Foot-type as a risk marker in chronic low back pain

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2004
Declarations

This work has not previously been accepted in substance for any degree and is not being concurrently submitted in candidature for any degree.

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This thesis is the result of my own investigations, except where otherwise stated. Other sources are acknowledged by footnotes giving explicit references. A bibliography is appended.

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Abstract

Foot function has been linked with various musculoskeletal pathologies. In recognition of the over-emphasised role of interventional trials and the under-developed role of observational studies in investigating such relationships, a case-control study was designed to examine the link with low back pain. Before this could proceed, several critical issues surrounding the validity and reliability of measures of ‘foot-type’ were examined to identify the optimal technique for use in observational research. Firstly, the ability of static measurements to reflect the dynamic state was investigated for two footprint and a calcaneal motion measure to examine a basic validity dimension. Although all measures differed between states, high correlations revealed a consistent dynamic increase. Subsequent content validity assessment involved examining the response of footprint and navicular motion measures to 5° changes in subtalar joint position. Navicular height was most sensitive (consistently changing value significantly with between 5° & 10° of calcaneal motion), whilst poor performance of footprint measures (requiring >15° of calcaneal motion to induce significant changes) compromised their further use. The original intention to categorise subjects according to subtalar axis orientation to increase the precision of this validity study was abandoned after its reliability was found to be poor. Finally, the optimal, motion-based, measures of foot-type identified were utilised in a case-control study, which recruited 64 cases with low back pain and 57 controls. A significantly higher magnitude of left-right asymmetry of calcaneal and navicular motion, and a significantly reduced score on a foot-health related quality of life assessment tool, the foot health status questionnaire, was found in cases. Despite concerns over the absolute reliability and validity of the motion-based measures used, and several limitations in the case-control design, the study implicates foot function with low back pain and suggests that further study to determine the extent of its involvement is warranted.
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<td>FHSQ</td>
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<td>Intra-class correlation coefficient</td>
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<td>LBP</td>
<td>Low back pain</td>
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<td>LLD</td>
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<td>NCSP</td>
<td>Neutral calcaneal stance position</td>
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<td>MTPJt</td>
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<td>NSAID’s</td>
<td>Non-steroidal anti-inflammatory drugs</td>
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<td>RCSP</td>
<td>Relaxed calcaneal stance position</td>
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<td>RCT</td>
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<td>SAI</td>
<td>Staheli’s arch index</td>
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<td>SD</td>
<td>Standard deviation</td>
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<td>SLR</td>
<td>Straight leg raise test</td>
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<td>STJt</td>
<td>Subtalar joint</td>
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Chapter 1
Introduction

Human walking is an integrated activity that requires co-ordinated interactions within the neuromusculoskeletal systems (Wernicke and Volpe, 1996). The lower limb skeletal chain is comprised of a series of bones connected via a complex arrangement of muscles and ligaments such that there is a kinematic link, where motion in one segment is transferred to the next in the chain. These functional links exist to satisfy demands for energy efficiency during gait, may influence motion proximal to the pelvis, are related to muscle balance and activity, and require precise neurological control (Inman et al., 1994). The involvement of multiple elements within the system, each of which may disrupt normal function, underpins the concept that a deficit in one part of the locomotor apparatus will have consequences for other parts within the system (Radcliffe, 1994).

The foot is acknowledged to contribute significantly to the locomotory process. The subtalar joint (STJ), the key component of the rearfoot, is responsible for resolving the rotations that occur within the limbs in response to the pelvic motions necessary for normal gait, and permits compensation for anomalies within the locomotory apparatus (Harris, 1991, Root et al., 1977). This role has been attributed to the location of the foot, as the interface between the limb and ground, and its triplaner motion capabilities (Mann, 1993). These theories are widely recognised, and have led to aberrant foot function being associated with various musculoskeletal pathologies. These range from those affecting the foot, such as plantar fasciitis (Martin et al., 2001, Pfeffer et al., 1999) and the widespread deformities of rheumatoid arthritis (Woodburn, 2000), to those affecting the leg, such as tibialis posterior tendonitis (Teitz et al., 1997), the knee, such as patellofemoral pain syndrome (Stergiou et al., 1999), the hip (Kendall et al., 1993) and the low back (Bird and Payne, 1999). Anatomical studies suggest a plausible pathway by which foot function may influence these pathologies (Bellchamber and van den Bogert, 2000a, McPoil and Cornwall, 2000; Minkowsky and Minkowsky, 1996), suggesting that foot orthoses, which aim to normalise foot function, may be useful in the treatment of these conditions. Evaluation of symptom response to orthoses has become one of the most common methods of evaluating the relationship between foot function and pathology, with a
favourable response taken as evidence of a causal link. The link remains largely theoretical, however, with only limited evidence available supporting the concept of a direct, causal, relationship.

The focus on interventional studies is most likely related to the emphasis on this design encouraged by the 'outcomes movement', which extols its virtues to the extent that it has become the solitary design deemed to provide acceptable evidence by regulatory and governmental agencies (Black, 1998a, Tanenbaum, 1999b). Although there are some high quality trials available that employ the randomised controlled trial (RCT) design in its more rigorous guise, in particular those relating to the treatment of the rheumatoid foot (Conrad et al., 1996, Woodburn et al., 2002a), the norm is for trials to fail to achieve the rigorous standards required to impact on clinical treatment protocols. This is evidenced by the routine rejection of such trials, on the basis of their poor quality, from systematic reviews of interventions for a variety of disorders affecting the foot and lower limb (Crawford and Thomson, 2004, Crossley et al., 2001, D'hondt et al., 2004, Ferrari et al., 2004, Gillespie and Grant, 2004, Yeung and Yeung, 2004). Since systematic reviews are generally accepted as the most robust form of evidence available, equivocal results pose a dilemma in that practices are deemed unsubstantiated if this form of support cannot be provided (Greenhalgh, 2001). This is despite positive findings from reviews that take into consideration the wider body of evidence (Landorf and Keenan, 2000b). Despite a current unwillingness within regulatory and government agencies to consider all available evidence, there is a growing, and convincing, literature base suggesting that the use of the RCT design to investigate 'cause' is inappropriate because this extends beyond the original aim, and theoretical limits, of the design (Black, 1998a, Clemence, 1998, Tanenbaum, 1999b).

In contrast to the emphasis on the single, RCT, design advocated by the outcomes movement, epidemiology describes an approach to examining cause that involves thorough examination of a range of evidence forms, from laboratory based bench and clinical studies to observational, and eventually, interventional studies (Gordis, 2000, Wald, 1996). In this way a picture is built up of the nature of the relationship between the suspected causative factor and the disease in question, that allows a balanced
judgement to be made of the likelihood that a ‘causal’ relationship exists. This process has been described as ‘the epidemiological approach’ (Wald, 1996).

Observational studies play a critical role in the epidemiological approach, and often constitute the first formal steps in examining a suspected link between a specific factor and a disease or condition (Vetter, 1999). The typical observational study designs are cohort and case-control, which involve comparison of subjects with a disease to those without. This permits disease rates in relation to exposures to be calculated to provide information on the strength of the association and the likely health benefit of removing or treating that factor. Longitudinal cohort studies require a long-term commitment and carry a significant cost, because they follow a group of subjects who do not yet have the disease to see who develops it. This can take many years. As individuals within the cohort develop the disease, any differences in the rate of occurrence between those with and without the exposure are assessed to provide an insight to the role of that factor. This approach is valuable in gathering information regarding the impact of a specific exposure, and is important in justifying subsequent trials of interventions targeting that factor. Case-control studies are similar in that they also permit calculation of disease rates and measures of risk. Subjects with the disease of interest are compared to control subjects, who are similar in many ways to subjects with the disease, with the exception that they do not have the disease in question. Because subjects who already have the disease are recruited, a case-control study yields results quicker, and is more cost effective. An important limitation of this design is recall bias and the possibility that the information required may not have been accurately recorded, but cost and time factors represent a major advantage (Gordis, 2000, Vetter, 1999).

Observational studies explicitly focus on measuring ‘exposure’ to specific factors and disease states or conditions. For example, cigarette smoking is an ‘exposure’ that is implicated with lung cancer and cardiovascular disease. Information regarding the involvement of this factor in these diseases was gathered by measuring the extent of the exposure in individuals and by measuring the occurrence of the disease. The quality of observational studies hinges on the use of accurate, reliable and valid methods of measuring both exposure and disease (Gordis, 2000, Rose, 1985, Rose, 1991, Vetter, 1999). Whilst foot function can be quantified accurately using multiple
expensive and time-consuming laboratory based techniques (Redmond et al., 2001), these methods are unsuitable for observational studies, which involve high numbers of subjects, and therefore require methods that are fast and cheap. In an effort to gather information regarding foot function a large range of simplified ‘foot-type’ measures have been used for both clinical and research purposes. Such measures typically focus on one particular aspect of foot structure, usually the medial longitudinal arch (MLA), and are based on the rationale that the mechanical characteristics of the foot will be reflected in this. Measures reported in the literature range from simple visual (Cowan et al., 1994) to radiographic techniques (Cavanagh et al., 1997, Kanalti et al., 2001, McClay and Bray, 1996), footprint measures (Busseuil et al., 1998, Cavanagh and Rodgers, 1987, Cureton, 1935, Didia et al., 1987, Welton, 1992) and quasi-static measures of tarsal motion such as navicular drop (Brody, 1982). Consideration of this literature clearly indicates that a majority of researchers have intuitively formulated measures but have inadequately examined the critical issues of validity and reliability. Information on reliability does exist for some measures, but little information exists regarding validity. In the absence of information regarding these measurement properties, results and conclusions are meaningless. It is clear that to have any confidence in the results of observational studies the method of measuring exposure to the factor of interest must be valid and reliable. Therefore, prior to conducting a case-control study the optimal measures for defining the exposures of interest, and the disease in question, must be established.

This study sought to examine the reliability, and various aspects of the validity, of potentially useful measures of foot-type, to identify the optimal method for use in a case-control study investigating the role of foot function in low back pain. The thesis is made up of 7 chapters, beginning with an introduction in chapter 1. The normal gait cycle and the contribution of the foot to this process is presented in chapter 2, to establish a context from which to consider the consequences of foot dysfunction. Chapter 3 comprehensively examines the relationship between abnormal foot function and musculoskeletal pathology, taking into consideration a wide range of evidence. Chapter 4 reviews existing measures of foot-type against a set of rationalised criteria for the ideal measure, to either identify a suitable technique or highlight measures that can feasibly be developed into a satisfactory method. Chapter 5 provides a summary literature review, drawing together the critical theory underpinning this thesis. A
description of the 5 studies undertaken is provided in chapter 6, which presents a focused background, method, results and discussion for each. Chapter 7 presents a more general discussion that extends beyond the details of the individual studies to consider the approach adopted and key methods involved, ending with the conclusions that can ultimately be drawn from the research programme.
Chapter 2

Foot function in the context of normal human locomotion

This chapter introduces the process of normal human locomotion, providing definitions and descriptions, and emphasising the integrated nature of the process. The basic demands of normal walking are discussed, and the mechanisms that have evolved to satisfy these requirements reviewed. Particular emphasis is placed on the contribution of the foot to locomotion, and this is supported from a range of sources, including medical, anatomical, orthopaedic and podiatric literature bases. This permits the formulation of a comprehensive list of contributions made by the foot to normal walking, and provides a context from which to consider the consequences of foot dysfunction. This sets the scene for chapter 3, which considers the relationship between foot dysfunction and musculoskeletal pathology.

2.1 Introduction and definitions of normal human walking

2.2 Evolutionary considerations

2.3 Normal gait

2.3.1 Introduction

2.3.2 The visual events of the gait cycle

2.3.3 The functional subdivisions of the gait cycle

2.4 The pre-requisites for an efficient gait

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2.7.2.4 Transference of body weight

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2.8 Conclusions
2.1 Introduction and definitions of normal human walking

Whilst locomotion is described as a feature of all animals, the bipedal method displayed by Man is a speciality (Gage, 1991). The ability to habitually walk on two legs has been ranked alongside the power of the human brain and the ability to use tools, as one of the three most distinctive features of the human species (Lovejoy, 1988). Few activities generate such innate interest as walking, and it has been contended that physicians often report that the first question asked by patients with back and leg injuries is 'will I walk again?' (Leonard, 1997). However, despite this fascination, and years of scientific enquiry, we still do not fully understand how we manage to get from point A to point B in an upright position.

Bipedal locomotion is extremely complex, requiring multiple co-ordinated interactions within the neuromusculoskeletal systems (Hunt et al., 1995). In order to fulfil the sole purpose of transporting us safely and efficiently across varying terrains with minimal expenditure of energy, the neuromuscular support system must provide appropriate shock absorption, prevent collapse, and maintain balance of the upper extremity (Winter, 1987). The integrated nature of the process has been emphasised, with the trunk and limbs contributing to the smooth functioning of the whole, where physical loss of one part results in the loss of the contribution of that part to the entire mechanism, necessitating compensation elsewhere (Radcliffe, 1994b).

The actual process of walking has been defined in several different ways. Simple definitions such as '...a method of locomotion involving the use of two legs, alternately, to provide support and propulsion...' (Whittle, 1992) p.48, focus on the most visibly apparent features. Running is excluded by adding that at least one leg must be in contact with the ground at all times. By contrast, a definition has been presented that is based on the overall aim of the locomotory process, as opposed to visually identifiable events, referring to locomotion as the translation of the centre of mass (C-o-M) through space along the path of least resistance (Saunders et al., 1953). Perhaps the most appropriate definition encompasses both approaches by describing walking as a means of:
‘...Moving from one geographical location to another. It includes starting and stopping, changes in speed and alterations in direction and modifications for changes in slope. These events, however, are transitory activities that are superimposed on a basic pattern. In walking and running this can be defined as a rhythmic displacement of body-parts that maintain the body in constant forward progression’.

(Inman et al., 1994) p.3

This definition fosters an appreciation of the nature of the process, building up the image of a repetitive sequence of events, and its comprehensive nature ranks it as perhaps the most appropriate definition of human walking available.

2.2 Evolutionary considerations

Development to biped by man is closely entwined with species survival and the development of cognitive abilities. Although prior consensus claimed that bipedality followed on from cognitive development, freeing the hands to use the tools made by the larger brain, this theory does not receive universal support. For example, the discovery of a partial Australopithecine skeleton, dated to some 3 million years ago, showed distinct skeletal features of bipedality, but in the absence of evidence of a unique brain, or of tool use. This has led to the suggestion that it was bipedality that formed the cornerstone of behavioural adaptations which allowed continuing cognitive development (Lovejoy, 1988).

Regardless of which theory is correct, it is agreed that development from quadriped to biped brought significant advantages. However, drastic adaptations to the muscular and skeletal systems, and to the neurological control system, were required to permit this. The quadriped is stable and agile, due to the position of the C-o-M, located just under the trunk, within the base of support, and the location of the body, interposed between front and hind limbs, which allows a greater stride length with increased power. The spine can be rolled up into flexion as the hind limbs are brought forward to be placed in front of the body, so that both flexors and extensors can be used to augment the ground reaction forces generating forward motion. After weight transfer to the hind limbs, the spine and hips can be powerfully extended to propel the body forward onto the forelimbs, which are also powerfully extended to maximise stride length (Gage, 1991). This is illustrated in figure 2.1.
In contrast to the quadriped, stability is challenged in the biped because the body is 'top heavy', with the C-o-M located above the base of support, somewhere around the S2 vertebrae. Walking stability is challenged by the continuous alteration of segment alignment, compelling the body to constantly modify the position of the trunk in space to maintain balance over the base of support. Forward progression is facilitated by the generation of a horizontal ground reaction force in the direction opposite to the line of progression. In the quadriped, this is easily performed due to the location of the C-o-M in front of the hind limbs. Hind limb extension therefore generates a large horizontal component whilst in the biped this results in large vertical forces that raise the body onto tiptoe. To overcome this problem Man must allow his C-o-M to move forward of the base of support so that extension of the limbs can generate a more significant horizontal force to facilitate progression. This has led to the observation that Man is constantly functioning on the verge of disaster, with only the outstretching of one limb in front of the body catching us as we fall forward, preventing collapse.

The control of bipedal gait is acknowledged as a greater challenge, with responsibility falling on the central nervous system, which must generate the locomotory pattern and appropriate propulsive forces, modulate changes in C-o-M location, co-ordinate multi-limb trajectories, adapt to changing conditions, co-ordinate visual, auditory, vestibular and peripheral afferent information, as well as account for the visco-elastic properties of muscle (Leonard, 1997). In addition, it must do this continually, within milliseconds, and in conjunction with the co-ordination of a multitude of other body functions and movement.
The demands placed on the neurological control system by bipedality are evidenced by examination of the structure of the central nervous system (CNS). Despite similarities, the neural circuitry required for Quadripedal and other forms of vertebræ locomotion might be entirely different from that required for bipedal locomotion. Neuroanatomical studies have revealed the existence of more descending supraspinal pathways in humans than any other species. For example, the cortico-spinal tract makes more mono- and poly- synaptic connections in the cervical and lumbar spinal column than in any other species. This difference supports the theory that Man has sacrificed the advantages of Central pattern generator (collections of neurones within the spinal cord responsible for generating the locomotory pattern in quadrupeds, independent of cerebral input), in favour of the added influences of descending systems, although the role of these systems remains controversial. Nevertheless, this anatomical data re-enforces the opinion that bipedal gait incurs unique challenges and the requirement for cerebral-driven coping strategies to satisfy complex demands.

2.3 Normal gait

2.3.1 Introduction

Walking is a complex activity that depends on the neuromuscular system to integrate motions at a series of joints, whilst satisfying total body goals related to stance stability and propulsion (Perry, 1992b). This complexity means that the process must be considered from various different perspectives to be fully appreciated and understood. Descriptions can relate to visually observable events (Gage, 1991, Gage, 1995, Sutherland et al., 1994), temporal and spatial parameters (Perry, 1992b, Wernicke and Volpe, 1996), or the functional goals of discrete periods within the cycle (Adams and Perry, 1994, Perry, 1992b). A comprehensive description of the process requires integration of these elements.

The term walking has been associated with a cyclic pattern of body movements that is repeated step after step (Inman et al., 1994). The process is conventionally discussed in terms of the gait cycle (Gage, 1991), which relates to an interval of time during which one regularly recurring sequence of events is completed. Although a period of walking may be divided into three phases (Lettre and Contini, 1967), beginning with development, involving acceleration from rest to some constant velocity, and ending...
with *decay*, involving deceleration from some constant velocity to rest, the central, *rhythmic*, phase that comprises the bulk of any period of walking serves as the major research focus. During this period the basic underlying pattern has been shown to be remarkably consistent (Inman *et al.*, 1994). The events of a single rhythmic phase gait cycle are described to characterise the general process, with the assumption that successive cycles are similar, and this is accepted as a reasonable approximation (Inman *et al.*, 1994). Information is available on the influence of changes in speed, environmental influences and specific pathologies on the gait cycle but this review will focus on normal gait.

### 2.3.2 The visual events of the gait cycle

As the body moves forward, one limb serves as a mobile source of support as the contra-lateral limb advances itself to a new support site (Perry, 1992b). These two functions delineate the basic sub-division of the gait cycle: *stance* is defined as the period of time during which the foot is in contact with the ground, and *swing* is defined as the period of time during which the foot is advancing forward. Transition between these two phases involves instants of initial and terminal contact for each foot, and these events – heel-strike and toe-off – have been used to further define each period. The gait cycle begins with heel-strike (0%), which signifies the start of the first double limb contact phase. This is also a transitional phase where the opposite foot is preparing to leave the ground as weight is transferred between the two limbs, and therefore involves a period of double limb contact. This ends with opposite toe-off (12%), which leads into the period of single limb stance. The functional demand during single limb stance is for stability as bodyweight is channelled through one foot as the centre-of-mass moves from posterior to anterior to the supporting foot. Single limb stance ends with opposite heel-strike (50%) which signals the end of the opposite swing phase and the start of the second period of double limb support. This period of double limb support lasts for 10% of the cycle, and signifies another period of weight transfer as the stance foot leaves the ground to enter its swing phase (60%). Stance phase lasts for approximately 60% of the cycle, with swing occupying the remaining 40%. The period of swing equates with the period single limb support (40%), meaning that double limb support periods account for 20% of the cycle. This
sequence of events is illustrated in figure 2.2, which also details the timing of critical events.

**Figure 2.2: Critical events of the gait cycle** (Sutherland *et al.*, 1994). This figure illustrates one gait cycle, for the shaded limb, and details both critical events and functional sub-divisions. Also included is the point where fore-aft shear reverses in the stance limb, which indicates a switch from deceleration to acceleration of the limb.

2.3.3 The functional sub-divisions of the gait cycle

Although the gait cycle can be described in terms of the visually identifiable ground contact patterns that define stance, swing, and the transitional phases, the gait cycle can also be described relative to the functional demands incurred during the cycle. These functional sub-phases have been widely discussed, and despite minor variations in terminology or emphasis, there is clear consensus regarding the mechanisms by which functional demands are satisfied. Perry (1992), provided a comprehensive description of these sub-phases, and a useful figure (figure 2.3) which breaks the gait cycle down sequentially, from a single stride, to the basic divisions of stance and swing, the tasks that have to be accomplished within the periods, and the specific functional sub-phases that are utilised to achieve these tasks. This description provides a useful framework from which to discuss the normal process.
Figure 2.3: The gait cycle and its subdivisions (Perry, 1992b). This figure illustrates the functional sub-division of a single gait cycle.

The gait cycle begins, with stance phase, when the foot contacts the ground. The first sub-phase is *Initial contact* (0-2%), and this is immediately followed by *loading response* (2-10%) (figure 2.4). These events have been collectively described as *contact* (Wernicke and Volpe, 1996). The functional demands incurred are weight acceptance and shock absorption, and these demands are satisfied by several related mechanisms. Firstly, the hip extensors resist the flexor torque generated by the initial contact point, and secondly, several motions occur to extend the time taken from initial contact, reducing impulse and absorbing shock. These mechanisms rely on a specific ground contact position. This should occur on the posterio-lateral aspect of the calcaneus to initiate plantarflexion and pronation moments at the ankle and STJts respectively. These motions are then controlled by eccentric contraction of the tibialis anterior (controlling ankle plantarflexion) and tibialis posterior (controlling STJt pronation) muscles to decelerate the foot as it moves from initial contact through loading response to foot flat. These actions promote an extended and smooth period of weight acceptance and shock absorption, satisfying the first functional demand of stance. Foot flat occurs as the opposite foot is leaving the ground, signifying the start of single limb stance, where the functional goal is to provide stability whilst the centre of mass of the body passes from a posterior to anterior position in relation to the supporting foot.
Figure 2.4: Initial contact & loading response (Perry, 1992b). This figure illustrates the first two functional sub-phases within stance. Firstly, the foot is presented to the ground with the ankle dorsiflexed, indicated by the shaded ankle in the first position. This contact point facilitates a normal loading response, during which the ankle plantarflexes to bring the ground into full contact, indicated by the shaded ankle in the second position.

Figure 2.5: Single limb stance (Perry, 1992b), comprising mid and terminal stance. These figures demonstrate how the centre of mass of the body moves forward during single limb stance. At the start of midstance the body is posterior to the supporting foot, and by the end of this period of single limb support it has moved anteriorly. Midstance is concerned with stability, as it is the sole point of contact with the ground. Terminal stance initiates the second double support period, as the opposite limb makes contact, and weight transfer begins.

At the end of single limb stance the swing limb contacts the ground, and the joint motions observed in terminal stance reverse. Knee and hip extension and ankle plantarflexion, that were effectively pushing against the ground to propel the C-o-M forward, become hip and knee flexion and ankle dorsiflexion. These motions occur to effectively shorten the limb for swing phase for safe passage through the air in swing
(figure 2.6), and persist into pre-swing (30-50%). The process begins in terminal stance involves heel lift as the limb advances forward trailing the advancing body. Terminal stance blends with pre-swing (50-60%), which involves weight release and transfer to the opposite limb that is entering stance.

**Figure 2.6. Terminal Stance / Pre-swing : Initial swing** (Gage, 1995). An illustration of the reversal of the ‘thrust’ motions of hip and knee extension with ankle plantarflexion into hip and knee flexion with ankle dorsiflexion, that occurs with the initiation of swing to shorten the limb. Left figure shows terminal stance, right figure the transition to pre-swing and initial swing.

The overarching demand is now for limb advancement, and this is achieved throughout the three sub-phases of swing – initial, mid and terminal swing. The preparatory posturing of pre-swing extends into initial swing (60-73%) that occupies the first third of this period. Initial swing persists until the swing limb is opposite the stance limb, and during this period foot clearance is achieved via hip and knee flexion and ankle dorsiflexion, whilst the limb is advanced forward from its trailing position. Mid swing (73-78%) begins when the swinging limb is opposite the stance limb and ends when the swinging limb is forward of the body and the tibia is vertical. During this period, limb advancement and foot clearance are maintained. In terminal swing (87-100%) the vertical tibia moves forward and limb advancement is complete as the leg moves ahead of the thigh and the foot is prepared for ground contact. These sub-phases are illustrated in figure 2.7.
Figure 2.7. Swing phase sub-divisions (Perry, 1992b). Swing phase can be divided into the three functional sub-phases linked to the smooth passage of the centre of mass. In the first picture, the limb moves from a position trailing the body to a position in line with the opposite limb. In the second, the limb moves forward of the supporting limb, and in the final picture the limb moves ahead of the supporting limb to move to a new support site and prepare for initial contact.

Throughout these sub-phases of gait there are numerous mechanisms acting at a range of sites throughout the lower limb that act to ensure that the functional demands met throughout the gait cycle are met. Consideration of these mechanisms provides an insight to the contribution of the foot to normal gait, but these must be viewed in terms of the over-arching functional demands of the gait cycle.

2.4 The pre-requisites for an efficient gait

Success as a biped was dependent on the development of a gait cycle incorporating appropriate coping strategies to satisfy the demands incurred by the transition from quadriped to biped. Numerous authors have discussed this concept in terms of ‘Pre-requisites for an efficient gait’ – a series of fundamental demands incurred by normal upright walking that must be satisfied to ensure success.

The concept of pre-requisites was first suggested by Inman, who through observational studies, suggested two basic requirements: continuing ground reaction forces and periodic movement of each foot from one position of support to the next in the direction of progression (Inman et al., 1994). They also commented that these elements were necessary for any form of bipedal walking, no matter how distorted by physical disability, and also that they were equally necessary when prosthetic or orthotic devices are used.
The concept has been developed by several authors, most notably by Perry, who aimed to define a series of overall requirements which were removed from the visual process, and instead were related to the overall objective of the translation of the centre of mass through space along the path of least resistance (Perry, 1985). Three aims were suggested: stability in stance, a means of progression and energy conservation. In contrast to previous descriptions of walking that focused on an account of the cyclic, repetitive sequence of events observable during each gait cycle, the pre-requisites concentrate on providing an explanation of the overall objectives of the segmental motions which characterise gait.

A list of 5 pre-requisites has subsequently been suggested (Gage, 1991), which overlap considerably with Perry’s original list: stability in stance, sufficient foot clearance in swing, appropriate swing phase foot pre-positioning, adequate step length and energy conservation. However, these contribute little to supersede and develop the original 3 pre-requisites presented by Perry (1985), instead choosing to detail observable events which are descriptive of the process rather than based on the overall objectives of gait. For example, adequate step length need not be a pre-requisite, because during any arbitrary walk by a normal individual there may be considerable variance in step length, which although incurring discrete changes in efficiency, remains stable, capable of progression, and reasonably energy efficient – to a level that is not detrimental to the continuation of the activity. In any case, these feature seem to exist solely to achieve the aim of an energy efficient gait cycle.

More recently, a revised list of pre-requisites, elaborating on the original list, has been presented (Adams and Perry, 1994). These seem to provide a coherent, and appropriate list of requirements:

- Stability to provide anti-gravity support of bodyweight;
- Mobility to allow smooth motion as body segments pass through a series of positions;
- Motor control to sequence multiple segments while transferring weight from one limb to another.
Contrary to certain lists of pre-requisites, explicitly detailing certain visible features, Adams and Perry have focused on a series of physical demands that must be satisfied to permit bipedal locomotion. The strategies employed by the body to satisfy these demands explains the individual joint motions observed during gait and described previously which characterise the gait cycle.

2.5 The determinants of gait

The pre-requisites for an efficient gait detail the basic functional demands that must be satisfied in normal locomotion. Of the three demands presented, energy conservation seems to be fundamentally important. Gait efficiency requires that the process operates within the confines of its aerobic capacity, which demands energy conservation (Gage, 1991), and it has been hypothesised that this prevailing requirement explains the uniformity of gait, and the tendency for subjects to self-select a walking speed that results in the natural integration of body motions to the most energy efficient pattern (Ralston 1958). Although it is conceded that there are probably many mechanisms by which the body conserves energy, three are currently acknowledged and understood. These are the control of momentum, maximising active and passive energy transfers between segments, and minimising the vertical excursion of the C-o-M of the body (Gage, 1991).

The control of momentum is important from a pragmatic perspective. If the total energy requirement for each step must be freshly generated for each step, there will clearly be a disadvantage, which can be reduced by preserving some energy from the previous step. One mechanism by which this is achieved is via control of ground reaction forces in front of the knee in the last half of stance, which produces an extension moment to stabilise the knee without using the quadriceps. Active and passive energy transfers between segments relate to bi-articular muscles that exert an action at two adjacent joints. Although the magnitudes of these transfers are difficult to estimate, they are undoubtedly important. An example of these transfers is the action of the rectus femoris muscle during pre-and initial-swing in fast walking. Proximally, concentric contraction augments hip flexion whilst distally eccentric contraction is decelerating the shank via its action on knee flexion through its insertion into the tibial tuberosity. The net effect is an overall contraction that may overall be nearly isometric to conserve energy (Gage, 1991).
The third mechanism relates to control of the vertical excursion of the C-o-M. Energy spent elevating the C-o-M is wasteful, as the object of gait is to transport the body horizontally. The importance of controlling the vertical excursion of the C-o-M can be appreciated by considering the energy cost of pedalling a bicycle with oval wheels, where energy spent on vertical movement is unnecessary and increases the energy cost. The body achieves tight control of the movements of the C-o-M by integrating the movements of nearly all the major parts of the body to produce a smooth, almost sinusoidal, pathway for the C-o-M in both the vertical and transverse planes (Inman et al., 1994). This is illustrated in figure 2.8. Vertically, the excursion of the C-o-M is controlled at approximately 5cm, with the summit of the oscillations occurring at single limb support in midstance, and the lowest point occurring during double limb stance. Lateral motions occur to position the C-o-M over the weightbearing foot during single limb stance. Both vertical and transverse pathways are sinusoidal, and such patterns are associated with major conservation of energy (Gage, 1991, Winter, 1987).

**Figure 2.8. Sinusoidal pathway of the C-o-M of the body during normal gait** (Inman et al., 1994). Note that both vertical and horizontal excursions smoothly fluctuate between maxima and minima of displacements. 'a' represents the medial-lateral displacement, 'b' represents the vertical displacement, and 'c' denotes the combined effect of these displacements on the overall pathway of the C-o-M. If a person is viewed from behind as they walk, and it was possible to see the motion of the C-o-M, it would describe the figure of 8.

The contribution of the individual motions acting towards the overall goal, of energy conservation through control of vertical movement of the C-o-M, was originally investigated by modelling the gait cycle of a lower limb unit articulating at hips capable only of sagittal plane motion, and then superimposing additional motions to examine their influence (Saunders et al., 1953). Saunders et al described these motions as '...the major determinants in normal and pathological gait', which
became known as the 'determinants of gait'. Although the contribution of upper limb motions such as transverse rotations in the thorax and shoulders, was acknowledged, the firm focus was on the triplaner rotations of the lower limb. These extended from hip to foot, and included pelvic rotation and list, knee flexion and ankle motion in stance, transverse rotations in the thigh and shank, and rotations within the foot (Saunders et al., 1953).

The basic model of a primitive gait cycle (figure 2.9) comprised a solid bar representing the pelvis, with the C-o-M depicted as a block in the middle of the bar. Legs were added as rigid levers, with no foot, ankle, or knee mechanisms, articulating at hips capable only of moderate amounts of flexion and extension. Stepping off distances with a pair of compasses can approximate the resultant gait cycle. In this model the pathway of the C-o-M is a series of intersecting arcs where the radius of the arcs is equal to the length of the limbs. This would require elevation of the C-o-M to its standing height with each step, and would also result in a jolt at the intersection of each arc where the direction abruptly changes. This would result in a loss of momentum due to the termination of one arc before the start of the next. Energy efficiency is increased through a sequence of motions which act to decrease the maximum height attained in midstance, increase the minimum height during the periods of double limb stance, and smooth the transition between successive arcs of motion of the C-o-M.

Figure 2.9. 'Compass gait' (Inman et al., 1994). The gait cycle minus complex rotations at the ankle and knee, and only moderate amounts of flexion and extension at the hips. The pelvis is represented by the rigid horizontal bar, which connects the two hips capable of only flexion and extension. The limbs are rigid levers, with no ankle or knee.

Pelvic rotation refers to rotation about a vertical axis that occurs alternately to the left and right relative to the line of progression (figure 2.10). At common walking speeds, and with a typical cadence and stride length, this rotation is approximately $4^0$ on either side, giving a total of $8^0$, although this increases with speed. These rotations
occur at the hip, and necessitate a deviation from pure flexion and extension. The effect is to flatten the ends of each arc of translation by elevating them in relation to the summit. In addition to reducing the total vertical excursion required, the force required to change the direction of the C-o-M for the succeeding arc is reduced, and the angular displacement of the hip in flexion and extension is reduced. A consequence of pelvic rotation is that the femur and tibia undergo internal and external rotation throughout stance. With the foot planted firmly on the ground as a stable platform, there must be some means of resolving this rotation, and this occurs at the STJt due to its triplaner, obliquely oriented, axis, and the rotations that take place about this axis represent additional important determinant motion.

**Figure 2.10. Pelvic rotation** (Inman et al., 1994). The ends of the arc of translation are elevated so that the overall vertical excursion of the C-o-M is reduced. The arc of passage of the C-o-M is shown in the top left corner of the figure.

A second motion, pelvic list, occurs at the hip also. This refers to a tilt downwards on the non-weightbearing side (figure 2.11). At moderate speeds the alternate angular displacement is about $5^\circ$ on each side. This list occurs as the swing limb is moving through past the stance limb, and reduces the total elevation required. An equivalent, relative, adduction of the supporting limb is required, and the list downwards also means that the knee must flex to facilitate ground clearance. The motion also contributes to the abductor mechanism of the hip whereby the abductors and iliotibial tract control dynamic stability, and when this mechanism is deficient the amount of list is grossly exaggerated.
Figure 2.11. Pelvic list (Inman et al., 1994). This motion reduces the height of the C-o-M in single limb stance, flattening the arc of passage of the C-o-M, but demands flexion of the swing knee for ground clearance.

Whilst the knee flexes during swing to shorten the limb for swing, and to compensate for the drop incurred by normal pelvic list, the knee flexion that occurs in stance phase is also important. This motion occurs in tandem with sagittal plane ankle motion to smooth the transition between successive arcs. At the beginning of stance the knee joint is in near full extension, and undergoes flexion of approximately 15° until the foot is flat on the ground. In preparation for the period of full weight-bearing the knee re-extends, and then in terminal stance flexion occurs which persists into swing phase. This terminal flexion coincides with ankle plantarflexion, and the synergistic actions of knee flexion and ankle plantarflexion smooth the transition from one arc to the next, producing the sinusoidal pathway and eliminating the abrupt changes of direction. Figure 2.12 shows knee flexion, and figure 2.13 illustrates the combined action of knee and ankle motion during stance, showing how they act together to smoothly lower body weight onto the ground, transport bodyweight forward over the stance limb, and propel the body forward into the next swing phase.

Figure 2.12. Stance phase knee flexion (Inman et al., 1994). The knee flexes to smooth the passage of the C-o-M onto the ground and then after re-extending for midstance, flexes again to smooth the transition between stance and swing, which reduces the abrupt change of direction between successive arcs of motion of the C-o-M.

Figure 2.13: Combined action of knee and ankle (Inman et al., 1994). Note how bodyweight is smoothly deposited on the ground, advanced over the stance foot and into propulsion. The influence of these motions on the arc of passage of the knee is important in smoothing the passage of the C-o-M.
These three mechanisms act to control the vertical movement of the C-o-M and to smooth the transition between successive arcs of motion. When these motions combine the vertical excursion of the C-o-M is minimised to approximately 5cm. In addition to the minor vertical displacements of the C-o-M, the horizontal pathway also fluctuates smoothly between maxima and minima of displacements. This occurs to position the C-o-M of the body closer to the foot to reduce the requirement for active frontal plane stabilisation of the foot. This lateral shift is approximately 4-5cm with each complete stride, is increased by walking with a wider base of gait, and is decreased by reducing the base of gait. Lateral shift is illustrated in figure 2.14.

**Figure 2.14. Lateral Shift** (Inman et al., 1994). A lateral shift of the C-o-M of the body occurs to more directly position it over the stance foot.

Pelvic rotation, pelvic list and knee flexion in stance all act towards the same goal – flattening the arc of motion of the C-o-M: pelvic rotation elevates the ends of the arc, whilst pelvic list and knee flexion in stance act to depress the summit of each arc. At the same time the transitions between successive arcs are smoothed so that there is a conservation of momentum. The net effect is the passage of the C-o-M through a segment of a circle, the radius of which is approximately 2.2 times longer than the lower limb. The effective lengthening of the limbs reduces the range of flexion and extension required at the hips to maintain the same stride length. Rotations within the foot are also included as determinants of gait. However, these will be discussed in the context of a discussion of the contribution of the foot to the overall aims of the locomotory process.

Recently, the contribution of each determinant has been re-evaluated (Della Croce et al., 2001, Gard and Childress, 1997, Gard and Childress, 1999, Kerrigan et al., 2000, Kerrigan et al., 2001b) in order to evaluate the degree of influence over the pathway
of the C-o-M that can be attributed to each motion. These investigations have all used mathematical modelling techniques. Firstly, the effect of pelvic list (Gard and Childress, 1997), and then knee flexion was investigated. Whilst each motion was found to contribute, it was concluded that neither pelvic list nor knee flexion contributed to the control of the C-o-M as much as originally suggested (Saunders et al., 1953). Most recently, the influence of ankle plantarflexion in terminal stance on C-o-M displacement has been investigated (Kerrigan et al., 2000). This investigation suggested that heel rise was critically important, accounting for almost 100% of the difference in C-o-M height in normal walking as compared to ‘compass gait’. However, in a balanced and informative discussion it was pointed out the other determinants, such as knee flexion and pelvic motions, despite accounting for only a few millimetres of control, probably remain important.

2.6 Foot function in gait: The sagittal plane perspective

The traditional perspective of foot function in gait emphasises the important of sagittal plane motion in facilitating the smooth deceleration of the foot and C-o-M towards the ground during the loading response, it’s smooth progression over the stable foot, and its upwards acceleration during propulsion. Even in one of the original accounts of the determinants of gait this mechanism, which emanates from the ankle joint, it was described as the single most important factor in achieving the conversion of the pathway of the C-o-M from a series of intersecting arcs towards the smooth, almost sinusoidal curve (Inman et al., 1994). Recent evidence seems to validate this statement (Kerrigan et al., 2000). Through its action the foot enables the pathway of displacement of the knee to remain relatively horizontal during the entire stance phase, which in turn augments the effect of initial knee flexion in smoothing the pathway at the hip. In the absence of the foot the C-o-M would still comprise a series of arcs, but the intersections would be subject to a sudden change in vertical displacement. By gradually changing the vertical displacement from downwards to upwards, what would be a series of intersecting arcs becomes more sinusoidal. This is illustrated in figure 2.15.
The role of the ankle in normal gait was developed in the concept of ‘Rocker theory’ (Perry, 1985, Perry, 1992b). This theory explains how three ‘rockers’, occurring about a series of fulcums located progressively more distally in the foot, smoothly deposit the C-o-M on the ground and transport the body forwards over the foot before accelerating it upwards into swing. The first rocker is termed the heel rocker, as the fulcrum is the posterior aspect of the calcaneus. The protrusion of the calcaneus posterior to the ankle joint creates a lever equal to approximately 25% of the total length of the foot, which creates a plantarflexion moment at heelstrike that accelerates the foot towards the ground. This externally generated moment is controlled by eccentric contraction of the pre-tibial muscles, a type of contraction that is associated with deceleration and shock absorption (Gage, 1991) that has also been shown to be between 1.5-6 times more efficient than concentric contraction (Winter, 1987). The use of such mechanisms is consistent with the concept that biological action follows the most energy-efficient path (Dananberg, 1995). Full contact of the plantar surface of the foot signifies the start of midstance, and the fulcrum shifts to the ankle joint. During heel rocker the tibia is dragged forward by ankle plantarflexion, and this facilitates the ankle dorsiflexion that occurs during midstance. As the ankle moves towards terminal stance soleus contract eccentric to control the forward tibial motion that is in effect causing ankle dorsiflexion, and permits the gastrocnemius to contract concentrically to lift the calcaneus off the ground and into plantarflexion. Simultaneously, sagittal progress is transferred to the forefoot rocker, which takes place at the metatarsophalangeal joint (MTPJ’s). Rocker theory is illustrated in figure 2.16.
Figure 2.16. Rocker theory (Perry, 1992b). Sagittal plane progression of the C-o-M is facilitated mechanically via rotations around a series of fulcrums within the foot.

The influence of Rocker theory was advanced significantly with the work of Bojsen-Moller (Bojsen-Moller, 1979a, Bojsen-Moller, 1979b, Bojsen-Moller and Lamoreux, 1979) through a sequence of investigations examining the functional implications of several inherent anatomical characteristics of the human foot. Evaluation of the normal metatarsal parabola (2<1<3<4<5 or 2>1=3<4<5) established that the second metatarsal is normally longer than the other metatarsals. This means that at propulsion there is no common axis connecting all 5 metatarsals, making load sharing between all 5 metatarsals impossible. Instead, the foot must choose between 2 possibilities — an axis connecting MTPJt’s 1 & 2, termed the Transverse propulsive, or high gear, axis, or an axis connecting MTPJt’s 2-5, termed the Oblique, or low gear, axis. These axes are illustrated in figure 2.17. The possibility of either axis affording greater efficiency was examined by measuring the distance from each axis to the ankle joint centre. Since the muscles inserting via the calcaneal tendon in the posterior calcaneus are the major ankle plantarflexors, which occurs simultaneously with MTPJt dorsiflexion, measuring the distance from the ankle to each axis can reveal whether there are differences in the moment that can be produced via each axis. The transverse axis lever arm was found to be approximately 20% longer than the oblique axis lever arm, and this was felt to be a clear indication that greater functional efficiency could be achieved by using the transverse axis in propulsion. It was suggested that for leisurely, undemanding, walking activities the oblique axis could be used, and for demanding, purposeful walking the transverse axis could be used (Bojsen-Moller and Lamoreux, 1979). The significance of transverse axis propulsion was further associated with the recruitment of various anatomical mechanisms that
enhance pedal stability, and this enhances the case for the importance of high gear propulsion during gait.

**Figure 2.17. The normal metatarsal parabola** (Bojsen-Moller, 1979b), showing how the normally longer 2nd metatarsal creates two MTPJt dorsiflexion axes that can be used in propulsion. Firstly, a transverse axis connecting MTPJt's 1-2 can be used, or secondly, an oblique axis connecting MTPJt's 2-5 can be used. The transverse axis seems to be associated with several mechanisms that contribute to propulsive stability.

Firstly, forefoot pronation, partially influenced by peroneus longus, was found to be important in shifting the C-o-M medially in terminal stance, and onto the transverse axis. Because peroneus longus passes around the cuboid to insert into the base of the first metatarsal this has the added effect of exploiting the anatomical configuration of the calcaneo-cuboid joint to move it into a more stable position. The configuration of the calcaneo-cuboid joint was likened to an hour-glass (figure 2.18), with only one stable, ‘close-packed’ position. This position is attained in full pronation, which is achieved under the influence of peroneus longus. In this position stability is also reinforced by an osseous block imposed by the dorsal process of the calcaneus, consistently found to protrude from the dorsal surface of the calcaneus, which locks against the calcanean process of the cuboid. This osseous stabilising mechanism was identified as a uniquely human characteristic in a comparative study of primates and humans, and was felt to be an important method by which the human foot achieves the midfoot stability that is lacking in primates (Bojsen-Moller, 1979b).

**Figure 2.18. Calcaneo-cuboid joint configuration** (Bojsen-Moller, 1979b), showing ‘hour glass’ shape. The close packed position is attained with forefoot pronation, which brings the dorsal border of the calcaneus into contact with the calcanean process of the cuboid, aiding stability.
Use of the transverse propulsive axis also results in increased tension in the plantar fascia. Coursing along the plantar aspect of the foot from its plantar calcaneal origin to its insertion in the proximal phalanges of each digit means that MTPJt dorsiflexion tightens the fascia (figure 2.19). This mechanism is termed ‘Hicks windlass’ (Hicks, 1954b), after the first description, which likened the metatarsal heads to the drum of a windlass around which ropes are wound. Because the 1st metatarsal head has the greatest radius, transverse axis propulsion occurring around this metatarsal results in increased tension in the fascia. The windlass mechanism links digital dorsiflexion with metatarsal plantarflexion, an increased calcaneal inclination, increased medial longitudinal arch height and supination of the STJt. Evaluation of the number of mechanisms occurring in response to manual hallux dorsiflexion by an examiner on a standing subject has been described as ‘Jack’s test’ and the ‘Hubscher manoeuvre’, which are used to differentiate between the fixed and flexible flatfoot. Finally, in addition to these mechanisms, a highly organised soft-tissue network in the plantar MTPJt region has been noted (Bojsen-Moller and Lamoreux, 1979). They found that dorsiflexion of the digits tightened this framework, restricting passive movements of the skin to transfer shear forces to the skeleton. Further, moderate reduction in dorsiflexion (15-25°) were found to result in 50% reduction in stresses, and 50° of hallux dorsiflexion was felt to be the critical amount to permit effective absorption of stresses. This emphasises the importance of near-maximal transverse axis propulsion during normal gait.

Figure 2.19 Hicks Windlass (Hicks, 1954b). Digital dorsiflexion increases tension in the plantar fascia, and aids resupination of the foot in propulsion. ‘A’ indicates full weightbearing, ‘B’ indicates propulsive function.

The most recent contribution to sagittal plane theory described the importance of transverse gear propulsion to general energy efficiency, and speculated that various musculoskeletal symptoms could result from inefficient propulsion (Dananberg, 1986, Dananberg, 1992, Dananberg, 1993a, Dananberg, 1993b, Dananberg, 1995, Dananberg, 1997, Dananberg, 2000, Dananberg and Guiliano, 1999). Dananberg suggested that failure to utilise the transverse propulsive axis, in the absence of a physiological limitation of motion, is associated with chronic musculoskeletal symptoms due to a blockade of sagittal plane progression, and has suggested the
'functional hallux limitus' to describe this condition. He also suggested the use of orthotic and manipulation techniques, explicitly attempting to facilitate normal 1st MTPJt motion (Danenberg et al., 2000). A recent clinical trial reports on the apparently successful use of these techniques in a group of 32 patients suffering with chronic LBP (Danenberg and Guiliano, 1999).

The work of Bojsen-Moller and Danenberg could be considered a coherent and logical development of Perry’s 'Rocker theory', due to the introduction of the concept that the foot possesses distinct anatomical characteristics which permit effective response to specific functional demands (Bojsen-Moller) and the presentation of a treatment approach that attempts to improve the efficiency of the Rocker mechanism (Danenberg).

2.7 Foot function in gait: the Podiatric perspective

2.7.1 Introduction

The podiatric perspective of foot function in gait emphasises the concept of a foot possessing specific functional attributes that allow it to contribute actively to stance phase demands. It has been asserted that the ankle and STJtJs must work in unison to provide a smooth transition of forces during load-bearing, and that the fascinating sequence of events required for this extend well beyond the commonly observed sagittal plane motion patterns of ankle dorsiflexion and plantarflexion (Harris, 1991). Intrinsic mechanisms which fall outside the description of ‘sagittal plane mechanisms’ include torque conversion (Inman et al., 1994, Wright et al., 1964) and the ability to provide both support and propulsion (Sangeorzan, 1991). Kerrigan et al (2000) have also alluded to the possibility of subtalar pronation contributing directly to control of C-o-M excursion, although this has not yet been investigated. The most comprehensive discussion of the contribution of the foot to the locomotory process was, however, provided by Root et al (1977) who recognised these previously mentioned characteristics but also proposed several additional contributions:

- Mobility at the major joints of the foot during the contact period allows the foot to adapt to terrain variances & positional deviations of the trunk, thereby maintaining postural equilibrium. STJt pronation provides mobility during the contact period;
• Stability at the major joints of the foot transforms the foot into a rigid lever that is necessary for normal function in propulsion. STJt supination during the midstance period, followed by midtarsal and subtalar supination during propulsion, achieves joint stability.

• Joint motion within the foot allows for sagittal and transverse plane motions of the leg and trunk around the weightbearing foot. This function of the foot provides maximum efficiency for the conversion of alternate transverse rotations into linear progression;

• STJt pronation contributes to shock absorption at heelstrike;

• Midtarsal joint pronation about its long axis is required for efficient transfer of bodyweight from one foot to another during locomotion.

Of prime importance in allowing the foot to fulfil these functions is the STJt. Sangeorzlan (1991) commented that the STJt plays a pivotal role in converting the foot from a mobile structure to a rigid lever, and also that it is involved in smoothing out gait, interfacing with uneven structures, and acting as a shock absorber at heelstrike. Such importance has been placed on the STJt that it has been described as the determinative joint of the foot, influencing the performance of the more distal articulations and modifying the forces imposed on the skeletal and soft tissues (Mann, 1986). These attributes originate from the orientation of the STJt axis, and from its interdependence with the MTJt. The specific functions of the foot during stance can be directly attributed to these two features.

2.7.2 The specific functions of the foot during stance

The separate functions of the foot proposed by separate authors can be collated into a list of five basic capabilities. The list presented by Root et al (1977) can be condensed by considering 2 separate qualities – intrinsic mobility and rigidity – as one, since the mechanism by which these capabilities are attained are related. The contributions of the foot to stance phase requirements are therefore:

• Torque conversion: The ability to absorb sagittal and transverse plane rotations of the pelvis and leg within the foot, providing maximum efficiency for the conversion of alternate rotations into linear progression during locomotion.
Mobility and Rigidity: Mobility at the major joints of the foot during contact allows the foot to adapt to terrain variances & positional deviations of the trunk, thereby maintaining postural equilibrium, and is attributable to STJt pronation. Conversely, stability at the major joints of the foot transforms the foot into a rigid lever which is necessary for normal function in propulsion.

Medio-lateral transfer of bodyweight: The foot is capable of both normal and abnormal compensation, with both capabilities arising from the triplaner axis of the STJt. Normal compensation refers to movement to adjust for irregularities of the supporting terrain, or for deviations in the position of the trunk or lower extremities. With abnormal compensation, the foot moves to adjust for abnormal skeletal structure or function of the trunk or lower extremity. Abnormal skeletal structure creates a recurrent or persistent demand for compensatory motion that may result in pathology.

Each of these functions will be considered in turn.

2.7.2.1 Torque conversion
A consequence of the pelvic rotation that occurs as a ‘determinant of gait’ is that transverse rotations are transmitted to the femur and tibia through the stance phase. However, because the foot is fixed to the floor, these must be some mechanism to absorb these rotations to prevent the foot from adducting and abducting. The required resolution of transverse motion within the foot occurs at the STJt axis, which has been shown in numerous investigations (Isman and Inman, 1969, Manter, 1941, Root et al., 1966) to course from the lateral, plantar and posterior aspect of the calcaneus to the medial, distal and superior aspect of the foot. The average axis shows an inclination of approximately 42° inclined from the transverse plane, and 16° inclined from the transverse plane (figure 2.20). This orientation has led to the STJt being compared to a mitred hinge which acts as a simple torque converter (Close et al., 1967). It was further commented that it is by virtue of the obliquity of this axis that input rotation of the talus about a vertical axis – corresponding to internal and external rotation – acquires a frontal plane component (Huson, 1991). The model closer approximates the true anatomical situation by including the talonavicular joint, splitting the horizontal segment into short proximal and longer distal portions (figure 2.21). This
midtarsal pivot allows the distal horizontal segment to remain plantigrade with vertical leg rotation, ensuring that the foot remains in ground contact despite the limb rotation occurring above it.

Figure 2.20. The STJt axis Michaud (1997). The oblique orientation of the axis allows it to act as a torque converter, resolving the transverse plane limb rotations that occur throughout stance at ground level, whilst the foot retains stable ground contact.

An important consequence of the oblique axis orientation is that the motion occurring at the STJt does not occur through a single body plane. Rather, composite motions occur, each comprising a transverse, sagittal and frontal component. In response to internal limb rotation the STJt is seen to pronate, a term denoting a composite motion of dorsiflexion, abduction and eversion, whilst with external limb rotation supination is seen, comprising plantarflexion, adduction and inversion. Transverse and sagittal motions occur in the talus whilst the frontal motion occurs at the calcaneus. In supination this is inversion, in pronation it is eversion (Nester, 1997). The torque conversion function is therefore dependent upon the couple between the distal tibia-fibular joint and the talus, and the triplaner movements of the talus on the calcaneus in response to leg rotation. The horizontal talocrural ligament fibres are vital in ensuring that rotations of the limb are transferred to the talus (Huson et al., 1986, van Langelaan, 1983).

Figure 2.21. The ‘torque-conversion’ function of the STJt (Inman et al., 1994). This shows how vertical rotation of the tibia is resolved within the rearfoot at the STJt, whilst the MTJt permits the forefoot to retain ground contact.
2.7.2.2 Contribution to shock absorption

The importance of shock absorption is evidence if the forces generated during locomotion, and applied to the skeleton with every step, are considered (Michaud, 1997b). Shock absorption is assisted by STJt pronation both directly and indirectly. Firstly, it prolongs the duration of the heel rocker by altering its direction of action, and the eccentric control of this rocker is shared between tibialis anterior and posterior. This occurs due to the slightly inverted STJt position at initial contact, which results in the generation of a plantarflexion moment – that occurs at the ankle joint – and a pronatory moment – that occurs at the STJt. The adduction and plantarflexion of the talus that results from this pronation also lowers the ankle mortise which affords the pre-tibial musculature a mechanical advantage that enhances their eccentric deceleration function. Eccentric muscle contraction has been suggested to the major contributor to shock absorption (Gage, 1991, Radin and Paul, 1970, Winter, 1987).

STJt pronation is also connected to knee flexion. Because the medial femoral condyle lies anterior to the lateral condyle, internal rotation allows the medial femoral plateau to glide posteriorly, allowing the knee to flex (figure 2.22). This knee flexion, which is controlled by eccentric quadriceps contraction, is undoubtedly the most significant shock absorbing mechanism, and is strongly associated with STJt pronation.

Figure 2.22. The influence of the relative position of the femoral condyles on knee flexion (Michaud, 1997b).

2.7.2.3 Intrinsic mobility and rigidity

Subtalar pronation during the contact phase results in the foot entering midstance in a pronated position, which is associated with an increase in midtarsal, and general
pedal, mobility, which allows the foot to interface with uneven walking surfaces. As midstance progresses intrinsic mobility is lost as the STJt re-supinates and the foot stabilises to permit efficient propulsion. The relationship between subtalar & MTJt position and pedal stability has been attributed to the interdependency between the two joints. Progressively more detailed accounts of the underlying mechanisms involved have been presented, and it is now warranted to reject the assertion that '...the changing of the foot from a mobile structure during the first part of stance phase into a rigid lever at push-off is a complicated and not completely understood mechanism' (Inman et al., 1994) p16.

The concept of interdependency was introduced by Manter who likened the motion in the STJt to a screw, based on the observation that the talus is seen to translate along a helical axis in response to subtalar motion (Manter, 1941). With pronation, the talus was noted to undergo forward displacement, initiating a reciprocal response in the longitudinal axis of the MTJt, which moves in the opposite direction to the STJt. Based on this observation it was suggested that the subtalar and MTJts behave as dual screws connected at the talonavicular joint in opposite directions. Therefore, motion in the STJt resulted in an opposing response in the MTJt – in such a manner that the forefoot may maintain ground contact as shown in figure 2.21. This concept was advanced with the suggestion that the relative positioning of the two MTJt axes in subtalar pronation and supination was a key determinant of mobility (Elftman, 1960). In the pronated position the two axes were suggested to assume a more parallel position, whilst in supination the relationship changed so that the two axes diverged. Axial divergence was associated with stability, as motion was effectively blocked, whilst in pronation the parallel position was associated with an increase in mobility. Figure 2.23 shows the MTJt axes, whilst figure 2.24, (both overleaf, illustrates the influence of subtalar position on the relative orientation of the two axes.
Figure 2.23: The MTJt axes (Root et al., 1971). The two axes felt to explain motion of the MTJt. As a functional joint, both anatomical elements contribute to the motion, and the two separate axes do not correspond to an individual joint. Anecdotally, clinical motion corresponds to these two axes, but functionally it is likely that other combinations occur as functional need demands.

Figure 2.24: MTJt axes in subtalar pronation and supination (Elftman, 1960). This figure shows the talus, superiorly, and the calcaneus, inferiorly, in pronation and supination with the two MTJt axes. The change in internal architecture which occurs with subtalar motion influences the relative orientation of the two axes to influence available motion.

Attempts have been made to quantify the influence of STJt position on midfoot mobility (Phillips and Phillips, 1983), by measuring the available midfoot motion in maximal pronation and supination. This investigation suggested that an average increase of 11.5° occurred in pronation. Although this has been attributed to changes in midtarsal axis orientation, frustration has been expressed that some researchers continue to promote the concept that the MTJt comprises two simple hinges that cooperate either in a state of free mobility or in a blocked condition. Bojsen-Moller (2000) suggested that divergent axes can be compatible with mobility as long as the axes involved can change direction or position during motion, basing this on experimental evidence, and instead suggested that ‘functional close packed’ positions help explain stability and mobility. However, he emphasised consideration of the role of ligamentous tethering and tension, gravitational forces, active motor torques and joint alignment as well as articular axis positioning (Bojsen-Moller, 2000, Vogler and Bojsen-Moller, 2000).
It seems probable that a series of related mechanisms are responsible for the change in mobility associated with subtalar motion, and various mechanisms have been satisfactorily described in recent years to support this. During the loading response shock absorption occurs because of the relationship between knee flexion, ankle plantarflexion and subtalar pronation, which all occur under eccentric muscle control. Achieving propulsive stability seems to be a greater challenge, requiring, as suggested by Bojsen-Moller (1979) the interaction of multiple muscular, ligamentous and skeletal mechanisms. Root et al (1977) described the vertical stabilising effect of peroneus longus on the 1st metatarsal that occurs with a supinated STJt (figure 2.25), and this seems to be related to the Hicks windlass mechanism, which can occur most efficiently with a stabilised 1st metatarsal. From a comparative anatomical study of humans and various primates, Bojsen-Moller (1979) described a calcaneo-cuboid joint ‘locking’ mechanism that seems to describe the stable human tarsus, and which seems to arise from maximal pronation under the influence of peroneus longus contraction. This muscle also appears to form a ‘cruciform’ cradle with tibialis posterior to exert a posterior and medio-lateral compression of the forefoot on the rearfoot (figure2.26), again enhancing stability. The importance of this mechanism has most recently been endorsed by Vogler & Bojsen-Moller (Vogler and Bojsen-Moller, 2000), who stated that these two tendon insertion directions are perpendicular to each other, producing a dynamic posterior axial and transverse compression, and noted that the wedge-like structure of the cuneiforms with their controlling dorsal ligaments, are likely to make an important contribution to stability.

Figure 2.25: Peroneus longus and 1st metatarsal stability (Root et al., 1977). With the medial longitudinal arch of the supinated foot, contraction of peroneus longus produces a vertical component of force that stabilises the first metatarsal. This seems to be related to an efficient Hicks windlass, and several other mechanisms that contribute to propulsive stability.
2.7.2.4 Transference of bodyweight

Inman, Ralston et al (1994) noted that the body is shifted slightly over the weightbearing foot with each step, moving approximately 4-5cm with each complete stride. Root et al (1977) explained that during propulsion the C-o-M of the body must be shifted towards the opposite foot, which requires lifting the lateral aspect of the foot using the peroneal muscles. This creates a pronation of the STJt to shift weight to the medial forefoot, and then onto the opposite foot which is in the contact period of its stance phase. They went on to suggest that this shift is facilitated primarily by calcaneo-cuboid joint pronation. This is illustrated in figure 2.14 in section 2.5.

2.7.2.5 Compensatory abilities

Discussion of the compensatory abilities of the foot has received most detailed attention from Root et al (1977), although many acknowledge that ‘...the locomotor system is completely integrated,...with physical loss of one part resulting in loss of the contribution of that part to the entire mechanism, necessitating compensation in other parts of the system...’ (Radcliffe, 1994b). Elftman (1960 p.41) alluded to these abilities when he stated that:

‘...proper management of the foot provides us with our final opportunity to compensate for deficiencies in control of other parts of the body’ and that
‘...conversely, when the foot is negligent in the performance of its function, additional loads, which may prove excessive, are transferred to other parts of the mechanism’.

Compensation is described as a change of structure, position or function of one part in an attempt by the body to adjust to a deviation of structure, position or function of another, and can be either normal or abnormal (Root et al., 1977).
Normal compensation describes the ability of the foot to adapt in response to irregularities of the supporting terrain, or for deviation in the position of the trunk or lower extremities, and contributes to the maintenance of postural equilibrium. Specifically, the foot is capable of adjusting to compensate for:

- Deviation of the trunk, or leg position, in each body plane;
- Deviation of one part of the foot relative to another e.g. forefoot – rearfoot mal-alignments;
- Deviation of the supporting terrain in any plane beneath the foot.

(Root et al., 1977)

Abnormal compensation refers to alterations in subtalar / midtarsal position in response to an abnormal structural or positional deviation within the lower extremity, and creates a persistent demand for abnormal compensatory motion of the foot. Although the motion which produces this position is the same motion occurring in normal compensation, it is always present when an individual stands or walks. Abnormal compensation usually results in abnormal locomotor function of the foot, where the mechanisms previously described as contributing to the specific functional demands of the sub-phases of gait, are compromised, resulting in abnormal position of the foot or part of the foot. This abnormal compensation has been organised into the three categories of abnormal pronation, restricted motion and abnormal supination.

Compensatory abilities originate from the triplaner nature of the subtalar and MTJs, which allow these joints to respond to demands for additional motion. Demands for compensation are usually made in one plane only, but the compensating response of the subtalar & MTJs must occur in all three body planes because of the nature of the coupled motions that occur at the STJt axis. Therefore, compensation satisfies the demand for motion in one plane while creating motion, or positional deviation, in the two additional body planes. If compensation were ideal, it would occur only in the required plane and would not be accompanied by additional motions. Root et al (1977) attribute demands for this type of compensation to numerous musculoskeletal pathologies because of a compromise of normal foot function and a resultant disturbance of structural integrity.
2.8 Conclusions

A considerable literature base exists supporting the concept that the foot is an adaptive and responsive segment which actively contributes to the specific demands of the subphases of stance, and the global demands of the locomotory process. Extrapolation of this idea leads to consideration of the consequences of foot dysfunction. It seems that the assertion of Elftman (1960 p.41), that

‘...exceptional responsibility is placed on the ankle (subtalar) joint...for the proper management of locomotor performance. Conversely, when the foot is negligent in the performance of its function, additional loads, that may prove excessive, are transferred to other components of the mechanism’

is accurate, and can be substantiated by an expanding body of research. This led him to determine that proper management of the foot provides us with our final opportunity to compensate for deficiencies in control of other parts of the body, and a conclusion which appears inescapable is that the foot and proximal skeletal chain – to the pelvis and beyond to rotations in the upper body - are interdependent for normal function. It seems logical, therefore, that if foot function is compromised there is a potential functional consequence that may result in pathology, either within the foot or in the proximal skeletal chain at a level as proximal as the low back. The next aim of the thesis is to examine evidence supporting the concept that abnormal foot function is related to low back pain, by sequentially considering the link with pathologies occurring at each level within the musculoskeletal chain – from intrinsic pedal pathology to pathology occurring at lower limb, knee, pelvic and lower spinal levels.
Summary points:
The literature reviewed in chapter 2 leads to several conclusions:

- Human locomotion is a complex process that requires the co-ordinated interactions of multiple body systems, including the skeletal, muscular and neurological control systems. Each component makes a vital contribution to the overall process;

- The integration of these systems is aimed at ensuring that a closely controlled sequence of joint motions take place during gait, to ensure that the overall process attains optimal efficiency;

- The foot is an integral part of the locomotory apparatus, carrying significant responsibility for the optimum transmission of load between the limb and the ground, and for several other vital weightbearing functions;

- Due to its position, connecting the lower limb with the ground, there is considerable responsibility placed on the rearfoot for the smooth transmission of load to the supporting surface;

- Triplaner compensatory capabilities within the rearfoot permits these articulations to respond to variations in skeletal alignment, muscle balance muscle tone;

- The interdependence between the rearfoot and lower limb, in a ‘skeletal chain’ suggests a significant possibility that changes in rearfoot mechanics will influence the function of adjacent and proximal segments, feasibly to the level of the lower back;

- The ultimate conclusion is that foot function is an important determinant of normal lower limb function during gait, and suggests that abnormal function may be associated with pathology in various segments to which it is kinematically linked;

- The next logical step is to review existing literature concerning the relationship between foot function and musculoskeletal pathology at various levels throughout the lower limb from intrinsic pedal to lower back pathology, and this will be the focus of chapter 3.
Chapter 3
Abnormal Foot Mechanics and Musculoskeletal Pathology

After considering the contribution of the foot to normal gait in the previous chapter, this chapter considers the literature supporting a relationship between abnormal foot function and musculoskeletal pathology. First, the concept of cause is discussed from an epidemiological perspective, emphasising the likely multi-factorial nature of any relationship, to provide an appropriate context for the analysis. The biological pathways by which foot function may induce pathology are presented, followed by a review of literature concerning the effect of orthoses on specific outcome measures and musculoskeletal pathologies. Pathologies at various levels are considered to examine the concept that abnormal foot function may influence the development of proximal pathology generally. Finally, the postulated mechanisms, and evidence, concerning a link between foot function and LBP are presented.

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3.5 Conclusions
3.1 Introduction

3.1.1 Essential considerations when investigating the relationship

The possibility that an association exists between foot function and musculoskeletal pathology can be traced to historical observations of a higher incidence of foot and limb pathologies in individuals with specific foot structures (Menz, 1998). More recent assertions that it seems logical that a relationship should exist (Ilahi and Kohl, 1998a, Powell et al., 1986) indicates that this belief persists. However, supporting research is ambiguous. Although foot orthoses—designed to optimise foot function—are acknowledged to be an important consideration in the treatment of foot, ankle and lower limb injuries (Heiderscheit et al., 2001), the conclusions drawn by reviews of their actual effectiveness conflict. For example, whilst systematic reviews provide only limited support for their use (Crawford et al., 2003, D'hondt et al., 2003), non-systematic reviews suggest them to be useful in the treatment of a variety of conditions (Kilmartin and Wallace, 1994b, Landorf and Keenan, 2000b). This conflict questions the strength of the relationship between foot function and musculoskeletal pathology, as it is reasonable to expect restoration of foot function to relieve symptoms if the two are related. However, to ensure that appropriate conclusions are drawn, the available evidence must be appraised from various perspectives. This includes consideration of the nature of the research upon which reviews are based and exploration of the concept of ‘evidence’ to ensure that important information is not overlooked or undermined. The likely complexity of the association between foot function and musculoskeletal pathology should also be considered.

3.1.1.1 Available evidence

The development and rapid growth of the ‘outcomes movement’, which endorses evidence-based healthcare (EBHC), has brought with it various concepts that have been embraced by both medicine and the allied health professions (Bristow and Dean, 2003). These concepts include the ‘hierarchy of evidence’ (table 3.1) (Greenhalgh, 2001), ‘levels of evidence’ and ‘grades of recommendation’ (Phillips et al., 2003, Sackett, 1986) that assign primacy to the randomised controlled trial (RCT), and state that systematic reviews of RCT's represent the best evidence available. The extent to which these principles have been adopted is illustrated by the recent proliferation of
systematic reviews and reviews of the levels of evidence achieved by research in specific fields (Pratt, 2000, Stuberg, 1995). The movement enjoys unprecedented political support, illustrated by government investment in initiatives such as the Cochrane Collaboration and the National Institute for Clinical Effectiveness in the UK, and similar ventures across the world (Bristow and Dean, 2003).

Table 3.1: The hierarchy of evidence (Greenhalgh, 2001)

<table>
<thead>
<tr>
<th>Hierarchy of Evidence</th>
<th>Description</th>
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<tbody>
<tr>
<td>Systematic reviews and meta-analyses</td>
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<tr>
<td>RCTs with definitive results</td>
<td>i.e. confidence intervals that do not overlap the threshold clinically significant effect.</td>
</tr>
<tr>
<td>RCTs with non-definitive results</td>
<td>i.e. A point estimate that suggests a clinically significant effect, but with confidence intervals overlapping the threshold for this effect.</td>
</tr>
<tr>
<td>Cohort studies</td>
<td></td>
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<tr>
<td>Case-control studies</td>
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<tr>
<td>Cross-sectional studies</td>
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<td>Case reports</td>
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The emphasis on RCTs and systematic reviews does not receive universal support, however. In an objective and informed discourse attempting to place RCT’s and systematic reviews in the context of medical evidence generally, Black acknowledged that a well-conducted RCT on a clearly defined issue can yield evidence of a probability approaching certainty, but also raised several important concerns that suggest the primacy assigned this design is inappropriate (Black, 1998a). He did acknowledge the development of the RCT by Doll and Hill as:

‘...both theoretically and practically a milestone in medical history...a brilliant response to the increasing problems set by the proliferation of agents that are highly effective but also potentially hazardous from their side effects...’

Black 1998 pp 24

However, he emphasised that they were devised for use in specific situations, and argued that their contemporary status may exceed both the theoretical and pragmatic limits of the design. At the heart of his argument were the strict conditions that must be met to ensure a quality RCT and the overt dismissal of other designs. The current situation may not be pre-meditated, however. The outcomes movement originally empowered the common doctor by permitting him, with the right training, to understand the evidence supporting a treatment, but the core principles seem to have developed into a dogma where it now seems that without a Cochrane Collaboration or Agency for Health Care Policy and Research recommendation or review, a
treatment is not considered evidence-based (Godlee, 1998). That the number of organisations conducting the reviews that produce guidelines is shrinking led to the further assertion that medicine may soon be practised on the basis of a few precepts.

The RCT design was aimed at common disorders, so that only one study centre was required, and demands minimal variation between patients, to reduce heterogeneity amongst study subjects. Whilst it is acknowledged that there are ways of organising multi-centre trials that largely preserve their validity (at the expense of increased complexity), controlling heterogeneity can be difficult. Black (1998) asserted the most important derogation of the RCT to be taxonomic complexity, where simple classifications are used in complex situations. This theme also runs through the CONSORT statement (Moher et al., 2001), which comprises 22 questions used to evaluate the quality of RCT’s, with each demanding a dichotomous response to receive either a positive or negative score. This fails to consider the complexity of the particular situation leaving no room for the indecision encountered in non-standard scenarios. The RCT seems, therefore, to be the archetypal quantitative design that is reductionist in nature and fails to consider the true complexity of an issue (Polgar and Thomas, 2000). The problem is summarised accurately by Greenhalgh who admitted that clinical problems are rarely discrete and uni-dimensional, and that considering one treatment decision per case necessarily reduces the complexities of each case to a single decision node (Greenhalgh, 1996). The implications of such a model of practice were explored further in a thought-provoking discourse considering on the implications for medical professionalism (Tanenbaum, 1999a). This focused on the shift from a willingness to integrate the experience of the health professional to the demand for exclusive empirical support, which was felt to undermine both the complexity of physicians experience and the immediacy and individuality of patients.

Tanenbaum (1999) emphasises that professionals think intuitively and in context, and urges professionals to protect this dimension of practice. Black (1998) asserted that such a reductionist approach results in inconclusive or conflicting results, and he would probably have agreed with the assertion that the emphasis on RCT’s suggest a belief that individuals are most clearly seen as a member of a group (Tanenbaum, 1999a). In the context of trials of foot orthoses, this seems to be a particularly relevant issue that has prevented at least one meaningful synthesis of results in a review (Ilahi and Kohl, 1998a). Whether this situation can be resolved satisfactorily has been
questioned on the premise that evidence-based medicine has its origins in medicine and may need to be adapted to fit the allied health professions (Clemence, 1998). In particular, the type of evidence required might be unattainable due to the complexities of the practitioner-patient interaction. Clearly, RCT’s will be seriously compromised by patient heterogeneity, as different conditions are unlikely to respond in the same way to a particular treatment, and it might not be possible to sufficiently control a group of patients to the level required to achieve the statistical outcomes required.

The primacy assigned to RCT’s can be challenged not only from the perspective of their universal suitability, but also from the perspective that there are other forms of evidence that offer important and useful information that should not be undermined. Black (1998) firmly advocates consideration of a range of evidence, arguing that

‘...the quality of evidence should be assessed not by the method by which it was obtained, but by its strengths and weaknesses...there is not here a hierarchy of methodological esteem, merely an order of difficulty, and the RCT must not take ‘gold standard’ precedence over all other methods of clinical investigation’.


It is further stated that information relevant to clinical decision-making is derived from many sources, such as the medical sciences and the observed natural history of a disease. The approach parallels that of epidemiology. Defined as the study of the incidence, distribution and determinants of disease with a view to bringing about their prevention (Wald, 1996), it is concerned primarily with understanding ‘cause’ and focuses on analysis of evidence from multiple sources. These sources are summarised in a series of ‘criteria for inferring causality’ (table 3.2) (Gordis, 2000, Vetter, 2000, Wald, 1996), which represent issues that should be considered if a causal relationship between an exposure and a disease is to be identified.
Table 3.2: Criteria for inferring causality (Wald 1997)

<table>
<thead>
<tr>
<th>Essential criteria</th>
<th>Additional criteria</th>
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<tr>
<td>- A real association i.e. one that is unlikely to be due to chance;</td>
<td>- Strength of association: a relative risk as high as 3 or 4 times is less likely to be due to bias than one of 2 or less;</td>
</tr>
<tr>
<td>- Exposure to the factor precedes the onset of the disease;</td>
<td>- Consistency in the evidence from several studies that are unlikely to share the same bias;</td>
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<tr>
<td>- The association cannot be reasonably explained by bias, either through systematic measurement error or through the effect of one or more confounding factors;</td>
<td>- Demonstration of a dose-response relationship between the factor and the disease in studies of individuals;</td>
</tr>
<tr>
<td>- The causal explanation is biologically plausible.</td>
<td>- The distribution and frequency of the disease in different groups and over time follows the distribution and exposure of the factor;</td>
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<td></td>
<td>- Support from animal or in-vivo laboratory evidence.</td>
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This approach recommends that the process of establishing cause should begin with descriptive studies that ask questions about the characteristics of patients with the disease, in the hope that from these observations a hypothesis will emerge. An analytical study can then be designed to allow calculation of the relative / absolute excess risk associated with the particular exposure, to provide information on the possible public health benefit of removing that exposure (Gordis, 2000, Vetter, 2000). Although a series of criteria were presented, the relative weighting that can be assigned to each warrants consideration. This issue was tackled by Gordis (2000) who recounted the problems faced by a committee commissioned by the U.S. Public Health Service in 1986 to examine the scientific basis of the content of prenatal programmes. It became clear that the issue of ‘cause’ was at the heart of the task, and a subcommittee was set up to review existing guidelines concerning the relationship between prenatal measures and health outcomes. Although focused on the subject of prenatal care, the modified guidelines provide important principles for weighting different forms of evidence for considering causation. Whilst the ‘major’ and ‘other’ criteria are essentially analogous to those presented in table 2.2, identification of a biologically plausible mechanism was elevated to the second major criteria, after the temporal nature of the relationship and before consistency between studies and the role of confounding factors (Gordis, 2000).

The epidemiological approach corroborates Black’s view that evidence concerning causal relationships should be sought from multiple sources. Although the rise of the
outcomes movement has seen prolific use of the RCT design, even prominent protagonists of EBHC recognise its limits. Over-dependence on RCT’s equates with acceptance of the ‘...diagnosis by therapeutic response...’ model as the default method for investigating cause. In this model, symptoms and signs lead to a provisional hypothesis, leading to empirical treatment and identification of the disease based on the response. Although this model may well have pragmatic appeal (Wald, 1996), especially in the clinical situation where the conventional model might be inappropriate, to dismiss evidence from other types of design would leave important questions unanswered. The role of RCT’s in diagnosis may develop, but their current function undoubtedly extends beyond the original intention of comparing the performance of several effective treatments, significantly challenging its prolific use. This assertion is supported by an excellent discourse on evidence in medicine which expressed frustration that even etiologic research seems to be motivated exclusively by a concern to identify opportunities for prevention, to the detriment of the needs of ‘etiognosis’, which results in a lack of the specificity required (Mietinnen, 1998).

3.1.1.2 Admissible evidence

The outcomes movement has led to pressure on every healthcare discipline to demonstrate that the treatments they provide are clinically and cost effective and safe (Bristow and Dean, 2003). Whilst it is acknowledged that any movement that encourages self-scrutiny has to be positive, it should stop short of ‘...aborting that modicum of self-confidence which enables us to live and practise, while aware of the strong element of uncertainty that is inescapable in all branches of healthcare...’ (Black 1998 pp.24). However, attaining the balanced perspective required is difficult in the current climate. For example, in a discussion of the current status of evidence based practice in Podiatry, Bristow & Dean (2003) point out that the extent of the actual research base relevant to AHP’s is only 6%, compared with 15% in nursing and 79% in medicine (although it has been claimed that such favourable figures for medicine are flattering, and that the majority of medical research is in fact either too poorly done or insufficiently relevant to be clinically useful (Godlee, 1998). This supports the estimate by Donaghy that it will take 30 years before a suitable evidence base is established in these professions (Donaghy, 1999). Although this is factual
information, no advice is provided on reconciling demands for evidence-based practice with the paucity of acceptable evidence available.

Despite this, attempts have been made to review the available evidence against Sackett’s ‘levels of evidence’ (Phillips et al., 2003). Perhaps unsurprisingly, given the paucity of literature, these reviews focus on the generally low levels of evidence achieved, and conclude that more high quality trials are a priority (Pratt, 2000). Such conclusions are common to reviews of the levels of evidence achieved in similar fields of practice (Stuberg, 1995). However, these conclusions are likely influenced by the pragmatic difficulties in designing a trial that employs the design features required to satisfy the demands of systematic reviews, such as blinding, for interventions like orthoses (Landorf and Keenan, 2000a). The tacit implication is that RCT’s are urgently required to satisfy the demands of the outcomes movement, dissuading researchers from considering the role of a variety of research designs. This further strengthens the argument for the inclusion of evidence from various sources, as opposed to reliance on the few, relatively poor quality, RCT’s available which may be capable of providing only weak evidence in the immediate future, or indeed, may never attain the level required for very good reasons (Clemence, 1998).

3.1.1.3 The Complexity of the relationship

Although it is sometimes possible to work out cause and effect relationships, the complexities of modern treatment and prevention strategies often obscure their true nature (Vetter, 1999). It has become clear that the observation of an association between 2 variables need not infer a cause and effect relationship, and that many diseases are multi-factorial in nature.

There is evidence that the multi-factorial nature of lower limb injuries is an important consideration. For example, in a literature review of the relationship between lower extremity morphology and overuse injuries, the failure to identify a relationship did not lead to rejection of the possibility, but rather, led to discussion of the ‘epidemiological triangle’ of agent–host-environment’ (Ilahi and Kohl, 1998a). In conclusion they suggested that more studies of the interactions between lower extremity alignment, personal and environmental characteristics were required. These conclusions echoed those of van Mechelen, who reviewed the evidence concerning
numerous possible aetiological factors and running injuries but identified that only a few associations were significant, including previous injury and experience (Van Mechelen, 1994). The conclusion that the role of a majority of factors was ambiguous seems important. If foot function is a factor involved in the development of musculoskeletal pathology, it is likely that a complex pathway is involved.

A framework for the analysis of the nature of the association between two variables has been suggested (Vetter, 2000) that focuses on the influence of bias and confounding (table 2.3; figure 2.1). The concept of necessary and sufficient factors, where individual factors might be independently or jointly involved with other(s) in the development of disease, is likely to be relevant (Gordis, 2000). Four models are used to illustrate the possible pathways involved, and it is notable that the most complex was also suggested as that which was most relevant in chronic conditions. In this model, where the factor of interest is neither necessary nor sufficient, multiple factors are involved which all contribute but are independently unable to produce the disease. It is clear that when examining variables that are likely to be neither necessary nor sufficient causes, it is vital to keep this fact in mind to avoid the possibility of a type II error, where the possibility of a relationship is inappropriately rejected.

Table 3.3: Basic considerations in the analysis of cause and association.
(Vetter & Matthews 1999, p.27)

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<tr>
<td>• Several causes affecting one disease may have a greater effect if they occur together than the simple sum of their individual effects.</td>
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</tr>
<tr>
<td>• Associations that are not causal can occur by chance and if selection or measurement procedures are biased.</td>
<td></td>
</tr>
<tr>
<td>• Confounding variables may erroneously appear to link causes directly with disease; common confounding variables are time, place and poverty.</td>
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Low back pain provides an excellent example of these concepts. Associated with over 100 suspected causative factors (Cole and Grimshaw, 2003), it has been estimated that the probability of a particular case having a specific cause is 0.2% (Ehrlich, 2003). This uncertainty has been related to inadequacies in precise knowledge of the anatomy of the lumbosacral spine, the multi-factorial nature of the condition, and the limitations of current diagnostic procedures (Giles, 1997). Any investigation of the
role of a particular factor in low back pain must, therefore, take cognisance of the likely complexity of aetiology.

**Figure 3.1: Investigating cause. (Vetter & Matthews 1999, p.27)**
Investigating the role of bias, chance and confounding helps to assess the likelihood of a relationship being causal. With each question, if that influence is considered likely, then the association is unlikely to be causal.

3.1.2 Conclusion

Whilst the outcomes movement asserts that the best evidence available in relation to a particular problem should be sought (Greenhalgh, 2001), inappropriate primacy may be being assigned to RCTs (Black, 1998b, Tanenbaum, 1999a). This undermines the more balanced approach advocated by epidemiologists, which promotes consideration of a range of different types of evidence (Gordis, 2000, Vetter, 2000). In relation to investigation of interventions utilised by the younger allied health professions, where the available evidence is limited (Bristow and Dean, 2003), this seems especially appropriate considering the relative paucity of literature (Bristow and Dean, 2003), the failure of this research to fulfil the requirements of the higher 'levels of evidence' (Phillips et al., 2003), and the likely length of time required to gather the required volume of quality research (Donaghy, 1999). A more appropriate approach may be to consider the available evidence in relation to the problem, which essentially relates to exploration of the biological plausibility of the causal explanation and the likely influence of bias / systematic measurement error on individual studies. Although evidence from reviews of trials of foot orthoses are useful, a variety of evidence sources should be considered to ensure that objective conclusions are drawn. This approach finds explicit support in a recent proposal to grade the quality of guidelines based on systematic review evidence that proposes a mechanism for factoring in various types of evidence (Atkins et al., 2004).
3.2 Analysis of the relationship I: Theoretical issues

3.2.1 The biological plausibility of the causal explanation

The biological plausibility of the causal explanation has been described as one of the major criteria that can support the concept of a causal relationship between two variables (Riddle et al., 2003), and this criterion figures prominently in epidemiological texts (Gordis, 2000, Vetter, 2000). Warnings that any links identified may be limited by current knowledge, with what is implausible today perhaps being plausible tomorrow (Vetter, 2000), have been made, and it has also been acknowledged that clinical observations and study results may precede the biologic knowledge to support a relationship (Gordis, 2000). However, the criterion remains important, and the identification of such a link represents a fundamental step towards identifying a causal relationship.

The mechanism by which foot function can induce proximal pathology as proximal as the low back is based on the acknowledged interdependency between transverse plane limb rotations and rearfoot motion. The couple for this link is the STJt, by virtue of its oblique axis (Close et al., 1967), which is positioned approximately 45° inclined from the transverse plane (figure 3.2). This creates a functional couple linking transverse plane limb rotations and pronation/supination within the foot — a critical function that permits resolution of the transverse pelvic rotations that occur to minimise the vertical excursion of the C-o-M and which are transferred to transverse limb rotations, at foot level. This relationship was demonstrated by (Rose, 1962) who inserted a steel rod into the anterior tibia in-vivo to demonstrate that internal tibial rotation leads to a decrease in MLA height and external tibial rotation leads to an increase in MLA height. This function has been compared to a mitred hinge (Bellchamber and van den Bogert, 2000b, Inman et al., 1994), where there is perfect translation of motion between two planes. Perfect translation of motion, however, requires that the axis lies at exactly 45° between two planes, and it is acknowledged that the actual orientation of the axis varies between individuals (Close et al., 1967, Kirby, 1989). It has been suggested that differences could account for variations in foot-type, and a foot-type classification system based on gross axis location has been proposed (Close et al., 1967) (table 3.4). Essentially, the theory states that for the same amount of subtalar
motion a high axis will result in greater transverse plane limb rotation and therefore an increased susceptibility to knee pathology, whilst a low axis will result in greater frontal plane foot motion resulting in increased susceptibility to pedal pathology (Green and Carol, 1983). This theory is mechanically sound, and several groups have investigated injury patterns in subjects grouped according to axis orientation (Bowden and Bowker, 1995, McClay and Manal, 1997, Stergiou et al., 1999, Williams and McClay, 2000, Williams et al., 2001). Results suggest that variations in axis orientation may indeed be significant and may explain differences in injury patterns between subjects with high and low arches.

Figure 3.2: Torque conversion function of the STJt. Internal rotation is shown producing subtalar pronation, with calcaneal eversion, lowering of the medial longitudinal arch and elongation of the foot. The figure on the left shows a model, and the figure on the right shows the foot superimposed. Left figure, Close, Inman et al (1967), right figure, Michaud (1997).

Table 3.4: A classification of the human foot based on subtalar joint axis position (Close et al., 1967)

<table>
<thead>
<tr>
<th>Foot-type</th>
<th>Stance phase motion</th>
<th>Total range of motion</th>
<th>Medial axis deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cavus foot</td>
<td>Slight: 3-4°</td>
<td>Least: 11°</td>
<td>Least: &lt;11°</td>
</tr>
<tr>
<td>Normal, somewhat pronated foot</td>
<td>Moderate: 5-6°</td>
<td>Moderate: 24°</td>
<td>Average: 16°</td>
</tr>
<tr>
<td>Flat foot</td>
<td>Pronounced: 16°</td>
<td>Greatest: 28°</td>
<td>Greatest: &gt;16°</td>
</tr>
</tbody>
</table>

The torque conversion mechanism is also important because of the unique compensatory capabilities it allows. In a system heavily reliant on integration, in which loss of one part results in loss of the contribution of that part to the entire mechanism (Radcliffe, 1994a), this capability is vital. The possibilities offered by the subtalar complex were acknowledged by Elftman, who asserted that:

'...proper management of the foot provides us with our final opportunity to compensate for deficiencies in control of other parts of the body...conversely, when
the foot is negligent in its function, additional loads, which may prove excessive, are transferred to other components of the mechanism'.

(Elftman 1960 pp.41).

3.2.2 The Concept of Compensatory Foot Function

Lee (2001) traces the origins of compensatory foot function to the concepts of stability and equilibrium that emerged in the early 20th century alongside the term ‘decompensation’, which was used to describe the foot’s ability or inability to conform to the underlying terrain (Lee, 2001b). He further asserts that the concept is tacitly implied in the term ‘balance’ widely discussed at the time (Bunch, 1956, Henenfield, 1956, Tripp, 1935). Recently, these concepts of stability, equilibrium and balance have been re-iterated by various authors who have emphasised the importance of applying such mechanical concepts to foot function (Fuller, 1999a, Fuller, 2000a, Kirby, 1989, Kirby, 2000, Southerland and Orien, 1995, Vogler and Bojsen-Moller, 2000). The seminal discourse of the concept was, however, provided by Root (Root et al., 1977), who presented a coherent clinical system of approach that has been described as a:

‘...logical and rationally based insight into what countervailing measures the foot might be undergoing in order to conform to the underlying terrain and maintain postural equilibrium, that is, balance’.  

Lee (2001 pp.607)

Root’s theory is notable for its comprehensive nature and coherence. Building on existing knowledge of normal STJt function, a discussion of the nature, origins, aetiology and consequences of abnormal motion was presented (Root et al., 1977). However, perhaps the most important contribution was the description of a clinical examination technique by which skeletal mal-alignments could be identified. A series of ‘criteria for normalcy’ were described, setting out the optimal skeletal alignments required for normal function, and these formed the basis of the clinical examination procedure. The approach focused on the triplaner nature of the STJt that permits it to respond to anomalies in alignment originating in any of the three cardinal body planes. This process was termed compensation, which was defined as ‘...a change of
structure, position or function of one part in an attempt by the body to adjust to a deviation in structure, position or function of another part’ (Root et al., 1977).

Normal compensation was defined as motion occurring in response to functional demands related, for example, to differing activities and terrains. Such motions are characterised by their transient, non-persistent nature, and generally occur within the normal ranges and planes of motion of the rearfoot and midfoot joints. An example is the hurdler requiring additional STJ pronation when landing. No abnormalities were associated with these motions due to their transient, non-persistent nature. By contrast, abnormal compensations were related to various intrinsic, consistently present, neuromusculoskeletal anomalies that demand recurrent excessive subtalar motion as compensation. The ability of the STJ to pronate and supinate led to the suggestion that ‘pronatory compensation’ and ‘supinatory compensation’ could occur, with the possibility that motion might be limited considered in a third category termed ‘restricted motion’ (Root et al., 1977). Clinical approaches to podiatric biomechanics that focus on these three categories of STJ dysfunction have recently been described (Blake and Ferguson, 1996, Subotnick, 1998), providing evidence of the enduring appeal of the system.

An appreciation of the multiple systems involved in gait leads to the conclusion that impairment of any of these systems may disrupt the locomotory process and produce subtalar compensation. Accordingly, Root et al (1977) proposed a variety of neuromusculoskeletal mechanisms capable of disrupting normal gait by inducing abnormal compensatory foot function. These include trauma, arthropathy, congenital coalitions of bone, neuromuscular disease and osseous / soft tissue abnormality (table 2.5). Although the long list of diseases that may impair a patients ability to walk may differ markedly in their primary pathology, the abnormalities they impose on the mechanics of walking have been categorised into four functional categories: deformity, muscle weakness, impaired control and pain (Perry, 1992a). The common thread linking each is disruption of equilibrium and balance, which compel the foot to alter its position of balance.

Although a range of factors may induce compensation, osseous, uniplaner ‘deformities’ were a major focus of Root’s thesis (Root et al., 1977). These were first identified via clinical observation of relatively minor mal-alignments that were
observed in various lower limb segments. The development of clinical measurement techniques permitting description of these anomalies relied upon identification of the subtalar ‘neutral’ position, which provided a reference position from which measurements could be obtained, and this led to the formulation of the criteria for normalcy and the clinical examination procedure.

Table 3.5: Categories of abnormal compensatory foot function and example aetiologies (Root et al., 1977)

<table>
<thead>
<tr>
<th>Class</th>
<th>Aetiology</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abnormal pronation</td>
<td>Osseous / soft tissue abnormality of the foot or lower extremity</td>
<td>Rearfoot varus / forefoot varus</td>
</tr>
<tr>
<td></td>
<td>Forces which prematurely load the medial side of the foot</td>
<td>Obesity</td>
</tr>
<tr>
<td></td>
<td>Muscle imbalance due to neuromuscular disease</td>
<td>External femoral torsion</td>
</tr>
<tr>
<td>Abnormal supination</td>
<td>Central nervous system pathology</td>
<td>Cerebral palsy</td>
</tr>
<tr>
<td></td>
<td>Lower motor neurone pathology</td>
<td>Hereditary motor and sensory</td>
</tr>
<tr>
<td></td>
<td>Everted forefoot anomalies</td>
<td>Neuropathies</td>
</tr>
<tr>
<td></td>
<td>Equinus conditions that prevent the heel contacting the floor</td>
<td>Congenital gastrocnemius equinus</td>
</tr>
<tr>
<td>Restricted motion</td>
<td>Trauma</td>
<td>Accident / injury</td>
</tr>
<tr>
<td></td>
<td>Destructive joint disease</td>
<td>Osteoarthritis</td>
</tr>
<tr>
<td></td>
<td>Muscle spasm / contracture</td>
<td>Peroneal spastic flatfoot</td>
</tr>
<tr>
<td></td>
<td>Congenital coalitions of bone</td>
<td>Talonavicular bar</td>
</tr>
</tbody>
</table>

The intrinsic anomalies described by Root et al (1977) included rearfoot and forefoot varus and rearfoot and forefoot valgus. The effect of these anomalies results entirely from the pursuit of stability and equilibrium. For example, in rearfoot varus, identified when the posterior calcaneus is inverted relative to the weightbearing surface when the STJt is in its neutral position, stable ground contact can only be achieved if this position can be compensated for. This will most commonly occur through STJt eversion which will bring the medial calcaneus into ground contact. This compensatory motion is explained by simple physics (Southerland and Orien, 1995) in response to the initial lateral calcaneal loading pattern created by the rearfoot varus position. Because the range of motion available at the STJt may vary, each anomaly was further divided into uncompensated, partially compensated or fully compensated to reflect this. However, in each case normal gait is affected, with both the timing and amount of motion occurring deviating from that normally required.
Recently, the criteria for normalcy (table 3.6) have been challenged by various criticisms (table 3.7), which ostensibly originate from their failure to withstand explicit interpretation. For example, the criteria have not yet been verified in a substantive normal population (Keenan, 1997), and an analysis of the measures in a population of 50 subjects revealed that values differed by between 4 and 6° (Astrom and Arvidson, 1995). However, the choice by some authors to interpret the criteria literally contrasts starkly with the concept of individuality that seems intrinsic to medicine, and is evidenced by the range of normal values for various tests, from clinical measurements to laboratory analyses, that are included in medical textbooks. In a recent appraisal of the major criticisms of the Root model, such an approach was recommended, based on the concept that a lower limb functioning closer to the normal position described by Root et al (1971) will more likely be asymptomatic than a limb which does not (Mathieson, 2001). Support for this viewpoint was drawn from various sources and seems entirely reasonable (Orien 1997; (Fuller, 1999b, Fuller, 2000b); Kirby 1987, (Kirby, 1989, Kirby, 1992). Although normative values have been investigated in an attempt to refine the original criteria for normalcy (Astrom and Arvidson, 1995), (table 3.6), the most rational approach presented seems to be that presented by Michaud (1997). In addition to providing a series of measurements for which a range of normal values are included, statements relating to holistic neuromusculoskeletal health are included (table 3.7).

Although the criteria for normalcy have been criticised, the assertion that ‘...such semantic arguments do not detract from the seminal value of Root's conceptual system of classification...’ (Lee 2001 pp. 401) seems justified, and it can be concluded that compensatory foot function, occurring through the STJt and driven by various aetiologies, represents a plausible mechanism by which foot function may be related to musculoskeletal pathology.
Table 3.6: The criteria for normal locomotory function provided by Root et al (1971) and two more recent interpretations of the concept (Astrom and Arvidson, 1995) and (Michaud, 1997a)

Root et al (1977):

- The distal ⅔ of the tibia is vertical;
- The knee, ankle and STJts lie in a transverse plane parallel to the supporting surface;
- The STJt rests in its neutral position;
- The bisection of the posterior calcaneus is vertical;
- The MTJt is maximally pronated;
- The plantar plane of the forefoot parallels the plantar plane of the rearfoot and both parallel the supporting surface. The sagittal bisection of the posterior calcaneus is perpendicular to the plantar plane of the foot;
- Metatarsals 2, 3 & 4 are maximally dorsiflexed and the plantar surface of the metatarsals describe a common plane parallel to the supporting surface;
- Metatarsals 1 & 5 are maintained in such a position that their plantar plane lies I the same plantar place as the 2nd, 3rd and 4th metatarsal heads.

Astrom & Arvidson (1995):

- Tibial position: 6° Inverted ± 2°
- STJt neutral position: 4° everted ± 3°
- Relaxed calcaneal stance position: 7° everted ± 4°
- Forefoot to rearfoot relationship: 6° inverted ± 4°
- Subtalar inversion: 28° ± 6°
- Subtalar eversion: 10° ± 4°

Michaud (1997):

- In the normal angle and base of gait, the lower ⅔ of the leg should be perpendicular to the ground ± 2°;
- In subtalar neutral & with the calcaneocuboid joint close-packed, the vertical calcaneal bisection should parallel the vertical bisection of the tibia and fibula (± 2°), the plantar forefoot should be perpendicular to the vertical bisection of the calcaneus and the plantar metatarsal heads should all rest on the same transverse plane;
- The distal extensions of the metatarsal heads should form a smooth, parabolic curve;
- The lower extremities should be of equal length;
- The various articulations of the lower extremity and pelvis should move through specific minimum ranges of motion;
- The lower extremities should be of equal length;
- Neuromotor co-ordination must be intact, and the peri-articular tissues must provide ample proprioceptive information;
- The supporting muscles must possess adequate strength, power and endurance;
- The articular architecture should protect against excessive and/or abnormal motions;
- Ontogeny must allow for the formation of a relatively straight lower extremity (in both the frontal and transverse planes) and for the development of a functional medial longitudinal arch.
Table 3.7: Selected synopses of anomalies surrounding the ‘criteria for normalcy’ (from Mathieson 2001)

<table>
<thead>
<tr>
<th>Author</th>
<th>Area of concern</th>
<th>Implications / Advice</th>
</tr>
</thead>
<tbody>
<tr>
<td>M'Poil &amp; Hunt (1995a, 1995b)</td>
<td>1. Reliability of measurement techniques</td>
<td>Adopt an approach favouring symptomatic reduction over restoration of alignment De-emphasise the role of functional orthoses Look for new paradigm</td>
</tr>
<tr>
<td></td>
<td>2. Validity of criteria for normalcy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Dynamic STJt position</td>
<td></td>
</tr>
<tr>
<td>(Michaud, 1997a)</td>
<td>1. Dynamic STJt position</td>
<td>Ideal casting position</td>
</tr>
<tr>
<td></td>
<td>2. Reliability of measurement techniques</td>
<td>Possible biases in kinematic-based research of dynamic subtalar motion Encourage practice to develop experience and use of weightbearing measurements, associated with higher levels of reliability.</td>
</tr>
<tr>
<td>(Keenan, 1997)</td>
<td>1. Single axis model of function</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Significance of frontal plane rearfoot motion</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Amount &amp; timing of rearfoot motion</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. Reliability of clinical measurements</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5. Correlation between static measures and dynamic function</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6. Questionable basis of the validity of normal foot function</td>
<td></td>
</tr>
</tbody>
</table>

3.3 Analysis of the Relationship II: Functional Foot Orthosis Research

3.3.1 Introduction

The functional foot orthosis (FFO) was defined as

‘...an orthopaedic device ...designed to promote the structural integrity of the joints of the foot and lower limb by resisting ground reaction forces that cause abnormal skeletal motion to occur during gait’


The use of these devices is based on the premise that abnormal foot function can disrupt the normal gait cycle to induce pathology, and that by eliminating the need for compensation pathologies can be treated. Some idea of the variety of conditions for which orthoses are commonly used can be gained by considering the guidelines of the American College of Foot and Ankle Orthopaedics and Medicine (Benard et al., 2002), who describe a range of five general areas in which orthoses may be helpful, including proximal lower extremity pathology, arthritides, mechanically-induced pain,
paediatric conditions and sensory neuropathies. With each category comes a series of individual conditions that can be treated, and it is also stated that this list is not exhaustive.

Whilst the efficacy of orthoses has been considered in terms of their influence on outcome measures such as patient satisfaction and pain, technical performance has also been examined. The ability of orthoses to influence kinematic, kinetic and muscle function parameters under in-vitro conditions has been investigated, and several high-quality experimental trials have been conducted in-vivo to determine the technical ability of the orthoses to influence positional parameters. This focus on numerous different outcome measures means that there is a substantial literature base concerning the efficacy of orthoses, and this may yield important information about the relationship between foot and lower limb function.

Evaluation of studies examining the efficacy of orthoses represents a useful approach to examining the relationship between foot-type and musculoskeletal pathology. Whilst previous systematic and non-systematic reviews of the literature concerning the efficacy of foot orthoses have been conducted and drew conflicting conclusions, this may be avoided if a more balanced approach is adopted. This involves considering a range of studies to determine whether their rejection from systematic reviews is legitimate, or whether they offer useful information that can legitimately influence conclusions. This approach is supported by Landorf, who warns against rejecting research out of hand because of relatively minor flaws when results concur with extant research, and argue that the most studies, if carefully planned, can contribute something to the body of knowledge (Landorf and Keenan, 2000a). Whilst random selection of studies for inclusion in a review cannot be supported, consideration of the deficits in the concept behind systematic reviews (see section 3.1) suggests that a more flexible approach is warranted.
3.3.2 The influence of FFO's on pain, deformity and disease in the lower limb

3.3.2.1 Patient Satisfaction with Orthoses

In a comprehensive review of the literature concerning the efficacy of foot orthoses, Landorf & Keenan (2000) began with patient satisfaction – an obviously important outcome measure. Four studies were identified, which focused on a range of patient groups including a series of 180 runners with a range of athletic injuries (Blake and Denton, 1985), a group of general patients (Donatelli et al., 1998), 500 long-distance runners (Gross et al., 1991) and a group of 530 heterogeneous patients (Moraros and Hodge, 1993). To these, a more recent study of 82 patients provided with orthoses in a small UK NHS Health Authority in a year, can be added (Rendall and Batty, 1998).

Despite cautioning that the methods used across these studies did not account for the use of other therapeutic modalities, and the fact that three were retrospective, Landorf & Keenan (2000) concluded that patients seem generally satisfied with their orthoses. However, each study calculated the best possible result by calculating satisfaction as a percentage of respondents, not of the patients who actually received orthoses. Adopting such a ‘worst-case-scenario’ approach involves classing all non-respondents as dissatisfied, and permits calculation of the minimum satisfaction rate. These rates are provided in table 3.8.

Set against these figures, which provide factual information concerning the minimum levels of satisfaction, complication rates should also be considered. As in the case of the complaint treated, the complaints for which the orthoses were unsuccessful were generally not presented. The exception was Blake & Denton (1985) who provided a list detailing each complaint treated, and whether the orthoses were ‘definitely’ to ‘not at all’ successful. The conditions for which orthoses failed were varied, and there were far more successes.
Table 3.8: Patient Satisfaction with FFO’s (FFO’s)

<table>
<thead>
<tr>
<th>Study</th>
<th>Patients contacted</th>
<th>Responses (%)</th>
<th>Quoted satisfaction rate</th>
<th>‘Worst-case scenario’</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Blake and Denton, 1985)</td>
<td>180</td>
<td>115 (64%)</td>
<td>70% - definitely helped</td>
<td>48% - definitely helped</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>78% - felt postural</td>
<td>50% - felt postural</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>improvement</td>
<td>improvement</td>
</tr>
<tr>
<td>(Donatelli et al., 1998)</td>
<td>81</td>
<td>53 (65%)</td>
<td>94% still wearing</td>
<td>62% still wearing</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>91% ‘very’ or ‘satisfied’</td>
<td>59% ‘very’ or ‘satisfied’</td>
</tr>
<tr>
<td>(Gross et al., 1991)</td>
<td>500</td>
<td>347 (69%)</td>
<td>76% Complete resolution</td>
<td>53% complete resolution</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>of great improvement</td>
<td>or great improvement</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>90% continued use</td>
<td>62% continued use</td>
</tr>
<tr>
<td>(Moraros and Hodge, 1993)</td>
<td>523</td>
<td>403 (77%)</td>
<td>62.5% completely resolved</td>
<td>48% completely resolved</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>83.1% ‘indicated</td>
<td>64% indicated satisfaction</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>satisfaction’</td>
<td></td>
</tr>
<tr>
<td>(Rendall and Batty, 1998)</td>
<td>81</td>
<td>58 (72%)</td>
<td>91% ‘described some</td>
<td>63% described some</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>improvement’</td>
<td>improvement</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>80% continued wearing</td>
<td>57% continued wearing</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>at least some of the time</td>
<td>at least some of the time</td>
</tr>
</tbody>
</table>

Table 3.9 provides more information on these outcomes, detailing the actual numbers of successes and failures, and suggests that orthoses may be considered successful in the treatment of a range of conditions. The most direct method of assessing orthoses failure involved the use of a Likert scale that allowed both positive and negative responses to a series of statements including ‘pain has been increased by wearing the orthoses’ and ‘pain has been reduced by wearing the orthoses’ (Rendall and Batty, 1998). They also explored the reasons for dissatisfaction, discovering that although use was stopped by resolution of symptoms in most cases, discomfort, new symptoms and bulk led to discontinuation of use in four, two and four cases respectively. This approach, giving equal attention to the possibility of negative experiences as well as positive experiences, could be considered the most objective and provides interesting and useful information.

Table 3.9: Success/failure rates of various condition treated with orthoses (Blake and Denton, 1985)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Successes</th>
<th>Failures</th>
<th>Success rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iliotibial band tendonitis</td>
<td>4</td>
<td>1</td>
<td>80%</td>
</tr>
<tr>
<td>Chondromalacia patellaiae</td>
<td>11</td>
<td>4 (inc. 2 lost to follow up)</td>
<td>73%</td>
</tr>
<tr>
<td>Severe gastrocnemius strain</td>
<td>1</td>
<td>1</td>
<td>50%</td>
</tr>
<tr>
<td>Plantar fascitis</td>
<td>44</td>
<td>3 (inc. 1 lost to follow up)</td>
<td>94%</td>
</tr>
<tr>
<td>1st MTPJ capsuleitis</td>
<td>2</td>
<td>1</td>
<td>67%</td>
</tr>
<tr>
<td>STJ synovitis</td>
<td>0</td>
<td>1</td>
<td>0%</td>
</tr>
</tbody>
</table>

Whilst these adjusted, ‘worst case scenario’ figures are less impressive than the figures quoted in the original papers, they must be viewed in perspective, particularly in terms of the varied complaints and age groups treated, the differing sex-distribution
of the patients, and variation in orthotic prescription protocols. Further, few details were provided regarding the diagnostic criteria or processes used to ensure that the conditions being treated were in actual fact the conditions that were present. Despite the emerging picture that orthoses have a role in the treatment of a variety of musculoskeletal conditions in a variety of patient groups, it seems entirely reasonable to speculate that increasing the homogeneity of study groups via tighter control of demographic variables would likely reveal areas where orthoses are most successful and those areas where their use is limited.

3.3.2.2 The Influence of Orthoses on Painful Conditions of the Foot and Lower Limb

Pain is an obvious outcome to assess in relation to foot orthoses, as they are routinely prescribed to treat painful conditions. In these circumstances their use is based on the premise that skeletal mal-alignments are related to both abnormal foot function and increased stress on specific tissues, and so attempt to relieve stress to resolve symptoms by controlling foot function. The importance of this concept is reflected in the recent proposal of the ‘tissue stress’ paradigm of podiatric biomechanics. Essentially a pragmatic clinically based model, the approach involves identification of the tissue under stress, and hence the source of pain, and the selection of treatment strategies ranging from orthoses to ultrasound as clinically appropriate (Lee, 2001b).

Much experimental work supports the concept that abnormal, or sub-optimal, foot function can result in increasing stresses on specific tissues. For example, (Simkin and Leichter, 1990) constructed a simple two-dimensional model, comprising two rigid inclined elements, representing the bony elements of the forefoot and rearfoot, hinged at the apex and connected by a horizontal tension spring, representing the plantar fascia and ligaments, at the bottom of the arch (figure 3.3). By varying the inclination angles of the bony elements and assessing the response to a constant load of 4000N, they showed that the energy storage capacity reduced with both low and high inclinations, but increased markedly at an intermediate value. They suggested this as an explanation for the increased incidence of stress fractures in individuals with both high and low arches. This conclusion recently found clinical support in an investigation of injury history in two groups of runners – one with a high arch and the other with a low arch (Williams et al., 2001). Although both groups sustained injuries,
there was a distinct difference in the type of injury sustained, with the high arch being associated with more ankle, bony and lateral injuries, and the low arch being associated with more medial, knee and soft tissue injuries. This indicates that optimal function is compromised by both the high and low arch, albeit in different ways.

Figure 3.3: An experimental model of the foot, constructed to examine the energy storage capacity of the plantar ligaments & fascia at varying arch heights. Results indicated that the normal, average height, arch is more efficient at storing energy than both high and low arches. (Simkin and Leichter, 1990). $\alpha =$ inclination of rigid elements, the variable manipulated in the experiment, $F =$ point of vertical load application, $L =$ equal-length rigid elements, $A, B, C =$ frictionless hinges, $TS =$ tension spring.

The relationship between foot structure and certain specific pathologies has been investigated, usually in circumstances where the pathology is particularly important. For example, lower limb and foot stress fractures have attracted considerable attention, especially in relation to army recruits, because they frequently occur during basic training and carry a high cost in terms of treatment and lost training time. Cowan et al. (1993) prospectively investigated susceptibility to injury in 246 US Army Infantry trainees followed up over their initial 12 week training programme. Subjects were classified as flat, normal or highly arched using 7 separate measures of arch height, and results revealed a significantly increased risk of injury and pain in the knee and foot in the highest arched group. In a further study (Cowan et al., 1996), this same group examined the relationship between injury and several lower limb morphology measures, including genu varum / valgum, knee angle at full extension and limb length discrepancy, that could influence foot function. Results suggested that valgus knees, with a relative risk of 1.9, and a Q-angle of $\geq 15^\circ$ (relative risk 5.4) were related to injury, re-enforcing the concept that lower limb morphology can influence pathology. The mechanism by which different arch heights may lead to pathology has also been investigated. For example, the influence of arch height on ground reaction forces (Nachbauer and Nigg, 1992) and on angular motion in the lower extremities during running (Nigg et al., 1993), has been investigated. Although no difference was
identified in ground reaction forces between arch categories, and an attempt was made to recruit subjects with a range of arch heights, the method involved separating asymptomatic subjects into arch categories based on inter-quartile ranges, and may have been dealing with essentially ‘normal’ subjects (Nachbauer and Nigg, 1992). The same process was used to categorise subjects to investigate the effect on angular motion in the lower extremity (Nigg et al., 1993), and this too failed to identify any relationship. An alternative approach was taken by Freychat which involved recording the transverse plane relationship between the rearfoot and forefoot to characterise the arch categories (Freychat et al., 1996). Measurements were taken from running footprints, and significant positive correlations with arch deformation and vertical, mediolateral and anteroposterior forces, and significant negative correlations with stance time, were identified. This led them to conclude that the medially rotated forefoot was associated with a rigid, inverted foot, and that a laterally rotated forefoot was associated with a flexible and everted foot. The same technique, was used to investigate risk of trauma in runners, and identified an increased risk of Achilles tendonitis, tibial stress fractures and periostitis, and plantar fasciitis amongst pronated, low-arched, subjects (Busseuil et al., 1998).

In addition to experimental research, and research focusing on the relationship between specific foot structures and particular pathologies, a range of studies have been conducted evaluating the response of explicit pathologies to intervention with foot orthoses. Orthoses have been used to treat a variety of conditions, both intrinsic and extrinsic to the foot. Conditions intrinsic to the foot for which orthoses have been used include metatarsalgia (Poon and Love, 1997), Morton’s neuroma (Kilmartin and Wallace, 1994b), ankle joint destruction in haemophilia (Slattery and Tinley, 2001) and plantar fasciitis (Crawford et al., 2003, Martin et al., 2001, Pfeffer et al., 1999).

Poon & Love (1997) investigated the efficacy of a custom made orthoses with incorporated metatarsal dome in a series of 14 patients complaining of ‘metatarsalgia’. No diagnostic criteria or tests were detailed. In addition to asking patients to rate the change in their condition at a mean of 15.5 weeks, visual analogue pain scale and plantar metatarsal pressures were recorded pre- and post- intervention. Over this short time period, over 90% of patients were wearing their orthoses all or most of the time, a figure probably related to the average 71% reduction in pain scale
scores and the 13% reduction in forefoot pressures. Both these changes were statistically significant. Another investigation sought to establish the efficacy of simple compressed felt orthoses intending to either pronate or supinate the foot on pain from Morton’s neuroma in 23 patients (Kilmartin and Wallace, 1994a). Diagnosis was via examination and standard clinical tests, and the randomisation procedure was described. Both orthoses were ‘cobra’ pads, the only difference being positioning on either the lateral or medial aspects of the foot to produce pronation or supination respectively. Patients were reviewed at 4, 8, 12 and 52 weeks, and the endpoint of the study was set at 1 year, and on each occasion MACTAR patient-specific measures of maximal function, a visual analogue pain scale and objective measurement of response to a series of simple clinical investigations were assessed. No statistically significant differences were identified between the two groups, although 50% of patients did report an improvement in their condition. Although this study may be criticised for the simplistic orthoses used, the study utilised a robust design that included a valid randomisation technique, outcome measures, and it also had a relatively long duration of 12 months. A protocol for a systematic review of interventions for treating Morton’s neuroma has been published (Thomson et al., 2003), and it will be interesting to see how orthoses fare in this review. A higher success rate was identified for orthoses being used to treat the pain and disability associated with haemophilia A (Slattery and Tinley, 2001). This study employed the Foot Function Index, which contains pain, disability and activity scores, and identified a statistically significant reduction in pain related to the use of the orthoses. All 16 study subjects reported a reduction in pain, and anecdotally a number of patients reported a return to work, an increase in stamina and activity levels, and a reduction in the levels of antihaemophilia factor required.

Plantar heel pain is a disorder affecting a substantial number of patients annually, and it has been estimated that at some time 10% of people may at some time experience pain under the heel (Crawford et al., 2003). A systematic review of interventions for treating this condition considered a variety of interventions, ranging from ultrasound to extracorporeal shock wave therapy (Crawford et al., 2003). Although several trials assessing the efficacy of FFO’s have been conducted, the methodological weaknesses of the majority precluded their inclusion, and the orthoses that were included were not true functional devices. For example, a moulded PPT insole with magnetic foil was
compared with a moulded PPT insole alone (Caselli et al., 1997), and Black (1996) has utilised a ‘sofspot’ heel orthosis which would have had little functional effect. A comparison of a true functional orthoses and the same orthoses plus steroid injection for the treatment of plantar fasciitis has been conducted (Kriss, 1990), which identified that steroid injections alone, as opposed to in conjunction with orthoses, produced the greatest benefit. However, the reviewers concerns over allocation concealment and the lack of a control group are probably irrelevant given the decision to exclude subjects who had pain radiating along the plantar fascia as it is likely that this criteria actually excluded patients with true plantar fasciitis. Although this review provides limited evidence supporting the use of orthoses, no superior alternative was identified. Since this review was published, two large-scale studies have been published dealing with the use of orthoses in plantar fasciitis. The first of these was a multi-centre trial that recruited 236 patients in 15 clinics across the USA, with the aim of evaluating the initial 8 weeks of treatment (Pfeffer et al., 1999). Subjects were randomised using an unidentified method into 1 of 5 groups, all of which received advice on stretches for the Achilles and plantar musculature. Four of the groups also received some form of orthosis, which ranged from simple silicone heel cushions to felt inserts. One group received a custom made, casted, polypropylene orthosis. The primary outcome measure was the pain subscale of the FFI, and additional information relating to rate of improvement generally and in relation to specific activities was also measured. Although a significant improvement was noted for all groups, silicone and rubber orthoses produced a significantly better response than custom orthoses, and it was concluded that, when used in conjunction with the stretching programme common to all study groups, prefabricated orthoses are more likely to produce improvement in symptoms. These results were largely echoed in a similar study performed on a group of 255 subjects who were randomised into three groups to receive custom orthoses, prefabricated orthoses or tension night splints. No additional treatments were used. Although all groups improved to a similar extent, custom orthoses were associated with better patient compliance and were recommended. This conclusion seems to be supported by the follow-up rates. An important source of bias in these studies may be the professional affiliations of each group: custom orthoses are undoubtedly favoured by Podiatrists, and the podiatry group found in favour of these devices, whilst the Pfeffer group represented orthopaedists, who commonly utilise alternative orthoses, and found in favour of
prefabricated devices. Unfortunately, there are methodological flaws with concealment of treatment, description of the randomisation process, and lack of control groups that will likely minimise the impact of these two large scale trials on the systematic review conclusions. If this is the case it will re-enforce the assertion that systematic reviews often omit important studies, by rejecting two that essentially concur on the issue of the efficacy of orthoses. The two studies differ only in terms of the type of orthosis that is best for treating plantar fasciitis.

Although the impact of FFO’s on a variety of painful conditions in the proximal limb have been considered in a series of small studies, several systematic reviews have also considered their value, and provide a summary of the use of FFO’s in the treatment of proximal pathology. For example, systematic reviews concerning the prevention and/or treatment of Achilles tendonitis (McLauchlen and Handoll, 2003), ankle ligament injuries (Handoll et al., 2004), stress fractures / reactions of the lower limbs (Gillespie and Grant, 2003) and patello-femoral pain syndrome (D’hondt et al., 2004) all identified studies that had used orthoses as a treatment. This provides evidence of their widespread usage. There are difficulties in drawing definitive conclusions from these reviews, due to differences in individual studies in terms of classification and diagnosis of injuries and the type of orthosis used. In some situations orthoses do seem to be useful, but in others there seems to be little benefit in using custom foot orthoses instead of simple heel cushions. For example, orthoses, in the form of ankle supports such as semi-rigid or air-braces, have been identified as useful in the prevention of ankle ligament injuries in high-risk sports such as basketball (Handoll et al., 2004), whilst a 50% reduction in the incidence of stress fractures of the tibia was associated with the use of orthoses based on pooled data from 3 studies (Gillespie and Grant, 2003). However, when the use of various types of orthoses for treating plantar fasciitis was considered, the use of custom devices was found to be no more beneficial than the use of heel cushions. Although orthoses were not considered as an independent treatment option in the systematic review of treatments for Achilles tendonitis (McLauchlen and Handoll, 2003) it is interesting to note that 3 studies used them in conjunction with other therapies, which indicates that orthoses are accepted as a routine adjunctive treatment. Although simple devices such as heel pads were used in some of these studies (DaCruz et al., 1988, Pforringer et al., 1994), the approach of Sundqvist is interesting because patients with a ‘...biomechanical error...' received
orthoses or heel lifts (Sundqvist et al., 1987). This inference of the routine use of orthoses indicates that their role is widespread and acknowledged. Importantly, few adverse consequences have been associated with the use of orthoses. The information available suggests that orthoses are important in the treatment of a variety of pathologies within the lower limb, although questions do remain over the most effective orthoses design for each condition.

3.3.2.3 The influence of orthoses on foot and lower limb deformity

Deformity within the lower limb and foot can arise from biomechanical dysfunction and also from neurological disorders such as cerebral palsy and spina bifida. Although the utility of foot orthoses in these latter conditions has been described, ankle-foot orthoses that aim to control spastic or flaccid paralysis are the more common type of orthoses used (Morris, 2002). Biomechanical abnormality, in the absence of neurological dysfunction, may however occur at various levels throughout the lower limb, leading to the development of a variety of deformities at, for example, the digits, first metatarsophalangeal joint, knees or hips. These anomalies may be more amenable to treatment or correction via the use of function foot orthoses, which aim to restore normal motion instead of controlling a paralysed joint. However, few studies have actually considered the effect that orthoses may have on the development or progression of these deformities. Hallux valgus has received some attention (Kilmartin and Wallace, 1994b); (Ferrari et al., 2003), whilst Redmond has recently reported on the technical efficacy of gait plates on the treatment of intoeing in children (Redmond, 1998) and the influence of this correction on several clinical indicators (Redmond, 2000).

The systematic review of treatments for hallux valgus considered the role of FFO's alongside other interventions including surgery and simple conservative treatments such as silicone wedges (Ferrari et al., 2004). Although this review considered both conservative and surgical treatments, only two trials utilising non-surgical therapy satisfied inclusion criteria, of which one concerned the use of FFO's in the treatment of juvenile hallux valgus (Kilmartin and Wallace, 1994b). This study screened 600 schoolchildren and identified 150 with clinical evidence of hallux valgus. After application of exclusion criteria, 122 children remained, and these were randomised into a control group and a treatment group who received custom-made rigid
thermoplastic orthoses. At the end of the study period of 3-4 years, during which 6-monthly reviews were performed, there was no difference in the progression of the deformity, leading the authors to conclude that FFO’s are of no value in the treatment of the condition. Although this study has created controversy (Landorf and Keenan, 2000a) it is interesting to note that when measured against the criteria used by Ferrari et al, only one study achieved a higher quality score. This review failed to identify a useful conservative therapy, and from its review of surgical procedures failed to identify any superior choice. Since the last update of this systematic review, a RCT of ‘...surgery versus orthoses versus watchful waiting...’ has been published (Torkki et al., 2001). This trial involved 209 consecutive patients presenting at 4 hospitals in Finland who were randomly assigned to receive either a distal chevron osteotomy (n=71), orthoses (n=69) or a 1-year waiting list (n=69). The presenting deformities were mild-moderate, although it was reported that the pain while walking was causing considerable disability. Outcome measures included radiographic measurements and the American Orthopaedic Foot and Ankle Society clinical rating system. Results suggested the Chevron osteotomy to be the superior intervention, although orthoses were recommended as an option when patients with disabling pain must wait for surgery. This trial has the potential to significantly influence the conclusions of the systematic review of interventions for treating hallux valgus (Ferrari et al., 2003).

The influence of a specific functional orthosis, the gait plate inlay, was investigated by Redmond, who reported on the technical efficacy (Redmond, 1998) and patient satisfaction (Redmond, 2000) with these devices in a study conducted on 20 children with symptomatic in-toeing. The main feature of this orthosis is a proximal-medial to lateral-distal metatarsal edging, designed to create a path-of-least-resistance for the limb in a less in-toeing attitude. Of the 20 children recruited, 18 completed the study, and the prime outcome measure, the footprint angle, was found to be reduced most in those with the most severe in-toeing, with the median angle reduced from -9.5° to -3.5°. The average correction was 6°, and the difference was found to be significant at the p<0.0001 level. In a subsequent report of the influence of this change on a series of patient-oriented and practitioner-oriented outcomes such as tripping, injury and parental concern, a positive effect was identified, with all but one parent indicating substantial satisfaction with the change in gait aesthetic, frequency of tripping and injury. These impressive results suggest that gait plate orthoses have a role to play in
the treatment of in-toeing, despite the absence of a control group in the study. Although Redmond (1998) claimed that the use of a placebo would be very difficult, it would actually have been very simple to use a simple unposted device with a normal distal edge as a placebo, and it would be worth repeating this study using such a placebo because of its simplicity. However, it is blinding the patients that might be difficult in this situation.

3.3.2.4 The influence of orthoses on arthritic / degenerative conditions in the lower limb

Both osteo- and rheumatoid- arthritis are conditions that cause considerable morbidity, and present a high burden to society (Lindgren, 1998). Despite differing in underlying pathology, with rheumatoid having an autoimmune component and osteo a degenerative origin, a considerable literature base exists concerning a relationship between foot function and both conditions. In rheumatoid arthritis, attention has focused on treatment of the valgus hindfoot, a frequent and important consequence of rheumatoid arthritis (Stockley et al., 1990). Considerable attention has also focused on foot function and osteoarthritis of the knee, with various groups examining the influence of simple wedges on pressures within the medial and lateral compartments of the knee, and associated changes in pain levels and functional capability.

Landorf & Keenan (1998) asserted that the best quality trials of foot orthoses currently available exist in relation to rheumatoid arthritis, with various groups examining a series of issues surrounding gait degeneration, pain, and the development and control of deformity in this disease (Budiman-Mak et al., 1991, Chalmers et al., 2000, Conrad et al., 1996, Woodburn et al., 2002a). Budiman-Mak (1991) and Conrad (1996) sought to establish the efficacy of FFO’s in the prevention of deformity in rheumatoid arthritis and in the treatment of painful, debilitating pain arising from the condition. Judging existing tools for measuring pain and disability in joint disease to be too generic to be sensitive to foot-specific disease, they firstly developed a Foot Function Index (FFI). Designed to measure the impact of foot pathology on function in terms of pain, disability and activity limitation, this index was developed and piloted in a multi-centre trial involving 87 patients examined every 3-6 months for 3 years whilst involved in a clinical trial examining the efficacy of FFO’s. Twenty-three items were devised through multi-professional consultation,
and these were organised into three domains. Consistency, construct and criterion validity and sensitivity to status change were all examined by repeated administration, and results suggested the instrument to have good internal consistency and excellent construct validity. The index was used as a primary outcome measure in a trial of foot orthoses which also used the Arthritis Impact Measurement Scale, Melzack’s foot pain scale, and measured forefoot deformities, wearing time, physician-assessment of painful joints, and measurement of foot pain and disability. Results indicated that orthoses may limit the rate of progression of hallux valgus, although serial measurements of pain and disability over 3 years failed to identify a significant reduction in pain in the functional orthosis group over the placebo group. This trial was high quality, utilising blinding protocols and a variety of methods to maintain objectivity. Although the failure to achieve pain reduction could be seen as a negative outcome, the prevention of deformity is a highly desirable goal in rheumatoid arthritis. However, longer-term results in rheumatoid arthritis are extremely important, and would help identify whether the slower rate of progression identified with the use of orthoses prevents or limits problems developing later in the disease.

A comprehensive research programme has been undertaken by Woodburn’s research group (Woodburn et al., 2002a, Woodburn et al., 2002b, Woodburn et al., 2000, Woodburn et al., 1999, Woodburn et al., 2002c). The programme of research involved a RCT of carbon graphite foot orthoses, assessment of rearfoot kinematics and plantar pressures before and after this intervention, as well as measurement of the effect on foot-health related quality of life using the FFI. This rigorous trial involved the customisation of a magnetic 3-dimensional kinematic measurement system to allow tracking of rearfoot kinematics, the design and development of a joint simulator to evaluate the validity and reliability of this system, and MRI evaluation of the influence of skin versus bone movement to justify the use of surface-mounted sensors. A group of 101 patients were recruited into a RCT, with 51 subjects allocated to receive no intervention and 50 in the intervention group. A further group of 50 normal subjects were recruited to provide normalised data with which to compare both the treatment and non-treatment rheumatoid arthritis groups. By the end of the trial, 38 controls and 43 intervention subjects remained. All measures, including kinematic, pressure, and pain variables, were found to differ significantly between groups, with the orthotic group faring better on all counts than the control group. This
comprehensive programme has therefore developed a magnetic tracking system to measure kinematics at the ankle joint complex (Woodburn, Turner, Helliwell et al 1999) which was subsequently used in rheumatoid patients and normals to evaluate the influence of the disease on rearfoot motion (Woodburn et al 2000), examined the influence of debridement of plantar forefoot callosities in rheumatoid patients (Woodburn, Stableford, Helliwell 2000), and conducted a rigorous RCT that suggests that orthoses control the pain and deformity associated with the disease. This group’s research programme continues to grow, and has recently included detailed magnetic resonance imaging studies of the 3-dimensional articular geometry of the hindfoot joints (Woodburn 2002) and the use of MR imaging to evaluate bone changes in early disease (Goldbach-Mansky et al., 2003). It involves a multi-disciplinary team, receives substantial financial backing from the Arthritis Research Campaign and Medical Research Council, and is producing the most rigorous research available concerning FFO’s.

Knee osteoarthritis is a disorder occurring symptomatically in approximately 6% of adults ≥ 30 and 11% of adults ≥ 65, which accounts for more disability in the elderly than any other disease (Kerrigan et al., 2001a). The medial tibiofemoral joint is affected more commonly because it carries approximately 71%-91% of the total joint load. In diseased joints this rises to 100% because of joint space narrowing, and treatment strategies aim to reduce these loads (Maly et al., 2002). This can be achieved with high tibial osteotomies, which aim to realign the joint to reduce medial load, and this seems to be successful. Simple insoles with wedges applied have been investigated as an alternative, cheaper means for achieving this reduction in medial compartment loading. The potential for a laterally wedged insole to influence knee mechanics was investigated by standing subjects on a 5° laterally inclined platform (Yasuda and Sasaki, 1987). This resulted in changes in the spatial positioning of the limb, leading to the conclusion that medial knee loading would be reduced. A subsequent study assessed the efficacy of 5° laterally-wedged insoles taken with NSAID’s compared to NSAID’s alone, with results indicating the orthoses to be beneficial (Sasaki and Yasuda, 1987). Similar trials have yielded comparable results, with 82% (Wolfe and Brueckmann, 1991) and 62% of patients (Keating et al., 1993) with medial compartment OA showing at least some improvement. The mechanism of action of these wedged insoles is controversial, however. Although Wickiewicz &
Simonian (1999) stated that the relationship between rearfoot function and knee pain has not been clearly established or described, three studies have attempted to address this issue. Crenshaw et al (2000) and Kerrigan et al (2002) both suggested that varus torque might result in an increase in medial compartment forces, and that a lateral wedge might influence pain by reducing this torque. Their investigations revealed that lateral wedges reduced the varus torque, by 7% in normal subjects (Crenshaw et al., 2000) and 6% on osteoarthritic subjects (Kerrigan et al., 2001a). However, a recent study also investigated the effect of two types of wedged insoles on knee adduction moment and centre of pressure excursion and could find only an antero-posterior change (Maly et al., 2002). Therefore, although simple wedged insoles designed to exert a mechanical influence on the rearfoot are associated with an improvement in symptoms, the mechanism by which this is achieved is not fully appreciated.

3.3.3 Technical efficacy of FFO’s: The influence on gait variables

Gait analysis has been defined as the systematic measurement, description and assessment of the quantities that characterise human locomotion (Gage et al., 1995). Although the gross walking pattern is remarkably similar between individuals, idiosyncrasies are the rule rather than the exception, and that these idiosyncrasies result from attempts to minimise energy expenditure through close integration of the neuromusculoskeletal functions that construct the gait pattern (Inman et al., 1994). Attempts to describe and understand the quantities that characterise human locomotion were initiated at the University of California at San Francisco / Berkeley, when a staff engineer became an amputee. Dismay at the lack of understanding of normal lower limb function, which was hindering prosthesis development, drove the launch of a collaborative project to study normal walking to permit the development of more functional prostheses.

Gait analysis can be divided into 4 basic areas. Kinematics refers to the study of motion of bony segments and joints; Kinetics refers to the calculation and analysis of forces acting on the body, arising from ground reaction forces, gravity and muscular contraction; Electromyography refers to the analysis of muscle contraction patterns; Energetics refers to the analysis of the physiological cost of movement patterns. Each branch of gait analysis provides information on a specific aspect of the normal walking pattern, has helped define normal gait, and has enhanced knowledge of
various disease processes on gait. Progress in the field of musculoskeletal research has been directly attributed to the development of instrumentation for conducting such analyses (Giannini et al., 1992), which also offers the opportunity to study the mechanism of action of orthoses. Gait analysis is important in the study of orthoses because, if there is a biomechanical basis for patient improvement with the use of these devices then they should alter at least one gait variable (Heiderscheit et al., 2001). This is consistent with the basic premise of podiatric biomechanics, which identifies abnormal foot function by assessing foot position and orientation, and associates these kinematic changes with alterations in kinetic parameters, patterns of muscle use and energy cost.

Diverse technologies, ranging from simple x-ray studies to more complex equipment such as electrogoniometers, accelerometers, interrupted light photography, and computer aided systems, have been used to conduct kinematic analyses. Whilst electrogoniometers can provide instantaneous information on 3-D joint rotations and accelerometers can measure acceleration information, computer-aided systems offer accurate information in 3-dimensions which utilise biomechanical modelling to provide simultaneous information on rotation, translation and acceleration (Kadaba et al., 1990). Despite the high cost of this type of equipment, they have been used in various studies, conducted under both in-vivo and in-vitro conditions to evaluate both normal motion within the foot and lower limb (Kitaoka et al., 1997, Kitaoka et al., 1995, Reischl et al., 1999) and the influence of orthoses (Kitaoka et al., 2002, McCulloch et al., 1993, Nawoczenski et al., 1995, Nester et al., 2001, Novick and Kelley, 1990, Stacoff et al., 2000). Whilst the cadaveric study of Kitaoka, Luo et al (2002) suggested that orthoses produce a minimal change in calcaneo-tibial alignment, arch height and metatarsal-talar motion of <2%, results from several in-vivo studies suggest that orthoses do have the potential to positively influence rearfoot mechanics. For example, a reduction in both calcaneal eversion and calcaneal eversion velocity (Novick and Kelley, 1990), and calcaneal eversion alone (McCulloch et al., 1993) has been noted with the use of orthoses. Whilst the latter study failed to identify a significant reduction in calcaneal eversion velocity, this may be due to differences in orthosis design, and differences in the length of time the orthoses were worn prior to data collection. Similar changes in rearfoot kinematics related to orthosis use have been noted (Nawoczenski et al., 1995, Nester et al., 2001).
2001), although a recent study suggests that the effect may be less during running (Stacoff et al., 2000). Although this study was based on only 5 subjects, questions clearly remain over the variables that are most consistently influenced by specific types of orthosis. However, the literature as a whole does support the conclusion that orthoses appear to be associated with significant, apparently beneficial, changes in rearfoot kinematics (Landorf and Keenan, 2000a).

Although kinematic analyses seems to dominate the gait analysis literature (Landorf and Keenan, 2000b), it has been asserted that this emphasis fails to consider and identify the guilty motor patterns that are responsible for creating the motion patterns (Winter, 1985). Although kinematic analysis commonly involves calculation of the power generated around selected joints, in the context of foot function ground reaction forces are the focus of attention. These may be analysed using force platforms such as Kistler or Bertec, which provide vertical, antero-posterior and medio-lateral force/time graphs, or through the use of pressure platforms/insoles such as the emed/Pedar, RS or F-Scan, which provide pressure maps of the plantar foot using different colours to indicate pressure magnitude.

A comprehensive review of the effect of forces acting on the foot has provided evidence associating high impulse forces with a variety of lower limb musculoskeletal pathologies ranging from osteoarthritis to prosthetic joint loosening and LBP (Whittle, 1999). Strategies suggested for reducing these forces included influencing joint alignment and incorporating better viscoelastic materials in footwear. The lack of information regarding mal-alignment was noted in this review, although it was acknowledged that if this influences the angle at which the foot contacts the ground it is likely to be very important.

Research in the area of pressure measurement is dominated by investigations of the diabetic foot (Donaghue and Veves, 1997), due to the potentially catastrophic effect of abnormal pressure distribution in the ischaemic and neuroischaemic foot (Edmonds, 2003). However, various studies have assessed the effect of foot orthoses on a various pressure parameters. These include medio-lateral movement of the centre-of-pressure (McPoil et al., 1989, Scherer and Sobiesk, 1994), assessment of the duration of specific gait events (Bennett et al., 1996, Cornwall and McPoil, 1997, Reed and Bennett, 2001) and measurement of the velocity of the centre-of-pressure...
through stance (Cornwall and McPoil, 2000). Despite the differing methodologies used, and the early stage of development of this technology, orthoses seem capable of significantly influencing pressure distribution through the foot (Cornwall and McPoil, 1997, Cornwall and McPoil, 2000, Freychat et al., 1996, Woodburn, 2000). However, it is likely that as understanding of the relevance of particular variables measured with this equipment develops, so too will understanding of the effects of foot orthoses.

The influence of foot orthoses on muscle activity and energy expenditure has also been assessed, but to a lesser extent than kinematics and kinetics. In addition, these variables seem most relevant in the context of neuromuscular disease such as cerebral palsy where there is gross disability that significantly increases energy cost as a result of spasticity or paralysis (Morris, 2002). The assessment of these parameters is based on the premise that muscle activation patterns may be altered by foot function, influencing both oxygen consumption and risk of pathology. Both are related to the concept of a ‘preferred motion pathway’, which abnormal foot function may disrupt, and which orthoses may restore (Dananberg, 1995).

Interpretation of muscle activation patterns is difficult due to inherent variability which is even observed in groups of similar subjects. This occurs due to the flexibility and redundancy afforded by the presence of multiple muscles within the limb capable of combining in various different ways to produce the same kinematic pattern (Wootten et al., 1990). Although only one study directly assessing the effects of orthoses on EMG has been conducted (Tomaro and Burdett, 1993), several others consider the influence of foot position, which is the target of orthotic therapy, on muscular activity at various sites in the lower limb. The influence of foot position on the outcome of a stretching programme for the gastrocnemius and soleus muscles was conducted to examine the assumption that these muscles are more effectively stretched when the foot is supinated rather than pronated (Worrell et al., 1994). In this experiment 19 subjects were recruited, and each pronated one foot and supinated the other whilst performing 10 sessions of 4x20 second stretches. A significant increase in ankle dorsiflexion was identified, but occurred in both limbs. A study of the influence of transverse plane foot position on quadriceps activity used EMG to record activity during maximal isometric contraction, and found that the degree of knee extension and foot position combined to influence quads activity (Signorile et al.,
The relationship between rearfoot motion and muscle activity was examined by correlating tibialis anterior EMG with 2-dimensional rearfoot function (Cornwall and McPoil, 1994). Data was captured from 23 feet which were assigned to one of two groups according to the time to minimal tibialis anterior activity, according to duration of pronation, and EMG activity between the two groups was compared. Although it was difficult to determine a specific relationship, they concluded that tibialis anterior does influence rearfoot motion but suggested that further investigations of the contribution of specific muscles to rearfoot motion are required.

The only study examining the effect of orthoses on muscle function involved assessment of the EMG activity of gastrocnemius, peroneus longus and tibialis anterior in a group of 10 volunteers (Tomaro and Burdett, 1993). A significant change was noted only in tibialis anterior. From this range of studies it is clear that muscle function is complex and requires further study, although orthoses do seem theoretically capable of exerting a considerable influence.

Measurement of metabolic energy expenditure provides global information on overall gait performance and a means of quantifying the overall physiologic penalty imposed by pathological gait (Waters, 1992). It is a primary consideration in decisions regarding therapeutic treatment (Rose et al., 1994). The consequence on energy expenditure of a variety of disabilities has been studied, including paraplegia and hemiplegia, joint fusions and fractures. However, whilst considering the influence of the relatively minor joint malalignments commonly treated by functional orthoses may be based on the same that any deviation from the normal pattern will carry an energy cost, study results have been equivocal. Initially, orthoses may increase oxygen consumption which later may return to, or below, normal, although this effect may be seen in a minority of subjects and depend on the condition being treated (Landorf and Keenan, 2000b). Further, establishing the potential for orthoses to decrease the energy cost of walking is complicated by the reality that any increase in limb mass will cause an increase in energy use (Myers and Steudal, 1985). It seems likely that a threshold energy cost must be incurred before orthoses can help, and that this threshold is higher than the cost typically incurred by the more minor malalignments treated by FFO's in populations who are reasonably fit and active. In common with the other forms of gait analysis, assessment of energy consumption appears to offer important information about normal and pathological gait, the
consequences of gait dysfunction, and the mechanism of action of orthoses. It is likely
that the evolution of more complex methods of gait analysis will yield greater
information about individual disorders and help in the selection of treatments for a
variety of conditions.
3.4 Foot Function and Low Back Pain

3.4.1 Introduction

The spinal column has been described as a remarkable structure that combines strength and flexibility by alternately interposing rigid bony vertebrae and deformable cartilaginous discs (Giles, 1997). The 33±1 individual vertebrae support the trunk along its long axis, serve as an attachment for muscles and also protect the spinal cord (Draves, 1986). The intervertebral discs comprise a central nucleus pulposus composed of water, collagen and a chondromucoprotein, surrounded by a concentric annulus fibrosus which controls disc deformation and optimises flexibility. Adjacent vertebrae are connected by two facet joints which combine with the disc and supporting ligaments to form the mechanical unit capable of transmitting and dissipating enormous mechanical forces whilst permitting flexibility (Belkin, 1992).

Figure 3.4 shows a section of the spine, illustrating these units.

Pain in the lower back, defined in terms of pain in the anatomical region at and adjacent to the lumbosacral spinal segments (Giles, 1997), is an extremely common, nonfatal, public health problem with significant direct and indirect costs (BenDebba et al., 2002), that amount to an estimated $38-$50 billion annually in the USA (Atlas and Deyo, 2001). A similar situation exists in the UK (Jenner and Barry, 1995). Despite the problems associated with determining the true frequency of the problem, which include variations in definition and measurement, the yearly incidence is probably between 1.4-4.9%, the point prevalence between 10-50% and the lifetime prevalence 14-70% (Shekelle, 1997). Even using conservative estimates, this means that millions of people are affected. However, LBP remains poorly understood,
inadequately diagnosed and ineffectively treated (BenDebba et al., 2000, Long et al., 1996).

Pain may arise in almost any spinal tissue, including muscle, ligament, intervertebral disc, zygapophyseal and sacro-iliac joints, originating from a variety of conditions. The differential diagnosis can be organised into mechanical, non-mechanical and visceral causes (Jarvik and Deyo, 2002). However, it has been suggested that the problem be viewed in the context of the clearly defined, and often more serious, spinal pathologies, and the less well-defined, but much more common condition of spinal pain of mechanical origin (Giles, 1997). Frank pathology can be reliably detected by history taking and examination, but it is only rarely possible to establish the pathological basis of pain in the remaining 80-90% of cases believed to be of mechanical origin (Atlas and Deyo, 2001, Giles, 1997). This diagnostic uncertainty has been attributed to various factors, including the extreme anatomical and functional complexity of the lumbo-sacral spine (Baldwin, 1977) and poor understanding of the relationship between radiological abnormalities and pain (Belkin, 1992). A range of common causes of LBP are shown in table 3.10.

**Table 3.10. Common diagnostic labels used in mechanical LBP**

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<tr>
<td>Lumbar strain or sprain&lt;br&gt;- degenerative disease / discs / facet joints&lt;br&gt;- Diffuse idiopathic skeletal hyperostosis</td>
<td>Posterior facet syndrome</td>
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<tr>
<td>Spondylolysis</td>
<td>Sacroiliac syndrome</td>
</tr>
<tr>
<td>Spondylolisthesis</td>
<td>Myofascial trigger points</td>
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<tr>
<td>Herniated disc</td>
<td>Radicular syndromes</td>
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<tr>
<td>Spinal stenosis</td>
<td>Low back strain</td>
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<tr>
<td>Osteoporosis with compression fracture</td>
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<tr>
<td>Fractures</td>
<td></td>
</tr>
<tr>
<td>Congenital disease&lt;br&gt;- Severe kyphosis / scoliosis</td>
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<td>Paget's disease</td>
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Mechanical derangement seems intuitively to be an important cause of LBP when its role in load transmission is considered. This has been blamed on Man’s bipedal posture (Calliet, 1968), which effectively doubles the load in the area in comparison with quadrupeds. However, an evaluation of human and other anthropoidal spines suggests that human spinal anatomy provides an overabundance of power to achieve and maintain erect posture (Farfan, 1978). The conclusion that the spine is probably a mechanically sound structure that is badly abused by it owner, in terms of an apparent disregard for good posture and a failure to avoid damage, seems reasonable (Giles,
This concept is supported by considering the range of factors that have been identified as related to back pain, which includes several mechanical factors strongly associated with back pain (table 3.11). These included heavy/repetitive lifting, heavy physical work and prolonged sitting or standing, which were strongly associated. Other factors that could possibly be related to mechanical function, including lumbar mobility and trunk strength were found to be only weakly associated. Whilst more than 100 suspected causative factors have been identified (Cole and Grimshaw, 2003), it is likely that the condition is multi-factorial, which adds to the difficulty in determining its exact cause (Speed, 2003). This problem is further confounded and complicated by emerging information concerning the role of mood disorders, perceptual styles, cognitive, social and even financial factors in determining who develops low back pain and who becomes disabled by it (Deyo, 2002).

### Table 3.11: Risk / Prognostic factors for LBP (Shekelle 1997)

<table>
<thead>
<tr>
<th>Strongly Associated</th>
<th>Moderately Associated</th>
<th>Weakly Associated</th>
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<tbody>
<tr>
<td>Prior history of back injury</td>
<td>Vibration</td>
<td>Male Gender</td>
</tr>
<tr>
<td>Increasing age</td>
<td>Smoking</td>
<td>Anthropometry</td>
</tr>
<tr>
<td>Job satisfaction / emotional distress</td>
<td>Obesity</td>
<td>Lumbar mobility</td>
</tr>
<tr>
<td>Heavy / repetitive lifting</td>
<td>Above average height</td>
<td>Trunk strength</td>
</tr>
<tr>
<td>Heavy physical work</td>
<td>Physical fitness</td>
<td>Radiographic structural abnormality</td>
</tr>
<tr>
<td>Prolonged sitting or standing</td>
<td></td>
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</table>

Whilst poor muscle tone and posture and traumatic injury are considered important factors in the aetiology of mechanical LBP (Giles, 1997), the role of repetitive micro-trauma arising from gait disturbances has begun to receive attention (Dananberg, 1995, Dananberg, 1997, Gracovetsky, 1997, Kendall et al., 1993, Minkowsky and Minkowsky, 1996). Although the mechanisms by which gait may influence spinal mechanics to induce pain are largely theoretical (Bird and Payne, 1999), they are based on established anatomical relationships and kinematic studies.

For example, five major structures have been described, including the piriformis, quadratus lumborum and psoas muscles, that travel between the spine and the lower limb forming a direct connection (Minkowsky and Minkowsky, 1996) (table 3.12 / figure 3.5). In addition there are skeletal connections, and both combine to directly link the spine with the lower limb and foot.
Table 3.12: Musculoligamentous connections between the spine and lower limb (Minkowsky & Minkowsky 1996).

<table>
<thead>
<tr>
<th>Connectors</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>Abdominals / Thigh adductors</td>
<td>Attach to pubis; may be capable of significantly influencing pelvic mechanics.</td>
</tr>
<tr>
<td>Quadratus lumborum</td>
<td>Connects 12\textsuperscript{th} rib to iliac crest.</td>
</tr>
<tr>
<td>Psoas</td>
<td>Links thoracolumbar junction to the lesser trochanter of the femur.</td>
</tr>
<tr>
<td>Piriformis</td>
<td>Connects sacrum to the greater trochanter of the femur.</td>
</tr>
<tr>
<td>Diaphragm</td>
<td>Extensive musculoskeletal attachments to upper lumbar vertebrae, lower six ribs, xiphoid process and lower extremity through psoas.</td>
</tr>
</tbody>
</table>

Figure 3.5: Muscular connections between the lower limb and pelvis / spine. This figure illustrates the arrangement of muscles connecting the spine with the lower limb. (Minkowsky and Minkowsky, 1996)

3.4.2 Proposed mechanisms of association

Five separate mechanisms by which foot function may be related to LBP have been proposed (Bird and Payne, 1999). These include shoe heel height, impaired shock absorption, excessive STJ pronation, limb length discrepancy and sagittal plane dysfunction. Although it was asserted that these mechanisms are theoretical, this statement ignores the recent emergence of a body of compelling experimental evidence indicating that each does significantly influence gait.

3.4.2.1 Shoe heel height

High heels have been associated with musculoskeletal effects ranging from changes in the location of the centre-of-mass, tightening of the hamstring muscles and changes in pressure distribution in the knee, to alterations in the muscle activity, balance and posture in the lower back. Until recently evidence supporting these contentions was
lacking. However, evidence is now emerging to suggest that wearing high heels can influence the normal function of the lower limb. For example, experiments have indicated that high heels increase forces across the patellofemoral joint and also raise pressure within the medial compartment of the tibio-femoral joint (Kerrigan et al., 1998). This seems to be an important finding given the greater incidence of medial compartment osteoarthritis, and it was further identified that the effect occurs independently of the width of the heel (Kerrigan et al., 2001a). When the effect proximal to the knee is considered, results are more variable. A small decrease in lumbar lordosis was identified in a group of men wearing high heels, but the effect was not seen in women (de Lateur et al., 1991). However, the variable response may be explained by previous high heel use, which although not recorded, could reasonably expected in women and may have influenced the experiment. However, the influence of heel height is also questioned by a study that examined the influence of a 5.1cm raise and identified an increase in the prominence of the gluteal fold. It was suggested that the perception of an increased lordosis might be attributed to this finding (Franklin et al., 1995). Whilst high heels seem capable of disrupting normal lower limb, pelvic and spinal posture, it seems that further research is required. Whilst heel height represents an extrinsic factor capable of causing back pain, there are several factors essentially relating to the intrinsic mechanical properties of the foot, which may be more important in back pain, and more difficult to treat than the simple modification of footwear.

3.4.2.2 Impaired shock absorption

As the foot contacts the ground at the end of swing, its movement is terminated rapidly. This results in a *heelstrike transient*, which is best illustrated graphically on the force-time curve for a single stance phase (graph). This results in the generation of a ‘shock wave’ that passes up the limb, and this will always be present to some degree. In an authoritative review of the generation, consequences and attenuation of these forces, Whittle discussed how the magnitude and time-course of these forces depend on various factors including the properties of both the foot and the ground interface (Whittle, 1999). Noting that raised heelstrike transients have been associated with various conditions including degenerative joint disease, tendinitis and prosthetic joint loosening, he stressed the importance of recognising this link because the
magnitude of these forces, and therefore that the incidence of these conditions, can be reduced by the use of visco-elastic materials, either in shoe construction or as an insole.

Heelstrike transients are felt throughout the skeletal chain. Accelerometers, both bone-mounted and skin-mounted, have been used at various sites up the skeleton from the tibia to the spine and forehead to examine the magnitude of these forces and their attenuation as they travel through the skeleton. For example, using bone-mounted accelerometers it was possible to calculate that the heelstrike transient can create an upward acceleration of up to 80m/s² in the tibia, but much less in the forehead, suggesting that passage through successive joints attenuates the acceleration and removes high frequency components (Light and McLellan, 1977). Accelerometers have been used in several studies in similar ways. In one study normal subjects were compared with groups with knee pain, knee menisectomy, and LBP. The only difference was that the LBP group had a reduced acceleration at the femur, and this was postulated to have occurred because of gait changes aimed at protecting the spine (Voloshin and Wosk, 1982).

Whittle (1999) suggested that joint alignment and the viscoelastic properties of the heel pad and joints represented the two major defence mechanisms against heelstrike transients. Much research has been conducted on the viscoelastic properties of the subcalcaneal fat pad, and it is though that it can absorb between 47-66% of the energy at impact (Aerts et al., 1995). The role of joint alignment and motion during contact seems intuitively to have a role to play in shock attenuation, even although research suggests that peak motions of the two joints most implicated – the ankle and knee – are not synchronised with the heelstrike transient. Whilst the finding that muscular fatigue increases transients has been suggested to indicate a significant role for muscles in shock attenuation (Mizrahi et al., 1997), this is still consistent with the theory that the joint alignment is important, because it is muscular activity that controls these joint motions.

Foot structure has been implicated as an important factor influencing the magnitude of heelstrike transients, with the highly arched, cavus, foot associated with greater rigidity, and the flat, planus, foot being more mobile (Root et al., 1977, Root et al., 1971). However, experimental evidence supporting this belief is limited and
inconsistent. For example, although a widely cited case study describes the successful treatment of LBP in a subject with cavus feet using shock absorbing orthoses (Builder and Marr, 1980), a larger study cited by Bird & Payne (1999), involving 93 adults with club feet, of whom 83% had residual deformity after childhood surgery, failed to identify a significant difference in LBP between the study group and a normal control group. A more recent experiment used accelerometers strapped to the L3 spinous process found a significantly lower acceleration amplitude and rate in the high arch group (Ogon et al., 1999). They hypothesised that the higher arch led to more internal rotation of the tibia at heel contact and earlier shock absorption that occurred more distally. Evidence from kinematic studies of arch behaviour might be expected to reveal less motion in the high arch foot, and more motion in the lower arch foot, but this is not the case. For example, an investigation of the kinematics of the medial longitudinal arch identified that only 17% of the variance in maximum rearfoot pronation could be explained by arch height (McPoil and Cornwall, 1996a), whilst a comparison of rearfoot eversion in low, normal and high arched subjects suggested that both high and low arches are associated with greater motion than normal (Kernozek and Ricard, 1990). It has been suggested that these different results may be attributed to differences in the methods used to categorise the arch (Williams et al., 2001), and it seems that identification of a valid and reliable method of categorising ‘arch’ or ‘foot’ type is a pre-requisite to resolving the controversy.

In an attempt to identify the fundamental mechanical differences between high and low arch structures, subjects with ‘extreme’ arch heights were compared (Williams et al., 2001). The group of 40 runners recruited included 20 low and 20 high arched runners who had previously suffered a lower limb injury, although none were currently injured. The ‘arch ratio’ was used to examine subjects for group assignment, and was defined as the height of the dorsum of the foot from the floor at 50% of the truncated foot length divided by the truncated foot length, where truncated foot length was the length from the posterior calcaneus to the medial joint space of the 1st metatarsophalangeal joint. Previous studies had simply recruited a series of runners and categorised arch height simply by taking the middle 60% as normal, the lower 20% as low arched and the upper 20% as high arched. This procedure is unlikely to have identified true low and high arched feet. Results revealed a significant difference in coupling characteristics, calcaneal eversion velocity and loading rate (table 3.13).
This excellent experiment suggests that there are indeed differences in the loading characteristics of high arched feet which seem capable of influencing the heelstrike transient and may be implicated in the development of LBP. This study is particularly useful because it defines the high and low arch mathematically, and the use of similar methods may provide further insight into differences in the mechanical behaviour of different arch types.

Table 3.13: Mechanical differences between high and low arched runners (Williams et al., 2001)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>High arch</th>
<th>Low arch</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arch ratio</td>
<td>0.367 (0.013)</td>
<td>0.271 (0.023)</td>
<td>0.000*</td>
</tr>
<tr>
<td>Eversion excursion (°)</td>
<td>11.90 (3.73)</td>
<td>13.96 (3.63)</td>
<td>0.047*</td>
</tr>
<tr>
<td>EV to tibial internal rotation ratio</td>
<td>1.29 (0.40)</td>
<td>1.71 (0.92)</td>
<td>0.037*</td>
</tr>
<tr>
<td>EV to knee internal rotation ratio</td>
<td>1.00 (0.37)</td>
<td>1.05 (0.48)</td>
<td>0.714</td>
</tr>
<tr>
<td>Eversion velocity (°/s)</td>
<td>165.06 (58.23)</td>
<td>219.30 (65.34)</td>
<td>0.006*</td>
</tr>
<tr>
<td>Peak knee flexion</td>
<td>46.48 (4.08)</td>
<td>49.19 (5.45)</td>
<td>0.040*</td>
</tr>
<tr>
<td>Loading rate</td>
<td>62.48 (13.62)</td>
<td>52.05 (10.79)</td>
<td>0.006*</td>
</tr>
</tbody>
</table>

3.4.2.3 Excessive STJt pronation

The lower limb operates as an integrated unit, with motion in one segment influencing motion in the adjacent segment. Integration between the rearfoot, tibia and knee has been investigated, and is reasonably well understood, with subtalar pronation and supination being coupled with internal and external rotation of the tibia to influence knee function (Stergiou et al., 1999, Wickiewicz and Simonian, 1999, Williams et al., 2001). Although it is more complex, attempts are being made to fully understand the integrated behaviour of the lumbo-pelvic-hip unit (Schache et al., 1999). Whilst rearfoot function is known to be coupled with tibial rotation (Rose, 1962), presenting a clear association between foot and knee function, the extent to which these rotations are transmitted proximally to the hip is uncertain (Nester, 2000). This is probably because of the absorption of some of this rotation by ‘lag’ within the musculoligamentous structures of the knee. Despite this, the acknowledged functional integration of the rearfoot-tibia-knee and lumbo-pelvic-hip units represents a convincing mechanism associating rearfoot and spinal motion. Two important pieces of this jigsaw – namely the influence of rearfoot motion proximal to the knee, and the nature of lumbo-pelvic-hip integration – require further research to substantiate the link.

Despite the uncertainty that exists concerning the exact nature of the transmission of STJt rotations proximally, the theoretical relationship is described with a mechanistic
precision, which belies its complexity. Various authors (Bird and Payne, 1999, Botte, 1981, Michaud, 1997a, Minkowsky and Minkowsky, 1996), state that subtalar pronation is coupled with internal tibial rotation, which is transmitted through the knee to the femur, onto the pelvis which tilts anterolaterally to place stress on the gluteus medius and minimus, iliopectos, piriformis and ultimately produce a functional lumbar lordosis that disrupts muscular function to induce fatigue and create pain. One of the difficulties in investigating the validity of this description is in employing gait analysis equipment in this complex anatomical area. However, as technology develops light will undoubtedly be shed on the relationship between foot function and spinal function.

Despite the paucity of literature concerning the transmission of subtalar rotations proximally to pelvic and spinal levels, foot orthoses aimed at controlling subtalar motion are regularly used in patients complaining of pain in these regions. This is evidenced by several reports describing the use of orthoses in the treatment of LBP. Botte (1981) discussed the relationship between various foot-types, including pes cavus and limb length discrepancy, and LBP, and although he described a range of features associated with excessive pronation, the emphasis of the paper was on pelvic imbalance associated with unilateral, as opposed to bilateral, pronation. It is perhaps easy to dismiss this paper because of its observational nature, but several of the measurements used were radiographic, and therefore less prone to the measurement errors that have dogged clinical goniometry. Results were purely descriptive, but endorse the concept that foot position and motion influences pelvic, sacral and spinal mechanics. However, although trends were described, it was added that the pattern of changes observed were variable and individual. (Rothbart and Estabrook, 1988) similarly reported on the association between excessive pronation and pelvic lists and Chondromalacia, but again the emphasis was on unilateral excessive pronation. A study of the prevalence of certain biomechanical anomalies within the foot did show more promise, in terms of an attempt to measure the biomechanical relationships in the feet of subjects complaining of LBP (Campbell, 1995). However, even if the error associated with the traditional biomechanical measurements used are accepted, this was a preliminary report of 20 patients, who despite being described as having a ‘...significant foot abnormality...' were not compared to a control group. Further
results from this project have not been published, despite it being described as preliminary work.

Whilst excessive pronation is perceived to link mechanically with altered pelvic and sacral function, there appears to be little experimental evidence that has investigated the relationship. Several descriptive studies are available, but these are characterised by their descriptive nature, their use of error-prone techniques, or both. However, a common theme is the perception that asymmetry in pronation between left and right limbs is associated with pelvic tilt, altered sacral mechanics and lumbar malalignment.

3.4.2.4 Limb Length Discrepancy

Limb length discrepancy (LLD), termed anisomelia, describes a condition where the two limbs are of uneven length, which is described as leg length discrepancy when the lower limbs are affected (Gurney, 2002). The condition can be divided into the two aetiological groups of structural limb length discrepancy, associated with a shortening of bony structures, and functional, defined as those that arise from altered mechanics of the lower extremities. Cases can be further divided into those present since childhood and those that developed later in life. Whilst Bird & Payne (1999) devote little attention to the association between LLD and LBP, Gurney (2002) provides a comprehensive account, with detailed and authoritative discussions of measurement techniques, the complications that may arise, and the association with LBP. This review encompasses a substantial literature base that deserves more attention than that provided by Bird & Payne (1999).

There is general agreement on the range of factors that can cause limb length discrepancy. These causes may be divided into classes such as congenital, traumatic, infectious, neurologic, metabolic and inflammatory (Dahl, 1996), or comprise a list of discrete conditions, from polio and fracture to unilateral cox vara and sacral deformity (Blustein and D'Amico, 1985). Regardless of aetiology, the link with LBP is based on the complications that may result. Changes in standing posture and balance, whereby the knee and hip of the long limb flex to shorten the long limb and the short limb extends at these joints to lengthen the short limb, may increase postural sway and disrupt balance. Dynamic gait changes include compensatory mechanisms.
that can shorten the longer leg (circumduction, increased hip or knee flexion, increased ankle dorsiflexion) or lengthen the shorter leg (increased pelvic obliquity, increased knee extension, vaulting, toe-walking). These disrupt the normal spatio-temporal parameters of gait, with decreased stance duration and step length on the short side, decreased walking velocity and increased walking cadence (Blake and Ferguson, 1993, Dahl, 1996, D'Amico et al., 1985b).

Ground reaction forces (GRF), hip joint forces, mechanical work, kinetic energy and oxygen consumption can also be altered by the presence of LLD. These effects are related to kinematic changes that occur throughout the lower limb musculoskeletal chain. A predictable pattern of compensation has been described, whereby the longer limb pronates, causing the lower limb to internally rotate and drop inferiorly, increasing tensile strain on the iliopsoas and piriformis and narrowing the greater sciatic notch to induce sciatica (Michaud, 1997a, Minkowsky and Minkowsky, 1996). The limb rotations also lower the ipsilateral inominate leading to a rotation of the L5 vertebral body to the short side, inducing the lumbar spine to straighten by lateral flexion towards the long leg, which compresses the lateral aspect of the discs on that side, which may result in joint degeneration. Although this sequence of effects finds some support in the literature (Friberg, 1982, Papaioannou et al., 1982), correlations between LLD and pelvic tilt of 0.843, sacral tilt of 0.639 and scoliosis of 0.338 (Hoikka et al., 1989) indicates that some inequalities may be absorbed as they progress up the skeletal chain, reducing the effects of smaller discrepancies. However, there remains a propensity for LLD to induce asymmetries that manifest in the lumbar spine, and ultimately these may lead to joint mal-alignment which may lead to arthrosis. The concept of asymmetric limb rotations being transmitted to the proximal skeleton to disrupt normal loading patterns is central to the relationship between LLD and pathology, and this is illustrated in figure 3.6.

Figure 3.6: Asymmetrical limb function due to LLD and its possible effects on the transmission of load (Michaud, 1997a). LLD, whether structural or functional, results in asymmetrical limb rotations, differing amounts of inferior and anterior pelvic tilt, and torsion within the spine due to left and right limbs rotating different amounts. The diagram shows the influence of asymmetrical pronation at low back level (inset diagram).
Ground reaction forces (GRF), hip joint forces, mechanical work, kinetic energy and oxygen consumption can also be altered by LLD. These effects are related to kinematic changes that occur throughout the lower limb musculoskeletal chain. The longer limb is believed to pronate more than the shorter (Blake and Ferguson, 1993), causing it to internally rotate and drop inferiorly, increasing tensile strain on iliopsoas and piriformis and narrowing the greater sciatic notch to induce sciatica. The ipsilateral inominate also drops inferiorly, leading to a rotation of the L5 vertebral body to the short side, inducing the lumbar spine to straighten itself by lateral flexion towards the long leg, compressing the lateral aspects of the discs on that side which may result in joint degeneration (Michaud, 1997a, Minkowsky and Minkowsky, 1996). Whilst the exact sequence of events requires elucidation, experimental evidence supports the concept that the result is abnormal load transmission within the vertebrae. For example, in a comparison of lumbosacral joint angles in a group of LLD subjects and a group of controls, it was found that the angle between these joints and the horizontal were smaller on the shorter side (Giles, 1981). These findings led to the conclusion that asymmetry could predispose to osteoarthritis in the lumbosacral region. These findings are supported by several additional studies (Friberg, 1982, Giles and Taylor, 1982, Young et al., 2000).

The relationship between asymmetrical foot pronation and spinal alignment is probably not as straightforward as suggested. A study of the relationship between LLD and pelvic tilt, sacral tilt and lumbar scoliosis revealed correlations of 0.843, 0.639 and 0.338 respectively (Hoikka et al., 1989), suggesting that some rotations are absorbed as they travel proximally, reducing the effects of the LLD. Such insight into the transmission of motion through the integrated lumbo-pelvic unit helps explain apparently contradictory results between studies that tend to use varying amounts of artificial or true LLD. It appears possible that the musculoskeletal system is capable of absorbing small amounts of LLD, and coupled with the inherent variation present in a biological system and functional differences, goes some way to explaining the range of results obtained. The suggestion that a significant LLD should be defined in terms of functional outcomes (Abraham, 1992) seems appropriate, and is supported by the consistently positive response of patients with symptoms apparently related to even small amounts of LLD to treatment (Gurney, 2002). The ultimate conclusion
must be that limb length discrepancy, whether of anatomical or functional origin, carries a potential for disrupting lower limb mechanics and altering alignment up to the spine, where they may result in pain.

3.4.2.5 Sagittal Plane Dysfunction
The concept of STI dysfunction, which manifests as frontal plane calcaneal motion, has for a long time dominated discussions of foot-type and pathology. An alternative model has been proposed in sagittal plane theory, which suggests sagittal plane motions to be primary, and more important than frontal plane motions. The concept was introduced with ‘Rocker theory’ (Perry, 1992a), which describes how the actions of three progressively more distally positioned pivots within the foot are at the centre of normal function (figure 2.16). This was titled ‘Rocker theory’, where the first pivot is the posterior-plantar aspect of the calcaneus which contacts the ground to initiate ankle plantarflexion and accelerate the foot towards the ground. The second pivot is the ankle joint, and sagittal motion at this joint allows the tibia, with the femur, hip, and upper body above it, to move from a position behind the weightbearing foot to a position in front of it. This can be observed as a change in the angle between the limb and foot from an obtuse to an acute angle. Finally, as the body moves to a position in front of the foot, stability is challenged, and further progression can only be achieved by lifting the calcaneus from the ground. For this ankle plantarflexion to occur, the metatarsophalangeal joints must dorsiflex, otherwise the only mechanism for advancing would be to flex the hip and knee to physically lift the foot off the ground. These motions are vital for the smooth deposition of the foot onto the ground, the passage of the body over the weightbearing foot, and forward motion.

The model was developed by Bojsen-Moller, who noted that the normal anatomical arrangement of the distal metatarsal heads described a parabolic curve, with the 2nd consistently the longest bones (Bojsen-Moller, 1979b). This creates two possible forefoot propulsive axes – one formed by connecting MTPJ’s 1 and 2, and one formed by connecting MTPJ’s 2 through 5 (figure 2.17). A programme of study that continues, involving examination of the normal anatomy of the plantar fascia, the structure of the fat pad plantar to the metatarsal heads, and evaluation of the calcaneocuboid joint in primates and man convinced him that the use of the axis connecting MTPJ’s 1 and 2 was associated with a series of important effects that stabilised the
foot for the transmission of propulsive loads (Bojsen-Moller, 1979a, Bojsen-Moller, 1979b, Bojsen-Moller, 2000, Bojsen-Moller and Lamoreux, 1979, Vogler and Bojsen-Moller, 2000). These mechanisms included the Hicks Windlass, the positioning the calcaneo-cuboid joint in a stable position, and organisation of the structure of the fat pad plantar to the metatarsals enabling the transmission of stresses to the skeleton below. It was also suggested that even a minor restriction of these mechanisms could de-stabilise the foot and lead to pathology, and this has led to the suggestion that forefoot flexibility is a critical design feature in footwear.

The relationship between faulty sagittal plane progression was explored fully, albeit theoretically, by Dananberg (Dananberg, 1986, Dananberg, 1993a, Dananberg, 1993b). He focused on the 1st MTPJ, and coined the term ‘functional hallux limitus’ to describe a situation where the 1st MTPJ displayed full and free dorsiflexion in non-weightbearing examination, but failed to utilise this motion dynamically. In functional hallux limitus, sagittal progression is abruptly halted, and Dananberg felt that this sudden blockage could have damaging consequences. The focus of work by Dananberg has been the association between sagittal blockade and LBP. An argument was built up based on the anatomical connections between the lower limb and pelvis and the implications of these anatomical arrangements for mechanical efficiency in gait. Central to this theory is the work of Gracovetsky (Gracovetsky, 1987, Gracovetsky, 1997) which expounded the concept that reciprocal pelvic rotations were closely related to energy return from the spinal musculature, which was crucial for driving the lower limbs. Gracovetsky proposed a simple, but effective analogy illustrating the dependence of normal gait on the spinal musculature, involving analysis of posterior spinal musculature EMG to show that an amputee can move on minimal femoral stumps by utilising the spinal musculature to drive transverse plane rotations (Gracovetsky, 1997). It was proposed that this is exactly what happens in normal gait. Dananberg (Dananberg, 1993b, Dananberg, 1995, Dananberg, 1997) suggested that sagittal plane blockage at the 1st MTPJ interrupted normal hip extension and reduced the energy storage, and thus return, in the spinal musculature. He related this to all manner of postural symptoms, including LBP and pain in the more proximal spine, and even went as far as to link headaches and temporal-mandibular joint pain with 1st MTPJ dysfunction. Dananberg has patented an orthosis which it is claimed can restore normal 1st MTPJ dorsiflexion, and has published an
article concerning the 23 patients whom he personally treated using his theories (Dananberg and Guiliano, 1999). However, 32 patients were originally recruited, but 9 failed to complete the final questionnaire, and there was no control group used. Whilst this study clearly carries a patient selection bias, there is little doubt that sagittal plane theory is coherent, and compelling, because of its strong anatomical basis. However, there is a clear need for high quality research concerning the use of this treatment approach.

3.5 Conclusions

Whilst there is clear evidence that gait is an activity that involves multiple body systems, from the distal lower limb to the pelvis, spine, and the upper body, the relationship between locomotory dysfunction and musculoskeletal pathology is ambiguous. When the epidemiological perspective is considered, it does appear that there is already compelling evidence to support a link. However, epidemiology also emphasises that most pathologies are multi-factorial, and this certainly seems true for musculoskeletal conditions that may be associated with gait. Certain pathologies seem to have a clear relationship to locomotory dysfunction whereas others may be influenced less. Whilst there are various plausible mechanisms by which abnormal foot function might be related to LBP, the evidence available this far is theoretical, and despite this being based on anatomical knowledge that is credible, there is a disturbing lack of basic observational studies that could provide information on the nature of the association. There have been several attempts to conduct trials evaluating the effect of orthoses on specific musculoskeletal conditions, including low back pain. However, in spite of recognition of the validity of the \textit{diagnosis-by-therapeutic-response} model of knowledge acquisition, there is a need for observational studies to provide information on both the nature of the association and possible benefits of dealing with this risk factor. Such studies require the identification of a robust technique of measuring the variable of interest – in this case foot function. Chapter 4 will therefore consider the literature concerning existing measures of foot-type that may be useful for observational studies.
Summary points:
The literature reviewed in chapter 3 leads to several conclusions:

- The process of compensatory foot function represents a plausible, if essentially theoretical, biological pathway by which abnormal foot function, driven by various factors, may result in musculoskeletal pathology at various levels including the low back;

- Whilst the ‘outcomes movement’ has created a climate in which RCTs and systematic reviews of these trials are deemed the principal admissible evidence source, there is a growing realisation that this approach is limited, and unsuited to the needs of various healthcare situations;

- A viable alternative approach is the ‘group evidence’ ideal, and in the context of the search for aetiological information, the epidemiological approach is of particular value. This demands information from various types of study that all contribute a different aspect to the overall picture;

- The group evidence ideal urges re-consideration of the entire literature base concerning the relationship between abnormal foot function and musculoskeletal pathology;

- Foot orthosis research, although not primarily utilising robust RCT designs, clearly suggests these devices to be at least moderately successful in the treatment of various conditions affecting the lower limb, as they have been shown to be capable of positively influencing the functional behaviour of proximal segments;

- Intervventional trials represent the most common form of evidence concerning the relationship, and there is a relative paucity of alternative forms of evidence;

- To provide comprehensive information on the relationship between foot function and musculoskeletal pathology, including low back pain, alternative evidence forms is required, which ideally will be explicitly designed to suit the needs of ‘aetiognosis’;

- A logical starting point is observational studies, which permit calculation of measures of risk associated with specific factors;

- These studies rely on the use of reliable and valid measures, which must either be identified from existing instruments / tools or developed for the purpose;

- Review of the literature concerning measurement / classification of ‘foot-type’ is the first step towards conducting an observational study, to determine whether a suitable measure already exists, or requires development. The next chapter will explore this issue.
Chapter 4
Classifying Foot-Type

After discussing the potential value of observational studies in chapter 3, this chapter considers the tools currently available for conducting such a study investigating the relationship between foot-function and musculoskeletal pathology. The pragmatic appeal of existing measures of foot-type is discussed, in terms of suitability for clinical and research use, and their theoretical background is also considered. A rationalised set of criteria for the ideal foot-type measure is presented, and the major categories of foot-type measure are reviewed against these criteria to identify measures demonstrating potential. The strengths and weaknesses are considered objectively to permit a judgement to be made on their suitability for use in epidemiological enquiry.

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4.1.1 The concept of ‘foot-type’
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4.2 Visual techniques

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4.7 Conclusion
4.1 Introduction

4.1.1 The concept of ‘foot-type’

Foot function is perceived to be an important factor in the development of a variety of musculoskeletal pathologies (Ilahi and Kohl, 1998b, van Mechelen, 1992). Although the association may be investigated in various ways, trials of foot orthoses dominate the literature. These trials provide conflicting results, suggesting a complex relationship between foot function and musculoskeletal pathology (van Mechelen, 1992). Epidemiological enquiry, primarily involving observation to compare foot function between groups with and without a condition, or tracking subjects to identify the foot-function characteristics of individuals who develop a condition, may aid understanding of the nature of the relationship (Gordis, 2000, Vetter, 2000). However, such studies rely on the validity and reliability of the method used to measure the exposure variable- in this context the method used to characterise foot function (Rose, 1991). Although valid, reliable and objective quantification of foot function is possible, it is an expensive and time-consuming laboratory-based process (Redmond et al., 2001). This has led to the routine use of simple measures of ‘foot-type’ that aim to short-circuit the need for detailed analysis. These measures are generally based on some anthropometric measure of foot structure recorded either externally, from radiographs or from footprints, and are thought to reflect dynamic function. Despite evidence supporting the existence of functionally distinguishable foot-types it is unclear how many distinctly different foot-types exist or what their distinguishing characteristics are (Song et al., 1996). ‘Foot-type’, therefore, appears to be a nebulous term that has been used to describe a range of measures of foot structure that can be grouped into several discrete categories, which are perceived to reflect dynamic function.

4.1.2 The background to ‘foot-type’ measures

Foot-type measures are based on the fundamental anatomical principle that structure reflects function. This concept has been discussed in terms of adaptation within soft tissues, but is exemplified in the adaptive re-modelling of bone that occurs in response to mechanical loading. A review of bone biology acknowledged that many factors contribute to bone growth, and that the relationship between bone structure and mechanical forces has been studied since at least the 17th century (Buckwalter et al., 1995). The observation of a relationship between bone size, body weight and activity
was attributed to Galileo, and the critical observation, that living bone adapts to alterations in load by modifying its internal structure, to Julius Wolff in 1892. Wolff’s thesis was supported by observation and experiment, and became known as Wolff’s law, and this is now regularly cited to support the relationship between structure and function (Forwood and Turner, 1995, KMO, 2001). Wolff’s law essentially summarises the relationship between structure, forces and movement (Oatis, 2003) (figure 4.1). Although the relationship is complex, the conclusion that bone shape can determine function and bone function can determine shape in an evolutionary time-averaged concisely summarises the relationship (Vogler and Bojsen-Moller, 2000). The relevance to ‘foot-type’ is illustrated by the assertion that the concept of foot-type is essentially one of architecture (Song et al., 1996) and the observation that it is a basic premise of podiatric biomechanics that a given foot structure will display certain functional characteristics, and that these characteristics are generally associated with pathomechanical function of the lower extremity (Menz, 1998).

Figure 4.1: The relationship between structure, function and force (Oatis, 2003)
This figure illustrates the interdependence between structure, force and function. In this triad, the three elements influence, and are influenced by, the others. It is difficult to assign primacy to one factor because of this mutual interdependence.

![Diagram of structure, forces, function, movement](image)

The first attempts to classify feet arose from the need to measure size and shape for shoe fitting, and noted attempts by 18th and 19th century anatomists to use factors such as ethnicity, occupation and even religion (Menz, 1998). However, perhaps the most rational approach was developed by Hiss (1949), who focused on the concept of arch height and flexible versus rigid foot types. Whilst approaches to measuring foot-type vary, a majority appear to relate directly to medial longitudinal arch morphology, and it has been stated that pes planus – the flat foot – and pes cavus – the highly arched foot – represent distinct clinical entities which differ in their mechanical behaviour.
(Cavanagh and Rodgers, 1987). This focus on the medial longitudinal arch is based on 2 related observations that were fully discussed in chapter one:

- The relationship between rearfoot, and more specifically STJt, position and the mechanical integrity of the foot;
- The consistent and predictable response of the architecture of the medial longitudinal arch to changes in rearfoot position.

The influence of rearfoot position on the mechanical integrity of the foot, whereby rearfoot supination induces stability which is lost with pronation, is acknowledged (Inman et al., 1994). Despite attributing this change to complex and inadequately understood mechanisms, a body of literature has since emerged that provides coherent and rational explanations. This body of literature focuses on the characteristics of the STJt, which forms the central element of the rearfoot, and includes descriptions of STJt function and subtalar-midtarsal interdependency (Close et al., 1967, Elftman, 1960, Manter, 1941) and the contribution of the plantar aponeurosis, through its influence on rearfoot position, to stability (Hicks, 1954a, Hicks, 1954b, Hicks, 1955).

Since this seminal research a series of investigations have been conducted which continue to reveal further insights into the mechanisms contributing to pedal stability and mobility.

Firstly, substantial evidence has been presented to support the contention that the tarsal bones are kinematically linked as a ‘constraint’ system, in which passive cooperation is imposed by articular geometry and ligaments (Huson, 1991, Huson, 2000). Secondly, it has been demonstrated that the plantar aponeurosis, tightened in response to 1st MTPJt dorsiflexion, makes an important contribution to overall stability (Bojsen-Moller and Lamoreux, 1979), by increasing calcaneo-cuboid joint contact (Bojsen-Moller, 1979b) and the efficiency of shear-force attenuation in the forefoot (Bojsen-Moller, 1979a). Finally, the two have been linked by exploration of the relationship between rearfoot position and hallux dorsiflexion, whereby increasing rearfoot eversion reduces and inversion increases hallux dorsiflexion (Harradine and Bevan, 2000). This evidence inextricably links normal rearfoot motion with several mechanisms crucial to the integrity of the foot. It is clear that a number of early
observations can now be considered experimentally verified, by a range of research that has utilised various methodologies.

The kinematic link between the tarsal bones has been described in detail (Nester, 1997), and details the relationship between rearfoot orientation and medial longitudinal arch height. Essentially, STJt pronation involves internal tibial rotation, talar adduction and plantarflexion, and dorsiflexion and abduction of the navicular and forefoot, to clearly reduce the height of the medial longitudinal arch. Conversely, STJt supination involves external tibial rotation, talar abduction and dorsiflexion, and plantarflexion and adduction of the navicular and forefoot, to clearly increase the height of the medial longitudinal arch (figure 4.2). These coupled motions were described as exactly defined and predictable (Huson, 1991), providing evidence on the strength of the link. Consideration of this chain of kinematic events, which directly influences medial longitudinal arch height, and the influence of STJt position on the mechanical integrity of the foot, entirely justifies the focus on medial longitudinal arch height as a foot classification system.

Figure 4.2: The influence of tibial rotation on rearfoot architecture. These figures show the pronated and supinated foot from anterior and posterior views, and illustrate the response in the medial longitudinal arch. Figures a & b show a posterior view of the pronated and supinated foot, with the lines representing the rearfoot and forefoot plantar planes to show how the forefoot responds to the change in the rearfoot. Figures c & d show an anterior view of the same feet, with the lines demonstrating the change in transverse plane alignment that occurs with pronation and supination. The lines drawn in the photos are included to highlight the major planar motions that characterise pronation and supination (Nester, 1997).

a.  

b.  

c.  

d.  

4.1.3 Categories of foot-type measures

Whilst the explicit aim of foot-type measures is to rapidly capture information regarding the functional characteristics of the foot, and the majority focus on the medial longitudinal arch to do this, a range of methods have been used to do this. These range from simple visual observation, to external or radiographic measurement.
of the height of a defined point on the arch (usually the navicular tuberosity), and evaluation of some aspect of a footprint. When additional systems that are based on either a series of measurements or questionnaire-based, this results in five categories of measure that includes >12 individual measures. These are:

- Visual techniques
- Radiographic techniques
- Anthropometric techniques
- Footprint techniques
- Questionnaire based assessment tools.

4.1.4 Criteria for assessing foot-type measures

Foot-type measures must be considered in the context of their fitness-for-purpose. Consideration of the attributes that characterise the ideal foot-type measure provides a benchmark by which the available methods may be assessed. These criteria can be formulated by considering both the research literature, which introduced concepts such as reliability and validity, and from clinical reports, which include pragmatic considerations such as clinical utility. Both perspectives are related, however, and in formulating the criteria for the ideal foot-type measure both need to be considered.

In pure research terms, the desirable properties of a measurement have received wide discussion. For example it has been stated that tools simply must yield measurements that are reproducible, accurate, applicable to the measurement task in hand and practical or easy to use (Polgar and Thomas, 2000). This makes clear reference to the importance of reliability and validity, but also to the need for practical measures that can successfully be transferred to the situations in which the variable they are measuring is routinely encountered. Reliability has been described as the amount of consistency between successive measurements of the same variable, on the same subject, under the same condition (Norkin and White, 1995). Although it has been suggested that good reliability is fundamentally important because of increasing scientific, governmental and public health demand for improved clinical outcomes at reduced costs (Lea and Gerhardt, 1995), it’s contemporary relevance has extended to make it fundamental to the processes of diagnosis, prognosis, prescription of
treatments, case management, and assessment of treatment outcomes (Griffith, 1995). Clearly it is vital that a measurement tool yields the same result on successive uses, if serial measurements are to be capable of monitoring the true progress of a condition.

Validity refers to measurement accuracy, which essentially relates to measurement error, and implies that we can know the true value of a test (Polgar and Thomas, 2000). Put simply, it relates to whether a measurement tool measures what it is supposed to (Gomm et al., 2000). There are at least four different notions of validity in common use, depending on the dimension of validity that is accessible. Firstly, face validity simply refers to the apparent suitability of the tool on first inspection, in relation to the variable being measured – if the tool seems to fit the bill, then it appears, on the face of it, to be valid (Polgar and Thomas, 2000). Face validity is regarded as a weak dimension (Gomm et al., 2000). Content validity involves closer scrutiny, to determine whether the separate dimensions of the variable are being measured. If it is known that there are a number of dimensions to a particular variable, and the tool examines each one, then the content is judged valid (Gomm et al., 2000). Criterion validity entails the comparison of results obtained with one instrument with the results obtained by an external gold standard tool (Daly and Bourke, 2000). If the two correlate then the tool fulfils a vital criterion. This type of validity is useful for validating cheaper/less invasive instruments to determine how close the results obtained are to those recorded using the more expensive, more accurate, instrument. If there is good agreement between a cheap and an expensive instrument, then the cheaper should be favoured. Finally, construct validity refers to the correlation between an instrument’s score and clinically important outcomes such as prognosis (Gomm et al., 2000). This is clearly a vital dimension of validity, without which the utility of the instrument can be challenged.

The criteria for the ideal foot-type measure must include details of their validity and reliability, but extends beyond these two concepts. However, detailed examinations of such criteria have rarely been explicitly discussed. A brief mention of desirable characteristics is often included in articles appraising specific tools, with most authors mentioning the issues of reliability and validity. For example, in one review of current methods of foot type classification it was stated that ‘...it is essential to apply a valid and reliable system...’ (Razeghi and Batt, 2002), whilst in another remarks that ‘...the
fundamental assumption...is that these foot-classification systems are valid' (Menz, 1998). Validity therefore seems to be a principal requirement of the optimal measure, but the ideal measure will also satisfy other requirements. The ability of measures to predict and relate to clinical diagnosis, prognosis and evaluation of treatments is also a desirable characteristic of the ideal tool (Griffith, 1995). Pragmatic considerations, such as clinical suitability, ease of use and cost have also been discussed (Redmond et al., 2001).

Recently, the proceedings of a 'Foot classification Conference' held in Annapolis, Maryland between May 19th-20th 2001 was published (McClay, 2001). These were prefaced by a consensus statement detailing key directions for future research on foot-type classification. The points raised provide useful information concerning fundamental issues that should be considered when evaluating, and developing, foot-type measures. These consensus points were:

- Foot classification systems should reflect the structural complexity of the foot;
- Both dynamic and static methods have identifiable strengths, and because both methods currently have unresolved shortcomings, neither can be dismissed at this stage;
- Some means of standardising approaches is a priority, as variation in nomenclature is contributing to confusion;
- Measures should preferably utilise continuous scales, in view of the overly simplistic categories created by the use of essentially artificial boundaries to divide feet into sub-types;
- Systems should recognise, and incorporate, multi-factorial variations in structure and function to reflect the interactions occurring between the bony components of the foot leg;
- The development of reliable and valid functional assessment tools should be a priority, and these should emphasise functional outcomes focused on both the patients and researcher-oriented, external measures;
- A multi-systems approach should be adopted which includes assessment of biomechanical, neuromuscular and physiologic variables;
- Databases should be established to permit effective sharing and comparison of data among clinicians, which can be facilitated by standardising terminology.
These criteria provide a useful benchmark from which to consider the characteristics of the ideal foot-type measure, and provide a foundation from which to devise criteria for evaluating existing measures. By combining theoretical, research and clinical considerations in a pragmatic manner, a set of criteria for the ideal foot-type measure can be suggested:

1. Measures should be reliable;
2. Measures should be valid, and this validity should be satisfied on various levels:
   - Face validity should be satisfied, in that the measure should focus on theoretically relevant aspects of the foot, which have clear relevance to both patients, clinicians and researchers;
   - Content validity should be satisfied, in that the various elements considered to contribute to foot function should be represented;
   - Criterion validity should be satisfied, in that there should be agreement between measures and dynamic foot function;
   - Construct validity should be satisfied, in that measures should correlate well with clinical and functional outcomes, and be predictive of future pathology.
   (Measures that are valid will therefore reflect, to some extent, the structural complexity of the foot, and will be sensitive to multi-system influences on foot function).
3. Continuous measurement scales should be favoured, due to the artificiality of instruments that create groupings according to arbitrary cut-off points.
4. Clinical appeal should be considered, in terms of appeal to clinicians, researchers and patients. It should be suitable for use in a variety of situations.
5. The ideal measure should reflect dynamic foot function.

In considering these criteria, there appears to be considerable overlap with the conditions formulated at the *Foot and Ankle Classification Conference* (McClay,
2001). For example, the ability of a measure to reflect the mechanical complexity of foot function clearly relates to construct validity. Although the consensus statement recognises that both static and dynamic measures have strengths and weaknesses and refused to reject either category, an important construct of foot-type relates to functional behaviour. It is for this reason that information concerning the dynamic relevance of measures has been included. Whilst evaluation of existing foot-type measures against these criteria is hampered by the inconsistent information available for individual measures, it remains an important task to use some form of criterion-based assessment. Prominent examples of foot-type measures from each category will therefore be assessed against these criteria.

4.2 Visual Techniques
Visual analysis of the foot is a simple method of classifying the foot, which is readily available to all clinicians. Various aspects of the foot can be assessed, and the process can be aided by using photographs or videos, where available, to aid reliability, and a range of anatomical features of the foot can be considered. Assessment can be either weightbearing, non-weightbearing or dynamic (Razeghi and Batt, 2002), and may be aided by the use of equipment such as the podoscope, which uses a mirror below a glass platform to allow analysis of plantar pressure distribution.

The major drawback with visual techniques, however, is that the process is qualitative, requiring the clinician to interpret visual information. The technique remains appealing, however, due to its simplicity, and two groups have examined the reliability of two methods of visual assessment. Using a visual technique based on qualitative assessment of the arch angle, rearfoot alignment, and the presence or absence of a talonavicular bulge, three experienced physical therapists achieved 73.3% agreement (Dahle et al., 1991). A more complex technique involved the use of a custom platform with three mirrors set at angles to allow a single photo to capture anterior, posterior, medial and lateral views (Cowan et al., 1994). A foot rest was attached for the contra-lateral foot, and a marking procedure to highlight specific areas such as the soft-tissue arch height and anatomical landmarks such as the inferior medial aspect of the navicular, was followed. A single photograph was then taken which was evaluated by four orthopaedic surgeons and 2 podiatrists after they had evaluated 40 slides from a series of individuals not involved with the study to set the
criteria they would use to assess the feet. The evaluation technique comprised a five-point scale, with choices ranging from clearly flat-footed (category 1) to clearly highly arched (category 5), and with 3 representing the normal foot. Despite a rigorous methodology that took several useful steps to reduce variability, the conclusion that even with anatomical landmarks clearly highlighted and visualisations of the four aspects of the foot there was very poor agreement, seems justified. It is clear that visual examination, even when assisted by standardised multi-dimensional photos, is associated with poor reliability and a more objective method is required.

4.3 Radiographic Techniques

Visual analysis of the medial longitudinal arch is essentially an attempt to evaluate the underlying bony structure, which determines arch architecture (Wearing et al., 1998). Although the angular relationships between the medial bony components of the foot - calcaneus, talus, navicular, medial cuneiform and 1st metatarsal (figure 4.3) - are a logical focus, the importance of the lateral column of the foot has also been discussed (Sangeorzan et al., 1993). Documented measures have focused on both areas, and include sagittal plane measures such as the calcaneal inclination and calcaneal – 1st metatarsal angles (Simkin et al., 1989, Wearing et al., 1998), and transverse plane measures such as the dorsoplantar talonavicular angle (Kalen and Brecher, 1988).

Focusing on bony architecture is clearly logical and justifiable, as underlying bony structure is clearly vital in defining arch structure. However, the use of a range of angles for evaluation of the foot has been criticised with the reminder that radiographs are essentially 2-dimensional images of a 3-dimensional geometric unit, and that decisions regarding the condition of the foot is a clinical, and not a radiographic, one (Rose, 1991). It was further argued that different diagnostic lines and angles should be interpreted with caution since they may often represent the same angle viewed along a different line. This concept was extended with the suggestion that the value of standing films is questionable without standardised positioning, which may require the use of a specialist jig. Such jigs have been used, and have yielded accurate measurements of the distribution of tarsal motion through the joints of the medial column under both in-vivo and in-vitro conditions, using roentgen stereophotogrammetry (Kitaoka et al., 1995, Lundberg, 1989, Winson et al., 1994), and videofluoroscopy has also been used to evaluate dynamic arch motion (Wearing et
Such studies demonstrate that radiographic techniques offer insights into static and dynamic structure and motion within the foot.

**Figure 4.3:** Example radiographic measures of arch structure: the profile of the medial longitudinal arch can clearly be seen to be a result of the alignment of the bony units. (Razeghi and Batt, 2002). CAI = calcaneal inclination angle; CA-MT1 = calcaneal – 1st metatarsal angle. The height to length ratio is also illustrated by H and L. However, it can equally be seen that the declination of the talus, navicular, cuneiform and metatarsal are compatible with evaluation of the medial longitudinal arch.

Although the use of videofluoroscopy offers a valuable insight into dynamic function, static radiological measures appear to have only a limited dynamic predictive ability (Cavanagh et al., 1997). X-ray measures do offer reliable quantification of foot function via a continuous scale, and satisfy the conditions for face validity in that they focus on a theoretically relevant aspect of the foot. However, the poor correlation between these measures and dynamic function, the failure to consider the various elements that contribute to foot function, and their correlation with clinical and functional outcomes compromise their ability to satisfy conditions of content, criterion and construct validity. These factors, coupled with concerns over radiation exposure, cost, time and the specialist facilities required (Razeghi and Batt, 2002) suggest radiographic evaluation to be more suitable for research which may yet identify valid measures. Clearly such techniques do not represent a measure that can be used for clinical purposes or to screen and quantify foot morphology quickly required for large-scale studies (Redmond et al., 2001)
4.4 Anthropometric techniques

Because evaluation of the architecture of the arch via radiography is inappropriate for epidemiological studies involving a large number of subjects, it seems obvious to consider instead external evaluation using bony landmarks. A range of anthropometric measures have been developed and used for various different types of study. Such measures tend to focus on the navicular, due to its location as the highest point of the arch, and its easy identification. Techniques include direct measurement from its inferior and superior aspects and tuberosity to the ground (Hawes et al., 1992, Nachbauer and Nigg, 1992, Saltzman et al., 1995, Williams and McClay, 2000), and attempts at measuring dynamic arch motion via quasi-static measures such as ‘navicular drop’ and ‘navicular drift’ (Menz, 1998, Vinicombe et al., 2001). Angular measurements such as the ‘supranavicular angle’, defined by drawing lines from the medial malleolus to the navicular and the 1st metatarsal and calculating the angle between these two lines (Cashmere et al., 1999), have also been reported. The focus of studies conducted utilising these measures vary from reliability analyses to assessment of the correlation between static measures and dynamic motion.

4.4.1 Arch Height Measures

The ability of a series of five footprints measures to predict arch height has been examined (Hawes et al., 1992). This was based on the rationale that footprint measures are often used as a function of arch height, due to the ease with which they can be obtained, despite the absence of information concerning validity. Measurements of arch height recorded with a Mitutoyo digital calliper failed to identify a correlation between arch height and any of the five footprint measures, but did provide details of the reliability of arch height measurement. Correlation of measurements obtained from the evaluation of 15 subjects on two separate occasions yielded a figure of 0.99, suggesting excellent reliability. Researchers from the same group were subsequently involved in a study attempting to establish the dynamic significance of arch height (Nachbauer and Nigg, 1992). This involved investigation of the relationship between static arch height, dynamic arch motion and ground reaction forces during running. Arch height was defined as the height of the highest point along the soft tissue margin of the medial plantar curvature, measured using Hawes et al’s technique. Dynamic arch motion was defined as ‘arch flattening’ calculated by subtracting the lowest from the highest height of a surface marker.
tracked using a high-speed video camera technique. Thirty-four subjects were analysed and divided into 'low', 'moderate' and 'high' groups based on both arch height and arch flattening. Kistler force plate measurements were obtained for all subjects, and data analysis revealed that impact forces did not differ for different arch height and arch flattening groups. However, the failure to identify statistically significant differences between the groups may be an artefact of the use of students from the campus of the university at which the investigation took place, with only 'cursory examination of foot-type in order to include a wide range of arch heights'. No assessment criteria were provided, and due to the recruitment strategy, it seems likely that the study was conducted on a range of 'normal' arch heights, rather than true low and high arch groups.

Despite the use of anthropometric measures of arch height for research purposes, concerns over validity have been raised (Saltzman et al., 1995), with variations in the surrounding soft-tissue structures noted as a particular concern. This led them to focus on comparative validity in relation to radiographic measurement of bony landmarks. Standardised radiographs and anthropometric measurements of arch height, talar height, navicular height and footprint length were recorded for a series of 100 orthopaedic patients to allow comparison of the techniques. An included reliability analysis unsurprisingly found that x-rays were most reliable, while intra-rater reliability of the anthropometric measurements were better than inter-rater. Pearson's correlation coefficients between measures recorded in the two states revealed a variable response, with coefficients of between 0.51 to 0.86. Talar height and foot length were identified as most reliable with correlations of 0.81-0.86, calcaneal – 1st metatarsal angle the next best at -0.71 - -0.77, with calcaneal inclination returning poor values of between 0.51 and 0.58. A similar, 3-stage, study has been conducted (Williams and McClay, 2000). This involved recording a series of linear and angular measurements, including navicular height and 1st metatarsal angle, in a group of 51 subjects to initiate a reference database. Next, a subset of 20 feet, from 10 subjects, was examined blindly by two clinicians to permit reliability assessment. Finally, validity was examined by obtaining standardised x-rays of the right foot of 10 subjects, and comparing results with the measurements obtained clinically. Intra-class correlations were typically better than inter-rater, falling between 0.804 – 0.995. Interrater reliability was lower, and varied considerably between the 10% and 90%
weightbearing conditions in which the measures were taken. Validity testing revealed consistently good results, indicating the clinical technique to be an excellent indication of radiographic measurement.

The acceptable correlation between anthropometric and radiographic measures suggests face and comparative, validity. A more important dimension of validity relates, however, to the ability of static anthropometric measures to predict dynamic function. This issue has been the subject of various studies that, using a range of measures, that have attempted to clarify the functional significance of a variety of anthropometric measures including arch height (Cashmere et al., 1999, Nachbauer and Nigg, 1992, Nigg et al., 1993) and rearfoot angle (Hamill, 1989, McPoil and Cornwall, 1996, McPoil and Cornwall, 1996a, McPoil and Cornwall, 2000). A further measure, navicular drop, has also been proposed that more directly attempts to measure motion.

The influence of the height of the arch on its deformation during running (Nachbauer and Nigg, 1992), and on angular motion in the lower limb (Nigg et al., 1993) have been investigated in an attempt to determine the functional significance of arch height. These two studies were conducted by the same researchers and utilised groups of students recruited from around their university campus who had their foot-type ‘...examined cursorily in order to include a wide range of arch heights’. However, these studies recruited only 18 and 15 subjects respectively from an ostensibly normal population, which are unlikely to have included extreme, or even moderate, examples of pathological foot-types. It is therefore unsurprising that these studies failed to identify any significant differences in ground reaction forces, dynamic arch deformation, or angular motion in groups organised according to arch height. Although no relationship was identified between arch height and maximal eversion moment or maximal internal leg rotation, greater transfer of calcaneal eversion into limb rotation was noted (Nigg et al., 1993), and may suggest a functional relationship. Similar subsequent investigations have also failed to identify an association between arch height measures and dynamic function (Cashmere et al., 1999, Torburn et al., 1998), suggesting that these linear anthropometric measures do not satisfy the demands for criterion validity, necessitating their rejection as feasible tools by which to classify foot type.
4.4.2 Navicular Drop / Drift

Evaluation of static measures, in the guise of radiographic or anthropometric evaluation, has failed to yield information about the dynamic function of the foot. There have been attempts to tackle this problem of predicting dynamic motion from a static measurement. ‘Navicular drop’ involves measuring the sagittal plane movement of the tuberosity of the navicular between the neutral and RCSPs in an attempt to estimate dynamic arch displacement (Brody, 1982). Although the original technique involved measurement of the change in navicular height between a seated, light weightbearing, STJt neutral position and a standing, 50% weightbearing, RCSP, this technique was developed for its next use. This involved the first measurement being recorded in a seated neutral position and the use of a full-weightbearing standing position in an investigation of the influence of anterior cruciate ligament injury on foot pronation (Beckett et al., 1992). This study found a significantly increased navicular drop in the injured group, and this was felt to support the concept of an association between foot function and anterior cruciate ligament injury. A year later, when the reliability of an instrumented method (Mueller et al., 1993) and a clinical method (Picciano et al., 1993) was investigated, the method had developed further to the use of a weightbearing neutral position. The instrumented method involved the use of the Metricom® electromechanical 3-d digitiser capable of measuring x, y and z co-ordinates for the location of the navicular to an accuracy of 0.9mm. Intra-class correlation coefficients of between 0.78 and 0.83 suggested acceptable reliability, superior to the clinical technique (Picciano et al., 1993), where ICC’s of 0.61 and 0.79. In addition to examining the reliability of the Metrecom® device, the association between navicular drop, forefoot to rearfoot position, and neutral and RCSPs was performed using paired correlations and multiple regression analysis. Simple correlations identified significant correlations of between 0.29 and 0.42 between navicular drop and both forefoot and rearfoot measurements. The multiple regression analysis suggested navicular drop to be influenced by both the forefoot and rearfoot, although the rearfoot influence was greater.

Navicular drop was further developed when it was realised that the transverse plane component of the triplaner motion measured by Meuller, Host et al (1993) could easily be included in the clinical technique (Menz, 1998). It was felt that including
this measure could provide further insight into the mechanics of the talonavicular joint, as well as providing a quantifiable indicator of the 'medial bulging' observed clinically in association with the pronated foot, which is an acknowledged indicator of pronation (Dahle et al., 1991, Redmond et al., 2001). The reliability of navicular drop and drift were recently evaluated in a study using 5 clinicians to measure 20 subjects twice after attending 3 x 1 hour training sessions, using a simple measurement system involving marking horizontal and vertical navicular position onto card held against the navicular and placed on the supporting surface (Vinicombe et al., 2001) (figure 4.4). A range of statistics including Pearsons $r$, intra-class correlation coefficients and the standard error of measurement, along with 95% confidence intervals, were detailed to provide a comprehensive overview of the individual and comparative reliability of drop and drift. Results revealed both measurements to be only moderately repeatable, with intra-tester better than inter-tester reliability (table 4.1) and little difference between the reliability of the two measurements. Whilst the techniques display only moderate reliability, their potential to provide an insight into dynamic foot function suggests a clinical utility warranting their further exploration as a foot-type measure.

**Figure 4.4a: Measurement of navicular drop**
The level of the navicular tuberosity in neutral and RCSPs is marked onto a piece of card for later measurement.

**Figure 4.4b: Measurement of navicular drift**
The subject stands on a piece of card, and the tuberosity of the navicular is projected onto it in neutral and relaxed. Navicular motion between the two positions is measured later.
The concept of measuring the amount of compensation between neutral and RCSPs, which was introduced with navicular drop, has also been extrapolated to the calcaneus (Sell et al., 1994). Given that the neutral calcaneal stance position represents the theoretical ‘ideal’ functional position and the relaxed represents the ‘actual’ function position, it seems entirely logical to measure how far away from the ideal the foot is actually functioning. The reliability of calcaneal and navicular positions in both neutral and RCSPs, and motion between these two positions, has been examined (Sell et al., 1994). Data analysis identified a significant improvement in both intra- and inter-rater reliability when motion was considered, as opposed to the individual positions (table 4.2), with measurement of calcaneal motion returning slightly higher intra-class correlation coefficients. The data show a good level of reliability for each measurement, and the robust design illustrates how acceptable levels of reliability can be achieved with an explicit protocol. This data suggests that measuring calcaneal motion and navicular motion between the neutral and RCSPs may be useful methods of assessing foot function.

Table 4.2: Reliability of measures of calcaneal and navicular position and motion (Sell et al., 1994): These data infer that the two techniques are essentially equally reliable, with intra-class correlation coefficients, standard error of measurement and 95% confidence limits that are very close.
4.4.3 The Root model

Whilst numerous foot-type assessment techniques are based on isolated measures, the Root model (Root et al., 1977, Root et al., 1971) proposes that each component of the lower limb musculoskeletal chain can influence foot function, and so must be examined to explain the foot's functional behaviour and to permit appropriate treatment to be prescribed. Therefore, the Root model utilises a comprehensive lower limb examination (Lee, 2001a). Of prime importance is the interaction between the separate segments and their combined influence on the foot. This combined influence is determined by assessment of the rearfoot in the NCSP, which provides information on the optimal functional position of the STJt in the absence of any musculoskeletal abnormality in the lower limb, and the RCSP, which describes the actual functional position of the STJt that is occurring due to the combined influence of anomalies throughout the lower limb musculoskeletal chain (Philps, 1995) (figure 4.5).

**Figure 4.5: Lower limb segment interactions and their impact on foot posture (Philps, 1995)**

This figure illustrates the central concept of the Root model: that dynamic foot behaviour is influenced by the alignment of the segments of the lower limb, and that systematic evaluation of these segments provides information allowing foot function to be understood and, perhaps most importantly, predicted.

Although the Root model has been lauded for its widespread appeal and adoption, and its coherent and rational nature (Lee, 2001a), it has suffered numerous criticisms that detract from its clinical and research utility. These include the reliability of the measurement techniques employed (Hunt and McPoil, 1995, McPoil and Hunt, 1995, Michaud, 1997b), the correlation between static measurements and dynamic function (Keenan, 1997) and the validity of the criteria for normal function suggested (Hunt...
and McPoil, 1995, Keenan, 1997, McPoil and Hunt, 1995). Although objective discussions of these criticisms have been published (Keenan, 1997, Mathieson, 2001) which contain pragmatic advice on how error can be minimised, flaws remain, most notably concerning the reliability of the examination techniques, the correlation between static measures and dynamic function (Keenan, 1997, Mathieson, 2001) and the assumption that frontal plane motions of the STJt are valid indicators of its actual, triplaner complex, movements (Razeghi and Batt, 2002).

4.4.4 Conclusion
Despite the appeal of a variety of anthropometric measures of foot function it appears that a common limitation is the lack of a convincing correlation with dynamic function. The fundamental value of dynamic foot function as the critical variable that is likely to be associated with musculoskeletal pathology suggests that criterion validity – agreement between measures and dynamic function – is satisfied by few measures. The one measure that stands out is navicular drop and navicular drift, which represent a direct attempt to measure dynamic function. Although both techniques have been described as moderately reliable, navicular drop has been shown to be associated with greater reliability, as evidenced by intra-class correlation coefficients of between 0.33 and 0.76, as opposed to 0.31 and 0.62 for navicular drift. Navicular drop addresses criterion validity most directly, and when used by a single operator and the associated increase in reliability, represents perhaps the best anthropometric foot-type measure available. It may also be the most useful measure because of its anatomical location in the midfoot, which permits it to reflect the functional behaviour of the entire foot. Extending this concept, measurement of calcaneal motion between the neutral and RCSPs also appears to be a potentially useful method, although it may be less useful due to its focus on the rearfoot. Whilst the Root model represents an important effort to understand the individual factors determining dynamic foot function (to provide information about how it can best be treated), efforts to understand the relationship between abnormal foot function and musculoskeletal pathology may not require information about the origin of abnormal foot function, merely the ability to measure it. Measures of compensatory foot motion such as navicular drop and calcaneal compensation therefore appear to be, at least initially, the most useful measures as they relate most directly to dynamic function.
Examination of criterion validity is considered a critical requirement for this category of measures.

4.5 Footprint techniques

Footprint measures have been a popular method of characterising foot-type for research purposes. They are based on the premise that the footprint responds predictably to variations in medial longitudinal arch structure, which is considered one of the most important structural characteristics of the foot (Cavanagh and Rodgers, 1987, McCrory et al., 1997). Early footprint measures included the FPA (Clarke, 1933), and a series of linear measurements such as the foot width and arch breadth (Cureton, 1935). Both of the measures illustrate that footprints have had attracted interest for some time, and each addressed the issues of validity and reliability using simple correlations. A variety of such measures have been used in investigations have used a variety of different measures for investigating either the state of the arch in a defined group (Didia et al., 1987, Qamra et al., 1980, Rao and Joseph, 1992, Sachithanandam and Joseph, 1995, Staheli et al., 1987), or for examining the relationship between foot-type and a specific pathology (Kilmartin and Wallace, 1992, Prichasuk and Subhadrabandhu, 1994).

4.5.1 Overview of footprint measures

Footprint measures are calculated from impressions obtained using simple ink pad techniques (Razeghi and Batt, 2002), Harris and Beath mats (Welton, 1992), or more recently, sophisticated pressure transducers (Razeghi and Batt, 2002). A range of indices, based on linear measurements of the width of the print at defined points, from analysis of clearly defined areas, or from angular measurements, have been described (table 4.3). All are based on the premise that the footprint responds predictably to variations in the structure of the medial longitudinal arch. After evaluation of 1015 footprints, Qamra et al asserted that forefoot and heel areas consistently show maximum ground contact with progressive changes in arch height, restricting changes in the footprint to the central portion (Qamra et al., 1980). The majority of measures seem to reflect this theory, as they involve a direct comparison of the contact areas in either the forefoot or heel with the midfoot. For example, the arch index (Cavanagh and Rodgers, 1987) involves comparison of the contact area of the midfoot with the contact area of the rest of the print minus the toes. The same rationale has resulted in
more convenient indices that are less time-consuming to calculate. These involve comparison of the midfoot width, firstly with forefoot width, to calculate the Chippaux-Smirak index (Forriol and Pascual, 1990), and secondly with the rearfoot width to calculate Staheli's arch index (Staheli et al., 1987) (table 4.3). This does not apply to all measures, however. For example, the midfoot contact index (Rao and Joseph, 1992) involves the division of the print into high, average or low categories based on the width of the print in the midfoot region (table 3.3). The foremost angular measure is the FPA (Clarke, 1933) which measures the angle between a medial reference line (connecting the most medial margins of the forefoot and rearfoot) and the most anterior and lateral margins. A further measure based on footprints, the valgus index, has been proposed (Rose, 1985). This involves projecting the apices of both medial and lateral malleoli vertically downwards onto the heel contact area to allow the centre of the intermalleolar line to be related to a longitudinal bisection of the foot extending from the centre of the heel print to the centre of the third toe print (figure 4.6, overleaf).
Table 4.3: Example angular, linear and area-based footprint measures

<table>
<thead>
<tr>
<th>Measure</th>
<th>Definition</th>
<th>Illustration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arch Index</td>
<td>A line segment is drawn between the centre of the 2nd toe and the most posterior point of the heel and is called the medial axis of the footprint. Parallel lines are drawn perpendicular to this line to divide the print into equal thirds. The arch index is calculated as the ratio of the area of the middle third of the toeless footprint to the entire toeless footprint area.</td>
<td><img src="image" alt="Illustration" /></td>
</tr>
<tr>
<td>Chippaux-Smirak Index</td>
<td>The CSI and SAI are similar in that they compare the midfoot width with either the forefoot width (CSI) or the rearfoot (SAI). The CSI involves dividing width A by width B. The SAI involves dividing width B by width C. Both provide information on the ratio of the width of the arch to the width of the forefoot or rearfoot.</td>
<td><img src="image" alt="Illustration" /></td>
</tr>
<tr>
<td>Staheli Arch Index</td>
<td>A line is drawn across the narrowest region of the arch. Classification is based on the width of the contact area using an arbitrary 1cm as normal.</td>
<td><img src="image" alt="Illustration" /></td>
</tr>
<tr>
<td>Midfoot width</td>
<td>The angle between the medial border of the footprint and the line connecting the most medial point of the metatarsal region of the footprint and the point where the slope of the inner segment of the longitudinal arch touches the metatarsal outline of the arch.</td>
<td><img src="image" alt="Illustration" /></td>
</tr>
</tbody>
</table>

Figure 4.6: The Valgus Index (Rose, 1985)

The valgus index uses a footprint, but technically falls outwith the category of footprint measures. It involves projection of the apices of the medial and lateral malleolus onto the heel area of the footprint and the application of a line running from the centre of the third digit to the centre of the heel which acts as a midline. A line is drawn between the malleoli, and the distance from the midline to each is measured. The formula is then used to calculate the valgus index.
4.5.2 The validity of footprint measures

Although moderate-to-good reliability of various footprint measures has been reported (Cavanagh and Rodgers, 1987; Saltzman et al., 1995), the fundamental issues of validity have received little attention. Although several studies have examined the ability of specific measures to predict arch height (Hawes et al., 1992; McCrory et al., 1997), the methods employed are similar to some suggested some 60 years earlier (Cureton, 1935). Whereas a sandbox impression was used to measure the height of the arch for comparison with footprints in the earlier study, specific arch landmarks and digital techniques have been recorded more recently. For example, one study examined the ability of a series of footprint measures to predict arch height, measured as the distance between the highest point of the soft tissue margin of the medial plantar curvature of the arch (Hawes et al., 1992). Footprints were digitised and 5 measures, including the arch angle, footprint index, arch index and arch length index were calculated. Reliability of all measurements was investigated, and intra-class correlations consistently exceeding 0.9 agreed with previous studies and indicated good reliability. Correlations between the individual measures and arch height varied from -0.39 to 0.39 for the 115 male subjects, and coefficients of determination of between 0.04 and 0.15 suggested that a small percentage of between 4 and 15% of the variability in arch height could be explained by variation in the footprints. An example scattergraph is included, showing the correlation between Clarke’s Angle and Arch Height, to illustrate the association (figure 4.7). This suggested a weak relationship between static arch height and footprint measures.

This focus on the ability of footprint measures to predict some measure of static arch height is theoretically flawed, however, and does not represent the final word on the validity of footprint measures. The problem can be conceptualised by considering the validity of attempting to measure the height of a building by measuring its width (Cureton, 1935). Although this oversimplifies the issue, because of the relationship between rearfoot position and arch height, this statement does articulate the essence of the issue. Given that the critical factor is the dynamic behaviour of the arch, it seems more reasonable that validity should be examined by considering the sensitivity of these measures to discrete, clinically significant, changes in STJt position – the critical determinant of arch height. This relates to criterion validity, and until this
dimension of validity is understood, the suitability of footprints for categorising foottype is unknown.

Figure 4.7: Correlation between Clarke's FPA and arch height, to illustrate the types of validity study that have been conducted. This scattergram equates with a significant, but weak, correlation of 0.39. The technique adopted does not, however, satisfy the conditions of criterion validity.

4.5.3 Conclusions
Footprint measures have a pragmatic appeal due to the ease with which a print can be obtained in clinic, or a variety of situations, and the potential for recording data from large numbers of people with maximal ease. Although good reliability data exists for a variety of measures, and suggests that these measures can demonstrate excellent reliability, there is less convincing information relating to validity. Studies claiming to investigate validity have proceeded by examining the relationship between the measures and arch height, itself a measure of dubious value. The issue of criterion validity, which relates to the relationship between static measures and dynamic function has received no attention, and without information on this critical dimension of validity the value of footprint measures if unknown. Examination of criterion validity would seem to be a priority for this category of measures.

4.6 Alternative techniques of foot function assessment
4.6.1 Foot health related quality of life assessment tools: the Foot Function Index & Foot Health Status Questionnaire
Research concerning treatment efficacy has recently shifted focus to recognise the importance of the patients perspective. This is evidenced by the proliferation of the number and types of patient-based outcome measures designed to measure the patient’s perspective of the effect of treatments (Bombardier, 2000). This de-
emphasises the disease process to instead focus on ill-health, taking a broader perspective on the person and his life (Bowling, 1997), and tools can be categorised under the two broad headings of *generic*, relating to global aspects of general health and well-being, and *specific* measures, which relate to either a particular medical condition or body region (Landorf and Keenan, 2002). It has been suggested that although outcomes assessment encompasses a wide range of measures, the focus on HRQoL has advanced to such a stage that this can be utilised as a primary outcomes measure.

HRQoL tools use questionnaires to ask a series of questions which are organised into separate areas known as ‘domains’. Domains can be assessed individually or combined to give an overall numerical score of health and well-being (Landorf and Keenan, 2002). Two foot-specific HRQoL tools have been suggested: the FFI (FFI) (Budiman-Mak et al., 1991) and the Foot Health Status Questionnaire (FHSQ) (Bennett et al., 1998). The existence of these tools indicates a high level of interest in the measurement of foot health, but also provide an additional means by which foot health status generally can be examined. Clearly, if foot function is impaired then it is reasonable to suspect that domains such as pain, disability and functional limitation will reflect this. HRQoL measures therefore provide an alternative approach to the assessment of foot-type – the healthy, asymptomatic and the symptomatic.

The FFI and FHSQ focus on essentially the same domains (table 3). Both tools have been subjected to rigorous reliability and validity testing, and have permitted valid investigation of the impact of rheumatoid arthritis (Conrad et al., 1996, Saag et al., 1996), podiatric surgery (Bennett et al., 2001) and FFO’s (Reed and Bennett, 2001) on foot function. Where several HRQoL tools exist in relation to a particular area, head-to-head comparisons have been recommended to determine the specific circumstances to which specific measures are suited (Bombardier, 2000). The FFI and FHSQ have recently been evaluated in this way (Landorf and Keenan, 2002). This involved administration of both questionnaires to a group of 17 patients who were prescribed functional orthoses for the treatment of plantar fasciitis. A review of both questionnaires was included, in terms of domains, reliability and validity data (table 4.4), which suggest both to have survived a rigorous evaluation process. The FFI was designed to measure the impact of foot pathology in terms of pain, disability and
activity restriction, and was validated on a group of people with rheumatoid arthritis. The FHSQ was developed primarily to assess subjects undergoing surgical treatment for common foot conditions, but it has been successfully used to assess general foot conditions, such as skin conditions and musculoskeletal pain (Bennett et al., 1996, Reed and Bennett, 2001). In a comparison of these tools, both were found to be responsive to improvements associated with the use of FFO’s, although the FHSQ was more universally responsive. The FFI did register improvements across all three domains, but changes measured for the activity limitation domain which was not significant (Landorf and Keenan, 2002). Despite noting concerns over discriminative ability in the General Foot Health domain, and suggesting that further questions may be required, the FHSQ was judged to be more responsive and well-suited to the purpose of examining subtler foot disability or impairment. The FFI was recommended for more debilitating conditions with more significant disability / impairment.

Table 4.4: Domains measured by the FFI and FHSQ, and details of the reliability and validity assessment data available for each.

<table>
<thead>
<tr>
<th>FFI Domains</th>
<th>FHSQ Domains</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>Pain</td>
</tr>
<tr>
<td>Disability</td>
<td>Functional Limitation</td>
</tr>
<tr>
<td>Activity limitation</td>
<td>Footwear satisfaction</td>
</tr>
</tbody>
</table>

Reliability data:
- **test-retest**: Intra-class correlations:
  - 0.69-0.87
- **Internal consistency data**: Cronbach’s alpha:
  - 0.74-0.92

<table>
<thead>
<tr>
<th>Reliability data: Intra-class correlations:</th>
<th>0.69-0.87</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internal consistency data: Cronbach’s alpha:</td>
<td>0.74-0.92</td>
</tr>
<tr>
<td></td>
<td>0.85-0.88</td>
</tr>
</tbody>
</table>

4.6.2 Conclusion

Traditionally, the effect of disease or abnormality has been measured by objective, clinician-based measures that focus on, for example, measurement of tumour-size to evaluate the outcomes of treatment for that problem (Landorf and Keenan, 2002). However, little attention has been paid to the effects of that treatment on the quality of life of the individual and the relationship between objective measures and quality of life (Bombardier, 2000). Two instruments have been developed for the explicit purpose of measuring foot-related quality of life, and these can provide invaluable information regarding the health status of the foot. Since it is reasonable to assume
that abnormal foot function may be associated with intrinsic changes that will influence the functionality, discomfort, or appearance of the foot, it is entirely reasonable to suggest that these measures represent an important alternative method for classifying foot function. Indeed, the process of validity and reliability testing that these tools have been subjected to combines with the limited information available on objective measures to present a compelling case for utilising these measures as a primary method for research and clinical purposes. The concept of triangulation, referring to the use of multiple measurement methods for the investigation of a problem to provide more robust evidence (Bowling, 1997), is of fundamental importance in research, and HRQoL measures represent a feasible means of triangulating the assessment of foot function. In cases where subtle aberrations of foot function are suspected, the FHSQ should be the measure of choice, and in more severe conditions, the FFI appears to be the most suitable (Landorf and Keenan, 2002).

4.7 Conclusion
A variety of techniques for evaluating and classifying foot-type have been suggested, and many of these are in regular use. Although data concerning the reliability of individual techniques is widely available, and indicates that many measures are available for which reliability can be assumed, data concerning the validity of a majority of measures is unavailable. When the criteria for the ideal foot-type measure are considered, it is clear that lesser forms of validity, such as face, are the normal, and few real attempts to determine the correlation between static measures and dynamic function exist. Where this type of study has been conducted, results have been concerning, in that the ability of static measures to predict dynamic function is at best limited. New anthropometric techniques have been suggested, which explicitly attempt to measure static compensatory motion, and initial signs are that these methods go some way to achieving criterion validity – defined as the ability of measures to predict dynamic function.

Several static measures are based on reasonable theories, and in particular footprint measures appear at least in theory, to be potentially capable of attaining criterion validity. However, more information on the validity of such measures is required before they can confidently be utilised to classify foot function in any meaningful
way. In particular, since the STJt is perceived to be the critical joint influencing foot architecture, with subtalar supination creating a high arch and subtalar and pronation creating a low arch. Since arch height is the overwhelming focus of foot-type measures, because of its influence on mechanical foot behaviour, and STJt motion influences this, it seems that the determinant of criterion validity is the responsiveness of individual measures to changes in STJt motion. It is therefore asserted that criterion validity can be determined by examining the sensitivity of individual measures to small, clinically relevant, amounts of STJt motion. Determining criterion validity is an important step that would confidently allow a foot-type measure to be used for research purposes.

A new method of foot classification, based on HRQoL is provided in the FFI and FHSQ, and these represent an innovative, reliable and valid insight into foot health, and these represent both an important primary assessment tool, and an important means of triangulation for research into abnormal foot function.

A table mapping the existing tools against the criteria for the ideal foot-type measure is shown in table 4.5 on the next page. This summarises the strengths and weaknesses of each measurement technique, and highlights that several techniques – in particular the Foot-health related Quality of Life measures and navicular drop – that seem to demonstrate greatest potential. However, it also demonstrates that no ideal measure is currently available, urging their further development.
Table 4.5: Mapping existing measures of foot-type against the criteria for the ideal. This table provides a summary of the major strengths and weaknesses of existing methods of categorising foot-type, and points to those that demonstrate most potential for contemporary use. The development of measures remains a priority, however.

<table>
<thead>
<tr>
<th>Technique</th>
<th>Reliability</th>
<th>Validity</th>
<th>Continuous?</th>
<th>Clinical Appeal</th>
<th>Dynamic Significance</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visual</td>
<td>Poor</td>
<td>Weak</td>
<td>No</td>
<td>Yes</td>
<td>Limited</td>
<td>Subjective, therefore can't be recommended.</td>
</tr>
<tr>
<td>Radiographic</td>
<td>Good</td>
<td>Weak</td>
<td>Yes</td>
<td>No</td>
<td>Limited</td>
<td>Cost &amp; radiation exposure compromise clinical utility.</td>
</tr>
<tr>
<td>Anthropometric</td>
<td>Moderate</td>
<td>Limited</td>
<td>Yes</td>
<td>Yes</td>
<td>Limited</td>
<td>Intuitively appealing, but suffer due to their variation, limited validity, and limited dynamic significance.</td>
</tr>
<tr>
<td>Navicular drop</td>
<td>Moderate</td>
<td>Unknown</td>
<td>Yes</td>
<td>Yes</td>
<td>Unknown</td>
<td>Interesting development of anthropometric techniques that demonstrate potential. Worth exploring further.</td>
</tr>
<tr>
<td>Root model</td>
<td>Poor</td>
<td>Poor</td>
<td>Yes</td>
<td>Yes</td>
<td>Limited</td>
<td>Suffer limitations that fatally compromise its use in traditional form, although some Rootian concepts retain appeal.</td>
</tr>
<tr>
<td>Footprint</td>
<td>Moderate</td>
<td>Unknown</td>
<td>Yes</td>
<td>Yes</td>
<td>Limited</td>
<td>Focus on arch height, which seems an appropriate focus. Worthy of further exploration.</td>
</tr>
<tr>
<td>FHRQoL</td>
<td>Good</td>
<td>Unknown</td>
<td>No</td>
<td>Yes</td>
<td>Unknown</td>
<td>A promising development constituting an appealing secondary measure of foot function.</td>
</tr>
</tbody>
</table>
Summary points:

The literature reviewed in chapter 4 leads to several conclusions:

- Various ‘foot-type’ measures have been described in the literature, and these can be organised into categories based on their focus;

- Although various ‘foot-type’ measures have been described, and information on reliability can commonly be found, measurement validity is rarely examined;

- Where validity has been examined, it involves comparison against a measure perceived, but not established, as a vital determinant of foot function;

- Formulating a series of rationalised criteria for the ideal foot-type measure established a benchmark by which to judge existing tools, and helps identify those demonstrating potential for use in epidemiological enquiry;

- Of the existing techniques, footprint, anthropometric and foot-health related quality of life questionnaires appear to be the most robust, warranting further exploration;

- Whilst foot-health related quality of life assessment tools and navicular drop can be identified as the most developed measures of foot-type available, other techniques – particularly footprint measures – demonstrate face validity and therefore warrant further study to determine their validity;

- Validity is clearly a multi-dimensional construct, and for foot-type measures a valid tool can be thought of as one that satisfies various criteria. These include the ability to reflect dynamic foot function, to focus on theoretically and clinically important aspects of the foot, and to be capable of detecting small, clinically relevant, changes in STJ alignment;

- The importance of sensitivity to small changes in STJ alignment is justified because of the acknowledged importance of this joint in determining the mechanical characteristics of the foot. Rationalised in terms of anatomical, mechanical and experimental studies, this requirement seems crucial.

- Prior to conducting an observational study, it is vital to further examine the validity of existing tools to determine their true utility, and this is what the programme of research was designed to investigate.
Chapter 5

Research Aims:
Justifying the approach and sequence of studies

This chapter provides a focused overview of critical theory underpinning the choice, and sequence, of studies conducted. The overall aim is stated, and difficulties with previous research, principally concerning measurement tools and the study designs utilised, are highlighted. Theory drawn from various disciplines, including anatomy, podiatry, orthopaedics and research is presented, together with key references, to justify the approach adopted. This serves as a highly focused prologue to an account of the 5 studies undertaken, which follows in chapter 6.

The aim of the study was to investigate the relationship between foot function and chronic LBP. LBP is a common musculoskeletal complaint with significant socio-economic costs (Atlas and Deyo, 2001, Long et al., 1996) that has been linked, largely speculatively, with abnormal foot function (Bird and Payne, 1999, Builder and Marr, 1980, Dananberg, 1995, Dananberg, 1997). Previous studies investigating this issue, and the relationship between foot function and musculoskeletal pathology generally, have tended to investigate the influence of FFO's (devices designed to optimise foot function), and a causal relationship is assumed if there is a favourable therapeutic response (Dananberg and Guiliano, 1999). Even if such studies were improved, for example by employing explicit randomisation techniques, inclusion criteria, and robust outcome measures, to make them more like the RCTs to which they aspire, the information provided would still be incomplete. Although the legitimacy of this diagnosis-by-therapeutic-response approach to investigating cause has been acknowledged (Greenhalgh, 1996), it short circuits the traditional epidemiological approach by considering only one type of evidence. Epidemiology is defined as the study of the incidence, distribution and determinants of disease (Wald, 1996), and advocates the use of a sequence of studies over a single, supposedly
superior design (figure 5.1). Such studies are based on observations, using designs such as case-control and cohort, to examine disease or pathology development relative to exposure to the suspected causative factor. The evidence derived from such investigations contributes to the 'group evidence' ideal, where evidence from various sources is considered. This approach acknowledges that evidence relevant to clinical decision making is derived from many sources (Black, 1998a). Although observational studies may be considered a weaker form of evidence in the sequence, they represent an essential phase, and offer clear ethical advantages over experimental studies, which essentially progress from a 'hunch' to the provision of an unproven intervention.

Figure 5.1: The epidemiological approach to investigating cause (Gordis, 2000)

- Surveys: case series
- Case-control studies
- Cohort studies
- Experimental trials
- Randomised controlled trials
  - Explanatory
  - Pragmatic

It is axiomatic that epidemiological studies depend on the reliability and validity of the methods used to measure the factor of interest. Without information on these dimensions of any measurement, the accuracy of the information gathered is compromised and the results meaningless. Therefore, the design of a case-control study concerning foot-function demands that a suitable -valid and reliable- measure be identified. Dynamic foot function is complex, comprising multiple triplaner joint motions, and whilst accurate measurements are possible, this requires expensive, laboratory-based techniques (Redmond et al., 2001). The term 'foot-type' has evolved as a nebulous term describing a range of more convenient measures recorded statically but perceived to reflect dynamic foot function. An initial review of the
literature reveals that many foot-type measures have been described and are in routine use, seemingly presenting a choice of suitable techniques. However, closer scrutiny reveals that whilst the technically less demanding issue of reliability has been assessed for various measures and is generally acceptable, only limited information exists regarding validity. Weaker dimensions such as face or content validity, relating to theoretical appropriateness and inclusion of the various important elements contributing to foot function respectively, have been addressed. However, since dynamic foot function – foot motion during the gait cycle – is the critical factor likely related to the development of pathology, an essential pre-requisite to criterion validity is the ability of foot-type measures to reflect dynamic foot function. The absence of information regarding this critical dimension of validity renders the results of research based on these measures meaningless. A critical determinant of criterion validity therefore appears to be the ability of the static measures to reflect dynamic foot function.

A majority of foot-type measures relate directly to medial longitudinal arch (MLA) structure, and it is acknowledged that pes planus – the flat foot – and pes cavus – the highly arched foot – represent distinct clinical entities with opposing mechanical behaviour (Cavanagh and Rodgers, 1987). This focus on the MLA appears justified when the relationship between rearfoot position, the mechanical integrity of the foot, and the grossly predictable response of the MLA to changes in rearfoot position are considered. Further, this information may be used to formulate an approach to the assessment of criterion validity.
The relationship between the mechanical integrity of the foot and rearfoot position is widely acknowledged. Although explanations for this phenomenon have been offered (Elftman, 1960, Hicks, 1954a, Hicks, 1954b, Hicks, 1955, Manter, 1941), they are not universally accepted (Inman et al., 1994). However, even cynics have asserted that it is easily demonstrable that rearfoot inversion produces widespread stability that is lost with eversion (Inman et al., 1994). Recent investigations provide ever-more compelling information on the mechanisms involved and show the foot to possess numerous related mechanisms that contribute to the observed effects (Benink, 1985, Huson, 1991, Huson, 2000, Vogler and Bojsen-Moller, 2000).

Just as pedal stability is directly influenced by rearfoot position, so too is MLA structure. The relationship between these three variables can be summarised by stating that rearfoot motion changes foot structure, which results in predictable changes in arch configuration, which determines the mechanical integrity of the foot. The relationship is driven by the STJt, by virtue of its oblique axis. This permits the joint to act as a ‘...torque converter...’ to absorb internal and external limb rotations at the foot, while it remains fixed on the floor. However, this demands that a predictable response occurs in adjacent segments. This results in the kinematic coupling of the tarsal bones as a ‘...constraint system...’ in which passive co-operation is imposed by articular geometry and ligaments (Huson, 1991, Huson, 2000). Thus, as the limb internally rotates the talus adducts and plantarflexes as the calcaneus everts, reducing the profile of the MLA, whilst the converse occurs with external limb rotation (Nester, 1997). Simultaneously, a series of anatomical structures including the peroneus longus (Root et al., 1977), calcaneo-cuboid joint (Bojsen-Moller, 1979b, Vogler and Bojsen-Moller, 2000) and plantar fascia (Hicks, 1954b), are influenced to
determine stability. That these relationships are easily recognisable clinically is illustrated by considering the 60 year old assertion that:

'...by appropriate rotations about all three axes of the principles tarsal joints, the foot can be brought into a position similar to that seen in flatfoot'

(Manter, 1941).

It is therefore clear that foot-type measures focusing on the MLA have a theoretically sound background, in that they are attempting to gain insight to the position of the STJt and therefore the mechanical integrity of the foot. Further, measures of foot-type generally should, to satisfy the demands of criterion validity, be strongly associated with STJt position. Extrapolation of this information leads rapidly to the conclusion that measures of 'foot-type' should be sensitive to discrete, clinically important, changes in STJt position to be proven valid. This would suggest them to be capable of reflecting the mechanical status of the foot. However, the geometric truism that variances in subtalar axis orientation will influence the distribution of these motions demands that the possibility of grouping subjects participating in a validity study according to this variable be explored.

This information forms the background to this study, and can be summarised:

1. Foot orthoses are widely used for the treatment of a variety of musculoskeletal pathologies that are perceived to be caused by abnormal foot function;

2. A favourable therapeutic response to foot orthoses is taken as supporting evidence for such a relationship;

3. This approach derogates the value of other forms of evidence and assigns primacy, inappropriately, to the RCT design;
4. The role of epidemiology, which utilises observational studies (such as the case-control design) to investigate the issue of cause, represents a much more balanced approach to data collection, and potentially provides important clues regarding the nature of the association between foot-type and musculoskeletal pathology;

5. Case-control studies depend on the valid and reliable measurement of both the suspected causative factor and pathology of interest;

6. Consideration of the substantial literature base concerning the structure and function of the STJt and its relationship with both the stability of the foot and with MLA architecture contributes to the face validity of MLA foot-type measures;

7. More importantly, this information suggests that a useful approach to examining the criterion validity of foot-type measures is to examine their response to discrete changes in STJt position;

8. It is a geometric truism that anatomical variations in subtalar axis orientation will influence the response of foot structure to STJt motion. Therefore, to fully appreciate the association between foot-type measures and subtalar motion it may be necessary to take consideration of subtalar axis orientation.

On the basis of this information a three phase project was developed:

- **Phase one**

  Phase one set out to examine preliminary issues concerned with the design of a validity study. This began with assessment of the feasibility of categorising patients according to STJt axis orientation. This recognises that whilst the relationship between linked tarsal motions is predictable, individual anatomical variations in STJt structure is likely to result in
important differences in precise subtalar axis location (Close et al., 1967). Therefore, the exact distribution of tarsal motions resulting from internal and external limb rotations is likely to differ amongst individuals, and categorising subjects according to gross STJt axis location, identified using the only feasible clinical technique possible (Green and Carol, 1983) may improve the quality of the validity study. However, prior to the incorporation of this classification technique, its reliability had to be assessed. This led to the first study, titled *Reliability of Clinical Estimation of Subtalar joint Axis Orientation*.

Prior to conducting a validity study, the measures to be assessed had to be identified. *Navicular drop* has been the subject of several investigations, including reliability assessments that suggest it to demonstrate acceptable intra-rater reliability (Vinicombe et al., 2001), to satisfy the important validity criterion of explicitly attempting to measure dynamic motion, and to be related to dynamic function (Cornwall and McPoil, 1999). This evidence suggests it to be an obvious measure to select for further validity testing.

*Navicular drop* involves measuring sagittal motion of the navicular between the Neutral and RCSPs, which theoretically relates to the amount of compensation occurring dynamically (Root et al., 1971), indicating face validity. A similar measure, also based on motion between the Neutral and RCSPs is *Static calcaneal compensation*. Although information regarding reliability is available, and is encouraging (Sell et al., 1994), the
relationship between *static calcaneal compensation* and dynamic calcaneal function has not been investigated. To permit an informed decision to be made regarding the suitability of *static calcaneal compensation* for inclusion in a validity study, the relationship between static and dynamic calcaneal function was felt to be a priority. Therefore, a study titled *Validity of measurement of static calcaneal compensation as an indicator of dynamic calcaneal motion* was designed to examine this dimension of validity prior to further testing.

Footprint measures were also felt to fall into the category of measures that whilst enjoying reasonable theoretical support, may be fundamentally flawed because of the inherent assumption that the static measure adequately predicts the dynamic. It was therefore felt important to assess the relationship between footprint measures calculated from static and dynamic footprints to determine the association between the two. Therefore, a study titled *Comparison of footprint parameters calculated from static versus dynamic footprints*, was conducted to determine whether footprint measures warranted inclusion in further validity testing.

- **Phase two**

Phase two centred around a study examining the validity of selected measures of foot-type. The measures evaluated in this study were identified from the literature, and from the ‘*static versus dynamic*’ studies conducted in phase one. The measures included were *navicular drop*, *static calcaneal compensation* and two footprint measures. This study was
titled 'Examining the validity of selected foot-type measures', and allowed identification of the most useful measures that could be used to conduct a case-control study. This study examined the sensitivity of each measure to sequential 5° changes in STJt, from a position of maximal comfortable calcaneal eversion through a range of 30°. Given that the reported range of motion of the joint lies somewhere between 10° and 40° according the reports in the literature, 5° increments represents between ½ and 1/6 the total range of motion.

- **Phase three**

The final phase of the study involved the utilisation of measures of foot-type identified as valid and reliable, and an additional, foot health related quality of life measure that had previously been subjected to rigorous reliability and validity testing, in a case-control study. This study involved the recruitment of a series of patients suffering with chronic LBP and a series of group-matched controls reporting no significant history of LBP. Back pain status was confirmed using the Quebec Back Pain Disability Questionnaire, which measured back pain severity. This study was titled *Foot-type and chronic LBP: a case control study*, and completed the series of investigations.

Whilst subject selection in observational research is clearly vital, it is also important for validity studies. Where there is evidence that the variable being measured is likely to differ significantly in the population, subjects must be selected to ensure that the measurement in question would not
inherently vary substantially from the final study population. Current knowledge of foot function measurement is derived from studies conducted in a variety of international research centres. Results are largely consistent, producing a picture of foot function which does not seem to differ substantially, in a way that would threaten validity, between populations that differ in terms of age, sex, activity levels and ethnicity. Further, there is no evidence that a specific population should be sought for this particular investigation; whilst it is suspected that foot function may differ between cases and controls, the intrinsic anatomical and physiological characteristics within the two populations should be ostensibly the same. This permits the use of convenience samples for reliability and validity testing.

This background links the five studies performed in the project:

1. Reliability of clinical assessment of Subtalar joint axis orientation;
2. Validity of measurement of static calcaneal compensation as an indicator of dynamic calcaneal motion;
3. Comparison of footprint parameters calculated from static versus dynamic footprints;
4. Examining the validity of selected foot-type measures;
5. Foot-type and chronic LBP: a case control study.

Each of these studies will be presented in the following chapter, which will provide a brief summary of the background, details of the method, data analysis and results.
Chapter 6

Account of the individual research studies conducted

This chapter provides details of the five studies conducted to investigate the relationship between foot function and chronic LBP. Since the approach was developmental, with the results of each stage influencing choices for the successive stage, the studies are presented sequentially, with an introduction, details of the method, statistical analysis, and results. Although a discussion follows in chapter 7, this focuses on the general approach, philosophy and outcomes of the whole project. Issues relating to the method and results of the individual studies are provided here, to place them in an appropriate context to understand their impact on the progression of the project.

6.1 Reliability of clinical estimation of subtalar joint axis orientation
6.1.1 Background
6.1.2 Method
6.1.3 Results
6.1.4 Discussion

6.2 Validity of statically measured calcaneal motion as an indicator of dynamic calcaneal function
6.2.1 Background
6.2.2 Method
6.2.3 Results
6.2.4 Discussion

6.3 Comparison of footprint parameters calculated from static versus dynamic footprints
6.3.1 Background
6.3.2 Method
6.3.3 Results
6.3.4 Discussion

6.4 Examining the validity of selected foot-type measures
6.4.1 Background
6.4.2 Method
6.4.3 Results
6.4.4 Discussion

6.5 Foot-type and chronic low back pain: a case control study
6.5.1 Background
6.5.2 Method
6.5.3 Results
6.5.4 Discussion
6.1 Reliability of clinical estimation of Subtalar joint axis orientation

6.1.1 Background

The STJt has been described as the ‘...determinative joint of the rearfoot, influencing the performance of the more distal articulations and modifying the forces imposed on the skeletal system and soft tissues’ (Mann, 1993). Such assertions are based on the predictable changes in structure and mechanical integrity that occur in the foot in response to STJt motion. These characteristics are attributed to the triplaner orientation of the STJt axis which permits it to function as a torque converter to absorb internal and external limb rotations while remaining fixed on the floor. However, maintaining pedal stability whilst these rotations occur demands that a predictable response occurs in adjacent segments. Such a response occurs by virtue of the kinematic coupling of the tarsal bones in a ‘...constraint system...’ in which passive co-operation is imposed by articular geometry and ligaments (Huson, 1991, Huson, 2000). Thus, as the limb internally rotates the talus adducts and plantarflexes as the calcaneus everts, reducing the profile of the MLA, whilst the converse occurs with external limb rotation (Nester, 1997). Simultaneously, a series of anatomical structures including the peroneus longus (Root et al., 1977), calcaneo-cuboid joint (Bojsen-Moller, 1979b, Vogler and Bojsen-Moller, 2000) and plantar fascia (Hicks, 1954b), are influenced to provide increasing stability.

Foot-type measures claim to offer an insight to the functional status of the foot, and focus directly on pedal structure. Since the STJt appears to be a vital determinant of foot structure, it seems reasonable to suggest that the ability of measures to respond to discrete changes in STJt motion is an important validity criterion. Identifying measures that consistently increase or decrease in value as the STJt changes position would provide robust support for the contention that they truly provide insight to the mechanical status of the foot.

A confounding variable that may obscure the relationship between foot-type measures and STJt motion is the variability of the axis between individuals. For example, whilst it is acknowledged that the talus adducts and plantarflexes as the calcaneus everts in response to internal limb rotation, this occurs because of the oblique orientation of the STJt axis. Therefore, it is a geometric truism that variations in axis orientation will influence the amount of each motion that results from a given amount of internal
rotation. The assertion that ‘...the orientation of the axis accounts for variations in the type of foot.’ (Close et al., 1967) seems reasonable as cadaveric studies of subtalar axis orientation reveal considerable variability (table 1) (Manter, 1941, Root et al., 1966). Such variations would be capable, at least theoretically, of significantly influencing the pedal structural response to STJt motion.

Whilst the subtalar axis has been the focus of attention, it has been contended that a composite, rearfoot complex axis should be the focus, on the basis that since there are several joints contributing to rearfoot function, focusing exclusively on the STJt is inappropriate. However, the rearfoot complex axis seems to lie in a position that is within the reported range of the STJt axis (table 6.1). This indicates the STJt to be either the dominant influence on, or functionally indistinguishable from, the rearfoot complex axis.

<table>
<thead>
<tr>
<th>Study</th>
<th>No. of Feet</th>
<th>Inclination from transverse plane</th>
<th>Inclination from Sagittal plane</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Average</td>
<td>Range</td>
</tr>
<tr>
<td>Subtalar axis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Manter, 1941)</td>
<td>16</td>
<td>42°</td>
<td>29-47°</td>
</tr>
<tr>
<td>(Root et al., 1966)</td>
<td>22</td>
<td>41°</td>
<td>22-55°</td>
</tr>
<tr>
<td>(Ismail and Inman, 1969)</td>
<td>46</td>
<td>41°</td>
<td>20-68°</td>
</tr>
<tr>
<td>Rearfoot Complex Axis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Downing et al., 1978)</td>
<td>50</td>
<td>51°</td>
<td>32-62°</td>
</tr>
<tr>
<td>(Bowden and Bowker, 1995)</td>
<td>27</td>
<td>48°</td>
<td>Not given</td>
</tr>
</tbody>
</table>

Several techniques for assessing the position of the STJt axis have been proposed. These include simple observational techniques for evaluating sagittal inclination (Green and Carol, 1983) and transverse deviation (Kirby, 1987), and a technique involving clinical measurement of sagittal, frontal and transverse motions which are then inserted in an equation to allow calculation of the ‘precise’ axis orientation (Phillips and Lidtke, 1992). Although the technique utilising equations appears most accurate, due to increased objectivity associated with the measurements recorded, there are important limitations of this technique. These principally arise from the accuracy of measurements obtained using subjectively identified landmarks and instruments / techniques with questionable reliability (Keenan, 1997). The time required for performing both the measurements and calculations is also considerable.
A similar technique has been proposed for assessing the *rearfoot complex axis* (Downing et al., 1978), but suffers from similar difficulties.

The two observational techniques differ significantly, in that one is focused on medial deviation of the axis (Kirby, 1987) and the other is focused on the sagittal inclination (Green and Carol, 1983). Medial deviation was discussed in the context of its effect on subtalar equilibrium, and a technique was devised for clinical evaluation of medial deviation (Kirby, 1987). The clinical utility of this information, in terms of understanding the balance of moments acting around the STJt, was then presented, and provided the theoretical base for the development of an orthotic technique that offered improved pronation control (Kirby, 1989, Kirby, 1992). The final technique relates to assessment of sagittal inclination which relates directly to, and was explained and justified in the context of, the torque conversion function (Green and Carol, 1983). This method involves subjective comparison of the arc of transverse plane motion of the forefoot relative to the arc of frontal plane motion of the calcaneus as the STJt is passively moved through its range of motion. A foot with a high axis will display large amounts of transverse plane forefoot motion, with a relatively small range of frontal plane calcaneal motion. Conversely, with a low axis frontal plane calcaneal motion dominates whilst minimal transverse plane forefoot motion occurs (figure 6.2).

**Table 6.2: Variations in subtalar joint axis orientation and the influence on motion.**

This figure illustrates the concept of axis height and the influence on the motion that results from STJt rotation (Green and Carol, 1983)

<table>
<thead>
<tr>
<th>High Axis</th>
<th>Normal Axis</th>
<th>Low Axis</th>
</tr>
</thead>
<tbody>
<tr>
<td>A high axis is closer to 90° to the transverse plane, increasing the amount of transverse plane limb rotation that results from subtalar motion.</td>
<td>A normal axis is approximately 45° from both frontal and transverse, resulting in equal amounts of motion in both these planes.</td>
<td>A low axis is closer to 90° to the frontal plane, increasing the amount of frontal plane calcaneal rotation that results from subtalar motion.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>30°</th>
<th>60°</th>
<th>300</th>
<th>60°</th>
<th>30°</th>
<th>60°</th>
</tr>
</thead>
</table>
Before a clinical evaluation technique is utilised for subject classification for research purposes, its reliability and validity should be assessed. Validity is a multi-dimensional construct, and whilst dimensions such as face validity, which looks superficially at a technique to assess its apparent suitability (Gomm et al., 2000), more detailed dimensions are required to truly convince. For example, criterion validity can be established through comparison of a new measure with an existing 'gold standard' where this is available. Although a 'gold standard' technique does exist for evaluating STJt axis orientation, the technique is invasive, expensive, and time-consuming, involving precise tracking of triplaner STJt motion to permit accurate calculation of axis orientation. Example 'gold standard' techniques include the use of highly accurate kinematic techniques to obtain measurements of triplaner joint motion to obtain values for inserting into equations. Options include the use of either expensive, multi-camera systems such as the VICON™ or MACREFLEX™, or roentgen stereophotogrammetry, which involves the insertion of metallic markers into the major osseous segments, followed by radiographic analysis of these markers through the range of motion to permit accurate measurement (Selvik, 1974). Therefore, although the face validity of the technique appears acceptable, use of the technique must be fully cognisant of the fact that comparative validity of the technique has not been established, and represents an extensive undertaking in its own right.

In contrast to validity, reliability has been defined as the amount of consistency between successive measurements of the same variable on the same subjects under the same conditions (Lea and Gerhardt, 1995). Two classes of reliability exist, with intra-rater describing the consistency of a single rater's performance, and inter-rater reliability describing consistency between separate observers (Norkin and White, 1995). Both classes of reliability can be assessed using repeated-measures study designs, where multiple clinicians are asked to judge the same subjects on multiple occasions. Comparison of single clinicians' successive ratings can then be evaluated to score intra-rater reliability, and comparing their performance can also assess consistency between clinicians. Establishing the reliability of a technique is a vital preliminary step if it is to be utilised for either clinical or research purposes.
The aim of the study was to investigate both intra-and inter rater reliability of the technique for clinical assessment of STJt axis orientation. Two hypotheses were devised:

1. The clinical technique for identifying the orientation of the STJt axis demonstrates acceptable intra-rater reliability;
2. The clinical technique for identifying the orientation of the STJt axis demonstrates acceptable inter-rater reliability.
6.1.2 Method

A group of eighteen participants was recruited into the study to be assessed, and four clinicians with a minimum of two years of experience in conducting biomechanical assessments were recruited to perform repeated assessments. Each clinician assessed each participant twice on two separate days, one week apart, to minimise recall bias. Participants were evaluated twice on each day to maximise the number of repetitions whilst minimising follow-up problems. Potential differences in axis orientation between the left and right limbs were inconsequential as reliability was the major concern, and so only the right foot was examined. All eighteen participants reported healthy lower limbs and feet, with no history of trauma or illness. The study methodology was approved by the Ethics committee of the School of Health and Social Sciences, University of Wales Institute, Cardiff.

Assessments were conducted in a room with four identical examination couches, and participants were randomly assigned to one of four groups of four and a group of two. Each group was seen individually. Upon entering the examination room participants self-selected an examination couch, took off shoes and socks, and lay in a prone position to allow a rearfoot examination to be easily conducted. The clinicians then entered the room and each stood next to an examination couch. Clinicians spent one minute with each participant, and a timekeeper signalled when this time period had passed. Clinicians then rotated clockwise around the participants until all had examined each subject. Clinicians prepared each participant by adjusting the examination couch to the required height and then rotating the limb to be examined into the frontal plane to reduce parallax error. This involved flexing the left knee, abducting the left hip and lowering the leg over the fully extended right limb. Each clinician determined the degree to which such positioning was necessary. An estimate of the orientation of the subtalar axis was then made using the technique described by (Green and Carol, 1983), using the categories Clearly low, Low, Average, High, Clearly high.

One week prior to data collection each clinician was provided with a copy of the article in which the original technique was described. A group discussion was held three days later to allow discussion of the technique, any questions to be answered, and to provide an opportunity to practice. This session lasted 40 minutes, and
involved assessment of a group of 4 volunteers. During this session all clinicians expressed dissatisfaction with the three available categories. All felt that there were feet in the practice group that could not comfortably be classed as normal, but neither could they truthfully be described as 'clearly' high or low. A proposal was made that two additional categories be added, 'clearly high' and 'clearly low', to provide five categories in all: clearly high, high, average, low, clearly low. All clinicians felt more comfortable with the use of this system after a further practice session, and it was decided to adopt this system for the actual study.

Four data collection sheets were issued to each clinician. This was laid out as a table with a row for each subject, and a column for each possible response. This meant that clinicians simply had to tick the box matching their selection. Participants were issued with a number between 1 and 18, and this was displayed at the end of the examination couch so that the clinicians knew which row to record their rating in. All 18 participants were rotated through twice to permit two rounds of data collection to take place with a gap to minimise recall bias. Each data collection sheet was used only once and surrendered at the end of each data collection round so that clinicians had no record of their previous response. Data collection sheets from each round were kept in a sealed envelope until the end of the study.

Each clinician assessed each participant 4 times. Data was labelled using a letter to denote the clinician (A,B,C,D), and a number to denote the 1st, 2nd, 3rd and 4th time the participants were assessed. A numerical value was assigned to each response category to facilitate analysis: 1= Clearly high, 2 = high, 3= average, 4= low, 5= clearly low. Although 18 subjects were recruited to the study, only 13 attended both data collection sessions, and statistical analysis was therefore conducted on this reduced group.
6.1.3 Results

Four clinicians examined 13 subjects on four separate occasions. This resulted in 52 observations per clinician. An insight to the responses provided by the clinicians, both as individuals and as a group, can be obtained by considering the descriptive statistics. The median response was ‘3’ for all clinicians except C, whose median response was ‘2’. The mode for all clinicians was ‘3’, and these figures reveal that the central, ‘normal’ category was the most common response. More detail on the responses selected by each clinician can be obtained in graph 6.1, which shows the frequency of selection of each response for each clinician. Graph 6.2 shows the responses assigned to each individual participant, and provides an important overview of the consistency of the scores assigned to each subject.

Graph 6.1: Spread of STJt axis orientation classification scores for each clinician
This graph shows a negative skew, as subjects were commonly rated average-high.

Graph 6.2: Subtalar joint axis orientation categories assigned to each subject over the entire trial
All subjects were evaluated 16 times – 4 times by each clinician. The majority were rated in >1 category, and some to 3. Only subject 8 was consistently ranked in one category by all clinicians, whilst subject 11 was ranked in four of the five categories possible.
Both *intra-rater* and *inter-rater* reliability were then assessed using the same inferential testing procedure. Kendall’s coefficient of concordance was used to examine overall agreement between multiple data sets. This is recommended as a solution to the problem of ascertaining the overall agreement among *k* sets of rankings without resorting the use of multiple Spearman’s correlations (Siegel and Castellan, 1988). An alternative method of assessing reliability could have been to use the Friedman’s ANOVA by ranks, which takes the alternative approach of determining whether significant differences exist between data sets. However, Kendall’s *w* and Friedmans tests are linearly related, with *n* and *k* being interchanged between the two tests (Siegel and Castellan, 1988). Since the same results are obtained from both tests only the most appropriate need be used, in this case the Kendall’s coefficient of concordance since this sets out to determine agreement.

Examination of intra- and inter-rater reliability involved similar analyses, differentiated only by the data sets evaluated. Intra-rater reliability involved comparison of the four data sets produced by each clinician independently, whilst for inter-rater reliability it involved comparison of each clinicians 1st, 2nd, 3rd and 4th data sets.

**Intra-rater Reliability**

Intra-rater reliability was examined by assessing the agreement between each clinicians four data sets. For example, clinician A’s 1st, 2nd, 3rd and 4th assessments of the thirteen subjects were evaluated as a set to examine the association, with the process repeated for clinicians B, C and D. Table 6.3 details the results, showing that *w* ranged from 0.108 – 0.229, equating with significance levels of between 0.09 – 0.3. Based on a null hypothesis that *k*=4 sets of data are independent, these results provide no reason to reject this, suggesting that there are indeed differences between the data sets.

<table>
<thead>
<tr>
<th>Data</th>
<th>Kendall's coefficient of concordance</th>
<th>result</th>
</tr>
</thead>
<tbody>
<tr>
<td>sets</td>
<td><em>N</em></td>
<td><em>w</em></td>
</tr>
<tr>
<td>A1-A4</td>
<td>13</td>
<td>0.14</td>
</tr>
<tr>
<td>B1-B4</td>
<td>13</td>
<td>0.23</td>
</tr>
<tr>
<td>C1-C4</td>
<td>13</td>
<td>0.11</td>
</tr>
<tr>
<td>D1-D4</td>
<td>13</td>
<td>0.16</td>
</tr>
</tbody>
</table>

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Inter-rater reliability

Inter-rater reliability was examined in the same way as intra-rater, with data sets from each of the four clinicians being tested together. Kendall’s \( w \) ranged from 0.05 to 0.66, equating with significance levels of 1 to 0.2 (table 6.4) Once again, these results suggest that the null hypothesis that the \( k=4 \) data sets are unrelated cannot be rejected.

Table 6.4: Kendall’s coefficient of concordance: inter-rater reliability assessment

<table>
<thead>
<tr>
<th>Data sets</th>
<th>Kendall’s coefficient of concordance result</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>( n ) ( w ) ( \chi^2 ) df Sig.</td>
</tr>
<tr>
<td>A1-D1</td>
<td>13 0.120 4.69 3 0.2</td>
</tr>
<tr>
<td>A2-D2</td>
<td>13 0.66 2.6 3 0.5</td>
</tr>
<tr>
<td>A3-D3</td>
<td>13 0.05 0.2 3 1</td>
</tr>
<tr>
<td>A4-D4</td>
<td>13 0.35 1.4 3 0.7</td>
</tr>
</tbody>
</table>

These results are consistent with graphs 1 and 2, which show that only one subject was consistently rated in one category, 7 subjects are placed in three different categories, and the remainder into two categories.
6.1.4 Discussion

It is a geometric truism that the orientation of the STJt will impact on the torque conversion mechanism of the STJt to influence the distribution of motion in the rearfoot. Consequently, this will influence motion in the mid- and fore-foot. Because foot-type measures focus on variables that are heavily influenced by STJt motion and position, the location of the subtalar axis may need to be considered when examining the sensitivity of these measures. This may avoid a type II error where they are rejected as insensitive, when it is actually differences in axis orientation that is responsible for a variable response between subjects. Therefore, sub-classification of subjects into axis orientation categories may potentially provide a more accurate insight to foot function (and subsequently its relationship with musculoskeletal pathology) than might otherwise be possible if it is ignored.

To allow categorisation of subjects by subtalar axis orientation, a reliable and valid evaluation technique is required. Since absolute measurement of axis orientation is only possible with the use of complex, expensive and time-consuming techniques, simple clinical procedures offer clear advantages for situations that require evaluation of large numbers of subjects. This leaves the clinical technique, involving comparison of the arcs of motion of the forefoot and calcaneus (Green and Carol, 1983) as the only pragmatic choice, as it offers the best compromise between speed, ease of use, cost, and face validity. However, prior to its use issues of reliability and validity must be addressed to increase confidence in its use. Information on robust dimensions of validity is difficult to gather and would involve, for example, comparison with an invasive, expensive and time-consuming ‘gold standard’, to satisfy the conditions of criterion validity. However, reliability involves evaluation of consistency between successive measurements of the same variable, and can be explored using repeated measure designs. Information on reliability is a fundamental pre-requisite to the use of the technique, whether clinically or for research purposes.

This study suggests that neither intra-rater nor inter-rater reliability is acceptable, prohibiting the use of the technique. Even before considering the results of inferential statistical tests, the limitations of the technique can be clearly seen in graphs 1 and 2. Firstly, graph one demonstrates that most subjects were ranked in the middle category, as average, and more were assigned to the ‘high’ and ‘clearly high’
categories than to the lower two categories. This in itself suggests that the technique is flawed, because it is accepted that the ‘normal’ foot that is most frequently encountered is slightly pronated, which would produce a lower and more medially deviated STJt axis (Close et al., 1967, Kirby, 1989). Therefore, although the technique seems to satisfy the conditions of face validity by appearing appropriately focused, this is compromised by the apparently disproportionate assignment of subjects to uncommon categories. The study did not attempt to recruit subjects with a range of STJt axis locations, therefore it is unlikely that the categories subjects were assigned to represent were accurate. Thus, although the validity of the technique was not explicitly addressed in the study, the negative skew displayed in graph 6.1 is enough to realistically suggest that the technique suffers from poor validity.

Graph 6.2 provides important information on the reliability of the technique, which independently of inferential statistics, indicates poor reliability. This graph shows that only one subject out of thirteen was consistently categorised by all clinicians on all occasions. The rest were assigned to either two or three separate categories, with wide variation. The multiple colours in each bar of the graph, which reveals substantial variation, illustrate this. Uniformly coloured bars, indicating that a single category was consistently used, would have indicated acceptable reliability.

Inferential statistics confirm the suspicions aroused by descriptive statistics and graphs, and further re-enforce the conclusions drawn from these. Kendall’s coefficient of concordance failed to identify any significant associations between data sets, for either intra- or inter-rater reliability. Results did, however, differ for intra-and inter-rater reliability. This is due to the greater difficulty in getting a group of individual clinicians to agree not only with themselves, as with intra-rater reliability, but with each other (Keenan, 1997). Where a measurement technique is to be used widely by different clinicians, both aspects are vital. For research purposes, where the measurement is to be used by single data collector, it could be argued that establishing intra-rater reliability may be enough, since it is the reliability of the measurement in the hands of the individual conducting data collection that is critical. Inter-rater reliability could be considered important if the technique was to be widely adopted in multiple clinics and by multiple clinicians. Achieving inter-rater reliability is likely to require extensive training of the individuals involved and may require the use of focus

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groups to ensure that they all respond in the same way when taking measurement, to ensure agreement (Norkin and White, 1995). This is supported in the current study by considering the intra- and inter-rater Kendall’s \( w \) results. It is no surprise that the values, although remaining non-significant at 0.108 – 0.229, are better than the inter-rater figures of 0.2-1. However, in this case even intra-rater reliability of the technique demonstrates weak reliability.

The expansion of the technique from the use of three categories to the use of five represents an important aspect of the study. Although this was intended to improve reliability, and was done only after careful consideration, it may actually have been detrimental to reliability. Further analysis of the data, involving collapsing the two additional categories into the three original categories, might have produced better results. However, performing this analysis would not be valid, since it would involve an assumption about the category into which ‘low’ and ‘high’ feet should be placed. Specifically, if only three categories were available then it would be flawed to assume that a ‘low’ axis would be assigned to ‘clearly low’: there is every chance that it would be categorised as ‘normal’ if only three categories were available. It seems likely that inconsistencies would exist, and therefore further analysis of this issue would require that the study be repeated using the original three categories.

Opportunities for improving the objectivity of an essentially subjective technique do exist, however. For example, one study assessed the reliability of visual assessment of arch height, but used standardised photographs taken using a bespoke mirror array, that illustrated multiple views simultaneously, to provide multiple standardised views (Cowan et al., 1994). Although such steps are undoubtedly useful, the technique was still found to have poor reliability. Therefore, although a more standardised approach could be employed to increase objectivity, it remains ultimately a subjective technique, and such steps provide no guarantee of good, or even acceptable, reliability levels. It therefore appears that whilst considering axis orientation represents a theoretically valid approach, it is currently not possible to achieve this due to the high cost and invasive nature of the techniques involved. Further, utilising this approach would bring the additional difficulty of recruiting sufficient numbers of subjects to each category to permit meaningful statistical analysis. The difficulty presented in recruiting and maintaining subjects is reflected in the loss of 5 subjects between the
two data collection sessions. This makes it clear that the use of two limbs is a better choice, as it permits the collection of maximal data from the subjects available. For a pure reliability study where the simple number of limbs assessed is important, it is a lost opportunity to only collect data from one limb when the other is also available.

Whilst it appears that axis orientation is difficult to reliably estimate using current clinical techniques, the implications of variations in axis orientation on the distribution of motion between tibia and calcaneus can be calculated precisely. This would involve calculating the distribution of motion that would occur with axes at the mean, upper, and lower locations reported in various cadaveric studies (Isman and Inman, 1969, Manter, 1941, Root et al., 1966). However, although the distribution of tibial and calcaneal motion that would occur around axes demonstrating different orientations can, and has been, investigated (McClay and Manal, 1997, Phillips et al., 1985, Phillips and Lidtke, 1992), this need not provide meaningful information on the resultant distribution of motion that would occur distally in the foot. It is this distal response that potentially impacts on foot-type measures, which focus not on the coupling characteristics between the tibia and calcaneus, but on foot structure. Although the intricacies of midfoot joints such as the talonavicular, naviculocuneiform and cuneiform-metatarsal have been investigated (Lundberg, 1989, Lundberg et al., 1989a, Lundberg et al., 1989b, Lundberg et al., 1989c), they are not yet understood to the extent that their response to subtalar motion can be consistently predicted.

The reliability of this, and indeed any, technique could likely be improved by laboratory and clinical development of the technique, by extensive practice and the development of standardised protocols. Therefore, two options remain. Further attention could be directed towards the development of the technique, to the detriment of the original study aim, or it can be conceded that accurate classification of subjects according to subtalar axis orientation is difficult due to the absence of a simple but valid and reliable clinical technique, and may in reality be beyond the scope of the project. The available evidence suggests this latter option to be most appropriate, and so the project will abandon its efforts to employ a sub-classification technique that represents what is perhaps an unnecessary complication. Whilst the organisation of subjects according to subtalar axis orientation for more accurate investigation of foot
function remains an attractive possibility, examination of exactly how this could be achieved is out with the scope of the current project.
6.2 Validity of statically measured calcaneal motion as an indicator of dynamic calcaneal function

6.2.1 Background

Epidemiologists recommend that the relationship between a particular factor and pathology should be understood before interventions targeting that factor are examined. Observational studies, using for example cohort or case-control designs, are recommended as the essential first step in examining cause (Gordis, 2000, Vetter, 2000). These studies recruit large numbers of participants and allow various calculations to be performed. These concern, for example, disease rates in populations with and without factors of interest to provide information on the cause of the disease and the potential public health benefit of removing that exposure. A critical design feature is the use of an appropriate – i.e. valid and reliable - technique for measuring the factor of interest (Rose, 1991). In the context of foot function and musculoskeletal pathology, this involved the use of a robust measure of foot function. Although laboratory based gait analysis permits objective and reliable quantification of foot function (Redmond et al., 2001), the time and cost involved render this type of analysis inappropriate for epidemiological enquiry. Numerous alternative measures have been proposed, including footprint indices, anthropometric and radiographic measures (Williams and McClay, 2000). An important limitation of these measures is that they are recorded in static stance. Since dynamic foot function is the prime concern, it is logical to suggest that the ability of static measures to predict dynamic function is a fundamental pre-requisite to validity.

Two foot-type measurement techniques have been proposed that explicitly attempt to assess dynamic rearfoot function. These are the navicular drop (Brody, 1982) and calcaneal motion (Sell et al., 1994) tests. Both of these bones are components of the STJt, with the calcaneus attaching to the inferior surface of the talus and the head of the talus articulating distally with the navicular. This arrangement of bones has together been referred to as a functional unit termed the talocalcaneonavicular complex (Draves, 1986). Whilst the talus lacks accessible landmarks from which to measure motion, both the posterior calcaneus and navicular tuberosity provide reliable and easily accessible landmarks that can be used for this purpose (Cornwall and McPoil, 1999, Mueller et al., 1993, Root et al., 1977, Vinicombe et al., 2001).
Therefore, measuring motion in these bones provides the opportunity of an insight to subtalar motion, which is accepted as an important determinant of foot stability and mechanical performance (Huson, 1991, Huson, 2000, Root et al., 1977).

Both techniques involve measurement of motion of the marked bone between the Neutral Calcaneal Stance Position (NCSP) and the Relaxed Calcaneal Stance Position (RCSP). These positions originate from the Root model, where the NCSP represents the optimal, and the RCSP represents the actual, functional position of the STJt (Lee, 2001a, Root et al., 1977, Root et al., 1971). This model acknowledges the interactions between the separate segments of the lower limb and asserts that they will combine to influence the foot in a largely predictable manner (Philps, 1995). This combined influence is determined by assessing the NCSP and RCSP positions on the basis that in the absence of any musculoskeletal anomaly the two positions should be practically the same. Any difference between the two positions will reflect the neuromusculoskeletal anomalies occurring within the limb. Therefore, measuring the motion of the calcaneus or navicular between the NCSP and RCSP positions should provide a valid indication of dynamic subtalar motion, provided that the bones assessed accurately reflect events at the STJt.

The navicular drop test was originally proposed as a practical method of pronation in runners (Brody, 1982), and involves marking the tuberosity of the navicular to allow measurement of sagittal motion between NCSP and RCSP. Three reliability studies (Mueller et al., 1993, Picciano et al., 1993, Sell et al., 1994), have been conducted which suggest reasonable intra-rater reliability. Development of the technique to include transverse motion has also been suggested as a more accurate reflection of true navicular motion (Vinicombe et al., 2001), although this technique requires further exploration. Dynamic navicular motion has also been examined using electromagnetic tracking equipment. Movement was referenced to the height measured in relaxed calcaneal stance (Cornwall and McPoil, 1999), and identified that the pattern of motion occurs around the relaxed position, undergoes significant sagittal and transverse excursions, and correlates well ($r=0.94$) with rearfoot motion. The $r^2$ statistic was calculated, and at 0.89, indicates that navicular and rearfoot motion are strongly predictive of each other.
The calcaneal motion technique involves measurement of frontal plane calcaneal motion between the NCSP and RCSP positions, using a posterior calcaneal reference line (Sell et al., 1994). This technique appears more reliable than the original measurements of neutral and RCSPs, which require an accurate calcaneal bisection line (Root et al., 1971), and represents a significant development of the original which was concerned with the assessment of absolute position rather than dynamic motion. Originally separate bisections were applied in both NCSP and RCSP as it was suggested that skin movement between the two would compromise the validity of the bisection line which was intended to accurately reflect STJt alignment. The improved reliability reported by Sell et al (1994) may be attributed to the use of a single line, and suggests that motion between the two positions can be reliably measured. However, although the motion between the NCSP and RCSP appears reliable, the functional significance of this motion, in terms of its relationship with dynamic calcaneal function, is unknown.

The aim of the study was to investigate the validity and intra-rater reliability of statically measured calcaneal motion. Three hypotheses were set:

1. Relating to the bench-testing of the electrogoniometer to be used in the study:
   a. The electrogoniometer can accurately measure motion taking place in a single plane on a testing jig.

2. Relating to the reliability of the static and dynamic data recording procedures:
   a. The procedure for recording static calcaneal motion between the NCSP and RCSP positions is reliable.
   b. The procedure for recording dynamic calcaneal motion is reliable.

3. Relating to the validity of static measurement of calcaneal motion:
   a. There is acceptable agreement between static and dynamic measurements of calcaneal motion.
6.2.2 Method

A convenience sample of 10 students were recruited to the study. The study aimed to investigate the relationship between static and dynamic calcaneal motion, and therefore it was unnecessary to select subjects representative of a given population. The study was approved by the University of Wales Institute, Cardiff research ethics committee. Participants were predominantly female, with only one male in the sample, age ranged from 20-42 years, weight ranged from 45-125 kg and height ranged from 1.58-1.87 metres. Subjects satisfied the following inclusion / exclusion criteria:

- No history of recent foot and ankle pain (within the previous six months);
- No history of any leg/foot injury or surgery;
- No signs of gait disturbance on visual observation;
- An ability to understand the nature of the trial, and to provide consent.

Consent was obtained from each subject prior to data collection.

A single observer conducted all investigations, because the purpose of the study was to identify a measure that could be used in the first instance by a single rater, with inter-rater reliability deemed a separate issue. It is also, for very good practical reasons, easier to achieve an acceptable level of intra-rater reliability.

Measurement of both static and dynamic calcaneal motion was undertaken using a Penny & Giles Twin Axis goniometer model M180 with data logger DL1001. The data gathered was downloaded data to a Viglen P5/233MHz MMX PC for analysis. The M180 goniometer is specified for the measurement of motion at the knee, ankle, hip and elbow, and comprises a strain gauge capable of measuring motion in two axes simultaneously. When fixed to the posterior aspect of the ankle according to manufacturers instructions, with one end block fixed to the posterior tibia and one fixed to the posterior calcaneus this permits simultaneous measurement of frontal and sagittal plane motion. Data is recorded at a frequency of 200Hz (Penny & Giles 1993).
Data was collected in three stages and commenced with investigation of the validity of the M180 goniometer, proceeded to evaluation of the reliability of both the static and dynamic data collection protocols, and ended with the actual data collection aimed at examining the relationship between static and dynamic motion measurements.

Firstly, the validity of the M180 goniometer was examined, to confirm the accuracy of the goniometer to be used in the study. This was achieved by attaching one end block to each arm of the goniometer to a tractograph. The tractograph was then moved through a range of 140° whilst the goniometer output in both channels was recorded. Between +70° and +10° the tractograph was moved in 10° increments, between +10° and −10° it was moved in 2° increments, and then between −10° and −70° it was moved in 10° increments once more. This permitted analysis of general accuracy through a large range of motion and examination of the accuracy through the smaller ranges of motion likely to occur at the calcaneus. Agreement between the tractograph and goniometer was examined to indicate validity, whilst the output from the second channel was also recorded to indicate the extent of any cross-talk between channels.

Secondly, the reliability of both the static and dynamic data collection protocols was examined. Using mefix tape, the goniometer was attached to the posterior aspect of the ankle, with one end block fixed to the distal tibia and the other fixed to the posterior calcaneus at a sufficient height to avoid ground contact. The goniometer was attached as straight as possible, but this was judged only visually. The study sought to measure motion of the calcaneus relative to the tibia, and would be using a static stance reference position from which all measurements would be recorded; therefore the absolute position of the goniometer was unimportant.

After completing the first two stages of the project, the final phase commenced, which investigated the relationship between statically and dynamically recorded frontal plane calcaneal motion to determine the ability of the static measurement to estimate dynamic. Static motion of the calcaneus was recorded with the subject standing in their angle and base of gait achieved by asking them to take 5 steps on the spot and then stop without moving their feet out of the contact position. If this position did not appear to correspond with the subjects normal angle and base of gait then the
procedure was repeated. Subjects were placed in their NCSP, which was determined by assessing equality between the inferior and superior lateral malleolar curvatures (figure 6.2), palpation of the medial and lateral margins of the talonavicular articulation to assess congruence, and by assessing the lateral aspect of the foot to ensure it described a straight line at the calcaneocuboid joint (Root et al., 1977). When this position had been achieved the subject was asked to maintain it for a few seconds to obtain a reference trace for the NCSP, and was then asked to relax both feet. Static calcaneal motion could then be easily measured by assessing the difference between the two distinctly different positions recorded by the electrogoniometer. Three measurements were obtained on three separate data collection sessions. The three measurements recorded at each session were averaged to increase reliability, and the averages from each of the three sessions were then compared to permit analysis of intra-rater reliability.

**Figure 6.1: Identifying the NCSP.** The method described by Root et al involves a series of criteria (Root et al., 1971). This figure shows three of these criteria: a vertical calcaneus, equality between the supra- and infra- malleolar curvatures and a straight lateral border. The STJt is in neutral.

Dynamic measurements were recorded immediately after measurement of static motion. The equipment was attached to each subject, and so data collection during free-speed walking was possible. Each subject was asked to walk along a corridor twice prior to data analysis, before the data logger was switched on. Dynamic calcaneal motion was obtained by measuring the difference between the angle at heelstrike and maximal eversion. The first four complete gait cycles were discounted from each recording and then the next three cycles were used. Heelstrike was identified using the heelstrike transient which has been shown to be a consistent event occurring immediately after heelstrike (Whittle, 1992). This a rapid event that lasts between 10-20ms, occurs because of the dorsiflexion ground reaction force created by the initial contact position of the calcaneus, and has been used previously as a
reference point from which to identify contact (Rendall and Abboud, 1999). Figure 6.3 illustrates the heelstrike transient, and figure 6.4 shows its identification on the electrogoniometer trace.

Figure 6.2: The heelstrike transient. The arrow shows the heelstrike transient recorded using a Kistler force platform. This figure shows the initial ground reaction force vector that results from the dorsiflexed position of the calcaneus at heelstrike, which initiates a rapid dorsiflexion moment at the instant of contact. This even has been shown to be consistent (Whittle, 1992).

Figure 6.3: Example electrogoniometer trace illustrating identification of heelstrike. Eversion is a response to heelstrike, so the point of contact can be identified as the point of maximal inversion prior to this motion. This is interrupted by a slight re-supination, before normal contact eversion resumes. There is a short period of eversion prior to this, which indicates a slight relaxation of tibialis anterior which is firing to dorsiflex and invert the STJt during swing. This is relaxed as heelstrike approaches, resulting in the short period of eversion that precedes contact. This eversion occurs prior to contact, and represents the end of swing phase.
6.2.3 Results

Data analysis sought to establish the validity and planar accuracy of the electrogoniometer, the reliability of both the static and dynamic frontal plane calcaneal motion measurement techniques, and finally, the association between static and dynamic measurements.

Planar accuracy was assessed by attaching the block ends of the electrogoniometer to a tractograph which was then moved in $10^\circ$ increments between $+70^\circ$ and $+10^\circ$, in $2^\circ$ increments between $+10^\circ$ and $-10^\circ$, and returning to $10^\circ$ increments between $-10^\circ$ and $-70^\circ$. Table 6.5 shows the tractograph reading and the electrogoniometer output in both channels. Channel 1 represents measurement of frontal plane motion, whilst channel 2 was recording the sagittal plane, where no motion was occurring. Accuracy can be assessed by considering the agreement between tractograph and channel 1 readings, which is within $1^\circ$ within the central $20^\circ$ range, and within $3^\circ$ even at the extremes of the range of motion tested. Channel 2 represents planar drift, and shows that the goniometer was again accurate to within $1^\circ$ in the central $20^\circ$ relevant to the study.

Table 6.5: Validity and planer accuracy of the electrogoniometer used in the study. This shows that the electrogoniometer was accurate to within $1^\circ$ in the central $20^\circ$ of the range of motion tested.

<table>
<thead>
<tr>
<th>Tractograph</th>
<th>Channel 1</th>
<th>Channel 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>+70</td>
<td>68.67</td>
<td>2</td>
</tr>
<tr>
<td>+60</td>
<td>59</td>
<td>2.67</td>
</tr>
<tr>
<td>+50</td>
<td>49</td>
<td>2.33</td>
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<tr>
<td>+40</td>
<td>39.33</td>
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<td>29.67</td>
<td>1.67</td>
</tr>
<tr>
<td>+20</td>
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<td>0.33</td>
</tr>
<tr>
<td>+10</td>
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<td>0</td>
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<tr>
<td>+8</td>
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<td>-2</td>
<td>-2</td>
<td>0</td>
</tr>
<tr>
<td>-4</td>
<td>-4</td>
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</tr>
<tr>
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<td>-8</td>
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<tr>
<td>-70</td>
<td>-68</td>
<td>-5.33</td>
</tr>
</tbody>
</table>
Further insight to the accuracy of the electrogoniometer used in the study can be obtained by considering graph 6.3. This illustrates the electrogoniometer readings obtained in both channels as the tractograph was moved through a range of 140°. This clearly illustrates a high level of accuracy and minimal planer drift, evidenced by the straight line corresponding to the measured motion, and the minimal deviation from zero measured by the second channel.

**Graph 6.3. Validity and Planer Accuracy of the Electrogoniometer used in the study** through a range of 140°. This clearly suggests the electrogoniometer to be both reliable, and to suffer from minimal cross-talk between channels.

The second stage of the study involved assessment of the reliability of the static and dynamic data collection techniques. Three recordings of static and dynamic motion were recorded three times, with each measurement calculated as the average of three trials. Graph 4 summarises the measurements obtained in each of the three data collection sessions, suggesting minor variation. The mean and standard deviations from each session are provided in table 6.4, and again suggest minor variation.
Graph 6.4. Box and Whisker plot for static calcaneal motion measurements, illustrating the median, inter-quartile ranges and maximum and minimum values for the nine ratings of each of the 10 subjects, for static measurements.

![Box and Whisker plot for static calcaneal motion measurements](image)

Table 6.6: Mean / SD of the three static measurements of calcaneal motion

<table>
<thead>
<tr>
<th>Subject</th>
<th>Trial 1 (mean / st. dev)</th>
<th>Trial 2 (mean / st. dev)</th>
<th>Trial 3 (mean / st. dev)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>6.1 (0.9)</td>
<td>6.89 (1.03)</td>
<td>5.48 (0.37)</td>
</tr>
<tr>
<td>2</td>
<td>6.27 (0.78)</td>
<td>6.93 (0.57)</td>
<td>4.9 (0.52)</td>
</tr>
<tr>
<td>3</td>
<td>7.46 (0.85)</td>
<td>10.26 (0.69)</td>
<td>11.44 (0.91)</td>
</tr>
<tr>
<td>4</td>
<td>8.82 (0.59)</td>
<td>7.20 (0.72)</td>
<td>6.34 (0.69)</td>
</tr>
<tr>
<td>5</td>
<td>5.03 (0.12)</td>
<td>3.37 (0.12)</td>
<td>4.83 (0.49)</td>
</tr>
<tr>
<td>6</td>
<td>1.7 (0.06)</td>
<td>1.83 (0.30)</td>
<td>1.78 (0)</td>
</tr>
<tr>
<td>7</td>
<td>6.93 (0.12)</td>
<td>6.01 (0.82)</td>
<td>7.78 (1.08)</td>
</tr>
<tr>
<td>8</td>
<td>5.56 (1.15)</td>
<td>3.34 (0.52)</td>
<td>6.48 (0.98)</td>
</tr>
<tr>
<td>9</td>
<td>8.92 (1.39)</td>
<td>6.86 (0.34)</td>
<td>6.34 (1.08)</td>
</tr>
<tr>
<td>10</td>
<td>3.63 (0.21)</td>
<td>3.2 (0.57)</td>
<td>3.56 (0)</td>
</tr>
</tbody>
</table>

Table 6.7: ICC’s: static calcaneal motion measurements.

<table>
<thead>
<tr>
<th>Evaluation</th>
<th>ICC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Three trials from data collection session 1</td>
<td>0.88</td>
</tr>
<tr>
<td>Three trials from data collection session 2</td>
<td>0.94</td>
</tr>
<tr>
<td>Three trials from data collection session 3</td>
<td>0.93</td>
</tr>
<tr>
<td>Averages from sessions 1, 2 and 3</td>
<td>0.76</td>
</tr>
</tbody>
</table>

The same process was used to evaluate the reliability of the dynamic data collection technique. Graph 6.5 displays graphically the average measurements obtained on each of the three data collection session. This suggests greater variation than the static measurements. The mean and standard deviations from each session are provided in table 6.8, and similarly suggests greater variation than the static procedure.
Graph 6.5: Box and Whisker plot for dynamic calcaneal motion measurements, illustrating the median, interquartile ranges, minimum and maximum values for the nine ratings of each of the 10 subjects, for dynamic measurements.

Table 6.8 Mean / SD of three dynamic measurements of calcaneal motion

<table>
<thead>
<tr>
<th>Subject</th>
<th>Trial 1 (mean / st. dev)</th>
<th>Trial 2 (mean / st. dev)</th>
<th>Trial 3 (mean / st. dev)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>8.64 (0.17)</td>
<td>9.8 (1.02)</td>
<td>8.47 (0.6)</td>
</tr>
<tr>
<td>2</td>
<td>7.80 (1.51)</td>
<td>7.09 (0.21)</td>
<td>6.01 (0.79)</td>
</tr>
<tr>
<td>3</td>
<td>7.35 (0.82)</td>
<td>17.53 (1.37)</td>
<td>10.8 (1.14)</td>
</tr>
<tr>
<td>4</td>
<td>9.61 (0.98)</td>
<td>8.38 (0.16)</td>
<td>10.65 (1.59)</td>
</tr>
<tr>
<td>5</td>
<td>9.54 (1.64)</td>
<td>5.6 (1.11)</td>
<td>7.91 (0.74)</td>
</tr>
<tr>
<td>6</td>
<td>2.52 (0.64)</td>
<td>3.36 (0.06)</td>
<td>3.47 (0)</td>
</tr>
<tr>
<td>7</td>
<td>5.88 (0.52)</td>
<td>6.6 (0.97)</td>
<td>8.63 (1.53)</td>
</tr>
<tr>
<td>8</td>
<td>3.99 (1.26)</td>
<td>3.43 (0.17)</td>
<td>4.96 (0.57)</td>
</tr>
<tr>
<td>9</td>
<td>11.57 (0.85)</td>
<td>8.62 (0.2)</td>
<td>8.17 (0.97)</td>
</tr>
<tr>
<td>10</td>
<td>4.85 (0.35)</td>
<td>4.31 (0.9)</td>
<td>3.89 (0.57)</td>
</tr>
</tbody>
</table>

These graphs and table suggest that the dynamic data collection technique is reliable, although less so than the static technique. Formal assessment of the level of reliability was again assessed using intra-class correlation coefficient. Firstly, the three trials from each data collection session were evaluated separately, to provide information on reliability on each occasion, and then the averages from occasion 1, 2 and 3 were evaluated to determine overall reliability. Results are shown in table 6.9, and range from 0.87 to 0.96 for the individual occasions but drops to 0.59 between occasions.
Table 6.9: ICC’s: dynamic calcaneal motion measurements

<table>
<thead>
<tr>
<th>Evaluation</th>
<th>ICC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Three trials from data collection session 1</td>
<td>0.88</td>
</tr>
<tr>
<td>Three trials from data collection session 2</td>
<td>0.96</td>
</tr>
<tr>
<td>Three trials from data collection session 3</td>
<td>0.87</td>
</tr>
<tr>
<td>Averages from sessions 1, 2 and 3</td>
<td>0.59</td>
</tr>
</tbody>
</table>

After assessing the reliability of the data collection techniques, the relationship between calcaneal motion measured using the two techniques was examined. Firstly, Pearsons correlation coefficients were calculated and returned a value of 0.89 (p=0.001). This correlation is illustrated in graph 6.6.

Graph 6.6 Correlation between average static and dynamic measures of calcaneal motion measurements across subjects

Correlations can exist in the presence of systematic differences in data, and therefore a paired-samples t-test was conducted to investigate the possibility that the dynamic measurements were consistently higher than the static. A one-tailed t-test revealed that significant differences do exist between the static and dynamic measurements (static mean = 5.84°, dynamic mean = 7.32°, t=-3.637, df=9, p=0.005, 95% confidence interval –2.4:-0.56). This suggested that the dynamic calcaneal motion measurements were significantly higher than the dynamic measurements. This difference ranged from -1° to 3.27°, with a mean of 1.5° (s.d. 1.3°). The actual differences between the average static and dynamic measurements are illustrated in graph 6.7, which illustrates the mean difference.
Graph 6.7: Differences between average static and dynamic calcaneal motion measurements across subjects. Although this graph suggests considerable variation in the actual magnitude by which dynamic measurements increase over static, variability is actually within a small range of less than 3°, and in all but one case dynamic measurements are greater than static.
6.2.4 Discussion

The study aimed to investigate the validity of using a static measurement technique for predicting dynamic calcaneal motion. This measurement is important because of the acknowledged relationship between STJt orientation and the mechanical properties of the foot (Huson, 1991, Huson, 2000, Root et al., 1977, Vogler and Bojsen-Moller, 2000), and by considering that, due to a lack of surface landmarks on the talus, calcaneal motion provides the only feasible opportunity for examining STJt motion (Woodburn et al., 1999). Given that the fundamental purpose of assessing the foot statically is to gather information on dynamic function, techniques explicitly focusing on measurement of motion, albeit in a quasi-static situation, seem a logical focus. There is a clear rationale suggesting that motion between the neutral and RCSPs may predict dynamic function (Lee, 2001a, Philips, 1995, Root et al., 1971), and so it seems justified to formally examine the association between the two.

The project was conducted in three phases. Firstly, dynamic measurement of calcaneal motion requires the use of specialist kinematic motion tracking equipment, with the Biometrics (formerly Penny & Giles) goniometer representing a cost-effective option with established intra-observer reliability (Ball and Johnson, 1996, Rome and Cowieson, 1996). However, prior to the use of this equipment to measure both static and calcaneal motion, it was prudent to confirm the validity and planer accuracy of the M180 twin axis goniometer to be used in the study. This suggested excellent validity over the range of motion occurring during the study, despite the error manifesting at the extremes of the range of motion. Further, cross-talk between the two channels of the electrogoniometer was minimal within the central 20° range of motion relevant to the study, which provided further evidence of validity. Again, this accuracy reduced at the extremes of the range of motion, but this range fell well outside the anatomical range of motion of the STJt.

After confirming the validity and planer accuracy of the electrogoniometer, the reliability of the static and dynamic data collection procedures was assessed. This involved a repeated measures design with 3 measurements taken on each of three data collection sessions to permit analysis of within-day and between-day reliability. Not surprisingly, results varied between the static and dynamic techniques. Whilst within-
day reliability was good for both techniques, evidenced by ICC’s of approximately 0.9, between day reliability varied for the two techniques, with the static technique returning an ICC of 0.76 and the dynamic 0.59. Whilst this indicates that slightly different amounts of motion were recorded on different days, with the dynamic technique displaying more variation than the static, there are some good reasons why this should have happened. In both static and dynamic situations there are likely to have been various influences that could account for differences in the amount of motion occurring between days including minor, but influential, variations in operator instruction, subject mood and responsiveness, and even differences in the time of day at which measurements were recorded, or subject activity prior to the data collection session. For example, at the end of a reasonably active day the STJt would be expected to undergo greater excursions than earlier in the morning. Differences between static and dynamic reliability can also be explained in terms of the inherent variation in a process driven by proactive, predictive, and reactive manoeuvres (Huxham et al., 2001). Therefore, the results are exactly as would be expected, with within-day measurements demonstrating less variation than between day, and the static technique showing less variation than the dynamic. Although the lowest ICC value of 0.59 for the between-day dynamic measurements falls short of the level required to inspire a high level of confidence in the technique, in the context of the series of results relating to within-day and static technique evaluation, they appear realistic and acceptable. It could be speculated that to achieve a much higher ICC value a prohibitive, artificially rigid protocol would have to be adopted that would represent a distortion of normal gait.

After establishing the reliability of both static and dynamic data collection techniques, the relationship between the two states was considered. This analysis was conducted using average measurements derived from the nine trials conducted over the entire study. Whilst comparison of measurements obtained on each individual data collection session could have been performed, the use of a global average derived from all three data collection sessions was felt superior, as it represents a ‘worst-case scenario’ because it considers more data and therefore greater variation. Selection of data from specific trials, for example the first static and first dynamic trials, could be speculated to be associated with a stronger relationship than that identified using average measurements because of increased within-day reliability. This evaluation
revealed a Pearson's correlation coefficient of 0.89, indicating a significant association between the two. However, this result does not automatically mean that there were no differences between the two conditions, as a significant correlation can still be returned in the presence of systematic differences. A t-test was therefore conducted to determine if there were significant differences between static and dynamic measurements, and revealed that differences did exist. This suggested a systematic difference, and plotting the differences graphically between the two states for each subject revealed a trend for dynamic measurements to be greater than static. Assessment of this graph and the t-test results indicate this dynamic increase to be approximately $2^0$. This result is entirely reasonable when the greater forces generated in walking are considered.

The study is limited in several ways. Firstly, a more accurate estimate of dynamic motion could have been obtained by recording data from more trials (perhaps as many as 5) in an attempt to achieve optimal consistency, and similarly, using a dynamically recorded angle and base of gait template to increase the accuracy of the static technique, could have provided more robust results. Goniometers attached to the skin surface are at risk from skin-movement artefact, where skin movement may not accurately reflect motion in the underlying bone. The magnitude of this error can be examined, but requires the use of imaging studies to accurately measure bony motion. Although the data collection process was time-consuming, a larger sample size could have been recruited to provide more robust results. The identification of heelstrike was achieved using a technique that involved assessment of the goniometer trace, and footswitches attached to the posterior-plantar aspect of the calcaneus and tip of the hallux would have allowed precise identification of the instant of heelstrike. These switches can be linked to the PC, and the graph can incorporate marks which show precisely when heelstrike and toe-off occur. However, the heelstrike transient is a widely acknowledged event (Whittle, 1992, Whittle, 1999), and the goniometer frequency of 200 hz is sufficiently fast to consistently identify it. The accuracy of this technique could have been confirmed by repeated assessments of a series of traces to ensure that the same amount of motion was recorded from them consistently. This pragmatic consideration should have been pursued to increase confidence in results. It is important when determining the weight that can be assigned results that all sources
of error are considered, and before further use of the technique described this should be examined.

In spite of the limitations, and although there is scope for developing the study, it appears justified to conclude that static measurement of frontal plane calcaneal motion between the neutral and RCSPs accurately predicts dynamic calcaneal function. There appears to be a general dynamic increase of approximately $2^\circ$, and it is reasonable to speculate that a greater increase would occur in running. Although these results should not be extrapolated to running as there is likely to be a different increase due to the increased forces associated with this activity, the technique can be recommended as a valid means of estimating dynamic walking calcaneal function, and as a useful and valid method of classifying foot-type.
6.3 Comparison of footprint parameters calculated from static versus dynamic footprints

6.3.1 Background

Navicular drop and calcaneal motion measures enjoy an important theoretical advantage over other foot-type measures because of their explicit focus on rearfoot motion. Nevertheless, some static measures seem potentially capable of satisfying the conditions of face and content validity, in that they are strongly related to STJt motion and position. Measures calculated from footprints fall into this category, and have been a popular method characterising foot-type for research purposes (Cavanagh and Rodgers, 1987, Cureton, 1935, Didia et al., 1987, Forriol and Pascual, 1990, Hawes et al., 1992, Kanalti et al., 2001). Such measures operate on the premise that the footprint responds predictably to variations in, and can reflect the alignment of, the medial longitudinal arch whose structure directly reflects STJt position (Nester, 1997). Although criticisms of this type of measure have been noted, they have been defended on the basis that they provide a rapid and useful insight to foot function (Kanalti et al., 2001), and it appears that footprint measure warrant further investigation as a potentially convenient and valid foot-type classification tool for use in epidemiological enquiry.

Footprint measures are calculated from impressions of the plantar aspect of the foot recorded during static stance. Example measures include the Arch index (Cavanagh and Rodgers, 1987), Stahelis arch index (Staheli et al., 1987) and the CSI (Forriol and Pascual, 1990). These measures find theoretical support in the observation that forefoot and heel areas consistently show maximal ground contact with progressive changes in arch height, restricting changes in the footprint to the central portion (Qamra et al., 1980). Several measures appear consistent with this theory, as they involve a direct comparison of the contact areas in either the forefoot or heel with midfoot. For example, the Arch index involves comparison of the midfoot with the contact area of the rest of the print minus the toes (Cavanagh and Rodgers, 1987). The same rationale has resulted in more convenient indices that are less time-consuming to calculate. These involve comparison of midfoot width, firstly with forefoot width, to calculate the CSI (Forriol and Pascual, 1990), and secondly with rearfoot width, to calculate the Stahelis arch index (Staheli et al., 1987). The FPA (Clarke, 1933)
(Schwartz et al., 1928) may also demonstrate potential as it appears to examine directly the response of the midfoot, through examination of the angle between a medial reference line (a line connecting the most medial margins of the forefoot and rearfoot areas) and the most anterior and lateral margin of the medial longitudinal arch, which may also change orientation with changes in arch height. These techniques are illustrated in figure 6.5.

It has been suggested that measures of foot-type be evaluated with special regard to the dynamic rather than the static situation (Cureton, 1935, Rose, 1985). This suggestion seems important because, as emphasised previously, it is dynamic foot function that is believed to be related to pathology. However, currently such measures are routinely calculated from static prints, which may not capture the true condition of the foot under dynamic conditions. The relationship between Arch indices calculated from static, walking and running conditions has been examined (Cavanagh and Rodgers, 1987), and despite noting large variation, an average increase of 10% between static and running conditions was suggested. The recommendation that the index should be calculated from static prints for the purpose of standardisation would have been compromised if static prints were found to differ significantly, or in a non-systematic manner, from dynamic. Therefore, the ability of static measures to predict the dynamic appears to be a fundamental, although not exclusive, pre-requisite to validity.
The study aimed to assess the level of agreement between the Stahelis arch index, the CSI and the FPA calculated from static vs. dynamic footprints. Three hypotheses were set:

1. The protocols for calculating the CSI, SAI and FPA from static and dynamic footprints obtained using the Musgrave system demonstrate acceptable reliability;
2. There is agreement between the statically and dynamically calculated CSI, SAI and Footprints angles;
3. There is a correlation between the individual footprints measures, which are purported to measure the same attribute.
6.3.2 Method

A convenience sample of 20 University student and staff volunteers was used: all participants satisfied the following inclusion criteria:

- no history of, or visually apparent, gait disturbance;
- no history of trauma, including repetitive minor trauma such as ankle sprains;
- no history of any systemic illness which may influence gait.

The sample comprised 14 females and 6 males with an average age of 25 (±9) and average body mass index of 23 (±3.2). The study was approved by the Ethics committee of the University of Wales Institute, Cardiff. Three static and three dynamic footprints were obtained for each subject using the Musgrave Footprint System™, which allowed images of the plantar surface of the foot to be easily captured and analysed to calculate the measures. The Musgrave™ plates were embedded mid-way along an 8-metre walkway. Electronic data capture was chosen as a straightforward method of obtaining dynamic footprints, and permitted subsequent analysis using standard Musgrave™ Footstats software.

Static Print Collection Method

The subject was asked to stand barefoot one step behind the first plate on the walkway with the right foot lined up with the plate. When ready they took one step forward, placing their right foot centrally within the plate. The left foot was then brought alongside the right, and the subject was allowed to vary the position of this foot until the angle and base of gait felt comfortable. With each subject standing relaxed, data capture was initiated. The Musgrave Footprint™ was set to record data for one second. This procedure was repeated until three footprints were obtained for each subject.

Dynamic Print Collection Method

Subjects were positioned at the start of the walkway, and were instructed to walk up and down it 5 times, ignoring the plates, in an attempt to naturalise their gait patterns. They then returned to the start of the walkway, lined up their right foot with the right plate, and were instructed to begin each walk with a right step. Another walk was undertaken, still ignoring the plates, and an observer advised of any changes to the
starting position to facilitate a central strike at a normal walking speed. This process was repeated until appropriate starting positions were identified. The subjects were instructed to begin walking up and down repeatedly, and were unaware of which footprints were being recorded. They were instructed to stop only when 3 satisfactory prints had been obtained. Any prints which failed to capture a clear image of the entire plantar aspect of the foot were rejected.

The study yielded 3 static and 3 dynamic prints for each subject, resulting in 120 prints. A single tester evaluated all prints, calculating FPA (FPA), and maximal forefoot width, minimal midfoot width and maximal rearfoot width to allow the calculation of the CSI (CSI) and Stahelis Arch Index (SAI).
6.3.3 Results

Reliability of Electronic Footprint Analysis Technique

Firstly, the reliability of the measurement technique used to extract the raw data used to calculate the measures was investigated. This was achieved by calculating the measures from the same prints on two separate occasions and examining agreement between them. The first static print for each subject was chosen for this purpose, and the two occasions were four days apart. Comparison of measures from S1a (first evaluation of static print 1) and S1b (second evaluation of static print 1) was performed using Pearson’s correlation coefficients, and are shown in table 6.10. In all cases, agreement between 1st and 2nd assessments of the same prints was excellent, being significant at the \( p<0.0001 \) level.

Table 6.10
Reliability of electronic footprint Analysis technique (Pearson’s rho)
Correlation’s between two separate evaluations of the same footprint. Values consistently above 0.9 equates with significance at the \( p<0.0001 \) level.

<table>
<thead>
<tr>
<th></th>
<th>FPA</th>
<th>Chippaux-Smirak</th>
<th>Stahelis Arch</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st vs. 2nd Evaluation</td>
<td>0.94</td>
<td>0.93</td>
<td>0.96</td>
</tr>
</tbody>
</table>

Reliability of Static and Dynamic Footprinting Techniques

The reliability of the footprinting technique was evaluated by examining agreement between measures calculated from different prints of the same foot. Separate analysis of static and dynamic reliability was performed using Pearson’s correlation coefficients. Results are shown in table 11. The FPA displayed unacceptable reliability when calculated from static prints, and therefore it was excluded from further analysis.

Table 6.11: Reliability of static and dynamic footprinting techniques (Pearson’s \( r \))
With the calculation method established as reliable, any change of value between separate prints of the same foot would suggest that the dimensions of the foot differ significantly between footprints. However, comparison of values derived from 3 separate prints indicates that linear based measures do not differ significantly between footprints for static and dynamic conditions. The FPA was found to differ between separate static prints.

<table>
<thead>
<tr>
<th></th>
<th>Static Footprints</th>
<th>Dynamic Footprints</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analysis</td>
<td>FPA</td>
<td>Chippaux-Smirak</td>
</tr>
<tr>
<td>1 Vs 2</td>
<td>0.51*</td>
<td>0.92*</td>
</tr>
<tr>
<td>1 Vs 3</td>
<td>0.29</td>
<td>0.95*</td>
</tr>
<tr>
<td>2 Vs 3</td>
<td>0.33</td>
<td>0.92*</td>
</tr>
</tbody>
</table>

All correlation’s marked * are significant at the \( p<0.01 \) level.
Comparison between statically and dynamically calculated measures
The relationship between measures calculated from static and dynamic prints was examined by comparing the mean static and mean dynamic values of each parameter. Firstly, paired t-tests were performed to investigate differences between the two states, followed by Pearson’s correlation coefficients to investigate the consistency of any differences.

Chippaux-Smirak Index (CSI)
Analysis demonstrated a difference between the two groups (t=2.5, df=19, p=0.02) with dynamic print values (mean = 24.7 s.d.=13.2) being higher than the static (mean = 21.03 s.d.=14.34), with the mean difference being 3.7 (95% CI = -6.7:-0.65). A Pearson’s correlation coefficient of 0.92 (p<0.0001) indicates that these differences are consistent, however. Expression of the difference as a percentage of the static value revealed a mean increase of 25.56% ± 43.36%, indicating large variation in the magnitude of this increase between static and dynamic prints. The correlation between static and dynamic is illustrated in graph 6.8.

Graph 6.8: Correlation between mean static and dynamic CSI
Graph illustrating the correlation between statically and dynamically calculated values for the CSI. Pearson's r = 0.89 (p<0.001)

Stahelis Arch Index
Analysis again demonstrated a difference between the two groups (t=2.6, df=19, p=0.018) with the dynamic (mean=0.38 s.d.=0.21) greater than the static (mean=0.32 s.d.=0.21) with the mean difference being 5.85E-02 (95% CI = -0.1:1.14E-02). A
Pearson’s correlation of 0.88 ($p<0.0001$) again demonstrated that these differences were consistent. Expression of the mean difference as a percentage of the static value revealed an average increase of 27.95% ± 57.65%, indicating large variation in the magnitude of this increase between static and dynamic prints. Again, the correlation between static and dynamic is illustrated in graph 6.9.

**Graph 6.9: Correlation between mean static and dynamic SAI**
Graph illustrating the correlation between statically and dynamically calculated values for Stahelis Arch Index. Pearson's $r=0.88$ ($p<0.001$)

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**Comparison between Measures**

A final correlation was performed to examine the agreement between the two separate measures which claim to be measuring the same condition. This was achieved by correlating the mean CSI and mean SAI for both static and dynamic conditions. Correlation’s of 0.99 ($p<0.0001$) for the static and 0.98 ($p<0.0001$) for the dynamic indicate that the measures do appear to be sensitive to the same feature.
6.3.4 Discussion
The concept that measures calculated from static footprints provide an accurate insight to dynamic foot function has led to the widespread use of footprint indices to classify ‘foot-type’. The use of such measures has persisted despite an absence of supporting evidence, and acknowledgement of the fact that examination of footprints offers only the possibility of an indirect statement about the medial longitudinal arch (Cavanagh and Rodgers, 1987), which is perceived to be an important determinant of mechanical function. Since statically calculated footprint measures represent an explicit attempt at gaining an insight to dynamic function, one essential, although not exclusive, assumption central to the validity of footprint measures concerns the ability of static prints to accurately reflect the dynamic.

This study indicates that statically calculated footprint measures do infer something of the dynamic situation. However, although a general increase of approximately 25% (Chippaux-Smirak) and 28% (Stahelis Arch Index) was found between static and dynamic states, large individual variations prevent any inferences from being made. Statically calculated measures must be viewed with caution, as they appear to inconsistently predict the dynamic dimensions of the foot. The relationship to dynamic motion – the variable perceived to be related to the development of pathology – remains unclear.

Acceptance of results pertaining to correlations between static and dynamic prints is dependant upon establishing the reliability of the data collection techniques. As such, the reliability of both static and dynamic print collection techniques and the software used to examine the footprints required evaluation. Firstly, the reliability of the electronic footprint assessment technique, involving the use of Musgrave Footprint™ software, was examined through correlation between two separate analyses of the first set of static prints. Correlation’s consistently above 0.9 (p<0.0001) suggest that this software is reliable, justifying its use, and allowing it to be recommended. Secondly, the reliability of the static and dynamic print collection techniques was examined by correlating the same parameter calculated from three separate prints obtained in the same state. Although correlations were excellent for the Chippaux-Smirak and Stahelis Arch indices for both static and dynamic states, the FPA failed to show such convincing reliability. Correlation’s were generally lower, and were non-significant.
for 2 of 3 tests performed between static prints. It is interesting that dynamic prints showed greater reliability than the static, given the inherent variability of the dynamic situation, which could have been expected to produce lower reliability for the dynamic. Although good reliability coefficients have been reported previously (Cureton, 1935), these figures relate to separate analyses of the same prints, both by single and multiple investigators. The likelihood that different prints of the same foot would return the same value was not investigated. Poor between-print reliability of the FPA is felt to be an important finding, necessitating their rejection, and suggests that linear measures hold more potential.

Additional methodological variables potentially influencing results include the use of forceplates embedded in a walkway, and the associated problem of ‘targeting’, which is often felt to reduce the validity of the resulting dynamic prints. This issue has been investigated at length (Grabiner et al., 1995, Harrison and Folland, 1997, Rietdyk and Patla, 1994, Sanderson et al., 1993), with the ‘conventional wisdom’ that targeting has a deleterious effect remaining unsubstantiated (Sanderson et al., 1993) Contrary to the belief that targeting has a negative effect, investigation of the effects of five different protocols for the collection of dynamic prints, conducted by examining the spatial distribution of forces on seven discrete areas of the foot, found minimal differences. Such evidence suggests that the impressions captured by force plates yields valid information, and supports their use. The study could also have utilised a larger group of subjects, with more repetitions, to obtain a more accurate insight to the reliability of the techniques. However, the sample selected, and the results obtained, yielded results that are entirely reasonable, concurring with existing theories of reliability (Ellasziw et al., 1994, Picciano et al., 1993, Rome and Cowieson, 1996, Sell et al., 1994), and therefore it would be unreasonable to reject the results on the basis of inadequate numbers.

Since this study was published in 1999 two studies conducted by the same research group have cited it (Urry and Wearing, 2001, Urry and Wearing, 2001b). In both cases the results of the study were not challenged per se. Rather, this work is cited as an example of the increasing tendency to use electronic pressure distribution analysis equipment to calculate measures that were developed using Harris & Beath plates, which produce an ink impression of the foot. These studies identified that the
dimensions of the footprints captured using electronic techniques differ significantly from those recorded using traditional techniques. This likely occurs due to the pressure required to activate individual sensors, and relates particularly to areas of low pressure, although other areas were also involved. This tends to impact most at the periphery of the foot where the pressures would be enough to produce an ink impression, but would be insufficient to activate some pressure sensors. Therefore, the two techniques produce different measure values for the same feet. This methodological problem was not recognized prior to the study, otherwise the manual method might have been selected as the most appropriate choice. The main reason for the selection of the electronic technique was the efficiency with which dynamic prints can be obtained, and the analysed. Although it can be suggested that the general increase between static and dynamic observed would also occur with the ink technique, meaning that results and conclusions are likely to be the same, this cannot be established without repeating the study using ink-based technique. However, although it is necessary to recommend that the study be repeated using ink impressions for detailed investigation of this issue, the fact that the technique represents a fixed effect, presumably acting in the same direction consistently, means that the results can be accepted and utilised. However, it remains important to recommend that the study is repeated using ink impressions to increase confidence with the validity of conclusions.

Whilst foot-type measures that directly measure rearfoot motion appear to be a superior choice because of the relevance of this motion dynamically, there is a plausible pathway by which footprint measures may indeed reflect, and respond consistently to, rearfoot position. It seems possible that these measures could be responsive to STJt motion and position, and therefore the linear measures investigated here will be included in a validity study alongside navicular drop and calcaneal motion.
6.4 Examining the validity of selected foot-type measures

6.4.1 Background
Validity is a multi-dimensional construct, and there are several classes that must be satisfied to ensure that a measurement tool is truly suitable for its intended purpose (Daly and Bourke, 2000). At the most superficial level, face validity refers to the apparent suitability of an instrument on 1st inspection, but more detailed dimensions should be satisfied to justify any claim that a measure is truly ‘valid’. For example, content validity assesses the inclusive nature of an instrument, determining whether the separate recognised dimensions of the condition being measured are represented (Polgar and Thomas, 2000). Criterion validity entails comparison of results obtained using the instrument under investigation with results obtained by an existing and accepted technique: if the two correlate then an important criterion has been fulfilled. Finally, construct validity relates to the correlation between an instruments score and an important outcome, such as the course of a disease or prognosis. If an instrument predicts a particular outcome, it is important that this is accurate, and if not then the instruments clinical utility is compromised. Construct validity is often evaluated via comparison between a measure and the ‘gold standard’ technique (Daly and Bourke, 2000).

Whilst several measures of foot-type have been proposed, and are in routine use for both clinical and research purposes, information regarding validity is limited. Although several measures could claim to satisfy the demands of face and content validity, in that their focus appears relevant and encompasses aspects of foot function perceived as important, information on dimensions such as criterion and construct validity is required to truly convince of their value. The relationship between rearfoot, and more specifically STJt, position and the mechanical integrity of the foot, and the consistent and predictable response of medial longitudinal arch structure to changes in rearfoot position, suggests that measures focused on the medial longitudinal arch are appropriately focused. One interpretation of this information is that a fundamental requirement for construct validity is the ability of measures of foot-type to respond to discrete, clinically important, changes in rearfoot alignment.
Considering the literature describing the importance of the rearfoot, and the response of the medial longitudinal arch to changes in rearfoot position supports this approach to examination of the criterion validity of the foot-type measures. Biomechanical theory emphasises the importance of the rearfoot in determining dynamic foot function, and recognises that alteration of STJt position produces changes in foot morphology. For example, STJt pronation, comprising talar adduction and plantarflexion and visible as calcaneal eversion, lowers the medial longitudinal arch, whilst subtalar supination, comprising talar abduction and dorsiflexion and visible as calcaneal inversion, raises the arch (Nester, 1997). Frontal plane calcaneal motion offers an insight into STJt motion, which is otherwise impossible due to the lack of surface anatomical landmarks on the talus (Root et al., 1977, Torburn et al., 1998). The link between subtalar motion and arch morphology occurs by virtue of the relationship between the tarsal bones, described as a ‘constraint system’, in which passive co-operation is imposed by articular geometry and ligamentous connections (Huson, 1991). In such a system, movement of one bone is associated with predictable changes in the entire complex. Huson’s discourse of this topic provides an important anatomical basis for relationships previously described (Elftman, 1960, Inman et al., 1994), and substantiates statements such as that by Manter, who stated that appropriate rotations about all three axes of the principal tarsal joints can bring the foot into a position resembling flatfoot (Manter, 1941). This information suggests that an important determinant of arch morphology is STJt position, and that examination of the frontal plane calcaneal angle provides the opportunity of an insight into subtalar motion. One interpretation of this information is that examination of the sensitivity of measures of foot-type to discrete changes in STJt position offers an insight to construct validity.

Foot-type measures have been organised into three general categories (Williams and McClay, 2000): radiographic, anthropometric and footprint measures, and these have been discussed previously. Although the proposed method of investigating validity can equally be applied to all measures, the study focused on the motion and footprint measures investigated previously. These measures enjoy a robust theoretical relationship with rearfoot function, and seem capable of reflecting STJt position and responding to STJt motion. The pertinent background to these measures is provided in
section 5.2.1, for navicular drop and calcaneal motion, and section 5.3.1 for footprint measures.

A critical aspect of the measures of foot-type discussed is the use of the RCSP. The classification of subjects according to examination of the foot in this position is supported by various considerations. Firstly, it has been suggested that the frontal plane angulation of the calcaneus in the relaxed position reflects the compensation taking place for any positional anomalies within the lower limb (Anthony, 1991, Philips, 1995). Secondly, it has been repeatedly observed that the relaxed position is closely related to rearfoot motion during gait (McPoil and Cornwall, 1994, Pierrynowski and Smith, 1996, Wright et al., 1964). Finally, comparison of the static frontal plane calcaneal angle and dynamic rearfoot motion has shown that the static position provides a good indication of the dynamic limit of subtalar motion (McPoil and Cornwall, 1996b, Torburn et al., 1998).

The study aimed to investigate the validity of selected measures of foot-type by examining their sensitivity to discrete alterations in STJt orientation, measured by assessing frontal plane calcaneal alignment. The measures of foot-type investigated were the Stahelis arch and Chippaux-Smirak indices and navicular height. The following hypothesis was set:

1. The measures of foot-type change significantly in value to detect the changes in pedal structure associated with 5° increments of frontal plane calcaneal motion.
6.4.2 Method
An opportunity sample of 20 subjects (15 females, 5 males) was recruited from a student population. The study was explained to all participants, who subsequently gave informed consent, and were debriefed taking part. The ethics committee of the University of Wales Institute, Cardiff approved the study methodology. The sample had a mean age of 21(±3), mean height of 166.2cm (s.d. 8.3) and mean weight of 68.9kg (s.d. 8.9). All subjects satisfied the following inclusion criteria:

- No history of, or visually apparent, gait disturbance;
- No history of trauma or surgery to any part of the locomotor system;
- No history of systemic illness which may influence gait;
- No evidence of a limited range of subtalar range of motion, as determined by clinical assessment.

The Musgrave Footprint™ System (Musgrave Medical, Llangollen, UK) was used to collect a series of five static footprints of the right foot - the dominant limb of all participants. The Musgrave platform was embedded mid-way along an 8-metre walkway. Two plates were embedded in the walkway, but only the first was used. All measurements were undertaken by one clinician.

Each subject had the tuberosity of the navicular marked with a fine felt tip pen. They were then asked to stand barefoot behind the first plate on the walkway and take a step forward to place the right foot in the centre of the plate. The left foot was brought alongside the right, and the subject was allowed to vary the position of the left until a comfortable stance position was attained. The subject was then asked to maximally pronate their right STJt by internally rotating the limb, whilst consciously maintaining their upper body in a stable position. Subjects were asked to pronate until they felt resistance, and not to forcibly pronate to discomfort. Once in the maximally pronated position a reference line was applied to the posterior aspect of the calcaneus perpendicular to the supporting surface using a tractograph set at 90° and placed flat on the supporting surface. The Musgrave was activated to record data for one second, and the height of the tuberosity of the navicular from the ground was measured using a ruler. This technique represents a variation on a previously reported (Sell et al.,
but instead of marking the height of the tuberosity on a piece of card for measuring later, direct measurements were taken. Although measurements of navicular height could have been recorded with greater precision using any one of various pieces of equipment, for epidemiological enquiry requiring the analysis of large numbers of subjects, a simple clinical technique is required. The subject was then asked to externally rotate their limb slowly until the calcaneal reference line was 5° inverted from the maximally pronated position, measured using a protractor. Again, this position was maintained, the Musgrave was activated to record, and the height of the navicular was measured. This procedure was repeated until the height of the navicular and images of the plantar surface of the foot had been recorded in 3 further positions: 10°, 15° and 20° inverted from maximal pronation. The investigator was positioned posterior to the participant when viewing and measuring the calcaneus, and medially when viewing and measuring the navicular, to reduce parallax error.

Images of the plantar surface of the foot were used to calculate the Stahelis and Chippaux-Smirak indices, using a technique previously established as reliable in study 6.3. The influence of incremental changes in STJt motion on each measure was then investigated to determine the nature of any relationships.
6.4.3 Results

Examination of 20 subjects in 5 separate positions resulted in a total of 100 footprints and 100 measurements of navicular height. Analysis aimed to identify the influence of incremental changes of $5^\circ$ calcaneal inversion on each measure of foot type.

Pearsons correlation coefficients were calculated to identify any trends, and results suggested a tendency for each measure to increase in value with progressive inversion. Correlations of 0.5, 0.6 and 0.8 were returned for SAI, CSI and Navicular Height respectively. Although these correlations are all significant at the p<0.01 level, navicular height correlated best with calcaneal motion. Correlations are displayed in graphs 6.10-6.12.

Graph 6.10. Association between calcaneal position and SAI: Pearson’s correlation coefficient: 0.5 (p<0.01)

Graph 6.11: Association between Calcaneal Position and CSI: Pearson’s correlation coefficient: 0.6 (p<0.01)
Although correlations suggested a tendency for measure values to increase with progressive inversion, further analysis was required to determine whether significant increases occurred with adjacent 5º increments, or were related only to increments of greater than 5º. ANOVA with Scheffe post hoc analysis was used to investigate this issue. The ANOVA test revealed that significant differences existed in measure values between calcaneal positions for all measures: Stahelis arch index: F=7.154, df=4, p<0.001; CSI: F=16.324, df=4, p<0.001; Navicular height, F=35.323, df=4, p<0.001.

Scheffe post-hoc analysis aimed to identify exactly where the differences identified by the ANOVA lay, to determine the incremental change required to produce significant differences in measure value. Analysis of the statistical significance of differences associated with all possible increments of 5º, 10º, 15º and 20º suggests that 10º of calcaneal inversion produced significant differences in navicular height, whilst Stahelis arch and Chippaux-Smirak indices required 15º or greater. Scheffe analysis therefore revealed that the origin of the differences detected by ANOVA were restricted to changes of greater than 5º for all measures, and that the sensitivity of each measure differed.

Clinical interpretation of these results can be aided by considering the actual change in measure value associated with each incremental change in calcaneal alignment. Table 6.12 displays, for each measure, the actual change associated with each increment, together with the 95% confidence interval. These figures suggest that a
change in navicular height of 7.8mm (95% CI: 6.2-9.4mm) would need to be measured clinically, to be sure that the calcaneus had moved a significant amount. Graph 6.13 shows the cumulative effect on navicular height of progressively increasing subtalar inversion, and allows visualisation of the actual differences between adjacent positions throughout the range of motion investigated. Each column equates to a 5° change in alignment, and this graph also shows a clear trend for navicular height to increase with STJt inversion.

Table 6.12: Summary of changes in measure values with 5°, 10°, 15°, and 20° changes in calcaneal position: mean (95% Confidence Limit)

<table>
<thead>
<tr>
<th>Measure</th>
<th>5° Increments</th>
<th>10° Increments</th>
<th>15° Increments</th>
<th>20° Increments</th>
</tr>
</thead>
<tbody>
<tr>
<td>SAI</td>
<td>0.7 (-0.5 : 0.2)</td>
<td>0.16 (0.02 : 0.3)</td>
<td>0.2 (0.1 : 0.3)</td>
<td>0.3 (0.2 : 0.4)*</td>
</tr>
<tr>
<td>CSI</td>
<td>5.9 (-1.1 : 12.9)</td>
<td>10.9 (-0.3 : 21.5)</td>
<td>22.7 (10.9 : 34.6)*</td>
<td>34.8 (25.2 : 44.4)*</td>
</tr>
<tr>
<td>Navicular Height (mm's)</td>
<td>3.2 (2.3 : 4.2)</td>
<td>7.8 (6.2 : 9.4)*</td>
<td>12.9 (11.2 : 14.6)*</td>
<td>18.2 (16.1 : 20.3)*</td>
</tr>
</tbody>
</table>

Graph 6.13: Change in navicular height with cumulative 5° calcaneal inversion increments. Blue column = mean, error bars = standard deviation. Measured in millimetres.

6.4.4 Discussion

Numerous researchers interested in the relationship between ‘foot-type’ and pathology have chosen to characterise foot-type using measures that focus on some aspect of foot structure. The purpose of this study was to examine the validity of three morphological measures previously described in the literature, and representative of
those that have been used for both clinical and research purposes. The approach adopted was based on two assumptions. Firstly, that the STJt is the determinative joint of the rearfoot, exerting a considerable influence on morphology, and that frontal plane calcaneal alignment offers some insight into true subtalar motion (otherwise impossible due to the lack of surface markings on the talus). The use of such a 'proxy' gold standard for investigation of validity when an absolute measure is unavailable is endorsed (Bowling, 1997, Daly and Bourke, 2000), and as such the approach could satisfy the demands of face (subjective assessment of relevance and appropriateness of procedure) and construct (comparison with a clinically important outcome / proxy gold standard) validity. Secondly, it assumes that a 5° change in frontal plane calcaneal alignment represents significant subtalar motion, capable of perceptibly changing foot morphology. The exact range of subtalar motion has been suggested to be between 5° & 11°, using a computerised tomography technique (Pearce and Buckley, 1999) and 30°, based on clinical measurement (Root et al., 1971). These figures suggest that a 5° change in calcaneal alignment represents between 1/2 and 1/6 of the range of motion of the joint – a substantial proportion of either reported range and therefore a clinically relevant amount.

Although correlations between all measures and calcaneal position achieve the level required for significance, it is clear that the correlation is low for the footprint measures, and does not reflect a strong relationship. This conclusion is supported by the Scheffe analysis, which indicates that changes in calcaneal position of greater than 10° (CSI) and 15° (SAI) are required to produce significant differences in measure values. This information suggests that different feet could have been classified as the same in studies utilising these measures, even considering that the real difference required to produce significant differences probably lies between the significant and non-significant values (10° and 15° for CSI and 15° and 20° for the SAI). Whilst the clinical significance of a 5° change in calcaneal alignment is essentially unknown, the failure of these measures to respond predictably to a 10° change in alignment suggests that they demonstrate weak precision (defined as the ability to detect small changes in the attribute (Bowling, 1997)) and cannot differentiate between what could be reasonably claimed to be significantly different subtalar positions.
Navicular height displayed greater sensitivity to changes in calcaneal position, (Pearson's rho = 0.8) with changes in alignment of 10° being associated with significant changes. The superiority of navicular-based measures in this study is further re-enforced by considering that the true change in calcaneal alignment required to produce a significant difference lies between the non-significant (5°) and the significant (10°) level. This finding is consistent with existing data. For example, a dynamic study of the relationship between triplaner navicular and frontal plane calcaneal motions identified a significant correlation of 0.94 (Cornwall and McPoil, 1999). Although the correlation identified in the current study falls below this level, the discrepancy can perhaps be explained by dynamic influences. For example, in another study investigating the relationship between 27 radiographic measures of foot structure and dynamic plantar pressures, a limited relationship was identified, leading to the conclusion that the dynamics of gait were likely to exert a major influence (Cavanagh et al., 1997). Therefore, although it is clear that dynamic evaluation is required for the most accurate evaluation of foot-function possible, it seems that static techniques do still provide useful information.

Although navicular height, measured simply as the vertical height of the navicular in relaxed stance, has been discussed (Saltzman et al., 1995), it is also used in a second measure, 'navicular drop' (Brody, 1982, Mueller et al., 1993, Picciano et al., 1993). Involving measurement of vertical movement of the navicular as the STJt is moved from the neutral to the RCSPs, this measure appears valuable, as it directly attempts to quantify the amount of compensatory motion taking place, which Root et al suggested to be important (Root et al., 1977). As opposed to a measure of static structure, the dynamics of gait would more likely be reflected in a measure based on static compensatory motion, given that the dynamics of gait have been suggested as important (Cavanagh et al., 1997). This would allow the foot to be easily assigned to one of the three categories of compensation presented by Root et al: excessive pronation, excessive supination and restricted motion (Root et al., 1977). This assertion is supported by the relationship between the RCSP and dynamic rearfoot motion (McPoil and Cornwall, 1994, Torburn et al., 1998, Wright et al., 1964) and the correlation with maximal dynamic eversion (McPoil and Cornwall, 1996b, Torburn et al., 1998).
The navicular drop test was originally proposed as a measure believed to offer advantages over evaluation of the neutral and RCSPs (NCSP; RCSP), which have been associated with reliability problems (Keenan, 1997). This measure does seem to offer additional information over measures based exclusively on static posture. It seems a basic requirement that the ability of static measures to predict at least a proportion of dynamic function is a pre-requisite to their use. Given the imperfect correlation between navicular drop and calcaneal motion of 0.8-0.9 (derived from the present study and McPoil & Cornwall (Cornwall and McPoil, 1999)), it seems that measuring one is not quite the same as measuring the other; and there are probably several factors, including subtalar axis orientation and ligamentous / capsular laxity, which determine the precise relationship between rearfoot and midfoot motion. The use of skin markings, which may not precisely reflect underlying bone movement, may also influence the relationship. Measurements of compensation recorded using both the calcaneus and navicular have been found to have acceptable reliability (Sell et al., 1994), although the calcaneal method was associated with higher intraclass correlations, a lower standard error of measurement and smaller confidence intervals. Improved reliability over measurement of RCSP and NCSP may be explained by the use of a calcaneal bisection which essentially acted as an arbitrary reference line, although placement of the STJt in its neutral position is still required. This information suggests that a better method of classifying ‘foot-type’ may be to examine static compensatory motion at the calcaneus and navicular.

The study suggests that measures of foot type calculated from static footprints display a limited ability to respond to discrete changes in STJt position. This suggests that such measures have a limited ability to accurately classify subjects for research purposes, potentially leading to inappropriate groupings, and they cannot, therefore, be recommended. This questions the value of studies that have utilised such measures. Measurements based on static estimation of compensation, using the calcaneus and navicular, appear to demonstrate potential, offering an insight to dynamic motion as opposed to static position. These techniques offer the opportunity of investigating the relationship between the three classes of compensation proposed by Root (Root et al., 1977) (abnormal pronation, abnormal supination and restricted motion) and musculoskeletal pathology. Whilst the validity of foot-type measures require further investigation to explore the multiple dimensions of validity, this study provides
evidence supporting the use of measures based on static estimation of dynamic function, and are a superior choice in comparison with the existing, commonly used, techniques that are recorded from a purely static foot posture.
6.5 Foot-type and chronic low back pain: a case control study

6.5.1 Introduction

Low back pain (LBP) is a common, potentially disabling, nonfatal public health problem with significant direct and indirect costs (BenDebba et al., 2002). These costs are attributed not only to the provision of medical care but also to lost working time, disability payments and diminished productivity, and result in a combined annual cost in excess of $38 billion (Atlas and Deyo, 2001). Although this figure relates to the USA, a similar situation exists in the UK (Jenner and Barry, 1995, Kendrick et al., 2001, Samanta and Beardsley, 1999) and across the western world (Long et al., 1996). Although LBP has been broadly divided into mechanical (no primary inflammatory or neoplastic cause), visceral (no primary involvement of the spine), and all other causes, it is acknowledged that a definitive diagnosis remains elusive in as many as 85% of patients, in whom general musculoligamentous / degenerative conditions are held responsible (Jarvik and Deyo, 2002).

It has been suggested that foot function influences LBP. In a literature review investigating the mechanism of association, 5 possibilities were identified: heel height, inadequate shock absorption, excessive pronation, functional limb length discrepancy and disrupted sagittal plane mechanics (Bird and Payne, 1999). Whilst heel height is an external variable that alters the location of the centre of mass of the body only when shoes are worn, the remaining factors represent intrinsic mechanical characteristics that disrupt lower limb function. Inadequate shock absorption, which may be related to arch height (Ogon et al., 1999, Simkin et al., 1989), is thought to influence heelstrike transients to damage proximal joints and the lower spine (Whittle, 1999). Excessive pronation is capable, at least theoretically, of disrupting normal spinal mechanics because of the interdependence of the foot and lower limb in normal function. For example, pronation is known to be coupled with internal tibial rotation (Inman et al., 1994, Rose, 1962), and although the nature of the association proximal to the knee is variable (Nester, 2000) it can produce internal femoral rotation which can result in anterior and inferior pelvic motion. These motions have been associated with tightening of the piriformis and iliopsoas muscles, increased lumbar lordosis, and may result in sciatic nerve symptoms and sacroiliac or lumbar disk compression (Minkowsky and Minkowsky, 1996). This motion pathway is also implicated in functional limb length discrepancy, where asymmetrical pronation arising from either
structural or functional limb length discrepancy, may lead to asymmetrical internal limb and pelvic rotation that may ultimately result in muscular imbalance and lumbar scoliosis to alter forces in the lower spine (Michaud, 1997b). Finally, sagittal plane theory describes the importance of normal sagittal plane motion about the three foot 'rockers' (Perry, 1992b), the importance of the forefoot rocker in stabilising the foot in propulsion (Bojsen-Moller, 1979b), and the link between impaired sagittal progression and pathology throughout the kinetic chain, and especially the lumbosacral region (Dananberg, 1995). Despite these varying aetiologies and causal pathways, a commonality between all mechanisms, except heel height, is their influence on rearfoot function and therefore pedal structure.

To examine the link between foot function and LBP, a valid method of assessing foot function is vital. Although 'foot function' essentially relates to dynamic function of the foot, this has not always been measured directly. For example, in a study of 20 subjects presenting at a physiotherapy department complaining of LBP, dynamic foot function was not directly measured, but rather, the incidence of rearfoot and forefoot anomalies perceived to produce pronation was assessed. In addition to this study representing essentially a 'case-series', a weak form of evidence (Greenhalgh, 2001), the approach is also compromised by the use of measurement techniques that have been consistently associated with poor-moderate reliability (Keenan, 1997, Van Gheluwe et al., 2002), and the questionable association between these measurements and dynamic foot function (Hamill, 1989, McPoil and Cornwall, 1996a, McPoil and Cornwall, 1996b). For example, in a study investigating the relationship between a series of lower limb alignment variables and dynamic function, it was found that the only measure that could predict maximal rearfoot pronation was the difference in navicular height between the neutral and RCSPs (McPoil and Cornwall, 1996a). This measure, along with calcaneal motion, has been identified as potentially useful measures of foot function that appears valid and reliable by earlier studies in the present investigation. In contrast to the rather convoluted approach adopted in previous studies, that utilised measures of lower limb alignment only perceived to predictably influence foot function, it seems more appropriate to look directly at foot function by using motion-based measures such as navicular drop and calcaneal motion. Earlier investigations suggest these techniques to be related to dynamic foot function, and to be more sensitive to small changes in STJt alignment than footprint
measures. If a relationship were to be identified then it would certainly then be warranted to investigate the aetiology of the abnormal foot function, but given the inadequacy of the measurement techniques involved, it seems both premature and ambitious to consider the actual series of measurements rather than the more global issue of foot dysfunction regardless of aetiology.

The current climate of evidence-based practice emphasises the role of RCTs (RCT’s) and systematic reviews of these trials. Although there is little doubt that these studies can provide important evidence about the efficacy of interventions, it is important that they are used appropriately (Black, 1998a, Gordis, 2000), that is, when the causal pathway is clearly understood (Gordis, 2000, Vetter, 2000). Epidemiologists emphasise the importance of observation in investigating cause, using cohort and case-control studies, prior to the use of RCT’s. Such observational studies depend on the availability of reliable and valid techniques with which to measure and record observations on subjects, and can provide valuable insight into the cause of disease. Given that the relationship between foot function and LBP is poorly understood, observational study designs such as case-control or cohort designs seem more appropriate.

The study aimed to investigate the relationship between foot function and low back, using measures of foot function based on calcaneal and navicular motion, employing a case-control design.
6.5.2 Method

Subjects
Case group patients were recruited from a local NHS orthopaedic outpatients clinic and control subjects were recruited from the staff and students of a nearby University. Ethical approval for the study was obtained from the Local Health Research Ethics Committee (Appendix 1), and the study was registered with the Local NHS Research and Development Office. All participants were over the age of 18, and patients had pain located in the lumbosacral spine, with or without leg pain, that was deemed to be of mechanical origin by the consulting physician. Although the inclusion criteria specified that symptoms should have persisted for \( \geq 6 \) months, the waiting list ensured that no patient had back pain of \(< 12 \) months duration. Controls reported no history of recurring LBP, although a history of no more than two episodes of low back was permitted where this was clearly exertional or accidental, and had fully resolved leaving no residual effects. As an example of the application of this criterion, one subject described an episode of back pain that developed during a game of squash that had completely resolved within 4 weeks with no re-occurrence or residual effects. Subjects from neither group had a history of trauma or surgery to their feet or limbs. All participants signed a consent form (appendix 2), after reading a standardised information sheet (appendix 3). In compliance with the conditions of ethical approval, a standard letter was sent to the G.P’s of all case subjects recruited (appendix 4).

Procedure
A standardised protocol was formulated (appendix 5) which encompassed various examination procedures, and all cases and controls were examined according to this procedure. Participation involved completing a questionnaire (appendix 6) aimed at gathering information on factors ranging from personal and demographic information to exposure to known risk factors for LBP, and undergoing a clinical examination. Cases and controls went through the same process, as the aim of the study was to determine whether there were any differences in a series of variables between the two groups. The questionnaire included the Quebec back pain disability scale (Kopec et al., 1995), questions permitting the sub-classification of back pain patients according to a validated technique, (BenDebba et al., 2000), and the FHSQ (Bennett et al., 1998, Bennett et al., 2001). The role of each element within the study is explained below:
1. **The Quebec Back Pain Disability Scale** (Quebec) (Kopec et al., 1995)

This scale was included as a measure of the severity / functional consequences of LBP, and allowed comparison of differences in back pain status between groups to ensure correct group assignment of subjects. Comprising a series of 20 questions concerning the difficulty associated with a series of activities of daily living, a score of 100 indicated completely debilitating pain and a score of zero the absence of pain. Quebec score was not used to determine group membership; this was determined solely by history. The scale was included to confirm that ‘cases’ were truly experiencing back pain and that ‘controls’ were not, and also to allow the possibility of a secondary analysis of any ‘dose-response relationship’ effect, by considering the correlation between back pain and foot function / health.

2. **Sub-classification of Back Pain Patients** (BenDebba et al., 2000)

A system proposed for classifying persistent LBP patients was adopted to permit a secondary investigation of the relationship between foot function and different types of back pain. This system collates information on the spatial distribution of pain with the response to the straight leg raise (SLR) test to assign individuals to one of four mutually exclusive, hierarchically organised back pain groups (BenDebba et al., 2000). These four groups were found to account for the vast majority (95.74%) of 1997 patients recruited as part of a National LBP Study, and comprised the following four categories:

1) Back pain only, with SLR +ve or –ve for back pain only;

2) Back pain and proximal leg pain with SLR +ve or –ve for back pain only;

3) Back pain and distal leg pain with SLR +ve or –ve for back pain only;

4) Back and distal leg pain with SLR +ve for leg pain

The authors recommended this as a useful method for reducing the heterogeneity of LBP patients by grouping similar types of pain together. Eighty-five (4.26%) of the 1997 patients recruited were excluded because they fell outside this classification, and to permit consideration of such patients in the current study, they were assigned to category 5 for the purpose of subgroup assessment.
3. The Foot Health Status Questionnaire (FHSQ) (Bennett et al., 1998, Bennett et al., 2001)

In addition to measurement of biomechanically based measures of foot function, this questionnaire was included as an additional means of investigating the relationship between foot function and LBP. The direct theoretical link between abnormal foot mechanics and foot pathology suggests that a majority of common foot pathologies result from abnormal foot function (Root et al., 1977). It is reasonable, therefore, to expect a higher prevalence of foot health problems in those with abnormal foot function. Identifying significantly lower (worse) FHSQ scores in LBP patients would therefore suggest an association between foot function and LBP. The FHSQ examines four domains of foot health – pain, functional limitation, footwear satisfaction and the subjects general perception of the condition of their feet. Introduced as a tool for evaluating the efficacy of footcare programmes, (Landorf and Keenan, 2002) recently compared it with the FFI (Budiman-Mak et al., 1991), a tool developed to measure the effect of rheumatoid arthritis in the foot. Findings suggested that the FHSQ is more sensitive to smaller changes in foot health, and it was recommended as the superior choice in circumstances where less dramatic foot changes are being treated / evaluated. The FFI was found to be sensitive to the larger changes typically associated with rheumatoid arthritis – the condition it was devised to investigate.

Clinical Examination Procedure

A SLR test was performed with the patient lying supine on an examination couch. With the knee extended, the examiner raised each leg in turn whilst the contra-lateral pelvis was stabilised with the other hand to prevent it from rising and influencing the test result. The patient was asked to indicate the point at which they felt pain. This information was used, in conjunction with information on the spatial distribution of pain, to assign participants to one of the four categories described previously (BenDebba et al., 2000).

Frontal plane motion of the calcaneus, and sagittal plane motion of the navicular, between the neutral and RCSPs was measured to provide information on dynamic foot function. All subjects underwent the same procedure. Shoes and socks were removed and the subject was asked to stand in the relaxed stance position. The tuberosity of the
navicular was marked using a fine felt tip pen and the relaxed height was measured using a tape measure with the examiner positioned directly in front of the patient to ensure an unrestricted view to reduce parallax error. The subject was then asked to supinate both feet simultaneously and slowly relax until the examiner instructed them to stop in the neutral position. This was determined using the documented technique that involves palpation of the talar head for congruence with the navicular and assessment of the equality of superior and inferior lateral malleolar curvatures (Root et al., 1977). A tractograph was set at 90° and placed flat on the ground behind the calcaneus so that the vertical arm could be used to apply a reference line to the posterior calcaneal perpendicular to the supporting surface. The height of the tuberosity of the navicular was again measured, to provide the NCSP measurement, and the patient was asked to relax. The angle between the calcaneal reference line and the ground was measured to provide a direct measurement of frontal plane motion between neutral and relaxed, and the RCSP navicular height was subtracted from the NCSP height to provide a measure of the change in vertical height of the navicular between the two positions.

Observer Error
Whilst the Quebec and FHSQ scales have undergone reliability and validity assessment, and can be considered robust tools (Bennett et al., 1998, Bennett et al., 2001, Kopec et al., 1995, Landorf and Keenan, 2002), the two biomechanical measures – navicular drop and calcaneal motion, whilst theoretically sound, are less clinically robust. Reliability and validity data does exist for navicular drop, with intra-class correlation coefficients ranging from 0.57 to 0.85 for inter-rater and 0.44 to 0.83 for intra-rater reliability. Calcaneal motion has only been discussed once (Sell et al., 1994), and was associated with an intra-class correlation coefficient for intra-rater reliability of 0.91 – satisfying a level suggested as required for the measurement to be of use clinically (Portney, 1993). Across this range of studies similar conclusions have been presented, with universal acknowledgement that the use of robust protocols, practice sessions and a single experienced clinician can all help improve reliability. Given the validity problems associated with alternative measures of foot-type, even although navicular drop and calcaneal motion measures have been associated with a range of reliability estimates, all of which lie below the 0.9 level suggested to be the minimum to render a measurement clinically useful (Portney,
1993), they are still considered to present an advantage over alternative techniques of foot-type assessment. This is because of the use of a single, experienced examiner using a robust practised protocol. The issue of reliability has been discussed in detail in this thesis, and it is clear from existing literature that intra-rater reliability is more consistent than inter-rater, that within day measurements are more consistent than between day, and that dynamic function is an intrinsically variable quantity. Therefore, although high levels of reliability (ICC's ≥0.9) have been suggested as the minimal acceptable, it is considered both realistic and justified to utilise measurements with reliability levels below this, so long as an awareness of the possible influence of the error is retained and results are interpreted with caution.

To provide information on the examiners reliability a small repeatability study was conducted. This involved the recruitment of 10 volunteers who had both left and right feet evaluated on two separate occasions. Data from the left and right feet were pooled, and a Pearson's correlation coefficient was used as a measure of agreement between the two occasions. For Navicular drop the correlation was 0.84, whilst for Calcaneal motion the correlation was 0.72. These correlations equate with those reported in previously, and whilst the level is acceptable for navicular drop, it is poorer for calcaneal motion. The study therefore proceeded using the Quebec back pain disability scale, the FHSQ, navicular drop and calcaneal motion tests, but acknowledges the limitations of the two foot motion measures.

Power Calculation
Power calculations are an important research design issue. They should be performed prospectively so that a sample size is recruited that is sufficient to minimise the chance of a type I and II errors (Bland, 2000). These errors relate to the erroneous acceptance or rejection of the null hypothesis (Petrie and Sabin, 2000). The calculation used is based firstly on the structure of the study, its design, and the type of variable being measured, and secondly, on the relationship between power, sample size, the minimal clinically significant difference, and the selected significance level (Daly and Bourke, 2000). The association between these variables for comparison of means between two groups is expressed as:

\[ n \geq \frac{2k \sigma^2}{\Delta^2} \]  

(Daly and Bourke, 2000)
where \( n \) = the minimum number of subjects per group; \( k \) = a constant expressing the relationship between power and significance level, \( \sigma \) = the variance and \( \Delta \) = the minimum clinically significant difference. Where several variables are being measured, the ‘most important’ should be selected.

Although it is recommended that power calculations are performed prospectively to ensure selection of an appropriate sample size, it is acknowledged that there are times when obtaining accurate estimates of variance and the minimal clinically significant difference is difficult (Daly and Bourke, 2000). Under these circumstances the equation can be re-arranged to examine the power associated with different sample sizes, and they can be employed at the end of the study to calculate the actual power of the study based on measurements obtained during data collection. Whilst the number of subjects recruited is often a compromise between the ideal and the realistic, as determined by available finance and time amongst other factors, it remains a vital consideration.

To allow a prospective calculation to be performed a power level of 80% at a significance level of 5% was selected, giving a value for the constant, \( k \), for a two-sided test of 7.8 (Daly and Bourke, 2000). Foot motion variables were of primary importance in the study, and therefore estimates of variance and minimal clinically significant difference were sought for these from the literature. These are summarised in table 15 over the page. Variance was estimated for navicular drop from 4 studies that measured a total of 188 feet, with a pooled standard deviation of 3.5. This permitted estimate of variance because variance = standard deviation\(^2\) (Petrie and Sabin, 2000). Estimates of the variance of calcaneal motion were only available from a single study (Sell et al., 1994), where the standard deviation derived from measurements of 60 feet was 2.8. The minimal clinically significant difference was set as 3° for the calcaneus and 5mm for the navicular. When these values are substituted in the equation it suggests that 107 subjects should be recruited per group for calcaneal motion, and 94 per group for navicular drop. The figure of 107 was adopted as the target, although a time-constrained data collection period of 8 months was set as a pragmatic limit, and it was acknowledged that in the time available this target would be difficult to achieve.
Table 6.13: Estimates of navicular drop and calcaneal motion for normal subjects.

<table>
<thead>
<tr>
<th>Study</th>
<th>n</th>
<th>Mean (St. Dev.)</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Navicular drop (mm's)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Picciano et al (1993)</td>
<td>30 feet</td>
<td>9 (4.2)</td>
<td>Standard clinical technique</td>
</tr>
<tr>
<td>• Sell et al (1994)</td>
<td>60 feet</td>
<td>6 (4)</td>
<td>Standard clinical technique</td>
</tr>
<tr>
<td>• Vinicombe et al (2001)</td>
<td>40 feet</td>
<td>9.5 (2.5)</td>
<td>Standard clinical technique</td>
</tr>
<tr>
<td><strong>Calcaneal motion (degrees)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Sell et al (1994)</td>
<td>60 feet</td>
<td>4 (2.8)</td>
<td>Only study to measure calcaneal motion between NCSP and RCSP</td>
</tr>
</tbody>
</table>
6.5.3 Results
Data analysis aimed primarily to determine whether significant differences existed between cases and controls for core study variables. This commenced with assessment of various demographics, such as age, sex, smoking status and hypermobility, between groups to determine whether these could have significantly influenced the results of the main analysis. The main analysis was then performed, which dealt with a series of hypotheses relating to differences between groups for core study variables including Quebec and FHSQ score, calcaneal and navicular motion measurements. These hypotheses are presented sequentially. All statistics were computed using SPSS® for Windows version 11 (SPSS, Chicago, Illinois).

Data was collected from a series of 64 patients and 57 controls. For both groups a number of subjects declined to take part, for several reasons, including lack of time and an unwillingness to participate in research. Eight potential cases declined to take part, and a further 6 had difficulty in performing the required manoeuvres or had difficulty complying with instructions. Five controls were also lost in this way. The flow of patients through the study is illustrated in figure 6.6.

Figure 6.5. Flow chart of subject flow through the trial

Participants recruited over a 10 month period in 2002

Cases
Recruited from local NHS orthopaedic outpatient clinic
- 78 Subjects approached
- 14 Declined / inadequately complied
- 64 Subjects formed group

Controls
Recruited from local university
- 62 Subjects approached
- 5 declined / inadequately complied
- 57 Subjects formed group

Participant demographics
All participants provided information regarding basic demographics and several variables associated with LBP that could potentially confound results. These included height, weight, age, details of joint pain outwith the spine and smoking status. Smokers were also asked how many cigarettes they smoked per day, and for how long they had smoked. Table 6.14 summarises these demographics. The Beighton hypermobility criteria (Beighton, 1973) were also employed, in recognition of the
potential for joint laxity to produce excessive foot motion, general joint pain including LBP, and to permit analysis of the role of this variable to be included. Assessment against these criteria involved asking the participant to demonstrate a series of manoeuvres to determine the flexibility of various joints, including dorsiflexion of the 5th metacarpophalangeal joints to 90°, apposition of thumb and volar aspect of the forearm, hypermobility of elbows and knees by >10°, and the ability to place both hands flat on the floor without bending the knees. Each motion successfully completed scored a point. Although there are limitations to this system, including a lack of consensus on the score that can be regarded as indicating the presence of the syndrome (Keer and Grahame, 2003) this scale is easily incorporated in an epidemiological study and provides a pragmatic measure of generalised hypermobility. Further, assessment of differences between groups negates the need for a cut-off point indicating the absence or presence of the condition. Results are included in table 6.14.

Table 6.14: Participant demographics / basic data summary

<table>
<thead>
<tr>
<th></th>
<th>Cases</th>
<th>Controls</th>
<th>Difference p=</th>
</tr>
</thead>
<tbody>
<tr>
<td>n=</td>
<td>64</td>
<td>57</td>
<td></td>
</tr>
<tr>
<td>Sex* (M:F)</td>
<td>35:29</td>
<td>25:32</td>
<td>=0.236</td>
</tr>
<tr>
<td>Joint pain* (Yes:No)</td>
<td>86% +ve</td>
<td>46%</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Smoking status* (Yes:No)</td>
<td>26:38</td>
<td>5:52</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Age</td>
<td>47 (11)</td>
<td>36 (12)</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Height (metres)</td>
<td>1.7 (0.1)</td>
<td>1.71 (0.09)</td>
<td>=0.809</td>
</tr>
<tr>
<td>Weight (kilograms)</td>
<td>80.2 (17.3)</td>
<td>74.7 (14.7)</td>
<td>=0.63</td>
</tr>
<tr>
<td>Beighton mobility score</td>
<td>1.1 (1.7)</td>
<td>1.8 (2.2)</td>
<td>=0.060</td>
</tr>
</tbody>
</table>

The significance of differences in sex, additional joint pain and smoking status was evaluated using Mann-Whitney tests. Mean and standard deviation are provided for age, height, weight and Beighton score, with independent, 2 tailed t-tests used to determine the statistical significance of group differences. * Denotes that a significant difference exists between the two groups.

Whilst the difference between groups in terms of the presence of additional joint pain and smoking status could reasonably be expected, because of the general increase in musculoskeletal pain that could be expected in a patient with chronic LBP and the documented increased prevalence of smoking (Shekelle, 1997) in this group. The difference in age is a potentially important confounding variable, and warrants further attention in the data analysis. Graph 6.14 further illustrates the nature of this difference.
Graph 6.14: Age distribution of cases and controls
This graph shows controls to be negatively skewed in comparison to cases. This is consistent with the average 10 year difference between groups shown in table 1, and necessitates further analysis of the influence of age on results.

After considering the characteristics of the participants making up the two groups, the main analysis was conducted. This was approached via the use of a series of hypotheses.

There is no significant difference in back pain severity between case and control groups.
The severity of LBP, measured using the Quebec back pain disability scale, was compared between cases and control. This was a confirmatory exercise conducted to ensure that individuals had been assigned to the appropriate back pain group. A mean score of 50 (s.d. 22) for cases and 2 (s.d. 3) for controls returned a 1-tailed t-test result that confirmed a highly significant difference between the two groups in the expected direction (t=16.639; df=119; p<0.0001). This interpretation is fully supported by considering the mean difference of 48.1 (95% confidence interval 42.36 – 53.81). The null hypothesis was rejected, and it was assumed that both groups represented the patient populations intended.

There is no significant difference in FHSQ scores between case and control groups.
Scores obtained in the four domains of the FHSQ, as well as the total score, were compared between groups to examine if there was an increased prevalence of foot disorders between the two groups. Table 6.16 summarises the descriptive statistics.
and t-test results. For all domains except footwear satisfaction there was a significant difference between the two groups, and this reflected in the difference in total FHSQ scores between the two groups, where a mean difference of 21.5 (95% confidence interval -28:-15) was associated with a significant t-test result of p<0.0001. Foot health status was significantly worse in cases than in controls.

Table 6.15. Differences in FHSQ scores between cases and controls. (all domains and total score)

<table>
<thead>
<tr>
<th>Domain</th>
<th>Cases</th>
<th>Controls</th>
<th>t-test results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (St. Dev)</td>
<td>Mean (St. Dev)</td>
<td>t</td>
</tr>
<tr>
<td>Pain</td>
<td>61.2 (29.3)</td>
<td>88.66 (12.4)</td>
<td>-6.6</td>
</tr>
<tr>
<td>Function</td>
<td>74.62 (26.2)</td>
<td>97.91 (5.3)</td>
<td>-6.6</td>
</tr>
<tr>
<td>Footwear</td>
<td>52.7 (32.5)</td>
<td>62.3 (29.6)</td>
<td>-1.7</td>
</tr>
<tr>
<td>General</td>
<td>47.7 (32.6)</td>
<td>73.5 (25.6)</td>
<td>-4.8</td>
</tr>
<tr>
<td>Total</td>
<td>59.1 (23.6)</td>
<td>80.57 (12.7)</td>
<td>-6.1</td>
</tr>
</tbody>
</table>

Results labelled* indicate statistically significant results.

There is no significant difference in navicular or calcaneal motion between the two groups.

In addition to assessing whether there were any differences in the total amount of compensatory motion measured between the NCSP and RCSP positions at the Navicular and Calcaneus in the left and right feet, the symmetry of motion between left and right was also considered. Analysis involved calculation of mean and standard deviation for both total motion in left, right and symmetry, followed by t-tests to determine if the differences identified were significant. Table 6.16 shows the results, which revealed non-significant differences in the motion occurring at left and right for both calcaneal and navicular motion measurements, but did reveal a significant difference in symmetry between the two groups. Cases showed greater asymmetry, averaging 3.2° at the calcaneus and 4.2mm at the navicular compared to controls that demonstrated 0.9° at the calcaneus and 1.2mm at the navicular. The mean difference at the calcaneus was 2.2° (95%CI: 1.8:2.7) equated to a significant t-test result of p<0.001. At the navicular the mean difference was 3mm (95%CI 2.1:3.9), again equating with a significant t-test result of p<0.001.
Table 6.16: Calcaneal and navicular motion in cases and controls: mean, standard deviation and t-test results for absolute motion at both navicular and calcaneus and asymmetry.

<table>
<thead>
<tr>
<th></th>
<th>Cases Mean (st. dev)</th>
<th>Controls Mean (st. dev)</th>
<th>t</th>
<th>df</th>
<th>Mean Difference (95% CI's)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>L Calc Total</td>
<td>4.98 (3.3)</td>
<td>5.4 (2.7)</td>
<td>-0.687</td>
<td>119</td>
<td>-0.38 (-1.5:0.7)</td>
<td>0.494</td>
</tr>
<tr>
<td>R Calc Total</td>
<td>4.9 (3)</td>
<td>5.2 (2.4)</td>
<td>-0.641</td>
<td>119</td>
<td>-0.32 (-1.3:0.6)</td>
<td>0.523</td>
</tr>
<tr>
<td>Calc symmetry</td>
<td>3.2 (1.5)</td>
<td>0.9 (0.9)</td>
<td>9.721</td>
<td>119</td>
<td>2.2 (1.8:2.7)</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>L Nav Total</td>
<td>6.8 (5.6)</td>
<td>7.3 (3.8)</td>
<td>-0.531</td>
<td>119</td>
<td>-0.5 (-2.2:1.3)</td>
<td>0.596</td>
</tr>
<tr>
<td>R Nav Total</td>
<td>8.5 (5.2)</td>
<td>7.4 (3.9)</td>
<td>1.267</td>
<td>119</td>
<td>1.1 (-0.6:2.7)</td>
<td>0.208</td>
</tr>
<tr>
<td>Nav symmetry</td>
<td>4.2 (3.3)</td>
<td>12 (1.1)</td>
<td>6.592</td>
<td>119</td>
<td>3 (2.1:3.9)</td>
<td>&lt;0.001*</td>
</tr>
</tbody>
</table>

Results labelled* indicate statistically significant differences.

There is no difference in Quebec score, FHSQ scores, or compensatory foot motion between back pain sub-groups.

A system has been proposed that assigns persistent LBP patients to one of four mutually exclusive, hierarchically organised groups based on the result of a straight leg raise test (SLR) and the spatial distribution of pain (BenDebba et al., 2000). This study identified a strong link between class membership and physical symptoms, and thus presents an opportunity to examine the influence of foot function variables on specific classes of LBP. This system was employed to attempt to further examine the relationship between foot motion / FHSQ scores and sub-types of persistent LBP, in an attempt to more closely examine the relationship between back pain sub-types and foot function. However, the numbers of subjects recruited into the case group were not sufficiently distributed through the subgroups to permit a meaningful analysis (bar graph 1).

Graph 6.15. Distribution of ‘cases’ by back pain sub-category. This chart shows the distribution of cases across back pain subgroups. As can be seen class 4 dominates, with uneven distribution across the other categories.
The influence of variation in age between case and control groups on results

Because age was identified to be significantly different between the case and control groups, further analysis was conducted to determine the influence of this variable on the results. This was achieved using an analysis of covariance (ANCOVA), which involves the use of an ANOVA model which can take into account selected covariables. The output from these tests details the significance of the covariate in isolation between the two groups, but also the significance of the relationship between the core variable between the two groups when the covariate is considered. When this analysis was performed it revealed that age exerted a significant influence on calcaneal symmetry. However, the results for FHSQ (total) and navicular symmetry suggested that age did not exert a significant influence. However, with p=0.035 for calcaneal asymmetry, this does not convince of a strong relationship. It is not, therefore, surprising that the differences between cases and controls for all three variables remained when age was factored in (illustrated in the table in the 'group effect' line). Full ANCOVA results are detailed in table 6.17.

Table 6.17: Controlling for age using ANCOVA. ANCOVA results examining the influence of the age difference between cases and controls on differences in calcaneal & navicular symmetry and total FHSQ scores identified by the study.

<table>
<thead>
<tr>
<th>Variable</th>
<th>df</th>
<th>F</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcaneal symmetry</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Age</td>
<td>1</td>
<td>4.568</td>
<td>0.035</td>
</tr>
<tr>
<td>- Group effect</td>
<td>1</td>
<td>96.645</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Navicular symmetry</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Age</td>
<td>1</td>
<td>0.002</td>
<td>0.964</td>
</tr>
<tr>
<td>- Group effect</td>
<td>1</td>
<td>34.962</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>FHSQ Total</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Age</td>
<td>1</td>
<td>3.893</td>
<td>0.051</td>
</tr>
<tr>
<td>- Group effect</td>
<td>1</td>
<td>22.655</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Odds Ratios

An important aspect of case-control studies is their use in measuring the strength of the relationship that exists between particular exposure variables and the disease or condition in question. Whilst direct estimates of absolute and relative risk are possible with cohort studies, which follow patients forward in time, this is not possible for case-control studies, due to the ‘flexible denominator’. This is because the number of subjects recruited into each group is flexible, and as such the calculation of risk would
be arbitrary and meaningless (Daly and Bourke, 2000). The preferred technique is the Odds ratio, which is calculated as the odds in the exposed group divided by the odds in the unexposed group (Kirkwood and Sterne, 2003).

The FHSQ total score and navicular and calcaneal symmetry measures were identified as significantly different between the case and control groups. Odds ratios were not calculated for the FHSQ, however, because of the essentially arbitrary selection of a cut-off point. Selecting a cut-off for navicular and calcaneal symmetry was related back to the differences identified by the t-test in these variables between the two groups. Although higher values could have been selected, selecting the cut-off on the basis of the actual difference provides a more realistic indication of the actual odds ratios associated with these variables. Therefore, an asymmetry of ≥ 3mm was compared with <3mm for navicular motion, and for calcaneal motion an asymmetry of ≥ 3° was compared with < 3°. The odds ratios resulting from these calculations are shown in table 6.20:

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No. of Patients</th>
<th>No. of Controls</th>
<th>Odds ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Calcaneal asymmetry</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥ 3°</td>
<td>38</td>
<td>2</td>
<td>16.9</td>
</tr>
<tr>
<td>&lt;3°</td>
<td>26</td>
<td>55</td>
<td></td>
</tr>
<tr>
<td><strong>Navicular asymmetry</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥ 5mm</td>
<td>41</td>
<td>7</td>
<td>12.7</td>
</tr>
<tr>
<td>&lt; 5mm</td>
<td>23</td>
<td>50</td>
<td></td>
</tr>
</tbody>
</table>

Table 6.18. Odds ratios showing risk of low back pain associated with calcaneal and navicular motion asymmetry.
5.5.4 Discussion

The study sought to examine the relationship between foot function and chronic LBP using a case-control study design. Whilst the two have been theoretically linked via several mechanisms (Bird and Payne, 1999), discussions are largely theoretical or commonly involve case studies / case series involving limited numbers of patients, or studies that describe the success of orthoses in the treatment of selected patients (Dananberg and Guiliano, 1999). Whilst this evidence suggests that LBP may be attributable to lower limb mechanics in specific situations, the wider issue of the frequency of involvement of foot function in mechanical LBP and the causal pathway remains unclear. LBP places a considerable burden on modern healthcare systems across the western world (Long et al., 1996), and when the integrated nature of the lower limb musculoskeletal chain and the attribution of approximately 85% of cases to general musculoligamentous / degenerative conditions is considered, there appears to be a compelling case for exploration of the influence of foot function on LBP.

The results of the study suggest that foot function may well be associated with LBP. The two measures of foot function – navicular drop and calcaneal motion - and the foot-health related quality of life measure, the FHSQ (FHSQ), were found to differ between groups. Although there was no difference in terms of total motion in the left and right feet there was a difference in symmetry of motion. In the absence of differences in total motion occurring in left and right feet, this suggests that a greater amount of motion did not occur predictably in one foot, but that both feet move varying amounts. Odds ratios of 16.9 for \( 3^0 \) or more of calcaneal asymmetry, and 12.71 for 3mm or more navicular asymmetry suggests that a strong relationship exists with LBP in the population studied. Whilst the reliability of the techniques might lead to this result being questioned, the possibility of an association is supported by the fact that both measures are suggesting the same thing, and the magnitude of the effect. The FHSQ results also supports this, although it is interesting that the footwear satisfaction subscale did not differ between the two groups. The overall result, however, does differ and indicates that subjects with LBP experience significantly reduced foot health status. This could be a result of general musculoskeletal pain arising from the same source as the back pain, but equally, may infer that subjects with LBP have faulty foot mechanics that is resulting in intrinsic pedal problems that
could be related to the general lower limb musculoskeletal disruption that is also implicated with LBP.

An appreciation of the limitations of case control studies generally and this study specifically establishes a context within which to consider results, and this can be achieved by review against two benchmarks. Firstly, the quality of the specific research methodology may be reviewed against a specifically designed critical appraisal tool, such as that provided by the CASP tool, which is summarised in table 6.19. Secondly, results can be considered in relation to the ‘Bradford-Hills criteria’ (table 6.20), which essentially considers conditions that when satisfied ‘criteria for inferring causality’ detailed in epidemiological texts (Gordis, 2000, Vetter, 2000). These criteria help identify sources of error, and provide a useful context for interpreting results. It is worth considering each of the Bradford-Hills criteria in turn.

Table 6.19: Synopsis of CASP case-control study appraisal tool (PHRU, 2004)

<table>
<thead>
<tr>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did the study address a clearly focused question?</td>
</tr>
<tr>
<td>Was an appropriate method used to answer the question?</td>
</tr>
<tr>
<td>Were cases and controls recruited in an acceptable way?</td>
</tr>
<tr>
<td>Was the exposure accurately measured to minimise bias?</td>
</tr>
<tr>
<td>Which potentially confounding factors have been considered, and were they considered in the data analysis?</td>
</tr>
<tr>
<td>What are the results of the study?</td>
</tr>
<tr>
<td>How precise are the results?</td>
</tr>
<tr>
<td>Do you believe the results?</td>
</tr>
<tr>
<td>Do the results of this study fit with other available evidence?</td>
</tr>
</tbody>
</table>

Table 6.20: Bradford-Hills criteria for assessing causality

<table>
<thead>
<tr>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did exposure precede the onset of the disease?</td>
</tr>
<tr>
<td>Is there a ‘dose-response’ relationship?</td>
</tr>
<tr>
<td>Is there a strong association?</td>
</tr>
<tr>
<td>Is there a clear, biologically plausible, biological pathway linking exposure and disease?</td>
</tr>
</tbody>
</table>

The study attempted to address the issues raised in the CASP guide at the design stage. A clearly focused question was asked, and a strong rationale for a case-control study was made. Cases and controls were recruited in a systematic manner, using a clear definition of LBP, and cases and controls were recruited from separate centres. Control subjects are often recruited from the same centre as cases, but the use of an alternative avoids the bias associated with the possibility that risk factors related to
one disease may also be related to different diseases (Petrie and Sabin, 2000). It was conceded that subjects recruited from a separate centre may not be as motivated to take part in a study, and this was found to be the case. This added to the difficulty in identifying older control subjects who had a history negative for LBP, which represented a major difficulty as the study progressed.

The choice of exposure variables presents an important aspect of the study. The dangers associated with researching ‘taxonomically complex’ diseases have been discussed (Black, 1998a), and specifically relate to the reduction of complex, heterogeneous conditions to simple categories, or even their amalgamation into a single condition. Although a simple method of sub-classifying LBP patients was employed, it is unfortunate that this system could not be used because of a failure to recruit sufficient subjects to each group to permit meaningful analysis. Similarly, the classification of foot-type represents an important issue exerting a major influence on the study. Reviews of foot-type measures have considered a range of techniques, which although in common use, have little or no supporting information concerning validity. A major emphasis of the current research programme was the identification of valid measures of foot function, and this determined the choice of measures. Although the reliability of the two static measures indicating dynamic foot function used here represents a limitation of the study, this should be balanced against the information concerning their validity that was provided, and which suggested these measures to be more valid than existing techniques. The choice of navicular and calcaneal motion measures is essentially based on the belief that they represent the best available compromise between reliability and validity. There is persuasive evidence available suggesting that navicular and calcaneal motion, measured between the neutral and RCSPs, accurately estimates dynamic rearfoot function. Although the reliability levels obtained by each of these measures are not exceptionally impressive, as indicated by correlations of 0.72 for calcaneal and 0.8 for navicular measures, they are still considered useful and appropriate for use in epidemiological enquiry.

The difference in symmetry identified by these two measures is considered to be an important finding. An important criterion for inferring causality involves the identification of a biologically plausible pathway linking the factor with the disease, and this exits in the form of the transference of differing amounts of internal tibial
rotation on left and right sides proximally up the musculoskeletal chain. Essentially, this asymmetrical function is association with greater internal tibial and femoral rotation, increased inferior pelvic drop and forward rotation, sacro-iliac rotation on one side (Minkowsky and Minkowsky, 1996). Ultimately this may result in a spinal scoliosis (Botte, 1981). Greater degrees of rotation are associated with the longer limb when the asymmetrical function results from an anatomical limb length discrepancy, although it has been emphasised that different patterns can occur (Michaud, 1997b, Subotnick, 1999). Asymmetrical function can also result from a functional limb length discrepancy where, for example, the degree of external femoral rotation or hamstring flexibility differs between the two limbs. However, in both situations the important point concerning asymmetrical STJt rotation is the influence this will have at the pelvis, which will lead to asymmetrical sacro-iliac joint function and alterations in the normal spinal curvatures, which will result in altered intra-articular pressure distribution in the spinal and sacro-iliac joints, and altered muscle balance.

Odds ratios of 16.9 and 12.71 for calcaneal and navicular symmetry respectively support the concept of a relationship. However, this needs to be interpreted in light of the lack of knowledge concerning the temporal nature of the relationship between the two. Essentially, it may well be that back pain leads to asymmetrical function due to the antalgic gait patterns that are routinely adopted to reduce pain in chronic debilitating conditions. Therefore, it is impossible to say that the asymmetrical foot function preceded the onset of the LBP, and it may very well be that it did in fact follow the onset of the LBP. Such questions can be assessed using cohort studies. A useful approach to this problem may be to conduct serial gait analyses, at diagnosis and annually for 5 years, and compare these with an age, sex, and occupation matched normative sample to characterise gait degeneration in the condition. This would provide information relating to the temporal relationship between asymmetrical limb function and LBP.

Although age was identified as a confounding variable, this was accounted for using the ANCOVA technique, and despite differing significantly between cases and controls, failed to adequately explain the difference in asymmetry between the groups for any of the core study variables. The difference in age originated from the difficulty in recruiting subjects in the required age groups who satisfied the inclusion
Identifying controls in their 70’s, 60’s and even 50’s who experience no back pain is difficult, and this was compounded by the time limit on data collection. Although age was discounted as a significant, sole explanation for the difference in back pain between cases and controls, it undoubtedly accounted for some of the difference. However, ANCOVA results suggested that this is an inadequate explanation for the differences observed, and does not fatally flaw results.

The FHSQ represents an important additional means of investigating the relationship between foot function and LBP. The reliability of this tool has been shown to be excellent (Bennett et al., 1998). However, identifying a significant difference in FHSQ scores between the two groups cannot be taken as an indicator that foot function is a predictor of LBP. Clearly there are a number of situations in which foot function will be impaired in the absence of any biologically plausible relationship with LBP. The difference identified merely suggests that foot function may be associated with LBP. Again, the study did not examine the temporal relationship between any foot function variable, and it may well be that LBP results in gait changes that are asymmetrical due to the primary anomaly. However, it is felt that there is a clear rationale for continuing to investigate the relationship. Studies examining gait deterioration in LBP patients, including assessment of triplaner hip, knee and ankle joint complex, may be warranted, to determine the temporal relationship. Since the initiation of this study a further, objective, foot-type classification tool has become available, the Foot Posture Index, which represents possibly the most comprehensive static assessment tool available. The sample size for this study was compromised due to time constraints, and it may be warranted to proceed with a further case-control study utilising this new measure, and employing multiple matching techniques, that proceeds until the requisite sample size is achieved.

Although the study is compromised by its failure to recruit sufficient subjects, and by the age difference between cases and control, and by the reliability of the foot function measures used, the results are felt to be important and useful. Given the paucity of literature concerning the relationship between foot function and LBP, an important step has been taken by employing a case-control design with more subjects than has been used in any similar study. It is significant that the calcaneal and
navicular motion measures re-enforce each other by acting in the same direction and revealing the same information, and the FHSQ result is also felt to be an important contribution. It has been asserted that when the majority of the literature supports a particular theory, then it is inappropriate and irrational to dismiss this evidence on the basis of relatively minor flaws (Landorf and Keenan, 2000b). Whilst there is a need for further, high quality, research on this topic, this study represents a significant contribution.
Summary points:
The studies described in chapter 6 support the following conclusions:

- Classifying subjects according to STJt axis orientation theoretically offers the possibility of a precise insight into the response of pedal architecture to discrete changes in rearfoot position. However, this cannot be pursued in the context of a study involving large numbers of subjects at this time due to the unacceptable reliability of the only available clinical technique;

- There is a high correlation between frontal plane calcaneal motion measured between the neutral and RCSPs and dynamic rearfoot function, indicating that this measure is a valid and reliable indicator of dynamic calcaneal function;

- A significant correlation between footprint measures calculated in static and dynamic states identifies these measures as demonstrating face validity, warranting their further study as a potentially useful foot-type classification method;

- Examining the response of navicular height and footprint measures to small changes in STJt alignment provided an important insight to their criterion validity. Although navicular height was identified as sensitive to relatively small changes in rearfoot alignment, footprint measures were responsive to larger changes, and thus demonstrated an inconsistent and unpredictable response. This necessitates their rejection as a useful measure of foot-type;

- A case-control study comparing foot-types, as measured by navicular drop and a pre-validated foot-health related quality of life tool, the FHSQ, suggested subjects with LBP to have a significantly reduced foot health status and to demonstrate significantly greater asymmetry of function. The existence of a clear biologically plausible pathway between this asymmetric function and LBP implicates foot function in LBP and suggests that the issue warrants further study.
Chapter 7

Discussion

Whilst chapter 5 included a discussion of issues specifically arising from the individual studies conducted, in this chapter a summary discussion is provided that focuses on issues such as the approach taken and the key findings of the study as a whole. Special consideration is given to issues deemed crucial to the study, such as reliability and validity assessment. The major limitations of the study are highlighted and discussed to determine the value that can be assigned to conclusions. Suggestions for improving the study and for further research are made.

7.1 Introduction

7.2 The approach adopted
    7.2.1 Introduction
    7.2.2 The limitations of the ‘outcomes’ approach
    7.2.3 The epidemiological approach

7.3 Investigating measures of “foot-type”
    7.3.1 Validity, its meaning and assessment
    7.3.2 Reliability, its meaning and assessment
    7.3.3 In conclusion: Balancing reliability and validity

7.4 Case Control Studies

7.5 The relationship between foot function and chronic LBP

7.6 Recommendations for further study
    7.6.1 Overcoming the weaknesses of the study
    7.6.2 Suggestions for further study

7.7 Conclusions
7.1 Introduction

The project described in this thesis explored the relationship between foot function and musculoskeletal pathology. Although further, substantial, exploration of the subject is required this project has enhanced existing knowledge significantly. Contributions include a robust critique of the limitations of the outcomes movement and the relative strengths of the epidemiological approach, detailed exploration of the concepts of reliability and validity and their application to foot-type measurement, and the completion of a case-control study. Such studies are rare in this field, and the investigation and support of this approach is felt critical for the future development of a robust podiatric literature base. Whilst the findings and limitations of the individual studies were presented in chapter 5, a summary discussion is provided here, highlighting important findings, limitations and proposals for further study.

7.2 The approach adopted

7.2.1 Introduction

The approach adopted has its roots in several factors related to the ‘outcomes movement’, whose philosophy appears to have been adopted as a new mantra in the NHS (Nolan et al., 1998). The nature, sphere of influence, and consequences of this movement underpin the whole thesis, and were discussed in chapter 2.1 to defend the range of evidence sources used to examine the relationship between foot function and musculoskeletal pathology.

7.2.2 The limitations of the ‘outcomes’ approach

The nature of the outcomes movement relates to its contemporary status. Although motivated by the worthy intention of empowering the common doctor, the core principles, primarily relating to the use and value of RCT’s, became a dogma (Godlee, 1998). Whilst a well executed RCT, conducted on a clearly defined issue, is acknowledged to be capable of providing evidence of a probability approaching certainty, their prolific use has become concerning (Black, 1998a, Mietinnenen, 1998). For example, Black (1998) asserted that when the original design boundaries of the RCT design are exceeded, for example when there are many variables influencing the outcome or when a simple label conceals diagnostic complexity, results tend to be
inconclusive or conflicting. However, the RCT has become the solitary research design deemed to provide acceptable evidence by regulatory and governmental agencies (Bristow and Dean, 2003). This derogates alternative designs and leaves considerable gaps in knowledge. Although the ‘hierarchy of evidence’ (table 2.1) acknowledges that alternative designs do exist, the primacy assigned the RCT renders these, in all practical terms, obsolete.

One of the most important knowledge gaps that has emerged concerns the investigation of ‘cause’. The philosophy of the outcomes movement has penetrated the collective research consciousness to instil a craving for ‘outcomes’ data to the extent that even aetiological research is still quite exclusively motivated by the concern to identify opportunities for prevention rather than focus on the needs of ‘aetiognosis’, which demands greater specificity (Mietinnen, 1998). This issue is particularly critical to the research, because the nature of the relationship between foot function and musculoskeletal pathology has been inadequately explored. Instead, the outcomes movement has achieved legitimacy for the ‘diagnosis by therapeutic response’ approach to identifying cause; indeed, it has been asserted that the most direct way to determine causality is to add or withhold a factor and observe whether the frequency of the disease changes (Wald, 1996). However, Miettenen (1998) expresses frustration at the use of the RCT for establishing cause, lamenting that much confusion has stemmed from the ‘malformed’ use of concepts such as ‘effectiveness’ and ‘generalisability’, and the methodological aberrations that flow from this.

These arguments, that underpin the challenge to the supremacy of the RCT, are borne out by experience. The literature concerning the relationship between foot-type and musculoskeletal pathology is replete with trials examining the efficacy of interventions, yet basic research attempting to elucidate the biological plausibility of the causal pathway between the two, or attempting to examine the effect of combinations of factors, is scarce. The confusion created by applying RCT methods to complex situations, where simple diagnostic labels are used or simplified treatment choices replace comprehensive regimens, has led to confusing and conflicting results as predicted by Black (1998). This is evidenced by considering a range of systematic reviews evaluating the efficacy of treatments for various lower limb musculoskeletal
pathologies (Crawford and Thomson, 2004, Crossley et al., 2001, D’hondt et al., 2004, McLauchlan and Handoll, 2004), which have yielded inconclusive results. Further, questions are being raised regarding the true role of RCT’s: for example, it has been asserted that the demand for RCT’s may be setting an unattainable goal for many specialities who deal with complex situations that cannot be reconciled with the rigid rules of the RCT (Clemence, 1998).

7.2.3 The epidemiology approach

Whereas the outcomes movement has resulted in an inappropriate emphasis on a single design – the RCT – to the detriment of other forms of evidence, the epidemiological approach offers an appealing alternative. This approach involves consideration of evidence from various sources, and overlaps with the ‘group evidence’ concept (Black, 1998a). This approach recognises that evidence relevant to clinical decision making is derived from many sources including the basic medical and social sciences and the observed natural history of a disease. The reliance on the RCT has left considerable gaps in the literature (Mietinnen, 1998), and there is a growing realisation that these gaps will increase if the dominance of the RCT persists (Clemence, 1998). Indeed, it is obvious that basing an argument on only one form of evidence is naive, and it seems entirely logical to consider the range of evidence on offer to form a comprehensive and accurate picture. Such an approach seeks to identify consistency between different types of evidence from within a body of literature to permit robust conclusions to be drawn. Whilst the outcomes movement accepts only RCT’s with the highest design quality score, this approach accepts RCT’s which may have been dismissed as irrelevant due to relatively small methodological flaws (Landorf and Keenan, 2000b). This is based on the assertion that all research, if carefully designed, can contribute to knowledge, even where there are small methodological flaws (Landorf and Keenan, 2000b).

Although the epidemiological approach accepts evidence from multiple sources, the relative value of different designs is still acknowledged. The concept of ‘major’ and ‘additional’ criteria has been used to rank evidence sources according to their merits (Gordis, 2000, Vetter, 1999, Wald, 1996). This concept provides information on the types of evidence that are most valuable when examining the relationship between a pathology and a suspected causative factor. ‘Major’ criteria include determining if an
exposure precedes the onset of the disease, scrutiny of sources of bias, chance and confounding to permit evaluation of their influence on the results of individual trials (figure 3.1 chapter 3), and, importantly, identifying a biologically plausible pathway connecting the two (table 3.2 chapter 3). Additional criteria such as the strength of association, consistency between studies, and demonstration of a dose-response relationship are also accepted as valid and important forms of evidence (Gordis, 2000, Wald, 1996). Several of these issues can be examined using observational research – such as the strength of the association and the examination of confounding factors. Although Gordis (2000) discussed the relative weighting of these factors, the major and additional criteria remained the same. In this discourse of ‘cause’ generally, concepts such as ‘threshold for observed effects’ were also discussed. Accepting that evidence from each tier of the ‘hierarchy of evidence sources’ and the understanding of the way that multiple factors interact to produce disease demonstrates a pragmatic understanding of the limitations of the RCT design, and the critical importance of accepting other forms of evidence. There is a convincing literature base suggesting that RCT’s are flawed in all but the simples disease processes, and it seems intuitive that the construction of a convincing argument cannot and should not be based on this single design. Evidence from a range of sources should be woven together to provide a comprehensive picture of the true nature and influence of a disease. This information provides robust support for the use of observational studies in the first instance to permit examination of several of the ‘major’ criteria for identifying cause, and underpins the approach adopted in this thesis.
7.3 Investigating measures of foot-type

7.3.1 Validity, its meaning and assessment

The concept of foot-type is crucial to this study. Epidemiological methods focus on the measurement of diseases and exposures, and the literature emphasises the importance of formulating explicit definitions to ensure measurement accuracy (Gordis, 2000, Vetter, 1999). For example, Gordis (2003 pp.63) states that regardless of the nature of the test being used to diagnose a disease, the same issues arises: ‘how good is the test in separating populations of people with and without the disease (condition) in question?’. Rose (1991) asserts that if the true nature of the relationship between foot-type and pathology is to be identified, it is first necessary to have a valid system of classification to allow accurate recognition of each state. The CASP case-control study evaluation similarly devotes considerable attention to this issue. For example, guidance notes for the question ‘was the exposure accurately measured to minimise bias?’ include a series of prompts focusing on clear definition and accurate measurement of the exposure, whether subjective or objective measurement techniques were used, and their validity. Essentially, if the instrument used to categorise subjects is not valid, and exposures cannot be measured accurately, then results are meaningless. This information provides robust support for the decision to devote the majority of this research programme to the investigation of issues of validity and reliability.

Validity can be determined with great accuracy, and relative ease, for specific measures, such as weight, where an international standard exists that can be used as a benchmark. However, the issue is more challenging for complex measures, which defy simple definition, and it is artificial to seek a simple dichotomous answer to the question of whether or not a particular instrument is valid. In such circumstances, validity is determined by examining specific aspects of the measure to determine how well it performs against several criteria which each represent a separate dimension of validity. Evaluating performance against these various criteria helps to form an overall picture of appropriateness. This concept of validity as a multi-dimensional construct that requires not just a single study, but the sequential exploration of different facets of a measure to determine its pragmatic utility for the intended
purpose, is vitally important. This concept underpins the approach adopted in this study.

The four major dimensions of validity were discussed in chapter 3, and were incorporated into the criteria for the ideal foot-type measure also presented in that chapter. These dimensions are *face, content, criterion and construct* validity. *Face* validity relates to the superficial assessment of the apparent suitability of the tool, and is considered weak due to its subjective nature (Gomm *et al.*, 2000). This facet of validity can be explored for foot-type measures. *Content* involves closer scrutiny to determine whether the separate dimensions of the variable of interest are being measured. For example, if it is known that there are a number of dimensions to the variable of interest, and the tool considers each, then the content is judged valid (Gomm *et al.*, 2000). This dimension of validity can also be explored for foot-type measures. *Criterion* validity involves comparison of results obtained using the new technique with those obtained using a gold, or pseudo-gold, standard (Daly and Bourke, 2000). This technique is of value in exploring new, perhaps less invasive or cheaper, tools to determine their agreement with the existing method. Clearly, if a new technique offering such advantages obtained results that agree with the benchmark, then it deserves to be adopted. The pre-requisite for investigation of criterion validity is the existence of a gold-standard, which does not truly exist for foot-type. Finally, *Construct* validity refers to the correlation between an instrument’s score and important outcomes such as prognosis (Gomm *et al.*, 2000). This dimension relates to the prognostic value of the technique. Comprehensive examination of validity requires that each dimension be addressed, and represents a considerable undertaking. Pursuing these investigations can also be limited by the state of the knowledge base concerning the construct being evaluated. For example, if the complexity of the construct is not truly appreciated then content validity cannot be established. Adherence to this model in this study is demonstrated by comparison of static and dynamic techniques in studies 5.2 and 5.3 to provide evidence of content validity, and by study 5.4, which investigated construct validity by considering the response of selected measures to changes in rearfoot position. The value of the information provided by these studies is pivotal to the study, and warrants exploration.
The approach adopted in this research was focused on the dimensions of validity it is currently possible to examine, given the state of current knowledge. For example, *Face* validity can be established with relative ease. Understanding that foot-type measures aim to reflect the mechanical behaviour of the foot, and that mechanical behaviour in turn is related to rearfoot alignment and medial longitudinal arch morphology, allows evaluation of this dimension. Measures focusing on alignment or motion of these segments appear to be appropriately focused, and therefore are intuitively valid. Whilst this information is available by simply considering the merits of a technique, it provides no real substantial information. To proceed on the basis of this information alone would result in little confidence in results, as essentially the technique may, or may not, have classified subjects appropriately. Therefore, further information on more robust dimensions of validity is clearly required, and methods of examining constructs such as *criterion, content* and *construct* validity were sought.

*Criterion* validity refers to comparison of measures against a gold standard, and therefore depends entirely on the availability of a gold standard. It has been claimed that valid, objective and reliable quantification of foot function is possible using laboratory based techniques (Redmond *et al.*, 2001), suggesting that assessment of criterion validity is possible. However, this is mis-leading. Whilst laboratory analysis of foot function is possible, it involves assessment of a range of variables including kinematics, kinetics, muscle activity and energy consumption, which cannot easily be synthesised into a single global score. Each of these variables is considered important (Winter, 1985), and therefore there is no clear benchmark measure that could be used for establishing criterion validity. These laboratory techniques offer a valuable assessment option, but are inappropriate for the numerous subject assessments required in epidemiological investigations due to financial and time constraints (Cowan *et al.*, 1994). Just as evaluation of criterion validity presents difficulties, so too does *construct* validity. This relates to the prognostic value of a measure. It can be established using relatively straightforward techniques, for example, by simply taking measurements in an inception cohort population and then tracking the cohort to determine who develops disease. Analysis of the predictive value of the measure is then relatively straightforward to assess. However, it generally takes time for a
disease to develop and therefore longitudinal study designs are required, which is not possible within the time-constrained data collection period available.

The primary, and most innovative, technique utilised for validity assessment in this study related to content validity. This refers to assessment of a measure to determine whether the separate dimensions are represented. A conceptual understanding of this involves comparison to a school exam (Gomm et al., 2000). The content validity of such a test can be examined by investigating whether the separate areas of the curriculum are represented at the correct level, and if they are weighted appropriately to reflect their importance. The approach devised for this study involved assessment of two separate, pre-requisite, requirements of a foot-type measure. These requirements are based on established biomechanical and anatomical theory, and the premise that since foot-type measures claim to reflect dynamic function, measures calculated in the static state should closely mirror those calculated in the dynamic state. Investigation of the latter requirement was investigated in studies 5.2 and 5.3, and involved the capture of static and dynamic measurements, which were then compared. The latter requirement was addressed in study 5.4.

In study 5.2 quasi-static and dynamic measurements of calcaneal motion were compared, and in study 5.3 three footprint measures calculated from static and dynamic states were compared. These investigations are theoretically sound, as there is little doubt that dynamic foot function is the critical variable. This is evidenced by the numerous investigations aiming to understand dynamic function, and how it can be predicted from more convenient techniques (Cavanagh et al., 1997, Cornwall and McPoil, 1999, Knutzen and Price, 1994, McPoil and Cornwall, 1996b). Therefore, the limitations of these studies relate to their execution, and not their theoretical background. Examination of calcaneal motion involved the use of the electrogoniometer. Criticisms of this equipment include difficulties in securely attaching this device to the segments to be measured, which questions the ability to accurately measure bony movement. However, the pattern of motion mirrored that identified in previous investigations (Brown et al., 1995, Cornwall and McPoil, 1994, McPoil and Cornwall, 1994, McPoil and Cornwall, 1996a, McPoil and Cornwall, 1996b). A major conceptual problem relates to the use of the NCSP (Keenan, 1997). However, the technique used in the study did not attempt to accurately define the
neutral position or measure it. It was identified using a series of criteria (Lee, 2001a, Root et al., 1971) and motion between this position and relaxed was evaluated. Traditionally the two positions were measured independently using calcaneal bisections, with the difference between the two measures assumed to represent the motion occurring between them (Anthony, 1991, Root et al., 1977, Root et al., 1971). However, separate bisections are applied in both positions to account for soft tissue movement, and whilst this step is intended to reduce error, it seems that it actually complicates matters. By dispensing with the use of separate bisections and simply measuring motion of a reference line (not a bisection) accuracy does improve (Sell et al., 1994), indicating that motion measurement is more accurate. The conceptual background to the neutral position is an area for further study, but the identified dynamic relevance of this position (McPoil and Cornwall, 1994, McPoil and Cornwall, 1996b, Pierrynowski and Smith, 1996) indicates that despite criticisms, it appears important and deserves further exploration.

Study 5.3 also focused on evaluation of the relationship between static and dynamic measurements, this time concerning footprint techniques. Again, established anatomical and biomechanical truths underpin the approach adopted in this study, and concerns over its execution represent the area of concern. This study was limited only by the use of electronic footprints, which have since been criticised (Urry and Wearing, 2001a, Urry and Wearing, 2001b). However, this criticism is unlikely to alter the conclusions drawn, because it was differences between static and dynamic prints that were investigated. The concept being tested remains sound, and it is unlikely that repeating the study using traditional ink-based techniques would materially alter results or conclusions. Additionally, automated techniques balance well against the weaknesses of ink-based techniques, which are messy, time-consuming and subject to significant variability.

One of the major contributions of this study to the literature base regards the final assessment of content validity performed. Essentially, foot-type measures hope to capture important information regarding the mechanical function of the foot during stance, when specific functional demands must be satisfied to prevent the development of pathology. When the foot fails to attain the required level of
mechanical integrity, function is compromised and pathology may feasibly result. As explained in chapter 3, two established, and related, anatomical/biomechanical facts underpin the approach adopted:

- The relationship between rearfoot, and more specifically STJt, position and the mechanical integrity of the foot, whereby a supinated rearfoot position reflects a stable foot and a pronated rearfoot position reflects a flexible, mobile foot.

- The consistent and predictable response of the architecture of the medial longitudinal arch to changes in rearfoot position. Specifically, rearfoot pronation produces talar adduction and plantarflexion, calcaneal eversion, and a reduction in height of the MLA, whilst rearfoot supination produces talar abduction and dorsiflexion, calcaneal inversion and an increase in the height of the MLA.

This information led to the conclusion that an important dimension of validity relates to the ability of foot-type measures to respond to changes in rearfoot alignment. Essentially, if these measures cannot differentiate between different rearfoot positions, then their ability to reflect the mechanical integrity of the foot is compromised. In study 5.4, this information was used to formulate an approach to examining construct validity, by investigating the sensitivity of footprint and navicular height measurements to $5^\circ$ changes in rearfoot alignment.

Whilst the approach adopted is substantiated by established anatomical/biomechanical facts, the execution compromises results. For example, measurements were recorded from a reference position (maximal comfortable eversion) that may not have been repeatable, and the $5^\circ$ increments may not have been totally accurate due to the subjective assessment method (measuring the position of a calcaneal reference line using a protractor). However, it seems unlikely that these variables would affect the conclusions drawn from this study, in that navicular drop was the most sensitive measure, and would likely remain so even with a more robust methodology. Any errors in the amount of calcaneal motion occurring between readings, to take it either below or above the specified $5^\circ$, is similarly unlikely to affect conclusions. It can still be confidently stated that navicular is the most sensitive measure. However, the actual sensitivity could be questioned, as the $5^\circ$ increments could have been slightly above or below that amount. It is difficult to speculate on the exact influence of this source of
error, and it can only be stated that the most sensitive measure was navicular drop. The rationale for this study is robust, and repeating the study using objective equipment would be very useful. Technological developments have made it possible to synchronise kinematic and kinetic systems. This opens up the opportunity to obtain synchronised data from the plantar aspect of the foot, navicular motion, and calcaneal motion, continuously throughout the stance phase. Therefore, for every degree of calcaneal motion from initial contact until toe-off, the corresponding image of the plantar foot could be used to calculate the footprint measures of interest, and navicular height could be measured. From this data the relationship between foot print and navicular measures and calcaneal position could be determined with great accuracy. Developing this study by utilising the technology described would provide a highly accurate insight to content validity. Further, the geometric truism that the distribution of motion about the subtalar axis, which is what was actually being measured via frontal plane calcaneal motion, will depend on its orientation also has the potential to further improve the accuracy of results from such a study. However, this would be dependent upon identification of a valid and reliable method of axis assessment.

7.3.2 Reliability, its meaning and assessment

Reliability refers to consistency. If successive measurements recorded by the same clinician on the same subject under the same conditions are analysed and found to agree, and there has been no change in the variable being measured, then the technique is reliable (Norkin and White, 1995). Although a basic assessment may involve a single clinician and subject, it has been suggested that increased numbers of both are required to permit accurate evaluation (Ellasziw et al., 1994). Reliability assessment formed a significant part of this study, and was aimed at establishing whether differences in a measure value could feasibly have occurred due to errors with the technique, as opposed to true changes in the measures of interest. Reliability studies commonly end with an expression of the reliability of a technique as ‘excellent’, ‘moderate’, or ‘good’. This practise was criticised in a recent editorial in Physical Therapy (Rothstein, 2003). This brief, but informative, discourse began with a reassurance that error is an unavoidable aspect of practise, and a request that researchers and clinicians provide brief, but detailed, accounts of their choice of
measures and the justification for their use. He warned against simply stating that reliability has been previously established. The use of descriptive terms such as 'good' was discouraged on the basis that these measurements are essentially arbitrary, as they ignore the context of the measurement because they fail to consider the intended use. As an example, he suggests that if two surgeons disagree on the need to operate 20% of the time, then this would be unacceptable if the procedure is life-threatening, but less concerning if the procedure is routine. Rather, he urged researchers to realise that reliability lies along a continuum, to determine where along this continuum the measure lies, and to evaluate it in terms of its intended purpose. Where reliability is less than ideal he recommended that the concept of redundancy be adopted, where multiple techniques are adopted to minimise the shortfalls of any individual measure.

A range of measures was used in the study, and the reliability of each was considered. In study 5.1 this related to subtalar axis orientation assessment; in 5.2 quasi-static and dynamic measures of calcaneal motion were assessed; study 5.3 involved assessment of footprint techniques, and this study led to the rejection of one technique because of poor reliability. Finally, in study 5.5 a cursory examination of the reliability of the two techniques to be used was included. Whilst the same basic test-retest procedure was used in all cases, the approach to examining results differed. This is because of the emphasis of each individual study, the differing complexity of each technique, and the existing literature base. Similarly, a number of statistical techniques are available for assessing reliability, ranging from the coefficient of variation to correlation coefficients and the standard error of measurement (Norkin and White, 1995). A variety of these techniques were employed to process the reliability data gathered by the study, again driven by the nature of the study. In addition to various descriptive statistical techniques, a range of inferential tests including Kendall's coefficient of concordance for categorical data and correlations for continuous data, were utilised. In all cases a pragmatic approach to the interpretation of results was adopted.

The most robust examinations of reliability were conducted in studies 5.1-5.3, dealing with subtalar axis orientation assessment (5.1), quasi-static and dynamic calcaneal motion (5.2), and footprint measures (5.3). In study 5.1 it is clear by simply considering graph 2, which shows that 8 of 13 subjects were assigned to $>3$
categories, that the technique is barely better than random allocation. Kendall's coefficient of concordance merely attached a probability level to the discordance. Footprint measures, evaluated in study 5.3, were evaluated using correlation coefficients. A series of Pearson's correlations were calculated in this study: firstly, the same footprints were evaluated on different occasions to ensure that the same measure value was obtained. Secondly, measures obtained in different states were evaluated to determine the reliability of measurements recorded in those conditions. On the basis of these results, the FPA was rejected. Correlations for the other footprint measures were not exceptionally high, either, however, and the decision to investigate them further was a pragmatic one. Correlations were consistently above 0.9 for statically calculated measures, suggesting that measure values are consistent between evaluations, suggesting adequate reliability. However, dynamic measurements could be criticised because of poorer correlations, which despite reaching 0.89, also fell as low as 0.57. This infers that successive measurements differed significantly. However, dynamically calculated prints cannot, and should not, be expected to display outstanding agreement: gait has been described as a responsive process that is driven by predictive, proactive and reactive manoeuvres (Huxham et al., 2001). Essentially, this means that variation is an inherent part of the process, and high correlations between measures recorded in successive steps or walks necessitates the use of an artificial level of standardisation. This is especially the case where a limited number of trials are assessed. It seems reasonable that correlations achieving only a moderate level of reliability be accepted. Therefore, although the FPA was rejected because of low correlations, the CSI and SAI were taken forward for validity testing. However, this decision also suggests the need to use multiple measurement techniques for triangulation of results. Rothstein (2003) terms this concept 'redundancy', where several measures are used when there are errors with an individual. If the effect is found to act in the same direction with each technique, then this supports the conclusions drawn.

The validity study led to the rejection footprint measures, and calcaneal and navicular motion measures were taken forward to be used in the case-control study. Navicular drop has been the subject of several reliability studies, which suggest moderate to good reliability (Mueller et al., 1993, Picciano et al., 1993, Vinicombe et al., 2001). A rudimentary assessment of the reliability of both these techniques was included in
study 5.5, which involved recording pairs of measurements from 10 volunteers and assessing agreement. Pearson's correlation coefficients were used, and values of 0.84 for navicular drop and 0.72 for calcaneal motion. At first glance, these measures seem poor. However, these techniques are quasi-static, in that they measure motion between the neutral and RCSPs. In addition to error arising from the dynamic element, the identification of the neutral position and subtle changes in the relaxed stance position and angle and base of gait selected by subjects represent sources of error that explain the correlation returned. Whilst the protocol could be improved, by recording accurately the patients' angle and base of gait onto a template that could be used for successive measurements, the practicality of this in the clinical situation limits it. This technique is feasible, but increases the time and resources required to take measurements.

The results and conclusions from the reliability studies essentially concur with those from previous studies addressing similar measurements used by various disciplines. These studies have consistently identified that intra-rater is better than inter-rater reliability, that within-day is better than between-day reliability, and that the use of rigorous protocols and practise helps improve both (Ellasziw et al., 1994, Elveru et al., 1988, Keenan, 1997, LaPointe et al., 2001, Lea and Gerhardt, 1995, Picciano et al., 1993, Rome and Cowieson, 1996, Sell et al., 1994, Van Gheluwe et al., 2002, Vinicombe et al., 2001). Further, it is clear that problems with reliability are encountered in all disciplines using clinical measurements and that this error is best dealt with by understanding the problem so that effective strategies for overcoming or dealing with deficiencies can be adopted (Lea and Gerhardt, 1995). In adopting navicular and calcaneal motion measures, therefore, it is acknowledged that they are limited by their absolute accuracy. However, the use of both increases their utility, and the additional use of the FHSQ provides a third method of investigating foot function.

Reliability was accepted on the basis of existing literature for the FHSQ and the Quebec Back Pain Disability Scale. In line with Rothstein's (2003) demand for justification of such decisions, this was felt to exist. These tools underwent robust development in populations that were similar to the population to be recruited to this study (Bennett et al., 1996, Bennett et al., 1998, Bennett et al., 2001, Kopec et al.,
1995, Landorf and Keenan, 2002, Reed and Bennett, 2001). These suggest that these tools were suitable for the intended purpose, which for the *Quebec* meant recording the level of back pain experienced in cases and controls, and for the *FHSQ* meant that the foot health status of subjects could be assessed. The major criticism relates to the possibility that cultural differences, related to the development of the questionnaires in Australia (*FHSQ*) and North America (*Quebec*) is a concern. However, review of both for phrases peculiar to each region revealed no idiosyncrasies that could cause a problem.

### 7.3.3 In conclusion: Balancing reliability and validity

Reflecting upon the conceptual background to validity and reliability, in light of the experience gained from conducting a series of studies on these two issues, leads to several conclusions. Firstly, there is a clear tension between reliability and validity. Gomm, Needham et al (2000) stated that it is very difficult to design an instrument that excels against all validity and reliability criteria, and that a strong performance on one criterion is often achieved at the expense of a poorer performance on another. This contention is echoed in this study in that simpler methods of foot-type assessment achieved a high level of reliability, but performed poorly in terms of content validity, because they focus on superficial dimensions that are easier to record consistently. In contrast, a technique performing well in terms of content validity, due to its inclusive nature, might well be more complex, to the detriment of its reliability. The case in point is the two footprint indices investigated, where correlations consistently ≥ 0.9 were achieved. However, these measures displayed a poor response to STJt motion, effectively meaning that there was a significant possibility that subjects with different foot-types could not be differentiated. Given the seemingly routine use of footprinting techniques in the evaluation of the paediatric flat foot (Kanalti et al., 2001, Rose, 1985) this is concerning: if these measures cannot respond consistently to 5° changes in STJt position then their use in tracking the development of flexible pes planus is compromised to the extent that they may be useless. By contrast, motion measures seem to offer the opportunity of a more accurate insight to rearfoot motion and position because of their performance in the validity study. Whilst the reliability of these techniques is poorer than footprint measures, it was felt that they were suitable for the intended purpose. That purpose was within a case-
control study aimed at providing initial evidence to stimulate further investigation of any inferred relationship in greater detail. Such further studies could, and would be expected to, use more accurate techniques on smaller populations. Therefore, in line with Rothstein’s (2003) recommendation that the intended use of a measure is kept in clear focus, it can be asserted that the measurement techniques selected were acceptable for the purpose of the project.

7.4 Case-control studies

In his critique of the RCT, Black (1998) was emphatic that several approaches were invaluable in gathering evidence related to cause. This recommendation echoes the approach of epidemiology, which aims to understand cause by examining evidence from multiple sources (Gordis, 2000, Vetter, 1999, Wald, 1996). In the initial stages the emphasis is on observation, where the characteristics of patients with the disease are noted and their occurrence in groups with and without the characteristic are compared. An important element of this type of studies is that they permit calculations of the risk of disease in individuals with the characteristics investigated. To this end odds ratios were calculated to quantify the risk associated with specific exposure levels. These calculations were performed, using cut-off levels of calcaneal and navicular asymmetry as determined by the average difference between the two groups measured by the t-test. These calculations suggested impressively high increases in risk associated with even the modest differences selected, of 3mm of navicular motion (odds ratio 12.71) and 3mm of calcaneal motion (odds ratio 16.9). This result is promising, and suggests that routine screening of patients for symmetry of foot function might identify a significant number of patients who could be treated.

A guide to the evaluation of case-control studies was provided by the CASP (PHRU, 2004). This tool is accepted as an excellent appraisal resource by one of the leading evidence-based medicine organisations, the Centre for Evidence Based Practice, Oxford (CEBM website). It focuses on the method of selection of cases and controls, the appropriateness of the design for the intended purpose, and the definitions of disease and exposure used. It provides an excellent benchmark by which to evaluate the case-control study conducted, and therefore provides an indication of just how much credence can be attached to the study and its results. The questions asked by the
tool are provided in table 7.1, which also provides a commentary on how satisfactorily these issues were addressed in this study.
<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening questions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did the study address a clearly focused question?</td>
<td>Yes</td>
<td>Target population clearly defined. Risk factors of interest explicitly stated. Study aimed to identify a harmful effect.</td>
</tr>
<tr>
<td>Was the case-control method appropriate?</td>
<td>Yes</td>
<td>Information on the exposure as a cause of the disease is rare, relying on interventional studies. There is a clear need for observational studies.</td>
</tr>
<tr>
<td>Detailed questions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Were cases recruited in an acceptable way?</td>
<td>Yes</td>
<td>Cases were defined precisely, were representative of the cases presenting in a clear geographical location, and were selected using a reliable system. There was a power calculation, although the target set was not achieved.</td>
</tr>
<tr>
<td>Were controls recruited in an acceptable way?</td>
<td>Could be questioned</td>
<td>Controls were recruited from a similar geographical location, but may have been from a different socio-economic background because of the use of a university setting. Population-based matching is a weakness, and the use of multiple matched-pairs would have been a superior approach. The number of controls could have been increased, or drawn from a better source, for example, from a hospital population attending for a completely un-related purpose.</td>
</tr>
<tr>
<td>Was the exposure accurately measured?</td>
<td>Yes</td>
<td>The techniques used were investigated prior to their use, and demonstrated reasonable reliability and validity. The techniques were objective. A temporal relationship could not be identified due to the nature of the study.</td>
</tr>
<tr>
<td>What confounding measures have been accounted for?</td>
<td>A few core</td>
<td>Sex, age, height, weight, hypermobility, additional joint pain and smoking status information gathered. Some differences considered in analysis, others useful for information purposes only, such as additional joint pain and smoking status. Further variable such as occupation should have been included.</td>
</tr>
<tr>
<td>What other factors might be important?</td>
<td>Several</td>
<td></td>
</tr>
<tr>
<td>What are the results of this study?</td>
<td></td>
<td>Bottom line result is that there appears to be a relationship between asymmetrical navicular and calcaneal motion and LBP. Odds ratio was high, re-enforcing the concept that the exposure and disease are related.</td>
</tr>
<tr>
<td>How precise are the results?</td>
<td></td>
<td>The reliability and validity of the motion measurement techniques impact on results, but do not overturn the results. The precision could be challenged, but the findings look as though they have identified a difference that does actually exist.</td>
</tr>
<tr>
<td>Do you believe the results?</td>
<td>Yes</td>
<td>Back pain is a complex area, but the results are believable. There is a biologically plausible pathway by which asymmetries, over a threshold level, may induce LBP, even though the condition is notoriously complex.</td>
</tr>
</tbody>
</table>
The tool ends with questions relating to the local application of results and the consistency of results with existing evidence. The application of results of this study to local populations is difficult, as further exploration of the issue is required before firm conclusions can be drawn. However, there certainly appears to be support for continuing to study this area. The results do fit in with existing evidence, in that there is information suggesting that asymmetrical function can induce LBP (Blake and Ferguson, 1993, Blustein and D'Amico, 1985, Cowan et al., 1996, Papaioannou et al., 1982).

Appraisal against CASP guidelines suggests that there are several weaknesses to this study, which may be largely inevitable. Two of the more critical weaknesses are control selection and the number of confounding variables considered. In retrospect it is clear that controls should have been selected from a hospital population to achieve a better match. LBP is a condition that cuts across socio-economic groups, age barriers and lifestyle, and there are diseases with a similar profile that could have been targeted as a source of control subjects. However, these controls must be in a fit state to participate so that the study remains ethical. An example that was contemplated was a fracture clinic, targeting patients presenting with upper limb fractures, so that the injury was out with the locomotor apparatus but this was discounted because of the inclusion of the Beighton hypermobility criteria, which involves assessment of the upper limbs. The problem is confounded by the need to recruit more controls, perhaps 2 or 3 per case, to permit a more robust analysis by accounting for more confounding variables. However, numerous variables have been examined in relation to LBP, which makes formulating a definitive list extremely difficult and impractical. For example, a ‘best evidence’ review conducted by Shekelle (1997) identified over 20 factors that were associated, to some degree, with LBP, ranging from smoking and weight to physical and mental stress. In addition to the problem of identifying the most important variables to investigate, the critical issue of their valid measurement must also be addressed. Clearly, LBP is a complex condition that cuts across age, socio-economic and various other boundaries, and is associated with a large number of factors. This reflects the very high numbers of individuals affected.

The case-control design is clearly a useful one, however, and there is an unquestionable role for observational studies. However, it is also clear that meticulous
planning and a prolonged data collection period is required to permit collection of data in the volume and detail required to produce a convincing study.

7.5 The relationship between foot function and LBP

LBP is unquestionably a complex condition that is associated with numerous factors (Shekelle, 1997). Whilst there is a convincing, biologically plausible, pathway linking foot dysfunction with the condition (Minkowsky and Minkowsky, 1996) previous studies investigating the issue have been methodologically weak. These have consisted of either case studies or case series (Bird and Payne, 1999, Botte, 1981, Builder and Marr, 1980, Campbell, 1995, Cibulka, 1999, Dananberg and Guiliano, 1999) which essentially describe hand-picked subjects where there is an overt involvement of foot function. Such an approach fails to consider the role of foot function in the condition generally, and lacks perspective. To gather information on the role of this variable in the general population better planned, observational studies are required, and these may provide a better insight into the interventions that may be most useful in treating the condition for a future experimental study.

Case-control studies have been described as the first formal approach to deciding whether a possible risk factor may be the cause of a condition, but cannot prove that a relationship exists. They can only overturn the hypothesis that the two are unrelated (Vetter, 1999). The results of this study do no more than this. It does not infer that a causal relationship exists, but does provide reasonably convincing evidence that foot function is not inconsequential in LBP. The nature of this involvement also warrants further investigation. Asymmetrical foot function has been linked to both structural and functional causes (Michaud, 1997b). The prime example of a structural cause is where there is an anatomical limb length discrepancy, where there is a physical difference in the length of the limb (Gurney, 2002), and this can be treated simply by increasing the length of the shorter limb using a raise (Blustein and D'Amico, 1985, D'Amico et al., 1985a). The second possibility is that the asymmetry has a functional origin. For example, figure 4.5 illustrates the fundamental podiatric biomechanical concept that dynamic foot behaviour is determined by a series of neuromusculoskeletal factors that were detailed in table 2. Symmetrical foot function depends on symmetry in all these factors between left and right sides. Where there is a difference, for example, in the frontal plane relationship between the tibia and the
supporting surface or in ankle joint dorsiflexion during midstance, this may result in asymmetrical foot function. Treatment of the asymmetry in this situation would require FFO’s providing different levels of control. Therefore, should an asymmetry be identified then the next step, to permit effective treatment, is to determine whether the origin is structural or functional. Ultimately, a trial of FFO’s in chronic LBP may reveal a cost-effective treatment modality.

7.6 Recommendations for further study

7.6.1 Overcoming the weaknesses of the study

If a similar project to the one described were conducted in future, it could benefit from improvements in several key areas. Firstly, reliability and validity investigations could be improved by the use of more robust methods. The tools used to measure the exposures of interest are of critical importance, and identifying a tool satisfying robust conditions of validity is of fundamental importance. Examining the response of foot-type measures to small changes in STJt orientation is a robust methodology for determining content validity, and whilst complex electronic equipment is impractical for measuring these variables clinically, such equipment can and should be used in validity studies. As stated previously, synchronising kinematic and kinetic equipment provides an opportunity to obtain matching data from the plantar foot (and therefore footprint measures) and motion data from navicular and calcaneus. This would permit the accurate evaluation of the true responsiveness of the foot-type measures to dynamic foot behaviour, to provide more robust information on content validity. The error associated with clinical techniques can then be evaluated to determine their accuracy in relation to a gold standard, followed by reliability assessment. Following this sequence would have permitted better determination of the validity of the techniques used.

The case control study could have been improved a great deal. A longer data collection period, the use of a better control group that utilised multiple controls per case, and the inclusion of information on more confounding variables would all have been beneficial. The age difference between the groups was an artefact of the time-constrained data collection period, and overcoming this issue would also have helped improve the quality of the study. Since the inception of the project a new foot-type
assessment tool has been developed (Redmond et al., 2001). This tool is based on a series of features of the foot based in the rear, mid and forefoot, and requires a categorical statement of the extent to which the feature is present. It has undergone substantial reliability and validity assessment, and appears to satisfy several conditions of both. Although the instrument gathers data on a categorical and not continuous scale, as recommended by the consensus of a group of experts (McClay, 2001), it appears to be the best available compromise between reliability and validity available so far. Repeating the study using this instrument, the FPI, would be worthwhile, but its failure to include a quasi-dynamic measurement suggests that the navicular drop and calcaneal motion measurements should be included. Performing such a study would provide an excellent opportunity for further assessment of the validity of both tools.

An important factor influencing the quality of the study relates to the resources available. Electronic equipment, patient incentives, researcher availability to attend clinics to undertake data collection and time all carries a financial cost. With limited financial resources the project was focused on clinical techniques and could only validate these technique using equipment already available. Whilst the use of clinical techniques represents a pragmatic choice due to their ease of use, the possibilities opened up by sophisticated electronic techniques are exciting. Such equipment permits more detailed comparisons of different groups of subjects, and although smaller groups would necessarily be involved, invaluable information can result. For example, 3-dimensional kinematic gait analysis equipment would permit more robust evaluation of foot-type, and could have been used as a gold standard against which to evaluate clinical measures. The availability of such equipment would have permitted a slightly different approach to be adopted, and would have been very valuable.

7.6.2 Suggestions for further study

The possibility that foot function may influence LBP is interesting, given that the foot is amenable to correction, and may represent a simple treatment possibility. The results of this study are significant enough to merit various suggestions for further studies to develop knowledge and understanding of the role of foot function in the development of LBP.
There appears to be a need for observational studies that track foot-type through childhood development to provide information on the natural history of foot posture. Continuing such studies into adulthood and investigating the development of conditions would provide information regarding the relationship between different foot-types and their relationship with pathology. Such studies should utilise measurements such as the FPI and the navicular and calcaneal motion measurements, and should avoid using footprint techniques due to their poor validity, and inability differentiate between feet with clinically significant differences in STJt position.

Comparison of gait performance between established LBP patients, who have been affected for 10 years, and age and sex matched controls would determine how gait degenerates in the condition. Evaluating any degeneration in the gait cycle that occurs in LBP represents an interesting possibility and this could be developed depending on findings. Serial recordings, at first diagnosis and then annually for 5 years, of hip, knee, ankle, subtalar and 1st MTPJt kinematics in LBP patients would provide information on the influence of the condition on normal locomotory performance. Such data would have to be considered alongside information from controls, and may lead to ideas for treatments attempting to maintain normal gait parameters. This idea could be developed to include evaluation of lower spinal muscle activity in relation to foot function. Such studies would necessarily involve smaller study groups, but could provide information on prognostic indicators and a benchmark by which to measure intervention response.

The FHSQ was found to differ between cases and controls, suggesting that back pain is associated with a reduced foot function. Although it is inappropriate to suggest a causal relationship between the two because of the increased incidence of general musculoskeletal pain in back pain patients, (Shekelle, 1997), the possibility that podiatry treatment may improve foot function to impact on quality of life is intriguing. Developing a foot-care programme involving orthoses to address mechanical dysfunction and routine podiatric techniques to address soft tissue lesions and general foot health problems, and examining the influence of this programme on LBP status represents an interesting possibility.

Critics of the outcomes movement focus on the need for evidence from multiple sources. It is therefore recommended that biomechanical 'bench' and laboratory
experiments be developed and conducted to examine the link between foot function and proximal musculoskeletal function. This would provide a robust rationale for future interventional studies.

Finally, it is recommended that future trials of interventions in low back patients (and indeed patients with other lower limb musculoskeletal pathologies) utilise blind or double-blind randomised controlled techniques, and be designed with explicit reference to the CONSORT statement to ensure that they satisfy the rigorous demands of the outcomes movement.

7.7 Conclusions

A theoretically robust technique for investigating the content validity was developed and used to examine several common methods of measuring foot-type. This involved examining their ability to detect discrete changes in STJt alignment.

The possibility of categorising subjects according to STJt axis orientation to increase the precision of the content validity study was discounted after the only pragmatic clinical technique of achieving this was found to be unreliable.

As a precursor to the main validity study, a fundamental dimension of criterion validity was assessed by examining agreement between measures calculated in static versus dynamic situations. This accounted for two studies. Firstly, static measurement of compensatory calcaneal motion between the neutral and RCSPs was found to correlate very well with dynamic calcaneal motion ($r=0.89$, $p<0.001$). Significant differences between the two states were also identified ($t=-3.637$, $df=9$, $p=0.005$), but in the presence of such a high correlation this suggests a mean dynamic increase of $1.48^\circ$.

Agreement between footprint measures, the Stahelis and Chippaux-Smirak indices, calculated from static and dynamic footprints was also performed. This yielded the same result, in that measures were found to differ between the two states, reflecting a mean dynamic increase of 25-28%, whilst correlations of 0.88-0.92 suggesting a consistent increase. The FPA was also included in this study but was rejected due to poor reliability.
The main content validity study involved examination of the sensitivity of navicular motion, the CSI and the SAI to discrete changes in STJt alignment. Navicular height was found to undergo a significant and consistent change in position with between 5° and 10° of calcaneal motion, whereas footprint measures were less responsive, requiring between 10° and 20° of calcaneal motion to change value significantly. Navicular height was identified as the most useful measure of STJt / rearfoot behaviour.

A case-control study was conducted using 64 cases and 57 controls. Quebec back pain disability questionnaire scores differed significantly between groups (p<0.0001), indicating correct group assignment. FHSQ scores differed between groups, suggesting poorer foot health in patients with LBP (mean difference −21.5; t=−6.1; p<0.0001). Although the amount of calcaneal and navicular motion did not differ between groups, symmetry of motion between left and right feet was found to differ between groups (calcaneal motion mean difference 2.2°, p<0.001 / navicular motion mean difference 3mm, p<0.001).

Whilst low back pain is a complex disorder of multi-factorial aetiology, in which a variety of factors interact in an intricate manner, this study does not permit rejection of the hypothesis that foot function may be involved with its development. An asymmetry was identified between cases and controls, and there is a biologically plausible pathway connecting asymmetrical foot function to low back pain. Further research to elucidate the influence of foot function on low back pain appears warranted.
What was already known on this topic:

- Back pain is a common, debilitating, condition associated with significant socio-economic costs;
- Despite being associated with numerous suspected aetiological variables, few firm links have been verified;
- Foot function is a factor that has been linked, essentially speculatively, with LBP;
- Little evidence exists supporting the link between foot function and LBP, and the evidence that does exist has employed methodologies that are either primitive (case studies) or inappropriate (trials of interventions, which if successful, are assumed to demonstrate that a causative relationship exists).

What this research programme adds:

- The study presents a robustly justified alternative framework for examining the relationship between foot function and musculoskeletal pathology;
- The approach focuses on the use of observational research to provide a foundation for the rigorous examination of the link between foot function and pathology, and this approach is considered vital for the development of a robust evidence base for podiatry;
- The study identified valid, reliable and responsive measures of foot function and employed these measures in a case control study. This study identified evidence that asymmetrical foot function may be implicated in chronic LBP in a proportion of cases, and provides support for the continued study of foot function in relation to LBP.
Chapter 8

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Appendices

1. Local research ethics committee approval
2. Case-control participant consent form
3. Case-control participant information sheet
4. Case-control GP letter for cases recruited
5. Study protocol
6. Case-control study questionnaire

N.B. All appendices related to the case-control study, as this was the only study to recruit NHS patients. All other studies received ethical approval from the School of Health and Social Sciences Ethics Committee at the University of Wales Institute, Cardiff.
05 November 2001

Mr I Mathieson,
Lecturer,
Wales Centre for Podiatric Studies,
University of Wales Institute, Cardiff,
Western Avenue,
Cardiff.
CF5 2YB.

Dear Mr Mathieson,

01/4173 - Foot-type as a risk marker in low back pain: A case control study

Thank you for your recent letter, regarding the above application for ethical approval.

The Chairman of the Bro Taf Local Research Ethics Committee (Panel C), Miss S M K Williams, has confirmed that your response is satisfactory.

Miss Williams has therefore taken ‘Chairman’s Action’ to grant full ethical approval to this application.

Yours sincerely,

Carl Phillips
Executive Officer
Local Research Ethics Committee

Tel: 029 20226470/20402451
Fax: 029 20402403
Subtalar Joint Motion and Low Back Pain: A Case Control Study
Participant Consent Form

The participant should complete the whole of this sheet himself/herself.

1. Have you read and understood the patient information sheet? (Please take a copy home with you to keep) YES/NO

2. Have you had the opportunity to discuss this study and ask any questions? YES/NO

3. Have you had satisfactory answers to all of your questions? YES/NO

4. Have you received enough information about the study? YES/NO

5. Who has given you an explanation about the study?
Dr/Mr/Mrs .................................................................

6. The investigator may inspect your medical notes. All personal details will be treated as STRICTLY CONFIDENTIAL.
Do you give your permission for this individual to have access to your medical records? YES/NO

7. Do you understand that you are free to withdraw from the study:
   - At any time?
   - Without having to give a reason?
   - Without affecting your future medical care?
   - That details of your participation up to the time of your withdrawal will be stored anonymously on file and may be used in the final analysis of data? YES/NO

8. Have you had sufficient time to come to your decision? YES/NO

9. Do you agree to take part in this study? YES/NO

---

**PATIENT**
Signed: ........................................................................
Date: ........................................................................
Name (BLOCK LETTERS): ...........................................

**WITNESS**
Signed: ........................................................................
Date: ........................................................................
Name (BLOCK LETTERS): ...........................................

**INVESTIGATOR**
I have explained the study to the above patient and he/she has indicated his/her willingness to take part.
Signed: ........................................................................
Date: ........................................................................
Name (BLOCK LETTERS): ...........................................
**Participant Information**

This study is investigating the relationship between foot function and low back pain. It is known that rotations in the leg and foot are related, and anecdotal reports that foot function can be involved in back pain has led to many Podiatrists treating people who have back pain with orthoses (special inserts worn inside shoes which alter foot function). However, such treatment approaches are not yet proven to be effective, as little is known about the true relationship between foot function and back pain.

This study is aiming to fill in some of the gaps in knowledge which surround this issue. Two groups of patients will be involved, one group of patients who have low back pain, and one group of patients who do not. Investigating the differences between these groups may reveal important differences, and provide information about how back pain might be treated.

Participation involves filling in a short questionnaire. Basic information such as your age, height and weight will be recorded, and you will also be asked some questions about back pain. The questions about your back pain will be used to categorise the broad category of back pain you have, and you will also be asked about the impact your back pain has on your life. The mobility of your joints will also be assessed. Finally, a short examination will be conducted, which will take 2-3 minutes, and will comprise two tests:

1. **A straight leg raise test:**
   This will involve you lying flat on an examination couch, and having your leg raised slowly, with your knee straight, to see if this causes you pain. The examiner will stop the second you tell them you feel any discomfort, but will then ask you where you felt discomfort;

2. **Examination of subtalar joint motion:**
   This procedure involves you standing up straight and rolling in and out between the inside and outside borders of your feet. The examiner will stop you somewhere in between, and you will be asked to balance there for a minute whilst some measurements are taken from the arch of your foot, and back of the heel. You will then be asked to relax and stand normally, and these measurements will be repeated.

Should you be interested in whether your foot function might be involved in your back pain, you should contact the Wales Centre for Podiatric Studies to make an appointment. This is a private clinic based at the University of Wales Institute, Cardiff (UWIC) on Western Avenue. Reception can be contacted on 02920 416 888. Appointments can be made for student clinics; there is a small charge (£5 per treatment) and the student is supervised by a fully qualified podiatrist.

Before the examination you will be asked to sign a consent form to certify that you agree to take part. Even although you sign this form, you are free to withdraw from the study at any time. Doing so does not influence your treatment in any way.

Thank you for your time.
Dear Dr.

Re: Patient Name Date of Birth Address

Further to your referral of this patient to the Orthopaedic spinal clinic, he/she was seen in the clinic on <<DATE>>.

Currently a piece of research is being conducted in the department, concerning the relationship between foot function and low back pain, by Ian Mathieson, a lecturer in Podiatry based at the University of Wales Institute, Cardiff. Approval for this study has been granted by the Local Research Ethics Committee, and the study is also registered with the Cardiff & Vale NHS Trust Research and Development Office.

After being provided with study information, by post prior to the clinic appointment, your patient agreed to take part in the study. Full informed consent was obtained.

Participation involved filling in a short questionnaire consisting of the Quebec Back Pain Disability Scale, the Foot Health Assessment Questionnaire, and some demographic questions. This was followed by a physical examination consisting of a straight leg raise test, measurement of calcaneal and navicular compensatory motion, and the Beighton hypermobility score.

Participation in this study was entirely supplementary to the consultation, and is completely separate from the treatment your patient will receive.

If you require any further information, please contact me directly on 0292041 6864.

Yours sincerely

Ian Mathieson
Lecturer, Podiatry
Foot-Type as a risk marker in low back pain – a case control study

Study Protocol

Cases and Controls, although recruited from separate centres, will go through the same process.

The consulting physician in each clinic will identify suitable patients to act as ‘case’ subjects. The process for selecting patients and gathering data is as follows:

**Cases**

1. Recruited from the Spinal Clinic at Llandough Hospital
2. All new patients will be considered subject to the following inclusion criteria:
   - Aged 18-65;
   - Back pain is located in the ‘low back’ region – defined as lumbo-sacral;
   - Back pain is not of traumatic or systemic origin;
   - Back pain did not begin in pregnancy;
   - Back pain must be of ≥ 6 months duration;
   - Subjects will have low back pain perceived by the consulting physician to be of mechanical origin;
   - Patients with conditions such as prolapsed disc should be included if it is believed to be due to an underlying mechanical problem;
   - Subjects will have no history of trauma to their feet or lower limbs;
3. Suitable patients will be identified to the principal researcher by the consultant, and asked to take part.
4. If interested, the patient will be given a study information sheet to read.
5. If the patient decides not to take part they will be thanked for their time.
6. Upon reading the information sheet the patient will have the opportunity to ask questions.
7. Informed consent will be sought from patients wishing to take part in the study.
8. A questionnaire will be issued to the patient to fill out immediately in the presence of the researcher.
9. Upon completion of the questionnaire a short physical examination will be performed in the following sequence:
   - **A straight leg raise test:** The patient will be asked to lie supine on an examination couch. One leg at a time will be raised, maintaining a fully extended knee, and will be recorded as either ‘Negative’, ‘Positive for back pain’, ‘Positive for leg pain’ or ‘Tight hamstrings’.
   - **Assessment of static compensatory motion:** The patient will be asked to stand in a comfortable stance position, looking straight ahead with arms by their sides. They will be asked to internally and externally rotate both limbs simultaneously to position the subtalar joint in the neutral position. The height of the navicular will be measured and a line perpendicular to the ground will be drawn on the posterior aspect of the calcaneus. The subject will be asked to relax into the relaxed calcaneal stance position and navicular height will again be recorded. The angle between the calcaneal reference line and the ground will again be measured.
   - **Assessment for Benign Joint Hypermobility Syndrome:** The subject will be asked to perform five simple tests to examine whether they are capable of the following manoeuvres: Hyperextension of the 5th metacarpalphalangeal joints of both hands; movement of each thumb towards the volar aspect of the forearm; hyperextension of the elbows; hyperextension of the knees; touching the floor with both hands whilst
maintaining full knee extension. The principal researcher will assist patients in performing each test and each will only be performed to the comfortable limit of motion.

10. Patients will be thanked for their time and for participating. Any patient expressing interest in the possibility that their foot function might be related to their back pain will be provided with details of the Wales Centre for Podiatric Studies, to make an appointment with the principal researcher.

Controls

1. Recruited from the student and staff population at UWIC;
2. Initial contact will be via an e-mail to staff within the School of Health and Social Sciences, providing information on the nature of the study, details of what is involved, and an invitation to reply if they are willing to volunteer;
3. Recruitment will commence 3 months after the start of recruitment of ‘cases’, when a profile of the group can be built up to enable group matching to take place. Additional criteria will be applied, and controls will have:
   • No history of back pain or trauma for which a doctors, or other health professionals, advice / treatment has been sought;
   • No history of trauma to their feet or lower limbs.
4. During the arranged data collection session, the inclusion criteria will be confirmed;
5. Subjects will go through the same process as ‘cases’ from step 8.
Foot Type and Low Back Pain Questionnaire

Date: ______/____/____  Subject No. __________

1. The following questions are about the way back pain can affect your daily life. People with back problems may find it difficult to perform some of their daily activities. We would like to know if you find it difficult to perform any of the activities listed below because of your back.

Please tick the box representing how difficult you would find it to perform each of the listed activities today. Be sure to answer all questions.

<table>
<thead>
<tr>
<th>Because of your back problems, how difficult do you find it today to...</th>
<th>Not at all difficult</th>
<th>Minimal difficulty</th>
<th>Somewhat difficult</th>
<th>Fairly difficult</th>
<th>Very difficult</th>
<th>Unable to do</th>
</tr>
</thead>
<tbody>
<tr>
<td>Get out of bed?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sleep through the night?</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Turn over in bed?</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Ride in a car?</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Stand up for 20-30 minutes?</td>
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<td></td>
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</tr>
<tr>
<td>Sit in a chair for several hours?</td>
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<td></td>
</tr>
<tr>
<td>Climb one flight of stairs?</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walk 100 metres?</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walk several miles?</td>
<td></td>
<td></td>
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<tr>
<td>Reach up to high shelves?</td>
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<tr>
<td>Throw a ball?</td>
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<td></td>
</tr>
<tr>
<td>Run 100 metres?</td>
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<td></td>
</tr>
<tr>
<td>Take food out of the fridge?</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Make your bed?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Put on socks or tights?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bend over to clean the bath?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Move a chair?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pull or push heavy doors?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carry two bags of shopping?</td>
<td></td>
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</tr>
<tr>
<td>Lift and carry a heavy suitcase?</td>
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<td></td>
</tr>
</tbody>
</table>

2. If you experience back pain, for how long has your back been painful? __________

3. Did it begin after an injury? (Please circle) Yes / No

If yes, please provide details of the incident:

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
4. Please tick the box beside any body regions in which you experience pain:

<table>
<thead>
<tr>
<th>The small of your back</th>
<th>Your left buttock</th>
<th>Your left heel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Your right hip</td>
<td>Your right thigh</td>
<td>Your right big toe</td>
</tr>
<tr>
<td>Your left hip</td>
<td>Your left thigh</td>
<td>Your left big toe</td>
</tr>
<tr>
<td>Your groin</td>
<td>Your right calf</td>
<td>Your right little toe</td>
</tr>
<tr>
<td>Your crotch</td>
<td>Your left calf</td>
<td>Your left little toe</td>
</tr>
<tr>
<td>Your right buttock</td>
<td>Your right heel</td>
<td></td>
</tr>
</tbody>
</table>

5. Is your back painful in any area outside the low back?  
   YES / NO

6. Please provide details of any area outside your low back that is painful:

   [Write down details here]

These next questions ask for your views about your foot health. 
For all questions, tick the box relating to the most appropriate answer

7. What level of foot pain have you had during the past week?

<table>
<thead>
<tr>
<th>None</th>
<th>Very Mild</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
</table>

    During the last week...

   | 6. How often have you had foot pain? |
   | 7. How often did your feet ache?    |
   | 8. How often did you get sharp pains? |

    During the last week...

   | 9. Have your feet caused you to have difficulties in your work or activities? |
   | 10. Were you limited in the kind of work you could do because of your feet? |
**During the last week...**  

<table>
<thead>
<tr>
<th>11. How much does your foot health limit your walking?</th>
<th>Not at all</th>
<th>Slightly</th>
<th>Moderately</th>
<th>Quite a bit</th>
<th>Extremely</th>
</tr>
</thead>
<tbody>
<tr>
<td>12. How much does your foot health limit you climbing stairs?</td>
<td>Not at all</td>
<td>Slightly</td>
<td>Moderately</td>
<td>Quite a bit</td>
<td>Extremely</td>
</tr>
</tbody>
</table>

13. How would you rate your overall foot health?

<table>
<thead>
<tr>
<th>Excellent</th>
<th>Very Good</th>
<th>Good</th>
<th>Fair</th>
<th>Poor</th>
</tr>
</thead>
</table>

The following questions are about the shoes that you wear:

<table>
<thead>
<tr>
<th>14. It is hard to find shoes that do not hurt my feet</th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Neither agree nor disagree</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>15. I have difficulty in finding shoes that fit my feet</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16. I am limited in the number of shoes I can wear</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

17. In general, what condition would you say your feet are in?

<table>
<thead>
<tr>
<th>Excellent</th>
<th>Very Good</th>
<th>Good</th>
<th>Fair</th>
<th>Poor</th>
</tr>
</thead>
</table>

18. If you have foot pain, for how long has this been present?  

_________________________
Finally, could you please answer some questions about yourself generally:

19. Do you smoke (Please Circle)  
   If yes:  
   How long have you smoked?  
   How many cigarettes do you smoke per day?  
   Do you have a persistent cough?  
   
20. What is your current or most recent job?  
   
21. Do you experience pain in any joints?  
   (Please circle)  
   How many of your joints are painful?  
   For how long have they been painful?  
   
22. Have you had any surgery on your back?  
   (Please circle)  
   
23. Date of Birth:  
   ___/___/_____  

24. Sex (Please circle)  
   Male   Female  

25. Height:  
   
26. Weight:  
   
Please do not write below this line

For official use only:

Please provide details of any diagnosis that has been made, and any diagnostic tests used to support this diagnosis:

Please provide details of any back surgeries performed: