Kinematics at the Ankle Joint Complex In Rheumatoid Arthritis

By

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The candidate confirms that the work submitted is his own and that appropriate credit has been given where reference has been made to the work of others.

Abstract

This thesis investigates the three-dimensional kinematics at the ankle joint complex in rheumatoid arthritis. Previous studies have identified the rearfoot as a common site for inflammatory activity in rheumatoid arthritis resulting in painful and disabling deformity for which there are no proven interventions.

A generic electromagnetic tracking system was developed to undertake three-dimensional kinematics at the ankle joint complex in the bare and shod foot during gait. A joint simulator was designed, manufactured and commissioned in house to test the accuracy of the system. The results indicated errors of less than 1° in rotation and 1mm in position measurements. Clinical testing of the measurement system was undertaken in both normal healthy adults and rheumatoid arthritis subjects. The technique was able to measure the characteristic three-dimensional kinematics for the ankle joint complex in the normal subjects and detected accurately abnormal angular rotations in the rheumatoid arthritis group. In both cohorts the within day repeatability of the measurements were good, and over a longer period data were stable in the rheumatoid arthritis group allowing the technique to be used in longitudinal studies. Finally, skin movement artefact where the electromagnetic sensor is attached on the heel was investigated using a magnetic resonance imaging technique and found to be less than 1° across the range of motion for the joint complex.

Kinematic measurements were undertaken in two cohorts of rheumatoid arthritis subjects randomised to receive or not custom manufactured foot orthoses to correct early valgus heel deformity. The orthoses were constructed in rigid carbon graphite and modified to offer the correct degree of movement control for each patient. Kinematic data were compared between the rheumatoid arthritis groups and that measured from an age- and sex-matched healthy adult population. In both rheumatoid arthritis groups abnormal kinematics were easily detected with significant alteration of inversion/eversion and internal/external rotation. With foot orthoses the inversion/eversion angular rotations were almost fully restored to normal, but little effect was observed for internal/external rotation.

The rheumatoid arthritis patients underwent repeat kinematic measurement over a period of 30-months. In the control group the angular rotations improved slightly from baseline, although in comparison with normal healthy population remained abnormal. In the intervention group the orthotic control of inversion/eversion was sustainable for 30 months. Furthermore, coupling between inversion/eversion and internal/external rotation was partially restored towards the end of the study. In barefoot walking the intervention group demonstrated a substantial correction of the deformity in the frontal plane. It was attempted to explain the results in terms of soft-tissue laxity and adaptation following correction of joint deformity. Three-dimensional kinematic measurements were also conducted at the knee and calcaneotalonavicular joint complex. Abnormal rotations and orthotic response were demonstrable at these joints but with less satisfactory results because of technical limitations of the measurement technique.

Plantar pressure distribution was also studied using an in-shoe measurement technique. Custom designed orthoses were found to alter the pressure and force distribution at the interface with the foot. The largest effects were observed at the heel and midfoot regions and these were sustainable and significantly different from the non-intervention control group.

The clinical effectiveness of the foot orthoses was also evaluated. A pragmatic randomised controlled trial was undertaken and serial measurements of foot pain and disability, using the Foot Function Index conducted at baseline and 3, 6 12, 18, 24 and 30-months. The results revealed an immediate and significant reduction in foot pain and disability with foot orthoses. Minor adverse reactions were reported but overall comfort levels and compliance were high. The overall reduction in foot pain and disability was sustained up to 30 months.

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The images used in chapters 2 and 3 were adapted from Grant's Atlas Images from Mediclip™ software, Williams and Wilkins, under permission from Business Presentations, Ashwell UK.

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Abbreviations

3-D	Three-dimensional
ACR	American College of Rheumatology
AJC	Ankle joint complex
ARP	Angular rotational position
AUC	Area under the curve
BF	Barefoot
BM	Bone markers
CMC	Coefficient of multiple correlation
CT	Computed tomography
DAS	Disease activity score
DF	Dorsiflexion
EM	Electromagnetic
EMG	Electromyography
EMT	Electromagnetic tracking
ER	External rotation
EVR	Eversion
FF	Foot flat
FFI	Foot Function Index
FO	Foot orthosis
HL	Heel Lift
HS	Heel strike
INV	Inversion
IQR	Inter-quartile range
IR	Internal rotation
MCU	Motion capture unit
MTP	Metatarsophalangeal
MRI	Magnetic resonance imaging
MS	Mid stance
NCSP	Neutral calcaneal stance position
PF	Plantarflexion
PPM	Plantar pressure measurement
RA	Rheumatoid arthritis

RCSP	Relaxed Calcaneus Stance Position
RCT	Randomised controlled trial
ROM	Range of motion
SD	Standard deviation
SH	Shod
SM	Skin markers
TO	Toe off
US	Ultrasonography
VAS	Visual analogue scale

CHAPTER 1

INTRODUCTION

This chapter provides an introduction and justification to the origins and objectives of the thesis. The central hypothesis is established and a framework for the thesis structure and content provided.

1.1 Justification of the subject matter

Rheumatoid arthritis (RA) is chronic systemic inflammatory disease of unknown origin characterised by persistent synovitis primarily affecting the peripheral joints. Accordingly, the feet are a common site for involvement with significant morbidity. Many patients present at onset with disease activity in the feet, and progress to develop characteristic signs and symptoms including forefoot metatarsalgia, hallux valgus, hammer and claw toe deformity, pes planovalgus, bursitis, skin pressure lesions, vasculitis and neurological deficit. A common often painful and disabling condition known as valgus heel deformity occurs in the rearfoot at the subtalar joint. Clinically this presents as frontal plane malalignment of the calcaneus relative to the leg. Patients complain of pain and stiffness in and around the ankle/subtalar region readily confirmed on joint examination. Gait is frequently modified and other objective findings include tenosynovitis of adjacent tendons, especially tibialis posterior, and synovitis in the sinus tarsi.

The subtalar joint is difficult to examine clinically because it is close structurally and simultaneously functionally dependent on a number of other joints forming the ankle and midtarsal joint complexes. Furthermore, there is evidence to suggest that measurement of open-kinetic chain joint motion has poor reliability and that static observation of segmental position (varus/valgus) may be a poor predictor of joint motion in gait. In quantitative gait analysis the talus is found deep to the skin surface and offers no prominent landmark suitable for the attachment of surface markers used in kinematic systems. Thus motion is determined for the ankle joint complex (AJC) [tibiotalar and subtalar joints] with inversion/eversion movement attributed to the subtalar component, or from full foot models that capture the motion as foot supination/pronation. The complexity of the subtalar joint causes a number of technical problems during motion measurement. This, however, has not deterred various groups from attempting to quantify this motion in three-dimensions (3-D) and sufficient evidence now exists to satisfactorily describe a pattern of normal inversion/eversion through the gait cycle. Deviation from the normal motion pattern, described as either excessive foot pronation or calcaneal

eversion depending on definitions and measurement technique, have been implicated as being contributory to a number of musculoskeletal disorders of the lower extremity.

In functional terms, valgus heel deformity in RA is a single static picture of an everted subtalar joint made unstable on weightbearing by a combination of soft-tissue weakness and joint destruction. A few cross-sectional gait studies have confirmed the presence of excessive and prolonged calcaneal eversion during stance phase in well-established RA cases. The deformity is progressive in nature and radiographic studies have demonstrated a close relationship between disease duration, prevalence and severity of the deformity. Functional deterioration is subtle and almost impossible to detect clinically in either static examination or observational gait analysis. As such interventions are frequently administered on the basis of pain severity and gait modification. Furthermore, this condition is not specific to RA. However, in an age and sex-matched case-control study using otherwise healthy individuals, it has been previously demonstrated that the deformity is measurably greater and produces worse symptoms in the disease condition (Woodburn, 1994). Substantial evidence produced more recently suggests that rearfoot pain and deformity are significantly related to disability and reduced mobility, more so than forefoot disease. These factors indicate strongly that site-specific local therapy is required for valgus heel deformity.

Various treatment strategies, including foot orthoses and insoles, bracing and splints, intra-articular glucocorticosteroid injections, footwear modifications and orthopaedic surgery have been recommended for valgus heel deformity. The literature, however, is dominated by orthopaedic surgery, in late disease, mainly describing various arthrodesis procedures. There is certain dissatisfaction communicated in this literature regarding the lost opportunity to initiate conservative intervention strategies much earlier in the disease calendar. The targeted therapy is functional foot orthoses intended for use when joint structure and function is near normal. What little evidence exists for the use of foot orthoses in RA does, however, indicate beneficial pain reduction and functional improvement in established disease. Importantly, a negative finding in one major controlled study emphasises the need to consider very carefully the type of orthosis prescribed and, more importantly, the precise timing of use. This viewpoint is polarised further when one considers recent advances in the medical management of RA. Here, emphasis has been placed on the detection of very early arthritis where advanced imaging techniques such as high-resolution ultrasound and magnetic resonance imaging (MRI) have shown established joint destruction previously undetectable in early disease by conventional plain radiography. On this basis, pharmacotherapeutics have been redefined with an earlier and more aggressive use of disease modifying drugs within a so-called therapeutic window of opportunity.

Since the 1980's, a design concept for foot orthoses has targeted the goal of motion control especially the frontal plane component of pronation. Custom-manufactured devices constructed on plaster models of the feet, in rigid thermoplastics, with angled contours incorporating corrective wedging appear to be strongly indicated for rearfoot disease in RA. Furthermore, if the medical model is followed, and if rearfoot disease can be diagnosed accurately in the early stages, then podiatrists are potentially armed with an intervention that may protect joint integrity. The concept of disease-staged management using functional foot orthoses is attractive. Qualitative tools exist to measure clinical dimension such as foot pain and disability in any evaluation study, but there is a need to quantify the motion characteristics of rearfoot to diagnose abnormal function and then any orthotic treatment response, and to apply this technique longitudinally in a large-scale clinical trial.

The aim of this study is to undertake the measurement of ankle joint complex 3-D kinematics in the early stages of rearfoot disease in RA and to evaluate both clinically and biomechanically the effectiveness of functional foot orthoses. The findings of this study may be relevant for clinical practice and research in the following ways:

i.) Development of an accurate and precise kinematic measurement system suitable for the ankle joint complex. This will facilitate the study of normal and abnormal foot function whilst permitting quantification of local therapies aimed at altering kinematic behaviour.

ii.) By providing baseline and prospective AJC kinematic data, the development of new disease-staged local therapies can be undertaken and assessed.

iii.) Influence evidence based practice by presenting clinicians with data-supported clinical recommendations and guidelines, concerning the potential effectiveness and optimum timing for the use of functional foot orthoses in this condition.

1.2 Previous approaches and limitations

The diagnosis and staging of valgus heel deformity in RA has been a difficult challenge. Epidemiological studies, mostly cross-sectional in design, suffer from small samples sizes, use patients invariably drawn from hospital based populations and show selection bias, thus making findings difficult to generalise. Valgus heel deformity lacks a standardised definition and a valid diagnostic test. Current data are drawn from weightbearing plain radiological studies and we have

little knowledge on rearfoot function in gait. Most studies lack sufficient detail and fail to make associations with disease duration and clinical data related to disease activity.

The pace of foot orthotic design has unfortunately not been matched with adequate evaluation studies. For rearfoot disease in RA, advanced clinical evaluation in the form of meta-analysis is simply not possible. The cross-sectional studies are devalued by small sample sizes, selection bias, limited detail to patient and disease characteristics, lack of adequate control and insufficient detail of orthotic design, manufacture and use. Outcome measures are often restricted to pain and disability, or basic gait data, but little or no association between the two has been pursued. There is clearly a need for clinical data to be collected alongside gait analysis data in a longitudinal and controlled study with the treatment effect quantified by the same outcome measures.

1.3 Hypothesis

Clinical evidence suggests that the subtalar joint is involved significantly in rheumatoid arthritis leading to the development of a disabling and painful condition referred to as valgus heel deformity. Furthermore, radiographic studies have demonstrated that the deformity is progressive with eventual total joint destruction and collapse in some cases. Few studies have attempted to understand the nature of this deformity in gait and how joint function changes over time, or how it is precipitated by joint inflammation and affected over time by disease activity.

Functional foot orthoses have been developed to correct the instability associated with the development of valgus heel deformity but not specifically in RA. Their use may be valuable if not to correct the deformity then to arrest or slow further development, particularly if combined with an associated reduction in foot pain and disability. Their initial use may be restricted to a small window of opportunity in early disease where instability is not associated with major joint destruction. In an era of evidence-based practice, any evaluation must take place under the robust test conditions of a clinical trial. Central to the evaluation of functional changes will be the employment of a kinematic measurement system that is accurate, precise and sensitive to detect changes as a true worsening or improvement of the condition or as a product of any intervention. Therefore, in light of current evidence and with a number of important challenges ahead the following hypotheses are put forward:

> ***"Rheumatoid arthritis significantly alters the 3D kinematics at the ankle joint complex in early disease in comparison with an age and sex-matched population".***

"In rheumatoid arthritis ankle joint complex kinematics will change over a 30-month period if left untreated".

"Custom-designed foot orthoses will significantly improve ankle joint complex kinematics. This effect will be sustainable over the medium term"

"Custom-designed foot orthoses will significantly improve ankle joint complex pain and disability. This effect will be sustainable over the medium term".

1.4 Aims and scope of the present study

In order to test the above hypotheses the present investigation has five main objectives:

i.) To determine the optimum time for early intervention, an appropriate orthotic intervention strategy and a clinically valid technique by which to assess that intervention.

ii.) To refine a generic tracking system for the purpose of 3D kinematic measurement specifically for the ankle joint complex in the in-shoe environment.

iii.) To use the system to determine normal ankle joint complex 3D kinematics in otherwise healthy individuals.

iv.) To use the system to undertake serial clinical measurements in two cohorts of RA patients undergoing a clinical trial.

v.) To use this kinematic data alongside other biomechanical parameters, namely plantar pressure measurement, to explain any differences found between the intervention and control groups in clinical outcomes such as pain and disability as found in the randomised controlled clinical trial.

1.5 Thesis structure

The literature review in Chapter 2 provides relevant background material used in the generation of the hypotheses established above.

Chapter 3 provides a description of the apparatus used to undertake 3-D joint kinematics. Refinement of the technique for measurement specifically at the ankle joint complex is described along with the findings from three original pieces of experimentation that set out to examine the accuracy and precision of the technique, clinical repeatability and reproducibility and an evaluation of the effects of skin movement artefact.

In chapters 4 a detailed description of the randomised-controlled trial methodology for evaluation of the foot orthoses is provided. The trial design is described in detail with specific reference to interventions, primary clinical outcome measures, clinical variables and the methods of statistical analyses. The results from the clinical trial are presented and discussed in detail. Appropriate conclusions are drawn with specific reference to the clinical significance of the findings.

In chapter 5 the 3-D kinematic data for the AJC are presented and described for the RA patients and the normal age- and sex-matched population. Changes in AJC kinematics following orthotic intervention are presented. Longitudinal data are presented for both RA groups from baseline to 30-months and appropriate groups comparisons to establish treatment efficacy are made. Kinematic data for the knee and calcaneotalonavicular complex are also presented and discussed. The findings and clinical interpretation of this data are discussed in detail.

In chapter 6 the plantar pressure and force measure data are summarised for the RA groups and compared with data from a representative cohort of normal subjects. Longitudinal changes in these variables are described for both RA groups and appropriate comparisons made. The immediate and medium term effect of foot orthoses on pressure and force distribution are discussed in detail.

In chapter 7 a summary discussion is provided for the main findings of the study. Implications for clinical practice are discussed along with the limitations of the study and finally, recommendations for future work is provided.

CHAPTER 2

LITERATURE REVIEW

This chapter reviews the literature relevant to this field of work. A description of rheumatoid arthritis alongside a detailed review of foot disease with special emphasis on rearfoot involvement is provided. The normal structure and function of the subtalar joint is discussed in detail with reference to articular geometry, ligaments and muscular control. Normal subtalar kinematics and kinetics are explored before a detailed review of joint failure in rheumatoid arthritis is given.

2.1 Rheumatoid arthritis and foot disease

2.1.1 Rheumatoid arthritis

Rheumatoid arthritis (RA) is a systemic disease with a clinical picture of widespread synovial joint involvement. The most characteristic features include: (I) persistent synovitis; (II) symmetrical small joint involvement; (III) progressive spread from small to large joints and (IV) destructiveness; and RA is associated with significant long-term disability, morbidity and mortality (Emery *et al.*, 1997; Conaghan *et al.*, 1999; Scott *et al.*, 2000). Rheumatoid arthritis has no disease specific clinical, radiological or immunological features and diagnosis is based largely on patterns of clinical and investigational findings, historically formulated into diagnostic criteria sets (Arnett *et al.*, 1988). The aetiology of RA is unclear but the clinical presentation may arise from different causes with a common pathogenic pathway in synovial joints. Traditional pharmacotherapeutic management of RA was largely conservative with non-steroidal anti-inflammatory drugs given for long periods followed by the least toxic second-line agent in a pyramid approach (van Gestel *et al.*, 1997a). The current strategy, influenced by imaging studies that show joint destruction in very early disease, is a more aggressive use of second-line agents, such as sulphasalazine and methotrexate, often used in combination. This strategy exploits a therapeutic window of opportunity in very early disease wherein inflammation can be arrested prior to the development of joint damage (Conaghan *et al.*, 1999; Emery, 1994; van Gestel *et al.*, 1997b; van Riel *et al.*, 1999). On-going research continues to refine quantitative prognostic factors enabling a better prediction of outcome.

It is helpful to adopt a regional approach, such as the Gait, Arms, Legs and Spine (GALS) system when describing the location and patterns of individual joint involvement in RA including tenderness, swelling and deformity (Plant *et al.*, 1993). Sites such as the hand and

knee joints are easily accessible in the clinic and generally well researched. There are areas, however, which do not attract proper emphasis when considering disease impact and its management and this is particularly relevant for the foot.

2.1.2 Rheumatoid arthritis and foot disease

2.1.2.1 Clinical features

The clinical manifestations of rheumatoid arthritis in the feet have been described extensively in the orthopaedic literature. In the forefoot, synovitis in the metatarsophalangeal joints (MTP's) leads to common deformities such as hallux valgus, forefoot widening, hammer/claw toes, and plantar bursae, callosities and ulceration (Dixon, 1969; Kerry *et al.*, 1994; Spiegel and Spiegel, 1982; Vainio, 1956). In the mid- and rearfoot pes planovalgus deformity causes further major structural changes to the foot characterised by flattening of the medial longitudinal arch, valgus deformity of the calcaneus and tibialis posterior tendon dysfunction (Dimonte and Light, 1982; Cracchiolo, 1993; Kitaoka, 1989; Vainio, 1956). Systemic features such as vasculitis, subcutaneous nodules, and neurological symptoms also manifest in the feet (Kitaoka, 1989; Nakano, 1975; Spiegel and Spiegel, 1982). For a lifetime disease with an average duration of 25 years an understanding of the early development and progressive course of foot disease is of major importance.

2.1.2.2 Forefoot involvement

Descriptive hospital-based studies have shown that between 20-50% of RA patients present at initial onset with painful feet, and that between 50-86% of all patients have clinical involvement on day of consultation. Furthermore, 90% complain of foot pain at some time during the course of their disease, and over 90% have radiological changes in their feet (Minaker and Little, 1973; Rydgren *et al.*, 1996; Vainio, 1956; Vidigal *et al.*, 1975; Wakefield *et al.*, 2000). Inclusion of the MTP joints in routine radiological screening techniques such as the Larsen scoring system has helped our understanding of the onset, rate of progression and degree of destructiveness in the foot. Priolo *et al.*, (1997) found that MTP erosions facilitated the identification of patients with early disease and was predictive of those with more aggressive disease. Early and extensive erosive changes have been found to occur in the MTP joints (Belt *et al.*, 1998). Haas *et al.*, (1999) found radiological progression and worsening of foot morphology in 97% of 70 RA feet over a 5 year time period. In a 20-year prospective study of 103 seropositive RA patients, Belt *et al.*, (1998) found erosions of Larsen grade ≥ 2 present in 6% of the investigated 1236 MTP joints at onset and in 62% after 20 years. At the end point, 24% of the joints were

severely damaged (Larsen grade 4-5) and 1 in 5 joints required arthroplasty procedures. Priolo *et al.*, (1997) at baseline found 11% of 284 patients with disease duration of ≤ 4 years had isolated foot erosions and that 12 months later the eroded joint count was more frequent in those with foot erosions at baseline than those without. Eberhardt *et al.*, (1995) found significant increase in Larsen feet scores over a 5-year period in 63 RA patients with a marked deterioration in MTP joint function in 55% patients after 2 years.

Diagnosis of forefoot involvement based on swollen or tender joints could be unreliable in RA. Predicted radiological Larsen scores from clinical examination were underestimated in the MTP's (Plant *et al.*, 1994). High resolution ultrasound found a 10 times greater number of MTP joints in 4 times as many patients compared with clinical findings (Plant *et al.*, 1994; Wakefield *et al.*, 2000). This suggests that MTP joints could probably be under-stressed during clinical examination when compared to forces generated during gait.

From clinical observation it is widely understood that gross structural morbidity in the forefoot is highly prevalent in RA and this have been documented in a number of studies (Dixon, 1969; Kerry *et al.*, 1994; Rydgren *et al.*, 1996; Spiegel and Spiegel, 1982; Vainio, 1956). The rate of progression is unknown but close association has been established between disease duration and severity of deformity. For example Spiegel and Spiegel (1982) grouped 50 RA patients by 4 stages of disease duration and qualitatively rated MTP deformity by four grades of severity. Both the frequency and severity of deformity increased with disease duration for all 5 MTP joints. The pattern of deformity was typified by lateral deviation and dislocation. Hallux valgus of the 1st MTP was severe in over 30% of patients with a disease duration >5 years. In early disease symptoms or function might improve as drug therapy is initiated. A cohort study of 39 patients with early RA, defined as a disease duration of <2 years, were followed for 24 months. Twenty percent had disease onset in the feet and deformities were present in 75%. Over 24 months there was no change in visual analogue scale pain or functional impairment whilst joint tenderness improved to 12 months, returning to baseline by 24 months (Rydgren *et al.*, 1996). The conclusion in RA is early and extensive forefoot disease, with high grades of destruction, possibly underestimated clinically leading to severe deformity over time.

2.1.2.3 Mid- and Rearfoot involvement

The time of onset, severity and prospective pattern of change are less well known for the mid- and rearfoot joints. Large joint disease is an early phenomenon in RA and is significantly related to radiographic damage in the feet, so mid- and rearfoot involvement should be expected (Kuper *et al.*, 1997). Furthermore radiographic changes in the midfoot usually occur in the

presence of MTP abnormalities. In three studies using consecutive hospital patients, radiological mid-foot damage was diagnosed in between 22-62% of cases- the greatest incidence at the talonavicular joint, the frequency here rapidly progressing over the early stages of disease (Bouysset *et al.*, 1987a; Minaker and Little, 1973; Vidigal *et al.*, 1975). Case studies have been used in two papers to describe midtarsal joint pathology consisting of erosions, joint space narrowing, diffuse osteoporosis and deformity (Pastershank, 1981; Resnick, 1976). However, clinical and radiological assessment of the midfoot is still widely regarded as difficult. Spiegel and Spiegel (1982) found the articular or juxta-articular regions difficult to palpate and could not locate synovitis accurately. Attention was drawn to the significance of medial longitudinal arch collapse, demonstrable on weightbearing X-ray, as an indicator of midfoot disease. Changes in the midfoot are often subtle and the pain in this regions less frequent and severe than other foot sites. Pain was found in only 1 in 10 cases in the study by Kerry *et al.*, (1994) and in 27 of 99 patients (5 rating the midfoot as causing the most symptoms), in a study by Michelson *et al.*, (1994). In a hospital population, 29 midtarsal sites from 204 feet were painful only on walking whilst 27 were painful on passive examination (Vidigal *et al.*, 1975).

In clinical practice the ankle region is not routinely assessed by x-ray and according to Belt *et al.*, 1997, this is justifiable as his prospective study showed 77 of 136 subtalar joints to be Larsen grade 0 at 20 years disease duration. For the 59 joints involved the mean Larsen score was 1.3 indicating only slight abnormality, whilst surgical fusion had been performed on 12 joints and 5 joints had fused spontaneously (Belt *et al.*, 1997). Using Larsen scoring techniques, 157 patients with disease duration of <1-year were studied prospectively for large joint involvement (Kuper *et al.*, 1997). At entry only 3 patients showed radiological damage (Larsen score 1) at the ankle and 2 at the subtalar joint. At three years this had increased to 18 and 13 respectively with Larsen scores of 2 and 3 recorded. At 6 years this increased to 24 and 23 respectively with surgical intervention necessary at 1 ankle and 4 subtalar joints (Kuper *et al.*, 1997). Grading pathology by Larsen scores tends to produce destruction rates lower than in previous retrospective or cross-sectional studies. For example, Bouysset *et al.*, (1987b) found 54% of patients with a disease duration >15-years to have subtalar and 24% to have ankle involvement, many with severe pathological changes (not stated but evidently greater than Larsen score-1). In established cases with medium to long disease duration, Vidigal *et al.*, (1975) noted x-ray ankle joint changes in 26%, and subtalar changes in 32% of cases. There is strong evidence that prevalence rises with disease duration and that joint status deteriorates over time, but variability in the radiological scoring makes comparison between studies difficult.

2.1.2.4 Pain, functional loss and disability

Anecdotal evidence states that foot disease in RA results in pain, loss of function and disability. Whilst this is not disputed clinically, only recently has the development of valid and reliable outcome tools across these domains permitted proper evaluation. An American group from the National Institutes of Health (Bethesda, USA) studied 31 RA patients rating qualitatively pain, functional ambulation and structural deformity and quantitatively gait analysis using validated outcome tools (Platto *et al.*, 1991). Gait was impaired in comparison with historical control data and characterised by reduced velocity, reduced stride length, prolonged double support and reduced cadence and these variables correlated well with impaired functional ambulation-measured qualitatively. These findings confirm earlier gait work and observational reports in clinical studies (Isacson and Brostrom, 1988; Locke *et al.*, 1984; Marshall *et al.*, 1980). Platto *et al.*, (1991) also showed a complex relationship between foot deformity and foot pain, emphasising the need to consider carefully the stage of disease. For example, the location of structural deformity (forefoot or rearfoot) did not always correlate with the location of pain, until the patients were grouped by preponderance of pain or deformity and disease duration. Then, hindfoot deformity correlated with forefoot pain but forefoot pain and deformity did not correlate as well. Functional ambulation correlated with hindfoot pain but not forefoot pain and this was unexpected. However, further work by this group demonstrated that forefoot pain does impact significantly on gait function and disability (O'Connell *et al.*, 1998). Importantly this study also demonstrated that pain was the most important feature that influenced functional mobility since structural deformity of the whole foot, or rearfoot or the forefoot did not correlate with the functional ambulation outcome at all (Platto *et al.*, 1991). Finally, this study showed that rearfoot rather than forefoot pain had a greater impact on specific gait variables prolonging double stance time, reducing velocity by shortening stride length, leading to a shuffling gait with loss of normal heel-to-toe progression. This shuffling gait and the impact it may have on the lower limb has also been described in other studies (Gerber and Hunt, 1985; Isacson and Brostrom, 1988; Locke *et al.*, 1984; Marshall *et al.*, 1980). In selected small groups of RA patients detailed gait analysis techniques, employing measurement of kinematics, kinetics, electromyography (EMG), and plantar pressure distribution have also confirmed gait disturbances and these will be considered in greater detail later in this chapter (Fransen and Edmonds, 1999; Siegel and Spiegel, 1982; Soames *et al.*, 1985; Woodburn and Helliwell, 1996).

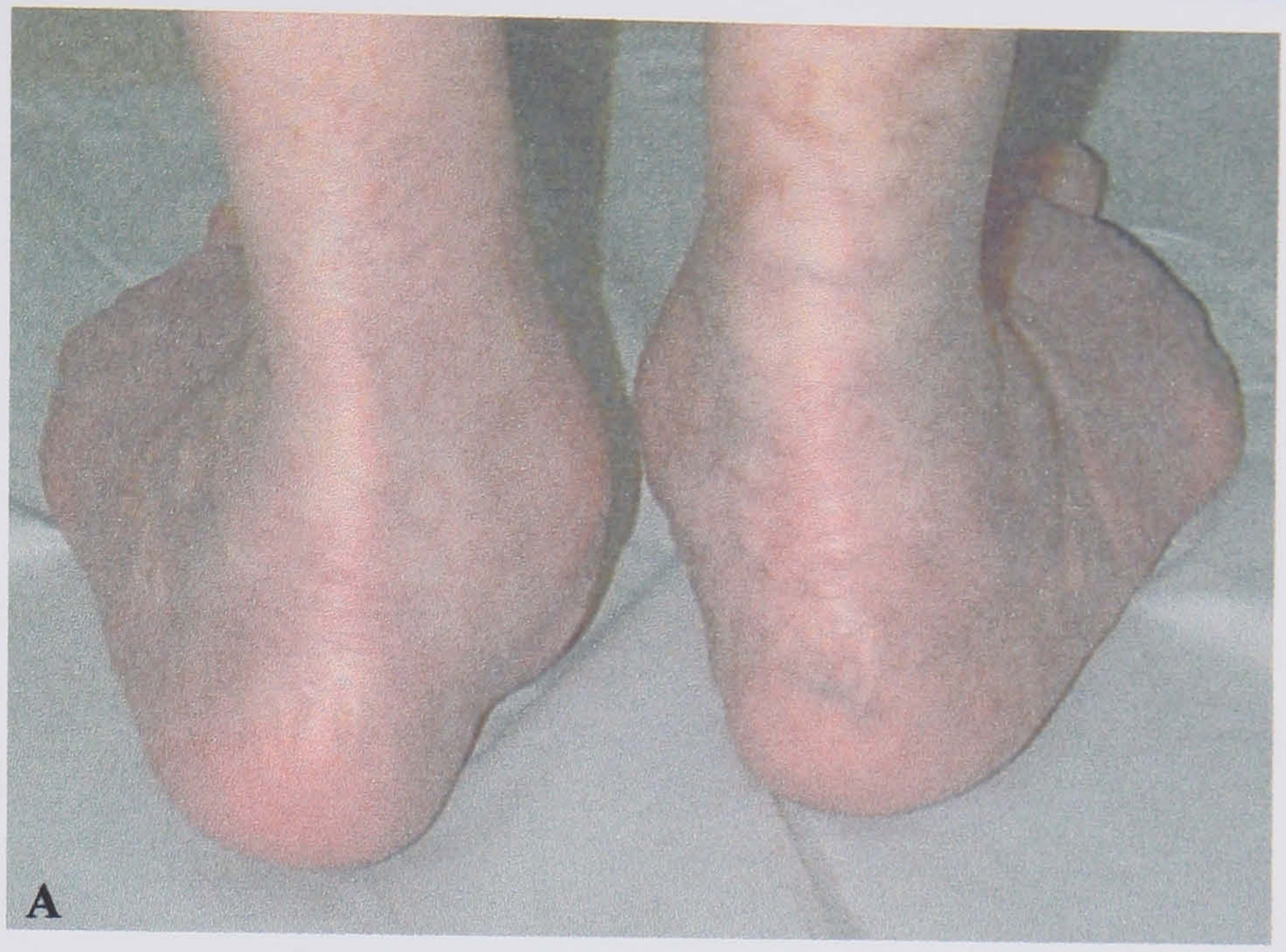
Because of its complex structure and function the rearfoot is more difficult to assess by clinical examination and is not routinely screened. The importance of pain and deformity at this site and the potentially devastating effects this may have on functional ambulation and disability has

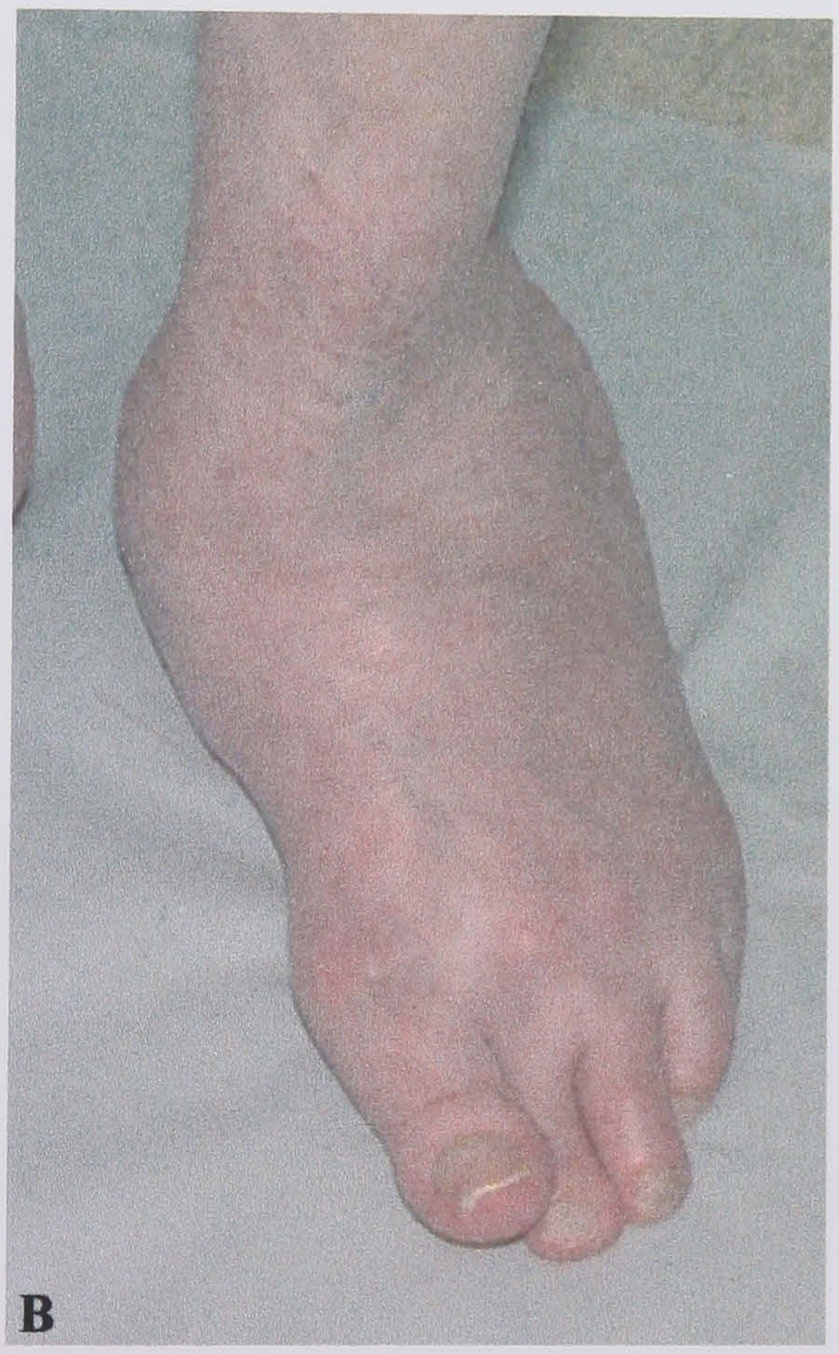
been clearly established. Furthermore, concerns have been raised regarding a general failure in clinic to consider the early development of rearfoot disease and to instigate early treatment (Conrad *et al.*, 1996; Kennan *et al.*, 1991; Platto *et al.*, 1991; Stockley *et al.*, 1990; Woodburn and Helliwell, 1996). This is reflected in orthopaedic practice, as rearfoot surgery is a major undertaking with few options to preserve or restore full function. Finally, early intervention has also been called for to protect other lower limb joints because rearfoot dysfunction, although not proven by good controlled studies, is thought to have causal associations with accelerated forefoot and knee problems.

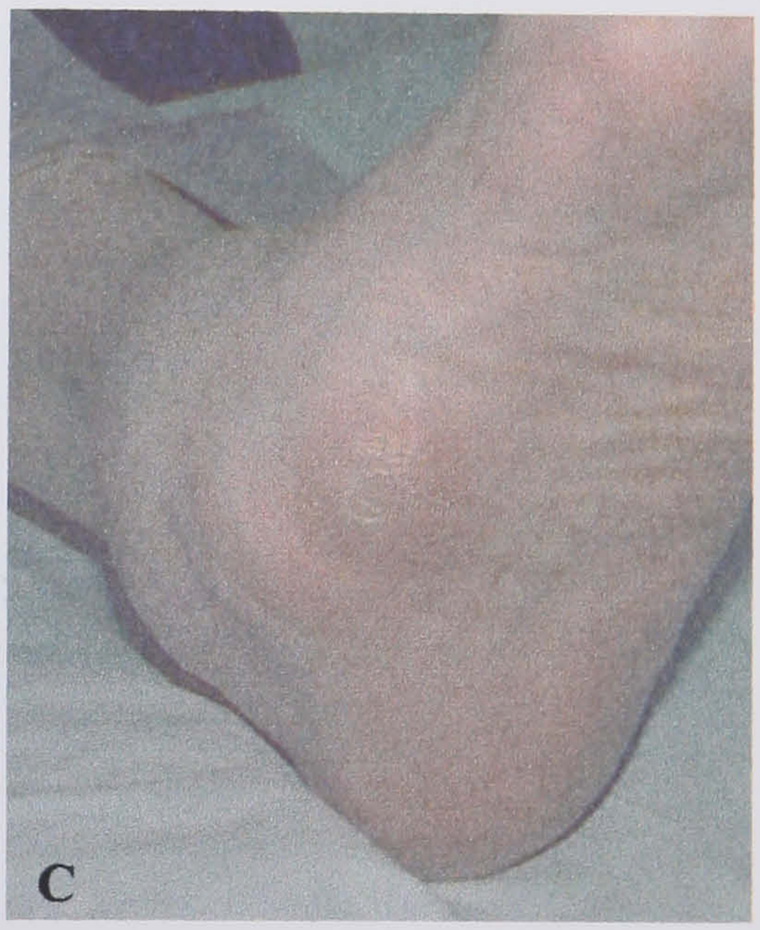
2.1.3 Rearfoot deformity in RA

The term 'valgus heel deformity' is used to describe the hallmark clinical sign of rearfoot disease. Although reduction in range of motion in the subtalar joint is common true ankylosis is rare (Locke *et al.*, 1984; Vainio, 1956). Deformity is accompanied by pain and swelling at the lateral ankle, in and around the sinus tarsi. In severe cases the lateral border of the calcaneum can impact on the tip of the lateral malleolus causing calcaneo-fibular impingement syndrome (King *et al.*, 1978). In severe cases total disruption of the rear- and midfoot can occur typified by total dislocation of the talonavicular joint (figure 2-1).

In established disease experienced clinicians can normally detect deformity by observation of an everted heel position relative to the leg on weightbearing. However, there has been no attempt to formulate strict diagnostic criteria and throughout the literature a variety of terminology, definitions and classifications have been used. At best one can attempt to make general conclusions based on the appraisal of clinical and radiological research. For example, evidence of a depressed medial longitudinal arch, valgus deformity of the heel and medial bulging of the talonavicular complex were sufficient for Jernberg *et al.*, (1999) to diagnose a hyper-pronated foot by gross postural appearance only. Simple observation lacks the necessary precision to be valid and reproducible but the technique, and variations thereof, has dominated clinical studies (King *et al.*, 1978; Marshall *et al.*, 1980; Vidigal *et al.*, 1975). Goniometry, whilst introducing quantification, is a static technique shown to be unreliable for subtalar joint position (Ball and Johnson, 1993; Buckley and Hunt, 1997; Pierrynowski *et al.*, 1996). Presently, bisection of the heel and measurement of its static position relative to the leg or ground appears to be an unsatisfactory diagnostic technique. This is illustrated further in several RA studies where the goniometric cut-off angles used for dichotomous classification of deformity (present/absent) have varied from any valgus position greater than 0° neutral, to any angle greater than 10° valgus (Keenan *et al.*, 1991; Stockley *et al.*, 1990; Woodburn and Helliwell, 1996).







A- Posterior view showing severe valgus heel deformity. **B**- Same left foot showing extensive rear- and mid-foot deformity with collapse of medial longitudinal arch. **C**- Pressure lesion corresponding to the subluxed head of talus in medial arch.

Figure 2-1: Severe rearfoot disease in well established rheumatoid arthritis

Disease Duration (yrs)	Varus (<0 degrees) (%)	Valgus (0-10 degrees) (%)	Marked Valgus (>10 degrees) (%)
<1	5	90	5
1-5	10	77	13
5-10	5	82	13
10-15	5	76	19
>15	3	63	34

Disease Duration (yrs)	Tibio-talar (%)	Sub-talar (%)	Talo-navicular (%)
<1	5	90	5
1-5	10	77	13
5-10	5	82	13
10-15	5	76	19
>15	3	63	34

TTJ, Tibiotalar joint. STJ, Subtalar joint. TNJ, Talonavicular joint

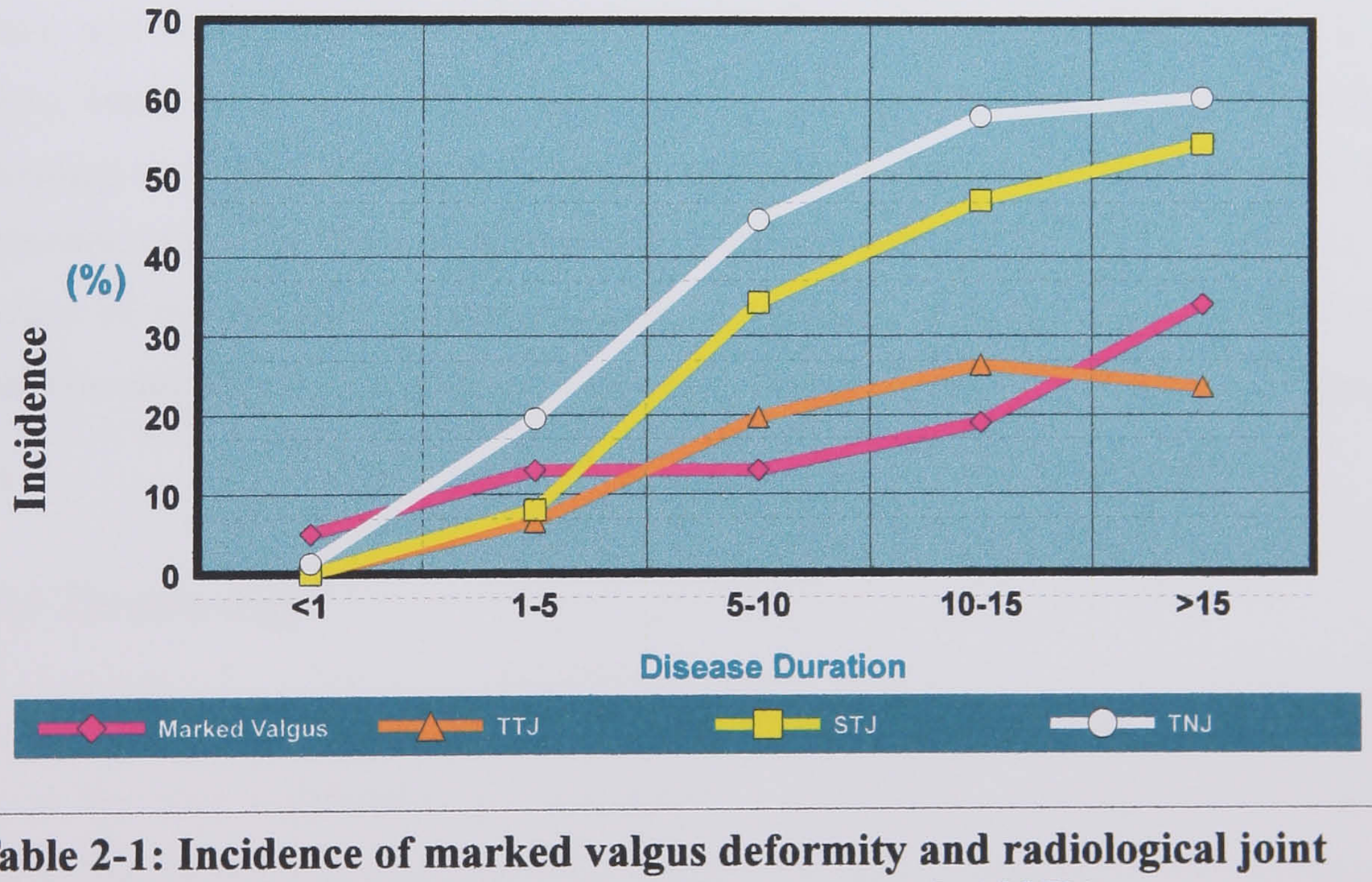


Table 2-1: Incidence of marked valgus deformity and radiological joint pathology by disease duration (after Bouysset *et al.*, 1987b)

Bouysset *et al.*, (1987b), measured the valgus alignment of the calcaneus from weightbearing X-rays of 397 RA feet with mean disease duration of 8.3 years, and found 6.6% had varus (valgus <0 degrees), 77.8% had valgus (valgus 0-10 degrees), 15.6% had marked valgus (valgus >10 degrees) deformity. The same group showed that the incidence of marked valgus deformity

(valgus <0 degrees), 77.8% had valgus (valgus 0-10 degrees), 15.6% had marked valgus (valgus >10 degrees) deformity. The same group showed that the incidence of marked valgus deformity alongside radiological pathology in the tarsus increased with the disease duration (table 2-1). Clinical estimates by observation place the prevalence anywhere between 58-72% (Kerry *et al.*, 1994; Vahvanen, 1967; Vainio, 1956). Others have found the prevalence in all disease categories to be 25-30% (Spiegel and Spiegel, 1982; Vidigal *et al.*, 1975). Diagnostic problems related to unsatisfactory measurement techniques along with patient selection bias are the main reasons why prevalence figures vary, but it occurs with sufficient frequency to cause concern. Investigating the pathomechanics more rigorously may help us understand how this deformity starts and progresses and the consequences it may have on the structure and function of the lower limb.

2.2 Pathogenesis of rearfoot disease with reference to normal structure and function

2.2.1 Subtalar joint structure and function

Valgus heel deformity has its origins in the subtalar joint and a closer examination of its structure and function is appropriate. The subtalar joint has been described as a flexible structure, which requires load to displace it by tissue deformation of ligaments (stretching and lengthening) and indentation of the articular surfaces (Leardini *et al.*, 1999). Displacement, in the presence of normal loads, is determined by the geometry of the articular surfaces, and the properties of the retaining ligament system. An attempt is made here to describe the key mechanisms that afford joint stability, and the possible mechanisms of failure in the presence of RA.

2.2.1.1 Terminology

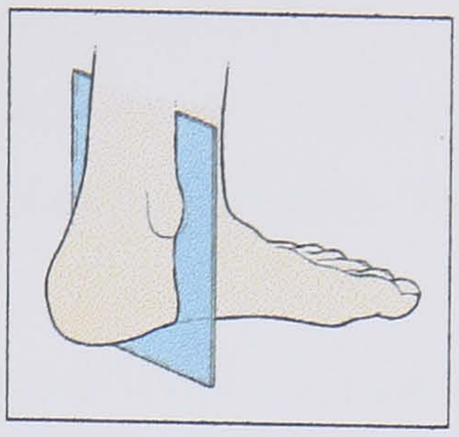
Huson (1987) provided a critical commentary on the terminology concerning motion of the joints of the foot highlighting the considerable ambiguity in the clinical and anatomical literature. For clarification standard definitions are provided for this thesis with consideration to terminology that encompasses both clinical understanding and kinematic measurement. The motion axis of the subtalar joint is not parallel to, or in alignment with, the main body axes. As we will see this axis is obliquely orientated and motion about it can be described about all three main body planes (table 2-2).

Table 2-2. Definition of terminology used to describe motion about the subtalar joint.

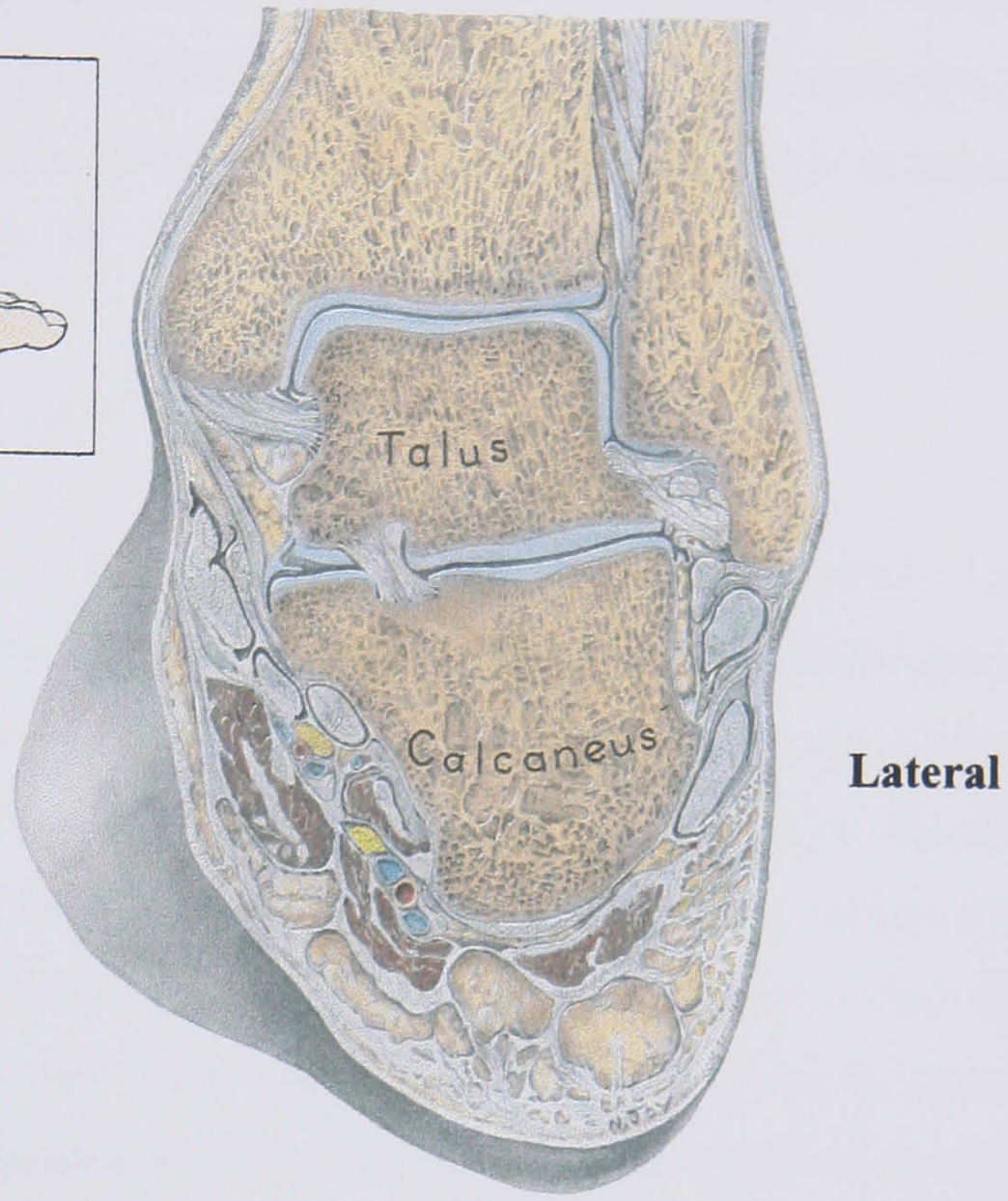
Terminology	Definition
Plantarflexion/ Dorsiflexion	Motion occurring in the sagittal plane during which the dorsal aspect of the foot moves toward the tibia, or the anterior surface of the tibia moves toward the dorsal aspect of the foot (*dorsiflexion*). In *plantarflexion* the foot moves away from the tibia, or the anterior border of the tibia moves away from the foot.
Inversion / Eversion	Motion occurring on the frontal plane during which the plantar aspect of the foot, or part of the foot, is tilted away from (*eversion*) or to face (*inversion*) the midline of the body.
Adduction/Abduction	Motion occurring on the transverse plane during which the distal aspect of the foot moves away from (*abduction*) or towards (*adduction*) the midline of body about a vertical axis of rotation at the aspect of the foot part.
Supination/Pronation	A compound name given for rotations about oblique axes comprising plantarflexion / inversion / adduction (Supination) and dorsiflexion / eversion / abduction (Pronation) of the foot relative to the leg.
Internal/External Rotation	During stance the tibia rotates about its long axis, but the foot is not permitted to adduct or abduct because it is fixed to the floor by body weight. The tibial rotation is resolved about the subtalar joint axis whereby *external rotation* of the leg produces supination of the foot relative to the leg and *internal rotation* of the leg produces pronation of the foot relative to the leg.
Varus/Valgus	These terms refer to structural deformities where the limb or part of the limb is abnormally angulated inwards (*varus*) or outward (*valgus*) with respect to the sagittal body axis. These terms are reserved to describe irreversible positional pathology and not motions, which are reversible changes in position.

2.2.1.2 Osseous components of the subtalar joint

The subtalar joint is found below the ankle joint and consists of the talus and calcaneus (figure 2-2). There are three articular surfaces on the inferior surface of the talus. The anterior surface is a flat quadrilateral or oval articular facet that rests on the anterior articular surface for the talus on the calcaneus. The middle facet, corresponding with the sustentaculum tali, is oval and slightly convex. The posterior facet forms a quadrilateral articular surface, rectangular medially and oval laterally. This surface forms an articulation with the posterior articular surface for talus on the superior surface of the calcaneus. The superior surface of the calcaneus has three

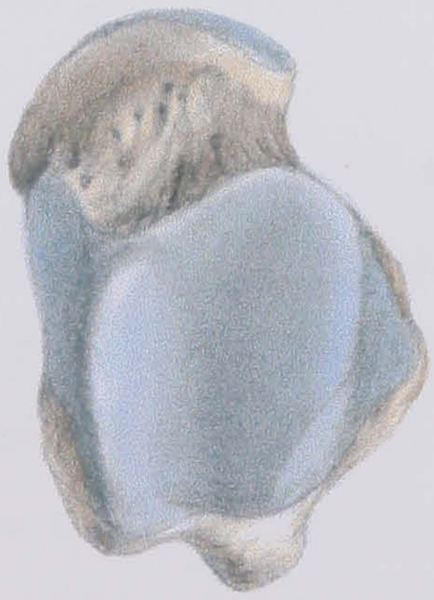


A



Medial

Lateral



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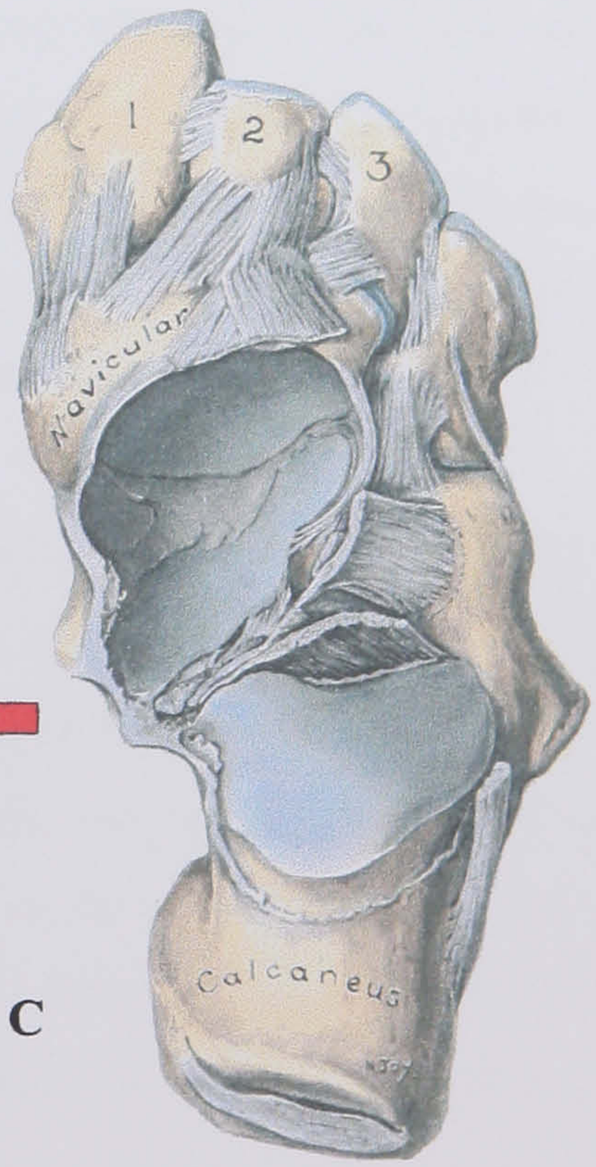


C

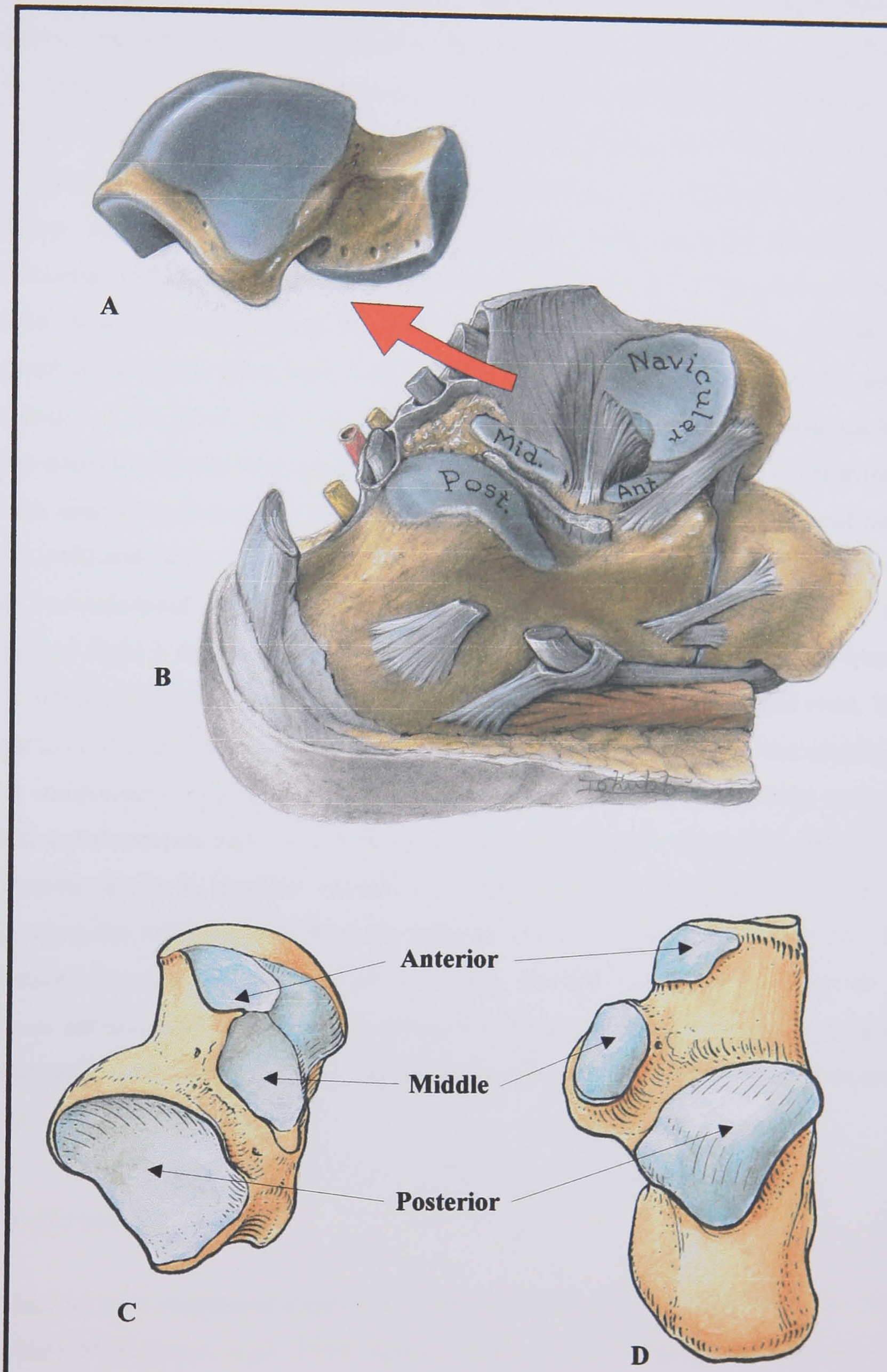
Figure 2-2: Subtalar joint. A- location of subtalar joint in rearfoot with position of talus and calcaneus relative to surrounding structures. B- Superior view of talus. C- Superior view of calcaneus with articular facets for the talus.

corresponding articular surfaces. The middle and anterior articular surfaces are concave corresponding to the convexity of the talar head. The middle articular surface covers the sustentaculum tali whilst a small calcaneal process supports the anterior surface. The posterior articular facet is steeply contoured as it inclines anteriorly (Figure 2-3). The surface is convex along its longitudinal axis that is directed forwards, downwards and outwards, representing a segment of the cone with the apex directed towards the sustentaculum tali.

2.2.1.3 Geometry of articular surfaces

The complex geometry of the articular facets plays an important role in the control of subtalar joint mobility and stability and has been extensively investigated. Lapidus (1963), noting that dislocation of the subtalar joint without fracture is uncommon, reasoned that the subtalar joint has excellent stability attributed to the alternating shape of the articular facets. He described the anterior chamber, convex above (talar head) and concave below (anterior and middle calcaneal facets), as a ball-and-socket joint, with the reverse relationship in the posterior chamber. The posterior calcaneal facet, the largest and most important articular surface, is curved and described functionally as a male ovoid surface. However, earlier experimental work by Manter (1941) had already advanced this simple description. By taking serial sections from cadaveric specimens through the posterior calcaneal facet perpendicular to the joint axis the surface contours were described as spiral rather than circular arcs resembling segments of a Spiral of Archimedes. This shape led him to conclude that the facet gave a screw-like surface with motion consisting of rotation and translation. Lapidus (1963) made a simpler observation describing the facet as part of a surface of a sharp cone.

Inman (1976) regarded Manter's description to be rigid and imposed engineering constraints to test the assumption. For true screw-like properties he required the posterior facet to show progressive change in contour when measured and a constant relationship between rotation and longitudinal translation in the presence of continuing congruence between joint surfaces. He contoured the entire surface of the posterior facet in 42 specimens and derived translation-displacement curves. In only 58% of subjects was a straight-line translation-rotation relationship observed indicating true screw-like motion. The remainder had varying forms of behaviour, some changing direction during input excursions, others showing pure rotation without linear displacement. Inman concluded that the individual variation was too considerable to formulate a normal behaviour pattern without causing confusion and inaccuracies, especially if transferred to clinical examination.



A-Talus, lateral aspect, disarticulated from subtalar joint. **B**- Superior surface of calcaneus in subtalar joint. **C**- Inferior surface of the talus and **D**- superior surface of calcaneus showing anterior, middle and posterior articular facets.

Figure 2-3: The osseous components of the subtalar joint

Donitz (1903); Henke (1885); Huson (1961) and Virchow (1899) noted only one congruent position for the subtalar joint surfaces, which they regarded as the neutral position. Motion starting from this congruent position was found to decrease the joint surface contact area. Since the posterior calcaneal facet has both a convex profile orientated in a medial, backward and upwards direction and a greater curvature in the medial and anterior part of the facet, greater incongruity occurs where surfaces glide over each other following their greatest and smallest curvature (Huson, 1961). However, if the gliding is combined with a turn the incongruity is limited to the circumscribed part of the articular aspect (figure 2-4). The congruent or, 'close-packed position' was a term adopted by MacConaill and Basmajian (1969) who studied the motion components generated by moving ovoid surfaces with reference to the subtalar joint. The surface areas of the facets that remained in contact during motion, the 'loose-packed position', were considered the motion guiding parts of the joint facet. The female ovoid surface of the posterior talar facet moving on the male ovoid surface of the posterior calcaneal facet slides, rolls or rocks and spins, with the roll in the direction of the sliding (figure 2-5). The roll is thought to maintain joint surface contact and the spin maximises congruency. Since the posterior calcaneal facet is orientated obliquely from posteromedial to anterolateral the female ovoid surface moving along this surface will dorsiflex or plantarflex, and invert and evert. The spin is thought to create the third motion component of adduction and abduction. The amplitude of the motion components is determined by the degree of orientation of the articular surfaces and again these measurements vary considerably in experimental studies (Sarrafian, 1993). The talus and calcaneus move in opposite directions to reach end positions and for our valgus deformity the calcaneus will have shifted to a dorsiflexed, everted and abducted position relative to a plantarflexed, inverted and adducted talus. Clearly articular surface geometry plays an important role in subtalar joint stability and joint motion. Since RA inevitably leads to cartilage destruction and bone erosion and over time any resultant geometrical changes may significantly influence joint motion and stability.

2.2.1.4 Axes of rotation

A number of studies have proposed a single axis of motion for the subtalar joint (Manter, 1941; Hicks, 1953; Hall, 1959; Isman *et al.*, 1969; Inman, 1976). The axis is generally understood to pass obliquely from the posterolateral corner of the calcaneus, upwards, forwards and medially, perpendicular to the canalis tarsi, exiting on the superomedial aspect of the neck of the talus (figure 2-6). In 16 adult cadaveric specimens, Manter (1941) found the axis to deviate from the sagittal plane on average by 16 degrees, ranging from 8 to 24 degrees. From the transverse plane the axis deviated on average by 42 degrees, ranging from 29 to 47 degrees. Manter (1941) described the screw-like nature of the articular facets and his experiments showed the

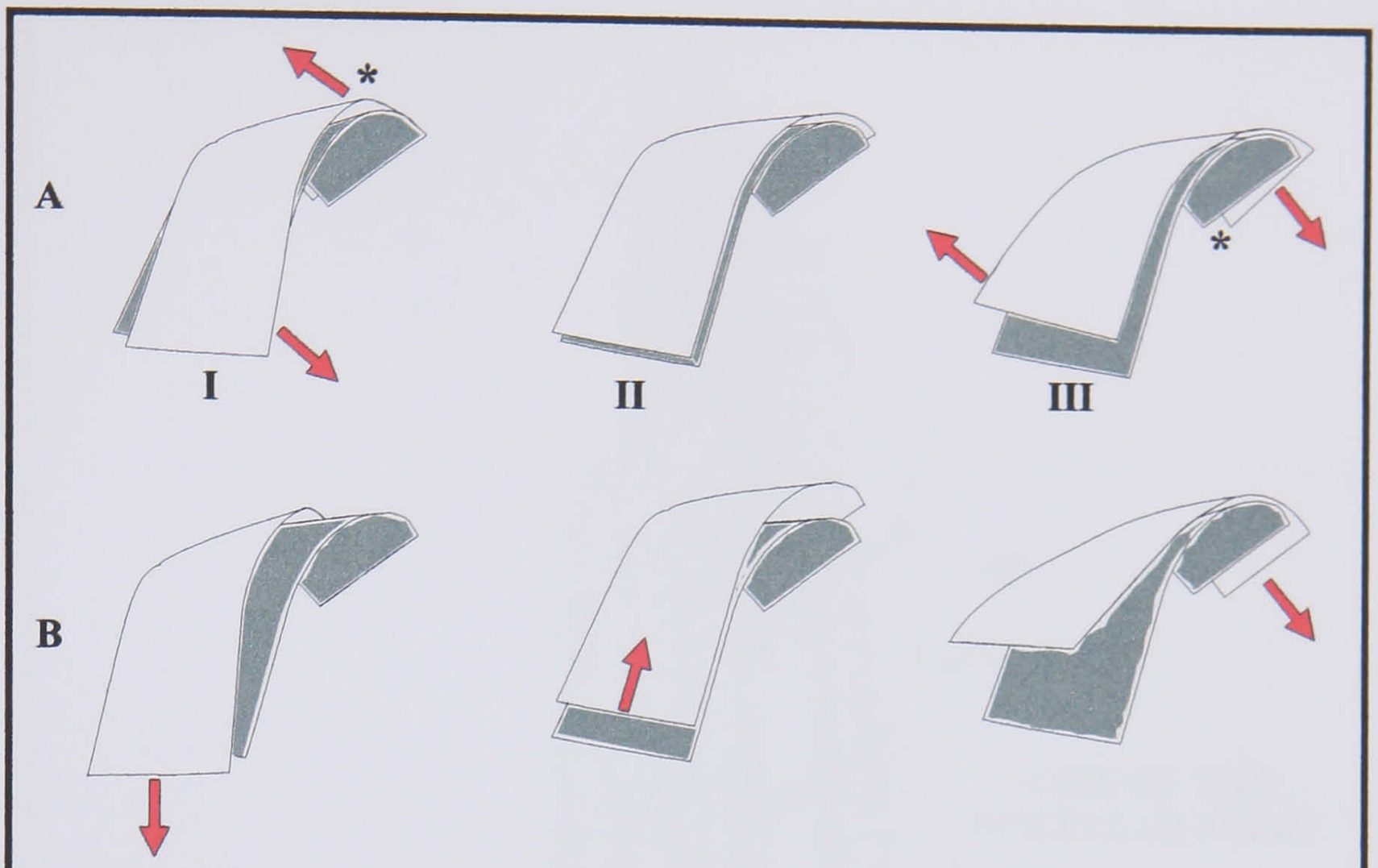


Figure 2-4: Diagrammatic representation of the posterior subtalar articular surfaces. In A, the congruent close-packed position is demonstrated (II) and with gliding and turn (I and III) incongruency is limited to to a circumscribed area of the articular surface (*). In B, curved surfaces gliding over each other will show greatest incongruency when they follow their strongest or weakest curvatures (adapted from Huson 1961).

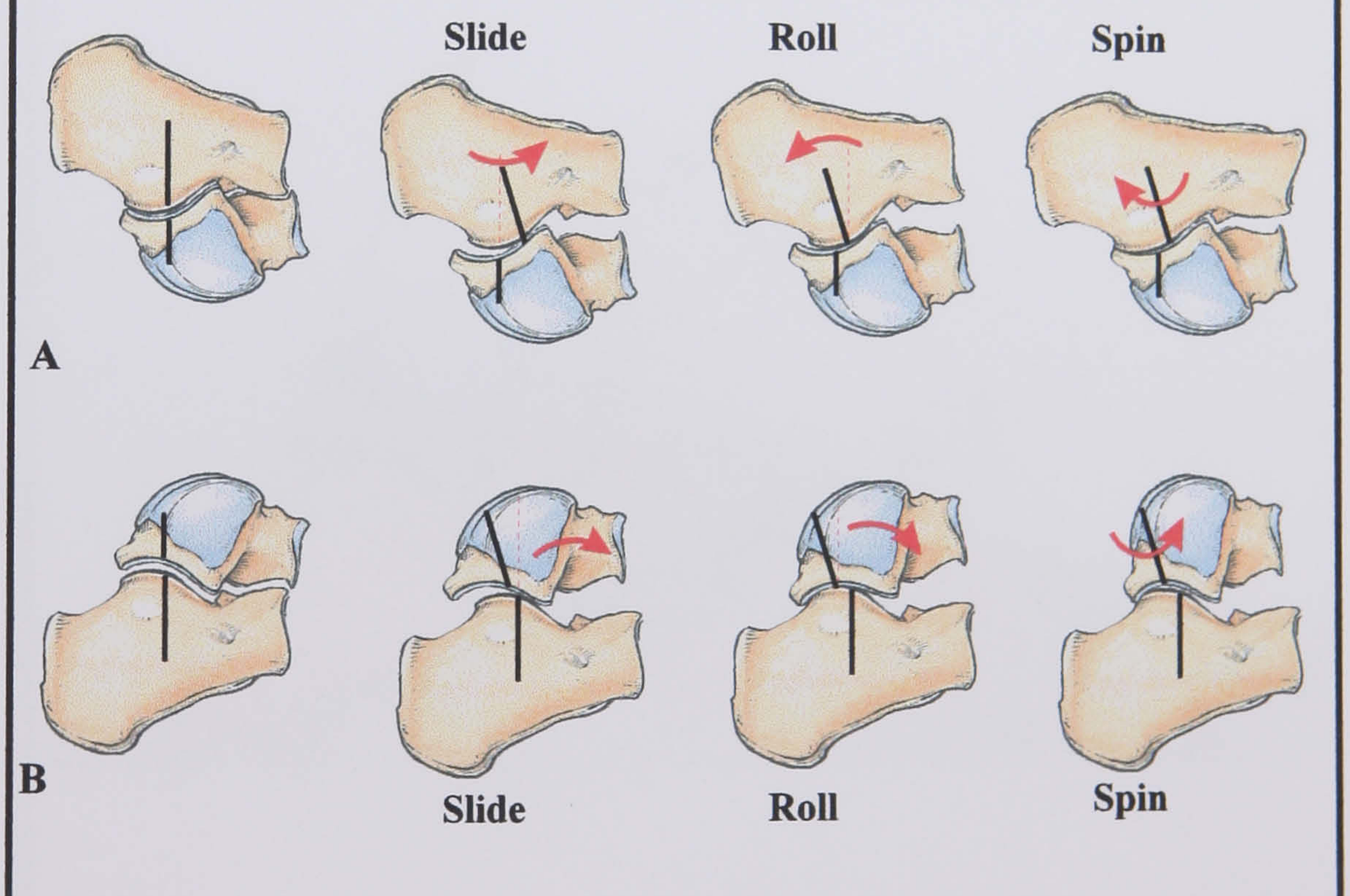


Figure 2-5: A, the posterior calcaneal articular surface (male ovoid) moving on the posterior talar articular surface (female ovoid) slides, rolls and spins. The sliding advances the moving surface but creates a gap which is closed by the reverse rolling, and the maximum surface contact is achieved by the spinning of the moving surface. In B, a female ovoid surface moving on a male ovoid surface slides, rolls and spins (concept of MacConaill *et al.*, 1969).

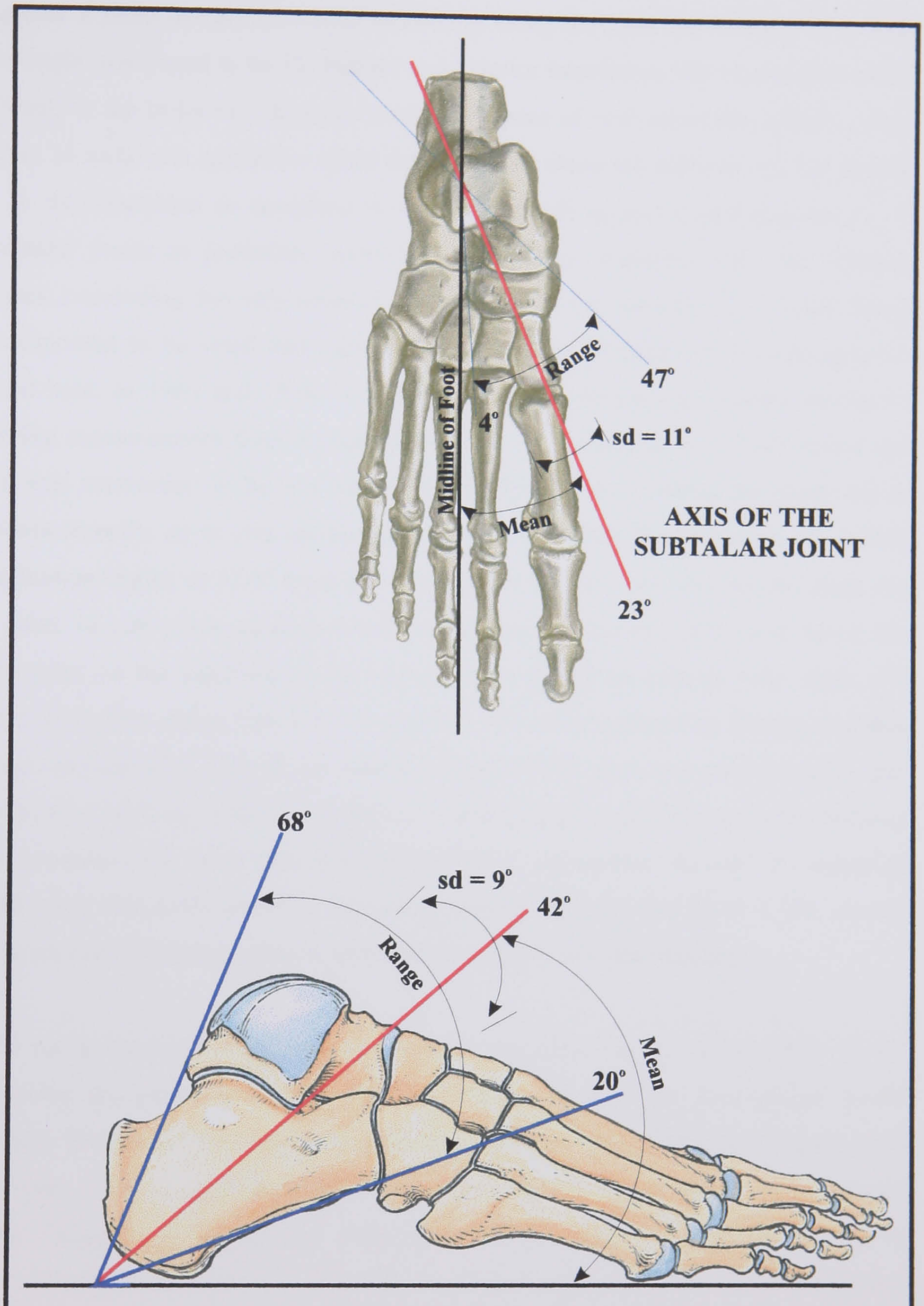


Figure 2-6: Mean, standard deviation and range for subtalar joint axis projected on the horizontal plane (A) and sagittal plane, after Isman *et al.*, (1969).

right subtalar joint to behave like a right-handed screw, pronation causing the talus to turn clockwise against a fixed calcaneus, whilst advancing along the joint axis (figure 2-7). The average helix angle was found to be 12 degrees and anterior translation was regarded as small and insignificant, in the order of 1.5mm for each 10 degrees of rotation in the subtalar joint. Hicks (1953) in 10 cadaveric specimens could detect no shift along the subtalar axis but agreed in principal to its orientation as described above. Hall (1959) superimposed radiographs of cadaveric subtalar joints in pronation, neutral and supination positions with and without embedded wires, concluding that only rotation occurred around the subtalar axis. Manter found translation component to be small and most likely beyond the accuracy of the radiographic technique used here. In 1969 and 1976, Isman and Inman conducted experiments similar to Manter, deriving measurements from a larger sample of 102 cadaveric feet. They found the subtalar joint axis orientation to be very similar to Manter and their results are presented in figure 2-6. More recently, an in vivo optimisation technique by Van Den Bogert *et al.*, (1994) predicted inclination angles of 37.4° from the horizontal and 18.0° from the sagittal plane for the subtalar joint, in very close agreement with earlier studies. Inman (1976) also found the motion of the talus on the calcaneus to be screw-like but found an average helix angle (25 degrees, S.D. = 6 degrees, range form 0 to 40 degrees) twice that reported by Manter, and that translation was only found in 50% of the samples. Inman (1976) also described a precise and definite relationship between trabecular patterns in the calcaneus and the articular surfaces reasoning that intrinsic joint forces were more important for joint motion. He used this argument to explain the wide variability found in the orientation of the posterior facet to the axis of motion and the motion behaviour patterns, although this theory was not validated.

Huson (1987) using mechanical engineering concepts described the interdependence of the tarsal bones using the principle of the 'closed kinematic chain'. This interlinkage would necessarily imply the presence of polyaxial articulations rather than the previously postulated hinge movements. Van Langelaan (1983) was the first to demonstrate this concept experimentally. Using 10 foot-lower leg preparations the position and orientation of metal marker pins embedded in tarsal bones were determined by X-ray photogrammetry as a loaded tibia was externally rotated in 5 degree steps through 30-35 degrees of unresisted motion. The axes of rotation for the subtalar joint were found to continually change position forming a discrete bundle (figure 2-8). The angle of the bundle ranged from 4.4 to 24.8 degrees in the sagittal plane and 2.8 to 26.3 degrees in the transverse plane. From pronation through supination the axis moved from an antero-medial to antero-lateral direction and in a steeper inclination. Importantly Van Langelaan noted how variation in the orientation of the axis affected planar dominance of resultant motion between inversion-eversion (steeply inclined axis), and abduction-adduction (lower inclined axis). Benick (1985) replicated this experimentation and

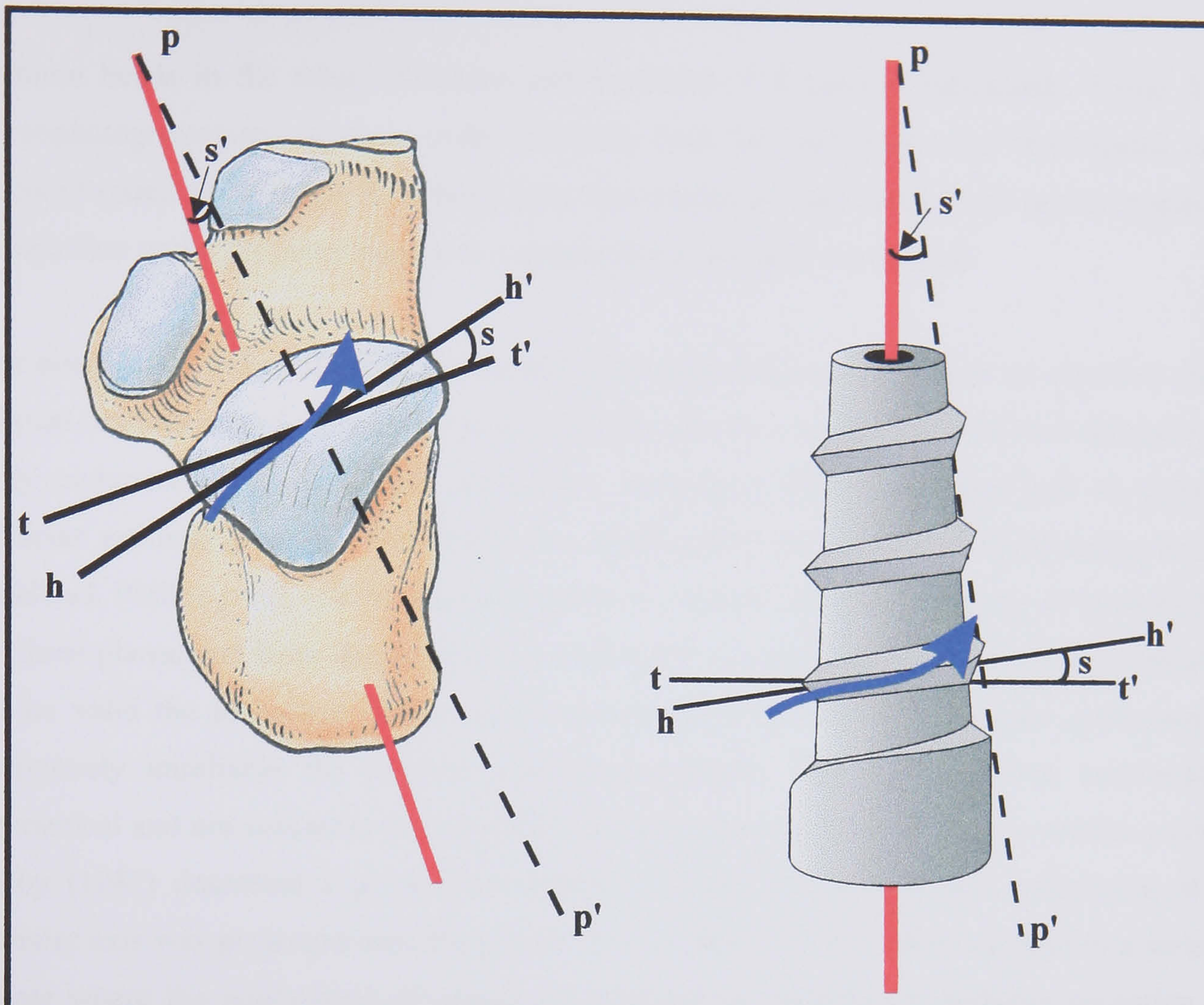


Figure 2-7: Comparison of the posterior calcaneal facet of the right subtalar joint with a right-handed screw. Arrow represents the path of a body following the screw. *hh'* is the horizontal plane in which motion is occurring. *tt'* is a plane perpendicular to the axis of the screw. *s* is the helix angle of the screw, equal to angle *s'* which is obtained by dropping a perpendicular *pp'* from the axis (after Manter 1941).

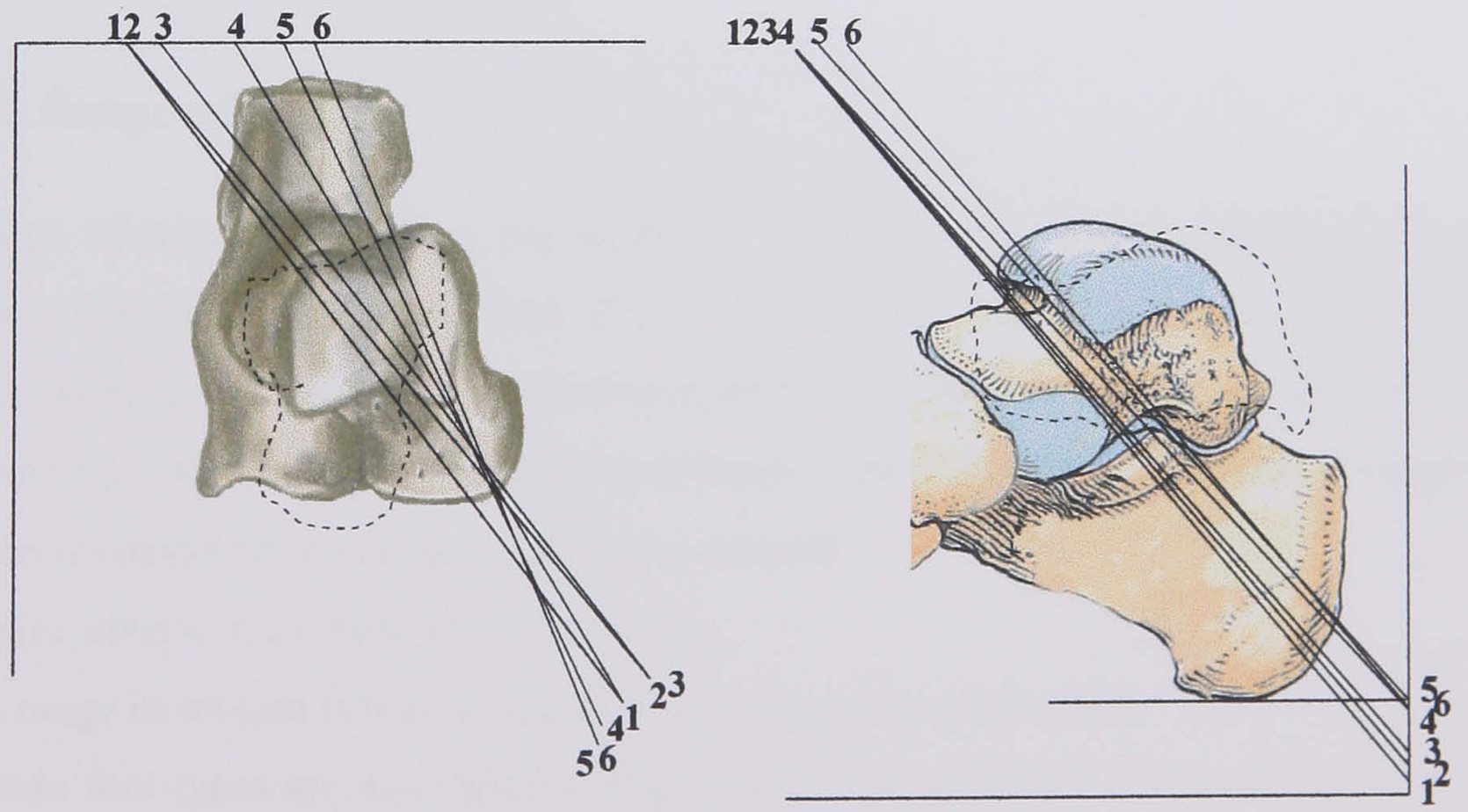


Figure 2-8: Projections of relative subtalar helical axes. 1 = starting position- tibia internally rotated with subtalar joint pronated, 2-5 = 10 degree steps of tibial exorotation, 6- tibia externally rotated with subtalar joint supinated (after van Langelaan 1983).

titanium beads in the talus, calcaneus and navicular of 8 healthy individuals. Using X-ray stereophotogrammetric analysis under full body load the joint axes were investigated under stepwise rotations about the three body axes. The results lack the detail of the earlier studies but nonetheless under different input arcs polyaxial hinge patterns were found.

The concepts of polyaxial hinge joints and screw-like motion are difficult to visualise during clinical examination of the subtalar joint and their relevance to the origins of foot deformity not fully understood. Palpation and goniometric techniques have been employed to help the clinician estimate joint axis orientation, but unfortunately they are non-weightbearing and not validated. Philips *et al.*, (1976) used goniometry to measure subtalar join range of motion about all three planes and from that proposed a mathematical solution to determine axis orientation. To be valid the technique would require precise angular measurements, and goniometry is notoriously unreliable for subtalar joint measurements. The technique was cumbersome, unpractical and not subject to formal validation and has never been adopted in routine practice. Kirby (1987) described a palpation technique whereby the position and orientation of the subtalar axis was projected onto the plantar foot surface. The projection equated to a series of points where the application of plantar force found the equilibrium between pronation and supination, i.e., no foot movement. This is a useful technique and has certain face validity but lacks sufficient precision and has never been validated. Finally an association has been demonstrated between subtalar joint axis orientation and foot-type classified as cavoid, normal or pes-planus but it is not clear whether the axis orientation is the cause or result of the foot-type (Close *et al.*, 1967; Engsberg *et al.*, 1987).

2.2.1.5 Range of motion

The range of subtalar motion is not extensive but plays an important part in the mechanical function of the lower limb and foot. Some studies determine only full range of motion and others movements of inversions and eversion from a neutral position and a selection of findings are presented in table 2-3. Accounting for different methodologies these findings suggest that:

1. There is considerable variability between subjects.
2. Passive inversion exceeds passive eversion.
3. The range of motion is less during gait when the joints are loaded.
4. Certain foot-types are associated with increased (pronated) or decreased (cavoid) range of motion.
5. With age the range of inversion and eversion decreases by about 20% (Wright *et al.*, 1964; Close *et al.*, 1967; Alexander *et al.*, (1982); Nigg *et al.*, 1992; Ball *et al.*, 1996).

Table 2-3. Range of motion data for the subtalar joint: a selection of findings from the literature.

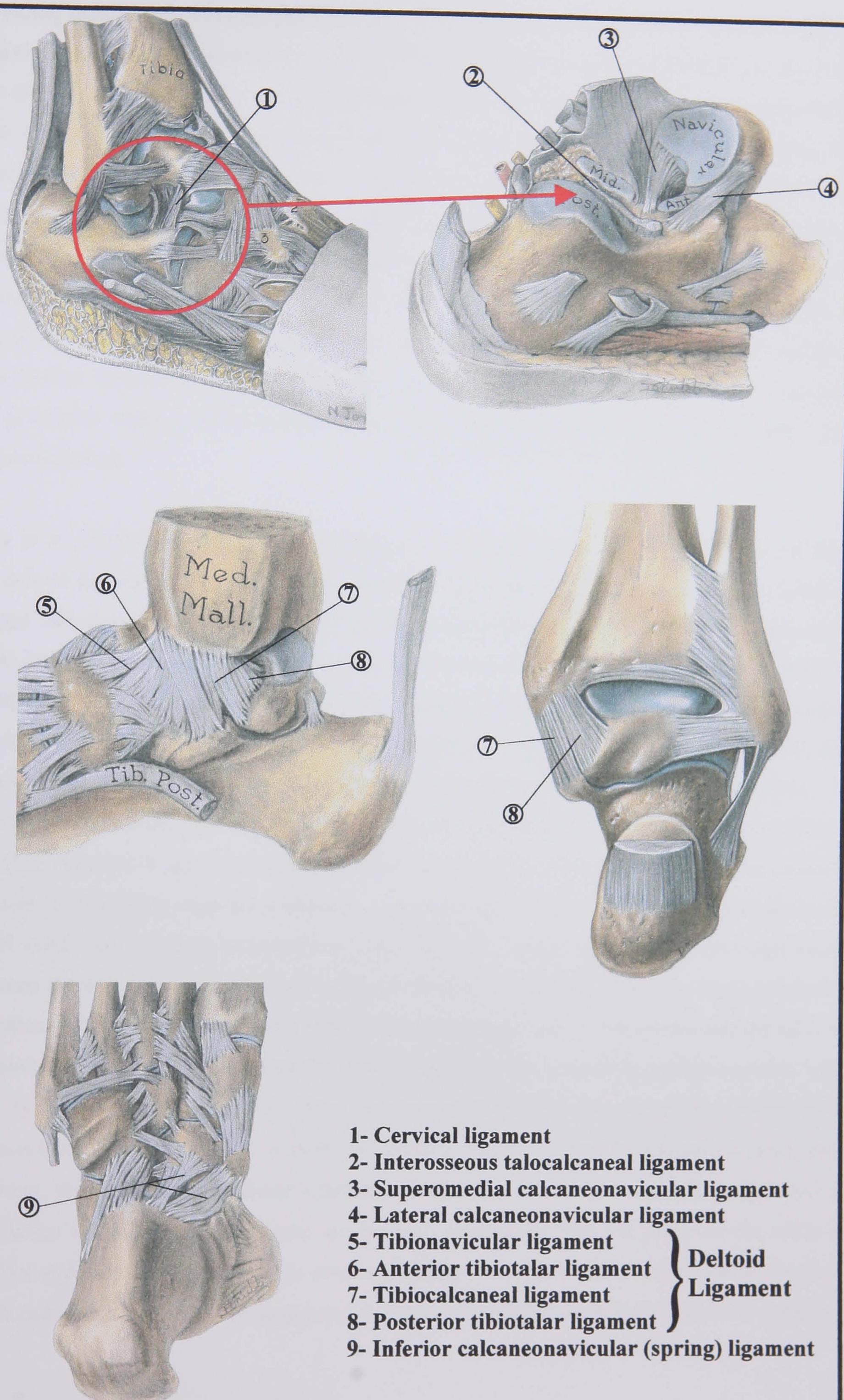
Author	Technique	Range of motion
Manter (1941)	Cadaver/jig apparatus	10-15°
Hicks (1953)	Cadaveric/jig apparatus	24°
Wright *et al.*, (1964)	Instrumented linkage apparatus for gait analysis	Total ROM= 6° Positive rotation (inversion)= < 5° Negative rotation (eversion)= < 5°
Close *et al.*, (1967)	Gait analysis. Tracking metal pins embedded in tarsal bones	Cavus foot= slight, 3-4° Normal, somewhat pronated= moderate, 5-6° Flatfoot= Pronounced, 16°
Inman (1976)	Cadaveric/jig apparatus Spherical goniometry on living subjects	N=47 specimens with intact ligaments= 18° (SD-6°) N=47 specimens with cut ligaments= 36° (SD- 10°) N=102 specimens= 24° (SD-11°) N=50 living subjects= 40° (SD-7°), range 20-65°
Alexander *et al.*, (1982)	In-vivo measurement jig testing active and passive movement in subjects grouped between 2nd and 8th decades of life	2nd decade Active Inv= 36.8°, Active Evr= 34.1° Passive Inv= 46.5°, Passive Evr= 37.5° 5th decade Active Inv= 38.2°, Active Evr= 23.6° Passive Inv= 45.3°, Passive Evr= 32.7° 8th decade Active Inv= 32.0°, Active Evr= 19.9° Passive Inv= 40.1°, Passive Evr= 28.6°
American Medical Association (1988)	-	50° (30° inversion, 20° eversion)
Nigg *et al.*, (1992)	6° of freedom ankle joint complex ROM testing machine. Data collected on 4 groups of normal subjects aged between 20-79 years.	Group 20-39, Inv= 20.6° (SD-6.7°), Evr= 14.9° (SD- 5.1°) 40-59, Inv= 20.7° (SD-8.0°), Evr= 13.8° (SD- 3.3°) 60-69, Inv= 17.1° (SD-5.8°), Evr= 12.3° (SD- 3.2°) 70-79, Inv= 17.1° (SD-5.7°), Evr= 11.4° (SD- 3.3°)
Ball *et al.*, (1996)	Electrogoniometry data for 100 normal subjects grouped between 3rd and 7th decades of life.	Sample results 3rd decade, Inv= 32.4° (SD-6.5°), Evr= 20.8° (SD-5.7°), ROM= 53.2° (SD-11.4°) 5th decade, Inv= 32.3° (SD-5.2°), Evr= 19.0° (SD-5.2°), ROM= 51.2° (SD-9.3°) 7th decade, Inv= 28.8° (SD-5.0°), Evr= 15.5° (SD-3.4°), ROM= 44.3° (SD-6.8°)

ROM- range of motion, Inv- inversion, Evr- eversion, SD- standard deviation

2.2.1.6 Ligaments that guide motion and provide subtalar joint stability

The subtalar joint must be stable yet flexible to adapt to changes in the walking surface and conditions of gait. To ensure stability the joint is secured by a complex system of ligaments which are contained within the tarsal sinus and canal and found external to the joint, in the ankle and talonavicular joint regions (figure 2-9). Persistent synovitis in RA may erode these structures, which will change their normal stability and motion guiding properties thus contributing to the development of valgus heel deformity. Understanding of normal structure and function, with emphasis on medial stabilisation given the pattern of deformity in this condition, is important. The human tarsal sinus and canal contains the interosseous talocalcaneal and cervical ligament, the former dividing this joint into 2 synovial chambers (Lapidus, 1963). Early observational studies have noted the closeness of the interosseous talocalcaneal ligament to the axis of rotation of the subtalar joint, Smith (1958) concluded that it restricts eversion whereas Cahill (1965) considered it to offer only slight mechanical stability with no particular dominance in restriction of either inversion or eversion. Experimental work conducted more recently suggests the cervical ligament tightens to prevent excess inversion and the interosseous talocalcaneal ligament tightens to prevent excess eversion. For example, Knudson *et al.*, (1997) and Kjaersgaard-Andersen *et al.*, (1988) compared rotation displacement of the subtalar joint in mounted cadaveric specimens under load between intact and sectioned ligaments. Knudson *et al.*, (1997) interested solely in the interosseous talocalcaneal ligament, found significantly greater supination displacement between intact and sectioned ligaments but not for pronation. Kjaersgaard-Andersen *et al.*, (1988) showed an increase in inversion-eversion displacement after sectioning each of these ligaments, without differentiating directional dominance, although their graphs suggest greater inversion displacement.

The deltoid or medial ligament has superficial and deep components. The superficial portion consists of the posterior tibiotalar, tibiocalcaneal and tibionavicular ligaments, which enhance medial stability of the ankle joint. The deep portion is the anterior tibiotalar ligament, which limits external rotation of the talus in the ankle mortise and contributes to the transmission of the internal rotation of the tibia to the talus (Saraffian, 1993). Parlasca *et al.*, (1979) in 10 normal cadaveric specimens created incomplete and complete injury to the deltoid ligaments and compared horizontal rotation in the ankle and subtalar joints. Incomplete injury resulted in increased internal rotation of the talus on the calcaneus, which increased further when the deltoid was severed. In 1985 Stormont *et al.*, introduced the concept of primary and secondary restraint mechanisms for the loaded ankle whereby the relative contribution of ligamentous structure to resist given displacement was calculated by dividing the amount of decrease in torque for that structure from the intact to the completely disrupted state. Any structure



1- Cervical ligament
2- Interosseous talocalcaneal ligament
3- Superomedial calcaneonavicular ligament
4- Lateral calcaneonavicular ligament
5- Tibionavicular ligament
6- Anterior tibiotalar ligament
7- Tibiocalcaneal ligament
8- Posterior tibiotalar ligament
} Deltoid Ligament
9- Inferior calcaneonavicular (spring) ligament

Figure 2-9: Ligaments that guide motion and stabilise the subtalar joint

providing greater than 33% of the restraint to a particular displacement was labelled a primary restraint. Structures responsible for 10% to 33% were called secondary restraints and those with less than 10% contribution were deemed insignificant. The deltoid ligament was responsible for 30% resistance to internal rotation of the foot on the leg the contribution increasing from plantarflexion through dorsiflexion. In unloaded conditions the deltoid contributed 83% resistance to eversion but during axial loading no ligaments contributed to stability. Stormont concluded that with physiological loading the articular surfaces becomes an important stabiliser, accounting for 30% stability in rotation and 100% version. Related to gait, loading and unloading were the suggested periods when ankle instability occurs but not once the ankle was fully loaded. Disruption to medial ligaments during the loading response in the early stages of the gait cycle when eversion motion occurs may be primary reason in early RA why valgus deformity arises.

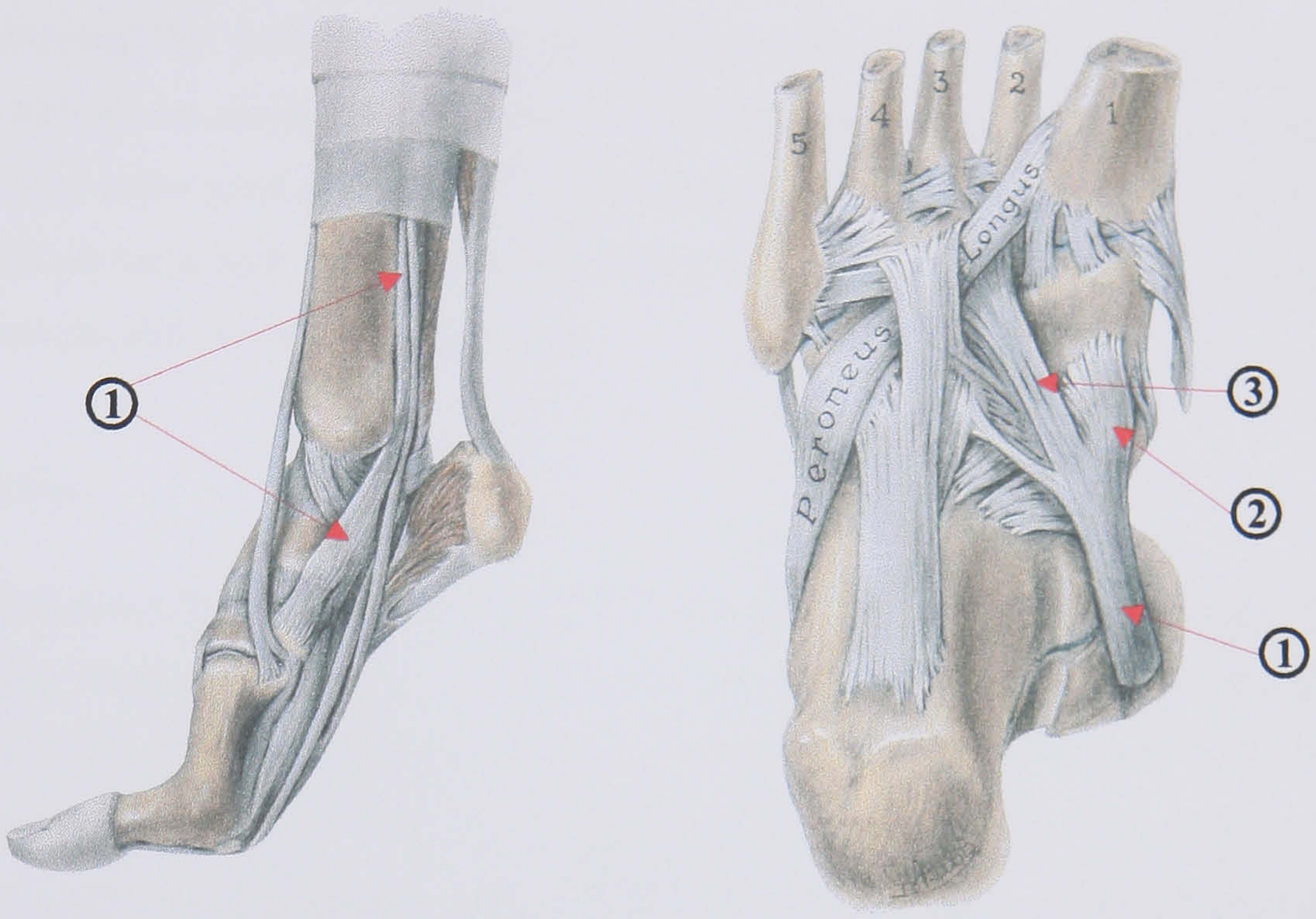
Nigg *et al.*, (1990) measured the force-elongation characteristics of ankle ligaments and found the deltoid ligament to be susceptible to loading injury with the foot plantarflexed, externally rotated and everted. Luo *et al.*, (1997) studied nine major ligaments surrounding the rearfoot joints including their lengths and orientations and then their physiological elongation in five positions relative to neutral ankle and subtalar joint positions. The input manoeuvres simulated passive foot motion and under the eversion condition the posterior tibiotalar and talocalcaneal components of the deltoid and the interosseous talocalcaneal ligaments elongated. The tibiocalcaneal component of the deltoid ligament was thought to offer most resistance to eversion. Kitaoka *et al.*, (1997) demonstrated that pes-planovalgus deformity is not caused by deficiency of a single supporting element. In preliminary testing, on cadaveric specimens under 445N axial load, no single structure was responsible for maintaining the arch although rotation between the calcaneus and talus was affected most be the long-short plantar ligaments and the talocalcaneal interosseous ligament whilst rotation between the 1st metatarsal and the talus was affected the greatest by sectioning the deltoid ligament. As a result a grossly unstable valgus foot type could be created in these specimens from the sequential sectioning of the tibionavicular portion of the superficial deltoid ligament, the talocalcaneal interosseous ligament, the medial talocalcaneal ligament, spring ligament, long-short plantar ligaments and the plantar fascia. These ligaments are in close association with the joints of the ankle and rearfoot and therefore vulnerable to erosion directly from synovitis or disruption mechanically by altered joint congruency through erosion and/or increased intra-articular synovial volume.

2.1.2.7 Muscle control of the subtalar joint

Perry (1992) categorised muscles controlling subtalar joint motion according to their position relative to the subtalar joint axis. Medially, five muscles cross the joint and according to their inverting leverage they are tibialis posterior, tibialis anterior, flexor digitorum longus, flexor hallucis longus, and soleus. In relation to the literature, the role of tibialis posterior in the control of an unstable subtalar joint in the presence of RA, and the development of tenosynovitis and, somewhat controversially, tendon rupture is of major importance (figure 2-10). Perry (1992) described a dominant pattern of muscle activity bringing early subtalar control. Sutherland (1966) found an onset of action in early loading response with two periods of peak activity, the first at the end of the loading response (a 20% maximum muscle test effort) and the second at the middle of terminal stance (a 30% maximum muscle test effort), see figure 2-11.

Klein *et al.*, (1996) and Hintermann *et al.*, (1994) found the tibialis posterior to have the most important inversion moment arm (about 20mm). Hintermann *et al.*, (1994) measured tibialis posterior tendon excursion and moment-arm lengths in 15 cadaveric specimens through foot eversion-inversion and flexion-extension input rotations. He found this muscle tendon to have the greatest invertor moment arm with significant tendon excursion through eversion-inversion but not flexion-extension. With this configuration Hintermann remarked that tibialis posterior produced high forces on its five major insertions in the tarsal bones with little tendon movement locking the bones together to produce strong rear- and midfoot stabilisation (figure 2-10).

Further insight to the role of this muscle tendon in medial arch support, and importantly mechanical failure, was described by Kitaoka *et al.*, (1997). In thirteen cadaver foot specimens three-dimensional movement in the talus, calcaneus and 1st metatarsal were measured with and without tibialis posterior loading. Statistically significant differences were detected in the subtalar joint for abduction, dorsiflexion and eversion rotations; all three movements greater following release of tibialis posterior loading. Furthermore overall arch height reduced when all tendons except tibialis posterior were loaded, the mean difference small but significant (0.5mm, $P<0.0001$).



1- Tibialis posterior muscle tendon
2- Anterior component with insertions to tuberosity of navicular and first cunieform
3- Middle component with insertions to second and third cunieforms, cuboid and the base of metatarsals 2-5
The posterior component (not indicated) inserts as a band on the anterior aspect of the sustentaculum tali (after Sarrafian 1993).

Figure 2-10: A- Tibialis posterior muscle tendon and its course into the foot. B- Plantar insertions of tibialis posterior muscle tendons.

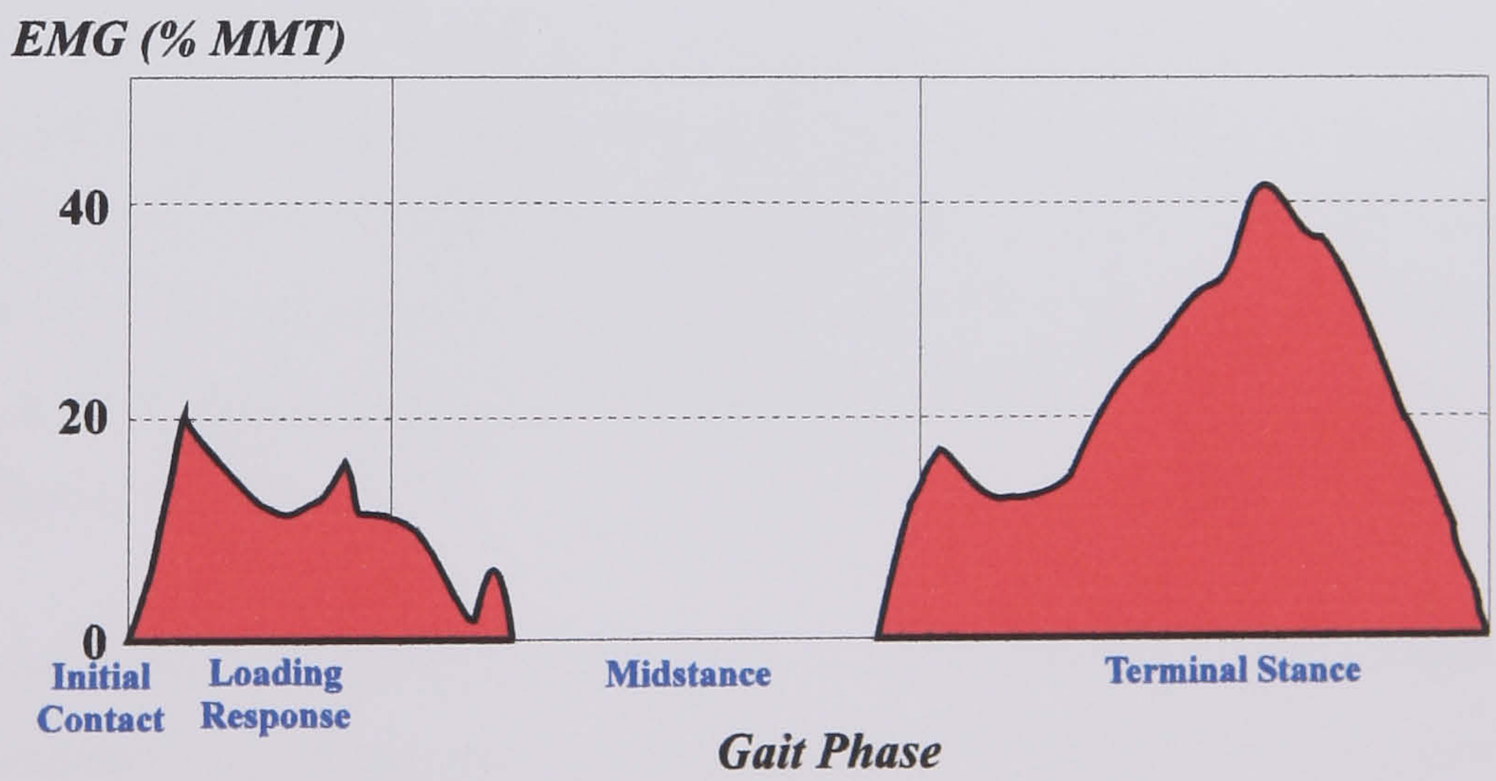


Figure 2-11: Normal mean intensity and timing of tibialis posterior muscle during free walking. Intensity as a percent of maximum manual muscle test (%MMT) indicated by height of red area. Vertical bars designate the gait phases (adapted from Perry (1992)).

2.2.2 Normal subtalar joint function in gait

2.2.2.1 Basic functions

Perry (1992) described the subtalar joint as having four main functional roles during gait including shock absorption during limb loading; foot stability in terminal stance; reduction in rotatory strain at the ankle joint and control of midtarsal joint mobility. These functions have been determined from basic and clinical research utilising kinematic, kinetic, EMG, mechanical analysis and biomechanical modelling techniques.

2.2.2.2 Kinematics

Subtalar joint motion has been measured in gait using a number of kinematic techniques. The inversion/eversion component operates within a range-of-motion envelope much smaller than that measured during non-weightbearing passive or active joint motion manoeuvres. The generally agreed motion sequence is an inverted heel position at heel strike followed by the onset of eversion as the loading response begins. Peak eversion is thought to occur by early mid stance at which point the motion arc slowly reverses towards inversion throughout terminal stance. Peak inversion is reached at the onset of pre-swing and from here the joint moves back to neutral, followed by inversion during the last 20% of the cycle, in preparedness for next heel strike (figure 2-12). This pattern is the basic description by Wright *et al.*, (1964) using data from one subject measured using an instrumented mechanical linkage apparatus. Close *et al.*, (1967) used motion picture cameras to track metal pins embedded in the neck of talus and calcaneus in eight subjects as they walked normally in barefoot. Captured motion patterns were studied and three stance phase periods of subtalar motion described, fitting closely the basic description provided earlier by Wright *et al.*, (1964). Scott and Winter (1991) used video digitisation of surface markers placed on the leg and calcaneus segments to measure pronation and supination about the subtalar joint in three young adults. At heel-strike the subtalar joint was supinated between approximately 2-12 degrees. Pronation through 10 to 17 degrees occurred before 20% of stance; followed by a gradual supination to 85% stance with a final pronation motion of between 2 to 12 degrees during push off.

Since this early work there have been disappointingly few studies of normal subtalar kinematics and the field is dominated by running studies driven, one suspects, by the boom in recreational jogging in the 1980's. Furthermore, it is often difficult to extract data from published articles for comparison because graphical techniques are poor and summary tables of key variables such as heel strike position, maximum inversion/eversion angles, and range of motion are seldom

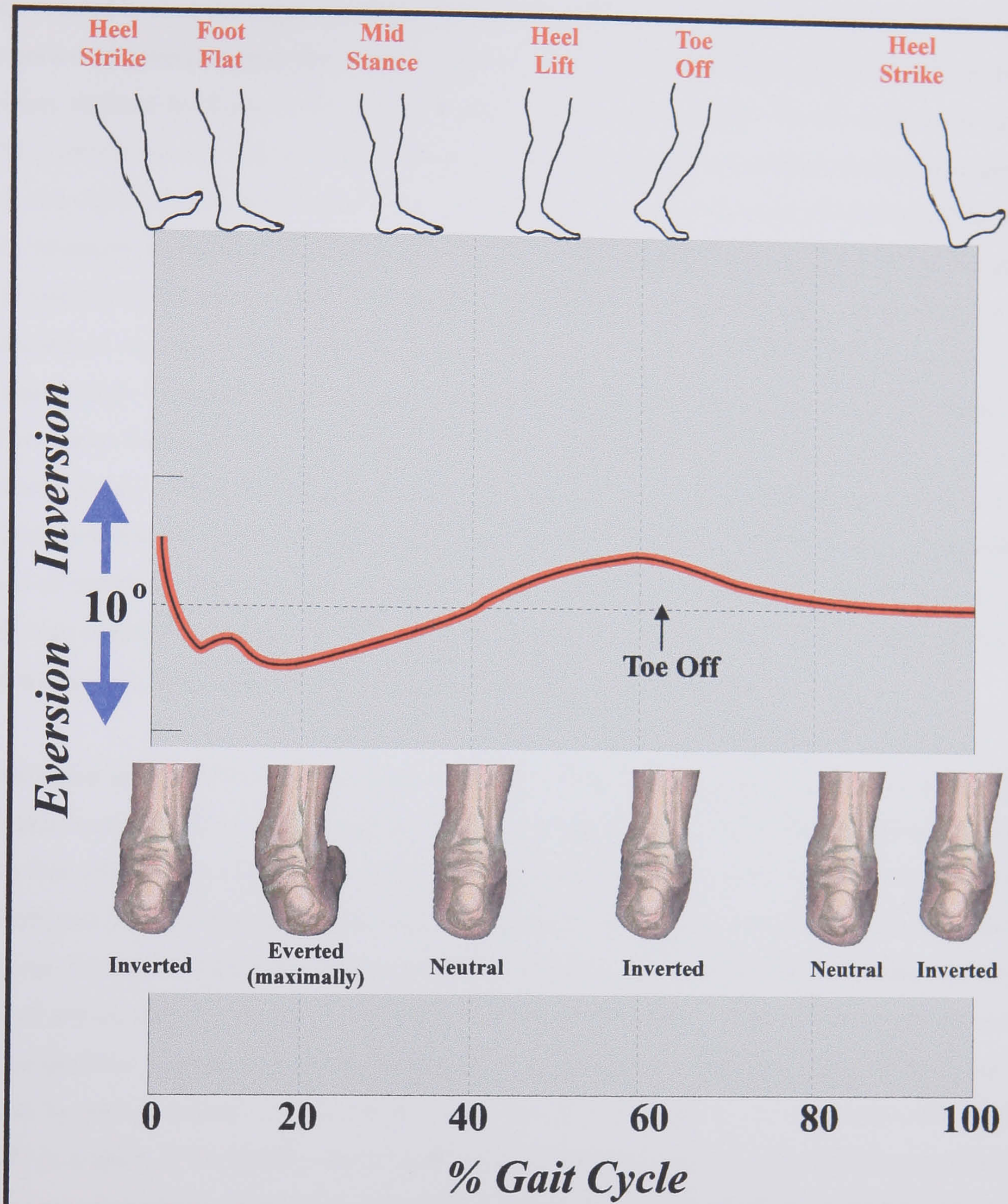


Figure 2-12: Normal subtalar joint motion during free walking (adapted from Wright *et al.*, (1964)

reported. Nonetheless, a series of articles in the 1990's have enabled a fuller examination of subtalar joint kinematics. Kepple *et al.*, (1990) using a video-based system found subtalar inversion/eversion to be complex and subject dependent. The heel-strike position was inverted in three and everted in two from five subjects. Three subjects showed the classic three stance phase periods of inversion/eversion as described by Close *et al.*, (1967) whilst one subject functioned around an everted motion envelope and one demonstrated inversion only at toe-off.

Moseley *et al.*, (1996) using a similar video analysis system measured rearfoot motion in 14 young adult males. His data challenges previous notions of subtalar motion in gait as he found a

mean everted heel-strike angle (approximately 2 degrees), gradual eversion from heel-strike and one period of inversion, past the neutral position at toe-off. Relative to a subtalar joint neutral position, defined by Root *et al.*, in 1977, Pierrynowski *et al.*, (1996) found an inverted heel strike position in only one of nine subjects confirming Moseley's findings of the same year. From the eight subjects whose heel strike position was everted, four showed an immediate but small inversion movement. Maximal eversion (mean- 7.2 degrees) occurred at 44% of the gait cycle and at toe-off all nine subjects demonstrated and inverted heel position. Swing phase was characterised by one to two degrees of inversion eversion motion. Kobayashi *et al.*, (1997) provided single case data using electromagnetic tracking (EMT) for the first time, producing a motion curve for inversion/eversion similar to the three period pattern of Close *et al.*, (1967). Cornwall *et al.*, (1999) developed this technique further and in a large sample of 153 normal subjects described a pattern of motion comprising of two inversion and one eversion periods. Range of inversion/eversion motion in this group was small (mean 8.7 degrees), the heel strike angle was slightly inverted (mean 2.5 degrees), eversion motion occurred through the mid-phase of stance period, and at toe-off the joint was inverted (mean 5.8 degrees).

Reinschmidt *et al.*, (1997) attempted to overcome some of the technical difficulties associated with skin marker techniques by studying subtalar motion using bone-embedded markers in vivo. From five subjects the shape of the inversion/eversion motion curves was similar and four from five subjects had inverted heel-strike angles. One subject functioned around an inversion motion envelope but showed along with the other four subjects, and eversion period during the first 50% of stance (mean eversion- 5 degrees). Four from five subjects had inversion motion past neutral position towards toe-off but the subject with the greatest eversion range, failed to reach neutral by end of stance. Camera-based techniques remain popular and Rattanaprasert *et al.*, (1999) in a study of 10 healthy adults reaffirmed the general motion patterns, range and timing of motions described earlier. Mean heel strike position was approximately1.5 degrees inverted with an eversion component through mid stance and a final inversion period to toe-off (mean 8 degrees) and total range of motion of 13.7 degrees.

The findings from these studies are summarised in table 2-4. Qualitatively, the movement patterns from heel strike through to toe off are in good agreement and characterised, in the frontal plane, with eversion from heel strike through mid stance. During late mid stance the motion changes to inversion reaching a peak at or just after toe off. Quantitatively, absolute parameters are more difficult to establish because the data vary so much between studies, caused, undoubtedly, by differences in the measurement technique. The most significant problem is related to how motion is described relative to a known or hypothetically known position of the subtalar joint. In most studies this is not reported at all and in others both the

Table 2-4: Comparative data derived from normal gait studies of the ankle joint complex.

Author N-subjects	Wri (1964) (n=1)*	Kep (1990) (n=5) *∇	Sco (1991) (n=3) #	Mos (1996) (n=14)	Pie (1996) (n=9)*
Age of subjects (years)	-	22-30	22, 22, 29	20-24	22-41
Measurement system	Pot	Video	Video	Video	Video
AJC- DF/PF					
ROM	-	13.6	22, 28, 27	14.0	-
Angular position at:					
HS	-	-2.0	2, 2, -4	2.3	-
FF	-	-	-	-6.3	-
MS	-	0	5, 0, 3	3.0	-
HL	-	-	-	5.0	-
TO	-	-5.5	-12, -26, -15	-2.6	-
AJC- INV/EVR					
ROM		13.0	12, 17, 18	11.1	9
Angular position at:	8				
HS		1.4	-6, -13, -2	-1.8	-1
FF	2	-	-	-3.8	-
MS	-2	-2.0	0, -3, -4	-7.0	-7
HL	-2	-	-	-7.0	-
TO	2	10.2	-7, -8, 2	3.8	-4
	2				
AJC – IN/EX ROT					
ROM	-	12.3	-	9.9	-
Angular position at:					
HS	-	6.8	-	2.0	-
FF	-	-	-	4.5	-
MS	-	6.8	-	6.2	-
HL	-	-	-	7.7	-
TO	-	-1.4	-	-2.8	-

Author N-subjects	Kob (1997) (n=1) *	Rei (1997) (n=5)†	Rei (1997) (n=5) †	Ratt (1999) (n=10) *	Cor (1999) (n=153)
Age of subjects (years)	39	Mean 28.6	Mean 28.6	22-45	Mean 26.2
Measurement system	EMT	Video (SM)	Video (BM)	Video	EMT
AJC- DF/PF					
ROM	17.0	21.0	17.2	20.2	17.0
Angular position at:					
HS	2.0	-3.6	-3.6	-3.0	-3.0
FF	-	-	-	-6.0	-10.0
MS	4.3	2.1	0	4.0	3.0
HL	-	-	-	4.0	4.0
TO	8.0	-15.7	-15.7	-12.0	-10.0
AJC- INV/EVR					
ROM	17.0	17.3	17.2	13.7	8.7
Angular position at:					
HS	6.4	1.8	0	1.5	2.5
FF	-	-	-	-3.0	2.0
MS	-10.7	4.5	-0.5	-2.0	-2.0
HL	-	-	-	2.0	-1.8
TO	0	6.9	2.2	8.0	5.8
AJC- IN/EX ROT					
ROM	17.1	13.7	11.5	10.3	10.8
Angular position at:					
HS	15.0	-3.6	0	0	-0.5
FF	-	-	-	3.0	3.7
MS	25.0	2.3	-2.2	0	1.0
HL	-	-	-	-3.0	0.5
TO	17.0	-3.6	-6.6	-5.0	-7.0

EMT- Electromagnetic tracking: DF/PF = dorsiflexion (+)/plantarflexion (-), INV/EVR = inversion (+)/eversion (-), IN/EX ROT = internal (+)/external (-) rotation: - data not presented in reference material: * angular positions estimated from motion/time curves and data tables: # Full data presented from 3 subjects: ∇ data estimated for one subject only: † data estimated from motion/time curves for subject 5: BM- bone markers, SM-skin markers: ROM- range of motion: HS- heel strike angle: FF- Foot flat angle: MS- mid stance angle: HL- heel lift angle: TO- toe off angle. Values are in degrees.

subtalar joint neutral position and the relaxed standing foot posture have been used. Although the ROM is small, typically less than 20°, it is important for clinical interpretation to know absolute movement from an anatomically valid reference point. The subtalar joint neutral position as described by Root *et al.*, (1977) is conceptually valid and represents the most reasonable position of maximum joint congruency from where eversion and inversion should be measured. From this reference position, data collected during gait is more valuable for functional interpretation. For example, RA and normal subjects may have the same motion pattern shape, but because of subtalar laxity in the RA group, the ROM may be occurring around a more everted position. Correction of the deformity may not change the movement pattern shape dramatically but a shift, relative to the normal position, into inversion may be significant. In this manner knowing a joint that previously did not function at all around its neutral position to do so under treatment may be important information missed by other techniques. Furthermore, a standard reference position is necessary when comparing groups of subjects with and without disease known to affect subtalar joint function, for intervention studies, and when assessing changes in joint movement over time.

2.2.2.3 Kinetics

The foot, and particularly the subtalar joint, is an important contributor to impact load attenuation in the lower limb (Perry, 1992; Perry *et al.*, 1995; Rosenbaum *et al.*, 1994). Shock associated with walking and running is absorbed by a number of passive and active mechanisms. Subtalar joint pronation is an active mechanism where upon ground contact muscle contractions permit controlled joint motion, which can provide a delay in the response load and store energy for future needs. Subtalar joint pronation has interdependent motion in the tarsal joints and through internal leg rotation. When restricted, force transmission through the joints is significantly increased and this has been associated with accelerated degenerative changes (Cowell and Elener, 1983; Klenerman, 1995). Gauffin *et al.*, (1993) showed that during standing a small inverting muscular torque is needed to counteract the external reaction force because the body of the calcaneus is lateral to the longitudinal axis of the tibia. During gait at heel strike the point of force application lies outside the subtalar joint axis of rotation and leads to an external moment that rotates the foot into pronation. Scott *et al.*, (1991) found an initial negative (indicating plantarflexion, inversion and adduction) subtalar joint moment during the first 10% of the stance phase of gait due to dominant activity of the dorsiflexors, evertors and abductors. For the remaining 90% of stance a positive moment reaching a peak of approximately 30Nm at 75% of stance, indicated that the plantarflexors, invertors and adductors were dominant. Internal joint forces have been studied less frequently for the subtalar joint.

Seireg *et al.*, (1975) found peak resultant force in the anterior facet of the talocalcaneonavicular joint was 2.4 times BW and 2.8BW for the posterior facet with peaks occurring late in the stance phase of the gait cycle. Reeck *et al.*, (1998) investigated the support characteristics of the talocalcaneal, talonavicular and superomedial calcaneonavicular ligament on the talus. In 18 cadaveric specimens the contact area, force and pressures were measured in under axial load in a jig simulating heel strike, mid stance and toe-off periods of the gait cycle. Contact area was found to be greatest in the posterior facet of the talocalcaneal joint, followed by the talonavicular joint, the anteromedial facet of the talocalcaneal joint and the talocalcaneonavicular articulation. Forces followed the same trend as the contact area rising from heel strike through to toe-off, particularly in the posterior facet of the subtalar joint (table 2-5). No significant changes in mean pressure were found for any of the articulations in the three static positions except for an increase in pressure in the posterior facet from mid stance to near toe-off.

Table 2-5. Contact force from heel strike to toe-off for structures supporting the talus. N, Newton; SMCN, superomedial calcaneonavicular ligament (Reeck *et al.*, 1998).

Joint	Heel-strike		Stance		Toe-off	
	Force (N)	Total Force (%)	Force (N)	Total Force (%)	Force (N)	Total Force (%)
Posterior	685	35	932	40	1492	47
Talonavicular	662	34	655	28	887	28
Anterior	391	20	538	23	523	17
SMCN	224	11	195	9	265	8

Finally, Parenteau *et al.*, (1998) investigated the mechanics of subtalar joint failure. In their experiment the calcaneus was rotated under four basic movements of dorsiflexion, plantarflexion, inversion and eversion with continuous measurement of moments, forces, linear and rotational displacement. Failure was defined as the initial drop in moment representing gross injury and this occurred in eversion at a mean of 48Nm (SD- 12.2Nm) at a mean eversion angle of 32.4 degrees (SD- 7.3 degrees) and injury was identified in all 32 specimens tested. Both the joint moment and angle at which injury occurred were greater than the normal limits. The mean eversion injury angle was also in excess of that measured passively or recorded during gait in published studies where extreme valgus heel deformity was evident.

Ground reaction forces show the magnitude and direction of loading directly applied to the foot during locomotion, and have components in all three principle body planes (vertical, lateral, fore-aft) (Whittle, 1996). The vertical force shows the characteristic double-hump, the first peak occurring at the onset of mid stance, exceeds body weight followed by a valley created in late

mid stance as the centre of gravity rises as the body rolls forward over the stationary foot. Finally a second peak, occurring in late stance, is found indicating downward acceleration and lowering of the centre of gravity over the forefoot rocker in terminal stance (Perry, 1992). The fore-aft pattern shows 'braking' during the first half of stance and 'propulsion' during the second (Whittle, 1996). The magnitude of this horizontal force and medial/lateral shear is small compared with vertical loading, peak medial shear (5% body weight) occurs in mid-loading response whilst lateral shear reaches a peak (7% body weight) in terminal stance.

Impact loading and subtalar joint pronation have been manipulated in a number of studies in an effort to determine the role of pronation as a shock reduction mechanism. Rosenbaum *et al.*, (1994) hypothesised that an increase in the force generated by walking faster would increase the pronation moment. He manipulated walking speeds thereby reducing or increasing ground reaction forces and found no statistical differences between slow, normal and fast walking for inversion at heel strike or maximum eversion. There were statistical differences between conditions for total eversion movement and speed of eversion, each variable rising with increased speed of walking. This study also considered different foot morphology of low arch, normal arch and high arch, and found the low arch foot type to have greater eversion movement. The conclusion was that foot pronation associated with low-arch foot type produced a flexible structure with shock-absorbing qualities and that extended pronation would increase the range of motion used for this purpose. Perry *et al.*, (1995) took a different approach to this question by quantifying the changes in load induced by modification to normal pronation using normal and varus and valgus wedged shoes. Varus footwear reduced the maximum rearfoot angle by 6.7 degrees from normal and valgus footwear increased it by 8.8 degrees during normal walking and running. However, constraining pronation (varus shoe) increased ground reaction forces, loading rate, peak acceleration and transient rate over the normal and valgus footwear conditions for running only. In RA because pain and general physical impairment slows down walking this may be protective to the subtalar joint by reducing the pronation moment. Furthermore maximum correction with footwear and orthoses may not increase joint stresses under walking conditions. However, the above studies were conducted with individuals who were otherwise healthy and therefore does not account for the role of inflammation and joint laxity. How inflamed joints at the AJC in the early stages of RA behave under different loading conditions has not been investigated.

The path of the centre of pressure, which represents the locating instantaneous point of application of the ground reaction force during walking shows a normal progression from just slightly lateral to the midline of the heel advancing along the midline of the foot. From here it progresses across the metatarsal heads to the second or first toe by toe-off period (Rodgers,

1988). The path shows significant inter-subject variability and weak association exists between certain foot-types and the pattern of location of the centre of pressure. Pronation in the foot is thought to direct the centre of pressure medially. Attempts to redress this with foot orthoses has yielded mixed results, all studies demonstrating wide subject variability in small sample sizes (McPoil *et al.*, 1998; Miller *et al.*, 1996; Scherer *et al.*, 1994; Scranton *et al.*, 1982). Conversely, pressure-distribution devices provide specific locations of pressure as they occur beneath the foot and can be measured barefoot or in-shoe. This is a vast field beyond the remit of this thesis but several good quality studies that have attempted to address normal regional pressure distribution (table 2-6).

Table 2-6. Comparison of regional peak pressures (kPa) from a selection of foot pressure studies (some data adapted from Rodgers, 1988).

Region	B	G	S	R	C	H
Medial heel	363	208	780	337	345	185*
Lateral heel	363	208	450	333	336	-
Medial midfoot	-	68	-	60	15	-
Lateral midfoot	-	6	550	103	113	-
Lateral metatarsals	281	151	550	312	446	180
Second metatarsal	392	212	510	336	533	260
First metatarsal	353	163	520	245	319	210
Lateral toes	-	-	200	163	206	125
Medial toes		-	300	180	238	210
Hallux	432	178	400	219	511	260

B, Betts *et al.*, (1980), G, Grieve *et al.*, (1984), S, Soames *et al.*, (1985), R, Rodgers, (1988), C, Cavanagh *et al.*, (1992), H, Hughes et al., (1991). * Estimates taken from graphical plots for full heel and all other sites.

Peak pressure is the commonest variable used to describe pressure distribution patterns in the human foot. The heel generally registers the highest pressures, and with matrix sensors this can register initially in the posterior lateral heel region. The concavity of the longitudinal arch is such that higher pressures are registered in the lateral midfoot region where ground contact is greatest. In the forefoot the second and third metatarsal heads register the highest pressures, followed by the first then the remaining lateral sites. Using cluster analysis techniques, Hughes *et al.*, (1991) demonstrated the wide variability in this general observation and produced four common peak pressure distributions where loading was dominated in central, medial central, central or central lateral patterns. At the toes studies consistently show the hallux to register the highest pressures, ranging from 30% to 55% of that of the heel, followed by the medial then the lateral toes. Although comparatively low, Hughes *et al.*, (1990), using pedobarography demonstrated the importance of the toes in walking, the toes being in ground contact for 75% of stance phase exerting peak pressures similar to those at the metatarsal heads. In table 2-6

variability in absolute values across studies is partly due to differences in equipment used, populations studied, data collection methodology and analysis techniques. Wide inter-individual variability is, however, a common feature and thresholds for tissue injury remain elusive (Cavanagh *et al.*, 1992).

2.2.2.4 Proximal and distal coupling with the rearfoot

Subtalar dysfunction in RA may impact significantly on joints proximal and distal to this site. Manter (1941) described the subtalar and midtarsal joints as dual screws whose members are connected by the contact of the talus with the navicular. The midtarsal joint allows the forefoot to rotate about a longitudinal axis to permit eversion/inversion and an oblique axis to permit dorsiflexion/plantarflexion and abduction/adduction. With subtalar pronation the axes of the talonavicular and calcaneocuboid joints are brought parallel and the midtarsal joint is free to move. The two screws involved turn in opposite directions and the midtarsal joint everts around the longitudinal axis and dorsiflexes and abducts about the oblique axis, the net effect a lowering of the medial longitudinal arch (Elftman, 1960; Hicks, 1953; Lapidus, 1963; Manter, 1941; Shephard, 1951). Furthermore work by Lundberg *et al.*, (1989, 1993) showed that the talonavicular joint had the greatest range of pronation-supination motion (ranging from 2.5 to 18 degrees) amongst the joints of the arch. This suggested to him that the foot not only had a torsion-transmitting mechanism transferring rotation to the leg but a torsion-dissipating mechanism. Thus the synergistic action between subtalar and midtarsal joints ultimately serves as a shock absorption mechanism during the loading response (Perry, 1992).

Simple wooden models of the foot and leg, joined by a mitred hinge, were described in the early literature to demonstrate coupled motion about an oblique axis representing the subtalar joint (Hicks, 1953; Jones, 1945). Close *et al.*, (1967) noted the vertical inclination of the subtalar axis of 42 degrees allowed a horizontal component of motion, approximately one half of the rotation recorded about the subtalar axis, and this accommodated a horizontally rotating tibia. With the foot fixed against the ground, the subtalar joint was described as a torque converter; pronation and supination coupled with internal and external leg rotation respectively in equal amounts. Inman (1976) supported this observation and described how variation in the horizontal alignment of the subtalar axis would increase or decrease transverse rotation. Olerud *et al.*, (1987) measured tibial torsion as the subtalar joint was moved stepwise from extreme pronation to 50 degrees supination in 10 cadaver specimens. External rotation of the tibia was coupled with subtalar supination, the average torsion being 0.42 degrees per degree of supination, in a linear fashion with a regression co-efficient of 0.98, and this indicates behaviour like a universal joint. This high degree of coupling is not supported fully in other studies. For example, the in-

vivo roentgen stereophotogrammetry set-up described by Lundberg *et al.*, (1989) measured tibial rotation from a 40 degrees pronation-supination arc. They found a transfer co-efficient of 0.2 for each degree of supination of the foot with higher coupling between neutral and 20 degrees supination of the subtalar joint. Hintermann *et al.*, (1994) agreed with this finding but separated the transfer coefficients to give 0.46 for eversion and 0.74 for inversion, matching the conditions of Olerud *et al.*, (1987), and 0.29 for eversion and 0.62 for inversion matching the conditions of Lundberg *et al.*, (1989). In this in vitro study Hintermann *et al.*, (1994), also found movement transfer to be significantly reduced when specimens were axially loaded above 200N. Kepple *et al.*, (1990) derived angle-angle plots for eversion-inversion and axial leg rotation using video gait analysis in five subjects. They found no association between the timing of the reversal point for these two motions; the tibial rotation reversal point occurred before the inversion-eversion reversal point in all subjects and the time lag, expressed as a percentage of stance phase, ranged from 12% to 31%. Furthermore there was no constant linear relationship between the two rotations.

Transfer of subtalar pronation into internal rotation of the tibia has been associated with a variety of musculoskeletal symptoms in the lower extremity, especially knee pain in runners (Clement *et al.*, 1981; James *et al.*, 1978; Nigg *et al.*, 1993). LaFortune *et al.*, (1994) were able to demonstrate a difference of up to 4 degrees tibial rotation by the use of varus/valgus shoe wedges. Increasing tibial rotation by valgus wedging produced only minor changes in knee kinematics, the rotation being resolved at the hip joint. Using regression analysis, Nigg *et al.*, (1993) showed a strong correlation ($P<0.001$) between inversion-eversion and axial rotation in 30 runners with a transfer co-efficient of 0.76. There was also a significant relationship between arch height and transfer coefficient but this only explained only 27% of the inter-subject variation in transfer of foot eversion to internal leg rotation. Nawoczenski *et al.*, (1998) demonstrated an imbalance of coupling rotations between two groups of runners with different planar dominance in subtalar motion. A low inclination angle for the subtalar joint favoured calcaneal eversion/inversion (coupling ratio 1.53) and a high angle internal/external tibial rotation (coupling ratio 0.91), the mechanisms for injury different for each group.

These studies demonstrate that coupling between leg rotation and subtalar joint pronation/supination does exist, and the relationship under certain conditions may be strong. Comparison between published data is problematic because of different techniques and different activities. The most significant source of variation is the methods employed in both in vivo and in vitro studies of fixing the foot segment to the ground and therefore the relative contribution of both rearfoot and forefoot joints in subsequent measurements. The results of LaFortune's and others work suggest that external moments increasing tibiofemoral rotation are probably greater

when internal tibial rotation occurs but that muscular and ligamentous structures preserve the integrity of knee joint function. In RA the knee is a common site for synovitis, perhaps disrupting the normal structural integrity and it is possible that excessive pronation increasing internal tibial rotation may have a detrimental influence on knee joint structure and function. This has been demonstrated in a number of cross-sectional studies, but to date no causal relationship has been fully established (Keenan *et al.*, 1991; Woodburn, 1994).

2.3 Evidence of failure of normal subtalar joint structure and function in rheumatoid arthritis

2.3.1 Structural changes and evidence

2.3.1.1 Synovitis

Clinical presentation with pain and soft-tissue swelling and the ability to alleviate this through local analgesic and/or intra-articular glucocorticosteroids are the simplest evidence for subtalar joint synovitis in RA. King *et al.*, (1978) studied 120 RA feet and found a strong association between valgus heel deformity and ankle/subtalar joint pain; symptoms occurring more frequently lateral aspect of the ankle region. Spiegel and Spiegel (1982) noting the diagnostic challenge of subtalar synovitis, located painful symptoms in the sinus tarsi area in 30% of 50 patients studied. Seltzer *et al.*, (1985) by computed tomography (CT) noted diffuse non-specific swelling around the subtalar joint but the patients in his series had advanced disease. Kerry *et al.*, (1994) found a positive correlation between lateral rearfoot pain and valgus heel deformity but the specific location and means of detecting the pain were not presented. Ultrasonography (US) and Magnetic Resonance Imaging (MRI) have the ability to image soft-tissue and bone and have improved knowledge of the pathogenesis in RA (Conaghan *et al.*, 1999; Wakefield *et al.*, 1999). Koski (1993) first described US investigation of the rearfoot in 10 RA patients with pain and 15 with swelling around the ankle or midtarsal regions. Joint effusion expanding the joint capsule outwards and an unechogenic space could be seen in 19 subtalar joints, the appearance differing significantly from an aged-matched control group. Jernberg *et al.*, (1999) unexpectedly found that a large number of patients (74%) with flat feet showed MRI abnormalities of the sinus tarsi, including replacement of the normal high signal fat with intermediate signal soft-tissue and bony erosions. Finally, guided diagnostic injections, containing analgesic and glucocorticosteroid have been shown to relieve subtalar joint pain for prolonged periods in most cases (Hay *et al.*, 1999)

Detection of subtalar synovitis by clinical examination lacks clarity and in the studies reported above tenosynovitis of adjacent muscle tendons or pain located to the ankle joint may be confounding factors. Advanced imaging techniques suggest that synovitis does occur but definitive disease-staged studies are still required. Nonetheless, synovitis in the early stages of the disease may increase the synovial volume within the subtalar joint. Indeed Resnick (1976) identified subtalar joint effusion by plain radiography, characterised by bulging posterior soft-tissue densities proximal to the calcaneal tuberosity. Increased synovial volume may alter normal joint congruency by expanding the joint capsule outwards and increasing the distance between articular surfaces. Indeed this has been demonstrated by ultrasonography for the ankle and metatarsophalangeal joints under non-weightbearing conditions; the effect under axial load is unknown (Koski, 1990). Persistent synovitis may further initiate valgus heel deformity by changing the stresses and strains on the joint capsule and ligaments with permanent deformation and laxity.

2.3.1.2 Articular cartilage and bone destruction

In RA the synovial membrane is transformed into a proliferating tissue (pannus) that invades and degrades articular cartilage. The cartilage-pannus junction represents the invading front of the inflamed synovial membrane and cells at this region take on specialised functions that promote cartilage damage from the secretion of tissue degrading enzymes. Cartilage and bone erosions occur at the margins of the joint and progress inwards over the joint surface. There are no studies that document or quantify precisely alteration of the joint surface geometry as a result of this process. Instead we know about gross pathological changes, and can speculate how these will affect geometry and overall subtalar joint function. Resnick (1976) showed classic radiological pathology of joint space narrowing, articular cartilage loss, and irregular subchondral bone in the subtalar joint with involvement of both talar and calcaneal components. This study gave no clinical details but advanced pathology was evident and included gross talonavicular joint involvement with significant cartilage loss and subchondral talar cyst formation. The posterior articular facet appeared vulnerable to cartilage loss with denuded and reactive sclerotic regions perhaps indicating focal areas of stress. Pastershank (1981) emphasised the importance of the talonavicular joint and presented cases where subluxation of the joint occurred. Finally CT has revealed flattening of the sustentaculum tali, fragmentation within the subtalar joint and medial and plantar drift of the talar head (Seltzer *et al.*, 1985).

2.3.1.3 Ligament pathology

Evidence of laxity within the subtalar joint has never been established in the early stages of rheumatoid arthritis. Apparatus exists for this purpose but valid clinical data may be difficult to obtain in inflamed joints. In the absence of pronounced cartilage and bone loss deformity in early disease is considered the result of ligamentous laxity. Within the sinus tarsi important ligaments are tightly packed in a small volume closely related to other fibres, the subtalar joint capsule and the synovial membrane (Smith, 1958; Cahill, 1965). Therefore increased synovial volume and joint distension may create disruption by stretching the ligaments and altering their alignment relative to the axis of the subtalar joint. There are no reported studies of rearfoot ligament structure or function in chronic disease.

2.3.1.4 Muscle tendon pathology

Muscle weakness in association with joint pain is a common finding in RA and the rearfoot is no exception (Jernberg *et al.*, 1999; Keenan *et al.*, 1991; Michelson *et al.*, 1995). More specifically tibialis posterior tenosynovitis and, controversially, tendon rupture are thought to have major consequences for rearfoot function (Downey *et al.*, 1988; Helal, 1989; Kirkham *et al.*, 1989). Coakley *et al.*, (1994) evaluated tibialis posterior tendon pathology from clinical, radiographic and ultrasonographic signs in 28 RA patients with rearfoot involvement against 14 control patients. The tendon was significantly thinner in those RA patients who could not perform a single-heel-rise test and this was significantly correlated with heel valgus and pes-planovalgus deformity. However, only one case of frank rupture was identified. Masterson *et al.*, (1995) used tenography in 17 RA planovalgus RA feet and found no evidence of rupture. The most detailed study in this area exploited the imaging capabilities of MRI to investigate 11 patients with and 9 without hyperpronated feet in RA (Jernberg *et al.*, 1999). Complete tendon tears were seen in 1 patient from each group, but partial tears were common and when grouped occurred in 68% of the hyperpronated group and 43% in the control group. Michelson *et al.*, (1995) using a sample of 99 RA patients found 11% fulfilled criteria for tibialis posterior dysfunction including loss of longitudinal arch, inability to perform heel-rise test and lack of palpable tendon. Paradoxically, Keenan *et al.*, (1991) found similar weakness on manual testing but during gait electromyography showed increased duration and intensity of tibialis posterior contraction in a valgus versus non-valgus heel group. The increased activity may be seen as a compensation mechanism in an effort, albeit unsuccessful, to correct the abnormal subtalar position and associated collapse of the medial longitudinal arch. The increased intensity was not explained in the paper, although, the percent of maximum EMG signal was based on the maximum EMG signal from manual muscle testing in the patients. Relative to normative data

the EMG intensity signal would probably have indicated muscle weakness in both groups, the degree of weakness greater in the non-valgus group with less functional demand.

2.3.1.5 Changes in kinematics and kinetics in rheumatoid arthritis

In RA the consequences of valgus heel deformity on the kinematics of the subtalar joint in gait have not been extensively studied. Locke *et al.*, (1984) using electrogoniometers measured peak varus/valgus at the ankle joint complex in 25 patients with RA. Subgroups defined by orthotic use and painful symptoms exhibited peak valgus ranging from a mean of 11 to 21 degrees compared with 7 degrees for healthy subjects. Isacson *et al.*, (1988) compared three-dimensional rotation at the ankle/subtalar joint in 17 RA women with mean disease duration of 12 years compared to 11 age-matched controls, again using electrogoniometry. The inversion/eversion motion was less in the RA group around the same range envelope indicating absence of deformity. Keenan *et al.*, (1991) were the first group to show marked differences in inversion/eversion in valgus heel deformity and used their data to speculate on how kinematic changes occur with time. Linked to normal motion patterns the sequence they predicted was progressive increase in valgus heel-strike position with increased peak valgus, increased duration of valgus motion and failure to toe-off in inversion. Eventually the full motion range was predicted to occur around a valgus envelope and this was clearly demonstrated in their cases and supported by others (Siegel *et al.*, 1995).

Valgus heel has also been associated with gross changes in temporal and spatial parameters include development of shuffling gait with slow cumbersome progression, loss of plantarflexion at heel strike and late heel-rise, reduced stride length, increased double-support, reduced swing period and reduced gait velocity (Dimonte and Light, 1982; Hunt *et al.*, 1987; Isacson and Brostrom, 1988; Locke *et al.*, 1984; Marshall *et al.*, 1980). A general reduction in gait activity is associated with a reduction in the vertical component of ground reaction force in RA but the effect of valgus heel deformity has not been reported (Simkin, 1981). A single case study of mobile valgus heel in RA found a centre-of-pressure pattern directed lateral to the midline, contrary to the notion of medial displacement with foot pronation, due to a large invertor muscular moment controlling the everted position of the rearfoot (Siegel *et al.*, 1995). Several plantar pressure distribution studies have found medial displacement of peak plantar pressures across the forefoot associated with valgus heel, with a predominant medial centre-of-pressure (Stockley *et al.*, 1990; Woodburn and Helliwell, 1996).

2.3.1.6 Coupling mechanisms

Excessive rearfoot pronation causing excessive internal rotation of the leg has not been demonstrated in RA. Co-existence of similar levels of rearfoot and knee valgus deformity lends support to the coupling mechanism described earlier but cause and effect are not self evident in these associations (Keenan *et al.*, 1991; Kettelkamp *et al.*, 1972; Shields *et al.*, 1966). General observations that forefoot deformity is worse when the rearfoot is involved have been reported (Anderson, 1990; Dimonte and Light, 1982; Klenerman, 1995). One cross-sectional study failed to show any strong association with forefoot and rearfoot deformity concluding that MTP synovitis was so prevalent and persistent that it dominated the pathogenesis of forefoot deformity (Woodburn, 1994).

2.3.2 Summary pathomechanical model

The pathomechanical model leading to the development of valgus heel deformity must be disease staged and account for inflammatory and biomechanical factors. Structures that guide and stabilise subtalar motion, especially ligaments, are vulnerable in the early disease stages when synovitis is dominant. Ligaments cannot contribute to the control of joint motion unless they are maintained tight within the normal limits of joint surface congruency during motion. Synovial activity will stretch and lengthen the ligaments and eventually erode them disrupting the surface areas of the joint facets under contact. The interosseous talocalcaneal ligament is most vulnerable because of its location and relationship with synovial membrane. The various components of spin, roll and slide of the subtalar articular facets, especially the posterior facet, may be increased allowing greater joint displacement under load, in the direction of pronation. Pronation motion under normal conditions occurs during the loading response, when ground reaction forces are approaching body weight and this mechanism initially may exacerbate the deformity. Pain accompanying subtalar synovitis may be a mechanism that triggers an overall reduction in gait function, and although disability is undesirable, some limitation on forces transmitted to inflamed rearfoot and midfoot joints may be protective.

The position and orientation of the subtalar joint axis will change where joint congruency is altered. In valgus heel the tendency is towards a lower inclination and medial displacement furthering the eversion component of motion around the joint. Greater translation of the talus along the screw-like axis may occur and we have seen the high rate of talonavicular radiological pathology and clinical observation of medial and plantar displacement of this bone, suggesting also failure in the superomedial calcaneonavicular and inferior calcaneonavicular ligaments.

Disturbance of the articular geometry might lead to jamming of the articular facets, reduced surface contact, and increased intracartilagenous stresses and strains during motion. The loose-packed position during motion with the reduction of the number of taut ligament fibres requires a muscular stabilisation of the joints and tibialis posterior shows increased activity during the stance phase of gait. This may augment intra-articular compressive forces increasing intracartilagenous stress and strain, whilst the tendon is also vulnerable to tenosynovitis with partial or late full tear.

With persistent synovitis plain radiography and imaging have revealed gross change in subtalar joint structure and function. Progressive loss of articular cartilage and bone erosion will further change the geometry and thus mobility and stability of the subtalar joint. By this stage deformity is usually severe and uncorrectable as secondary changes take place. The challenge with rheumatoid arthritis is to promote specific disease-staged interventions with emphasis on early recognition and management using a kinematic technique that can facilitate diagnosis and monitor progress.

CHAPTER 3

DEVELOPMENT OF ANKLE JOINT COMPLEX THREE-DIMENSIONAL KINEMATIC TECHNIQUE USING ELECTROMAGNETIC TRACKING

This chapter describes the development and clinical application of electromagnetic tracking for three-dimensional kinematics at the ankle joint complex. A basic description of the instrumentation is provided alongside its adaptation for gait analysis. A number of experiments are presented which investigate the accuracy and precision of the system for position and orientation measurement specifically at the ankle joint complex. Gait studies are presented which investigate the feasibility (discriminatory validity) in clinical studies and repeatability in normal and rheumatoid arthritis subjects. Finally a technique using magnetic resonance imaging is described to quantify skin movement artefact at the attachment site of the heel sensor.

3.1 Background

3.1.1 Kinematics of the subtalar joint

The ability to accurately measure subtalar joint kinematics may be beneficial for the diagnosis and evaluation of rearfoot dysfunction in RA. A number of techniques have been developed for this purpose and applied across a diverse range of clinical and laboratory research fields. Weightbearing and non-weightbearing assessment, using simple goniometry, of the subtalar joint relaxed and neutral position, range of motion and joint axis orientation and alignment represents kinematics in the simplest form (Cook *et al.*, 1988; Lattanza *et al.*, 1988). Employed diagnostically, chiefly for the purposes of differentiating normal and abnormal function, these clinical-based techniques have consistently been shown to be inaccurate and unreliable. Errors are generated from heel bisection lines (using markers pens), manual placement of goniometer arms over bisection lines, and visual recording of angular data from the goniometers (Payne and Richardson, 2000; Pierrynowski *et al.*, 1996; Sell *et al.*, 1994). More complex three-dimensional measurement jigs have been developed for in vivo use by other groups for range of motion and flexibility and stability testing and have been extensively validated (Allinger *et al.*, 1993; Grimston *et al.*, 1993; Hintermann *et al.*, 1994; Lundberg *et al.*, 1989a 1989b 1989c; Siegler *et al.*, 1994, 1996; Stefanyshyn *et al.*, 1994). These studies have yielded interesting results for normal function and some disease conditions such as lateral ankle instability but the techniques are prohibitively invasive or too cumbersome for routine clinical practice. Laboratory biomechanics are dominated by the use of various jig apparatus and cadaveric

specimens for the purposes of studying normal AJC mobility, load-displacement characteristics, joint axis orientation and alignment, ligament forces, and arch function (Allard *et al.*, 1987; Hintermann *et al.*, 1995; Hollis, 1995; Kitaoka *et al.*, 1995 and 1997; Parenteau *et al.*, 1998; Rastegar *et al.*, 1980; Siegler *et al.*, 1988; Stahelin *et al.*, 1997). Many of these unique experiments yield data that is difficult to directly compare largely because of methodological differences and very few findings impact directly on clinical practice.

Instrumented gait analysis offers a more relevant approach for the clinician but many technical issues surround its successful use for the subtalar joint. The preferred technologies are video camera systems that track the position and orientation of skin surface markers. Access to the talus using surface markers is not possible so measurement is extended to include the shank or leg segment with distal markers placed on the calcaneus, establishing combined subtalar and talocrural motion referred to as the ankle joint complex (AJC). These systems have been employed to measure kinematics of normal walking and the effects of a limited number of disease states (Close *et al.*, 1967; Cornwall *et al.*, 1995; Kobayashi *et al.*, 1997; Moseley *et al.*, 1996; Lafortune *et al.*, 1994; Louwerens *et al.*, 1996; McCulloch *et al.*, 1993; Pierrynowski *et al.*, 1996; Rattanapresert *et al.*, 1999; Reinschmidt *et al.*, 1997; Scott and Winter, 1991; Siegel *et al.*, 1995; Wright *et al.*, 1964). Surprisingly, because of the boom in recreational jogging and associated overuse injury, more is known about AJC kinematics under running conditions, the influence of over-pronation and coupled motion with the knee joint (Areblad *et al.*, 1990; De Wit *et al.*, 2000; Clarke *et al.*, 1983; Engsberg *et al.*, 1987 and 1996; Nawoczenski *et al.*, 1995 and 1998; Nigg *et al.*, 1993; Reinschmidt *et al.*, 2000; Soutas-Little *et al.*, 1987; Stacoff *et al.*, 1991; Taunton *et al.*, 1985). Attenuation of AJC kinematics by shoe, insole, orthosis or heel wedge, in otherwise healthy individuals, sometimes mistakenly assumed to be intervention studies, have been reported (Nigg *et al.*, 1987 and 1997; Perry *et al.*, 1995; Rosenbaum *et al.*, 1994; Stacoff *et al.*, 1992 and 2000). The findings of these orthotic studies cannot be generalised to disease states such as RA, because rearfoot dysfunction may be more severe with underlying disease and treatment response may be influenced by other factors such as pain and disability. Kinematic analysis is a time and labour consuming process and its use in true intervention studies is rare. Unfortunately evidence-based practice demands clinical trial data and many studies fail to impact clinically because of insufficient sample size or lack of methodological rigour, such as randomisation and blinding of outcomes (Eng *et al.*, 1994; Johanson *et al.*, 1994).

For the AJC, where the range of motion in the frontal plane is typically less than 15-20 degrees accuracy would appear to be a major requirement of any kinematic measurement system. Furthermore variability of motion patterns during gait are found at the AJC so any study that

attenuates or intervenes on this motion must employ a measurement system with sufficient precision to differentiate variability from a true intervention effect. In longitudinal studies, a design seldom if ever undertaken in gait analysis, stable data are necessary so reproducibility should be high. In the gait studies reported above, accuracy and repeatability specifications for the technology used are seldom reported. The specified accuracy of the system is important but a number of other factors general to this field and specific to the AJC will influence measurement accuracy and repeatability and include:

- The calibration technique for the equipment.
- The assembly, location and method of fixation of skin markers on rigid bodies representing proximal (leg) and distal (calcaneus) segments.
- The tracking precision and effect of line of sight and markers loss during data capture.
- Skin movement artefact.
- The choice of system to define and calculate joint angles from various coordinate and reference frame options including joint co-ordinate, Euler and finite helical axis systems.
- The choice of technique for determining a common neutral or zero position from which to calculate positive and negative rotations.
- Post-data collection processing and digitisation for manual or automated techniques.

Furthermore, in reported studies presentation of graphical and tabular data are generally poor and thus difficult to compare. A core set of common variables for AJC kinematics either linked to motion parameters such as range, minima and maxima or specific gait-timed events would be a simple but yet unadopted remedy to this problem. These specifications need to be fully established in any study wishing to measure AJC kinematics during gait.

3.2 Electromagnetic tracking technology

3.2.1 Background

Electromagnetic tracking systems (EMT) have been developed for a number of helmet-mounted sight applications, for example, to enable fighter aircraft pilots to transfer visually acquired targets to an electronic tracking system (Raab *et al.*, 1979). Adapted for biomechanics the technique is favoured by a number of research groups because of its reported high accuracy, flexibility and ease of use and has been employed in a number of clinical and laboratory based studies (table 3-1). In kinematic analysis the technique has helped provide solutions for technically difficult regions such as the shoulder complex. With similar constraints and challenges its use for the AJC may be appropriate and because of its availability within our own

Table 3-1. Examples highlighting the diverse clinical and laboratory research use of electromagnetic tracking using AC constant magnetic field systems.

Author/date	Field	Site	System	Investigation
Rendall & Abboud (1999)	Gait kinematics	Ankle/subtalar joint complex	Isotrak	Developmental description of novel technique including accuracy and repeatability
Cornwall (1999)	Gait kinematics	Ankle joint complex	Fastrak	Description of 3D kinematics at the ankle joint complex
Kobayashi *et al.*, (1997)	Gait kinematics	Lower limb (Hip, knee and ankle)	Fastrak	Description of 3D kinematics at hip, knee, and ankle in dynamic gait
Weiner *et al.*, (1997)	In vivo joint measurement	Subtalar joint	Isotrak	Intra-/intertester positional reliability study of open kinetic chain subtalar joint measurement
Mannon *et al.*, (1997)	Gait kinematics	Ankle joint complex	Fastrak	Comparison of rearfoot motion between video-based kinematic system and electromagnetic tracking
Pearcy *et al.*, (1989, 1993), Hindle *et al.*, (1990) & Russell *et al.*, (1992, 1993)	In vivo joint measurement	Spine	Isotrak	Description of the normal kinematics of the lumbar spine including ROM and coupled movement defined by age and sex , investigation of postural effects on twisting mobility within spine, and variation in lumbar spine mobility monitored over a 24hr period
Smutz (1998)	Cadaver	Thumb	Isotrak	Description of the mechanical role of intrinsic and extrinsic muscles of the thumb with specific measurement of the moment arms
Ishikawa *et al.*, (1997)	Cadaver	Carpal joints	Isotrak	Description of the kinematics of the 3rd metacarpal, scaphoid and lunate at different wrist positions with comparisons made between biplanar radiography and EM tracking
O'Driscoll *et al.*, (1992)	Cadaver	Elbow joint	Isotrak	Description of elbow kinematics before and after implantation of a 'loose-hinged' elbow prosthesis
Johnson *et al.*, (1990, 1993)	In vivo joint measurement	Shoulder complex	Isotrak	Graphical description of shoulder joint movement and scapular plane rotations
Itoi *et al.*, (1992)	Cadaver	Shoulder	3Space Tracker	Description of the influence of scapular inclination on the stability of the glenohumeral joint
Zoghi *et al.*, (1992)	Morphometrical	Femur	3Space Tracker	Description of 3D geometry of the distal femur.
Hefzy *et al.*, (1992, 1994)	Cadaver	Knee & patellofemoral joint	Isotrak	Comparison between two surgical techniques on lateral collateral ligament stability at the knee and a description of the influence of tibial rotations on patello-femoral contact areas and tracking
McKellop *et al.*, (1993)	Cadaver	Tibia	Isotrak	Analysis of the interfragmentary motions and the effect of a functional brace on simulated oblique mid-shaft tibial fractures
Sidles *et al.*, (1988)	Cadaver	Knee	Isotrak	Quantitative description of the ligament insertion sites for normal motion in intact knees
Kitaoka *et al.*, (1995, 1997a, 1997b, 1997c, 1998, 1998)	Cadaver	Foot	3Space Tracker	A number of laboratory experiments using test rig apparatus and cadaveric specimens to study kinematics of arch function, normal and abnormal motion, ligament stability and muscle function
Luo (1997)	Cadaver	Ankle joint complex	Isotrak	Description of the anatomical and biomechanical characteristics (elongation) of the ligaments surrounding the ankle joint complex
Sands (1998)	Cadaver	Talocalcaneal, talonavicular and tibiotalar joints	Fastrak	Description of the 3D kinematics of the joints of the rearfoot and midfoot

laboratory an attempt is made here to develop EMT for the AJC during gait. Within this unique application a number of studies are proposed with the specific aim to investigate:

- The adaptation of a generic EMT system, supplied with commercial kinematic software, for 3-D kinematics at the ankle joint complex measured in gait.

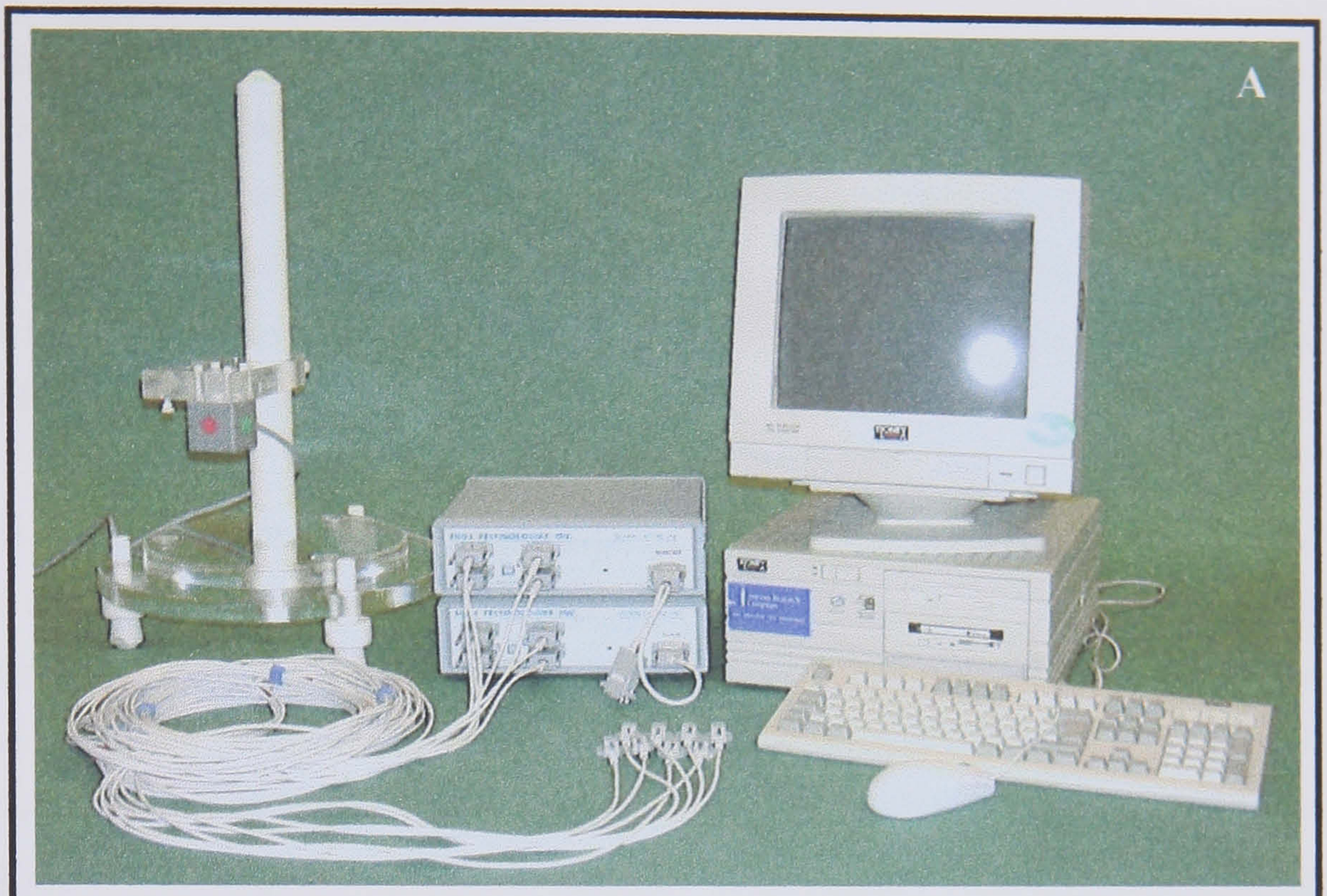
- The refinement of the technique for clinical use, including in-shoe measurements for the purposes of supporting measurement in a randomised clinical trial.
- The accuracy and precision of the technique for the purposes described.
- The repeatability and discriminative validity of EMT in normal and rheumatoid arthritis subjects.
- The influence of skin movement artefact.

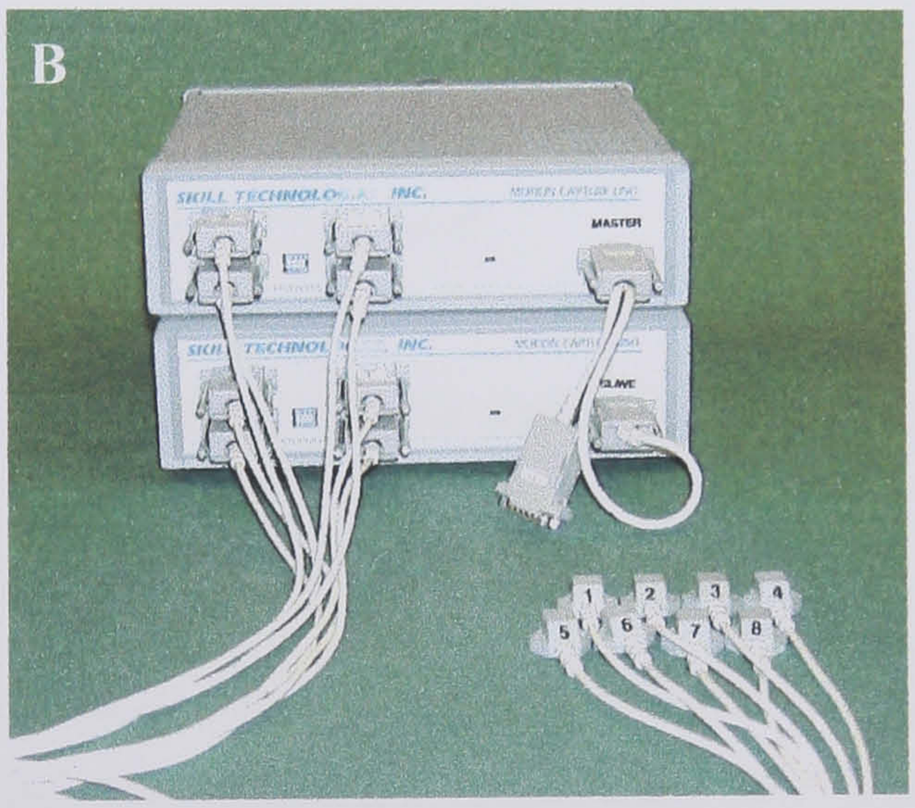
3.2.2 Hardware

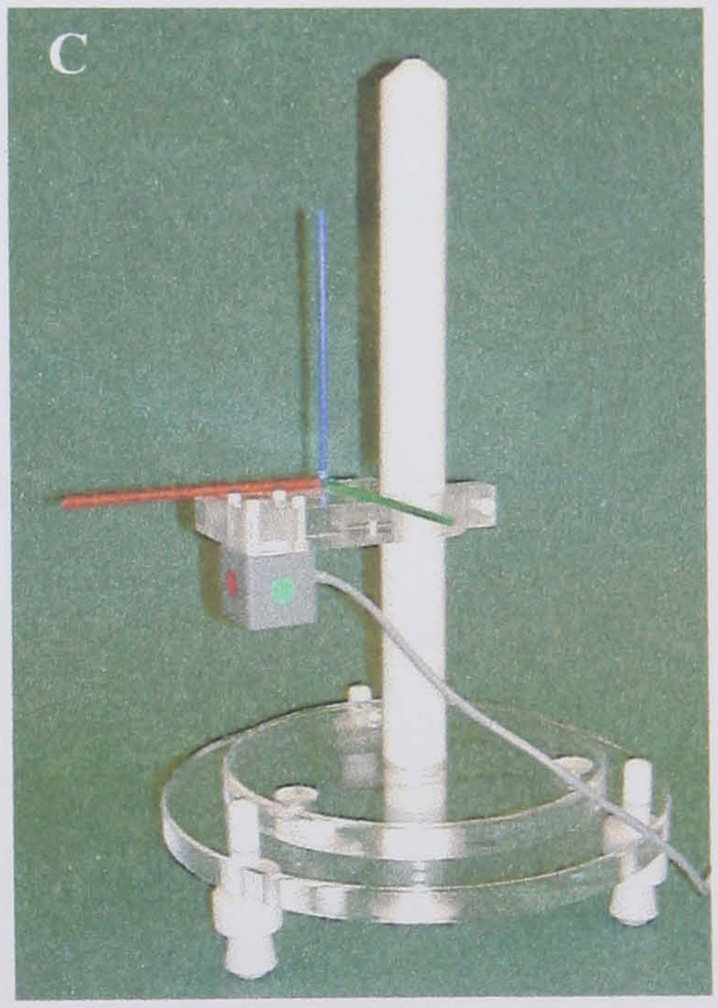
A commercial electromagnetic tracking system- 6DRESEARCH (Skill Technologies Inc, Phoenix, Arizona, USA) was used throughout this study. This system employs Fastrak® sensors (Polhemus Inc, Colchester, Vermont, USA) integrated with custom-designed kinematic software. The 6DRESEARCH system consists of three main components: a motion capture unit (MCU), a three-axis magnetic-dipole source and four three-axis magnetic sensors (Figure 3-1). Low-frequency quasi-static magnetic fields are generated by the MCU and emitted by the source. The instantaneous field strengths vary according to distance from the source and range from 1-30,000x10^{-9} Tesla between 0.1-3.0m respectively (personal communication, Polhemus Inc.). The sensors are connected to the MCU by 3m cables where the three detected outputs are pre-amplified, multiplexed and then synchronously demodulated and digitised by a 12-bit analogue-to-digital converter. The excitation of the source and the resultant sensor output are represented as vectors and all source axes are excited simultaneously with signals of the same frequency and phase. The resultant set of three sensor output vectors contain sufficient information to determine both position and orientation of sensor relative to source (Raab *et al.*, 1979). The system tracks the position and orientation of the sensor, with a full 6 degrees of freedom, by determining small changes in the co-ordinates and then updating the previous measurements, between 30-120 times per second. The MCU communicates with custom-software on a host personal computer through an RS-232C serial interface port. A second slave MCU was multiplexed with the master MCU using a single source (from master) employing 8 sensors to allow simultaneous multiple joint measurements.

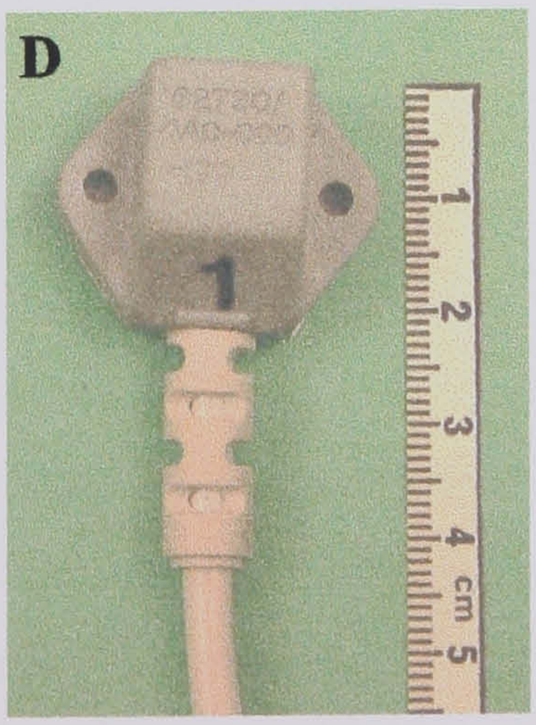
3.2.3 Software

The dedicated software is used to construct user-defined kinematic models consisting of one or more joints. Sensors are used to locate anatomical sites with each joint named and defined between a proximal and distal sensor. For example, eight sensors can be used to identify the left and right femur, tibia, calcaneus and navicular, to define knee, ankle joint and calcaneotalonavicular joint complexes. Calculation of rigid body orientation in three-dimensions









A- Components of the electromagnetic tracking system including personal computer
B- Motion Capture Unit (MCU)
C- Source transmitter mounted on adjustable stand
D- Sensor

Figure 3-1 Principle components of the electromagnetic tracking system

is user-specified from Euler angles, projected angles or a joint co-ordinate reference system, from which angular parameters are defined for each joint and calculations specified to include displacement, velocity and acceleration. Options are provided to interface kinematic data with up to 4 channels of synchronous data whilst the software permits time-skew correction, which synchronises data from multiple sensors, and digital data smoothing (Butterworth filter with a default 6Hz cut-off frequency).

The data capture sequence is triggered from a mouse-driven on-screen interface panel and includes capture, playback, store and analysis commands. For the kinematic models the sensors are assigned rendered skeletal models, used to animate the body, and these can be viewed in real-time. Animated gross movement patterns such as gait sequences can be stored and reviewed when required using an interface analogous to a video playback system. Joint orientation and position data are analysed instantaneously according to the reference system chosen and displayed graphically, orientations defined by axis of rotation and translation by Cartesian co-ordinates plotted over the data capture time sequence. For more complex analyses, data is stored as tab-delimited files ready to import to packages such as Microsoft Excel® or Statistical Package for the Social Sciences®.

3.2.4 Application to the ankle joint complex in gait analysis

3.2.4.1 Joint co-ordinate reference system for the ankle joint complex

The purpose of a co-ordinate system is to allow the relative position between two rigid bodies to be specified. The description of motion is the characterisation of how their relative position changes with time. Clinicians who use kinematic data for diagnostic and decision-making purposes need to receive such data defined by commonly employed clinical terminology. Grood and Suntay (1983), with application to the knee joint, described a convenient joint co-ordinate system where joint displacements within the system are independent of the order in which the component translation and rotations occur. Widely employed in biomechanics the system has the advantage of representing three-dimensional orientation analogous to the anatomical representations that both clinicians and researchers understand. For the purposes of this study, with a strong clinical focus, three-dimensional kinematics for the ankle joint complex will be described using a joint co-ordinate system. Furthermore, terminology applied will be specifically related to the joint co-ordinate system for the ankle joint complex, defined by the International Society for Biomechanics Standardisation and Terminology Committee (Allard *et al.*, 1995). The system is defined in Table 3-2 and Figures 3-2 and 3-3.

Table 3-2: Definition of a joint co-ordinate system for the ankle joint complex

Terminology The talocrural (ankle) joint- the articulation formed between the talus and the tibia/fibula. The subtalar (talocalcaneal) joint- the articulation between the talus and the calcaneus. The "Ankle Complex" is defined as the structure composed of the talocrural and the subtalar (talocalcaneal) joints.
Anatomical Landmarks M1- Tip of the medial malleolus M2- Tip of the lateral malleolus M3- The most medial point on the border of the medial tibial condyle M4- The most lateral point on the border of the lateral tibial condyle located just above the fibular head. M5- Tibial tuberosity O1- The point midway between the medial malleolus and lateral malleoli (M1 and M2) O2- The point midway between the medial and lateral tibial condyles (M3 and M4)
Definition of segmental, body fixed orthogonal reference frames **A. Definition of standard anatomical planes** Frontal plane of the tibia/fibula- the plane containing points O1, M3 and M4. Sagittal plane of the tibia/fibula- plane perpendicular to the frontal plane and containing the long axis of the tibia/fibula. (The long axis of the tibia/fibula being defined as the line connecting points O1 and O2). Transverse plane of the tibia/fibula- the mutual perpendicular to the frontal and sagittal planes.
B. Definition of body fixed anatomical frame of the tibia/fibula- XYZ (note: definition for a right leg) O1- The origin is located midway between the medial and lateral malleoli. X- The line connecting the medial and lateral malleoli (M1 and M2). Positive X is in the direction from the medial malleolus to the lateral malleolus. Y- Line perpendicular to the frontal plane of the tibia at the origin- O1. Positive Y is in the direction from posterior to anterior. Z- The common perpendicular forming a right handed Cartesian frame.
C. Definition of body fixed anatomical frame for the calcaneus- xyz (note: definition for a right leg) The Origin coincides with that of the tibia/fibula frame (O1) in the neutral configuration. z- with the ankle complex in neutral configuration, this axis coincides with the long-axis of the tibia/fibula (i.e.- the line connecting points O1 and O2). Positive z is from O1-O2. y- with the ankle complex in its neutral configuration this axis is perpendicular to the frontal plane of the tibia/fibula. Positive y is from posterior to anterior. z- the common perpendicular to y and z and forming a right-handed Cartesian frame.
Definition of joint co-ordinate system axes and description of relative angular and linear displacements. **e1**- is the axis fixed to the tibia/fibula and coincides with the X-axis of the tibia/fibula frame. Rotation about it- α, correspond to dorsiflexion (α+) / plantarflexion (α-). Displacement along it- s1 is the medial (α-)/lateral shift (α+), **e2**= the common perpendicular (floating axis) to e1 and e3. Rotation about it- β, is defined as inversion (β+) /eversion (β-). Displacement along it- s2 is the anterior (β+)/posterior drawer (β-) **e3**= is the axis fixed to the calcaneus and coincides with the z-axis of the calcaneal frame. Rotation about it- γ correspond to internal (γ+) / external (γ-) rotation. Displacement along it- s3 correspond to compression (γ+)/distraction (γ-).
Definition of the neutral configuration of the ankle joint complex Neutral dorsiflexion/plantarflexion is defined as zero degrees between the projections of the sagittal plane of the tibia of a line connecting the lateral malleolus- M1 with the lateral tibial condyle M4 and the line perpendicular to the plantar aspect of the foot. Neutral inversion/eversion is defined as zero degrees between the projections on the frontal plane of the long axis of the tibia/fibula and the line perpendicular to the plantar aspect of the foot. Neutral internal/external rotation is defined as zero degrees between the projections onto the transverse plane of a line going through the second metatarsal and the line connecting the tibial tuberosity M5 with the midpoint between M1 and M2-O1.

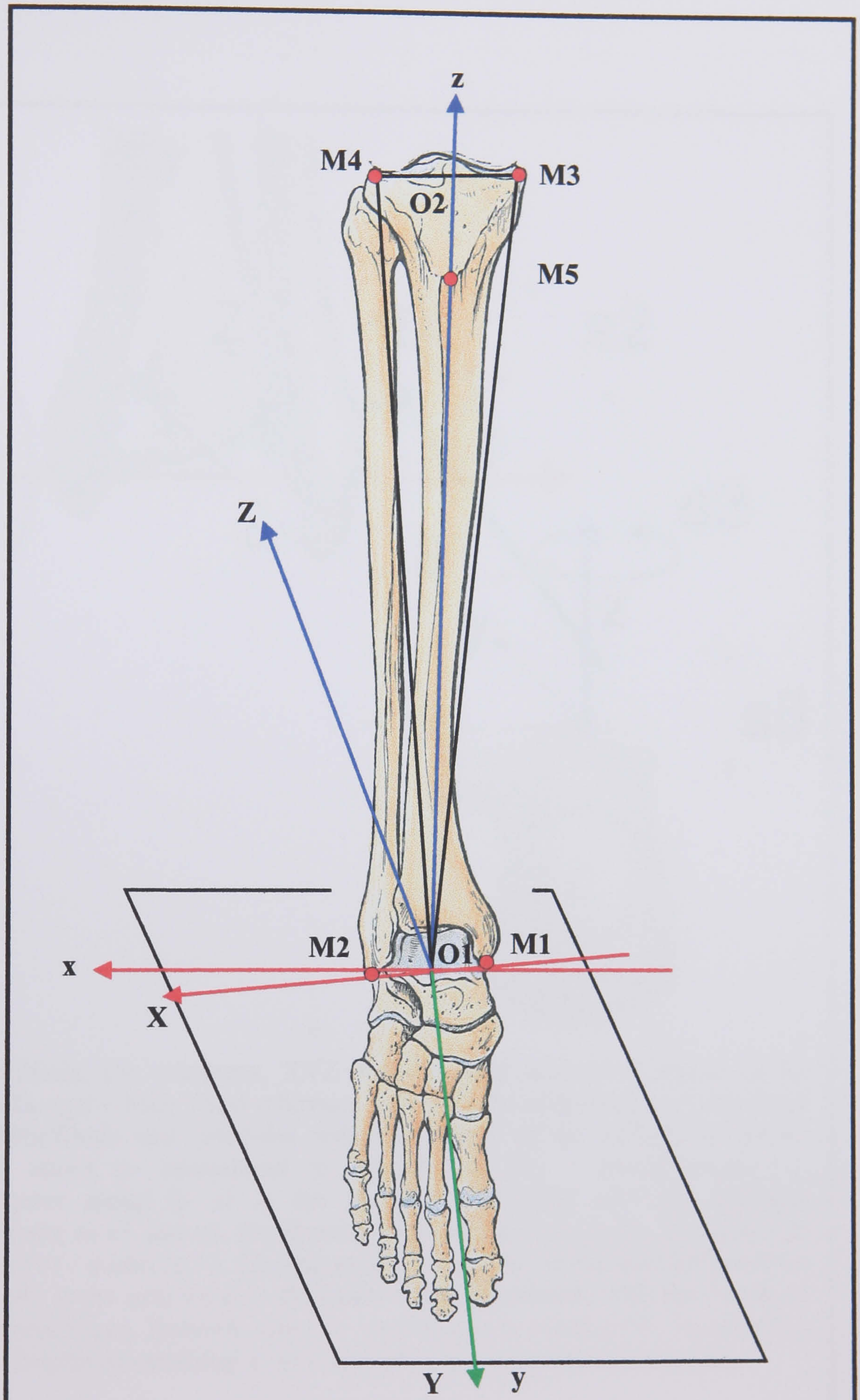
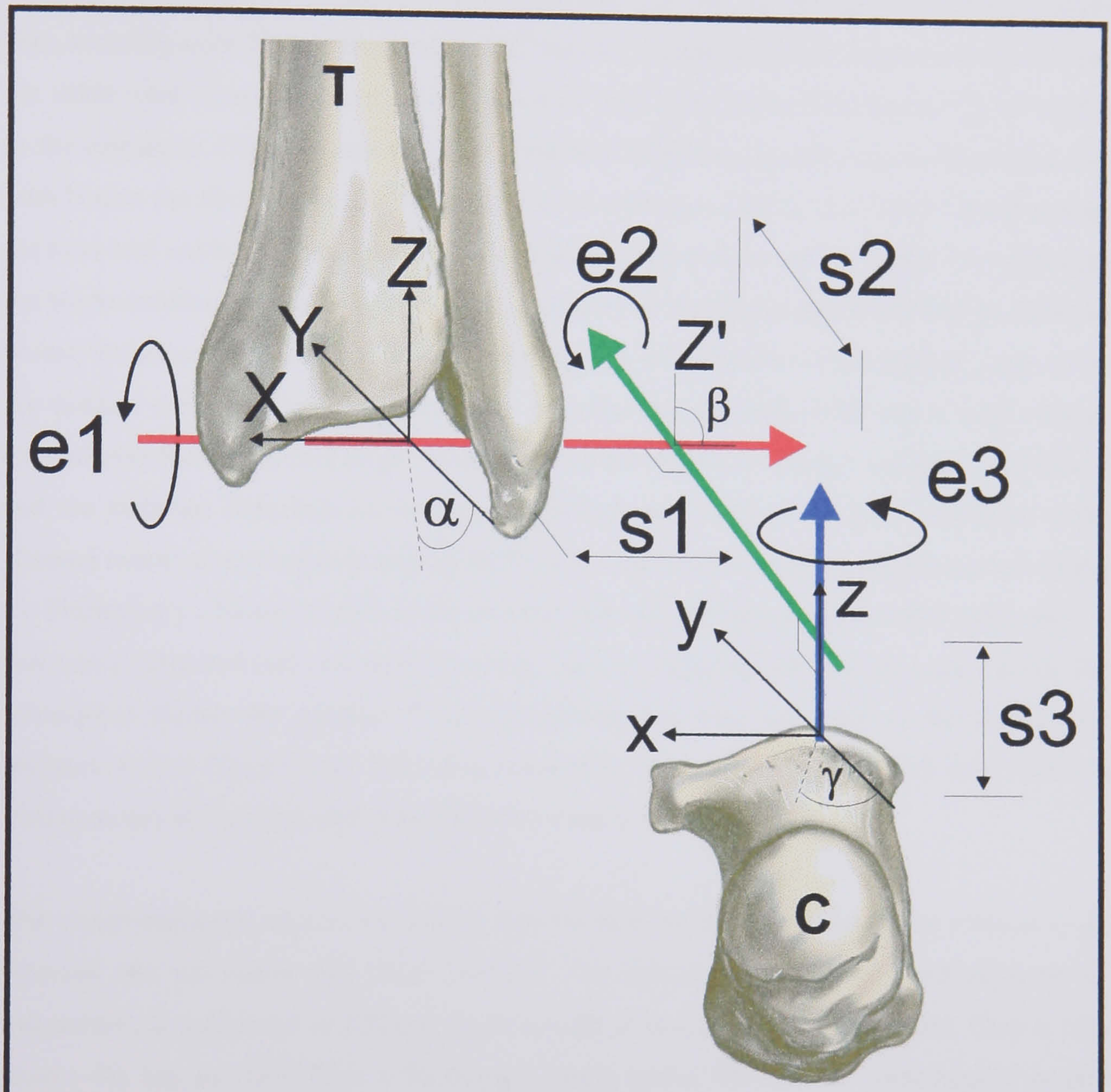


Figure 3-2: Definition of body fixed anatomical frame for tibia/fibula and calcaneus



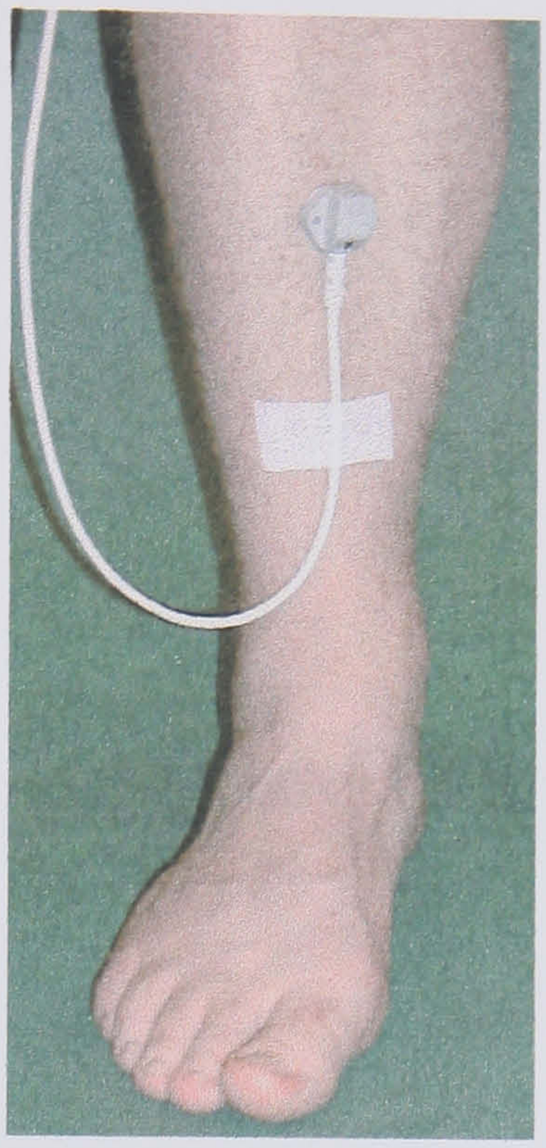
T= tibia/fibula, C= calcaneus, XYZ = body fixed anatomical frame of the tibia/fibula, xyz = body fixed reference frame for the calcaneus, e1= axis fixed to the tibia/fibula and coincides with the X-axis of the tibia/fibula frame. Rotation about it- correspond to dorsiflexion (+) / plantarflexion (-). Displacement along it- s1 is the medial/lateral shift, e2= the common perpendicular to e1 and e3, the floating axis. Rotation about it-, is defined as inversion (+) / eversion (-). Displacement along it- s2 is the anterior/posterior drawer, e3= is the axis fixed to the calcaneus and coincides with the Z-axis of the calcaneal frame. Rotation about it- correspond to internal (+) / external (-) rotation. Displacement along it- s3 correspond to compression/distraction.

Figure 3-3: Joint coordinate system for the ankle joint complex (adapted from Allard *et al.*, 1995).

3.2.4.2 Method of clinical application

Electromagnetic tracking employs skin-mounted sensors and like all marker systems the location and method of attachment it is important. For the leg and calcaneus bony anatomical sites avoiding underlying subcutaneous fat, muscle, muscle tendon or ligament were chosen. For the ankle joint complex we define the proximal rigid body as the tibia and the distal rigid body as the calcaneus. Close inspection of the superficial surfaces revealed good attachment sites for both bones; the tibia was accessible on the subcutaneous medial surface at mid position between the knee and ankle joint lines and the calcaneus on the posterior surface below the attachment of the tendo-achilles (figure 3-4). The optimal attachment technique employed double-sided tape to secure the sensor to the skin reinforced by a top cover of flexible hypoallergenic tape to extend the contact surface. Kinematics was also recorded for the knee joint and a third sensor was located over the lateral mid thigh region between the greater trochanter and knee joint line. Heel and toe switches (Interlink Electronics, Santa Barbara, California, USA), interfaced with a 4-channel events-detection-unit and the MCU, were used to record temporal parameters (figure 3-4). Preliminary clinical studies in rheumatoid arthritis patients suggested that the hallux, often deformed, retracted and non-weightbearing, was an inappropriate site for a toe switch. For all subsequent studies the plantar 1st metatarsophalangeal joint was used as the site for the toe pressure switch (figure 3-4). All wires connecting the sensors to the MCU were tidied using Velcro straps at the thigh and retained at the waist by an elastic belt.

The electromagnetic source transmitter was fixed to an upright stand at the vertical midpoint between the calcaneus and tibial sensors. The subject is asked to stand adjacent to the transmitter, at a distance of 250mm, in an upright anatomically neutral posture. Care is taken to ensure the leg and foot form a 90 degrees angle whilst the subtalar joint neutral position is found, referred to as the neutral calcaneal stance position (NCSP) (Root *et al.*, 1977; McPoil *et al.*, 1990; McPoil *et al.*, 1994). At this stage, with sensors attached, the software-driven boresight or neutral orientation procedure is undertaken (figure 3-5). The orientation of the sensors placed on both sites during set-up is not critical because a 'boresight' command is undertaken prior to data capture to assign a zero orientation of both sensors and source. This command is undertaken when the ankle joint complex is located in a neutral configuration, and this alignment of proximal and distal rigid body segments is estimated clinically. As a result orientation angles are measured in the reference frame specified with zero points shifted to the neutral point where boresight occurred. Repeatability studies for NCSP measurement have produced mixed data; some studies show poor, others good repeatability, and outcome appears to depend on technique and equipment used and the experience of the examiner (Freeman, 1990; Menz, 1995; Menz and Keenan, 1997). The technique involves



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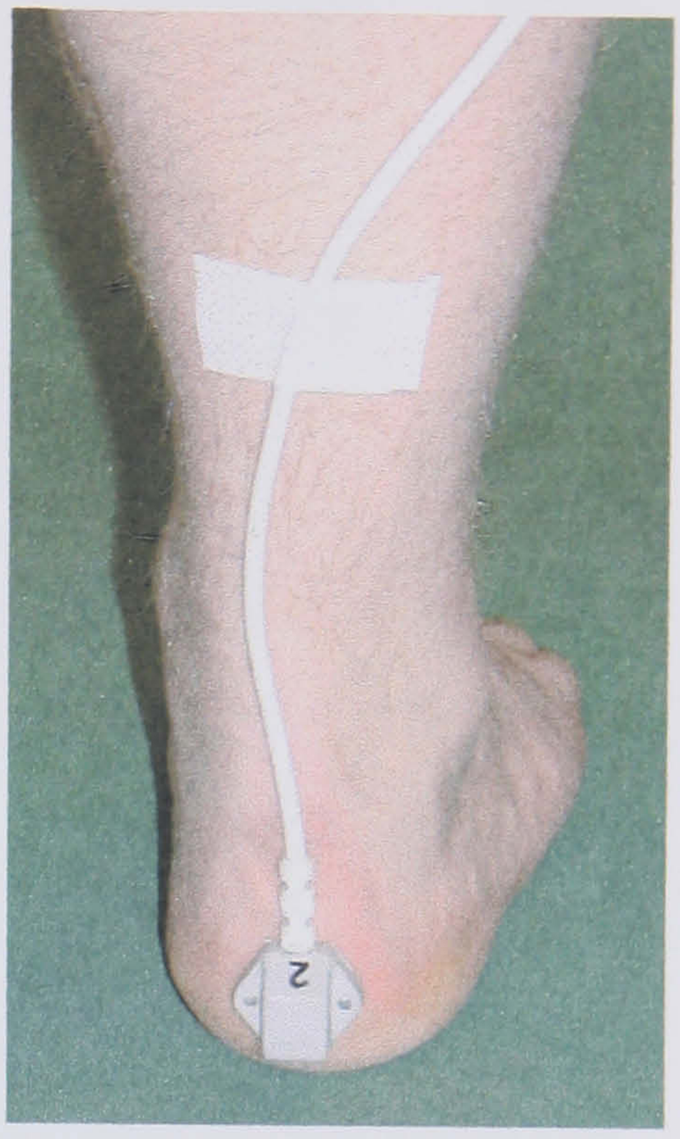

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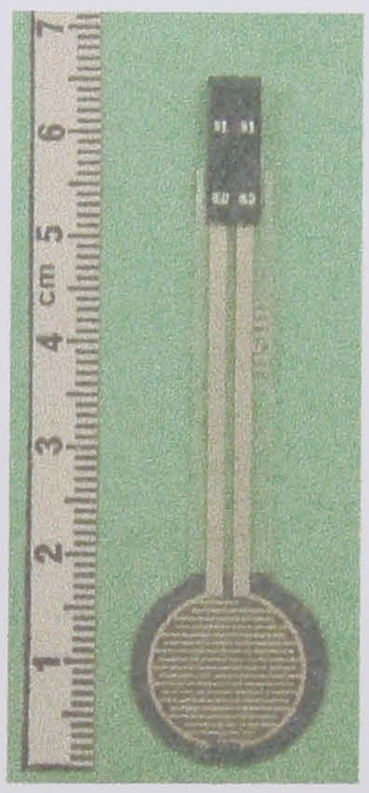

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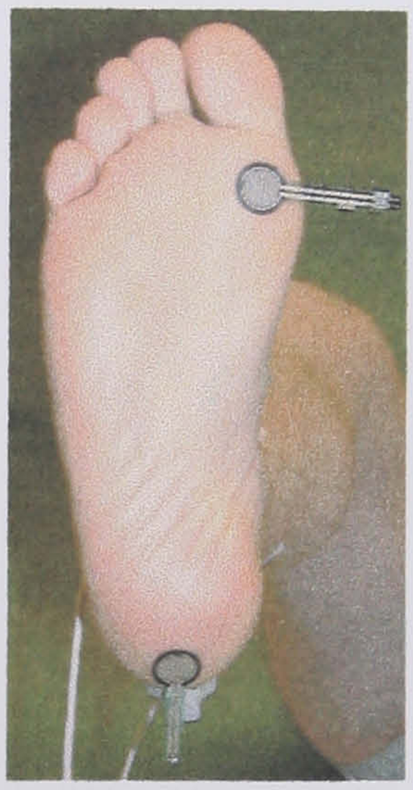

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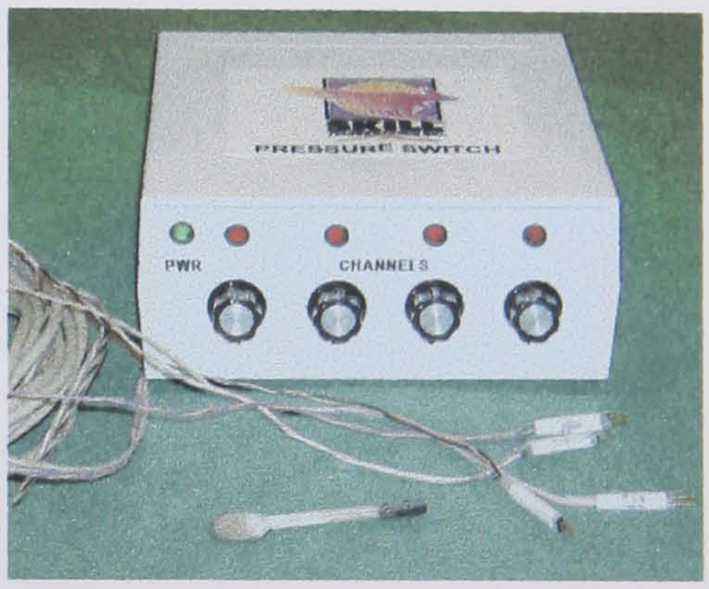
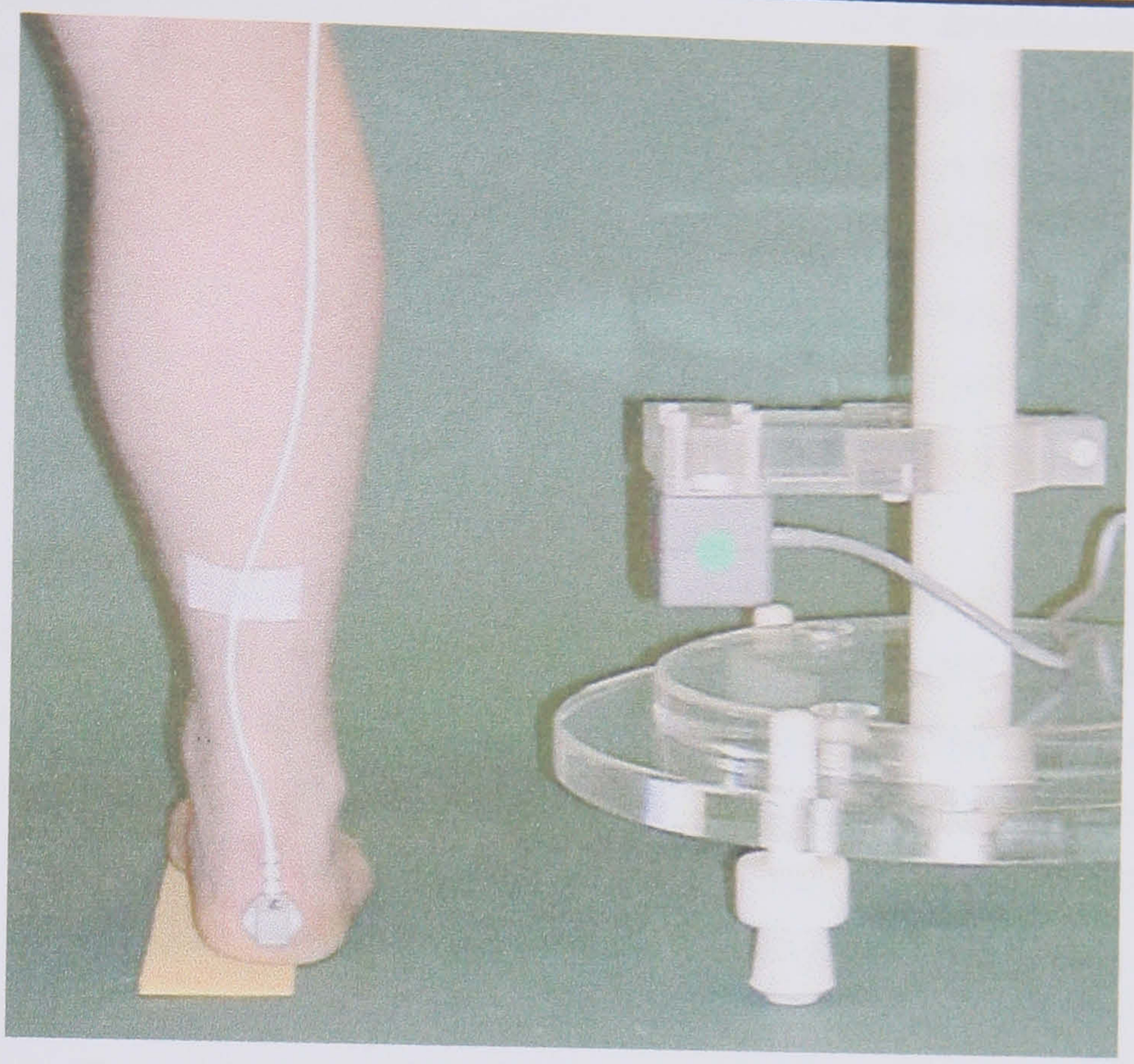


E

A- Proximal sensor located over medial tibial surface
B- Distal sensor placed over posterior calcaneal surface
C- Interlink pressure switch
D- Pressure switches located over the heel and plantar 1st metatarsophalangeal joint area
E- 4-channel events-detection-unit permitting left and right heel and toe switch data to be recorded

Figure 3-4: Skin mounting positions for tibial and calcaneal sensors, and footswitch equipment.



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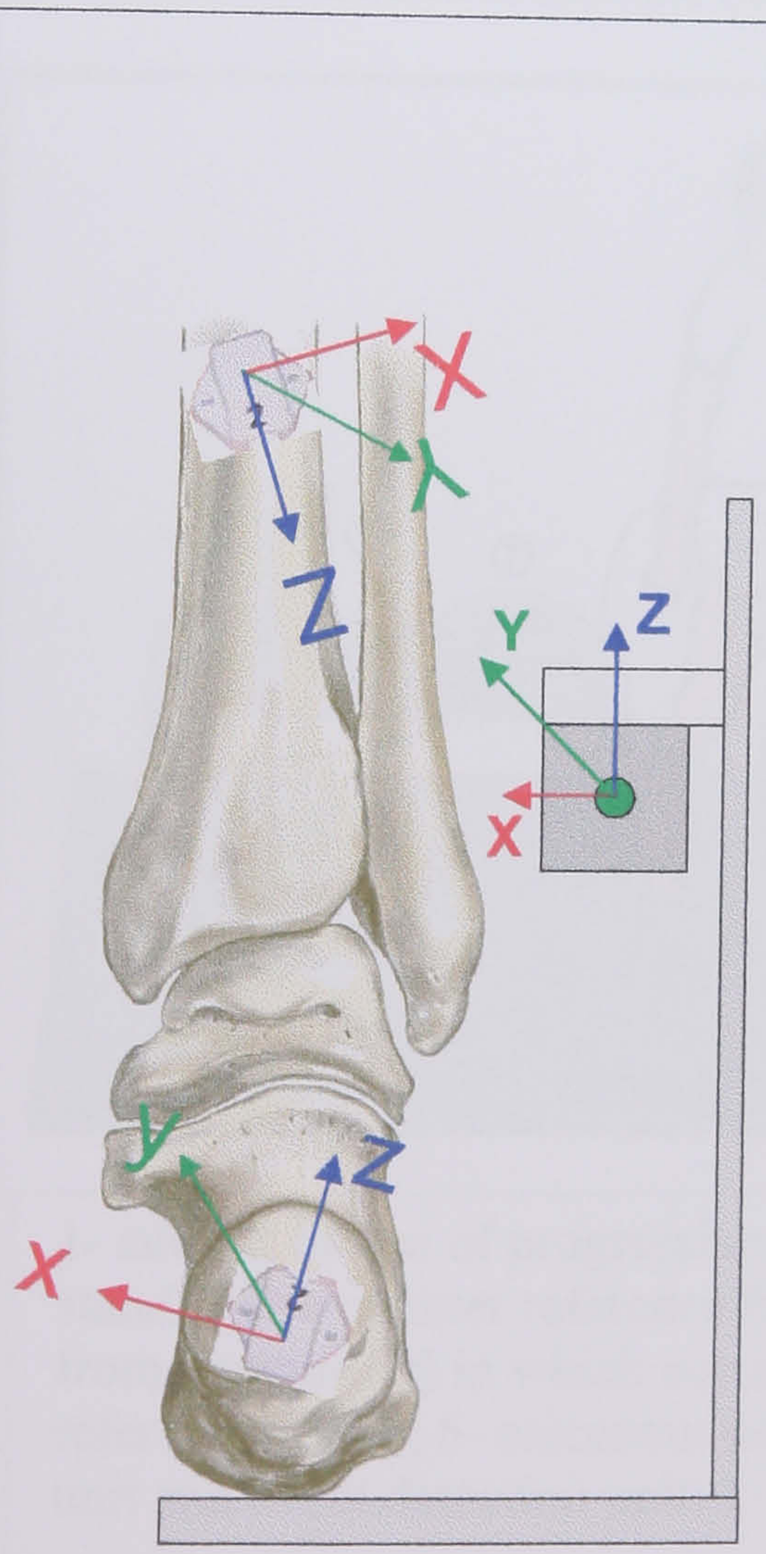

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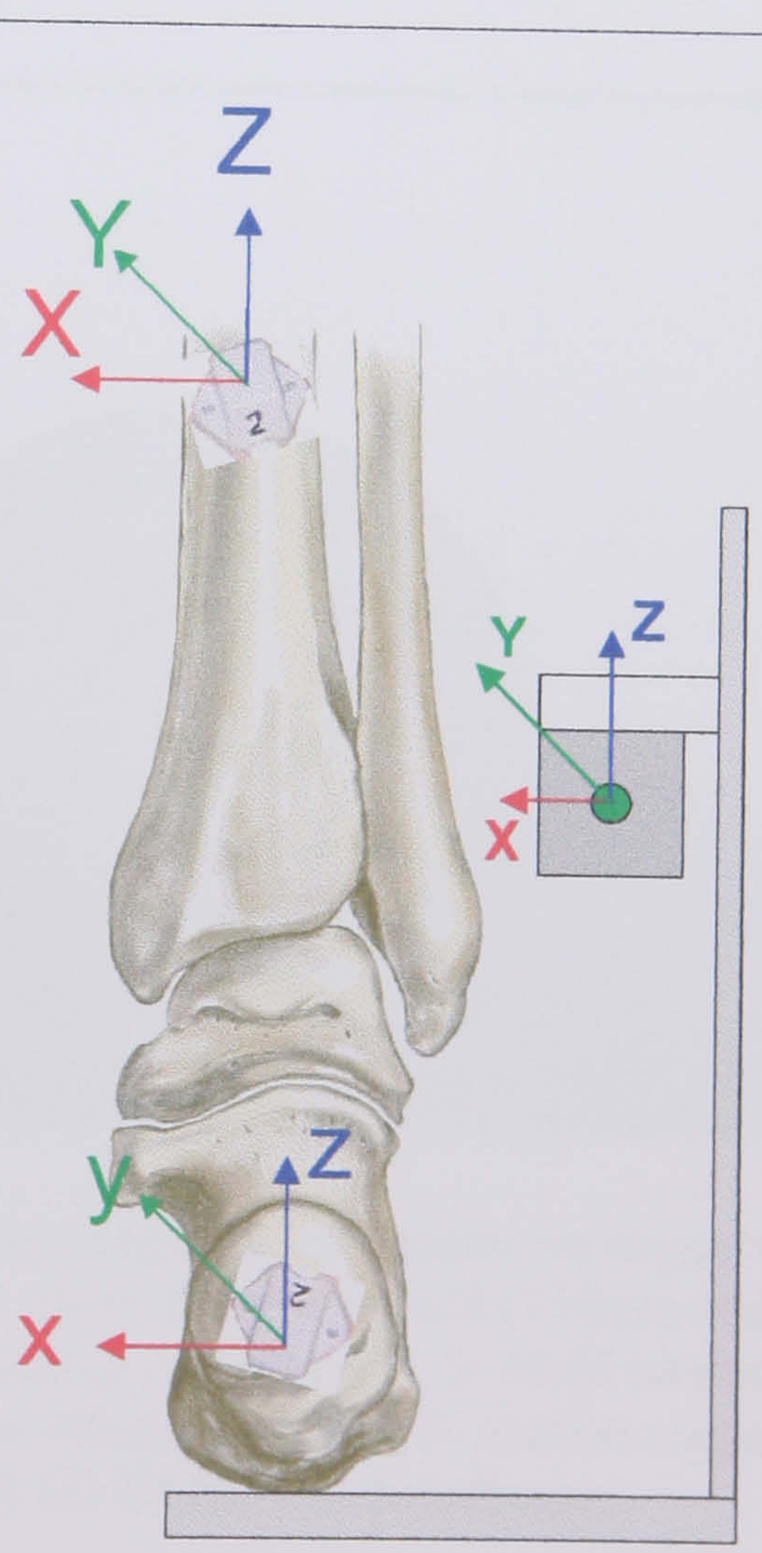
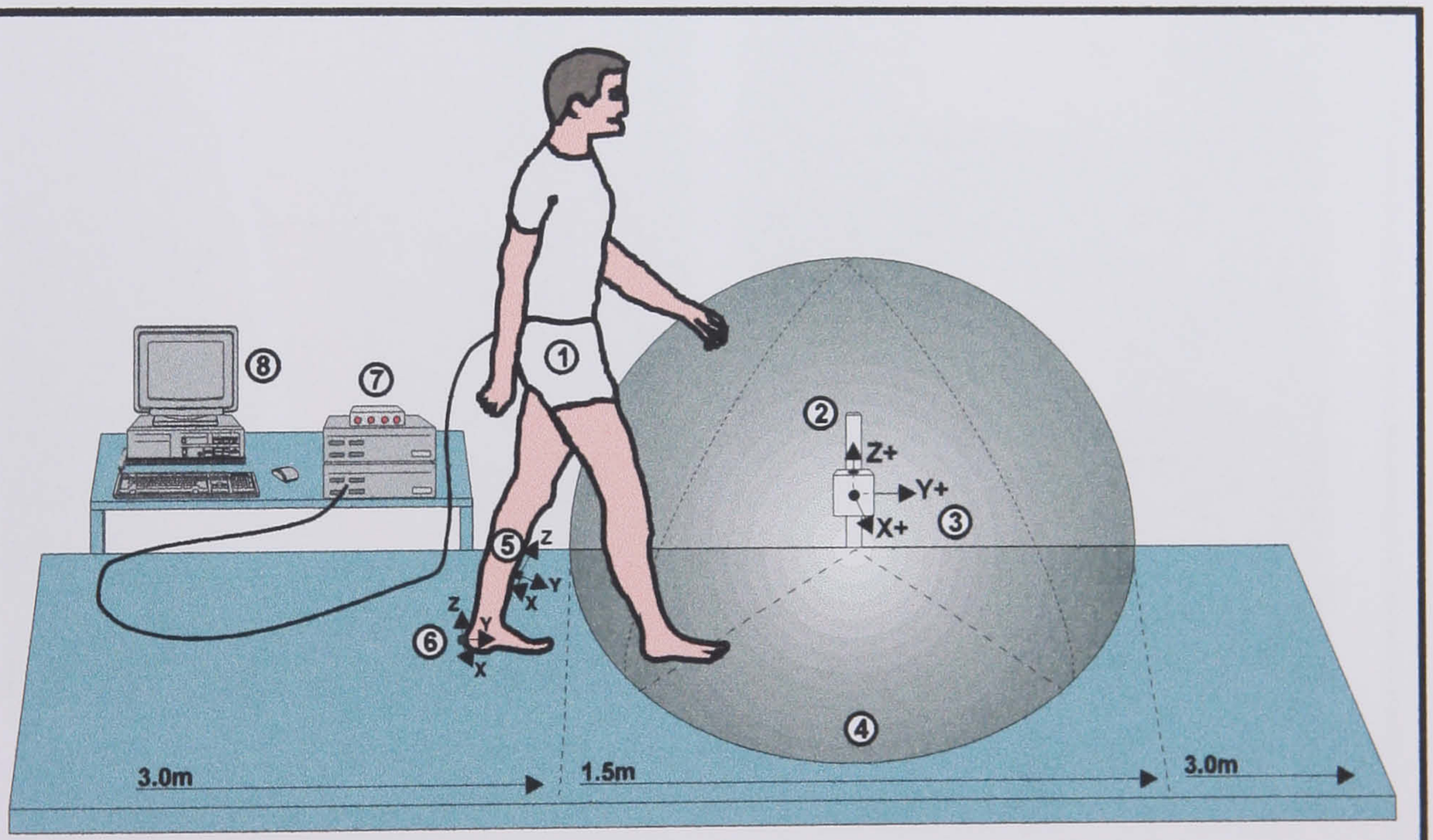


C

Figure 3-5: Clinical boresight procedure to align source and sensor reference frames in anatomically neutral position

manual manipulation of the foot into a desired position whilst simultaneous goniometric measurements are made over poorly defined landmarks bisected with reference lines. There have been no reported studies made with instrumented techniques where the clinician is freed up to concentrate solely on positioning of the foot. Therefore, the EMT boresight technique, restricted to manual manipulation of the foot into the required position, may show improved repeatability. This will become clearer in the repeatability testing undertaken later in this chapter.

To undertake data collection patients are instructed to initiate gait approximately 3 metres before entering the electromagnetic field, and continue gait for a further 3 metres after exiting the field (Figure-3-6). Discrete floor-markings guide the operator to restrict data capture to the measurement envelope of ±750mm from the source. Captured data is stored on a personal computer for review and processing. Output data was analysed using 6D-NORM analysis software (M Cornwall, Northern Arizona University, USA), which generates motion-time curves, normalised to the gait period, along with calculations of the timing of stance phase events and the coefficient of multiple correlation.

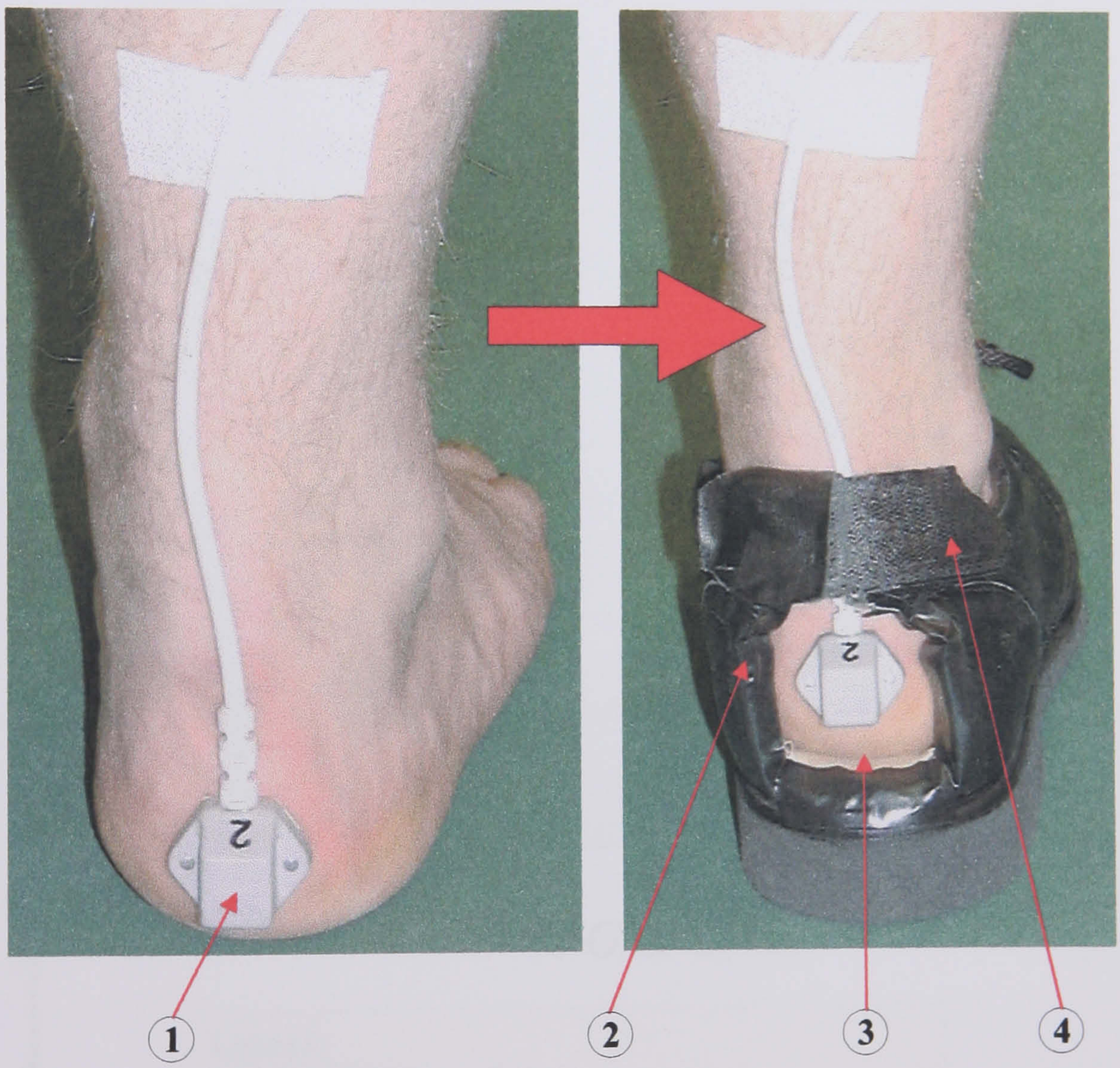


1- subject in line of progression; 2- electromagnetic transmitter on support stand; 3- transmitter reference frame; 4- electromagnetic field (750mm radius from transmitter) in which accurate measures can be made; 5- tibial sensor and reference frame; 6- calcaneus sensor and reference frame; 7- motion capture unit and event detection unit; 8- PC with 6D RESEARCH software.

Figure 3-6: Arrangement diagram of data capture set-up.

3.2.4.3 Advancement to in-shoe measurement

To expand the clinical usefulness of EM tracking the technique required adaptation to measure kinematics of the AJC in shod and orthotic conditions. Previous studies suggest that markers placed externally on the shoe do not represent accurately the underlying kinematics of the calcaneus (Stacoff *et al.*, 1992; Reinschmidt *et al.*, 1992 and 1997; Rendall *et al.*, 1999). Therefore we modified a standard shoe by cutting out a rear window, the opening of which was secured by Velcro fastening (Figure 3-7). In shod conditions the Velcro heel strap permitted entry and removal of the foot to the shoe without disturbing the boresight orientation.



1- Distal sensor attached to posterior calcaneal surface
2- Stock shoe
3- Adaptation created by cutting out window over the heel counter region approximately 50mm X 50mm. Edges reinforced with flexible tape.
4- Heel counter split to provide open heel access and secured with Velcro fastening system

Figure 3-7: Footwear adaptation to facilitate in-shoe calcaneal sensor placement

3.2.4.4 Core set of kinematic variables for ankle joint complex

Preliminary data analysis combined with data from the literature were used to identify a core set of kinematic variables for AJC orientation related to motion curve parameters and gait cycle intervals (Figure 3-8). Using frontal plane motion as an example curve parameter variables identified were maximum eversion, time to maximum eversion, maximum inversion, time to maximum inversion and range of motion. For gait cycle intervals orientation at heel strike, foot flat, mid stance, heel lift and toe-off were identified.

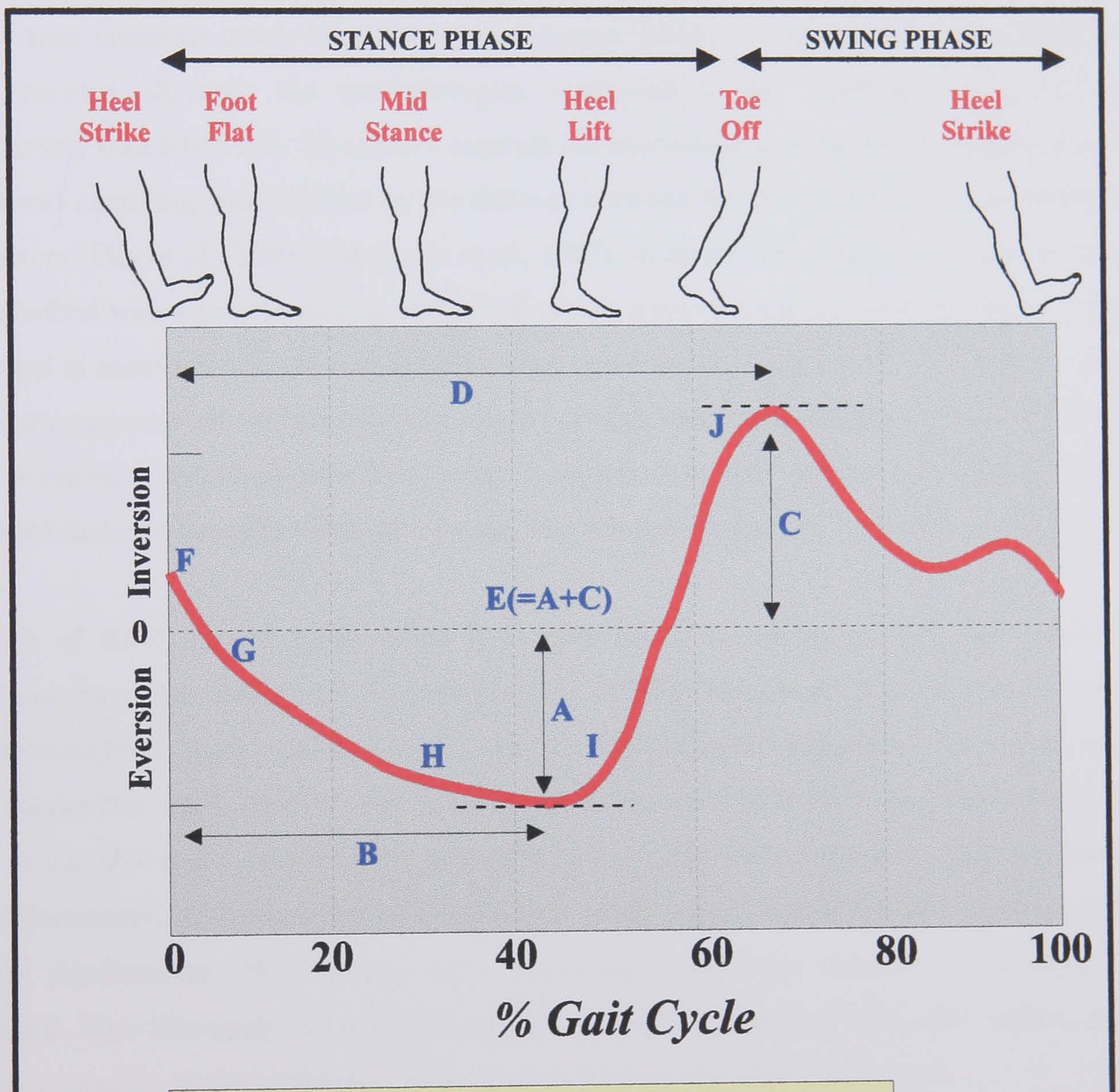


Figure 3-8: Kinematic variable core-set with example provided for frontal plane rotation at the ankle joint complex.

3.3 Accuracy of the electromagnetic tracking system

3.3.1 Background

Fastrak® (Polhemus Inc, Colchester, Vermont, USA) are third-generation three-axis magnetic sensors, ready to use after factory calibration with a reported accuracy of 0.15° root mean square (RMS) in rotation and 0.76mm RMS in translation. A number of groups have independently validated Fastrak® (and earlier versions) and their findings are reported in table 3-3. In most instances errors of <1° root mean square (RMS) in rotation and <1mm RMS have been reported although the methodologies employed in the validation exercises vary considerably (see table 3-3). To achieve accurate measurements data have to be captured within an optimal operating zone defined by the distance between the electromagnetic transmitter and the sensors (Day *et al.*, 2000; Kobayashi *et al.*, 1997). In most studies quasi-static test protocols are described where joint motion is performed within a pre-defined test volume. This is simple to control in cadaveric studies with fixed test-rigs and overcome in clinical studies by mounting the electromagnetic transmitter and receivers on or very near the patient (see table 3-1). Finally EMT is sensitive to interference from metallic objects in or near the electromagnetic field, an important factor to consider when developing both laboratory and clinical test protocols.

The use of EMT in gait applications is a more recent development and two contrasting techniques have been developed. Kobayashi *et al.*, (1997); Mannon *et al.*, (1997) and Cornwall and McPoil (1999) used tracking sensors to define limb segments and walked the subject past a fixed transmitter whilst Rendall and Abboud (1999) mounted both the transmitter via a special brace to the tibia and a sensor to the calcaneus or shoe. The fixed transmitter option limits the spatial parameters of data collection to one single stride or step, whilst the dual-mounted option appears cumbersome. Nonetheless, both techniques have been reported as accurate and repeatable. Our laboratory has adopted a fixed transmitter approach and what follows are a number of studies investigating the accuracy and repeatability of the technique.

Table 3-3: Independent validation of accuracy and precision of electromagnetic sensors. Note: Fastrak is a third generation sensor; its predecessors are Isotrak and Tracker, all manufactured by Polhemus Inc.

Author & Year	Sensor type	Method	Results
Polhemus Inc	FASTRAK & ISOTRAK	Polhemus test gimbal (Polhemus application note APB8500-001A (1992) calibrated with national Bureau of Standards certified tools. 5 repeated measurements of 11 angles at 27 positions at distance ranges of 200mm, 400mm and 600mm	Isotrak (operating < 762mm)= 6.4mm RMS translation, 0.85degrees rotation Fastrak (operating <762mm)= 0.76mm RMS translation, 0.15 degrees rotation
Skill Technologies Inc	FASTRAK	Using the Polhemus gimbal, 14 motion protocols were performed at a set distance of 406mm from source, modelling 5 degree step-through input rotations for cervical spine motion (±45 degrees)	Mean RMS 0.19 degrees (range-0.05 – 0.44 degrees)
Day *et al.*, (2000)	FASTRAK	Sensors mounted on calibration frame and jig and orientation and position measured at increasing distances (8640 data points) from source with short- and long-range transmitters.	Short-range transmitter errors less than 1.2mm and 1.2 degrees up to 1.2m from transmitter. Long-range transmitter errors less than 1.8mm and 1.2 degrees up to 1.8m from transmitter.
Sands *et al.*, (1998)	FASTRAK	Unspecified custom-fabricated apparatus allowing input of precise rotations and translations of FASTRAK sensors	Accuracy (defined as the ratio of measured output to known input in the same direction) ranged from 0.944 to 1.006 in rotation and 0.996 to 1.045 in translation.
Kobayashi *et al.*, (1997)	FASTRAK	Sensors mounted on plastic blocks at vertical heights representative of the pelvis, thigh, leg and foot. Cartesian co-ordinates measured ±1200mm from transmitter. Orientation measured by sensors mounted on the arms of goniometers. Multiple trials conducted at different orientation positions up to ±12000mm from source	Cartesian co-ordinate measurement error for x, y and z < 20mm. Error in angular measurements for sagittal, coronal and transverse planes <1.0 degree
Luo *et al.*, (1996)	ISOTRAK	Technique unspecified	At sensor source separation distances between 100-200mm, RMS error in translation is 0.2mm and 0.5 degrees RMS in rotation
McKellop *et al.*, (1993)	ISOTRAK	Sensors were mounted on a Plexiglas jig, placed in a servohydraulic test-frame on which precise sets of translations and orientations were input	Spatial accuracy defined as 0.3mm for translation and 0.3 degrees for rotation
Zoghi *et al.*, (1992), Hefzy *et al.*, (1992), Hefzy *et al.*, (1994)	ISOTRAK	An instrumented Plexiglas stand was developed with markers precisely located on fixed and moving blocks. The process consisted of digitising these markers. Orientation error calculation not specified	The mean maximum position error did not exceed 0.9mm. The error in orientation did not exceed 0.3 degrees
Sidles *et al.*, (1988)	ISOTRAK	10-cm Plexiglas cube with 14 fiducial points etched on its faces, the co-ordinates of which were known to ±0.025mm. These points were digitised using a sensor mounted in a stylus in three independent trials.	RMS error in measured fiducial point position over three trials was 0.38, 0.31 and 0.37mm. Maximal error were 0.59, 0.62, and 0.58mm

3.3.2 Method

3.3.2.1 Ankle joint complex model construction

A 1:1 scale model of the AJC was manufactured in Perspex and consisted of a proximal tibial shaft and a distal calcaneal block, separated by a joint mechanism (figure 3-9 and 3-10). Sensors were rigidly fixed to both these sections at the equivalent mid-tibial shaft and posterior calcaneal region relative to the ground and to each other in the x, y and z directions using our own anthropometric data and those from Vaughan (1992). Referring to figures 3-9 and 3-10, the

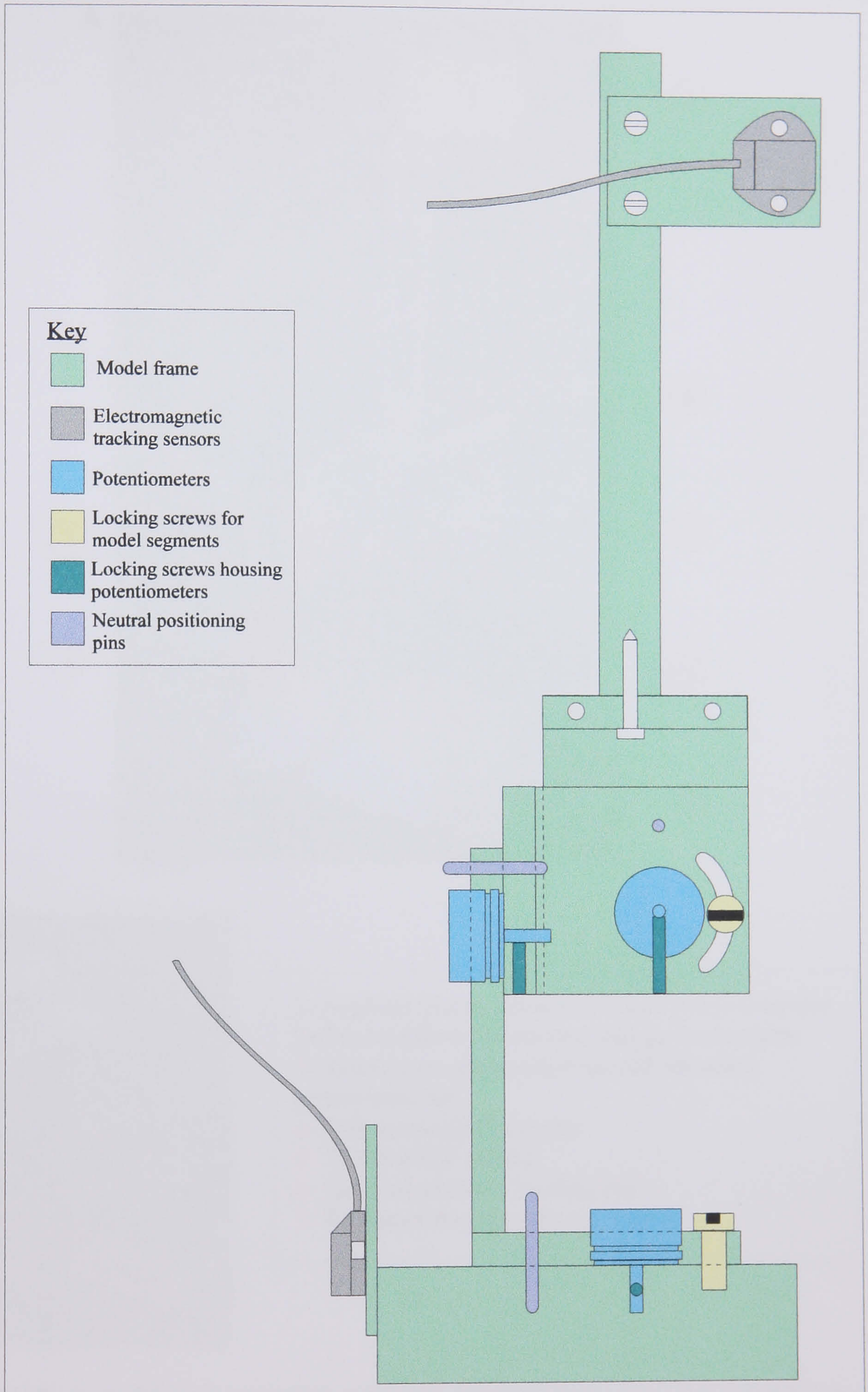
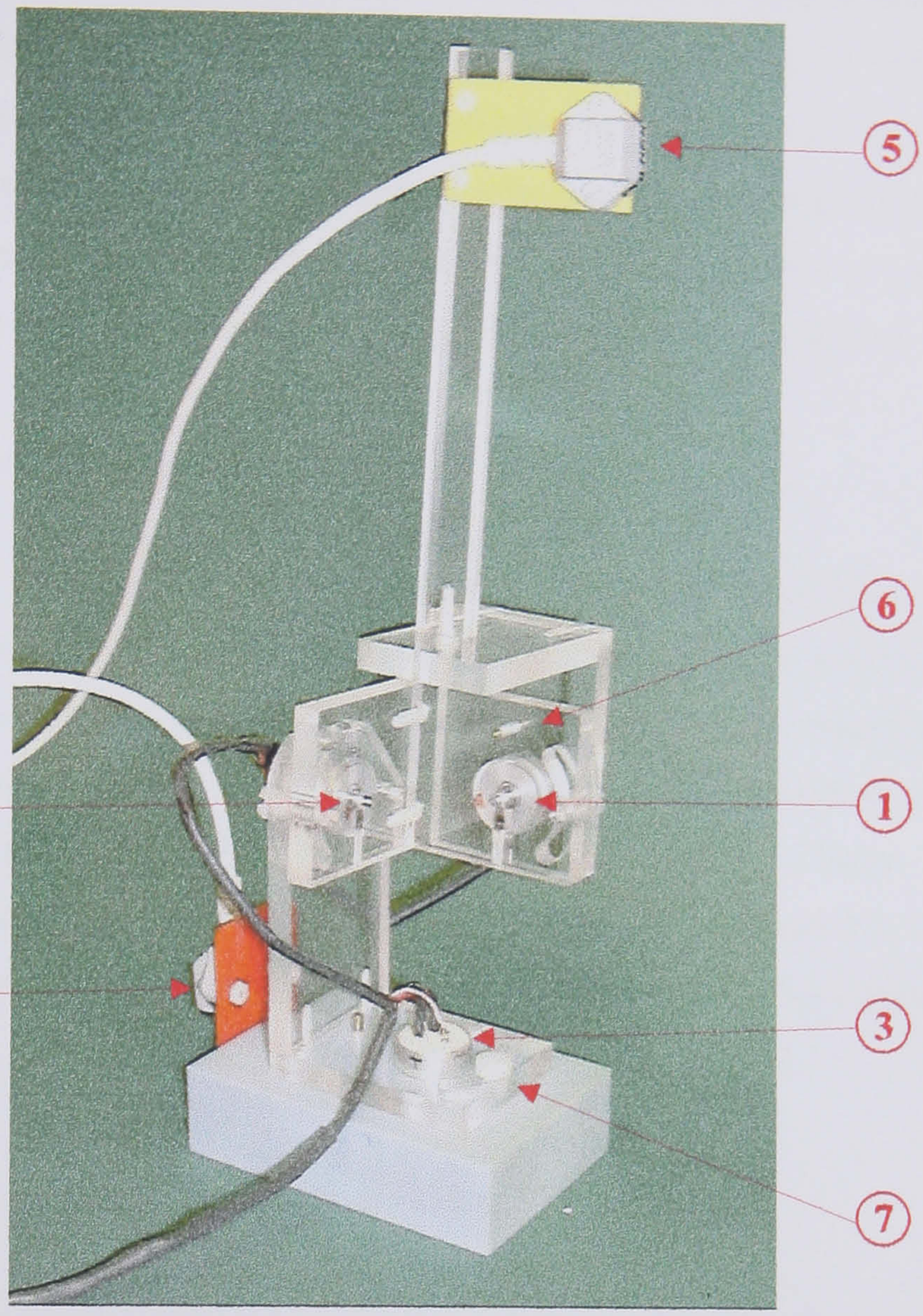


Figure 3-9: Arrangement diagram of the main assemblies of the ankle joint complex model (side elevation)

A



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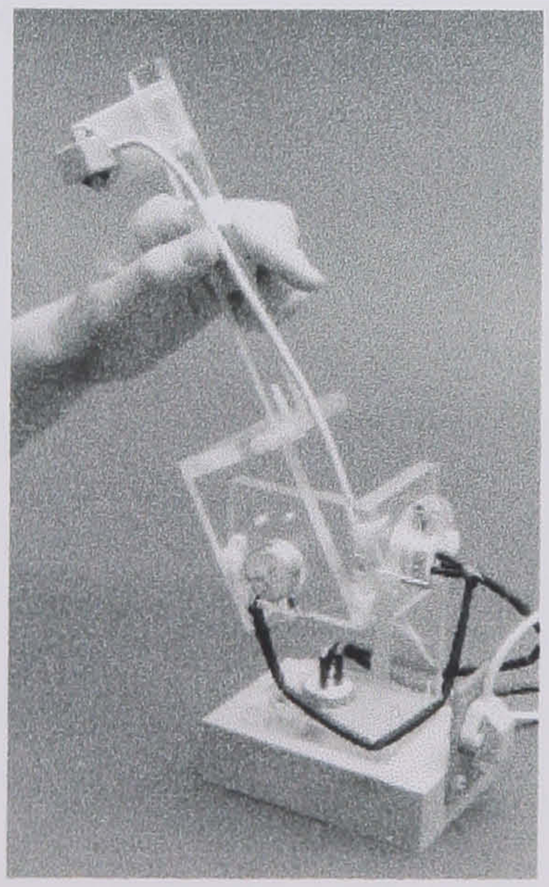


1- Sagittal (dorsi-/plantarflexion) potentiometer
2- Frontal (inversion/eversion) potentiometer
3- Transverse (internal/external rotation) potentiometer
4- Calcaneal EMT sensor
5- Tibial EMT sensor
6- Neutral position locking pin
7- Range of motion guiding screw

Figure 3-10: A- Ankle joint complex model, B- Manual input rotation about the x-axis for dorsi/plantarflexion

joint mechanism was formed by 3 'L'-shaped Perspex sections each housing a precision potentiometer (RS Components Ltd, Corby, Northants, UK), the arm of which linked two adjacent sections. The arrangement permitted restricted rotations (up to ±45° from neutral) about 3 mutually orthogonal axes. A locking mechanism allowed repeatable neutral joint alignment between tests. To calibrate each potentiometer voltage output was measured against angular rotation up to ±45° in 1° increments using a dividing head tool (figure 3-11).

3.3.2.2 Test-grid platform construction

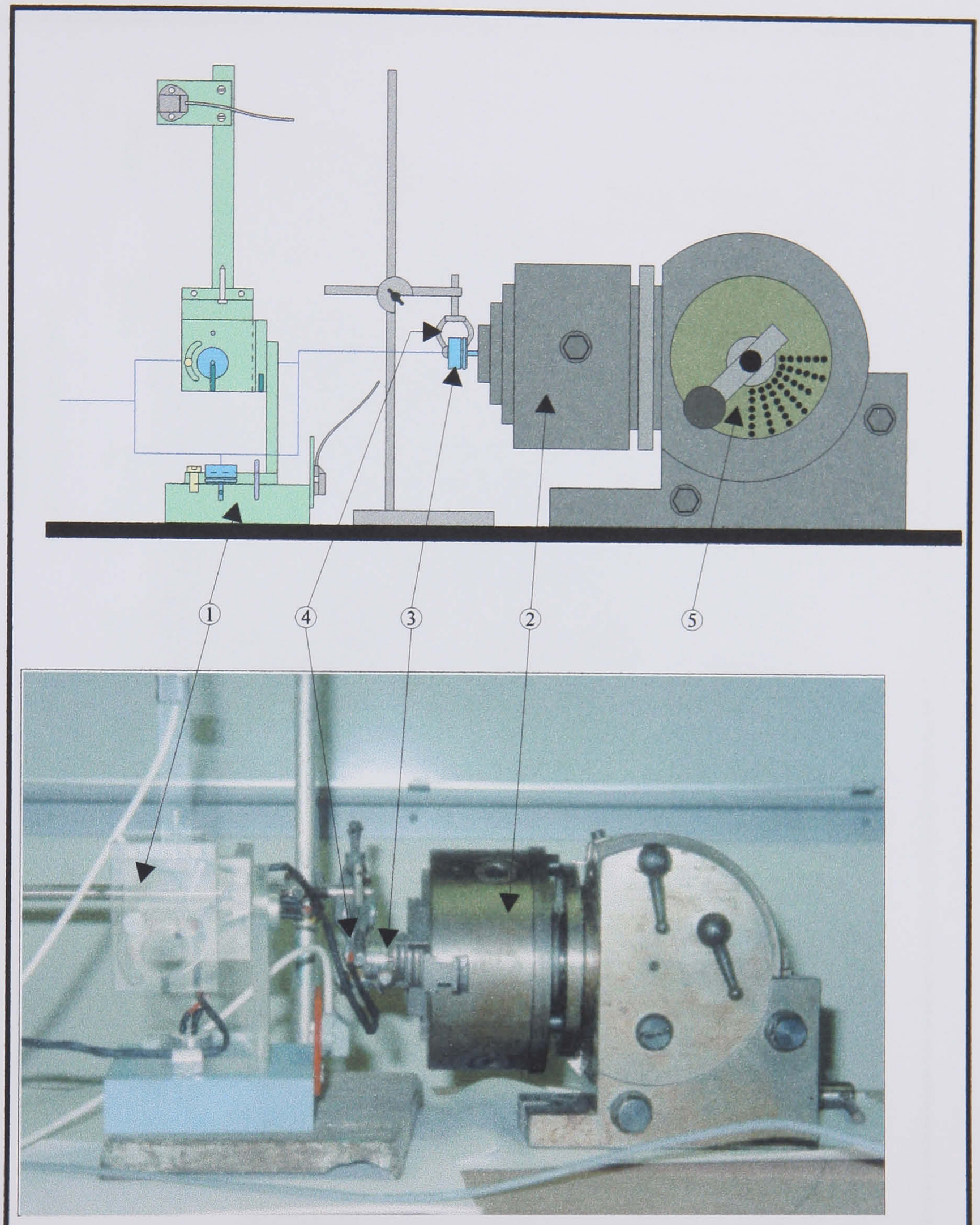
Tests were conducted within half of the available electromagnetic quartersphere using a test grid constructed in fibreboard. The electromagnetic transmitter was fixed on a Plexiglas stand with x, y, z positional co-ordinates of 0, 0, 137.5mm respectively (the z co-ordinate being mid-position between the 'calcaneal' and 'tibial' sensors). Sixteen simulated foot placement positions were marked on the grid in 4 zones at radial distances of 250mm from the 0 xy transmitter origin and along lines subtending angles of 0°, 30°, 60° and 90° with the y-axis (figure 3-12). The undersurface of the AJC model contained two pegs that slotted securely into slots on the test-grid.

3.3.2.3 Electromagnetic tracking system

The 6D RESEARCH system (Skill Technologies Inc, Phoenix, Arizona, USA) as previously described was used in this study.

3.3.2.4 Accuracy of positional measurements

The AJC model was locked in a neutral position and a software driven, 'boresight' procedure undertaken, to rotate and align the axis reference frames for the transmitter and sensors. At each foot placement position 3 measurements were made in a randomly generated sequence. The initial 3 seconds of captured data was then extracted and means of the x, y, and z co-ordinates determined for both sensors. Since the dimensions of the ankle model and the test grid were known, error was calculated by subtracting the measured co-ordinate value from the corresponding known value. The separation distance of the sensors on the fixed model, which should remain constant, was also known and error in its measurement was also determined.



Key

1- Ankle joint complex model.
2- Dividing head apparatus.
3- Potentiometer located within dividing head.
4- Clamp to lock potentiometer during input rotations.
5- Rotation apparatus on dividing head (hidden on photograph).

Figure 3-11: Arrangement diagram and photograph of dividing head apparatus used to calibrate potentiometers in ankle joint complex model.

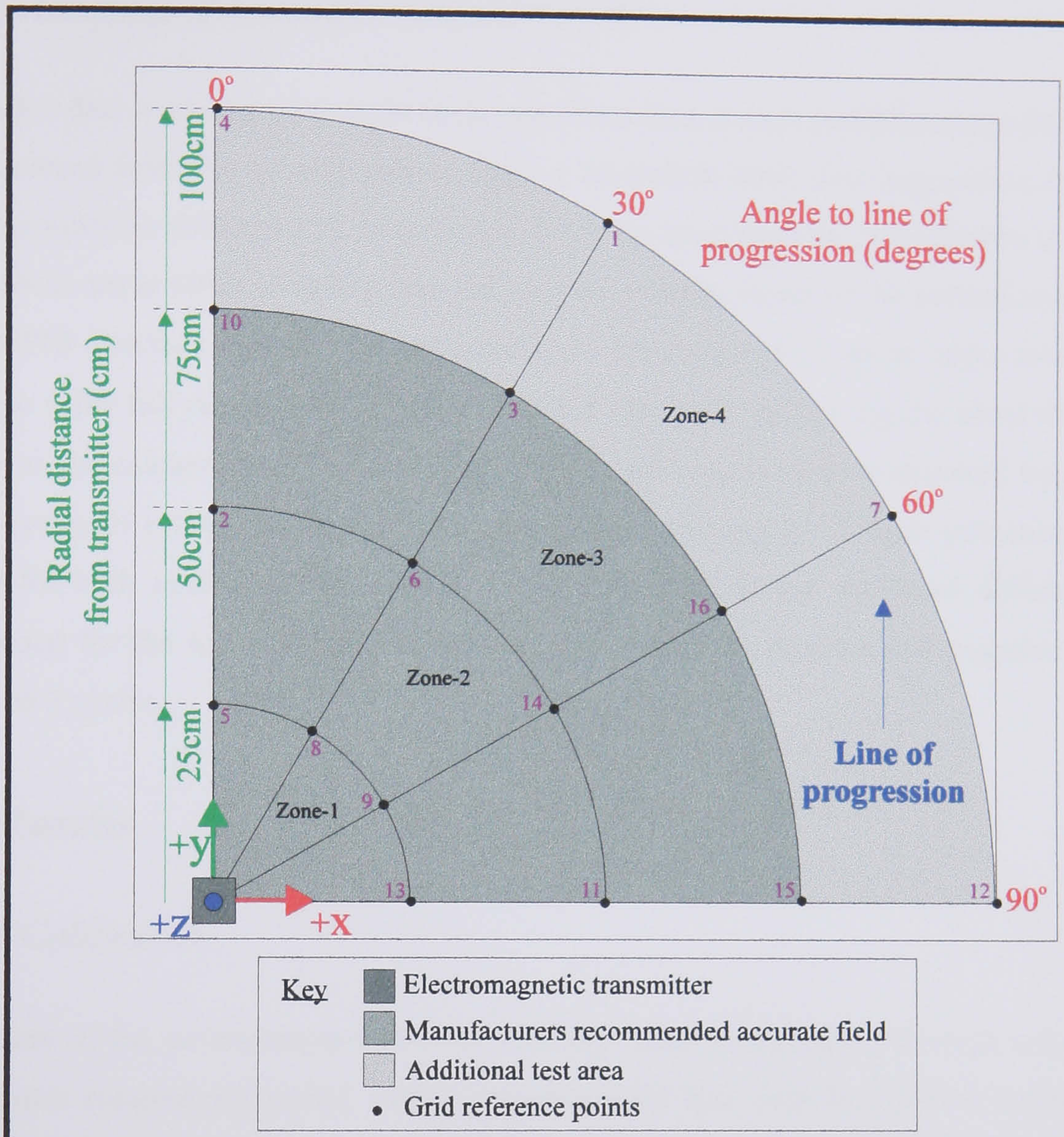


Figure 3-12: Arrangement diagram of the test grid (top and side elevation) and orientation of EM transmitter relative to grid.

3.3.2.5 Accuracy of orientation measurements

Orientation data were captured about each axis of rotation at each foot placement position. Data were captured from the potentiometers using a Microlink 4000 data acquisition system with Wavecap software (Biodata Ltd, Manchester, UK). An input module controlled by a 4010 time-base module set at 60Hz sampling rate sampled the voltage signal of the potentiometers. A PC with a GPIB interface card was used to control the data acquisition set-up. Input rotations from neutral to ± the full range of motion were effected manually by moving the tibial shaft section relative to the calcaneal section. Data output from both systems were matched by time point over 3 cycles of rotation with error, calculated by subtracting EMT from potentiometer data, derived for each point. Average error expressed as RMS of the measured differences were summarised for the full ROM and at 15° increments in both positive and negative directions across the 3 cycles.

3.3.3 Results

3.3.3.1 Calibration

Calibration of the potentiometers showed a strong linear relationship between voltage output and angular rotation permitting simple conversion of this data for further analysis (x-axis potentiometer: $Y= 0.001 + 0.012X$, $R^2= 0.999$, $P<0.001$, y-axis potentiometer: $Y= -0.002 + 0.013X$, $R^2= 0.999$, $P<0.001$, z-axis potentiometer: $Y= 0.001 + 0.013X$, $R^2= 0.999$, $P<0.001$, figure 3-13).

3.3.3.2 Positional data

At zone-1, for both sensors, no difference was observed between actual and measured co-ordinates in 11/24 grid points (table 3-4). At 13 grid locations where errors occurred this was systematic error at 9 and random error at 4 locations (mean error 1.0mm, SD= 0.6mm). At 4/12 positions accurate sensor separation measurements were observed. In 8 positions error ranged from 0.3mm-1.7mm but in 6 of these the error was systematic across 3 repeated measures. For combined data, mean error in zone-1 for the tibial and calcaneal sensors was 0.7mm and 1.1mm respectively (table 3-5).

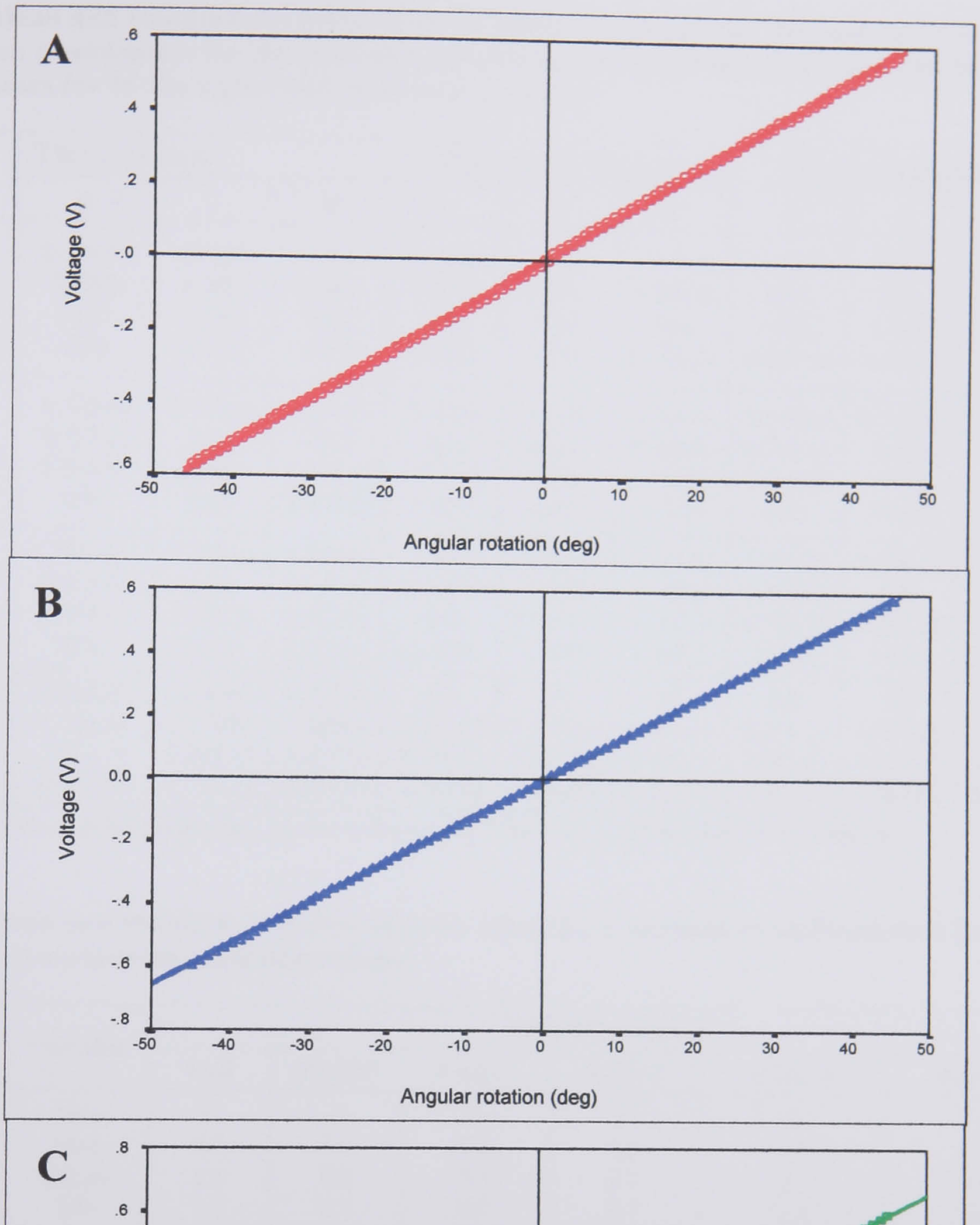


Figure 3-13: Relationship (regression line with 95% confidence interval of the slope) between angular rotation (deg), delivered in 1 increment using dividing head apparatus, and voltage output (V) for X (A), Y (B), and Z (C) potentiometers.

Table 3-4: Mean and standard deviation of error (mm) between actual and measured x, y & z Cartesian co-ordinates for the tibial and calcaneal sensors and the separation distance between sensors for 16 simulated foot placement positions.

Zone	ϕ	Tibial Sensor			Calcaneal Sensor			Sensor Separation		
		x	y	z	x	y	z	x	y	z
1	0	0.7(0.6)	1.0(0)	2.0(0)	2.0(0)	0(0)	2.7(0.6)	1.7(0.6)	0(0)	1.0(0)
	30	2.0(0)	1.0(0)	1.0(0)	3.0(0)	0(0)	1.7(0.6)	0(0)	0(0)	1.0(0)
	60	0(0)	0(0)	0(0)	0(0)	0(0)	0(0)	1.0(0)	1.0(0)	0(0)
	90	0(0)	1.0(0)	0(0)	3.0(0)	0(0)	0.7(0.6)	0.3(0.6)	0.3(0.6)	1.0(0)
2	0	0.7(0.6)	0.7(0.6)	2.7(1.2)	2.0(0)	1.0(0)	2.7(0.6)	2.3(0.6)	0.7(0.6)	0.7(0.6)
	30	0.3(0.6)	0(0)	0(0)	0(0)	0(0)	0.7(0.6)	0.7(0.6)	1.0(0)	1.0(0)
	60	0.3(0.6)	0(0)	1.3(0.6)	1.7(1.2)	0(0)	2.0(0)	0.3(0.6)	1.0(0)	0.7(0.6)
	90	0(0)	0(0)	2.3(0.6)	1.0(0)	0(0)	3.0(0)	0(0)	1.0(0)	0.7(0.6)
3	0	1.791.2)	0.7(0.6)	1.3(0.6)	2.0(0)	1.0(0)	1.7(0.6)	1.3(1.2)	0.7(0.6)	0.7(0.6)
	30	0.7(0.6)	0(0)	1.0(1.0)	1.3(0.6)	1.0(0)	1.0(0)	1.7(0.6)	0(0)	1.7(1.2)
	60	0.7(0.6)	1.3(1.2)	2.7(2.1)	0(0)	0.7(0.6)	3.7(1.2)	0.7(0.6)	1.0(1.0)	1.7(0.6)
	90	0(0)	1.0(0)	3.3(1.5)	2.0(0)	1.0(0)	4.7(0.6)	1.0(0)	1.0(0)	2.3(1.2)
4	0	2.0(2.0)	1.0(0)	1.3(2.3)	SE	SE	SE	SE	SE	SE
	30	1.3(0.6)	0.7(0.6)	1.7(0.6)	2.0(2.6)	1.3(0.6)	1.0(1.0)	2.3(1.2)	1.0(1.0)	2.0(0)
	60	2.7(1.5)	2.0(3.5)	3.0(3.5)	0.7(0.6)	1.0(1.0)	6.7(3.1)	4.0(1.0)	3.3(2.5)	3.7(0.6)
	90	0.3(0.6)	1.7(2.1)	4.0(4.4)	8.3(0.6)	4.7(0.6)	8.7(0.6)	1.0(1.0)	1.0(1.0)	6.3(5.0)

ϕ- angle to the line of progression; SE, system error (invalid data collected outside the EM field).

Table 3-5: Mean and standard deviation of error (mm) for combined co-ordinate data for both sensors at various test-grid dimensions.

Sensor	Variable	Grid Dimensions					
		Full	MOOD	Zone-1	Zone-2	Zone-3	Zone-4
Tibial	Min	0	0	0	0	0	0
	Max	9.0	5.0	2.0	4.0	5.0	9.0
	Mean	1.1	0.9	0.7	0.7	1.1	1.8
	SD	1.0	0.9	0.7	0.7	1.0	1.0
Calcaneal	Min	0	0	0	0	0	0
	Max	10.0	5.0	3.0	3.0	5.0	10.0
	Mean	1.8	1.3	1.1	1.1	1.7	3.6
	SD	2.0	1.2	1.3	1.3	1.3	3.2

MOOD= Manufacturers Optimal Operating Distance (up to 750mm sensor-source separation).

In Zone-2 accurate co-ordinate measurements were made at 9/24 grid locations, with no increase in mean error for any single co-ordinate and only an increase in combined mean error for the calcaneal sensor (1.2mm) was observed. For sensor separation error in zone-2, the number of instances of systematic error (11/12) and random error (7/12) over 3 repeated trials increased, as did the magnitude of the error (0.7mm-2.3mm). In zone-3, the outer limit of the optimal operating field, accurate positional measurements were recorded at 3/24 grid locations; and where error occurred the magnitude and variability increased (0.6mm-2.1mm). Mean error at zone-3 increased for the tibial sensor (1.1mm) and for the calcaneal sensor (1.7mm). Sensor

separation distance error increased for all grid locations (0.7mm-2.3mm) in zone-3 with increased variability and only 1 position where an accurate measure was observed.

When the optimal operating field was extended a further 250mm (to 1000mm) at zone-4. random error and variability increased at all grid locations for both sensors. At the tibial sensor random error ranged from 0.7mm-4.0mm with a mean error for combined data of 1.8mm. For the calcaneal sensor no data were available for foot-strike position-4, the system detecting invalid data collection outside the EMT field. For all other positions error ranged from 0.7mm-8.7mm with a mean error for combined data of 3.6mm (SD- 3.2mm). The sensor separation distance errors also increased in magnitude (1.0mm-6.3mm) and were more variable (SD-0.6mm-5.0mm) at zone-4.

3.3.3.3 Orientation data

Visual inspection of the overlay plots suggested that the EM system could accurately track the orientation angles of the AJC model through simulated rotations (figure 3-14). Root mean square error averaged across all axes of rotation ranged from 0.70° in zone-1 to 0.96° in zone-4 (table 3-6, figure 3-15). Staying within the optimal operating distance of 750mm (zone-3) gave an average RMS error of 0.72°. In general RMS error increased from zone-1 to zone-4 for most axes of rotation when examined separately. Around the x-axis RMS error in dorsiflexion increased from 0.61° (zone-1) to 0.84° (zone-4) and in plantarflexion from 0.60° to 0.83°. Around the y-axis RMS error ranged from 0.59° (zone-1) to 1.04° (zone-4) for inversion and from 0.64° to 1.19° for eversion. Root mean square error around the z-axis varied by only 0.07° across the whole grid from zone-2 (0.78°) to zone-1 (0.85°) for internal rotation and by 0.10° from zone-2 (0.83°) to zone-4 (0.93°) for external rotation.

Further analysis of the data by dividing the ROM into 15° increments was conducted. In zones 1-3 for all axes of rotation we observed no consistent relationship between magnitude of RMS error and ROM (table 3-7, figure3-16). By axis of rotation and ROM the largest RMS error occurred on 11/17 occasions in zone-4. Here in contrast with other zones the RMS error consistently increased as the ROM increased about all axes of rotation. Differences in the minimum and maximum RMS error across the ROM ranged from 0.18° to 0.35° for the x-axis in dorsiflexion and from 0.10° to 0.18° in plantarflexion for zones 1-3. In zone-4 RMS error increased as the ROM increased from 0.59° to 1.02° for dorsiflexion and from 0.74° to 0.89° for plantarflexion.

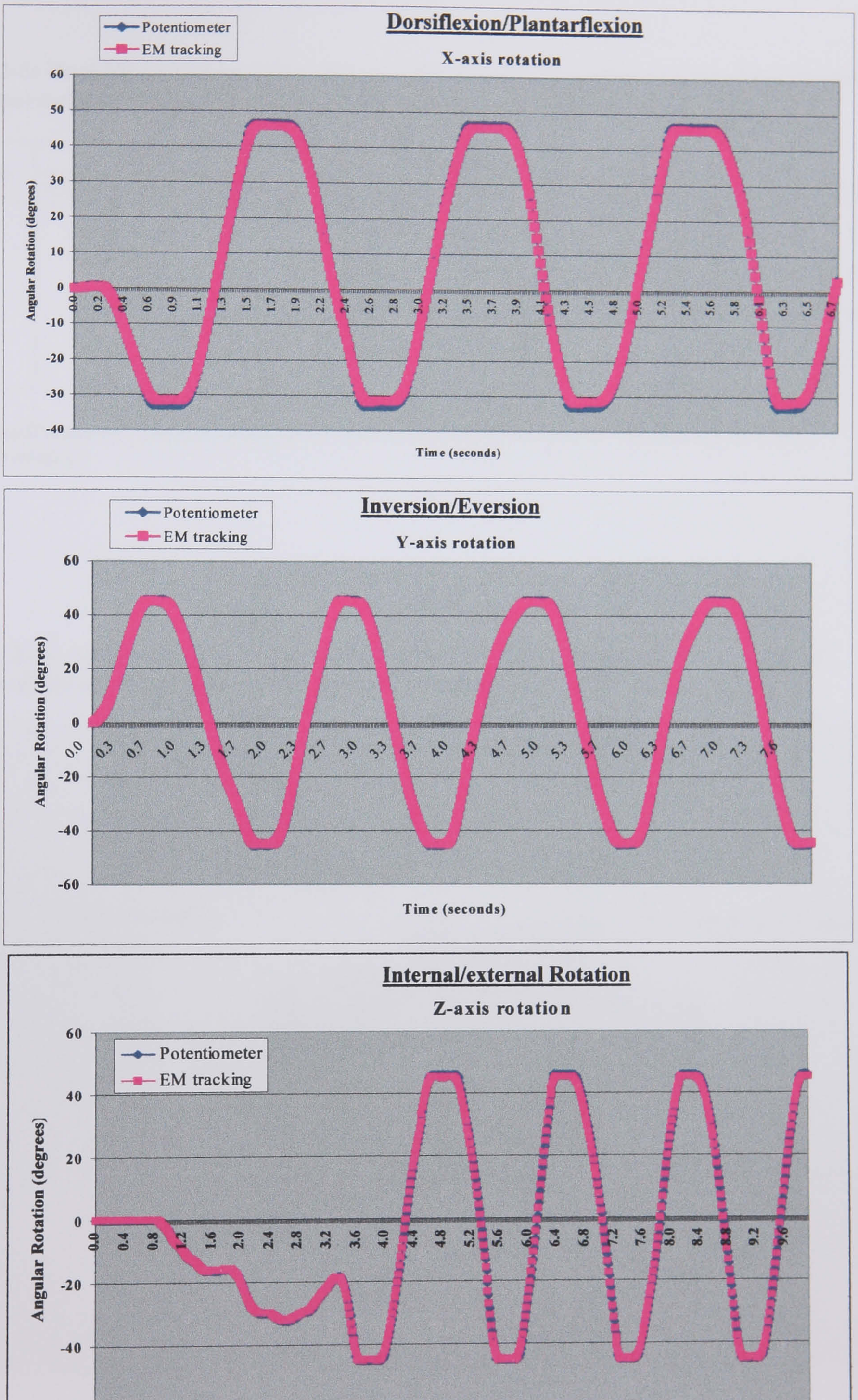


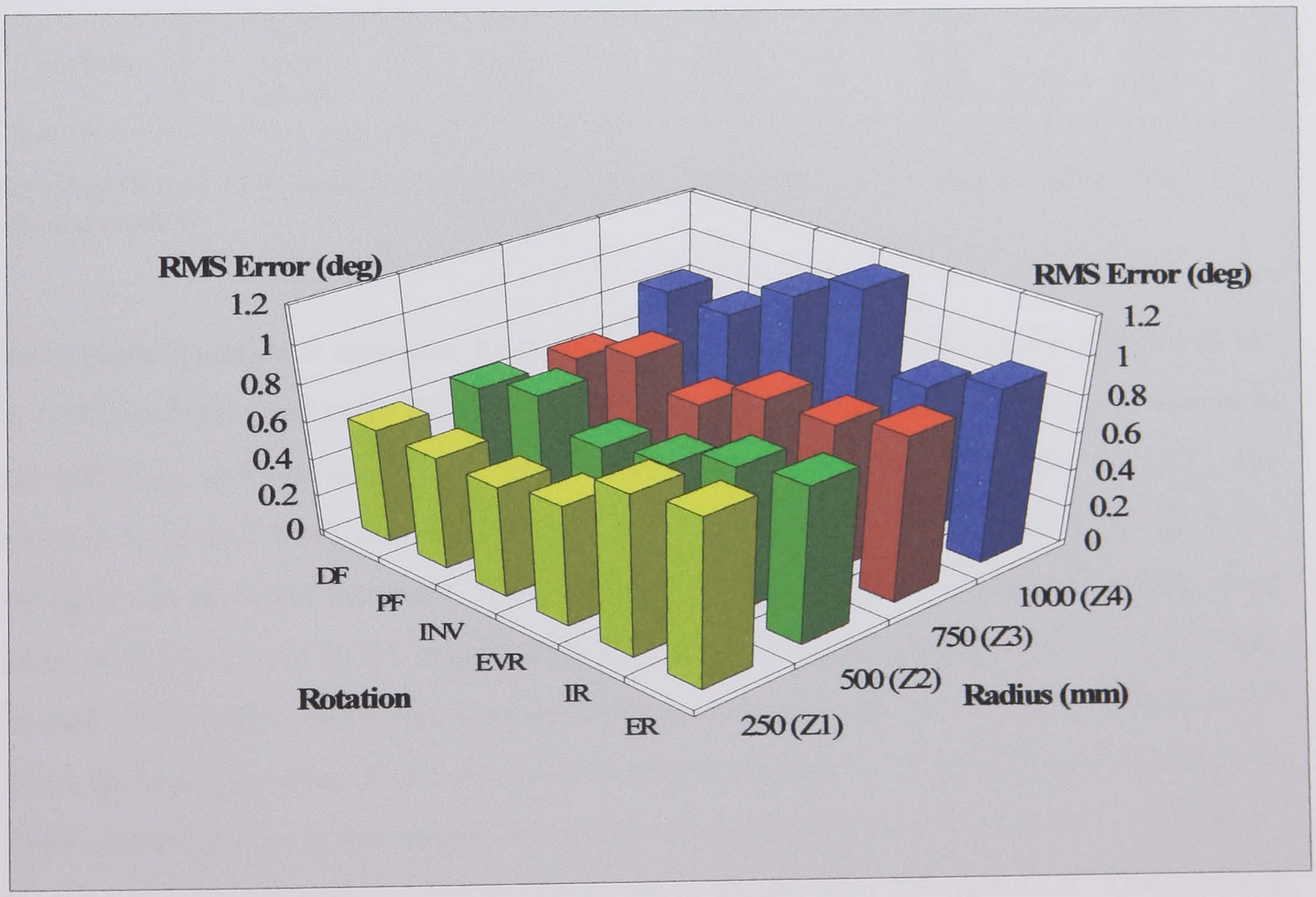
Figure 3-14: Examples of overlay plots for each axis of rotation for combined Potentiometer and EM tracking data.

Table 3-6: Root Mean Square error (degrees) for 3 cycles of motion combined for all axes and separately for single axis rotations summarised by test zone.

Zone	Rotation						
	Combined	DF	PF	INV	EVR	IR	ER
1	0.70	0.61	0.60	0.59	0.64	0.85	0.89
2	0.69	0.65	0.74	0.60	0.65	0.78	0.83
3	0.76	0.64	0.77	0.64	0.80	0.80	0.88
4	0.96	0.84	0.83	1.04	1.19	0.81	0.93

DF= dorsiflexion, PF= plantarflexion, INV= inversion, EVR= Eversion, IR= internal rotation, ER= external rotation.

Figure 3-15: 3D-riser plot of RMS error (degrees) for data combined for full range of motion about each axis summarised by test-grid zone.



DF= dorsiflexion, PF= plantarflexion, INV= inversion, EVR= Eversion, IR= internal rotation, ER= external rotation.

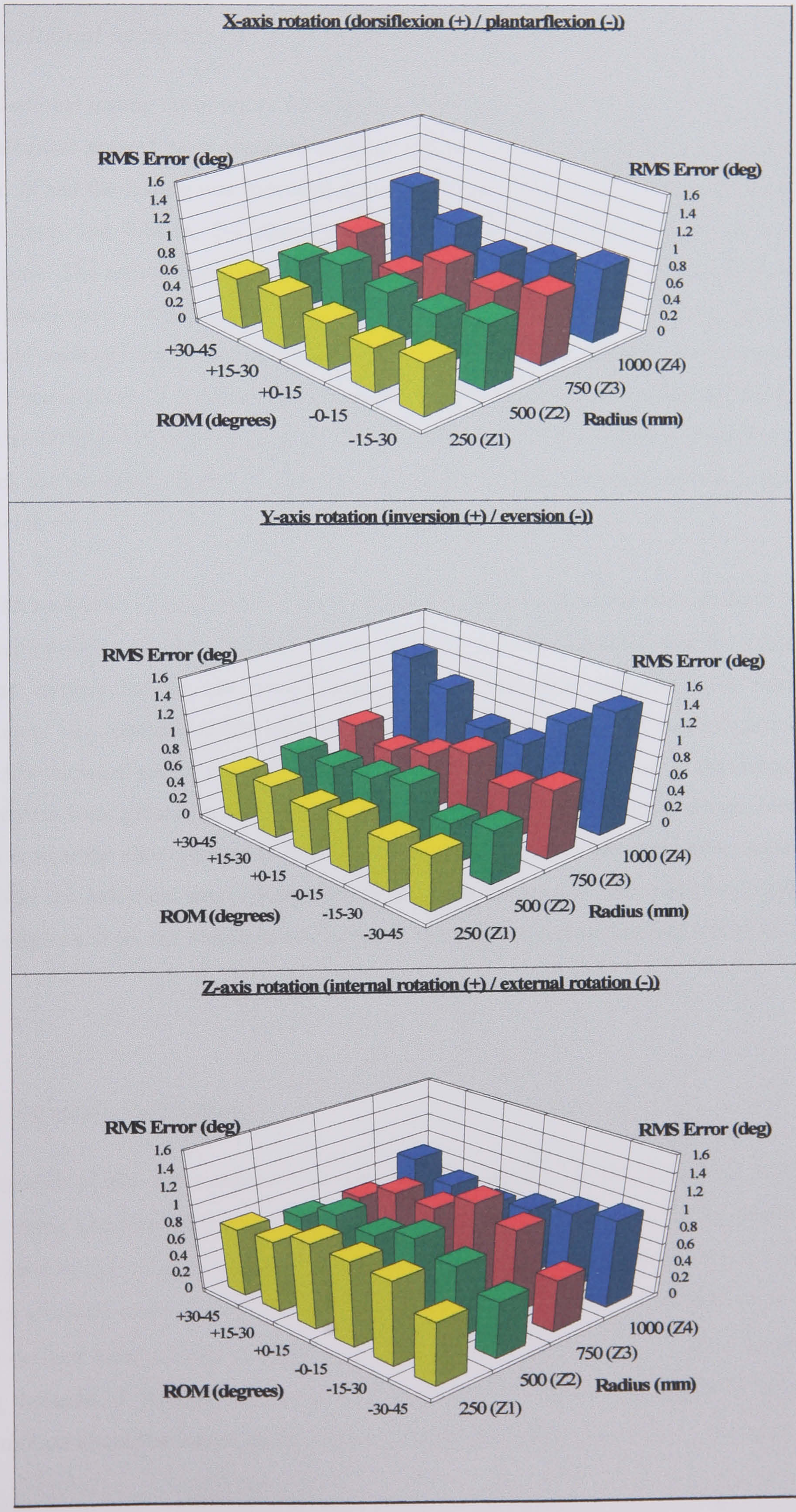
Table 3-7. Root Mean Square (RMS) error (degrees) for defined ranges of motion about each axis summarised by test zone.

Axis of Rotation	RMS Error				
	ROM	Zone-1	Zone-2	Zone-3	Zone-4
X+ (DF)	0-15 15-30 30-45	0.57 0.64 0.61	0.66 0.75 0.58	0.75 0.40 0.69	0.59 0.77 1.02
X-(PF)	0-15 15-30 30-45	0.54 0.64 -	0.65 0.79 -	0.66 0.84 -	0.74 0.89 -
Y+(Inv)	0-15 15-30 30-45	0.56 0.62 0.58	0.65 0.60 0.58	0.67 0.54 0.68	0.74 1.06 1.28
y-(Evr)	0-15 15-30 30-45	0.66 0.60 0.66	0.77 0.51 0.64	0.87 0.65 0.82	0.73 1.14 1.44
Z+(IR)	0-15 15-30 30-45	0.99 0.82 0.78	0.82 0.88 0.68	0.88 0.89 0.67	0.68 0.75 0.91
z-(ER)	0-15 15-30 30-45	0.98 0.97 0.73	0.97 0.85 0.65	1.11 0.98 0.60	0.79 0.92 1.01

DF= dorsiflexion, PF= plantarflexion, INV= inversion, EVR= Eversion, IR= internal rotation, ER= external rotation.

For y-axis orientation in inversion, RMS error was always greatest at zone-4 for all ROM (0.74° to 1.28°) and increased as the ROM increased. Within the optimal operating field differences in the minimum and maximum RMS error across the ROM ranged from 0.06° to 0.13°. For eversion in zone-4 RMS error ranged from 0.73° to 1.44°, the largest error in the database, increasing as the ROM increased. Within zones 1-3 differences in the minimum and maximum RMS error across the ROM ranged from 0.06° to 0.26°. In comparison with x and y axis rotation, Z axis RMS error was consistently higher across zones 1-3 in the 0-15° and 15-30° ROM divisions for internal and external rotation. Differences in the minimum and maximum RMS error across the ROM ranged from 0.14° to 0.21° for internal rotation and 0.25° to 0.51° for external rotation within zones 1-3. Root mean square error consistently decreased as the ROM increased in zones 1-3 with an opposite effect in zone-4.

Figure 3-16: 3D-riser plot of RMS error (degrees) plots defined by axis of rotation with data summarised by range of motion (ROM) and zone.



3.3.4 Discussion

3.3.4.1 Positional accuracy

In static positional testing mean errors for combined data of between 0.9mm (tibial sensor) and 1.3mm (calcaneal sensor) were observed at distances up to 750mm from the electromagnetic transmitter. When the testing was extended a further 250mm (to 1000mm) errors increased to between 1.8mm and 3.6mm, 2-3 times greater than those determined within the optimal operating zone. The sensor separation distance error was greater than that for any single sensor in all test positions, a combination of error from both sensors. The AJC model was physically removed and replaced between trials and we were encouraged to observe many repeatable measures. Systematic error was observed at a number of grid-points, in the order of 1.0-3.0mm, and this was attributed to both the manufacturing tolerance for both the test-grid platform and AJC model and the ability of the examiner to reposition the model correctly between repeated measurements.

System errors detected via the software occurred for the calcaneal sensor at the outermost 'foot-strike' position along the line of progression. Here the software detected that the calcaneal sensor had moved outside the electromagnetic field and data captured were rejected. Measurements were possible at this location for the tibial sensor because it was located 17mm medial to the calcaneal sensor and fell within the electromagnetic field. Errors in the calculation of position data were greater in all directions and at all zones for the calcaneal sensor. Metallic objects in or near the electromagnetic field can cause distortions that adversely affect accuracy. In our model the calcaneal sensor was close to the joint mechanism and could have suffered some interference from the aluminium housing of the potentiometers and the wiring between them.

3.3.4.2 Orientation accuracy

For orientation angles we conducted simulated joint rotations in the model at each foot placement point and compared data from the potentiometer and EMT systems. Raw data plots gave satisfactory indication of identical dynamic orientation for the two measurement systems, confirming a similar observation by An *et al.*, (1988), for an earlier version of the sensor tested here. We derived a mean RMS error for combined measurements of 0.72° within the optimal operating distance of 750mm. We found no consistent relationship between RMS error and range of motion about the 3 axes up to 750mm transmitter-sensor separation. This is important

for the AJC because although we measured rotations between 30-45° either side of the neutral position, the joint complex has a much smaller ROM during locomotion. Measurement errors of <1° are acceptably small enough for this technique to be used at the AJC and should increase our confidence when examining frontal and transverse plane measurements.

By extending the transmitter-sensor separation to 1000mm, RMS error approached 1.0° as the electromagnetic fields weakened. Furthermore certain tibial displacements at this distance increased the sensor-source separation increasing error as the ROM increased. The manufacturers recommend that small metallic objects be placed at least twice the electromagnetic source-sensor separation distance from either the source or sensor. The largest errors were observed for internal/external rotation (see table 3-6 and figure 3-15), movement that brought two of the potentiometers close to the calcaneal sensor possibly causing disturbance in the electromagnetic field.

3.3.4.3 Comparison with literature data

Calibration techniques adopted elsewhere have used highly accurate instrumentation in the form of precision etched Plexiglas cubes, joint simulators or jigs mounted in servohydraulic test-frames with short sensor-source separation distances and quasi-static protocols. In these studies positional accuracy of between 0.2mm- 0.9mm RMS and orientation accuracy of between 0.3°-0.5° RMS are reported albeit for the earlier Isotrak sensor (Harryman *et al.*, 1990; Hefzy *et al.*, 1995; Luo *et al.*, 1996; McKellop *et al.*, 1993; Zoghi *et al.*, 1992). For the Fastrak® sensor Sands *et al.*, (1998) produced input/output error ratios of 0.944-1.006 in rotation and 0.996-1.045 in translation. The accuracy and precision in our own experiments are slightly less than those reported elsewhere (table 3-3) but very satisfactory and within acceptable limits for the purpose required. The calibration techniques adopted in many of these other studies do not resemble the final test conditions in which clinical data is captured so accuracy may be over-estimated. The approach in this study was pragmatic, set within the gait laboratory and defined specifically for the joint complex to be studied. Accuracy and precision may have been affected by magnetic field distortion caused by metal interference, manufacturing imperfections in the model and test-grid and experimental error during manual input of rotations in a non-rigid Plexiglas model. Magnetic field distortion is known to occur when large metal objects come between the electromagnetic source and sensor, when metal objects are found within the measurement volume and from nearby power lines and electrical equipment (Day *et al.*, 2000; Irby *et al.*, 2000; Milne *et al.*, 1996). Some groups have adopted quantification and correction techniques where reproducible field distortion, adversely affects use, for example from metal-reinforced floors (Day *et al.*, 2000; Kobayashi *et al.*, 1997). Data here was collected in a

Victorian building with wooden floors and brick walls and all large metal objects were removed from the immediate vicinity of testing, following the manufacturers recommendations. This may not be problem in future studies as software is now available to map and correct field distortion within the calibration volume.

The position and angular accuracy from gait-related validation of Fastrak® based systems conducted by Day *et al.*, (2000) and Kobayashi *et al.*, (1997) are close to the findings in this work. Kobayashi *et al.*, (1997) used 4 sensors on a model of the lower limb incorporating the pelvis, thigh, leg and foot. Static positional measurements and incremental rotations with sensors placed on plastic blocks and a goniometer were conducted over a walking surface at varying distances up to ±1200mm sensor-source separation. Accuracy at this distance was found to be insufficient for normal gait applications but when restricted to ±600mm in y direction then errors were reduced for position to <10mm (the technique did no permit exact determination of this parameter) and rotation <1.0°. In comparison we limited our gait model to a single joint complex and reduced the sensor-to-sensor and sensor-to-transmitter distances, which may explain our improved findings. Day *et al.*, (2000) found the operating distance for gait could be extended to 1.8m (3.6m pathway) with the use of a long-range transmitter, maintaining an accuracy of 1.2 degrees in orientation and 18mm in translation, parameters comparable with video-based systems.

3.2.4.4 Practical application and limitations

Electromagnetic tracking provides satisfactory levels of accuracy and precision to measure AJC kinematics. There are advantages over video-based systems such as the need for a single sensor to define a rigid body, no manual digitisation of images and no line of sight required. However, disadvantages were encountered such as presence of trailing wires, metal interference and restricted measurement volume. The measurement distance along the line of progression (1500mm) is sufficient to capture date within the normal population stride characteristics. In older subjects or in those with functional disabilities where stride length and walking speed are reduced, accurate data collection will comfortably encompass a full gait cycle. Since only one stance period can be collected per trial multiple runs are needed to derive summary measurements. The researcher must also look for, or check positional data, to validate a foot-strike within the optimal operating area. This may necessitate the need for floor markings, which, despite creating a larger area than a typical force platform, may introduce related problems such as targeting. In conclusion the EMT technique developed here was found to be accurate enough to allow the technique to undergo pre-clinical testing.

3.4 Intra-observer repeatability

3.4.1 Materials and method

3.4.1.1 Subjects

Gait analysis was undertaken in two groups consisting of:

A- 20 healthy adults (mean age- 48.5 years, SD- 14.4 years, 14 female and 6 male subjects) with no history of musculoskeletal disease or trauma to the lower limb or foot.

B- 20 patients fulfilling the ACR criteria (Arnett et al., 1988) for RA (mean age- 48.2 years, SD- 11.0 years. 18 female and 2 male patients and mean disease duration- 2.8 years, SD-1.5 years).

3.4.1.2 Subject preparation and data collection

Subject preparation was undertaken according to the detailed protocol set out in 3.2.4.2 to 3.2.4.4 under barefoot and shod conditions. There were 5 consecutive trails barefoot, and 5 shod, with the sensors remaining in place throughout (see figure 3-7). All subjects were allowed several test runs to acclimatise to the procedure.

3.4.1.3 Data Analysis

6D-RESEARCH software was used to calculate joint co-ordinate system angles for the right ankle joint complex of each subject and then analysed within 6D-NORM analysis software (Dr M Cornwall, Northern Arizona University, USA) to generate motion time curves, normalised to 100% of gait cycle. Repeatability for the motion time curves was calculated using a statistical technique described by Kadaba *et al.*, (1989) for kinematic, kinetic and EMG data for normal gait. The similarity between waveforms, across the gait cycle, were evaluated using the adjusted coefficient of multiple determination, R_a^2 (Kadaba *et al.*, 1989, Neter *et al.*, 1985, Rawlings *et al.*, 1998) given by:

$$R_a^2 = 1 - \frac{\sum_{i=1}^{M}\sum_{j=1}^{N}\sum_{t=1}^{T}\frac{\left(Y_{ijt} - \overline{Y}_{it}\right)^2}{MT(N-1)}}{\sum_{i=1}^{M}\sum_{j=1}^{N}\sum_{t=1}^{T}\frac{\left(Y_{ijt} - \overline{Y}_{i}\right)^2}{M(NT-1)}} \qquad (1)$$

where Y_{ijt} is the *t*th time point on the *j*th run on the *i*th test day, $\overline{Y}_{it}$ is the average at time point *t* on the *i*th test day (since all experiments for one subject were conducted the same day, *i*=1) where:

$$\overline{Y}_{it} = \frac{1}{N}\sum_{j=1}^{N} Y_{ijt} \qquad (2)$$

$\overline{Y}_i$ is the grand mean on the *i*th day and is given by:

$$\overline{Y}_i = \frac{1}{NT}\sum_{j=1}^{N}\sum_{t=1}^{T} Y_{ijt} \qquad (3)$$

The coefficient of multiple correlation (CMC) is a measure of waveform similarity for a group of curves, and in expression (1), the numerator of the ratio represents the variance about the mean at time point *t* for a particular day. The denominator of the ratio in expression (1), represents the total variability about the grand mean for a particular day. When the waveforms are similar, the numerators of the ratio on the right-hand side in expression (1) tend to 0 and *R* tends to 1. When waveforms are dissimilar, both the numerator and denominator approximately represent the estimate of the same variance and the ratio tends to 1 and R tends to zero. The positive square root of the adjusted coefficient of multiple determination is called the adjusted coefficient of multiple correlation, referred to by Kadaba *et al.*, (1989) as the coefficient of multiple correlation (CMC).

3.4.2 Results

The CMC for the normal and RA subjects for barefoot and shod conditions are presented in tables 3-8 and 3-9, and in figure 3-17. In the normal subjects repeatability was greater for sagittal plane rotations in both barefoot and shod conditions with means of 0.948 and 0.943 respectively. These CMC values also showed the least inter-subject variability demonstrated by the standard deviation and range values. Frontal plane rotation CMC values were excellent for both barefoot and shod conditions- 0.939 and 0.910 respectively. This data was slightly more variable than for sagittal plane rotation especially in shod conditions. Transverse plane rotations were less repeatable but still had mean CMC values of 0.885 and 0.843 for barefoot and shod conditions respectively. On inspection this data shows greater variability especially in shod conditions.

Table 3-8: Coefficient of multiple correlation for the right ankle joint complex sagittal, frontal and transverse rotations under barefoot and shod conditions for 20 healthy individuals.

Subject	Barefoot			Shod		
	Sagittal	Frontal	Transverse	Sagittal	Frontal	Transverse
1	0.971	0.966	0.904	0.962	0.918	0.918
2	0.931	0.962	0.907	0.914	0.889	0.813
3	0.907	0.927	0.876	0.925	0.814	0.907
4	0.948	0.948	0.719	0.951	0.934	0.652
5	0.943	0.923	0.912	0.969	0.900	0.931
6	0.958	0.938	0.805	0.975	0.958	0.847
7	0.955	0.953	0.904	0.965	0.861	0.790
8	0.961	0.926	0.954	0.927	0.939	0.919
9	0.921	0.886	0.887	0.942	0.914	0.807
10	0.950	0.970	0.887	0.971	0.758	0.776
11	0.966	0.943	0.931	0.923	0.894	0.948
12	0.973	0.962	0.851	0.903	0.883	0.735
13	0.926	0.941	0.948	0.951	0.952	0.939
14	0.965	0.950	0.851	0.895	0.915	0.896
15	0.914	0.924	0.913	0.899	0.914	0.903
16	0.961	0.898	0.839	0.946	0.959	0.872
17	0.953	0.902	0.863	0.956	0.933	0.735
18	0.952	0.948	0.931	0.966	0.947	0.898
19	0.948	0.950	0.891	0.954	0.965	0.702
20	0.965	0.958	0.917	0.971	0.952	0.880
MEAN	**0.948**	**0.939**	**0.885**	**0.943**	**0.910**	**0.843**
SD	**0.019**	**0.023**	**0.054**	**0.026**	**0.052**	**0.087**
MIN	**0.907**	**0.886**	**0.719**	**0.895**	**0.758**	**0.652**
MAX	**0.973**	**0.97**	**0.954**	**0.975**	**0.965**	**0.948**

SD- Standard deviation; Min- Minimum CMC; Max- Maximum CMC; Sagittal- dorsi/plantarflexion; Frontal- Inversion/eversion; Transverse- internal/external rotation.

Table 3-9: Coefficient of multiple correlation for the right ankle joint complex sagittal, frontal and transverse rotations under barefoot and shod conditions for 20 rheumatoid arthritis patients.

Subject	Barefoot			Shod		
	Sagittal	Frontal	Transverse	Sagittal	Frontal	Transverse
1	0.954	0.920	0.832	0.929	0.869	0.734
2	0.985	0.970	0.973	0.951	0.951	0.972
3	0.928	0.877	0.754	0.98	0.960	0.925
4	0.916	0.907	0.743	0.86	0.892	0.791
5	0.843	0.880	0.81	0.963	0.904	0.638
6	0.954	0.953	0.813	0.97	0.953	0.790
7	0.97	0.905	0.866	0.959	0.954	0.893
8	0.971	0.866	0.607	0.976	0.897	0.838
9	0.919	0.884	0.905	0.977	0.921	0.861
10	0.953	0.936	0.675	0.975	0.900	0.707
11	0.970	0.963	0.953	0.981	0.953	0.896
12	0.927	0.925	0.936	0.970	0.970	0.917
13	0.902	0.937	0.800	0.960	0.926	0.931
14	0.956	0.979	0.905	0.965	0.911	0.909
15	0.848	0.862	0.498	0.914	0.878	0.548
16	0.963	0.954	0.842	0.970	0.956	0.675
17	0.930	0.856	0.698	0.979	0.783	0.791
18	0.910	0.878	0.872	0.973	0.951	0.847
19	0.971	0.975	0.687	0.931	0.949	0.785
20	0.962	0.962	0.875	0.907	0.862	0.793
MEAN	**0.937**	**0.919**	**0.802**	**0.955**	**0.917**	**0.812**
SD	**0.039**	**0.041**	**0.122**	**0.031**	**0.046**	**0.110**
MIN	**0.843**	**0.856**	**0.498**	**0.860**	**0.783**	**0.548**
MAX	**0.985**	**0.979**	**0.973**	**0.981**	**0.970**	**0.972**

SD- Standard deviation; Min- Minimum CMC; Max- Maximum CMC; Sagittal- dorsi/plantarflexion; Frontal- Inversion/eversion; Transverse- internal/external rotation.

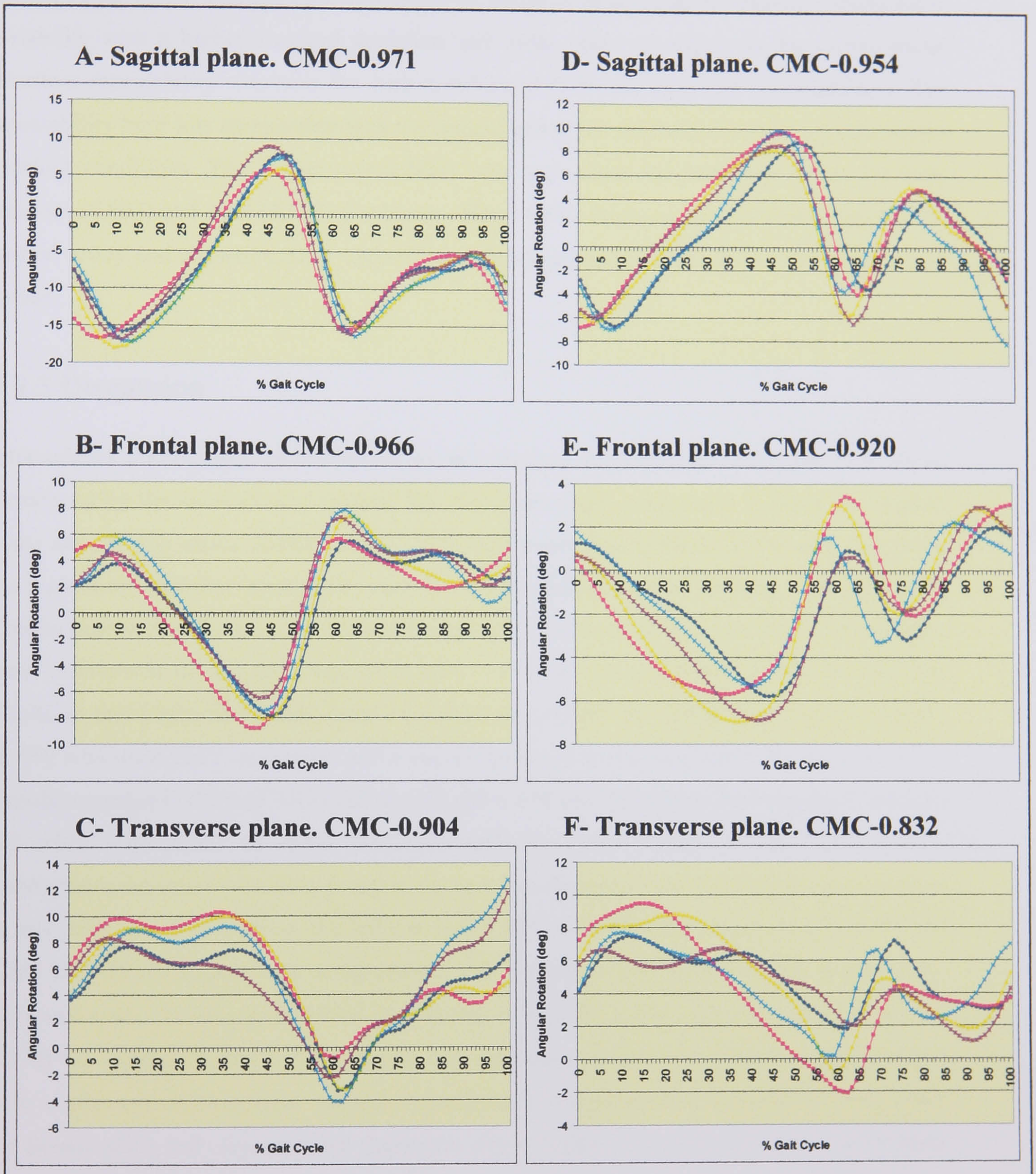


Figure 3-17: Ankle joint complex motion curves for five repeated trials for A- Sagittal plane (dorsiflexion[+]/plantarflexion[-]), B- Frontal plane (inversion[+]/eversion[-]) and C- Transverse plane (Internal rotation[+]/external rotation[-]) for subject 1 in normal group (A-C) and subject 1 in RA group (D-F) under barefoot conditions.

In the RA patients similar results showed the greatest repeatability for sagittal followed by frontal then transverse rotations for both barefoot and shod conditions. The mean barefoot sagittal CMC, 0.937, was comparable with 0.948 for the normal group but showed slightly more variability with a higher standard deviation and wider range of values. In the frontal plane excellent repeatability was seen for both barefoot (0.919) and shod (0.917) conditions. The repeatability here was comparable with the normal group but was slightly more variable under barefoot conditions. The lowest repeatability was seen about the transverse plane for both barefoot (0.802) and shod (0.812) conditions. These CMC values were both lower than for the normal group and showed greater variability with higher standard deviations and wider range values.

3.4.3 Discussion

Intra-subject repeatability is influenced by the inherent physiological variability and errors introduced by the measurement system. The direction of gait progression is along the sagittal plane and for this reason Kadaba *et al.*, (1989) postulated that rotations in this direction show the highest repeatability because the neuromuscular system exercises a higher level of control. Kadaba demonstrated this using video gait techniques and found better repeatability for sagittal plane rotations at the hip, knee and ankle joint over transverse and frontal plane rotations. The results in this study follow the same trend and importantly are verified by Cornwall *et al.*, (1999) who used EMT equipment and a similar protocol to that used here. At the ankle joint, Kadaba reported CMC's of 0.975 (SD-0.018) and 0.978 (SD-0.010) for three repeated right and left trials respectively of ankle dorsi-/plantarflexion, very similar to the findings here. Furthermore the small variability found in the standard deviation values of Kadaba was repeated in this study. For foot rotation, the left and right CMC's were smaller at 0.853 (SD-0.080) and 0.885 (SD-0.053) respectively, in agreement with the transverse rotation values in this study. Cornwall *et al.*, (1999) reported CMC's of 0.946 (SD-0.278), 0.846 (SD-0.205) and 0.846 (SD-0.270) for sagittal, frontal and transverse AJC rotations respectively, from 153 young adults with a mean age of 26.2 years. The data reported here is consistent for the sagittal plane, better for frontal plane and consistent for transverse plane rotations, albeit that less and more older subjects were used here.

Electromagnetic tracking demonstrates good within-day repeatability over five trials for the AJC in RA patients. Conducting trials within a standard shoe does not adversely affect repeatability and this permits the use of this technique for intervention studies. Rheumatoid arthritis increases the variability about all axes of rotation under barefoot conditions. Painful foot joints, especially in unaccustomed barefoot conditions, are the likely source of this

variability as patients consciously or unconsciously adopt protective strategies to unload painful sites. Under shod conditions the variability decreased slightly in this group and although the shoes were new patients much preferred to walk in this state, which causes less discomfort. Variability is reflected more for frontal and transverse plane rotations, which are linked motions through the subtalar joint, and both the results here and those of Cornwall *et al.*, (1999) support this observation. Inter-trial sources of error may be attributed to skin movement artefact and errors in gait cycle timing from activation of the heel and toe switches and the subsequent calculation errors in gait data.

3.5 Inter-observer repeatability in normal subjects and medium-term repeatability in rheumatoid arthritis patients

3.5.1 Materials and methods

3.5.1.1 Subjects

Reproducibility testing was conducted on a second cohort of subjects consisting of:

A- 5 healthy adults with a mean age of 29.0 years (SD- 10.4 years), 4 females and 1 male.

B- 20 patients fulfilling the ACR criteria (Arnett *et al.*, 1988) for RA (mean age- 48.2 years, SD- 11.0 years. 18 female and 2 male patients and mean disease duration- 2.8 years, SD-1.5 years).

3.5.1.2 Subject preparation and data collection

Subject preparation and gait analysis were undertaken in barefoot conditions for the right AJC according to the detailed protocol set out in 3.2.4.2 to 3.2.4.4. The experiments were conducted by two observers, who were qualified podiatrists, with a similar level of experience using EMT for gait analysis. Each subject was prepared for gait analysis, a boresight procedure was undertaken and three runs conducted under the same conditions. On completion all equipment was removed from the subjects and re-applied by the second observer and testing repeated for a further three runs. Importantly, each observer between each trial repeated the boresight procedure. This procedure was repeated 10 times alternating between observers to provide two sets of five trials for each observer. The same subjects underwent the same protocol 7 days later. From the data collection protocol repeatability, both within and between-day, and inter-observer reproducibility was established.

To accurately monitor progression of joint dysfunction or the kinematic effects of orthotic interventions medium term repeatability would have to be high. The clinical trial proposed for this study aimed to measure RA subjects longitudinally for 30 months. For this reason gait analysis was conducted on a representative cohort of RA patients on two separate occasions, 3 months apart, using a mean of 5 trials on each day.

3.5.1.3 Data analysis

Data analysis was undertaken as described in section 3.4.1.3 with between day and inter-observer repeatability evaluated using the CMC formula where R_a^2 is given by,

$$R_a^2 = 1 - \frac{\sum_{i=1}^{M}\sum_{j=1}^{N}\sum_{t=1}^{T}\frac{(Y_{ijt} - \overline{Y}_t)^2}{T(MN-1)}}{\sum_{i=1}^{M}\sum_{j=1}^{N}\sum_{t=1}^{T}\frac{(Y_{ijt} - \overline{Y})^2}{(MNT-1)}} \tag{4}$$

where $\overline{Y}_t$ is the average at time point t over NM gait cycles,

$$\overline{Y}_t = \frac{1}{MN}\sum_{i=1}^{M}\sum_{j=1}^{N}Y_{ijt} \tag{5}$$

and $\overline{Y}$ is the grand mean over time and is given by,

$$\overline{Y} = \frac{1}{MNT}\sum_{i=1}^{M}\sum_{j=1}^{N}\sum_{t=1}^{T}Y_{ijt} \tag{6}$$

Since repeatability for AJC has been shown to be high we considered the boresight position of the foot, where a neutral or zero starting position is given, to be the potentially greatest source of variability. To address this, absolute and relative CMC data were derived for between-day and inter-observer reproducibility where relative data was determined by normalising the heel-strike angle to zero for all motion:time curves.

3.5.2 Results

The CMC data for the normal subjects for observers 1 and 2 are presented in table 3-10. Experimental error lead to the loss of data from subject 5 for observer 2 on day 2 and, unfortunately, this subject was not available for repeat testing. Repeatability for all rotations was excellent to good for both observers and these levels were maintained when the procedure was repeated 7 days later. Sagittal plane rotation exhibited the highest repeatability followed by frontal and then transverse rotation. There are two individual instances of poor repeatability with CMC values below 0.5. On inspection these motion:time curves had good general shape agreement but were offset on the y (angular rotation) axis. Inter-observer repeatability CMC (absolute) data for day 1 and day 2 are presented in table 3-11. Inter-observer repeatability on both days was excellent for the sagittal plane with CMC values exceeding 0.9 on both days. For frontal and transverse plane rotations inter-observer repeatability was poorer than intra-observer repeatability. A large y-axis offset was seen for subject-1 in the transverse plane (CMC- 0.374), which improved on normalising the data to the heel-strike value (CMC- 0.768, see table 3-13). For sagittal plane rotation the inter-observer repeatability improved between test days (day 1 mean CMC- 0.793, day 2 mean CMC- 0.872). This trend was also observed for transverse rotation although the improvement was less than that for the sagittal plane (day 1 mean CMC- 0.710, day 2 mean CMC- 0.760).

Table 3-10: Coefficients of multiple correlation for 2 observers on 5 subjects repeated over 2 days. Data presented for absolute sagittal, transverse and frontal plane rotations.

	Observer 1					
	Sagittal (absolute)		**Frontal** (absolute)		**Transverse** (absolute)	
Subject	**Day 1**	**Day 2**	**Day 1**	**Day 2**	**Day 1**	**Day 2**
1	0.976	0.984	0.972	0.957	0.488	0.764
2	0.946	0.913	0.898	0.697	0.970	0.858
3	0.956	0.955	0.895	0.935	0.882	0.809
4	0.821	0.903	0.916	0.873	0.896	0.867
5	0.933	0.953	0.896	0.883	0.874	0.883
Mean	**0.926**	**0.942**	**0.915**	**0.869**	**0.822**	**0.836**
SD	**0.061**	**0.033**	**0.032**	**0.102**	**0.191**	**0.049**
	Observer 2					
	Sagittal (absolute)		**Frontal** (absolute)		**Transverse** (absolute)	
Subject	**Day 1**	**Day 2**	**Day 1**	**Day 2**	**Day 1**	**Day 2**
1	0.838	0.937	0.416	0.709	0.508	0.728
2	0.975	0.973	0.770	0.957	0.692	0.908
3	0.952	0.967	0.952	0.941	0.665	0.786
4	0.816	0.944	0.742	0.891	0.604	0.91
5	0.928	-	0.939	-	0.879	-
Mean	**0.902**	**0.955**	**0.764**	**0.875**	**0.670**	**0.833**
SD	**0.070**	**0.017**	**0.217**	**0.114**	**0.137**	**0.091**

Table 3-11: Inter-observer repeatability CMC values. Data presented for absolute rotations about the sagittal, frontal and transverse planes.

	Inter-observer repeatability (day-1)		
	Sagittal (absolute)	**Frontal** (absolute)	**Transverse** (absolute)
Subject	**Day 1**	**Day 1**	**Day 1**
1	0.907	0.590	0.374
2	0.939	0.733	0.797
3	0.952	0.919	0.790
4	0.836	0.809	0.707
5	0.928	0.914	0.883
Mean	**0.912**	**0.793**	**0.710**
SD	**0.045**	**0.137**	**0.198**
	Inter-observer repeatability (day-2)		
	Sagittal (absolute)	**Frontal** (absolute)	**Transverse** (absolute)
Subject	**Day 2**	**Day 2**	**Day 2**
1	0.945	0.840	0.470
2	0.933	0.816	0.870
3	0.951	0.941	0.809
4	0.918	0.89	0.892
5	-	-	-
Mean	**0.937**	**0.872**	**0.760**
SD	**0.015**	**0.056**	**0.197**

Repeat CMC's for relative motion:time curves further improved the repeatability for all rotations (table 3-12). The two very low absolute CMC values of 0.416 and 0.488 improved to 0.963 and 0.711 respectively. The improvement in mean CMC values was also accompanied with reduced inter-subject variability with decreased standard deviation and range values for relative data. Inter-observer repeatability was excellent for sagittal plane rotation and good for frontal and transverse plane rotations (table 3-13). The mean CMC values were greater for both days when relative data was analysed and compared with absolute values and no between day differences in the mean values were seen.

Week to week intra-observer repeatability for observer No-2 in normal subjects is given in table 3-14 and figure 3-18. Repeatability was excellent for the sagittal plane (mean- 0.917) and moderate for both the frontal (mean- 0.793) and transverse (mean- 0.682) planes. About all axes the CMC improved when relative data was analysed. The sagittal plane had a high mean CMC of 0.976 with low inter-subject variability (SD- 0.004). Subject 1 demonstrated a low absolute frontal CMC (0.610), which improved when relative data was analysed (0.970) and overall the relative mean CMC was 0.932. In the transverse plane absolute repeatability was poor for subject 1 (0.465) but improved when relative data was analysed (0.824). Conversely the CMC for subject 3 decreased from an absolute value of 0.702 to a relative value of 0.534. Overall the

mean relative CMC (0.781), indicating moderate between-day repeatability, was better than the mean absolute value (0.682).

Table 3-12: Coefficients of multiple correlation for 2 observers on 5 subjects repeated over 2 days. Data presented for relative sagittal, transverse and frontal plane rotations.

	Observer 1					
	Sagittal (relative)		**Frontal** (relative)		**Transverse** (relative)	
Subject	**Day 1**	**Day 2**	**Day 1**	**Day 2**	**Day 1**	**Day 2**
1	0.982	0.990	0.980	0.973	0.711	0.911
2	0.944	0.968	0.911	0.700	0.975	0.931
3	0.987	0.958	0.834	0.894	0.829	0.714
4	0.970	0.957	0.964	0.822	0.851	0.868
5	0.939	0.968	0.907	0.891	0.767	0.905
Mean	**0.964**	**0.9682**	**0.919**	**0.856**	**0.827**	**0.866**
SD	**0.022**	**0.013**	**0.06**	**0.102**	**0.100**	**0.088**
	Observer 2					
	Sagittal (relative)		**Frontal** (relative)		**Transverse** (relative)	
Subject	**Day 1**	**Day 2**	**Day 1**	**Day 2**	**Day 1**	**Day 2**
1	0.983	0.989	0.963	0.971	0.812	0.895
2	0.982	0.980	0.936	0.962	0.953	0.931
3	0.98	0.968	0.950	0.952	0.239	0.833
4	0.951	0.991	0.878	0.982	0.712	0.947
5	0.958	-	0.97	-	0.955	-
Mean	**0.971**	**0.982**	**0.939**	**0.967**	**0.734**	**0.900**
SD	**0.015**	**0.01**	**0.037**	**0.013**	**0.230**	**0.050**

Table 3-13: Inter-observer repeatability CMC values. Data presented for relative rotations about the sagittal, frontal and transverse planes.

	Inter-observer repeatability (day-1)		
	Sagittal (relative)	**Frontal** (relative)	**Transverse** (relative)
Subject	**Day 1**	**Day 1**	**Day 1**
1	0.968	0.966	0.768
2	0.924	0.79	0.936
3	0.979	0.901	0.846
4	0.957	0.883	0.789
5	0.947	0.904	0.863
Mean	**0.955**	**0.888**	**0.840**
SD	**0.021**	**0.064**	**0.067**
	Inter-observer repeatability (day-2)		
	Sagittal (relative)	**Frontal** (relative)	**Transverse** (relative)
Subject	**Day 2**	**Day 2**	**Day 2**
1	0.984	0.971	0.800
2	0.953	0.827	0.900
3	0.948	0.911	0.798
4	0.968	0.804	0.916
5	-	-	-
Mean	**0.963**	**0.878**	**0.854**
SD	**0.016**	**0.077**	**0.063**

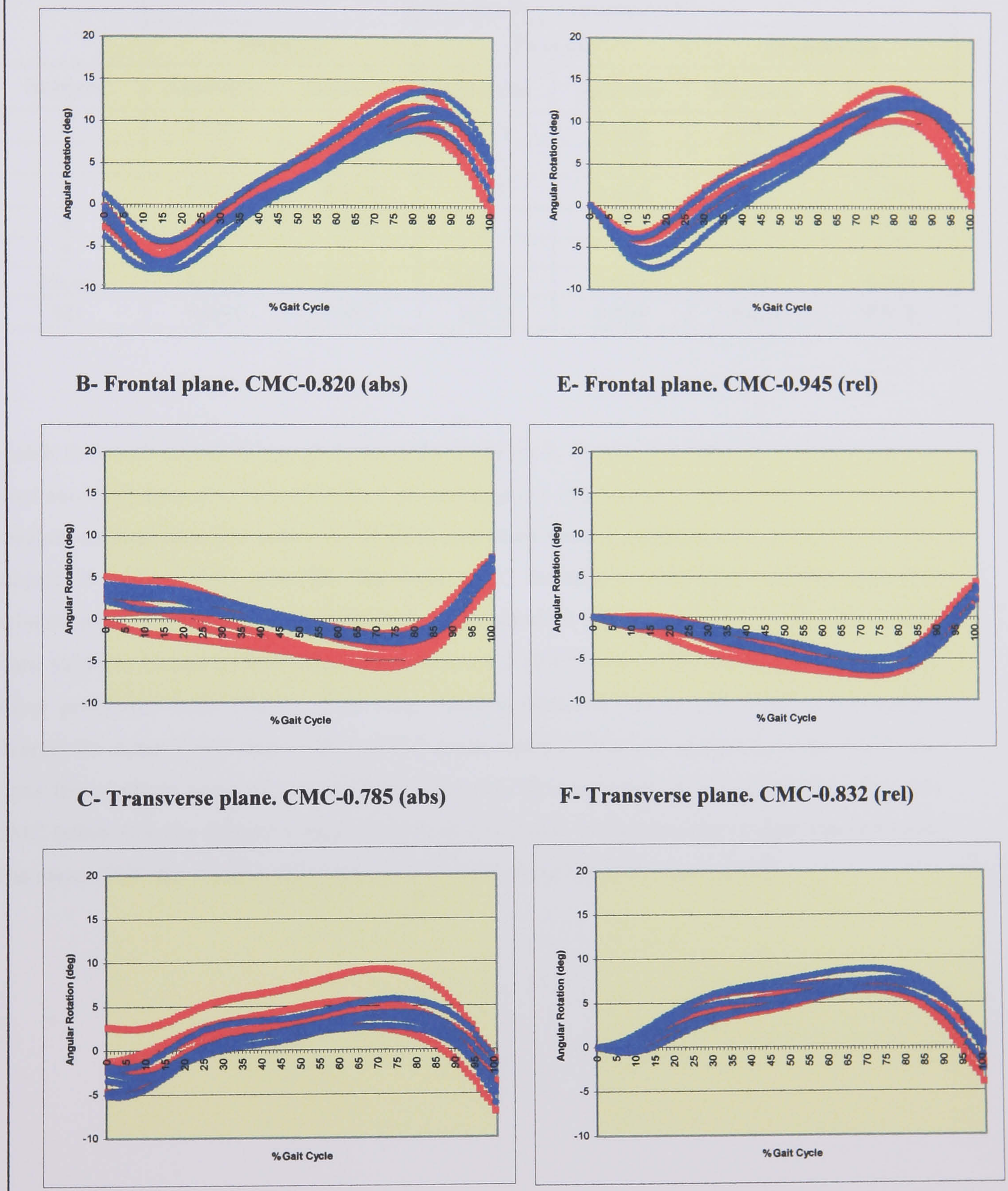


Figure 3-18: Example of between-day repeatability for the ankle joint complex for observer No-2 on subject no-2. Red lines represent day-1, blue lines represent day-2. Motion curves for 10 repeated trials for A- Sagittal plane (dorsiflexion[+]/plantarflexion[-]), B- Frontal plane (inversion[+]/eversion[-]) and C- Transverse plane (Internal rotation[+]/external rotation[-]). A-C represents absolute data, D-F represents relative data.

Table 3-14: Coefficients of multiple correlation for between-day reproducibility for observer N°-2 on 5 subjects with 5 repeated trials on two separate days. Data presented for relative and absolute sagittal, transverse and frontal plane rotations.

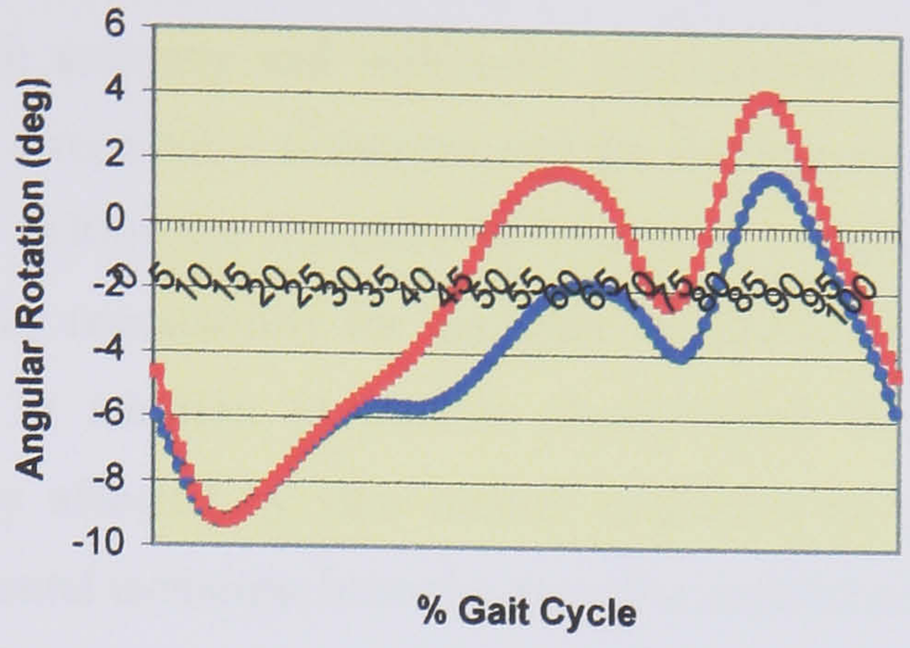
	Between-day repeatability					
	Sagittal		Frontal		Transverse	
Subject	Absolute	Relative	Absolute	Relative	Absolute	Relative
1	0.904	0.981	0.610	0.970	0.465	0.824
2	0.970	0.976	0.820	0.945	0.785	0.924
3	0.958	0.973	0.929	0.934	0.702	0.534
4	0.864	0.972	0.811	0.880	0.779	0.843
5	-	-	-	-	-	-
Mean	**0.917**	**0.976**	**0.793**	**0.932**	**0.682**	**0.781**
SD	**0.061**	**0.004**	**0.133**	**0.040**	**0.150**	**0.170**

Month to month repeatability, undertaken by observer-2, for the RA subjects was moderate to good about all axes of rotation (Table 3-15 and figure 3-19). Under this condition the CMC for absolute sagittal data fell below 0.9 (0.852) and there were 5 subjects with values below 0.8, subject 18 with a CMC of 0.295. The mean CMC for relative data improved to 0.903 with reduced inter-subject variability reflected in the standard deviation values. About the frontal plane subjects 15 and 20 had CMC values below 0.5 (0.477 and 0.455 respectively) with y-axis offset problems, both CMC's improving when normalised (0.916 and 0.967 respectively). Overall the mean CMC improved to 0.911 when relative data was analysed. In the transverse plane the common trend of lowest CMC was again demonstrated (0.765). Here there was one CMC below 0.5, for subject 3 improving from 0.451 to 0.740 when relative data was analysed. The mean CMC for relative data improved to 0.827 showing good repeatability.

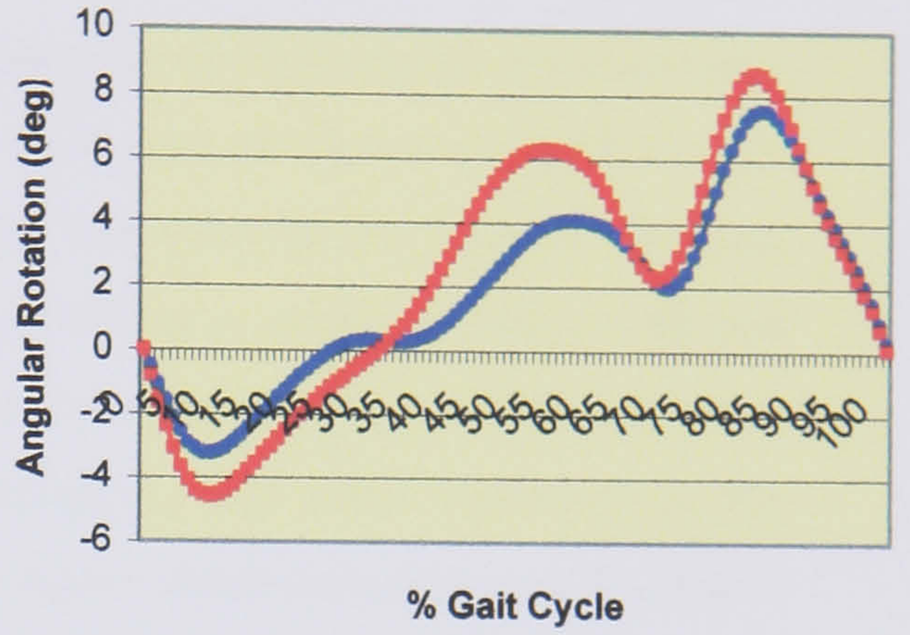
Table 3-15: Coefficients of multiple correlation for month-to-month repeatability on 20 rheumatoid arthritis subjects with 5 repeated trials conducted on two separate days. Data presented for relative and absolute sagittal, transverse and frontal plane rotations.

	Repeatability					
	Sagittal		Frontal		Transverse	
Subject	Absolute	Relative	Absolute	Relative	Absolute	Relative
1	0.904	0.941	0.959	0.952	0.730	0.397
2	0.762	0.953	0.827	0.850	0.748	0.526
3	0.973	0.973	0.722	0.921	0.451	0.740
4	0.905	0.837	0.975	0.957	0.850	0.955
5	0.858	0.918	0.882	0.965	0.977	0.978
6	0.940	0.913	0.927	0.956	0.540	0.890
7	0.895	0.818	0.815	0.863	0.566	0.870
8	0.990	0.962	0.821	0.742	0.881	0.829
9	0.780	0.962	0.881	0.917	0.832	0.946
10	0.902	0.993	0.773	0.742	0.830	0.911
11	0.811	0.574	0.777	0.896	0.925	0.881
12	0.969	0.969	0.975	0.986	0.877	0.968
13	0.987	0.887	0.906	0.939	0.802	0.844
14	0.855	0.970	0.973	0.973	0.808	0.774
15	0.916	0.936	0.477	0.916	0.925	0.927
16	0.774	0.898	0.850	0.983	0.653	0.828
17	0.832	0.856	0.676	0.843	0.760	0.859
18	0.295	0.822	0.926	0.931	0.882	0.884
19	0.794	0.924	0.927	0.929	0.638	0.609
20	0.897	0.956	0.455	0.967	0.630	0.918
Mean	**0.852**	**0.903**	**0.826**	**0.911**	**0.765**	**0.827**
SD	**0.149**	**0.094**	**0.150**	**0.070**	**0.144**	**0.153**

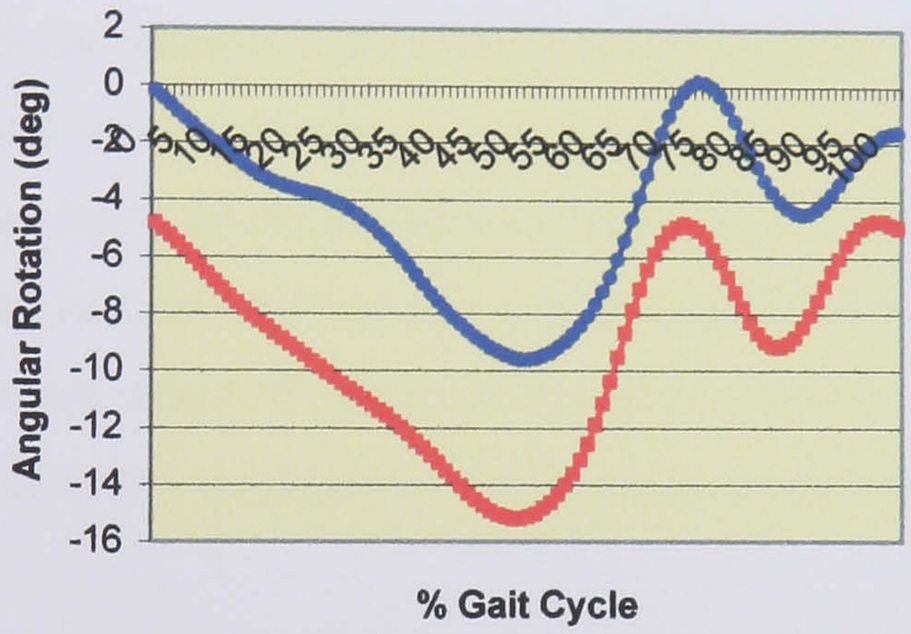
A- Sagittal plane. CMC-0.897 (abs)



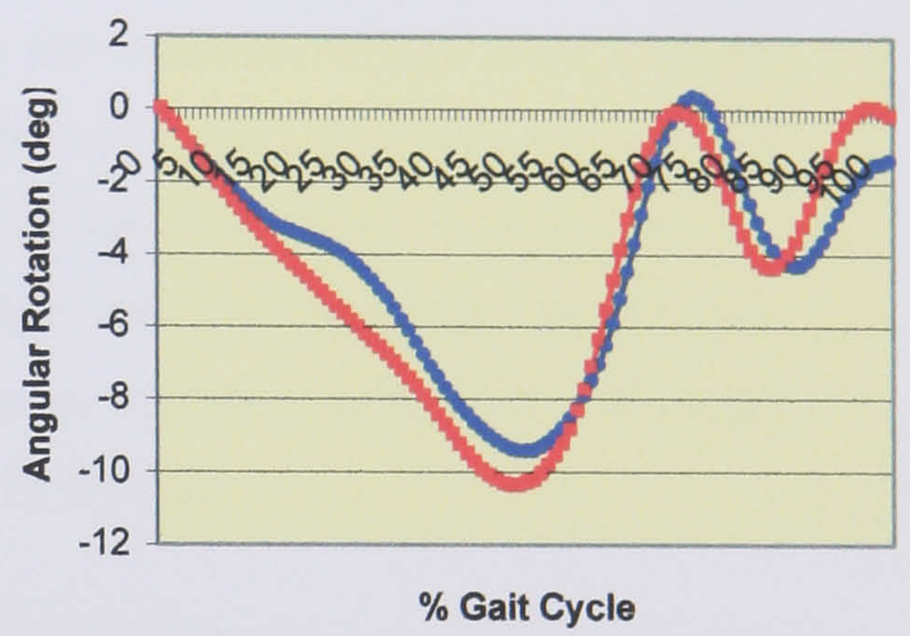
D- Sagittal plane. CMC-0.956 (rel)



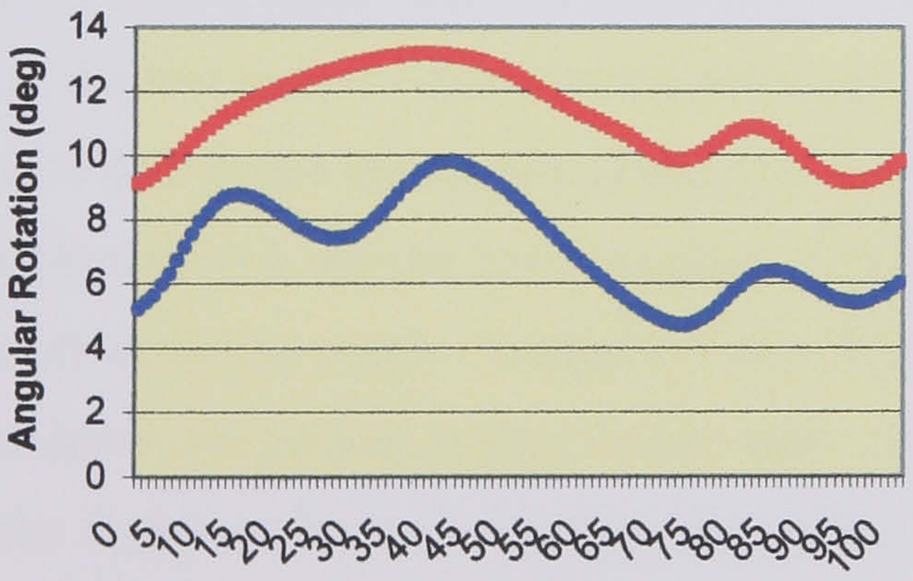
B- Frontal plane. CMC-0.455 (abs)



E- Frontal plane. CMC-0.967 (rel)



C- Transverse plane. CMC-0.630 (abs)



F- Transverse plane. CMC-0.918 (rel)

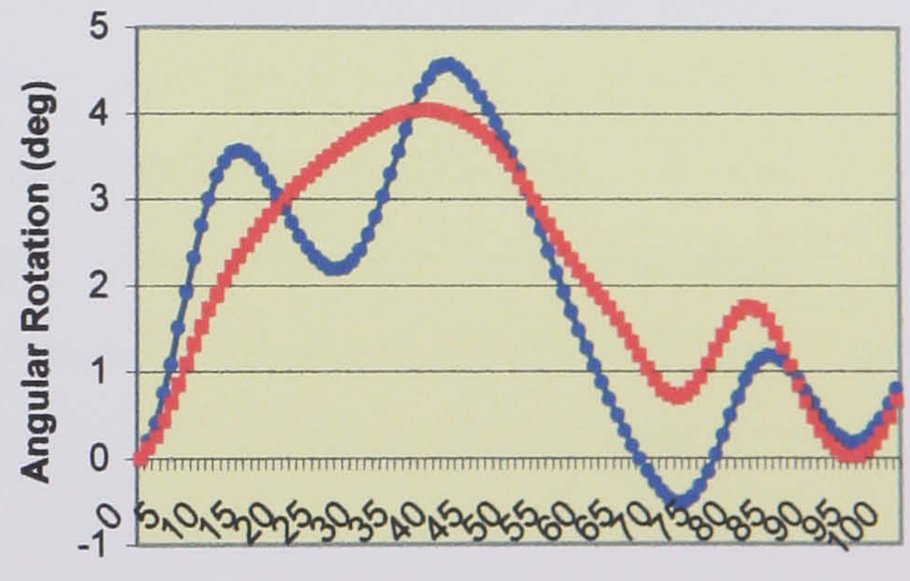


Figure 3-19: Example of between-day repeatability for the ankle joint complex for on rheumatoid arthritis patient No-20. Red lines represent the mean motion curve of 5 trials on day-1, blue lines represent the mean of 5 trials on day-2. A- Sagittal plane (dorsiflexion[+]/plantarflexion[-]), B- Frontal plane (inversion[+]/eversion[-]) and C- Transverse plane (Internal rotation[+]/external rotation[-]). A-C represents absolute data, D-F represents relative data.

3.5.3 Discussion

Descriptive gait analysis studies tend to be cross-sectional in design so may concern themselves only with accuracy and within-day repeatability. To undertake accurate serial measurements requires a repeatable technique and the findings of this study support the use of EMT for this purpose. Within the literature Kadaba *et al.*, (1989) found less between-day repeatability than within-day repeatability for hip, knee and ankle joints and this is a common finding with gait studies. In addition to normal physiological variation between-day repeatability is most adversely affected by skin marker re-placement, re-calibration, and other variations in the experimental technique between days. For sagittal plane rotation about the ankle joint Kadaba *et al.*, (1989) found only a slight decrease in CMC's from within- to between-day repeatability (0.975 Vs 0.937). For foot rotation the CMC fell from 0.853 for within day to 0.582 for between-day repeatability. For absolute between-day repeatability two observers in this study produced consistently high CMC's for the sagittal plane and moderate to high CMC's for the frontal and transverse planes with higher repeatability than Kadaba's data. The use of EMT overcomes many of the problems of marker placement since only one sensor is used to define a rigid body and calibration uses a more simplified technique with this technology. In this study sensors were attached direct to the skin avoiding slippage problems associated with target markers mounted on plates or elastic cuffs as undertaken by Kadaba.

A significant portion of the variability with the between day CMC's are associated with the boresight procedure. When relative data was analysed the CMC's improved for all axes of rotation resulting especially in moderate to high CMC's for the frontal and transverse planes, in excess of 0.9 for 4/8 mean data sets. Very few of these studies describe how a common neutral position is derived prior to data capture, although in some cases graphical data suggests that alignment of data points during processing may have taken place. From tables 3-10 to 3-12 and figures 3-18 and 3-19 we can see a number of individuals where motion curve shape is very close but offset on the y-axis. Analysis of data relative to a common zero heel-strike position produced closer overlapping motion curves and increased the CMC values. If absolute data is to be used the ability to derive a common boresight position is essential. The data here suggests that on most occasions this can be achieved using a simple relaxed foot posture. However, this position itself may change over time in diseases like rheumatoid arthritis suggesting that a common position such as subtalar joint neutral may be more appropriate. The literature however, suggests than only experienced clinicians may be able to find and replicate this position successfully (Freeman, 1990). The alternative solution would be to reference the foot in a boresight jig, a technique undertaken by Moseley *et al.*, (1996), but unfortunately not validated. However, Moseley reports between day repeatability, from correlation coefficients on

one subject, measured on two separate days as 0.986 for sagittal, 0.976 for frontal and 0.73 for transverse plane rotation. In the present study inter-observer repeatability was excellent for the sagittal plane but gave CMC's below 0.8 for the frontal and transverse planes, moderately improved when relative data were analysed. Variation in experimental technique may largely account for these differences and suggests that the same observer should be used when longitudinal studies using serial measurements are proposed.

Within-day repeatability was acceptably high for the RA subjects for sagittal, frontal and transverse plane rotations for both shod and barefoot conditions. Five trials may be regarded as sufficient in the clinical situation to yield repeatable data without the possibility of altering the gait by causing patient fatigue or by provoking or exacerbating joint pain. The stability of data over a longer time period could be affected by a number of factors. During boresight procedure standing barefoot may be uncomfortable for these patients, whom through conscious or unconscious mechanisms, may shift their foot position to lessen or avoid painful symptoms. Indeed all 20 RA patients had active foot pain ranging from between 18-83 points on a 100mm visual analogue scale, and active disease. The researcher was required to minimise the standing time for each patient and to use their skill and experience to place the AJC in the desired neutral position. The researcher used had 12 years experience of this clinical manoeuvre and during the study no patient reported painful symptoms during the technique. During gait for the same reasons, foot pain or pain in other lower limb joints may increase physiological variations so the CMC values below healthy individuals were expected. Since the standing foot posture may change in RA subjects over time the subtalar neutral technique was used for this party of the study. The absolute CMC data, with all these factors in mind, was acceptably high (0.852-0.765) suggesting that the technique can be employed for longitudinal studies. For frontal plane inversion/eversion the variability was estimated from selected measurement of error relative to the mean of 5 trials and, across the full gait cycle, was typically less than 2°. The CMC's for relative data was greater than absolute data for sagittal, frontal and transverse plane rotations. This may help overcome some of the variability associated with the factors described above but offers limited value for clinical interpretation of longitudinal data. Whilst it would have been desirable to analyse both absolute and relative data in the clinical trial, time constraints on data processing prohibited this. Undertaking 5 repeated trials on each day using the subtalar joint neutral boresight technique appears to be a pragmatic solution, which will permit repeatable serial measurement and evaluation of response to orthotic intervention.

3.6 Discriminatory validity

3.6.1 Introduction

The experiments outlined above, conducted under controlled laboratory conditions, provide valuable data establishing accuracy and repeatability specifications for the EMT system. In this section a feasibility study was undertaken under clinical research conditions testing areas of consensual and discriminatory validity.

3.6.2 Materials and method

3.6.2.1 Subjects

Gait analysis was undertaken in two groups consisting of ten healthy adults (mean age- 27.9 years) with no history of musculoskeletal disease or trauma to the lower limb or foot, and ten patients fulfilling the ACR criteria for RA (mean age- 52.3 years and mean disease duration-6.3 years) (Arnett *et al.*, 1988). The RA cases all presented with flexible valgus heel deformity, diagnosed using the criteria established in section 4.2.2 (Locke *et al.*, 1984; Keenan *et al.*, 1991). The healthy adult group were measured barefoot whilst the RA group were measured both barefoot and shod with a custom in-shoe foot orthosis designed to reduce hyperpronation. Local hospital ethics committee approval was granted for this study and informed consent was obtained.

3.6.2.2 Subject preparation and data collection

Subject preparation was undertaken according to the detailed protocols set out in 3.2.4.2 - 3.2.4.4. Five barefoot trials were conducted in both the normal healthy adult and RA group. In the RA group a further 5 trials were undertaken with a shoe and orthosis fitted without disturbance of the sensors or the barefoot boresight alignment. All subjects were allowed several test runs to acclimatise to the procedure.

6D-RESEARCH software was used to interpret raw kinematic data by calculating joint co-ordinate system angles. 6D-NORM analysis software (M Cornwall, Northern Arizona University, USA) was used to generate motion time curves, normalised to stance phase of gait, along with calculations of the timing of stance phase events and the coefficient of multiple correlation. A descriptive between-group comparison of the kinematic data was undertaken. Data extracted from published material was compared to our normal data, including motion curve shape comparison (classified as excellent, good or poor by consensual agreement between

two gait analysis researchers), range of motion (ROM) and angular rotation position (ARP) relative to gait cycle timings.

3.6.3 Results

The coefficients of multiple correlation for the five repeated trials in the normal group ranged from 0.851-0.971 for dorsi/plantarflexion, 0.808-0.966 for inversion/eversion, and 0.805-0.926 for internal/external rotation. In the RA group these values ranged from 0.833-0.927 for dorsi/plantarflexion, 0.811-0.922 for inversion/eversion and 0.809-0.913 for internal/external rotation.

The kinematic data for the 2 study groups are presented in table 3-16 and figure 3-20 for inspection. The ROM about each axis of rotation was similar between conditions except for the RA group following orthosis intervention where this was increased by approximately 5 degrees for dorsi/plantarflexion (table 3-16). Differences between the normal and RA group are evident in the ARP data at each key event in stance phase for inversion/eversion and internal/external rotation. In the RA group the AJC is more internally rotated and everted throughout stance so much so that maximal internal rotation is achieved at heel-strike (2 times greater than normal group) and persists until heel-lift (5 times greater than normal group). For frontal plane rotation both the normal and RA group function around everted positions throughout stance but the RA group has ARP two to three times greater than the normal group. Late stance inversion past the heel-strike position is evident in only the normal group. There is a suggestion in the RA group that the AJC has slightly greater dorsiflexed ARP at key events in comparison with the normal group.

The introduction of a foot orthosis in the RA group changes the kinematic variables about each axis of rotation. The shoe and orthosis change the sagittal pitch of the foot such that rotation starts from a more plantarflexed heel-strike position; the range of dorsiflexion is increased but is insufficient to reach barefoot maximum. The inversion/eversion rotation curve following intervention resembles the pattern of motion seen in the normal group, achieving a heel-strike position about the neutral position, a 57% change in maximum eversion position and a toe-off position inverted relative to the heel-strike position. The orthosis also alters internal/external rotation permitting internal rotation early in stance, by reducing the pre-orthosis internally rotated heel-strike position by 68%, and throughout stance the intervention motion curve closely resembles the normal pattern.

Table 3-16: Data report describing mean angular positions defined by stance phase event for each study group with comments.

Condition	ROT	Mean angular position by stance phase event					Comments on key events in stance phase
		HS	FF	MS	HL	TO	
Healthy adults (Barefoot) N=10	DF/ PF	-3.8	-7.9	0.6	2.6	-0.5	Max 1st plantarflexion = -8.0°, max dorsiflexion = 7.2°, max 2nd plantarflexion = -0.5°, total ROM = 15.2°. Max eversion = --8.3°, maximum inversion = -0.2° (still everted), total ROM = 8.1° (performed about an everted position during stance). Max internal rotation = 9.5°, maximum external rotation = 1.8° (still internally rotated), total ROM = 7.7° (performed about an internally rotated position during stance).
	Inv/ Evr	-2.7	-3.3	-7.4	-7.9	-0.2	
	I/R Rot	6.6	8.8	8.1	7.6	1.8	
Pronated foot RA (Barefoot) N= 10	DP/ PF	-3.1	-4.3	1.6	6.1	5.4	Max 1st plantarflexion = -4.9°, max dorsiflexion = 10.2°, max 2nd plantarflexion = 5.4°, total ROM = 15.1°. Max eversion = -16.9°, maximum inversion = -14.7° (still everted), total ROM = 9.1° (performed about an everted position during stance). Max internal rotation = 17.2°, maximum external rotation = 10.7° (still internally rotated), total ROM = 6.5° (performed about an internally rotated position during stance).
	Inv/ Evr	-7.8	-9.5	-14.5	-16.3	-14.7	
	I/R Rot	17.0	17.1	16.8	16.4	10.7	
Pronated foot RA (Shod&orthosis) N= 10	DF/ PF	-12.5	-15.9	-8.1	-1.7	-2.6	Max 1st plantarflexion = -16.1°, max dorsiflexion = 5.5°, max 2nd plantarflexion = -2.6°, total ROM = 21.6°. Max eversion = -7.2°, maximum inversion = 1.4°, total ROM = 8.6°. Max internal rotation = 9.2°, maximum external rotation = 1.8° (still internally rotated), total ROM = 7.4° (performed about an internally rotated position during stance).
	Inv/ Evr	0.4	-1.4	-6.0	-7.1	1.4	
	I/R Rot	5.4	8.6	8.1	7.6	1.8	

All data are degrees. ROT- rotation; DF/PF- Dorsi/plantarflexion; Inv/Evr- Inversion/eversion; I/R Rot- Internal/external rotation; RA= Rheumatoid arthritis; FO= Foot orthosis; HS= Heel-strike, FF= Foot-flat, MS = Mid-stance, HL= Heel-lift, TO= Toe-off; ROM= Range of motion. Positive angular rotations represent dorsiflexion, inversion and internal rotation; Negative angular rotation values represent plantarflexion, eversion and external rotation.

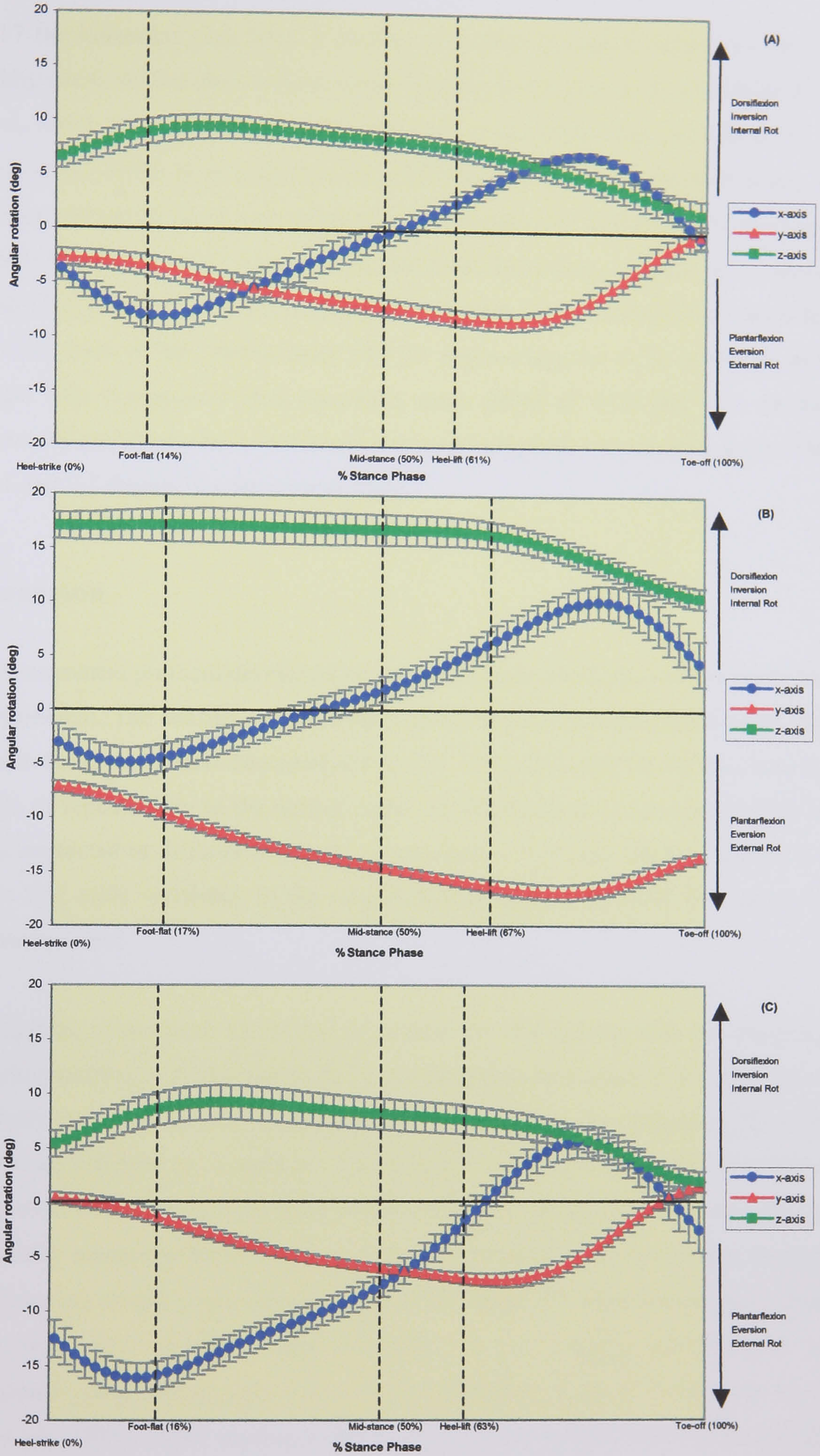


Figure 3-20: Angular displacement curves for stance phase of gait in normal healthy subjects (a), rheumatoid arthritis subjects with pronatory dysfunction at AJC (b), and same group following orthotic intervention (c). Average time series data with 95% confidence intervals for each axis of rotation is presented and key stance-phase events highlighted.

In table 3-17 the kinematic data from a number of reference sources related to the AJC in normal healthy adults for the stance phase during walking is summarised (Cornwall *et al.*, 1999; Kepple *et al.*, 1990; Kobayashi *et al.*, 1997; Moseley *et al.*, 1996; Peirrynowski *et al.*, 1996; Rattanprasert *et al.*, 1999; Reinschmidt *et al.*, 1997; Scott *et al.*, 1991; Wright *et al.*, 1964). Curve-shape agreement about all axes of rotation was found to be moderate in 9, good in 8 and excellent in 4 for a total of 21 comparisons, all cases following accepted gross movement patterns. The dorsi/plantarflexion ROM averaged 17 degrees for the comparative data in table 3-17 and thus the mean in the present study of 15.2 degrees appears to be within an accepted normal range. The comparative data showed a mean ROM of 14.0 and 12.2 degrees for inversion/eversion and internal/external rotation respectively, both considerably greater than the means of 8.1 and 7.7 degrees for the present study.

3.6.4 Discussion

The EMT measurement protocol developed here was relatively straightforward to undertake in a clinical environment. The coefficient of multiple correlation for axes of rotation were high and consistent with the experimental data presented earlier. Kinematic data for the RA cases showed similar levels of repeatability to the normal cases. Standardisation of the AJC zero or neutral position was neglected or differed within the cross-referenced studies (table 3-16) and it is not surprising to find wide variability in the relative kinematic data for ARP data at key events during the stance phase.

About the sagittal plane good agreement is evident for the timings but not magnitude of dorsiflexion/plantarflexion during stance. For most kinematic techniques it is relatively easy to define and carry out a zero position alignment in the sagittal plane, by positioning the foot at 90 degrees to the leg, achieved in a standing or sitting posture. For the frontal and transverse planes a neutral position definition is technically more difficult to standardise and reproduce hence greater variability across the material reviewed here. For example, the data in this study shows subjects functioning around a persistent everted ARP, whilst all other studies show inversion positions at heel-strike, toe-off or both. Similarly all our subjects are internally rotated throughout stance phase whilst others show external rotation of up to 7.0 degrees by toe-off (Cornwall *et al.*, 1999). Other methodological variations particularly related to sample size numbers and technical issues such as skin-marker placement also contribute to variability between this and other.

Table 3-17: Comparative data derived from normal gait studies summarising number of subjects, measurement technique, curve shape agreement and range of motion and angular position data by stance phase event for each axis of rotation.

Author N-subjects	Present (n=10)	Wright(1964) (n=1)*	Kepple(1990) (n=5) *∇	Scott(1991) (n=3) #	Moseley(1996) (n=14)	Pierrynowski (1996b) (n=9)*
Measurement technique	EMT	Pot	Video	Video	Video	Video
AJC (x-axis)						
Curve shape agreement	-	-	Good	Excellent	Good	-
ROM	15.2	-	13.6	22, 28, 27	14.0	-
Angular position at:						
HS	-3.8	-	-2.0	2, 2, -4	2.3	-
FF	-7.9	-	-	-	-6.3	-
MS	0.6	-	0	5, 0, 3	3.0	-
HL	2.6	-	-	-	5.0	-
TO	-0.5	-	-5.5	-12, -26, -15	-2.6	-
AJC (y-axis)						
Curve shape agreement	-	Moderate	Moderate	Moderate	Excellent	Good
ROM	8.1	8	13.0	12, 17, 18	11.1	9
Angular position at:						
HS	-2.7	2	1.4	-6, -13, -2	-1.8	-1
FF	-3.3	-2	-	-	-3.8	-
MS	-7.4	-2	-2.0	0, -3, -4	-7.0	-7
HL	-7.9	2	-	-	-7.0	-
TO	-0.2	2	10.2	-7, -8, 2	3.8	-4
AJC (z-axis)						
Curve shape agreement	-	-	Moderate	-	Good	-
ROM	7.7	-	12.3	-	9.9	-
Angular position at:						
HS	6.6	-	6.8	-	2.0	-
FF	8.8	-	-	-	4.5	-
MS	8.1	-	6.8	-	6.2	-
HL	7.6	-	-	-	7.7	-
TO	1.8	-	-1.4	-	-2.8	-

Author N-subjects	Kobayashi(1997) (n=1) *	Reinschmidt(1997a) (n=5)†	Reinschmidt(1997a) (n=5) †	Rattanapresert(1999) (n=10) *	Cornwall(1999) (n=153)
Measurement technique	EMT	Video (SM)	Video (BM)	Video	EMT
AJC (x-axis)					
Curve shape agreement	Excellent	Moderate	Moderate	Good	Good
ROM	17.0	21.0	17.2	20.2	17.0
Angular position at:					
HS	2.0	-3.6	-3.6	-3.0	-3.0
FF	-	-	-	-6.0	-10.0
MS	4.3	2.1	0	4.0	3.0
HL	-	-	-	4.0	4.0
TO	8.0	-15.7	-15.7	-12.0	-10.0
AJC (y-axis)					
Curve shape agreement	Excellent	Moderate	Moderate	Good	Good
ROM	17.0	17.3	17.2	13.7	8.7
Angular position at:					
HS	6.4	1.8	0	1.5	2.5
FF	-	-	-	-3.0	2.0
MS	-10.7	4.5	-0.5	-2.0	-2.0
HL	-	-	-	2.0	-1.8
TO	0	6.9	2.2	8.0	5.8
AJC (z-axis)					
Curve shape agreement	Moderate	Moderate	Moderate	Excellent	Good
ROM	17.1	13.7	11.5	10.3	10.8
Angular position at:					
HS	15.0	-3.6	0	0	-0.5
FF	-	-	-	3.0	3.7
MS	25.0	2.3	-2.2	0	1.0
HL	-	-	-	-3.0	0.5
TO	17.0	-3.6	-6.6	-5.0	-7.0

AJC- Ankle Joint Complex. EMT- Electromagnetic tracking; x-axis = dorsiflexion (+)/plantarflexion (-); y-axis = inversion (+)/eversion (-); z-axis = internal (+)/external (-) rotation; - data not presented in reference material; * angular positions estimated from motion/time curves and data tables; # Full data presented from 3 subjects; ∇ data estimated for one subject only; † data estimated from motion/time curves for subject 5; SM- skin marker; BM- bone marker; HS- heel strike; FF- foot flat; MS- mid stance; HL- heel lift; TO- toe off. Data units are degrees.

The three-dimensional kinematics at the AJC in RA cases was markedly different and consistent with the mechanical consequences of AJC instability and deformity, even when age-related differences are considered. Whilst the ROM is the same, frontal and transverse plane rotations for the RA cases are more everted and internally rotated at heel-strike and the joint fails to invert and externally rotate prior to toe-off, back to the heel-strike position. This kinematic pattern has been found in other studies suggesting good consensual validation (Keenan *et al.*, 1991; Locke *et al.*, 1984).

The final data set was obtained to determine whether the measurement protocol was sensitive enough to distinguish change in AJC kinematics as a product of intervention. In this case we used a functional orthosis primarily designed to invert the AJC about the frontal plane of the subtalar joint component. Because the boresight protocol was not disturbed valid comparisons could be made between barefoot and shod with orthosis data. The height of the shoe and heel section of the orthosis increased the sagittal pitch of the foot such that the sagittal plan position at heel-strike was more plantarflexed (3.1 degrees barefoot, 12.5 degrees shod with orthosis). The greatest changes occurred around in the frontal and transverse planes such that the position of eversion between heel-strike and toe-off between conditions decreased by 8-16 degrees, with greater inversion efficacy in late stance phase (figure3-20). Internal and external rotation was consistent with that seen in the normal study group both in terms of ROM, direction and absolute ARP at key stance phase events. Finally, it is interesting to note the interdependency between these two axes of rotation as further support for the coupling mechanism between the rearfoot and leg.

Armed with prior knowledge of both normal and abnormal AJC function, the protocol was able to detect very different kinematic profiles for a normal study group and a cohort of rheumatoid arthritis patients. Furthermore changes in AJC kinematics as a product of a foot orthosis intervention were readily detected. The data for this study closely matched that of Cornwall *et al.*, (1999) using EMT and Moseley *et al.*, (1996) using video gait analysis and despite inconsistency with some other work, acceptable curve shape agreement throughout establishes excellent face validity in the clinical research environment.

3.7 Skin movement artefact

3.7.1 Background

The final experiment of this chapter investigates skin movement error for the proposed EMT technique. The ability of skin markers to precisely measure the movement of underlying bone is a problem common to many gait systems. A number of factors have been identified by Lundberg (1996) which influence the magnitude of this problem and include the technique for mounting the sensor or marker on the skin between skin glue, double-sided tape, or mounting plate or cuff, the shape of the marker and the dimensions of the contact surface, its mass and the presence of connecting wires where passive or active sensors are used, the quality and abundance of the soft-tissue layer at the anatomical site for the marker and the nature of the specific movement under consideration. Very few techniques have quantified skin movement and the problem is highly dependent upon the anatomical region (Maslen *et al.*, 1994).

Techniques to investigate this problem have been invasive or utilised radiographic imaging techniques so only a limited number of studies exist and findings as pointed out by Holden *et al.*, (1997) may only be applicable to the technique under investigation. Tranberg and Karlson (1998) using 2D roentgen photogrammetry glued 2mm spherical markers to six surface anatomical sites in the foot including the medial surface of the calcaneus. The foot was placed on a moving platform and images taken in the horizontal, at 20 degrees of dorsiflexion and at 30 degrees of plantarflexion. In six healthy subjects errors in the x and y co-ordinates (in mm) were determined from the two imposed rotations. For the calcaneal marker mean error at 20 degrees dorsiflexion was 2.12mm for the x co-ordinate and 2.56mm for the y co-ordinate and at 30 degrees plantarflexion was 0.59mm for the x co-ordinate and 1.04mm for the y co-ordinate. Maslen *et al.*, (1994) used a similar technique and imposed two rotations about the frontal plane, 5 degrees of eversion and 10 degrees of inversion, maintained by Styrofoam wedges during radiographic exposure. The dimensions of the steel marker were not defined but when placed over the sustentaculum tali an offset displacement between attachment and neutral film exposure was found to be 5.8mm in the horizontal and 2.0mm in the vertical. In eversion rotation discrepancy between skin and bone markers amounted to 0.4mm for the horizontal and 2.5mm for the vertical and in inversion 4.0mm for the horizontal and 6.8mm for the vertical, excursions of the calcaneus being over-estimated with the use of skin markers.

Reinschmidt *et al.*, (1997a, 1997b, 1997c) conducted definitive research in this area through the use of bone-mounted markers for the AJC and knee joints in normal walking and running. These series of studies showed that sagittal knee motion is generally well reflected with the use of skin

markers (mean difference- 2.1 degrees) but transverse and frontal knee motions were highly variable (Reinschmidt *et al.*, 1997c). In running the same pattern was demonstrated but error margins increased for the sagittal plane (Reinschmidt *et al.*, 1997b). For the ankle joint complex the shoe was used to mount the external marker and under walking and running conditions rotations about all axes were smaller from bone pins than shoe-mounted markers (Reinschmidt *et al.*, 1997a). For inversion/eversion the difference was highest from around 20-60% of stance phase, by 5 degrees. Internal/external rotation motion patterns were closely aligned between bone pin markers and shoe markers. For sagittal rotations external markers overestimated both plantar/dorsiflexion motion by as much as 5.8 degrees in one subject in plantarflexion and between 1 to 8 degrees in dorsiflexion. However, since this group had earlier demonstrated that movement occurs between the shoe and the heel, skin rather than shoe mounted markers or sensors will provide a more realistic and valid indication of true calcaneal motion and thus AJC motion (Reinschmidt *et al.*, 1992; Reinschmidt *et al.*, 1997a; Stacoff *et al.*, 1992).

Pragmatically, in the absence of experimental data supporting modelling or numerical correction, researchers can at least ensure that physical measures are undertaken to reduce or minimise skin movement artefact. For the AJC EMT protocol outlined in section 3.4.2 there are a number of helpful solutions aided mostly by optimum anatomical conditions. The medial tibial and posterior calcaneal surfaces are flat with relatively thin soft-tissue layers allowing markers to be relatively well attached to the underlying bone. In this area there is little or no soft-tissue movement resulting from phasic muscle contraction and relaxation during the gait cycle transition phases, nor during swing phase from oscillations of quiescent muscle masses (Holden *et al.*, 1997). The sensors used are small, lightweight and unobtrusive and can be attached well with double-sided tape. Unfortunately trailing cables need to carefully tidied to avoid adverse movement or tension on the fixed sensor.

There was no opportunity in this study to consider invasive techniques and we wished to avoid using ionising radiation. More recently kinematic techniques using magnetic resonance imaging have been reported for the rearfoot and after some pilot work adaptation for the purpose of quantifying skin movement was realised (Stindel *et al.*, 1999; Stindel *et al.*, 2000; Udupa *et al.*, 1998).

3.7.2 Materials and method

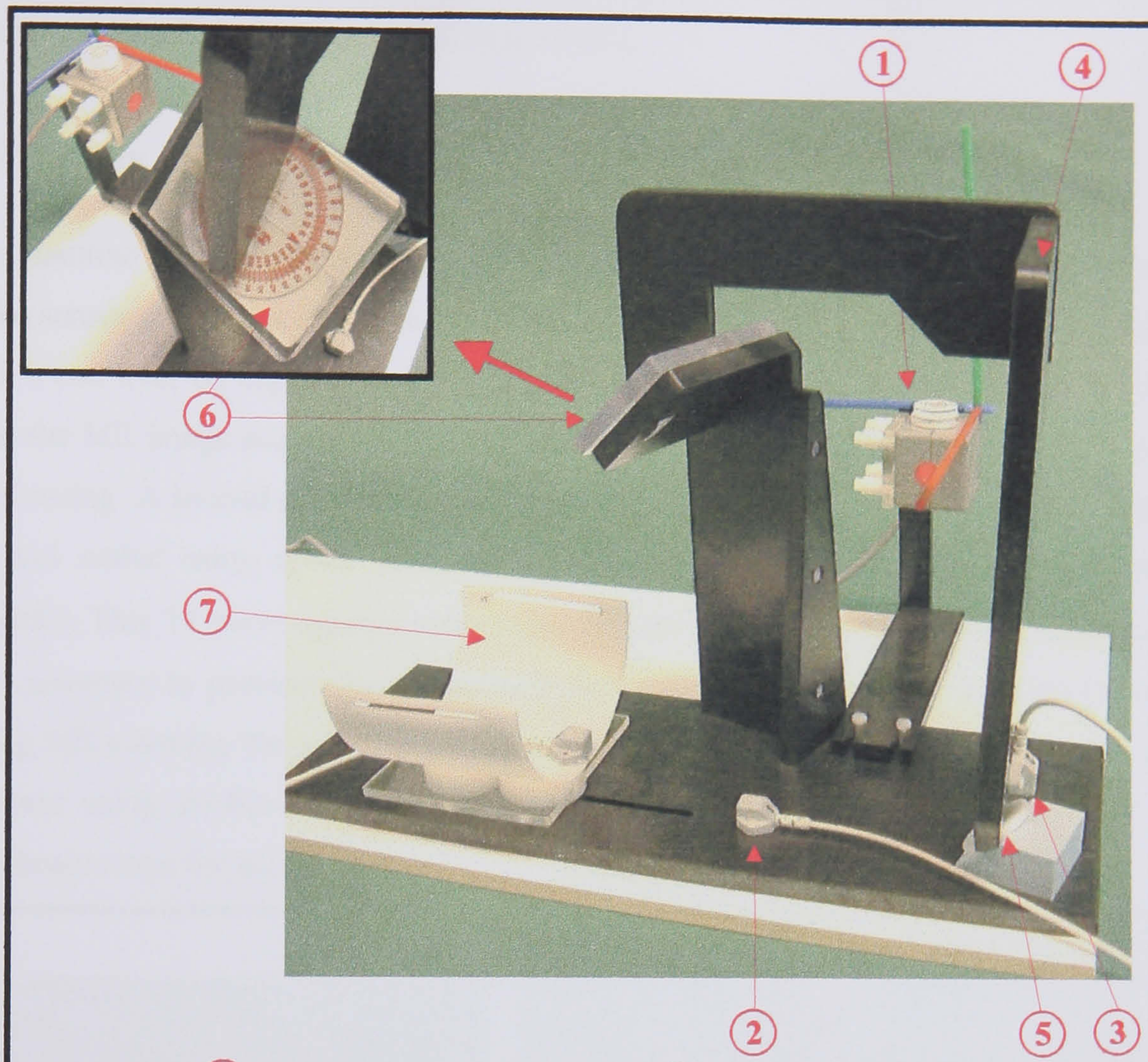
3.7.2.1 Subjects

Magnetic resonance (MR) imaging was undertaken in 5 healthy adult subjects, 4 male and 1 female, with a mean age of 35.2 years (SD- 6.8 years). Each subject was screened for suitability to undergo MR imaging and full informed consent was obtained. No subject reported any significant history of lower limb or foot musculoskeletal disease or injury. Examination of foot joint structure and function placed all subjects within normal acceptable ranges for clinical testing.

3.7.2.2 Pronation-supination MR imaging jig

Foot position within the MRI scanner was standardised using a pronation-supination jig adapted from the design of Udupa *et al.*, (1998). The jig allows for consistent study of open kinetic chain passive pronation-supination kinematics the motion induced largely around the subtalar and talocalcaneonavicular joints. The jig was constructed in rigid thermoplastic with no ferromagnetic parts to avoid metal interference in the static magnetic field. It consisted of a horizontal leg rest, with support and strapping to accommodate the middle third of the leg (figure 3-21). The foot was placed on a vertical plate and attached securely by double-sided adhesive tape on the plantar aspect with an elastic wrap across the forefoot. The vertical plate pivots around an axis orientated to align with the mean subtalar joint axis; deviating 42° from the transverse plane and 17° from the sagittal plane. Unfortunately the, sagittal plane deviation value used by Udupa *et al.*, (1998) from the reference material of Inman (1976) is incorrect (Inman cites the mean sagittal deviation as 23° not 17°). However this value is within normal limits (see Manter 1941) and was used here to ensure true replication of the method.

Placed within the scanner the jig was orientated such that the footplate is in the axial plane and the long axis of the leg is parallel to the axis of the bore of the magnet. Each subject lay supine and the foot was attached to the plate such that the centre of the heel and the long axis of the 2nd ray of the foot were aligned on a bisection line of the vertical plate. The foot was positioned such that observation of the rotation axis between the pivot point and the upper fixation containing the measurement dial passed through the centre of the sinus tarsi. The plate was locked in this position, representing neutral with zero degrees rotation. The leg resting on a support fixture was stabilised with elastic strapping and sandbags. From the neutral position the footplate could be rotated in a supination or pronation direction, the magnitudes of the rotation measured on a dial on the upper support fixture, locked and repeat images acquired. The jig was also used to test AJC kinematics out with the MR scanner by attaching EMT sensors to the leg



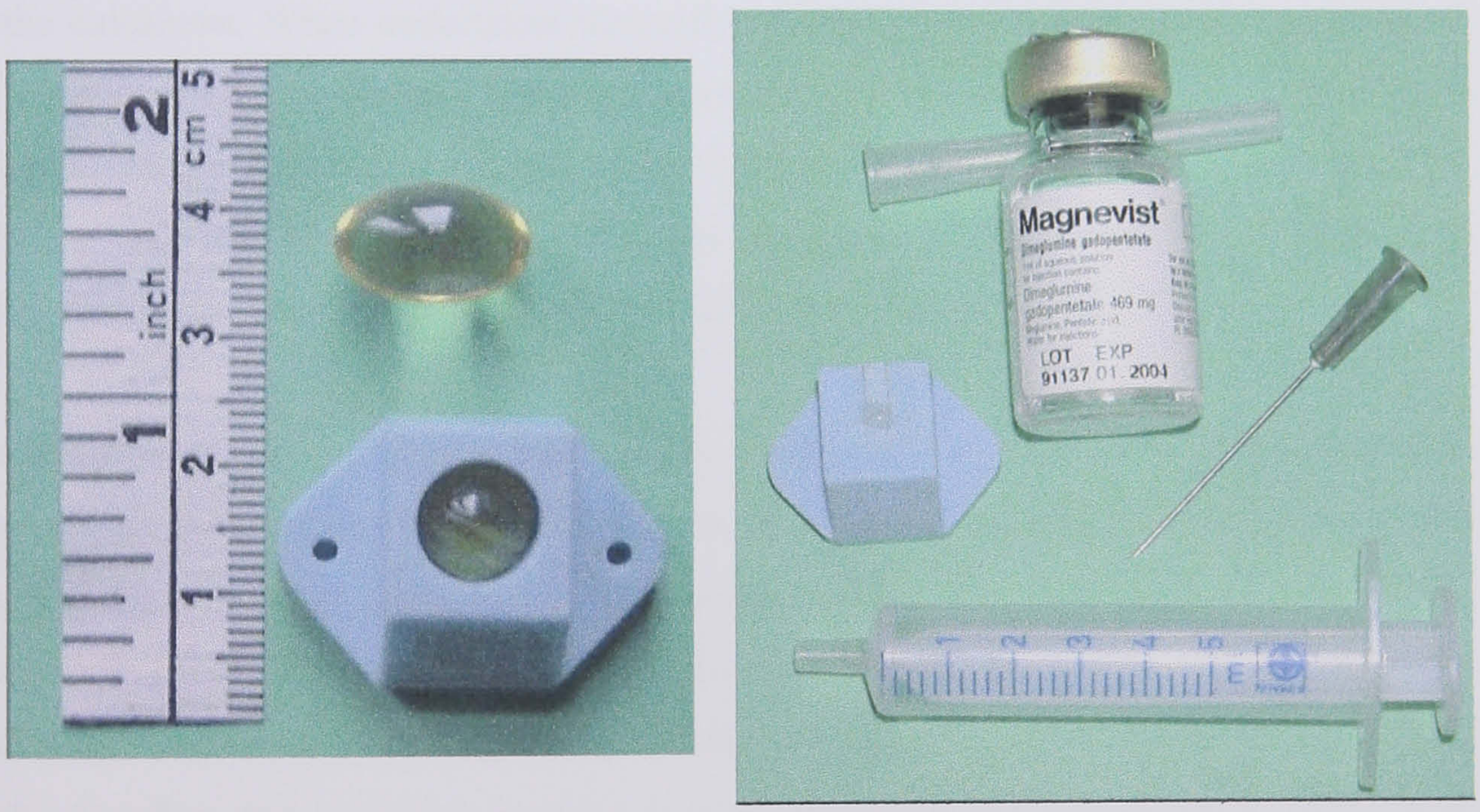
1- Electromagnetic transmitter
2- Fixed horizontal electromagnetic sensor
3- Fixed vertical electromagnetic sensor
4- Vertical moving plate
5- Pivot for vertical plate (about average subtalar joint axis)
6- Rotation axis measurement dial with screw lock
7- Moveable support plate for leg
8- Foot secured to vertical plate with double-sided tape and elastic wrap
9- Sand-bags to stabalise leg

Figure 3-21: Kinematic MRI jig (adapted from Udupa *et al.*, 1999).

and calcaneus as described previously and 2 further sensors to the horizontal and vertical plates to measure jig orientation characteristics (figure 3-21).

3.7.2.3 Phantom EMT sensor

A plastic phantom sensor was constructed to the precise dimensions of an EMT sensor. To identify the sensor on the MR image sequences the central portion a cylinder was drilled out and filled with a cod liver oil capsule (figure 3-22). Pilot testing successfully revealed the oil-filled capsule on the MR image sequence but edge definition was poor and difficult to segment during image processing. A second phantom sensor was designed containing a central vessel, filled by injection and sealed using epoxy resin, with a 1% solution of Dimeglumine Gadopentetate (Magnevist®). This T1 paramagnetic enhancement agent produces a bright white signal on the MR image sequence to provide clearer structure edge definition for image processing (figure 3-22). During MR scanning the sensor was attached to the posterior surface of the calcaneus in the usual manner using double-sided adhesive tape for skin attachment and covered with thin flexible adhesive tape for anchorage.



(A) (B)

A- Phantom marker constructed with oil capsule for image enhancement
B- Phantom marker filled with Dimeglumine Gadopentetate T1 enhancement agent

Figure 3-22: Phantom markers designed for use in MR scanner to evaluate skin movement artefact.

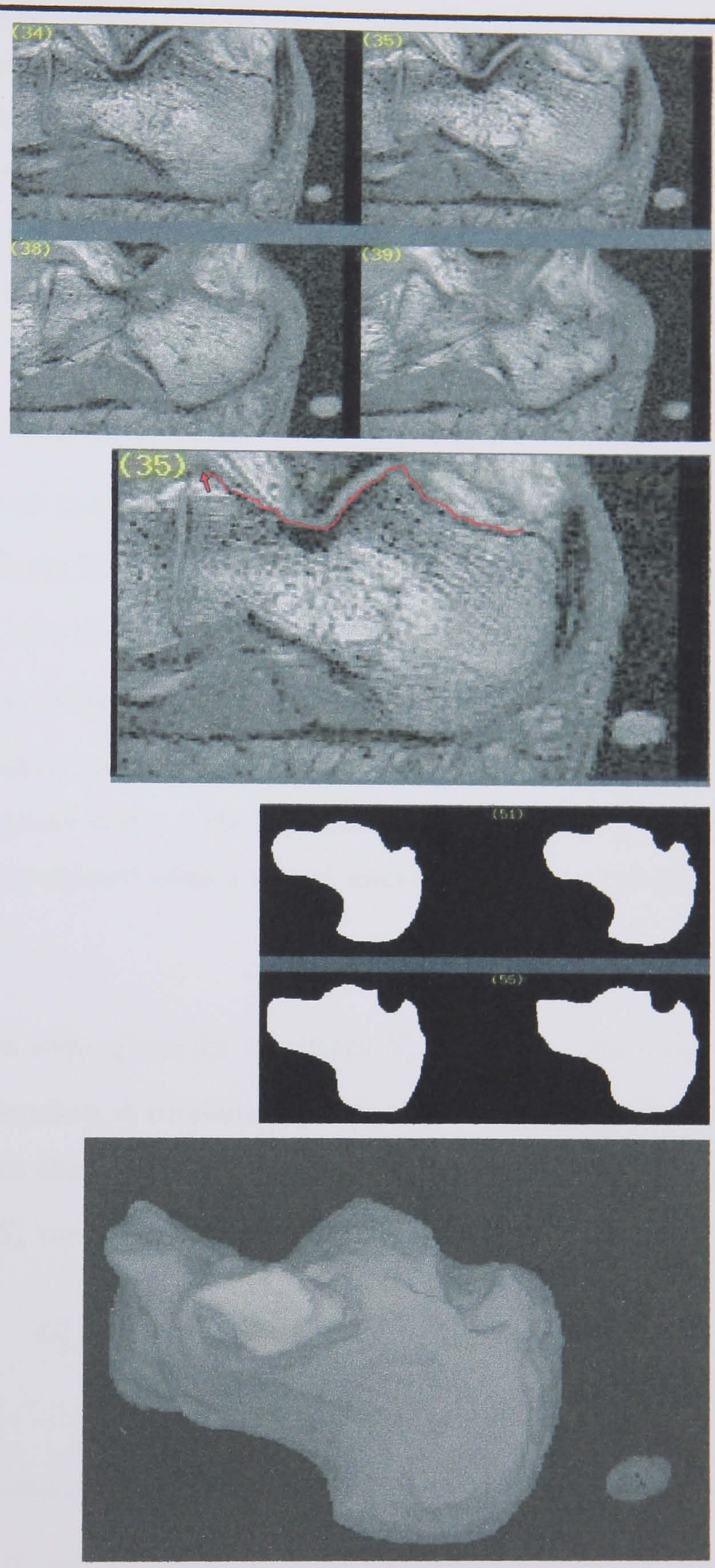
3.7.2.4 Magnetic resonance imaging

Time sequence MR images for the right ankle region were acquired for each subject using a commercial 1.5T MR machine (Philips Gyroscan ACS-NT). Each volume image consisted of 50 slices of 1.5mm thickness. The imaging protocol used was a 3D steady-state T gradient echo sequence with TR/TE flip angle = 22ms/9.2ms/55. Each slice was 256x256 pixels and the pixels were 0.50x0.50mm. The field of view was 190x90mm. An E1 surface coil was attached to the subject around the ankle region to obtain the best possible signal. The right foot of each subject was placed in the pronation-supination jig and images acquired in a sequence of four positions- subtalar joint neutral, 20° pronation, 20° supination, 40° supination.

3.7.2.5 Data processing

A pilot study was initially conducted to process the acquired MRI images using ANALYZE AVW software. However, a number of problems were encountered with this software and the repeatability for the segmentation of the lower third of the tibia, calcaneus and phantom marker was poor. In particular, automatic boundary identification algorithms created errors when used on the calcaneus. When undertaken manually this task was not accurate or repeatable for the purposes of the study. Further literature searches were undertaken and the work of the MIPG (Medical Image Processing Group) at the University of Pennsylvania, using 3DVIEWNIX software was identified. This software was available by anonymous FTP from the MIPG website and was downloaded and installed for use in the present study.

The image data acquired by the MR scanner were stored on tape and transferred to a Silicon Graphics workstation in the CoMIR (Centre of Medical Imaging Research) unit of Medical Physics, University of Leeds. All processing, visualisation and analysis operations were undertaken using 3DVIEWNIX software (Medical Image Processing Group, Department of Radiology, University of Pennsylvania) (Stindel *et al.*, 1999; Stindel *et al.*, 2000; Udupa *et al.*, 1998). The first step in motion analysis is to identify from the time sequence of T scenes the surface S_b^t of each bone b in each scene C^t, for $1 \le t \le T$, and for being $b \in B, B$ being the set of bones studied. In our analysis, B is confined to the calcaneus and the phantom marker, using the notation $B = \{ca, pm\}$, where the elements refer to the calcaneus and phantom marker respectively. Using the *volume of interest* operation a separate scene was created for the calcaneus and phantom marker, enclosing the structure in question but as little as possible of irrelevant objects. A user-steered segmentation method called *"live wire"* was then used to define the boundaries of the calcaneus and phantom marker in a slice-by-slice fashion (figure 3-23). Here a point on the boundary on a display of the slice was identified using the cursor of a



A- A set of representative MR slices of the right calcaneus and phantom marker
B- Live-wire segmentation of the right calcaneus
C- A sequence of 3D binary scenes for the right calcaneus
D- Rendered model of right calcaneus and phantom marker

Figure 3-23: Magnetic image data acquisition and image processing steps for 3DVIEWNIX software

pointing device. A "live-wire" path (a sequence of pixel edges) was then created between this initial point and any subsequent position taken by the cursor around the edge of the structure. This task is displayed in real-time and with the cursor close to the boundary the live wire snaps onto the boundary. If acceptable the current cursor position was deposited to become the new initial point for the live wire segment. For the calcaneus this was typically undertaken in about 6 live wire segments and the phantom marker about 3 segments. The segmentation procedure from the calcaneus and phantom marker 3D scenes $C^t, 1 \le t \le T$, created a sequence of 3d binary scenes $C_b^t = \left(C_b^t, f_b^t\right)$, $1 \le t \le T$, where the voxels have intensities of either zero or one such that any voxel $c \in C_b^t$, within the boundary, then $f_b^t(c) = 1$ and $f_b^t(c) = 0$ otherwise. To create surfaces S_b^t, C_b^t was converted to binary scenes C_{bi}^t with a "shape-based" interpolation algorithm that minimised artefacts in the final rendering and made the spaces between the slices equal the pixel size (0.5mm). C_{bi}^t was then filtered using a smoothing Gaussian 3D filter to create grey scenes C_{bif}^t. Surfaces were then created from C_{bif}^t using a threshold and surface tracking algorithm each as an orientated, closed, connected surface. Each surface is expressed as a set of square facets of voxels together with a surface normal assigned to each facet using a gradient operator. Surfaces are then rendered using a surface tracking algorithm (Udupa *et al.*, 1998).

From the initial surface construction steps, given the T surfaces $S_b^t, 1 \le t \le T$, a description of the motion of bone $b \in B$ was undertaken. A coordinate system affixed to b, called the *bone-axes system* of b was defined and its changes during the motion of b quantified (Udupa *et al.*, 1998). The geometric centroids of S_b^t were defined as a three-component vector

$$G_b^t = \frac{1}{N_{tb}} \sum_{i=1}^{N_b^t} F_b^t(i) \tag{1}$$

where $F_b^t(i), 1 \le i \le N_b^t$ are three-component vectors representing the coordinates of the centre of each of the facets that comprise S_b^t and N_b^t is the number of facets in S_b^t. Three unit vectors α_b^t, β_b^t and γ_b^t are then determined to indicate the direction of the principle axes of the set of points $\left\{F_b^t(i) \middle| 1 \le i \le N_b^t\right\}$ constituting surface S_b^t via principle component analysis. The bone-axes system of b at time t is formed by the point G_b^t and the unit vectors α_b^t, β_b^t and γ_b^t. The bone-axes system is then utilised to match surfaces S_b^t for successive values of t (Udupa *et al.*,

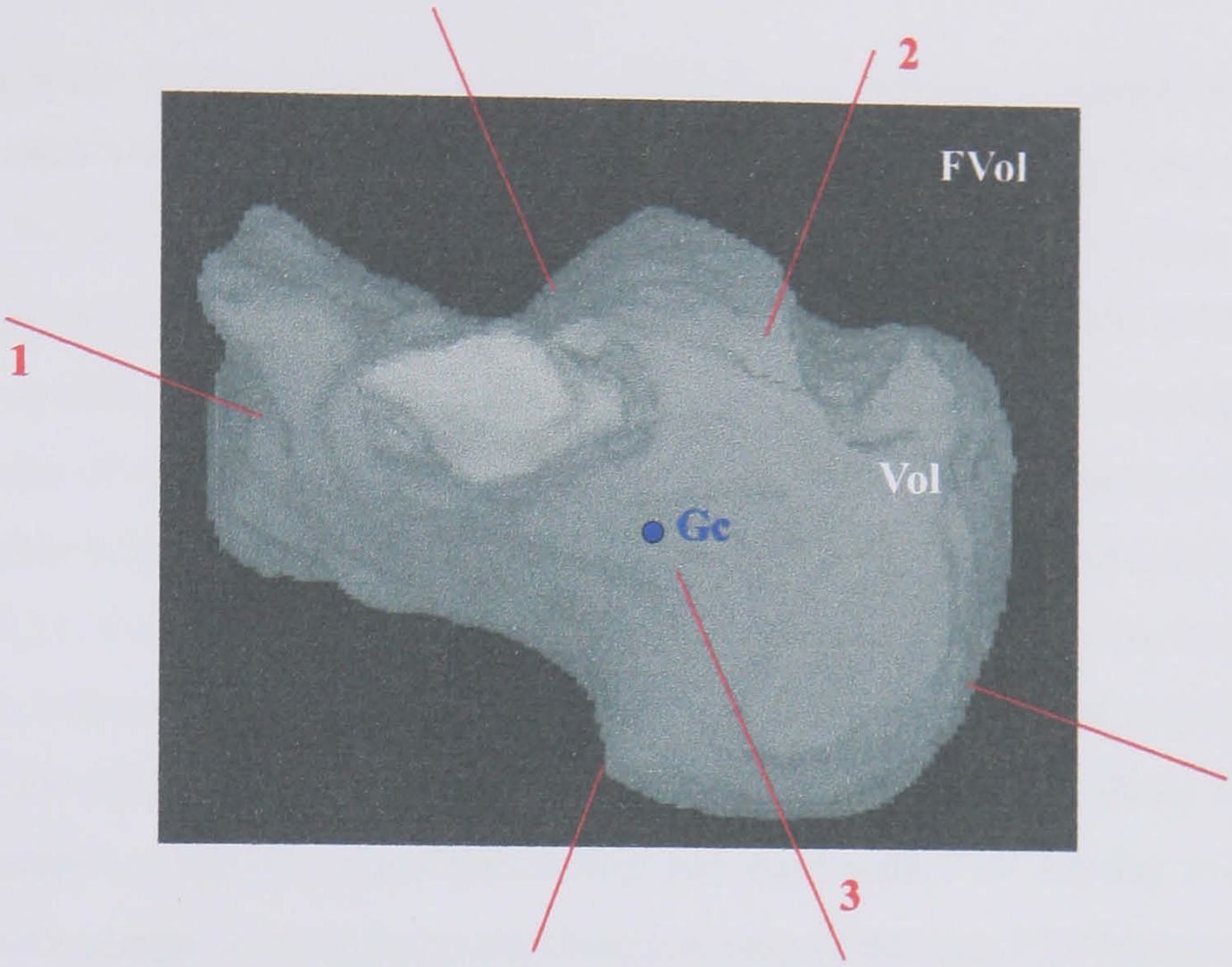
1998). Given the T bone-axes systems, $1 \le t \le T$, the motion description of each bone b as a pair is derived

$$M_b(t) = \langle X_b(t), R_b(t) \rangle, \qquad \text{for } 1 \le t \le T \tag{2}$$

consisting of a translation component $X_b(t)$ and a rotation component $R_b(t)$ of b. $X_b(t)$ represents the translation of the geometric centroids of G_b^t of S_b^t to the centroids G_b^{t+1} of S_b^{t+1} in the scene coordinate system, and $R_b(t)$ is itself expressed as a pair

$$R_b(t) = \langle A_b(t), \phi_b(t) \rangle, \qquad \text{for } 1 \le t \le T \tag{3}$$

consisting of an *instantaneous axis* $A_b(t)$ and an *instantaneous angle* of rotation $\phi_b(t)$, all expressed in the scene coordinate system. $A_b(t)$ represents an axis passing through the centroids G_b^t of S_b^t, such that when S_b^t is rotated by $\phi_b(t)$ it matches as best as possible S_b^{t+1}. The above equivalent axis technique is a powerful method for quantifying the relative motion between two rigid bodies. In our experiment we assume that the phantom marker and calcaneus move identically and any difference accounts for skin movement. Udupa *et al.*, (1998) in a validation study using an isolated talus rigidly suspended within a Magnevist contrast medium bath MR scanned at known orientations and translations, defined errors in translation and rotation to range between 0.3-2.2mm and 0.9-1.3°. Intraoperator repeatability of live-wire segmentation and its effects on motion description had errors of 0.4mm in translation and 1.1° in rotation. Finally intra-operator error in determining the location of the geometric centroids was 0.2mm. Repeatability can also be determined by the shape parameters of the bones studied in terms of proportions and orientation (Stindel *et al.*, 1999). The principal axis orientation is very stable with respect to different orientations of the objects in the magnetic field of the MR device (Stindel *et al.*, 1999). Therefore in this study repeatability was conducted on the calcaneus and phantom marker for one subject in the neutral position from 5 measurements repeated on two separate days. Data considered included principal axis orientation, principal axis length, centroids location, axis length ratio, structure volume and structure volume relative to a rectangular cuboid (figure 3-24).



1,2&3- Principle axes of the calcaneus.
Gc- Geometric centroid of the calcaneus.
Vol- Volume of the calcaneus enclosed by the surface of the bone.
FVol- Ratio of the volume of the rectangular box defined by the axes segments and the volume of the bone.

Figure 3-24: Morphological parameters of the calcaneus

3.7.3 Results

3.7.3.1 General remarks on MR image quality

The MR image sequence for the calcaneus produced high quality images for processing. However, the boundary on the inferior surface of the calcaneus did not respond well to live-wire segmentation. In the mid section many new initial points were required as the live-wire segment failed to snap to the actual boundary edge. This was overcome by changing to a "live lane", a segmentation process that overcomes this problem by working in a restrictive band around the vicinity of the boundary. The phantom marker on inspection during image acquisition appeared to give excellent image quality. Within 3DVIEWNIX we encountered problems with boundary definition because of excessively high MR signal, likened to a 'sunburst' effect around the boundary of the structure. This was partially overcome initially be reducing the grey-scale level and width and then through image interpolation and filtering steps. The reason for this is unclear but the concentration of Magnevist® may have been too high.

3.7.3.2 Repeatability of morphological parameters of the calcaneus and phantom marker

After the grey scale intensities were adjusted the phantom marker appeared as a bright white solid structure and thus during live-wire segmentation the boundary edges were easy to identify. Subsequently the process was fully repeatable with no variability in any of the morphological parameters. The repeatability data for the morphological parameters for the rendered calcaneus are presented in table 3-18. The orientation angles for the principal axes were highly repeatable with coefficients of variation ranging between 0.22 to 2.10%. The geometric centroid location was highly stable both within (mean- 134.28, SD- 0.07, CoV- 0.05%) and between days (mean 134.07, SD- 0.11, CoV-0.08%). Repeatability for the axis lengths and axis length ratios were excellent both between and within day, the greatest variability seen at principal axis 3, the shortest axis (for axis length: day 1 CoV- 1.96%, day 2 CoV- 1.62%). Bone volume showed excellent repeatability for the measurement over two days with CoV for day 1- 0.86% and day 2- 1.09%. The closeness of the bone to a rectangular cuboid through FVol measurement showed slightly more variability with a CoV of 2.50% on day 1 but only 1.09% on day 2 indicating excellent repeatability.

Table 3-18: Repeatability measurements of the morphological characteristics of calcaneus.

Day	Trial	1st PA ang1	1st PA ang2	1st PA ang3	2nd PA ang1	2nd PA ang2	2nd PA ang3	3rd PA ang1	3rd PA ang2	3rd PA ang3
1	1	19.59	75.86	103.27	97.41	26.34	64.88	71.98	111.73	28.85
	2	20.16	75.09	103.25	98.65	25.25	66.47	71.94	109.90	27.41
	3	20.52	74.97	103.64	98.43	25.72	65.89	71.43	110.37	28.15
	4	19.96	75.47	103.38	97.89	26.03	65.37	71.79	111.10	28.47
	5	20.23	74.77	103.00	98.99	25.53	66.32	72.04	109.98	27.40
	Mean	20.09	75.23	103.31	98.27	25.77	65.79	71.84	110.62	28.06
	SD	0.35	0.43	0.23	0.63	0.43	0.66	0.25	0.70	0.64
	CoV	1.74	0.57	0.22	0.64	1.67	1.00	0.35	0.63	2.28
2	1	20.15	75.01	103.15	98.44	26.12	65.48	71.84	110.87	28.25
	2	19.84	75.33	103.06	98.06	26.32	65.13	72.00	111.34	28.52
	3	19.94	75.62	103.51	97.71	25.96	65.38	73.04	111.12	28.53
	4	20.19	75.09	103.30	98.51	25.56	66.09	73.22	110.26	27.77
	5	20.12	75.23	103.34	98.59	24.95	66.76	73.24	109.63	27.20
	Mean	20.05	75.26	103.27	98.26	25.78	65.77	72.67	110.64	28.05
	SD	0.15	0.24	0.17	0.37	0.54	0.66	0.69	0.70	0.57
	CoV	0.75	0.32	0.16	0.38	2.10	1.00	0.95	0.63	2.03

Day	Trial	CL	AL_1	AL_2	AL_3	R_1	R_2	R_3	VOL	FVOL
1	1	134.19	72.60	38.79	28.07	0.534	0.387	0.723	53196.5	0.673
	2	134.32	73.23	39.46	27.59	0.539	0.377	0.699	53573.2	0.672
	3	134.31	72.05	39.45	27.82	0.548	0.386	0.705	52804.4	0.668
	4	134.24	71.94	39.19	29.01	0.545	0.403	0.740	52505.6	0.642
	5	134.35	73.46	39.40	28.36	0.536	0.386	0.720	52551.5	0.640
	Mean	134.28	72.66	39.26	28.17	0.540	0.388	0.718	52926.3	0.659
	SD	0.07	0.68	0.28	0.55	0.005	0.010	0.016	453.8	0.017
	CoV	0.05	0.94	0.72	1.96	0.99	2.48	2.25	0.86	2.50
2	1	134.18	73.44	38.98	28.28	0.531	0.385	0.725	53802.7	0.665
	2	134.14	73.63	39.01	27.36	0.530	0.372	0.701	52148.9	0.663
	3	134.02	73.04	39.60	27.77	0.542	0.380	0.701	52177.0	0.650
	4	133.91	73.22	38.71	27.24	0.529	0.372	0.704	52418.9	0.666
	5	134.11	73.24	38.82	28.09	0.530	0.384	0.724	52294.9	0.655
	Mean	134.07	73.31	39.03	27.75	0.532	0.379	0.711	52568.5	0.660
	SD	0.11	0.23	0.35	0.45	0.006	0.006	0.012	698.2	0.007
	CoV	0.08	0.31	0.89	1.62	1.05	1.69	1.74	1.33	1.09

1st PA: First principal axis (defined by angles 1-3), **2nd PA**: Second principal axis (defined by angles 1-3), **3rd PA**: Third principal axis (defined by angles 1-3)

CL- Centroid location (length of the resultant vector from origin to centroid in scene co-ordinate system determined from x, y and z centroid co-ordinates)

AL_1- Principal axis l length (mm)

AL_2- Principal axis 2 length (mm)

AL_3- Principal axis 3 length (mm)

R_1- Axis ratio 1 (AL_2/ AL_1)

R_2- Axis ratio 2 (AL_3/ AL_1)

R_3- Axis ratio 3 (AL_3/ AL_2)

VOL- Structure volume (mm^3)

FVOL- Structure volume as ratio of field volume

SD- Standard deviation

CoV- Coefficient of variation

3.7.3.3 Translation of the calcaneus and phantom marker

Translation of the calcaneus and phantom marker are presented in table 3-19. There is considerable inter-subject variability in the translation characteristics along the x, y and z-axes between the different input rotations. Between 20° pronation and the neutral position the phantom marker underestimated bone translation and in the y-axis mean translation was in the opposite direction to the calcaneus. The mean differences were 2.38mm, 3.35mm and 6.16 mm for the x, y and z-axes respectively. From the neutral position to 20° supination the phantom marker about all 3 axes underestimated the underlying bone translation and in the z-axis is in the opposite direction to the calcaneus. Mean differences were 2.12mm, 3.65mm, and 5.42mm for the x, y and z-axes respectively. From 20° supination to 40° supination the phantom marker underestimated bone translation in the x-axis and over-estimates about the y- and z-axes. Mean differences were 1.45mm, 3.53mm and 9.15mm for the x, y and z-axes respectively.

Table 3-19: Translation (mm) of the calcaneus and phantom marker presented by axis for 3 input rotations with mean and standard deviation and difference between calcaneus and marker.

Subject	20Pron - Neutral			Neutral – 20Sup			20Sup – 40Sup		
	x	y	z	x	y	z	x	y	z
1									
Calc	-3.38	0.81	-6.50	9.84	13.78	-1.53	-16.34	-19.23	7.85
Marker	-0.76	-1.16	-2.37	13.13	9.66	6.22	-13.36	-22.59	18.20
2									
Calc	-2.47	1.83	-8.42	-1.20	2.41	-4.10	1.68	3.84	1.89
Marker	0.37	-2.08	-3.26	0.32	-1.41	1.14	2.35	1.04	10.43
3									
Calc	-3.61	3.15	-7.23	-14.15	6.12	-3.35	-5.62	-5.33	0.31
Marker	-2.77	-2.44	3.26	-12.73	2.56	0.09	-3.85	-8.87	8.37
4									
Calc	-3.72	5.34	-7.66	-2.09	1.25	-9.56	-11.08	0.08	6.77
Marker	-1.35	3.24	-1.76	-0.93	-1.11	-4.07	-9.77	-4.42	17.26
5									
Calc	-4.74	1.77	-9.36	-10.59	13.28	-3.24	-9.04	-6.79	0.48
Marker	-1.49	-1.42	-4.24	-7.39	8.88	1.96	-8.54	-10.22	8.81
Mean (C)	**-3.58**	**2.58**	**-7.83**	**-3.64**	**7.37**	**-4.36**	**-8.75**	**-5.49**	**3.46**
SD	**0.81**	**1.75**	**1.10**	**9.34**	**5.91**	**3.06**	**5.54**	**8.78**	**3.59**
Mean (M)	**-1.35**	**-0.77**	**-1.67**	**-1.52**	**3.72**	**1.07**	**-6.63**	**-9.01**	**12.61**
SD	**0.91**	**2.30**	**2.91**	**9.73**	**5.31**	**3.70**	**6.07**	**8.77**	**4.75**
Difference									
1	2.62	1.97	4.13	3.29	4.12	7.75	2.98	3.36	10.35
2	2.84	3.91	5.16	1.52	3.82	5.24	0.67	2.80	8.54
3	0.84	5.59	10.49	1.42	3.56	3.44	1.77	3.54	8.06
4	2.37	2.10	5.60	1.16	2.36	5.49	1.31	4.50	10.49
5	3.25	3.19	5.12	3.20	4.40	5.20	0.50	3.43	8.33
Mean	**2.38**	**3.35**	**6.16**	**2.12**	**3.65**	**5.42**	**1.45**	**3.53**	**9.15**
SD	**0.92**	**1.49**	**2.50**	**1.04**	**0.79**	**1.54**	**0.99**	**0.61**	**1.17**

The Euclidean distance between the geometric centroids of the calcaneus and phantom marker for each input rotation was measured. This distance should remain constant in the absence of skin movement between the sensor and the underlying calcaneus, and the results are presented in table 3-20. In general the difference in the distance between the centroids through the range of motion was small. This distance increased through the range of input rotation the magnitude rising with each step through 20° pronation to 40° supination (mean 0.10mm, 0.36mm, 0.61mm). Subject 1 demonstrated the greatest difference with a total of 3.26mm difference for the full range of motion. For subject 3 the distance shortened by 1.26mm from 20° pronation to neutral. For subject 5 this also occurred by 0.82mm between 20° supination to 40° supination.

Table 3-20: Euclidean distance (mm) between the geometric centroids of the calcaneus and the phantom marker.

Subject	20Pron	Neut	20Sup	40Sup	Difference			
					20Pron-Neut	Neut-20Sup	20Sup-40Sup	Total
1	54.19	54.73	55.39	57.45	0.54	0.66	2.06	3.26
2	52.35	52.86	52.98	53.16	0.51	0.12	0.18	0.81
3	59.90	56.24	56.19	57.02	-1.26	0.35	0.95	0.04
4	57.15	57.47	57.37	58.06	0.32	-0.10	0.69	0.91
5	59.54	59.95	60.71	59.89	0.41	0.76	-0.82	0.35
Mean **SD**	**56.63** **3.31**	**56.25** **2.69**	**56.53** **2.84**	**57.12** **2.47**	**0.10** **0.77**	**0.36** **0.36**	**0.61** **1.06**	**1.07** **1.27**

3.7.3.4 Rotation of the calcaneus and phantom marker

The rotation of the calcaneus and the phantom marker for each input rotation from the MR kinematic jig are presented in table 3-21. The mean step-by-step rotation from 20° pronation to 40° supination and total range of motion are very similar for the calcaneus and phantom marker. Between 20° pronation and neutral (mean- 11.45° calcaneus, 11.83° skin marker) the phantom marker underestimated calcaneal rotation in 2 subjects by 1.03° and 0.41°. The largest difference was an overestimation of calcaneal rotation from the phantom marker by 2.50° for subject 3. The overall mean difference for the 5 subjects was 0.96°. Between neutral and 20° supination (mean- 11.45° calcaneus, 10.90° skin marker) the skin marker underestimated underlying bone rotation by 0.68° and 3.4° in 2 subjects and the overall mean difference was 1.26°. Between 20° supination to 40° supination (mean- 10.89° calcaneus, 10.67° skin marker) the skin marker underestimated underlying bone rotation between 0.56° to 2.05° in 3 subjects. The overall mean difference was 1.57°. The mean total range of motion was 33.79° (SD- 3.34°)

for the calcaneus and 33.40° (SD- 4.83°) for the phantom marker and the mean difference was 3.2°. The input rotations were stepped through the range of motion in 20° increments and this appeared to induce a constant mean rotation of 11.26° for the calcaneus and 11.13° for the phantom marker per step.

Table 3-21: Rotation (degrees) of the calcaneus and phantom marker for each input rotation.

Subject	Structure	20Pron - Neut	Neut – 20Sup	20Sup – 40Sup	Total Rotation
1	Calcaneus	10.00	10.22	10.12	30.34
	Marker	8.97	10.57	9.56	29.10
2	Calcaneus	11.41	13.48	12.34	37.23
	Marker	11.84	14.87	14.71	41.42
3	Calcaneus	13.74	7.13	9.23	30.10
	Marker	16.24	6.45	10.24	32.93
4	Calcaneus	10.48	14.12	11.48	36.08
	Marker	10.07	13.70	9.60	33.37
5	Calcaneus	11.62	12.31	11.27	35.20
	Marker	12.04	8.91	9.22	30.17
Mean (Calcaneus)		**11.45**	**11.45**	**10.89**	**33.79**
SD		**1.44**	**2.84**	**1.22**	**3.34**
Mean (Marker)		**11.83**	**10.90**	**10.67**	**33.40**
SD		**2.77**	**3.45**	**2.29**	**4.83**
Difference (M-C)					
1		-1.03	0.35	-0.56	-1.24
2		0.43	1.39	2.37	4.19
3		2.50	-0.68	1.01	2.83
4		-0.41	-0.5	-1.88	-2.71
5		0.42	-3.4	-2.05	-5.03
Mean		**0.96**	**1.26**	**1.57**	**3.20**
SD		**0.90**	**1.26**	**0.76**	**1.46**

3.7.4 Discussion

A non-invasive approach to the evaluation of skin movement artefact using MR imaging is presented. To determine accurate translation and rotation of the structures under consideration repeatability of the segmentation and rendering processes must be established. For the phantom marker significant image manipulation was required to remove artefacts associated with enhancement agent in the central vessel of the structure. However when this was achieved the relative size of the structure, in a region of interest typically 33 by 22 pixels, was small with

exact boundary such that repeat segmentation and rendering produced no variability. The calcaneus demonstrated excellent repeatability for morphological characteristics for all parameters, consistent with the findings of Stindel *et al.*, (1999). Of these variables the location of the geometric centroids showed the least variability, less than 0.1% for 10 repeated measurements, in agreement with the findings of Stindel *et al.*, (1999). Udupa *et al.*, (1998) and Stindel *et al.*, (1999) both remarked that image processing could be undertaken successfully in operators with limited experience. The findings of this study using a novice operator appears to verify this assumption and is mostly due to the use of a semi-automated procedure (live-wire) to define the boundary edges of the calcaneus.

The translation of the calcaneus and phantom marker between each rotation position was characterised by marked differences. The error margins were consistently greater along the y-axis in comparison with the x-axis and the z-axis in comparison with the y-axis. Individual differences were as high as 3.29mm for the x-axis, 5.59mm for the y-axis and 10.49mm for the z-axis. Results from other studies suggest that skin markers over-estimate translation of underlying bone but in this report, between 20° pronation and 20° supination, the phantom marker consistently under-estimated skin translation with mean differences as high as 6.16mm (Holden *et al.*, 1997; Maslen *et al.*, 1995; Tranberg and Karlson, 1998). Indeed for the z-axis between neutral and 20° supination translation of the skin marker was in the opposite direction from the underlying bone. Between 20° supination to 40° supination the phantom marker underestimated underlying bone translation in the x-axis but over-estimated this by 5.53mm and 9.15mm on average for the y- and z-axes respectively. These differences were unexpected and excessive in magnitude and overall trend. Re-inspection of the morphological characteristics of the sensor in each time sequence position revealed discrepancies in the orientation of the principal axes. These differences may be associated with image processing errors related to the rendering of a cylindrical structure (personal communication, D. Odhner, MIPG, University of Pennsylvania). The software in certain input rotation positions failed to differentiate correctly the 2nd and 3rd principal axes, which were equal to the diameter of a circle but in two different orientations (width and height). Therefore this data could not be relied on for the purposes of accurately measuring translation between the bone and phantom marker.

The Euclidean distance between the geometric centroids of the calcaneus and phantom marker was a more precise measure of translation because the centroids location is a very stable measure. Here very little skin movement was found between the marker and the calcaneus and for subject 1 who demonstrated the greatest translation (a total of 3.26mm) on palpation the heel region was fleshier in comparison with the other subjects, establishing a certain degree of face

validity. The manner in which the EMT sensor is attached to the posterior calcaneal surface would suggest that little skin movement should occur, because an anchorage strap can be applied, which is not possible with reflective markers in video systems. Furthermore the data in table 3-18 suggests skin movement increased towards the outer range of motion where in supination, both plantarflexion and inversion serve to crease the skin overlying the calcaneus.

Pre-armed with some knowledge on the influence of axis alignment errors second segmentation was undertaken on the phantom marker for each data set omitting initial and end slices in an attempt to facilitate differentiation of the 2^{nd} and 3^{rd} principal axes. This created a sensor with average 1^{st}, 2^{nd} and 3^{rd} principal axis lengths of 12.15mm, 8.79mm and 7.2mm respectively. The validity of this process is unknown but it served to orientate the axes correctly with respect to each other in each of the 4 image sequences. In this manner table 3-19 shows that the phantom sensor, given error margins between 0.9-1.3°, closely matched the rotation of the underlying calcaneus. The mean differences between the marker and underlying bone are within the error limits for all 4 image positions and for the mean range of motion. In 8/15 instances motion was underestimated by the phantom marker from between 0.41° to 3.40°, and in 7/15 instances motion was overestimated from between 0.35° to 2.50°. There is no literature pertaining to estimates of bone and skin markers motion errors for this anatomical region exist.

The technique adopted was excellent for studying motion characteristics of the calcaneus but experienced limitations with a small artificial structure. Problems were related to the saturation of the MR signal, the small size of the vessel holding the enhancement agent and subsequent difficulties, especially with principal axis orientation during image processing. Furthermore the overall technique is non-weightbearing and static, and skin movement artefact may be different under gait conditions. The field of view during MR image capture was limited to the ankle region so there is no account of the additional effect of sensor movement effect at the proximal medial tibial site. The kinematic jig inputs open kinetic chain rotations about the subtalar joint and talocalcaneonavicular joint and these may not be representative of gait motion in these joints. Furthermore we found the flat vertical plate of the jig inadequate to impose rotations around the subtalar joint. The subjects in this study were measured within the jig with EMT sensors applied to measure AJC rotations (sensors on tibia and posterior calcaneus) against jig (sensors on vertical and horizontal plates) (table 3-22, figure 3-25). Around all three axes of rotation AJC rotations were significantly below that recorded for the jig throughout the pronation-supination range except for dorsiflexion, which was over-estimated in vivo towards the end of motion range. From 20° pronation to 40° supination the AJC exhibited rotations below physiological normal ranges in gait for dorsiflexion/plantarflexion, within normal limits

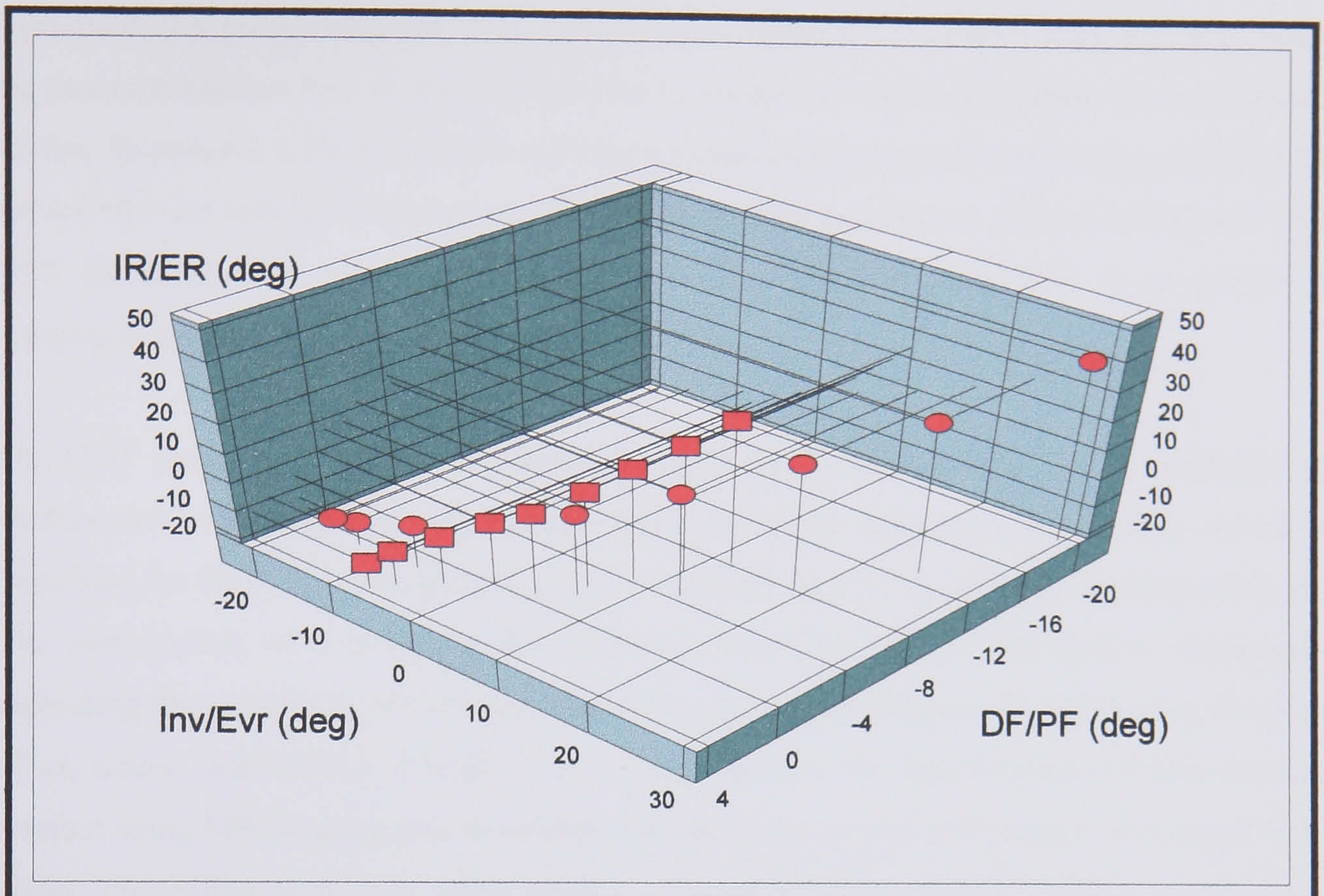
for inversion/eversion and beyond normal limits for external rotation. Input rotation from the jig to the foot are clearly resolved at other joints, mainly the talonavicular site and the current design may be unsuitable to replicate AJC motion during gait. Future jigs would require greater stabilisation of the tibia, and a fixation structure to secure the calcaneus so that input rotation are made through this bone and not across the entire plantar foot surface.

Table 3-22: Comparison of rotation (degrees) measured in vivo for 5 subjects at the ankle joint complex against input rotations from a kinematic jig.

	X (DF/PF)		Y (INV/EVR)		Z (IR/ER)	
	Jig	In-vivo	Jig	In-Vivo	Jig	In-Vivo
30Pron	1.0	3.8 (1.7)	-17.9	-6.8 (1.2)	-17.9	-12.5 (2.9)
20Pron	1.3	2.8 (1.3)	-13.9	-5.8 (0.8)	-13.6	-9.8 (1.8)
10Pron	1.1	1.4 (0.6)	-7.0	-3.1 (0.5)	-6.8	-5.2 (0.6)
Neutral	0	0	0	0	0	0
10Sup	-1.6	-0.5 (0.9)	6.5	3.8 (1.3)	6.7	6.6 (0.9)
20Sup	-4.4	-2.4 (1.2)	12.8	6.1 (2.3)	14.0	11.9 (1.1)
30Sup	-8.1	-4.2 (1.3)	18.9	7.9 (3.0)	22.0	17.1 (1.5)
40Sup	-12.9	-6.2 (1.6)	24.6	9.9 (3.6)	30.6	22.4 (2.3)
50Sup	-19.6	-8.2 (1.6)	29.5	11.7 (4.2)	40.7	27.9 (2.5)

	X (DF/PF)	Y (INV/EVR)	Z (IR/ER)
	Difference (jig-in vivo)	Difference (jig-in vivo)	Difference (jig-in vivo)
30Pron	2.76 (1.7)	-11.1 (1.4)	-5.3 (2.0)
20Pron	1.5 (1.2)	-8.1 (0.8)	-3.8 (1.8)
10Pron	0.3 (0.6)	-3.9 (0.5)	-1.6 (0.8)
Neutral	0	0	0
10Sup	1.1 (1.1)	-2.7 (1.2)	-0.1 (0.9)
20Sup	-2.0 (1.3)	-6.7 (2.3)	-2.1 (0.7)
30Sup	-3.9 (1.3)	-11.0 (2.9)	-4.9 (1.1)
40Sup	-6.7 (1.5)	-14.7 (3.6)	-8.2 (1.9)
50Sup	-11.3 (1.7)	-17.7 (4.0)	-12.8 (2.3)

DF/PF- dorsi/plantarflexion; INV/EVR- inversion/eversion; IR/ER- internal/external rotation.



Input rotation by axis from kinematic jig

In vivo rotation output from EMT tracking system at AJC

Figure 3-25: 3D plot of ankle joint complex output rotation against input rotation from kinematic jig

3.8 Summary and conclusions

This chapter described how a generic tracking system coupled with commercial motion analysis software has been developed for specific use for kinematics at the ankle joint complex in gait. The method of clinical application with special consideration to in-shoe measurement has been described and advantages and disadvantages over other techniques discussed. A validation experiment specifically for the AJC found errors for orientation of <1° and position <1mm when measurement is contained during gait within an optimal operating zone. Using the coefficient of multiple correlation for curve shape agreement the repeatability of kinematic data for the ankle joint complex was excellent for barefoot and shod conditions for both healthy individuals and patients with rheumatoid arthritis. Repeatability for the technique was excellent when tested for 2 independent observers for within day testing. Improved reproducibility was achieved when relative data was analysed alongside the absolute data. Between-day reproducibility for one observer produced high and moderately high CMC values for the kinematic data, all values improved when relative data corrected for variability in the boresight position. Inter-observer

reproducibility produced good CMC values, again better when relative data was analysed, but the recommendation here is for one observer to conduct all serial measurements in longitudinal studies. In patients with rheumatoid arthritis between day reproducibility testing produced CMC values >0.9 for relative motion-time data for the sagittal and frontal plane rotations and a value >0.8 for transverse plane rotation. Physiological variability resulting from painful foot symptoms accounted for the weaker reproducibility.

The EMT protocol was tested in a small group of rheumatoid arthritis patients with pronatory dysfunction in the rearfoot undergoing orthotic treatment. Abnormal motion:time curves were described for the AJC in the patient group in comparison with those from a healthy adult group. The introduction of a corrective foot orthosis served to improve the motion characteristics indicating the sensitivity of the measurement system to detect kinematic changes as the product of an active intervention. Finally a novel approach to the measurement of skin movement artefact using MR imaging was described. Despite some technical limitation associated with the image processing technique some evidence suggested that an EMT sensor attached to the posterior calcaneal surface closely measures the orientation and translation of the underlying bone with minimal skin movement. In the clinical protocol the technique has been developed to permit barefoot, shod and shod with orthosis measurements without disturbing the boresight procedure hence any skin movement artefact, although minimal, will be systematic through the test protocol. The system has some disadvantages as data can only be captured within a small volume necessitating the need for repeat measures, and trailing cables form sensors need to be tidied and supported away from the patient to avoid interference with normal gait. However the ease of use, coupled with the good accuracy and repeatability characteristics suggest this system is robust enough to permit in-shoe evaluation of foot orthoses longitudinally in the presence of rheumatoid arthritis.

CHAPTER 4

FOOT ORTHOSES IN RHEUMATOID ARTHRITIS- A CLINICAL EVALUATION

This chapter provides a detailed description of the methods employed to evaluate clinically the effectiveness of foot orthoses in early rearfoot disease in rheumatoid arthritis. The rationale for the method employed is established and a detailed description of the protocol is provided. Detailed reference is made to the study population, interventions, outcome measures, randomisation and assignment techniques and statistical analyses. The results relating to the clinical outcomes and clinical variables are presented and discussed in detail with reference to existing evidence.

4.1 Background and rationale

4.1.1 Management of valgus heel deformity in rheumatoid arthritis

There are no published clinical guidelines for the management of valgus heel deformity in RA. A limited number of studies have focused on interventions to alleviate painful symptoms, stabilisation of the deformity and surgical correction (Conrad *et al.*, 1996; Cracchiolo *et al.*, 1992; Hay *et al.*, 1999; Hunt *et al.*, 1987; Locke *et al.*, 1984; Merritt, 1987). Treatment strategies are seldom disease-staged in a manner analogous to drug management and are dominated by rehabilitation in advanced foot disease. Very few interventions have been subjected to rigorous evaluation under clinical trial conditions.

4.1.2 Foot orthoses and their use in rheumatoid arthritis

The Cochrane Musculoskeletal Group database failed to reveal any systematic review completed or underway in the field of foot orthoses in RA. Electronic and hand searching of the literature revealed 6 studies. Two contained data from the same randomised controlled trial (RCT) and the remainder were non-randomised studies. In the latter patient numbers ranged from only 1 to 10, with outcome measurements focused on pain and spatio-temporal gait parameters. Locke *et al.*, (1984) in 10 orthosis users found a significant increase in velocity and single-limb support time with shoes and a further significant increase with orthoses, 9 from 10 patients reporting decrease in ankle and rearfoot pain after using the orthosis. Hunt *et al.*, (1987) in a single case design found a custom-designed leg-hindfoot orthosis increased gait velocity, cadence and stride length along with an increase in the single-limb support time and substantial relief of pain. In 8 subjects with a mean disease duration of 11.1 years MacSween *et al.*, (1999), noted improved comfort levels with the use of custom-moulded foot orthoses in RA patients all

with forefoot pain and 4 from 8 with hindfoot pain. Gait analysis revealed a statistically significant increase in average stride length with orthoses with increased gait velocity and cadence but not at statistically significant levels. Hodge *et al.*, (1999) demonstrated reduced forefoot pain and average pressure with a number of custom and pre-fabricated devices but did not study rearfoot symptomatology or mechanics.

These studies offer evidence of best practice to date but methodological weaknesses either with respect to design, sufficient patient numbers or targeting of sub-populations, limit their true value and generalisability. Under the scrutiny of more rigorous testing such as the randomised control trial (RCT) Conrad *et al.*, (1996) suggests that orthoses for this patient group may be less effective than previously thought. This group conducted a randomised control trial using rigid orthoses in 102 RA patients. The study had excellent design features including randomisation, use of a placebo orthosis, double blinding to the intervention and independent post-test evaluation of the primary outcome measure. For inclusion patients had to demonstrate flexible functional discrepancies, amenable to orthotic correction, but no severe structural deformities limiting gait. The precise rationale is not stated but presumed to be functional correction in an attempt to lessen pain and disability. Conducted over a 36-month period the findings indicated no benefit of functional posted-device over placebo on disability and pain measures. However, the devices were associated with a decreased rate of hallux valgus deformity in the intervention group over control (Budiman-Mak *et al.*, 1995). These findings whilst disappointing and contrary to the findings of previous studies were not unexpected when, albeit not fully described in the results, the subjects were, "older males with a long duration of illness". Long duration illness is infrequently associated with foot types that are truly flexible and deformity free, and suited to rigid orthoses in the manner described. Furthermore exclusion of female patients and patients with early disease severely limits the generalisability of this otherwise very well conducted study. Whilst rehabilitation of foot problems in established disease is important the opportunity to test orthotic interventions in a more preventative manner in early disease has yet to be undertaken. This chapter describes the development and execution of a RCT for this purpose.

4.1.3 Model for early interventions

Rearfoot deformity in RA occurs at different rates with perhaps 25% of all cases vulnerable to moderate to severe deformity within the first 5 years. A so-called 'window of opportunity' exists during this period to intervene before irreversible changes to structure and function occur. In figure 4-1 a model is proposed whereby the course of the deformity (from mild to moderate to severe- however determined) (Y1) is plotted against time (X) from disease onset and

alongside treatment strategy (Y2). Patients who develop severe deformity within 5 years from onset (pathway-A) have only a short time period in which to initiate preventative management. Others may develop deformity in a more linear fashion (pathway B), with progressive changes in the joint structure following repeated inflammatory attacks (hence the "saw tooth" appearance), and finally a smaller group still where cumulative damage may be resisted until the later stages followed by rapid deformity (pathway-C), perhaps triggered by an acute incident such as rupture of tibialis posterior muscle tendon. There are no data on the proportion of patients who follow each of the hypothetical pathways.

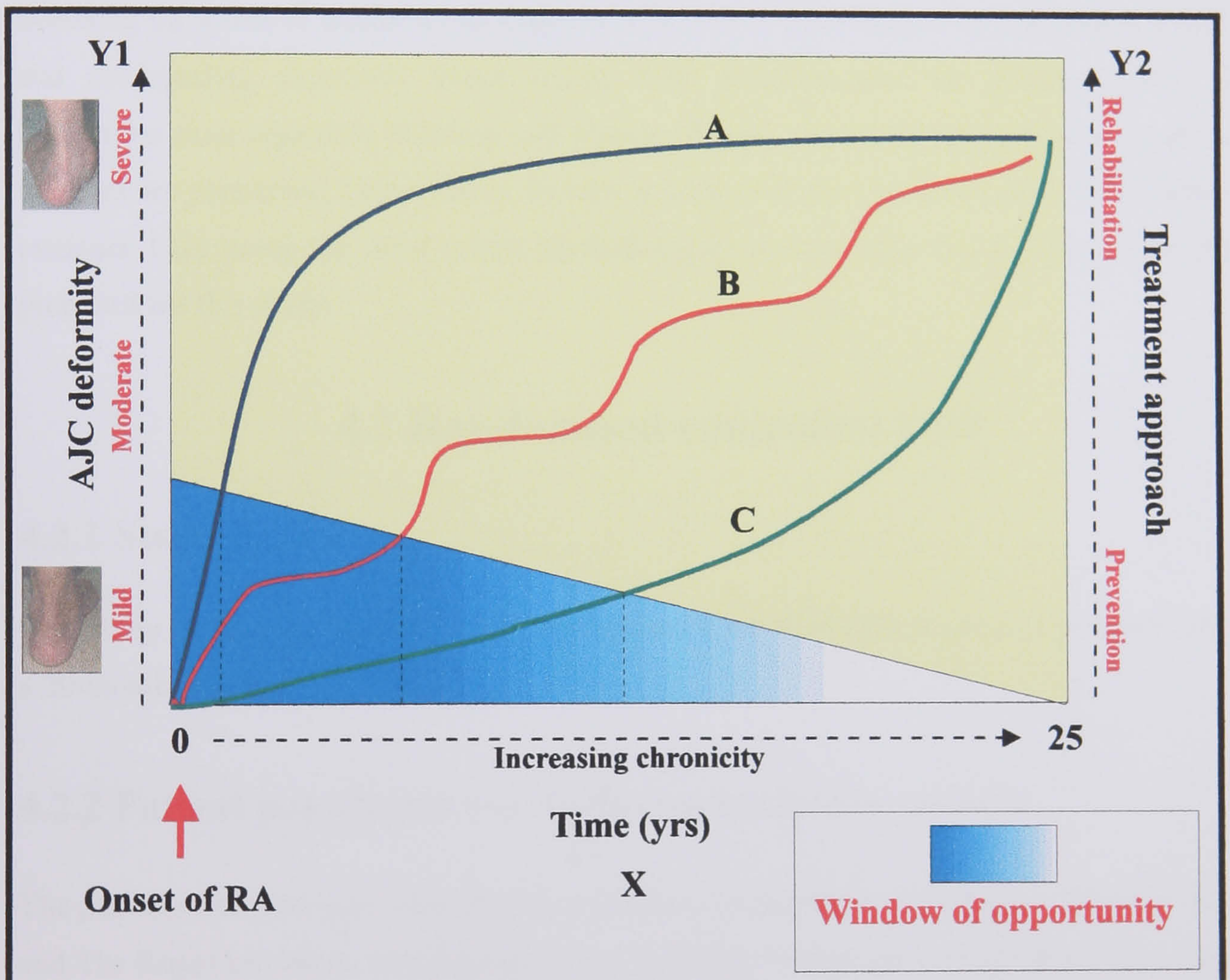


Figure 4-1: Early intervention model for foot orthoses in rearfoot disease in rheumatoid arthritis. Curves A to C represent three hypothetical states of disease progression.

The aim of this study is to identify patients within the very early stages of disease who show signs of correctable valgus heel deformity. As yet there are no prognostic indicators as to which pathway these patients will follow, and in the face of repeated or persistent inflammatory disease, foot orthoses may not prevent deformity from progressing at all. Realistic goals may lie in either slowing the rate of deformity or changing the clinical course (e.g., converting pathway A to B or C) with associated reduction in symptoms and maintenance or improvement in function.

The ability to accurately and repeatedly measure deformity and its progression is central to evaluating this proposed model. Previously only static radiographic techniques have attempted to do this, but the kinematic protocol developed in chapter-2 may provide a way forward to establish initial diagnosis then monitor the rate of change over time, alongside the mechanical effect of the orthotic intervention.

4.1.4 Rationale

The randomised controlled trial (RCT) is considered the most robust form of evidence for assessing all forms of health technology (Woolf, 1997). This method is designed to avoid bias and confounding especially those arising from selection and the placebo effect. Some limitations exist regarding blinding and placebo design where physical therapies such as foot orthoses are concerned. Nonetheless, therapy groups, including podiatry, must contribute to the evidence base using the most robust methodologies and for this reason a pragmatic RCT is proposed for this study.

4.2 Randomised controlled trial

4.2.1 Study design

This study is designed as a pragmatic randomised controlled trial conducted prospectively over a 30-month period.

4.2.2 Patient population and inclusion/exclusion criteria

The patients were recruited from the Rheumatology Departments at St Luke's Hospital Bradford and The Royal Infirmary, Huddersfield. Four inclusion criteria were established, (1) a diagnosis of rheumatoid arthritis, (2) a disease duration of ≤5 years, (3) correctable valgus heel deformity and, (4) current history of foot pain. The same rheumatologist conducted clinical consultations to establish the diagnosis of RA based on the 1987 ARA revised criteria for rheumatoid arthritis (Arnett *et al.*, 1988). The same podiatrist using existing clinical techniques based on observation, examination and clinical judgement made the diagnosis of early valgus heel deformity if all the following criteria were satisfied:

1- Observation on static weightbearing of an everted calcaneus (relative to the ground).
2- Observation on static weightbearing of medial talar head bulging in the region of the talonavicular joint.
3- Observation on static weightbearing of low medial longitudinal arch height.

4- Observation on static weightbearing of abducted forefoot with positive 'too many toes' sign (from posterior view appearance of lesser toes on the lateral side of the heel).
5- On passive examination physiological normal limits of subtalar, ankle and midtarsal joints range of motion with subtalar joint inversion component $\geq 10°$.
6- No severe asymmetry in the extent of deformity.

The willingness of patients to return for serial assessments and participate in gait analysis was also assessed and a period of 24-48 hours provided for patients to consider the study conditions fully. The following exclusion criteria were applied to the patients entering this study:

1- A current or past history of other musculoskeletal diseases or overlap syndrome, or any co-morbid disease likely to affect lower limb and foot structure and function as determined by the rheumatologist and podiatrist. Neurological disease and endocrine diseases such as diabetes were carefully excluded because of effects on peripheral nerves, foot structure and function and pain perception.
2- A history of lower limb or foot trauma resulting in fracture, dislocation or soft-tissue injury requiring hospital or other medical care.
3- A history of lower limb or foot surgery regardless of cause.
4- Current or past usage of rigid functional foot orthoses.
5- Unsuitable footwear in which to accommodate the orthoses. Patients fulfilling this criterion but still interested in entering the study were offered advice and asked to return for further consideration if footwear changes were implemented. No special footwear were allocated to this study, but patients were required to have footwear with adequate width and depth in all parts, suitable retaining medium such as laces or Velcro straps, low heel height and rigidity and support around the heel counter region, worn for most days of the week.
6- An unwillingness to comply with attendance schedule or undergo gait analysis.

Foot pain was assessed from the patient history given on day of recruitment and examination for swollen and tender foot joints conducted by the same podiatrist throughout.

4.2.3 Interventions and timings

4.2.3.1 Intervention group

The intervention group underwent a new early intervention foot orthosis programme using rigid carbon-graphite foot orthoses, custom designed for each patient. Each foot orthosis was manufactured to a non-weightbearing subtalar neutral cast using the suspension technique described by Root *et al.*, (1971). Briefly, this comprises the application of plaster bandage to the

foot, allowing it to set as the subtalar joint neutral position is maintained. This position is achieved by palpation using one hand whilst the other gently dorsiflexes the foot by application of pressure in the 4th and 5th toe sulci to bring the ankle joint to 90° to the leg and the midtarsal joint maximally pronated and locked against the rearfoot. The slipper cast was then removed, allowed to set, boxed and forwarded to a commercial laboratory for orthotic manufacture (Langers Biomechanics Group (UK) Ltd, Cheadle, UK).

At the orthotic laboratory a special protocol was designed to ensure standardised manufacture of all devices. The shell specifications and posting instructions were standardised and varied only by the amount of correction built into each device. The negative cast was assessed for any imperfections and returned to the centre for repeat casting if necessary. Positive cast correction for intrinsically posted devices was undertaken using the methods described by Root (1994), Jones (1996) and others. On the corrected positive cast a Root shell was formed for each device in Super-Lyte® carbon graphite composite with heel cup heights of 14mm medially and 12mm laterally (figure 4-2). All devices were posted intrinsically in the rearfoot with maximum forefoot balance. The degree of posting varied according to the balance need of each foot and specific measurements were taken from the positive cast cross-checked with alignment information from the clinical examination recorded on an orthosis prescription form. All devices were finished with a top cover of 1.6mm PPT and vinyl extending to the toe sulcus region. Each device was reviewed under a factory quality control scheme and distributed to the centre for fitting.

4.2.3.2 Control group

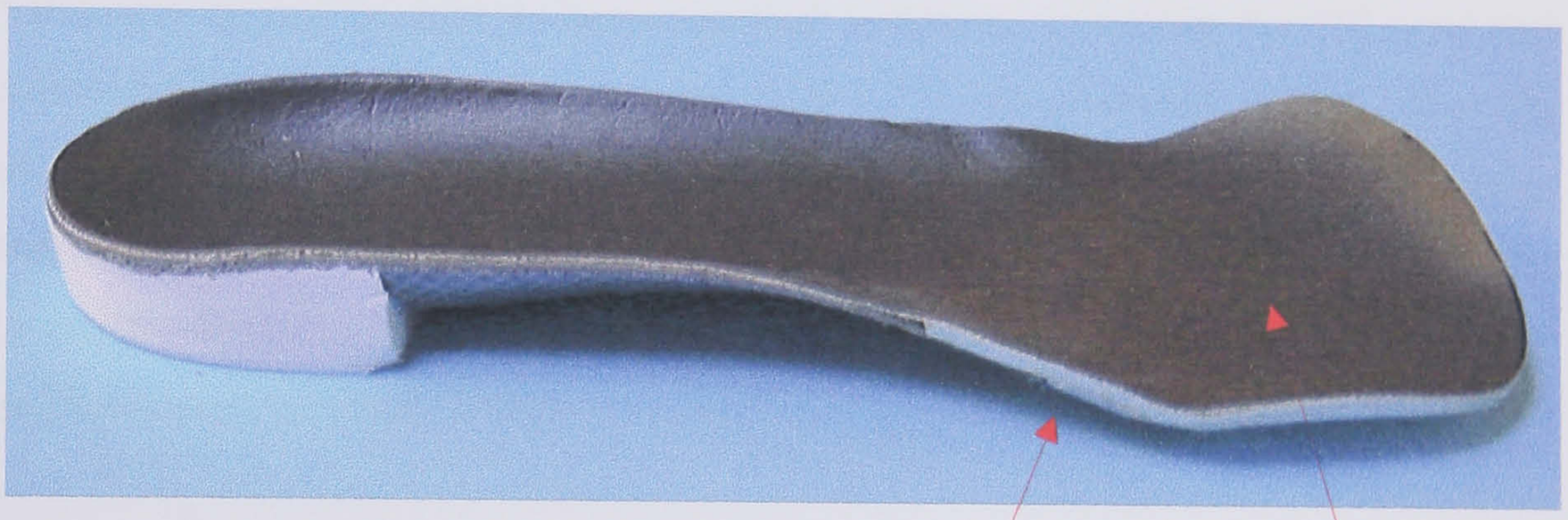
Patients randomised to the control followed conventional management and thus received no active foot orthotic intervention at baseline. Over the duration of the study the patients were permitted to receive an orthosis if prescribed by the attending doctor on any outpatient clinic, the pool of medical staff blinded to the patients inclusion in the study. The hospital appliance department supplied the devices following instructions from the doctor in the usual manner, and a record of this intervention was made at follow up.

4.2.4 Primary clinical outcome measurement

The primary clinical outcome was the Foot Function Index (FFI) a composite measurement of foot pain, disability and functional limitation (Budiman-Mak *et al.*, 1991). It was designed specifically for rheumatoid arthritis for the purposes of supporting a foot orthotic intervention study (as described earlier from Conrad *et al.*, 1996). This questionnaire-based tool consists of

A

B



C

1- Heel cup section
2- Medial longitudinal arch section
3- Forefoot section
4- Maximum forefoot intrinsic balance
5- Heel platform
6- Forefoot PPT extension to toe sulci

Figure 4-2: Rigid intrinsically posted carbon-graphite foot orthosis

23 items grouped into three domains- foot pain (9 items), disability (9 items) and activity limitation (5 items). All items are rated using visual analogue scales (VAS) consisting of a horizontal line (100mm) with verbal anchors representing the opposite extremes of the dimension being measured. Patients complete the questionnaire unaided by marking a vertical line through the scale at a position that best represented their experience in the past week. To score an item the position of the vertical mark (mm) from the left anchor is measured. To obtain a subscale score the item scores are totalled and divided by the total number of items the patient indicated were applicable. Calculating the average of the three sub-scale scores derives a total FFI score. The tool does not differentiate left and right sides.

Extensive validation shows the tool to have excellent test-retest reliability for FFI total and subscale scores (0.87-0.69), internal consistency (0.96-0.73) and construct validity. The FFI total and subscale scores correlate highly with clinical measures of foot pathology establishing good criterion validity. In their validation studies the tool was also sensitive enough to detect changes at 6 months for pain, this subscale score correlating strongly with increased joint pain count scores (Budiman-Mak *et al.*, 1991).

4.2.5 Kinematics and kinetics

Kinematic measurement for the left and right AJC were undertaken using the methodology outlined in chapter 3. An expanded kinematic model was established which also included measurement for the knee joint (third sensor placed on the lateral thigh), and the calcaneotalonavicular joint (fourth sensor placed on the navicular). In-shoe plantar pressure measurement was conducted using a flexible capacitance transducer system (PEDAR, Novel GmbH, Munich, Germany). The insole was placed within a standard shoe for each subject and measurements taken at the foot:shoe interface and repeated at the foot: orthosis interface (in the intervention group). Data was also collected using the same protocol in an age and sex-matched normal population.

4.2.6 Study variables

4.2.6.1 Demographic data

For all patients, age (years), sex (male/female), ethnic origin (% Caucasian) and disease duration (years) were recorded. All data were recorded on a standard proforma.

4.2.6.2 Clinical data

The clinical course of RA varies and to account for any potential group differences disease activity was measured over the duration of the study. This study employed the European League Against Rheumatism (EULAR) Disease Activity Score (DAS) (Prevoo *et al.*, 1995, van Gestel *et al.*, 1996). This validated core set comprises a 28 tender and swollen joint count, the erythrocyte sedimentation rate, a VAS score of patient global health assessment and a VAS score of pain, the latter not included in the final DAS. The DAS was derived using the formula:

Disease Activity Score (DAS)= $0.56\sqrt{28T} + 0.28\sqrt{28S} + 0.70 * \ln ESR + 0.014 * GH$

Where: T= Tender Joint Score (0-28).

S= Swollen Joint Count (0-28).

LnESR= Natural logarithm of the Erythrocyte Sedimentation Rate (mm/hour).

GH= Patient global assessment of own health (0-100mm VAS).

Prevoo *et al.*, (1995)

In clinical practice, C-reactive protein and plasma viscosity are used as alternative acute phase reactants to the ESR. Where this occurred the variables were converted to ESR values using the formulas defined by Wolfe (1997). A DAS $\leq$2.4 indicates low disease activity, 2.4<DAS$\leq$3.7 indicates moderate disease activity and DAS>3.7 indicates high level of disease activity. A change of 1.08 represents significant improvement or deterioration and EULAR response criteria based on change from baseline have been set (good >1.2, moderate >0.6, no response $\leq$0.6), Van Gestel *et al.*, (1996).

The Stanford Health Assessment Questionnaire (HAQ), a validated and well-documented questionnaire for rheumatoid arthritis was used to measure global function (Fries *et al.*, 1980, Kirwan *et al.*, 1986). This is a 20-item self-administered questionnaire with scores ranging from 0 (no disability) to 3 (unable to do at least one task in the 8 domains covered by the HAQ). The radiographic technique of Larsen *et al.*, (1977) was used to score joint erosions in the hands and feet. Radiographs were read by the same experienced observer blinded to the study group and time point of the X-ray. The degree of joint damage was graded 0-5 using standard radiographs at the proximal interphalangeal and metacarpophalangeal joints and the wrist joints (score multiplied by 5) in the hands and the 2nd to 5th metatarsophalangeal joints and interphalangeal joints of the hallux in the foot. The maximum scores achievable were 150 and 50 for the hands and feet respectively.

4.2.6.3 Drug management and other medical/paramedical care

Over the duration of the study drug management including non-steroidal anti-inflammatory (NSAID's), disease-modifying anti-rheumatic (DMARDS), and oral, bolus or intra-articular glucocorticosteroid drugs was monitored for each patient. A record was also kept of in-patient care, physiotherapy, surgical appliance, podiatry, and orthopaedic surgery interventions.

4.2.6.4 Treatment adherence and adverse reactions

A structured interview schedule for face-to-face or telephone response was designed to record information related to treatment adherence and adverse reactions associated with orthotic intervention. Items included yes/no responses to wearing of orthoses on day of interview and general comfort, number of hours and days per week orthoses worn, increased symptoms elsewhere in the feet and legs. Specific problems such as new tender spots, blisters, skin bruising, skin thickening, cramping and tenderness were also recorded.

4.2.7 Assignment

A central research office generated the allocation schedule designed as a balanced block of four, with the patient as the unit of randomisation. Prior to each recruitment clinic the schedule for that day was accessed by telephone from the central office. Group allocations (A- intervention, B- control) were recorded on paper slips then sealed in envelopes numbered in sequence. A research nurse was appointed as the executor of the schedule, independent of the protocol above, and at recruitment an envelope was opened, in sequence, to allocate the patient appropriately.

4.2.8 Procedure

Local Research Ethical Committee approval was granted for this study. Patients deemed suitable for inclusion in the study were recruited from rheumatology outpatient clinics. A research nurse and podiatrist conducted in-depth interviews and examinations to ascertain eligibility using the inclusion/exclusion criteria defined earlier. The background, objectives, methods and requirements of participation were explained to patients in lay-terms supported by a standard information sheet (Appendix A). Patients uncertain about participation were allowed a period of consideration and followed up for final decision. Patients willing to participate but whose footwear was unsuitable were offered footwear education including demonstrations of

good footwear, verbal advice and written literature. Those followed up in clinic that changed their footwear to more suitable types were re-invited to participate. All patients agreeing to participate signed a consent form (Appendix B).

Patients allocated to the intervention group had neutral casts taken and a follow-up appointment for orthotic fitting within 28 days. On return orthoses were checked for immediate comfort and fit and minor alterations made (restricted to the removal of uncomfortable edges either from the shell or PPT/vinyl cover). The use and maintenance of the devices were explained to patients supported by a written information sheet (Appendix C). At baseline the research nurse administered the FFI and conducted clinical examinations to generate clinical data as outlined above. Information was collected on current drug management and other medical/paramedical interventions and blood tests and x-rays were arranged to complete the data portfolio.

The same researcher was used throughout the study to set patients up for gait analysis including the placement and attachment of EMT sensors and heel switches. Standard modified orthopaedic stock shoes, of appropriate size (P.W Minor, Batavia, USA), were used when collecting shod data and used to accommodate the orthosis for testing under that condition. All patients were given a period to acclimatise with the set-up and the shoes following which 5 trials under barefoot, shod, and shod and orthosis conditions (intervention group) were captured. For in-shoe plantar pressure measurement data was collected from a single gait trial over a 10m distance.

To reduce attrition rates patients were offered help with transport to and from clinic, a telephone support line was made available for rapid access to advice and help from the research nurse, interpreters were used to help non-English speaking participants complete the questionnaires and evening appointments were offered to prevent loss of work time.

The protocol was repeated for all subjects in the control and intervention groups at 3, 6, 12, 18, 24 and 30-months. Adherence interviews were conducted between 0 and 3, 3 and 6, 6 and 9 months and at study exit (30-months).

4.2.9 Statistical analyses

The baseline demographic details by group (intervention versus control) were prepared as mean (SD) or median (inter-quartile range- IQR) values based on Shapiro-Wilks test for normal distribution. Clinical data and FFI subscale and total scores were prepared as median (IQR) values and drug and other interventions data as proportions (%). For the treatment adherence

and adverse reaction variables data were prepared as N (number) and proportion (%) of group giving a yes response to each interview item.

Longitudinal clinical data was analysed using the technique of summary measures outlined by Matthews *et al.*, (1990). For each variable the response, given as change from baseline score, was calculated for each review time point. This was then plotted against time for each patient with improvement in status deemed negative change and deterioration positive change. Using the trapezium rule a single summary measure, the area under the curve (AUC), was calculated for each subject. The median (IQR) AUC was derived for the intervention and control group and between group differences analysed using a Mann-Whitney U test. The significance level P was set at 5% (2 tailed tests). A hypothesis was set that over time the clinical efficacy of the foot orthosis would diminish and to analyse this the AUC summary measure was used to find and then compare the peak response and time to peak response for the two groups.

This pragmatic study was designed with intention-to-treat principles and as such data for all individuals should be included with conservative rules adopted to replace missing data with assigned data (Herxenberg *et al.*, 1999; Hill, 1999). Various techniques, ranging from imputing the last observed value to predictive modelling can be undertaken for this purpose (Little, 1999). Sophisticated techniques were not used in this study but sensitivity analysis revealed no change in the statistical level of significance when between group analyses were conducted on FFI data using either last value carried forward, mean value from all previous values or random value from within the range of previous values. This was conducted for data at the 12-month review only. Subsequently missing values were replaced by last value carried forward.

4.3 Results

4.3.1 Patient recruitment and participant flow

Two hundred and fifty-four patients who fulfilled the American Rheumatism Association 1987 revised criteria for rheumatoid arthritis (Arnett *et al.*, 1988) were screened for inclusion in the study (figure 4-3). One hundred fifty-three patients were excluded for the following reasons:

- Unable to fulfil trial commitments (N=48, 18.9%).
- Presence of co-morbidity likely to influence outcome measures such as diabetes and cerebrovascular accident (N=29, 11.4%).
- Severe ankle joint complex involvement contra-indicated towards the use of functional foot orthoses (N=27, 10.6%).

- Unsuitable footwear (N=26, 10.2%).
- Current orthosis users (N=21, 8.3%).
- Unable to undergo gait analysis (N=2, 0.8%).

One hundred and one patients (39.8%) gave informed consent and were recruited and randomised. Three patients in the control no-intervention group (N=51) subsequently withdrew from the study within 24hrs, all citing disappointment at not receiving the intervention as the reason. Therefore at baseline 98 subjects were entered to the study, N=50 in the experimental and N=48 in the control group. At 30-months, 7 (14%) of patients in the intervention group and 10 (21%) of the control group were lost to follow-up. The attrition alongside non-attendance for review appointments is presented in figure 4-3.

4.3.2 Patient demographics at baseline

The baseline demographic details are presented in table 4-1. In the control group 32 female and 16 males and in the intervention group 34 female and 16 males patients participated in the study. In the control and intervention groups, 6.2% and 10% respectively of patients were recruited from within the ethnic minority populations (Asian and Afro-Caribbean). The mean age for both groups was similar at 53.1 years and 54.0 years for control and intervention groups respectively. There was no imbalance in disease duration the median of 3 years the same for both groups, the inter-quartile range suggesting a slightly wider spread in the upper value for the intervention group.

Table 4-1. Baseline demographic details for control and intervention study groups.

Variable	Control group (*N*=48)	Intervention group (*N*=50)
Sex (F:M)	32:16	34:16
Ethnic Origin (% Caucasian)	93.8	90.0
Age (yrs)	53.1 (11.1)	54.0 (11.8)
Disease duration (yrs)	3 (2, 6)	3 (1, 7)

Values are mean (SD) or median (inter-quartile range) based on Shapiro-Wilks test for normal distribution.

Figure 4-3. Recruitment details, trial profile, participant flow and number lost to follow-up.

4.3.3 Foot Function Index scores

4.3.3.1 Median FFI subscale and total scores from baseline to 30-months

The median (IQR) for FFI subscales and total score for both study groups from baseline to 30-months are presented in table 4-2. The intervention group had a higher median baseline pain subscale score (51mm) than the control group (39mm). The initial review at 3 months revealed an increase in foot pain (45mm) in the control group and a decrease (32mm) in the intervention group. In the control group over the next 5 assessments the pain score levelled between scores of 40-46mm and at final assessment the pain score decreased to 34mm, a value below the initial baseline score.

Table 4-2. Median (IQR) FFI pain, disability and functional limitation subscales and total score (VAS mm, 0-100) from baseline to 30-months.

	PAIN						
Group	**Baseline**	**3-months**	**6-months**	**12-months**	**18-months**	**24-months**	**30-months**
Control							
Median	39	45	40	42	46	41	34
IQR	(19, 61)	(20, 57)	(21, 61)	(18, 60)	(11, 59)	(12, 59)	(9, 51)
Intervention							
Median	51	32	36	38	42	42	44
IQR	(36, 81)	(19, 63)	(16, 58)	(19, 60)	(24, 66)	(19, 65)	(21, 67)
	DISABILITY						
Group	**Baseline**	**3-months**	**6-months**	**12-months**	**18-months**	**24-months**	**30-months**
Control							
Median	37	43	39	42	43	40	36
IQR	(19, 60)	(22, 54)	(22, 55)	(16, 56)	(16, 57)	(14, 55)	(15, 52)
Intervention							
Median	50	34	37	34	34	41	33
IQR	(21, 66)	(16, 63)	(14, 57)	(16, 62)	(13, 53)	(11, 58)	(9, 51)
	FUNCTIONAL LIMITATION						
Group	**Baseline**	**3-months**	**6-months**	**12-months**	**18-months**	**24-months**	**30-months**
Control							
Median	9	15	13	13	15	14	14
IQR	(1, 36)	(5, 38)	(5, 38)	(4, 27)	(4, 28)	(5, 37)	(4, 34)
Intervention							
Median	20	10	13	11	17	20	17
IQR	(7, 29)	(4, 27)	(4, 30)	(3, 32)	(3, 30)	(3, 36)	(2, 28)
	FFI						
Group	**Baseline**	**3-months**	**6-months**	**12-months**	**18-months**	**24-months**	**30-months**
Control							
Median	29	33	34	35	35	32	31
IQR	(16, 48)	(22, 48)	(19, 50)	(14, 42)	(10, 52)	(10, 46)	(15, 44)
Intervention							
Median	41	28	34	32	32	34	30
IQR	(24, 56)	(14, 48)	(15, 46)	(14, 48)	(18, 47)	(19, 48)	(18, 47)

In the intervention group the median pain score increased gradually over the review period from 32mm at 3-months to 44mm at 30-months, the final assessment value still less than the baseline score. The median disability subscale score for the control group did not vary much over the 30-month duration of the study. The initial and final scores were similar at 37mm and 36mm respectively with a variation over time of only 6 points. At baseline the intervention group reported more foot-related disability than did the control group (median score- 50mm). At first review of the orthoses at 3-months the score had decreased to 34mm and this was maintained within 3 points until 24-months where the value increased to 41mm. At final assessment the treatment effect appeared to be sustained with a final score of 33mm, very similar to the initial review score of 34mm at 3-months.

The functional limitation subscale scores were greater in the intervention group when compared against control (20mm versus 9mm). At 3-months the median score had increased to 15mm in the control group and this was maintained over the course of the study, the final assessment score being 14mm. In the intervention group the first review score at 3-months fell to 10mm sustainable within 3 points until 12-months. From 18-months the value increased to 17mm with a peak of 20mm at 24-months and a final assessment value at 30-months of 17mm.

The FFI total score followed the trends reported above. The intervention group had a higher median score at baseline than control (41mm versus 29mm). Over the 30-month period the control group median score varied slightly between 31-35mm with a final review score of 31mm, a slight overall increase from baseline. In the intervention group, the 3-month review indicated a net improvement from 41-28mm. This median score increased slightly after this varying from 32-34mm with a final review score of 30mm, indicating a sustainable effect over the duration of the study.

4.3.3.2 Area under the curve statistical analyses of FFI data

The change in scores from baseline to 30-months for the FFI subscales and final score and the area under the curve analysis are presented in tables 4-3 to 4-6. For the FFI pain subscale (table 4-3) the control group showed little change over time until the final assessment (median improvement in pain by 8 VAS points). This group showed a net increase in pain over time with an area under the curve score of 25 units. The intervention group showed a median improvement of 16mm at 3-months, the improvement sustainable but diminishing over 30-months, the final score being 12mm. This group showed a net decrease in pain over the duration of the study with an area under the curve of 376 units. A Mann-Whitney U test revealed a

statistically significant group difference for pain subscale over the duration of the study (P=0.013).

Table 4-3: Change in FFI pain subscale (VAS mm, 0-100) from baseline to 30-months with area under the curve analysis

Group	ΔBL-3M	ΔBL-6M	ΔBL-12M	ΔBL-18M	ΔBL-24M	ΔBL-30M
Control						
Median	0	0	-1	3	0	-8
IQR	(-9, 13)	(-14, 13)	(-11, 16)	(-14, 22)	(-14, 16)	(-23, 7)
Intervention						
Median	-16	-14	-13	-7	-12	-12
IQR	(-30, 0)	(-30, 0)	(-24, 0)	(-25, 5)	(-24, 0)	(-32, 7)
Z-score	**-3.00**	**-2.92**	**-2.76**	**-2.08**	**-1.98**	**-0.71**
P-value	**0.003**	**0.004**	**0.006**	**0.038**	**0.048**	**0.48**

Area under the curve	
Control:	**25 (-314, 359)**
Intervention:	**-376 (-662, 34)**
Z-score:	**-2.49**
P-Value*:	**0.013**

(Median with inter-quartile range in parentheses. * Mann Whitney U-Test).

For the FFI disability subscale (table 4-4) the control group showed no significant change in scores across the duration of the study, the final review score an improvement of only 1mm. Over time this group showed a net decrease in disability with an area under the curve score of 30 units. The intervention group showed a median improvement of 7mm at 3-months, the improvement sustainable but variable over 30-months, ranging from 7mm at 24-months to 17mm at the final 30-month review. This group showed a net decrease in disability over the duration of the study with an area under the curve of 320 units. A Mann-Whitney U test revealed a statistically significant group difference for disability subscale over the duration of the study (P=0.026).

Table 4-4: Change in FFI disability subscale (VAS mm, 0-100) from baseline to 30-months with area under the curve analysis.

Group	ΔBL-3M	ΔBL-6M	ΔBL-12M	ΔBL-18M	ΔBL-24M	ΔBL-30M
Control						
Median	0	-4	-2	-1	-1	-1
IQR	(-13, 13)	(-14, 10)	(-16, 15)	(-14, 16)	(-14, 10)	(-21, 11)
Intervention						
Median	-7	-9	-8	-13	-7	-17
IQR	(-28, 0)	(-19, 0)	(-29, 3)	(-32, 0)	(-32, 4)	(-36, 3)
Z-score	**-1.99**	**-1.95**	**-1.70**	**-2.36**	**-1.46**	**-1.78**
P-value	**0.046**	**0.051**	**0.089**	**0.018**	**0.101**	**0.075**

Area under the curve	
Control:	**-30 (-404, 267)**
Intervention:	**-320 (-736, 0)**
Z-score:	**-2.23**
P-Value*:	**0.026**

(Median with inter-quartile range in parentheses. * Mann Whitney U-Test).

For the FFI functional limitation subscale (table 4-5) the control group showed no significant change in scores across the duration of the study. Over time this group showed a net slight increase in functional limitation with an area under the curve score of 5 units. The intervention group showed a median improvement of 2mm at 3-months, the slight improvement sustainable over 30-months, the final 30-month review score being 1mm improvement. This group showed a net improvement in functional limitation over the duration of the study with an area under the curve of 102 units. A Mann-Whitney U test revealed no statistically significant group difference for functional limitation subscale over the duration of the study (P=0.140).

Table 4-5: Change in FFI functional limitation subscale (VAS mm, 0-100) from baseline to 30-months with area under the curve analysis

Group	ΔBL-3M	ΔBL-6M	ΔBL-12M	ΔBL-18M	ΔBL-24M	ΔBL-30M
Control						
Median	0	0	0	-1	0	0
IQR	(5, 38)	(-8, 11)	(-7, 6)	(-10, 8)	(-6, 8)	(-11, 7)
Intervention						
Median	-2	-3	-3	-3	-1	-1
IQR	(-11, 3)	(-16, 5)	(-14, 5)	(-13, 2)	(-10, 6)	(-11, 6)
Z-score	**-1.53**	**-1.46**	**-1.43**	**-0.78**	**-0.62**	**-0.59**
P-value	**0.127**	**0.143**	**0.154**	**0.436**	**0.534**	**0.555**

Area under the curve
Control: 5 (-210, 157)
Intervention: -102 (-273, 36)
Z-score: -1.48
P-Value*: 0.140

(Median with inter-quartile range in parentheses. * Mann Whitney U-Test).

For the FFI total score (table 4-6) the control group showed no significant change in scores from baseline to 24-months (with only an increase of 1mm at 12-months). At 30-months the final review score showed a median improvement of 6mm. Over time this group showed no overall change in FFI status with an area under the curve score of 0 units. The intervention group showed a median improvement of 5mm at 3-months, increasing to 10mm at 6-months, then decreasing from 9mm to 5mm from 12 to 24-months. The final change from baseline at 30-months showed the largest improvement of 12mm. The intervention group showed a net improvement in FFI status over the duration of the study with an area under the curve of 220 units. A Mann-Whitney U test revealed a statistically significant group difference for FFI total score over the duration of the study (P=0.029).

Table 4-6: Change in FFI total score (VAS mm, 0-100) from baseline to 30-months with area under the curve.

Group	ΔBL-3M	ΔBL-6M	ΔBL-12M	ΔBL-18M	ΔBL-24M	ΔBL-30M
Control						
Median	0	0	1	0	0	-6
IQR	(-12, 7)	(-13, 7)	(-14, 12)	(-13, 12)	(-16, 10)	(-15, 10)
Intervention						
Median	-5	-10	-9	-7	-5	-12
IQR	(-21, 0)	(-17, 0)	(-15, 0)	(-15, 0)	(-15, 0)	(-24, 2)
Z-score	**-2.39**	**-2.51**	**-2.16**	**-1.84**	**-1.00**	**-1.16**
P-value	**0.017**	**0.012**	**0.031**	**0.066**	**0.315**	**0.248**

Area under the curve

Control:	**0 (-370, 279)**
Intervention:	**-220 (-464, 0)**
Z-score:	**-2.18**
P-Value*:	**0.029**

(Median with inter-quartile range in parentheses. * Mann Whitney U-Test).

The change in FFI scores from baseline to 30-months was plotted for each patient for both the control and intervention groups. A representative sample of 10 patients demonstrating typical control and treatment response are illustrated in figure 4-4. The plots demonstrate one advantage of the summary measure approach in that the variability to treatment response can be clearly illustrated. In the control group (A) the numbers of subjects improving and deteriorating over time are equally split above and below the baseline and that the range of values are mostly contained within ±20mm of the baseline. In the intervention group (B) the majority of patients show an immediate improvement in FFI status and that this improvement ranges from baseline to a 60mm change in score. The response is sustainable in most cases but patterns vary between slight improvement and deterioration around initial response at 3-months (a saw-tooth response), a level response over time and a level response with gradual fall-off towards the end of the study. There were 11 patients who showed a deterioration in FFI status at first review at 3-months. Five of these subjects showed an overall improvement in FFI status at 6-months then steady deterioration at different rates to show negative response between 12 to 30-months. Three of these subjects showed improvement at 6-months sustainable for the remainder of the study. Two subjects showed improvement and deterioration within a small band over the 30-month period. One patient maintained a level score showing no change in status over time.

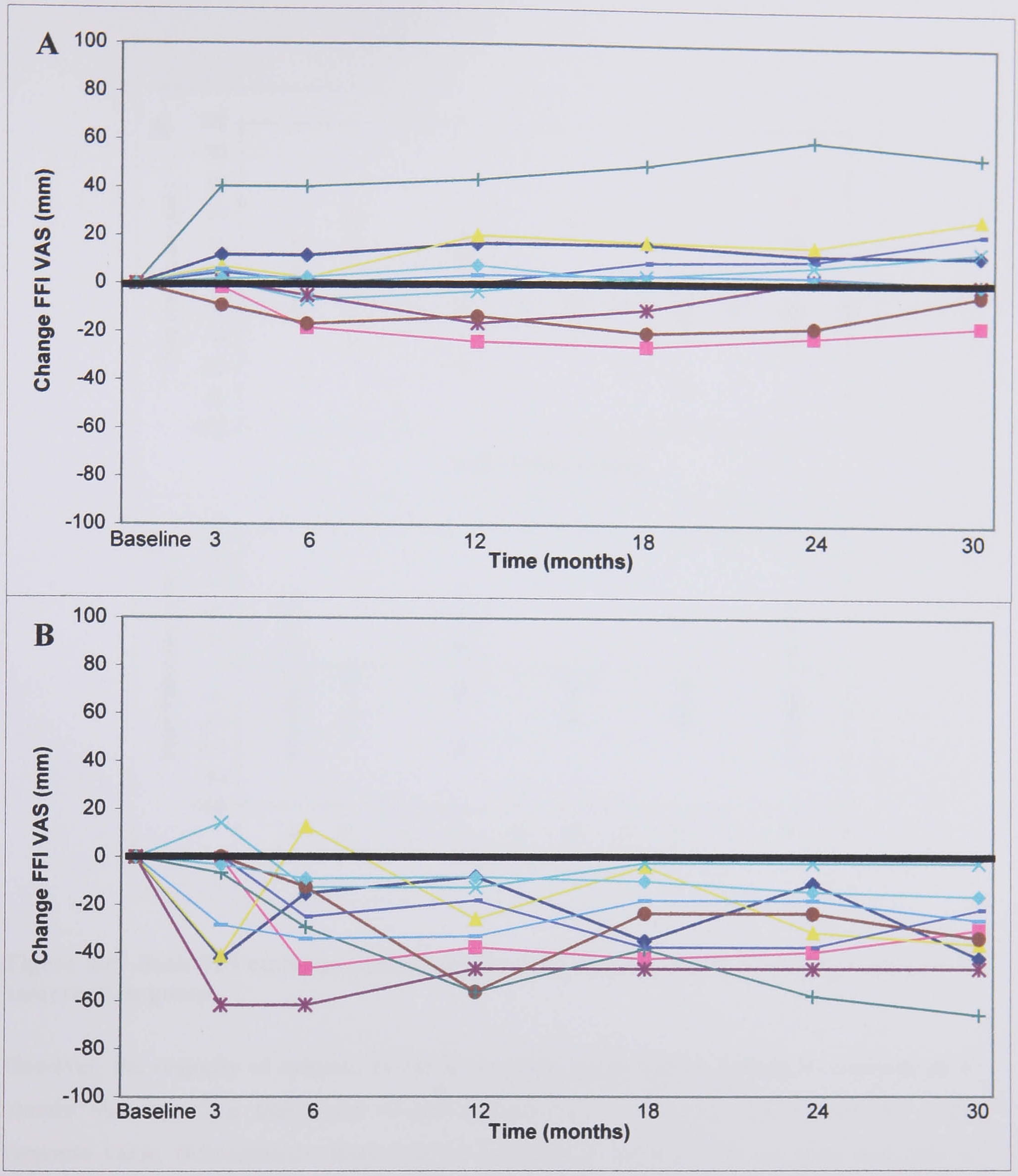


Figure 4-4: A representative series (N=10) of individual patient plots of change in FFI total score (mm) from baseline by time from baseline to 30-months. A- Control group, B- Intervention group.

From this data the peak FFI response and time to response was determined for each subject in the two groups. When these variables are plotted (figure 4-5) we can see the difference in the peak values that tend to be negative in the intervention group and distributed equally between positive and negative in the control group, confirming the trend in figure 4-4.

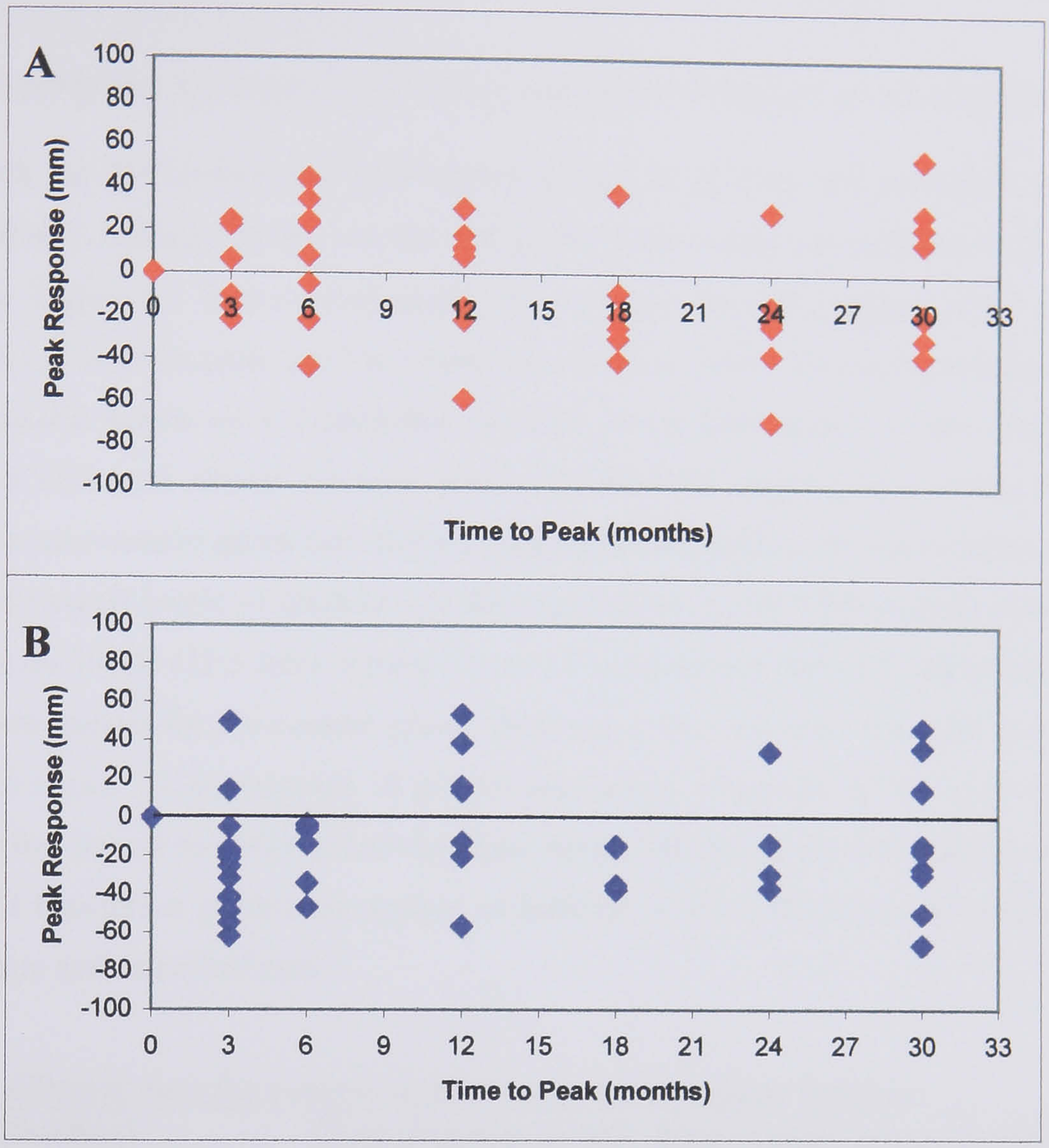


Figure 4-5: Peak FFI response plotted against time to peak for A- Control group and B- Intervention group.

However, the majority of subjects in the intervention group had an immediate response at 3-months that was then maintained or saw-toothed within a narrow band around the initial response value. Subsequently, there was no relationship between peak response and time to reach the peak in the intervention group, nor a between group difference.

In the control group the median (IQR) peak response was –3mm (-22,23) and time to peak response 12 months (6,24). In the intervention group the median (IQR) peak response was –17mm (-34,0) and time to peak response 12 months (3,24). There was no statistically significant difference in the time to peak response between the groups (χ^2= 7.194, P=0.207) but the intervention group had a statistically significant higher peak response (z-score= -2.01. P=0.044).

4.3.4 Clinical data

4.3.4.1 Descriptive summary of clinical data from baseline to 30-months

Clinical data for the control and intervention groups at baseline are presented in table 4-7. Disease activity, indicated by the swollen and tender joint count, was very low for both groups, but slightly higher for intervention group. Accordingly the intervention group experienced higher levels of arthritis pain (median 38mm intervention versus 30mm control) but overall the levels of general health were comparable (median 34mm intervention versus 35mm control). The median ESR was similar for both groups (22.8mm/hr^{-1} intervention versus 24.9mm/hr^{-1} control), the intervention group had slightly greater median DAS (3.42 intervention versus 3.06 control) but overall levels of disability (1.00 intervention versus 1.00 control) were the same. Erosions in the hands (12.5 intervention versus 18 control) and feet (5.5 intervention versus 9 control) were greater for the control group. Body mass was the same for both groups (73.7kg intervention versus 73.2kg control). A greater percentage of patients in the intervention group were receiving disease modifying anti-rheumatic drugs and glucocorticosteroids by all modes of delivery. At baseline a greater percentage of patients in the intervention group had received physiotherapy and in-patient care.

Table 4-7: Clinical data for control and intervention groups at baseline.

Variable (Baseline)		**Control group (N=48)**	**Intervention group (N=50)**
Tender joint count (0-28)		0 (0, 1.75)	1 (0, 2.25)
Swollen joint count (0-28)		0 (0, 3)	1 (0, 4)
Pain (0-100mm VAS)		30 (11, 59)	38 (22, 69)
GAH (0-100mm VAS)		35 (5, 49)	34 (10, 54)
ESR (mm/hr^{-1})		24.9 (10.0, 34.8)	22.8 (12.1, 31.3)
DAS		3.06 (2.06, 3.95)	3.42 (2.58, 4.04)
HAQ (0-3)		1.00 (0.375, 1.75)	1.00 (0.4688, 1.75)
Larsen Index- Hands (0-150)		18 (6, 41.75)	12.5 (1.5, 29.25)
Larsen Index- Feet (0-50)		9 (4, 18.75)	5.5 (0, 13.75)
Body mass (kg)		73.2 (12.6)	73.7 (15.1)
Interventions (%)			
Pharmacology	None	4	0
	NSAIDS	69	58
	DMARDS	66	80
	Oral GCS	8	10
	Bolus GCS	0	10
	IAI GCS	2	10
Physiotherapy		4	16
Inpatient		4	8
Surgery		0	0

Values are median (IQR), mean (SD) or percentage (%). VAS, Visual Analogue Scale. GAH, Global Health Assessment. ESR, Erythrocyte Sedimentation Rate. DAS, Disease Activity Score. HAQ, Health Assessment Questionnaire.

Clinical data for the control and intervention groups at the 3-month review are presented in table 4-8. Disease activity, indicated by the swollen and tender joint count, remained very low with the same median values of zero for both groups. In both groups pain had worsened and was still higher in the intervention group over control (median 47mm intervention versus 42mm control). General health scores were comparable for both groups but worsened in comparison with baseline scores (median 38mm intervention versus 40mm control). Conversely the ESR decreased for both groups in comparison with baseline measurements (19.6mm/hr^{-1} intervention versus 11.0mm/hr^{-1} control). The DAS also decreased in comparison with baseline for both groups but remained higher in the intervention group (3.14 intervention versus 2.66 control). Disability and Larsen scores were not measured at the 3-month review period. There was no significant change in median body mass for either group (72.6kg intervention versus 73.4kg control). In both groups DMARD usage increased coupled with increased NSAID usage in the intervention group. Numbers of patients receiving intra-articular and bolus glucocorticosteroid increased in the control and decreased in the intervention group. Physiotherapy care increased in the control group and 1 (2%) patient from both groups underwent orthopaedic surgery.

Table 4-8: Clinical data for control and intervention groups at 3-months.

Variable		**Control group (N=48)**	**Intervention group (N=50)**
Tender joint count (0-28)		0 (0, 2)	0 (0, 2)
Swollen joint count (0-28)		0 (0, 2)	0 (0, 4)
Pain (0-100mm VAS)		42 (20, 70)	47 (17, 80)
GAH (0-100mm VAS)		40 (11, 60)	38 (6, 57)
ESR (mm/hr^{-1})		11.0 (8.9, 19.6)	19.6 (10.0, 32.0)
DAS		2.66 (1.91, 3.82)	3.14 (2.19, 4.64)
HAQ (0-3)		N\A	N\A
Larsen Index- Hands (0-150)		N\A	N\A
Larsen Index- Feet (0-50)		N\A	N\A
Body mass (kg)		73.4 (13.0)	72.6 (13.9)
Interventions (%)			
	None	2	2
	NSAIDS	70	64
	DMARDS	74	92
Pharmacology	Oral GCS	7	9
	Bolus GCS	2	4
	IAI GCS	7	4
Physiotherapy		15	15
Inpatient		2	0
Surgery		2	2

Values are median (IQR), mean (SD) or percentage (%). VAS, Visual Analogue Scale. GAH, Global Health Assessment. ESR, Erythrocyte Sedimentation Rate. DAS, Disease Activity Score. HAQ, Health Assessment Questionnaire.

Clinical data for the control and intervention groups at the 6-month review are presented in table 4-9. Disease activity, indicated by the swollen and tender joint count, remained very low but he upper inter-quartile values were increased in the intervention group over control. In the intervention group pain decreased towards the baseline value and remained level in the control group (median 37mm intervention versus 40mm control). General health scores were comparable for both groups tending towards baseline scores (median 37mm intervention versus 35mm control). The ESR remained level for the control group but continued to decrease against baseline for the intervention group (14.2mm/hr^{-1} intervention versus 13.1mm/hr^{-1} control). There was a moderate increase in the DAS for both groups but remained higher in the intervention group (3.53 intervention versus 2.75 control). Disability and Larsen scores were not measured at the 6-month review period. There was no significant change in median body mass for either group (73.3kg intervention versus 72.5kg control). In both groups there was another moderate increase DMARD use coupled with a moderate increase in NSAID use in the control group. Numbers of patients receiving intra-articular glucocorticosteroids increased in the intervention and decreased in the control group. Physiotherapy care decreased in the intervention group and 1 (2%) patient from the control group underwent orthopaedic surgery.

Table 4-9: Clinical data for control and intervention groups at 6-months.

Variable		**Control group (N=48)**	**Intervention group (N=50)**
Tender joint count (0-28)		0 (0, 3)	1 (0, 4)
Swollen joint count (0-28)		0 (0, 2)	1 (0, 7)
Pain (0-100mm VAS)		40 (20, 61)	37 (15, 61)
GAH (0-100mm VAS)		35 (11, 55)	37 (10, 52)
ESR (mm/hr^{-1})		13.1 (8.9, 30.3)	14.2 (10.0, 30.0)
DAS		2.75 (1.99, 4.01)	3.53 (2.44, 4.51)
HAQ (0-3)		N\A	N\A
Larsen Index- Hands (0-150)		N\A	N\A
Larsen Index- Feet (0-50)		N\A	N\A
Body mass (kg)		72.5 (15.7)	73.3 (13.0)
Interventions (%)			
	None	2	0
	NSAIDS	72	64
	DMARDS	76	96
Pharmacology	Oral GCS	9	9
	Bolus GCS	2	2
	IAI GCS	4	9
Physiotherapy		15	9
Inpatient		4	6
Surgery		2	0

Values are median (IQR), mean (SD) or percentage (%). VAS, Visual Analogue Scale. GAH, Global Health Assessment. ESR, Erythrocyte Sedimentation Rate. DAS, Disease Activity Score. HAQ, Health Assessment Questionnaire.

Clinical data for the control and intervention groups at the 12-month review are presented in table 4-10. Disease activity, indicated by the swollen and tender joint count, increased from baseline for both groups, the median values the same for both groups but the upper inter-quartile values greater in the intervention group over control. In the control group global pain remained level but in the intervention group increased (median 50mm intervention versus 41mm control). General health remained level for the intervention group but increased moderately in the control versus baseline score (median 36mm intervention versus 40mm control). The ESR remained level for the control group but reversed trend and increased in the intervention group ($28.0mm/hr^{-1}$ intervention versus $12.1mm/hr^{-1}$ control). The DAS for both groups increased but remained higher in the intervention group, the increase driven by the elevated ESR score (4.15 intervention versus 3.5 control). Median disability HAQ scores were the same for both groups and remained level against baseline. Larsen scores increased in the control group over baseline scores for both the hands and feet. In the intervention groups there was a sharp rise in the hand score and a moderate increase in the feet score over baseline. There was no significant change in median body mass for either group (73.3kg intervention versus 71.5kg control). NSAID and DMARD use in the intervention group remained level but DMARD use sharply increased in the control group. Similarly there was an increase in glucocorticosteroid use, in all modes of delivery for the control group. Other medical care did not change significantly.

Table 4-10: Clinical data for control and intervention groups at 12-months.

Variable		**Control group (N=48)**	**Intervention group (N=50)**
Tender joint count (0-28)		3 (0, 6.25)	3 (0, 10)
Swollen joint count (0-28)		2 (0, 4)	3 (0, 6)
Pain (0-100mm VAS)		41 (10, 62)	50 (24, 73)
GAH (0-100mm VAS)		40 (9, 53)	36 (9, 60)
ESR (mm/hr^{-1})		12.1 (6.425, 26.875)	28.0 (15.3, 33.6)
DAS		3.5 (2.5, 4.5)	4.15 (3.15, 5.51)
HAQ (0-3)		1 (0.625, 1.593)	1 (0.375,1.687)
Larsen Index- Hands (0-150)		22.5 (9, 49.75)	21 (5, 32)
Larsen Index- Feet (0-50)		11.5 (6, 20)	8 (3, 19)
Body mass (kg)		71.5 (16.4)	73.3 (13.3)
Interventions (%)			
	None	2	0
	NSAIDS	67	60
	DMARDS	85	94
Pharmacology	Oral GCS	13	9
	Bolus GCS	11	0
	IAI GCS	9	4
Physiotherapy		15	11
Inpatient		4	2
Surgery		0	0

Values are median (IQR), mean (SD) or percentage (%). VAS, Visual Analogue Scale. GAH, Global Health Assessment. ESR, Erythrocyte Sedimentation Rate. DAS, Disease Activity Score. HAQ, Health Assessment Questionnaire.

Clinical data for the control and intervention groups at the 18-month review are presented in table 4-11. The swollen and tender joint count increased for the intervention group but remained level for the control group. Global pain decreased moderately for both groups, but still elevated in comparison with baseline scores (median 45mm intervention versus 33mm control). General health assessment decreased in the control group and increased in the intervention group (median 42mm intervention versus 31mm control). The median ESR increased sharply in the control group and decreased sharply in the intervention group (18.5mm/hr^{-1} intervention versus 21.7mm/hr^{-1} control). The median DAS for both groups continued to increase but still remained higher in the intervention group (4.23 intervention versus 3.75 control). Disability and Larsen erosion scores were not measured at 18-months. There was no significant change in the median body mass for either group (72.3kg intervention versus 72.9kg control). NSAID and DMARD use in both groups sharply fell but the use of glucocorticosteroids increased in the intervention group. Physiotherapy care fell for both groups and 1 (2%) patient from both groups underwent orthopaedic surgery.

Table 4-11: Clinical data for control and intervention groups at 18-months.

Variable		**Control group (N=48)**	**Intervention group (N=50)**
Tender joint count (0-28)		3 (0, 7.25)	4 (2, 9.75)
Swollen joint count (0-28)		2 (0, 5)	3.5 (1, 6)
Pain (0-100mm VAS)		33 (11, 63)	45 (24, 74)
GAH (0-100mm VAS)		31 (6, 54)	42 (14, 62)
ESR (mm/hr^{-1})		21.7 (12.1, 30.88)	18.5 (10.53, 32.3)
DAS		3.75 (2.72, 4.93)	4.23 (3.13, 5.41)
HAQ (0-3)		N\A	N\A
Larsen Index- Hands (0-150)		N\A	N\A
Larsen Index- Feet (0-50)		N\A	N\A
Body mass (kg)		72.9 (13.5)	72.3 (16.5)
Interventions (%)			
	None	2	0
	NSAIDS	52	47
	DMARDS	80	80
Pharmacology	Oral GCS	9	9
	Bolus GCS	4	9
	IAI GCS	7	4
Physiotherapy		4	2
Inpatient		4	2
Surgery		2	2

Values are median (IQR), mean (SD) or percentage (%). VAS, Visual Analogue Scale. GAH, Global Health Assessment. ESR, Erythrocyte Sedimentation Rate. DAS, Disease Activity Score. HAQ, Health Assessment Questionnaire.

Clinical data for the control and intervention groups at the 24-month review are presented in table 4-12. The swollen and tender joint count remained level for the control group and decreased slightly in the intervention group. Global pain remained level for both groups, but still elevated in comparison with baseline scores (median 45mm intervention versus 34mm control). General health assessment increased in the control group and decreased in the intervention group (median 36mm intervention versus 45mm control). The median ESR remained level for both groups (20.6mm/hr^{-1} intervention versus 19.8mm/hr^{-1} control). The median DAS remained level for the control group but decreased for the intervention group (3.79 intervention versus 3.80 control). Disability HAQ scores remained unchanged after 24-months in comparison with baseline (1 intervention versus 1 control). Larsen erosion scores were not measured at 24-months. There was no significant change in the median body mass for either group (73.1kg intervention versus 72.3kg control). NSAID and DMARD use in both groups increased to levels seen at 12-months. Glucocorticosteroid use remained level for both groups but physiotherapy and in-patient care increased for both groups and 1 (2%) patient in the control and 2 (4%) patients in the intervention group underwent orthopaedic surgery.

Table 4-12: Clinical data for control and intervention groups at 24-months.

Variable (24-months)		**Control group (N=48)**	**Intervention group (N=50)**
Tender joint count (0-28)		3.5 (1.75, 6)	3 (1.25, 6.5)
Swollen joint count (0-28)		1 (2, 5)	2 (1, 4)
Pain (0-100mm VAS)		34 (15, 60)	45 (21, 72)
GAH (0-100mm VAS)		45 (14, 54)	36 (6, 55)
ESR (mm/hr^{-1})		19.8 (11.75, 35.425)	20.6 (10.25, 35)
DAS		3.80 (3.36, 4.65)	3.79 (2.98, 4.90)
HAQ (0-3)		1(0.375, 1.78125)	1(0.25, 1.25)
Larsen Index- Hands (0-150)		N/A	
Larsen Index- Feet (0-50)		N/A	
Body mass (kg)		72.3 (13.3)	73.1 (16.6)
Interventions (%)			
	None	2	7
	NSAIDS	63	58
	DMARDS	94	87
Pharmacology	Oral GCS	4	7
	Bolus GCS	11	7
	IAI GCS	11	11
Physiotherapy		9	11
Inpatient		7	7
Surgery		2	4

Values are median (IQR), mean (SD) or percentage (%). VAS, Visual Analogue Scale. GAH, Global Health Assessment. ESR, Erythrocyte Sedimentation Rate. DAS, Disease Activity Score. HAQ, Health Assessment Questionnaire.

Clinical data for the control and intervention groups at the 30-month review are presented in table 4-13. The swollen and tender joint count increased slightly in both groups to reach the

highest values seen at 18-months. Global pain remained level for the control group and decreased slightly in the intervention group, both levels elevated in comparison with baseline scores and higher in the intervention group (median 40mm intervention versus 36mm control). General health assessment decreased sharply in both groups (median 30mm intervention versus 35mm control). The median ESR fell slightly for both groups (16.4mm/hr^{-1} intervention versus 15.7mm/hr^{-1} control). The median DAS remained level for the control group but increased for the intervention group (4.07 intervention versus 3.48 control). Disability HAQ scores remained unchanged after 24-months in comparison with baseline (1 intervention versus 1 control). Larsen erosion scores increased in the hands and feet for the control group over 12-month and baseline scores. In the intervention group Larsen scores increased in the feet over 12-month and baseline scores but scores remained level for the hands in comparison with 12-month scores. There was no significant change in the median body mass for either group (72.6kg intervention versus 72.4kg control). DMARD use was global for the control group by 30-months with level use of NSAID's in comparison with 24-month scores. In the intervention group NSAID and DMARD use remained level. There was a sharp rise in glucocorticosteroid use by all modes in the control group with no significant change in the intervention group. In the control group there were 2 new cases reported who underwent orthopaedic surgery.

Table 4-13: Clinical data for control and intervention groups at 30-months.

Variable (30-months)		Control group (N=48)	Intervention group (N=50)
Tender joint count (0-28)		2.5 (0, 6)	4 (2, 6)
Swollen joint count (0-28)		2 (0, 4)	3 (1, 5)
Pain (0-100mm VAS)		36 (13, 51)	40 (23, 67)
GAH (0-100mm VAS)		35 (12, 54)	30 (18, 52)
ESR (mm/hr^{-1})		15.7 (8.0, 28.8)	16.4 (10.5, 33.6)
DAS		3.48 (2.09, 4.86)	4.09 (3.39, 5.04)
HAQ (0-3)		1 (0.25, 1.5)	1 (0.22, 1.5)
Larsen Index- Hands (0-150)		25 (10, 45)	20 (4, 48)
Larsen Index- Feet (0-50)		14 (7, 21)	12 (5, 20)
Body mass (kg)		72.4 (13.4)	72.6 (16.3)
Interventions (%)			
	None	8	0
	NSAIDS	60	36
	DMARDS	100	93
Pharmacology	Oral GCS	10	12
	Bolus GCS	18	12
	IAI GCS	8	19
Physiotherapy		5	12
Inpatient		5	7
Surgery		5	0

Values are median (IQR), mean (SD) or percentage (%). VAS, Visual Analogue Scale. GAH, Global Health Assessment. ESR, Erythrocyte Sedimentation Rate. DAS, Disease Activity Score. HAQ, Health Assessment Questionnaire.

4.3.4.1 Statistical analysis of clinical data

Summary measures using area under the curve analysis was undertaken for the clinical data variables. The median change (IQR) in DAS for the control and intervention groups are shown in table 4-14. The control group shows no change between baseline and 3-months, a slight improvement in disease activity between from baseline and 6-months then an increase in activity to the final review at 30-months. The intervention group shows no change between baseline and 3-months and 6-months then a steady increase in activity to the final review. There is a net increase in disease activity over time as calculated by AUC with a greater change in the intervention group (18.5 versus 8.3) but no statistically significant difference between the two groups (P=0.541).

Table 4-14: Change in Disease activity score (DAS) from baseline to 30-months with area under the curve analysis.

Group	ΔBL-3M	ΔBL-6M	ΔBL-12M	ΔBL-18M	ΔBL-24M	ΔBL-30M
Control						
Median	0	-0.12	0.27	0.30	0.39	0.13
IQR	(-1.39,0.79)	(-0.98,0.70)	(-0.36,1.12)	(-0.28,2.14)	(-0.13,1.42)	(-0.88,1.95)
Intervention						
Median	0	0	0.43	0.50	0.72	0.75
IQR	(-0.86,0.83)	(-0.71,1.59)	(-0.1,2.29)	(0.10,2.11)	(-0.31,2.01)	(-0.30,1.74)
Z-score	**-0.324**	**-0.825**	**-1.336**	**-0.721**	**-0.856**	**-0.831**
P-value	**0.746**	**0.410**	**0.181**	**0.421**	**0.392**	**0.406**

Area under the curve
Control: 8.3 (-16.5, 45.7)
Intervention: 18.5 (-3.2, 41.6)
Z-score: -0.611
P-Value*: 0.541

(Median with inter-quartile range in parentheses. * Mann Whitney U-Test)

Change in global arthritis pain over time is presented for the two study groups in table 4-15. The control group shows increased pain over time between baseline and all review points except 18-months and 30-months where no change is reported. In the intervention group there is little change in the median pain score over time with a difference from baseline reported at 6-months (decrease of 1.5mm) and 12-months (increase of 2mm). The control group shows a net increase in pain over time with a median increase of 154 units by AUC analysis. The intervention group shows no net change in global pain, the median score zero but there was no statistically significant difference between the two groups (P=0.449).

Table 4-15: Change in global pain score (VAS mm, 0-100) from baseline to 30-months with area under the curve analysis.

Group	ΔBL-3M	ΔBL-6M	ΔBL-12M	ΔBL-18M	ΔBL-24M	ΔBL-30M
Control						
Median	2	1	3	0	4	0
IQR	(-6, 21)	(-10, 31)	(-12, 27)	(-16, 30)	(-17, 27)	(-17,13)
Intervention						
Median	0	-1.5	2	0	0	0
IQR	(-6, 15)	(-16, 4)	(-18, 18)	(-17, 21)	(-16, 16)	(-22, 20)
Z-score	**-0.755**	**-1.679**	**-0.345**	**-0.182**	**-0.402**	**-0.046**
P-value	**0.450**	**0.093**	**0.730**	**0.852**	**0.688**	**0.963**

Area under the curve
Control: 154 (-262, 449)
Intervention: 0 (-291, 331)
Z-score: -0.757
P-Value*: 0.449

(Median with inter-quartile range in parentheses. * Mann Whitney U-Test)

Change in the HAQ global function scores are presented for both groups in table 4-16. In the control group there was no change in functional status between baseline and 12-month, 24-month and 30-month. In the intervention group change in status with an improvement in function was seen between the baseline and 30-month review value only. The net area under the curve for both study groups was zero and non-parametric statistical analysis revealed no significant group difference (P=0.808).

Table 4-16: Change in HAQ scores (range 0-3) from baseline to 30-months with area under the curve analysis.

Group	ΔBL-12M	ΔBL-24M	ΔBL-30M
Control			
Median	0	0	0
IQR	(0,0)	(-0.5, 0.125)	(-0.375, 0.125)
Intervention			
Median	0	0	-0.06
IQR	(0,0)	(-0.5, 0.125)	(-0.37, 0.125)
Z-score	**-0.787**	**-0.076**	**-0.506**
P-value	**0.431**	**0.940**	**0.613**

Area under the curve
Control: 0 (-6.188, 0.4688)
Intervention: 0 (-6.469, 0.6563)
Z-score: -0.243
P-Value*: 0.808

(Median with inter-quartile range in parentheses. * Mann Whitney U-Test)

The radiological scores of Larsen are presented for the hands and feet for both study groups in table 4-17. In both groups a median increase in pathology was noted for both the hands and feet between baseline and 12-months and baseline and 30-months. For the AUC analysis both the hand and feet sites showed net increase in joint scores with similar median scores and no

statistically significant difference between groups for the hands (P=0.620) and the feet (P=0.948).

Table 4-17: Change in radiological pathology Larsen scores from baseline to 30-months with area under the curve analysis.

Group	ΔBL-12M (Hands)	ΔBL-12M (Feet)	ΔBL-30M (Hands)	ΔBL-30M (Feet)
Control				
Median	2	2	2.5	4
IQR	(1, 6)	(1, 5)	(1, 9)	(0.75, 7.25
Intervention				
Median	2	2	2	3
IQR	(0, 3)	(0, 4)	(0, 7.75)	(0, 7.5)
Z-score	**-0.787**	**-0.076**	**-0.496**	**-0.068**
P-value	**0.431**	**0.940**	**0.620**	**0.948**

Area under the curve (hands)		**Area under the curve (feet)**	
Control:	**57 (32, 158)**	**Control:**	**62 (29, 146)**
Intervention:	**51 (0, 80)**	**Intervention:**	**57 (2, 110)**
Z-score:	**-0.496**	**Z-score:**	**-0.068**
P-Value:	**0.620**	**P-Value:**	**0.948**

(Median with inter-quartile range in parentheses. Range 0-150 hands, 0-50 feet. * Mann Whitney U-Test)

4.3.5 Treatment adherence and adverse reactions

4.3.5.1 Initial review of treatment

The responses to the interview items are reported in table 4-18. Between baseline and 3-months 49 patients (98%) patients were wearing their orthoses, 46 patients (92%) said they were comfortable and the mean number of hours per day and days per week used was 6.2 (SD-3.4) and 6.5 (SD-1.1) respectively. A self-reported increase in foot pain from initiation of orthotic therapy was reported in 10 (20%) patients, localised to the right foot (n=2), the ankle (n=2), the full foot (n=1), the toes (n=1), the sole of the foot (n=1), the top of the foot (n=1), the bunion (n=1), and the metatarsal heads (n=1). Fifteen (30%) patients reported pain elsewhere in the legs: 6 patients reported knee pain, 4 reported pain in the calves, 2 reported pain in the ankle region, 2 reported pain in the front of the legs and 1 reported pain in the hips. Of the 6 patients who reported the development of tender spots these were located on the toes (n=3), the instep (n=1), the top of the foot (n=1), and the heel area (n=1). Four patients reported blister formation occurring on the 2nd toe (n=1), the bunion (n=1), the heel (n=1), and the top of the foot (n=1). All 5 patients whom developed thickened or callused skin did so around the heel region. A cramping feeling in the feet was reported by 14 patients occurring generally in the feet (n=9), around the ankles (n=3), in the toes (n=1), or in the left leg (n=1). A general feeling of tiredness

in the feet was reported in 12 subjects. Patients appeared to continue orthosis use and during interview still considered them comfortable despite these reactions, but, minor alterations, limited to adjustment of the top PPT cover or smoothing of the edges of the orthoses, was undertaken in 3 cases.

Table 4-18: Summary of interview responses documented for time periods between baseline and 30-months.

Interview Item	Responses by time period			
	0-3 months	3-6 months	6-12 months	30 months
Wearing orthoses	49/50 (98%)	45/47 (96%)	46/47 (98%)	40/43 (93%)
Orthoses comfortable	46/50 (92%)	43/45 (96%)	45/46 (98%)	40/40 (100%)
No of Hrs/Day	6.2 (3.4), 1-19	6.1 (3.9), 0-18	6.4 (3.3), 0-14	6.6 (3.4), 0-18
No of Days/Week	6.5 (1.1), 1-7	5.8 (2.3), 0-7	5.9 (2.2), 0-7	6.1 (2.0), 0-7
Increased foot pain	10 (20%)	7 (15%)	10 (21%)	2 (5%)
Pain elsewhere in legs	15 (30%)	8 (17%)	3 (6%)	9 (21%)
Difficulty with fit	14 (28%)	15 (32%)	6 (13%)	5 (12%)
No room in shoe	7 (14%)	11 (23%)	2 (4%)	2 (5%)
Shoe too tight	5 (10%)	7 (15%)	3 (6%)	2 (5%)
Heel slipping	7 (14%)	8 (17%)	2 (4%)	1 (2%)
Specific problems				
Tender spots on foot	6 (12%)	9 (19%)	5 (11%)	2 (5%)
Skin blisters	4 (8%)	3 (6%)	0	2 (5%)
Skin bruising	0	0	0	0
Thick skin	5 (10%)	10 (21%)	3 (6%)	4 (10%)
Developing				
Cramping in feet	14 (28%)	17 (36%)	9 (19%)	2 (5%)
Tiredness in feet	12 (24%)	17 (36%)	18 (38%)	8 (19%)

(N and % Yes response to interview item, or mean (standard deviation) and range). Proportions based on those wearing orthoses)

4.3.5.2 Second review of treatment

Between 3-months and 6-months of the 47 patients still in the intervention group 45 (96%) patients were wearing their orthoses, 42 patients (89%) said they were comfortable and the mean number of hours per day and days per week used was 6.1 (SD-3.9) and 5.8 (SD-2.3)

respectively. Self-reported increase in foot pain was reported in 7 (15%) patients, localised to the big toe (n=2), both feet (n=2), the heels (n=2), and the ankle (n=1). Eight (17%) patients reported pain elsewhere in the legs: 3 patients reported knee pain, 2 reported pain in the calves, 2 reported pain in the ankle region, and 1 reported pain in the arch region. Of the 9 patients who reported the development of tender spots these were located on the toes (n=7) and the heel area (n=2). Three patients reported blister formation, all occurring on the toes. Ten patients whom developed thickened or callused skin did so on the toes (n=4), in the medial arch (n=4) and around the heel region (n=2). A cramping sensation, located in the calves (n=10) or the toes (n=7) was reported in 17 patients. A general feeling of tiredness in the feet was reported in 17 subjects.

4.3.5.3 Third review of treatment

Between 6-months and 12-months of the 47 patients still in the intervention group 46 patients (98%) patients were wearing their orthoses, 45 patients (98%) said they were comfortable and the mean number of hours per day and days per week used was 6.4 (SD-3.3) and 5.9 (SD-2.2) respectively. Self-reported increase in foot pain from instigation of orthotic therapy was reported in 10 (21%) patients, localised to the ankle region (n=5), the ball of the foot (n=3), the toes (n=2), and the whole foot (n=1). Three (6%) patients reported pain elsewhere in the legs: 2 patients reported knee pain and 1 reported pain in the calves. Of the 5 patients who reported the development of tender spots these were located on the ankle (n=2), the toes (n=2) and the heel area (n=1). No patients reported the development of skin blisters but thickened or callused skin occurred in 3 patients at the heel region (n=2) and in the medial arch (n=1). Cramping was still present and reported by 9 (19%) patients, located to the toes (n=5), the feet generally (n=1) and the ankle region (n=1). A general feeling of tiredness in the feet was reported in 18 (38%) subjects.

4.3.5.4 Final review of treatment

At 30-months of the 43 patients still in the intervention group 40 patients (93%) were wearing their orthoses, 40 patients (100%) said they were comfortable and the mean number of hours per day and days per week used was 6.6 (SD-3.4) and 6.1 (SD-2.0) respectively. Self-reported increase in foot pain was reported in only 2 (5%) patients, localised to the ankle regions in both patients. Nine (21%) patients reported pain elsewhere in the legs: 7 patients reported knee pain and 2 patients reported ankle pain. Numbers reporting specific foot problems was low and included 2 patients who reported tender spots (1 heel and 1 toes), 2 who reported skin blisters

(toes) and 4 who reported thick skin (heel). Two patients reported cramping around the toes and the feeling of tiredness in the feet was still present in 8 (19%).

A retrospective survey of patient records also revealed that 6 patients in the intervention group and 2 patients in the control received extra-depth stock shoes over the duration of the study. Two patients in the control group were supplied appliance type insoles consisting of a valgus filler on a flat-bed insole and one patient this insole type combined with stock shoes. One patient in the intervention group, who stopped wearing the custom orthosis, was supplied with ethyl vinyl acetate semi-rigid orthoses following referral to community podiatry services. Four patients in the control group and 2 in the intervention group were referred to community podiatry for care to pressure lesions and troublesome nail conditions. One patient in the intervention group received bilateral forefoot corrective surgery between baseline and 3-months and was unable to continue orthosis use. One patient in the control group underwent excision of a plantar digital neuroma at 6-months.

4.4 Discussion

4.4.1 Patient participation and attrition

Twenty-two percent of patients were excluded on clinical grounds related to co-morbidity or severe foot disease. Diabetes mellitus was the commonest co-morbidity and factors such as peripheral neuropathy would have compromised both rigid orthosis use and measurement of pain. Severe foot disease manifested as multiple painful foot joints with reduced range of motion and fixed deformities, contra-indicating rigid orthosis use. Inappropriate footwear excluded patients not for fear of diluting the clinical effect (by no or low orthosis usage) but pragmatically because in a great many the orthosis would simply not fit the footwear worn. This finding alone is important because if an orthotic management strategy begins with footwear screening (rather than referral where the obligation of the provider- orthotist or podiatrist, is usually to supply) then 1 in 10 patients will be unsuitable for treatment. Current orthosis users could have been brought into the study following a washout period. However assessing orthosis use was difficult as very few of the 21 patients identified were wearing or brought their devices to clinic and to avoid contamination all were excluded on the grounds that their device could have been functional in design.

Almost 20% of patients did not wish to participate because of an unwillingness to attend for review appointments, for many an extra burden on a busy hospital schedule. The final recruitment of 39.8% of patients screened is low but typical where follow-up studies run over

years and extra clinical attendance is required. These rates are better than the 16% recruited from 636 patient screenings in the study of Conrad *et al.*, (1996). The randomisation procedure was effective for patient allocation at baseline with no apparent imbalance with respect to sex, age, ethnic origin or disease duration variables.

Good communication and support was established between the research team and the study participants in an effort to reduce attrition. This good rapport was essential in the control group who received neither a treatment nor placebo orthosis. The support of a dedicated research nurse and facilities such as a telephone help-line were useful for this purpose, but care was taken to avoid over-familiarisation to minimise any Hawthorne effect. In fact 83% of the total population completed the study, with attrition higher in the control group (79% completion) than the intervention group (86% completion). The rates are similar to those of Conrad *et al.*, (1996) who over 36-months found a completion rate of 86% for their total study population and 85% and 88% completion for their intervention and control groups respectively.

4.4.2 Foot Function Index scores

The median FFI subscale and total item scores at 30-months were similar to those reported by Conrad *et al.*, (1996) except for pain, which was higher in the present study for both the control and intervention groups (table 4-19). The observed difference may be related to disease duration as those patients with established disease may have less inflammatory pain than the early cases used here. Statistical analyses conducted by Conrad *et al.*, (1996) revealed no significant differences at final visit between active and placebo orthosis for FFI components. Both groups apparently responded to treatment (no details provided) but lack of treatment effect was confirmed in a random effects model. No data was presented but no time or group-by-time treatment effect was observed in the Conrad *et al.*, (1996) study. These findings contrast sharply with the results of the present study which demonstrated a significant treatment effect for FFI subscales of pain and disability and FFI total score over a 30-month period. The negative outcome in the Conrad study surprised the authors but not others who have remarked on the inappropriateness of rigid orthoses in such a homogenous subpopulation of RA patients (Marks and McKendry, 1996).

Table 4-19: FFI data (VAS mm, 0-100) at final assessment for Conrad *et al.*, (1996) and present study.

FFI component	Conrad (1996)		Present Study	
	Control*	Intervention$^{\nabla}$	Control*	Intervention$^{\nabla}$
Pain	29.1	28.2	34	44
Disability	38.3	34.1	36	33
Functional Limitation	14.9	16.5	14	17
Total	27.9	26.5	31	30

***Mean score (standard deviation). $^{\nabla}$Median score (inter-quartile range)**

This study used a control group who received no form of orthosis and the FFI score from baseline to 30-months showed no change by AUC analysis. This might support the notion that the placebo effect in the Conrad study served to dilute an observed effect in the treatment orthosis group. The counter argument might be that a placebo orthosis exacted a true effect on the foot and was therefore an active intervention. Indeed, Conrad *et al.*, (1996) offered no data to support the assumption that their device was truly inert and surprisingly both their study groups perceived equally that they were receiving active treatment. Whether these patients felt that they were in the study group because of the placebo effect or because of real changes in foot function or mechanoreception at the foot:orthosis interface, perceived as comfort and stability is unclear. Further work is necessary to clarify these issues and there is still an element of uncertainty in the present study where no placebo group was included.

The orthoses have an initial effect to reduce both foot pain and related disability consistent with findings from uncontrolled studies and the prevailing beliefs of good clinical practice (Dimonte and Light, 1982; Hunt *et al.*, 1987; Locke *et al.*, 1884; Marks and McKendry, 1996). However there are few longitudinal studies to compare and the most promising finding of this study is the sustainability of the treatment effect. The use of summary measures and advance decisions on data analysis allowed us to discover that most patients have an initial response, the magnitude of which varies, followed by a sustainable but variable response over the 30-month period. This individual variability is important but not unexpected and reflects what is seen in routine clinical practice. The maintenance of the effect however was confirmed in the lack of relationship between peak effect and time to peak effect, the variance around the initial change at 3-months small but enough to effect an even distribution of peak effects over the intervening assessments. Eight patients reported deterioration in FFI status following administration of the orthoses and this may have been related to a number of factors including an increase in disease activity

generally with increased inflammatory activity in the feet and discomfort associated with 'bedding-in' new orthoses. In clinical practice discomfort following first fitting of orthoses are not unusual, especially if patients do not follow the instructions outlining a gradual build-up in use. These findings are important and should be included in any future guidelines for orthotic use in the group, because the results indicated that minor problems are outweighed by longer-term clinical benefits and that many of the problems can be remedied within the short-term.

The FFI instrument worked well in this project but problems, previously not described in the literature, were encountered with the activity limitation subscale. Some patients expressed difficulty attempting to differentiate the contribution of foot problems from other lower limb or more general problems to the interference of major activities of daily living. This component, although not intended, may be more indicative of general functional limitation and this was the only component of the FFI where no statistically significant group difference was seen. This was surprising, as the construct at face value appeared to be related to foot disability, which showed a statistical between-group difference. This observation may warrant further investigation in a more formal evaluation of the FFI.

4.4.3 Clinical data

The tender and swollen joint counts, global pain, global health and ESR clinical measurements varied over the duration of the study, related to the change in disease patterns between patients at different times during the study. However, when the composite DAS score was analysed this showed moderate to high levels of disease activity maintained throughout for the intervention group and moderate levels of disease activity maintained throughout for the control group. The intervention group had a higher DAS score at baseline and when change in DAS scores from baseline were analysed there were only very small changes over time for both groups. In the face of higher levels of disease activity and more active foot pain and disability (the FFI subscale and total scores in the intervention group was greater than control at baseline) the treatment effect may be more significant than first considered. Furthermore since there was no significant group difference in change of DAS from baseline between the two groups the clinical effect could not be diluted by improvement in overall disease status. The relationship between DAS and FFI scores was explored further by comparing the mean AUC FFI score by DAS group created by inter-quartile scores (table 4-20). In the intervention group improvement in FFI score was seen in all DAS quartiles but with a diminished effect as the DAS increased. For the control group improvement in FFI was seen for the two lower DAS quartiles the effect diminishing as the DAS increased. For the 3rd and 4th quartiles FFI had deteriorated, the effect

increasing as the DAS increased. These interactions did not reach statistical significance under analysis of variance testing.

Table 4-20: AUC FFI scores by AUC DAS quartiles for intervention and control groups and F-statistic and P-values from analysis of variance.

Intervention		Control	
DAS AUC Quartiles	**AUC FFI**	**DAS AUC Quartiles**	**AUC FFI**
< -6.2	-444.2	< -13.0	-307.5
-6.2 – 18.5	-235.7	-13.0 – 12.4	-23.0
18.5 – 42.2	-163.4	12.4 – 43.5	68.2
≥ 42.2	-128.9	≥ 43.5	154.5
F-statistic	**1.16**	**F-statistic**	**2.07**
P-value	**0.34**	**P-value**	**0.12**

Other indicators (global pain and HAQ disability) that the disease activity may have behaved differently between the groups over the course of the study showed no significant group difference by AUC analysis over the 30-month period. Joint pathology scores by Larsen Index for hands and feet changed at the same rate over time for both study groups and were not significantly different. The hands were included as a control site to account for the disease as a whole and no between group difference was found, with only small changes in median scores over 30-months. In the feet the rigid orthoses failed to offer significant early joint protection to the MTP joints (where Larsen scores are recorded) with no significant between group differences. Conrad *et al.*, (1996) in their study showed that orthoses slowed the progression of hallux valgus deformity. The mechanism for doing this may be different to that for joint protection and the activity of inflammation at the MTP joints may be unresponsive to mechanical alleviation of joint stresses, especially where erosions are well established, as was the case for many of these patients. Analysis of the kinetic data may provide a better understanding of this relationship.

Disease activity determines pharmacological management and perhaps the use of paramedical and other services. The current strategy is to use DMARDs earlier in the course of the illness reflected here as DMARD use increased over the first 6 to 12-months. Numbers using these drugs combined with NSAID's and glucocorticosteroids (by any mode) did not differ significantly so no clinical effect for foot disease could be attributed to imbalance in the management strategies for the study groups. Furthermore the use of paramedical and other services varied across the duration of the study but there was no obvious imbalance between the study groups. Despite these interventions the DAS score remained high, driven primarily by the

ESR and global health assessment scores. It is not obvious why this occurred, but the variability of the data suggested that both cohorts had mixed patients with high and low levels of DAS and numbers improving and deteriorating throughout. Furthermore the ESR is known to change slowly in response to changes in inflammatory activity and there were examples of discordance between the two scores at various time points. Finally, sensitivity analysis for last value carried forward data substitution was not conducted for DAS and this may have influenced the scores between time periods.

4.4.4 Treatment adherence and adverse reactions

This study embarked on the provision of rigid orthoses to be fitted within every day shoes that were adequate to accommodate them. The construction of the orthoses in thin carbon-graphite helped but minor reactions to the devices were anticipated and subsequently found. Within 3-months, build-up time to maximum use was achieved covering a significant proportion of the day (6.2 hours for 6.5 days per week) where activities of daily living are undertaken. The initial problems related to shoe fit were typical to those seen in clinical practice and caused by increased pressure between the shoe and bony prominences especially toes. Although there were reports of minor skin trauma the effects clearly were not related to significant numbers seeking podiatry care as cases numbered only 2 and in both of these the problem pre-existed the start of orthotic management.

The reporting of new pain sites was of greater concern and notably 6 patients reported knee pain. The knee is a common site for inflammation in RA but if the orthoses caused changes in the movement transfer patterns between the AJC and knee then this could have been a trigger to initiate problems whether the mechanical effects were beneficial or detrimental. The problem appeared to persist in only 2 patients up to 12-months but at 30-months had increased again to 7 patients. The interviewer reported that the symptoms may not have been new and again many patients failed to exercise discrimination between foot-related and other problems. Nonetheless the problem was severe enough to merit individual study of kinematic data to identify any possible mechanical deficit. Interestingly Conrad *et al.*, (1996) reported no adverse reactions over 36-months for 52 RA patients treated with a rigid orthosis. This does contrast sharply with the findings here but no explanation is possible because the previous study fails to define an adverse reaction or state how this monitored over the study duration.

Conrad *et al.*, (1996) in their study reported an association between longer orthosis wearing time and less foot pain and disability. In this study a 'mean time of wear' was derived and subjects

were divided into four groups based on inter-quartile range. Against this the AUC FFI subscales and total score was set and between quartile group analysis conducted. There was no statistically significant difference between inter-quartile group usage time and FFI pain (P=0.474), FFI disability (P=0.378), FFI activity limitation (P=0.431) and FFI total score (P=0.325). The inter-quartile groups varied within a narrow band (<5 hrs, 5-6.3 hrs, 6.3-7.8 hrs, and >7.8 hrs) because patients were wearing them for most of their weightbearing time. A maximum mean difference of 2 hrs usage per day between subjects would not be expected to bring about significant difference in foot status as measured by the FFI. The mean usage hours are not presented in the Conrad study so no additional comments can be made.

Problems with shoe fitting were reported by significant numbers up to 6-months. Individual advice was provided to all these patients and in all but 2 cases the problem was remedied. The question on whether these orthoses should be supplied with extra depth shoes was raised but dismissed on the strength of the data provided. However during the course of routine outpatient follow-up 6 patients in the intervention group were supplied with these shoes against only 2 in the control group. Pragmatically the solution would be to consider patients on individual merit whilst persisting with the initial approach of utilising good high-street bought shoes.

Despite these problems self-reported levels of orthosis use and comfort were high throughout the study. At final review of the 43 remaining patients 40 (93%) were still wearing the devices. Conservatively if we regard the 3 patients from above and the 7 lost to follow up as treatment failures the overall wear rate is 80%, better than that reported by Conrad *et al.*, (1996) where 31% of patients had not worn their orthosis in the last 30 days.

4.4.5 Summary

The outcomes of this RCT support the use of rigid custom-made functional foot orthoses in early rearfoot disease in RA. These devices cause an initial improvement in foot related pain and disability and the effects are sustainable over a period of 30-months. The treatment response is variable between patients and a number will show no improvement or deterioration in foot disease. If no intervention is received no change in foot status is expected over this period. Disease activity may have some bearing on treatment response as those in whom the disease worsens experience less improvement in foot health status.

These custom designed orthoses were well tolerated amongst patients but minor problems can be expected and shoe fit problems might require further footwear advice. Care should be taken to assess knee involvement prior to and during follow-up to monitor new or exacerbated

symptoms although the remedy for this is not clear. Extra-depth stock shoes will be necessary in a small number of patients but these do not need to be routinely prescribed. This study did not use a placebo control group but valuable information has been gained from the study group who received no intervention. Notably the problem of rearfoot deformity and pain in early disease does not receive routine clinical attention as only 3 patients in the control group, eligible by entry criteria to orthosis management, received this form of treatment over the 30-month follow up period. Although the doctors providing general care to these patients were supposed to be blinded to their inclusion in the study, some may have known and thus held back on orthosis treatment. Evidence is now sought in the form of kinematic and kinetic data to explain the clinical improvements seen. Furthermore it will be interesting to see if there is concordance between clinical and mechanical data for the control group where no overall change in clinical status was seen.

CHAPTER 5

KINEMATICS AT THE ANKLE JOINT COMPLEX IN RHEUMATOID ARTHRITIS

In this chapter a detailed analysis of the three-dimensional kinematics of the ankle joint complex in rheumatoid arthritis is undertaken. Data is collected initially from two populations of rheumatoid arthritis patients and analysed alongside that from an age and sex matched healthy population. From the randomised controlled trial, kinematic data was then analysed serially over a 30-month duration and comparisons made between control and orthotic intervention groups.

5.1 Baseline kinematics in rheumatoid arthritis and age and sex-matched population

5.1.1 Material and methods

5.1.1.1 Study population

The RA control and intervention study groups have been described previously in section 4.3.2. An age-by-sex sampling frame was constructed from the baseline demographics of these groups to which a matched population was recruited from healthy volunteers. Forty-five subjects were successfully recruited with 8.9% of the population non-Caucasian. The group consisted of 29 females and 16 males with a mean age of 51.8 years (SD- 12.4 years) and a mean body mass of 76.2kg (SD- 12.3kg).

5.1.1.2 Data capture

Three-dimensional kinematic measurement of the AJC was undertaken using the technique developed in section 3.2 and the clinical protocol described in section 4.2.8.

5.1.1.3 Data Analysis

For each subject kinematic measurement data were prepared using the protocol developed in section 3.2. The data were normalised to 100 data points each representing 1% of the gait cycle. Preliminary analyses found no asymmetry between left and right sides and data was combined. For each study group a mean angular rotation:time curve with 95% confidence intervals was plotted and a summary table constructed to give mean maximum positive and negative angle values, range of motion and angles at key gait cycle periods, with data scatter represented by the standard deviation of the mean. For statistical analysis the angular rotation:time integral was

derived for each axis of rotation and a mean (standard deviation) derived for each group by walking condition (barefoot, shod and shod with orthosis). Since the observed angular rotation about all three axes was assumed to cross the neutral or zero position negative and positive area integrals were summated.

A descriptive summary comparing 3-D motion in the study groups, in barefoot and shod walking conditions, at baseline is provided. Analysis of variance (ANOVA) was applied to the mean angular rotation:time integrals in a comparison of barefoot and shod gait between normal subjects and both RA groups at baseline. The post-hoc test of Tukey was used for pairwise comparisons when three groups were in the model and paired t-tests for two groups. The significance level used was $P<0.05$ (2-tailed tests) and all analyses were conducted using SPSS 9.0 for Windows (SPSS, Chicago, Il, USA). The ANOVA technique was applied in a second analysis to determine the immediate impact of foot orthoses at baseline.

5.1.2 Results

5.1.2.1 Sex and age-matched adult population

The barefoot and shod angular rotation:time curves are presented in figure 5-1 and summarised in table 5-1. During barefoot gait three phases of dorsi/plantarflexion were recorded during stance phase through a range of motion of 15.2°. Heel strike position was slightly plantarflexed (-1.8°) continuing in this direction to a maximum, at foot flat, to -9.1°. The second phase was a longer period of dorsiflexion during mid stance and heel lift passing through the neutral joint position to maximum dorsiflexion of 6.2°. The final phase was a more rapid period of plantarflexion towards toe-off, the final position at toe-off being –0.2° plantarflexed. During swing phase plantarflexion continued to reach a smaller second maximum before a final dorsiflexion rotation occurred followed by a return to the neutral position during the terminal swing phase.

The mean range of inversion/eversion motion was 9.1° with two phases of inversion/eversion during the stance phase of gait. From an initial mean inverted heel strike angle of 3.1° a long period of eversion was recorded through foot flat (1.1° inverted), mid stance (-2.2° everted) and heel lift (-3.5° everted). A mean maximum eversion angular rotation of –3.8° was recorded at 44% of the gait cycle. The second phase involved a more rapid period of inversion bringing the joints back through the neutral position to a mean maximum of 5.3° (67% gait cycle). During swing small eversion and then inversion angular excursions were recorded with a final inverted position during terminal swing.

Internal/external rotation was the smallest ROM (6.7°) and showed two phases during stance. From heel strike (0.2°) a phase of internal rotation to a mean maximum of 3.8° (18% gait cycle) was recorded. From here a second phase of external rotation through mid stance (2.9° internally rotated) and heel lift (2.2° internally rotated) was recorded reaching maximum values of –2.9° after toe-off (67% gait cycle). For all rotations the standard deviation of the mean angular positions during stance phase periods indicated greater variability during the loading response and pre-swing phases of gait.

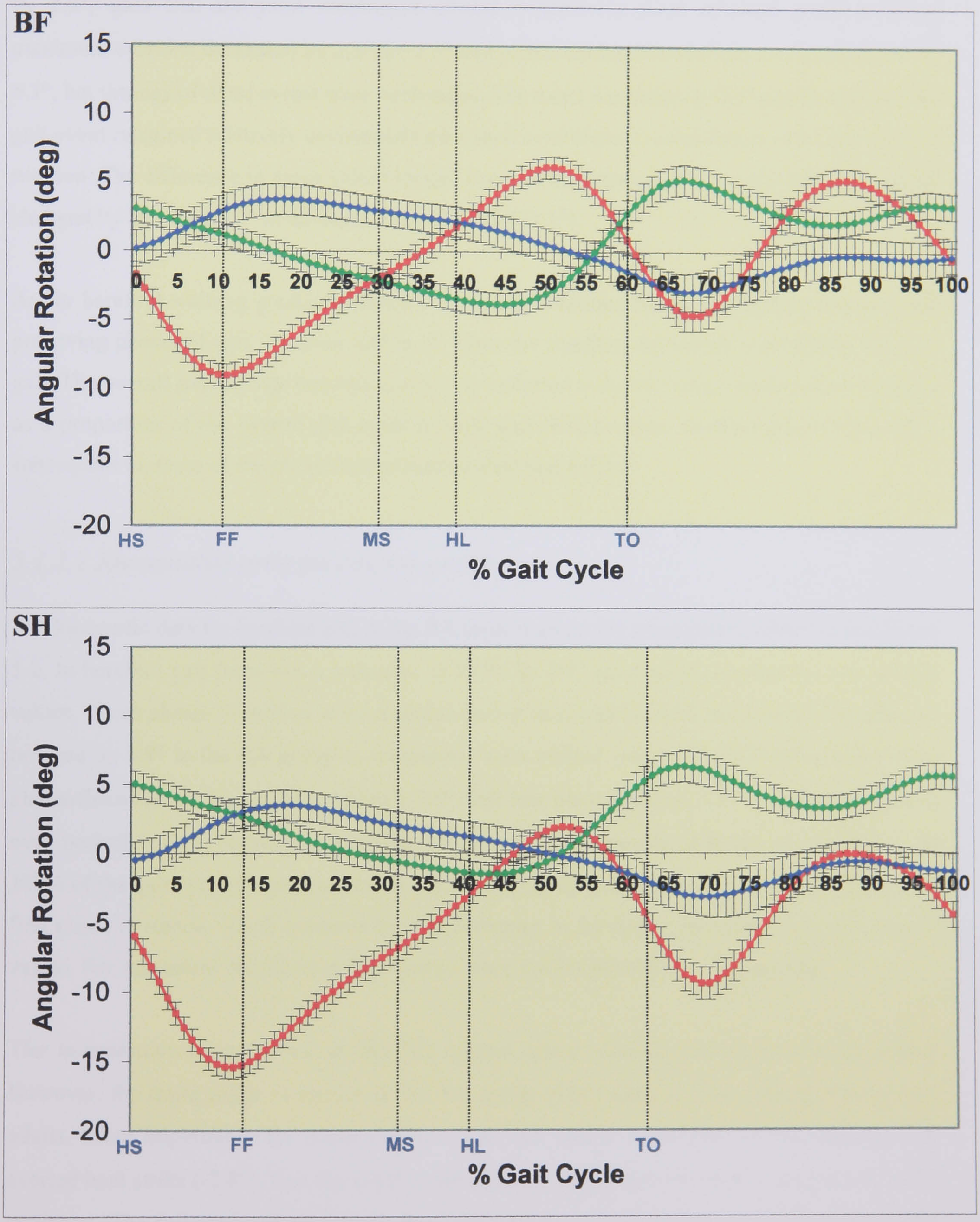
Table 5-1: Mean kinematic data for the ankle joint complex by maximum values and timed events during gait in normal population walking barefoot (BF) and shod (SH).

EVENT (BF)	% GAIT CYCLE	DF/PF	SD	INV/EVR	SD	INT/EXT ROT	SD
HS	0	-1.8	4.7	3.1	3.5	0.2	4.3
FF	11	-9.1	3.9	1.1	3.0	3.1	4.3
MS	30	-1.8	3.8	-2.2	3.4	2.9	4.1
HL	39	1.8	4.0	-3.5	3.4	2.2	4.1
TO	61	-0.2	5.1	3.5	3.9	-1.7	4.5
	MAX (-)	-9.1		-3.8		-2.9	
	%GC	11		44		67	
	MAX (+)	6.2		5.3		3.8	
	%GC	51		67		18	
	ROM	15.2		9.1		6.7	
EVENT (SH)	**% GAIT CYCLE**	**DF/PF**	**SD**	**INV/EVR**	**SD**	**INT/EXT ROT**	**SD**
HS	0	-6.0	5.0	5.0	4.4	-0.5	5.1
FF	13	-15.3	3.8	2.7	4.1	3.0	4.9
MS	32	-6.8	3.8	-0.7	4.2	2.0	4.8
HL	41	-2.8	4.0	-1.5	4.2	1.1	4.6
TO	63	-5.4	5.6	5.6	4.2	-2.2	5.6
	MAX (-)	-15.4		-1.5		-3.2	
	%GC	12		43		70	
	MAX (+)	1.9		6.3		3.5	
	%GC	52		67		18	
	ROM	17.3		7.8		6.7	

Angles are in degrees. %GC- percent gait cycle, SD- standard deviation, MAX(-)- maximum negative joint angle, MAX(+)- maximum positive joint angle, ROM- range of motion, DF/PF- dorsiflexion/plantarflexion, INV/EVR- inversion/eversion, INT/EXT ROT- internal/external rotation, HS- heel strike, FF- foot flat, MS- mid stance, HL- heel lift, TO- toe off.

On observation, the overall curve shape did not differ between barefoot and shod conditions (table 5-1, figure 5-1). The ranges of motion were increased for dorsi/plantarflexion (17.3°), slightly decreased for inversion/eversion (7.8°) with no change for internal/external rotation (6.7°). The mean dorsi/plantarflexion angular rotation:time curve was shifted negatively on the ordinate such that the mean heel strike angle (-6.0°) decreased by -4.2° and the mean maximum plantarflexed value (-15.4°) decreased by -6.3°. The mean maximum dorsiflexion value (1.9°)

Figure 5-1: Angular rotation:time curves for the ankle joint complex in normal healthy adults during barefoot (BF) and shod (SH) gait (N=90).



(---) dorsiflexion(+) / plantarflexion(-), (---) Inversion(+) / Eversion(-), and (---) Internal(+) / External rotation(-). Gait events represented by: HS- Heel strike, FF- Foot Flat, MS- Mid-stance, HL- heel lift, and TO- Toe off. Bars represent the 95% confidence interval of the mean.

also decreased (by 4.3°) permitting dorsiflexion relative to neutral of 1.9°. There were no significant changes in the timings of the maximal events. For inversion/eversion the angular rotation:time curve was shifted positively on the ordinate, the mean heel-strike position increased by 1.9°, such that the joint functioned around a relatively more inverted position. Mean maximum eversion decreased by 2.3° to –1.5° and mean maximum inversion increased by 1.0° to 6.3°, but timings of these events were unchanged. The mean internal/external angular rotations by gait event remained relatively unchanged under shod conditions in comparison with other axes of rotation. The difference in mean values by gait event or maximum positive and negative rotations changed by less than 1.0° in all cases except heel lift (1.1°).

As for barefoot walking greater variability in angular rotations during the loading response and pre-swing phases of gait was seen and in all cases the standard deviations were higher for shod gait. The overall gait timings between conditions indicated a slightly longer stance phase duration as a proportion of the overall gait cycle in shod gait (63%) versus barefoot gait (61%) with a subsequent increase of the phasic components within that period.

5.1.2.2 Rheumatoid arthritis control group

The kinematic data for barefoot gait in the RA control group are presented in table 5-2 and figure 5-2. In barefoot gait there was a reduction in ROM by 1.9° for dorsi/plantarflexion over normal values. Three phases of motion were recorded during stance phase with maximum plantarflexion reduced by 1.9° in the RA group in comparison with normal values. The RA group had a more plantarflexed mean heel strike position (-3.9°) but less plantarflexion (-3.3°) from that position over normal values. Maximum dorsiflexion (6.0°) was comparable with the normal value. At 100% of the gait cycle the plantarflexion angle was slightly greater than the maximum during the first phase in stance, which accounts for the difference in the timing in comparison with normal values. For maximum dorsiflexion gait timings were similar between the two groups.

The inversion/eversion motion in the RA control group showed two phases during stance. However, the mean range of motion in the RA group (6.6°) was 2.5° less than that for normal adults. More importantly the mean motion curve was shifted negatively on the ordinate with everted heel strike (-2.9°), foot flat (-4.0°), mid stance (-7.8°), heel lift (-9.4°) and toe off (-3.8°) positions. The full range of motion occurred through an everted ROM and in comparison with normal values the mean maximum eversion (-9.5°) increased by a factor of 2.5. Mean maximum inversion shifted by 8.1° from 5.3° inverted (normal value) to –2.8° everted (RA group). There was no difference between groups in the timings during the gait cycle for maximum values.

In the RA group there was a notable flattening and positive shift on the ordinate for the internal/external rotation motion curve and the mean ROM (4.0°) decreased by 2.7° over normal values. The motion occurred within an internally rotated range and at no stage during the gait cycle did the joint reach neutral or become externally rotated. From heel strike (6.7° internally rotated) to maximum (8.7°) only 2.0° of motion in the direction of further internal rotation occurred. From foot flat (8.6°) through mid stance (8.3°) and heel lift (7.5°) motion very slightly changed towards external rotation with a maximum (4.7°) reached shortly after toe-off. The RA group showed a later heel-lift (44%) within the same proportion of stance within the gait cycle and greater variability during the loading response and pre-swing phases over normal values.

In shod gait (table 5-2, figure 5-2) dorsi/plantarflexion ROM were increased from barefoot gait and was consistent with that seen in the normal population (17.1°). The angular rotation:time curve shifted negatively on the ordinate increasing the heel strike position (-11.3°) by -7.4° from the barefoot condition and –5.3° in comparison with normal. Maximum plantarflexion (-15.0°) increased by a factor of 2.1 over barefoot condition but was comparable with normal values. The inversion/eversion ROM (6.7°) was unchanged from the barefoot condition but the angular rotation:time curve shifted positively on the ordinate. The heel strike position was approximately neutral (-0.3°), but remained more everted than in the normal population for barefoot and shod conditions. Mean maximum eversion (-6.2°) was 3.3° more inverted than the barefoot condition but still more everted in comparison with barefoot or shod data in the normal population. During stance the mean motion pattern occurred through an eversion ROM and only crossed the neutral position (by <1°) shortly after toe off and during terminal swing.

Shod gait did not significantly alter the internal/external rotation ROM (4.4°) in the RA control group, and the AJC ROM functioned around an internally rotated position. Positive and negative maximum angles of internal/external rotation remained relatively unchanged as did angular positions by gait time events, the angular rotation:time curves being flat in shape. For dorsi/plantarflexion and internal/external rotation the variability of data was similar between barefoot and shod condition whilst for inversion/eversion the variability was greater under shod conditions. The gait timings for stance phase events were similar between the two conditions with the stance phase duration increasing by 2% under shod conditions.

Table 5-2: Mean kinematic data for the ankle joint complex by maximum values and timed events during gait in RA (control) group walking barefoot (BF) and shod (SH).

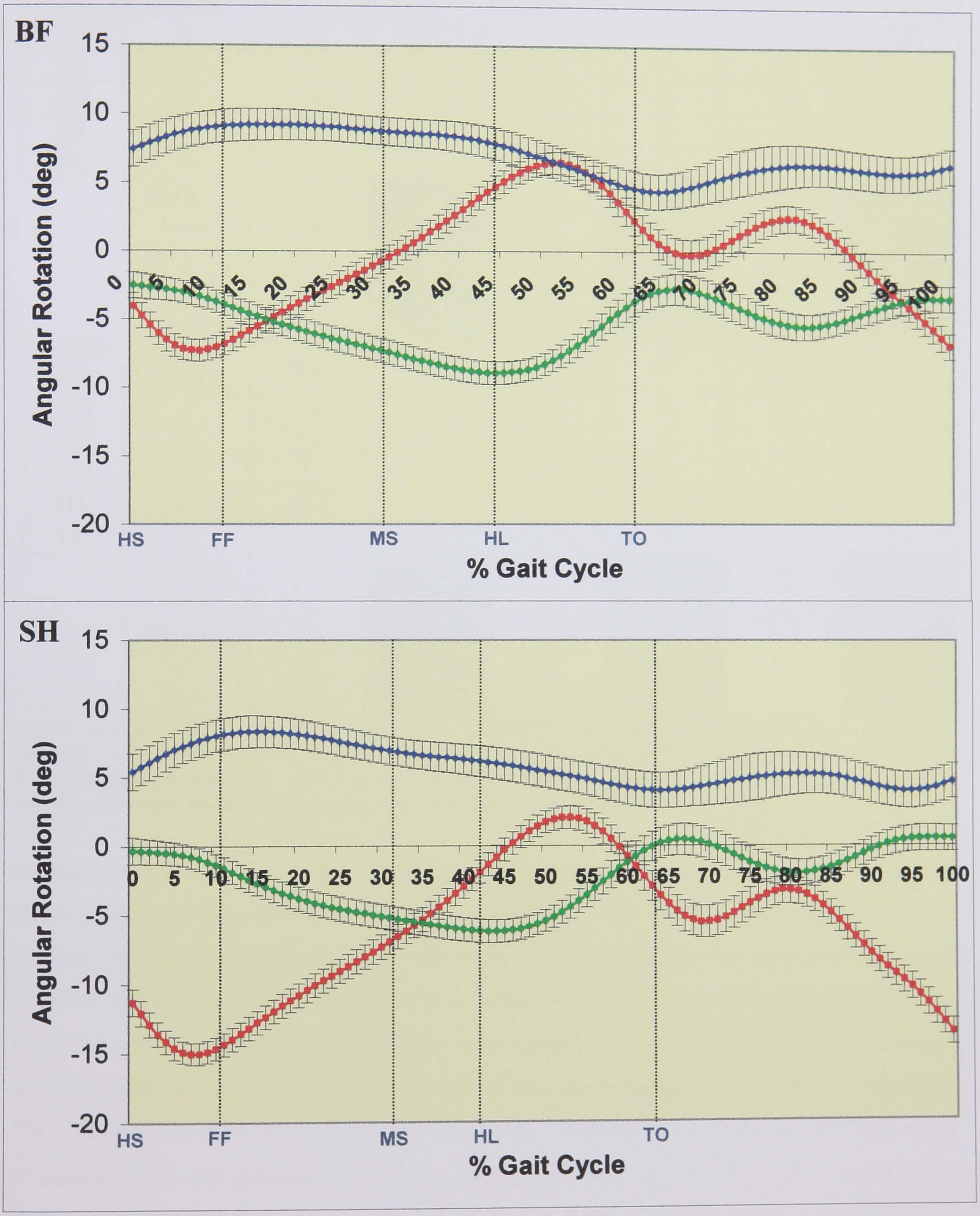
EVENT (BF)	% GAIT CYCLE	DF/PF	SD	INV/EVR	SD	INT/EXT ROT	SD
HS	0	-3.9	5.9	-2.9	3.3	6.7	5.1
FF	11	-6.7	5.9	-4.0	3.4	8.6	4.6
MS	31	-0.7	6.0	-7.8	3.8	8.3	4.7
HL	44	4.2	6.0	-9.4	4.1	7.5	4.9
TO	62	1.7	7.2	-3.8	5.4	4.8	5.4
	MAX (-)	-7.2		-9.5		4.7	
	%GC	100		44		64	
	MAX (+)	6.0		-2.8		8.7	
	%GC	52		67		16	
	ROM	13.3		6.6		4.0	
EVENT (SH)	**% GAIT CYCLE**	**DF/PF**	**SD**	**INV/EVR**	**SD**	**INT/EXT ROT**	**SD**
HS	0	-11.3	5.3	-0.3	4.5	5.4	5.1
FF	11	-14.4	5.3	-1.6	4.3	8.1	4.8
MS	32	-6.6	4.9	-5.3	4.5	6.8	4.3
HL	42	-1.9	4.6	-6.2	4.6	6.2	4.6
TO	64	-3.6	7.1	0.2	6.2	4.0	5.4
	MAX (-)	-15.0		-6.2		4.0	
	%GC	7		43		95	
	MAX (+)	2.1		0.5		8.4	
	%GC	53		97		15	
	ROM	17.1		6.7		4.4	

Angles are in degrees. %GC- percent gait cycle, SD- standard deviation, MAX(-)- maximum negative joint angle, MAX(+)- maximum positive joint angle, ROM- range of motion, DF/PF- dorsiflexion/plantarflexion, INV/EVR- inversion/eversion, INT/EXT ROT- internal/external rotation, HS- heel strike, FF- foot flat, MS- mid stance, HL- heel lift, TO- toe off.

5.1.2.3 Rheumatoid arthritis intervention group

For the RA intervention group the barefoot kinematic data are presented in table 5-3 and figure 5-3. In barefoot gait three phases of dorsi/plantarflexion motion were recorded during stance phase with <1° reduction in ROM in comparison with normal values. Rotation from heel strike in the RA intervention group started from -2.2° and was therefore consistent with normal values, but during terminal swing an increased drop towards plantarflexion is noted. The mean maximum plantarflexion (-6.5°) decreased by 2.6° and 0.7° in comparison with normal population and RA control group values respectively, whilst maximum dorsiflexion (7.8°) was slightly greater than that for the RA control and normal population. Overall curve shape for dorsi/plantarflexion was consistent with that for the RA control group.

Figure 5-2: Angular rotation:time curves for the ankle joint complex in rheumatoid arthritis (control group) during barefoot (BF) and shod (SH) gait (N=96).



(---) dorsiflexion(+) / plantarflexion(-), (---) Inversion(+) / Eversion(-), and (---) Internal(+) / External rotation(-). Gait events represented by: HS- Heel strike, FF- Foot Flat, MS- Mid-stance, HL- heel lift, and TO- Toe off. Bars represent the 95% confidence interval of the mean.

Table 5-3: Mean kinematic data for the ankle joint complex by maximum values and timed events during gait in RA (intervention) group walking barefoot (BF) and shod (SH).

EVENT (BF)	% GAIT CYCLE	DF/PF	SD	INV/EVR	SD	INT/EXT ROT	SD
HS	0	-2.2	5.6	-3.2	4.5	6.0	5.0
FF	12	-5.1	5.5	-4.7	4.6	7.8	4.5
MS	30	0.6	5.3	-7.9	4.8	7.3	4.4
HL	44	5.6	5.4	-9.7	5.1	6.6	4.4
TO	59	6.1	6.3	-5.7	6.7	4.0	4.7
	MAX (-)	-6.5		-9.8		3.5	
	%GC	100		46		64	
	MAX (+)	7.8		-2.5		7.8	
	%GC	53		99		14	
	ROM	14.3		7.3		4.3	
EVENT (SH)	**% GAIT CYCLE**	**DF/PF**	**SD**	**INV/EVR**	**SD**	**INT/EXT ROT**	**SD**
HS	0	-10.0	6.3	-0.1	5.0	4.7	4.9
FF	12	-12.5	5.6	-2.1	5.2	7.5	4.3
MS	32	-5.1	5.3	-5.6	5.2	6.1	4.3
HL	40	-1.4	5.4	-6.3	5.2	5.5	4.3
TO	64	-1.8	7.0	0.2	7.6	2.8	5.3
	MAX (-)	-13.6		-6.3		2.6	
	%GC	7		42		61	
	MAX (+)	3.8		0.4		7.6	
	%GC	53		66		15	
	ROM	17.4		6.7		5.0	

Angles are in degrees. %GC- percent gait cycle, SD- standard deviation, MAX(-)- maximum negative joint angle, MAX(+)- maximum positive joint angle, ROM- range of motion, DF/PF- dorsiflexion/plantarflexion, INV/EVR- inversion/eversion, INT/EXT ROT- internal/external rotation, HS- heel strike, FF- foot flat, MS- mid stance, HL- heel lift, TO- toe off.

Inversion/eversion motion in the RA intervention group demonstrated two phases during the stance phase with the motion curve shifted negatively on the ordinate. A neutral or inverted position was not achieved at any stage during the gait cycle such that the mean motion pattern occurred within an everted ROM. Mean heel strike (-3.2°), foot flat (-4.7°), mid stance (-7.9°), heel lift (-9.7°) and toe off (-5.7°) positions were everted and maximum eversion was increased in comparison with normal values by a factor of 2.6. The mean maximum inversion shifted by 7.8° from 5.3° inverted (normal) to –2.5° everted (RA intervention) and the overall mean range of motion (7.3°) was decreased by 1.8° in comparison with normal values. The overall curve shape and stance phase event mean angles were consistent with those for the RA control group.

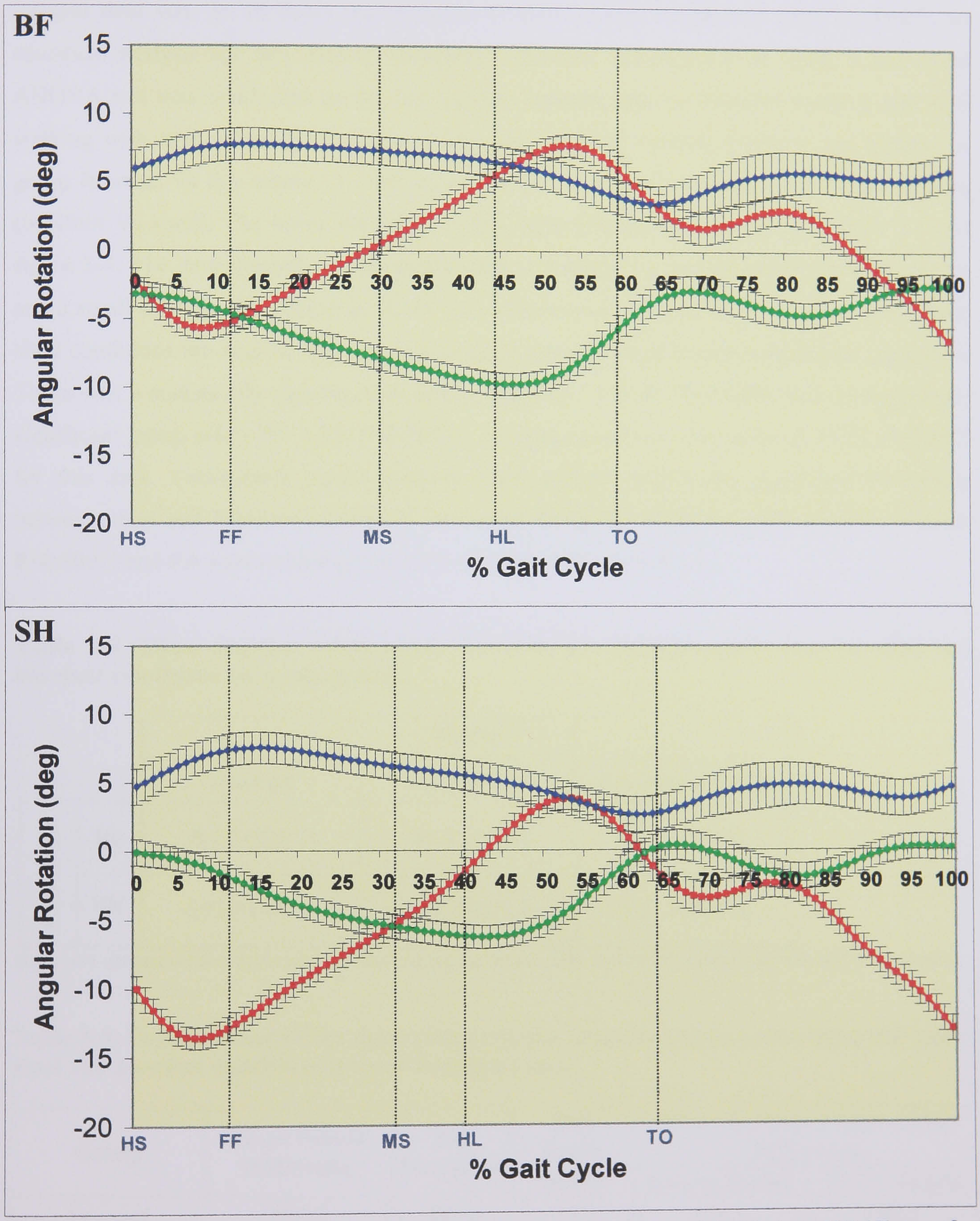
In the RA intervention group there was a notable flattening and positive shift on the ordinate for the internal/external rotation motion curve and the ROM (4.3°) decreased by 2.4° over normal values. The motion occurred within an internally rotated range and at no stage during the gait

cycle did the joint reach neutral or become externally rotated. From heel strike (6.0°) to maximum (7.8°) only 1.8° of motion in the direction of further internal rotation occurred. From foot flat (7.8°) through mid stance (7.3°) and heel lift (6.6°) motion changed towards external rotation to a negative maximum of 3.5° reached shortly after toe-off. The overall curve shape and stance phase time event angles were consistent with those for the RA control group. This group showed a later heel-lift within the same proportion of stance within the gait cycle and greater variability during the loading response and pre-swing phases over normal values.

In shod gait (table 5-3, figure 5-3) dorsi/plantarflexion ROM (17.4°) was increased from barefoot gait and consistent with that seen in both the normal population and RA control group. The angular rotation:time curve shifted negatively on the ordinate increasing the mean heel strike position (-10.0°) by -7.8° from the barefoot condition. Mean maximum plantarflexion (-13.6°) increased over barefoot condition but was reduced in comparison with normal population and RA control group but by less than 2°. Mean maximum dorsiflexion (3.8°) was increased slightly over both the normal population and RA control group mean values. The inversion/eversion ROM (6.7°) was decreased in comparison with the barefoot condition but the angular rotation:time curve shifted positively on the ordinate. The heel strike position was slightly everted (-0.1°) and consistent with that for the RA control group but more everted than in the normal population for barefoot and shod conditions. Mean maximum eversion was –6.3° indicating a greater everted position than either barefoot or shod conditions in normal population, but highly consistent with that for the RA control group. A period at and just after toe off (0.2°) found the joint reaching a neutral position but the greater proportion of stance saw a range of motion through everted positions.

During shod gait the mean internal/external ROM (5.0°) increased by 0.7° over the barefoot condition, the joint still functioning around an internally rotated ROM. Positive and negative maximum angles remained relatively unchanged as did angular positions by gait time events, the angular rotation:time curve being flat in shape. During weight acceptance and terminal stance the variability of data increased in shod condition over barefoot for all axes of rotation. For gait timings maximum external rotation occurred slightly earlier under shod conditions. A larger proportion of the gait cycle was taken up in stance (64%) with a shorter duration to heel lift (40%) when shod and barefoot data are compared.

Figure 5-3: Angular rotation:time curves for the ankle joint complex in rheumatoid arthritis (intervention group) during barefoot (BF) and shod (SH) gait (N=100).



(---) dorsiflexion(+) / plantarflexion(-), (---) Inversion(+) / Eversion(-), and (---) Internal(+) / External rotation(-). Gait events represented by: HS- Heel strike, FF- Foot Flat, MS- Mid-stance, HL- heel lift, and TO- Toe off. Bars represent the 95% confidence interval of the mean.

5.1.2.4 Comparison between barefoot and shod gait

Normality plots with Shapiro-Wilks test were applied to a random selection of 10 rotation:time integral data sets. In all cases the variables showed normal distribution plots confirmed by statistical analysis and this allowed parametric statistical techniques to be used. A two-factor ANOVA test was conducted on the motion-time integral data for baseline barefoot and shod walking with separate analyses conducted for each axis of rotation. Factor-1 was defined as group (normal Vs RA control Vs RA intervention) and factor-2 defined as walking condition (barefoot Vs shod). The mean integrals for dorsi/plantarflexion are presented in table 5-4 and figure 5-4. The data showed a small mean negative integral for normal and RA control groups and a small mean positive integral for the RA intervention group in barefoot conditions. Under shod conditions the angular rotation:time integrals showed large negative means for all groups. There was a statistically significant condition effect ($F= 149.95$, $P<0.0001$) but no statistically significant group effect ($F= 1.80$, $P=0.167$) or group-by-condition interaction ($F=0.21$, $P=0.809$) for this data. Two-sample paired students t-test showed statistically significant differences between shod and barefoot conditions for normal ($t=14.22$, $P<0.0001$), RA control ($t=10.46$, $P<0.0001$) and RA intervention groups ($t=14.64$, $P<0.0001$), table 5-5.

Table 5-4. Mean angular rotation:time integrals for dorsi/plantarflexion for shod and barefoot conditions for study groups.

		Group		
		Normal	**RA Control**	**RA Intervention**
Condition	**BF**	-36.2 (326.7)	-61.0 (404.6)	69.5 (405.6)
	SH	-573.0 (307.0)	-588.2 (423.9)	-523.3 (393.6)

Data are means with standard deviation in parentheses. BF- barefoot condition, SH- shod condition.

Table 5-5: Post-hoc analysis for dorsi/plantarflexion (angular rotation:time integrals) under shod and barefoot conditions (paired 2-sample t-test).

Group	Mean Paired Difference	Std. Deviation	Std. Error Mean	95% Confidence Interval for Difference	
				Lower Bound	Upper Bound
Normal	536.9	253.2	37.7	460.8	612.9
RA Controls	527.1	349.0	50.4	425.8	628.5
RA Intervention	592.8	286.3	40.5	511.4	674.2

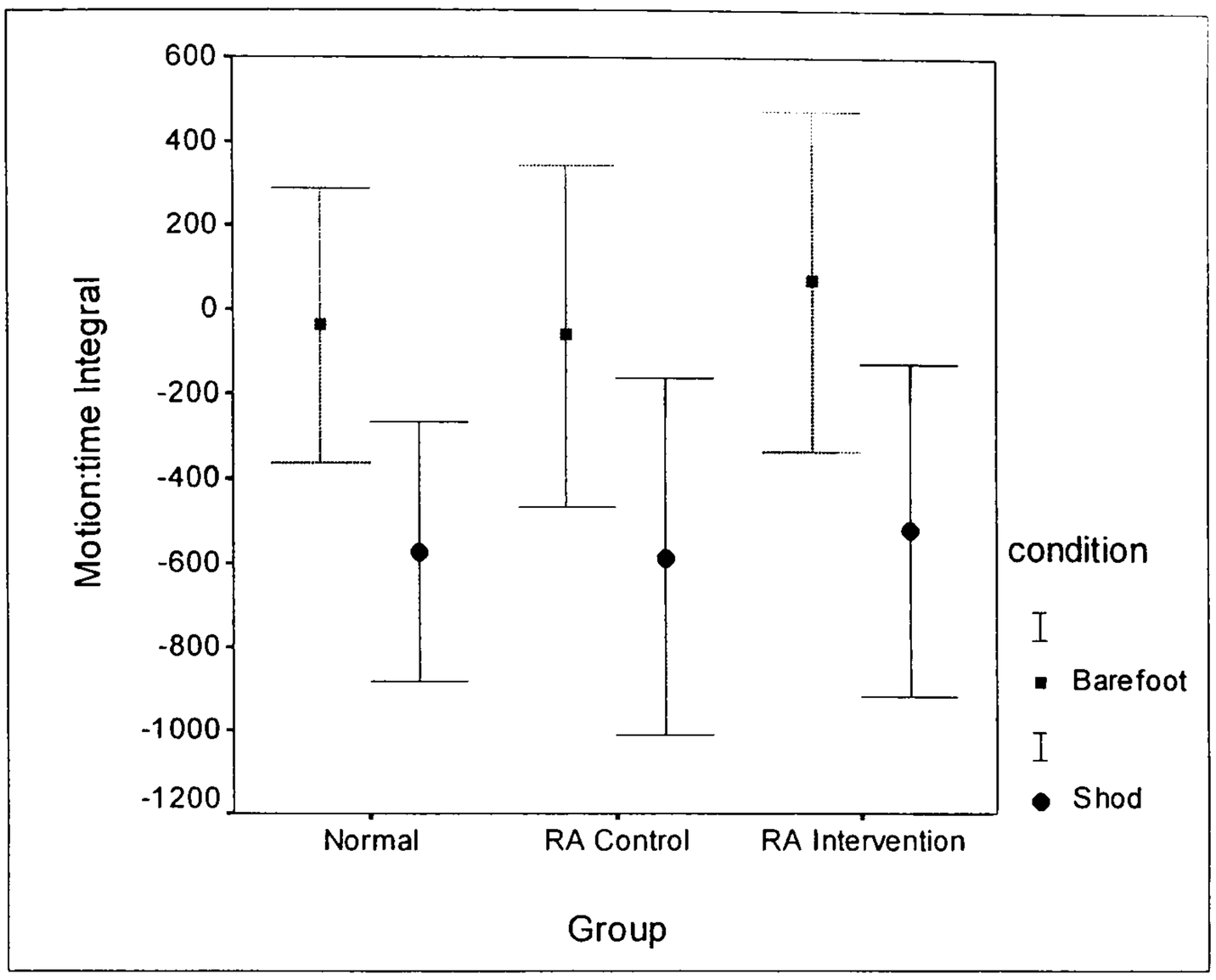


Figure 5-4: Dorsi/plantarflexion angular rotation:time integrals for barefoot and shod conditions in the study groups. Error bars represent one standard deviation about the mean.

The mean integrals for inversion/eversion are presented in table 5-6 and figure 5-5. The data showed a mean positive angular rotation:time integral for normal subjects under barefoot conditions whilst both RA groups had large mean negative integrals. Under shod conditions the angular rotation:time integral for the normal population increased and for both RA groups decreased but overall remained negative. There was a statistically significant condition effect ($F= 41.60$, $P<0.0001$) and group effect ($F=93.99$, $P<0.0001$) but no significant group-by-condition interaction ($F= 1.32$, $P=0.809$) for this data. For the group effect post-hoc analysis using Tukey's test revealed statistically significant differences in pairwise comparisons between the normal population and both RA groups but not between the two RA groups (table 5-7). Two-sample paired students t-test showed statistically significant differences between shod and barefoot conditions for normal ($t=-4.59$, $P<0.0001$), RA control ($t=-10.22$, $P<0.0001$) and RA intervention groups ($t=-10.84$, $P<0.0001$), table 5-8.

Table 5-6: Mean angular rotation:time integrals for inversion/eversion for shod and barefoot conditions for study groups at baseline.

		Group		
		Normal	RA Control	RA Intervention
Condition	BF	87.3 (244.3)	-546.1 (282.6)	-563.4 (366.7)
	SH	247.8 (330.7)	-252.3 (331.2)	-264.1 (387.7)

Data are means with standard deviation in parentheses. BF- barefoot condition, SH- shod condition.

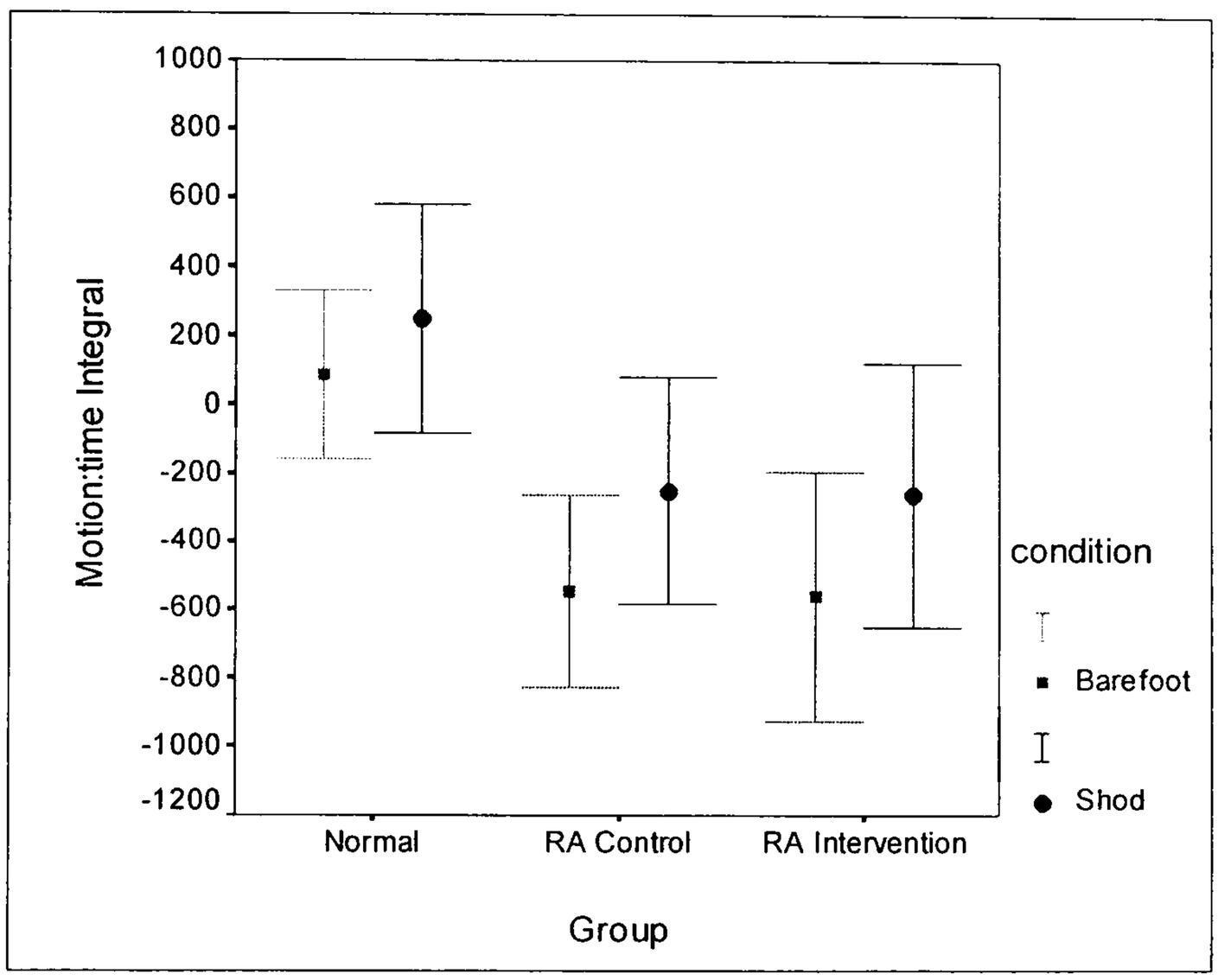


Figure 5-5: Inversion/eversion angular rotation:time integrals for barefoot and shod conditions in the three study groups. Error bars represent one standard deviation about the mean.

Table 5-7: Post-hoc analysis of group effect using Tukey's test for pairwise comparisons of angular rotation:time integrals for inversion/eversion in the study groups at baseline.

Group pairs		Mean Difference	Std. Error	Sig.	95% Confidence Interval for Difference	
Group	Group				Lower Bound	Upper Bound
Normal	RA Control RA Rx	566.7 581.3	48.3 47.8	P<0.0001 P<0.0001	471.7 487.2	661.7 675.4
RA Control	Normal RA Rx	-566.7 14.5	48.3 47.0	P<0.0001 P=0.757	-661.7 -78.0	-471.7 107.1
RA Rx	Normal RA Control	-581.3 -14.5	47.8 47.08	P<0.0001 P=0.757	-675.4 -107.1	-487.2 78.0

Table 5-8: Post-hoc analysis of condition effect for inversion/eversion under shod and barefoot conditions for study groups at baseline (paired 2-sample t-test).

Group	Mean Paired Difference	Std. Deviation	Std. Error Mean	95% Confidence Interval for Difference	
				Lower Bound	Upper Bound
Normal	-160.5	234.7	35.0	-231.0	-89.9
RA Controls	-293.7	199.1	28.7	-351.5	-235.9
RA Intervention	-299.3	195.3	27.6	-354.8	-243.8

The mean integrals for internal/external rotation are presented in table 5-9 and figure 5-6. Under barefoot conditions all study groups had positive mean angular rotation:time integrals the values for both RA groups similar but considerably greater than that for the normal population. Under shod conditions the angular rotation:time integral for all 3 groups decreased but remained positive. There was a statistically significant condition effect ($F= 4.45$, $P=0.036$) and group effect ($F=77.55$, $P<0.0001$) but no significant group-by-condition interaction ($F= 0.18$, $P=0.838$) for this data. For the group effect post-hoc analysis using Tukey's test revealed statistically significant differences in pairwise comparisons between the normal population and both RA groups but not between the two RA groups (table 5-10). Two-sample paired students t-test showed statistically significant differences between shod and barefoot conditions for normal ($t=2.43$, $P=0.019$), RA control ($t=5.95$, $P<0.0001$) and RA intervention groups ($t=5.73$, $P<0.0001$), table 5-11.

Table 5-9: Mean angular rotation:time integrals for internal/external rotation under shod and barefoot conditions for the study groups at baseline.

		Group		
		Normal	**RA Control**	**RA Intervention**
Condition	**BF**	65.7 (335.4)	695.0 (357.7)	610.1 (361.0)
	SH	12.6 (390.0)	584.2 (336.1)	507.6 (351.6)

Data are means with standard deviation in parentheses. BF- barefoot condition, SH- shod condition.

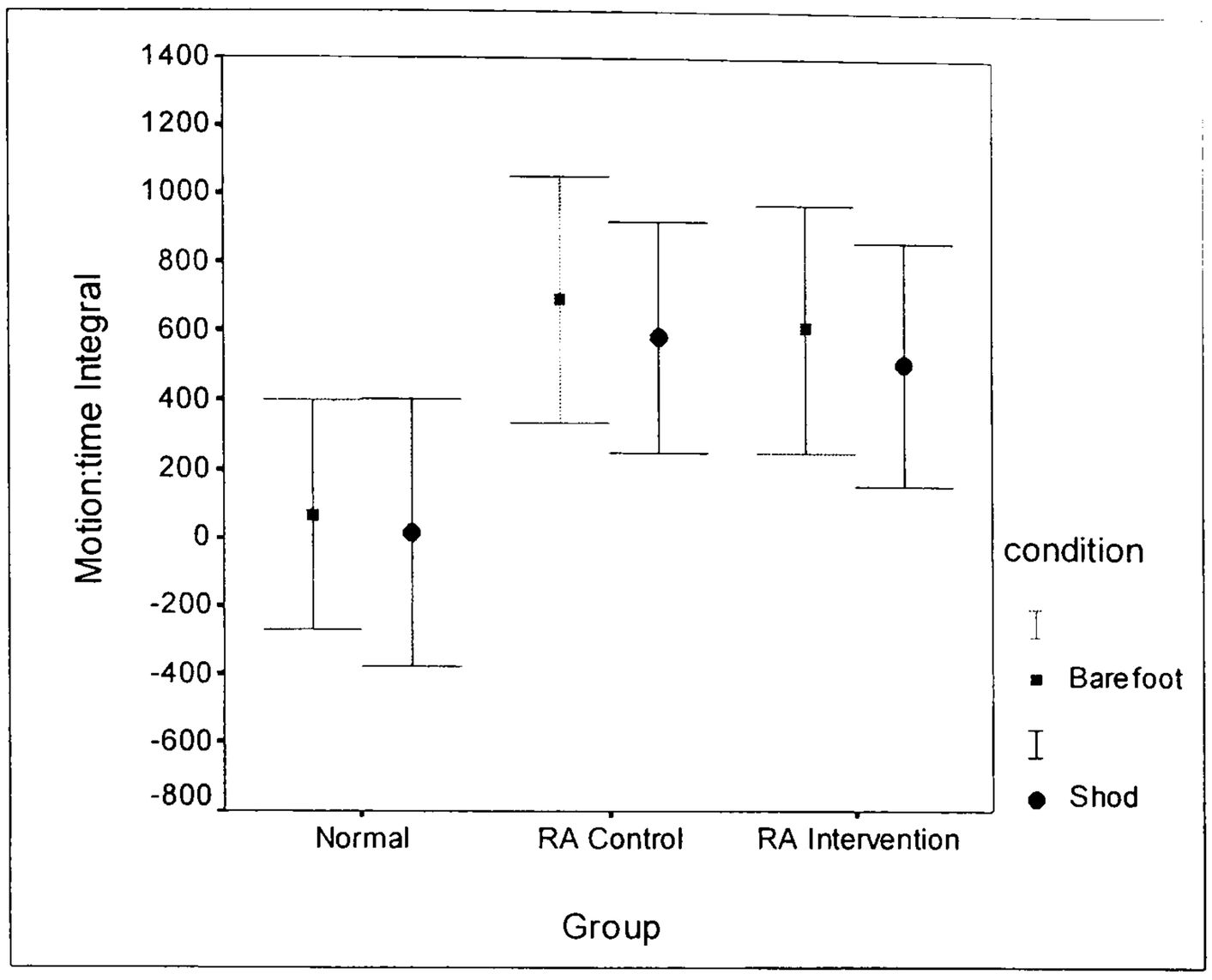


Figure 5-6: Internal/external rotation angular rotation:time integrals for barefoot and shod conditions in the study groups. Error bars represent one standard deviation about the mean.

Table 5-10: Post-hoc analysis table using Tukey's test for pairwise comparisons of angular rotation:time integrals for internal/external rotation in the study groups at baseline.

		Mean Difference	Std. Error	Sig.	95% Confidence Interval for Difference	
Group	Group				Lower Bound	Upper Bound
Normal	RA Control RA Rx	-600.5 -519.7	52.2 51.7	P<0.0001 P<0.0001	-703.2 -621.5	-497.8 -418.0
RA Control	Normal RA Rx	600.5 80.7	52.2 50.8	P<0.0001 P=0.757	497.8 -19.3	703.2 180.8
RA Rx	Normal RA Control	519.7 -80.7	51.7 50.8	P<0.0001 P=0.757	418.0 -180.8	621.5 19.3

Table 5-11: Post-hoc analysis of condition effect for internal/external rotation (angular rotation:time integrals) under shod and barefoot conditions for study groups at baseline (paired 2-sample t-test).

Group	Mean Paired Difference	Std. Deviation	Std. Error Mean	95% Confidence Interval for Difference	
				Lower Bound	Upper Bound
Normal	53.1	146.5	21.8	9.1	97.1
RA Controls	110.8	128.8	18.6	73.3	148.2
RA Intervention	102.5	126.5	17.9	66.5	138.5

5.2 Orthotic intervention at baseline

5.2.1 Results

5.2.1.1 Descriptive summary of kinematic data

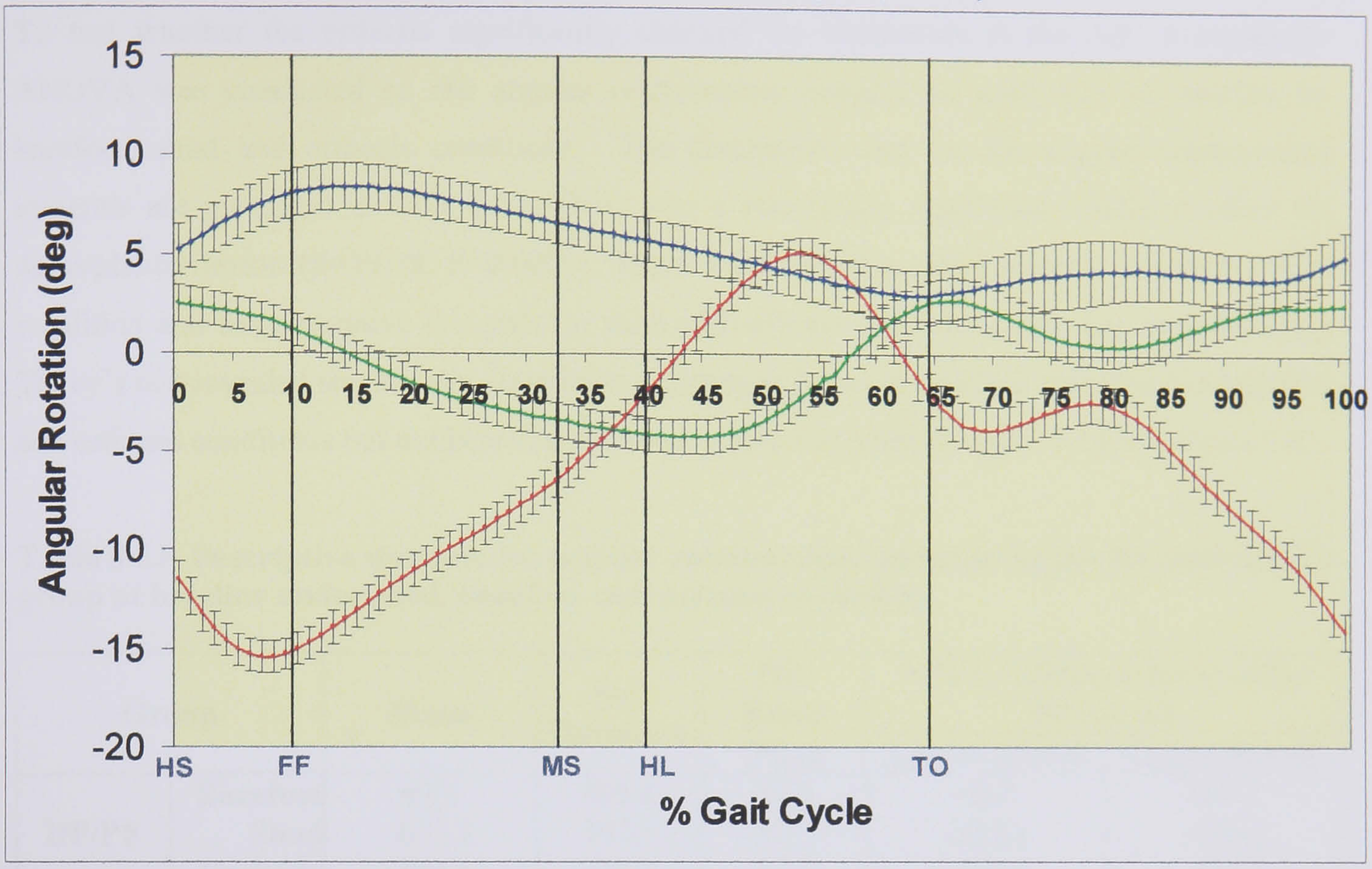
The RA intervention group had 3-D kinematics for the AJC measured in-shoe with the orthoses in-situ. The angular rotation:time curves are presented in figure 5-7 and summarised in table 5-12. Three phases of dorsi/plantarflexion were recorded during the stance phase of gait with a mean ROM of 20.5°, an increase from the barefoot and shod conditions of 6.2° and 3.1° respectively. The motion-time curve was shifted negatively on the ordinate and both the mean heel strike (-11.5°) and foot flat (-15.0°) angles were greater than those for barefoot and shod condition. The second phase of dorsiflexion brought the joint through neutral position shortly after heel lift rising to a maximum mean dorsiflexion angle of 5.1° at 53% gait cycle indicating that this range of motion was preserved in comparison with the shod condition. A final phase of plantarflexion occurred towards toe off and during swing phase a small dorsiflexion movement occurred followed by a significant plantarflexion drop during terminal swing.

Table 5-12: Mean kinematic data for the ankle joint complex by maximum values and timed events during gait in RA (intervention) group walking with foot orthoses (FO).

EVENT	% GAIT CYCLE	DF/PF	SD	INV/EVR	SD	INT/EXT ROT	SD
HS	0	-11.5	6.0	2.5	6.1	5.2	4.6
FF	10	-15.0	5.4	1.1	6.2	8.1	4.2
MS	33	-5.9	5.6	-3.5	6.1	6.5	4.3
HL	40	-1.8	5.9	-4.1	6.2	5.7	4.4
TO	65	-2.7	7.5	2.8	8.2	3.1	5.3
	MAX (-)	-15.4		-4.2		3.0	
	%GC	7		43		63	
	MAX (+)	5.1		2.8		8.4	
	%GC	53		66		15	
	ROM	20.5		7.0		5.4	

Angles are in degrees. %GC- percent gait cycle, SD- standard deviation, MAX(-)- maximum negative joint angle, MAX(+)- maximum positive joint angle, ROM- range of motion, DF/PF- dorsiflexion/plantarflexion, INV/EVR- inversion/eversion, INT/EXT ROT- internal/external rotation, HS- heel strike, FF- foot flat, MS- mid stance, HL- heel lift, TO- toe off.

Figure 5-7: Angular rotation:time curves for the ankle joint complex in rheumatoid arthritis (intervention group) during shod with orthosis gait (N=100).



(---) dorsiflexion(+) / plantarflexion(-), (---) Inversion(+) / Eversion(-), and (---) Internal(+) / External rotation(-). Gait events represented by: HS- Heel strike, FF- Foot Flat, MS- Mid-stance, HL- heel lift, and TO- Toe off. Bars represent the 95% confidence interval of the mean.

The overall inversion/eversion curve shape and ROM (7.0°) was similar for the orthotic condition in comparison with barefoot and shod walking. However, the angular rotation:time curve was shifted positively on the ordinate in comparison with barefoot and shod conditions such that an inversion rotation of >1° beyond neutral occurred. Both the mean heel strike (2.5°) and foot flat angles (1.1°) were positive with inversion maintained for approximately 15% of the gait cycle before a period of eversion to a maximum of –4.2° was observed. A second phase of inversion was recorded where again the neutral position was passed with maximum inversion (2.8°) reached at shortly after toe-off. Through swing phase, only small motions, about an inverted position, occurred. Internal/external rotation was qualitatively and quantitatively similar to that measured under shod conditions with a slight positive shift on the ordinate of approximately 0.5° for all gait event and maximum angles. Under orthotic walking conditions there were no marked changes in the timing of gait cycle events but a slight increase in the variability of the data, especially for inversion/eversion than for barefoot or shod conditions.

5.2.1.2 Statistical analysis between barefoot, shod and orthosis conditions

To test whether the orthosis significantly changed the kinematics at the AJC a one-factor ANOVA was conducted on the angular rotation:time integral for each axis of rotation for barefoot, shod and orthosis conditions. The descriptive data for the angular rotation:time integrals are presented in table 5-13. There was a statistically significant condition effect for dorsi/plantarflexion ($F=39.78$, $P<0.0001$). There was a small positive integral for the barefoot condition and large negative integrals for shod and orthosis conditions. Post-hoc analysis using Tukey's test revealed statistically significant differences between barefoot and shod and barefoot and orthosis conditions but not between shod and orthosis conditions (table 5-14 and figure 5-8).

Table 5-13: Descriptive statistics for angular rotation:time integrals for the RA intervention group at baseline under shod, barefoot and orthosis conditions.

Group		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval for Difference	
					Lower Bound	Upper Bound
DF/PF	Barefoot	69.5	405.4	57.3	-45.7	184.7
	Shod	-523.3	393.6	55.7	-635.1	-411.4
	Orthosis	-544.6	372.7	52.7	-650.5	-438.7
INV/EVR	Barefoot	-563.4	366.7	51.9	-667.6	-459.2
	Shod	-264.1	387.7	54.8	-374.3	-153.9
	Orthosis	-26.1	454.7	64.3	-155.4	103.1
I/E Rot	Barefoot	610.1	361.0	51.1	507.5	712.7
	Shod	507.6	351.6	49.7	407.7	607.6
	Orthosis	529.8	315.4	44.6	440.2	619.4

DF/PF- dorsi/plantarflexion. INV/EVR- inversion/eversion. I/E Rot- internal/external rotation

Because the AJC functioned around an everted ROM under barefoot conditions a large negative integral was found. When analysed under shod and orthosis conditions the angular rotation:time integral for both these conditions was negative. Both values were reduced significantly, relative to zero, in comparison with barefoot walking ($F=22.12$, $P<0.0001$). Post-hoc analysis revealed statistically significant differences between barefoot and shod, barefoot and orthosis and orthosis and shod conditions (table 5-14 and figure 5-9). The integrals for internal/external rotation increased for barefoot to shod to orthosis conditions but the effect was not statistically significant (table 5-14).

Table 5-14: Post-hoc analysis table using Tukey's test for pairwise comparisons of angular rotation:time integrals for the RA intervention group baseline.

			Mean Difference	Std. Error	Sig.	95% Confidence Interval for Difference	
Motion	Condition	Condition				Lower Bound	Upper Bound
DF/PF	Barefoot	Shod	-592.8	78.2	P<0.0001	-776.0	-409.6
	Barefoot	Orthosis	-614.1	78.2	P<0.0001	-797.3	-430.9
	Shod	Orthosis	-21.3	78.2	P=0.96	-204.5	161.9
INV/EVR	Barefoot	Shod	299.3	81.0	P=0.001	109.6	489.0
	Barefoot	Orthosis	537.2	81.0	P<0.0001	347.5	727.0
	Shod	Orthosis	237.9	81.0	P=0.009	48.2	427.7
I/E Rot	Barefoot	Shod	-102.5	68.6	P=0.294	-263.4	58.4
	Barefoot	Orthosis	-80.3	68.6	P=0.471	-241.2	80.5
	Shod	Orthosis	22.2	68.6	P=0.944	-138.7	183.0

DF/PF- dorsi/plantarflexion. INV/EVR- inversion/eversion. I/E Rot- internal/external rotation

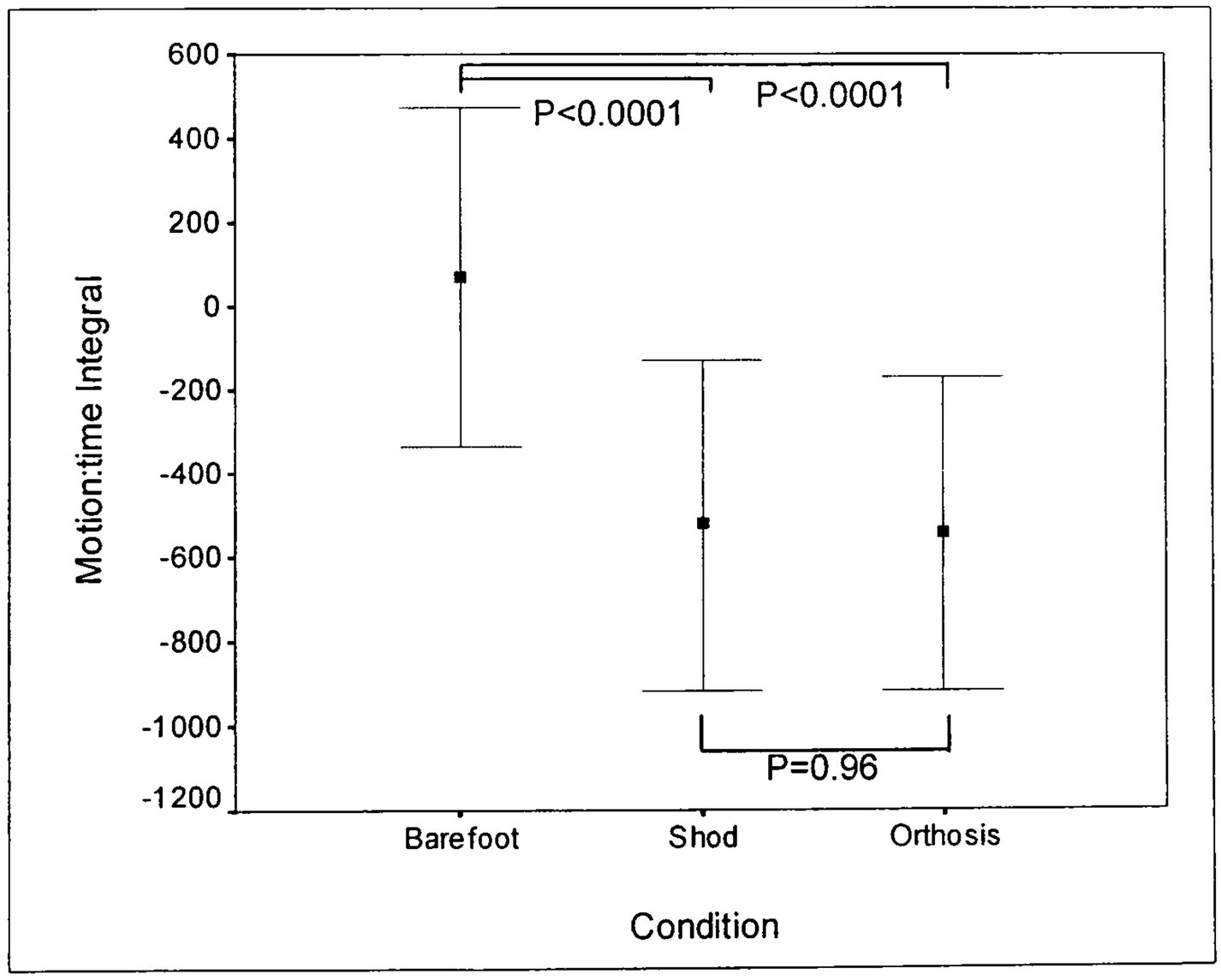


Figure 5-8: Error bar plot of dorsi/plantarflexion rotation angular rotation:time integrals for barefoot, shod and orthosis conditions in the RA intervention group at baseline. Error bars represent one standard deviation about the mean.

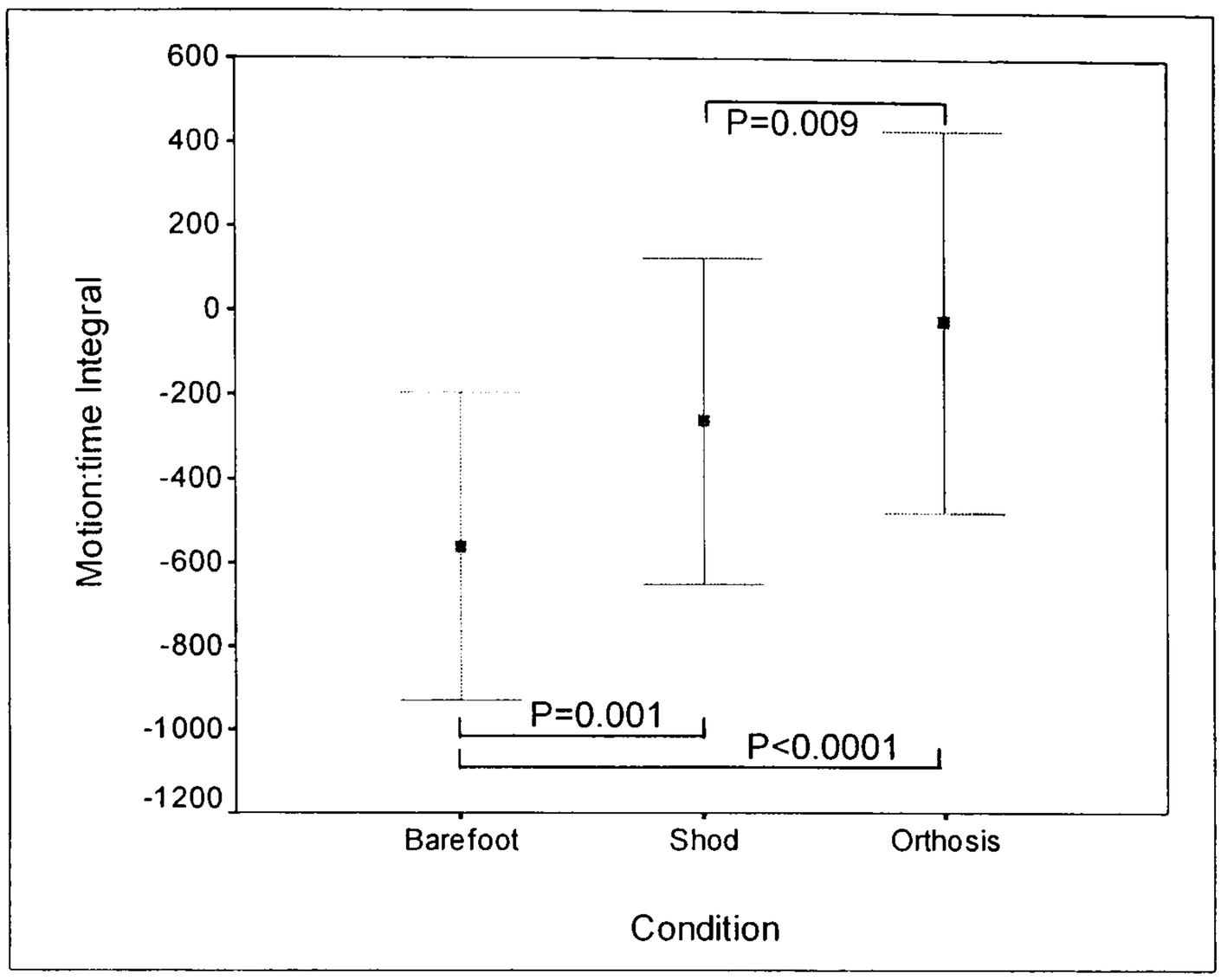


Figure 5-9: Error bar plot of inversion/eversion rotation angular rotation:time integrals for barefoot, shod and orthosis conditions in the RA intervention group at baseline. Error bars represent one standard deviation about the mean.

5.2.1.3 Between-group statistical analyses

The effect of the intervention was investigated further by comparing the kinematic data from the RA intervention group with orthoses against both the RA control group and normal population under shod conditions. One-factor ANOVA revealed statistically significant between group effects for inversion/eversion ($F=20.26$, $P<0.0001$) and internal/external rotation ($F=38.15$, $P<0.0001$) but not for dorsiflexion/plantarflexion ($F=0.17$, $P=0.841$) (table 5-15). For inversion/eversion, post-hoc analyses with Tukey's test revealed statistically significant between group differences for normal population against RA control ($P<0.0001$), normal population against RA intervention ($P=0.001$), and RA control against RA intervention ($P=0.009$). For internal/external rotation post-hoc analyses found statistically significant between group differences for normal population against RA control ($P<0.0001$), normal population against RA intervention ($P<0.001$) but not between RA control and RA intervention ($P=0.718$).

Table 5-15: Post-hoc analysis table for pairwise comparisons of angular rotation:time integrals for the RA control and normal population under shod conditions and RA intervention group with orthosis at baseline.

			Mean Difference	Std. Error	Sig.	95% Confidence Interval for Difference	
Motion	Group	Group				Lower Bound	Upper Bound
DF/PF	Normal	RA Con	-15.1	77.3	P=0.979	166.0	-196.3
	Normal	RA Int	28.5	76.5	P=0.927	207.8	-150.9
	RA Con	RA Int	43.6	75.3	P=0.831	220.0	-132.8
INV/EVR	Normal	RA Con	-500.1	78.6	P=0.001	-315.8	-684.4
	Normal	RA Int	-273.9	77.9	P<0.0001	-91.4	-456.4
	RA Con	RA Int	226.2	76.6	P=0.009	405	46.8
I/E Rot	Normal	RA Con	571.7	72.0	P<0.0001	740.5	402.8
	Normal	RA Int	517.2	71.3	P<0.0001	684.4	350.0
	RA Con	RA Int	-54.4	70.2	P=0.718	110.0	-218.8

DF/PF- dorsi/plantarflexion. INV/EVR- inversion/eversion. I/E Rot- internal/external rotation

5.3 Longitudinal kinematic data

5.3.1 Statistical analyses

Kinematic measurement data were analysed for the AJC at the 3, 6, 12, 18, 24 and 30- month review periods for both RA study groups. Tabular and graphical summaries of mean (standard deviation or standard error of the mean) angle by gait cycle event, maximum values, ROM and angular rotation:time integral were prepared and changes within and between groups over time described. Statistical analyses of between group and time effects were conducted on angular rotation:time integral data only using a two-factor repeat measure ANOVA statistical technique. Missing data were handled by carrying forward the last complete kinematic data set following the intention-to-treat model for the clinical data. In the ANOVA factor-1 was defined as group (RA control Vs RA intervention), factor-2 was defined as condition (barefoot Vs shod Vs orthosis) and the repeat measure defined as time with 7 levels (0, 3, 6, 12, 18, 24, and 30 months).

5.3.2 Rheumatoid arthritis control group

In this group, under barefoot conditions, the angular rotation:time curves for all three axes of rotation were qualitatively similar across the duration of the study. The mean ROM varied only slightly between review periods, within a 1.6° range for dorsi/plantarflexion, a 0.7° range for inversion/eversion and a 0.8° range for internal/external rotation (table- 5-16). The mean angular rotation:time integrals for dorsi/plantarflexion were negative throughout demonstrating a

dominance of plantarflexion over dorsiflexion motion. Eversion motion dominated in the frontal plane with large negative mean integrals whilst internal rotation dominated in the transverse plane with large positive mean integrals across the time points. A trend towards a shift of the angular rotation:time curves on the ordinate was observed for dorsi/plantarflexion and inversion/eversion integrals. In the case of dorsiflexion/plantarflexion a large negative shift was noted at 3-months followed by a constant decrease between 12 and 24 months with a slight positive increase at 30-months. This corresponded with a subsequent shift over time in the mean angles at key gait events and also the maximum negative and positive angles. This negative shift over time trend indicates a joint functioning around a more plantarflexed ROM.

For inversion/eversion between baseline and 6-months the mean angular rotation:time integral decreased then returned to baseline followed by a constant decrease, in comparison with baseline, through 12 to 30 months (table 5-16). This shift was accompanied by relative change in the mean angles for key gait events and for maximum negative and positive values. The AJC still functioned around a large everted ROM in comparison with parameters defined in our normal population; however, the observed trend indicated an overall improvement over time. For internal/external rotation the large positive integral for this motion remained constant over time and markedly greater than that for the normal population (table 5-16). In the latter stages of the study the data suggests that the integral decreased with a relative reduction in the mean gait event angles and the maximum positive values. Internal/external rotation had the smallest ROM over the other two axes.

The trend observed at baseline whereby footwear allowed the AJC to function around a more plantarflexed (negative shift on ordinate for angular rotation:time integral) and less everted (positive shift on ordinate for angular rotation:time integral) ROM was observed across the duration of the study for the RA control group (table 5-16). Furthermore the changes over time described for barefoot conditions above were carried forward to the shod condition. Therefore for dorsi/plantarflexion the ROM remained constant but between 6- and 30-months the angular rotation:time integral decreased with a subsequent shift, except for heel strike, in the mean and maximum angles by gait event. For inversion/eversion the mean heel strike angle changed from an everted to an inverted position between 3- and 6-months, increasing further from here to 30-months. The change was small, only 1.5°, relative to the inherent error of the system (0.72°) (table 5-17). The ROM remained constant over the duration of the study but the shift for mean heel strike angle was also observed for other gait events, for the mean maximum positive and negative angles and for the angular rotation:time integrals. For internal/external rotation footwear tended to increase the ROM and permit the joint to function around a less internally rotated ROM reflected in the mean gait event angles, the maximum positive and negative values and the mean

angular rotation:time integrals. Over time the AJC ROM in the transverse plane occurred around an internally rotated angular positions in comparison with normal parameters (table 5-17). However between 12- and 30-months the mean angular rotation:time integral decreased indicating a slight improvement in joint function.

Table 5-16: Mean 3D kinematic data presented by gait cycle event, maximum angles, range of motion and angular rotation:time integral for the RA control group measured barefoot over 30-months (N=98 feet).

DF/PF	**Month**						
Event/variable	**BL**	**3**	**6**	**12**	**18**	**24**	**30**
Heel Strike	-3.9	-4.6	-4.8	-4.9	-4.8	-4.7	-3.5
Foot Flat	-6.7	-7.1	-7.5	-8.4	-8.2	-9.1	-9.7
Mid Stance	-0.7	-0.9	-1.2	-1.7	-2.1	-3.1	-3.4
Heel Lift	4.2	4.3	4.0	3.0	2.5	1.2	2.0
Toe Off	1.7	1.4	0	0.7	0.1	0.1	0.3
Max (-)	-7.2	-8.2	-8.8	-8.7	-8.7	-9.3	-9.8
Max (+)	6.0	5.7	5.9	5.3	4.4	4.0	4.3
ROM	13.3	13.9	14.7	14.0	13.1	13.4	14.1
Integral	-61.0	-117.4	-82.4	-128.0	-151.7	-193.3	-178.4
INV/EVR	**Month**						
Event/variable	**BL**	**3**	**6**	**12**	**18**	**24**	**30**
Heel Strike	-2.9	-3.6	-3.0	-1.8	-2.3	-1.6	-1.5
Foot Flat	-4.0	-4.8	-4.5	-3.0	-3.7	-2.9	-2.1
Mid Stance	-7.8	-8.4	-8.1	-6.4	-6.8	-6.2	-5.9
Heel Lift	-9.4	-10.3	-9.8	-8.0	-8.4	-7.8	-7.8
Toe Off	-3.8	-4.1	-3.8	-2.4	-2.7	-2.4	-2.5
Max (-)	-9.5	-10.3	-9.8	-8.1	-8.5	-8.0	-7.9
Max (+)	-2.8	-2.9	-2.5	-1.4	-1.7	-1.2	-1.0
ROM	6.6	7.4	7.3	6.7	6.8	6.8	6.9
Integral	-546.1	-513.5	-549.8	-409.2	-461.5	-397.1	-393.4
INT/EX ROT	**Month**						
Event/variable	**BL**	**3**	**6**	**12**	**18**	**24**	**30**
Heel Strike	6.7	7.0	6.1	5.3	5.8	5.7	4.7
Foot Flat	8.6	9.0	8.3	7.2	7.8	7.8	6.9
Mid Stance	8.3	8.5	7.9	6.8	7.3	7.3	7.1
Heel Lift	7.5	7.8	7.3	6.3	6.8	6.8	6.3
Toe Off	4.8	5.4	4.9	4.0	4.6	4.7	4.2
Max (-)	4.7	5.4	4.9	3.9	4.6	4.7	4.1
Max (+)	8.7	9.1	8.3	7.3	7.9	7.9	7.6
ROM	4.0	3.7	3.4	3.4	3.3	3.2	3.5
Integral	676.9	711.4	646.7	573.6	614.7	617.5	571.6

Angles are in degrees. DF/PF- dorsi/plantarflexion. INV/EVR- inversion/eversion. INT/EXT ROT- internal/external rotation. BL- baseline. ROM- range of motion.

Table 5-17: Mean 3D kinematic data presented by gait cycle event, maximum angles, range of motion and angular rotation:time integral for the RA control group measured shod over 30-months (N=98 feet).

DF/PF	**Month**						
Event/variable	**BL**	**3**	**6**	**12**	**18**	**24**	**30**
Heel Strike	-11.3	-12.4	-12.6	-11.0	-10.8	-11.6	-9.4
Foot Flat	-14.4	-14.8	-15.5	-15.1	-15.7	-16.6	-16.7
Mid Stance	-6.6	-7.3	-7.4	-7.0	-7.8	-8.9	-9.4
Heel Lift	-1.9	-2.7	-2.7	-2.2	-4.3	-5.1	-5.0
Toe Off	-3.6	-4.2	-4.4	-3.5	-4.9	-4.9	-5.3
Max (-)	-15.0	-15.5	-16.3	-15.6	-16.0	-17.0	-16.7
Max (+)	2.1	1.0	1.5	2.0	0.8	0	0.1
ROM	17.1	16.5	17.8	17.6	16.8	17.0	16.8
Integral	-588.2	-719.9	-637.5	-628.8	-689.8	-727.6	-731.5
INV/EVR	**Month**						
Event/variable	**BL**	**3**	**6**	**12**	**18**	**24**	**30**
Heel Strike	-0.3	-0.5	0.1	0.8	0.7	0.8	1.2
Foot Flat	-1.6	-2.1	-1.5	-0.7	-0.7	-0.4	0.5
Mid Stance	-5.3	-5.8	-5.6	-4.2	-4.5	-3.9	-3.7
Heel Lift	-6.2	-6.7	-6.5	-5.0	-5.2	-4.7	-4.8
Toe Off	0.2	-0.2	0.5	1.3	0.9	1.4	1.6
Max (-)	-6.2	-6.7	-6.5	-5.0	-5.4	-4.9	-5.0
Max (+)	0.5	0.7	0.9	1.5	1.3	1.9	2.1
ROM	6.7	7.4	7.5	6.5	6.7	6.8	7.1
Integral	-252.3	-274.5	-166.9	-168.6	-175.6	-150.6	-116.4
INT/EX ROT	**Month**						
Event/variable	**BL**	**3**	**6**	**12**	**18**	**24**	**30**
Heel Strike	5.4	5.9	4.8	4.4	4.5	3.9	3.7
Foot Flat	8.1	8.6	7.8	7.1	7.5	7.1	6.4
Mid Stance	6.8	7.8	7.1	5.6	6.5	6.2	6.5
Heel Lift	6.2	7.2	6.3	4.9	5.8	5.6	5.6
Toe Off	4.0	4.9	4.4	2.8	3.3	3.2	3.2
Max (-)	4.0	4.3	3.9	2.8	3.3	3.2	3.2
Max (+)	8.4	9.0	8.1	7.3	7.8	7.3	7.3
ROM	4.4	4.7	4.2	4.5	4.5	4.1	4.1
Integral	584.2	633.4	580.3	476.2	524.0	495.9	493.0

Angles are in degrees. DF/PF- dorsi/plantarflexion. INV/EVR- inversion/eversion. INT/EXT ROT- internal/external rotation. BL- baseline. ROM- range of motion.

5.3.3 Rheumatoid arthritis intervention group

For the RA intervention group the angular rotation:time curves were qualitatively similar for barefoot, shod and orthosis conditions over the duration of the study. Dorsi/plantarflexion under barefoot conditions demonstrated a consistent ROM over time with some slight variability in the mean angles at each gait event and for the maximum positive and negative angular rotations (table 5-18). The angular rotation:time integral was similar to the barefoot reference value from the normal population. When compared against the RA control group the integrals were consistent between baseline and 12-months from where they diverged, the intervention group showing a trend towards a positive increase in the integral. The joint maintains a normal balance of dorsi/plantarflexion motion whilst the RA control group shows a move towards motion occurring around a more plantarflexed ROM.

The inversion/eversion motion under barefoot conditions remained abnormally everted, within a consistent ROM, in comparison with normal parameters, across the duration of the study. The mean angular rotation:time integrals were comparable to the RA control group until 12-months, both groups showing a decrease in the mean value of the integral. After 12-months the mean angular rotation:time integral decreased more sharply in the intervention group in comparison with control. This was associated with a positive shift on the ordinate over time in the mean angles by gait event and the mean maximum positive and negative angles. By 30-months the mean heel-strike angle had changed by 3.2° from everted to almost a neutral position (0.1°). The same trends were noted for internal/external rotation under barefoot conditions with a sharp reduction in the mean angular rotation:time integral from 18 to 24-months in the RA intervention group over control. The ROM was consistent across the duration of this study although, and despite of the improvements observed late in the study, joint rotations occurred about internally rotated positions in comparison with normal parameters.

The RA intervention group also demonstrated kinematic changes with footwear although the response was different for some axes of rotation in comparison with the RA control group (Table 5-19). For dorsi/plantarflexion the ROM was consistent over time and the mean angular rotation:time integral was similar to normal shod parameters. The baseline and 30-month mean angular rotation:time integrals show no overall change over time, although the mean angles by gait cycle event suggest a negative shift towards a more plantarflexed ROM. The footwear had a significant impact over time on the inversion/eversion motion pattern in this group. The ROM remained consistent over time but a steady rate of change over time was noted for the mean angles by gait event, the maximum positive and negative angles and the mean angular rotation:time integral. At baseline the integral showed dominance towards eversion motion with a

heel strike position of nearly neutral (0.1°). Steadily decreasing over time the integral by 30-months showed a dominance of inversion motion with a mean inverted heel-strike position of 2.6°. The improvement over time was greater in comparison with RA control group but still abnormal in comparison with both the barefoot and shod values for the normal population.

The internal/external rotation ROM was increased over barefoot conditions and showed a negative shift over time indicating an overall improvement (table 5-19). The rate of improvement was greater than in the RA control group occurring between 12 and 30-months, although in comparison with normal parameters the joint still functioned around an abnormally internally rotated ROM.

The use of functional orthoses increased the ROM for dorsi/plantarflexion over barefoot and shod conditions and this relationship was maintained for the duration of the study (table 5-20). Comparison of the angular rotation:time integral data suggests that the orthosis has no additional impact over the shod condition for dorsi/plantarflexion motion, other than to increase the amount of dorsiflexion motion. This contrasted sharply with inversion/eversion motion, which improved further under orthotic intervention. After an initial decrease in the mean angular rotation:time integral between baseline and 3- and 6-months, showing dominant eversion motion, the integral increased, becoming positive at 12-months through to 30-months. By 18-months the mean angular rotation:time integral was consistent with that for the normal population under barefoot conditions but did not reach the normal shod mean value. This positive shift in the integral was accompanied by a shift in the mean gait event angles and the maximum positive and negative angles. The change in the internal/external rotation motion patterns over time were closely related to the changes under shod conditions and no additional benefit with orthosis use was observed. Even with orthosis use over the duration of the study the AJC functioned around an abnormally internally rotated ROM, although this was seen to decrease of the latter stages of the study.

Table 5-18: Mean 3D kinematic data presented by gait cycle event, maximum angles, range of motion and angular rotation:time integral for the RA intervention group measured barefoot over 30-months (N=100).

DF/PF	**Month**						
Event/variable	**BL**	**3**	**6**	**12**	**18**	**24**	**30**
Heel Strike	-2.2	-3.5	-3.6	-4.6	-3.5	-3.1	-1.7
Foot Flat	-5.1	-6.7	-6.4	-7.9	-7.9	-7.7	-7.8
Mid Stance	0.6	-0.3	-0.3	-1.6	-1.9	-1.7	-1.5
Heel Lift	5.6	4.6	4.5	4.0	3.2	3.2	4.0
Toe Off	6.1	3.8	3.5	1.8	1.8	2.1	3.1
Max (-)	-6.5	-7.0	-7.7	-8.2	-8.0	-7.9	-7.8
Max (+)	7.8	6.8	7.1	5.5	5.5	5.5	6.3
ROM	14.3	13.8	14.8	13.7	13.5	13.4	14.1
Integral	69.5	-16.6	-22.4	-91.2	-59.3	-34.6	27.2
INV/EVR	**Month**						
Event/variable	**BL**	**3**	**6**	**12**	**18**	**24**	**30**
Heel Strike	-3.2	-3.2	-2.5	-1.8	-1.0	-1.1	0.1
Foot Flat	-4.7	-4.5	-4.4	-3.1	-2.1	-2.4	-0.9
Mid Stance	-7.9	-8.4	-8.0	-6.7	-5.1	-5.5	-4.7
Heel Lift	-9.7	-10.1	-9.6	-8.2	-6.4	-7.1	-6.4
Toe Off	-5.7	-4.7	-3.7	-2.4	-1.5	-2.1	-1.3
Max (-)	-9.8	-10.2	-9.7	-8.2	-6.5	-7.1	-6.4
Max (+)	-2.5	-2.5	-2.3	-1.5	-0.8	-0.8	0.8
ROM	7.3	7.7	7.4	6.7	5.7	6.3	7.2
Integral	-563.4	-584.2	-540.3	-424.3	-311.4	-337.8	-217.0
INT/EX ROT	**Month**						
Event/variable	**BL**	**3**	**6**	**12**	**18**	**24**	**30**
Heel Strike	6.0	6.5	5.8	5.7	4.3	4.6	3.6
Foot Flat	7.8	8.3	7.7	7.8	6.2	6.9	5.6
Mid Stance	7.3	8.0	7.4	7.0	5.8	6.5	5.9
Heel Lift	6.6	7.3	6.9	5.8	4.8	5.5	4.7
Toe Off	4.0	4.7	4.0	3.4	2.3	2.9	2.4
Max (-)	3.5	4.5	3.9	3.4	2.3	2.9	2.2
Max (+)	7.8	8.5	7.9	7.9	6.5	7.1	6.3
ROM	4.3	4.0	4.0	4.5	4.2	4.2	4.1
Integral	610.1	685.2	632.1	585.3	461.7	525.8	436.7

Angles are in degrees. DF/PF- dorsi/plantarflexion. INV/EVR- inversion/eversion. INT/EXT ROT- internal/external rotation. BL- baseline. ROM- range of motion.

Table 5-19: Mean 3D kinematic data presented by gait cycle event, maximum angles, range of motion and angular rotation:time integral for the RA intervention group measured shod over 30-months (N=100).

DF/PF	Month						
Event/variable	**BL**	**3**	**6**	**12**	**18**	**24**	**30**
Heel Strike	-10.0	-10.6	-10.9	-10.6	-9.8	-9.6	-7.1
Foot Flat	-12.5	-13.3	-14.2	-14.5	-14.8	-14.7	-14.7
Mid Stance	-5.1	-5.2	-5.8	-6.8	-7.3	-7.8	-8.0
Heel Lift	-1.4	-1.4	-1.8	-1.8	-2.3	-4.2	-2.6
Toe Off	-1.8	-2.0	-2.9	-4.2	-3.9	-3.2	-2.5
Max (-)	-13.6	-14.0	-14.7	-15.2	-15.2	-15.1	-14.7
Max (+)	3.8	4.0	3.3	1.9	2.0	1.5	1.9
ROM	17.4	18.0	18.0	17.1	17.2	16.6	16.6
Integral	-560.7	-542.4	-610.6	-586.7	-597.9	-618.7	-560.6
INV/EVR	**Month**						
Event/variable	**BL**	**3**	**6**	**12**	**18**	**24**	**30**
Heel Strike	-0.1	0.3	0.4	1.2	1.4	1.9	2.6
Foot Flat	-2.1	-1.5	-1.1	-0.5	0.1	0.3	1.2
Mid Stance	-5.6	-5.3	-5.0	-4.0	-3.0	-2.9	-2.2
Heel Lift	-6.3	-6.2	-5.7	-4.6	-3.7	-3.7	-3.2
Toe Off	0.2	0.2	1.0	1.9	2.1	2.5	2.7
Max (-)	-6.3	-6.4	-5.8	-4.6	-3.7	-3.8	-3.3
Max (+)	0.4	0.3	1.1	1.9	2.2	3.0	3.4
ROM	6.7	6.7	6.9	6.5	5.9	6.8	6.7
Integral	-264.1	-241.3	-186.1	-106.2	-47.4	-28.7	27.1
INT/EX ROT	**Month**						
Event/variable	**BL**	**3**	**6**	**12**	**18**	**24**	**30**
Heel Strike	4.7	5.4	4.8	4.2	2.9	3.1	2.5
Foot Flat	7.5	7.8	7.5	6.9	5.8	6.2	5.3
Mid Stance	6.1	6.6	6.0	5.6	4.5	5.2	4.7
Heel Lift	5.5	6.0	5.2	4.5	3.4	4.2	3.4
Toe Off	2.8	3.4	2.2	2.3	1.2	1.4	1.4
Max (-)	2.6	3.4	2.0	2.1	1.0	1.3	1.3
Max (+)	7.6	8.0	7.7	7.1	6.0	6.5	5.7
ROM	5.0	4.6	5.7	5.0	5.0	5.2	4.4
Integral	507.6	563.1	497.6	449.9	331.5	372.3	333.9

Angles are in degrees. DF/PF- dorsi/plantarflexion. INV/EVR- inversion/eversion. INT/EXT ROT- internal/external rotation. BL- baseline. ROM- range of motion.

Table 5-20: Mean 3D kinematic data presented by gait cycle event, maximum angles, range of motion and angular rotation:time integral for the RA intervention group measured with orthosis over 30-months (N=100).

DF/PF	**Month**						
Event/variable	**BL**	**3**	**6**	**12**	**18**	**24**	**30**
Heel Strike	-11.5	-11.7	-12.3	-12.1	-10.5	-10.1	-8.0
Foot Flat	-15.0	-15.5	-16.2	-16.3	-15.7	-16.1	-15.7
Mid Stance	-5.9	-6.8	-7.0	-7.9	-7.8	-8.7	-8.5
Heel Lift	-1.8	-2.3	-2.4	-3.1	-2.9	-4.0	-3.7
Toe Off	-2.7	-2.2	-3.6	-3.3	-3.3	-2.6	-0.7
Max (-)	-15.4	-15.6	-16.3	-16.9	-16.2	-16.6	-15.8
Max (+)	5.1	4.7	4.6	3.8	3.6	2.6	3.6
ROM	20.5	20.3	20.9	20.7	19.8	19.2	19.4
Integral	-544.6	-579.3	-649.2	-637.5	-594.7	-657.7	-579.5
INV/EVR	**Month**						
Event/variable	**BL**	**3**	**6**	**12**	**18**	**24**	**30**
Heel Strike	2.5	2.8	2.9	3.6	3.6	4.0	4.2
Foot Flat	1.1	1.6	2.0	2.2	2.5	2.8	2.9
Mid Stance	-3.5	-3.4	-2.9	-1.8	-0.8	-0.8	-0.8
Heel Lift	-4.1	-4.3	-3.8	-2.6	-1.6	-1.6	-1.8
Toe Off	2.8	2.3	3.1	4.1	4.1	4.3	3.6
Max (-)	-4.2	-4.5	-4.0	-2.7	-1.6	-1.7	-2.1
Max (+)	2.8	3.2	4.0	4.3	4.2	4.8	4.7
ROM	7.0	7.7	8.0	7.0	5.8	6.5	6.8
Integral	-26.1	-162.7	-80.9	34.5	75.4	101.2	127.8
INT/EX ROT	**Month**						
Event/variable	**BL**	**3**	**6**	**12**	**18**	**24**	**30**
Heel Strike	5.2	5.9	5.5	4.7	3.4	3.6	2.3
Foot Flat	8.1	8.2	8.0	7.8	6.5	6.9	5.5
Mid Stance	6.5	7.6	6.8	6.0	5.2	5.6	4.8
Heel Lift	5.7	6.7	6.0	4.7	3.9	4.3	3.7
Toe Off	3.1	4.0	3.3	2.3	1.1	1.5	0.9
Max (-)	3.0	4.0	3.3	2.2	1.1	1.5	0.8
Max (+)	8.4	8.8	8.5	7.9	6.7	7.1	5.8
ROM	5.4	4.8	5.2	5.7	5.6	5.6	5.0
Integral	529.8	601.5	570.0	483.1	380.4	412.9	311.0

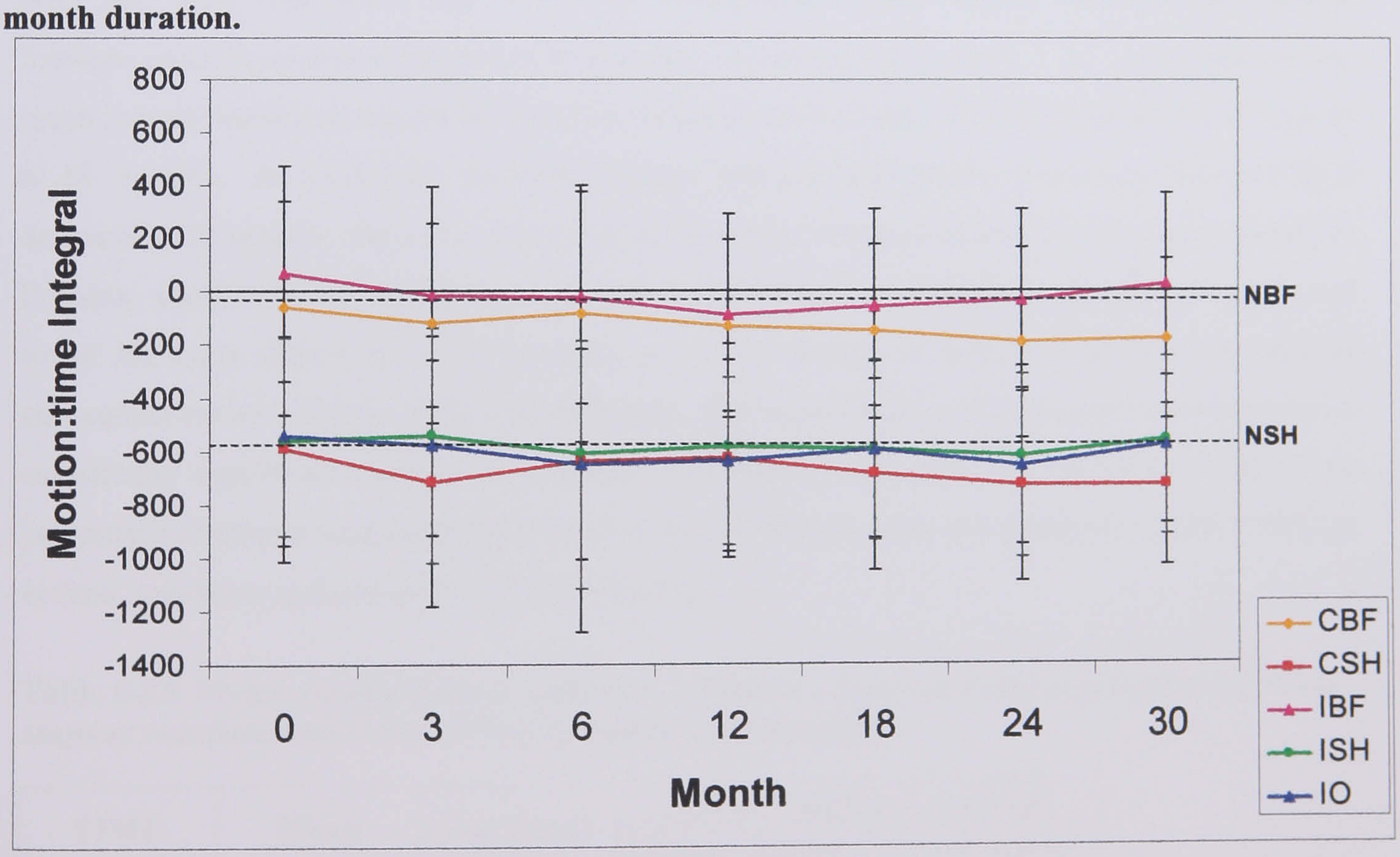
Angles are in degrees. DF/PF- dorsi/plantarflexion. INV/EVR- inversion/eversion. INT/EXT ROT- internal/external rotation. BL- baseline. ROM- range of motion.

5.3.4 longitudinal analysis of angular rotation:time integrals

5.3.4.1 Dorsi/plantarflexion

The longitudinal data for the study groups are presented in figure 5-10. Integrals for both groups under barefoot, shod and orthosis conditions were similar to reference values in the normal population. Shod and orthosis conditions demonstrated large negative integrals in comparison with barefoot conditions, the relationship maintained for the duration of the study. The ANOVA model found a statistically significant condition ($F=120.0$, $P<0.0001$) but no significant group effect ($F=0.035$, $P=0.853$). The mean, standard error and 95% confidence interval of the dorsi/plantarflexion angular rotation:time integral between conditions over the duration of the study are presented in table 5-21. Post-hoc analysis using Tukey's test was used for pairwise comparisons and found large and statistically significant differences between barefoot and shod and barefoot and orthosis conditions but not between shod and orthosis conditions, the effect sustainable from the initial analysis of baseline data (table-5-22). There was no statistically significant interaction between group and condition effects ($F=0.094$, $P=0.760$).

Figure-5-10: Dorsi/plantarflexion angular rotation:time integral by study group over a 30-month duration.



Data represents mean with error bars donating one standard deviation about the mean. CBF- RA control barefoot, CSH- RA control shod, IBF- RA intervention barefoot, ISH- RA intervention shod, IO- RA intervention orthosis, NBF- barefoot reference value from normal population, NSH- shod reference value for normal population.

Table 5-21: Mean, standard error and 95% confidence interval of the dorsi/plantarflexion angular rotation:time integral for barefoot, shod and orthosis walking conditions.

Condition	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
Barefoot	-78.726	27.075	-132.061	-25.392
Shod	-625.958	27.075	-679.292	-572.624
Orthosis	-606.089	37.897	-680.741	-531.436

Table 5-22: Post-hoc analysis with Tukey's test between conditions for dorsi/plantarflexion angular rotation:time integrals.

Condition (a)	Condition (b)	Mean Difference (a-b)	Std. Error	P-Value	95% Confidence Interval for Difference	
					Lower Bound	Upper Bound
Barefoot	Shod	547.231	38.290	<0.0001	471.805	622.658
	Orthosis	527.362	46.576	<0.0001	435.615	619.109
Shod	Barefoot	-547.231	38.290	<0.0001	-622.658	-471.805
	Orthosis	-19.869	46.576	0.670	-111.616	71.878
Orthosis	Barefoot	-527.362	46.576	<0.0001	-619.109	-435.615
	Shod	19.869	46.576	0.670	-71.878	111.616

ANOVA revealed a statistically significant time effect (F=3.158, P=0.005). The mean, standard error and 95% confidence interval of the dorsi/plantarflexion angular rotation:time integral between conditions over the duration of the study are presented in table 5-23. From baseline the mean integral increased negatively between baseline and 6-months and maintained this change up to 18- months. At 24-months the mean integral had a further negative increase followed by a decrease at 30-months, the value at the end of the study increased negatively relative to baseline. Post-hoc analysis using Tukey's test (see table 5-24) was used for pairwise comparisons and found the main difference to lie between an initial change (negative) from baseline and all subsequent review months. Only one other pair, that between 24- and 30-months demonstrated a statistically significant change (an increase) over time. There were no statistically significant interactions between time and condition (F=0.424, P=0.954), time and group (F=1.698, P=0.122) or time, condition and group (F=0.310, P=0.931).

Table 5-23: Mean, standard error and 95% confidence interval of the dorsi/plantarflexion angular rotation:time integral from baseline to 30-months.

TIME	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
0-mths	-329.5	25.5	-379.7	-279.2
3-mths	-395.1	26.4	-447.1	-343.0
6-mths	-412.9	30.8	-473.7	-352.1
12-mths	-414.4	22.8	-459.5	-369.3
18-mths	-418.7	22.0	-462.1	-375.2
24-mths	-446.3	22.3	-490.3	-402.4
30-mths	-404.5	20.3	-444.7	-364.3

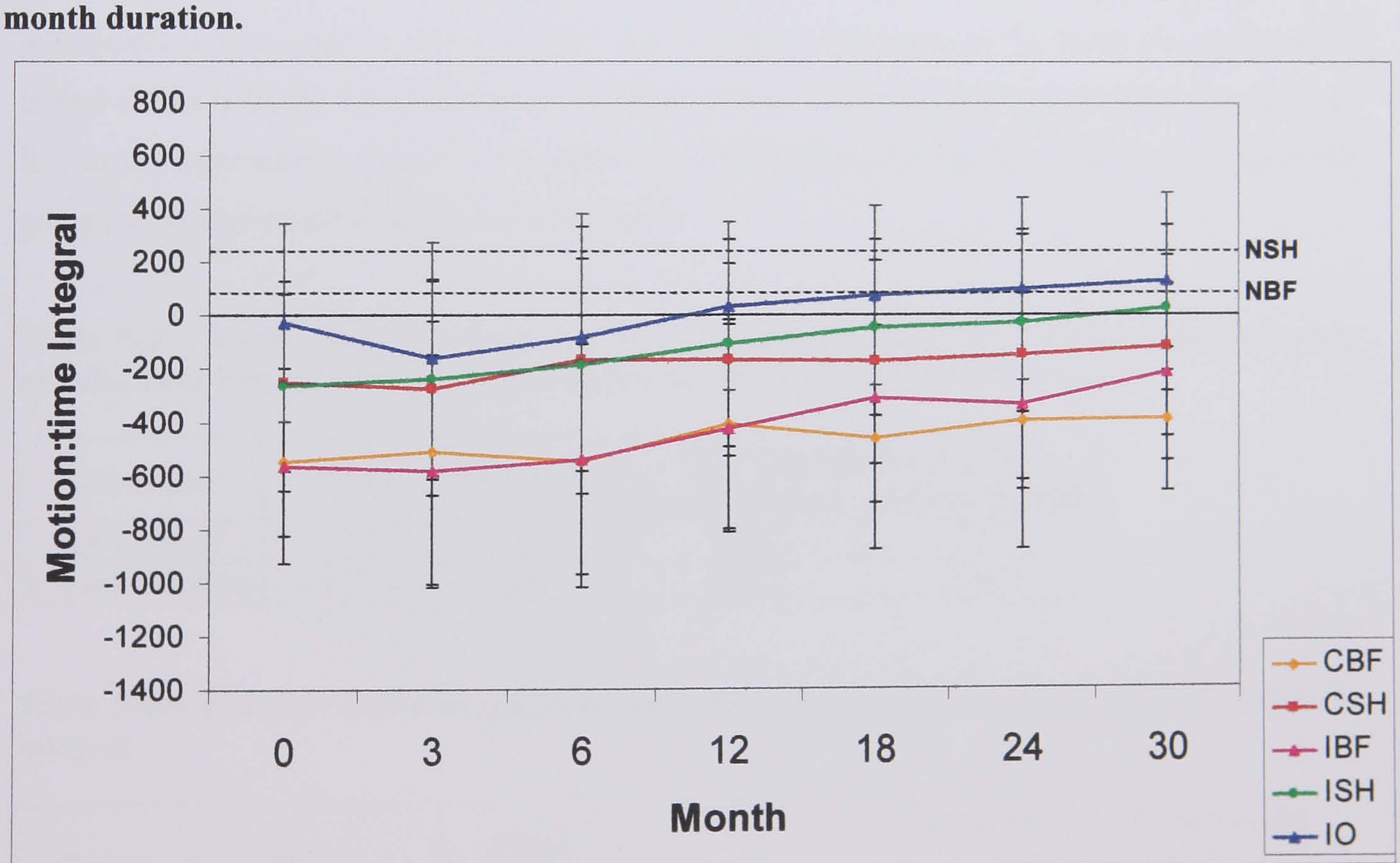
Table 5-24: Post-hoc analysis with Tukey's test between time intervals for dorsi/plantarflexion angular rotation:time integrals.

TIME (a) (mth)	TIME (b) (mth)	Mean Difference (a-b)	Std. Error	P-Value	95% Confidence Interval for Difference	
					Lower Bound	Upper Bound
0	3	65.6	29.0	0.025	8.4	122.7
	6	83.4	31.7	0.009	20.9	145.8
	12	84.9	26.7	0.002	32.1	137.7
	18	89.2	28.1	0.002	33.7	144.6
	24	116.9	28.1	<0.0001	61.4	172.2
	30	75.0	27.2	0.006	21.3	128.7
3	0	-65.6	29.0	0.025	-122.7	-8.4
	6	17.8	34.6	0.607	-50.3	85.9
	12	19.3	28.2	0.494	-36.2	74.9
	18	23.5	26.9	0.382	-29.4	76.6
	24	51.2	30.3	0.092	-8.4	110.9
	30	9.4	28.8	0.743	-47.2	66.2
6	0	-83.4	31.7	0.009	-145.8	-20.9
	3	-17.8	34.6	0.607	-85.9	50.3
	12	1.5	29.6	0.959	-56.8	59.
	18	5.7	29.7	0.846	-52.8	64.3
	24	33.4	28.5	0.243	-22.8	89.6
	30	-8.3	30.6	0.786	-68.8	52.0
12	0	-84.9	26.7	0.002	-137.7	-32.1
	3	-19.3	28.2	0.494	-74.9	36.2
	6	-1.5	29.6	0.959	-59.8	56.8
	18	4.2	20.3	0.835	-35.8	44.4
	24	31.9	22.2	0.152	-11.8	75.6
	30	-9.8	23.6	0.676	-56.3	36.6
18	0	-89.1	28.1	0.002	-144.6	-33.7
	3	-23.5	26.9	0.382	-76.6	29.4
	6	-5.7	29.7	0.846	-64.3	52.8
	12	-4.2	20.3	0.835	-44.4	35.8
	24	27.6	15.6	0.078	-3.1	58.4
	30	-14.1	18.2	0.440	-50.1	21.8
24	0	-116.8	28.1	<0.0001	-172.2	-61.4
	3	-51.2	30.3	0.092	-110.9	8.4
	6	-33.4	28.5	0.243	-89.6	22.8
	12	-31.9	22.2	0.152	-75.6	11.8
	18	-27.6	15.6	0.078	-58.4	3.1
	30	-41.7	18.4	0.025	-78.1	-5.4
30	0	-75.0	27.2	0.006	-128.7	-21.3
	3	-9.4	28.8	0.743	-66.2	47.2
	6	8.3	30.6	0.786	-52.0	68.8
	12	9.8	23.6	0.676	-36.6	56.3
	18	14.1	18.2	0.440	-21.8	50.1
	24	41.7	18.4	0.025	5.4	78.1

5.3.4.2 Inversion/eversion

The longitudinal data for the study groups are presented in figure 5-11. The mean angular rotation:time integrals for the barefoot and shod conditions in both RA groups were negative for the duration of the study, the values decreasing over time at different rates in each group but always less than the normal barefoot reference value for the normal population (figure 5-11). In the intervention orthotic group the mean integral is negative for the first 6-months and becomes positive after that period. At 12-months the values are similar to those in the normal population under barefoot but not shod walking conditions. The ANOVA model found statistically significant condition ($F=52.66$, $P<0.0001$) and group ($F=16.83$, $P<0.0001$) effects. For each condition the mean, standard error and 95% confidence interval of the inversion/eversion angular rotation:time integral over the duration of the study are presented in table 5-25. The barefoot condition was dominated by eversion motion with a large mean negative integral, which decreased significantly under post-hoc analysis when measured under shod conditions (table 5-26). The orthotic effect changed the mean integral to a small positive value with a statistically significant effect over the shod condition.

Figure-5-11: Inversion/eversion angular rotation:time integral by study group over a 30-month duration.



Data represents mean with error bars donating one standard deviation about the mean. CBF- RA control barefoot, CSH- RA control shod, IBF- RA intervention barefoot, ISH- RA intervention shod, IO- RA intervention orthosis, NBF- barefoot reference value from normal population, NSH- shod reference value for normal population.

Table 5-25: Mean, standard error and 95% confidence interval of the inversion/eversion angular rotation:time integral between conditions from baseline to 30-months.

Condition	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
Barefoot	-446.354	27.881	-501.277	-391.432
Shod	-153.686	27.881	-208.608	-98.763
Orthosis	9.857	39.026	-67.018	86.732

Table 5-26: Post-hoc analysis with Tukey's test between conditions for inversion/eversion angular rotation:time integrals.

Condition (a)	Condition (b)	Mean Difference (a-b)	Std. Error	P-Value	95% Confidence Interval for Difference	
					Lower Bound	Upper Bound
Barefoot	Shod	-292.6	39.4	<0.0001	-370.3	-214.9
	Orthosis	-456.2	47.9	<0.0001	-550.6	-361.7
Shod	Barefoot	292.6	39.4	<0.0001	214.9	370.3
	Orthosis	-163.5	47.9	0.001	-258.0	-69.0
Orthosis	Barefoot	456.2	47.9	<0.0001	361.7	550.6
	Shod	163.5	47.9	0.001	69.0	258.0

For the group effect the mean, standard error of the mean and 95% confidence interval of the inversion/eversion angular rotation:time integral over the duration of the study are presented in table 5-27. In both the RA study groups the mean integral was negative but an order of magnitude less in the intervention group over control. Post-hoc analysis found the difference between the groups to be statistically significant (table 5-28).

Table 5-27: Mean, standard error and 95% confidence interval of the inversion/eversion angular rotation:time integral between groups from baseline to 30-months.

Condition	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
RA Control	-326.8	28.1	-382.3	-271.3
RA Intervention	-178.8	22.5	-223.2	-134.4

Table 5-28: Post-hoc between group analyses for inversion/eversion angular rotation:time integral.

Group (a)	Group (b)	Mean Difference (a-b)	Std. Error	P-Value	95% Confidence Interval for Difference	
					Lower Bound	Upper Bound
RA Control	RA Intervention	-147.9	36.0	<0.0001	-219.0	-76.9

For the repeated measures the ANOVA model found a statistically significant time effect (F=12.77, P<0.0001). For the time effect the mean, standard error and 95% confidence interval of the inversion/eversion angular rotation:time integral over the duration of the study are presented in table 5-29. Over the duration of the study the ankle joint complex showed a dominance of eversion motion with a mean negative integral at all time periods. From baseline to 3-months the mean value showed a further negative increase in the integral. From 6-months onwards the opposite trend was observed with the integral showing a steady decrease negatively, with the final value at 30-months significantly reduced in comparison with baseline values. Post-hoc testing found no statistically significant differences in pairwise comparisons between baseline, 3- and 6-months (table 5-30). This lack of effect can be seen in figure 5-11 for both groups under all conditions were relative small changes between time intervals are observed. When data are compared from these first three time intervals with the time points from 12-months onwards statistically significant differences are found. Between 12- and 18 and 18- and 24-months no statistically significant time effects are noted and again the changes within these time periods are small for all groups and conditions as noted in figure 5-11. Comparisons between 12-, 18- and 24-month against the final data point at 30-months revealed statistically significant differences in all cases. As the mean integral values continue to change over time larger differences between time intervals of 18- and 12- months duration would be expected and the final statistically significant difference between 24- and 30-months indicates a final time effect. From Figure-11 a sharp positive shift in the mean values can be seen for the intervention group under both shod and barefoot conditions in comparison with the control group.

There was a statistically significant time by group interaction (F=2.380, P=0.030) but no significant time by condition (F=1.119) or time by condition by group interaction (F=0.645, P=0.694). The time by group interaction showed a sharp decrease in the overall angular rotation:time integral from 12- to 30-months for the intervention group against no overall change in mean integral between 24- 30-months for the control group.

Table 5-29: Mean, standard error and 95% confidence interval of the inversion/eversion angular rotation:time integral from baseline to 30-months.

TIME	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
0-mths	-330.3	23.5	-376.8	-283.9
3-mths	-355.2	28.8	-412.1	-298.3
6-mths	-304.8	28.6	-361.2	-248.3
12-mths	-214.7	24.5	-263.1	-166.3
18-mths	-184.1	24.3	-232.0	-136.1
24-mths	-162.6	25.2	-212.3	-112.8
30-mths	-114.3	20.6	-155.0	-73.6

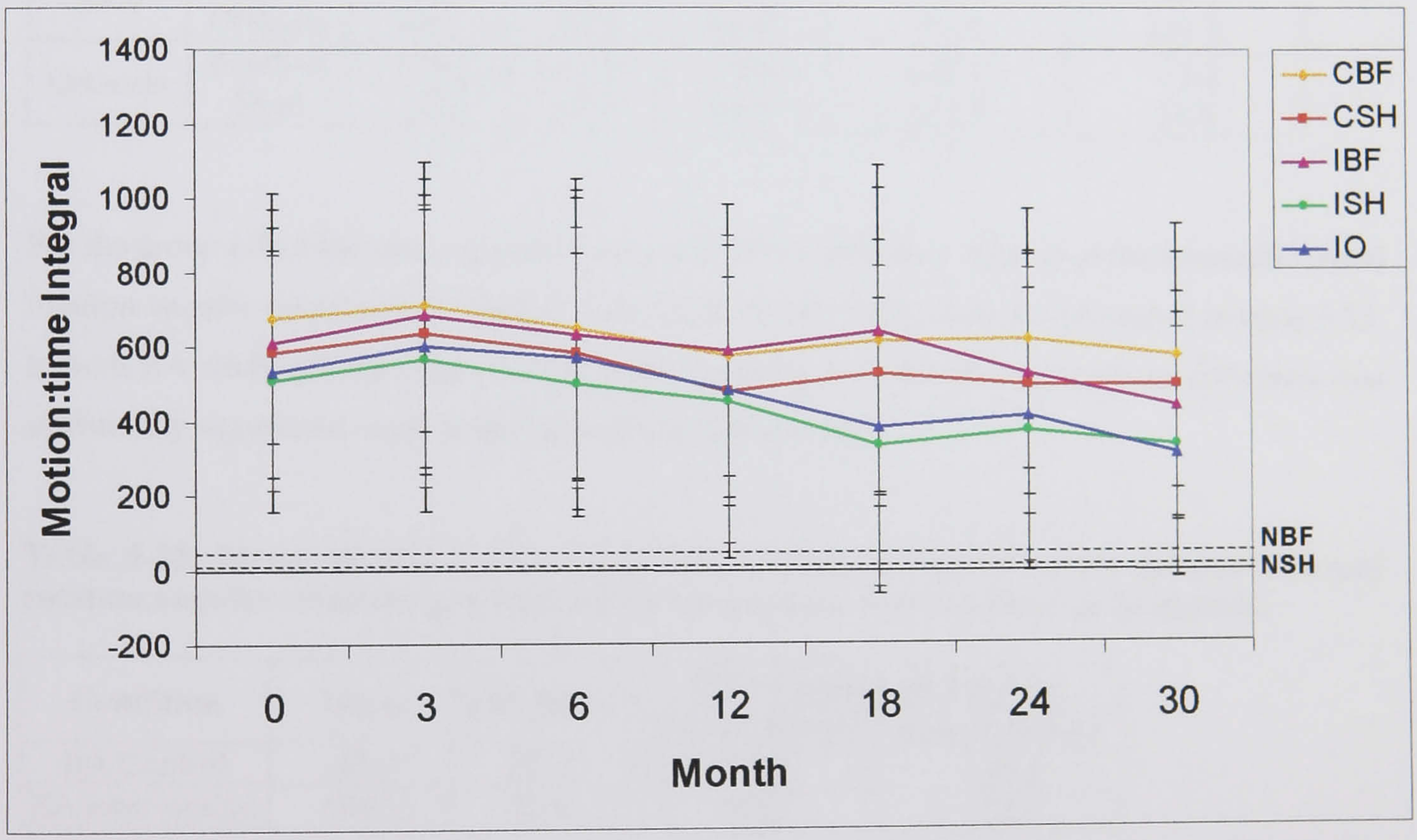
Table 5-30: Post-hoc analysis with Tukey's test between time intervals for inversion/eversion angular rotation:time integrals.

TIME (a) (mth)	TIME (b) (mth)	Mean Difference (a-b)	Std. Error	P-Value	95% Confidence Interval for Difference	
					Lower Bound	Upper Bound
0	3	24.8	22.7	0.276	-19.9	69.6
	6	-25.5	25.1	0.310	-75.1	23.9
	12	-115.6	26.2	<0.0001	-167.3	-63.8
	18	-146.2	27.7	<0.0001	-200.9	-91.6
	24	-167.7	27.6	<0.0001	-222.2	-113.3
	30	-216.0	26.6	<0.0001	-268.6	-163.4
3	0	-24.8	22.7	0.276	-69.6	19.9
	6	-50.4	32.4	0.121	-114.3	13.4
	12	-140.4	31.2	<0.0001	-202.0	-78.8
	18	-171.1	33.4	<0.0001	-236.9	-105.2
	24	-192.6	34.8	<0.0001	-261.3	-123.9
	30	-240.8	31.5	<0.0001	-302.9	-178.7
6	0	25.5	25.1	0.310	-23.9	75.1
	3	50.4	32.4	0.121	-13.4	114.3
	12	-90.0	23.9	<0.0001	-137.2	-42.7
	18	-120.7	27.3	<0.0001	-174.5	-66.8
	24	-142.1	30.3	<0.0001	-202.0	-82.3
	30	-190.4	32.2	<0.0001	-253.9	-126.8
12	0	115.6	26.2	<0.0001	63.8	167.3
	3	140.4	31.2	<0.0001	78.8	202.0
	6	90.0	23.9	<0.0001	42.7	137.2
	18	-30.6	20.6	0.139	-71.3	10.0
	24	-52.1	22.9	0.024	-97.4	-6.8
	30	-100.3	28.0	<0.0001	-155.5	-45.1
18	0	146.2	27.7	<0.0001	91.6	200.9
	3	171.1	33.4	<0.0001	105.2	236.9
	6	120.7	27.3	<0.0001	66.8	174.5
	12	30.6	20.6	0.139	-10.0	71.3
	24	-21.4	18.5	0.248	-58.0	15.0
	30	-69.7	26.8	0.010	-122.5	-16.8
24	0	167.7	27.6	<0.0001	113.3	222.2
	3	192.6	34.8	<0.0001	123.9	261.3
	6	142.1	30.3	<0.0001	82.3	202.0
	12	52.1	22.9	0.024	6.8	97.4
	18	21.4	18.5	0.248	-15.0	58.0
	30	-48.2	24.2	0.048	-95.9	-0.4
30	0	216.0	26.6	<0.0001	163.4	268.6
	3	240.8	31.5	<0.0001	178.7	302.9
	6	190.4	32.2	<0.0001	126.8	253.9
	12	100.3	28.0	<0.0001	45.1	155.5
	18	69.7	26.8	0.010	16.8	122.5
	24	48.2	24.2	0.048	0.4	95.9

5.3.4.3 Internal/external rotation

The longitudinal data for internal/external rotation are summarised in figure 5-12. Integrals for both groups under barefoot, shod and orthosis conditions were markedly greater than reference values for the normal population, differences maintained for the duration of the study. The ANOVA model found statistically significant condition (F=5.288, P=0.006) and group (F=7.342, P=0.007) effects but no condition by group interaction (F=0.222, P=0.638). The mean, standard error, and 95% confidence interval of the internal/external rotation integral between conditions over the duration of the study are presented in table 5-31. Post-hoc analysis using Tukey's test revealed statistically significant differences between barefoot and shod and barefoot and orthosis conditions but not between shod and orthosis conditions (table 5-32).

Figure-5-12: Internal/external rotation angular rotation:time integral by study group over a 30-month duration.



Data represents mean with error bars donating one standard deviation about the mean. CBF- RA control barefoot, CSH- RA control shod, IBF- RA intervention barefoot, ISH- RA intervention shod, IO- RA intervention orthosis, NBF- barefoot reference value from normal population, NSH- shod reference value for normal population.

Table 5-31: Mean, standard error and 95% confidence interval of the internal/external rotation angular rotation:time integral between conditions from baseline to 30-months.

Condition	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
Barefoot	596.4	27.4	542.2	650.5
Shod	488.7	27.3	434.9	542.5
Orthosis	469.8	38.2	394.4	545.1

Table 5-32: Post-hoc analysis with Tukey's test between conditions for internal/external rotation angular rotation:time integrals.

Condition (a)	Condition (b)	Mean Difference (a-b)	Std. Error	P-Value	95% Confidence Interval for Difference	
					Lower Bound	Upper Bound
Barefoot	Shod	107.6	38.7	0.006	31.3	183.9
	Orthosis	126.5	47.0	0.008	33.8	219.3
Shod	Barefoot	-107.6	38.7	0.006	-183.9	-31.3
	Orthosis	18.9	47.0	0.687	-73.6	111.5
Orthosis	Barefoot	-126.5	47.0	0.008	-219.3	-33.8
	Shod	-18.9	47.0	0.687	-111.5	73.6

For the group effect the mean, standard error and 95% confidence interval of the internal/external rotation angular rotation:time integral over the duration of the study are presented in table 5-33. In both RA study groups large positive mean integrals were found but the mean difference was statistically significant under post-hoc analysis (table 5-34).

Table 5-33: Mean, standard error and 95% confidence interval of the internal/external rotation angular rotation:time integral between groups from baseline to 30-months.

Condition	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
RA Control	585.6	27.7	531.0	640.3
RA Intervention	489.6	22.0	446.1	533.0

Table 5-34: Post-hoc between groups comparison for internal/external rotation angular rotation:time integrals.

Group (a)	Group (b)	Mean Difference (a-b)	Std. Error	P-Value	95% Confidence Interval for Difference	
					Lower Bound	Upper Bound
RA Control	RA Intervention	96.0	35.4	0.007	26.2	165.9

For the repeat measures the ANOVA model found a statistically significant time effect ($F=10.24$, $P<0.0001$). The mean, standard error and 95% confidence intervals of the internal/external rotation angular rotation:time integrals over the duration of the study are presented in table 5-34. The ankle joint complex functioned around an internally rotated ROM for all groups under all conditions such that for all time periods large mean positive integrals were observed. Post-hoc analysis allowed pairwise comparisons between months and found statistically significant differences between baseline and 3-months but not between baseline and 6-months (table 5-36). Between these time periods both groups under all conditions showed an initial increase from baseline at 3-months followed by a decrease to baseline again at 6-months. From figure 5-12 the mean data for all groups respond differently from 12-months to the end of the study tending towards a greater decrease in mean value for all conditions in the intervention group in comparison with RA control group. Subsequently statistically significant differences were found between pairwise combinations of baseline, 3- and 6-month means and all subsequent time points up to 30-months. Furthermore statistically significant differences were found between 12- and 18-months, and 12- and 30-months but not between 12- and 24-months. There was no statistically significant difference between 18- and 24-months and 18- and 30-months, but a significant difference was found between 24- and 30-months.

Table 5-35: Mean, standard error and 95% confidence interval of the internal/external rotation angular rotation:time integral from baseline to 30-months.

TIME	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
0-mths	581.7	21.7	538.8	624.6
3-mths	638.9	24.5	590.4	687.3
6-mths	585.3	24.5	536.9	633.8
12-mths	513.6	24.1	466.0	561.1
18-mths	462.4	26.3	410.5	514.3
24-mths	484.8	23.2	439.1	530.6
30-mths	429.2	22.0	385.8	472.7

Table 5-36: Post-hoc analysis with Tukey's test between time intervals for internal/external rotation angular rotation:time integrals.

TIME (a) (mth)	TIME (b) (mth)	Mean Difference (a-b)	Std. Error	P-Value	95% Confidence Interval for Difference	
					Lower Bound	Upper Bound
0	3	-57.1	18.7	0.003	-94.1	-20.2
	6	-3.6	20.7	0.861	-44.4	37.1
	12	68.1	24.5	0.006	19.6	116.5
	18	119.2	29.2	<0.0001	61.6	176.8
	24	96.8	23.1	<0.0001	51.1	142.5
	30	152.4	25.2	<0.0001	102.7	202.2
3	0	57.1	18.7	0.003	20.2	94.1
	6	53.5	23.4	0.023	7.3	99.7
	12	125.3	28.8	<0.0001	68.5	182.0
	18	176.4	30.9	<0.0001	115.4	237.4
	24	154.0	26.9	<0.0001	100.9	207.1
	30	209.6	28.9	<0.0001	152.5	266.7
6	0	3.6	20.7	0.861	-37.1	44.4
	3	-53.5	23.4	0.023	-99.7	-7.3
	12	71.7	24.1	0.003	24.2	119.2
	18	122.1	27.1	<0.0001	69.5	176.2
	24	100.4	24.0	<0.0001	53.1	147.7
	30	156.1	26.1	<0.0001	104.6	207.5
12	0	-68.1	24.5	0.006	-116.5	-19.6
	3	-125.3	28.8	<0.0001	-182.0	-68.5
	6	-71.7	24.1	0.003	-119.2	-24.2
	18	51.1	24.0	0.034	3.7	98.5
	24	28.7	20.3	0.159	-11.2	68.7
	30	84.3	25.7	0.001	33.5	135.1
18	0	-119.2	29.2	<0.0001	-176.8	-61.6
	3	-176.4	30.9	<0.0001	-237.4	-115.4
	6	-122.9	27.1	<0.0001	-176.2	-69.5
	12	-51.1	24.0	0.034	-98.5	-3.7
	24	-22.4	22.0	0.311	-65.9	21.0
	30	33.1	27.9	0.236	-21.8	88.2
24	0	-96.8	23.1	<0.0001	-142.5	-51.1
	3	-154.0	26.9	<0.0001	-207.1	-100.9
	6	-100.4	24.0	<0.0001	-147.7	-53.1
	12	-28.7	20.3	0.159	-68.7	11.2
	18	22.4	22.0	0.311	-21.0	65.9
	30	55.6	21.0	0.009	14.2	97.0
30	0	-152.4	25.2	<0.0001	-202.2	-102.7
	3	-209.6	28.9	<0.0001	-266.7	-152.5
	6	-156.1	26.1	<0.0001	-207.5	-104.6
	12	-84.3	25.7	0.001	-135.1	-33.5
	18	-33.1	27.9	0.236	-88.2	21.8
	24	-55.6	21.0	0.009	-97.0	-14.2

5.4 Kinematics proximal and distal to the ankle joint complex

5.4.1 Statistical analyses

Three-dimensional kinematic data were prepared for the knee joint and calcaneotalonavicular joint complex for the sex- and age-matched normal population and both RA study groups under barefoot, shod and orthosis conditions at baseline and 30-months. The data are summarised in tabular and graphical formats and descriptive comparisons made between groups over time.

5.4.2 Three-dimensional knee joint kinematics

For all study groups the knee position at heel strike was approximately 5° flexed (figure 5-13). From heel strike through the loading response the normal population in both barefoot and shod conditions had knee flexion of about 10°. In comparison both RA groups under barefoot, shod and orthosis conditions had knee flexion of about 5° this phase of gait. During mid stance all groups demonstrated gradual knee extension (less so in both RA groups) about midway in terminal stance (approximately 40% gait cycle) reaching a

Table 5-37: Knee joint kinematics at baseline and 30-months for the normal and rheumatoid arthritis study populations under barefoot, shod and orthosis conditions.

Group	Variable	Motion					
		Flex(-)/Exten(+)		Abd (-)/Add(+)		Int (-)/ext (+)rot	
		BL	30mths	BL	30mths	BL	30mths
Norm BF	MIN	-55.4		-1.4		-1.2	
	MAX	-4.7	-	3.7	-	9.6	-
	ROM	50.7		5.1		10.8	
Norm SH	MIN	-59.5		-1.5		-1.1	
	MAX	-3.9	-	4.0	-	9.6	-
	ROM	55.6		5.5		10.7	
RACon BF	MIN	-47.2	-48.9	-1.4	-1.4	0.2	-0.8
	MAX	-3.8	-4.9	6.0	5.6	8.3	8.0
	ROM	43.4	44.0	7.4	7.0	8.1	8.8
RACon SH	MIN	-53.1	-53.0	-1.9	-1.8	-1.2	-1.6
	MAX	-3.2	-4.2	7.5	6.4	9.1	8.5
	ROM	49.9	48.8	9.4	8.2	10.3	10.1
RAInt BF	MIN	-45.5	-48.9	-2.3	-1.6	-0.1	-1.6
	MAX	-4.0	-4.9	5.4	5.3	8.0	6.7
	ROM	41.5	44.0	7.7	6.9	8.1	8.3
RAInt SH	MIN	-51.6	-51.9	-2.8	-1.8	-1.4	-2.5
	MAX	-3.3	-4.8	5.6	6.0	8.7	6.8
	ROM	48.3	47.1	8.4	6.9	10.1	9.3
RAInt Orth	MIN	-51.1	-52.1	-3.1	-1.9	-1.9	-3.1
	MAX	-3.2	-4.4	6.0	6.1	8.6	7.1
	ROM	47.9	47.7	9.1	8.0	10.5	10.2

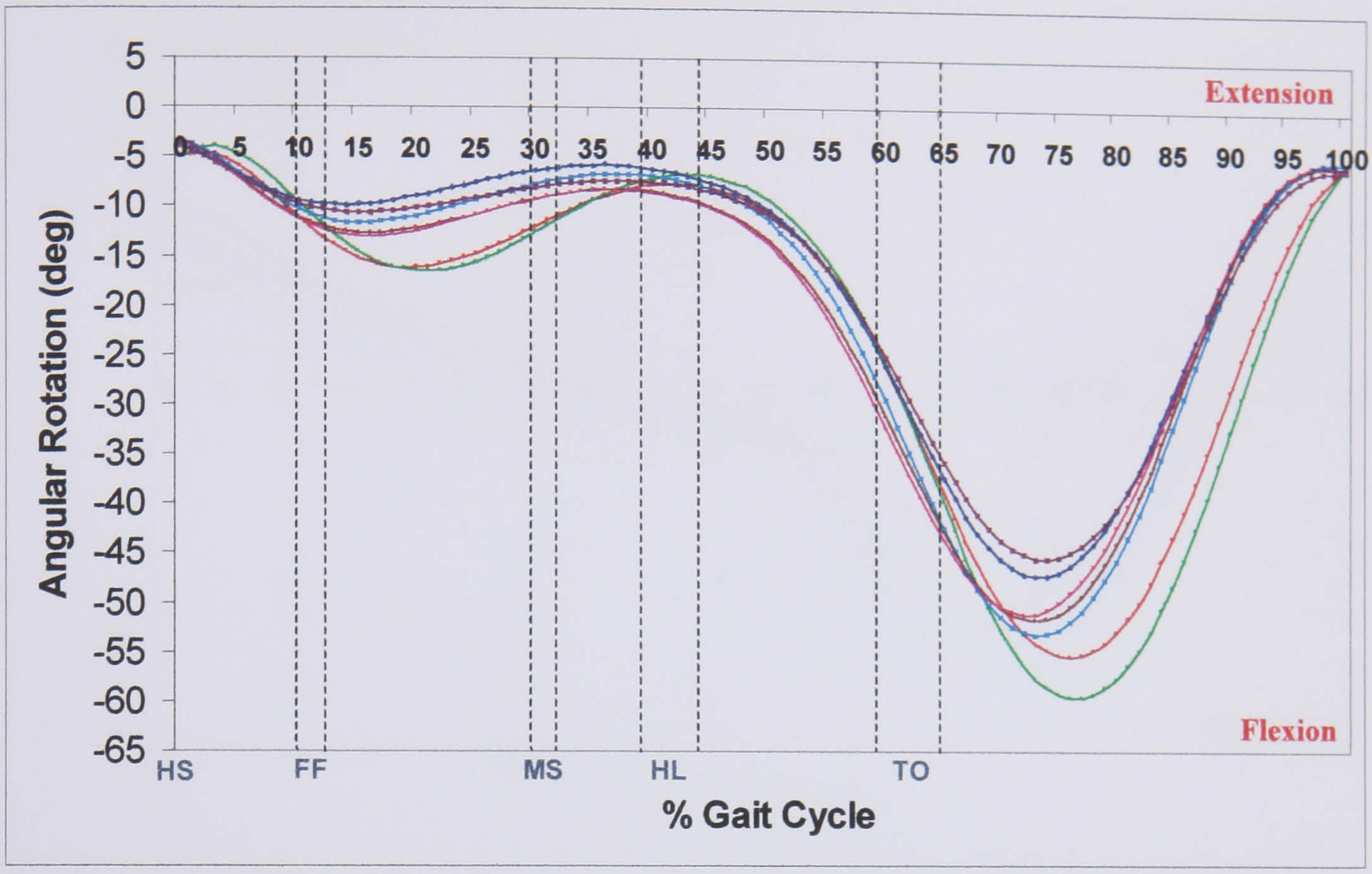
Angles are in degrees. Norm- normal population, RACon- Rheumatoid arthritis control group, RAInt- rheumatoid arthritis intervention group, BF- barefoot, SH- shod, Orth-orthotic condition.

flexion angle between 5-8°. In all groups a second phase of knee flexion is observed during the end of terminal stance and by the end of pre-swing (60-65% gait cycle) flexion ranges from 25-40°. Knee flexion continues through initial swing reaching maximums between 45-60° depending on group and walking condition. There was no apparent difference between minimum knee flexion angles between groups but both RA groups demonstrated reduced maximum knee flexion by 8.2° in the RA control group and 9.9° in the RA intervention group. In all groups maximum knee flexion was increased between barefoot and shod conditions between 4.1-6.1°. In the intervention group no additional kinematic effect on knee flexion/extension was introduced by the use of orthoses. Over the duration of the study there were no obvious changes in kinematic parameters in any of the RA study groups under each walking condition. However, figure 5-14 does demonstrate an improvement in both RA study groups in initial knee flexion during the loading response.

In figure 5-15 all study groups had a slightly adducted knee at heel strike followed by a period of abduction through mid stance. In all study groups a sharp abduction movement occurred during terminal stance and was measurably greater in both RA groups under all walking conditions in comparison with the normal population. Maximum abduction occurred shortly after toe off the mean maximum angles greater in both RA groups (table 5-37). In the RA groups the maximum angle increased further, along with the ROM between barefoot and shod and shod and orthosis (intervention group only) conditions. During swing phase a sharp adduction motion was observed in all study groups. At 30-months the same trends were observed and it was noticeable that the ROM had slightly decreased in both RA study groups under all walking conditions (figure 5-16).

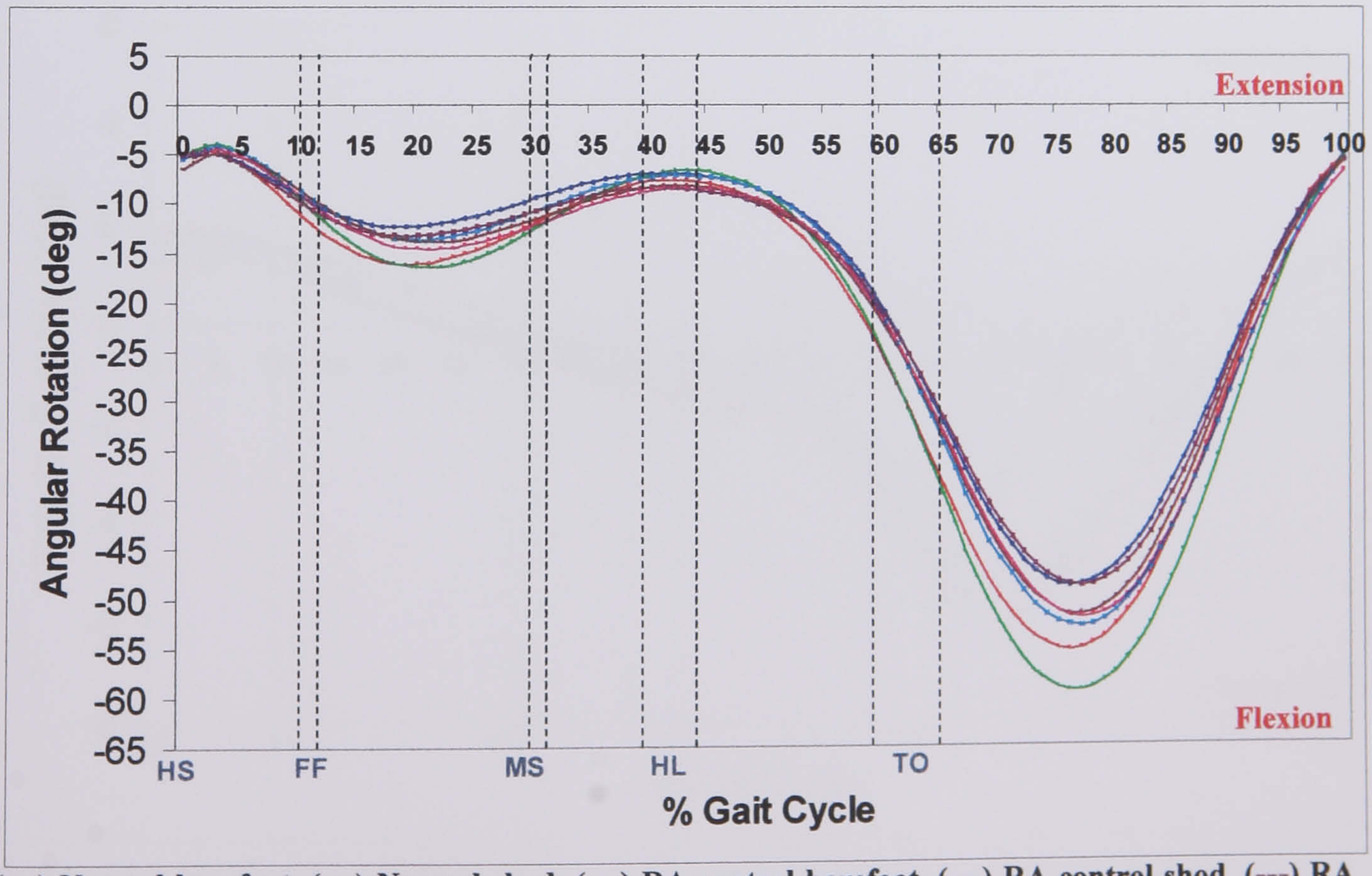
The knee joint was internally rotated (tibia internally rotated on femur); slightly more so in the RA study groups in comparison with the normal population, at heel strike and continued this movement during the loading response (figure 5-17). During mid stance towards heel lift external rotation was recorded in all groups lasting to between heel lift and toe off. From there a second phase of internal rotation was recorded at the end of stance and throughout the swing phase. The normal population demonstrated a greater range of internal/external rotation movement than the two RA study groups under barefoot conditions but mean values were comparable when shod and orthosis data were compared (table 5-37). Over the duration of the study there was no change in the ROM for both RA study groups (table 5-37, figure 5-18). However the motion curves were shifted negatively on the ordinate the knee joint functioning around a more externally rotated ROM and the change in minimum and maximum mean angles can be seen in table 5-37.

Figure 5-13: Knee joint extension/flexion at baseline for normal study population and both RA groups under barefoot, shod and orthosis conditions.



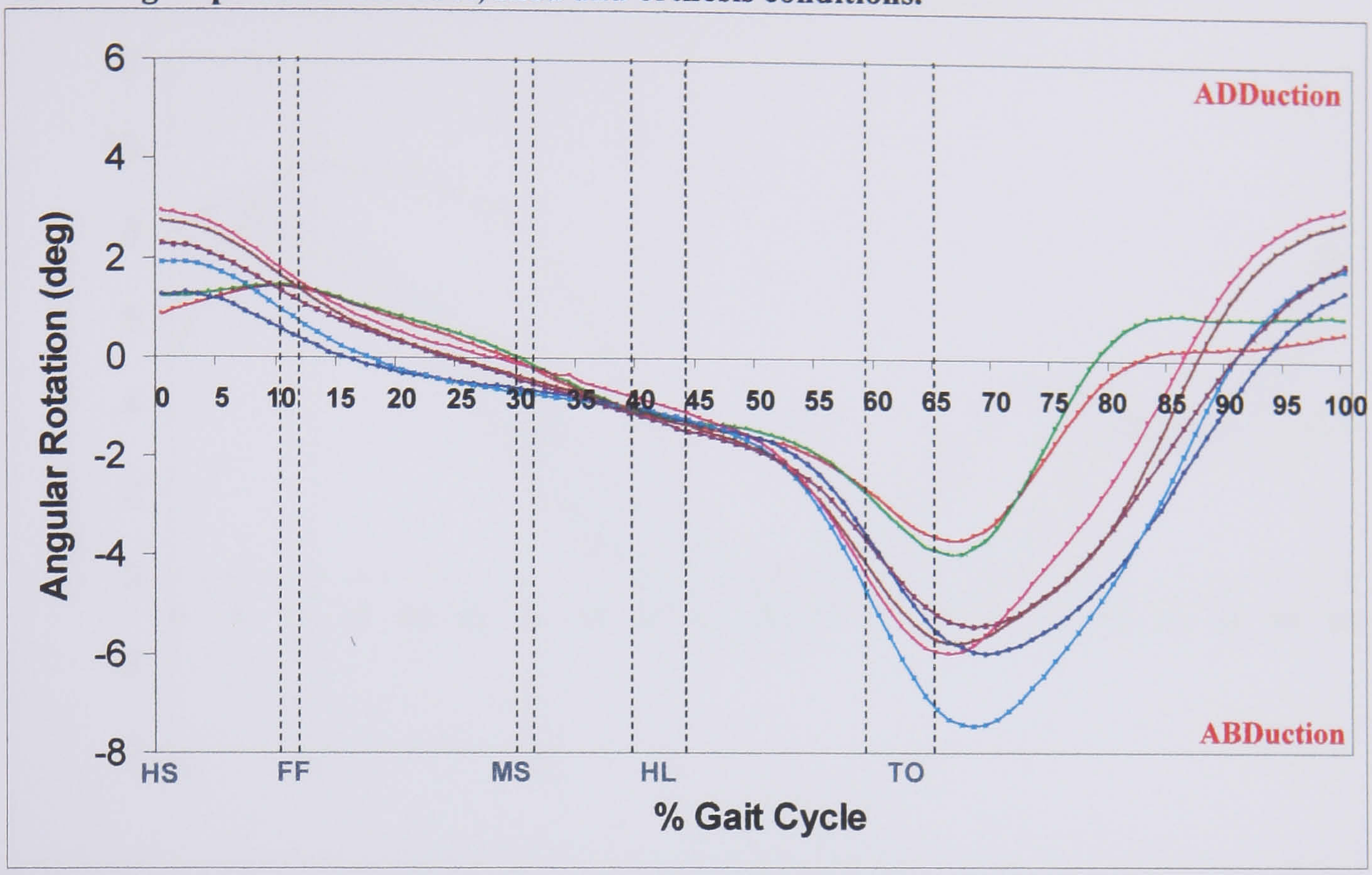
(---) Normal barefoot, (---) Normal shod, (---) RA control barefoot, (---) RA control shod, (---) RA intervention barefoot, (---) RA intervention shod, (---) RA intervention orthosis. Gait events are identified within a range for all the study groups, Extension (+), Flexion (-)

Figure 5-14: Knee joint extension/flexion at 30-months for normal study population and both RA groups under barefoot, shod and orthosis conditions.



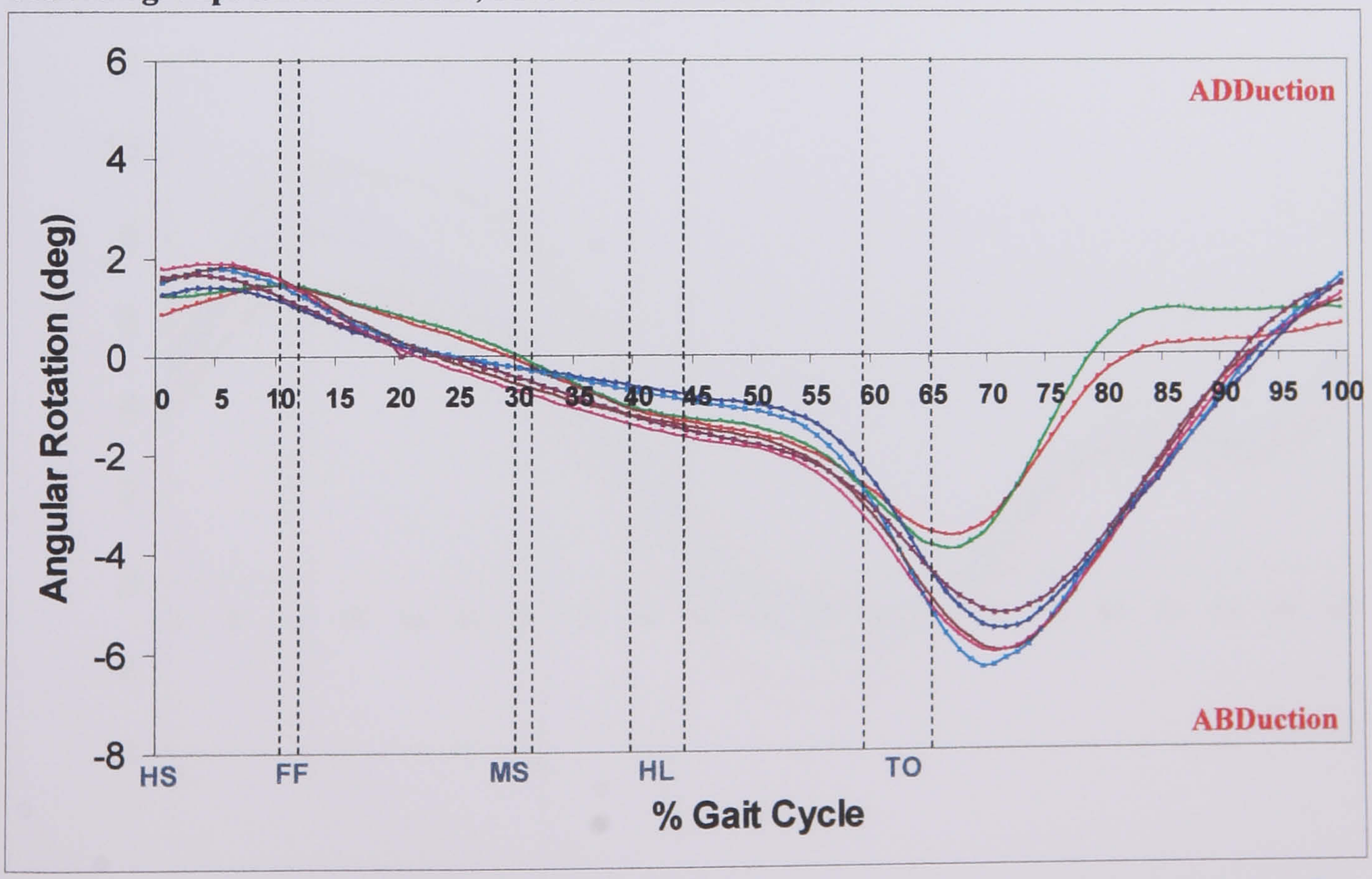
(---) Normal barefoot, (---) Normal shod, (---) RA control barefoot, (---) RA control shod, (---) RA intervention barefoot, (---) RA intervention shod, (---) RA intervention orthosis. Gait events are identified within a range for all the study groups. Extension (+), Flexion (-)

Figure 5-15: Knee joint abduction/adduction at baseline for normal study population and both RA groups under barefoot, shod and orthosis conditions.



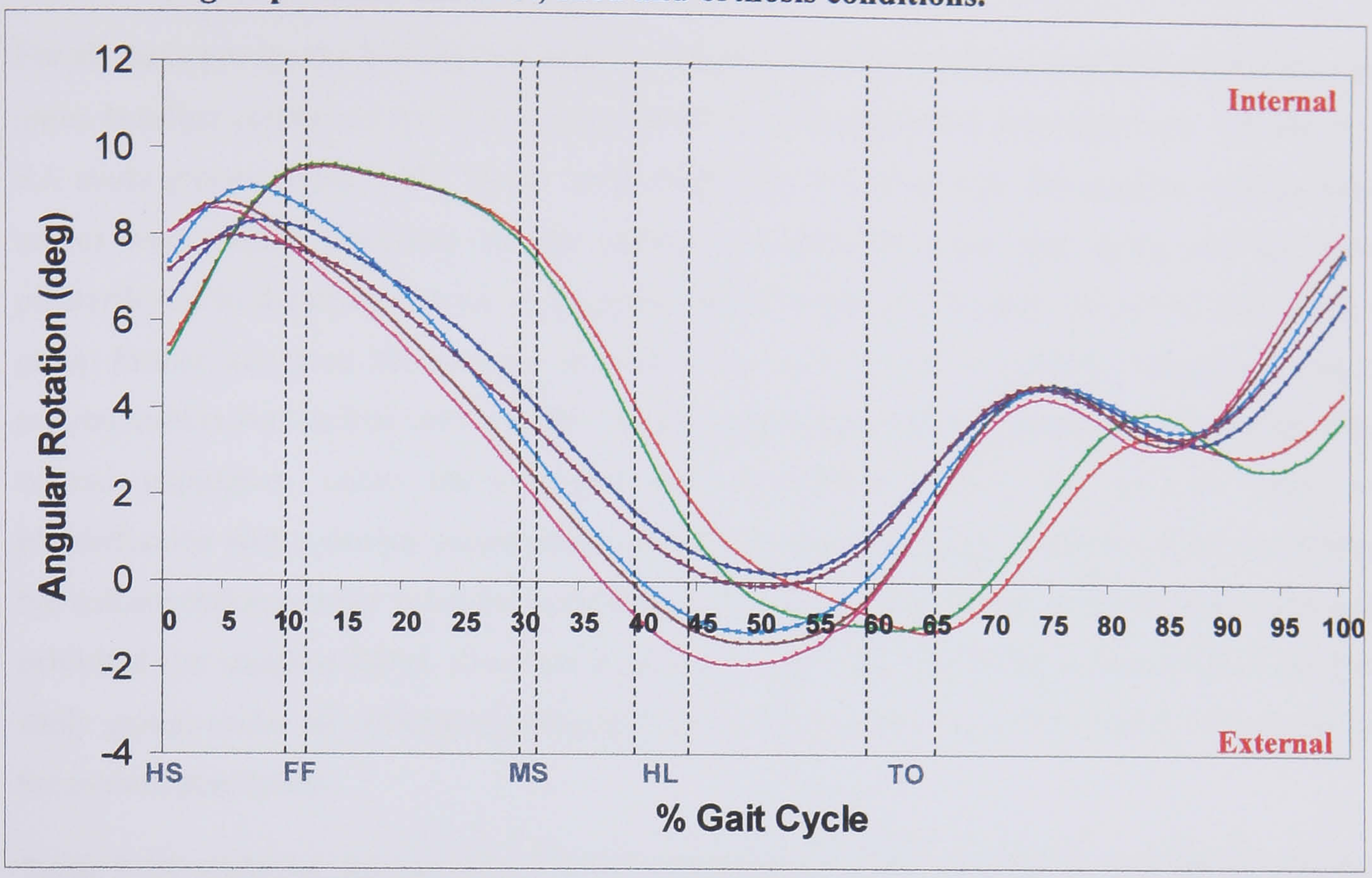
(---) Normal barefoot, (---) Normal shod, (---) RA control barefoot, (---) RA control shod, (---) RA intervention barefoot, (---) RA intervention shod, (---) RA intervention orthosis. Gait events are identified within a range for all the study groups, ADDuction (+), ABDuction (-).

Figure 5-16: Knee joint abduction/adduction at 30-months for normal study population and both RA groups under barefoot, shod and orthosis conditions.



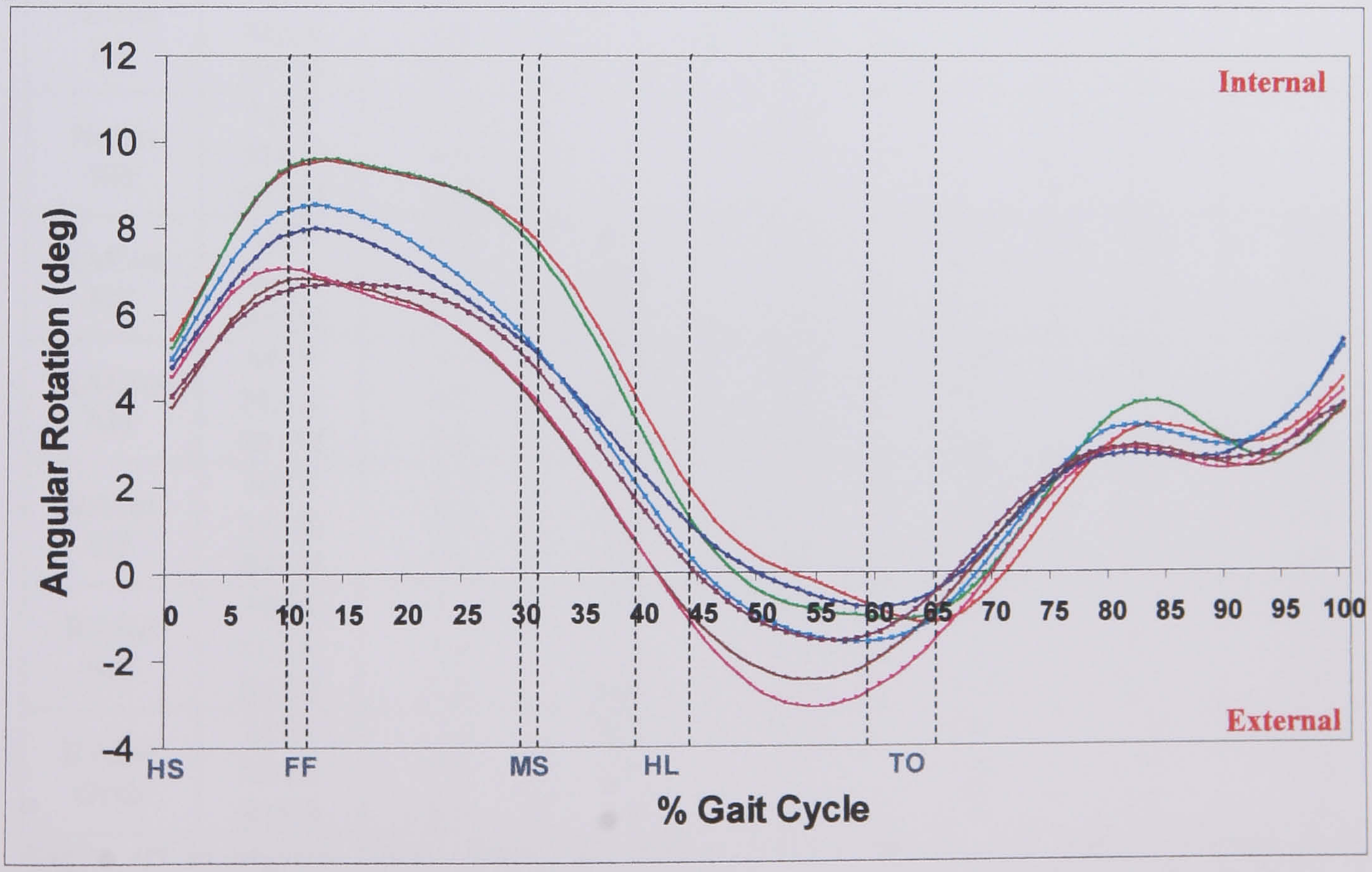
(---) Normal barefoot, (---) Normal shod, (---) RA control barefoot, (---) RA control shod, (---) RA intervention barefoot, (---) RA intervention shod, (---) RA intervention orthosis. Gait events are identified within a range for all the study groups, ADDuction (+), ABDuction (-).

Figure 5-17: Knee joint internal/external rotation at baseline for normal study population and both RA groups under barefoot, shod and orthosis conditions.



(---) Normal barefoot, (---) Normal shod, (---) RA control barefoot, (---) RA control shod, (---) RA intervention barefoot, (---) RA intervention shod, (---) RA intervention orthosis. Gait events are identified within a range for all the study groups, Internal rotation (+), External rotation (-).

Figure 5-18: Knee joint internal/external rotation at 30-months for normal study population and both RA groups under barefoot, shod and orthosis conditions.



(---) Normal barefoot, (---) Normal shod, (---) RA control barefoot, (---) RA control shod, (---) RA intervention barefoot, (---) RA intervention shod, (---) RA intervention orthosis. Gait events are identified within a range for all the study groups, Internal rotation (+), external rotation (-).

5.4.3 Three-dimensional calcaneotalonavicular joint kinematics

For all study groups the loading response was characterised by small amounts of dorsiflexion and under barefoot conditions this was greater for the normal population in comparison with the two RA study groups (table 5-38). Under shod conditions, for all groups, the angular rotation:time curves were shifted positively on the ordinate changing the mean heel strike position from plantarflexed to dorsiflexed with an increased ROM observed. Orthotic use in the intervention group further increased the dorsiflexed heel strike position and the ROM. During mid stance sagittal motion was locked until heel lift, which signalled the onset of plantarflexion motion. The normal population under barefoot and shod conditions showed the greatest range of plantarflexion with a further period of dorsiflexion during mid swing. Under barefoot conditions the calcaneotalonavicular joint for both RA groups operated within a plantarflexed ROM and exhibited the smallest ROM. Over the duration of the study the ROM increased for both RA study groups under all walking conditions, but the mean values were still smaller than those for the normal population.

Table 5-38: Calcaneotalonavicular joint complex kinematics at baseline and 30-months for normal and rheumatoid arthritis study populations under barefoot, shod and orthosis conditions.

Group	Variable	Motion					
		Dorsi/plantarflex		Inversion/Eversion		Internal/external rot	
		BL	30mths	BL	30mths	BL	30mths
Norm BF	MIN	-7.0		-2.0		-1.4	
	MAX	1.9	-	0.2	-	1.8	-
	ROM	8.8		2.2		3.2	
Norm SH	MIN	-4.9		-1.0		-4.1	
	MAX	4.6	-	2.7	-	-1.4	-
	ROM	9.5		3.7		2.7	
RACon BF	MIN	-3.9	-3.5	-6.3	-4.9	-3.0	-3.4
	MAX	-1.0	0.9	-3.5	-2.2	-0.6	-0.9
	ROM	2.9	4.4	2.8	2.7	2.4	2.5
RACon SH	MIN	-1.3	-1.9	-2.9	-2.0	-6.3	-5.6
	MAX	4.2	4.5	1.3	0.6	-4.4	-3.6
	ROM	5.5	6.4	4.2	2.6	1.9	2.0
RAInt BF	MIN	-3.9	-3.2	-5.3	-3.7	-2.5	-2.1
	MAX	-0.8	2.0	-3.3	-1.6	-0.5	0.2
	ROM	3.1	5.2	2.0	2.1	2.0	2.3
RAInt SH	MIN	-1.6	-1.1	-1.9	-0.5	-6.8	-4.9
	MAX	3.9	5.5	2.0	1.7	-4.5	-2.9
	ROM	5.5	6.6	3.9	2.2	2.3	2.0
RAInt Orth	MIN	-2.4	-3.0	-0.6	0.8	-7.6	-5.4
	MAX	5.6	5.9	2.7	2.6	-4.8	-3.2
	ROM	8.0	8.9	3.3	1.8	2.8	2.2

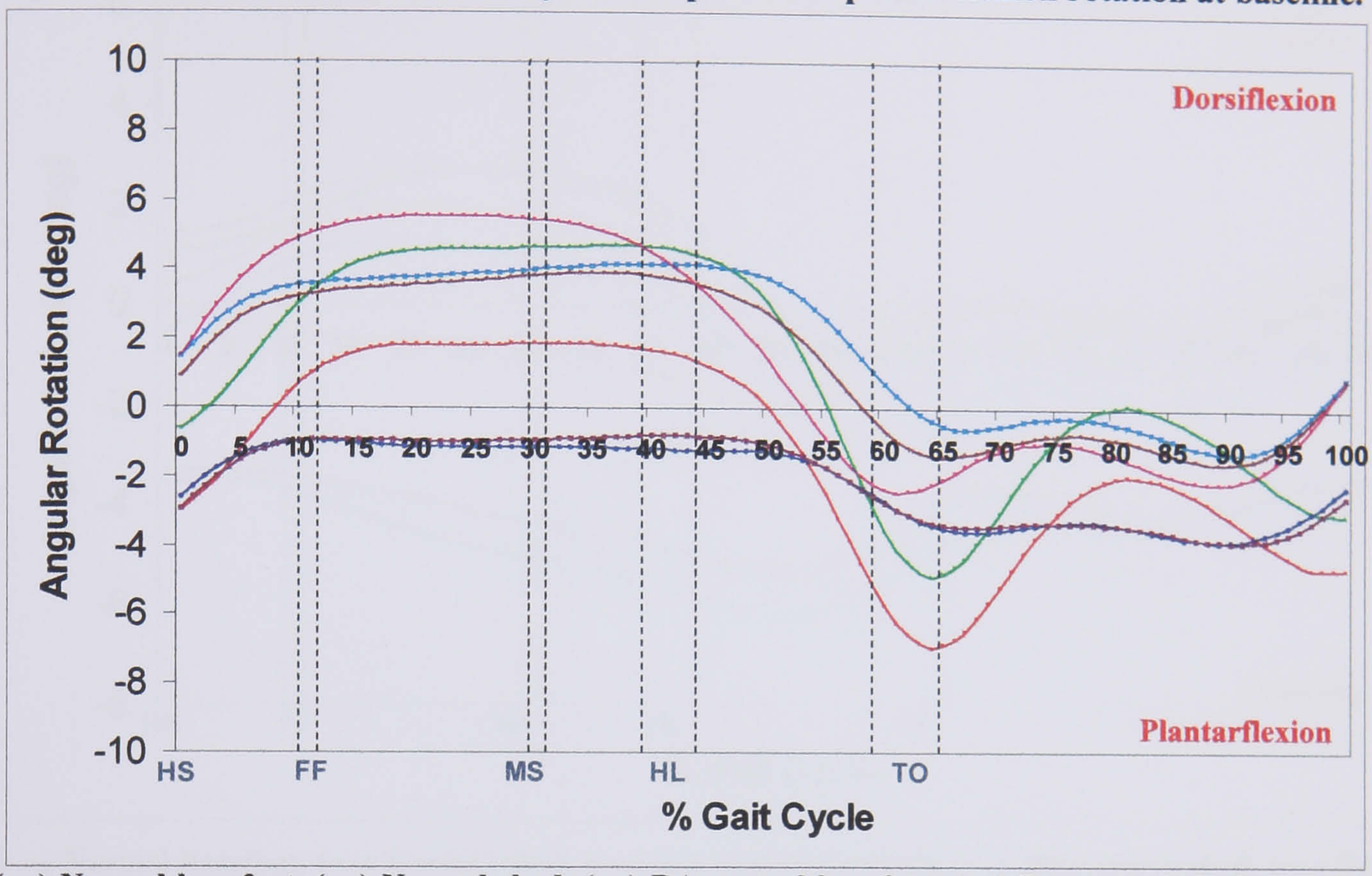
Angles are in degrees. Norm- normal population, RACon- Rheumatoid arthritis control group, RAInt- rheumatoid arthritis intervention group, BF- barefoot, SH- shod, Orth-orthotic condition.

The most notable change was a shift of the barefoot angular rotation:time curves permitting the joint complex to dorsiflex and plantarflex around a neutral position with a similar pattern during stance to that of the normal population although plantarflexion towards toe-off was still reduced (figures 5-19 and 5-20).

The inversion/eversion motion patterns about the calcaneotalonavicular joint complex for all three groups under barefoot conditions were similar, however, those for the two RA groups functioned around an everted position (figures 5-21 and 5-22). The ROM under barefoot conditions was small and this increased under shod conditions with no additional effect with orthosis use in the intervention group. However, the footwear and orthoses for all groups did alter the nature of the motion, changing initial motion at heel strike to a short period of inversion followed by a period of static motion during mid stance and a final period of eversion during terminal stance. This was associated with an increased ROM under shod conditions with no additional change with orthosis use in the intervention group. During pre-swing a final period of inversion was noted for all conditions and motion remained relatively static through mid swing with a short period of inversion at terminal swing. Over the duration there was no observed change in motion curve shape or ROM for barefoot conditions, although in both groups the curves were shifted positively on the ordinate the joint functioning around a less everted position. Under shod and orthosis conditions the ROM were unchanged from barefoot conditions although the curves were shifted positively on the ordinate.

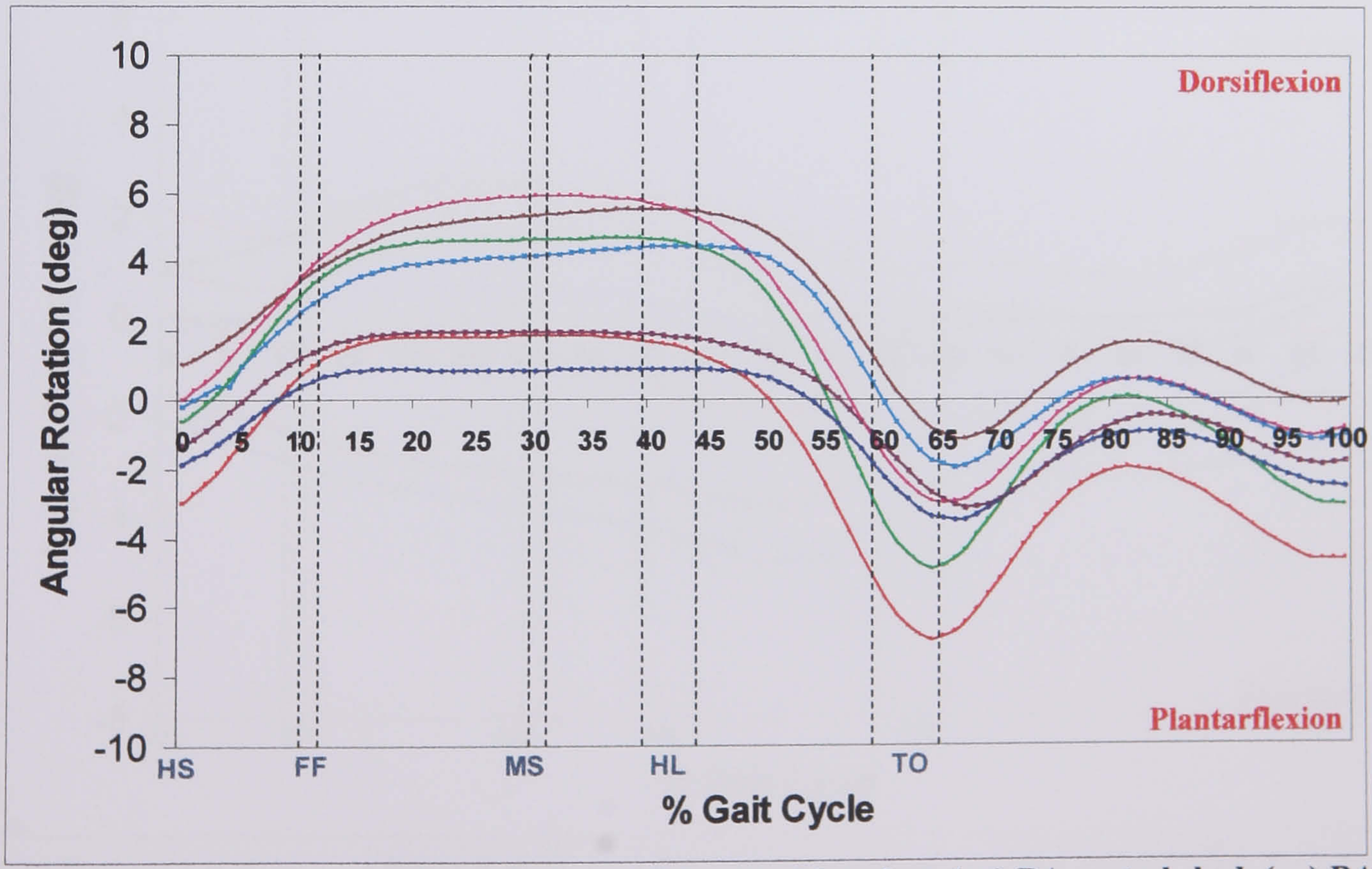
Internal/external rotation about the calcaneotalonavicular joint complex demonstrated the smallest ROM, typically between 2-3° (figures 5-23 and 5-24). The normal population was the only group to demonstrate internal and external rotation about the neutral position. Shod and orthotic conditions in all cases shifted the angular rotation:time curves negatively on the ordinate such that the joint functioned around internally rotated positions. Orthotic use in the intervention groups served to increase the shift further although no additional effect on ROM was observed. Stance phase was characterised by a gradual period of internal rotation towards terminal stance followed by external rotation during pre swing, which was continued more gradually during the swing phase. By 30-months there were no significant changes in ROM for both RA groups under any walking condition. As described for other rotations the angular rotation:time curves were shifted positively on the ordinate indicating improvement in joint function but achievement of normal patterns of motion were not achieved under shod or orthosis walking conditions. Although not displayed on the motion graphs the inter-subject variability for calcaneotalonavicular joint motion was large in comparison to the mean.

Figure 5-19: Calcaneotalonavicular joint complex dorsi/plantarflexion rotation at baseline.



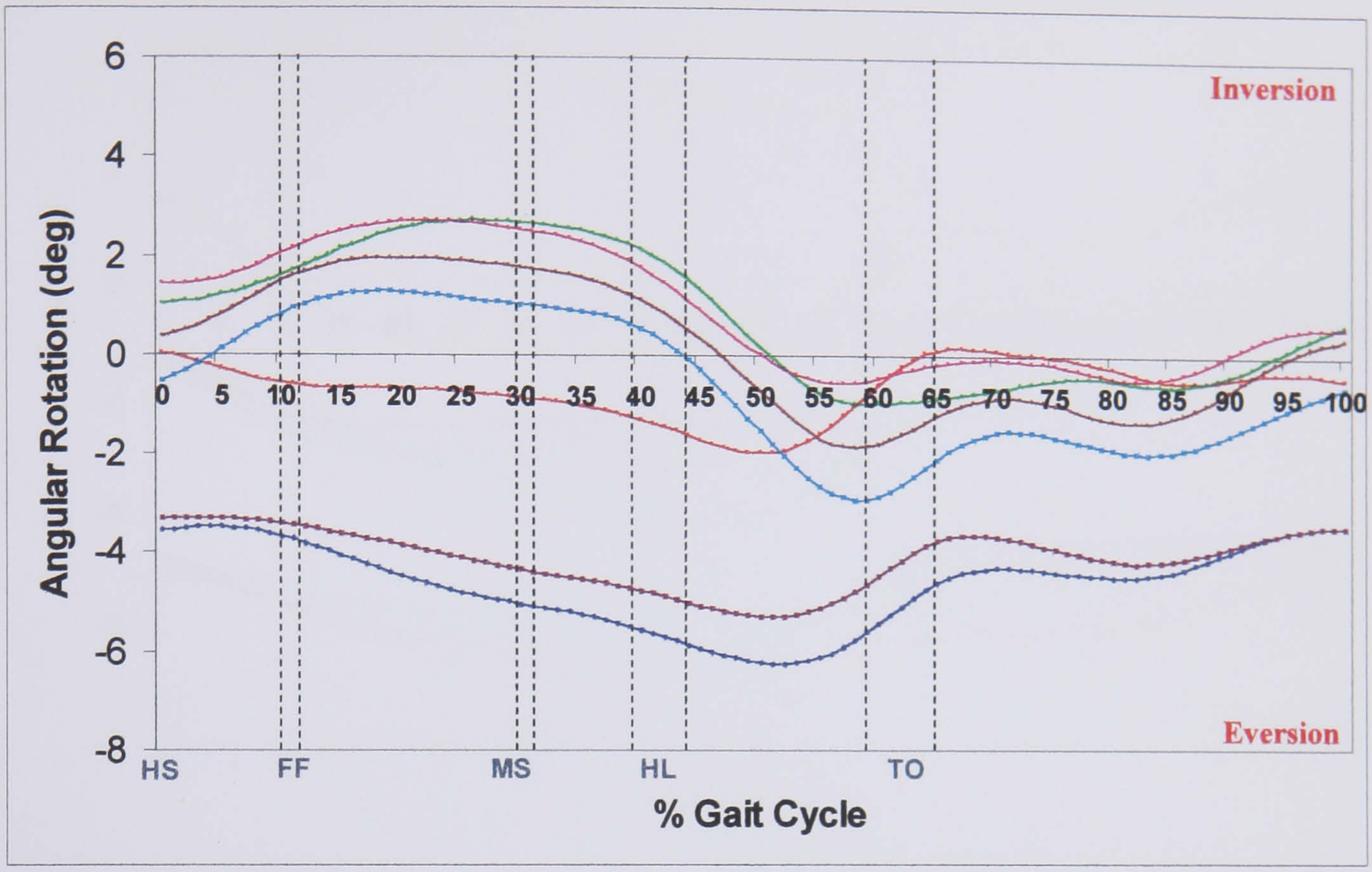
(---) Normal barefoot, (---) Normal shod, (---) RA control barefoot, (---) RA control shod, (---) RA intervention barefoot, (---) RA intervention shod, (---) RA intervention orthosis. Gait events are identified within a range for all the study groups, dorsiflexion (+), plantarflexion (-).

Figure 5-20: Calcaneotalonavicular joint complex dorsi/plantarflexion rotation at 30-months.



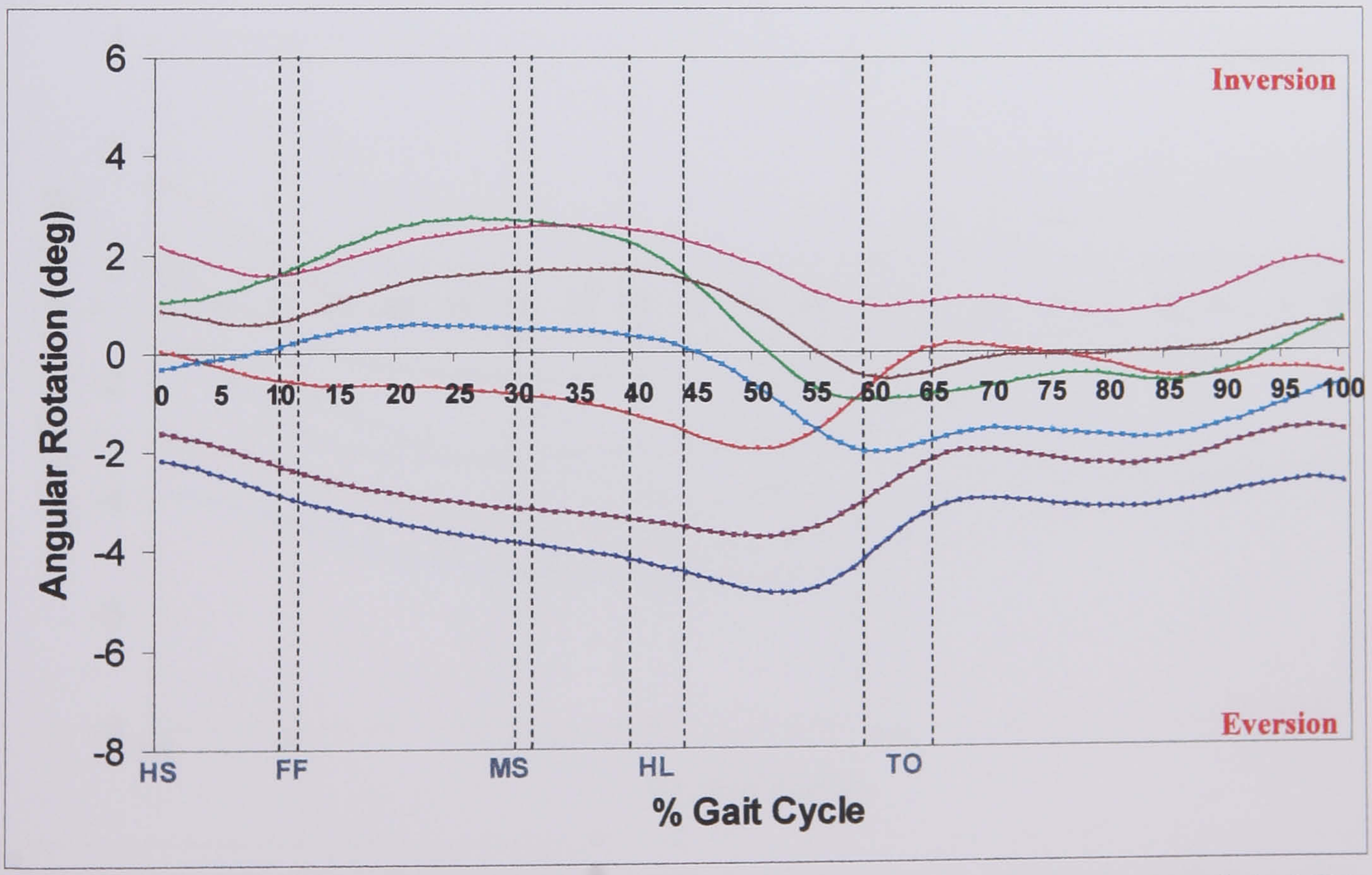
(---) Normal barefoot, (---) Normal shod, (---) RA control barefoot, (---) RA control shod, (---) RA intervention barefoot, (---) RA intervention shod, (---) RA intervention orthosis. Gait events are identified within a range for all the study groups, dorsiflexion (+), plantarflexion (-).

Figure 5-21: Calcaneotalonavicular joint complex inversion/eversion rotation at baseline.



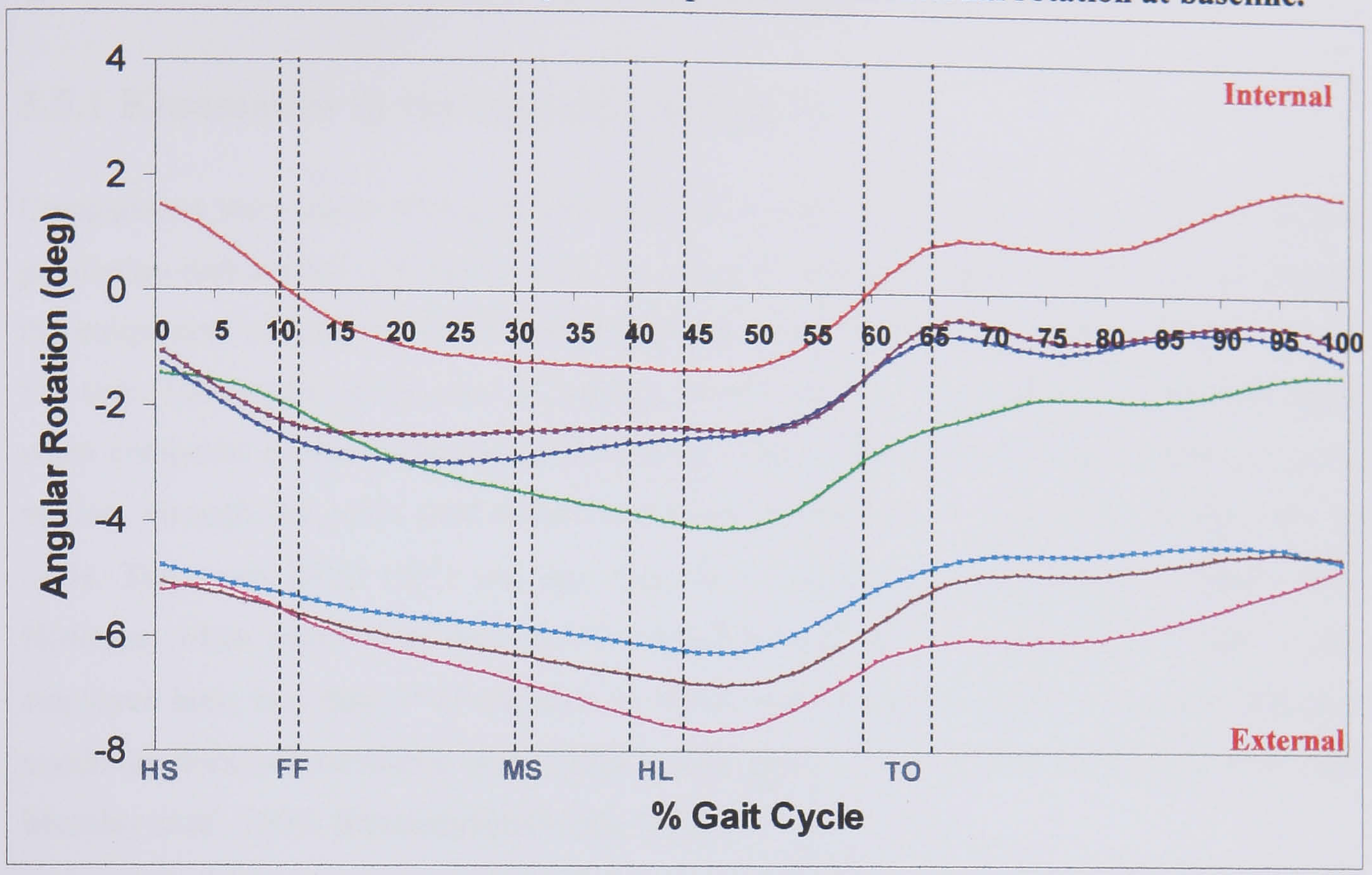
(---) Normal barefoot, (---) Normal shod, (---) RA control barefoot, (---) RA control shod, (---) RA intervention barefoot, (---) RA intervention shod, (---) RA intervention orthosis. Gait events are identified within a range for all the study groups. Inversion (+), Eversion (-).

Figure 5-22: Calcaneotalonavicular joint complex inversion/eversion rotation at 30-months.



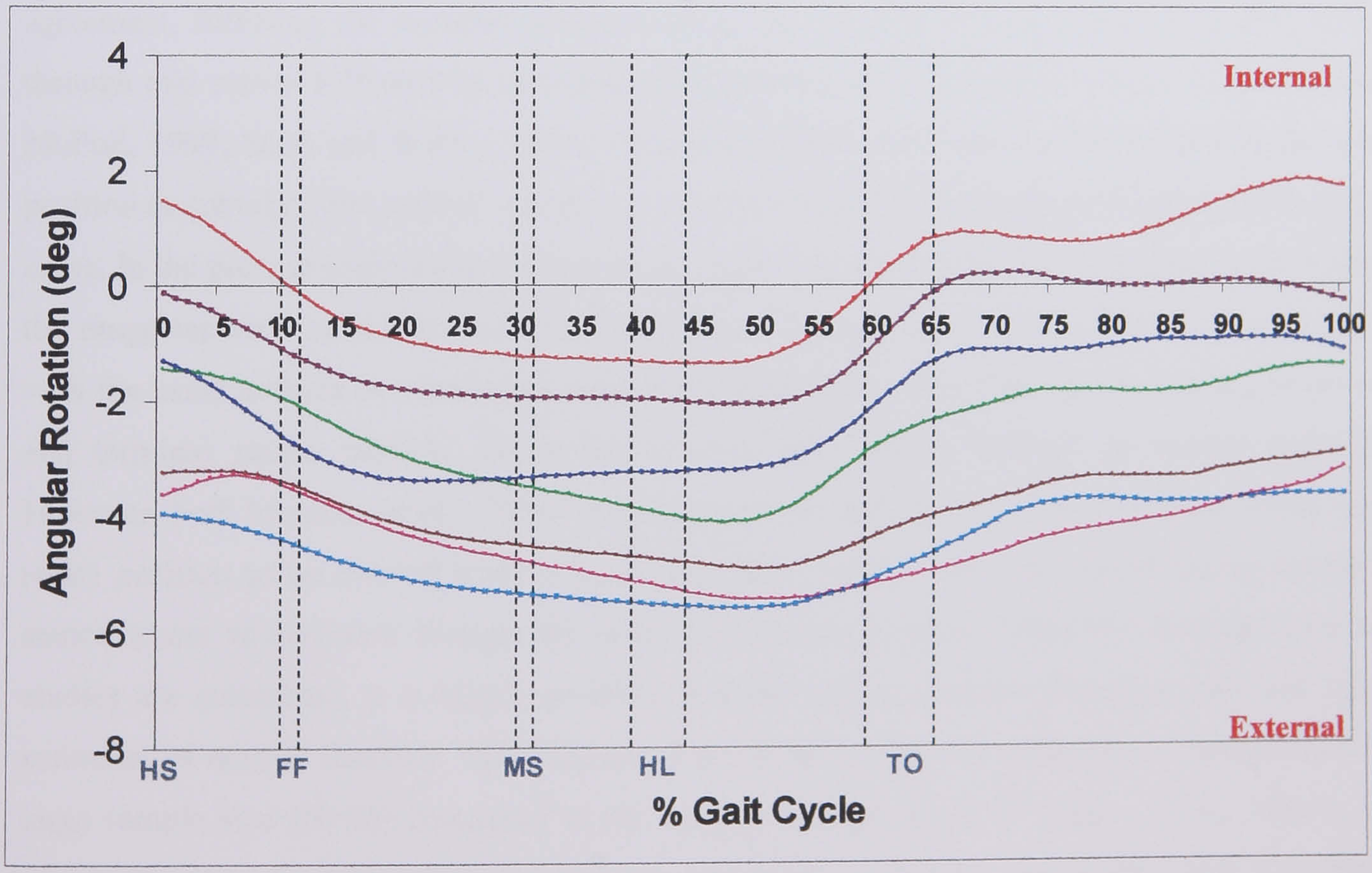
(---) Normal barefoot, (---) Normal shod, (---) RA control barefoot, (---) RA control shod, (---) RA intervention barefoot, (---) RA intervention shod, (---) RA intervention orthosis. Gait events are identified within a range for all the study groups. Inversion (+), Eversion (-).

Figure 5-23: Calcaneotalonavicular joint complex internal/external rotation at baseline.



(---) Normal barefoot, (---) Normal shod, (---) RA control barefoot, (---) RA control shod, (---) RA intervention barefoot, (---) RA intervention shod, (---) RA intervention orthosis. Gait events are identified within a range for all the study groups. Internal (+), External (-) rotation.

Figure 5-24: Calcaneotalonavicular joint complex internal/external rotation at 30-months.



(---) Normal barefoot, (---) Normal shod, (---) RA control barefoot, (---) RA control shod, (---) RA intervention barefoot, (---) RA intervention shod, (---) RA intervention orthosis. Gait events are identified within a range for all the study groups. Internal (+), External (-) rotation.

5.5 Discussion

5.5.1 Kinematics in the normal population

Comparisons were made with published figures to establish whether the age- and sex-matched population had normal AJC kinematics. No standard reference tables exist for this purpose and the uniqueness of various methods employed previously necessitate a degree of flexibility with this task. The results, for all axes of rotation, were generally consistent with published material when compared qualitatively and quantitatively. The sagittal plane dorsi/plantarflexion arcs of motion, through the ankle joint component, were similar both in shape and timing in the gait cycle. The mean ROM (15°) was less than the consensus figure of 30° ±10° (Perry 1992). However, when matched against data from studies derived using techniques closest to those employed here, less than 5° of variation in ROM, mean angles by gait event and minimum and maximum dorsi/plantarflexion were found (Cornwall and McPoil, 1999; Kobayashi *et al.*, 1997; Moseley *et al.*, 1996; Rattanaprasert *et al.*, 1999).

The inversion/eversion motion measured by the EMT technique occurs around the subtalar joint component of the AJC. Compared with studies where no neutral position was defined, or a position other than subtalar joint neutral was used, curve shape and ROM were in close agreement, fulfilling the accepted understanding that eversion motion occurs from heel strike through mid stance followed by inversion from heel lift through terminal stance (Cornwall and McPoil, 1999; Scott and Winter, 1991). Absolute comparisons with studies that define the zero position as subtalar joint neutral, albeit by a variety of techniques, show good agreement in some cases. In the present study the mean heel strike angle was inverted by 3.1° and found to be within the range reported by Kobayashi *et al.*, (1997) and Rattanaprasert *et al.*, (1999). In agreement with the same authors two instances were found in the gait cycle - during the loading response and terminal stance periods, where the subtalar joint passed through its neutral position. However, both Moseley *et al.*, (1996) and Pierrynowski and Smith (1996) found the initial heel strike position to be everted relative to subtalar joint neutral with one period during terminal stance where re-inversion brought the joint past neutral position. When the findings from all studies are summated, it is highly probable that the motion patterns described here are valid estimates of normal function. The findings of the present study are taken from a comparatively large sample size (N=45) compared to the studies reported above (N-range= 1-14). This is an important consideration when population parameter estimates are made, and alongside methodological variation may explain some of the observed differences.

There was limited opportunity for comparative analyses of transverse plane internal/external rotation. Mechanical coupling between leg rotation and subtalar motion is highly variable between subjects and influenced by certain foot types (Hintermann *et al.*, 1994; Kepple *et al.*, 1990; Lundberg *et al.*, 1989; Nawoczenski *et al.*, 1998). Whilst some studies have demonstrated 'high' coupling where rotations are linked for the entire stance period, this inter-relationship was found only to be true between eversion and internal rotation during the loading response and, to a lesser extent, between inversion and external rotation during terminal stance (Moseley *et al.*, 1996). A small range of external rotation in the presence of subtalar joint eversion during mid stance was found, and this feature is evident in the graphical data presented by Cornwall and McPoil (1999) and Rattanaprasert *et al.*, (1999). The range of motion and timings in relation to stance events were consistent with those of other groups (Cornwall and McPoil, 1999; Lafortune *et al.*, 1994; Nawoczenski *et al.*, 1998; Rattanaprasert *et al.*, 1999).

Normative kinematic data for shod conditions was established to accurately reflect the behaviour of the foot during activities of daily living. New in-shoe data shows that the sagittal pitch of the foot is increased anteroposteriorly, which shifts the foot into a more plantarflexed position and increases the dorsi/plantarflexion ROM. Plantarflexion of the ankle joint coupled with stiffness in the medial counter of the shoe served to invert the subtalar joint slightly and reduce the available amount of rotation. In addition internal/external rotation was shifted to rotate around a slightly more externally rotated heel strike position although total ROM was the same. These kinematic changes could be regarded as therapeutically important given the nature of subtalar dysfunction in RA. It was therefore valid to persist with this measurement into the therapeutic trial and to allow comparison of both shod and barefoot kinematic data in the RA control group against orthosis data in the intervention group.

Large between-subject variability in normal AJC kinematics was evident in this study and has been reported elsewhere for AJC and other gait variables (Engsberg and Andrews, 1987; Kepple *et al.*, 1990; Moseley *et al.*, 1996; Winter, 1984). Normal boundary definitions (Mean ±2 x SD) were not used to diagnose abnormal kinematics in this study. If conservative rules were applied a barefoot heel strike angle, for example, would range from 10° inverted to 4° everted, yet this boundary may contain patients whom in the presence of RA would be at danger of developing significant AJC deformity. Therefore kinematic data from normal and RA patients groups were presented for the full gait cycle with the true mean expressed within a 95% confidence interval. Comparison of these patient groups over time with the confidence interval for the mean between group differences was considered the most valuable way of expressing the treatment effect.

5.5.2 Kinematics in rheumatoid arthritis

The hypothesis generated in chapter-1, which states that significant changes in AJC kinematics occur in early RA, is supported by the findings of this study. The changes were comparable in two matched RA groups (N=98) with average disease duration of 3 years. A small reduction in dorsi/plantarflexion ROM was noted but joint laxity was evident in the frontal and transverse planes. The inversion/eversion curve shape was well maintained but the ROM was reduced. The entire motion occurred within an everted ROM and at no stage was the neutral subtalar joint position reached. Instability of this nature in RA has been documented previously by Keenan *et al.*, (1991); Locke *et al.*, (1984) and Siegel *et al.*, (1995), but much later in the disease calendar. For the first time the findings of this study suggest that medial joint laxity is an early phenomenon occurring in significant number of patients.

Keenan *et al.*, (1991); Locke *et al.*, (1984) and Siegel *et al.*, (1995), all found the inversion/eversion ROM for their subjects to be within normal limits (6-10°), with periods of inversion and eversion about an unstable eversion range. Keenan's work is of particular interest because her patients had mean disease duration of 25 years. Her kinematic measurements showed a mean heel strike position of 10° everted, with a 10° ROM, the joint never reaching neutral during stance. Based on a comparison of absolute values for the present study with Keenan's data, despite dissimilar techniques, further laxity is likely to occur as the disease progresses. However, subtalar joint ROM appears to be relatively well preserved in all of these studies, for disease durations up to 25 years perhaps indicating that inflammation causes irreversible joint laxity through synovitis and soft-tissue pathology only. Mann (1982) and Rosenbaum *et al.*, (1994) both found increased subtalar joint ROM with flexible pronated foot types in non-RA subjects and subtalar joint bony ankylosis has been reported as uncommon in RA (Vidigal, 1975). Furthermore Belt *et al.*, (1997) showed little evidence of advanced subtalar radiological pathology over 20 years in a cohort of 68 RA patients. However, the gait studies above provided neither adequate controls nor normative reference values for the techniques used. In the present study the RA patients had a 24% reduction in inversion/eversion ROM in comparison with age- and sex- matched normals. Furthermore 11% of patients initially assessed for inclusion in the study, with disease duration of less than 5 years, were excluded on the grounds that their passive subtalar joint motion was significantly reduced. Further work is needed to determine whether reduced ROM in early disease as found in this study is the result of soft-tissue adaptation or articular cartilage pathology or a combination of both.

Valgus heel deformity in RA is also characterised by increased AJC internal rotation that lasts for the entire gait cycle. Examination of motion curve shape and mean angular data suggests high coupling between internal rotation and eversion especially during loading response and terminal stance. The coupling mechanism and manipulation thereof by footwear and orthoses has been demonstrated in a number of running studies but not previously for disease states such as RA. Lafortune *et al.*, (1994) demonstrated that during walking muscular and ligamentous structures maintained the integrity of the knee joint even when valgus footwear increased the internal-external tibiofemoral rotation. Increased internal lower leg rotation associated with excessive AJC eversion may be undesirable in RA where persistent inflammation may weaken the protective soft-tissue mechanisms in and around the knee that resist the deforming forces. Apart from inflammatory arthritis a number of studies have demonstrated that excessive pronation can be reduced with modified footwear or foot orthoses with a concomitant reduction in internal tibial rotation, but the response can often be small and subject specific (McPoil and Cornwall, 1991; Nawoczenski *et al.*, 1995; Nigg *et al.*, 1998; Stacoff *et al.*, 2000). Therefore the impact of foot orthoses in early RA may have an important role beyond correction of a rearfoot deformity.

A standard test shoe was used for all subjects because of the over-riding need, based on current evidence, to measure motion directly from the calcaneus (Stacoff *et al.*, 1992; Reinschmidt *et al.*, 1992; Reinschmidt *et al.*, 1997). The data of the present study suggests that the rigid medial heel counter in the test shoe provided some stabilisation and control of calcaneal movement. Maximum eversion was reduced by 3.5° for both RA groups with an inversion shift of the angular rotation:time curves. This was a substantial improvement over barefoot movement but insufficient control to establish normal movement patterns. Internal/external rotation ROM was slightly increased with a small improvement in function, although the maximum internal rotation during the loading response was unaffected. An increase in dorsi/plantarflexion ROM and a plantarflexion shift about the sagittal plane were observed, similar to that in the age and sex-matched normal population. The author cannot be certain that the characteristics of the test shoes matched those of the patients worn day-to-day over the duration of the study. Every effort was made to ensure that footwear met certain criteria, including good medial support and appropriate advice, mostly heeded, was provided throughout.

By definition the angular rotation:time integral is a summary measure for the entire gait cycle and its use appears to be novel but conceptually valid. Statistical tests confirmed that dorsi/plantarflexion is not significantly changed in RA. However, footwear significantly changes motion for both RA and otherwise healthy individuals with the same level of effect. For the important frontal plane motion statistical testing of the mean angular rotation:time integrals confirmed that abnormal motion was present in both RA groups under both barefoot and shod

conditions in comparison with normal. The small differences observed for internal/external rotation motion patterns were found to be significantly different on statistical testing between RA and normal population and between barefoot and shod conditions for all groups. Reflecting on the model for early intervention presented in 4.1.3 these findings suggest that AJC instability occurs before 3 years, the average disease duration for both RA groups in this study. Therefore with appropriate screening intervention could take place earlier than the timing in this study. Screening would require the development of new diagnostic criteria, based on gait analysis since the variability of the kinematic data suggests that some patients functioned within a normal range of motion. Inclusion was based on clinical examination and it is assumed that there is some discordance between inclusion criteria based on clinical features and static measurements and gait analysis data. In other words segmental alignment of the AJC under static weightbearing conditions may not be a strong predictor of AJC function in gait. Delayed treatment has always been associated with increased risk of irreversible deformity and there is already sufficient evidence from the first stage of this study to support the concept of early intervention (Keenan *et al.*, 1991; Shields and Ward, 1966; Stockley *et al.*, 1990).

5.5.3 Orthotic intervention in rheumatoid arthritis

It was evident from the initial results that footwear offered a therapeutic effect and the main question arose as to whether any significant additional orthotic effect occurred. If kinematic changes by gait event are examined for inversion/eversion for the intervention group then the mean heel strike position improved by 3.1° from barefoot to shod and by 2.6° from shod to orthosis conditions with an overall improvement of 5.7°. At mid stance the mean changes were 2.3° and 2.1° from barefoot to shod and shod to orthosis conditions respectively with an overall improvement of 4.6°. At toe-off the mean change overall was 8.5° consisting of a 5.9° mean change from barefoot to shod and 2.6° from shod to orthosis conditions. Under statistical analysis the angular rotation:time integral was significantly improved between shod and orthosis conditions. The mean difference was 237.9, which equates to an average difference of 2.4° (mean difference/100) across the gait cycle with a 95% confidence interval of 0.5°-4.3°. Although the additional effect size appears to be small, it was significant enough in qualitative terms to bring about an inverted heel strike position, two phases where motion crossed the subtalar joint neutral position and marked improvement in maximum eversion.

There was no additional orthotic effect with the dorsi/plantarflexion angular rotation:time integral in the RA intervention group at baseline. More importantly, however, was the lack of statistical effect for internal/external rotation between all three walking conditions. The most reasonable

explanation for this lack of effect, confounding the presupposed coupling under treatment between frontal and transverse rotations, is soft-tissue laxity within the subtalar and ankle joints. Equally, the integrity of supporting structures at the knee could also affect the coupling action but further work is required to understand more clearly the pathogenesis of this mechanism in RA. The construction of the rigid orthoses with medial wedge correction and forefoot balance behaved as expected, altering the angular relationship between the plantar surface of the foot and the floor to realign the joint towards its neutral position and reduce the joint moment (Bowker, 1993). However, soft-tissue laxity must be present, where stiffness was not a prominent feature, to allow adaptation of the AJC to the untreated deformed position. Therefore correction of the deformity in one plane in the presence of residual laxity does not permit translation of motion (leg rotation) about a second plane. This finding merits closer attention when the longitudinal data is analysed to see if adaptation and coupling occurs over time where joint function is restored. There are also implications for rehabilitation perhaps calling for physical therapy to complement early orthosis use. The amount of eversion correction brought about by the shoes and orthoses was not uniform over the stance phase period of the gait cycle. Importantly, the effect appeared to be greatest during loading response, as found by Nigg *et al.*, (1986) and terminal stance periods where, according to Stormont *et al.*, (1985) and others, the AJC is most vulnerable to becoming unstable because the articular surfaces are not fully loaded.

Modification of rearfoot pronation by foot orthoses has been well documented but the treatment effect has not always been significant. The literature is dominated by studies where subtalar joint pronation is manipulated with orthoses in otherwise healthy individuals, usually under running conditions or intervention studies in over-pronators, again related to running activities. These studies are useful in the sense that they have shown varied response; pronation reduced significantly in the case of some (Clarke *et al.*, 1983; Milani *et al.*, 1995; Nawoczenski *et al.*, 1995; Smith *et al.*, 1986; Taunton *et al.*, 1985) but not other (Nigg *et al.*, 1998; Rodgers *et al.*, 1982) studies. Orthotic response when positive appears also to be variable both in terms of magnitude and planar dominance for main effect and timing in the gait cycle (Nawoczenski *et al.*, 1995; Nigg *et al.*, 1988; Stacoff *et al.*, 2000). Some of these features have been demonstrated in this study but for the first time a significant orthotic effect has been demonstrated in RA and the findings are significant for clinical practice.

Data from Keenan *et al.*, (1991) and others, which show more advanced deformity with longer disease duration but with an apparently normal ROM, suggest that orthotic intervention may be successful at any stage of RA. Early intervention is still advocated because these studies contained small homogenous samples with limited evidence of the status of general joint structure and function in the foot. This study demonstrated loss of inversion/eversion ROM by 3

years and clinical experience suggest in advanced disease permanent joint changes do occur. Loss of flexibility often demands orthotic intervention with a three-point force device applied below and above the AJC, similar to an ankle-foot-orthosis of the type described by Abery and Harris (1983), and Hunt *et al.*, (1987).

5.5.4 Longitudinal kinematic data

The hypothesis that custom-designed foot orthoses significantly improve ankle joint complex kinematics and that the response is sustainable over the medium term is supported by the data presented. The initial changes in dorsi/plantarflexion angular rotation:time integral between barefoot and shod conditions for both RA groups and the age- and sex-matched normal population were maintained for the duration of the study. There was a statistically significant time effect but when examined closely the maximum difference amounted to an average change over the gait cycle of 1.2° between time periods and was therefore not considered clinically significant.

The most interesting change over time occurred for inversion/eversion movement. Statistical analyses found that the baseline differences between study groups and conditions were maintained for the duration of the study. There was also a significant time effect and on close inspection the mean angular rotation:time integrals decreased, denoting improved kinematics, in both groups under all conditions between baseline and 30-months. The magnitude of change was greater in the intervention group and, when averaged across the duration of the gait cycle, amounted to a mean change from baseline to 30-months of 3.5° for barefoot, 2.9° for shod and 1.5° for orthotic conditions. In the RA control group the changes were 1.5° for barefoot and 1.4° for shod conditions. The largest improvement was seen in the RA intervention group under barefoot conditions suggesting that orthotic improvement of AJC stability improves soft-tissue laxity. Examination of figure 5-11 (P.200) indicates that this effect takes up to 12-months to occur, with gradual improvement over time. Deterioration of AJC function over time in the untreated group might have been expected, but the inversion/eversion motion time integral improved over time, albeit with a smaller effect than that for the intervention group. This finding might challenge the 'repair' hypothesis above. However, a therapeutic footwear effect would not be totally unexpected if the patient's footwear matched that of the test shoes. Footwear advice was provided to all of these patients at the start of the trial but it was difficult to tell from 6 monthly reviews how effective this was.

If joint laxity was improved with orthotic control then coupling between frontal and transverse rotation might be re-established. The internal/external angular rotation:time integral for the RA

intervention group followed the same trend for inversion/eversion with improvement from baseline to 30-months. Averaged across the duration of the gait cycle the improvement amounted to a change from baseline to 30-months of 1.7° for barefoot and shod conditions and 2.2° for the orthotic condition, in comparison with 1.1° and 0.9° for barefoot and shod conditions respectively in the RA control group. These relatively small changes may be significant within the total amount of available motion in this direction. Qualitatively the angular rotation:time curve was closer to that of the age- and sex-matched normal population by the 30-month review period, although the important criteria of passing neutral into a period of external rotation was not fulfilled.

The hypothesis that ankle joint complex kinematics will change over the medium term if valgus heel deformity is left untreated is also supported by the data presented. The directionality of the effect was opposite to that expected and highlights the potential therapeutic nature of footwear alone where the physical construction of the shoe may reduce excessive joint rotations. Finally, the author was unable to find any published studies that have undertaken serial kinematic measurements to evaluate foot orthotics. The findings here suggest that custom-prescribed orthoses manufactured in rigid carbon graphite can reduce excessive rearfoot motion, especially eversion, and sustain that effect for the medium term. This mechanical restoration of normal AJC kinematics may provide the environment for soft-tissues to adapt and repair thereby reducing joint laxity and reduce the potentially harmful effects of valgus heel deformity on foot structure and function.

5.5.5 Proximal and distal joint kinematic data

The measurement of knee rotations other then flexion/extension may be affected by substantial errors when skin markers such as those for EMT are used (Lafortune *et al.*, 1992; Reinschmidt *et al.*, 1997b; Reinschmidt *et al.*, 1997c). Consequently the data collected for this joint were compared qualitatively between baseline and 30-months with an overall observation of possible trends for frontal and transverse plane rotations. Valgus heel and knee deformities regularly occur together in RA accompanied by knee flexion deformity and reduced ROM (Coomes, 1966; Kettelkamp *et al.*, 1972; Shields and Ward, 1966). Figure 5-13 demonstrates a loss of initial knee flexion during the loading response and from initial through to mid swing. Reduced flexion correlates significantly with the extent of knee pathology, pain, flexion contracture, valgus deformity and weakness in quadriceps muscle group, features found commonly in the early stages in a significant numbers of patients in this study (Kettelkamp *et al.*, 1972). Suggestions have been made that treatment of the foot may improve knee motion during gait and prevent or minimise deformity (Kettelkamp *et al.*, 1972; Keenan *et al.*, 1991; Stockley *et al.*, 1990).

Orthotic management appeared to increase the range of knee flexion but the effect was no greater than for shoes alone. Over the duration of the study knee flexion/extension did not change and the shoe and orthosis response was maintained.

Despite the recognised problems of measurement accuracy knee adduction/abduction was abnormal in both RA groups in comparison with normal. The range of motion was small for all conditions but excessive abduction was noted during pre- and initial swing phases during the period of maximum knee flexion. No differences were observed between barefoot, shod and orthosis walking conditions either at baseline or 30-months. The trends observed are interesting because increased abduction, although not pronounced in the early stages of disease may be associated with valgus knee deformity, which is associated with pronation of the rearfoot in RA. Furthermore footwear or orthoses appear to offer no correction of this excessive rotation. A small range of internal/external knee rotation was recorded for all study groups and appeared reduced slightly for both RA groups under all measurement conditions. The data suggest that overall the increased internal rotation at the AJC had not altered knee joint transverse rotation and at this stage of the disease the excessive foot movement may be resolved at the hip joint.

The ranges of motion about all three axes for the calcaneotalonavicular joint complex were small and highly variable. Skin movement of an EMT sensor over the navicular appeared vulnerable to substantial skin movement error, although this was not formally recorded for this study. Therefore overall trends suggest that the midtarsal joint, represented by this joint complex, may be plantarflexed, everted and externally rotated in RA under barefoot conditions in comparison with normal. With shoes and orthoses the motion changes direction to function around a more dorsiflexed position with improved rearfoot to forefoot plantarflexion during terminal stance. Inversion/eversion rotation was modified to function around a more inverted position with footwear, and with orthoses the movement was almost fixed around the neutral position for the entire stance period. Footwear and orthoses acted to increase the external rotation position of the joint within a very small range of active motion.

5.5.6 Conclusion

In summary, this study has offered some new insights into the development of rearfoot deformity in the early stages of RA. Eversion and internal rotation of the AJC characterise the deformity when kinematic data are compared alongside and age- and sex-matched normal population. The findings of the study support the early use of custom-designed orthoses with the effect sustainable for a period of 30-months. The devices have maximum effect on the reduction of eversion with a later effect on internal rotation when mechanical coupling is re-established as

joint laxity diminishes. In an untreated group, footwear may offer partial correction of the deformity but the effect is statistically less than when combined with orthoses. Surprisingly improvement of deformity may also occur in this group but with a reduced effect in comparison with the orthosis group. Changes in joint kinematics proximal and distal to the AJC have been described and may also be altered by foot orthotic control but limitations of accuracy within the methodology restrict exact quantification of these observations.

CHAPTER 6

PLANTAR PRESSURE MEASUREMENT AND ORTHOTIC EVALUATION IN RHEUMATOID ARTHRITIS

This chapter describes in-shoe plantar pressure and force measurement in rheumatoid arthritis. At baseline, measurements were undertaken in two RA study groups and an age- and sex-matched control population. A number of pressure and force variables were statistically analysed at discrete plantar regions of the foot and comparisons made between the study groups. Serial measurements were undertaken in the two RA groups up to 30-months and comparisons made between pressure and force distribution with and without foot orthoses.

6.1 Background and rationale

6.1.1 Plantar pressure measurement in rheumatoid arthritis

In RA, early studies concentrated on describing abnormal pressure distribution patterns associated with foot deformity, especially in the forefoot (Collis and Jayson, 1972; Godfrey *et al.*, 1967; Minns and Craxford, 1984; Sharma *et al.*, 1979; Simkin, 1981; Soames *et al.*, 1985). A number of studies have demonstrated an association between high medial forefoot pressures and valgus heel deformity (Stockley *et al.*, 1990; Woodburn and Helliwell, 1996). The use of PPM as an outcome tool in intervention studies has appeared in a number papers where pressure reduction and pain relief following forefoot reconstruction surgery have been described (Dereymaeker *et al.*, 1997; Betts *et al.*, 1988; Sammegard *et al.*, 1990).

Plantar pressure measuring (PPM) devices were originally developed as plate systems using a variety of measuring elements including capacitor, conductor and piezoceramic sensors. More recently, in-shoe measuring systems have provided a method to assess the pressure distribution at the interface between the foot and the shoe or the foot and an orthosis. Reports on orthotic intervention in RA using PPM are rare, and the studies that exist focus on relief of painful forefoot symptoms with various metatarsal insoles, pre-fabricated and custom designed orthoses (Hodge *et al.*, 1999; Veves *et al.*, 1992).

6.1.2 Rationale

This study provides the opportunity to undertake PPM assessment in the early stages of the disease and to compare pressure distribution patterns with age- and sex-matched controls. With a longitudinal design, this study will describe for the first time how foot pressure and force change over time. Finally, using an in-shoe PPM technique will allow quantification of the response to orthotic management in correctable valgus heel deformity.

6.2 Materials and methods

6.2.1 Equipment

Plantar pressure data were acquired using the PEDAR in-shoe system (Novel GmbH, Munich, Germany). The system consisted of a flexible insole, 2.6mm thick, constructed from a matrix of 99 capacitance sensors with an average sensor size of 25mm^2 (as squares in the central region and along straight edges of the insole). The insole is connected to a small A/D conversion electronics unit fixed to the patient's waist by a small belt, with communication to a PC via 8-metre cables. During gait each sensor within the insole matrix is simultaneously sampled at 50Hz over a 20 second data collection period. Calibration was undertaken using a manufacturer supplied calibration chamber consisting of an air bladder inflated by compressed air. Each insole is inserted into the chamber and pressure applied at discrete levels from 0-600kPa. A calibration curve for each sensor is then generated and stored for future comparison. Regular calibration of the pressure insoles was undertaken throughout the duration of this study. For the pressure range encountered clinically McPoil *et al.*, (1995) found errors under static testing of <5% (estimated from graphs). Both Kernozek *et al.*, (1996) and McPoil *et al.*, (1995) found intra-class correlation coefficients for within and between day repeatability testing in excess of 0.90.

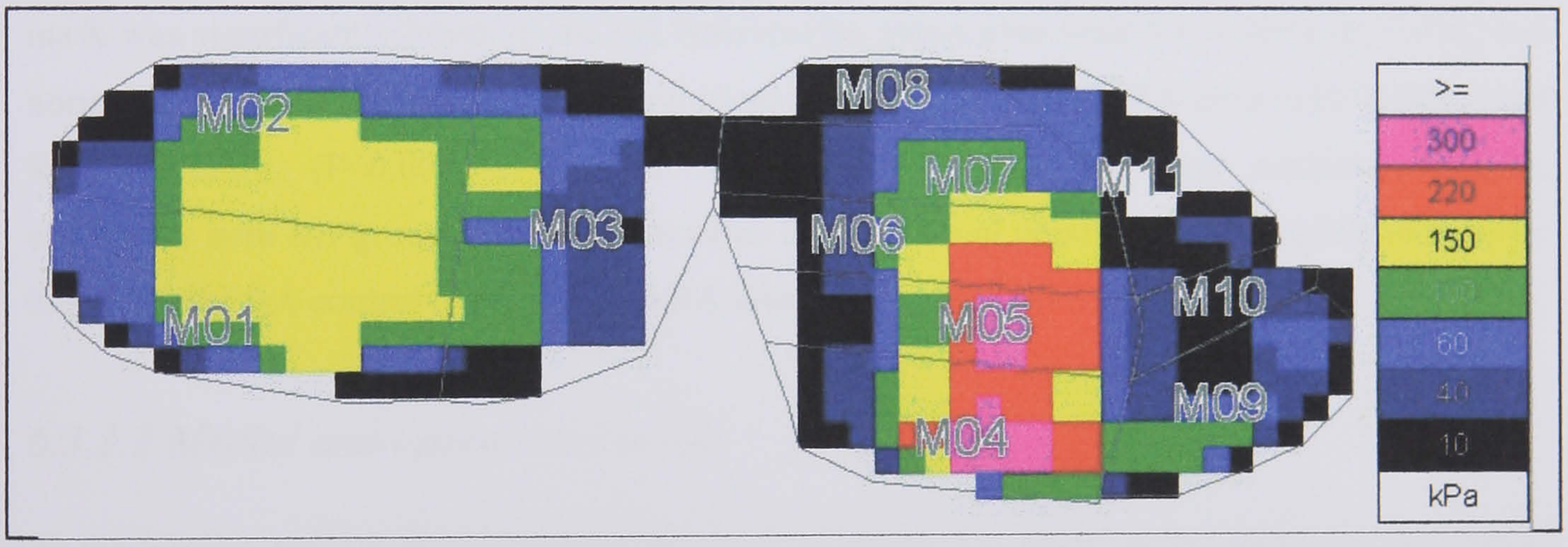
6.2.2 Plantar pressure acquisition

Plantar pressure measurement was conducted for all subjects using the standard test shoes as described in section 3.2.4.3. Two insoles, with size options, were carefully fitted to the shoes and connected to the system electronic unit, which was then attached to a waist belt. Cables between the electronics unit and the insoles were secured with Velcro straps at the ankle and mid thigh. Patients were given a short period to acclimatise to the protocol prior to data collection. During data capture patients were instructed to walk at their own pre-determined speed over an unmarked floor for a distance of 10 meters. Normal walking velocity was reached before data capture was started with a minimum of 5 left and right steps recorded.

6.2.3 Data analysis

In-shoe plantar pressure data were analysed using NOVEL-WIN, and NOVEL-ORTHO software. From the captured data, 5 left and right steps were extracted from the mid-portion of the walking sequence. Software driven automated procedures were used to create a single left and right averaged step and a series of 12 areas of interest (masks) on the plantar foot. These masks were defined for the full contact pressure map (TOT), the medial heel (MH), the lateral heel (LH), the midfoot (MF), 1^{st}-5^{th} metatarsal segments (MT1-5), the hallux (HLX), the 2^{nd} toe area (T2) and the 3^{rd}-5^{th} toe area (T3-5), see figure 6-1. For each mask peak pressure [PP] (kPa), pressure:time integral [PTI] (kPa.sec), peak force (PF) as a percentage body weight (%BW), force:time integral [FTI] (%BW.sec), contact area [CA] (cm^{-2}) and contact time [CT] as a percentage of the total contact time (%) were calculated. Data were available in ASCII format for storage and transfer for analysis using Microsoft Excel and SPSS software.

Figure 6-1: Automasks used to identify areas of interest on the plantar aspect of the foot



MO1- medial heel, MO2- lateral heel, MO3- midfoot, MO4-8- 1^{st} to 5^{th} metatarsals, MO9- hallux, MO10- 2^{nd} toe, MO11-3^{rd} to 5^{th} toes. Key represents pressure scale (kPa) .

At baseline, ANOVA techniques were used to compare six pressure/force variables between subject groups (normal shod, RA control shod, RA intervention shod) by site (MO1-MO11 and total mask). Where significant groups effects were seen post hoc analysis, Tukey's test was applied in pairwise comparisons of mean values. The baseline pressure/force response to the in-shoe orthosis in the RA intervention group was analysed using paired students t-test (2-tailed). Change in pressure/force variables from baseline to 3, 6, 12, 18, 24 and 30-months at each plantar mask was calculated for each subject. Response:time curves were generated and a single summary variable- the area under the curve (AUC) using the trapezium rule- calculated (Matthews *et al*., 1990). At each time point a mean (SD) AUC was derived for the RA control (shod) and RA intervention (orthosis) groups for all variables at each plantar mask. Derivation of a single summary measure permitted between group comparisons using students t-test with the

intention-to-treat principle applied. For all statistical analyses the levels of statistical significance was set at $P<0.05$.

6.3 Results

6.3.1 Baseline plantar pressure and forces

The baseline data for the normal population and both RA groups under the shod walking conditions are summarised in table 6-1.

6.3.1.1 Total mask

For the total mask there was no statistically significant difference for peak pressure. Mean PTI values were similar for both RA groups, but the RA control ($P<0.0001$) and RA intervention ($P=0.047$) mean values were significantly lower than control. The mean peak force in the total mask was significantly lower in the RA intervention group over both RA control ($P=0.020$) and normal ($P=0.024$). The mean FTI was significantly greater in both the RA control ($P<0.0001$) and RA intervention ($P=0.001$) over the normal population mean. The mean contact areas were similar for both RA groups but the mean value for the normal population was significantly lower than both the RA control ($P=0.001$) and RA intervention ($P<0.0001$) groups.

6.3.1.2 Medial and lateral heel masks

At the medial and lateral heel masks the peak pressure was significantly higher in the normal population in comparison with RA control ($P<0.0001$) and RA intervention ($P<0.0001$). Furthermore at the medial heel mask the mean peak pressure was significantly higher in the RA control group over RA intervention ($P=0.015$). The mean PTI at the medial heel mask was statistically significantly higher in the RA control group over RA intervention ($P=0.034$) and normal population ($P=0.012$). At the lateral heel mask the mean PTI was again highest in the RA control group but only reaching statistically significant level of difference in comparison with normal population mean value ($P=0.04$). The peak force was higher in the normal population in comparison with both RA groups for both heel masks, reaching statistical significance in post-hoc analysis with the RA intervention group only ($P<0.0001$) for the medial mask and the RA intervention ($P=0.02$) and control ($P<0.0001$) groups for the lateral mask. The mean FTI was lower in the normal population in comparison with both RA groups for both heel masks, but only statistically significant in the case of normal versus RA control ($P=0.01$) group for the medial heel mask. There were no statistically significant between-groups differences in contact areas for

Table 6-1: Mean (SD) of pressure/force variables for plantar masks for normal population (NORM), RA control (RA-Con) and RA intervention (RA-Int) groups.

NORM	MASK					
Variable	TOT	MH	LH	MF	MT1	MT2
PP	363 (108)	247 (50)	253 (51)	89 (43)	255 (102)	254 (84)
PTI	138 (25)	66 (19)	68 (21)	29 (16)	61 (25)	65 (25)
PF	94 (13)	37 (8.4)	38 (8.1)	9.0 (5.3)	20 (7.1)	17 (4.0)
FTI	45 (11)	9.5 (3.1)	10 (3.6)	2.6 (1.9)	4.7 (1.9)	4.1 (1.4)
CA	135 (17)	23 (3.2)	23 (3.3)	16 (6.3)	12 (2.3)	10 (1.7)
CT	100 (0)	70 (14)	72 (14)	67 (17)	71 (15)	74 (16)
Variable	MT3	MT4	MT5	HLX	T2	T3-5
PP	239 (84)	193 (65)	115 (55)	302 (133)	118 (49)	122 (46)
PTI	63 (25)	54 (21)	35 (19)	64 (31)	25 (12)	34 (16)
PF	16 (4.5)	11 (3.8)	5.3 (3.0)	18 (9.0)	3.8 (2.6)	8.0 (4.0)
FTI	4.1 (1.7)	3.1 (1.5)	1.5 (1.0)	3.4 (1.9)	0.7 (0.6)	1.7 (0.9)
CA	10 (1.6)	9.6 (2.0)	6.5 (1.8)	11 (2.7)	4.8 (2.6)	12 (3.3)
CT	77 (15)	78 (14)	75 (16)	71 (18)	55 (19)	70 (17)
RA-Con	MASK					
Variable	TOT	MH	LH	MF	MT1	MT2
PP	354 (115)	216 (65)	214 (60)	82 (36)	268 (137)	249 (119)
PTI	164 (59)	77 (27)	79 (26)	37 (21)	86 (44)	81 (37)
PF	96 (19)	34 (10)	34 (9)	10 (5.1)	20 (10)	15 (5.9)
FTI	56 (15)	12 (4.2)	12 (4.4)	3.8 (2.6)	6.4 (3.4)	4.9 (2.1)
CA	147 (21)	23 (4.8)	23 (4.2)	19 (5.8)	12 (2.4)	9.9 (1.9)
CT	100 (0)	80 (15)	84 (12)	78 (13)	86 (9.4)	88 (8.7)
Variable	MT3	MT4	MT5	HLX	T2	T3-5
PP	213 (99)	160 (65)	112 (57)	234 (120)	95 (49)	91 (41)
PTI	69 (31)	57 (23)	43 (24)	74 (48)	28 (18)	32 (18)
PF	14 (5.9)	10 (4.8)	5.4 (3.2)	14 (8)	3.2 (1.7)	5.6 (3.1)
FTI	4.5 (2.2)	3.7 (2.0)	2.0 (1.3)	3.9 (3.2)	0.8 (0.5)	1.6 (1.1)
CA	9.9 (2.7)	9.3 (2.5)	6.5 (1.8)	10 (2.8)	5.5 (1.7)	12 (4)
CT	85 (12)	84 (12)	82 (9.5)	80 (18)	68 (20)	78 (16)
RA-Int	MASK					
Variable	TOT	MH	LH	MF	MT1	MT2
PP	338 (132)	195 (58)	193 (59)	84 (44)	238 (125)	227 (113)
PTI	152 (43)	69 (24)	70 (24)	37 (23)	79 (42)	77 (38)
PF	88 (18)	32 (11)	31 (10)	10 (7.8)	17 (7.9)	14 (5.5)
FTI	52 (14)	11 (4.4)	11 (4.1)	3.9 (3.4)	5.3 (2.8)	4.5 (2.2)
CA	150 (27)	24 (4.9)	24 (4.6)	21 (8.7)	12.1 (2.4)	10 (2.1)
CT	100 (0)	82 (12)	84 (12)	79 (16)	87.1 (10)	89 (9.3)
Variable	MT3	MT4	MT5	HLX	T2	T3-5
PP	214 (129)	163 (88)	111 (70)	215 (138)	102 (53)	89 (38)
PTI	74 (41)	61 (30)	44 (27)	67 (44)	32 (21)	32 (17)
PF	13 (5.7)	10 (4.6)	5.0 (3.0)	12 (8.6)	3.7 (2.4)	6.0 (3.6)
FTI	4.6 (2.4)	3.8 (1.8)	1.8 (1.1)	3.3 (2.4)	1.0 (0.8)	1.8 (1.4)
CA	11 (2.3)	10 (2.2)	6.9 (1.7)	9.7 (3.1)	5.7 (1.8)	13 (4.9)
CT	88 (8.1)	89 (7.6)	83 (10)	81 (15)	76 (17)	78 (17)

PP= Peak pressure, PTI= Pressure:time integral, PF= peak force, FTI= Force:time integral, CA= Contact area, CT= Contact time. TOT= Total contact area, MH= Medial heel, LH= Lateral heel, MF= Midfoot, MT1-MT5= Metatarsals 1-5, HLX= Hallux, T2= 2nd toe, T3-5= Toes 3-5. Units for each variable as defined in 6.2.3.

both the medial and lateral heel mask. The contact time was longer in both RA groups at both heel masks over normal population mean value reaching statistical significance in both cases (P<0.0001 normal versus RA control lateral and medial masks, and P=0.03 medial and P<0.0001 lateral masks normal versus RA intervention).

6.3.1.3 Midfoot mask

There was no significant difference in the mean peak pressures or peak forces between all groups in the midfoot mask. The mean PTI values were higher in both RA groups over normal reaching statistically significant levels for RA control versus normal (P=0.027) and RA intervention versus normal (P=0.015). The FTI was higher in both RA groups over normal, but statistically significant on post-hoc comparison between normal and RA intervention (P=0.018). The mean contact area was larger in both RA groups in comparison with normal values (normal versus RA control P=0.016, normal versus RA intervention P<0.0001). Significant differences were found between normal and RA control (P<0.0001) and RA intervention (P<0.0001) for contact time in the midfoot mask, the duration being longer in both RA groups over normal values.

6.3.1.4 Metatarsal masks

A medial central (1=2>3>4>5) pressure distribution was found across the metatarsal heads in the normal population whilst both RA groups showed a medial distribution (1>2>3>4>5). However there was no significant between group differences for mean peak pressures at metatarsal sites 1,2,3 and 5. At metatarsal 4 the normal group peak pressure was significantly higher in comparison with RA control (P=0.02) and RA intervention (P=0.039). At the 1st metatarsal the mean PTI was significantly higher in the RA control group over normal (P<0.0001) and RA intervention over normal (P=0.009). At the 2nd metatarsal the same trend was observed but differences in mean PTI were found between RA control over normal (P=0.021). Peak force recorded at metatarsals 1, 3 and 5 were similar between the 3 study groups with no statistically significant differences between mean values. At the 2nd and 3rd metatarsals the peak force was higher in the normal groups over both RA groups reaching statistical significance at both sites in normal over RA intervention (P=0.007 2nd metatarsal, P=0.017 3rd metatarsal). The FTI was higher in both RA groups over normal mean values at the 1st metatarsal head reaching statistical significance in post-hoc testing between normal and RA intervention group (P=0.001). For the remainder of the metatarsals there were no statistically significant between group differences in mean FTI values. Across all metatarsal heads the contact area was the same between all 3 groups with no statistically significant group effect in the ANOVA. In both RA groups all 5 metatarsals were in contact with the shoe for significantly longer periods in the gait cycle in comparison with

normal. Post hoc testing found differences, with a level of significance of P<0.0001, between RA control and normal and RA intervention and normal for the 1st and 2nd metatarsals. At the 3rd metatarsal P=0.007 RA control versus normal and P<0.0001 RA intervention versus normal. At the 4th metatarsal statistically significant differences were found only between normal and RA intervention (P<0.00001). At the 5th metatarsal both the RA control group (P=0.04) and the RA intervention (P=0.003) contact times were statistically significantly longer than control.

6.3.1.5 Hallux and lesser toe masks

The mean peak pressures were higher in the normal population over both RA groups at the hallux and the 2nd toe masks. In post-hoc analysis significance levels of P=0.003 and P<0.0001 were reached for normal versus RA control and normal versus RA intervention groups respectively for the hallux. At the 2nd toe statistical significance was reached when normal mean was tested against RA control group only (P=0.043). At the mask incorporating the 3rd-5th toes the peak pressures were higher in both RA groups over normal mean values reaching a significance level of P<0.0001 in both pairwise comparisons under statistical analysis. The cumulative pressure effect measured with the PTI was the same for all groups at the hallux, 2nd toe and 3rd to 5th toe mask with no statistically significant group effect under ANOVA. The peak force recorded at the hallux was higher, and statistically significantly different, in normal population in comparison with RA control (P=0.012) and RA intervention group (P<0.0001). At the 2nd toe mask there was the mean PF recorded for all 3 groups were similar with no statistically significant group effect. At the 3rd-5th toe mask peak force was higher in normal population in comparison with, and reaching statistical significance under post-hoc testing, RA control (P=0.001) and RA intervention (P=0.015) groups. There was no statistically significant group effect at the hallux and 3rd-5th toe mask for the FTI, however, at the 2nd toe mask a statistically significant group effect was observed with the FTI higher in the RA intervention group in comparison with normal (p=0.025) under post-hoc testing. The contact areas showed no group effect under ANOVA for the hallux and 3rd-5th toe masks. At the 2nd toe mask the contact area for the RA control (P=0.026) and RA intervention (P=0.004) groups were significantly larger than the normal population mean. The trend towards longer contact times in the RA groups in comparison with normal values was also observed for the hallux, 2nd toe and 3rd-5th toe masks, with significant group effects under ANOVA. At the hallux post-hoc testing found differences between RA control (P=0.026) and RA intervention (P=0.015) over normal mean values. At the 2nd toe mask pairwise comparisons, with a significance level of P<0.0001 were found for RA control versus normal and RA intervention versus normal. At the 3rd-5th toe mask pairwise comparisons, with a significance level of P<0.005 and P=0.001 were found for RA control versus normal and RA intervention versus normal respectively.

6.3.2 Baseline orthotic intervention

The baseline pressure and force variables for the intervention group under orthosis walking conditions are summarised in Table 6-2. Against shod walking conditions the introduction of a custom-designed orthosis had most impact on the pressure/force variables at the heel and midfoot. In the total mask orthoses reduced the mean PP and PTI, increased PF with no change in FTI and increased the total contact area. However, statistical significance was only reached with PTI (P=0.0002). At the medial and lateral heel masks peak pressure was significantly reduced with orthoses over shod walking (P<0.0001 for both heel masks). The mean PTI at both heel masks was also reduced in comparison with shod conditions reaching statistical significance in both cases (P<0.0001). The PF recorded at both masks was reduced significantly from shod to orthosis walking conditions (P<0.0001 medial heel mask, P=0.013 lateral heel mask). The FTI was reduced also with orthoses, the difference in mean values reaching statistical significance (P=0.019 medial heel, P=0.044 lateral heel). In the midfoot mean PF, FTI, and contact area was increased with the use of orthoses and the difference in comparison with shod condition was statistically significant for all variable (P=0.005 PF, P=0.001 FTI and P<0.0001 contact area).

Table 6-2: Mean (SD) of pressure/force variables for plantar masks for RA intervention group (orthosis)

	MASK					
Variable	**TOT**	**MH**	**LH**	**MF**	**MT1**	**MT2**
PP	302 (121)	144 (45)	147 (47)	78 (29)	211 (103)	206 (100)
PTI	129 (44)	55 (22)	54 (21)	37 (16)	68 (34)	70 (35)
PF	91 (18)	26 (9.2)	27 (10)	14 (7.4)	16 (8.3)	14 (5.6)
FTI	52 (14)	9.1 (3.8)	9.3 (4.0)	5.8 (3.8)	4.8 (2.6)	4.5 (2.0)
CA	157 (28)	24 (5.2)	23 (5.7)	28 (9.2)	12.3 (2.7)	10 (2.3)
CT	100 (0)	84 (14)	83 (14)	84 (13)	86 (12)	90 (10)
	MASK					
Variable	**MT3**	**MT4**	**MT5**	**HLX**	**T2**	**T3-5**
PP	190 (101)	155 (74)	104 (50)	218 (136)	112 (57)	104 (46)
PTI	67 (36)	60 (32)	44 (24)	66 (46)	34 (19)	39 (18)
PF	13 (5.7)	9.6 (4.2)	4.7 (2.5)	14 (9.3)	4.3 (2.7)	6.6 (4.0)
FTI	4.4 (2.3)	3.7 (2.1)	1.9 (1.2)	3.8 (3.0)	1.1 (0.8)	1.9 (1.3)
CA	10 (2.9)	9.0 (2.4)	6.3 (1.8)	9.6 (3.7)	5.5 (1.6)	11 (3.7)
CT	87 (9.6)	87 (10)	82 (13)	78 (21)	76 (19)	83 (13)

PP= Peak pressure, PTI= Pressure:time integral, PF= peak force, FTI= Force:time integral, CA= Contact area, CT= Contact time. TOT= Total contact area, MH= Medial heel, LH= Lateral heel, MF= Midfoot, MT1-MT5= Metatarsals 1-5, HLX= Hallux, T2= 2nd toe, T3-5= Toes 3-5. Units for each variable as defined in 6.2.3.

In the forefoot the PP decreased across all metatarsal masks whilst the PTI decreased medially across metatarsal 1-3 with orthoses. No change in PF, FTI, CA or CT was observed and under statistical analysis there were no statistically significant differences for any of the pressure/force variables at any of the 3 masks. At the hallux and lesser toe masks some differences in mean values between shod and orthosis walking conditions were observed but overall there were was no statistically significant differences for any of the pressure/force variables.

6.3.3 Longitudinal data analysis

6.3.3.1 Peak pressure area under the curve analysis

Area under the curve analysis revealed statistically significant groups differences for peak pressure over the duration of the study at the medial and lateral heel and 3rd-5th toe masks (table 6-3). At the medial heel mask the intervention group recorded a large negative integrals, indicating net reduction of pressure over time, whilst the control group showed no change over time. A similar trend was observed for the lateral heel mask except that peak pressure increased over time in the control group. At the 3rd-5th mask both the intervention and control groups had positive integrals but the mean value was significantly greater in the intervention group over control.

6.3.3.2 Pressure:time integral area under the curve analysis

There were no statistically significant differences between the mean AUC for the pressure:time integral at all plantar masks (table 6-4).

Table 6-3: Area under the curve summary data for peak pressure

	Group	Mean	SD	P-value	Mean Difference	95% Confidence Interval of the Difference	
						Lower	Upper
TOT	Int	-167.4	3194.5	0.468	-309.2	-1151.0	531.1
	Con	142.5	2770.7				
MH	Int	-843.8	1417.8	<0.0001	-845.6	-1245.3	-445.0
	Con	1.8	1423.8				
LH	Int	-722.6	1276.2	<0.0001	-823.2	-1202.8	-444.5
	Con	100.6	1406.5				
MF	Int	139.4	902.4	0.497	-79.0	-311.1	151.9
	Con	219.2	734.6				
MT1	Int	-261.6	2586.7	0.769	-111.3	-857.6	634.9
	Con	-150.2	2703.1				
MT2	Int	35.6	2541.3	0.594	202.2	-545.3	951.3
	Con	-167.3	2760.3				
MT3	Int	27.8	2567.5	0.747	-105.9	-751.2	540.5
	Con	133.4	1991.1				
MT4	Int	535.5	1816.1	0.081	409.6	-50.7	869.8
	Con	125.9	1433.2				
MT5	Int	306.8	1502.7	0.385	162.1	-204.6	529.4
	Con	144.6	1074.6				
HLX	Int	620.3	2947.1	0.203	481.4	-262.5	1225.4
	Con	138.8	2303.7				
T2	Int	-60.9	1440.3	0.794	-50.3	-431.0	330.2
	Con	-10.4	1261.4				
T3-5	Int	575.1	1269.7	0.013	420.6	88.1	753.7
	Con	154.3	1087.2				

TOT= Total contact area, MH= Medial heel, LH= Lateral heel, MF= Midfoot, MT1-MT5= Metatarsals 1-5, HLX= Hallux, T2= 2nd toe, T3-5= Toes 3-5. Peak pressure units are kPa.

6.3.3.3 Peak force area under the curve analysis

For the total mask the area under the curve indicated an increase in PF for both control and intervention groups but the response was significantly larger in the intervention group (table 6-5). The same effect was seen for both the medial and lateral heel masks but a statistically significant difference was found between intervention and control groups for the medial heel mask only. There was a small increase in peak force over time at the midfoot for the intervention group with the same but larger effect in the control group, the difference not reaching statistical significant. The three lateral metatarsals showed increased PF over time against the same but much smaller effect in the control group, significant levels of statistical difference reached in all three cases. At the 2nd toe mask both groups showed a decrease in peak force over time the response larger and statistically significantly different in the intervention group over control.

Table 6-4: Area under the curve summary data for pressure:time integral variable

	Group	Mean	SD	P-value	Mean Difference	95% Confidence Interval of the Difference	
						Lower	Upper
TOT	Int	-54.6	1104.1	0.172	212.2	-93.7	517.6
	Con	-266.8	1062.4				
MH	Int	44.1	516.5	0.118	112.8	-28.2	253.2
	Con	-68.5	486.3				
LH	Int	41.1	441.2	0.099	114.6	-21.4	249.4
	Con	-72.9	515.8				
MF	Int	32.3	351.9	0.839	10.7	-93.0	114.4
	Con	21.6	385.6				
MT1	Int	1.3	732.7	0.126	175.0	-49.0	401.7
	Con	-174.6	862.0				
MT2	Int	3.8	807.2	0.096	196.0	-35.9	428.0
	Con	-192.8	836.8				
MT3	Int	7.1	792.6	0.351	95.1	-105.8	296.3
	Con	-88.2	629.6				
MT4	Int	46.2	733.5	0.332	88.9	-90.6	267.8
	Con	-42.0	524.1				
MT5	Int	16.1	588.2	0.487	54.5	-100.7	210.8
	Con	-38.9	514.4				
HLX	Int	-66.6	1003.9	0.592	78.3	-210.5	368.3
	Con	-145.4	1047.3				
T2	Int	-182.3	491.1	0.094	-115.3	-250.3	19.4
	Con	-66.9	467.4				
T3-5	Int	-29.5	500.9	0.867	-11.7	-144.1	121.1
	Con	-18.2	443.3				

TOT= Total contact area, MH= Medial heel, LH= Lateral heel, MF= Midfoot, MT1-MT5= Metatarsals 1-5, HLX= Hallux, T2= 2nd toe, T3-5= Toes 3-5. Pressure:time integral units are kPa.sec.

Table 6-5: Area under the curve summary data for peak force variable

	Group	Mean	SD	P-value	Mean Difference	95% Confidence Interval of the Difference	
						Lower	Upper
TOT	Int	191.1	491.7	0.014	171	34	307
	Con	19.8	476.8				
MH	Int	116.0	199.6	0.001	96	38	154
	Con	19.6	210.4				
LH	Int	116.4	231.2	0.059	61	-2	125
	Con	55.1	221.7				
MF	Int	9.6	139.7	0.127	-27	-62	7.8
	Con	36.8	107.8				
MT1	Int	19.7	181.8	0.051	56	-0.2	113
	Con	-36.8	218.2				
MT2	Int	21.8	133.6	0.117	31	-7.9	70
	Con	-9.6	145.1				
MT3	Int	51.2	141.9	0.045	37	0.7	74
	Con	13.4	119.9				
MT4	Int	56.6	116.8	0.014	38	7.8	69
	Con	17.8	101.9				
MT5	Int	33.0	72.2	0.034	20	1.5	40
	Con	12.0	65.4				
HLX	Int	14.3	189.0	0.279	25	-20	72
	Con	-11.4	139.9				
T2	Int	-24.3	59.4	0.026	-16	-30	-1.9
	Con	-8.1	39.4				
T3-5	Int	-.3	90.1	0.874	1.3	-20	24
	Con	-2.1	67.5				

TOT= Total contact area, MH= Medial heel, LH= Lateral heel, MF= Midfoot, MT1-MT5= Metatarsals 1-5, HLX= Hallux, T2= 2nd toe, T3-5= Toes 3-5. Peak force units are %BW.

6.3.3.4 Force:time integral area under the curve analysis

The mean AUC for the FTI by mask are summarised in table 6-6. The FTI increased over time for the RA intervention group with orthosis in comparison with a net decrease for the RA control group (P=0.036). In the midfoot the AUC showed a decrease in FTI for orthosis intervention against a small increase for RA control (P=0.012). At the 1st metatarsal the AUC there was a small negative mean AUC for the RA orthosis intervention group against a larger negative mean AUC for RA control.

Table 6-6: Area under the curve summary data for force:time integral variable

	Group	Mean	SD	P-value	Mean Difference	95% Confidence Interval of the Difference	
						Lower	Upper
TOT	Int	-1.3	430.6	0.223	68.2	-41.2	178.5
	Con	-69.6	348.0				
MH	Int	18.8	87.6	0.036	26.3	1.8	51.1
	Con	-8.1	90.3				
LH	Int	18.1	97.0	0.248	16.1	-11.2	44.1
	Con	1.6	102.7				
MF	Int	-16.2	84.0	0.012	-24.6	-44.5	-5.4
	Con	8.7	49.7				
MT1	Int	-2.9	57.9	0.019	21.4	3.5	39.4
	Con	-24.4	68.8				
MT2	Int	-1.7	54.3	0.160	9.9	-3.9	23.8
	Con	-11.6	44.1				
MT3	Int	4.6	59.7	0.210	9.3	-5.2	23.3
	Con	-4.7	43.1				
MT4	Int	8.2	55.3	0.287	7.6	-6.5	21.3
	Con	.5	45.2				
MT5	Int	4.5	34.7	0.490	3.2	-5.9	12.3
	Con	1.3	30.5				
HLX	Int	-7.0	62.7	0.488	5.5	-10.6	21.1
	Con	-12.6	49.7				
T2	Int	-8.4	17.5	0.066	-3.9	-8.1	0.2
	Con	-4.5	11.8				
T3-5	Int	-3.9	33.9	0.717	-1.5	-10.2	6.9
	Con	-2.4	26.0				

TOT= Total contact area, MH= Medial heel, LH= Lateral heel, MF= Midfoot, MT1-MT5= Metatarsals 1-5, HLX= Hallux, T2= 2nd toe, T3-5= Toes 3-5. Force:time integral units %BW.sec.

6.3.3.5 Area of contact area under the curve analysis

The mean contact area under AUC analysis increased over time at the total mask for the intervention group against an overall decrease for the RA control group (P=0.043), table 6-7. At the midfoot the contact area in the RA orthosis intervention group increased over time, as did the RA control group, but with a smaller mean AUC (P=0.002). At the 2nd metatarsal mask the orthosis intervention group showed an overall increase in the contact area over time, as did the control group but the response was significantly greater in the orthosis group (P=0.006). At the 4th metatarsal there was a small increase in contact area for the orthosis intervention group against a much larger increase for the control group (P=0.003).

Table 6-7: Area under the curve summary data for contact area variable

	Group	Mean	SD	P-value	Mean Difference	95% Confidence Interval of the Difference	
						Lower	Upper
TOT	Int	118.0	518.3	0.043	134.2	3.9	264.3
	Con	-16.2	400.5				
MH	Int	14.9	115.7	0.996	0.06	-28.1	28.8
	Con	14.8	84.0				
LH	Int	-12.6	119.5	0.068	-27.3	-57.2	2.1
	Con	14.9	89.1				
MF	Int	91.1	216.3	0.002	80.7	29.2	131.6
	Con	10.8	139.4				
MT1	Int	10.4	63.0	0.468	6.1	-10.4	22.3
	Con	4.2	55.9				
MT2	Int	22.7	58.7	0.006	21.6	6.0	35.3
	Con	1.8	46.7				
MT3	Int	18.9	65.2	0.113	-14.1	-33.5	3.5
	Con	33.9	66.7				
MT4	Int	2.2	62.5	0.003	-26.3	-43.9	-8.9
	Con	28.7	61.8				
MT5	Int	5.2	51.1	0.283	-7.4	-21.3	6.2
	Con	12.6	46.1				
HLX	Int	-1.3	77.9	0.758	3.5	-19.1	26.1
	Con	-4.9	82.3				
T2	Int	-30.8	56.4	0.615	3.7	-10.9	18.0
	Con	-34.6	48.1				
T3-5	Int	-60.0	112.4	0.711	5.3	-23.0	33.1
	Con	-65.4	89.4				

TOT= Total contact area, MH= Medial heel, LH= Lateral heel, MF= Midfoot, MT1-MT5= Metatarsals 1-5, HLX= Hallux, T2= 2nd toe, T3-5= Toes 3-5. Contact are units are cm^{-2}.

6.3.3.6 Contact time under the curve analysis

The AUC data for the contact time by mask are summarised in table 6-8. Analysis of mean AUC from baseline to 30-months between RA orthosis intervention and RA control groups did not detect any statistically significant differences between at any plantar mask.

Table 6-8: Area under the curve summary data for contact time variable

	Group	Mean	SD	P-value	Mean Difference	95% Confidence Interval of the Difference	
						Lower	Upper
TOT	Int	-	-	-	-	-	-
	Con	-	-				
MH	Int	-81.1	429.5	0.287	-60.2	-170.7	50.1
	Con	-21.1	354.4				
LH	Int	-45.5	409.2	0.993	-0.4	-106.4	105.3
	Con	-45.0	338.7				
MF	Int	-48.1	336.2	0.301	-51.6	-149.5	46.1
	Con	3.4	358.4				
MT1	Int	1.9	305.0	0.426	31.4	-46.5	109.0
	Con	-29.7	248.4				
MT2	Int	-30.9	307.9	0.969	1.5	-77.3	81.5
	Con	-32.4	254.7				
MT3	Int	10.8	282.2	0.259	45.4	-33.9	123.7
	Con	-34.4	276.5				
MT4	Int	22.9	312.4	0.686	17.6	-67.1	101.1
	Con	5.5	288.3				
MT5	Int	28.4	384.2	0.307	47.8	-43.1	138.1
	Con	-19.0	251.0				
HLX	Int	31.9	513.8	0.352	65.1	-73.8	204.3
	Con	-33.7	471.1				
T2	Int	-179.4	616.9	0.292	-94.0	-272.3	82.3
	Con	-84.5	640.8				
T3-5	Int	-73.8	464.9	0.719	22.1	-102.3	148.0
	Con	-96.7	422.8				

TOT= Total contact area, MH= Medial heel, LH= Lateral heel, MF= Midfoot, MT1-MT5= Metatarsals 1-5, HLX= Hallux, T2= 2nd toe, T3-5= Toes 3-5. Contact time units are % of contact time.

6.4 Discussion

6.4.1 Baseline plantar pressure/force distribution

The results of the baseline study confirmed some general observations of foot function in RA, in particular plantar/force pressure distribution. In RA local foot deformity may account for some of the observed differences from normal limits at specific anatomical sites identified by the smaller heel, midfoot, forefoot and toe masks. Pronated foot-types on the whole are associated with medially displaced pressure/force distribution (McPoil and Cornwall, 1992; Rosenbaum *et al.*, 1994). More general changes, especially the temporal component of the pressure/force distribution are attributed to changes in overall gait style related to joint pain, loss of function and disability of the lower limb and feet. However, the interaction between these factors is complex and can be demonstrated with peak force within the total mask, which was significantly lower in

the RA intervention group compared with RA control and normal group. The most reasonable explanation may be related to overall gait style as the intervention group had more foot pain and disability and generally higher disease activity than the RA control at baseline, a factor that could not be controlled for because of the random allocation of patients to respective groups.

The mean contact times in stance were calculated retrospectively and averaged 0.86 seconds for both RA groups combined in comparison with 0.70 seconds for the normal population. Although peak forces may be similar or less in the RA groups, cumulative load measured by the force:time integral was significantly higher in both RA groups over normal values. Both RA groups had significantly larger, between 12-15cm^2, plantar weightbearing surfaces. A feature of valgus heel deformity is pes plano-valgus deformity with associated medial longitudinal arch depression, therefore, it was not surprising to see this effect and indeed a large component of the increase was identified in the midfoot mask. The contact times in all masks in both RA groups were significantly longer than normal limits, which are indicative of loss of normal heel-to-toe progression, and confirm the observations of Betts *et al.*, (1988); Simkin (1981) and Soames *et al.*, (1985).

The contact time within specific masks was also important when peak pressure and force were compared with total loading from the time integrals of both these variables. There was no difference for heel contact area between the study groups. Therefore higher peak force meant also higher peak pressure at the heel masks in the normal population then in both RA groups. However contact times in the heel masks were significantly longer in both RA groups over normal population limits and as consequence the pressure and time integrals were higher in the RA groups than normal, but not always reaching statistical levels of significance. In the important midfoot region peak pressure and forces were not statistically different between groups but again both integrals of these variables were higher in the RA groups over control. The contact area and weightbearing contact time in the midfoot region were both higher in the RA groups than in the normal group. These mechanisms may represent a form of body defence in response to painful stimuli generated internally in the form of joint inflammation, and externally from footwear compression on inflamed and deformed joints. Slower walking speeds must contribute to a reduction in peak forces and pressure, especially during the loading response and in terminal stance where these observed changes have the greatest effect, and the increased weightbearing surfaces may distribute the load over a larger area.

In the forefoot the weightbearing contact area was the same in all study groups across all 5 metatarsal regions, but the contact times were consistently longer in both RA groups than in the normal group. The forefoot loading pattern by peak pressure measurement was shifted medially

in both RA groups. Coincidentally, peak pressures were higher in the lateral three metatarsal regions in the normal population over both RA groups. Peak force were higher on the 1st metatarsal region relative to the central metatarsal regions in both RA groups over control and total loading was also dominant on the medial aspect with PTI and FTI values higher in both RA groups over normal population limits. Medially and laterally dominant forefoot loading patterns have been described in RA (Collis and Jayson, 1972; Minns and Craxford, 1984; Sharma *et al.*, 1979; Soames *et al.*, 1985). However, studies that specifically measured the pattern in relationship to valgus heel deformity, found medial dominance in agreement with the findings here (Stockley *et al.*, 1990; Woodburn and Helliwell, 1996).

At the hallux and lesser toe regions some changes were observed in peak force and pressure values, contact times were longer in RA and only at the 2nd toe mask was the contact area larger in the RA groups in comparison with normal values. There was no difference in PTI between groups for all toe sites but an increase at the 2nd toe region in FTI in one of the RA groups over normal. These findings suggest that toe-deformities were not well established for the RA population in comparison with normal. Other studies have demonstrated, in more advanced disease states, significant reduction in toe loading associated with well-developed triggered hallux, clawed and hammered toe deformity (Sharma *et al.*, 1979; Simkin, 1981; Soames *et al.*, 1985). However, the measurements may have been affected, especially at the 2nd toe, by poor resolution of the sensors in the in-shoe system.

6.4.2 Baseline orthotic intervention

In the RA intervention group the custom-designed orthoses caused significant changes in the pressure/force loading with the greatest impact at the heel and midfoot regions. The orthoses were constructed to individual plaster models modified to incorporate the correction element whilst retaining the plantar topography and this is reflected in the increase in contact area in the midfoot by $7cm^2$. Peak pressures were reduced by 26% and 24% at the medial and lateral heel masks respectively and, because contact time was not affected, this had a significant impact on total loading as the PTI was also reduced by 20% and 23% for these regions. Peak force was reduced by 19% and 13% and the FTI by 17% and 15% respectively for the medial and lateral heel masks. The orthosis design created a new artificial weightbearing surface in the midfoot region medially which served to redistribute load and both the PF and FTI were increased by 29% and 33% respectively from the shod walking condition. The magnitude of some variables was changed but there was no strong evidence to suggest that the loading pattern was significantly altered in the forefoot by the orthoses. The peak force in the total mask was

increased overall, which suggests that patients walked a little faster with orthoses than with just shoes only. However, the mean value (92%BW) was still below normal and in absolute terms, not indicative of high impact loading during the loading response in stance. The orthoses were built with medial posting to correct the eversion deformity. Fears raised by Perry *et al.*, (1994) that this technique may expose lower limb musculoskeletal structures vulnerable to impact loading, because of reduced motion, are not supported by the findings of the present study. However some caution needs to be exercised because loading threshold levels for joint and soft-tissues in the presence of inflammatory arthritis are as yet unknown. In the present study reduction of peak forces at the heel during the loading response and redistribution of load to the midfoot are encouraging findings. Furthermore, reduction of peak force, in line with the observations of Rosenbaum *et al.*, (1994), may be associated with a reduction in the AJC pronation moment further assisting the action of the orthosis.

6.4.2 Longitudinal plantar pressure/force measurement

The impact of custom-designed foot orthoses on plantar pressure/force distribution in RA valgus heel deformity was evaluated longitudinally. From baseline, changes in pressure and force variables were anticipated for both groups; the intervention group in response to orthotic treatment and the control group as a result of progressive foot deformity. Orthoses maintained the baseline reduction in PP at the medial and lateral heel masks. Although no significant groups differences were found, PP also increased in both groups in the midfoot region. In the intervention group the response was smaller and attributed to medial midfoot loading introduced by the curved surface of the orthosis in that region. In the control group increased loading may have been indicative of progressive arch collapse associated with valgus heel deformity. Across the metatarsal heads in the intervention group the PP was reduced over time at the 1st metatarsal, increased slightly at the 2nd and 3rd metatarsals and increased sharply at the 4th and 5th metatarsals. The change in loading pattern may be indicative of an orthotic response with off-loading of the medial forefoot and increased loading laterally, and this would be desirable for overall foot function. The total pressure loading as measured by the PTI showed no statistical differences between treated and untreated conditions at any of the plantar regions.

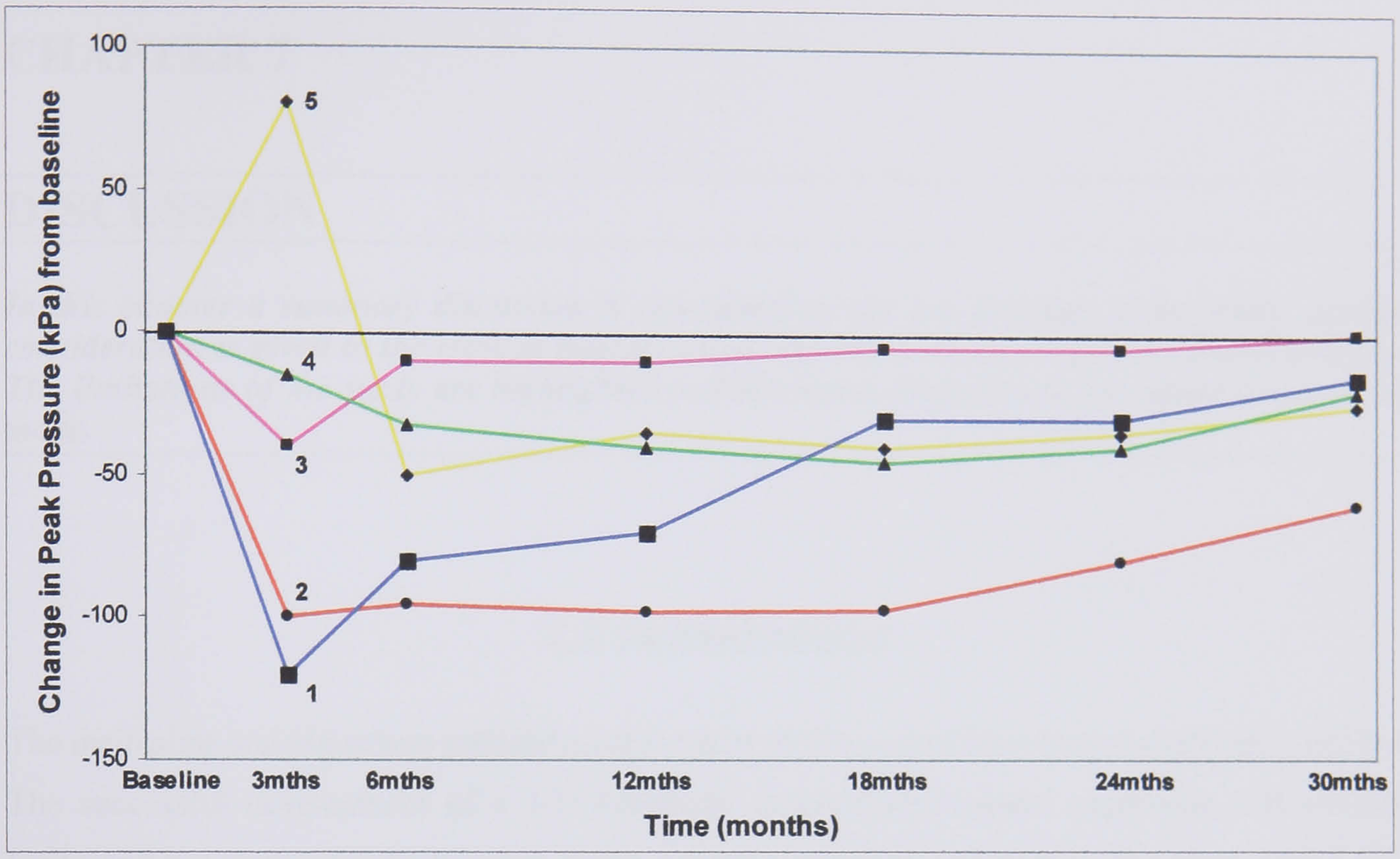
Peak force increased significantly over time in the intervention group in the total mask. The time:response curve showed a steady increase in peak force over time reaching a maximum of 96%BW. The most likely reason for this is a change in gait style related to an improvement in foot pain and disability with orthosis use, a response that has been demonstrated in a number of other studies (Hunt *et al.*, 1987; Locke *et al.*, 1984; McSween *et al.*, 1999). Walking velocity was

not recorded for patients in this study so the above statement cannot be confirmed. Peak force at both heel masks was significantly reduced at baseline but this response was not carried forward over the medium term. In fact the overall peak force was increased at both heel masks over slight and moderate increases at the medial and lateral sites respectively for the control group. This reverse in trend was also associated with an increase in total load as seen in the FTI results. Both findings suggest that impact loading increases with orthoses in RA as the result of either walking faster in response to reduced symptoms or a reduction in eversion motion by medial posting as suggested by Perry *et al.*, (1994), or a combination of both. In fact the kinematic data with orthoses showed the smallest eversion motion, which improved over time reducing eversion ever further. The orthoses appear able to control motion when the eversion moment increases under higher ground reaction forces.

The load across the forefoot was laterally redistributed in the intervention group demonstrated by increased peak force values at the 3rd to 5th metatarsals in comparison with the 1st and 2nd metatarsals with a statistically significant effect over the control group. The same effect was also observed for the FTI variable but between group differences did not reach statistical significance. In the midfoot region the PF was increased over time in both groups, higher in the control group but not statistically significant. However, the FTI decreased in the intervention group against an increase in the control group, the difference accounted for by a decrease in the midfoot contact time with the orthosis. Although the time difference was not statistically significant it perhaps indicates further that the orthosis unloads the medial side of the foot. Across the metatarsals the contact time was increased for the 3 lateral metatarsals and remained the same or was reduced on the medial two metatarsals, although the differences were not statistically significant in comparison with control. Finally no between group differences were noted for the toe masks other than a reduction in peak force at the 2nd toe mask in the intervention group over control but this was not considered relevant to overall orthotic effect.

Qualitative observation of the response:time curves for the two groups for each plantar region by pressure or force variable showed no strong association between peak response and time to peak response. When these two variables were plotted, 60-70% of cases in the intervention group had an initial response within the first 3 to 6 months, and was maintained over the duration of the study. Because the response levelled after the initial change in many of these patients, the peak effect could also occur at any of the remaining time points up to 30-months. Several common response pathways were identified and examples are provided for peak pressure at the medial heel mask in the intervention group in figure 6-2.

Figure 6-2: Peak pressure:time response patterns in the RA intervention group at the medial heel region.



Five typical response:time curves for change in peak pressure at the medial heel mask in the intervention group with orthosis. Plot 1 shows the largest decrease in peak pressure to 3 months, returning to baseline steadily over the next 12 months. Plot 2 shows an immediate reduction sustained for a further 12 months, with some increase from 18-months. Plot 3 shows an immediate reduction, less so than in plots 1 and 2, with a steady return towards baseline. Plot 4 shows a steady and consistent negative rate of change from baseline. Plot 5 shows an immediate increase in peak pressure at 3 months changing to a decrease by 6 months which is maintained through to 30 months.

In summary, valgus heel deformity in RA results in redistribution of pressure and force. With orthotic intervention changes to loading patterns can be achieved in comparison with no intervention and response maintained for the medium term. Change in pressure distribution can occur as a result of the mechanical action of the orthosis and also due to changes in overall gait style as symptoms improve.

CHAPTER 7

DISCUSSION

In this chapter a summary discussion is conducted on the key findings of the study. Special consideration is given to the clinical interpretation and implications for future clinical practice. The limitations of the study are highlighted and discussed. Suggestions for future research are made.

7.1 Introduction

The main aims and objectives established at the start of this project have been successfully fulfilled. The successful development of a 3-D kinematic measurement system employing EM tracking facilitated the study of AJC function in the normal population and in RA. The study found AJC movement to be abnormal in RA and the cause of valgus heel deformity. This clinical problem is associated with significant and disabling foot pain. At recruitment, in patients with mean disease duration of 3 years, rearfoot deformity was pronounced but still amenable to orthotic intervention. Under rigorous clinical trial conditions custom-designed foot orthoses were found to significantly reduce foot pain and disability when compared against no intervention. These symptomatic improvements were associated with improvement in AJC function as determined by kinematic and PPM measurements in-shoe with orthoses in situ. These main findings have already been discussed within the previous chapters so a summary discussion of the outcome of the research work is provided, highlighting the clinical implications, limitations of the study and proposals for future work.

7.2 Kinematics

The kinematic technique developed in the early stages of this study produced valid and repeatable measurements of 3-D movement at the AJC. The findings were consistent with published data where EMT has been used. It was possible to develop the technique for in-shoe measurements whilst the accuracy permitted quantification of small changes in angular rotations either as the joint movement changed or as a response to orthotic intervention. The technique was straightforward to apply and a relatively large database of kinematic data from the normal population, age- and sex-matched to two RA cohorts was established. Rheumatoid arthritis patients with valgus heel

deformity showed abnormal movement patterns, especially for inversion/eversion and internal/external rotation consistent with the clinical presentation and in agreement with previous reports. Not withstanding the large variability, the RA data compared against the progression model described in section 4.1.3 suggests the route to valgus heel deformity is rapid within the first three years. Since the deformity was almost fully correctable under orthotic control the pathomechanical model appears to be joint laxity caused by inflammatory arthritis in the ankle and tarsal joints, which under weightbearing load causes the AJC to become unstable medially. This model has been proposed previously but never supported by biomechanical data as presented here (Bouysset *et al.*, 1987; Dimonte and Light, 1982; Platto *et al.*, 1991; Vahvanen, 1967). The present study is not definitive and further work is required to combine kinematic data with AJC laxity characteristics. Successful in vivo techniques have been developed for the purpose of quantitative diagnosis of injury to ankle ligaments and could be successfully employed in the context described above (Kovaleski *et al.*, 1999; Siegler *et al.*, 1988, 1994 & 1996).

The foot orthoses had significant effects on the 3-D movement patterns at the AJC. The overall movement pattern was not dramatically affected in terms of curve shape but the medial correction allowed the AJC to function from a more inverted condition than in the untreated state. Qualitatively, the orthoses allowed the subtalar joint component to function through the neutral subtalar position with periods of inversion and eversion. This conforms to prevailing beliefs about optimal subtalar function and whilst not fully corrected against the normative data, represented excellent treatment response. Furthermore the kinematic response was sustainable for the medium terms and this has not been demonstrated previously. The improvement in AJC function under barefoot condition was a surprise finding. By improving joint congruency and realigning ligament orientation, the orthoses, hypothetically, could create conditions for adaptation to occur and laxity to decrease. Alternatively the effect may have been created by the development of joint stiffness. Either way the finding merits further attention and ligament testing apparatus and advanced image processing techniques could be employed longitudinally to test either of these suppositions.

During the course of the study some major limitations, primarily related to identification of the navicular for marker placement and large amounts of skin movement, restricted the interpretation of the calcaneotalonavicular joint motion. Mid- and forefoot motion may have been equally important in understanding the orthotic treatment response. Without this evidence it could be argued that simple uni-planar medial wedges placed inside the shoe or built into the heel could achieve the same kinematic effect. Within the context of these limitations orthoses did restore

calcaneotalonavicular joint motion to normal limits about the frontal and transverse plane and pressure and force distribution data did demonstrate that the midfoot region was loaded under orthotic conditions, and that forefoot loading was redistributed laterally. These changes may have been desirable for forefoot-to-rearfoot stability but further work is required to address these problems. Until skin marker problems are resolved an alternative approach would be to model the whole foot by using more distal skin markers, placed on the metatarsal heads for example, to account for the contribution of more distal joints (Reischl *et al.*, 1999; Nester *et al.*, 2000).

The surface contours of the orthosis interacted with the plantar aspect of the foot to resist motion for the desired orthotic effect. Although the association between improved AJC motion and reduction in symptoms was established, the mechanisms through which this occurs are not clear. Indeed this is a neglected area of research and only the work of Kogler *et al.*, (1996 & 1999), studying the plantar aponeurosis, has shown how strain in soft tissues can be modified with orthosis use. In the case of RA the response of vulnerable tissues such as the medial and interosseous ligaments, the joint capsules, the inflamed synovium and articular surfaces to the mechanical stresses imposed by valgus heel deformity need to be considered. Imaging techniques are invaluable for quantifying response in synovium and articular cartilage and more recently ligament and muscle tissue and this technique could be combined with various in vivo and in vitro experiments of injury and orthotic response biomechanics.

Static lower extremity measures have been shown to be of limited value in predicting lower extremity function (Hamill *et al.*, 1989). The issue has yet to be resolved clinically so at the outset of the project, adopting best practice at the time, diagnosis of valgus heel deformity was based on static foot observation and measurement. This may partly explain the large variability of the kinematic data and overlap between the population parameters established for the normal and RA groups. This discordance may in the future be partially overcome by utilising dynamic data for the purposes of establishing normal and abnormal function.

The EMT approach bypasses some of the problems associated with other systems by not having to track surface markers from remote cameras. Problems such as metallic interference and trailing cables between sensors and the systems electronic unit are negative features of the system. Since the inception of this project these problems have been overcome by the development of interference mapping and correction algorithms and telemetry for sensor to receiver signals. Fast data collection and processing is a positive feature facilitated by easy to use software and graphical interfaces.

However, the collection of a large dataset presented problems with database assembly and data preparation for analysis when motion data had to be defined by joint, axis of rotation, time point in study, study group and walking condition. The processing was undertaken using macros developed in Microsoft Excel and in the future the analyses should be integrated into the main system software.

7.3 Orthotic management

Conrad *et al.*, (1990) found no significant orthotic effect in RA in advanced disease, and he supposed that rigid custom manufactured orthoses might be more effective in early disease. The reduction in pain and disability was significant and the treatment well tolerated. The latter result will be surprising to many clinicians who are used to patients not wearing their devices. In most cases this is related to poor fit of the orthosis inside the shoes, which are often unsuitable in terms of adequate width, depth and support. In this study satisfactory footwear was an important inclusion criteria and this factor clearly facilitated better treatment tolerance. Improvements in symptoms were associated with alteration of mechanical variables, namely kinematics in the rearfoot and plantar pressure and force redistribution although it is recognised that other factors, unaccounted for in the present study, may also be important. The sustainable effect of the orthotic intervention was a significant and previously unreported finding. The evidence base now suggests that custom-designed orthoses made in rigid materials are effective in the early stages of RA but not in advanced disease. More work is therefore required to offer successful treatment in established disease and to improve on the current advances reported here.

In routine practice clinicians tend to vary orthotic prescriptions on a patient-by-patient basis including the negative impression technique, the orthotic materials, and the method of correction for underlying functional abnormalities. However, the criteria for undertaking these modifications have no strong scientific basis. Nonetheless, the uniqueness of the joints of the foot and the complexity of the interactions between articulations proximal and distal to the AJC cause considerable variation in kinematic, kinetic or other outcome parameters. For these reasons some of the major research groups advocate the individual approach to foot orthotic management. However, the assumption that outcomes will be better by this approach has not been supported by large-scale clinical trials. Furthermore, how individual modifications are established scientifically and more importantly transferred to routine clinical practice are not clear. The findings of this study based on a rigid

protocol designed to reduce variation are significant and offer a good starting point from which to develop some of the ideas raised by other groups. On a similar theme, recent reports suggest orthoses offer only limited movement control and other mechanisms may be important (Nigg *et al.*, 1999; Nurse *et al.*, 1999; Stacoff *et al.*, 2000). The generalisability of this statement is questionable in the face of the results presented here. Indeed the work conducted by Nigg *et al.*, (1999); Nurse *et al.*, (1999); and Stacoff *et al.*, (2000) are restricted to evaluation on otherwise healthy individuals and thus bears no resemblance to the conditions faced in this study. The same workers however, have demonstrated how afferent feedback may be an alternative or co-existing mechanism that allows foot orthotics to control movement (Nigg *et al.*, 1999; Nurse *et al.*, 1999; Stacoff *et al.*, 2000). This has significant implications for RA feet because sensory information must be significantly altered when pain is increased or decreased either by effective intervention and worsening of disease status. Antalgic gait invariably occurs in RA and loading patterns, as demonstrated by the pressure and force data in the present study, change over time in response to orthotic intervention. This area merits further consideration in future studies.

7.4 Implications for clinical practice

Prior to this study, in the context of evidence-based practice, custom-designed orthoses used in early RA were based on clinical experience and expert opinion and, according to the Agency for Health Care Policy and Research (1992) this is the lowest form of clinical evidence (Grade C IV). This study now provides evidence at a much higher level (Grade A Ib) and should facilitate the development of clinical guidelines. However, a major criticism of clinical trials is that outcomes may differ in clinical practice because study patients and protocols may differ from those seen and undertaken in routine clinical practice. For this reason guideline development must be an interactive process accounting for differences in clinical and organisational services, and in patients, professionals and support services. To address this the author proposes to conduct post-marketing surveillance, by recruiting a cohort of rheumatology centres in the UK where the treatment can be implemented and evaluated in routine clinical practice. The present study was a pragmatic trial, and other than evaluating gait, the protocol is readily transferable to routine clinical practice. Therefore evaluation of clinical outcomes such as foot pain and disability and other information such as adverse reactions should be straightforward to collect, assimilate and compare against present results. This could be conducted with the devices used here and those that replicate the design but are manufactured in each podiatry unit.

7.5 Future Work

The positive outcomes in this study are significant enough to merit several proposals for further investigative studies to expand and develop our knowledge and understanding of foot disease in rheumatoid arthritis and how best to treat it. Four key areas have been identified and these are:

- Further development of the EMT measurement technique.

- Investigation of AJC and other foot pathologies in very early arthritis, i.e., within weeks or months of onset of inflammatory arthritis.

- Development of orthotic and other management strategies for AJC and other foot pathologies in very early arthritis, including clinical trials of various types of foot orthoses.

- Development of clinical and biomechanical experiments to identify treatment response mechanisms for AJC and other foot pathologies in RA.

Further work is necessary to integrate the kinematic measurement system with other gait analysis techniques to provide a total biomechanical assessment of the lower limb and foot. Since this project was initiated a non-metallic force-plate and electromyographical measurement equipment along with electromagnetic interference mapping algorithms have been developed and integrated with the system. In this way, albeit in smaller study cohorts, more robust data including kinetics and muscle activity can be integrated with kinematics to improve our understanding of dysfunction in the RA, to identify prognostic indicators for poor function and to measure intervention response.

To find advanced deformity in a large number of patients within 3 years of the onset of disease was an important finding in this study and indicates that earlier identification and intervention may be necessary. One of the main areas of research with the rheumatology unit at the University of Leeds is the approach to early identification and management of inflammatory arthritis. The unit in a regional centre for this research and registers patients under the YEAR (Yorkshire Early Arthritis Register) programme. The environment and infrastructure is therefore in place to implement screening of patients within days or weeks since first diagnosis. This opens up major possibilities for identifying prognostic indicators, both clinical and biomechanical, for foot disease and to target

suitable patients and develop appropriate intervention strategies evaluated using the clinical trials skills gained during the present study.

Post-marketing surveillance of the current orthoses has already been proposed and this should be set alongside a wider programme of clinical trials that evaluate a variety of interventions. Priority should be given to the comparison of custom and pre-fabricated orthoses, the evaluation of patient specific orthotic management and the combined therapies including orthoses, footwear, pain management, and physical rehabilitation. Disease-staged orthotic management needs to address not only those with early disease but also the significant numbers with advanced disease and well-established foot deformity, pain and disability. Finally as with all new health technologies evidence based cost-effectiveness must be incorporated into all of these clinical studies.

A multidisciplinary approach involving bioengineering, rheumatology, imaging and podiatry among others is necessary to develop experimental studies investigating AJC structure and function, disease mechanisms in the foot, and response to interventions. Work of this nature will help to improve our knowledge and understanding of RA and foot disease and lead to the development of better treatments initiated at the correct stage of the disease and based on strong clinical and research evidence.

7.6 Conclusions

7.6.1 Development of kinematic system

The main conclusions of the research work described in this thesis are:

- Electromagnetic tracking technology can accurately and precisely measure ankle joint complex 3-D kinematics. Measurement error was <1° for orientation and approximately 1mm for translation within a maximum sensor-source separation distance of 750mm.
- Within-day repeatability, determined by the coefficient for multiple correlation (CMC) for curve-shape agreement, is excellent with CMC values ranging from 0.939 to 0.843 in normal and 0.937 to 0.812 in RA subjects.

- Between-day repeatability is good for normal subjects with CMC values between 0.932 and 0.682, and patients with RA, CMC values between 0.852 and 0.765.

- The EMT system is accurate enough to discriminate between normal and abnormal AJC motion and to quantify orthotic treatment response. Consensual validity is high when motion data are compared alongside published studies.

- Skin movement artefact at the site of attachment for the calcaneal sensor was estimated to be less than 1.0°. No data was available for the tibial sensor.

7.6.2 Foot orthoses in rheumatoid arthritis

- Over the duration of 30-months the use of custom-designed rigid foot orthoses in early RA resulted in a significant and sustainable improvement in foot pain and disability as measured by the foot function index. The intervention is well tolerated but minor adverse reactions can arise.

7.6.3 Ankle joint complex kinematics in rheumatoid arthritis

- The 3-D movement at the AJC is abnormal in comparison with age- and sex-matched normative data. Range of motion for inversion/eversion is reduced by 24% and the joint complex functioned around an excessively everted and internally rotated ranges of motion. In comparison with normative data, inversion/eversion rotation was approximately 8° more everted across the duration of the gait cycle

- Footwear can alter kinematic movement and medial support within a shoe can partially restore inversion and external rotation (the former by 3.1°).

- Custom-designed rigid foot orthoses significantly improved inversion/eversion motion, restoring function around subtalar joint neutral position with an overall inversion shift of approximately 2.6°. There was no immediate orthotic effect on transverse internal/external rotation.

- Over the medium term the orthosis intervention effect was maintained and amounted to a mean change in inversion/eversion motion from baseline to 30-months of 3.5° for barefoot, 2.9° for

shod and 1.5° for orthotic conditions. In the RA control group the changes were 1.5° for barefoot and 1.4° for shod conditions. Improvement in internal/external rotation was also noted.

7.6.4 Plantar pressure measurement in rheumatoid arthritis

- Valgus heel deformity in early RA alters the distribution of plantar pressure and force in comparison with normative data. Custom-designed rigid foot orthoses alter the pressure and force distribution with significant effects on the heel and midfoot regions; the effects were sustainable and significantly different from those measured in a non-intervention control group.

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Enquiries on this matter
should be made to:

Tel:

Fax:

Our ref:

Your ref:

Appendix A

Patient Information Sheet

Bradford HOSPITALS NHS TRUST

St Luke's Hospital
Little Horton Lane
Bradford
BD5 ONA

Tel: (01274) 734744

PATIENT INFORMATION SHEET

Study Title: A randomised controlled clinical trial investigating the efficacy of foot orthoses in rheumatoid arthritis.

Name of Researchers: Mr J Woodburn, Dr P Helliwell, Mrs S Barker

Background information: Rheumatoid arthritis can cause pain and deformity in the foot. In particular the posture of the back part of the foot can change with a tendency for the heel to roll in and the foot to become flat. In some hospitals patients with rheumatoid arthritis are referred to see a podiatrist (chiropodist) who sometime prescribe foot orthoses (insoles) to correct poor foot posture. Some patients benefit from this treatment whilst others find the orthoses make no improvement. There is little information which tells us how the foot orthoses work and who benefits best from the treatment.

Study aims: This study aims to look at how foot orthoses (insoles) work for patients with rheumatoid arthritis in terms of foot posture correction, pain relief and gait (walking) improvement.

How the study will work: The study will be done as a randomised controlled trial. Here some patients are selected by chance to have and some not to have the foot orthoses treatment. Both sets of patients are then checked at regular intervals over a chosen time period. Comparisons can then be made between the two groups on who did better with or without the foot orthoses.

What the study will entail for you: If you volunteer to take part in this study you will be picked at chance to be in the treatment group which gets the foot orthoses or to be in the control group which gets no treatment. In both groups measurements will be made at the start of the study and at **3, 6, 12, 18** and **30** months. We will measure the way you walk (motion analysis and foot pressure measurement), how much foot pain and disability you have and the severity of your rheumatoid arthritis generally. Foot x-rays will be taken annually as part of the routine assessment of your rheumatoid arthritis. The measurements will take about 30 minutes.

If you are in the treatment group you will be provided with full information on how to use the foot orthoses. Also our research nurse will contact you at home via telephone or letter to check how well you are managing with the treatment.

Questions: If you are unsure about any part of this study please ask the research nurse now.

Consent: If you are happy to take part in this study please read and complete the attached consent form.

Contact: Should you require any further advice please contact Mrs Sharon Barker (research nurse) at Ward F4, St Luke's Hospital, Little Horton Lane, Bradford, BD5 0NA. (Telephone 01274 365685- direct line on Tuesday mornings/all day Thursday).

Enquiries on this matter
should be made to:

Tel:

Fax:

Our ref:

Your ref:

Appendix B

Patient consent form

Bradford HOSPITALS NHS TRUST

St Luke's Hospital
Little Horton Lane
Bradford
BD5 ONA

Tel: (01274) 734744

PATIENT CONSENT FORM

Name of Researcher: Dr/~~Mr~~/Mrs/~~Miss/M~~s

The patient should complete the whole of this sheet himself/herself

Please cross out as necessary

Have you read the patient information sheet?	**YES / NO**
Have you been given a copy to keep?	**YES / NO**
Have you had the opportunity to ask questions and discuss this study?	**YES / NO**
Have you received satisfactory answers to all your questions?	**YES / NO**
Have you received enough information about the study?	**YES / NO**

Whom have you spoken to? .....

Do you understand that you are free to withdraw from the study:

- **At any time**
- **Without having to give a reason for withdrawing**
- **Without affecting your future rheumatology care**

YES / NO

DO YOU AGREE TO TAKE PART IN THE STUDY **YES / NO**

Signed: ..... **Date:** .....

Name in block letters: .....

Signature of researcher: .....

Appendix C

Orthotic Information sheet

How do I start to use these foot orthoses?

The orthoses are made out of a hard plastic material and may take a little while to get used to. We recommend that you wear them for an hour on the first day. After this increase the amount of time by an hour each day until you are wearing them throughout the day.

Which are the best types of shoes to wear them in?

The foot orthoses should be worn in an enclosed shoe. We recommend lacing, T-bar, buckle or Velcro fastening which holds the shoe more snugly to the foot and keeps the foot orthosis in place. You might think you need a bigger shoe size to give room for the foot orthosis to fit but this is not usually the case. Your shoe should have good width and depth in the front part and good depth around the heel. The shoe should have a low heel- no more than 1 inch. Good fitting winter boots or training shoes are also suitable.

Do I have to wear them all the time?

You should try to wear your foot orthoses for the longest part of the day when you are wearing your shoes. So always wear them when you are at work or doing daily household chores. We do not recommend that you wear them in slippers or sandals. If for a particular occasion you need to wear a dress shoe, such as a court shoe, you will probably find the foot orthosis will not fit and you should not use them in this type of shoe.

What should I look for in the way of problems?

When used correctly foot orthoses cause little in the way of problems to the foot. The commonest problem you might experience when the foot orthoses are used at first are cramping or tiredness in the feet. You might also find that your shoes are a little tight causing pressure on the toes of the sides of the foot. Others find that the foot slips out of the back of the shoe. If you develop any of these problems reduce the amount of time you use the foot orthoses until symptoms ease, or try them in different shoes to see if you can find a better pair. Other problems to look for are skin blisters, the start of thickened skin in an area where the foot orthosis is rubbing or increased foot pain, which wasn't there prior to using the devices. If you cannot remedy any of these problems then use the contact information on the back of this leaflet for further advice.

Are the orthoses easy to look after?

These devices are hard wearing. You can clean them by wiping over with a damp cloth and some mild detergent.