported from Spike 2 as Matlab® (.mat) files that were then uploaded into Matlab®. A customised programme identified the peak torque (Nm). The maximal torque recorded relative to a 0.5 s baseline pre-contraction level was determined to give a measure of isokinetic maximal voluntary contraction (MVC) for inversion.

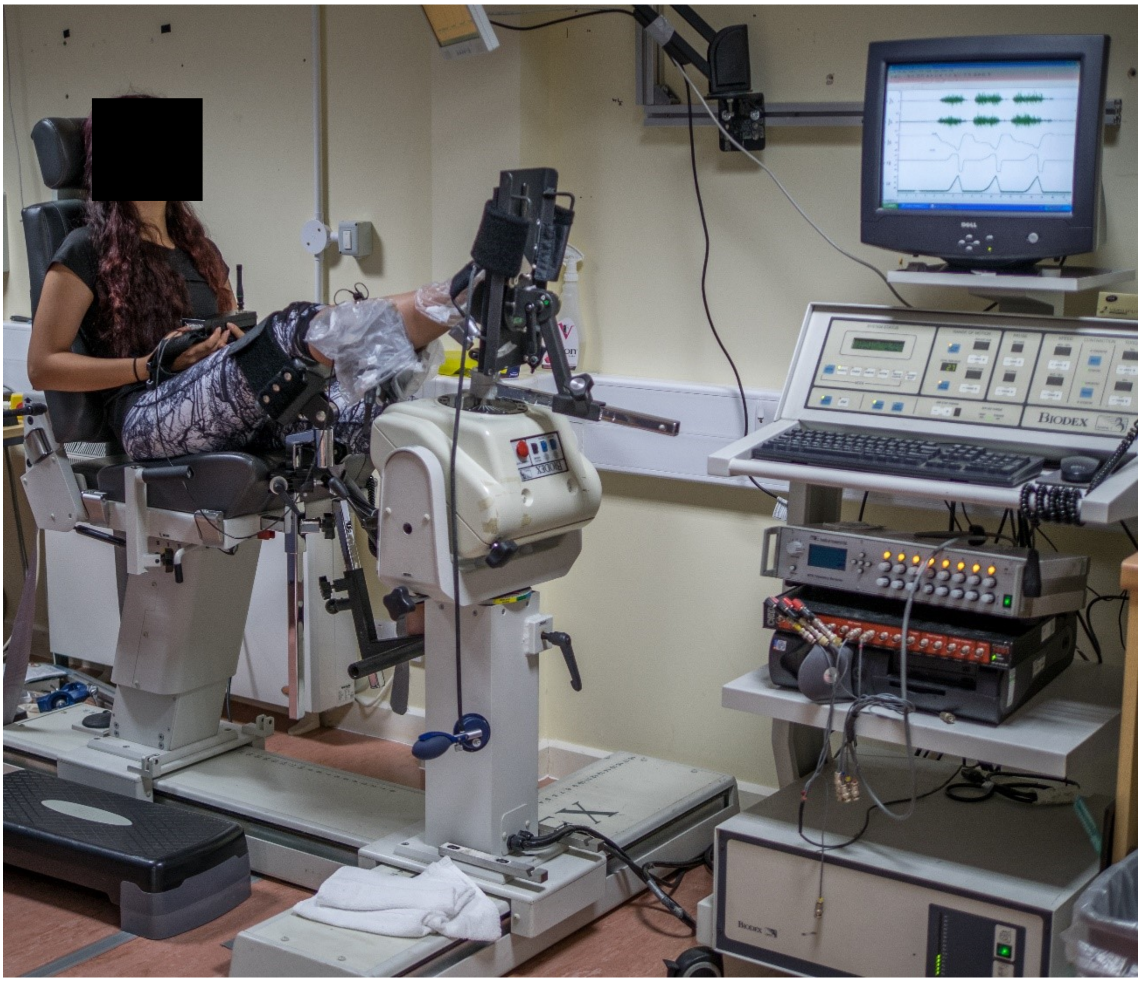
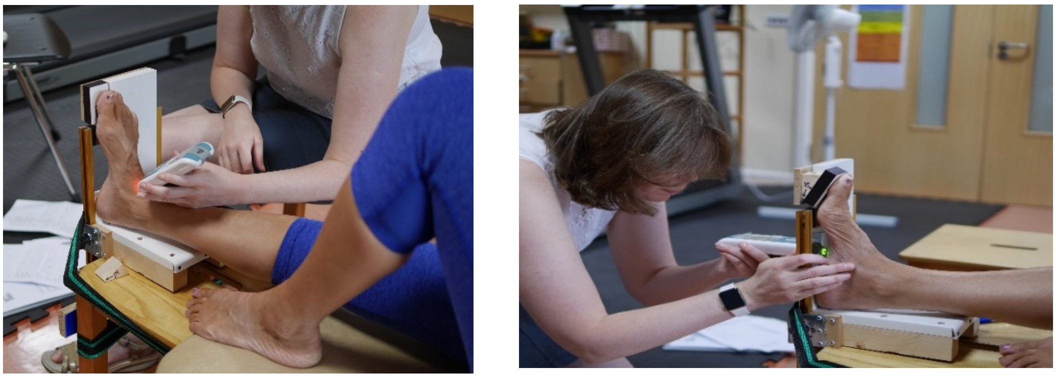


Figure 2.5 Recording of analogue signals during MVC trials

2.3.3.3 Plantar fascia and tibialis anterior tendon stiffness testing method

A novel size-adjustable rig was set up to ensure repeatable and fast measurement of the plantar fascia and tibialis anterior tendon following prolonged treadmill running (chapter 7). The participant was seated on a clinical plinth with the knee extended and foot secured to a platform at 90° to the leg (figure 2.5). The axis of the "toe extender" was aligned to the medio-lateral axis of the 1st MTPJ (figure 2.6).



A B

Figure 2.6 A) Foot positioned whilst the tibialis anterior tendon is tested with the MyotonPRO™. This position was maintained for the stiffness testing of the plantar fascia with the hallux; B) Foot positioned with hallux extended to 30° for the second measurement

Plantar Fascia

Two perturbations using the probe were performed firstly with the hallux at 0° extended and then with a wooden wedge passively supporting the hallux at 30° extension to place the plantar fascia onto tension within early elastic range (figure 2.6 A and B). The MyotonPRO™ probe was angled perpendicular to the skin surface.

Tibialis anterior tendon

The participant was relaxed during testing and the tendon of the tibialis anterior was palpably compliant prior to initiating the MyotonPRO™ probe which was positioned perpendicular to the tendon at its most acute angulation at the level of the ankle joint.

For both tibialis anterior and plantar fascia measures three perturbations were applied and the arithmetic mean value for the MyotonPRO™ readings calculated.

Stiffness, frequency and decrement were automatically calculated by the MyotonPRO™ software and recorded where:

Stiffness = a_{max} . m p_{robe} / Δl

a_{max} = maximum acceleration of the probe; m_{max} = mass of the probe; Δl = maximum displacement of the probe (figure 2.6).

Frequency = maximum frequency calculated from a power spectrum

Logarithmic decrement = ln (a1/a2)

Where a1 and a2 are the 2nd and 3rd acceleration peaks (see figure 2.7)

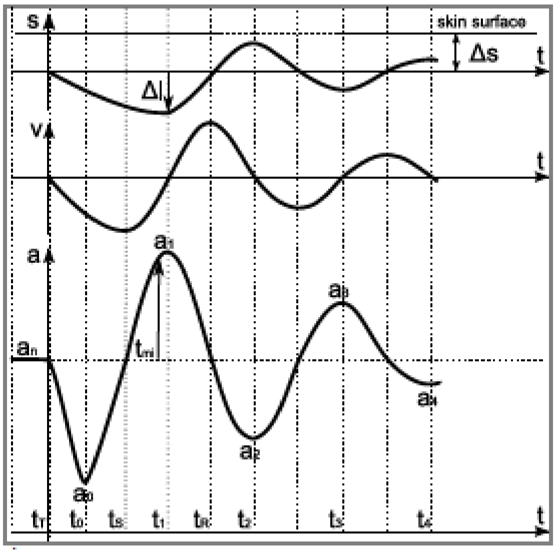


Figure 2.7; Motion of the MyotonPRO™ probe where s = displacement; v = velocity and a = acceleration

2.4 Analysis

Data were analysed by calculating ICCs in SPSS. Intra-rater reliability was assessed using an ICC model (3,1) indicating that each subject is assessed by one rater who is the only rater of interest (Weir, 2005; Koo and Li, 2016). In SPSS (version 22) this corresponds to a two-way mixed model with absolute agreement. Inter-rater reliability was assessed using an ICC model ICC (3,k) indicating that each subject was assessed by multiple raters (Weir, 2005; Koo and Li, 2016). ICC levels were graded according to Cicchetti *et al*. (1994).

Measures with an ICC >0.6 (i.e good) were deemed reliable (Fitzpatrick *et al.*, 1998) and used in further work.

Bland-Altman plots allowed an assessment of systematic error between trial 1 and 2 (Bland and Altman, 1986).

2.5 Results

2.5.1 Navicular height and Foot Posture Index

The intra-rater reliability ICC for the FPI-6 was 0.98 (95% CI=0.96–0.99, P=0.000) and for the NH test was 0.94 (95% CI=0.85–0.98, P=0.000). Inter-rater ICC for the FPI-6 was 0.94 (95% CI=0.77–0.98, P=0.000) and for the NH was 0.96 (95% CI = 0.86–0.99, P=0.000) indicating excellent reliability (Table 2.3). Median values for the NH and FPI-6 raw measures in this group were 39.5 mm and 5 respectively.

The Bland Altman plots for intra-rater reliability indicated that there were no systematic biases from measurement 1 and 2 and all but one value fell within ±2 standard deviations (figure 2.8 A, B). Similar plots were seen for the inter-rater reliability (not shown).

Factor	n	ICC	95% CI	Smallest detectable difference
Navicular height intra-rater reliability	10	0.94	0.85-0.98	5.85
Navicular height inter-rater reliability	10	0.96	0.86-0.99	4.96
Foot Posture Index intra-rater reliability	10	0.98	0.96-0.99	2.12
Foot Posture Index inter-rater reliability	10	0.94	0.77-0.98	1.28

Table 2.3 Inter- and intra-rater reliability of navicular height and foot posture index with smallest detectable differences

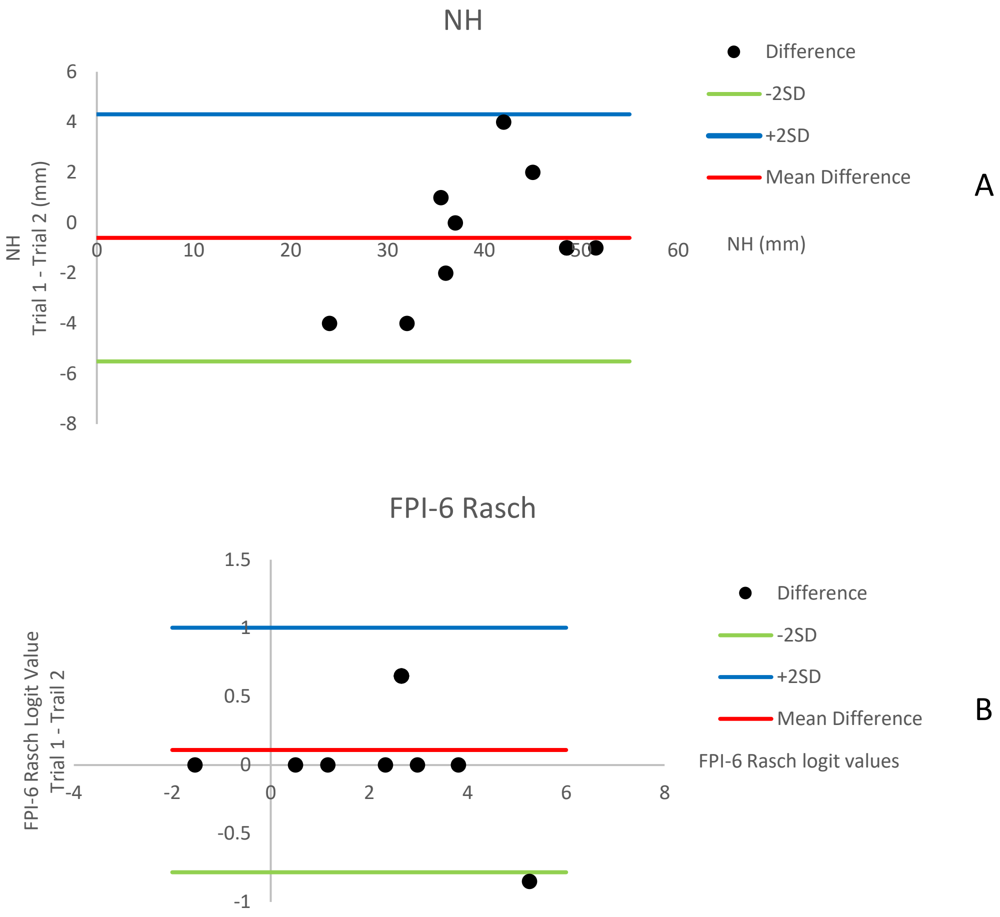


Figure 2.8 Bland Altman plots for A NH and B FPI-6. 1 rater measured on two occasions

2.5.2 Ankle invertor eccentric strength, and medial ankle and plantar fascia stiffness

The intra-rater reliability for the strength and stiffness tests were assessed on 16 participants as there was an error in scaling parameters in one participant. Results are indicated in table 2.4. Eccentric ankle invertor strength reliability was excellent (ICC=0.85). Bland Altman plots show the mean difference was 2.84 indicating that the second measure tended to be higher suggesting a slight practice effect (figure 2.9A). One participant had their value outside the 2 standard deviations line.

Medial ankle (invertor) stiffness reliability was good (ICC=0.74). The 95 % confidence intervals were however broad (table 2.4). Bland Altman plots of the stiffness data indicate that the mean difference was 0.02 for stiffness indicating no systematic error between trial 1 and 2. Only 1 measure fell outside the 2 standard deviations line (figure 2.9 B).

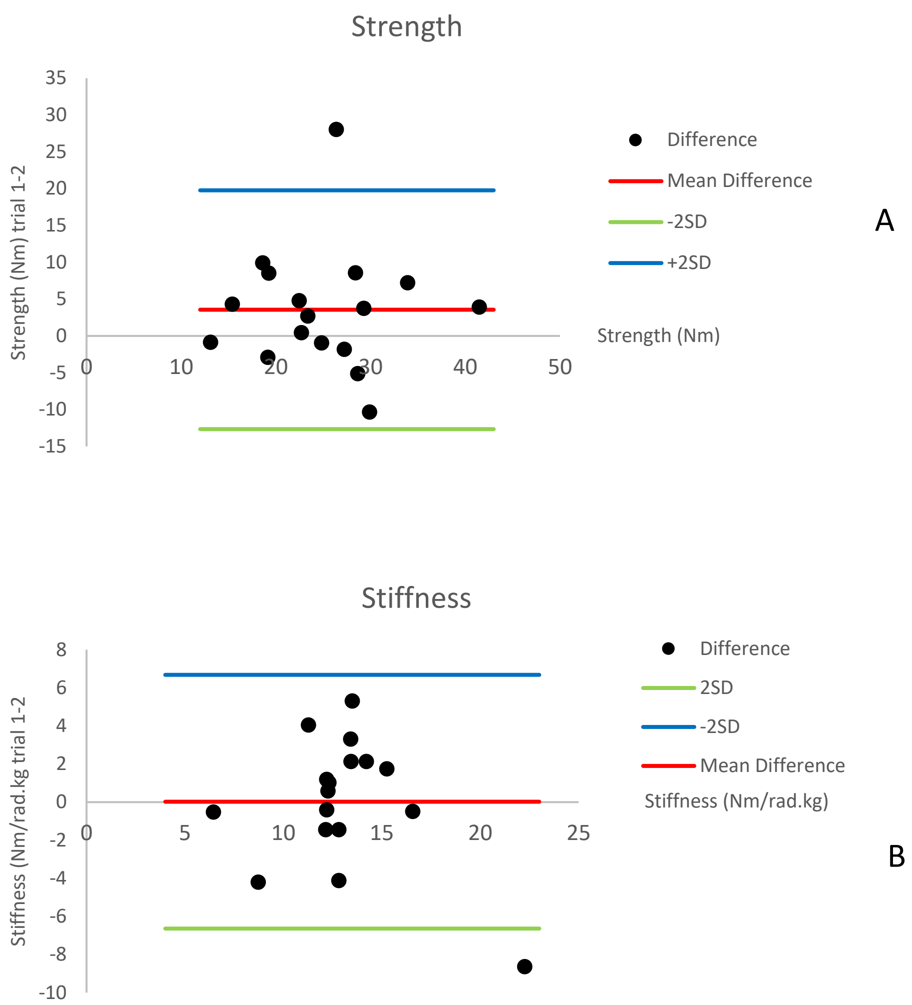


Figure 2.9 Bland Altman plot for: A) eccentric invertor ankle strength and B) medial ankle stiffness

Factor	**n**	**Mean (*SD*)**	**ICC**	**95% CI**	**Smallest detectable difference**
Eccentric Ankle Invertor Strength	16	26.86(7.00)	0.85	0.58-0.95	20.07
Medial Ankle Stiffness	16	13.04(3.64)	0.74	0.24-0.91	7.32
MyotonPRO™: Tibialis Anterior: Frequency	17	22.14(2.32)	0.61	-0.09-0.86	6.71
MyotonPRO™: Tibialis Anterior: Logarithmic Decrement	17	0.80(0.14)	0.76	0.36-0.91	0.30
MyotonPRO™: Tibialis Anterior: Stiffness	17	452.74(96.16)	0.79	0.30-0.93	195.01
MyotonPRO™: Plantar fascia Hallux 0^o: Frequency	17	32.50(3.14)	0.85	0.59-0.94	5.21
MyotonPRO™: Plantar fascia Hallux 0^o: Logarithmic Decrement	17	1.26(0.22)	0.51	-0.34-0.82	0.76
MyotonPRO™: Plantar fascia hallux 0^o: Stiffness	17	785.59(120.84)	0.85	0.58-0.94	200.06
MyotonPRO™: Plantar fascia Hallux 30^o: Frequency	17	32.93(3.34)	0.84	0.54-0.96	5.73
MyotonPRO™: Plantar fascia Hallux 30^o: Logarithmic Decrement	17	1.18(0.24)	0.89	0.69-0.96	0.34
MyotonPRO™: Plantar fascia hallux 30^o: Stiffness	17	813.03(140.86)	0.86	0.61-0.95	218.13

Table 2.4 Intra-rater reliability for the objective measures of foot and ankle stiffness and strength with smallest detectable differences

2.5.2.1 MyotonPRO™ measurement of tibialis anterior stiffness

MyotonPRO™ measurement of the visco-elastic properties of tibialis anterior ranged from good (frequency ICC=0.61) to excellent (logarithmic decrement ICC=0.76; stiffness ICC=0.79, table 2.4). Smallest detectable differences for all MyotonPRO™ are reported in table 2.4. The 95 % confidence interval were however broad. Bland Altman plots revealed minimal systematic error with 1 person falling outside the 2 standard deviation limits in each case (figure 2.10).

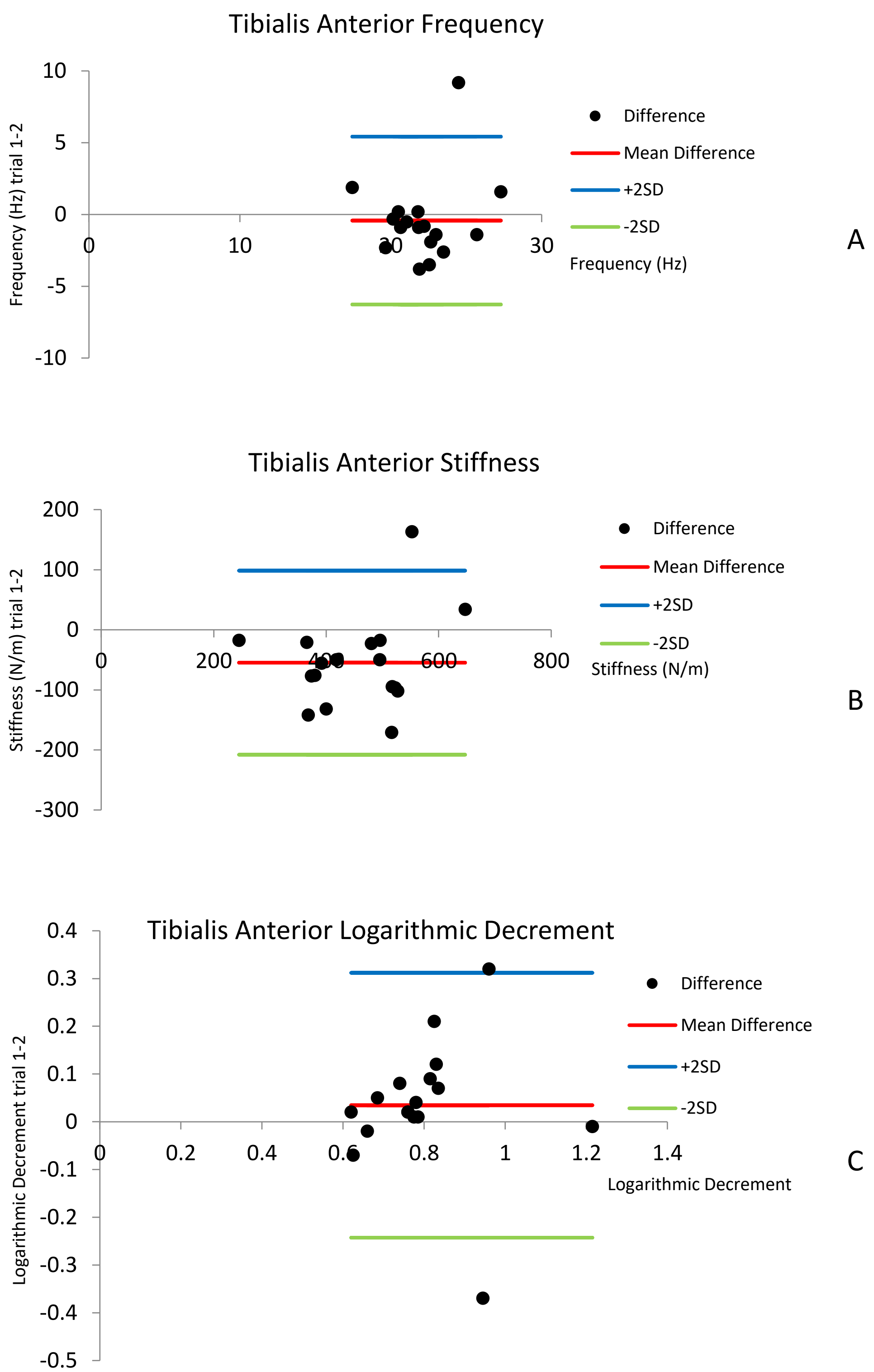


Figure 2.10 Bland Altman plots for tibialis anterior measure of: A) frequency of oscillation B) logarithmic stiffness and C) tendon decrement following a perturbation of the tibialis anterior tendon

2.5.2.2 MyotonPRO™ measure of plantar fascia visco-elastic properties

Myotonometer measures were taken with the hallux in 0^o and 30^o extension. The difference between these measures was also explored. The ICC tended to be higher when the hallux was in 30^o extension compared to 0^o (table 2.3). Reliability was excellent for frequency (ICC=0.84-0.85) and stiffness (0.85-0.86) but poor–excellent for the logarithmic decrement (ICC=0.51-0.89) depending on hallux position (table 2.4). An assessment of the difference between the measures at 30^o and 0^o showed minimal change in the reliability for frequency (ICC=-0.86) and stiffness (ICC=0.88) but was poor (ICC=-0.31) for the logarithmic decrement. The Bland Altman plots were similar for 0^o and 30^o hallux position and are illustrated for 30^o only (figure 2.11). For the all three measures data was within 2 standard deviations. However, there was a tendency for a systematic change from trial 1 to trial 2; the mean difference decreasing for stiffness and frequency on trial 2 and increasing for the logarithmic decrement (figure 2.11).

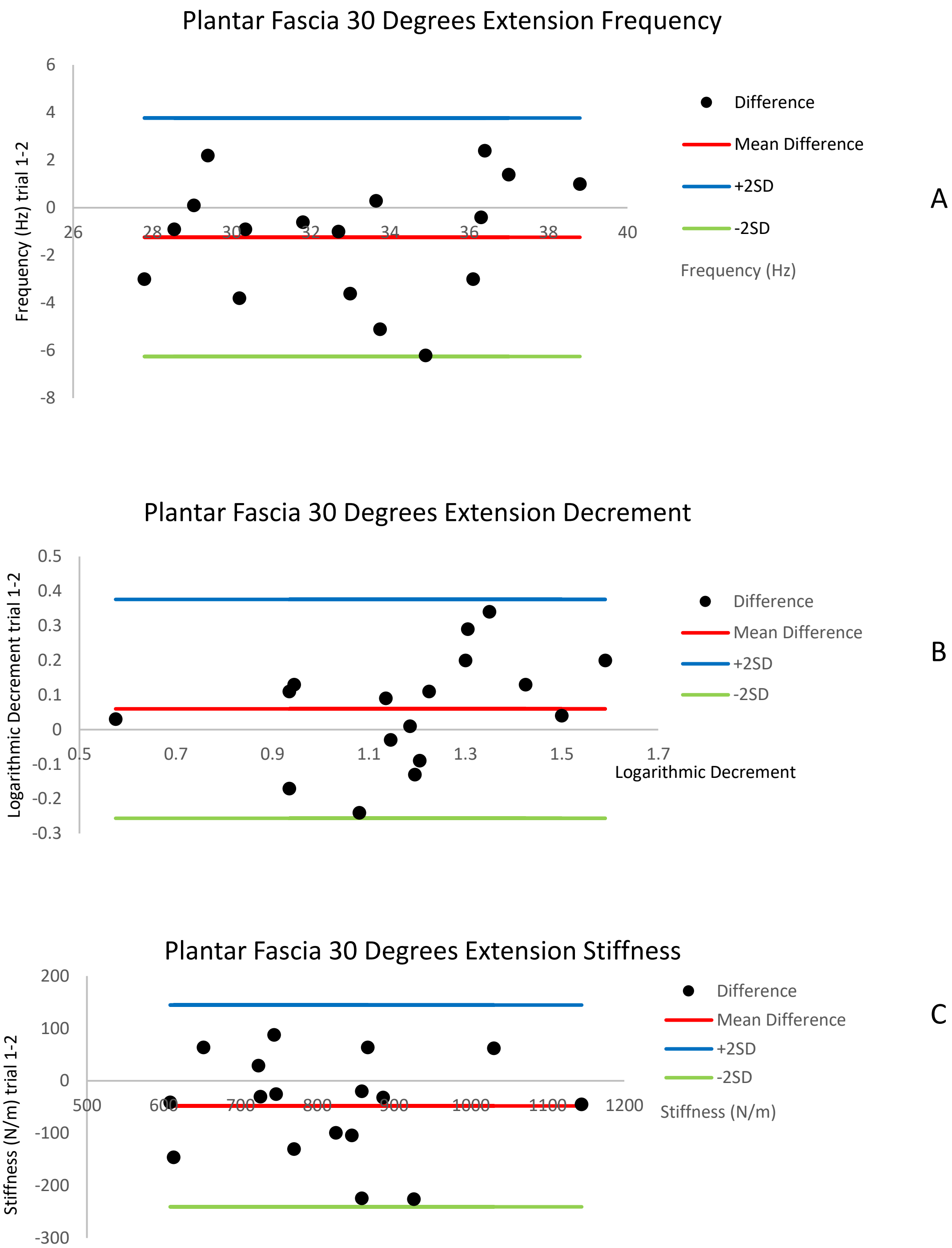


Figure 2.11 Bland Altman plot for plantar fascia measure of A) frequency of oscillation, B) logarithmic decrement of oscillation and C) stiffness using the MyotonPRO™

2.6 Discussion

2.6.1 Foot Posture Index and navicular height

The results from the above reliability studies show that the FPI-6 and NH have excellent reliability in this thesis and are more reliable than reports in the literature (Menz, 1998; Weiner-Ogilvie and Rome, 1998; McPoil *et al.*, 2008), except for studies where collaborative training was undertaken as part of the research protocol (Morrison and Ferrari, 2009; McLaughlin *et al.*, 2016) as in the current study. The mean Rasch converted (Keenan *et al.*, 2007) FPI-6 measure was 2.3 ± 1.89 (raw score converted = +4) reflecting the normative values for the FPI-6 in adults reported as +4 (Redmond, Crane and Menz, 2008).

A study of NH in 3968 army recruits (Abdel-Fattah *et al.*, 2006) reported mean values of 41.2 ± 7.7 mm and 39.4 ± 8.1 mm for men and women respectively. The mean value from this reliability study was 40 mm ± 7.9 mm. The study of army recruits measured navicular height with an internal calliper from the floor to the plantar aspect of the navicular rather than the very slightly superior navicular tuberosity which was the landmark used in this thesis. The difference in measurement techniques does not appear to have influenced the mean values however.

The smallest detectable change for the FPI-6 was found to be 2.12 for intra-rater and 1.28 for inter-rater measurement. For the NH the smallest detectable changes were intra-rater = 5.85 mm and inter-rater = 4.96 mm. These are the values considered to be change due to effect rather than specifically related to the risk of injury currently the minimal clinically important difference remains unknown.

2.6.2 Ankle invertor strength

The average baseline ankle invertor strength in this thesis was 26.86 (±9.15) Nm which is slightly lower than reported control data in a study of similarly aged male only participants who had a mean strength of 32.8 (±4.9) Nm at midrange during an eccentric isokinetic contraction (Yildiz *et al.*, 2003). The samples in this thesis are mixed sex and this would likely account for the reduction in mean strength being slightly lower. The reliability of measuring strength using the Biodex™ in this thesis was good although the confidence intervals were large in contrast to a study of invertor strength reliability by Aydoğ et al. (2004). The method used was similar to the present study with the same Biodex™ isokinetic dynamometer but reliability was reported as excellent (ICC=0.92-0.96). The sample in the study by Aydoğ et al. (2004) was also mixed gender but they repeated the trials three times and calculated the mean rather than taking the peak force which was done in the current study. Using the mean, including the first trial, reduced the intra-tester ICC to 0.86 in the study by Aydoğ et al. (2004) and reliability was increased (ICC=0.96) when the first measurement was eliminated. The smallest detectable difference for invertor strength force in this thesis was 20.07 Nm.

In the present study the potential for a practice effect was acknowledged and eliminated by selecting the highest force from the three trials although this meant the peak was recorded not the mean and a mean of the peak forces of more trials could have improved the reliability. Another difference in the methods used was that the current study motor speed was 20 deg/s whereas the reported ICCs in Aydoğ et al. (2004) cover two trial speeds: 60 deg/s and 180 deg/s. They noted that the variance was higher in the slower motor speed trials which may relate to the lower speeds not triggering a stretch reflex and the higher speeds eliciting the reflex in some individuals (Meinders *et al.*, 1996). Exercise-induced fatigue has, however, been shown to reduce latency in hamstring reflex initiation (Behrens *et al.*, 2013) but only in women. It is not known if this effect applies to distal muscles of the lower limb so while the stretch speed used in the current study was slower than other invertor strength studies of healthy individuals, the potential for reflexive force in addition to volitional force affecting some participants in the study but not others was negligible. Reflexive activity is, however, part of normal human power generation in walking and running (Ishikawa and Komi, 2007) which should be taken into consideration when interpreting the results of studies of strength at different stretch rates.

2.6.3 Medial ankle and plantar fascia stiffness

2.6.3.1 Motor driven stretches (stiffness)

The average ankle invertor stiffness was 13.04 (3.64) Nm/rad.kg. This compares to previous estimates of 39.5 (±21.2) Nm/rad.kg (Jain, Wauneka and Liu, 2016) and 35.7 ±9.45 Nm/rad.kg (Zinder *et al.*, 2007). The smallest detectable difference for medial foot and ankle soft tissue stiffness in this thesis was 7.32 Nm/rad.kg.

Zinder *et al*.(2007) assessed ankle invertor stiffness using a novel spring based system in standing. Therefore, differences in stiffness measures could be attributable to ankle position which was not measured directly in the study but as participants were standing on a platform, and from diagrams / description, it is assumed that it is quite close to neutral between inversion-eversion and plantar-dorsiflexion, and also compressed with bodyweight. In contrast, the ankle was in 10° plantarflexion and was perturbed 15° in the current study.

Having the ankle midway between inversion – eversion should lead to a decrease in ankle inversion stiffness compared to the present study but the ankle position in neutral between dorsi-plantarflexion is its closed packed position and so would increase stiffness. More importantly in Zinder *et al*.'s (2007) study the person was not passive and so additional stiffness due to volitional and reflexive muscle contraction would have increased the stiffness (figure 2.12).

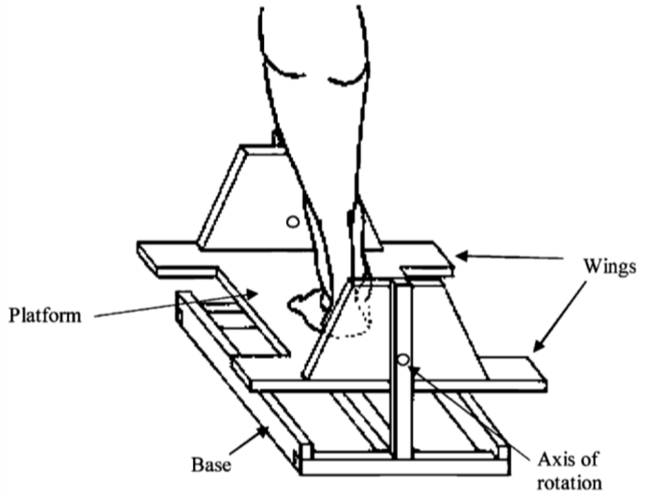


Figure 2.12 Standing rig for testing ankle invertor stiffness in Zinder *et al.* (2007)

Jain *et al*. (2016) used a dynamometer to measure ankle inversion / eversion stiffness. The leg position was the same as in the current study and the ankle in 20° plantarflexion compared to 10° plantarflexion in the current study (figure 2.13). In contrast to the current study, full range eversion-inversion was tested. Participants were asked to relax although, unlike the current study, this was not confirmed with surface electromyography (sEMG). To measure stiffness Jain *et al*. firstly defined a neutral zone which was the range from the neutral joint position to when a 10 % increase in resistance occurred. Stiffness was measured from the slope of the load-displacement curve from the end of the neutral zone to the maximum of the curve (i.e the end of range). In figure 2.14 Jain *et al.* (2016) provided the end range was 35° everted. This greatly exceeds the range of 15° everted used in the current study; in fact the end of their eversion neutral zone (which would have stretched the invertors) was 12.6 (±6.6)°.

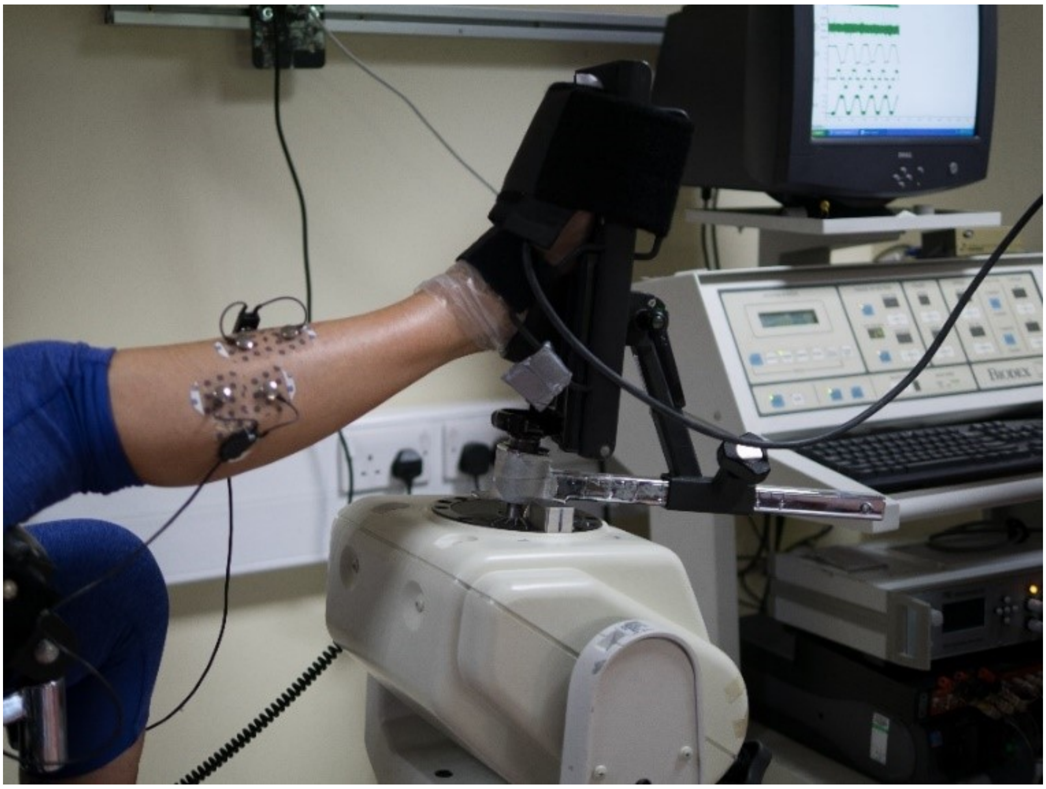


Figure 2.13 Position of participant in Biodex™ dynamometer for measuring ankle invertor stiffness

Thus in Jain *et al*. (2016) stiffness is measured over a range when the soft tissues are more stretched and so, more stiff. Their illustrative example (figure 2.14) provided highlights that the increase in resistance from 0–15° is ~3.0 times less than the increase from 20 to 35°.

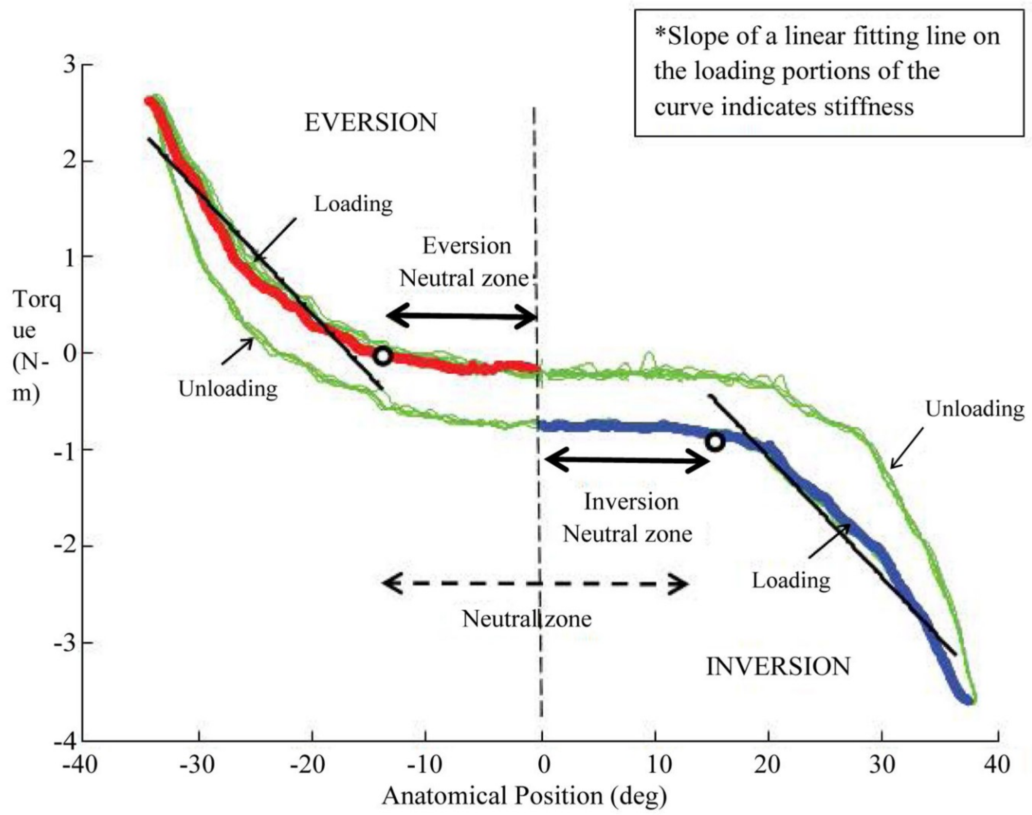


Figure 2.14 Illustrative example showing stiffness increasing towards ends of range of motion (Jain et al., 2016)

This would equate to the ratio of stiffness measures reported in the two studies (39.5/13.04=3.0). However, one final point to note is that manually determining the slope from the figure provided in Jain *et al*. (2016) shows a change of 0.5 Nm to 2.0 Nm from 20 to 35° eversion; this would result in a stiffness of 5.7 Nm/rad; much lower than that reported. This suggests that the illustrative example provided may not represent the group as a whole; it is also not stated whether the illustration was of an ankle affected by chronic ankle instability (CAI) or an uninvolved ankle as those affected by CAI had significantly lower measures of ankle stiffness.

The differences in measurement techniques between the studies calls into question which measure of stiffness is preferable. As stated, the method of Zinder *et al*. (2007) does not measure passive stiffness but could be considered to reflect a more functional test as the participant is standing. When assessing ankle dorsi-plantar-flexion stiffness there are differences in stiffness between seated and standing positions. The measurement of end range stiffness as in Jain *et al*. (2016) may be more sensitive to changes in pathology and with activity (e.g prolonged running). However, this approach has the disadvantage of assessing a variable range between participants as their end-of-range will show inter-subject variability. Furthermore, the ankle does not reach the end of eversion range normally while running instead it has a range of 10-17° (Kuhman *et al.*, 2016; Dudley *et al.*, 2017; Fischer *et al.*, 2017) with slightly higher values (mean 20.4 (3.7)°) in runners with lower limb injuries (Kuhman *et al.*, 2016). Thus, the range assessed in the current study reflects the range used while running. As the aim is to see whether changes in stiffness affect changes in the loading response (pronation / ankle eversion) of the foot and ankle with prolonged running, it is felt that measuring in the range of 0-15° is appropriate.

2.6.3.2 Myotonometer (stiffness)

The reliability of the MyotonPRO™ measures of stiffness showed all but the decrement measure of the plantar fascia in the 0° dorsiflexed position, to be highly reliable. The decrement measure for the measurement of plantar fascia stiffness, therefore, will not be reported in chapter 7.

The MyotonPRO™ (Myoton AS, Estonia) is an instrument developed to aid assessment of muscle and biological soft tissues using local damped natural oscillation (Myoton AS, 2016b). The instrument has applications in the measurement of tone, elasticity and stiffness, the latter being relevant to this thesis (Myoton AS, 2016a). Myotonometry has been employed in studies investigating muscle tone and stiffness (Janecki *et al.*, 2011; Davidson *et al.*, 2017) and generally found to have very good to excellent reliability (Bizzini and Mannion, 2003; Leonard *et al.*, 2003b; Agyapong-Badu *et al.*, 2013; Davidson *et al.*, 2017) but the application in this thesis is in the investigation of tendon and fascia stiffness which has not been reported so widely in the literature.

The MyotonPRO™ employs a damped oscillatory technique but applied very locally to the skin and underlying tissue structures via a probe rather than to a whole joint such as the knee (e.g when measuring knee stiffness using the Wartenburg’s pendulum test (Valle *et al.*, 2006) (figure 2.15).

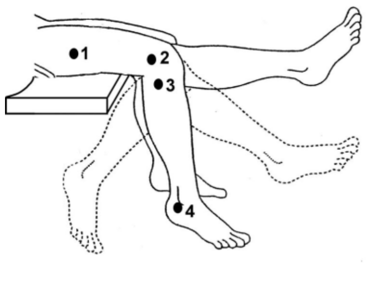


Figure 2.15 Wartenburg's Pendulum Test for knee stiffness (Valle *et al.*, 2006)

The damped oscillatory technique, when applied on a larger scale (eg. in the context of knee joint stiffness has been shown to yield very different absolute values from the handheld Myotonometer™, a device similar to the MyotonPRO™ (Pamukoff *et al.*, 2016). For example, the measures of biceps muscle-tendon unit stiffness using the Myotonometer™ were 23.2 (±13.6) N/m/kg vs. 87.0 ±24.0 N/m/kg (r=0.03, P=0.875) for the dampened oscillation of the limb technique (Pamukoff *et al.*, 2016).

There are several potential reasons for this discrepancy. The first reason may simply be that adipose tissue covering a superficial structure may obscure the underlying structure of interest and yield erroneous results. Secondly the local perturbation achieved with the MyotonPRO™ only stretches a subset of the tissues of interest. Another explanation lies in the difference between transverse tendon compression being achieved with the probe of the handheld Myotonometer™ (and MyotonPRO™ in chapter 7) versus more functional stiffness measures from oscillating the limb at a joint and measuring active stiffness with a motor across range. In these later examples the tissue(s) of interest are being stretched longitudinally.

When normalised to body mass to allow across study comparison the current stiffness of the tibialis anterior was 6.52 (±1.48) Nm/kg compared to the biceps femoris tendon (23.2 (±13.6) Nm/kg). This may reflect differences in tendon size and architecture and the degree of stretch on the tendon when assessed. The differences in stiffness measures for the plantar fascia when measured at 0 and 30° highlights the importance of tissue stretch and the need to standardise position when measuring stiffness.

2.7 Conclusion

The results of the experiments in this chapter confirmed excellent intra- and inter-rater reliability for the measures of foot posture (FPI-6 and NH tests) as well as for the test-re-test reliability for ankle invertor strength and medial ankle stiffness using the Biodex™.

Medial foot and ankle stiffness test-retest reliability using the Biodex™ was good whilst measures of stiffness with the MyotonPRO™ varied. For the tibialis anterior tendon reliability with the MyotonPRO™ was moderate to excellent for the three measures reported (frequency, stiffness and logarithmic decrement).

Test-test reliability varied from poor to excellent for the plantar fascia with resting at 0° extension but improved overall to excellent across all three measures when extended at 30°. The stiffness measure from the MyotonPRO™ for tibialis anterior, plantar fascia at 0° and 30° hallux extension, however, was excellent.

In addition, limits of agreement have been within two standard deviations across all measures studied in this chapter. The findings are similar to or improving upon similar studies – particularly the Foot Posture Index. For the measures of stiffness the results of the MyotonPRO™ for the tibialis anterior and plantar fascia have not been specifically reported elsewhere using this methodology, and this study adds to the body of evidence for use of the instrument in lower limb stiffness measurement.

2.8 Summary

This chapter has evaluated a number of measures to be employed throughout several studies in this thesis to demonstrate reliability of the measures of foot posture. In addition, reliability of strength and stiffness measures have been evaluated for both the Biodex™ and MyotonPRO™ and values have been compared with published data and variations accounted for with the different methodologies used. All measures have been shown to be very reliable although some with large confidence intervals should be interpreted with caution when used in the studies in this thesis. The FPI-6 and NH will now be used in chapters 3, 5 and 7 while the Biodex™ measures of ankle invertor strength and medial foot and ankle soft tissue stiffness will be used in chapters 5 and 7 and the MyotonPRO™ used in chapter 7 to measure stiffness of the plantar fascia and tibialis anterior in isolation.

Chapter 3 : Determining changes in foot posture after prolonged over-ground running: a repeated measures study of half marathon runners using clinical measures

3.1 Introduction

The evidence that arch height changes after running remains equivocal after a 45 minute sub-maximal run (Hageman, 2010; Boyer, Ward and Derrick, 2014; Bravo-Aguilar *et al.*, 2016), but is found to consistently change after 60 minutes (Escamilla-Martínez *et al.*, 2013; Fukano and Iso, 2016). Marathon distance running has also been shown to affect foot posture (Fukano *et al.*, 2018) with run times of over 4 hours.

Half marathon (13.1 miles or 21.1 km) average run times are around 2 hours 5 minutes (men) to 2 hours 24 minutes (women) (Luff, 2019) with 93 % men and 81 % women achieving times under 2 hours 30 mins and 64 % men and 31 % women running sub-2 hour times (Marastats, 2019). A half marathon run is longer than the 2016 study (Fukano and Iso, 2016) but shorter duration than the 2018 study (Fukano *et al.*, 2018).

The former study (Fukano and Iso, 2016) involved twenty-two runners with measures taken after undertaking a thirty-five-kilometre run. Navicular height dropped by 1.5 mm after the run and, whilst this is potentially a small change in real terms, it had an effect size of 0.62 and was highly significant ($P<0.001$). A limitation of the study was pooling data from left and right foot measurements into the inferential statistics which breaches the assumption of independence of data (Menz, 2004). Whilst frequently there is a clinical difference between each foot of a single person, and there may also be significantly different mechanics in each foot, other factors remain in common such as age, sex, BMI and systemic illness. Without justification for pooling the data it is unclear if the feet were sufficiently different to be considered independent samples and further research is required to strengthen the findings of this study.

Measuring foot posture in fatigued athletes requires the use of validated, reliable and quick tools. The foot posture index (FPI-6) and navicular height (NH) was shown in chapter 2 to have excellent reliability in keeping with other studies (Vinicombe, Raspovic and Menz, 2001; Evans *et al.*, 2003; Menz, 2005; Shrader *et al.*, 2005; Cornwall *et al.*, 2008). In addition to being reliable and valid, the FPI-6 and NH are quick to execute which is critical when determining the immediate effects of running in athletes who recover quickly. Fukano and Iso (2016) noted that they were able to record the post-run measurements within 3.5 minutes of ending the run and in this period the participants' heart rates dropped by 18 % on average. Another study which fatigued the tibialis posterior muscle and measured maximum voluntary contraction strength before and after the fatiguing protocol (Pohl, Rabbito and Ferber, 2010) found that the muscle had recovered from 67 % of baseline strength to 80 %

immediately after the post-fatigue walking trials within two minutes of completing the fatiguing exercises. It is imperative therefore, that any measurement of strength after a fatiguing run is undertaken within 3.5 minutes and ideally other measures where muscle fatigue and recovery eg FPI-6 and NH, may contribute, should also be measured in this timeframe. With good validity of the FPI-6 and NH tests and test-retest and inter-rater reliability being moderate to excellent for the tests, they were deemed fit for use in a fast-paced data collection session during a half marathon after-race period. In chapter 2 excellent reliability was established for the primary outcome measures (FPI-6 and NH) used in this study.

3.1.1 Aim

This study aims to measure the change in foot posture after running a half marathon using the FPI-6 tool and navicular height test.

3.1.2 Hypothesis

Null:

Static foot posture will not change after running a half marathon

Alternative:

Static foot posture will change after running a half marathon with the foot becoming more pronated.

3.2 Methods

3.2.1 Ethical approval and data security

Ethical approval was sought from the Faculty of Health, Education and Society ethics committee, Plymouth University. All participants were given a unique randomly generated code and personal information (name / contact details) was kept separate and destroyed at the end of the study.

All data and information collected in the study was stored on the University storage drive which is password protected and any backup copies were password protected, encrypted and stored in a locked cabinet at the PAHC building of Plymouth University when not in use.

The study information and consent forms can be found in Appendix 3.

3.2.2 Sample size calculation

Previous work on 3968 army recruits found that the navicular height was 40.4 mm ±7.2 for people defined as having a normal plantar shape (Swedler *et al.*, 2010). It was estimated that to detect a 10 % change in navicular height following the half marathon (an effect size of 0.4/7.2=0.56) would require 30 participants (power=0.85; α=0.05).

3.2.3 Recruitment of participants and sampling

Convenience sampling was used for this study. Volunteers were sought via advertisements on the Plymouth Half Marathon website and the University of Plymouth website, and the advert highlighted the need for healthy volunteers registered to run the Plymouth Half Marathon.

3.2.4 Eligibility criteria:

Inclusion criteria

People registered to run the Plymouth Half Marathon between the ages of 18 and 65 were eligible to enter this study. The age caps were intended to reduce the chance of introducing variance in the data associated with childhood development or ageing as foot posture norms differ with age with a 'U' shaped distribution with more pronated feet being common on average in younger and older individuals (Redmond, Crane and Menz, 2008).

Exclusion criteria

Any participant with a history of significant foot injury or surgery, current foot pain or on-going use of foot orthoses, a diagnosis of diabetes mellitus or arthritis affecting foot and ankle joints was excluded. Diabetes and arthritis can influence foot posture, stiffness and / or strength while surgery, pain and foot orthosis use may affect running gait in a way that affects change in foot posture.

No volunteers were excluded upon initial assessment and the first 30 gave informed consent (12 female and 18 male, aged 20 - 53 yrs (median 35 yrs), BMI range 16.6-29.7 (median 24.6)). Footwear was not controlled for in this study although no runners trained or raced in footwear deemed by the primary author to be unsuitable for their foot type and most runners wore neutral running shoes. All footwear worn by the participants was in good condition and runners were advised to tie shoelaces well in order to minimise foot slippage in the shoe and ensure a good fit throughout the race.

3.2.5 Data collection protocol

In the week prior to the half marathon participants attended a pre-race measurement session in a non-fatigued state having been instructed not to run on the day. An experienced podiatrist (see chapter 2) collected all the pre-race data.

Height, weight and age were recorded and FPI-6 and NH were determined as outlined in chapter 2.

Records were kept using the runners' race numbers to identify study participants. The participants were given instructions for race day to immediately attend the research station for post-race measurement, using the same measures, in their fatigued state (figure 3.1).

There were 2 data collectors; one podiatrist with over fifteen years' experience and one undergraduate podiatrist who had undertaken training in performing the FPI-6 and NH and whose reliability was established (chapter 2). This was required as the runners arrived at the research station in quick succession. By ensuring the next available data collector recorded the measurements the time to measurement for the runners remained under five minutes from the race finish time (and finish line), and ensured the runners were measured in their fatigued state as they were escorted at a fast walking pace to the research station by research team helpers. All runners arrived at the station, were seated and asked to remove their footwear by the helpers, and briefly questioned and examined for injuries sustained during the race. Minor injuries such as open erosion lesions, blisters and toenail lysis were not considered likely to affect FPI-6 or NH unless they directly affected the areas needed to record the data or the ability to stand pain-free. No runners sustained injuries in this category. Furthermore, injuries such as ankle sprains, or significant musculoskeletal pain would have also affected the measurements and participants would have been excluded from the study in this instance. No runners were found to have sustained such injuries and all thirty remained in the study.

It was an ethical consideration that runners would be considerably fatigued after the race and would possibly require immediate rest and refreshment prior to measurement. This was allowed for during the initial seating and shoe removal stage where members of the research team aided them in shoe removal if necessary and ensured they were able to stand in order to be measured. One runner felt faint upon arrival at the station and was allowed time to eat a snack in order for him to be able to stand safely on the research stand and another suffered calf cramps for a couple of minutes prior to data collection but was still able to be measured within the five minutes following their race finish times. To ensure that weight was evenly distributed between left and right feet, and that upright posture was maintained during measurement, the runners placed each foot on an analogue weighing scale, as in the pre-race measurement, and data were only recorded when each foot was taking 50 % of bodyweight. The stand also included a waist height handrail in front of the runner to enable them to maintain balance.

Figure 3.1 Research station at the Plymouth Half Marathon for post-race collection of NH and FPI-6 data

3.3 Analysis

Navicular height and Rasch logit converted foot posture index scores (table 2.1 in chapter 2), age, BMI, change in foot posture (FPI-6 and NH) for each gender, race time and overall pre-race foot posture were all normally distributed as determined by the Shapiro-Wilk test ($P>0.05$) and parametric tests were therefore selected. Results were analysed in SPSS (version 20, IBM) using a repeated measures analysis of variance with factors being TIME (pre vs post-race) and SIDE (right vs left).

No relationship was found between the change in foot posture as measured using the FPI-6 or navicular height and age, gender, BMI, race time and pre-race foot posture. Results were taken as significant if $P<0.05$; mean and standard deviations are reported unless indicated.

3.4 Results

Thirty people were assessed (12 female and 18 male, aged 20 - 53 yrs (median 35 yrs), with a BMI range of 16.6 - 29.7 (median 24.6)). Participant characteristics are summarised in table 3.1. The average time to complete the race was 124.6 ±2.4 minutes. Baseline median FPI-6 was + 3 (raw score) for both feet (inter quartile range=3.5) and median navicular height was 47 mm (mean=47.39 mm). The pre and post-race results are shown in table 3.2.

Parameter	Value
Gender	N = 12 female N = 18 male
Shoe type worn	N = 14 Neutral N = 14 Stability N = 2 Anti-pronatory
Parameter	**Mean (*SD*)**
BMI	24.26 (3.03)
Age	34.5 (9.4) years
Race time	124.55 (22.36) min
Right baseline FPI-6 score *(Rasch)*	2 *(1.33 (2.17))*
Left baseline FPI-6 score *(Rasch)*	3 *1.76 (1.4))*
Right baseline NH	48 (8) mm
Left baseline NH	47 (2) mm
Shoe size	8.9 (2.6)

Table 3.1 Demographics of participants

3.4.1 Navicular height

Mean navicular height significantly decreased following the half marathon in the right foot by -5 mm and left foot by -4.2 mm (TIME $F(1,29)=26.9$ $P<0.001$, Figure 3.2A). There was no effect of side or side x time interaction.

Mean NH (mm)					
Pre-race L	Post-race L	Change L	Pre-race R	Post-race R	Change R
46.4	42.2	-4.2	48.4	43.4	5
Mean FPI-6 Rasch Logit Values					
Pre-race L	Post-race L	Change L	Pre-race R	Post-race R	Change R
1.76	3.40	1.64	1.33	2.10	0.77
Median FPI-6 Raw Values					
Pre-race L	Post-race L	Change L	Pre-race R	Post-race R	Change R
2.5	5	2.5	3	3	0

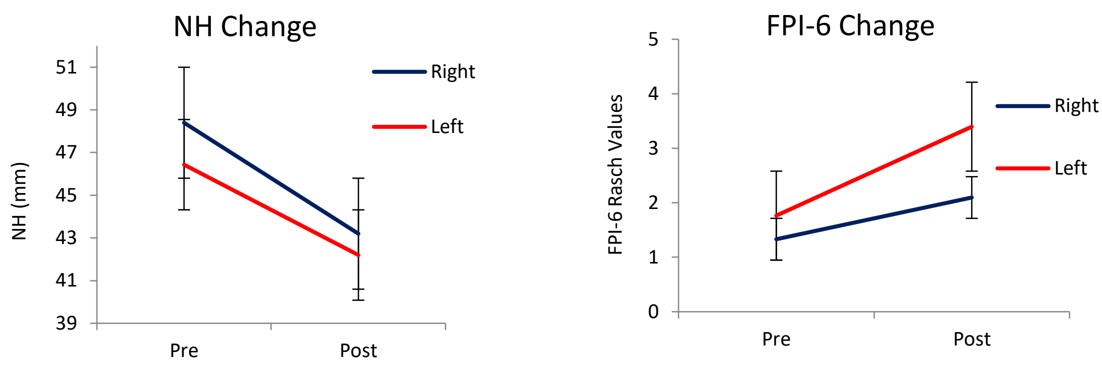
Table 3.2 Pre- and post-race values for the NH and FPI-6 measures

3.4.2 Foot Posture Index

The FPI-6 scores converted to Rasch logit values (table 2.1 in chapter 2) significantly increased following the half marathon (TIME $F(1,29) = 15.9$ $P<0.001$) (table 3.2). There was a significant time x side interaction (TIME X SIDE $F(1,29) = 15.1$ $P<0.001$). The interaction indicates that following the half marathon the FPI-6 Rasch scores increased significantly more on the left (+1.64 rounded to 2 as the FPI-6 only uses integers) and although the right side changed too (+ 0.77 rounded to 1) this was not statistically significant (Figure 3.2).

3.4.3 Relationship between baseline measures and change in foot posture

There was no relationship between the change in FPI-6 scores or navicular height with the half marathon and the participants' age, gender, BMI, race time or pre-race foot posture as assessed by the average FPI-6. Where the mean pre-race navicular height was higher there was a significantly greater drop in navicular height post-race (R^2=0.43 P<0.001).



A B

Figure 3.2: A) change in NH after running a half marathon and B) change in FPI-6 after running a half marathon (mean and SE shown)

3.5 Discussion

This study showed that arch height decreased after running a half marathon although there were differences between the two measures of foot posture used. Age, gender, BMI, and race time did not predict the change in arch height. The change in NH was larger in people with a higher pre-race NH.

A significant drop was seen in the left FPI-6 only with a change of 1.64 (Rasch logits) which exceeded the threshold of the smallest detectable difference (SDD) (1.28) for two raters. The NH change was significant in both feet at 4.2 and 5.0 mm (left and right) but only the right foot reached the threshold of the SDD (4.96 mm). Whilst the changes in both variables reflect prior work (Escamilla-

Martínez *et al.*, 2013; Fukano and Iso, 2016) in at least one foot, further testing would be beneficial to glean a clearer picture of the change in foot posture using these measures.

The asymmetry in findings may reflect the influence of leg dominance resulting in differences in lower limb kinematics and kinetics between the two sides. However, this is speculative and leg dominance was not recorded in the current study. An additional explanation is that this reflects the limited sample size; to detect an effect size of 0.38 on the right would require a sample size of 137 participants (power=0.85 α=0.05).

Bone pin studies (Nester, 2009) indicate that arch lowering through sagittal plane plantarflexion and frontal plane eversion is found variably between individuals to be comprised of movement primarily at the ankle and talonavicular joint and to a lesser extent through the other tarsal joints. It is difficult, therefore, to infer which soft tissue structures may be yielding most in any one individual to lower the arch under weightbearing conditions following a prolonged run. It is possible that creep of passive soft tissues upholding the medial longitudinal arch may have occurred (Thorpe *et al.*, 2017) and also muscle fatigue in anti-pronatory (ankle invertor) muscles (Pohl, Rabbito and Ferber, 2010).

Some feet appeared to have increased in volume at the medial midfoot perhaps resulting from increased perfusion to the abductor hallucis and other local muscles. Engorgement and an increase in blood volume could potentially affect the interpretation of the FPI, which is done visually, whilst the measure of navicular height to a bony landmark should be unaffected. Studies investigating this phenomenon have, however, concluded that no significant change in overall foot volume occurs with prolonged exercise (Boni, Takacs and Wilson, 2012; Chlíbková *et al.*, 2014) and foot volume was not recorded in this study.

Anecdotally the testers noticed an apparent abduction of the forefoot relative to the rearfoot post-race which may be real and a result of fatigue of the medial foot soft tissues which are the stabilisers of the tarsus (Pohl, Rabbito and Ferber, 2010; Murley, Menz and Landorf, 2014). It would be useful to investigate the transverse plane response of the foot to prolonged running and walking in future studies.

The navicular height pre-race was ~5 mm higher than that recorded by Swedler *et al*. (2010) in large scale study of army recruits. This may reflect the difference in the points of measurement; the inferior border of the navicular bone in the study by Swedler *et al*. (2010) and the navicular tuberosity in the current study. Of note, NH was not normalised to foot length in the current study to avoid further time lost to testing as participants quickly recovered from their runs. A study by Hill *et al*. (2017) found no relationship in sixty two healthy participants between foot length and arch height so the original method of measuring NH (Brody, 1982; Vinicombe, Raspovic and Menz, 2001) was used throughout this thesis. People with larger feet would, however, tend to have a higher navicular tuberosities (NH) and, depending on foot shape, could demonstrate a larger change in height after running. It is not known from this study if the drop on NH or change in FPI-6 score was related to foot size as the sub-sets foot sizes were not equally distributed in the sample nor the study powered to detect the change in differently sized feet. A validity study of navicular height and the FPI-6 (Menz, 2005) showed that the non-truncated test was valid and other work has confirmed excellent intra- and inter-rater reliability (Menz, 1998; Menz *et al.*, 2003).

Time to return to baseline FPI-6 score and navicular height was not recorded for the participants and further research into this might be useful for half marathon runners. The cause of the changes in foot posture seen in this study are not clear and could be the result of damage to soft tissues or yielding within elastic limits in the soft tissues due to neuromuscular and mechanical fatigue. Furthermore, the impact of these changes on foot and ankle function is also unknown nor the effect of running a longer distance than a 13.1-mile half marathon. The changes may indeed be clinically significant enough to predispose the bones, joints and soft tissues to damage if running were to continue after the changes have taken place, for example in a full marathon. The levels of pain anecdotally reported after the race by the runners were not considered to indicate significant injury but this may be erroneous due to general systemic fatigue and raised endorphin levels which have been reported in trained athletes during sporting activity (Scheef *et al.*, 2012) The perception of pain and function may be potentially important in modification of activity after clinically significant changes have occurred and should be investigated further.

Footwear was not controlled in this study although discussion about footwear was offered in the pre-race data collection sessions and advertised as an incentive to participate in the study. Participants were advised to continue with their planned footwear for the race and consider any advice given by the researcher when only buying new training footwear in future. Participants were advised on lacing techniques, however for the race to ensure that shoes fitted well to reduce the risk of skin erosions.

A final note relates to the convenience sample. In this study the volunteers were of similar socio-economic backgrounds and ethnicity and there were more men than women recruited. There is under-representation of black and ethnic minority runners in Plymouth running communities, consistent with the local population demographic, so this sample was comprised entirely of Caucasians which may affect the generalisability of the study results to the wider UK population.

3.6 Conclusion

This study showed a change in foot posture to a more pronated position following running a half marathon race allowing rejection of the null hypothesis. The magnitude of increase in pronated foot position in different foot types, associated changes in function and time to recover original foot posture and the impact of footwear are not yet known although people with greater NH at the baseline showed a larger drop in NH after the half marathon race.

The results of this study state only an observation of static foot posture after a half marathon run, and do not explain the reasons for the change.

3.7 Summary

The findings of this study align with findings of previous work showing a change in foot posture in running distances of 60 minutes or longer. Furthermore, this study was undertaken in real-world, outdoor, over ground conditions adding to the body of evidence around change in foot posture in different running conditions as other studies have been conducted in laboratory and controlled outdoor running conditions to date. The extent of foot posture change is not known to be clinically significant as to date there are no prospective studies which have investigated the relationship between change in foot posture and RRI incidence and prevalence. More research is required to clarify the minimally clinically important change in foot posture for long distance runners.

The mechanism for the change in foot posture in this and other studies remains unexplored. Chapter 5 presents an experiment to determine the potential for changes in ankle invertor strength and medial foot and ankle stiffness to explain the change in foot posture. Regardless of the mechanism, it is also not known when changes in the foot and lower limb occur that could precipitate a change in foot posture.

Chapter 4 will report the development and validation of a novel proxy measure of in-shoe foot movement which will be used in hour-long running trials in chapter 5 to help address these questions.

Chapter 4 : Development of a tool to estimate shod foot kinematics using 3D motion analysis and in-shoe pressure analysis

4.1 Introduction

Changes in foot posture after a half marathon run were identified in chapter 3 but the mechanism and timing of the changes remains unknown and static measures of foot posture do not predict when kinematic changes occur that could be associated with the mechanisms for change in foot posture.

The laboratory-based study in chapter 5 will involve participant runners to use a treadmill and so provides the opportunity to assess how foot and ankle motion changes during an hour-long running task. Participants will, however, be wearing shoes during their trials meaning that it will not be possible to directly measure the kinematics of the foot. Proxy tools based on limited 3D motion analysis (3DMA) and plantar pressure analysis (pedobarography) will, therefore, need to be used to infer in-shoe foot motion.

The reliability of the FScan™ plantar pressure and Codamotion™ 3D motion analysis systems are discussed in chapter 1 and offer good to excellent reliability respectively. When used in isolation, plantar pressure measured with the FScan™ is only poor to moderately reliable and valid when used as a proxy for foot and ankle kinematics, although may be improved when combined with 3D kinematic data from the leg and shoe. Various methods have been reported to measure in-shoe foot kinematics including cutting the shoe to allow skin-mounted markers (Shultz and Jenkyn, 2012; Bishop *et al.*, 2015; Halstead *et al.*, 2016), dynamic radiography and fluoroscopy (McHenry, 2013; Peltz *et al.*, 2014). In chapter 5 runners will wear their own footwear and so the method requiring cutting into the shoe upper is not an option. The equipment and expertise required for dynamic radiography and fluoroscopy is not available and rules out this option leaving the only option being to develop a novel proxy tool using available reliable technology.

4.1.1 Aim

This chapter aims to investigate the validity of leg and shoe kinematics and pedobarographic parameters as proxy measures for in-shoe foot motion by comparing them to a 3D model of foot motion measured using 3DMA.

4.1.2 Objectives

To determine the correlation at different walking speeds between:

(a) dynamic arch index (DAI)

(b) internal rotation of the tibia relative to the shoe

(c) eversion–inversion of the shoe relative to the tibia (shoe-shank angle)

The goal was to use external shoe and shank markers and plantar pressure data as a proxy for in-shoe foot kinematics while running. A secondary aim was to assess the internal tibial rotation–heel-midfoot inversion-eversion coupling ratio.

4.2 Methods

4.2.1 Ethical approval and data security

Ethical approval was sought from the Faculty of Health, Education and Society ethics committee, Plymouth University. All participants were given a unique randomly generated code and personal information (name / contact details) was kept separate and destroyed at the end of the study.

All data and information collected in the study was stored on the University storage drive which was password protected and any backup copies were password protected, encrypted and stored in a locked cabinet at the PAHC building of Plymouth University when not in use.

4.2.2 Sample size calculation

A correlation of >0.75 (R^2=0.56) between a proxy measure and the gold standard was deemed to be sufficient to allow the proxy measures to be used in the laboratory-based study. This is similar in magnitude to correlations found between pedobarographic data and kinematic data (sagittal: R^2=0.59±0.16, frontal: R^2=0.42 ±0.2, and transverse: R^2=0.53 ±0.17) with the movement at the heel-midfoot segment (Giacomozzi, Leardini and Caravaggi, 2014). To find a correlation between the proxy measure and the gold standard of $r>0.75$ for $\alpha=0.05$ and power=0.85, ten participants were required.

4.2.3 Recruitment

A convenience sample of 10 healthy participants were recruited by local advert from the School of Health Professions at the University of Plymouth.

4.2.4 Eligibility criteria

Inclusion criteria

Volunteers were aged 18-65 years with normal BMI and who could walk on a treadmill.

Exclusion criteria

Volunteers were excluded from the study if they had any neurological or orthopaedic problems that affected their walking.

4.2.5 Data collection protocol

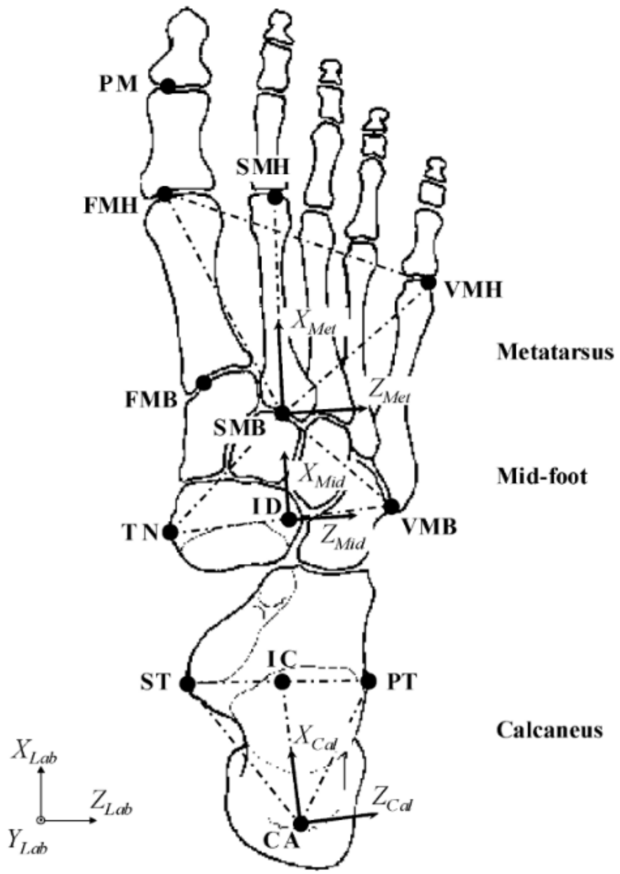
Participants wore a laboratory hiking sandal that allowed markers to be placed on bony landmarks and also allowed an FScan™ sensor insole to be inserted between the foot and shoe. The following measures were taken:

3D motion of the midfoot relative to the heel:

Markers were placed on the bony landmarks as shown in figure 4.1 (Leardini *et al.*, 2007). Data was collected at 200 Hz using a 3D motion analysis system (Codamotion™, Leicestershire, UK). Midfoot eversion and inversion were calculated (see analysis).

Shoe-shank angle:

Markers were placed on the lateral aspect of the shoe, parallel with the floor at the heel (= heel marker) and level with the 5th metatarsal head (=toe marker). Markers were also placed on the tip of the lateral malleolus (LM) and over the knee axis (KA) joint line to define the longitudinal aspect of the shank. A wand was then attached to the leg parallel to the transverse axis of the knee to define an axis orthogonal to the longitudinal axis of the shank via two markers (W1 and W2). Rotation of the shank relative to the shoe and shoe inversion-eversion relative to the shank was measured.



CA: Achilles tendon attachment

ST: most medial aspect of the sustentaculum tali

PT: lateral aspect of peroneal tubercle

IC: midpoint between ST and PT

TM: most medial aspect of navicular tuberosity

TC: most lateral aspect of cuboid tuberosity

ID: Midpoint between TC and TN

MC: Base of second metatarsal

Figure 4.1 Showing marker placement on the foot (Leardini *et al.*, 2007)

Dynamic Arch Index (DAI)

An FScan™ in-shoe sensor was inserted and calibrated using each participant's body weight. The position of the sensory arm as it attached into the cuff was displaced posteriorly so as to avoid obscuring motion analysis markers. This involved a slight posterior displacement of the sensor relative to the shoe.

A Power 1401 (CED, Cambridge, UK) was used to simultaneously trigger the 3D motion analysis hub (Codamotion, Leicestershire, UK) and the FScan™ software via the trigger box/RS232 serial port. Data was sampled at 200 Hz for 10s.

Participants were asked to walk at 3 different speeds (3.0, 4.5 and 6.0 km/h). Once the participant had reached a steady state at a new speed three recordings were taken.

4.3 Analysis

4.3.1 FScan™:

Due the slight posterior shift of the FScan™ sensor, medial and lateral midfoot areas of interest (AOI) were defined using the FScan™ automatic software (Figure 4.2).

1. *Medial AOI:*

Antero-posterior: From the base of the metatarsal heads to the apex of the heel

Medio-lateral: From the medial edge of the foot to a line joining the middle of the heel to the border between the 2nd and 3rd metatarsal.

2. *Lateral AOI:*

Antero-posterior: From the base of the metatarsal heads to the tip of the heel

Medio-lateral: From the border between the 2nd and 3rd metatarsal to the lateral edge of the foot.

The AOIs were defined at the slowest walking speed and saved. The same AOI were imported and used to define subsequent trials / speeds. The vertical force data for the whole foot (to help define stance phase onset / offset) and the total medial and lateral areas of contact within the AOIs were exported as ascii files for analysis in Matlab®.

3. *The Dynamic Arch Index was defined as:*

$$Peak\ medial\ area \div (peak\ medial + peak\ lateral\ AOI)\ x\ 100$$

An index of 25 % therefore indicates that the peak area covered by the medial AOI was a quarter of the total peak area of contact.

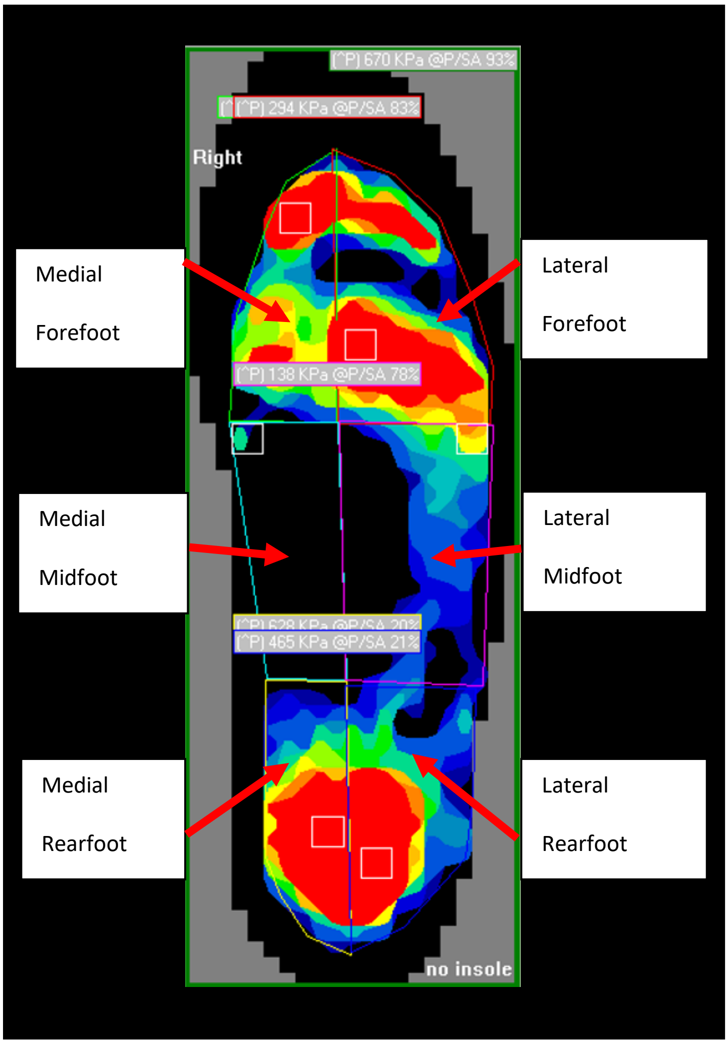


Figure 4.2 Definition of AOIs

4.3.2 3D Motion analysis

Heel and midfoot body segments were defined in “ODIN” software (Codamotion, Leicestershire, UK) according to the Leardini foot model (Leardini *et al.*, 2007). A minimum of 3 markers per segment were used (see also figure 4.1).

Heel segment

Origin is at CA

X axis joins origin with IC

X axis lies in the transverse plane defined by the x axis and ST

Y axis is orthogonal to the xz plane

Midfoot segment

Origin is at ID

X axis joins the origin with MC

Z axis lies in the transverse plane defined by the x axis and TN

Y axis is orthogonal to the xz plane

Shoe

Origin is at the heel marker

X axis joins heel with toe marker

Z axis lies in the transverse plane defined by the x axis and LM marker

Y axis is orthogonal to the xz plane

Shank (leg)

Origin is at the LM

Z axis joins KA with LM

X axis in the sagittal plane defined by the z axis and W1

Y axis is orthogonal to the xz plane

Euler angles defining the relative motion between the heel and midfoot segments and between the shank and shoe were defined and the data subsequently filtered at 100 Hz. Data was exported as text files for analysis in Matlab®.

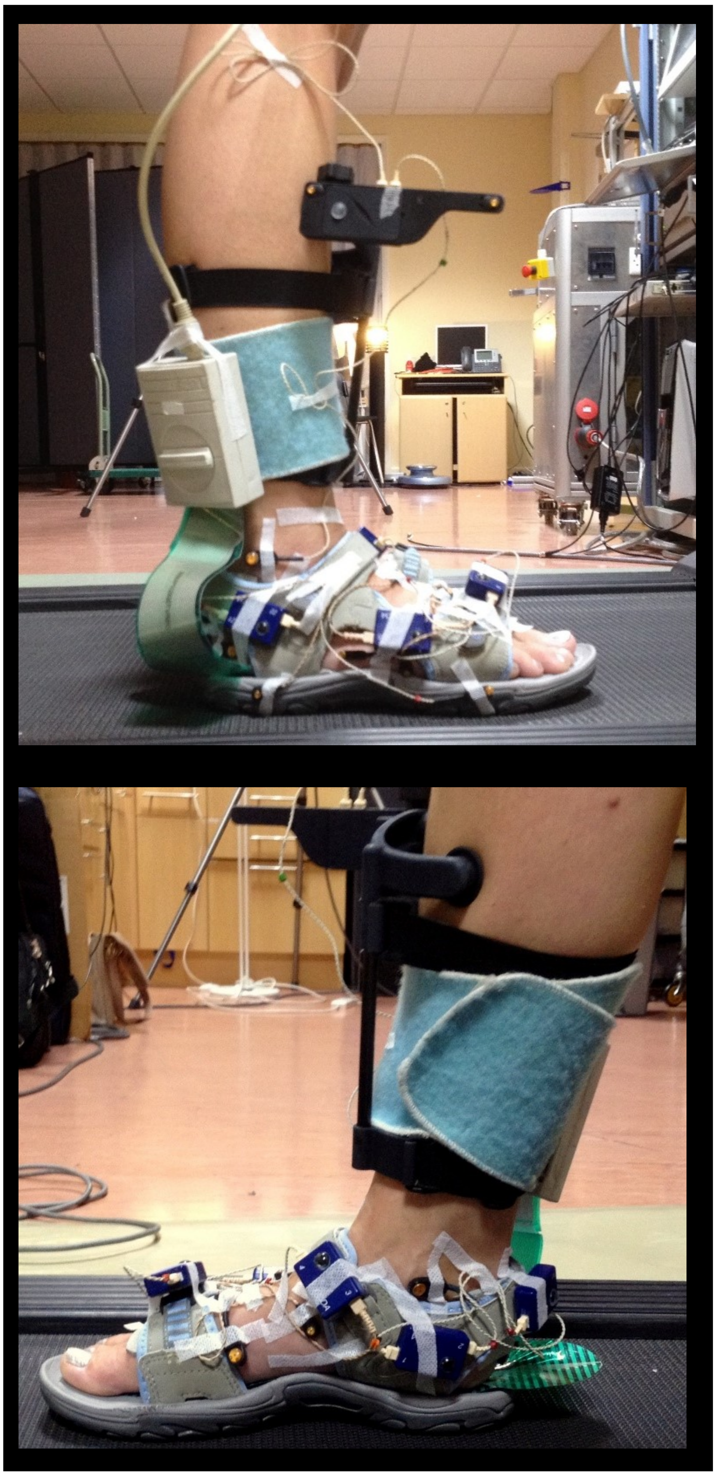


Figure 4.3 Codamotion markers and FScan sensor in-situ with running sandal for validation study trials

4.3.3 Secondary analysis

FScan™ and 3D motion analysis data was imported into Matlab®.

The onset / offset of stance phase was determined in two ways. This reflected the fact that the FScan™ and Codamotion™ data were not perfectly synchronised in time (~0.2 s delay).

(a) FScan™ vertical force records. Loading onset / offset was defined as when the data first rose above / fell below a level 5% of the total applied force.
(b) Kinematic data used the technique of O'Connor *et al*. (2007). Here a virtual foot marker was defined halfway between the heel and toe marker. The velocity of the virtual foot marker shows a characteristic profile which was used to define stance onset–offset. This was achieved through an automatic peak detection program written in house the accuracy of which was verified through visual inspection. Data exported from ODIN software was then aligned to these onset-offset times and a grand average taken of 3 steps.

Heel relative to midfoot motion (inversion-eversion) was defined as the gold standard. The peak heel to midfoot motion, shank-shoe-internal tibial rotation and shank-heel eversion (shank relative to the shoe) and DAI were calculated. The correlation between gold standard (heel-midfoot angle) and the proxy measures at each locomotor speed was calculated using a Pearson's correlation. Differences in ankle, foot motion and DAI with speed were calculated using a repeated measures ANOVA with factors being speed (3 levels).

4.4 Results

In total 12 people were assessed. Records from 4 people were discarded due to artefact in one of the 3 methods of data collection. The grand average of the kinematic data across the 3 treadmill speeds from the 8 remaining people (4 male, 4 female age 32.5 yrs (±10.1)) is shown in figure 4.4. '100 %' indicates 100 % of the stance phase and the angles described are in keeping with past work (Leardini *et al.*, 2007).

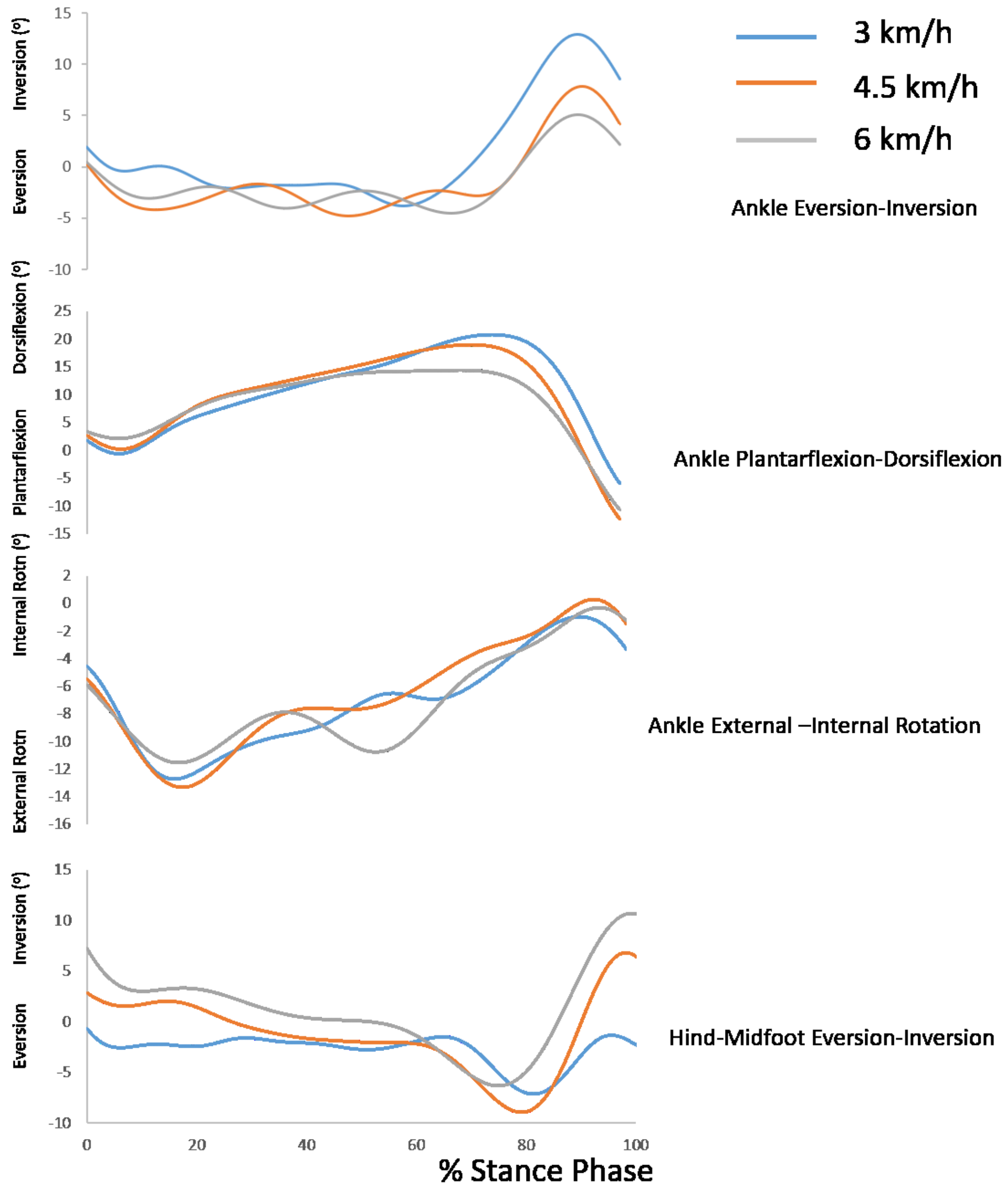


Figure 4.4 Ankle kinematics at 3, 4.5 and 6 km/h walking speeds. Ankle refers to shank-shoe motion, Heel-Midfoot refers to inversion and eversion between the heel and midfoot segments

As highlighted in table 4.1 there were small changes in ankle, heel-midfoot kinematics and DAI with speed but these were not significantly different (P>0.05).

	3 km/h	**4.5 km/h**	**6 km/h**
Ankle Eversion (°)	-9.7(6.9)	-11.1(9.4)	-7.8(8.4)
Tibial Internal Rotation (°)	-11.9(4.9)	-10.3(3.2)	-8.6(5.8)
Heel-Midfoot Rotation (°)	-10.5(10.2)	-13.9(9.0)	-16.7(11.9)
DAI (%)	30.0(19.1)	27.9(17.0)	25.4(13.6)

Table 4.1 Changes in ankle and heel-foot ranges of movement, and DAI with speed

4.4.1 Correlations with heel-midfoot angle

Table 4.2 indicates the correlation between the peak heel-midfoot eversion and (a) peak ankle eversion (B) peak tibial internal rotation (C) DAI.

R^2 values indicated Speed (km/h)	**Ankle Eversion**	**Tibial Internal Rotation**	**DAI**
3	0.05	0.26	0.42 †
4.5	0.52*	0.35	0.55*
6	0.3	0.04	0.09

Table 4.2 Correlations between peak heel-foot eversion and a) peak ankle eversion, b) peak tibial rotation and c) DAI (*=P<0.05, †=P<0.01)

4.4.2 Correlations with internal tibial rotation-eversion ratio

The ratio between the peak internal tibial rotation and heel-midfoot eversion became more variable with faster walking speeds (table 4.3)

3 km/h	4.5 km/h	6.0 km/h
2.18(0.95)	1.43(0.89)	1.97(1.44)

Table 4.3 Ratio of internal tibial rotation:heel-midfoot peak eversion (ankle to midfoot kinematic coupling)

4.5 Discussion

The results showed a moderate to good correlation of the DAI with peak heel-midfoot eversion angle up to 4.5 km/h (R^2=0.42 (P<0.001) at 3km/h and 0.55 (P<0.05) at 4.5km/h) but became poor at 6 km/h (R^2=0.09 (P>0.05). In keeping with this Giacomozzi *et al*. (2014) found significant correlations between pedobarograph measures and ankle kinematics. In their study, however, foot pressure could be affected by more proximal changes. For example, increases in hip adduction while running could move the centre of pressure more laterally (with all other factors being constant) and so affect the DAI. Thus, at best this measure is an indirect proxy for foot function and foot motion.

Peak heel-midfoot eversion to ankle eversion was poor except at 4.5 km/h (3 km/h R^2 = 0.52 (P>0.05); 4.5 km/h 0.52 (P<0.05) and 6 km/h 0.05 (P>0.05)). Peak heel-midfoot eversion to internal tibial rotation correlation was moderate to poor at all speeds (R^2=0.26 and 0.35 and 0.04 for 3, 4.5 and 6 km/h respectively (P>0.05), however, and not significant.

A possible reason for the higher correlations at 4.5 km/h was that at 6 km/h some participants reported having to abnormally elongate their stride to avoid transitioning into a running gait. At 4.5 km/h participants appeared to be closest to their normal walking speed with 3 km/h feeling slow to most. As such, the moderate correlation in two of the three parameters indicates coupling in a comfortable moderate speed walking gait. A study of comparative co-ordination patterns in people walking vs running at the same speed (8.6 m/s) showed general similarities in joint kinematics and in joint-joint angle phase plots between the two types of gait. The greatest difference between the two gaits in the relative phase (the difference in phase between the thigh and leg) was in the 20-40 % period of the gait cycle (Li *et al.*, 1999) corresponding to late stance phase. Thus, at points of transition between walking and running there is an increased variability in joint co-ordination. Although this study did not measure kinematics of the ankle and did not report any differences in shank-foot coupling it supports the suggestion that faster walking speeds close to walking-running transition may be more variable in terms of joint-joint coupling. A limitation of the current study, therefore, was that participants were not choosing their own comfortable walking speed and walking a set percentage faster or slower on a case by case basis which would have standardised the effort.

Participants in the current study were all comfortable at 4.5 km/h walking speed but became less comfortable at 6 km/h. In the study in chapter five, participants self-selected a running speed at a light to somewhat hard level of exertion with no pain and were also comfortable in each case. It would be reasonable, then, to refer to the findings at 4.5 km/h in this study that showed a significant moderate correlation of peak midfoot-heel eversion with ankle and use these with caution as a secondary measure in the laboratory running study in chapter 5.

Direct measures of heel-shank coupling have been reported while running and walking. In running it is common for initial contact to vary from a heel strike to a midfoot strike or forefoot strike and this may even change for an individual during a run. A study of different strike patterns in running investigated the differences in coupling of the shank and foot and found little difference in coupling between strike patterns at self-selected jogging speeds (Pohl and Buckley, 2008). A review of the literature in 2004 (DeLeo *et al.*, 2004) reported a number of studies investigating shank-foot coupling at varying speeds. The authors reported the speed of running in the studies they included that ranged from 2.5 m/s to 4 m/s. The highest speed of the current study in m/s was 1.7 m/s (6 km/h). Ratios reported at the lowest speeds in the review were 1.23 – 1.72 whilst at the highest speed of 4 m/s a study found a ratio of 1.32. This is a confusing picture indicating that speed may not be the factor that caused alteration in coupling ratio of the shank and foot. In the current study participants maintained a walking gait (ie no walk-run transitioning traits or float phase) throughout all treadmill speeds. There was no statistically significant effect of speed. Ankle internal rotation and DAI coupling increased with speed ($P>0.05$), and heel-midfoot rotation decreased ($P>0.05$) but none reached statistical significance. The lack of coupling-speed relationships may be due to the study being underpowered due to elimination of four unusable data sets and/or reflect a lack of coupling with speed as reported elsewhere (Wilken *et al.*, 2011).

Other than speed, factors such as arch height, footwear and injury can affect coupling. DeLeo et al. (2004) in their narrative review noted that arch height was a factor that affected the ratio of coupling with higher arches being closer to a ratio of 1.0 (one degree of heel eversion per degree of internal tibial rotation) and lower arches tending to increase the ratio (i.e. greater eversion for a given amount of tibial rotation). This has also been reported in walking (Wilken *et al.*, 2011) and appears to be a factor that is not affected by gait speed or walking vs running gaits. In this validation study only people with normal FPI-6 scores were included so the variation of coupling across different arch heights at different speeds was not captured. Further, footwear was standardised. People with extreme foot types were not included in the study in chapter five with the FPI-6 baseline score ranging from -3-+6 (supinated to pronated but not highly supinated or highly pronated). Similarly, foot deformity was also excluded which would include midfoot deformities deemed to be clinically abnormal such as midfoot arthritis with enlargement of the medial column joints.

Injuries also seem to affect coupling (DeLeo *et al.*, 2004). Coupling, for example is affected in chronic ankle instability. People with chronic ankle instability can show variations in coupling. however these mainly affect the swing phase with greater coupling and less variability in early swing and less coupling in late swing (Drewes *et al.*, 2009; Herb, Chinn and Hertel, 2016). Anterior knee pain may also be associated with altered coupling. Here an increase in heel eversion and internal tibial rotation coupling has been reported. In the current study and in chapter 5 no participants had any injury (or history of injury) and were pain free while running.

Limitations of this study include walking speeds that were not comfortable and at the point of transition to running as discussed above and the fact that running at the speeds used in later studies (chapter 5) were not assessed. This was a pragmatic approach as there were difficulties in keeping the markers in view for 3D motion analysis of the heel and midfoot at faster speeds. Techniques such as the use of elasticated tape (eg Coban™) to secure markers was not possible because of the anatomical proximity of the markers. Cyanoacrylate ('Superglue') may not be helpful due the skin being glabrous and prone to sweating. The use of superglue to attach markers also posed ethical considerations. Another limitation was the fact that to view the heel and mid markers a sandal was used. This may have implications for generalisability to other shoe types that vary in terms of contact with the foot. Finally, to allow positioning of the in-shoe sensor this had to be positioned shifted posteriorly (figure 4.3). This is therefore not the standard fitting procedure that has been used in previous reliability studies. Although positioning was standardised and felt to be repeatable this was not directly measured.

4.6 Conclusion

This study showed that coupling was greatest when people walked at comfortable speeds and was greatest between the heel-midfoot eversion and DAI and ankle eversion. This suggests that these measures could be used with caution to assess dynamic changes in foot posture while running in study 5. In particular, pedobarograph measures show promise as they indirectly measure foot function and are not as subject to variations in shoe type and function during running as measures that use shoe-attached markers.

4.7 Summary

A novel tool to measure foot and ankle movement during in-shoe running was developed in this chapter. The correlation with foot kinematics at a comfortable brisk walking speed was moderate for ankle eversion and the dynamic arch index although poor for leg on foot rotation despite coupling of tibial rotation with rearfoot:midfoot eversion being consistent with previous studies. There was a significant but poor relationship between ankle eversion and leg rotation at fast walking speed when participants reported using a forced walking gait to avoid transition to running. The correlation of the ankle eversion and DAI measures allows these to be used with caution to evaluate in-shoe kinematic changes during the running trials in chapter 5.

Chapter 5 : A study to measure the changes in ankle invertor strength, medial ankle soft tissue stiffness and foot posture after an hour of treadmill running

5.1 Introduction

The results of the foot posture study conducted at the Plymouth Half Marathon in chapter 3 showed that navicular height (NH) and foot posture index (FPI-6) measures changed after athletes had run the 13.1-mile over ground distance. The NH measure showed a drop of 5.2 mm in the right foot and 4.23 mm in the left. The FPI-6 score increased (statistically significant on the left foot only) by two points in the left foot – the same as a previous study of 60 minutes of over ground running (Escamilla-Martínez *et al.*, 2013).

The mechanism for the change in foot posture (in the absence of overt injury) during prolonged running remains unknown. Similarly, the timing of changes in foot function and biomechanics that lead to the change in foot posture also remain vague. With respect to the mechanism of change, as discussed in chapter 1, an increase in soft tissue volume has been negated as a reason (Chlíbková *et al.*, 2014) leaving changes in soft tissue stiffness and muscle strength as the likely underlying cause.

Understanding the extent of foot posture change along with the mechanism and timing of the changes in foot function and biomechanics in prolonged running would help understand the differences in foot function at different stages of a long-distance run and may, in future, be useful in understanding more about RRIs.

5.1.1 Running trial duration

Foot posture has consistently been shown to alter with 60 minutes or longer duration of running (Fukano and Iso, 2016; Fukano *et al.*, 2018); including the findings of the half marathon study in chapter 3 of this thesis. At 45 minutes, however, there is more variation (Boyer, Ward and Derrick, 2014; Bravo-Aguilar *et al.*, 2016) as discussed in chapter 1.

In this study, controlled laboratory conditions will replace the over ground running conditions of the half marathon study of chapter 3 to facilitate repeated measurement of foot kinematics and plantar pressure at ten-minute intervals during prolonged treadmill running trials.

An hour duration of running was selected for this study for both pragmatic and biomechanical reasons. Running on a treadmill can be tedious, and recruitment to the study would likely have suffered with a longer duration but foot posture also consistently alters at and beyond 60 minutes of running negating the need for longer trial times. Studies have also demonstrated muscle strength and stiffness reduction in an hour or less of running (Lepers *et al.*, 2000; Rahnama, Lees and Reilly, 2006; Peltonen *et al.*, 2012). Finally, changes measured during 60 minutes of running will help to understand foot and ankle biomechanics and function within 5 km (average run time of 28.14 minutes (ParkRun, 2017), 10 km, half marathons and longer runs. The average time to complete the half marathon in chapter 3 was 2 hours 2 minutes (*SD* ±22.36) which is very close to other half marathon average run times (2 hours 1 minute) (Marastats, 2019).

5.1.2 Trials running velocity and the Borg Scale

To ensure the measures compare like to like with respect to the forces generated at different gait speeds, run speed needs to be controlled throughout the trial – a method used in other laboratory running research where 70 % of maximum running speed was used for trials after determining peak rated perceived exertion (Boyer, Ward and Derrick, 2014).

In the current study people were required to achieve a running velocity with constant exertion rated at 'light to somewhat hard' on the Borg rating of perceived exertion scale (RPE) (Borg, 1998; Lamb, Eston and Corns, 1999; Fletcher *et al.*, 2013). This aided recruitment as runners with a range of abilities were able to participate in the study reflecting current mass sporting events. The rating of light-somewhat hard equates to approximately 70 % of maximal running exertion reflecting work by Boyer, Ward and Derrick (2014). The Borg RPE score has excellent validity to numerous physiological variables affected by exertion including heartrate and blood lactate levels (Chen, Fan and Moe, 2002). Reliability in rating exertion during fifteen minutes of running is excellent at running velocities of 11-13 km/h (Lamb, Eston and Corns, 1999; Coquart and

Garcin, 2007). The running velocities cited in Boyer, Ward and Derrick (2014) were 10.34-12.24 km/h indicating that the Borg RPE score will be a reliable measure of exertion in this study.

5.1.3 Footwear in the running trials

Runners in all but one of the foot posture studies cited in Table 1.1 used their own running shoes for the trials with no noted controlling for design, fit or fatigue of the footwear. The study that did control footwear (Escamilla-Martínez *et al.*, 2013) used the Mizuno Wave Rider 12 shoe which was released in 2009 and described as a shoe for 'neutral runners' (Figure 5.1). The current study controlled for footwear by only entering participants who could run in their own or the laboratory's neutral running shoes (similar to those in Figure 5.1) where fit was secure and comfortable and the shoe was in good condition without signs of midsole fatigue. Runners who wore minimalist or maximalist footwear to run in were not entered into the study to avoid the effect of footwear on the running biomechanics or the accommodation of the in-shoe FScan™ sensor. Controlling for footwear may be less important than previously thought after a recent study (Jafarnezhadgero, Alavi-Mehr and Granacher, 2019) showed no difference between any kinetic or kinematic variables in women during a fatiguing run.

Figure 5.1 Mizuno Wave Rider 12 shoe used in study by Escamilla-Martinez et al. (2013) due to its neutral shoe design (*Mizuno Wave Rider 12*, 2019)

5.1.4 Aim

This study aimed to measure foot posture, strength and stiffness before and after an hour-long treadmill run and obtain pedobarographic and kinematic data at intervals during the run to determine when changes in foot movement occurred that may lead to the change in foot posture demonstrated in chapter 3.

The primary study aims are to determine if:

1) foot posture changed after running for an hour on a treadmill
2) maximal voluntary isokinetic eccentric strength reduced after an hour of treadmill running

3) mean medial foot and ankle soft tissue stiffness increased after an hour of treadmill running

The secondary study aims are to determine:

when any changes in foot kinematics occur using the two proxy measures of heel-midfoot eversion/inversion assessed in chapter 4.

The study will also investigate if there is any relationship between changes in proxy measures of foot movement (eg Dynamic Arch Index / ankle eversion) during an hour of treadmill running and:

(a) changes in maximal isokinetic muscle strength

(b) medial foot and ankle soft tissue stiffness

(c) baseline foot posture, age

(d) Body condition / fitness

5.1.5 Hypotheses

The following primary hypotheses were formed relating to the above aims:

1. *Null:*

   There will be no change in foot posture after an hour of treadmill

Alternative:

There will be a change in foot posture after an hour of treadmill running with the foot becoming more pronated in resting stance.

2. *Null:*

There will be no change in foot and ankle invertor maximal voluntary eccentric isokinetic contraction strength after an hour of treadmill running.

Alternative:

There will be a change in foot and ankle invertor maximal voluntary eccentric isokinetic contraction strength after an hour of treadmill running with a reduction in foot and ankle invertor maximal voluntary eccentric isokinetic contraction strength.

3. *Null:*

There will be no change peak stiffness of the medial foot and ankle passive soft tissues after an hour of treadmill running.

Alternative:

There will be a change peak stiffness of the medial foot and ankle passive soft tissues after an hour of treadmill running with a decrease in peak stiffness of the medial foot and ankle passive soft tissues.

4. *Null*

There will be no relationship between changes in proxy measures of foot movement (Dynamic Arch Index / ankle eversion) during an hour of treadmill running and:

(a) changes in maximal isokinetic muscle strength

(b) medial foot and ankle soft tissue stiffness

Alternative

There will be a relationship between changes in proxy measures of foot movement (Dynamic Arch Index / ankle eversion) during an hour of treadmill running and:

(a) changes in maximal isokinetic muscle strength

(b) changes in medial foot and ankle soft tissue stiffness

5. *Null*

There will be no relationship between:

(a) FPI-6 and NH
(b) FPI-6 and changes in maximal isokinetic muscle strength
(c) FPI-6 and medial foot and ankle soft tissue stiffness
(d) NH and changes in maximal isokinetic muscle strength

(e) NH and medial foot and ankle soft tissue stiffness

Alternative

There will be a relationship between:

(a) FPI-6 and NH

(b) FPI-6 and changes in maximal isokinetic muscle strength

(c) FPI-6 and medial foot and ankle soft tissue stiffness

(d) NH and changes in maximal isokinetic muscle strength

(e) NH and medial foot and ankle soft tissue stiffness

5.2 Methods

5.2.1 Ethical approval and data security

Ethical approval was sought from the Faculty of Health, Education and Society ethics committee, Plymouth University. All participants were given a unique randomly generated code and personal information (name / contact details) was kept separate and destroyed at the end of the study.

All data and information collected in the study was stored on the University storage drive which is password protected and any backup copies were password protected, encrypted and stored in a locked cabinet at the PAHC building of Plymouth University when not in use.

The study information and consent forms can be found in Appendix 3.

5.2.2 Sample size calculation

In chapter 3, foot posture, using the navicular height (NH) measurement, was assessed before and after a half marathon. Navicular height dropped on average by 4.7 mm (±6.5) from a mean baseline height of 47.3 mm. This demonstrated an increase in pronated resting foot posture. To detect a similar effect size in the current study 33 participants were required (alpha= 0.05 power=0.8) for the test of running. This would also allow for multiple regression with up to three variables.

5.2.3 Recruitment

Participants were recruited through convenience sampling from adverts placed in local running / sports club houses, pop-up recruitment stands at running clubs and events, social media websites as well as via adverts placed around the University. It was made clear that for students who volunteered that participation or withdrawal from the study would not affect their studies in any way.

People who replied to the adverts were sent an information sheet via post / email. Volunteers had at least a twenty-four-hour period during which they could ask questions about the study prior to providing fully informed written consent. All participants were free to withdraw from the study at any point whereupon all data pertaining to them was permanently destroyed. Each running trial data collection session took up to two and a half hours to complete.

5.2.4 Eligibility criteria

Inclusion

Volunteers were included in the study if they met the following eligibility criteria:

- Adults between the ages of 18 and 65 were eligible to enter the study
- Able to comfortably complete an hour of running at self-selected speed on a treadmill and had achieved similar tasks in the previous 3 months without detriment to health

Exclusion

Volunteers were excluded from the study if they:

- Had a history of cardiorespiratory conditions that limited exercise capacity (cardiac arrest, stroke, angina, exercise induced asthma)
- Were unable to safely use a treadmill under supervision
- Had pacemakers or other internal medical devices
- Had current foot, ankle or leg pain, or any disease or condition that affected the neuromuscular system, connective tissue or joints including surgery that had significantly altered function eg hallux valgus surgery or joint arthrodesis or arthroplasty

- Wore foot orthoses in daily life

  Wore motion control footwear to run or who usually run barefoot or in minimalist footwear
- Wished to run in their own neutral running shoes but these were deemed by the data collector to be in inadequate condition to withstand the trial, interfere with data collection, not be of similar enough design to the lab shoes or likely to adversely affect the measurements being taken during running trials
- Had foot / ankle deformity eg tarsal coalition
- Had reduced foot or ankle range of movement (determined clinically with manual screening) with associated changes in the joint eg osseous end feel
- Was pregnant or post-partum up to 12 months

Whilst participants were not explicitly asked about recent changes to their running technique, it was assumed that they were running comfortably and authentically if they had not recently injured according to the above criteria.

5.2.5 Data collection protocol

Following the pre-entry screening process including manual screening of joint range of movement in the feet and observation for deformity, participants confirmed consent to enter the study (they had been given >24 hours to consent prior to this, with study information and form sent by email to them in the days before attending for their running trial). With the trial consent completed the first measures were taken (height, weight, FPI-6, NH, invertor strength and medial foot and ankle soft tissue stiffness) according to the protocols in chapter 2.

Participants were then asked to familiarise themselves with the treadmill controls and talked through safety procedures to abort the trial if needed. Participants had brought with them running attire that allowed access to the leg for application of markers. Socks that allowed the malleoli to be exposed were supplied if required. Participants could wear their own neutral footwear where they had it or else wear the laboratory trainers which are neutral however no runners chose to use the laboratory footwear and all had suitable neutral running shoes.

The 3DMA markers and a plantar pressure sensor were fitted to their right lower limb and shoe. The calibration offset for the 3DMA was conducted while seated on the stationary treadmill belt on a chair, and then a standing step calibration of the FScan™ sensor was undertaken. The chair was removed, and the participant offered a further comfort break and for anything else they needed such as a drink of water or fans trained on them while running which was undertaken immediately.

Participants then spent up to two minutes determining a self-selected running speed which they could maintain comfortably for an hour at a Borg RPE level of light-somewhat hard at about 70 % of maximal effort. This had been communicated to them prior to visiting the lab to enable them to determine this in their own time too. This helped ensure there was artefact-free data collection. After this there was a two-minute rest prior to data collection.

Crash mats were placed at the back and both sides of the treadmill since the rails had been removed to ensure minimal missing data from motion analysis markers occurred, and the laboratory was kept cool with fans. Paper towels were available at the request of the participant and a glucose drink, water, bananas and biscuits were available and a chair to sit on to recover after the tests. A telephone was available in the laboratory in case of emergency and a first responder was on alert that an endurance test was being undertaken. During out of hours trials a further person was present in case of emergency. Infection control was ensured with disinfectant wipes for the treadmill and chlorhexidine gluconate 2 % spray for the inside of lab trainers.

During the trial, measurements of leg and shoe movement (kinematics) and plantar pressure data samples were taken every 10 minutes. A ten second recording of at least five right steps at a frequency of 100 Hz was required to inform the Dynamic Arch Index pressure map. Additionally, participants were asked to rate their perceived exertion on the Borg scale and to indicate the site and severity of any pain on a 0-10 numerical rating scale.

The test and subsequent tests were stopped before the 1 one-hour period elapses if any of the following occurred:

- Pain exceeding level 5 out of 10 on the numerical rating scale
- Chest pain
- Signs of poor perfusion (cyanosis, pallor)
- Participant asks to stop
- Signs of asthma (wheezing, high respiratory rate, paraesthesia, shallow breaths)

Points above include absolute and relative indications for terminating exercise test as given by the American College of Cardiology / American Heart Association task force on practice guidelines (Fletcher *et al.*, 2013).

- Faults develop in hardware eg sensors fail

Additionally, we stopped the test if their perceived exertion (Borg RPE score) exceeded 17 (very hard). In this case we performed the post-trial measures if the participant was willing.

Baseline demographic data and training history

The following data were collected at the start of the trial:

- Age
- Height and weight

- Shoe size
- Weekly running mileage
- Footwear type and condition currently worn for running long distances
- Oral contraceptive pill use and history of pregnancy for females - this was assessed due to the known effects of oestrogen and progesterone on collagen stiffness

5.2.6 Outcome measures

Primary outcome measures

These were measured before the onset of running and within the 5-minute period after the cessation of running. The order of testing was static foot posture (FPI-6 then NH) then stiffness and strength.

1. *Static foot posture*

Static foot posture was assessed before and immediately after the run using the FPI-6 and NH as outlined in chapter 2

2. *Medial foot and ankle soft tissue stiffness*

Medial foot and ankle soft tissue stiffness was assessed as outlined in chapter 2.

3. *Eccentric invertor muscle strength*

Eccentric invertor muscle strength was assessed as outlined in chapter 2.

Secondary outcome measures

As highlighted in chapter 4, three proxy measures of heel-midfoot eversion were assessed:

1. *Ankle eversion measured using 3D motion analysis*

2. *Tibial internal rotation measured using 3D motion analysis*

3. *DAI measured using a pedobarograph*

These secondary outcome measures were taken after 1 minute, 10, 20, 30 40, 50 and 60 minutes of running. Pedobarograph data and 3DMA data were synchronised using a Power1401 (CED, UK) which sent TTL triggering signals to both devices.

5.3 Analysis

5.3.1 Analysis of changes before, after and during running

FPI, NH, strength and stiffness data were assessed for normality using a Shapiro-Wilks Test and were found to be normally distributed. This allowed selection of parametric comparison of means between pre- and post-running measures which were analysed using paired t-tests. A Bonferroni correction was given to account for multiple comparisons (n=4 P=0.05/4=0.01) reducing the chance of a type 1 error in comparison of strength, stiffness, FPI-6 and NH.

Kinematic and pedobarograph measures taken during the run at 10 min intervals were analysed using a repeated measures ANOVA with factors being time (7 levels 0, 10, 20, 30, 40, 50, 60 mins).

5.3.2 Analysis of factors associated with changes in static and dynamic foot posture

The association between the change in FPI and NH and change in (a) invertor eccentric strength and (b) medial foot and ankle stiffness was assessed using linear regression.

A stepwise multiple regression was used to explore the relationship between the change in DAI at the start and end of the exercise trial and:

- change in medial foot and ankle soft tissue stiffness and change in isokinetic (eccentric) invertor ankle strength
- baseline characteristics of foot posture, gender, age, strength and stiffness

5.4 Results

5.4.1 Participant characteristics and demographics

In total 28 healthy people were recruited (19 men, 9 women, aged 36.7 (12.3)yrs). The demographics for the participants are shown in more detail in tables 5.1 and 5.2.

Parameter	**Value**
Male:Female ratio	19:9
Age [yrs] (SD)	36.7 (12.3)
BMI [kg/m^2] (SD)	21.8 (1.2)
Usual weekly mileage [miles] (SD)	22.1 (15.0)
Trial running speed [km/h] (SD)	9.6 (2.3)
Last time ran [days] (SD)	4 (5.5)
Best mile time [mins] (SD)	7.8 (1.3)
Miles run in shoe [miles] (SD)	444.7 (398.6)

Table 5.1 Participant demographics and characteristics

Factor	Categories	Frequencies	Percent
Other exercise	Aerobics	1	3.6
	Cycling	3	10.7
	Hockey	1	3.6
	Turbotrainer	1	3.6
	None	22	78.6
Shoe type	Neutral	25	89.3
	Stability / control	3	10.7
Shoe condition	New	3	10.7
	Good	23	82.1
	Moderate	2	7.1

Table 5.2 Further participant demographics and information

5.4.2 Changes in primary outcome measures with running

28 records were recorded for foot posture measures and FPI-6 significantly increased following running by +1.3 Rasch points (±0.9) ($P<0.001$) while navicular height significantly decreased by -1.6 mm (±2.2) ($P<0.001$). 28 records were available for analysis of strength and stiffness and there was a statistically significant decrease in stiffness of -1.12 Nm/rad.kg (±2.86) ($P<0.05$) and strength decreased by -6.11 Nm (±8.94) ($P<0.001$) with running (table 5.3). The magnitude of change in strength was a reduction of 21.2 % and stiffness reduction of 10.8 %.

N=28	**Pre-mean (SD)**	**Post-mean (SD)**	**Change (SD)**
FPI [Rasch]	0.93(1.70)	2.27(2.00)	1.34(0.92)†
NH [mm]	47.71(6.77)	46.09(6.59)	-1.63(2.17)†
Stiffness [Nm/rad.kg]	10.41(4.56)	9.29(4.17)	-1.12(2.86)*
Strength [Nm]	28.80(10.05)	22.70(7.64)	-6.11(8.93)†

Table 5.3 Changes in FPI-6, NH, medial ankle stiffness and invertor strength after 1h of treadmill running (±SD) (*=P<0.05, †=P<0.01)

5.4.3 Changes in the secondary outcome measures during the running trial

Due to difficulties maintaining artefact-free recordings records gathered decreased over time; this varied depending on the measure taken and there was greater artefact with the pedobarograph recordings (table 5.4).

Twenty seven complete data sets for the kinematic data variables were analysed and then a separate analysis was made for the 17 participants who had consecutive, artefact-free pedobarograph data and kinematic data up to 60 mins (table 5.4).

Recording time (mins)	Pedobarograph records	Kinematic records
0	28	28
10	27	27
20	26	27
30	24	27
40	21	27
50	19	27
60	17	27

Table 5.4 Number of records available for pedobarographic measures and kinematics

Changes in ankle eversion

Data was normally distributed. There was a significant effect of time (Time $F(6,156)=4.67$, $P<0.001$), with ankle eversion (shank on shoe) increasing over time. A priori contrasts compared the baseline ankle eversion with measures taken at each time point. There was significant difference in eversion from 30 mins onwards (table 5.4). There was also a significant effect of time ($F(6,84)=3.13$, $P<0.001$) when the 17 data complete sets were analysed (table 5.5). Here, a priori contrasts showed a difference in ankle eversion from 50mins onwards although this did not reach statistical significance ($P=0.052$). As highlighted in table 5.5 the increase in eversion plateaued after 30 mins.

Changes in tibial internal rotation

Data was normally distributed and included here due to the close relationship identified with coupling findings in other work although should be taken with extreme caution due to no significant relationship being found in chapter 4 with midfoot:rearfoot kinematics.

There was a significant effect of time (Time $F(6,156)=7.85$, $P<0.001$) with an increase in tibial internal rotation (shank on shoe) over time. A priori contrasts compared the baseline tibial internal rotation with measures taken at each time point. There was significant difference in tibial internal rotation from 30 mins onwards (table 5.5). There was also a significant effect of time ($F(6,84)=6.95$, $P<0.001$) when the 17 data complete sets were analysed.

Changes in Dynamic Arch Index (DAI)

Data was normally distributed. There was a significant effect of time (Time $F(6.96)=4.47$, $P<0.001$) with an increase in the DAI over time. A priori contrasts compared the baseline DAI with measures taken at each time point. There was a significant difference in DAI from 10 mins onwards with a significant effect of time ($F(6,84)=4.64$, $P<0.001$) (table 5.5) when the 17 data sets were analysed. A priori contrasts showed a significant difference after 10 mins and then from 30 mins onwards.

	0 mins	10 mins	20 mins	30 mins	40 mins	50 mins	60 mins
Ankle eversion [deg] (n=17)	12.3 (8.69)	16.73 (11.60)	15.94 (9.88)	18.66* (13.04)	21.04* (14.51)	19.92* (12.41)	18.34* (11.14)
Tibial internal rotation on shoe [deg] (n=17)	6.67 (4.26)	6.60 (3.63)	7.26 (4.23)	8.08* (4.02)	8.71* (3.81)	8.88* (4.12)	9.03* (4.37)
DAI [%] (n=17)	33.93 (8.39)	35.03* (8.06)	35.31* (8.26)	35.23* (8.23)	35.74* (8.38)	36.07* (8.37)	35.88* (8.24)

*indicates significant difference from baseline (0 min) measure

Table 5.5 Changes in kinematics and pedobarograph recordings (mean ± standard deviation)

5.4.4 Relationships between foot posture and strength and stiffness

The change in FPI-6 was negatively associated with a change in NH (r=-0.41 P<0.05). There was, however, no relationship between FPI-6 or NH change and the change in strength (r=-0.16, r=0 P>0.05 respectively) or the change in stiffness (r=0.14, r=0 P>0.05 respectively).

People with higher baseline stiffness and higher baseline strength showed larger reductions in stiffness (r=-0.44 P<0.05) and strength (r=-0.68, P<0.0001) following running.

5.4.5 Relationship between the change in foot posture, strength and stiffness, and secondary outcome measures

There was no relationship between any of the secondary outcome measures (DAI, ankle eversion or tibial internal rotation) at 60 minutes and the change in either foot posture measure (FPI-6 and NH) (table 5.6).

Secondary outcome measure after 60 minutes running	r value FPI-6 (Rasch) change	r value NH change
DAI (n=17)	0.30	0.15
Ankle eversion (n=17)	0.25	0.40
Tibial internal rotation (n=17)	0.38	0.46

Table 5.6 Relationship of secondary outcome measure changes at 60 mins and FPI-6 and NH (none reached statistical significance)

Secondary outcome measure after 60 minutes running	r value invertor strength change	r value medial ankle stiffness change
DAI (n=17)	0.06	0.22
Ankle eversion (n=17)	0.25	0.10
Tibial internal rotation (n=17)	0.07	0.19

Table 5.7 Relationship of secondary outcome measure changes at 60 mins and change in invertor strength and medial foot and ankle soft tissue stiffness (none reached statistical significance)

5.4.6 Relationship between change in foot posture measures and baseline characteristics

The change in FPI-6 was positively associated with running speed (r=0.4 P<0.05).

Males ran further than females (P<0.05) in the trials, and older people ran higher weekly mileages (r=0.39, P<0.05), but there was no relationship between trial running speed and age (r=0.35, P>0.05) (figure 5.2). There was a significant association, however, between trial running speed and weekly mileage (r=0.48, P<0.05) and quoted mile times (figure 5.2). There was a low–moderate relationship between trial running speed and quoted weekly mileage and mile times (figures 5.2). Runners who quoted faster mile times ran faster in the trial (R^2=0.39).

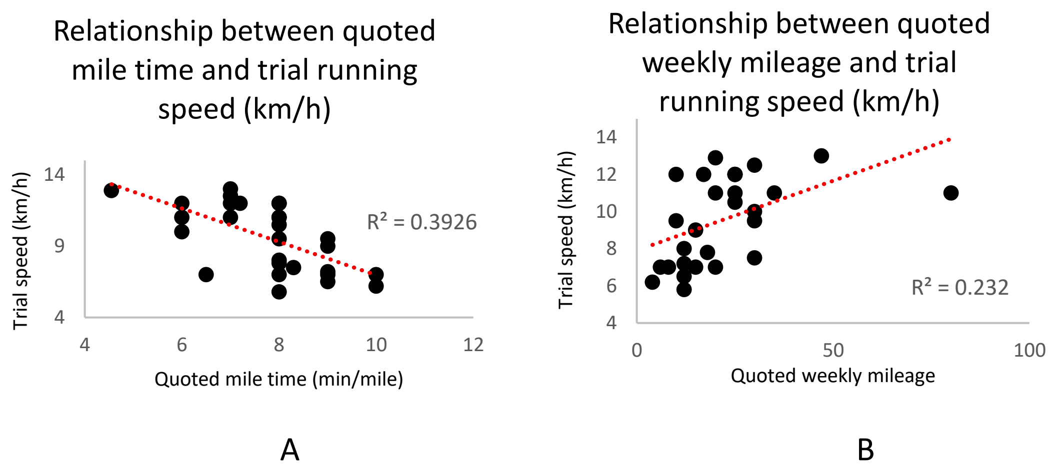


Figure 5.2 A) Relationship between quoted mile time and trial speed and B) Relationship between quoted weekly mileage and trial speed

5.4.7 Relationship between strength, stiffness, fitness and baseline characteristics

There was no relationship between peak isokinetic eccentric invertor strength and trial running speed.

There was also a low relationship (R^2=0.23) between self-selected trial running speed and weekly mileage and only a very low relationship between trial speed and FPI-6 change; there was negligible relationship between change in NH and trial speed (figure 5.3).

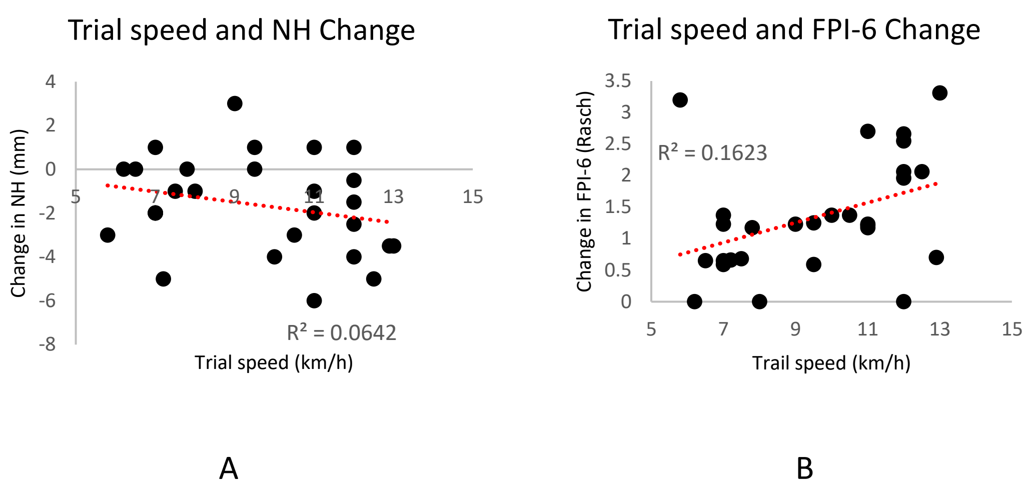


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Figure 5.3 Relationship between trial speed and A) NH and B) FPI-6

5.5 Discussion

The results showed a similar change in foot posture as in chapter 3 although with a smaller effect reflective of the shorter duration of running, but also possibly the effect of running on a motorised treadmill. In the half marathon study the reduction in NH was -4.75 mm (chapter 3) and in this study, -1.62 mm

whilst the FPI-6 increased +2 in chapter 3 and +1 here. These changes reported to 2 decimal places, did not meet the smallest detectable difference (SDD) threshold described in chapter 2 by 0.21 mm for the NH and 0.5 of a Rasch logit point for FPI-6, and so could be interpreted to be a result of chance. The accuracy of the measure used, however, was 1 mm increments and so missing the SDD by a margin less than that, when the number would be rounded up to 5 mm for replication with standard rulers in a clinical environment, should arguably be disregarded and the SDD threshold considered to be met.
Reliability was, excellent for both foot posture measures and since the study was slightly underpowered (n=28 for foot posture measures), the margin over the threshold may have been greater if the study had fully recruited.
The FPI-6, missed the SDD threshold by 0.45 (0.55) Rasch logits and the smallest Rasch logit difference reported by Keenan et al. (2007) is 0.51. The next logit from -1.62 is -2.12 so if rounded to this number, the change in FPI-6 score also meets the threshold for SDD.
There was a significant moderate relationship between the FPI-6 and NH measures of foot posture in this study which contradicts findings in other work (Langley, Cramp and Morrison, 2016). The size of the change in foot posture in this study may or may not be of clinical relevance but the form of the foot determines lever arm function (and dysfunction) so deformation of the MLA would alter the mechanics of the tendons and muscles acting on it in gait, similar but on a smaller scale, to that seen in adult acquired flat foot. Further work is needed to evaluate this.

The stress on internal soft tissues and bone was not measured during running in this study but stiffness and strength both reduced in the leg and ankle indicating that greater stress may be placed onto the intrinsic muscles and passive soft tissues such as the plantar fascia.

The magnitude of change in strength was a reduction of 21.2 % and stiffness reduction of 10.8 %. The change in strength was -6.11(8.93) and the SDD was 20.07 Nm whilst the change was at first quite stark, this is some way under the SDD threshold and may be the result of chance. The finding was highly statistically significant, however, and whilst the standard deviations were large the detected change is encouraging since the number of records available for analysis of this variable was also 28 when the study was powered for 33. With a fully powered data set the variance in the data may have reduced although the change in strength would likely still not meet the SDD threshold of 20.07 Nm. A change of 20.07 Nm, however is extremely large and not likely to be experienced by a typical runner ever as it equates to 74 % loss of strength and changes of ~20% are more commonly reported (Lepers *et al.*, 2000; Petersen *et al.*, 2007; Saldanha, Nordlund Ekblom and Thorstensson, 2008). The same is true for the measure of stiffness. The SDD for medial foot and ankle soft tissue stiffness in chapter 2 was 7.32 Nm/rad.kg and given the mean baseline stiffness in this thesis was 13.04 Nm/rad.kg this would equate to a 56 % increase in compliance during running. The values for change of stiffness in other studies were in the region of zero (Peltonen *et al.*, 2012) to 11 % (Obst, Barrett and Newsham-West, 2013) so detecting a 56 % loss of stiffness would likely indicate injury and as such the SDD in this thesis is considered to be statistically rather than clinically useful.

A secondary aim of this study was to determine when changes in foot movement occurred during the hour of running. All participants demonstrated changes in DAI, internal tibial rotation and ankle eversion by 30 minutes into the run. A further 30-minute running trial would be required to test whether a change in static foot posture occurs after 30 minutes of running as neither DAI, internal tibial rotation or ankle eversion correlated to the change in either foot posture measure after 60 minutes of running in this study. The study was underpowered due to insufficient recruitment and incomplete data sets for the secondary outcome measures due to data artefact, but the changes after 30 minutes of running are consistent with other patterns of exercise-induced fatigue which also manifest at 30 minutes (Stirling *et al.*, 2012).

Of note, the participants in this study included one runner with a 4-minute mile time. This participant also changed DAI and kinematics within the 30 minute period indicating that the change may be common to highly conditioned and less conditioned runners, although tolerance of the change may not be equal as less conditioned runners tend to injure more frequently than highly conditioned runners (van der Worp *et al.*, 2015).

The cause of changes in foot posture were explored. Although muscle strength and stiffness significantly reduced this was not related to a change in static foot posture. This may be due to changes occurring elsewhere that could affect foot posture.

Changes in strength and stiffness have been reported to occur in other muscles proximal to the ankle (and will be discussed below) although another explanation relates to the calf muscle not significantly weakening or becoming less stiff during running, and continuing to exert a flattening force across the medial longitudinal arch. Several studies (Farris, Trewartha and McGuigan, 2012; Peltonen *et al.*, 2012; Obst, Barrett and Newsham-West, 2013) have reported no change in strength or stiffness in the calf muscle and Achilles tendon to at up to two hour running bouts.

There was a correlation between running trial speed and foot posture change which may indicate that foot posture changes are greater in people with higher impulse at initial contact. FScan™ force data could be used to explore this but was not undertaken here. A future study designed around BMI, running speed and running style may address this. Impulse has been found to be higher in military recruits with stress fractures than uninjured counterparts (Nunns *et al.*, 2016) although any relationship to foot posture has not yet been demonstrated.

5.5.1 Limitations of the study

There were challenges in data collection and limitations in the study design which may have affected the outcomes. The study was powered for sample size of 33 to detect a similar change as at the half marathon. Recruitment was difficult despite a road trip around numerous running clubs, shops and regatta events alongside a social media campaign and advertising across the University of Plymouth and the University of St Mark and St John (which specialises in sports science with a high demographic of sportsmen and women). Data collection mostly took place after 6pm to enable participants to enter the study with trials booked after work. The lab was not climate controlled and data collection took place in the summer months but fortunately the lab was cooler in the evenings allowing the use of directional electric fans to keep runners cool during trials.

People with very flat feet (with the midpoint of the medial longitudinal arch in contact with the ground) were considered to have foot abnormality and were excluded at assessment since change in NH was impossible. People with very low arches, however, were entered into the study as theoretically they could demonstrate a reduction in NH. Should their personal capacity for reduction in NH have exceeded the gap between the plantar surface and the floor a false negative result would potentially be recorded.

There were limitations with data collection from confusion about how to invert the foot at the ankle to trigger the Biodex™, to sweaty skin causing loss of adhesion with the Codamotion™ markers. This was overcome with lots of adhesive clinical tape although this may have had a minor effect on the running style of the participants. None reported feeling constrained or consciously different, however.

The time taken to work through the testing protocol, even though it was very well rehearsed, was time consuming when every second counts towards defatigue. The Biodex™ was awkward for some to climb up to despite provision of a step up and assistance. Data was all collected very swiftly, however, and within two minutes.

Convenience sampling has the advantage of swift recruitment but can have drawbacks with those within easiest reach being included in the study. In this study the volunteers were quite homogeneous and of similar socio-economic backgrounds and ethnicity but with a good gender mix. There is under-representation of black and ethnic minority runners in Plymouth running communities, consistent with the local population demographic, so this sample was comprised entirely of Caucasians.

5.6 Conclusion

This study revealed a change in foot posture after an hour of treadmill running at sub-maximal, self-selected speeds. The FPI-6 score increased by 1.34 (Rasch logits) and the NH decreased by -1.63 mm an arguably clinically insignificant difference. Ankle invertor strength reduced by -6.11 Nm, and there was a decrease in stiffness in the medial foot and ankle soft tissues of -1.12 Nm/rad.kg, a reduction of 21.2 % strength and 10.8 % stiffness.

No correlations were found, however, between the changes in invertor strength, medial foot and ankle stiffness and foot posture but the foot posture measures did correlate. Null hypotheses were, therefore, rejected for strength, stiffness and foot posture measures. There were changes in all kinematic and plantar pressure variables after 30 minutes of running although these did not correlate to the changes in foot posture or ankle invertor strength or medial foot and ankle soft tissue stiffness.

The plantar fascia was not tested in isolation during this study but was incorporated in the stiffness testing, to some extent, of the medial structures of the foot and ankle. With evidence emerging suggesting an important role of the plantar fascia, as discussed in chapter 1, testing of the plantar fascia in isolation may reveal changes in stiffness that help explain the change in foot posture during prolonged running.

The study was underpowered for the secondary outcome measures and results should be viewed with caution.

5.7 Summary

In this chapter a change in foot posture was demonstrated after an hour of treadmill running although the mechanism for change remains ambiguous. There were changes in the movement of the foot and ankle at 30 minutes of running and these appeared to plateau up to an hour of running with only very small changes from 30 minutes onwards. This finding, however, requires further testing due to the analysis being underpowered. It is not within the remit of this thesis to undertake this and so the measures will not be used for the last running study in chapter 7.

With recent work demonstrating a key role for the intrinsic structures of the foot in maintaining arch integrity as discussed in chapter 1, it is possible that stiffness of the plantar fascia may change and be more strongly associated with the change if foot posture after prolonged running.

In chapter 1 the role of foot orthoses which prevent arch deformation was discussed, including the reduction of energy return from the plantar fascia during and subsequent greater metabolic demand in running as muscular activity is supplemented to generate the forces required for propulsion where MLA deformation is prevented. The next chapter will explore the development of the novel foot orthosis technology used in both Appendix 1 and chapter 7 aiming to modulate the changes in strength and stiffness of the extrinsic and intrinsic muscles and soft tissues through variable rather than total restriction of proximal arch deformation during running – the aim being to economise on plantar fascia recoil at the midportion and distal MLA, and reduce metabolic demand during running.

Chapter 6 : Proof of concept testing of a novel foot orthosis component versus a frequently used open cell foam

6.1 Introduction

Patent art written prior to this thesis (Appendix 2) introduced the notion of variable resistance and deformation in orthosis componentry, with the aim of providing support when needed as the structures supporting the medial longitudinal arch fatigue, but allowing for small amounts of arch deformation with less resistance when the structures are able to maintain MLA integrity and function at other times. Since the publication of the patents understanding of the weightbearing response of the foot, and the role of the structures in the MLA, has developed to acknowledge the prominent role the intrinsic muscles and plantar fascia have in the maintenance and function of the foot and MLA in particular; this is discussed in chapter 1. Despite the change in understanding of foot function, foot orthosis therapy has remained centred around constant application of force against the foot irrespective of how the foot interacts with the orthosis; foot orthosis shells are still mostly made of semi-rigid designs customised to contour closely with the foot (Menz *et al.*, 2017) similar to the designs used in studies showing a reduction in arch deformation and elastic recoil of the plantar fascia (Stearne *et al.,* (2016); McDonald *et al.*, (2016). Indeed a further study (Maharaj, Cresswell and Lichtwark, 2018) since has demonstrated that 4mm thick polypropylene orthotic shells add no significant energy absorption capacity to the shoe-orthosis system at different walking speeds, due to rigidity of the device. The seemingly obvious solution is to either make the contour of the orthosis shell less contoured to the foot leaving a gap that the foot can lower to during activities leading to a reduction in MLA height; or to create a less rigid orthosis shell which yields more constantly. The first option would potentially leading to the same issue of a 'biphasic' orthosis response as the foot either has no force applied against it or an almost unyielding semi-rigid shell which would create a breaking force against the foot which could be uncomfortable if applied at the point of most movement, the region of the talonavicular joint, where there is an absence of fibrofatty padding. The second option of a less stiff orthosis shell leaves a small envelope of variability where the orthosis will apply the force needed to modulate arch deformation as the forces applied are sufficient to bend but not collapse the shell, the latter event being potentially injurious to the foot with sudden yielding.

The solution proposed here is a layered design with a mouldable semi-rigid shell to achieve constant contact with the foot, with a variable resistance component mounted atop the shell contacting the medio-plantar aspect of the talonavicular joint and a thin top cover to avoid skin abrasion.

This chapter will focus on the design of a variable resistance and deforming component which could be mounted on a semi-rigid, mouldable foot orthosis

(FO) shell to provide curvi-linear orthosis reaction force dependent on the force applied in any one step.

6.1.1 Aim

This chapter will describe the development and testing of a novel FO component that aimed to limit medial longitudinal arch (MLA) deformation loadbearing soft tissue strain dynamically in conditions where there is a variable application of forces such as seen in healthy people during a fatiguing task e.g prolonged running.

6.2 Considerations about the material components of action

Applying orthotic forces in the medial arch was certainly not new. Podiatrists and other health professionals wishing to offer comfortable passive support under the medial longitudinal arch (MLA) of the foot often insert a piece of durable open cell foam between the plantar aspect of the foot and the top surface of a semi-rigid moulded foot orthosis (insole) (Landorf, Keenan and Rushworth, 2001; Bellamy, 2007). Open cell foams have been shown to compress in two phases (Corporation Rogers, 2007):

1) the initial collapse of the cell walls as the air escapes
2) a later phase where the ceilings and floors of the foam cells make contact and the foam ‘bottoms out’. It then begins to act as an increasingly dense block of the material; it will continue to compress but to a lesser extent per unit force

Whilst Poron 4000™ has been shown to have excellent compression qualities for the purposes of ulcer prevention in people with diabetes (Garcia *et al.*, 1994; Paton *et al.*, 2007), it has not been tested widely as a material aiming to respond to increasing rate of loading at the MLA region of the foot. Poron 4000™ is frequently referred to as a 'shock absorbing material' in marketing with this extract taken from a typical sales website:

"Poron 4000™ is used in a wide variety of products. It's firmness offers, high energy return and excellent impact absorption for demanding work/outdoor, athletic & casual applications." (Algeos Ltd, no date)

Shock absorption may be a material characteristic useful in avoiding impact trauma to the bones and joints of the MLA should the rate of loading increase with fatigue during a day of walking or a long distance run. Being a medium durometer open cell foam, however, it may be useful in attenuating lower impact force ranges generated in slower walking but not the higher force ranges generated in faster walking or running where there is a risk of bottoming out of the foam very quickly. Furthermore, no studies have tested whether the effects of Poron 4000™ layered over a semi-rigid shell change foot kinematics.

Private correspondence with commercial orthotic companies working with podiatrists confirmed that the materials placed under the arch most frequently were open cell foams. Another group developing a FO design conducted semi-structured interviews with clinicians prescribing FOs and one of the main themes in the responses to the researchers was that the materials currently available for use in the medial arch provided

> "insufficient resistance to downward motion of the medial arch and eversion motion of the heel." (Majumdar *et al.*, 2013)

This view was shared in part by the author with speculation that offering any constant orthotic support to the foot regardless of activity, velocity of locomotion or time of day, was too simplistic given the evidence emerging about the change in foot posture following prolonged weightbearing (Nagel *et al.*, 2008) in runners. Thus the FO used in this study had a novel design with stiffness (and therefore proposed support) varied according to the rate and magnitude of applied force. The aim of the design was to create a predictable graded response of the FO reaction force according to the rate of loading applied; where acceleration of arch drop is seen alongside invertor muscle fatigue and loss of strength (Pohl, Rabbito and Ferber, 2010) in prolonged weightbearing exercise such as running.

A material or component that could offer a graded orthosis-reaction force response, and which was applied in a similar way (added to the top surface of a semi-rigid foot orthosis) might improve the effect of moulded foot orthoses yet further. By only increasing the orthosis reaction force when necessary the bones and soft tissues would only receive the support when needed, and not when unfatigued. It was proposed to create an FO component that could be inserted into the midfoot that would support the talonavicular joint dynamically.

6.3 Development of a novel foot orthosis component

Together with a team from the University of Plymouth (Cowley, Woolner and Achilles, 2008; Cowley and Achilles, 2009) in 2008, the author proposed a new method of addressing foot overuse conditions that is related to the changing needs of the foot in various gaits, activities and phases of the day and targeted around medial midfoot joints (especially the talonavicular) rather than the subtalar joint alone, after bone pin studies revealed greater excursion of movement in the midfoot than rearfoot joints (Nester, 2009). Prototypes were made but following initial proof of concept tests, there was no means of reproducing them and so the patent and prototyping fell dormant prior to this study.

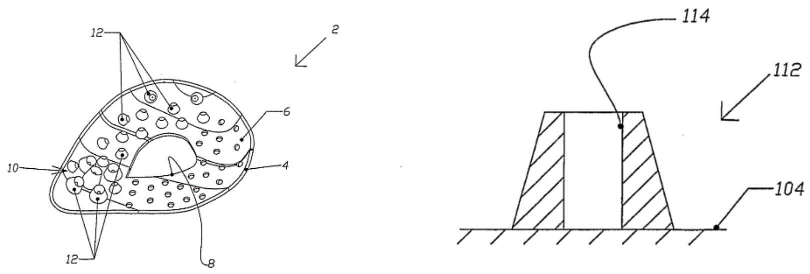


Figure 6.1 Patent art demonstrating the frustoconical design of the active orthosis

6.4 Design process, refinement and prototyping

The initial component was made by 'Innovate', a University of Plymouth spin out company. They produced a hand-crafted prototype which was not reproducible for manufacturing. This prototype was closely related to the designs in the patient (figures 6.1 and 6.2) as described in the patent abstract as follows:

> "An apparatus is provided that responds to the varying pressures applied to the foot of a subject during different activities, in particular walking, jogging and running, comprising a member with a surface for contacting the plantar surface of the foot of the subject; and structures for absorbing and reacting to various pressures in the foot whilst in use. The structures preferably extend from the surface of the member - and are in the form of units having a longitudinal axis extending in the direction of expected impact from the foot of the user, the units being compressible under the action of pressure from the foot, the resistance of the units to compression increasing progressively or stepwise as the unit is compressed. The units are preferably hollow and have an internal or external taper to provide the variable resistance to compression." (Cowley, Woolner and Achilles, 2008)

The prototypes were tested for proof of concept in house (Marsden, Cowley and Essex, 2008, Appendix 1). The results showed a non-linear but gradual increase in force generation with increasing rates of loading.

Figure 6.2 The handmade prototypes used for proof of concept testing with the cones visible in the medial arch area

Development of the prototypes was undertaken by consultancy with 'Simpleware', a University of Exeter spin-out company specialising in digitisation of analogue models. Computed tomography scans of the prototype were taken and the engineers were able to build a surface model, then a CADCAM model (figure 6.3) to be used for finite element testing of various configurations of cones under forces typical of walking and running. The finite element model of the cones set on an 'orthotic shell' and were then re-arranged in various geometric and thickness configurations to determine the most optimal configuration to provide the varied orthotic reaction force to the region of the talonavicular joint and associated structures.

Figure 6.3 First CADCAM model produced from CT scan (top) of the prototype orthosis (bottom) (Simpleware, 2010)

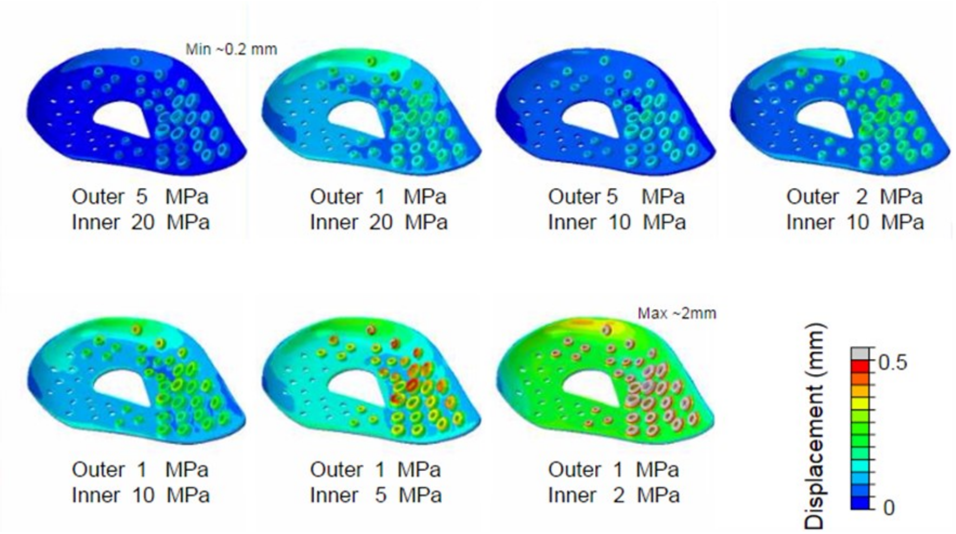


Figure 6.4 Finite element model testing various configurations of cones (height, clusters, geometry) on a semi-rigid shell under loads typical of walking and running.

As the phases of testing continued it became clear that a core set of cones were most operational (figure 6.5).

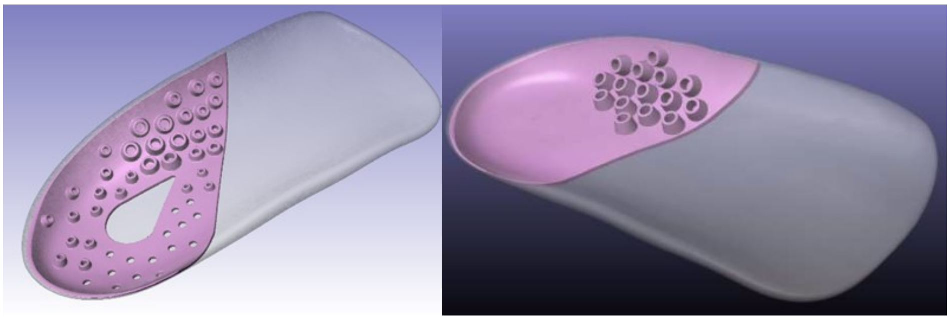


Figure 6.5 The configuration of cones with associated geometry and material characteristics (left) and after the non-operational cones had been removed the area of interest is apparent (right) (Simpleware, 2010

This design was then passed to a mechanical engineer (Mike Felstead, Ideas Realised Ltd, Crediton, UK) who used computer aided design and three dimensional (3D) printing to produce a second prototype seen in figure 6.6.

Figure 6.6 Second prototype of the cones orthotic component without open lumens in the cones

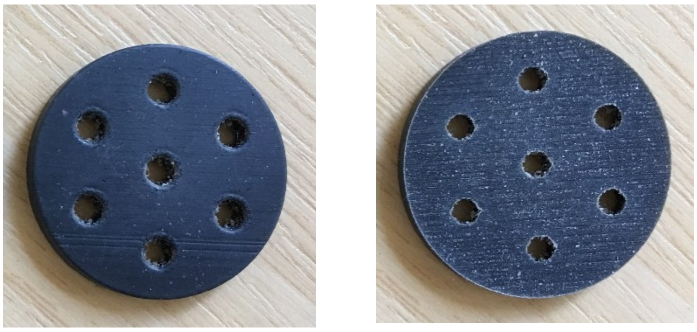
This component was a 30 mm diameter, 6 mm thick, and manufactured from a stiff viscoelastic 3D printing material. The bores of the cones were filled and surrounded by a less stiff version of the same material to provide a matrix or scaffold to stabilise the cones.

This prototype component (figure 6.6) was assessed mechanically in collaboration with Staffordshire University. Here the aim was to use an Instron™ materials testing system to load the component. The test was aborted, however, as the component was deemed to be too stiff as it did not allow compression to 50 % thickness (figure 6.7). The conclusion was that this component design would feel hard and uncomfortable underfoot too and work on a third prototype began.

Figure 6.7 Prototype two in 3 mm and 6 mm thick versions

A subsequent iteration in the design, prototype 3, provided empty lumens in the cones to allow expansion (bulge) of the walls of the cones when compressed (figure 6.8). They were only produced in 3 mm thick discs based on the 6 mm version appearing too thick to be comfortable in the running trials in chapter 7.

This iteration had been shown to produce the variable stiffness effect in the finite element modelling by Simpleware (figure 6.4). The discs were 30 mm diameter, 3 mm thick with evenly distributed cones (figure 6.8).



A B

Figure 6.8 Prototype 3 A) top showing the thin rims of the cones, B) bottom the cones thicker bases

This final iteration was palpably more compliant to compression (figure 6.9) and mechanical testing proceeded at the University of Plymouth. Proof of concept trials were undertaken using the application of different forces at different rates of application to mimic those seen at the midfoot during the running trials in chapter 5 (45.69 N (±18.81 N)).

6.5 In vitro testing of the Cones orthotic component and Poron 4000™

Figure 6.9 Prototype 3 in 3 mm thicknesses x 30 mm diameter discs, visibly compressed with digital pressure

This study was designed to determine proof of concept in the third prototype of the 'Cones' orthotic component through assessment of the physical properties – in particular, its stiffness with different rates of force application.

6.6 Hypotheses

The aim of the experiment was to test the following hypotheses:

1. *Null:*

   There is no difference in the generation of peak force between the Cones and Poron 4000™ discs with increased loading velocity.

   Alternative:

   There is a difference in the generation of peak force between the Cones and Poron 4000™ discs with increased loading velocity – the Cones peak force will be higher.

2. *Null:*

   There is no difference in the rate of loading of the Poron 4000™ and Cones discs with increased loading velocity.

Alternative:

There is a difference in the rate of loading of the Poron 4000™ and Cones discs with increased loading velocity – the Cones rate will be faster.

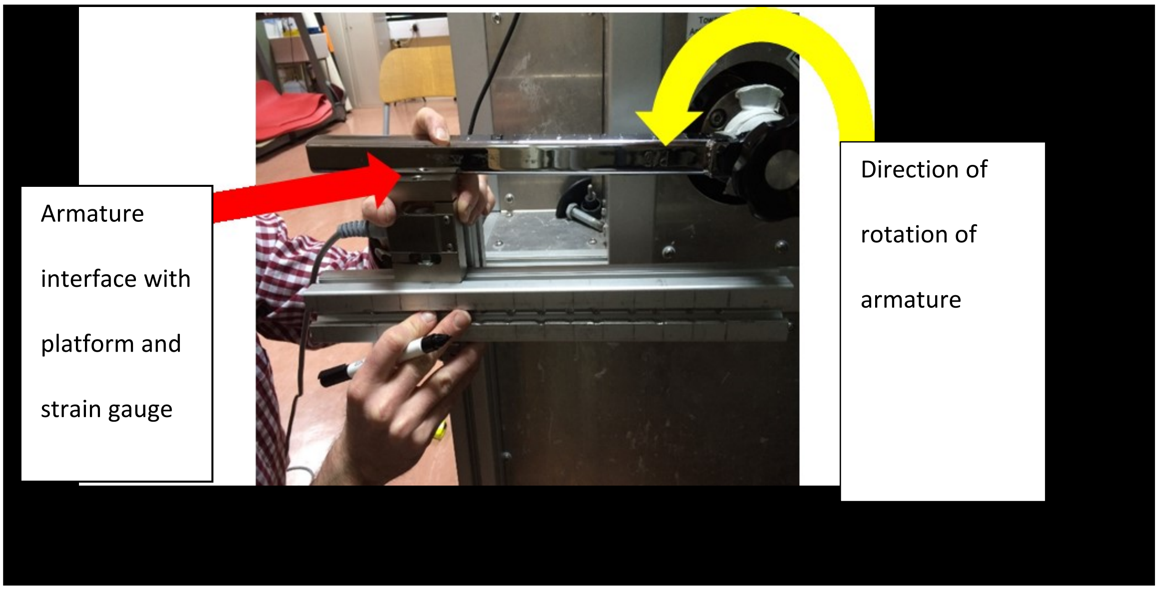


Figure 6.10 Testing rig for the orthotic components. Red arrow shows the platform on which the discs are placed, yellow arrow shows the armature applying compressive force to the disc.

6.7 Methods

A rig was constructed with a stable plate to rest discs of either Poron 4000™ or the Cones (figure 6.10). A strain gauge was placed underneath the plate to record generated forces. Forces were applied using a customised motor with a 10 inch metal armature attached to the motor axis (figure 6.10). As the motorised arm rotated it impacted the discs from above. The compression trials were conducted with the motorised arm moving at 50, 100, 150, 200 and 250 deg / s to create increasing rates of loading. The armature was either unloaded (0 N) or loaded with a 2 kg load (20 N).

Three discs of the Poron 4000™ and Cones were assessed. Their dimensions were identical (30 mm diameter, 3 mm thickness).

Analogue signals from the strain gauge were sampled at 1000 Hz (1401 CED, Cambridge) using SPIKE 2 software.

The maximal transmitted force and the rate of force loading as measured using the strain gauge was measured using SPIKE 2 software. The underlying theory is that a stiffer material will transmit more force with less absorption of kinetic energy.

6.8 Analysis

Data was assessed for normality using a Shapiro-Wilks test. A between group repeated measures ANOVA was conducted for each loading condition (0 and 20 N) with the group being disc type (2 levels disc: Cones vs Poron 4000™) and factor being velocity of loading: (5 levels, 50, 100, 150, 200, 250 deg/s). Alpha was set at $P<0.05$.

6.9 Results

6.9.1 0 N Loading condition

1. *Maximal force transmitted*

There was a significant difference between groups with Poron 4000™ generating lower forces than the Cones (mean 31.24 (SE 0.50) vs 34.55 (SE 0.5) P<0.05, figure 6.12).

There was a significant effect of velocity with higher forces being seen with higher velocities of loading (P<0.05, figure 6.11).

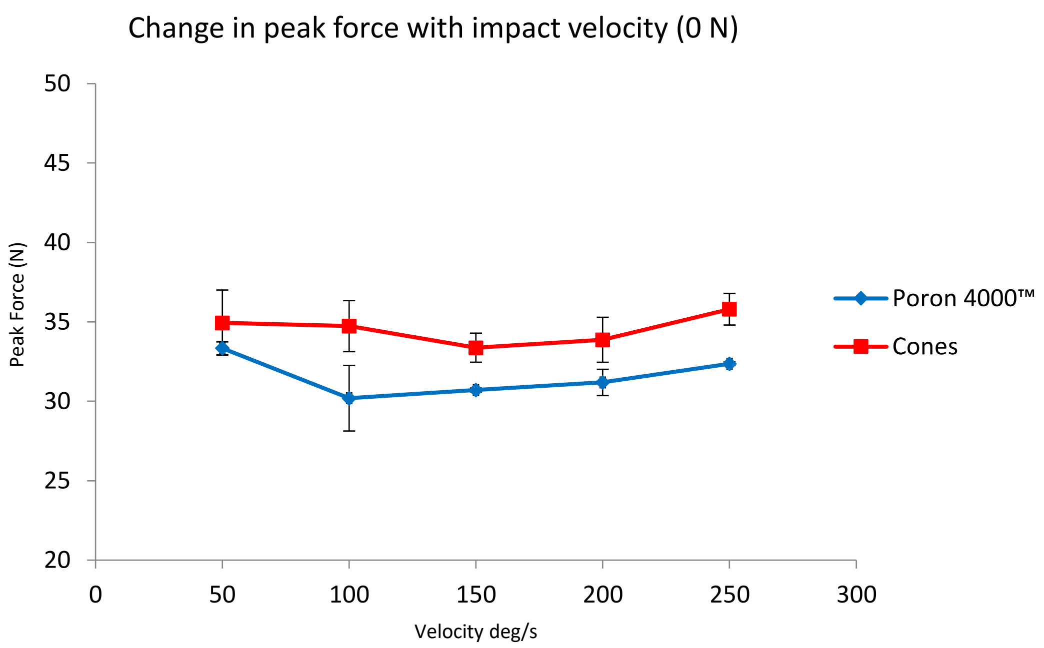


Figure 6.11 The peak force generation of the Cones and Poron 4000™ discs as they are compressed with increased velocity by the unweighted arm

There was a significant interaction between velocity of loading and disc type (P<0.05). At first (with a 50 deg/s rate of loading) transmitted force was similar between the disc types. With an increase in rate of loading to 100 deg/s there was a decrease in transmitted force with Poron 4000™ and no change with the Cones. With an increase in rate of loading to 150 deg/s there was a reduction in transmitted force in the cones but an increase in transmitted force with Poron 4000™. After this there was an increase in maximal transmitted force with an increase in velocity of loading with both discs.

2. *Rate of force generation*

With respect to force generation rate a clearer difference between the two disc types emerged. There was no effect of disc type ($P>0.05$) and a significant effect of loading velocity with higher rates of loading being associated, as expected, with higher rates of force generation (figure 6.12). There was a statistically significant disc X velocity interaction ($P<0.05$).

Poron 4000™ showed a marked biphasic pattern. At loading velocities of 50 and 100 deg/s there was no change in the rate of force development after which it increased relatively linearly. In contrast the Cones showed a more curvilinear response with a lower change in the rate of force development from 50 to 150 deg/s and then a more steep increase with subsequent velocities which parallels the change seen with the Poron 4000™.

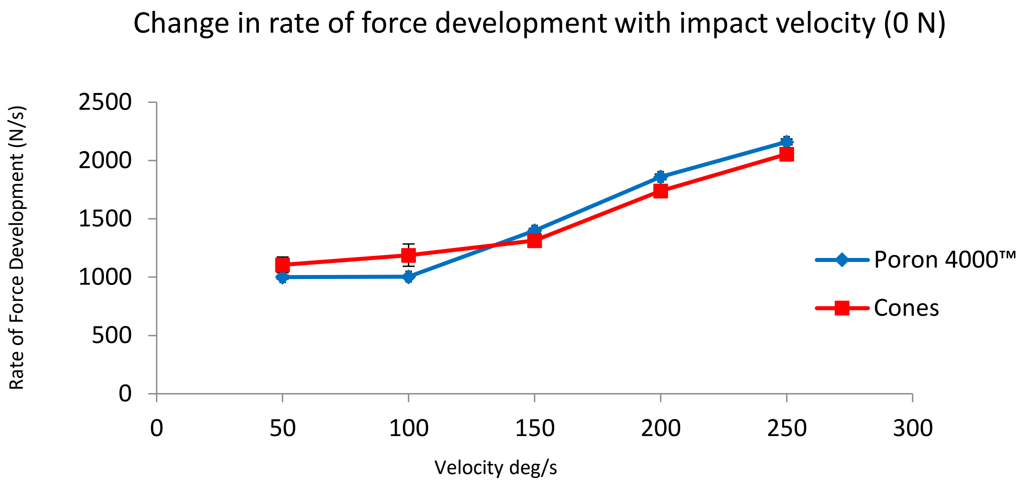


Figure 6.12 The change of rate of force development with impact velocity in the unweighted arm condition

6.9.2 20 N Loading condition

1. *Maximal force transmitted*

The tests were repeated with the arm loaded with a 2 kg weight over the section contacting the discs. There was a significant effect of loading velocity ($P<0.05$, figure 6.12); transmitted forces were higher with higher rates of loading. There was no significant effect of disc type ($P>0.05$). There was no significant velocity x disc interaction ($P>0.05$) (figure 6.13). The peak force generation of the Cones and Poron 4000™ discs as they are compressed with increased velocity by the arm weighted by 20 N

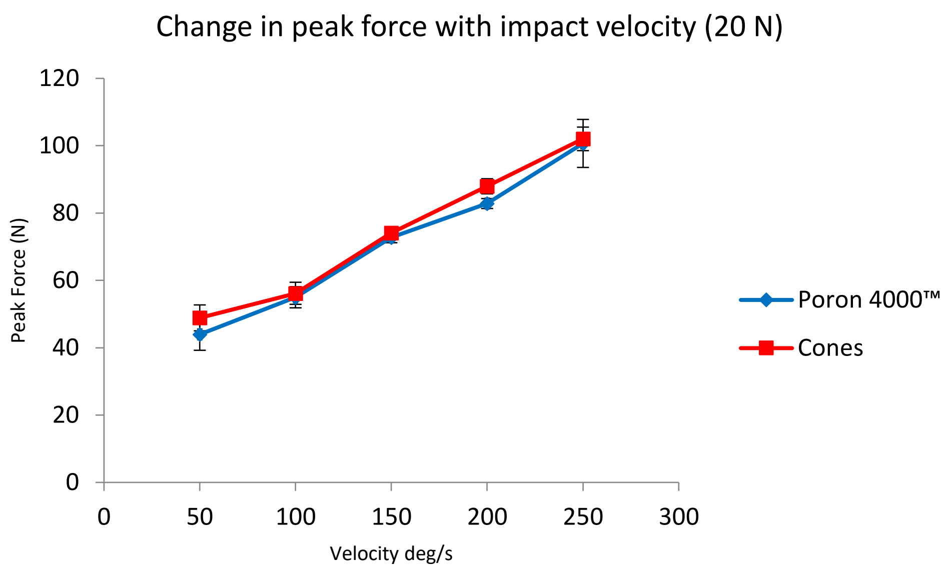


Figure 6.13 The change of peak force under 20 N at different loading rates

2. *Rate of force generation*

There was a significant effect of loading velocity ($P<0.05$) but no velocity x disc interaction. The rate of loading was higher for the Cones but this was not significantly different from the Poron 4000™ ($P=0.084$) (figure 6.14).

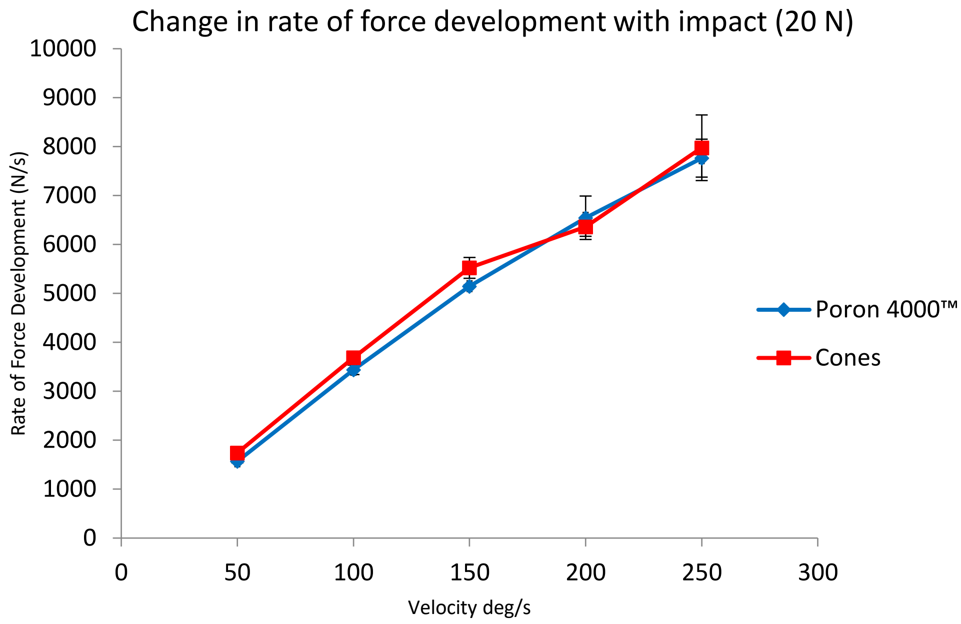


Figure 6.14 Showing the change of rate of force development with impact velocity with the arm weighted by 20 N

6.10 Discussion

This study has demonstrated some significant differences between the performance of the Cones and Poron 4000™ discs prior to testing them in human trials.

The Poron 4000™ responded as expected for an open foam cell design. When the armature was not loaded (0 N condition) the total force transmitted at first decreased with an increase in the rate of loading from 50 to 100 deg/s. After this it steadily increased. Further, the rate of force transmission at first did not vary with loading velocities of 50 and 100 deg/s. After this there was a progressive increase in the rate of loading. This is interpreted in the 2-phase model described in the introduction. With low rates of force transmission there is an initial phase consisting of the collapse of the cell walls as the air escapes leading to higher energy absorption and low transmission of forces and similar rates of force transmission. At higher rates of loading the ceilings and floors of the foam cells make contact and the foam 'bottoms out'. It then begins to act as an increasingly dense block of the material; here forces are transmitted readily and there is a clear linear increase in force and rate of force as the armature velocity increases. When the armature is loaded (20N) the response of Poron 4000™ even at low velocities is linear with increasing rates of loading there is an increase in force and rate of force transmission. Here it is assumed that the Poron 4000™ is in the second phase (i.e behaving as a dense material) as the forces applied have caused a "bottoming out."

The novel cone design had a different profile when the armature was not loaded (0 N). Overall the Cones were stiffer than the Poron 4000™. There were minimal changes in peak force with increasing armature velocities up to 150 deg/s and the rate of force transmission was linear. After this there was a steeper rise in the rate of force transmission and force. This is interpreted as the Cones showing a curvilinear response increasing stiffness (and thus reducing absorption) as the rate of loading increased. At first this was gradual increase but with greater rates of force application (>150 deg/s) this was more marked. The initial response could reflect the flattening of the cones as they bulge into the gaps provided. The latter response could reflect the now flattened Cones which has taken up the gaps provide producing a stiff dense material -similar to that seen with the Poron 4000™ but slightly stiffer. When the armature was loaded (20 N) it is assumed that the loading was such that the Cones collapsed and acted as a stiff dense material i.e their curvilinear properties were only seen with lower rates of force application.

In summary the Cones behaved as expected in that they showed a non-linear response especially at lower rates of force application when the armature was unloaded. With the motorised arm unloaded the forces generated with impact were in the range of walking at the rearfoot for an average 70 kg person running (Chuckpaiwong *et al.*, 2008). This is supported by the data obtained from study 5. When running the peak force in the medial AOI as measured using the FScan™ was 45.69 N (±18.81 N). With no weight on the armature peak force varied from 30 to 35 N. With the arm loaded it varied from 40 to 100 N.

6.11 Conclusion

This study has demonstrated some significant differences between the performance of the Cones and Poron 4000™ discs with a view to testing them in human trials. If the differences in the discs' performance has clinical significance, there should be physiological signs such as an effect on strength, stiffness or metabolic demand in running. This will be reported in the next study. Here the design and testing of a novel foot orthosis component was reported to add to semi-rigid foot orthosis shells in substitution of more commonly used open cell foams. The aim of the component was to offer a graded level of support to the region of the talonavicular joint (TNJ) of the foot since recent evidence has demonstrated that much of the weightbearing response of the foot takes place at this joint rather than the subtalar joint as previously thought (Nester, 2009). The dynamic stabilisers and mobilisers of the TNJ include the invertors and the medial intrinsic muscles whilst passively the joint is stabilised by its capsule and surrounding ligaments such as the inferior calcaneonavicular (spring) ligament. Both the tibialis posterior tendon and spring ligament are frequently affected by degenerative pathology associated with overuse (Mengiardi *et al.*, 2005; Toye *et al.*, 2005; Shibuya, Ramanujam and Garcia, 2008; Tryfonidis *et al.*, 2008) and, in rehabilitation, clinicians often aim to offload the structures to reduce the normal tissue stress to tolerable limits to allow healing to take place prior to strengthening (Davenport *et al.*, 2005; Bowring and Chockalingam, 2009, 2010). The next study will test the effect of the orthoses component in running.

6.12 Summary

In this chapter novel foot orthosis technology was designed, developed and tested. The aim was to add an alternative to open cell foam which typically has a biphasic function, and is often applied in foot orthosis designed under the MLA on foot orthosis shells to modify the rate of arch deformation.

The component was designed to generate variable forces (orthosis reaction force) against the foot proportionate to the rate and magnitude of force applied in the stance phase of the gait cycle; applying engineering principles of how frustoconical structures respond to compression. Results in-vitro showed a curvilinear increase in stiffness of magnitude of force and rate of force generation with an increase of rate of force applied where the forces applied in reflected forces measured in the medial heel and MLA in chapter 5. Higher forces did not produce the same effect which may indicate that scaling the Cones to respond to larger forces may be required.

The Cones component can be fitted to the top surface of foot orthosis shells to modify the rate of generation of orthosis reaction force. The final experiment in this thesis in chapter 7 aims to compare the Cones component with a frequently used open cell foam to test the effect on change in foot posture, invertor strength and stiffness of the medial foot and ankle tissues and plantar fascia.

Chapter 7 : Changes in foot posture, ankle invertor strength, and medial ankle and plantar soft tissue stiffness with a traditionally used open cell foam versus a novel foot orthotic component: a double blind randomized controlled cross-over trial

7.1 Introduction

In this thesis a change in foot posture has been demonstrated after an hour of treadmill running, and within-run indirect measures of foot movement suggest that exercise-induced fatigue related changes occur at thirty minutes into a prolonged run in concordance with other work (Stirling *et al.*, 2012). Some measures of static foot posture have been shown to change after 45 minutes of running (Bravo-Aguilar *et al.*, 2016) although navicular height has been shown to remain unchanged in one study (Boyer, Ward and Derrick, 2014) and foot posture changes have not to date been reported after thirty minutes of running. As discussed in chapter 1, the selection of two static foot posture measures in this thesis aims to capture changes in both skeletal posture (NH) and soft tissues (FPI-6) after prolonged running. Several studies have linked foot and ankle function with the risk of running related injuries (RRIs), and podiatrists and other health professionals frequently aim to address RRIs with foot orthoses (Nester *et al.*, 2018). A recent prospective study (Messier *et al.*, 2018) of 3000 runners has, however, found that arch height, rearfoot motion, lower extremity strength, weekly mileage or foot are not significant aetiological factors in the development of RRIs. Neither the stiffness of plantar fascia nor invertor strength was considered in this study, however, so further research is warranted. Furthermore, there is building evidence for the role of foot orthoses in healthy runners to reduce the risk of running related injuries (Bonanno *et al.*, 2017) although there is debate about which attribute or attributes of foot orthoses are likely to be having the greatest effect. Bonanno and colleagues (2017) note that shock absorbing orthoses are not effective in reducing injury incidence but the studies using shock absorbing materials used unmoulded or contoured orthosis designs which would not likely contact the midfoot area in-shoe. It is not known then, if the application of shock absorbing materials applied to the midfoot area atop a moulded semi-rigid orthosis would be effective in modifying the changes in running more than the novel Cones component. Semi-rigid shell orthoses have been demonstrated to reduce injury risk in military recruits during a seven week basic training programme (Franklyn-Miller *et al.*, 2011). The risk of using similar devices, fitted for comfort and with the medial column free to move, for a short running trial at sub-maximal effort, were deemed negligible given that no adverse effects were reported in the studies included in the systematic review and meta-analysis of many different types of moulded orthosis by Bonanno et al., (2017).

7.1.1 Foot orthosis materials used in the modification of arch deformation acceleration

Velocity of navicular drop in walking and running has been demonstrated to be greater in people with running related injuries such as medial tibial stress syndrome (Rathleff *et al.*, 2012) and patellofemoral pain syndrome (Barton *et al.*, 2010) which clinicians address with foot orthoses incorporating ‘arch pads’ or areas of open cell foam eg Poron 4000™ located on the superior surface of foot orthosis shells (Choate, 2010; Nester, 2016).

The materials available to clinicians include numerous foams in sheet form and one of the most commonly procured foam is Poron 4000™ (Algeos Ltd, no date; Birke, Foto and Pfiefer, 1999; Paton *et al.*, 2007). Poron 4000™ is a highly durable open cell foam originally applied in the aviation industry (Corporation Rogers, 2007). Typically, open cell foams resist compression through the strength of the cell walls as opposed to closed cell foams that form closed bubbles of air to create resistance with walled cells. As such, stress strain curves show a phasic output during compression of open cell foams where the walls collapse and yield in the early stages of loading before the ceiling and floor of the cell meet and increase the resistance and the material becomes devoid of air.

Studies of human tendon as it strains due to stress show a more variable pattern of yielding. As discussed in chapter 1, in vitro studies of human Achilles tendon under repeated cyclic tensioning show a conditioning phase with changes in hysteresis and elasticity followed by a more rigid elongated phase where the force is transmitted more directly to the muscle from the bone (Maganaris, 2003). While the overall stiffness of the Achilles tendon does not change after prolonged running (Farris, Trewartha and McGuigan, 2012; Peltonen *et al.*, 2012) muscular fatigue with exercise has been demonstrated in the lower limb (Millet and Lepers, 2004a). It is not known from these studies if the intrinsic muscles of the foot fatigue to the same extent as other muscles in the lower limb, but assuming even a small exercise-induced reduction in strength, the MLA will be less resistant to loading deformation (Headlee *et al.*, 2008) which would be exacerbated with the flattening force from the Achilles tendon in running (Cheung and Zhang, 2006) placing strain on the passive plantar structures such as the plantar fascia. The aim of the novel orthosis component, then, was to oppose the MLA as it yields with a non-linear increasing stiffness response to loading as the MLA continues to deform with decreased intrinsic muscle strength and increased MLA deformation. The orthosis component discussed in chapter 6 was constructed of multiple cones encased within a connecting substance and shall be referred to as the 'Cones' condition herein.

The Cones demonstrated a pattern of curvilinear increase in force generation rate and peak force with machine loading at different velocities over a range of forces typical of those generated in the medial heel / MLA in the cohort in chapter 5. Theoretically the behaviour of the Cones should reduce the amount of muscle demand in fatigued running by increasing the orthosis reaction force in midstance if placed medio-plantarly against the talonavicular joint on a semi-rigid foot orthotic shell where arch deformation is greatest (Nester, 2009). With reduced muscle strength loss and plantar soft tissue stiffness, static foot posture changes should be smaller than after an hour of running with the Cones than the open cell foam.

The semi-rigid shells that house the Cones or Poron 4000™ discs needs to be rigid enough to apply an orthosis reaction force to the foot without buckling when the foot loads onto it but to be mouldable to allow accommodation of first ray plantarflexion distally. This way the MLA will be able to function for propulsion distally but the effect of the discs tested proximally.

7.1.2 The MyotonPRO™: design, validity and application

Previously in this thesis, the Biodex™ isokinetic dynamometer has been used to measure soft tissue stiffness but it is not possible to isolate the stiffness of the plantar fascia with this system. Methods for measuring the stiffness of the plantar fascia are discussed in chapter 2 and include the MyotonPRO™. The excellent reliability and ease of use and function of the MyotonPRO™ are also discussed in chapter 2 and it was, therefore, selected to measure the stiffness of the plantar fascia in this study. The Biodex™ and The MyotonPRO™ each measure different variables of stiffness, however, with the former using strain and the latter compression to do so.

The plantar fascia has a different structure from the tibialis anterior (invertor) tendon previously tested with the Biodex™. The midportion of the plantar fascia has a flat aponeurotic structure rather than the cylindrical, cordlike form of the midportion of the tibialis anterior tendon. The plantar fascia is superficial at the level of navicular on the plantar aspect with minimal overlying soft tissue, and is around 3 mm thick (Abul *et al.*, 2015) and similarly the tibialis anterior tendon is as superficial at the level of the ankle joint line. The absence of adipose tissue helps increase the accuracy of measurement with the MyotonPRO™ (Agyapong-Badu *et al.*, 2013).

7.1.3 Aim

This study aimed to investigate the effect of a novel foot orthosis component compared to a traditional open cell foam component (Poron 4000™ disc) on static foot posture, invertor strength, medial foot and ankle soft tissue stiffness and plantar fascia stiffness.

7.1.4 Hypotheses

After a thirty-minute treadmill run there will be:

1. *Null:*

   No changes in foot posture with either the Cones or Poron 4000™ orthotic condition.

Alternative:

A change in foot posture in the Poron 4000™ condition greater than the Cones.

2. *Null*

No loss of ankle invertor strength (MikVC) with either the Cones or Poron 4000™ orthotic condition.

Alternative:

Change in ankle invertor strength (MikVC) with Poron 4000™ orthotic condition losing more strength than the Cones condition.

3. *Null*

No change in tibialis anterior tendon and ankle invertor stiffness with either the Cones or Poron 4000™ orthotic condition.

Alternative:

Change in tibialis anterior tendon and ankle invertor stiffness with greater reduction in stiffness with Poron 4000™ orthotic condition than the Cones.

4. *Null*

No change in plantar fascia stiffness with either the Cones or Poron 4000™ orthotic condition.

Alternative:

Change in plantar fascia stiffness with the Poron 4000™ orthotic condition showing less stiffness than the Cones orthotic condition.

7.2 Methods

7.2.1 Trial design

A double blind, randomised controlled cross-over trial design was designed with two orthotic conditions: Cones and Poron 4000™. Each participant was exposed to each condition in random order and ran for thirty-minute trials on a treadmill. Trials for each condition were conducted on the same participant on different days at least two days apart.

7.2.2 Ethics and data management

Ethical Approval and Data Protection Ethical approval were sought and obtained from the Faculty of Health and Human Sciences ethics committee, University of Plymouth.

All participants were given a unique randomly generated code. Personal information (name / contact details) was kept separate and destroyed at the end of the study. All data and information collected in the study was encrypted using an encryption disc and stored on the University storage drive which is password protected and any backup copies were passworded, encrypted and stored in a locked cabinet in the room of the chief investigator at the PAHC building of the University of Plymouth when not in use, for a period of 10 years.

This randomised controlled trial was akin to a phase 0 drugs trial where the availability of effect of the drug would be tested on healthy human participants using different dosages. In this instance, however, the effect was not to determine a clinical dose for guideline development but rather to detect an effect in healthy humans that theoretically could reduce risk of injury. With no a prior data available to define a clinically therapeutic 'orthotic dose' to reduce injury risk foot posture measures patient feedback was essential as a safety feature of the trial. Both pain and exertion are good indicators of potentially adverse effects of orthotic intervention and ensuring abortion of the trial (by either the runner or the data collector) in the event of either variable reaching a pre-determined threshold in the lower quartiles of normal performance, ie 0-3 on a pain score with a maximum pain score of 10 and below 17 on the Borg score of rated perceived exertion, acts as a 'rip-cord' to reduce the likelihood of injury to being negligible during treadmill running trials.

This randomised controlled trial was not registered as it was not undertaken in a clinical environment, nor subject to clinical ethical approval. Participants were healthy volunteers and exposure to intervention dosages did not exceed those previously used in studies demonstrating a protective effect of orthoses in runners.

Previous work has shown a protective effect for RRIs with orthoses similar to the Vectorthotics™ selected for use in this study (Bonanno *et al.*, 2017) and ensuring comfort and stability at the point of fitting orthoses helps minimise the likelihood of adverse effects.

7.2.3 Sample size calculation

In chapter 3, foot posture using the foot posture index (FPI-6) was assessed before and after a half marathon. Combining the results of the left and right feet the FPI-6 changed by 1.2 ±1.85; indicating an increase in pronation. To detect a similar effect size in the current study required 17 people (alpha=0.05 power=0.8) per condition for the orthosis running trials.

7.2.4 Recruitment

Participants were recruited from previous participant lists where consent had been given, adverts placed in local running / sports club houses / magazines and websites as well as via adverts placed around the University. It was made clear that for students who volunteered that participation or withdrawal from the study would not affect their studies in any way. People who replied to the adverts were sent an information sheet via post / email or were sent a link to a dedicated Facebook page. Volunteers had a minimum of a 24 hour period during which chance they could ask questions about the study prior to providing fully informed written consent. All participants were free to withdraw from the study at any point whereupon all data pertaining to them would have been permanently destroyed (n=0).

Tests were scheduled to take up to 2 hours to complete and all trials took place in the Peninsula Allied Health Centre (PAHC), University of Plymouth with time of day matched trials for each participant.

7.2.5 Eligibility criteria

1. *Inclusion*

Adults between the ages of 18 and 65 were eligible to enter the study

2. *Exclusion*

- Participants had to be able to comfortably complete 30 minutes of running or running at self-selected speed on a treadmill and so were asked to confirm that they had achieved similar tasks in the last 3 months without detriment to health
- A history of cardiorespiratory conditions that limit exercise capacity (cardiac arrest, stroke, angina, exercise induced asthma)

- Participants had to be able to safely use a treadmill under supervision and not have pacemakers or other internal medical devices eg auto-defibrillator
- Participants did not have current foot, ankle or leg pain, any disease or condition that affected the neuromuscular system or joints and had not had joint surgery that had significantly altered function eg hallux valgus surgery, joint arthrodesis or arthroplasty
- Volunteers did not have any connective tissue disorders
- Volunteers who wore prescription foot orthoses in daily life were not entered into the study
- Volunteers who wore motion control footwear to run or usually run barefoot or in minimalist footwear were excluded due to the possible habituation issues in altering footwear to a neutral shoe in this study (see chapter 1)
- If a participant wished to run in their own neutral running shoe they had to be deemed by the researcher to be in adequate condition to withstand the trial, not interfere with data collection and of similar enough design to the lab shoes not to adversely affect the measurements being taken during running or running trials
- Foot and ankle deformity eg tarsal coalition as assessed by the researcher (a podiatrist of over fifteen years' experience)
- Pregnant and post-partum women up to 12 months

7.2.6 Baseline demographic data and training history

The following data was collected at the start of the trial:

- Age
- Height and weight
- Shoe size
- Weekly mileage running and running
- Footwear type and condition and foot orthoses or inserts currently worn for running or running long distances
- History of surgery and injury
- Foot and ankle examination and range of movement tests – this was screened clinically to allow for exclusion due to deformity
- History of oral contraceptive pill use (women only)
- History of number pregnancies including those longer than 4 weeks but not to term

Maximum isokinetic voluntary contraction (MikVC), muscle-tendon stiffness (MTS) and foot posture (NH and FPI-6) before and immediately after the trials were measured.

7.2.7 Interventions

Volunteers from a cross sectional sample who had responded to calls for runners who could comfortably run for 30 minutes to join a study testing orthoses, were sent a link to access study information, consent forms and a participant survey. They were invited to take time to read the information sheet and read the consent form in preparation for signing should they enter the study and to complete the eligibility survey. Volunteers were sent a code along with their emailed link and asked to use this instead of their name when completing the online survey. The survey was a Google form (see appendices) and due to the code not being held with the person's identifying details, could be collated on Google servers in a self-populating spreadsheet without breach of confidentiality. The code and personal details were held on a separate encrypted drive with additional password protection on the document. This drive was kept in a locked cabinet in a lockable office at PAHC.

Once the survey was returned the volunteer was invited for an assessment which, if successful, would lead immediately to consenting to enter the study and undertaking the initial trial of two. The volunteers were able to schedule this themselves using an automatic booking system (https://youcanbook.me) and this allowed arrangement of laboratory time and an assistant to help with the orthoses as described later.

7.2.8 Randomisation

Participants were randomised by a member of the research team (JM) using a computer based randomisation program (randperm function in MATLAB) to start in the vector orthotic + Cones or Vectorthotic + Poron 4000™ orthotic group.

7.2.9 Blinding

Envelopes were then prepared by JM to contain the following (figure 7.1):

- A slip of paper denoting the code and randomisation order of the orthosis conditions
- A pair of Cones discs and a pair of Poron 4000™ discs
- Double sided adhesive strips to affix the discs to the orthosis shells when provided

Envelopes had the code written on the front and were self-sealing to contain the contents and maintain blinding. They were large envelopes allowing for storage of the orthoses after the first trial.

Figure 7.1 Envelope prepared for a participant

7.2.10 Initial assessment

Participants attended the University at their allotted time and were assessed by the data collector to screen for deformities, joint restrictions or other factor not declared in the participant survey. Participants' running shoes were also assessed at this point to decide if they could be used in the trial. Visible signs of fatigue or damage immediately eliminated them from being used, but also the number of miles run in them was recorded and shoes with over 500 miles use were not allowed to be worn in running trials. Each participant's footwear passed this screen and the same shoes were worn for both trials.

All 17 participants who were eligible from the survey passed this assessment and consented to enter the trial. All confirmed that they had read the information about the study and had had at least 24 hours to raise questions. Volunteers had the option to speak to the data collector, or a named member of University staff external to the research team who had many years' experience in research and had volunteered to be on standby for questions.

Participants brought with them running attire that did not affect gait style eg baggy, low slung trousers. Participants wore their own neutral footwear where they had it (n=17) although neutral laboratory trainers were available if needed.

Upon entry to the study, all participants were reminded that at any time they were welcome to ask questions and to withdraw without explanation, should they wish, and were reassured that their data would be immediately destroyed in this event.

Prior to each trial session a set of dummy discs of Cones and Poron 4000™ were tested for temperature and, if cooler than room temperature, the trial discs were warmed in an optometry spectacle heater by the assistant and checked for temperature prior to fitting. This was to ensure that the material properties of the discs were comparable as they changed temperature inside the shoe from similar baseline temperatures. Data collection took place during the months of July and August when ambient temperature was about 23 degrees Celsius so this was only necessary on a few occasions.

7.2.11 Pre-trial assessment

Each participant was asked for their shoe size and the appropriately sized Vectorthotics™ selected from stock held in the lab. The Vectorthotics™ were fitted in a method typical of podiatry practice as follows:

- With participant seated and limb supported by the plinth, the orthotic shell was held against the plantar aspect of the foot and the forefoot loaded into dorsiflexion to extend the length of the foot as in weightbearing. The orthoses were deemed to be the correct length if the distal edge reached the metatarsal necks of the first and second metatarsals as these are longer than the 3rd, 4th and 5th.
- The Vectorthotics™ kit was supplied with rearfoot and forefoot wedges and the 2 degree rearfoot wedge was applied to the inferior aspect of the rounded shell heel cup to ensure it was stable by forming a tripod with the two distal edge corners of the shell when placed on a flat surface.
- This was repeated for the opposite foot
- The participant was then asked to stand, as the orthoses were placed a few centimetres apart on the floor, and step onto the orthoses.

- The area of the shell under the talonavicular joint was checked to be in close contact with the shell of the orthosis and if not, a heat gun was used to modify the shell until it did so comfortably. The shell was allowed to cool to room temperature after this.
- Jack's test (passive weightbearing hallux dorsiflexion) was undertaken to check that the first ray was free to plantarflex without asymmetry or undue force. If a borderline result was noted the test was repeated off the orthoses to ensure it was not the orthoses causing it.
- The shell of the orthosis was also checked to be not in contact with the plantar soft tissues distal to the 1st navicular-cuneiform joint. If it was the heat gun was used to mould the shell away from the foot in this region.
- The final stage was to mark the Vectorthotics™ shells with a dummy disc to show the assistant where to position the test discs. This was at the level of the talo-navicular joint on the superior aspect of the Vectorthotics™ shells.
- At the end of the modification process the Vectorthotics™ were passed through a screen to the assistant waiting and they opened the envelope, selected the appropriate discs (Poron 4000™ or Cones) according to the randomisation order, and used the adhesive tape to fit the discs securely to the shells. They then applied the top cover as they had been trained to do so by the data collector prior to the session, and used opaque clinical tape to mask any visible part of the discs (figure 7.2).

- Once this was complete they fitted the Vectorthotics™ into the participant's running shoes so that only the generic top cover could be seen from the outside by either the data collector or the runner.
- If at any point the assistant forgot how to undertake this task they were free to come into the lab from behind the screen to be shown using a dummy Vectorthotic™ / disc kit by EC.

As this process was taking place behind the screen with the assistant, the data collector undertook baseline measurements from the participant as follows:

- Height and weight – using a set of calibrated weighing scales and a stadiometer
- Recent training history, current weekly volume of running, recent pain and shoes worn

Figure 7.2 Positioning and blinding of the discs on the Vectorthotic™ shell

1. *FPI-6*

- The participant then was asked to stand with a foot on each of two weighing scales positioned adjacently with a tape indicating a 10 cm inter-malleolar gap. The participant was shown the supporting handrail to steady themselves and asked to stand bearing weight as evenly as possible on each scale – they were able to see the division of bodyweight on each scale. They were asked to stand with their feet relaxed and to look straight ahead once they had balanced their weight
- The FPI-6 was taken at this point with the code of the participant on the data sheet and the protocol described by Redmond (1998) followed therein (also see chapter 2)
- The scores for the six criteria were written in raw form on the form but not totalled

2. *NH*

- The navicular tuberosity was palpated – and the foot moved into supination and pronation with palpation if not initially easy to find before relaxing again. A dot from a pen with a 1mm tip was applied to the skin and a pre-prepared strip of stiff card with the participant's code and 'pre' written on it taken and positioned edge on to the navicular. The mark was copied onto the card to reflect the NH but the distance from the scales (base of the strip) to the mark was not measured at this point

- The FPI-6 data sheet and NH strip of card were handed to the assistant for storage in the envelope until data processing began. This process took about a minute.

3. *MyotonPRO™*

    - The participant was positioned on a plinth in straight lying then asked to flex the left knee to 45 degrees for comfort and to free space around the rig at the level of the right foot
    - The right foot was placed in the rig and secured using adjustable belts to standardise the foot position at 90 degrees to the leg passively. The rig was adjusted so that the hinge of the hallux extender section of the rig was in line with the axis of the 1st metatarsal phalangeal joint.
    - With the participant comfortable and secure, the MyotonPRO™ was used to perturb the tibialis anterior tendon three times, then the plantar fascia was perturbed three times at the level of the navicular via a window cut out of the rig plantarly to facilitate clear access with the probe. Finally the hallux was dorsiflexed by 30 degrees using a wedge placed under the hallux extender section and the plantar fascia was probed three more times in this tensioned position (figure 2.5).

This process took about 90 seconds

4. *Strength and Stiffness*

- The participant was seated and secured using the belts of the Biodex™ and the seat positioned to allow comfortable relaxation for the stiffness task, and maximal voluntary contraction for the strength task
- The right foot was placed in the same position, and the Biodex™ set to the same settings as in chapter 5 and described in chapter 2.
- The stiffness and strength protocols were repeated

This took about 2-3 minutes for both Biodex™ measures.

7.2.12 Exercise trial

A crash mat was placed at the back of the treadmill, the lab kept cool with fans available at the request of the participant, and glucose drinks, water, bananas and biscuits were available on request. A chair to sit on to recover after the tests was also provided. A telephone was available in the laboratory in case of emergency and a first responder was on alert that an endurance test was being undertaken. Infection control was undertaken with disinfectant wipes for the treadmill and chlorhexidine spray for the inside of lab trainers.

Once the Vectorthotics™ were in the shoes, and the baseline measures taken, the participant was asked to don their running shoes with Vectorthotics™ in and check for comfort and ankle stability by pacing up and down the lab. Every participant was satisfied that no changed were needed but had they been the assistant would have removed the shoes and behind the screen removed the disc before passing the shell to me for adjustment and re-passing it back for disc fitting and comfort checking a second time.

The participant then stepped onto the treadmill, was familiarised with the settings and safety facilities, and asked to start the belt and select a speed that they were confident they could maintain at Borg level 11-13 (light to somewhat hard) for thirty minutes. The data collector communicated to runners that at first it may feel like less than 11-13 and at the end, more but the peak should not exceed 16 and the mean should be aimed at 12 ideally. The participants had two minutes to undertake this task and the preferred treadmill speed was recorded.

The treadmill was then stopped and the participant asked to remove their shoes to allow them to take a comfort break without unblinding accidentally or to gather any music devices or snacks needed for the run. They also could select a programme from Netflix if they wished as a TV was positioned in front of the treadmill for entertainment during the run. At this point fans were positioned as required around the treadmill for cooling.

Once the runner was prepared, a time check was made to ensure that at least two minutes had elapsed since the short bout of treadmill running to select their speed. Once this period had elapsed, they redonned their shoes with

Vectorthotics™ fitted, and stepped onto the treadmill, fixing the safety cord to their shorts, and over the space of a few seconds brought the treadmill belt to the speed selected before.

At one minute they were asked to report their Borg (6-20) and pain scores (0-10) which was recorded by the data collector. The entertainment was started, and they were left to run with the data collector close by in case they needed paper towels, more water to drink or another fan. The data collector ensured that they appeared to be running safely and appeared comfortable on the treadmill in case of an accident ensuing.

During the trial participants were asked at one minute then every 10 minutes to rate their perceived exertion on a Borg scale and to indicate if they had any pain on a 0 - 10 numerical pain scale with description and the site of any pain. The test and subsequent tests were stopped before the thirty minutes period elapses if any of the following occur:

1. Pain exceeding level 5 out of 10 on a numerical pain scale

2. If the heart rate exceeds 85% of their maximal heart rate as calculated by:

$Max\ Heart\ Rate = 220 - Age$ where a heart rate monitor was worn by the participant

3. Chest pain

4. Signs of poor perfusion (cyanosis, pallor)

5. Technical difficulties that prevent the recording of heart rate

6. Participant asks to stop

7. Signs of asthma (wheezing, high respiratory rate, shallow breaths, paraesthesia)

Points 2-6 include absolute are relative indications for terminating exercise test as given by the American College of Cardiology/ American heart association task force on practice guidelines(Fletcher *et al.*, 2013). Additionally, the test was stopped if their perceived exertion (Borg) exceeded 17 (very hard). In this case we still performed the post-trial measures if the participant was willing.

Once thirty minutes had elapsed the treadmill was brought to a halt and the participant helped to the nearby chair to remove their shoes and socks as fast as possible. They quickly moved to the FPI-6 and NH stand and the measures were taken by the data collector using the same method as before, the participant then quickly moved to the plinth, was secured and the MyotonPRO™ measures retaken before finally moving to the Biodex™ for the strength and stiffness measures. This was all accomplished within 4-5 minutes – sometimes faster depending on the participant needing sugar or water, or not being able to get into position easily on the Biodex™.

7.2.13 Data reduction

Invertor muscle strength and stiffness data was subsequently exported from Spike 2 as text files into Matlab (Mathworks) for secondary data reduction as described in chapter2.

MyotonPRO™ measures (stiffness and decrement) were stored on the MyotonPRO™ machine under the participants' code and subsequently transferred to a spreadsheet.

7.3 Analysis

Data was tested for normality using the Shapiro-Wilks test. Results of measures taken pre- and post-running were analysed using a repeated measures ANOVA with factors being group (Cones vs Poron 4000™) and time (pre vs post). Measures of Borg and pain levels during the run were analysed using a repeated measures ANOVA with factors being group (Novel (Cones) vs usual (Poron 4000™)) and time (baseline vs 1 minute vs 10 minute vs 20 minutes vs 30 minutes).

The changes in MikVC, MTS and NH / FPI-6 with running were analysed with repeated measures ANOVA with factors being time (pre vs post) and orthotic (Vectorthotic™ + Cone vs Vectorthotic™ + Poron 4000™).

7.4 Results

7.4.1 CONSORT reporting

The results of this randomised trial have been reported in line with the CONSORT Extension for Non-Pharmacological Treatment Checklist (Consort, 2010) (figure 7.1). In the second quarter of 2016 self-assessment questionnaires were sent out to twenty nine volunteers and twenty eight were completed and returned. Of the respondents, seventeen were eligible to enter the study and invited to run on two occasions in the trial. All seventeen participants completed both runs in the third quarter of 2016, with one participant aborting the first run at twenty five minutes and repeating a twenty five minute run in the second orthosis condition a week later.

All participants had at least three days between running trials but no longer than two weeks between running trials.

Intention to treat analysis

All participants remained allocated to their groups and adhered to treatment. No participants dropped out of the study and all completed the required exposure to the intervention with the exception of one runner who only completed 25 minutes of running for both trials after overheating in the first.

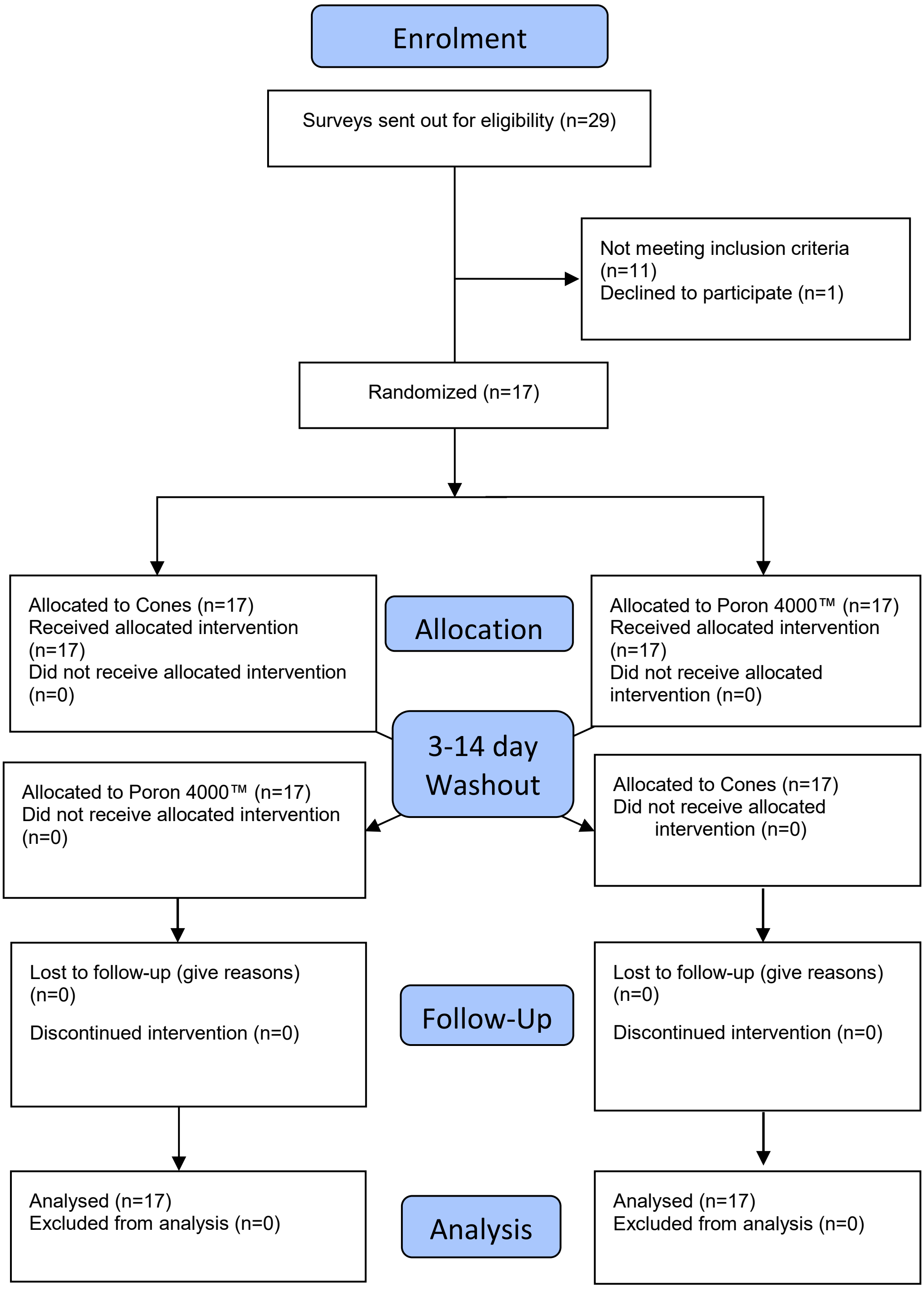


Figure 7.3 CONSORT 2010 flow diagram

7.4.2 Demographics

Seventeen people were assessed with 9 people undertaking the novel orthosis condition first and the remaining 8 undertaking the usual orthosis condition first. Group demographics are outlined in table 7.1.

Participants ran at an average speed of 8.9 (2.6) km/h. One person stopped running at 25 minutes in the second trial (usual orthosis) due to excessive heat. Pre-post measures were taken for this participant and data included in the dataset for analysis.

Parameter	Value
Gender	10 Female, 7 Male
Age (yrs)	38.7 (11.7)
Weight (kg)	70.5(11.2)
Height (cm)	171.6(11.0)
Shoe size	7.3(2.0)
Usual running speed minute/mile	8.5(2.2)
Running speed on treadmill km/h	8.9(2.6)

Table 7.1 Group demographics (mean and (standard deviation))

7.4.3 Primary outcome measures: changes in foot posture

Foot posture index

FPI-6 data was converted into logit scores. The data was normally distributed. FPI-6 increased over time by 10.6 and 1.29 (Cones and Poron 4000™), P<0.005, table 7.2). There was no group effect (P>0.05) or group x time interaction (P>0.05, table 7.2).

	Pre Cones	**Post Cones**	**Change Cones**	**Pre Poron 4000™**	**Post Poron 4000™**	**Change Poron 4000™**
NH (mm)	45.14 (8.72)	42.11 (9.59)	*-3.03 (2.98)	45.0 (8.8)	43.2 (8.4)	*-1.76 (2.32)
FPI Rasch converted logit scores	0.56 (1.45)	1.43 (1.72)	*1.06 (1.14)	0.60 (1.39)	1.49 (1.69)	*1.29 (0.84)

Table 7.2 Changes in foot posture before and after running with each orthotic condition (mean (SD)) *Significant P<0.05

Navicular Height

Results were normally distributed. Navicular height decreased over time by 1.76 (±2.32) mm (Poron 4000™) and 3.03 (±2.98) mm (Cones) (P<0.001). There was no difference between the groups (P>0.05), table 7.2.

7.4.4 Secondary outcome measures

Ankle invertor strength

Data was normally distributed. The strength of the ankle invertors decreased over time ($P<0.05$) with a mean decrease of -1.19 Nm in the Cones group and a decrease of -3.92 Nm in the Poron 4000™ group. There was no difference between groups ($P>0.05$) or significant group x time interactions ($P>0.05$, table 7.3). As previously, the smallest detectable change for this variable was not reached by some margin although but -1.19 and -3.92 represent a smaller change than previously reported in prolonged running suggesting a 14% reduction in strength overall vs ~20 % reported in the literature (Millet and Lepers, 2004b; Saldanha, Nordlund Ekblom and Thorstensson, 2008).

Medial ankle stiffness

Data was normally distributed. The stiffness of the ankle invertors decreased over time ($P<0.005$) showing an average -2.25 Nm/rad.kg decrease in the Cones group and a -2.04 Nm/rad.kg decrease in the Poron 4000™ group. The Cones group tended to have lower stiffness but this was not significant (-2.25 Cones vs -1.19 Nm/rad.kg Poron 4000™, $P=0.08$). The group x time interaction was non-significant ($P>0.05$, table 7.3).

	Pre Cones	Post Cones	Change	Pre Poron 4000™	Post Poron 4000™	Change
Ankle Stiffness (Nm/rad.kg)	12.52 (2.99)	10.30 (2.57)	†-2.25 (2.42)	13.56 (4.23)	11.51 (3.42)	†-2.04 (2.16)
Strength (Nm)	23.85 (8.0)	22.65 (7.5)	*-1.19 (3.60)	26.0 (8.5)	22.1 (7.1)	*-3.92 (7.18)

Table 7.3 Changes in whole ankle stiffness and eccentric invertor strength before and after running with each orthotic condition (mean (SD)) *P<0.05, †=P<0.006

Plantar fascia stiffness

Changes in stiffness in the plantar fascia assessed using the MyotonPRO™ frequency, and stiffness parameters are reported in table 7.4. All data for the plantar fascia measurements were normally distributed.

Frequency: There was an effect of time with frequency decreasing over time ($P<0.001$). There was an effect of angle ($P<0.05$); with an increase in frequency observed when the hallux was at 30°. There was a time x group effect ($P<0.05$) with the Cones showing the larger decrease in frequency with time. The angle x group interaction was also significant ($P<0.05$) with the Poron 4000™ showing the larger increase in frequency when the hallux was extended from 0 to 30 °. The time x angle interaction was significant ($P<0.05$) with the increase in frequency from 0° to 30° being larger in the pre-compared to the post run condition. Finally, there was a significant time x angle x group effects. It highlights that with running there was a decrease in frequency of oscillation in the Cones group for both positions of testing whilst in the Poron 4000™ group this remained about the same in the 0° position. There was no group effect (P>0.05). Comparisons of plantar fascia stiffness with the hallux at 0° and 30° extension with the Cones and Poron 4000™ are seen in figures 7.4 and 7.5. There was no significant difference in frequency or stiffness at 0° or 30° hallux extension with the MyotonPRO™.

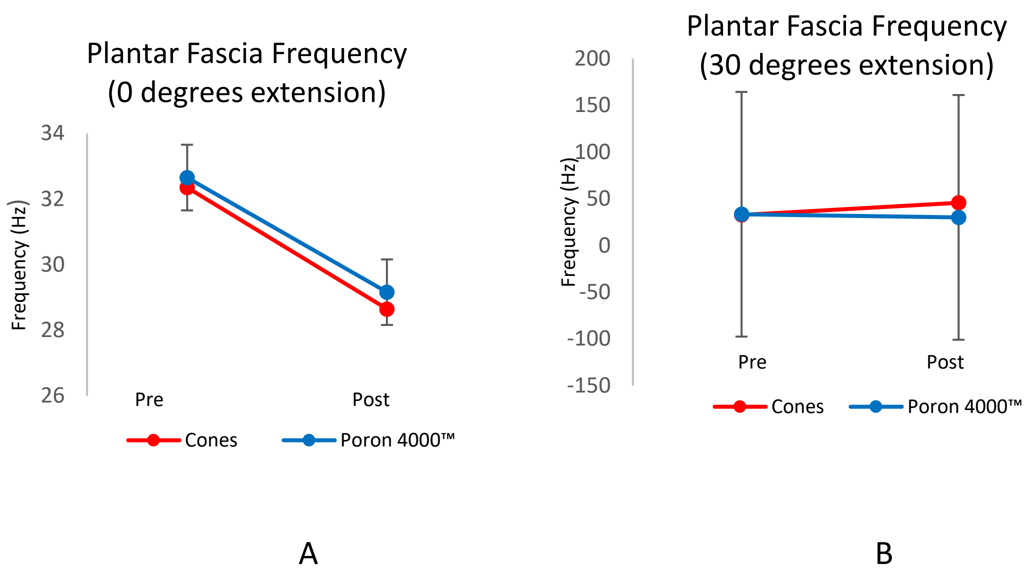


Figure 7.4 Change in plantar fascia frequency of oscillation at A) 0° and B) 30° extension before and after running with each orthotic condition

Stiffness: There was an effect of time with stiffness decreasing after running (P<0.05). There was an effect of angle with stiffness being higher when the hallux was extended to 30°. There was a time x angle x group effect (P<0.05). As summarised in figure 7.2B the pre-run stiffness with the hallux at 0 ° was lower in the Poron 4000™ group compared to the cones group. Post run there was minimal change in stiffness at 0° in the Poron 4000™ group whilst it decreased in the cones group in line with the more consistent changes see with the hallux at 30^{o}.

Tibialis Anterior Stiffness

There was no effect of time, or group on tibialis anterior stiffness as measured using the MyotonPRO™ (table 7.4).

Parameter	Starting Position Hallux Extension= 0 ^{o}				Starting Position Hallux Extension = 30 ^{o}			
	Pre Cones	Post Cones	Pre Poron 4000™	Post Poron 4000™	Pre Cones	Post Cones	Pre Poron 4000™	Post Poron 4000™
Plantar Fascia Stiffness (N/m)	780.0 (136.0)	700.2 (93.5)	791.2 (93.5)	725.2 (131.6)	799.7 (142.6)	746.8 (97.0)	826.3 (157.5)	768.8 (155.8)
Plantar Fascia Frequency (Hz)	32.35 (3.92)	28.65 (2.33)	28.64 (2.33)	29.16 (2.65)	32.54 (3.67)	29.67 (2.40)	33.31 (3.52)	29.96 (3.50)
Tibialis Anterior Tendon Stiffness (N/m)	449.2 (116.7)	458.5 (114.0)	456.3 (96.8)	502 (176.8)	NA	NA	NA	NA

Table 7.4 Changes in plantar fascia and tibialis anterior tendon biomechanical properties as measured using the MyotonPRO™ before and after running with each orthotic condition (mean (SD))

7.4.5 Relationship between changes in secondary outcome and changes in foot posture

The change in foot posture with running and the change in secondary outcome measures was explored. To account for the multiple comparisons (n=8 per measure) a Bonferroni correction was performed where data was considered significant if P=0.05/8=0.006. Comparisons were made between FPI-6, NH, strength, stiffness (Biodex™) for each orthotic condition.

There was no significant relationship between changes in plantar fascia stiffness or frequency of oscillation (measured at 30 ^{o} hallux extension) and the change in FPI or NH. There was no relationship between the change in invertor strength or whole ankle stiffness and foot posture and the change in FPI or NH (Table 7.4).

Parameter		**Change in FPI (post-pre)**	**Change in NH (post-pre)**
Frequency (30 deg)	Cones	0.19	0.002
	Poron 4000™	0.00	0.017
Stiffness (30deg)	Cones	0.21	0.005
	Poron 4000™	0.001	0.004
Strength (Nm)	Cones	0.05	0.03
	Poron 4000™	0.05	0.06
Ankle Stiffness (Nm/rad.kg)	Cones	0.00	0.20
	Poron 4000™	0.14	0.3

Table 7.5 Association between changes in foot posture measures (FPI or NH) with running and secondary outcome measures. R^2 values are indicated – none were significant (P<0.006).

There was, however, a small but significant relationship between the change in NH and the product of the speed of running and BMI (figure 7.6).

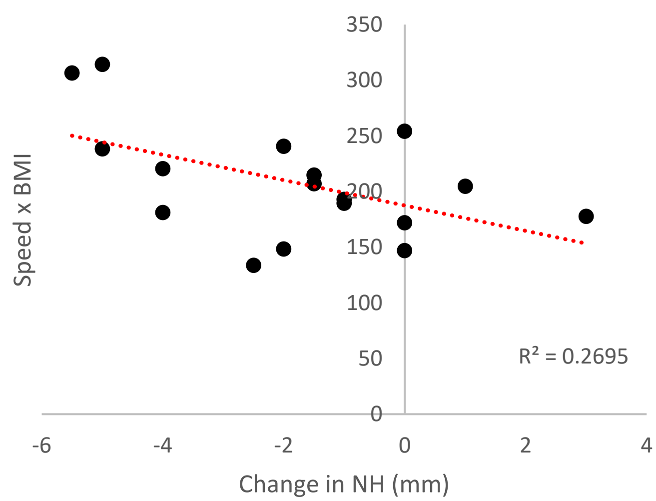


Figure 7.5 Relationship between the change in NH and the product of speed of running x BMI

7.4.6 Effort and pain during the run

Participants did not report any pain specific to the orthoses. Pain levels were rated at a maximum of 2/10 (n=3) and in all cases (n=5) the pain, or rather discomfort (when asked, all five participants objected to the word pain saying it was not pain but mild discomfort), was in the leg and reported as being normal for them. The pain score did increase over time (P=0.03) but there was no group difference (P>0.05) or group x orthosis effect (P>0.05, figure 7.7) and the mean score (0.14/10) and peak score (2/10 score) would not likely affect running. The participants all reported that they felt they were running normally during the trials.

All participants ran at the same, self-selected speed throughout the trials in both conditions. The Borg scale increased over time (P<0.005) reaching an average level of 12(±0.82) equivalent to between a rating of "fairly light" to "somewhat hard" – the same as that in chapter 5. The perceived exertion was higher in the Poron 4000™ orthosis group (P<0.05) during the run, however, and there was a significant group X time interaction (P<0.05) with people in the Poron 4000™ orthosis condition tending to plateau after 10-15mins of running (figure 7.5B).

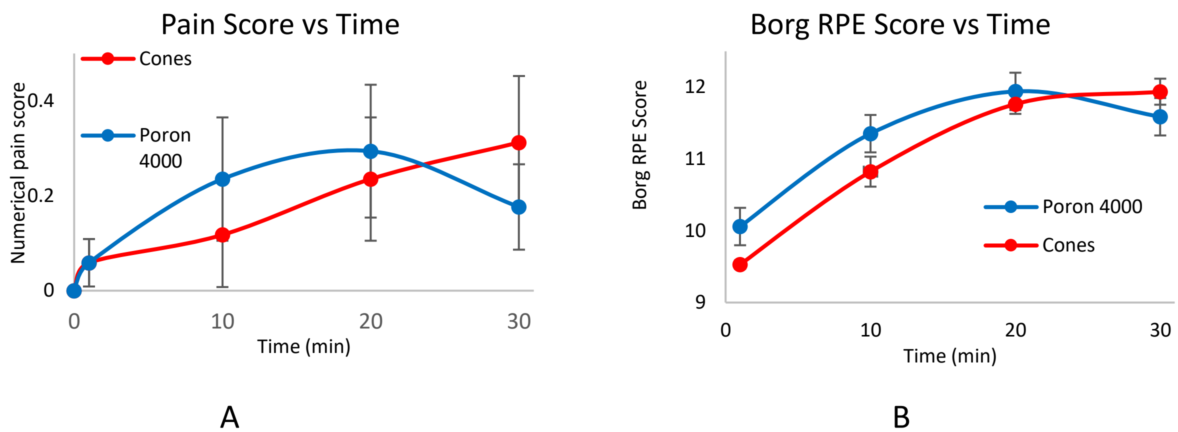


Figure 7.6 Changes in A) pain, and B) perceived effort during the run. (Mean ± SEM is indicated)

7.4.7 Effectiveness of blinding

The blinded assessor indicated which group she felt each participant belonged to at the end of session 1 (table 7.6). A Fisher's Exact test showed there was no difference between the correct and incorrect groups ie they performed at chance level. The orthosis condition was correctly guessed on 9 occasions and incorrectly guessed on 8 occasions. The number of incorrect-correct responses for the two orthoses varied (table 7.6) but this distribution was not significant (Fisher's exact test P>0.05).

	Correct	**Incorrect**
Cones	3	6
Poron	6	2

Table 7.6 Number of correct vs incorrect estimates of group allocation by the blinded assessor

7.5 Discussion

7.5.1 Effect of orthoses on primary outcome measures

There were no significant differences between orthotic conditions on the primary outcome measures. This may reflect several factors (a) there is no difference in the clinical effect of the Cones vs Poron 4000™ inserts (b) the Vectorthotics™ to which the Cones vs Poron 4000™ were fitted dominated any effects of the inserts (c) the trial was not long enough to induce the more marked changes required to see any effect. A comparison to the other studies undertaken in the thesis can help us to understand some of these areas.

7.5.2 Comparison with previous studies

The changes in the FPI-6 score were 1.06 Rasch logits for the Cones and 1.29 for Poron 4000™ and while the change in FPI-6 with Poron 4000™ was greater the change was not statistically significant from the Cones. Neither the Cones nor Poron 4000™ condition met the smallest detectable difference threshold for both orthotic conditions (5.85 mm for NH and 2.12 Rasch logits) and the NH change similarly reduced in both conditions but without reaching statistical significance or the SDD threshold. This indicated that there was no change in the measures of foot posture that wasn't due to chance in contrast to the findings of chapters 3 and 5.

The differences between the changes in foot posture in this study compared to the previous laboratory and field-based half marathon study show an effect of time but likely also the effect of foot orthoses on the change in foot posture as theoretically, 30 mins of running was sufficient to evoke a change in foot posture based on the secondary outcome measures of chapter 5.

The secondary outcome measures of chapter 5 did not, however, correlate to the change in foot posture and so it does remain possible that the running trial of 30 mins was too short to elicit the smallest detectable changes in foot posture that the orthoses could affect concurring with other laboratory work on foot posture over a 45 minute run (Boyer, Ward and Derrick, 2014). That the NH dropped in this study within the range of that which occurred with an hour of running without an orthosis compared to 30 mins with an orthosis (1.63 mm vs 1.62-1.82 mm) may relate to the orthoses creating more work in the invertors or plantar intrinsic muscles as shown in EMG studies of tibialis posterior (Murley, Landorf, *et al.*, 2009). These are however small numbers and there may also be accuracy errors with the navicular tuberosity as in this cohort the tuberosity was ambiguous in some feet making it difficult to palpate a single point – the tuberosity sometimes appeared to be more of a facet. The pen marks were semi-permanent and did remain visible after the trials although with sweat, some had blurred slightly increasing the chance of error to ~1 mm. This hadn't occurred before and may relate to the warmer environment as this trial took place in the summer months in a laboratory with only fan cooling available.

7.5.3 Effect of orthoses on secondary outcome measures of strength and stiffness

There were no significant differences between orthotic conditions on the secondary outcome measures. The reductions in strength and stiffness were either less or similar to that seen after 1h of running. The strength changes in this study were -1.2 and -3.9 Nm for the cones and Poron 4000™ respectively. This is less for both conditions than the hour of running with no orthoses in chapter 5 (-6.1 Nm). The stiffness changes in this study were -2 and -2.1 Nm/rad.kg respectively for the Cones and Poron 4000™ conditions. This is a similar reduction in medial ankle stiffness than in the hour of treadmill running in chapter 5 (-1.18 Nm/rad.kg). These results suggest that strength reductions may have been less in the current running trial. This may reflect an effect of the orthoses and/or an effect of a shorter running time. The changes in stiffness did not, however, reach the smallest detectable difference threshold (7.32 Nm/rad.kg) and so could be due to chance although as discussed in chaper 5, a change of 7.32 Nm/rad.kg equates to a 56 % reduction in stiffness and this has not been reported to date in the literature so is not a realistic value.

The novel measure of plantar fascia biomechanical properties did show differences with both running time, joint angle and interactions with the orthotic condition. With running, stiffness and frequency of oscillation decreased. In contrast when the hallux was extended to 30^{o} the stiffness and frequency of oscillation increased. This is in keeping with what would be expected; running led to a reduction in stiffness as supported by the whole ankle measures of stiffness and extending the hallux tensions the plantar fascia and so stiffness would be expected to increase. The frequency measure will also change. Soft tissues such as the plantar fascia will have visco-elastic properties. The natural harmonic motion of a spring is proportional to its stiffness:

$\omega=\sqrt{\frac{K}{M}}$ (where ω= angular frequency k=stiffness m= mass.)

The changes in stiffness and frequency with hallux angle and running highlight the validity of this technique and its potential use in future studies.

The lack of changes in the tibialis anterior may reflect that the tendon did not change or that the measure was not valid. As discussed previously tendon strain usually occurs longitudinally and the stimulus was a perturbation orthogonal to the usual direction of strain. The perturbation will place the structure under some strain in the orthogonal direction (ie longitudinally) but this may be small compared to that seen physiologically. In contrast, the plantar fascia, especially when put under tension to the hallux at 30^{o}, may have been strained more in the direction of its usual action when perturbed by the MyotonPRO™. In future testing tendon properties with the MyotonPRO™ should look at the structure when it is placed under different degrees of physiologically appropriate strain.

7.5.4 Study limitations

The 30-minute running time was chosen as the results of the 1 hour running trial proxy measures (DAI and ankle eversion) suggested that changes in foot posture were occurring after 30 minutes. Future work should look at longer running times of 1 – 2 hours. It may be that the effects of orthoses are only clinically significant if more marked changes in arch height occur as highlighted above. As well as a short run time that was different to previous studies another potential limitation is that the Cones-insert orthosis was compared to a Poron 4000™-insert orthosis with both inserts being attached to a Vectorthotic™. This was performed to allow a comparison with a usual care condition. This design does not however, allow one to assess the effect of the orthosis compared to a no orthosis condition nor to distinguish between the effects of the Vectorthotic™ and the inserts. Previous iterations of the novel orthotic has the Cones design integrated into an orthotic (figure 6.2). Such a design in future could allow a direct comparison of orthoses to be made. Alternatively, the insert could be designed to fit in directly into the shoe thus avoiding the need to attach to a Vectorthotic™.

7.5.5 Effects on efficiency

One finding was that the Borg score did not increase as much in the Cones condition compared to the Poron 4000™ condition up to 20 minutes. It is unclear why this is the case. The Borg score is correlated with measures of energy consumption (Chen, Fan and Moe, 2002; Irving *et al.*, 2006) so it is tempting to speculate that running efficiency may have been improved wearing the Cone orthotic. However, more direct measures would need to be taken looking at (a) whether ankle and foot motion is differentially affected by the Cones-orthotic (e.g using the proxy measures used in chapter 5) (b) there are indeed changes in peak VO_2 as measured directly. This raises another area of interest namely that orthoses may not only be useful for injury prevention but may also affect task performance. This will be explored in more detail in the discussion chapter.

7.5.6 Factors affecting changes in static foot posture

Although changes in plantar fascia stiffness with running were seen alongside changes in invertor eccentric strength and stiffness these changes were not associated with any change in static foot posture as measured by the FPI-6 and NH. In keeping with the finding in chapter 5 of an association between the change in foot posture with running speed here a tendency for a significant correlation between the change in NH and the product of the BMI and running speed. This raises the possibility that changes in foot posture are not uniform across participants but are affected by multiple factors including the impact force which is in turn affected by both the weight of the participant and their running speed. In addition, as discussed earlier, longer run durations (>1h) are associated with greater foot posture changes suggesting that duration of exposure to forces may be important. It may be that these factors have to be considered in the future when assessing anatomical contributors to foot posture changes. This will be further discussed in the final chapter.

The significant changes in FPI-6 and NH measures across the orthotic conditions leads to rejection of the null hypothesis that there is no difference in change of foot posture for either condition.

Strength in the Cones condition reduced less than in the Poron 4000™ condition but was not significant, leading to acceptance of the null hypothesis that the Cones component is no more effective at preserving strength than Poron 4000™. Medial stiffness reduced in both orthosis conditions but more in the Cones condition than the Poron 4000™. This, again, leads to acceptance of the null hypothesis that the Cones are not more effective at maintaining stiffness.

7.6 Conclusion

This study was not able to detect a difference in the performance of the two orthotic conditions tested with respect to foot posture, strength and stiffness. There was a difference in perceived exertion during the 30-minute run but the mechanism for this change is not explained by this study.

7.7 Summary

This chapter tested a novel orthotic component, which aimed to provide a variable orthosis reaction force against the foot, against an open cell foam commonly used in orthosis modification, Poron 4000™, which has a biphasic response to compression. The effect which was demonstrated for each of the components in chapter six was not found in this randomised controlled trial in terms of the effect on the foot as running for 30 mins in both orthotic conditions led to a small change in foot posture, strength and stiffness – all statistically significant but not reaching the threshold for smallest detectable difference. In this study a further set of stiffness measures was taken using a MyotonPRO™ and every measure changed by the smallest detectable difference but with some measures having large standard deviations (with confidence intervals crossing the zero point), the strongest variable for the measurement of stiffness of the plantar fascia with the MyotonPRO™ was stiffness since at both 0 and 30 degrees of dorsiflexion it had excellent reliability (0.85 and 0.86 respectively) and was able to detect change in stiffness of the plantar fascia above the threshold of the smallest detectable difference.

Chapter 8 : Discussion

In this thesis changes of measures of foot posture, ankle invertor eccentric strength and medial foot and ankle soft tissue stiffness have been used as a primary outcome measure having been shown to be highly reliable, to explore the extent to which foot posture changes with prolonged running by what mechanism it occurs. Overall, there was an effect of time (duration of running) on the changes in both measures of foot posture and strength and stiffness although foot posture change did not correlate significantly to either ankle invertor strength or medial foot and ankle stiffness. Furthermore, the foot posture change after 30 minutes of running was so minimal (and did not reach the SDD threshold) that exploring a relationship with this and the significant change in stiffness of the plantar fascia would be futile. More work with studies powered to detect the change in plantar fascia stiffness as a primary outcome measure may reveal the relationship. The relationship between whole ankle (medial foot and ankle soft tissue) stiffness was, however explored in chapter 5 and, after an hour of running, there was no relationship between foot posture change and strength or stiffness change.

To date the stiffness of the plantar fascia measured with the MyotonPRO™ has not been reported and this thesis presents the first reliable measure of the plantar fascia, with smallest detectable difference, with the instrument. Smallest detectable differences (SDDs) are presented here for the stiffness of the plantar fascia, tibialis anterior tendon, medial foot and ankle soft tissues and the eccentric strength of the ankle invertors - which have not been reported elsewhere with the Biodex™ isokinetic dynamometer and MyotonPRO™.

The minimal clinically important difference, however, remains unknown. This thesis did not explore the changes in people with pain and pathology or any systemic conditions. Further work is needed to understand the importance of changes in foot posture, medial foot and ankle soft tissue stiffness and ankle invertor strength in these populations.

The changes in the primary outcome measures throughout the thesis are small and may have questionable relevance at first glance. The effect sizes were, however 10 % or larger overall and loadbearing tendons normally only strain by 5-6 % with the toe region strain accounting for 1-4 % and with gross failure at 8-14 % (Screen *et al.*, 2004). Furthermore, fully transecting the plantar induces an arch drop of 7.4 mm and the plantar fascia will rupture at between 12 and 15 % strain (Pavan *et al.*, 2011). The change in strain has a curvilinear relationship with stress in collagenous structures so a change in foot posture due to yielding in passive collagenous soft tissues may be more indicative of the risk of injury. The change in muscle strength measured in this thesis may indicate that as a run progresses, the tendon begins to take more load as the muscle reduces force generation, again rendering the foot prone to injury. Cyclic fatigue testing of tendon has shown that even with a 4 % strain that fibrils in tendon lose the ability to slide back in recoil (Wren *et al.*, 2001) rendering them increasingly inelastic and elongated. The margin for change before the tissues of the foot become injured appears small and in the region of the findings of the studies in chapter 3 and 5. The participants in these studies were conditioned runners who were able to complete a half marathon or hour-long treadmill run so the margin for strain and foot posture change in the foot may be smaller in less conditioned individuals.

The gold standard for the measurement of strength and stiffness is an isokinetic dynamometer such as the Biodex™ used in this thesis. The changes required to occur to detected using this instrument were however extremely large with a 74 % change in stiffness being needed to occur before the Biodex™ could confidently show a change not due to chance, and a 56 % reduction in invertor muscle strength being required to show the same. Since the SDDs were calculated in quite small and in a mixed gender samples this may account for the large values required as the data sets showed relatively high variance. A change of this magnitude in stiffness would be indicative of failure of the tissues but muscle strength has been reported to drop by up to 70 % following fatigue programmes (Pohl, Rabbito and Ferber, 2010) so the values in this thesis that reach the threshold of the SDD indicate the Biodex™ is an appropriate tool to measure invertor strength with. Similarly, the SDDs for the foot posture measures were met in chapters 3 and 5 with two- and one-hour durations of running but not after 30 minutes with orthoses. The SDDs for foot posture are useful for evaluating changes in foot posture in people who run for an hour or more but possibly not less although without orthoses the change in foot posture may reach the threshold.

The measures of strength, stiffness and NH have all been shown to be highly reliable but the FPI-6 presents a more variable picture. The studies, including chapter 2 of this thesis, with the highest reliability report having undertaken dedicated training to reach agreement on interpretation of the factors described in the FPI-6 manual (Redmond, 1998). This is problematic for external validity of the studies undertaken following training vs those without. The manual is publicly available, but the individual training and interpretation agreement remains only within the team that undertakes it. For this reason, in publication of work using the FPI-6, a description of the interpretation of the factors should be given to help others replicate the work. In chapter 2 the protocol used is described for the FPI-6 testing in this thesis.

While the primary aim of the thesis was to measure foot posture changes and the contribution of the medial tissues and muscles to the change, a secondary aim was to determine when the changes occurred. In chapter 4 proxy tools were developed using 3DMA and plantar pressure analysis which resulted in poor to moderate correlations to midfoot on rearfoot rotations during walking at three speeds. The study was designed with fixed speeds of walking, however, and not normalised to percentages of self-selected walk speed as this made comparison of results more achievable. Some participants found walking at the fast speed was uncomfortable as they wanted to transition into running. The reason that this was not part of the design was that running generates higher forces and the sensors on the foot and ankle were prone to becoming loose in pilot trials of running due to the higher impact forces. This is, then, a limitation of the proxy tools as walking kinematics not running kinematics were recorded and correlated, and the data were prone to artefact leaving a high number of missing records for processing. It is possible that with a larger sample to process that the correlation of ankle eversion, tibial internal rotation and dynamic arch index would increase but for chapter 5, the measures were reported with caution despite the agreement that all three measures changed significantly possibly due to exactly this – a larger sample size.

At this stage then, the mechanism for the change in foot posture during prolonged running remains unclear. The reasons for this may lie in the diversity of the population tested in this thesis. Runners in each study ran at self-selected speeds and some ran at elite speeds while others ran in the amateur range. Those who ran faster also ran further in a week and the effect of conditioning on tendon resilience, which occurs in committed and highly performing runners, is well reported (Andarawis-Puri, Leni and May, 2011; Videbaek *et al.*, 2015). Tendon has been shown to demonstrate strain-rate dependency and so the fast runners may have run with stiffer tendons and slower runners with more compliant tendons which could have affected the change in stiffness after a prolonged duration of running. By narrowing the speed range and selecting runners with similar bodyweight and running speed, the picture may become clearer. Indeed, there was a small relationship between run speed and NH in chapter 5. The exclusion criteria aimed to reduce the likelihood of age, weight, gender, ill health or injury affecting the studies but running speed or other measures of fitness were not controlled for.

The changes in foot posture, strength and stiffness across 2, 1 and 0.5 hours of running are summarised in table 8.1.

Variable	30 mins (with orthoses, mean of both conditions P>0.05))	1 hour	2 hours
FPI-6	1.18	1.34	1.67
NH	-2.4 mm	1.63 mm	4.60 mm
Ankle invertor strength	-2.55 Nm	-6.11 Nm	-
Medial foot and ankle stiffness	-2.04 Nm/rad.kg	-1.12 Nm/rad/kg	-

Table 8.1 Summary of primary outcomes after different running durations

Later in the thesis the novel orthosis component was developed and showed a promising characteristic pattern of rate and peak force generation with different rates of loading. The effect did not translate into the RCT, however, as none of the measures taken were different for the biphasic Poron 4000™ component or the novel Cones. Both components were positioned atop a semi-rigid orthotic

(Vectorthotic™) shell which had been moulded to achieve contact with the proximal MLA in each participant.

The Vectorthotic™ can be moulded away from the first ray to avoid potential restriction of plantarflexion of the metatarsal head which could in turn increase strain in the plantar fascia during propulsion. As with all tests of orthotic effectiveness the desired outcome is not always directly measurable, however. Use of pedobarography, for example, can show the position of the centre of force relative reduction in pressure with orthoses, but there is no way of knowing which tissues internally are offloaded. Surface EMG is a method of determining changes in muscle activation with orthoses and could be used in conjunction with kinematic and kinetic force plate data, but these are seldom instruments used in a typical podiatry or physiotherapy clinic and very prone to artefact in running. Instead, the clinician must infer the orthotic dose from indirect measures: visible contact of the orthosis with the desired region of the foot, correct fit for foot and shoe size, pain reduction (in patients with mechanical pain), overall comfort, and ease of passive dorsiflexion of the hallux. Improvement of certain gait parameters may be used in addition and some clinicians use the supination resistance test (Noakes and Payne, 2003) to infer a change in tissue stress as a function of moving the centre of force laterally in a pronated foot. This ambiguity in research on foot orthoses has resulted in criticism from clinicians (Griffiths and Spooner, 2016) since the above checks (or similar) are rarely described in research protocols and do not translate easily into clinical practice where orthotic dosing (ensuring a mechanical effect against the foot) is critical to clinical effectiveness. The same ambiguity lies in exercise prescription protocols in research (Holden and Barton, 2018) and a recent tool to address this was published to aid clinicians translate research findings into practice (figure 8.1) (Slade, Dionne, Underwood and Buchbinder, 2016; Slade, Dionne, Underwood, Buchbinder, *et al.*, 2016).

Item Category	Item No.	Abbreviated Item Description
WHAT: materials	1	Type of exercise equipment
WHO: provider	2	Qualifications, teaching/supervising expertise, and/or training of the exercise instructor
HOW: delivery	3	Whether exercises are performed individually or in a group
	4	Whether exercises are supervised or unsupervised
	5	Measurement and reporting of adherence to exercise
	6	Details of motivation strategies
	7	Decision rules for progressing the exercise program
	8	Each exercise is described so that it can be replicated (eg, illustrations, photographs)
	9	Content of any home program component
	10	Nonexercise components
	11	How adverse events that occur during exercise are documented and managed
WHERE: location	12	Setting in which exercises are performed
WHEN, HOW MUCH: dosage	13	Detailed description of the exercises (eg, sets, repetitions, duration, intensity)
TAILORING: what, how	14	Whether exercises are generic ("one size fits all") or tailored to the individual
	15	Decision rule that determines the starting level for exercise
HOW WELL: planned, actual	16	Whether the exercise intervention is delivered and performed as planned

Figure 8.1: Consensus on Exercise Reporting Template (CERT) (Slade, Dionne, Underwood and Buchbinder, 2016; Slade, Dionne, Underwood, Buchbinder, *et al.*, 2016)

To reflect a similar process although without the benefit of expert agreement on the criteria here, the following table aims to capture the essence of the CERT for transparency:

Item Category	Item number	Abbreviated item description	RCT Chapter 7 Orthoses
Therapeutic objective(s)	1	Therapeutic objective(s)	Reduce change in foot posture to below 1.67 on FPI-6 and 1.3 mm on NH, Reduce loss of invertor stiffness & strength to <0.72 Nm/rad.kg and 3.32 Nm respectively
What (custom / not)	2	Custom, semi-custom, off the shelf	Semi-custom
	3 CUSTOM ONLY	Impression method (if used),	N/A
	4 ALL	Shell materials, prescription	2 mm semi-rigid heated to contact foot under distal heel and TNJ, moulded away (>1mm) from 1st ray, 12 mm heel cup, distal edge to metatarsal necks 1-5
	5 ALL	Posting (intrinsic or extrinsic) at forefoot, midfoot or rearfoot (degrees, materials, plane of action eg frontal, shape of posts	2 degree rearfoot frontal plane hemi-posts
	6	Forefoot extension (material, length eg to sulcus or full length)	N/A
	7	Top cover (material, thickness	Open cell foam moulded full length top cover (1-5 mm thick)
	8	Additional information eg adhesives, active componentry	Addition of 30 mm diameter disc of either: 3.4 mm thick Poron 4000™ of shore A hardness of 15 (constant); or 3 mm thick novel 3D printed disc of viscoelastic cones in a matrix of shore A hardness of 25 (reducing to 5 over 1 second) on a type A durometer
Who (provider)	9	Qualifications, teaching/supervising expertise, and/or training of the clinician or technician	Podiatrist of >10 years clinical experience in manufacture, prescription and fitting of FOs. Assistant trained by same podiatrist

How (delivery)	10	Measurement and reporting of adherence to advice on use of orthoses	Podiatrist modified and fitted basic shell. Assistant addedtion disc. Participant and researcher not allowed to remove or inspect orthoses in shoes.
	11	Details of advice upon dispensing including protocol for habituation and adverse reactions	Donned shoes with orthoses fitted in. Checked comfort and balance in standing, walking and treadmill running. Habituation: immediate use in walking then running
	12	Progression of prescription ie static or modifiable	Static
	13	Image or detailed description of orthoses provided	See chapter 7
Where	14	Footwear and activities orthoses to be worn in	Human Movement and Function Laboratory, PAHC, University of Plymouth
Application	15	Use of orthoses	For two 30 min running trials only
	16	Limitations of use	Neutral running shoes in good condition with adequate fastening
Outcome	17	Outcome measure(s)	FPI-6, NH, ankle invertor strength and medial ankle stiffness (Biodex™), plantar fascia and tibialis anterior tendon stiffness (MyotonPRO™)

Table 8.2 Novel template reporting the characterististics of the the FOs used in chapter 7

For further work in the field of foot posture change the question of selection of foot posture measures arises again. In this thesis, rationale is given for the selection of the FPI-6 and NH and they each served the studies fairly well with excellent reliability and high clinical utility. They are not particularly accurate, however, and as the RCT showed, variance in navicular shape in the population can mean that reliability is affected from time to time – the sample used for the reliability of NH in chapter 2 all had easily palpable navicular tuberosities but in the studies some were less palpable. The FPI-6 and NH have been used in other studies of foot posture change making comparison easy but other measures of foot posture have been found to be equally, if not more, valid, reliable and possibly less prone to surface anatomy variation. These measures, eg the longitudinal arch angle, should be considered for future work in this field.

Another limitation of the running studies in this thesis, was the rate of de-fatigue. While foot posture changes have been reported not to recover for about eight days after a marathon (Fukano *et al.*, 2018), muscle fatigue has been reported to recover by 80 % in two minutes after exertion ends (Pohl, Rabbito and Ferber, 2010). It was imperative that data collection after running was very swift and mostly it was. In one case, however, the process took longer due to technical difficulties with the Biodex™ and while all data was collected within 5 minutes, it is possible that every second lost after the run was leading to runner recovering.

Another limitation with the running studies in this thesis lies with the sampling. Convenience sampling was used and so the age and gender mix was skewed slightly, and the ethnic diversity was poor with just one person from BAME background and the rest being Caucasian. There are ethnic and age-related variations in feet (Redmond, Crane and Menz, 2008; Castro-Aragon *et al.*, 2009) and a more evenly distributed sample may be more generalisable.

Furthermore, dominance and baseline foot type were not controlled for beyond excluding extreme foot postures. Different FPI-6 scores between left and right feet have been reported (Rokkedal-Lausch *et al.*, 2013) although the study did not report limb dominance so it remains unknown if FPI-6 score is affected by dominance or other factors affecting asymmetry.

In this thesis results were not stratified for baseline foot type. The samples for each study had mean Rasch FPI-6 scores of 1.45 (chapter 3), 0.93 (chapter 5) and 1.20 (chapter 7) – a grand average of 1.2 (2 when converted back to the ordinal) score. As such the generalisability of the work relates to the population of long distance runners with neutral to very slightly pronated feet. Further work could explore the differences between high and lower arched feet in running to determine if the effect of change in foot posture is greater in more polarised foot types.

It would be logical to also test the intrinsic muscles of the foot for change since these are the remaining missing piece of information in the foot and ankle relating to change in foot posture. In addition, changes in strength and stiffness more proximally would be of interest since knee stiffness has been correlated to high impact forces (Tam *et al.*, 2017) a parameter of interest in people with RRIs.

The work presented in this thesis has shown that there is an effect of duration of running on foot posture, and that changes likely occur at 30 minutes into a run. The mechanism that influences the change in foot posture, however, remains unknown and further work is required to explore other muscle groups.

Chapter 9 : Conclusions

This thesis incorporates a review of the literature surrounding the change of foot posture after prolonged running, the variables to be considered during prolonged running research, and the use of foot orthoses in the management of changes in foot posture.

The measures used in each experimental chapter were tested for reliability and a moderately valid method developed to measure in-shoe kinematics and plantar pressures as a proxy for changes occurring that may relate to changes in static foot posture after a prolonged run.

A change in foot posture measured with the FPI-6 and NH was demonstrated after 2 hours, 1 hour and 30 minutes of running (with orthoses in-situ in the latter). The change in invertor strength and medial foot and ankle stiffness were measured after an hour and 30 minutes of running and changes were identified after both durations of running with a reduction in strength greater after an hour than half an hour with orthoses in situ. A further test of plantar fascia stiffness after a 30-minute run with foot orthoses revealed a reduction indicating that the orthoses did / NOT influence the stiffness of the plantar fascia. A novel measure of plantar fascia stiffness is presented along with the smallest detectable differences for the

FPI-6, NH, eccentric ankle invertor strength, medial foot and ankle soft tissue stiffness, tibialis anterior tendon and plantar fascia stiffness.

A novel orthotic component (Cones) was developed and tested and showed different stiffness responses when loaded at different speeds compared to Poron 4000™. The Cones showed a curvilinear response in peak force and rate of force generation compared to the more biphasic response of the Poron 4000™. The effect did not translate across to the response to running, however, with no significant difference between the change in foot posture, eccentric ankle invertor strength or medial foot and ankle soft tissue or plantar fascia stiffness.

Perceived exertion during an hour, during 30 minutes of running increased over time but the Borg score reported for foot orthoses combined with a novel Cones component designed and was less than for Poron situated on a semi-rigid orthosis shell indicating that there may be an effect of the Cones on the economy of running. While there was a change in foot posture, ankle invertor strength and medial foot and ankle soft tissue stiffness, there were no relationships between either foot posture measure and strength or stiffness.

It is not known how clinically significant the changes observed in this thesis are as no prospective work has yet been undertaken to establish a minimal clinically important difference for the changes of foot posture. The mechanism for the change in foot posture, as well as the extent to which the change is meaningful with respect to the risk of running-related injury risk, remains unknown following this work. Further research is needed to explore other mechanisms of foot posture change as well as the significance of the change to the risk of running-related injury.

Appendices

Appendix 1 : A pilot study investigating the effect of the first prototype Cones orthosis in walking

(E Cowley and J Marsden with research assistant D Essex, 2008)

Background:

The “Optimal Health Orthosis” (OHO) was a patented insole consisting of a medially sited array of air-filled buttressed cones. With an increase in the rate of vertical force application the stiffness of this coned area is felt to increase. It was hypothesised that with faster walking the relative lowering of the arch would be less when wearing the OHO.

A1.1 Aims:

To investigate the effects of walking speed on a proxy measure of arch height.

A1.2 Methods:

A1.2.1 Inclusion / exclusion criteria:

Healthy subjects with no current lower limb pain or history of lower limb orthopaedic or neurological problems in the age range 18-65 years were included.

A1.2.2 Baseline measures:

FPI-6, age and gender, foot length, weight and height.

A1.2.3 Procedure:

People walked at 5 different velocities between 0.75-1.75 m/s (2.7-6.3 km/h) with and without the OHO in standardised footwear (sandals). People practised at each speed until the velocity was +/- 0.2m/s, pacing via a metronome was provided for assistance. The order of the trials was randomised between subjects using a Latin squares design.

The motion of a marker attached to the dorsum of the skin overlying the tuberosity of the navicular bone was measured at 200 Hz using a 3D motion analysis system (CODAmotion™, UK).

A1.2.4 Sample size:

Mündermann *et al.* assessed the effects of different orthoses on ankle kinematics, kinetics and vertical force. In the control condition the vertical force on impact was 1499.1 N (+/- 255.6 *SD*) whilst with a combined posted/moulded orthosis the vertical force was 1352.3 (+/- 233.6). This produces an effect size of (1499.1-1352.3)/244.5=0.60. For a paired two-tailed with 80% power at a 0.05% significance level the estimated sample size was 24 (calculated using http://www.stat.uiowa.edu/~rlenth/Power/index.html).

A1.3 Analysis:

Navicular motion was be analysed using a repeated measures ANOVA with factors being orthosis (2 levels Control vs OHO) and velocity (5 levels v1-v5). Results were taken as significant if $P<0.05$.

A1.4 Results:

Twenty-four people were assessed. There was a significant effect of velocity with NH excursion being higher at higher walking speeds (table 0.1). There was a tendency for the excursion of the NH to be less when people wore the OHO (P=0.062). This effect was significant at higher velocities i.e V4 and V5 (P<0.05, figure 0.1).

	V1 **[0.75 m/s]**	**V2** **[1.0 m/s]**	**V3** **[1.25 m/s]**	**V4** **[1.5 m/s]**	**V5** **[1.75 m/s]**
Control	56.58 (1.27)	60.58 (1.56)	62.67 (1.50)	64.24 (1.46)	65.54 (1.65)
OHO	55.14 (1.41)	60.53 (1.45)	61.84 (1.42)	62.49 (1.39)	63.54 (1.47)

Table 0.1 Total excursion of navicular (mm) at 5 different velocities (mean (+/- *SD)* indicated)

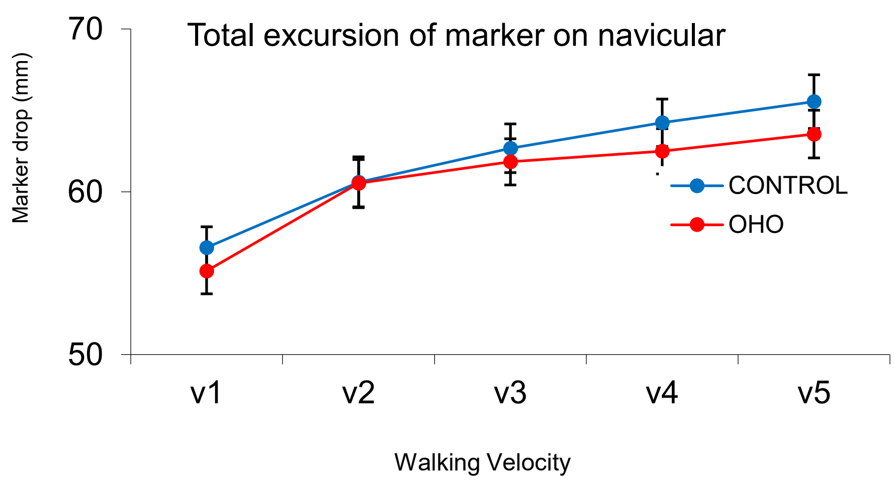


Figure 0.1 Total excursion of navicular (mm) at 5 different velocities (mean (+/- *SD)* indicated)

A1.4 Discussion

This study aided the development of the Cones technology (chapter 6 and 7). It also highlighted the effects of speed on proxy measures of pronation and helped to inform the half marathon study looking at foot posture changes (chapter 3).

Appendix 2 : Patent informing the Cones orthotic component

The patent cited in chapter 6 can be accessed at this link:

Cowley, E E. and Achilles, A. (2009) *Foot Orthoses Apparatus*, GB Intellectual Property Office Patent no. 0705094.1 GB2447646

PEARL: https://pearl.plymouth.ac.uk/handle/10026.1/1574

Appendix 3 : Information sheets and consent forms

A study to identify the effects of a half marathon on foot posture

Subject Information: Please read before completing the consent form

Dear Subject

In order to give informed consent to enter the study please read this letter before you complete the consent form.

Who is conducting the research?

The study is being conducted by Emma Cowley (lecturer in the University of Plymouth Faculty of Health and Social Work) and Jon Marsden (professor of rehabilitation in the University of Plymouth Faculty of Health and Social Work). Ethical approval has been granted by the University of Plymouth Faculty of Health and Social Work ethics committee.

What will happen to the data taken from me?

All data obtained will be anonymised and accessed only by the researchers and authorised members of the research team. Following publication of the study the data will be destroyed.

Who can I contact to find out more or notify of any changes to my circumstances?

Please contact Emma Cowley:

Emma.cowley@plymouth.ac.uk Tel: 01752 588838

What is my commitment to the study?

You are volunteering to enter the study as a registered runner in the 2009 Plymouth Half Marathon. You may withdraw from the study at any point without giving a reason.

There will be two events for data collection, one a few days prior to the half marathon and one immediately after you finish the half marathon.

Data collection will involve:

- Taking two photographs of your feet
- Marking your feet with a small biro dot on the inside border
- A researcher palpating (gently feeling for a bone)

Data will be taken from both feet while you stand, with support for balance, on one foot at a time. Data will be stored under your Plymouth Half Marathon registration number.

Where will data be collected?

You will be invited to visit the Peninsula Allied Health Centre (PAHC) situated on the University College Plymouth Marjon campus in the Derriford area of Plymouth (PL6 8BH for your sat nav).

The date prior to the half marathon will be agreed with you and the post-half marathon data collection will take place in one of the tents on the Hoe as you come off the finish line. A member of the research team will be at the finish line to guide straight to the research tent and see to your immediate refreshment needs. It is important that we measure your feet within 5 minutes of you finishing the race so please endeavour to come straight to us. Please hand you tag in AFTER the data collection – the clock stops when you cross the finish line so don’t worry about us extending your race time.

What is the risk to me?

The risk to you from this study is absolutely minimal with the greatest risk being the exertion of the half marathon itself. To negate fatigue related hunger and thirst following the race, refreshments will be available to you in the research tent.

Eligibility Criteria

Please ensure you can answer all the following with the ‘answer needed to enter the study’

Question	Answer needed to enter the study
Are you aged between 18 and 60 years?	Yes
Do you normally wear foot orthoses (insoles prescribed for you by a health professional or bought from a shop)?	No
Will you be wearing foot orthoses during the Plymouth Half Marathon?	No
Have you had any surgical treatment (operations) on your feet or legs?	No
Do you have any ongoing cardiovascular (heart or lung) disease?	No
Have any history of foot injury in the last six months?	No

What do I need to bring? Are there any special instructions?

PRE-half marathon data collection

- When you come to PAHC please **do not run** for the two hours prior to your appointment
- Bring with you
  - **Your race number**
  - **Your signed consent form**
  - **Your expected race completion time** (roughly) and any distinguishing features that our research team can look out for(e.g. colour of your tee shirt) when you arrive at the finish line
  - Your trainers that you intend to run the half marathon in and any others you are training in
  - Your running shorts (or usual running attire)

- If you intend to drive onto campus in office hours for your data collection I can arrange parking for you – please contact me at least 24hrs prior to coming in with your car registration number

POST-half marathon data collection

- **Your race number**

Many thanks for your time and attention **– if you are happy to go ahead please now complete and sign the consent form.**

Kind regards

Emma Cowley

Study Title: Identifying the effects of a half marathon on foot posture	
I am prepared to be involved in the study and am happy that my anonymous data is included in the research.	
WRITTEN CONSENT FORM	Please Initial
• I understand what is in the written information about the research.	
• I have had the chance to find out more about the study if I wished to.	
• I know what my part will be in the study and I know how long it will take.	
• I know how the study will affect me. I have been told if there are any possible risks.	
• I know that the appropriate Research Ethics Committee has seen and agreed to this study.	
• I understand that I should not actively take part in more than 1 research study at any time.	
• I understand that personal information is strictly confidential: I know that the only people who may see information about my part in the study are the research team or an official representative of the organisation that funded the research.	
• I freely consent to be a participant in the study. No one has put pressure on me.	
• I know that I can stop taking part in the study at any time.	
• I know that if there are any problems I can contact: **Emma Cowley**	

School of Health Professions Faculty of Health and Social Work University of Plymouth PL6 8BH

Tel 01752 588838

emma.cowley@plymouth.ac.uk

Your signature: ………………………………… Date:…………………………………

Your name (Please print)………………………..

Contact Address…………………………………………………………………………

…………………………………………………………………………….

If you wish to receive an executive summary of the research please tick the box.

The chief investigator responsible for the research should sign the following.

As the chief investigator responsible for this research or a designated deputy, I confirm that the nature and purpose of this research have been explained to the participant named above.

Investigators Name: …………………………………

Investigators Signature: ………………………………… Date: …………………..

Emma Cowley
Plymouth University
School of Health Professions
Peninsula Allied Health Centre
Derriford Road
Plymouth
PL6 8BH

Email:
ecowley@plymouth.ac.uk
Tel: 01752 588838

Information form for prospective participants of the Foot-ProEx study

Dear prospective participant

You are invited to take part in a research project investigating the response of the foot and leg to prolonged running. We are interested in assessing how the muscles and other soft tissues in the foot and leg change their characteristics such as strength and stiffness and also whether the foot changes shape slightly following such prolonged exercise.

The project will contribute towards a PhD degree being undertaken by Emma Cowley at Plymouth University and will form an important foundation for future work in the response of muscles and tendons to prolonged exercise.

What will it involve?

Summary

- Reading information sheet and asking any questions you have
- Completing and returning the self-selection questionnaire and consent form
- Visiting PAHC for tests including walking or running on a treadmill for an hour with sensors on your right leg
- Before and after the hour of running having strength and stiffness tests and a measurement of your foot posture

You are eligible to take part if you are:

1. Aged between 18 and 65 years, 2. Able to give informed consent

You are not eligable to take part if you:

1. Cannot run for one hour at self-selected speed on a treadmill, **2.** Have a history of cardiorespiratory (heart and lung) or musculoskeletal conditions that limit exercise, **3.** Have had surgery affecting your lower limbs or feet in the last year or any surgery which has significantly altered lower limb function such as joint fusion or repacement etc, **4.** Have any leg, ankle or foot pain or significant foot deformity, **5.** Wear prescription foot orthoses in normal walking or running, **6.** Wear motion control footwear normally or have any other reason why you could not run for an hour in neutral footwear, **7.** Are not willing to wear neutral training or walking shoes which are in good condition and well fastened to your feet during the trial, **8.** Are pregnant or up to 12 months post-partum, **9.** Are using anabolic steroids, **10.** Have any pacemakers or other internal devices fitted such as auto-defibrillators

Full description of participant involvement

The self-screening questionnaire at the end of this form should be completed prior to consenting to enter the study. It allows you to assess yourself to see if you meet the inclusion (and none of the exclusion) criteria for the study. Once completed you can email it to Emma Cowley at ecowley@plymouth.ac.uk where she can check your responses and invite you visit the the Human Movement and Function Laboratory at the Peninsula Allied Health Centre (PAHC), Plymouth.

During the visit to PAHC your lower limbs and feet will be assessed by Emma Cowley who is an experienced podiatrist registered with the Health and Care Professions Council. She will also check for any further problems with you entering the study. It is unlikely that having completed the self-screening questionnaire that you will not be eligable to enter the study but this is a quick and necessary part of the process to ensure that any data collected will be useful. There is a small chance, however, that you may not be entered into the study following this assessment and there is no opportunity to claim back travel expenses etc but you will be still be eligable for the incentivisation package so shouldn't feel that you've had a wasted journey.

Incentivisation Package

All volunteers who have completed the self-selection form and visited PAHC will have a brief free consultation regarding running or walking. In addition you will have a short burst of high speed video footage recorded during your treadmill running trial which will be reported on clinically and sent by email to you. This is not a full clinical assessment, however, and you may decide to seek a full podiatric assessment with another podiatrist and take the footage along with you.

Running Trial

With all checks completed Emma will then take some measurements of your height, weight, foot posture and other simple tasks and ask you some questions about your fitness and other related items.

Your right leg will then be fitted with electromyography (EMG) sticky pads with wires attached you will be secured with seat belt type straps in a machine that tests your ankle strength and also performs gentle stretches on your ankle. This will involve you putting in effort for the strength tests but will not hurt.

After that you will have several motion markers stuck to your leg with sticky tape, a 'wand' secured around the top of your leg below your knee and other EMG pads fitted and these will all be secured well with tape and other adhesives to ensure they don't fall off during the walking or running trial.

We will test the system then ask you to put on your running shoes which will have a pressure sensor fitted inside temporarily before asking you to step onto the treadmill.

We will ensure you are familiar with the treadmill controls and then, with the treadmill started we will test the system further to ensure it is collecting data effectively. In that time you can get used to the treadmill moving and select your preferred speed for the hour ahead.

We will then begin the trial with you aiming to run at an easy to somewhat hard pace that you can maintain for an hour.

During the hour we will trigger the system to collect data from the equipment fitted to you every ten minutes.

After the hour we will quickly repeat the initial strength and stiffness tests and foot posture before removing all the equipment.

You will be offered rest, refreshment and a warm blanket if needed while you recover after the trial.

If at any point you need to stop the trial due to pain, exhaustion, or other non-emergency reason we will take the strength, stiffness and foot posture measurements as if you had completed the hour unless this is not possible.

You are eligible to take part if you are:

1. Aged between 18 and 65 years
2. Able to give informed consent

You are not eligable to take part if you:

1. Cannot run for one hour at self-selected speed on a treadmill.
    a. You will be asked if you have achieved similar tasks in the last three months without detriment to your health
2. Have a history of cardiorespiratory (heart and lung) or musculoskeletal conditions that limit exercise (cardiac arrest, stroke, angina, exercise induced asthma, chronic compartment syndrome, painful arthritis in the lower limbs and feet etc
3. Have had surgery affecting your lower limbs or feet in the last year or any surgery which has significantly altered lower limb function such as joint fusion or repacement or tendon transfers etc.

4. Have any leg, ankle or foot pain or significant deformity (see pictures in self-selection form)

5. Wear prescription foot orthoses in normal walking or running

6. Wear motion control footwear normally or have any other reason why you could not run for an hour in neutral footwear

7. Are not willing to wear neutral training shoes which are in good condition and well fastened to your feet during the trial

8. Are pregnant or up to 12 months post-partum

9. Are using anabolic steroids

10. Have any pacemakers or other internal devices fitted such as auto-defibrillators

If you agree to participate in the study you will be asked to sign the consent form at the end of this form. You will be provided with a copy of this information sheet.

The whole study will take approximately 2 hours to complete and parking can be arranged for you with prior notice.

All hard copy data will be stored securely in locked cabinets and labelled to anonymise it and electronic data will be encrypted and kept at the PAHC building in accordance with the Data Protection Act (1998). Data will only be accessed by the research team.

If you wish you can request an executive summary of the research when completed and the opportunity to read the full version if requested. All data collected will remain confidential, used only for this piece of research, and will not be linked to you by name.

You should not feel under any pressure to take part in the study. If you choose to take part you are free to withdraw yourself and your data at any stage, upon which all personal details will be immediately destroyed. Withdrawal from the study will not affect you in any way at all and you do not have to give any reason for stopping the trial. If you are a student at the University declining to take part in the study or withdrawal from the study will not affect your studies in any way.

This study has been approved by the Plymouth University, Faculty of Health, Education and Society Ethics Committee.

Please feel free to ask any questions that you might have before you make your decision regarding this study. If you have any questions after the study please feel free to contact the investigator Emma Cowley whose contact details are given at the top of this letter.

If you decide to participate, then please complete the following self-selection and consent forms and return to Emma Cowley.

When invited to PAHC, you will be asked to wear or bring your regular neutral trainers, thin socks, shorts that sit above the knee and light, breathable top with you. These will be worn during the running trial and we have changing facilities at

PAHC. You may also need warmer clothes for after the trial. We have shower facilities at PAHC which you are welcome to use if you bring shower gel and a towel along. Please bring with you any hair ties, music, screw top drinks bottles and hand towels (to mop brow). We will ensure the lab is conducive to a prolonged run with fans and fresh circulating air and can offer energy drinks for the period during and after the run if needed.

Thank you

Emma Cowley

Emma Cowley
Plymouth University
School of Health Professions
Peninsula Allied Health Centre
Derriford Road
Plymouth
PL6 8BH

Email:
ecowley@plymouth.ac.uk
Tel: 01752 588838

Consent form for prospective participants of the Foot-ProEx study

Please circle your responses

I have read and understood the information sheet informing me about the nature of the Foot-ProEx study	YES	NO
I have had opportunity to ask any questions I have and have received satisfactory and clear answers	YES	NO

I have had 24 hour's opportunity to cool off and withdraw consent	YES	NO
I understand that I can withdraw at any time from the study and all my data and all my data will be destroyed and not used for the study	YES	NO
I understand that I will be undertaking the treadmill trial and biodex tests at my own risk	YES	NO
I understand that the treadmill trial or any test can be stopped immediately at my request	YES	NO
I understand that I will bring any medication needed to control an asthma attack or other change in health that may occur due to my underlying health	YES	NO
I consent to data being used if I cannot walk or run for the full hour but still manage to fulfil the pre- and post-trial tests	YES	NO
I consent to entering the Foot-ProEx study to take part in the (select either or both options although the trials would be conducted on separate days if both are selected)	WALKING TRIAL	RUNNING TRIAL

Thank you for completing this form

Please return it to Emma Cowley at ecowley@plymouth.ac.uk or at the land address at the top of the page.

Emma Cowley
Plymouth University
School of Health Professions
Peninsula Allied Health Centre
Derriford Road
Plymouth
PL6 8BH

Email:
ecowley@plymouth.ac.uk
Tel: 01752 588838

Information form for prospective participants of a study investigating the effects of prolonged exercise on the foot - the Foot-ProEx study

Dear prospective participant

Invitation to participate

We would like to invite you to participate in a research study. Before you decide whether or not to participate, it is important for you to understand why the research is being done and what it will involve. This information sheet explains the background and aims of the study. Please take time to read it carefully and discuss it with others if you wish. If there is anything that is unclear, or if you would like more information, please ask us. Your participation in this study is entirely voluntary.

What is the aim of the study?

We are interested in assessing how the muscles and other soft tissues in the foot and leg change their characteristics such as strength and stiffness and also whether the foot changes shape slightly following such prolonged exercise.

What will it involve?

Study Summary

- Reading the information sheet and asking any questions you have
- Completing and returning the self-selection questionnaire and consent form
- Visiting the Peninsula Aliied Health Centre twice for tests including running on a treadmill for half an hour
- Before and after the thirty minutes of running, having strength and stiffness tests and a measurement of your foot posture

You are eligible to take part if you are:

3. Aged between 18 and 65 years,

4. Able to give informed consent

You are not eligible to take part if you:

11. Cannot run for thirty minutes at self-selected speed on a treadmill,

12. Have a history of cardiorespiratory (heart and lung) or musculoskeletal conditions that limit exercise

13. Have had surgery affecting your lower limbs or feet in the last year or any surgery which has significantly altered lower limb function such as joint fusion or replacement

14. Have any leg, ankle or foot pain or significant foot deformity

15. Wear prescription foot orthoses in normal walking or running

16. Wear motion control footwear normally or have any other reason why you could not run (depending on trial) for half an hour in neutral footwear

17. Are not willing to wear neutral training or walking shoes which are in good condition and well fastened to your feet during the trial

18. Are pregnant or up to 12 months post-partum

19. Are using anabolic steroids

20. Have any pacemakers or other internal devices fitted such as auto-defibrillators

Full description of participant involvement

The self-screening questionnaire at the end of this form should be completed prior to consenting to enter the study. It allows you to assess yourself to see if you meet the inclusion (and none of the exclusion) criteria for the study. Once completed Emma can check your responses and invite you visit the the Human Movement and Function Laboratory at the Peninsula Allied Health Centre (PAHC), Plymouth.

During your first visit to PAHC your lower limbs and feet will be assessed by an experienced podiatrist (Emma Cowley) registered with the Health and Care Professions Council. She will also check for any further problems with you entering the study. It is unlikely that having completed the self-screening questionnaire that you will not be eligible to enter the study but this is a quick and necessary part of the process to ensure that any data collected will be useful. There is a small chance, however, that you may not be entered into the study following this assessment.

Running Trial

With all checks completed we will then take some measurements of your height, weight, foot posture and other simple tasks and ask you some questions about your fitness and other related items. For women this will include asking whether you regularly use the oral contraceptive and your pregnancy history as these are things that can affect the stiffness of your joints.

Muscles on your right leg will then be fitted with pads which attach via wires to a device that straps around your waist; this device will measure the activity in your muscles. The muscle strength and stiffness in the right ankle will then be assessed. Here your foot will be placed in a support that will attach to a motor that will either very gently move your ankle, to measure muscle stiffness, or provide resistance while you push against it, to measure muscle strength.

During this period, Emma and her assistant will prepare an insole to fit into your shoe. You will wear this insole only during the run and on each visit to the lab the insole will be very slightly different. Neither you or Emma will know which variation you are running in as they will feel and look very similar. The assistant will, therefore, take your running shoes behind a screen to fit the insoles in and again, at the end of the run, remove them and place them in an envelope so you and Emma never see them. This is to satisfy the ‘blind’ nature of the experiment so that we don’t influence the results. The insole variations are very similar to shop-bought insoles and not a prescription that should hurt or harm you in any way.

After the insole fitting you will then have opportunity to prepare yourself for your run and be asked to put on your running shoes. We will ensure you are familiar with the treadmill controls and then, with the treadmill started you can get used to it moving and select your preferred speed for the thirty minutes ahead. If, during the fitting phase or run, you feel that the insoles are hurting you or making you feel unsteady you can choose to stop the trial and exit the study immediately and all data up until that point will be deleted and / or trashed.

Assuming you are happy to proceed, we will then begin the trial with you aiming to run at an easy to somewhat hard pace that you can maintain for half an hour.

During the run we will check your comfort and exertion status every ten minutes but you are free to offer information in the periods in between this. After the run we will quickly repeat the initial strength and stiffness tests and foot posture and you will be offered rest, refreshment and a warm blanket if needed while you recover after the trial.

If at any point you need to stop the trial due to pain, exhaustion, or other non-emergency reason we will take the strength, stiffness and foot posture measurements as if you had completed the thirty minutes. During the run we will be continuously monitoring you to ensure you do not get over-fatigued.

Who can take part in the study?

You are eligible to take part if you are:

1. Aged between 18 and 65 years
2. Able to give informed consent

You are not eligible to take part if you:

1. Cannot run for half an hour at self-selected speed on a treadmill
    a. You will be asked if you have achieved similar tasks in the last three months without detriment to your health
2. Have a history of cardiorespiratory (heart and lung) or musculoskeletal conditions that limit exercise (cardiac arrest, stroke, angina, exercise induced asthma, chronic compartment syndrome, painful arthritis in the lower limbs and feet
3. Have had surgery affecting your lower limbs or feet in the last year or any surgery which has significantly altered lower limb function such as joint fusion or replacement or tendon transfers
4. Have any leg, ankle or foot pain or significant deformity (see pictures in self-selection form)
5. Wear prescription foot orthoses in normal walking or running
6. Wear motion control footwear or run / walk barefoot or in minimalist footwear normally or have any other reason why you could not run for half an hour in neutral footwear
7. Are not willing to wear neutral training or walking shoes which are in good condition and well fastened to your feet during the trial
8. Are pregnant or up to 12 months post-partum
9. Are using anabolic steroids
10. Have any pacemakers or other internal devices fitted such as auto-defibrillators

If you agree to participate in the study you will be asked to sign the consent form at the end of this form. You will be provided with a copy of this information sheet.

The whole study will take approximately 2 hours to complete and parking can be arranged for you with prior notice.

What should I wear?

When invited to PAHC, you will be asked to wear or bring your regular neutral running shoes, thin socks, shorts and a light breathable top with you to keep you cool. We only have fans in the lab – not air conditioning. These will be worn during the trial and we have changing facilities at PAHC. You may also need warmer clothes for after the trial. We have shower facilities at PAHC which you are welcome to use if you bring shower gel and a towel along. Please bring with you any hair ties, music, screw-top drinks bottles and hand towels (to mop brow). We will ensure the lab is conducive to a prolonged run with fans and fresh circulating air plus fluids and refreshments but you may prefer your own.

Will my records be confidential?

All data will be stored securely in locked cabinets and labelled to anonymised it or encrypted electronic files and kept at the PAHC building in accordance with the Data Protection Act (1998). Data will only be accessed by the research team.

If you wish, you can request an executive summary of the research when completed and the opportunity to read the full version if requested. All data collected will remain confidential, used only for this piece of research, and will not be linked to you by name.

Do I have to take part?

You should not feel under any pressure to take part in the study. If you choose to take part you are free to withdraw yourself and your data at any stage, upon which all personal details will be immediately destroyed. Withdrawal from the study will not affect you in any way at all and you do not have to give any reason for stopping the trial. If you are a student at the University declining to take part in the study or withdrawal from the study will not affect your studies in any way.

What are the possible benefits of taking part in this study?

There are no direct benefits to you in participating in the study except that all volunteers who have completed the self-selection form and visited PAHC will have a brief free consultation regarding running. This is not a full clinical assessment, however, and you may decide to seek a full podiatric assessment with another podiatrist.

What are the possible disadvantages of taking part in this study and what happens if something goes wrong?

The study may make you feel tired that day and the next day but we are not asking you to exert yourself any more than you normally do in everyday life / while training. In the unlikely event that something goes wrong there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay for it. If you are unhappy with this study please approach the researchers of this study, or alternatively you may wish to discuss your concerns with an independent researcher at the University of Plymouth – Dr Lisa bunn on 01752 588882 email: lisa.bunn@plymouth.ac.uk

Who has reviewed this study?

This study has been approved by the Plymouth University, Faculty of Health and Human Sciences Ethics Committee.

Your rights

Your participation in this study is entirely voluntary. You may withdraw at any time without it affecting your current or future health care treatment in any way.

Contact for further information

Please feel free to ask any questions that you might have before you make your decision regarding this study. If you have any questions after the study please feel free to contact the investigator Emma Cowley whose contact details are given at the top and bottom of this letter. If you decide to participate, then please complete the following self-selection and consent forms and return to Emma Cowley.

Emma Cowley
Phone: 01752 588838
e-mail: emma.cowley@plymouth.ac.uk

Thank you
Emma Cowley

Self Selection Survey:

You will be sent a link to this form in an email.

Emma Cowley's Running Study: Self Assessment Questionnaire

There are 18 questions that shouldn't take more than 5 minutes to complete

*Required

Please type in the 3 digit code sent to you by Emma Cowley *

It should look something like this CBA

Do you have any medical conditions? *

eg diabetes, asthma or epilepsy. Please write 'no' if you do not have any

What is your shoe size (UK)? *

eg 5 or 8

Have you had any joints fused with surgery (arthrodesis)? *

eg big toe joint (1st MTPJ) during bunion surgery

- No
- Yes

Have you had any tendons cut or repaired with surgery? *

eg Achilles tendon, toe tendons

- No
- Yes

Have you had any lower limb joints replaced? *

eg knee, hip

- No
- Yes

What medication or dietary supplements are you taking (including self 'prescribed' medication)? *

eg Salbutamol (asthma), paracetamol (pain), protein shake (diet). If none type 'none'

What medication or dietary supplements are you taking (including self 'prescribed' medication)? *

eg Salbutamol (asthma), paracetamol (pain), protein shake (diet). If none type 'none'

Have you had a steroid injection into any joints or soft tissues in your lower limbs in the last six months? *

- No
- Yes

Female volunteers: Are you pregnant or up to twelve months post-partum?

Male volunteers please skip to question 12

- No
- Yes

Female volunteers: Are you taking the oral contraceptive pill?

Male volunteers please skip to question 12

- Yes
- No

Female volunteers: How many pregnancies of any length have you had in your lifetime?

Please include pregnancies not resulting in childbirth. Male volunteers please skip to question 12

- 0
- 1
- 2
- 3
- More than 3
- Prefer not to say

Do you wear any insoles / arch supports / inserts / heel cushions / orthoses etc in your shoes? *

Include any bought from a shop or prescribed by a health professional

- Yes
- No

If you answered yes to the last question, can you run for half an hour without your inserts without pain?

If you answered 'no' to the last question please skip to the next question.

- Yes
- No
- Other:

When standing barefooted, can you move your big toes easily up towards the ceiling without pain or joint stiffness? *

Do they easily come away from the ground?

- Yes, easily and they move upwards to almost a right angle to the ground
- Yes but a bit stiff and / or painful. The toes only move a little way from the ground
- No - this was painful and / or the toes were very stiff and did not move away from the ground without moving my whole foot
- Other:

Do you have bunions? (hallux valgus) *

This is either where your big toes have moved across towards the outer side of your foot or a 'lumpy' or enlarged big toe joint causes your joint to be stiff or painful

- Yes - severe
- Yes - moderate
- No
- Other:

What make and model are your current running shoes? *

eg Nike Free 3.0. Please feel free to add more than one make / model if you wear more than one for different sports or terrains

Could you run for half an hour in your 'neutral' running shoes without pain? *

ie running shoes with no special features or specific sport intended

- Yes
- No
- Not sure

How long does it take you to run a mile? *

Emma Cowley
Plymouth University
School of Health Professions
Peninsula Allied Health Centre
Derriford Road
Plymouth
PL6 8BH

Email:
ecowley@plymouth.ac.uk
Tel: 01752 588838

Consent form for prospective participants of the Foot-ProEx study

Please circle your responses

I have read and understood the information sheet informing me about the nature of the Foot-ProEx study	YES	NO
I have had opportunity to ask any questions I have and have received satisfactory and clear answers	YES	NO

I have had 24 hour’s opportunity to cool off and withdraw consent	YES	NO
I understand that I can withdraw at any time from the study and all my data will be destroyed and not used for the study	YES	NO
I understand that I will be undertaking the treadmill trial and tests at my own risk	YES	NO
I understand that the treadmill trial or any test can be stopped immediately at my request	YES	NO
I understand that I will bring any medication needed to control an asthma attack or other change in health that may occur due to my underlying health	YES	NO
I consent to data being used if I cannot run for the full thirty minutes but still manage to fulfil the pre- and post-trial tests	YES	NO
I understand that personal information is strictly confidential: I know that the only people who may see information about my part in the study are the research team or an official representative of the organisation that funded the research	YES	NO

I know that I can stop taking part in the study at any time	YES	NO
I know that if there are any problems I can contact Name: Emma Cowley E mail: emma.cowley@plymouth.ac.uk Tel 01752 588838		
I consent to entering the Foot-ProEx study to take part in the trials	YES	NO

Your signature: ……………………………….…

Date:……………………………….…

Your name (Please print)………………………..

Contact Address………………………………………………………………………

…………………………………………………………………………

If you wish to receive an executive summary of the research please tick the box. ☐

As the chief investigator responsible for this research or a designated deputy, I confirm that the nature and purpose of this research have been explained to the participant named above.

Investigators Name: ……………………………….…

Investigators Signature: ……………………………… Date: …………………..

Thank you for completing this form

Appendix 4: Contribution to knowledge and declarations of interest

Contribution to knowledge:

The aspects this thesis that contribute new technology to the existing body of evidence are highlighted in table A1:

Chapter	Contribution to knowledge	Published / conference
2	Development and establishment of the Reliability of the MyotonPro™ for the measurement of plantar fascia stiffness	
3	Identified changes in foot posture after running a half marathon	Yes
4	A new proxy tool validated for the use of measuring in-shoe foot and ankle kinematics	
5	Identified timing of changes in Dynamic Arch Index during a prolonged treadmill run	
5	Identified changes in strength of the ankle invertors after a prolonged treadmill run	Yes
6	Designed and tested proof of concept of novel foot orthosis component	
7	Demonstrated effects of novel foot orthosis component vs commonly used orthosis component on foot posture and plantar fascia stiffness	Yes

Table A1: Contribution to knowledge

Declarations of interest:

- Tuition fees for this PhD were provided by the University of Plymouth, School of Health Professions.
- The foot orthoses (Vectorthotics™) used in the randomised controlled trial (chapter 7) were purchased by the University of Plymouth.
- The patents in appendix 2 were developed with University of Plymouth proof of concept funding.
- The Journal of Foot and Ankle Research open access publication fees for the article entitled 'The effects of prolonged running on foot posture: a repeated measures study of half marathon runners using the Foot Posture Index and navicular height' were funded via membership of the first author with the College of Podiatry.

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