Bournemouth University

# A quantitative fluoroscopic study of the relationship between lumbar inter-vertebral and residual limb/socket kinematics in the coronal plane in adult male unilateral amputees.

(Exploring the spine and lower limb kinematics of trans-tibial amputees)

By

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A thesis submitted in partial fulfilment of the requirements of Bournemouth University for the degree of Doctor of Philosophy (Ph.D.)

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# Abstract

Title: A quantitative fluoroscopic study of the relationship between lumbar inter-vertebral and residual limb/socket kinematics in the coronal plane in adult male unilateral amputees.
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**Introduction**

Much of lower back pain (LBP) is thought to be mechanical in origin and lower limb amputees have an increased prevalence. There is also evidence that a large proportion of them also have altered spinal posture and it is commonly thought that the movement between the vertebrae (kinematics) may be affected. The current study was designed to explore the kinematics of the lumbar spine segments in trans-tibial amputees and compare it to a similar population with intact lower limbs using quantitative fluoroscopy (QF). The study also investigated possible relationships between lumbar spine stability and the motion between the prosthetic socket and residual limb. It is hoped that these investigations will improve understanding of the importance of limb-socket fit to the functional integrity of the lumbar spine in lower limb amputees

**Methods**

A literature review and three preliminary QF studies were carried out; one to the determine the best plane of motion and orientation of participants during QF imaging of the spine, a second to inform the optimal imaging protocol for the limb-socket interface and the third to validate a QF measurement of inter-vertebral stability. This phase determined the measurement parameters and investigative protocols. Given the complexity of the technique, 12 male below knee amputees and 12 healthy male controls of similar age and body mass index were recruited and received passive recumbent coronal QF imaging of their lumbar spines. This was followed immediately by anterior-posterior QF imaging of their limb-socket interfaces during three different forms of simulated gait. Differences between amputee and control spine kinematics and relationships between limb-socket motion and inter-vertebral kinematics in amputees were investigated.

**Results**

Passive recumbent coronal plane QF appears to be a valid method for measuring inter-vertebral stability. Although there were no systematic differences between the magnitude of inter-vertebral kinematics variables of amputees and controls, there was a trend towards greater variability in both inter-vertebral range and symmetry of motion in amputees and a significantly higher proportion of correlations in attainment rate between levels among amputees than controls (2-sided $p < 0.04$). There was also a substantial, statistically significant inverse linear relationship between passive inter-vertebral motion symmetry and limb-socket telescoping in amputees.

**Conclusions**

This thesis provides evidence that the kinematics of the lumbar spine may be affected by lower limb amputation – particularly in respect of socket fit. The importance of consistency and symmetry of restraint by the intrinsic spinal holding elements in trans-tibial amputees has been highlighted. An indication of a relationship between limb socket telescoping and spine kinematics was identified, suggesting the need for replication of this part of the study in a larger amputee population. The variables of interest and the basis for this have been identified.
Finally, inter-vertebral motion pattern variation has been associated with chronic low back pain in the literature. It was discovered that there was more interdependence in passive inter-vertebral motion between and across levels in below knee amputees than controls in terms of laxity, but not range of motion. The apparent relationship between this and socket fit in amputees suggests a possible mechanism and diagnostic subgroup in this population.

# Abbreviations

The first time abbreviations are used in the text their meaning is given. They are also given in the table below for reference.

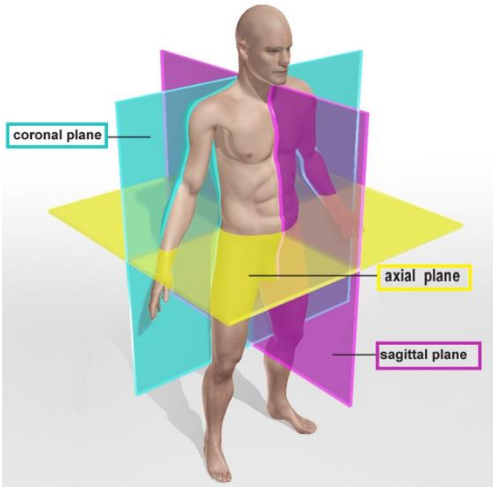
| | |
|---|---|
| AECC | Anglo-European College of Chiropractic |
| ALARA | As Low As Reasonably Achievable |
| AP | Anterior-Posterior |
| BK | Below Knee |
| BKA | Below Knee Amputee |
| BMI | Body Mass Index |
| CAD | Computer Aided Design |
| CI | Chief Investigator |
| CNSLBP | Chronic Non-Specific Low Back Pain |
| CT | Computed Tomography |
| DAP | Dose Area Product |
| DRSA | Dynamic Roentgen Stereogrammetric Analysis |
| EZ | Elastic Zone |
| GUI | Graphic User Interface |
| HPA | Health protection Agency |
| ICC | Intra Class Correlation |
| ICR | Instantaneous Centres of Rotation |
| IMRCI | Institute for Musculoskeletal Research and Clinical Implementation |
| IQR | Interquartile Range |
| IRAS | Integrated Research Application System |
| IV | Inter-Vertebral |
| IVA | Inter-Vertebral Angle |
| IVFE | Inter-Vertebral Flexion-Extension |
| kVp | Peak kilovoltage |

| | |
|---|---|
| LAT | Lateral |
| LBP | Low Back Pain |
| LLA | Lower Limb Amputation/Amputees |
| LLD | Limb Length Discrepancy |
| LOA | Limits of Agreement |
| mA | milliamp |
| MRI | Magnetic Resonance Imaging |
| NA | Not Applicable |
| NEAT | New and Emerging Applications of Technology |
| NHS | National Health service |
| NREC | National Research Ethics Committee |
| NS | Not Significant ($p>0.05$) |
| NZ | Neutral Zone |
| OSMIA | Objective Spinal Motion Imaging Assessment |
| PTB | Patellar Tendon Bearing |
| QF | Quantitative Fluoroscopy |
| REC | Research Ethics Committee |
| RMS | Root Mean Squared |
| ROM | Range of Motion |
| RSA | Roentgen Stereophotogrammetric Analysis |
| SD | Standard deviation |
| SEM | Standard Error of Measurement |
| TSB | Total Surface Bearing |
| ULA | Upper Limb Amputation/Amputees |

# Glossary / terms of use

| | | |
|---|---|---|
| Rotation | = | angular displacement of a body about some axis |
| Translation | = | a direction of movement relative to a fixed point |
| Range of motion | = | the difference between two points of physiologic extremes of movement is the range of motion. Translation is expressed in Meters (or millimetres) and rotation is expressed in degrees. The range of motion can be expressed for each of the six degrees of freedom. |
| Lateral | = | direction away from the plane of symmetry of the body, off to the side |
| Medial | = | closer to the plane of symmetry of the body |
| Medio-lateral | = | relating to, extending along, or being a direction or axis from side to side or from medial to lateral |
| Abduction | = | any motion of the limbs or other body parts away from the midline of the body |
| Adduction | = | the movement of a body part toward the body’s midline |
| Proximal | = | situated nearer to the centre of the body or the point of attachment. |
| Distal | = | situated away from the centre of the body or from the point of attachment. |
| Proximo-distal | = | relating to, extending along, or axis from body centre to end or from proximal to distal |
| Superior: | = | upward (in the body) direction |
| Inferior | = | downward (in the body) direction |
| Caudally | = | direction toward the tail or posterior part of the body. |
| Superolateral | = | diagonal direction up and to the side (i.e. both in the superior and lateral directions) |
| Posterior/Dorsal | = | at or toward the back of the body |
| Anterior/Ventral | = | front or forward portion of the body |

Sagittal plane = plane of symmetry of the body, splitting the slices body into a left and a right




Coronal plane = divides the body into posterior and anterior, perpendicular to the sagittal plane

Axial plane = divides the body into superior and inferior parts. It is perpendicular to the coronal and sagittal planes

Prone = lying flat, face downwards

Supine = lying face upwards.

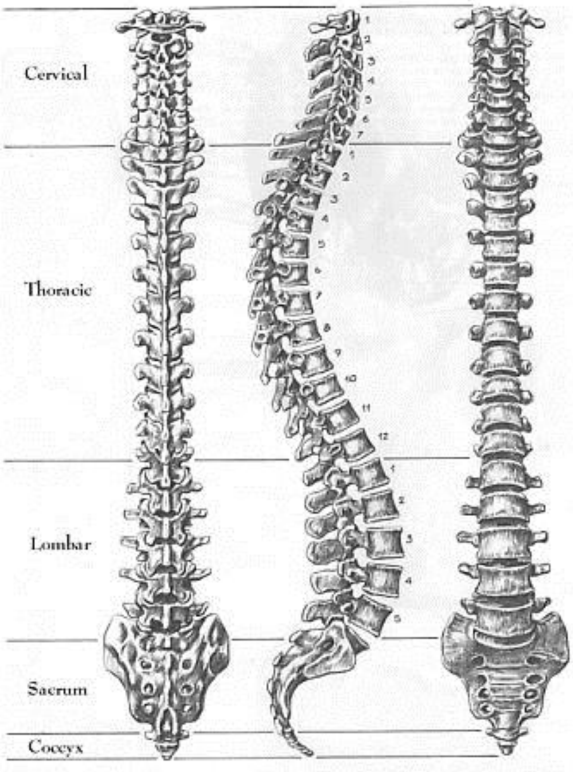
Ipsilateral (to amputation) = belonging to or occurring on the same side of the body

Contralateral (to amputation) = relating to or denoting the side of the body opposite to that on which a particular structure or condition occurs.

Vertebrae = each of the series of small bones forming the spine

Thoracic vertebrae = each of the twelve bones of the spine to which the ribs are attached

Lumbar vertebrae = five vertebrae between the thoracic vertebrae and sacrum




Sacrum = a triangular bone in the lower back formed from fused vertebrae and situated between the two bones of the pelvis.

Ilium = the large broad bone forming the upper part of each half of the pelvis.

Iliac crest = the superior border of the wing of the ilium and the superolateral margin of the Ilium.

# Table of Contents

# Table of Figures

## List of Tables

## Author's declaration

It is hereby declared that the work contained within this thesis has not been submitted to meet the requirement for this award at this, or any other, educational institution, other than that which this submission is made for. The Thesis contains no material previously published or written by another person, except where due reference is made. This work has not been previously published, nor has been submitted for presentation (in full or part) except for the academic publications outlined in 'Published materials' below.

## Preface

All of the work presented henceforth was conducted in the Radiography unit of the Anglo-European College of Chiropractic, Bournemouth, UK. All projects and associated methods, which required it, were approved by the NRES (National Research Ethics Service) Committee South West – Frenchay, Health Research Authority, NRES reference 13/SW/0248 in November 2013 (Appendix A.IV "National research ethics approval of research protocol letter – gained 15/11/2013"). I was the lead investigator in these studies, responsible for all major areas of concept formation, data collection and analysis.

## Acknowledgements

I would like to thank staff at the Anglo-European College of Chiropractic (AECC) and Bournemouth University who financially supported this project. Particularly I would like to thank those within the IMRCI team of the AECC for their support, wisdom and specialist knowledge that has helped me in many of the key stages of this study.

My deepest thanks to the staff at the *Dorset Prosthetic Centre* of Royal Bournemouth Hospital, who helped inform my research and recruit the majority of participants. Others who helped me in my recruitment were *Dorset Orthopaedic* prosthetic and orthotic clinic in Ringwood and the Charities *LimbPower* and *The Douglas Bader Foundation* whose enthusiasm for this project was inspiring.

Thank you to my friends and family for all their support. To my supervisory team, Dr. Mihai Dupac, Professor Siamak Noroozi and Dr Neil Osborne, I would like to offer my deepest gratitude for their continuous support, availability and encouragement throughout this experience and for giving me free reign on this thesis along with the opportunity to make it my own.

Finally my deepest thanks to the participants, whose involvement made data collection enjoyable and without whom, this thesis would not exist.

# Published materials

## Papers

van Loon, I. H. M., Mellor, F. E. and Breen, Ax., 2012. Accuracy and repeatability of sagittal translation of lumbar vertebrae in vitro and in vivo using quantitative fluoroscopy. Clinical Chiropractic 2012, 15, 135-146.

Breen, Ax., Dupac, M., Osborne, N., Attainment rate as a surrogate indicator of the intervertebral neutral zone length in lateral bending: an in vitro proof of concept study. Chiropractic & Manual Therapies.2015, 23:28 DOI: 10.1186/s12998-015-0073-8

Breen, Ax., Breen, A., Accuracy and repeatability of quantitative fluoroscopy for the measurement of sagittal plane translation and instantaneous axis of rotation in the lumbar spine. Medical Engineering & Physics (submitted)

## Presentations

Breen, Ax., F. Mellor, and A. Breen, *Lumbar Inter-vertebral Motion in Vivo: A Preliminary Comparison of Recumbent and Weight-bearing Motion Patterns in Adult Males*. Bone and Joint Journal, 2013. 95-B(Supp 17 20). (Presented at SBPR conference Nov. 2012)

Breen, Ax., *Exploring the spine and lower limb movement of amputees* (Presented at Royal Bournemouth and Christchurch Hospital trust research interest group March. 2014)

Breen, Ax., et al., A pre-operational study magnification measurement and error estimation of residual tibia kinematics within below knee prosthetics, in Engineering Optimization IV, Rodrigues et el (Eds), Editor 2014, Taylor & Francis Group: London. p. 927-930. (Presented at EngOpt conference Sept. 2014)

Breen, Ax., Dupac, M., Osborne N., (to be presented at SBPR conference Nov. 2015)

Breen, A., Mellor, F., Breen, Ax., Hilton, A., Intersegmental kinematics in patients with persistent back pain: A review of Quantitative Fluoroscopy referrals (to be presented at SBPR conference Nov. 2015)

Breen, Ax., Dupac, M., Evaluation of stump and socket kinematics of lower limb amputees using quantitative fluoroscopic imaging: a case study (to be presented at BioEng conference Nov. 2015)

## Future publications

A. Breen, M. Dupac, Evaluation of angular kinematics of lower limb amputees using quantitative fluoroscopic imaging, European Congress on Computational Methods in Applied Sciences and Engineering, ECCOMAS Congress 2016, 5-10 JUNE 2016, Crete Island, Greece (Submitted)

A. Breen, M. Dupac, Assessment of lower limb kinematics effects on spinal kinematics of amputees using quantitative fluoroscopic imaging: a methodological approach, European Congress on Computational Methods in Applied Sciences and Engineering, ECCOMAS Congress 2016, 5-10 JUNE 2016, Crete Island, Greece (Submitted)

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# Chapter 1: Introduction

Amputation has been part of human civilization for thousands of years with evidence of early prosthetic replacement limbs being found in Egyptian tombs. While elective amputation is not an easy decision, it is the surest treatment for certain chronic diseases (including diabetes, ulcers, infections, and vascular disease), tumors and trauma. Moreover, amputation surgery can be useful for those with congenital diseases in conjunction with prosthesis where these persons are born with malformed or missing limbs.

The prosthesis is a potentially restorative technology which has allowed many amputees to live relatively normal lives and, as recently highlighted in the 2012 Olympics, perform to a high standard in athletics. Lower limb prostheses have improved dramatically since the early ‘peg leg’ fabrications used up to the 19th century. However, even with huge advances in materials, design and ergonomics of lower limb prostheses, there is still an increased occurrence of secondary disability among this population (Gailey et al. 2008). These secondary conditions include musculoskeletal problems such as osteoarthritis and osteoporosis and activity limiting pain conditions from the residual limb, phantom limb and back pain (Kulkarni et al. 2005).

Low back pain (LBP) as a secondary disability following lower-limb amputation (LLA) is a significant problem that is still largely without adequate explanation (Behr et al. 2009b). Evidence suggests that the 1-month prevalence of LBP among LLA (52%-71%) far exceeds that of the general population (23.2%) (Ehde et al. 2001; Hoy et al. 2012; Smith et al. 1999). However, studies that have included magnetic resonance imaging (MRI) suggest the back pain is not due to degenerative changes in the spine but is more likely to be mechanical (myofascial) in origin (Kulkarni et al. 2005). The onset of back pain post amputation may also be partly due to the reduced physical lifestyle adopted.

Back problems in lower limb amputees have traditionally been addressed by balancing leg lengths (Friberg 1984), however, recent research has found no difference between the limb length discrepancy (LLD) in amputees with and without back pain (Kulkarni et al. 2005). Due to the difficulties involved in creating a comfortable, durable and sustainable interface between the residual limb and the prosthetic socket, LLAs often suffer from a dynamic LLD. This occurs when the residual limb is able to slide or lengthen within the socket, effectively making the limb longer every time weight is removed and the weight of the prosthetic limb creates a traction force on the residual limb.

While many studies have measured the magnitude of this residual limb slippage (known as "pistoning" or "telescoping") using motion capture, continuous motion analyses between the residual limb bones (i.e. the tibia) and prosthetic limb are needed to determine the actual skeletal displacements. Only then can true residual limb slippage be ascertained. However, this is not accessible from surface measurements and requires imaging of the residual tibia during the motion. This form of investigation has been utilised in very few studies because of a lack of access to the technology needed to measure it and none have investigated the motion continuously, however, this current study will attempt this. The term 'telescoping' is often used interchangeably with 'pistoning' throughout the literature. However, since the residual bones, soft tissue, socket liner and socket do not move together; in this thesis the term 'pistoning' will describe the movement of the whole residual limb in and out of the socket as measureable externally to the socket. 'Telescoping' will be used to describe the manner in which the bones move in comparison to the socket. This is discussed further in Section 2.6.2.

The Institute for Musculoskeletal Research and Clinical Implementation at the Anglo-European College of Chiropractic (AECC) has developed a quantitative fluoroscopy (QF) technology for the assessment of the mechanics of the bones of the spine. This is capable of semi-automated continuous motion analysis and the location of multiple images of the osseous linkages (Breen et al. 2006; Breen 1989). This current study adapted and applied QF to the analysis of kinematics between the tibia and prosthesis in below knee amputees as well as to the assessment of the kinematics of their spines and explored possible relationships between the two.

As defined by White and Panjabi in their foundational text on the subject, '*Clinical Biomechanics of the Spine*', *kinematics* is that branch of mechanics concerned with the study of movement of rigid bodies, with no consideration of the forces involved. Since clinical biomechanics of rigid bodies, such as the vertebra of the spine, are considered in this thesis using radiographic imaging techniques the kinematics properties which are taken into account are rotation, range of rotation (ROM), translation, patterns of motion and the instantaneous centers of rotation (ICR) in respect to uniform co-ordinate system made up of three orthogonal planes (the coronal, sagittal and axial planes) (White 1978). All terms and definitions used here can be found in the "Glossary / terms of use" of page v onwards.

## 1.1 Justification of the research

While there is evidence to suggest that there is a higher prevalence of LBP in LLAs (Ehde et al. 2000; Ehde et al. 2001; Elliott 1999; Smith et al. 1999) and postural changes in persons with limb length discrepancies (LLD) (Friberg, 1983b), there is limited evidence to link mechanical problems with lower limb prostheses and mechanical problems in the back. It is reasoned that prolonged exposures to asymmetries in gait and aberrant spinal kinematics resulting from repeated use of a prosthetic device might play a part (Gaunaurd et al. 2011; Hendershot 2012; Hendershot et al. 2013) . It is therefore desirable to explore relationships between the two in order to improve understanding and thus inform both prosthesis design and back pain prevention and rehabilitation.

## 1.2 Rationale

Musculoskeletal imbalances or pathologies often develop into secondary physical conditions or complications that may affect the mobility and quality of life of lower limb amputees (Gailey et al. 2008). It is reasoned in this thesis that the resultant asymmetry may be attributed to the mechanics of the limb-prosthesis interface. The importance of understanding the relationships between the mechanics of the residual limb-prosthesis interface and issues such as stability and symmetry in spinal motion have highlighted the need for study. To do so objectively requires the development of physical measurement and analysis procedures for measuring the functional biomechanics of these two joint systems, including the establishment of descriptive variables to reliably, accurately, safely and comprehensively detect and determine aberrant motion characteristics.

The rationale for this study is based on the established premise that the functional stability of the spine is reflected by its ability to maintain patterns of displacement between vertebrae during physiological movement (White 1990). QF has been demonstrated to have acceptable reliability and accuracy for measuring inter-vertebral motion. This has been previously utilised to compare persons with chronic (persistent) non-specific low back pain (CNSLBP) and healthy volunteers (Breen A.C. et al. 2012; Mellor et al. 2009; Mellor F.E. et al. 2014). In this thesis, QF will also be developed to measure the movement of the limb-prosthesis interface under measureable physiological loads.

## 1.3 New Approach

### 1.3.1 The Spine

If back pain is made better or worse by movement or position (mechanical back pain) (NHS 2010) it could be argued that it should be assessed by measuring mechanical function. The need to be able to measure inter-vertebral motion in the diagnosis of spine mechanics has been recognised for over a century (Fick 1904). Cadaveric studies of spinal motion in healthy, degenerate and diseased spines have been conducted (Gardner-Morse 2004; Mimura 1994; Zhao 2005). However, historically the measurement of spinal movement *in vivo* has been lacking. Some imaging modalities are good at depicting spinal anatomy (CT, MRI, plain film radiographs) but are unable to capture functional information. Furthermore, the measurements obtained by these methods have high variability and poor sensitivity and specificity in relation to symptoms (Deyo 1985; Jarvik and Deyo 2002).

Most studies that have accurately measured motion using these techniques have been restricted to measurements of end range positions (Adams and Dolan 1991; Patwardhan et al. 1999) (Adams et al. 2000; Panjabi 2007) and some are associated with high radiation dosage, for example, computed tomography (HPA 2010). Attempts have been made to measure vertebral motion using MRI (Kulig 2007; Powers 2003), but the time needed to acquire an image, which is even longer for the low field open coil/upright scanners needed to allow trunk motion, has prevented the collection of continuous motion data (McGregor et al. 2002).

Until recently, the most common method used in clinical practice to assess inter-vertebral motion has involved manually drawing lines on vertebral body images on plain radiographs.

**Figure 1: Traditional line drawing and measuring method for inter-vertebral angulation and translation on lateral lumbar spine radiographs**

Other methods of measuring motion of the human spine exist. Examples are goniometry (Monie et al. 2015) and roentgen stereophotogrammetric analysis (RSA) (Anderst et al. 2008). However RSA is invasive (due to the need to implant metal beads) and goniometry can only measure surface motion and is not robust enough to measure inter-vertebral motion with any accuracy. However, while it is currently considered the gold standard, RSA is impractical due to its complexity, cost and invasiveness.

A more accessible and low dose alternative to the above, which has been found to be repeatable and valid, is the adaptation of fluoroscopic imaging to allow the measurement of osseous displacements (Breen et al. 2006; Yeager et al. 2014). This was therefore the technology of choice for this study.

The pre-existing QF data collection techniques applied at IMRCI are in a form which is suited to measuring variables from the spine that are relevant to this study. Preliminary studies (outlined in Chapter 3) compared the various QF collection methods to determine which were best suited to the task of detecting a kinematic difference between amputees and healthy controls as well as determining which kinematic variables would best to be used in the assessment.

### 1.3.2 The Limb-Prosthesis Interface

To date QF has mostly been applied to the measurement of the kinematics of the spine (Breen A.C. et al. 2012; Mellor 2009). However, the ability to measure the kinematics of the lower limb as well affords a unique opportunity to explore the relationships between their function by collecting information from these in the same subjects. As with the spine, such continuous motion information would provide a much more comprehensive mechanical assessment than static imaging.

No methodology for using QF to measure osseous pistoning within prosthetic sockets existed prior to this study. However, to provide this in a form that allows comparison of limb-prosthesis and lumbar inter-vertebral kinematics would open a new avenue for biomechanics research into back pain in amputees. This thesis therefor also presents the development of a methodology for determining limb-prosthesis interface kinematics and its use in determining relationships to lumbar spine mechanics.

### 1.3.3 Hypothesis

The hypothesis of this study is that there is a relationship between the extent to which the residual tibia moves within the prosthetic socket and the kinematics of the lumbar vertebrae in amputees. It is also hypothesised that the patterns of motion between lumbar vertebrae are different between amputees and asymptomatic (non-amputees) healthy controls.

### 1.3.4 Aim

The aim of this research was to develop and implement a measurement system to determine the relationship of the motion between the bones in the spine (inter-vertebral motion) and that of the residual limb bones within a prosthetic socket in a cross-sectional cohort study of adult males with unilateral below knee amputation.

## 1.4 Report Structure

In order to investigate possible relationships between limb-prosthesis kinematics and the kinematics of the lumbar spine, it is necessary to have special knowledge of their functional anatomy and biomechanics, as well as the methods available for quantifying them. To also consider them in the context of low back pain requires additional knowledge of the epidemiology of this condition. To draw all these rather disparate areas into context and at the same time place them within the chronology of this work, the literature review contained within Chapter 2 first considers the epidemiology of both conditions, then introduces their separate functional anatomies and methods for measuring them. With this as a foundation, the choice, development and implementation of the necessary methodologies to investigate relationships between prosthetic fit and lumbar spine mechanical impairment follows in context.

Having underpinned the choice of methodologies, including the measurement parameters and their analysis, Chapter 3 details three preliminary studies to test these measurements and assist in the development of the research protocols detailed in Chapter 4. These include a passive spinal motion imaging protocol mutual to both a unilateral below knee amputee (BKA) population and a population of healthy controls. This is followed by a residual limb imaging protocol, posture measurements and questionnaire exclusive to the amputee population.

In Chapter 5 the participant characteristics of those persons recruited into this study are given, including the differences between amputee participants and healthy controls in terms of age and body mass index (BMI).Results from the questionnaires given to amputees as well as the radiation doses received by both populations are then summarised.

Chapter 6 defines each of the spinal kinematic measurements collected with Chapter 4’s protocols in terms of symmetry. It compares the populations and discusses these in relation to the study hypothesis and the literature in the field.

Chapter 7 examines the interactions within and between inter-vertebral joints of each population.

Chapter 8 details the visualisation, quantification and limitations of measuring the telescoping motion of the residual limb.

Chapter 9 examines the relationships between the kinematic measures in the spine and residual limb of amputees collected in Chapters 6 and 8 .

Lastly Chapter 10  concludes this thesis and discusses the limitations of the work, its implications and the potential for further work to expand upon it.

# Chapter 2: Literature review

## 2.1 Search methodology

Biomedical literature databases were searched to identify the current extent of knowledge in the area of secondary disabilities, post-amputation epidemiology, back pain among lower limb amputees, management and care of residual limbs and prostheses, lumbar spine biomechanics and residual limb biomechanics. After reviewing the initial papers, a secondary hand search was performed using journal articles and books from the reference lists and bibliographies of interest and identified as frequently referenced, supportive research or classic articles. The remaining references were resources from personal bibliographic databases made available to the author.

Search engines were used to obtain additional citations using these same key words and by utilising the “related citations” option. The search engines employed were Pubmed, Scopus, Web of science, Science Direct, Elsevier, Springerlink and Google Scholar. These also provided citations. Professional networking profiles were created on the LinkedIn and Research Gate websites where authors’ publications and research topics can be shared and followed. Pubmed, Google Scholar and Research Gate alerts were generated to provide an update of articles published and notifications of new publications which cited the articles already accessed. Clarification and background information was obtained by personal communication with authors.

## 2.2 Epidemiology (Back Pain and Lower Limb Amputation)

Back pain is not a disease but a constellation of symptoms that are usually acute and self-limiting. (Hodges et al. 2003) The impact of back pain disability has recently been updated in a 2012 systematic review by Hoy et al. (2012). This demonstrated that LBP is a major problem throughout the world. Of all people complaining of disabling LBP, the pain is attributable to pathology in only 1% and to nerve root pain in 14%. The remainder and vast majority is described as 'non-specific back pain' (85%) where pain is not attributable to either pathology or neurological encroachment (Deyo et al. 1992). This 'non-specific' back pain is widely considered to be "a mechanical problem… caused by disturbance of function, not by serious structural damage" (Koes 2010; NHS 2010; van Tulder 2006). It has been determined to have the greatest health and economic impact of all the musculoskeletal disorders and globally cause more 'years lived with disability' than any other condition (Hoy et al. 2014). Hoy et al.s' 2012 review included data from 165 studies from 54 countries. After adjusting for methodological variances, the authors estimated the mean global 1-month prevalence to be 23.2% (Hoy et al. 2012). Despite Hoys' review taking into account age, sex, urbanicity and economy; studies which have concentrated on unilateral lower limb amputees (LLAs) have generally found the amputee population to have a much higher prevalence of back pain (52-63%) when compared to the general population (Ehde et al. 2000; Ehde et al. 2001; Elliott 1999; Kulkarni et al. 2005; Smith et al. 1999). (The matter of back pain among LLAs is discussed further in section 2.4 of this report.)

More than 100,000 lower-limb amputations are performed each year in the United States (Pearson et al. 2011), while approximately 5,000 are carried out in the United Kingdom (UK) annually (Spinelli et al. 2015; United National Institute for Prosthetics & Orthotics Development 2013). This is seldom elective, as amputation surgery is used in the preservation of life or quality of life when other options are unfeasible or too costly. This is discussed further in section 2.5 of this Thesis.

## 2.3 Anatomy of the Spine

The spine is an extraordinary structure which maintains several vital functions such as providing support for vital organs and freedom of movement and protection for the spinal cord, all while also allowing motion in three planes (sagittal, coronal and axial). This is achieved through the contribution of a series of 23 individual joint linkages.  The spinal column is the body's main upright support and is characterised as containing 26 bones stacked one upon the other; twenty-four unique vertebrae and the sacrum and coccyx. The 24 individual vertebrae, as seen in Figure 2, consist of 7 cervical vertebrae, 12 thoracic vertebrae and 5 lumbar vertebrae with the sacrum and coccyx at the base of the spine.

The each vertebral pair is composed of vertebrae and inter-vertebral discs, spinal ligaments and the muscles which adjoin them (Figure 3 &Figure 4). These structures collectively distribute motion in response to external forces and adopted postures (Wong et al. 2011).

The 5 lumbar vertebrae are often referred to as L1, L2, L3, L4 and L5 when numbered from the top down. The lowest vertebra of the lumbar spine, L5, connects to the top of the sacrum, a triangular bone at the base of the spine that fits between the two pelvic bones, or ilia (Figure 2). The sacrum is normally made up of 5 segments which are fused together (Bogduk 1997).

There are anatomical variations in which some people have an extra lumbar vertebra known as a lumbarised sacrum, or one less, known as a sacralised lumbar segment or transitional lumbosacral vertebra which is only partially naturally fused to its subjacent neighbour. The transitional vertebra condition is not generally associated with back pain (Southworth and Bersack 1950).

Each joint is comprised of a pair of vertebrae and the interaction of 6 individual surfaces; 2 'superior articular process' of the inferior vertebra interacting with the 2 'Inferior articular processes of the superior vertebra to create the facet joints and superior and inferior inter-body joints, connected by an intervertebral disc. The inter-vertebral disc, along with a number of ligamentous structures both passively constrains and controls the velocity and range of inter-vertebral movement.

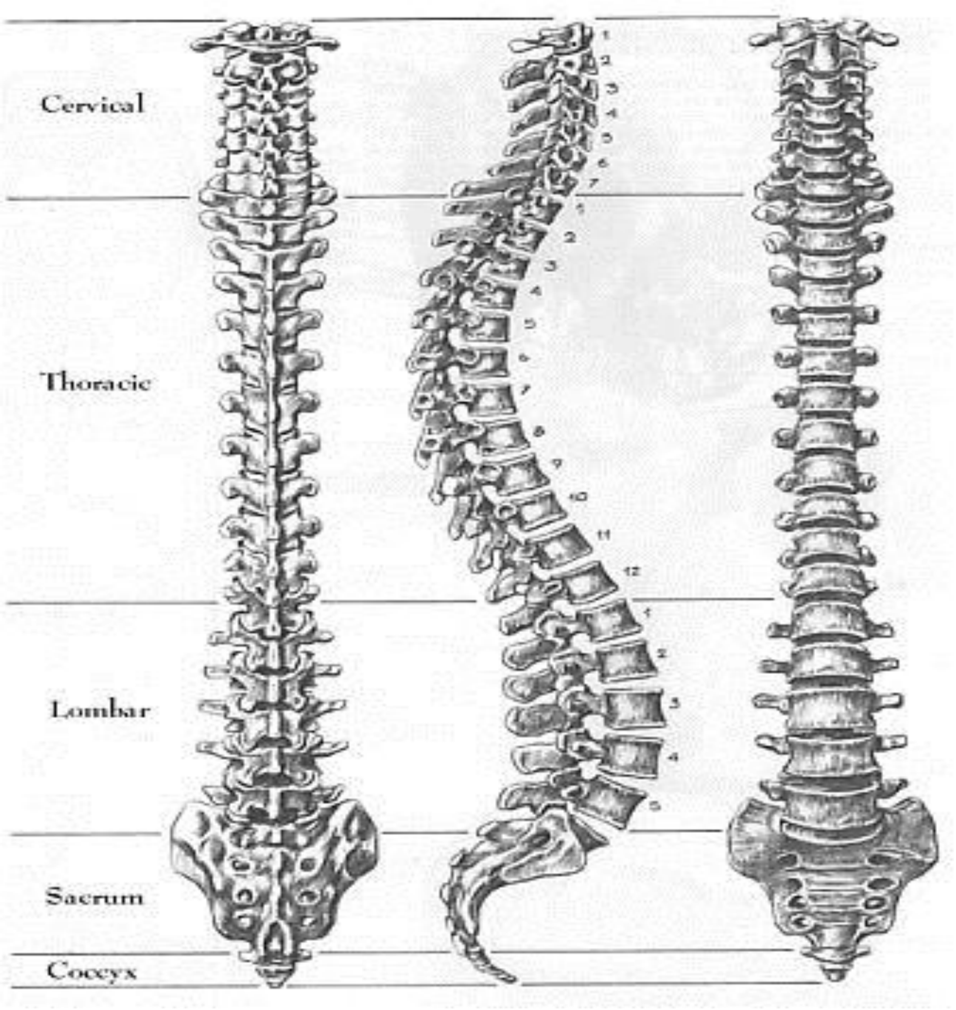



**Figure 2: The human spine (http://www.eorthopod.com/content/lumbar-spine-anatomy) [accessed online Sept. 2013]**

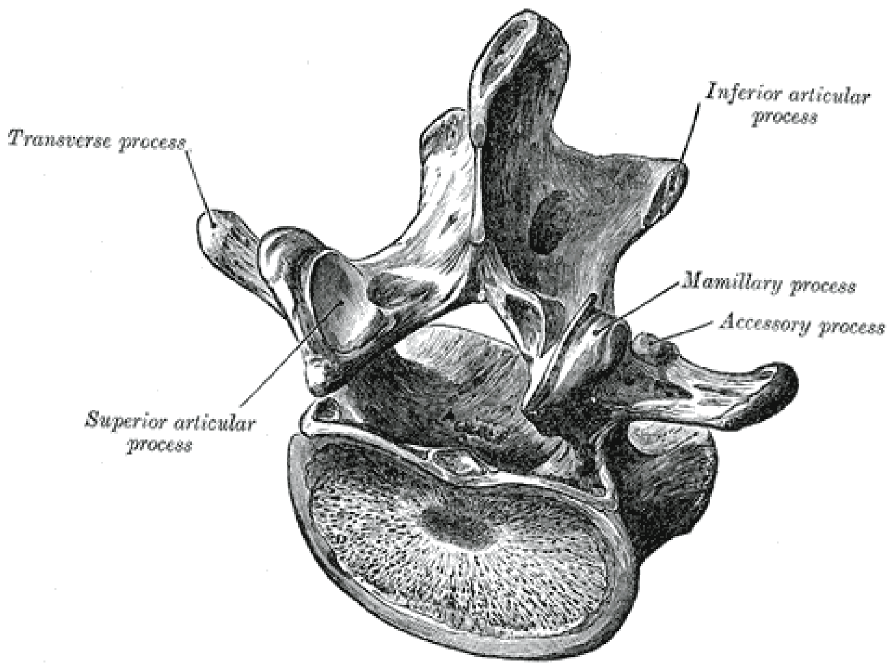



**Figure 3: Single lumbar vertebra (Gray 1918)**

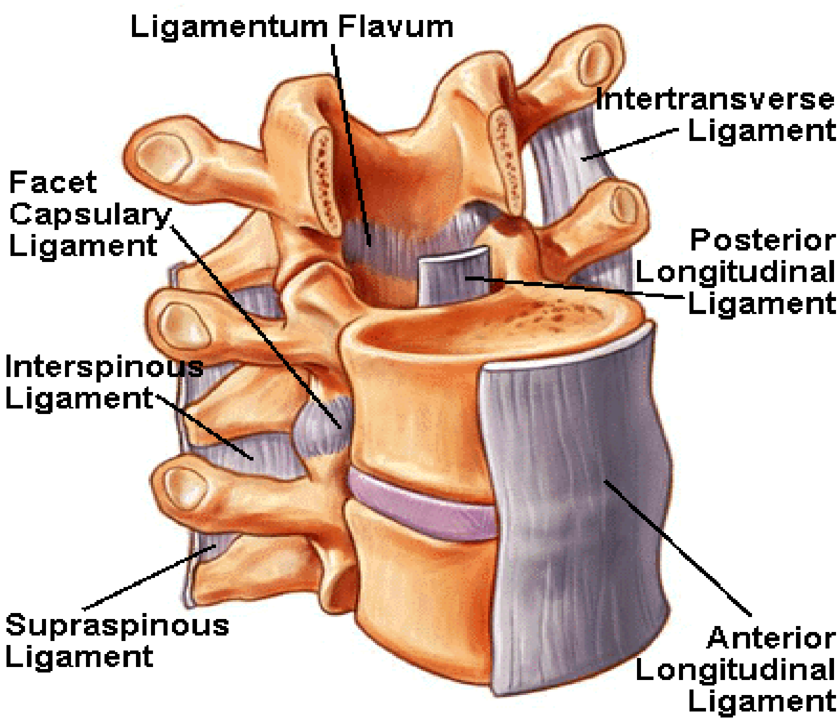



**Figure 4: Ligamentous attachments of the lumbar spine**

## 2.4 Lower Limb Amputation and Back Pain

As briefly outlined in section 2.2 "*Epidemiology* (Back Pain and Lower Limb Amputation)" LBP is a global issue spanning all ages, sexes and social or economic lifestyles, however, amputees have been found to have between 2 and 3 times greater prevalence of LBP in a given month, compared to a non-amputee population (Ehde et al. 2001; Hoy et al. 2012; Smith et al. 1999). Seventeen different studies have been identified which investigated the question of how prevalent or frequent the occurrence of back pain was as a secondary illness post amputation (Table 1). These studies varied in population size from 17 to 812 participants, in total reviewing less than 3000 lower limb amputees (Table 2).

Studies which did not include trans-tibial amputees (the most common of lower limb amputations, discussed in Section 2.5) were not included in this review. However, many studies reported their outcomes when measured across a population which contained persons with various amputation levels (including trans-tibial amputees) and did not focus on trans-tibial amputees alone. The levels of amputation covered in the literature are summarised in Table 4. Moreover, there is a lack of consistency in definitions of severity, duration and location of pain (i.e. back, low back, posterior aspect of the body from the lower margin of the twelfth ribs (R12) to the lower gluteal folds (GFs)) which makes a comparison across the literature difficult.

**Table 1. Documents the most common types of pain experienced among amputees**

| Study | Residual limb pain | Painful phantom limb | Non painful phantom limb | Back pain |
|---|---|---|---|---|
| **Smith et al. 1999** | 76.10% | 63.30% | 80.40% | 70.80% |
| **Ehde et al. 2000 & 2001** | 74.00% | 72.00% | 79.00% | 52.00% |
| **Friberg 1984** | - | - | - | 94.69% |
| **Kulkarni et al. 2005** | 56.93% | 61.88% | - | 62.87% |
| **Stam et al. 2004** | - | - | - | 74.71% |
| **Burke et al. 1978** | - | - | - | 47.62% |
| **Morgenroth et al. 2009** | - | - | - | 52.94% |
| **Ephraim et al. 2005** | 66.00% | 83.00% | - | 64.00% |
| **Smith et al. 2008** | 56.10% | - | - | 47.70% |
| **Rahimi et al. 2012** | 0.00% | 66.60% | - | 60.9% (34.9% LBP) |
| **Abdul-Sattar, 2007** | 62.00% | 78.00% | - | 64.00% |
| **Kusljugic et al. 2006** | - | - | - | 89.60% |
| **Hagberg and Branemark 2001** | 51.00% | 48.00% | _ | 47.00% |
| **Hammarlund et al. 2011** | - | - | - | 86.96% |
| **Taghipour et al. 2009** | 92.20% | 89.40% | 85.10% | 76.60% |
| **Behr et al. 2009** | - | - | - | - |

**Table 2. Available studies of lower limb amputee populations**

| Study | Population (n=) | Male % | Mean (SD) |
|---|---|---|---|
| **(Smith et al. 1999)** | 92 | 86.00% | 49 (13.7) |
| **(Ehde et al. 2000; Ehde et al. 2001)** | 255 | 81.00% | 55.1 (14.3) |
| **(Friberg 1984)** | 113 | 100.00% | 65.1 (-) |
| **(Kulkarni et al. 2005)** | 202 | 86.14% | 48 (-) |
| **(Stam et al. 2004)** | 240 | 32.92% | - (-) |
| **(Burke et al. 1978)** | 42 | 90.48% | 48.4 (-) |
| **(Morgenroth et al. 2009)** | 17 | - | 52 (11.3) |
| **(Abdul-Sattar 2007)** | 914 * | 60.40% | 50.3 (13.3) |
| **(Smith et al. 2008)** | 107 | 82.24% | 51.1 (14.3) |
| **(Rahimi et al. 2012)** | 335 | 96.70% | 42.05 (6.32) |
| **(Ephraim et al.) 2005** | 53 | 70.00% | 45.3 (11.2) |
| **(Kusljugic et al. 2006)** | 37 | - | 46.2 (10.92) |
| **(Hagberg and Branemark 2001)** | 97 | 61.86% | 48 (-) |
| **(Hammarlund et al. 2011)** | 46 | 73.91% | - (-) |
| **(Taghipour et al. 2009)** | 141 | 100.00% | 45.2 (-) |
| **(Behr et al. 2009a)** | 42 | 83.00% | 55.1 (11) |
| * 812 LLA, 100 ULA, 2 were not specified | | | |

While the duration and severity of LBP in lower limb amputees (LLA) is not well researched with few publications reporting comparable tests, there are a few key points that are generally agreed upon:

1. LLAs are more likely to suffer from back pain than the general population. While Hoy et al.s', 2012 review of LBP studies, referred to above, reported the 1-month global prevalence of back pain in the general population to be 23.2%, Smith et al. reported a 1-month prevalence in LLA to be 71% (Smith et al. 1999). This heightened prevalence has been confirmed in later studies. Ehde et al. used the same methodology in a larger population group finding a one month prevalence of 52% (Ehde et al. 2001) and Ephraim et al.s's cross-sectional survey, which incorporated the largest population of LLAs, found 64% of LLAs to have suffered from back pain in the 4-weeks prior to taking part (Barker et al. 2006). Other studies have reported prevalences of back pain among LLAs ranging from 26.3% to 62.9% (Kulkarni et al. 2005; Stam et al. 2004), however, it is unclear if these are single point prevalences or relate to longer periods of time (Table 3).
2. It has been reported that the incidence of new back pain increases after amputation (Hammarlund et al. 2011; Kulkarni et al. 2005) (Table 3).
3. While more than half of all LLAs report bothersome LBP it is also often worse than that at other pain sources related to amputation, such as phantom limb pain or residual limb pain (Ehde et al. 2001; Kulkarni et al. 2005; Smith et al. 1999).
4. Incidents of back pain are not limited and are frequent in occurrence (Abdul-Sattar 2007; Ehde et al. 2000; Ehde et al. 2001; Friberg 1984; Hammarlund et al. 2011; Smith et al. 1999) (Table 5)
5. Back pain is also commonly found to be more bothersome in trans-femoral than trans-tibial amputees (Ehde et al. 2001; Kulkarni et al. 2005; Smith et al. 1999).

**Table 3. Prevalence of back pain where determined by the available studies**

| Study | Point | 1 month | 1 year | post amputation | Lifetime |
|---|---|---|---|---|---|
| **Smith et al. 1999** | - | 70.80% | - | - | - |
| **Ehde et al. 2000 & 2001** | - | 52.00% | - | - | - |
| **Friberg 1984** | - | - | - | - | 94.69% |
| **Kulkarni et al. 2005** | 62.87% | - | - | - | - |
| **Stam et al. 2004** | 26.30% | - | - | - | - |
| **Burke et al. 1978** | 47.62% | - | - | - | - |
| **Morgenroth et al. 2009** | - | - | - | 52.94% | - |
| **Ephraim et al. 2005** | - | 64.00% | - | - | - |
| **Smith et al. 2008** | 47.70% | - | - | - | - |
| **Rahimi et al. 2012** | - | - | - | - | - |
| **Abdul-Sattar, 2007** | 64%. | - | - | - | - |
| **Kusljugic et al. 2006** | - | - | - | - | - |
| **Hagberg and Branemark 2001** | 47.00% | - | - | - | - |
| **Hammarlund et al. 2011** | - | - | - | - | - |
| **Taghipour et al. 2009** | - | 76.60% | - | - | - |
| **Behr et al. 2009** | - | - | - | 45.24% | 57.14% |

**Table 4. Level of amputation in the studies listed in Table 1.**

| Study | Unilateral | Bilateral | Transfemoral (above knee) | Knee disarticulation | Trans-tibial (below knee) | Symes level (ankle disarticulation) | Other (hip, toes) |
|---|---|---|---|---|---|---|---|
| **Smith et al. 1999** | 100.00% | 0.00% | 25.00% | 3.30% | 63.00% | 8.70% | 0.00% |
| **Ehde et al. 2000 & 2001** | 100.00% | 0.00% | 30.00% | 5.00% | 54.00% | 8.00% | 8.00% |
| **Friberg 1984** | 99.10% | 0.88% | 25.66% | - | 74.34% | - | 3.54% |
| **Kulkarni et al. 2005** | - | 4.95% | 38.12% | 0.00% | 56.93% | - | - |
| **Stam et al. 2004** | 100.00% | - | 100.00% | - | - | - | - |
| **Burke et al. 1978** | 100.00% | 0.00% | 45.24% | 0.00% | 52.38% | 0.00% | 2.38% |
| **Morgenroth et al. 2009** | 100.00% | 0.00% | 100.00% | 0.00% | 0.00% | 0.00% | 0.00% |
| **Ephraim et al. 2005** | - | 9.60% | 38.60% | - | 40.70% | - | - |
| **Smith et al. 2008** | - | 9.30% | 29.90% | 3.70% | 53.30% | 1.90% | 1.90% |
| **Rahimi et al. 2012** | - | 100.00% | - | - | - | - | - |
| **Abdul-Sattar, 2007** | 100.00% | 0.00% | 26.00% | 0.00% | 74.00% | 0.00% | 0.00% |
| **Kusljugic et al. 2006** | - | - | 13.50% | - | 73.00% | 13.50% | - |
| **Hagberg and Branemark 2001** | 100.00% | 0.00% | 100.00% | 0.00% | 0.00% | 0.00% | 0.00% |
| **Hammarlund et al. 2011** | - | - | 41.30% | 19.57% | 39.13% | - | - |
| **Taghipour et al. 2009** | 100.00% | 0.00% | 30.50% | 27.00% | 42.50% | 0.00% | 0.00% |
| **Behr et al. 2009** | 0.00% | 0.00% | 33.33% | 33.33% | 33.33% | 0.00% | 0.00% |

It is unsurprising that people with limb loss commonly complain of back pain as it has been linked, in the general population, to functional problems such as postural changes, leg-length discrepancy and physical deconditioning (Giles 1981). All these functional problems are intrinsic issues that LLAs are obliged to deal with. However, a MRI study which investigated amputees both with and without back pain for pathological differences did not find any significant differences between the two groups in terms of disc degeneration, concluding that a biomechanical rather than a degenerative origin is more likely to be the cause of the back pain (Kulkarni et al. 2005).

**Table 5. Overall frequency of back pain where determined by the available studies**

| Study | Never | Sometimes | Always (>50%) |
|---|---|---|---|
| **Smith et al. 1999** | 9.20% | - | 32.60% |
| **Ehde et al. 2000 & 2001** | 2.00% | 26.00% | 72.00% |
| **Friberg 1984** | 5.30% | 22.12% | 28.32% |
| **Kulkarni et al. 2005** | - | - | - |
| **Stam et al. 2004** | - | - | - |
| **Burke et al. 1978** | - | - | - |
| **Morgenroth et al. 2009** | - | - | - |
| **Ephraim et al. 2005** | 37.70% | 44.80% | 17.50% |
| **Smith et al. 2008** | - | - | - |
| **Rahimi et al. 2012** | - | - | - |
| **Abdul-Sattar, 2007** | - | - | - |
| **Kusljugic et al. 2006** | - | - | - |
| **Hagberg and Branemark 2001** | - | - | - |
| **Hammarlund et al. 2011** | 13.04% | 52.17% | 34.78% |
| **Taghipour et al. 2009** | - | - | - |
| **Behr et al. 2009** | - | - | - |

### 2.4.1 Leg length discrepancies

As a possible contributor to back pain, LLDs are an obvious area of interest, having been implicated in affecting gait and standing posture, as well as an increased incidence of scoliosis, osteoarthritis of the hip and spine, loosening of hip prostheses and lower extremity stress fractures (Friberg 1983a, 1984; Kulkarni et al. 2005; Raczkowski et al. 2010). Among LLAs an initial LLD is often incorporated into the design of the prosthetic limb, to provide patient specific comfort and ameliorate the intrinsic inability to control ankle flexion and the lack of proprioception of the prosthetic limb causing a trip when walking on uneven surfaces (Friberg 1984; Nolan and Lees 2000).

LLD has also been linked to symptoms of back pain in non-amputee populations since it appears, at least in part, to affect the lumbar spine by causing a scoliosis (Gurney 2002). Friberg measured leg length inequality of a non-amputee population both with and without back pain using plain x-ray techniques of the pelvis to measure the difference between the heights of the highest articular points of the femoral heads. The repeatability of this technique is claimed to be 0.6mm RMS (Friberg 1983a). In a population of Finnish army conscripts, it was found that persons with an LLD of more than 15mm were 5.32 times more likely to be suffering from back pain (Friberg 1983a). When Friberg went on to investigate the leg length discrepancies in unilateral amputees and their correlation to other joint pains (i.e. hip, knee and back pain), his results showed that 34% of 113 Finnish war-disabled amputees had an LLD of greater than 20mm (Friberg 1984). Twenty-eight per cent (32 subjects) of these amputees suffered from frequent or constant and severe low back pain and had a mean leg length discrepancy of 21.7mm. However, Kulkarni et al. (2005) found no obvious correlation with back pain in subjects with LLD of less than 30mm (Kulkarni et al. 2005). This has also been supported by other studies (Grevsten and Erikson 1975; Lilja et al. 1993; Narita et al. 1997; Soderberg et al. 2003).

It has also been demonstrated that non-amputees with a leg length inequality of up to 20 mm were mostly unaware of the asymmetry (Friberg 1983b). This inconsistency in findings may be due to the variability in methods of assessing

LLD, from radiographs of the pelvis to simple measures using palpation and measuring tape. Kulkarni et al. (2005) did not detail how they measured LLD, whether the “physical examination” took place weight-bearing or recumbent, and what anatomical sites the “average of three measures” were from.

As pointed out by Gurney (2002); authors throughout the literature disagree on the extent to which LLD causes secondary illnesses, and if so, what magnitude of LLD is necessary to generate problems. An association between LLD and pathological conditions does not demonstrate a cause and effect relationship and must be treated with caution. However, factors such as age and level of physical activity must also be taken into account. In the case of mature amputees, their tolerance for LLD at a later stage in life, despite remaining active, could be considerably lower than a younger person who is inactive and has had LLD their entire life (Gurney 2002).

### 2.4.2 Changes in Posture

Lower limb changes can affect posture. In a review, Gailey et al (2008) reported that “Some of the more common changes observed as a result of a leg-length discrepancy are lateral tilting of the pelvis in the frontal plane, pelvic torsion in the sagittal plane, and lumbar scoliosis”. Conversely, Hoikka et al. (1989) reported that in a study of 100 adults suffering from chronic low-back pain, LLD had a poor correlation with the lumbar scoliosis but a moderate correlation with sacral tilt. Sacral tilt, correlated well with the lumbar scoliosis, but only when the tilt was more than 3° (Hoikka et al. 1989).

In 2003 Lee at al. studied the influence of the length of the lower-limb prostheses itself on global spinal kinematics using an electromagnetic tracking device (3SPACE Fastrak) attached to the skin over the spine and pelvis to measure bending while subjects exercised with the prosthetic limb set at different lengths. Fastrak’s accuracy in orientation when static is reportedly 0.15° RMS and Lee at al. found in reliability studies that the mean error of movement measurement was 1.2° ±0.5° (Lee and Turner-Smith 2003).

This study provided initial evidence that changes in the prosthetic length or leg-length difference measurably altered the movement patterns and range of the lumbar spine by significantly altering the starting position of the lumbar spine and pelvis. While the participant was standing, LLDs led to lateral tilt of the pelvis and lateral bending of the spine which in turn led to asymmetric ranges of motion and changes in the directions of movement coupling in both the coronal and axial planes.

Lee et al. concluded that; “The kinematic changes brought about by the prosthetic leg being too short apparently were more significant than those associated with a prosthesis that was too long.” (Lee and Turner-Smith 2003)

The former, as mentioned above in “2.4.1 Leg length discrepancies”, is often the case, allowing for greater ease of ambulation across uneven surfaces.

#### *2.4.2.1 Scoliosis*

The most commonly reported postural change in LLA is scoliosis, even though it reportedly correlates poorly with it (Hoikka et al. 1989). Scoliosis is an abnormal lateral curvature of the spine (Figure 5) (Burke et al. 1978). Scoliosis is typically broken down  into 3 categories: congenital, (caused by vertebral anomalies present at birth); idiopathic (cause unknown, sub classified as infantile, juvenile, adolescent, or adult, according to when onset occurred), or secondary to another condition (Kim et al. 2010). Burke et al (1978) reported abnormal radiographic findings in the spines of 42 subjects with lower-limb amputation, observing scoliosis in 43% of this group (Burke et al. 1978).

Scoliosis is thought to be related to back pain since the prevalence of back pain in people with scoliosis has often been reported to be high. For example, people with adolescent idiopathic scoliosis can expect lifetime, 1- year and point prevalences 1.3 to 2.4 times greater than that of those with no scoliosis In addition, people with scoliosis have been shown to experience significantly more severe pain for a significantly longer durations and with more frequent recurrences in comparison to non-scoliosis groups.  (Mayo 1994; Sato et al. 2011).

Functional scoliosis (Figure 5) as a secondary condition, is thought to be sometimes caused by biomechanical compensation for LLD (Raczkowski et al. 2010) (discussed in 2.4.1) . LLD causes one hip to sit higher than the other, which in turn can cause sacral angulation and lateral bending of the lumbar motion segments, coupled with axial rotation and a pelvic rotation opposite to that caused by lumbar coupling (Papaioannou et al. 1982). Papaioannou quantified this relationship and noted “scoliosis was minor in patients with discrepancies of less than 2.2 centimetres” (Papaioannou et al. 1982). Moreover, the sway of the lumbar spine during gait in a case of LLD creates a scoliotic response within every gait cycle, subjecting the lumbar motion segments to constant, repeated, asymmetrical bending and torsional loads which can cause fatigue of the restraining ligaments and discs. In time, this may permanently change their holding properties (Panjabi 2006; Reeves 2007). It remains to be seen at the inter-vertebral level whether the altered kinematics, resulting from these changes, such as those observed by Lee et al. (2003), is related to LBP or spinal pathologies such as scoliosis as demonstrated by Friberg, 1983 (Friberg 1983a; Lee and Turner-Smith 2003).

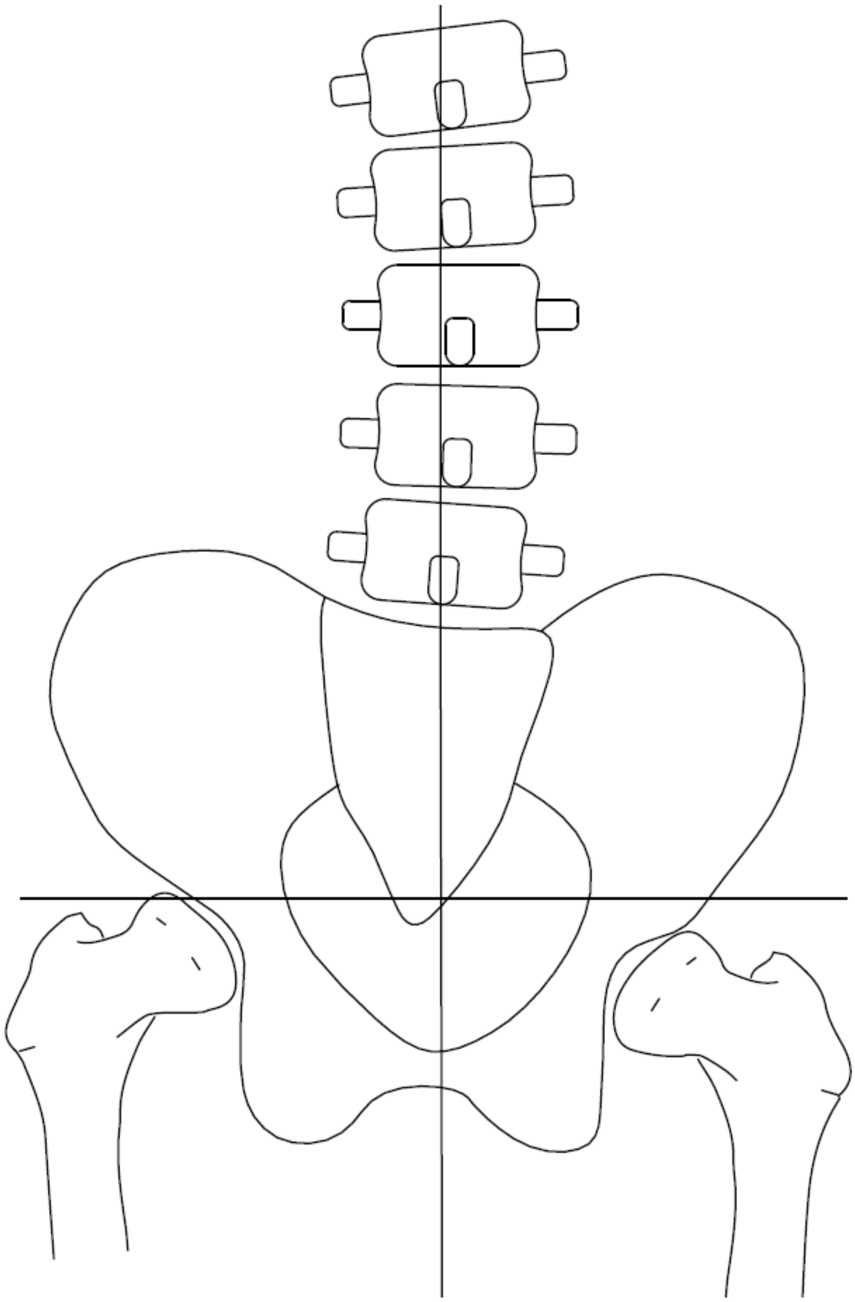


**Figure 5: Functional scoliosis, indicated to be as a result of leg length discrepancy causing pelvic tilt towards the shorter leg.**

### 2.4.3 Gait

Gait Analysis is the systematic study of ambulatory locomotion by way of measuring body movement, often in conjunction with muscle activation and ground reaction forces. The quantification of gait biomechanics allows researchers and clinicians to assess the efficiency of ambulation and identify possible posture or movement related problems in persons with injuries, which may, in themselves, lead to secondary illnesses. Many studies have measured the gait of unilateral amputees, conducted under the hypothesis that asymmetries in ambulation due to discrepancies in muscular control and limb length discrepancies may relate to degenerative joint disease or disability. The majority of people with amputation who use a prosthesis daily but have associated socket instability, discomfort, or residual limb pain have been shown to adopt a gait strategy that places greater dependence on the intact limb (Murdoch and Bennett-Wilson 1998). Regardless of the cause of the gait deviation, people with amputation have a longer stance phase on the intact limb than the prosthetic limb during ambulation (Chang et al. 2014). Increased loading of the intact limb has been attributed to an effort to avoid pain in the residual limb, however, this often causes pain and degenerative changes in the intact limb joints (Chang et al. 2014). Furthermore, altered gait, reduced activity, and other adaptations additionally stress the entire body.

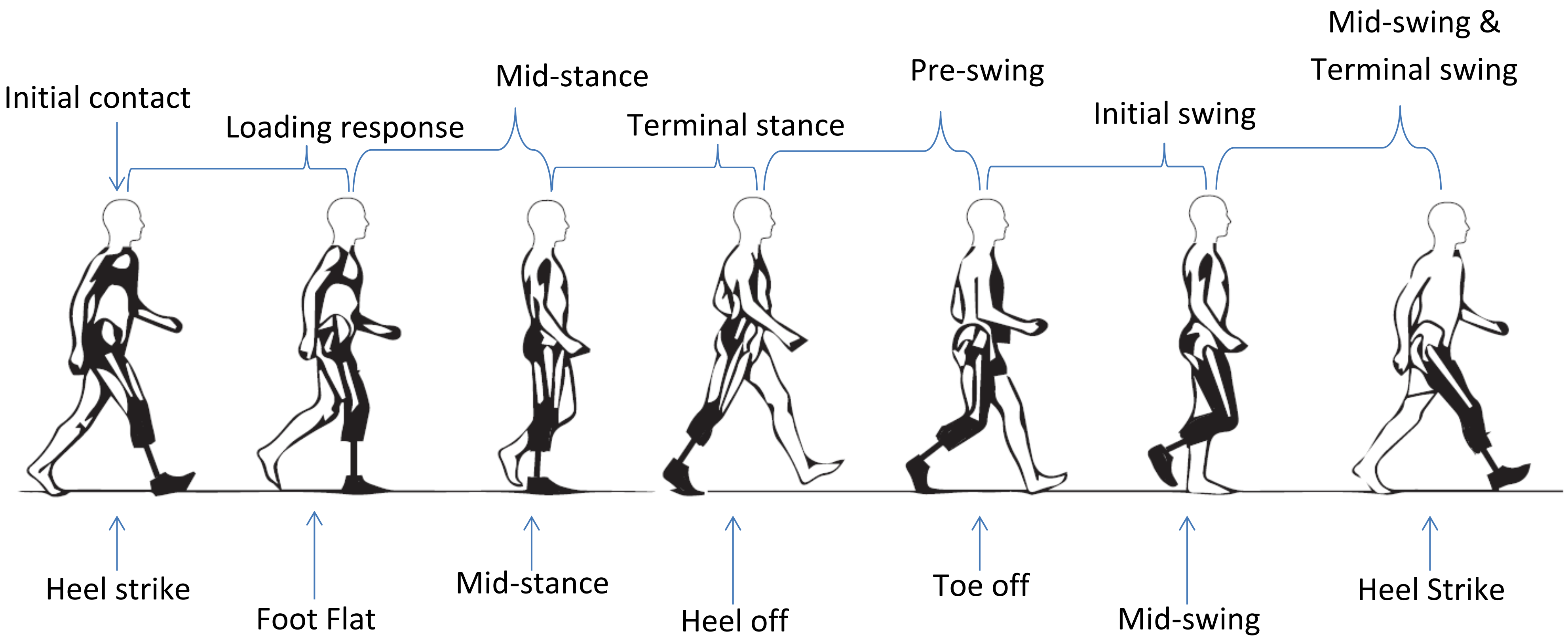



**Figure 6: The complete gait cycle, with stance phases (above diagram) and boundary positions (below diagram) indicated.**

#### 2.4.3.1 *The gait cycle*

The gait cycle is split in to two main phases; the stance phase and the swing phase. These can be broken down into the following eight phases: Initial contact, Loading response, Mid-stance, Terminal stance, Pre-swing, Initial Swing, Mid-swing and Terminal Swing. The boundaries of these are defined by six distinct positions: Heel strike, Foot flat, Mid-stance, Heel-off, Toe-off and Mid-swing before repeating (Figure 6).

Among LLAs three factors have been identified as leading contributors to asymmetries in gait:

- Limb length discrepancy (LLD); as discussed in section 2.4.1, is often incorporated into the design of the prosthetic limb, causing LLAs to compensate though mechanisms such as 'hip hiking' to overcome the differences in leg length while walking.
- Lack of limb control; due the intrinsic inability to control ankle flexion/pronation and the lack in proprioception of the prosthetic limb.
- Socket fit; the ability of the residual limb to move optimally within the prosthetic socket during ambulation. (During the swing phase of gait a load is induced along the length of the limb. This negative (traction) force during the swing phase is due to gravity and inertial forces acting on the limb (Zahedi et al. 1987)). Among LLAs this can cause changes in the socket positioning on the residual limb, generating an active LLD (2.4.1) and changes in alignment between the prosthetic and the residual limb (2.6.1).

#### 2.4.3.2 *Spinal effects*

These asymmetries and the compensatory processes that amputees undertake to overcome them have been thought in turn to have an effect on the kinematics of the spine. In particular, lateral trunk flexion has been described as an observable postural and gait deviation in amputees (Gailey et al. 2008; Gaunaurd et al. 2011). A number of studies have addressed the implications of lower limb amputation on gait and some have investigated the responses of the spinal kinematic chain. Measuring the motion responses in the trunk to walking with a prosthetic, compensation mechanisms in the hip and spine have been observed (Chang et al. 2014). These compensatory mechanisms have been demonstrated in the range of motion of the spine (Goujon-Pillet et al. 2008), increased muscle contraction of the back and hip muscles (Yoder et al. 2015) and greater energy expenditure (Willigenburg et al. 2012).

Gait asymmetry thus has the effect of causing increased lumbar spine moments and metabolic energy costs which is likely to cause fatigue and injury due to repeated exposure (Hendershot and Wolf 2015; Willigenburg et al. 2012). However, further considerations of gait are beyond the scope of this thesis.

## 2.5 Lower limb amputation

Lower limb amputation surgery used to be performed purely for the removal of a useless or debilitating part, rather than a reconstructive procedure to restore ambulatory function. However, currently the reasons for amputation can be broken down informally in to the 3 “D”s (Aiyangar et al.):

- Dangerous limb (eg. Malignant Tumours, Potentially lethal sepsis, Crush injury)
- Dead (or Dying) limb (eg. Gangrene, Vascular disease)
- Damn nuisance (eg. Pain, Gross malformation, Recurrent Sepsis)

Vascular disease, brought about by atherosclerosis or diabetes is the most common reason for elective amputation, followed by trauma.

This section describes the range of amputation surgery the ultimate goal of which is to create a residual limb and prosthesis mechanism that will interface well and restore or, in the case of congenital disorders, improve function.

### 2.5.1 Anatomy and the lower limb prosthesis

Amputation can occur at a number of levels, the most common of which are below knee (trans-tibial) 50.6%, mid-thigh (trans-femoral) 8.8%, and knee disarticulation 2.8%. Amputation at other levels still occur, for example, partial foot (0.7% of amputation surgery’s), ankle disarticulation 0.6%, hip disarticulation 0.2% , toes 2.3% & bilateral amputation (i.e. amputation of both lower limbs 3.9%) (Castellvi et al. 2015; Rahimi et al. 2012). The locations of these amputation sites of these are shown in Figure 7 below.

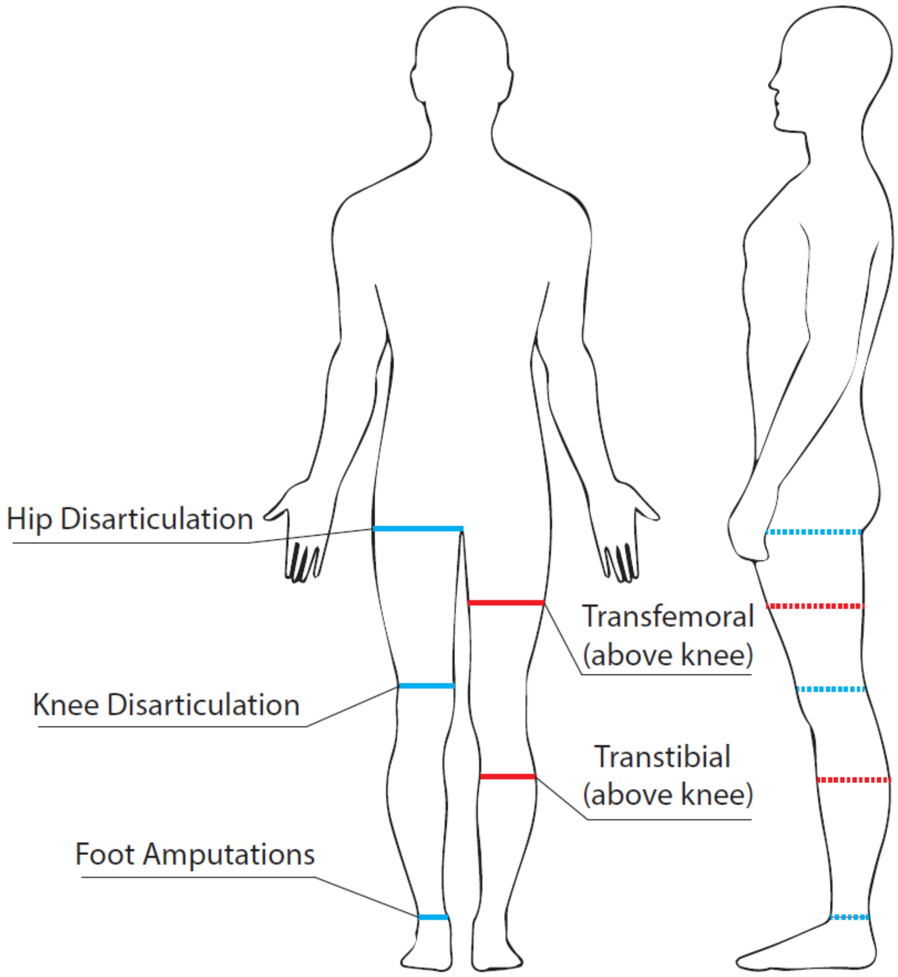



**Figure 7: Locations and terms for different levels of amputation surgery.**

It has been long known and generally accepted that more a proximal amputation is associated with more energy consumption while walking (Oh et al. 2009). This is due to the difficulty in recreating the functionality (degrees of freedom and control) of a healthy limb with the use of prosthetic devices. For this as well as the increased occurrence of secondary illnesses such as residual limb pain, phantom limb pain and back pain (as discussed in 2.4

Lower Limb Amputation and Back Pain) surgeons are advised to preserve the knee joint whenever it is practical to do so and will fashion the residuum at the lowest practical level (Casler 1992). Moreover, short residual limbs make fitting difficult, although very long residual limbs may be prone to circulation problems. As a guide, it has been recommended that 8cm below the tibial plateau is retained to allow optimal control of the socket (Henrot et al. 2000).

The sequence of events for amputee rehabilitation usually consists of, surgical intervention, consultation with a physical therapist and consultation with a prosthetist on design, fit and alignment of the prosthesis. Care is supported by all these professionals, but eventually, unless a mechanically derived ambulatory problem is encountered; further care is provided almost exclusively by the prosthetist (Newton et al. 1988). A key step in the rehabilitation of amputees starts with the surgery and the optimal technical management of tissues during the procedure. If the surgical procedures are not carried out with sufficient care and forethought, all the subsequent steps become far more difficult and may even result in revision surgeries that reduce the eventual residual limb from the ideal size (Bovvker et al. 1992).

During amputation, the surgery is designed to keep enough muscle tissue to adequately pad the residuum (Henrot et al. 2000). This additional soft tissue padding serves two distinct roles; firstly to enhance control, stability and proprioception and secondly, to reduce discomfort which may lead to tissue trauma (Neumann et al. 2012). It does this by creating a splinting effect when pressure is applied to the residual limb though the socket when body weight is applied (i.e. during gait).  One technique to generate this padding is the ‘posterior flap’, and example of which can be seen in Figure 8. However, studies of the variety of flap configurations, including ‘Anterior and posterior flaps’, ‘medial and lateral flaps’ and ‘Skew Flaps’  have found that incision placement is not crucial so long as the incisional scar is not adherent to the underlying bone (Bowker et al. 1992). The end of the remaining bones are blunted and beveled to reduce the patient’s discomfort and facilitate rehabilitation and tissue adaption when weight is finally applied to the residual limb within the socket.

In the case of trans-tibial amputation the fibula is made approximately 2cm shorter than the tibia to minimise secondary conflicts, such as bayoneting of the fibula into the soft tissue below when load is applied. These considerations are largely aimed at obtaining sustainable load bearing of the residual tibia by the cushioning flap. The distal end of the tibia after amputation is not meant to support much of the amputees' weight, but a longer tibia is preferable as it aids stability and provides the leverage to control knee flexion. However, the movement of the tibia within the soft tissue has only been investigated at discrete load intervals and not dynamically *in vivo* .

#### *2.5.1.1 Osseointegration*

Osseointegration (sometimes referred to as Osteointegration) is a very different type of post amputation restorative surgery. It consists of a transcutaneous bone-anchored prosthesis which means it does not require a prosthetic socket or a residual limb suspension since the prosthetic limb is directly attached to the bone of the amputated limb. As such, while it is worth mentioning here as a solution to create a static limb length with good sensory feedback as a result of the direct link with the skeletal system, this technique will not be considered further in this report as it is not a solution that is available to the majority of amputees since it is only considered for those who have been unable to achieve a satisfactory level of rehabilitation using conventional socket techniques (Sullivan et al. 2003).

**Figure 8: Trans-tibial amputation surgery technique using an extended posterior flap for cushioning of the tibia.**

#### 2.5.1.2 *Prosthetic socket design*

Socket designs are often classified in one of two categories: Patellar Tendon Bearing (PTB) and Total Surface Bearing (TSB). PTB sockets are designed so that a large proportion of the loading, when body weight is applied, is supported by the patellar tendon. The patellar tendon attaches the anterior thigh muscles (quadriceps femoris) through the bottom of the kneecap (patella), to the top of the tibia and inserts into the anterior tibial tubercle. PTB sockets concentrate the load just above this. TSB sockets on the other hand, are intended to distribute weight throughout the surface of the residual limb within the socket. Anterior, medial, and lateral counter pressures are therefore employed to stabilise the residual limb within the prosthesis and to prevent excessive pressure over the distal end of the tibia. However despite this, the majority of weight is still generally supported at the site of the patellar tendon to avoid tibial bayoneting, which may lead to pressure sores and discomfort. Ultimately, the socket style is used highly dependent on the materials and technology available to the prosthetist. Within designs, there is a large variety of sockets which are tailored to the each amputee individually.

#### 2.5.1.3 *Residual limb retention*

While the socket design focuses on how weight is distributed to the residual limb when body weight is applied, it is also important to take into account the suspension and distraction of the socket away from the residuum when loading is removed or reversed during the swing phase of gait (causing centrifugal forces) (described in section 2.4.3 and Figure 6). To retain the prosthesis and minimise distraction of the residual limb in and out of the socket, numerous suspension techniques and liners have been developed in an attempt to accommodate individuals of different physical morphologies and lifestyles. This is because some aspects of suspension design that are implemented to minimise distraction of the residual limb may adversely alter the biomechanics of the prosthesis.

The prosthesis can be retained to the residuum by a number of methods. Examples include; a strap above the knee cap, the shape of the brim of the socket itself, or by suction created between the socket and residual limb by an elastic sleeve or flexible inner liner of silicone which is attached mechanically to the prosthesis. A diagram of some of the more common suspension systems is shown in Figure 9. The appropriateness of a given suspension system has been thought to largely depend upon the length of the residual limb, and whether its shape is cylindrical or conical. (Wirta et al. 1990)

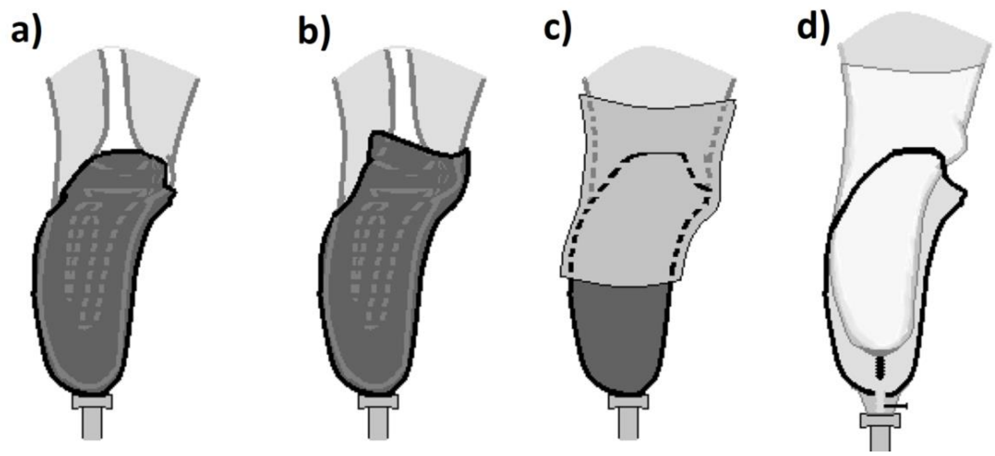



**Figure 9: Examples of socket suspension systems a) Supracondylar Brim b) Supracondylar Supra-patellar Brim c) Elastic Sleeve d) Silicone Liner. http://www.oandp.com/manuals/7.htm.[Accessed online Sept. 2013]**

It can be seen that there is considerable variation in prosthesis design, making it challenging to investigate their implications for the functional mechanical integrity of the rest of the amputees body, including, but not limited to, the hips and spine. What is common to all however, is their potential effect on the stability of the amputee during locomotion, and through compensatory gait mechanisms, the mechanical stability of the lumbar spine.

## 2.6 Methods for assessing socket fit

### 2.6.1 Alignment

Socket fit is often considered to be the most important factor in the success of a lower-limb prosthesis. However, alignment, defined as the relative orientation of the prosthesis to the residual limb and manifested as the angle between to the residual limb and socket, also affects the walking ability of the user. Poor alignment causes stress on the both the residual and contralateral limbs and can contribute to poor socket fit which leads to undesirable pressure distribution at the residual limb/socket interface (Gailey et al. 2008). Improper alignment can cause discomfort, pain, and potential tissue breakdown (Mason et al. 1996).

Modern sockets are formed to provide a pressure distribution over pressure tolerant sections of the residual limb and pressure relief where it can cause discomfort (this is discussed in further detail in section 2.5.1.2 “Prosthetic socket design” of this thesis). However, although this pressure distribution operates when the prosthesis is under load, during the swing phase of gait, traction forces cause the prosthesis to distract away from the residual limb. Under these traction conditions, medio-lateral movement at the distal end of the residual limb can occur.

Currently, the effects of alignment on the gait of people with amputation are not fully understood and no studies have investigated the relationship between prosthetic alignment and back pain (Gailey et al. 2008). Furthermore, the variability in alignment that is considered acceptable by the amputee appears to vary across individuals (Murdoch and Bennett-Wilson 1996; NASA 2008)

### 2.6.2 Residual limb suspension – “pistoning” and “telescoping”

A major indicator of lack of adequate fit of a lower limb prosthesis is “pistoning”, where the residual limb is able to slide in and out of the prosthetic socket during gait. Manufacturers have developed innovative ways to reduce pistoning of the soft tissue (i.e. skin, muscle and fat) by creating suspension techniques and socket liners to counteract the slip of the prosthesis out of the socket. Of all types of suspensions, suction has been considered the “gold standard” due to increased proprioception, intimate fit, and decreased pistoning (Tanner and Berke 2001). The suction suspension is achieved using a socket liner with a valve at the base. The socket liner is then placed into the prosthesis and an air pressure less than 1 atmosphere is induced giving to the name ‘suction’ or ‘vacuum’ suspension (Board et al. 2001).

As mentioned briefly in Chapter 1, for the purposes of this thesis the term ‘pistoning’ is used to describe movement of the whole residuum in and out of the socket while ‘telescoping’ is used to describe the manner in which the bones, soft tissue and liner move semi-independently within the socket causing an effective elongation of the residuum within the limb, which remains in the socket.

Measures of pistoning are however, often performed either subjectively though observation of an amputee’s gait or through external motion capture systems, although this does not account for the above elongation (Gholizadeh et al. 2011). Instead it compares the distances between reflective markers placed on the prosthesis and skin directly above the prosthesis during weight transfer.

Pistoning measurements (Figure 10) assume that the residuum moves as a single unit, much like a reciprocating engine piston within a cylinder, and that the movement of the skin outside of the prosthesis reflects the motion that is happening inside the prosthesis. However, this does not account for elongation of the limb or the differences in positions between the residual bone and skin. It therefore, may, underestimate the true elongation of the limb during gait. Radiographic imaging therefore is necessary to assess this.

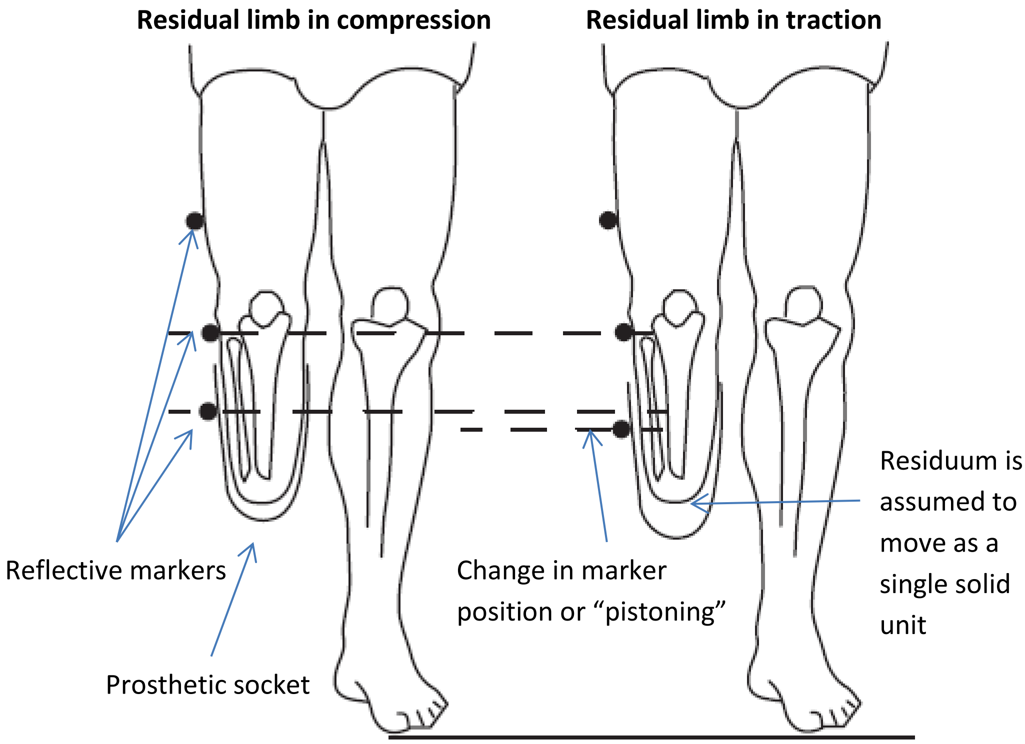



**Figure 10: Pistoning measurement gained by calculating the variations in distances between surface markers placed on the prosthesis and skin.**

The term ‘telescoping’ is used to describe the elongation of the residuum that occurs if the residual bones (tibia and fibula) move within the soft tissue which deforms against the socket liner and socket. This incremental elongation of the residuum is analogous to a telescope.

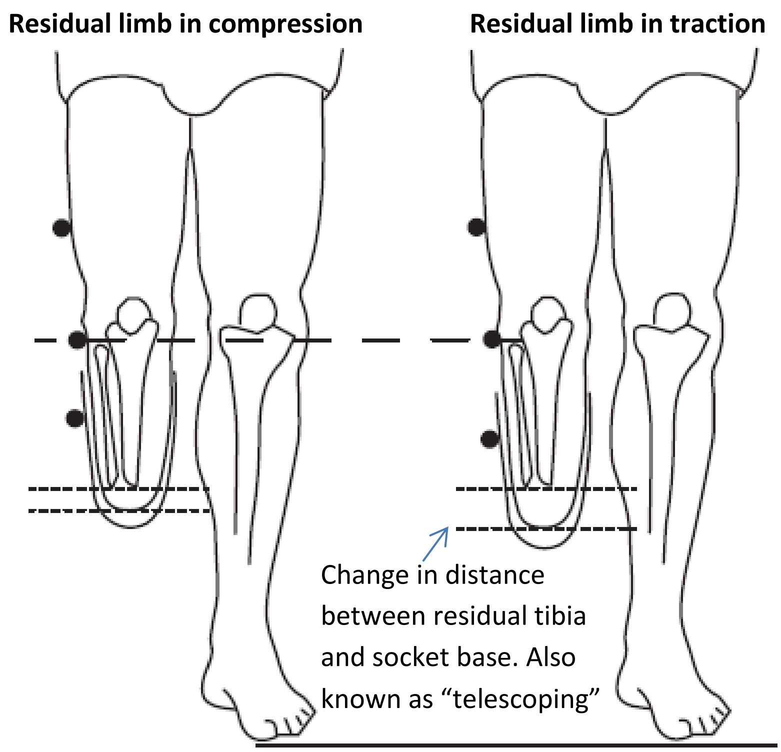



**Figure 11: Telescoping measurement gained by visualising and quantifying the movement of the residual bone within the socket.**

Evaluation of telescoping motion has been performed with various prosthetic sockets and liner interfaces in multiple studies which utilised radiographic techniques (Commean et al. 1997a; Grevsten and Erikson 1975; Grevsten and Eriksson 1974; Narita et al. 1997; Soderberg et al. 2003) seen in Table 6.

**Table 6. Radiological studies of tibial vertical displacement with different suspension systems, study populations and outcomes.**

| Study | Sample size | Age | Cause of amputation (%) | Socket build | Suspension type | Vertical displacement of tibia (mm) | Variance of measurement |
|---|---|---|---|---|---|---|---|
| **Söderberg (2003)** | 1 male, | 69 | Trauma | PTB | Supracondylar suspension | 35 | unknown |
| | | | | | PTB strap | 7 | unknown |
| | | | | | Distal pin suspension | ≈15 | unknown |
| | | | | | Vacuum suspension | 35 | unknown |
| **Lilja (1993)** | 5 male, 2 female | median 72 (61-79) | Diabetes mellitus (71%) Arteriosclerosis (29%) | PTB | unknown | 28 | variation 20mm-40mm |
| **Commean (1997)** | 1 male | 56 | unknown | PTB | unknown | 10.5 | unknown |
| **Narita (1997)** | 8 male, 1 female | (19-74) | Traumatic injury (66%), Tumours (22%), Burns (12%) | PTB | unknown | 36 | ± 5.6mm |
| | | | | TSB | Silicone liner | 25.3 | ± 9mm |
| **Tanner (2001)** | 1 male | 37 | unknown | unknown | neoprene sleeve | 20 | unknown |
| | | | | | silicone suction socket | 2 | unknown |
| | | | | | pin lock suspension | | |
| **Grevsten (1974/1975)** | 22 (sex unknown) | (28-66) | unknown | PTB | Patellar tendon bearing strap | 22.5 | SD 14.5mm |
| | | | | | Vacuum suspension | 11.3 | SD 7.4mm |
| **Tucker (2012 )** | 15 (male) | (22-32) | Trauma | TSB | pin lock suspension | 18.24 | ± 1.52mm |
| | | | | | suction sleeve suspension | 21.42 | ± 1.78mm |

PTB = Patellar tendon bearing, TSB Total surface bearing, SD = standard deviation

In 1974, Grevsten and Eriksson compared suction suspension to another method of suspension 'called a supracondylar strap' (a leather strap which supports the socket from above the knee) by examining skeletal and soft-tissue movement in trans-tibial participants (Grevsten and Eriksson 1974). Plain radiographs were used to demonstrate that there is less tibial translation in the proximo-distal direction (i.e. telescoping) within a suction socket (11.0 mm) than with one using a supracondylar strap (22.5 mm). It was concluded that this reduction was primarily due to reduced movement of soft tissue with the suction suspension. Lilja et al. reported that in 7 subjects using PTB sockets the mean value of residual tibia movement in the socket was 28 mm in the proximo-distal direction (Lilja et al. 1993). However, this was not compared to the pistoning component.

These studies suggest that during a gait cycle, the limb length can change by an amount near to the threshold of what is considered to be mild limb length discrepancy and that while socket liners play a part in reducing this telescoping action from the socket itself, the residual tibia and fibula are still relatively free to move within the cushioning tissue. Socket design with regard to body weight and pressure distribution, does not affect the level to which the residuum telescopes within the socket. This was most apparent in a telescoping measurement study reported by Tucker et al. in 2012 which showed that the majority (>60%) of the distal descent of the tibia had taken place before 20% of a subject's body weight had been applied to the residual limb (Tucker et al. 2012).   This movement and its influence on the rest of the lower kinetic chain is determined by the surgical procedure.  It is independent of socket fit but may affect the lumbar spine kinematics.

In summary, while recent refinements to amputation surgery and prosthetic sockets and liner design are aimed at amputee comfort and limb retention, without inclusion of an adequate assessment of the telescoping phenomenon, their consequences for dynamic LLD remains in question. As discussed above (2.4.1 Leg length discrepancies), LLD has been inconsistently correlated with spinal asymmetry and subsequently with back pain in unilateral amputees. A distinction needs to be made between LLD and changes in limb length due to telescoping as opposed to pistoning alone of the residual limb in and out of the prosthetic socket or tibial movement. The variations within subjects' own limb lengths due to pistoning and changes to the residual limb structure (deformation and volume changes) may lead to greater or lesser LLD throughout a given day or even during a single gait cycle. The high prevalence of scoliosis and back pain in unilateral amputees in the presence of gait and stance asymmetry implicates LLD as a possible cause. This raises questions about the measurement of these mechanisms and their contributions to mechanical low back pain.

### 2.6.3 Residual limb shape and volume changes

Shape and volume changes in the residual limb are believed to have a causal relationship to changes in limb-socket interface pressure and shear stress distributions, which in turn may lead to discomfort (Sanders et al. 2005). This discomfort can also be associated with socket fit problems, being adjusted too loose or too tight to account for discomfort and result in gait instability and possibly skin breakdown (previously discussed in 2.5.1.3) (Bovvker et al. 1992).

Regardless of the reason for or method of amputation/restructuring, the residual limb (residuum) of adults with lower-limb amputation undergoes substantial change in shape and volume in first 12-18 months after amputation (Berke 2004). In the mature residual limb, both daily changes and long-term changes over weeks or months can occur. Changes in shape and increases and decreases in the volume of the residuum affect the quality of the socket fit over the course of a day (Zachariah et al. 2004). For this reason amputees may feel required to carry additional prosthetic liners (socks) to compensate. Zachariah et al's. 2004 paper demonstrated within-day volume changes by measuring these in the residual limbs before and after activities. The authors used optical scanning equipment which was able to map the residual skin surface to a high degree of accuracy. They demonstrated that across their small population group (6 male volunteers) there was an average 11% increase in the volume of the residuum after walking 200m. Ninety-five percent of this volume change was found to happen within the first 8 minutes of rest after walking. Volume changes over 24 hour periods in mature residual limbs are believed to be the result of three interrelated mechanisms: pooling of blood in the venous compartment, arterial widening with muscle relaxation, and changes in the tissue fluid volume (Sanders et al. 2005; Zachariah et al. 2004).

Clearly these changes are likely to have implications for both socket fit and the telescoping motion of the tibia within the residuum. Quantitative biomechanical methods of assessing socket fit are becoming more important in the design of prosthetic sockets. However, most measurements are taken of the external shape of the residual limb since they are less costly (Zheng et al.

2001). However, there are a few techniques which are currently being used to measure the geometry and biomechanics of the inside of the residuum. These show great promise in helping unveil the mechanics of the socket-residuum interface and what is necessary to create a better prosthetic fit to optimise the amputees' mobility. Indirect (internal) measurements of socket/residuum and prosthetic joint kinematics are currently used by prosthetists in a trial and error format for prosthesis-socket performance maximization.

### 2.6.4 External assessments

Some tried and tested techniques have endured as reliable methods of measuring the volume of the residual limb by water displacement, using negative casts of the residual limb and measuring the continual circumferences along the length of the residuum (Board et al. 2001; Commean et al. 1996). More recent and advanced techniques to perform this same function and measure volume and shape of the residuum are; the hand held digitiser, moiré contourography, laser video scanning and silhouetting (Zheng et al. 2001).

### 2.6.5 Internal assessments

While the techniques for measuring the external shape and shape change of the residuum have had a profound effect on the design and development of prosthetics, allowing for a better fit and utility, these techniques are only able to suggest the degree of movement that may be happening below the surface of the residual limb. However, with the development of medical imaging techniques many studies have attempted to ascertain the motion of the residual tibia/fibula against the socket and soft tissues, these are discussed in the following sub sections.

#### 2.6.5.1 *Ultrasound*

Ultrasound seems to be the most common method for performing residual limb assessments. It can produce detailed information on structure and composition of the residual limb being able to measure the changes in densities of tissue types and the geometry of objects with a resolution and accuracy of approximately 3mm (Zheng et al. 2001).

There is some suggestion that ultrasound can be used during gait to measure residual bone movement with a reasonable accuracy. However, the use of ultrasound to monitor the skeletal motion within the socket during gait was not supported for use exclusively for clinical evaluations, due to the complexity of the method needed to mount the transducers in the socket and the time-consuming nature of the manual analysis of results (Convery and Murray 2000). Furthermore, any mal-alignment of the transducers during scanning will cause blurring of images when reconstructed from multiple samples.

#### 2.6.5.2 *Computed Tomography (CT)*

The use of CT is often sought in medical examinations due to its ability to generate 3D images of objects and reveal their composite parts from their relative densities. The use of the 3D data reconstructed from a series of 2D slices can give great insight into volumetric profile of the residuum and be used to create finite element models of the residual limb.

From these static 3D images, individual materials (socket, soft tissue bone etc.) can be identified allowing users to create 3D representations of each of the socket-residuum component parts. These can be visualised individually to demonstrate the effects of load when applied through the socket-residuum interface. (Commean et al. 1998; Commean et al. 1997b; Faulkner and Walsh; Kalender; Smith et al. 1996; Steege and Childress). Furthermore, it is possible to achieve a resolution of less than 1 mm with this technology, allowing measurements of the changes in bone orientation and soft tissue displacement to be determined with a high degree of precision and accuracy (Commean et al. 1996). However, significant movement artefacts have been reported leading to the conclusion that spiral CT scans are only sufficiently precise and accurate for static geometric and volumetric studies and not the measurement of function. In addition, the high dose of ionising radiation received by the amputee during CT, as well as its cost, means that its use must be justified clinically by its cost/benefit and safety.

### *2.6.5.3 Plain film x-rays*

Plain x-rays are used to generate a classical 2D image of the residual limb, revealing information about the skeletal tissues and giving approximate dimensions for soft tissue displacement. Many studies have been performed to evaluate prosthetic fits using X-rays due to their inherent ability to display the pathology in the socket-residuum with very little setup time (Erikson and Lemperg 1969; Grevsten and Erikson 1975; Grevsten and Eriksson; Lilja et al. 1993).

With the addition of radio opaque dyes injected directly into the subject's vascular system it is also possible to monitor atrophy of the arteries and veins in conjunction with x-rays and to measure variations in residual bone movement in one or more static positions, both weight-bearing and non-weight-bearing (Janssen et al. 2011). However, having a much lower radiation dose than CT and a higher resolution, the lack of 3D data means it is impossible to estimate volumetric data to a high accuracy. The images produced, while often of high resolution, are of fixed moments in time and can only demonstrate the gross range of movement between a few images in pre-selected positions. Without information about the path it takes to get there, the dynamics of tibial motion through the residuum is not assessed.

### 2.6.5.3 *Magnetic Resonance Imaging (MRI)*

MRI, much like CT, allows the operator to gain a 3 dimensional output of the pathology of residual limbs and tissue distortion under loading conditions with the added benefit that there are no known detrimental effects, as with ionising radiation. MRI is able to distinguish the different types of tissues that make up the residual limb and its soft tissues (muscle, bone, fat and water) more subtly than CT. This can be useful in determining changes to the soft tissue (i.e. fat infiltration and musculature atrophy) (Zheng et al. 2001). Like CT, MRI requires the subjects to lie down; therefore, to investigate the effects of load, devices must be created to apply force to the residual limb. However, with the development of open coil upright MRI scanners it will be possible to have the subject stand. The drawback of MRI is that the scan can take a long time especially for high resolution images, (up to 8 minutes to scan just the residual limb) and the subject must remain still throughout the acquisition so to avoid image blurring, which is sometimes not possible. Furthermore, due to the use of high powered magnets, no ferrous metals can be allowed in the vicinity. This restricts the type of prosthetics and equipment that can be used.

#### 2.6.5.4 *Fluoroscopy*

Fluoroscopy is used to view the residual limb and various anatomical markers in motion (Bocobo et al. 1998). However, when measurements are taken, plain film x-ray is preferred due to its higher image quality. Fluoroscopy can be used in conjunction with other technologies and has been used before for registering the position of knee implants using accurate 3D representations (CAD models) (Banks and W.A. 1996; Mahfouz 2003) and for continuous measurements of the vertebrae under motion using computer tracking systems (Breen 2003, 2006; Breen 2011a; Breen et al. 2006; Mellor 2007, 2009) (see 2.6.5.6).

#### 2.6.5.5 *Roentgen Stereophotogrammetric Analysis (RSA)*

Roentgen Stereogrammetric Analysis is the gold standard for measuring special positioning in vivo, using radio-opaque markers attached directly to the surface of the object which is intended to be measured (usually surgically implanted metal beads directly attached to the bone) to serve as well-defined artificial landmarks. Two synchronised x-ray units are set up at an oblique angle to obtain a stereo image of the bone and the prosthesis (Papaioannou et al. 2010). After calibration, it is possible to calculate the three dimensional spatial coordinates of these markers when the information is reconstructed within specialised RSA software. Lastly, the change in the position of the markers relative to the surface to which they are attached is determined and the displacements and rotations can be calculated.

A study by Papaioannou et al (Papaioannou et al. 2010) used a new method of assessment implementing the use of fluoroscopes to generate biplane Dynamic Roentgen Stereogrammetric Analysis (DRSA). The use of radio opaque markers in conjunction with Dual Fluoroscopy allowed the authors to measure the socket/residuum and residual bone telescoping motion with as much as 0.03 mm translational and 1.3 degrees rotational accuracy. Combining this with 3D CT scans of the residual limb and knee joint and 3D scans of the surface using a laser scanner, they were able to measure movement to a high accuracy including the shear across the skin/socket interface.

#### 2.6.5.6 *Quantitative Fluoroscopy*

Quantitative fluoroscopy (QF) has been demonstrated to be reliable and accurate to a high degree for the measurement of vertebral segments in motion (Breen 2003, 2006; Breen 2011a; Breen et al. 2006; Mellor 2007, 2009) (section 2.7.1 "*Quantitative Fluoroscopy and spine mechanics"*). These techniques can be adapted and applied to the analysis of the tibia/socket interface of lower limb amputees to measure the rotation, translation and centres of rotation. To date, while this technology has mostly been applied to the measurement of the kinematics of the spine, the ability to measure the kinematics of both the lower limb and spine affords a unique opportunity to probe the possible relationships between their functioning by collecting information from these in the same subjects, making it suitable as a technology for the scope and aims of this thesis (1.3.4).

## 2.7 Spine kinematics and stability

In the absence of a specific cause, chronic non-specific back pain (CNSBP) is often assumed to be mechanical in nature (European Commission 2006). However, measuring the mechanics of the spine within living people is problematical, since only static methods such as MRI and plain x-rays, have been used for measuring movement, leaving the link between functional biomechanical derangements and pain difficult to investigate.

The mechanical function of the intact spine is thought to be governed by two subsystems: the active control system and the passive restraint system (Panjabi 1992b). The active neuromuscular control system incorporates both voluntary and reflexive control of trunk muscles (Bergmark 1989; Panjabi 2003), while the passive lumbar spine is composed the vertebrae, their various surface interactions and the passive mechanical properties of the muscles, discs and spinal ligaments. These structures distribute movement in response to external loads and changes in posture (Panjabi 1992b). These movements, in the absence of considerations of force, are termed ‘kinematics’ (White 1990).

Previous radiological studies have utilised technologies such as plain radiographs of the spine and have concentrated on the range of motion (ROM) of adjacent inter-vertebral segments. This is usually measured by hand from two or more static images and has been used in studies of mechanical causes of back pain. QF is currently utilised as an objective assessment of the spine in continuous motion using low-dose digital fluoroscopy and automated computer tracking algorithms to measure inter-segmental kinematics throughout the motion. The additional information gained from continuous kinematic measurements allows motion features thought to cause LBP to be measured throughout a subject’s bending. This was previously only measureable in cadaveric studies. Such measures include the range of inter-vertebral rotation in terms of stiffness or laxity, hyper-mobility (excessive rotation or translation) and paradoxical motion (rotation between vertebrae in the opposite direction to the trunk bend). This represents a considerable advance (Ahmadi et al. 2009; Breen A.C. et al. 2012; Teyhen 2005; Wong 2006).

It has long been suspected that abnormalities in the mechanics of spine that cause pain are related to ‘instability’. However, the meaning of spinal instability varies between disciplines such as clinicians, bioengineers and radiologists (Leone 2007; Reeves 2007).

A biomechanical definition of instability is a lack of robustness, or resistance to force whilst the spine is at, or near, its neutral position (Panjabi 1992b). This is known as the neutral zone (NZ) and has been validated from cadaveric studies (Crawford 1998; Gay 2008).

As depicted in Figure 12, the NZ theory proposes that the total range of motion (ROM) of a joint is subdivided into the neutral zone (NZ) which is the zone with minimal resistance to force near the neutral position and the elastic zone (EZ). The elastic zone follows the neutral zone, where passive restraint due to molecular bonds within ligaments, joint capsules and muscles resists segmental motion through elastic restraint. Panjabi found in cadaveric studies that if a segment is unstable, the neutral zone will be increased. This is known as ‘laxity’ (Panjabi 1992a). The controversy in the biomechanics literature is mainly because of the difficulty of fitting a simplistic model of stability from non-biological systems to the complex, and largely inaccessible linkages of the living human spine. In light of this, some researchers have preferred to characterise the concept of stability as that of ‘control’ (Hodges et al. 2013; van Dieen 2003) in order to reflect its multifactorial nature. However, laxity has remained the main aspect of control that is considered in orthopaedic research and the NZ has been its main expression, albeit mostly in cadaveric specimens (Wilke et al. 1998). With the emergence of QF however, it is possible to measure laxity *in vivo* using the Laxity Index.

NZ theory is the preferred indicator of the biomechanics of the spine than due to its high relationship to injury compared with IV-RoM taken from end of global range images (Crawford 1998; Kaigle 1995; Oxland 1992; Panjabi 1992a, 1992b; White 1990) and more able to detect instability (Panjabi 2003). This is because if the structures restrain the segments stable in the initial parts of their motion (disc and ligaments) undergo micro-injury; structures which normally restrain motion further from the neutral position are loaded earlier. Therefore, following injury or initial degeneration of these passive holding elements, the NZ increases, since the structures no longer completely limit movement (Brayda-Bruno et al. 2013; Chan et al. 2012). However, the EZ remains unchanged as other more intact structures take over to limit further motion (Crawford 1998). The application of NZ theory to *in vivo* spine kinematics is described in further detail later in section 2.7.1.1 *The Neutral Zone in vivo* and investigated in section 3.4 of this thesis.

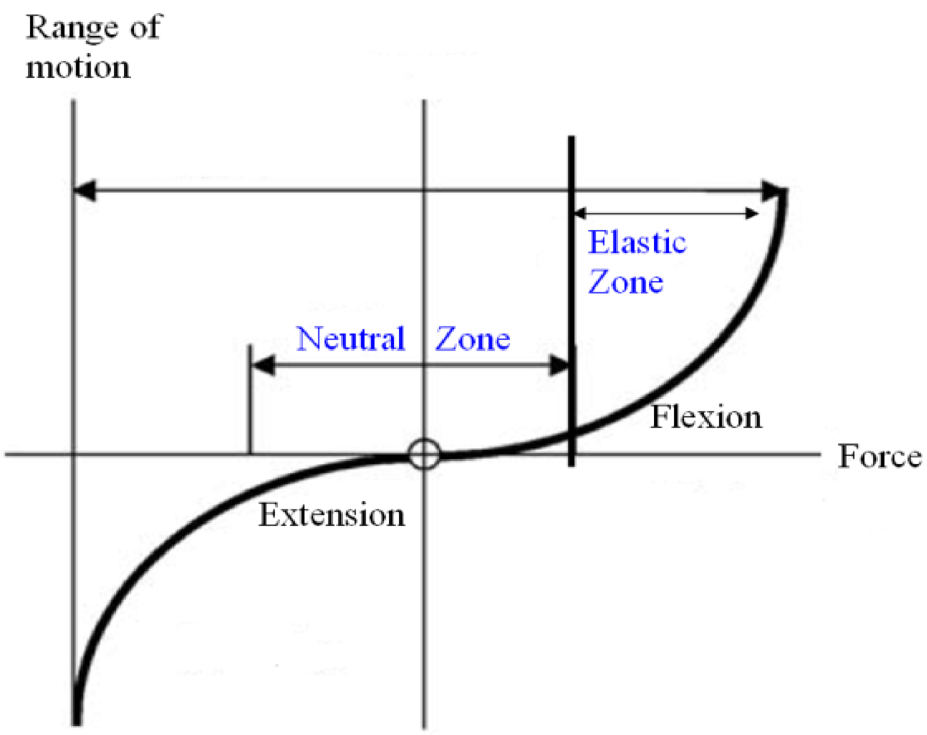



**Figure 12: Diagram of the neutral zone and elastic zone theory, (Panjabi 1994)**

### 2.7.1 Quantitative Fluoroscopy and spine mechanics

The technology of quantitative fluoroscopy, can objectively quantify the rotational and lateral movements of pairs of vertebrae within the fluoroscopic image field (known as inter-vertebral motion) using automated computer processing algorithms which calculate inter-segmental kinematic parameters throughout the motion (Breen 2003, 2006; Breen 2011a; Breen et al. 2006; Breen A.C. et al. 2012; Mellor 2007, 2009). This technique outputs displacement values such as inter-vertebral rotation and sliding (translation) for every motion increment throughout the image sequence. This gives an objective output of the continuous motion with a radiation dose which is the same, or less than conventional radiographic examinations (Mellor et al. 2014b).

In 2009 three research groups (UK, US, Hong Kong) utilising similar techniques, found that the differences in their reporting of spinal motion characteristics meant that combining or comparing data was impractical. During an international forum held in San Francisco in 2009 they reached a consensus on how best to record, analyse, and communicate QF information for research and clinical purposes (Breen et al. 2012). The Forum recommended that images should "*…be acquired during regular trunk motion that is controlled for velocity and range, in order to minimise externally imposed variability as well as to correlate inter-vertebral motion with trunk motion*." One of these research groups, IMRCI (Institute for Musculoskeletal Research and Clinical Implementation), developed a QF method under the NHS R&D's New and Emerging Applications of Technology (NEAT) program from 2001-3 and currently have the only facility for conducting clinical QF investigations in the UK. In 2006 the IMRCI published a study (Breen et al. 2006) describing the repeatability and validity of inter-vertebral rotation measurement using QF (then called OSMIA; Objective Spinal Motion Imaging Assessment). This was replicated in a subsequent US study (Yeager et al. 2014). The 2006 protocol was designed to allow the participant's muscles to be relaxed and inactive, thereby isolating the passive system. In this study, both inter-observer and intra-subject repeatability were determined. It was found that this method for measuring inter-vertebral range of rotation was accurate to within 1 degree, with inter-observer and intra-subject errors of less than 3 degrees (Breen et al. 2006). These studies reported high interclass correlations, suggesting excellent discriminating capabilities between populations. Figure 13 (below) gives an example of continuous inter-vertebral rotational data generated for one vertebral body pair.

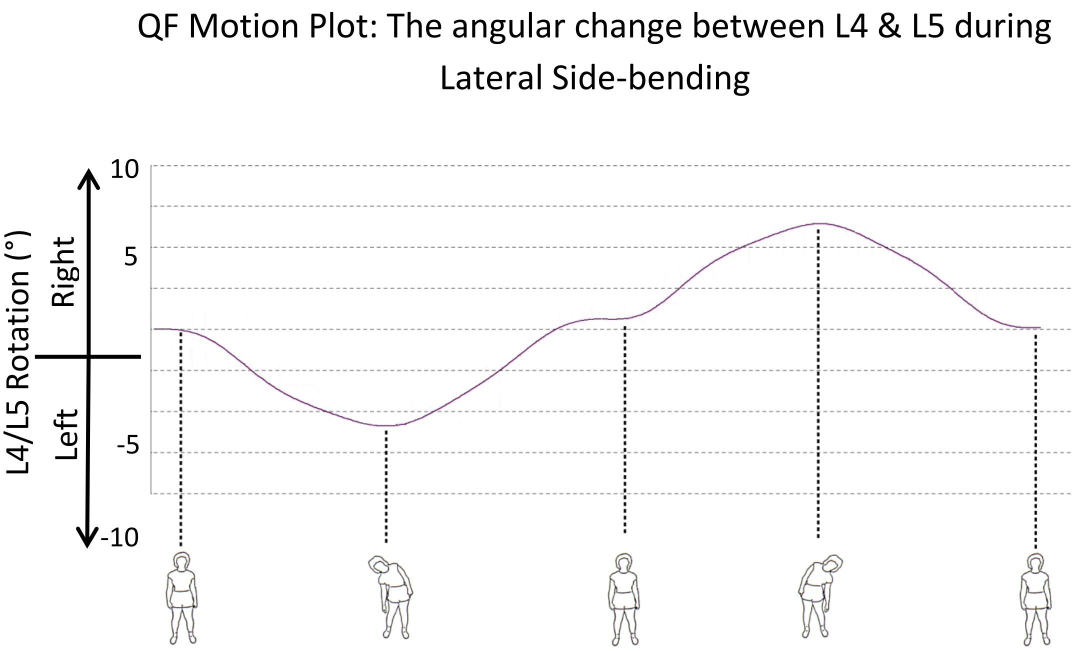



**Figure 13: Example of continuous inter-vertebral angle change between two adjacent vertebrae (L4-L5) over time, acquired by Quantitative Fluoroscopy (QF) techniques.**

This has allowed the NZ theory (outlined above in the beginning of section 2.7) to be tested *in vivo* with promising initial results (Breen 2006; Lee 2002; Mellor 2009; Teyhen 2005; Wong 2006). The process and justification for this is given below.

#### *2.7.1.1 The Neutral Zone in vivo*

Until recently, motion in the NZ has only been measurable in cadaveric and animal models using force deformation equipment (Cannella 2008; Crawford 1998; Oxland 1992; Thompson 2003). The Laxity Index was first proposed by Mellor et al (2009) as a refinement of the overall attainment rate. The latter was proposed by (Teyhen 2004) in response to the suggestion that the Neutral Zone (NZ) in an intervertebral motion segment could be represented by the *in vivo* ratio of the slopes of the intervertebral and lumbar spine motion curves (Kanayama 1996). However, this has never been substantiated. Furthermore, the overall attainment rate, unlike the NZ, reflects the laxity over the whole motion range, whereas the NZ confines its measurement to the mid-range. Therefore, the Laxity Index is represented by only the Initial Attainment rate. However, the NZ which is a measure or the relation of force and displacement is purely a cadaveric measure; this has highlighted the need to validate the Initial Attainment rate for the measurement of laxity *in vivo*. This validation will be explored in this thesis.

Due to the non-linear relationship between segmental motion and trunk bending over the range of trunk motion, a linear correlation between only the first 10° of trunk motion (incorporating the neutral zone) against that of the inter-segmental level is calculated to discover the rate at which a spine's motion is attained by each a singular inter-vertebral level, this is known as the Initial Attainment rate. An example can be seen in Figure 14. The theory, as described by Panjabi (Panjabi 1992b) is that the less the passive holding elements restrain the segment, the higher the correlation between the segmental and trunk motion. It was noted by Mellor et al. (2009) that muscle contraction and disc stiffening during loading may conceal increased laxity of the disc and ligaments due to voluntary or involuntary contractions (e.g. guarding or muscle spasm) (Mellor 2009). Therefore, imaging a patient during passive motion in this recumbent position reduces the neuromuscular activity during measurement (Breen 2006; Breen 2011b).

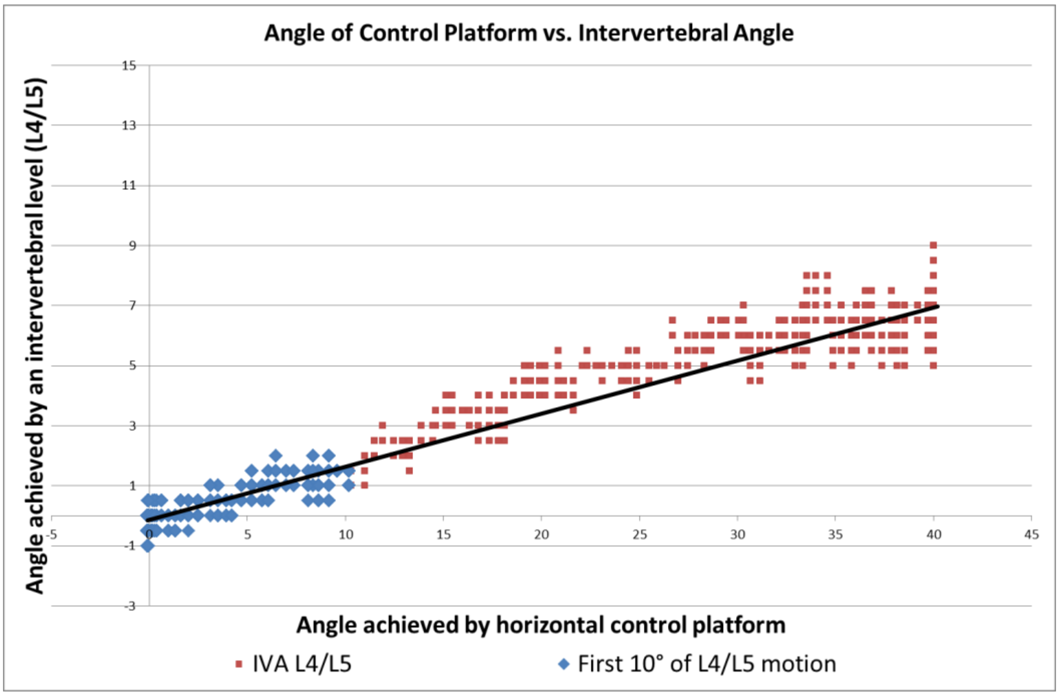



**Figure 14: Laxity calculated as 'initial attainment rate'. Inter-vertebral motion compared to global 'trunk' motion.**
**The figure above displays the global (horizontal control platform) angle vs segmental (L4-L5) angular change over time. The red (square) markers indicate the intervertebral angle achieved for every degree of global motion. The blue (diamond) markers relate only to the intervertebral rotation during the first 10° of global motion. The linear correlation shown is the linear trend of the first 10° projected forward to 40°. The gradient of this trend is given as the 'Laxity index'.**

### 2.7.2 Displacement

Displacement is a combination of rotation and translation (coupled motion). While rotation of a vertebra can be displayed as inter-vertebral angulation (as outlined above), translation is the sliding of one vertebra over its subjacent neighbour (Mellor 2007). Methods defined by Frobin et al. (Frobin 2002) are used in QF to measure translation (Figure 15) so as to reduce distortion errors in measurements caused by out of plane or coupled motion (the tendency for a tilting vertebrae to also rotate in the axial plane, causing out of plane distortion). As rotation and translation usually happen at the same time *in vivo* but do not change at the same rate, Frobin's method is able to measure translation in a way which removes the effect of rotation on translational motion (Figure 15).

Van Loon et al. investigated the reliability of this method for use with QF (van Loon et al. 2012). These preliminary findings suggested that this method is accurate and repeatable to within 1 mm (Breen 2011a).

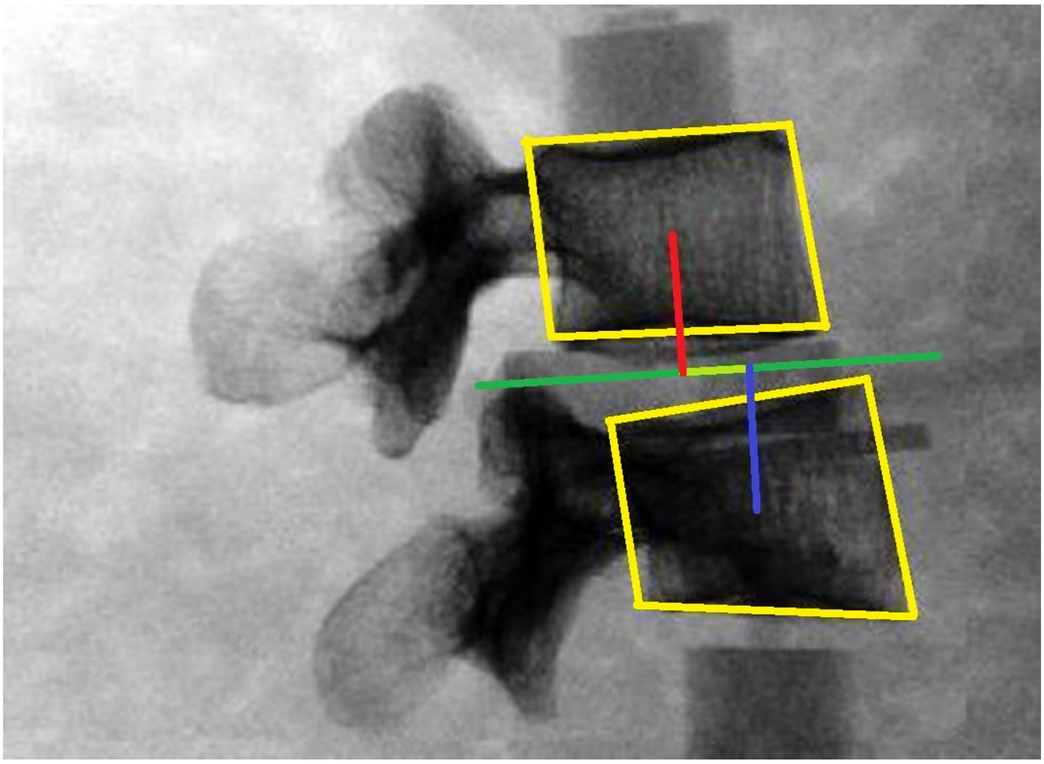


**Figure 15: Radiographic images of a model displaying the computer generated translation between vertebrae (horizontal green line) (Breen 2011a)**

### 2.7.2.1 *Centres of rotation*

Displacement can also be described as the combination of both rotation and translation rather than a separation of the two. For this the measurement of finite centres of rotation can be used to depict overall movement. In unpublished studies (performed by the author as part of a masters dissertation (Breen 2011a)) preliminary findings demonstrated that this method was accurate to within 1 mm, with inter-observer and intra-subject errors of less than 1 mm (Breen 2011a).

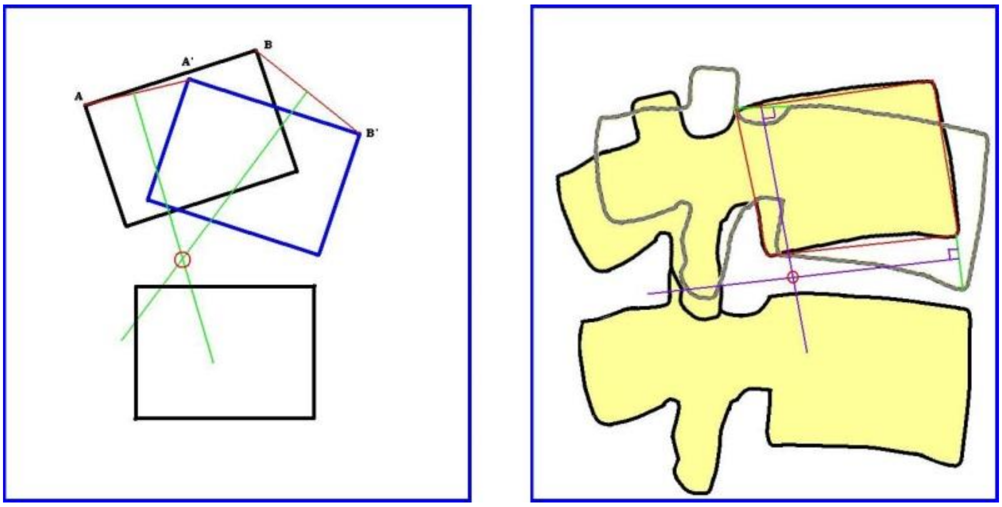



**Figure 16: a) (left) simplified outline of a vertebral body pair used to calculate ICR position between two images b) (right) graphical representation of ICR calculations from superimposed radiographic images of vertebrae.**

## 2.8 Conclusion

The role of mechanics in both low back pain and trans-tibial prosthetics suggests that an objective of investigation of possible relationships between the kinematics of the two may improve our understanding of why amputees have a higher prevalence of low back pain. Any differences in the lumbar spine kinematics between amputees and controls would also suggest routes to investigate why the prevalence is higher in the former. Furthermore, any association between spine and limb-prosthesis kinematics would support future clinical diagnostic research into the mechanism of pain generation in amputees with back pain. QF provides, at least in theory, the means to perform these assessments, but will require some development and adaptation to investigate the limb-prosthesis interface.

# Chapter 3: Development of quantitative fluoroscopy image acquisition and analysis protocols for measuring spine and residual limb motion

## 3.1 Introduction

Quantitative fluoroscopy has been demonstrated to have high precision for measuring inter-vertebral kinematics in vivo - mainly for the purpose of assessing spine stability (Branney and Breen 2014; Breen et al. 2006; Mellor F.E. et al. 2014; Yeager et al. 2014). This chapter reports the development and use of additional QF protocols to measure both the kinematics of the lumbar spine and of the limb-prosthesis interface in amputees for the assessment of residual limb slippage and socket fit. These QF protocols were also intended to enable studies to be carried out to determine whether socket fit has an effect upon the kinematics of the spine.

The development of acquisition protocols for measuring spine and residual limb motion using QF was split into three preliminary studies as outlined below:

Study 1 - The development and testing of lumbar spine imaging and analysis protocols using QF in a population of healthy controls, to determine which parameters should be used for assessing lumbar spine kinematics in an amputee population and for comparing it with a similar population with intact lower limbs.

Study 2 – The development and testing of an imaging protocol for measuring residual limb movement within prosthetic sockets to determine which imaging view and measurement parameters would produce the most relevant data with least measurement error.

Study 3 – A study to assess the use the 'initial attainment rate', quantified by QF, as a proxy for the NZ as a measure of biomechanical stability at individual inter-vertebral levels for this thesis (see section 2.7).

QF combines the use of standard fluoroscopic C-arm equipment as used in hospitals, with semi-automated tracking software to objectively quantify 2-dimensional rotation and translation of solid structures (such as bones) in vivo. It has been demonstrated to be reliable and accurate to a high degree in the measurement of the range of inter-vertebral rotational motion (Breen 2003, 2006; Breen 2011a; Breen et al. 2006; Mellor 2007, 2009). These techniques could be adapted and applied to the analysis of the residual limb/socket interface kinematics of lower limb amputees. The ability to measure the kinematics of both the lower limb prosthesis and the spine affords a unique opportunity to explore possible relationships between their functioning.

## 3.2 Study 1: Lumbar spine imaging and analysis protocol

### 3.2.1 Background

Since QF utilises X-radiation to acquire its images, the minimisation of dose and the optimisation of data were primary considerations in generating protocols (Mellor et al. 2014a). This study therefore also sought to determine which spine kinematic parameters were best suited to comparing the inter-vertebral motion of unilateral below knee amputees and asymptomatic healthy controls. These parameters would also have to be suitable for determining any relationship between limb-prosthesis and inter-vertebral kinematics. To achieve this, fluoroscopic image sequences of the lumbar spines of 20 asymptomatic volunteers were analysed.

Image sequences were acquired using imaging protocols previously developed by the author while working within a research group to establish a reference database of lumbar inter-vertebral motion in healthy controls (Breen et al. 2012). The image recordings and analysis were performed by the author under National Research Ethics Committee (NREC) approval (REC Ref: 10/H0106/65).

In order to determine the most suitable plane (coronal or sagittal) and orientation (recumbent or erect) for comparing the lumbar inter-vertebral kinematics of amputees and controls, samples from the latter were analysed for inter-vertebral range of motion for all directions (left, right, flexion, extension) and levels from L2 to S1. The results and the studies that followed are presented in this Chapter. The characteristics of recumbent and weight-bearing lumbar inter-vertebral motion were therefore assessed from L2-S1 in either flexion - extension or side-bending in the same participants in terms of range of motion (IV-ROM rotation), individual level contribution to L2-S1 motion and individual level laxity (see 2.7 page 51) in 20 asymptomatic adults.

### 3.2.2 Methods

#### 3.2.2.1 *Selection criteria*

In an attempt to ensure that the results would be representative of a typical amputee population, only male participants between the ages of 30 and 70 were selected to take part in this study. This was derived from the studies detailed in Table 2 of section 2.4 allowing this study's results to be compared to unilateral amputees undergoing the same protocols who have had extended use of a prosthesis. Furthermore, inclusion of participants was restricted to those with a BMI of less than 30 (to reduce image degradation from soft tissues) and a maximum age of 70 to control for bone loss. These limitations allow for a greater chance of tracking the positions of the vertebrae in each image.

This study's results to be compared to previous and subsequent studies and participants' sex was limited to males to control for gender related effects on results and to employ a more certain degree of gonadal shielding as in males the gonads can be more readily located and shielded using lead sheeting. None of the participants recruited into this study had a history of back pain in the previous year. This was to create a baseline for 'normal' kinematics in the healthy population.

### 3.2.2.2 *Image acquisition*

The QF Image acquisition equipment consisted of a Siemens Arcadis Avantic VC10A digital fluoroscope (CE0123) and two computer-controlled motion frames manufactured by Atlas Clinical Ltd (declared conformity under MDD93/42/EEC). The first motion frame, the ‘passive recumbent system’, is a swing table that stabilises half the participant’s body while slowly moving the other half (either torso or legs) through an arc up to 40° either side of the central position (Figure 17 a, Figure 18 & Figure 19). This system has been demonstrated to remove the neuromuscular control and body weight compression from effecting spinal kinematics (Mellor 2009). The second motion frame is the ‘weight-bearing active control system’, which guides the standing participant at a standard rate and range of motion through an arc while their own muscle activity provides the motion under their own body weight (Figure 17 b & Figure 20).

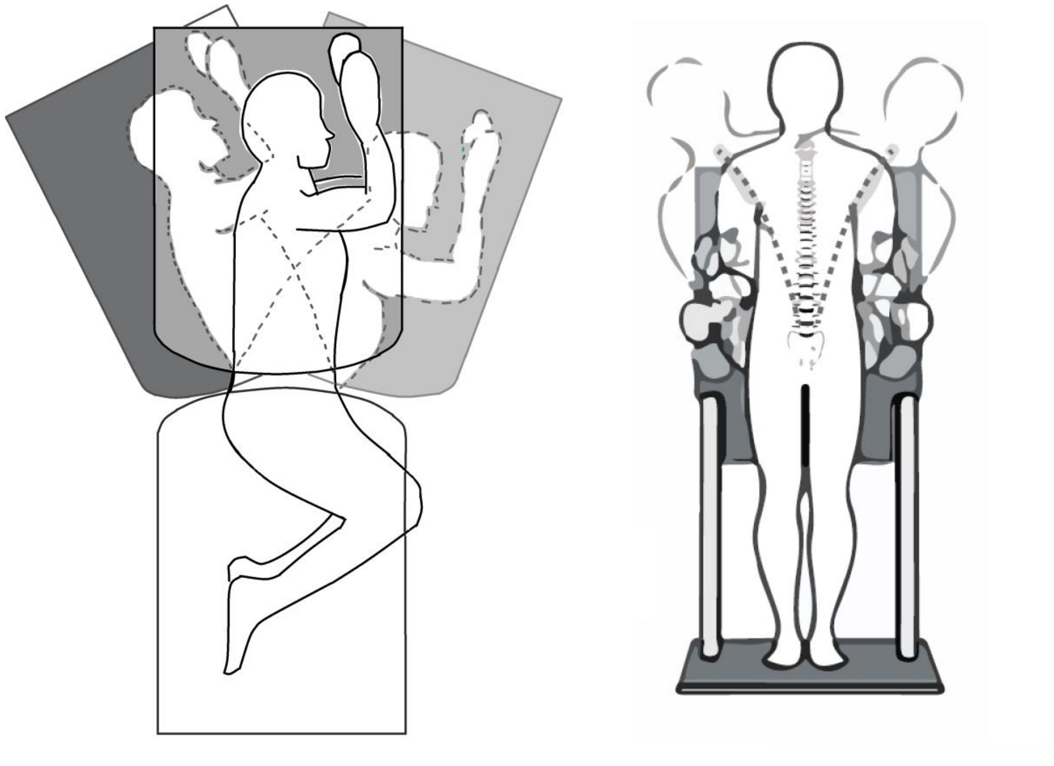


**Figure 17, a) depicts recumbent flexion and extention protocol of control platform (left), b) depicts Lateral flexion motions during weight-bearing protocols.**

Digital fluoroscopic image sequences of 20 asymptomatic adult males with no history of back pain were acquired. To reduce the radiation dose per participant, the participants were split into two groups of ten, to be either imaged in the coronal plane (front to back), performing lateral flexion movements left to right or in the sagittal plane (from the side) while performing bending forward and back (flexion and extension) tasks. Both groups undertook these motion types under weight-bearing and recumbent configurations so that direct comparisons of weight and neuromuscular control of the spine could be compared to spinal kinematics when in passive recumbent motion.

- Prior to the day of image acquisition, participants are asked to fill in a pre-study form to ensure that they fulfilled all the Inclusion/Exclusion criteria of this study.
- On arrival they were talked though the experiment and any queries/questions they had were addressed.
- If they were happy to continue an 'informed consent' form was signed by both the participant and investigator.
- Participants were then asked to change into radiolucent clothing and remove any jewelry which may obscure the view of the lumbar spine by the fluoroscope.
- The participants then were taken though the imaging procedure to which they were assigned (outlined below), firstly in the recumbent (section 3.2.2.2.1) and then in the weight-bearing position (section 3.2.2.2.2).

In both procedures (weight-bearing and recumbent) the rate of motion was set at 6° per second with a gradual acceleration to begin motion and deceleration at end of range so as to avoid sudden movements which would cause image blurring and prevent accurate vertebral tracking. These speeds were also found to be optimal for patient comfort. Images were acquired at a frame pulsed frame rate of 15 frames per second (fps) which further reduces image blurring as very little movement happens between frames. Vertebral images from L2-S1 were recorded and tracked throughout the motion sequences using bespoke frame to frame registration codes (outlined in

3.2.2.3 ‘Image analysis’ page 71) written in the Matlab (R2011b) environment (Mathworks Ltd.). This has previously demonstrated accuracy for sagittal angular range of $0.32^0$, a coronal angular range of $0.52^0$ (Breen et al. 2006) and an RMS error in measuring sagittal translation against the reference standard was under 0.8 mm in respect to a standard lumbar vertebra of 35 mm depth. With the exception of L5-S1 extension, the SEMs from the in vivo agreement studies were below0.5 mm for all levels and directions (flexion—extension), and for reliability the ICCs were above 0.84. (van Loon et al. 2012).

#### *3.2.2.2.1 Recumbent protocol*

- The participant was asked to mount the passive recumbent system and lie on their back (if they are in the coronal view group) or on their right hand side (if in the sagittal view group) with their head upon pillows.
- A radiographic marker (which will show up in images) was placed on the underside of the table at the fulcrum in order to centre the spine and was subsequently removed before image recording.
- The participants were then positioned with the midpoint of their fourth lumbar vertebra (L4) over the fulcrum of the table
    - The coronal group had a triangular pad placed under their knees as a knee support to flatten the lumbar lordosis and placed their arms across their chest with their hands touching their shoulders (Figure 18).
    - Sagittal group were asked to bend their legs with their hands together in front of their face in a ‘praying’ or ‘diving’ position to help support them while on their side and reduce axial rotation of the spine (Figure 19).

**Figure 18 Supine passive lateral flexion protocols, (torso swing left and right)**

**Figure 19 Recumbent passive flexion-extension protocols**

- The fluoroscope was then positioned around the participant to check positioning using the aforementioned radiographic marker to identify the table's fulcrum. After this the marker was removed.
- Lead sheeting was placed over the gonads, breast and thyroid. Up to 6 brief (0.1 sec) positioning exposures (fluoro-grabs) were taken before the full motion sequences were acquired. The maximum (upper third quartile) effective X-ray dose for this procedure was in the range of 0.58mSv including the fluoro grabs (Appendix A.III.1). Participants had access to an emergency stop button, which would halt the motion of the table if they wished.
- The participants were then taken through the full range of motion (A range of $40^{o}$ was be aimed for) in 10 degree increments to acclimatise them to the movement and ascertain their overall comfortable trunk range. In previous studies even pre-surgical back pain patients had been found to tolerate this motion easily (Breen et al. 2006).
- Once participants were happy with the overall range and speed of movement, data collection began. This involved the motion frame movement and fluoroscopic recording beginning simultaneously (Breen A.C. et al. 2012). The motion frame slowly moved the upper half of the torso from neutral to the left, back to neutral or neutral to the flexion, back to neutral. The same procedure was then repeated to the right or in extension. Each motion procedure took approximately 15 seconds. Videos of these movements can be viewed on the host institution's website at: http://www.aecc.ac.uk/research/imrci/osmia.aspx
- The fluoroscope was then removed and the participant was helped in to a sitting position while images were confirmed and the weight-bearing system was connected to the control box.

The velocity of the motion platform was standardised to initially accelerate at 6°$s^{-2}$ in order to move the platform through the first 3° if its arc. This was followed by a constant velocity of 6° per second speed until the table reached 37° when there was a deceleration of -6°$s^{-2}$ over the last 3° to 40°. This sequence took approximately 15 seconds. The process was then reversed to return to the original position.

Variations in participant weight, resistance to movement and lag in commands/recording times may cause small differences in the velocity of the motion frame. A sample of the first 5 participants' motion control data was analysed, revealing a mean time of 15.12 seconds (0.12SD) of motion and a variability of ±0.01° in the maximum platform range achieved.

Motion platform positions were sampled at approximately 20 Hz along with time stamps from the laptop CPU clock for each recording to control for fluctuations in capture rate. These data, along with inter-vertebral rotation data (obtained after processing the vertebral images) allowed for comparison of each segment's motion and the global trunk motion to enable the calculation of initial inter-vertebral attainment rate as described in sections 2.7.1.1 and 3.2.2.4.2.

### *3.2.2.2.2 Weight-bearing protocol*

**Figure 20 depicting weight-bearing active protocols, a) flexion-extension (left) and b) lateral flexion (right)**

- The participant was then asked to dismount the recumbent system and move to the weight-bearing system.
    - In the coronal protocol, the participant placed their back to the motion control frame with their arms in supports on either side (Figure 20 b).
    - In sagittal protocol, the participant placed their right side to the motion control frame with their arms in a single support directly in front of them (Figure 20 a).
- A radiographic marker was placed on the back of the motion control frame to indicate the centre of the control frames rotation.
- The participant was positioned and the height of the control frame was adjusted to ensure that an exposure showed the centre of the control frame was aligned with the midpoint of the fourth lumbar vertebra (L4).
- The arm rests were adjusted so that the participant’s arms were lightly resting in the rests and their shoulders were relaxed.
- The participants were then taken through the full range of motion
    - In the coronal protocol a range of $40^{o}$ was aimed for each direction (left & right) in 10 degree increments to acclimatise them to the movement

  - In the sagittal protocol a range of $60^{o}$ was aimed for in flexion and $20^{o}$ in extension in 20 degree increments.

- Lead sheeting was suspended over the gonads and thyroid. Positioning exposures (fluoro-grabs) were taken before the full motion sequences were acquired.
- Participants had access to an emergency stop button, which would halt the motion of the table if they wished.
- Once participants were happy with the overall range and speed of movement, data collection began.

The image sequences were then confirmed and the participant was then asked to change back into their clothes.

#### 3.2.2.3 *Image analysis*

Images are transferred from the fluoroscope to a dedicated workstation computer for enhancement and analysis. Each fluoroscopic image sequence typically contained up to 250 individual DICOM images and was 500 megabytes in size. Individual image frames were extracted from the sequence into '.jpg' format files using 90% lossy JPEG compression performed in the Matlab environment (R2011b).

### 3.2.2.3.1 *Image enhancement*

The individual JPEG Image files were enhanced to embolden the edges of each object in the field of view to allow for easier identification of the vertebral bodies, which were outlined in the first image of the sequence. Further enhancements which highlight the vertebral body edges facilitated the tracking algorithms to identify the vertebral body positions in subsequent images (Figure 21).

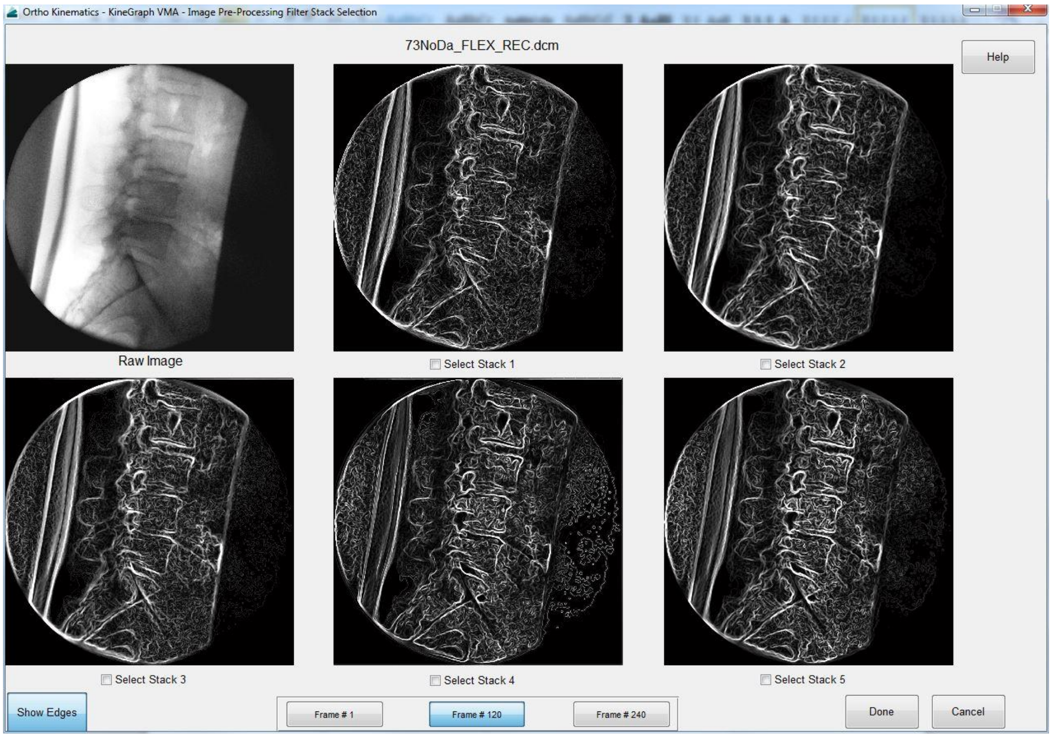



**Figure 21: Image enhancement Graphic User Interface (GUI)**
**The operator is given an option of 5 possible edge enhancements and is asked to choose which enhancement process best emboldens the edges of the vertebrae while producing the least amount of image artefacts that could confound tracking.**

### *3.2.2.3.2 Analysis and image registration*

Following enhancement of the images, individual vertebrae in each image sequence were tracked by bespoke pixel recognition and cross correlation software written in the MatLab environment (R2011b). This involves an observer marking the borders of each vertebra with two templates. Manual registration of vertebral bodies with these templates are performed with an enhanced version of the first image of a sequence (depicted in Figure 22), followed by automatic vertebral tracking in the edge enhanced version of the image sequence (Muggleton 1997) .

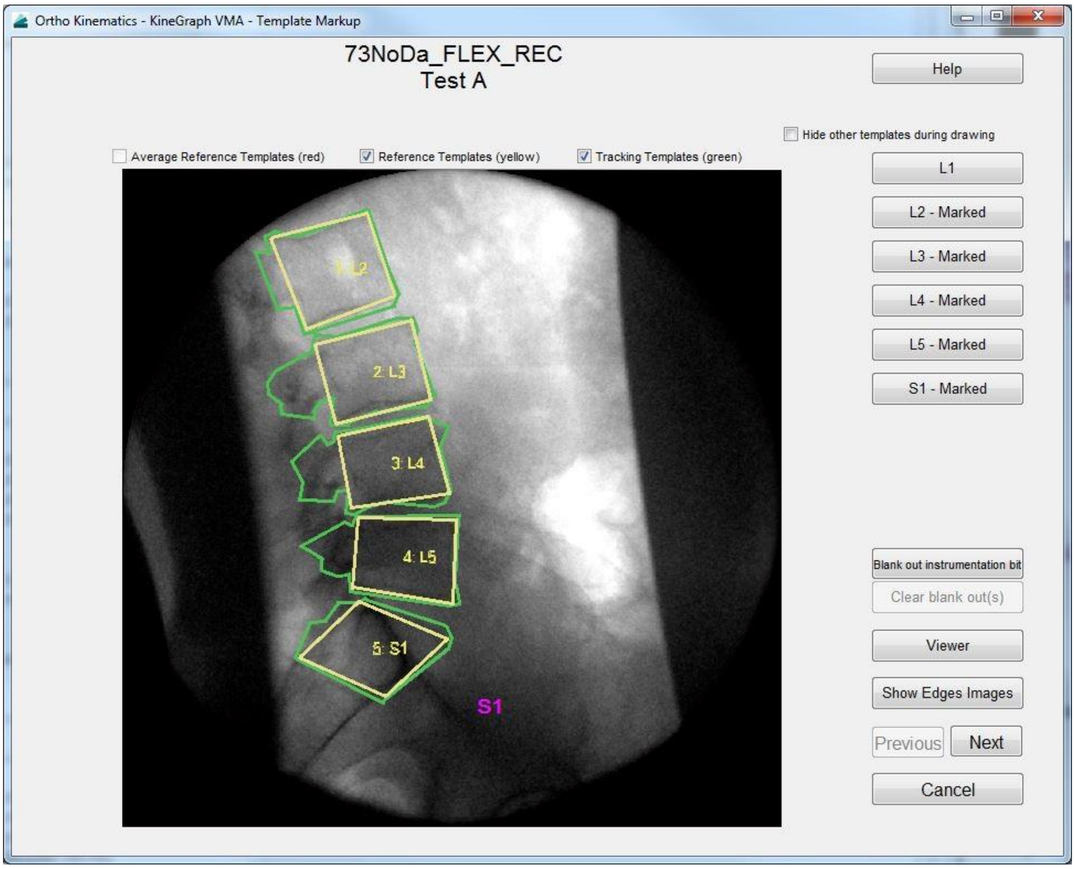



**Figure 22: Manual registration of vertebral body locations Graphic User Interface (GUI) The operator is requested to mark the positions of each vertebra using two templates: Firstly, the reference template, a four point template which notes the location of the four corners of the vertebra**
**Secondly the 'tracking template', a snug outline of the vertebral body and any radio-opaque structures that are rigidly attached (e.g. the pedicels) and do not overlap with another structure (i.e. the facet joints of the superior of inferior vertebra)**

The first template is a four point template which indicates the four corners of the vertebra. These templates are called the 'reference templates' and are used the verification process as well as a simplified representation of the vertebral body shape. The second template is a snug outline of the vertebral body. This is used to track the position of the vertebra as it moves through each image (known as the 'tracking template'). Values for the angular rotation of the vertebra are taken from the positions of these templates.

The tracking algorithm makes note of the grayscale pixel information contained within each tracking template, as well as its location in the image. This information is then compared to the pixel data for the same location in the next frame. The template is then automatically moved both laterally and in rotation by small increments into locations near to its previous location and the process is repeated. Via cross-correlation methods, each image in each position is compared to that of the previous image. The tracking template whose content has the highest correlation with the previous images data is taken to be the vertebral position in this image. This process is then repeated for each subsequent image and tracking template for that image sequence (Muggleton 1997).

### 3.2.2.3.3 Data extraction and tracking verification

To resolve any small errors in tracking, each body is tracked by 5 unique tracking templates defined by the operator and their positions are verified in post processing.

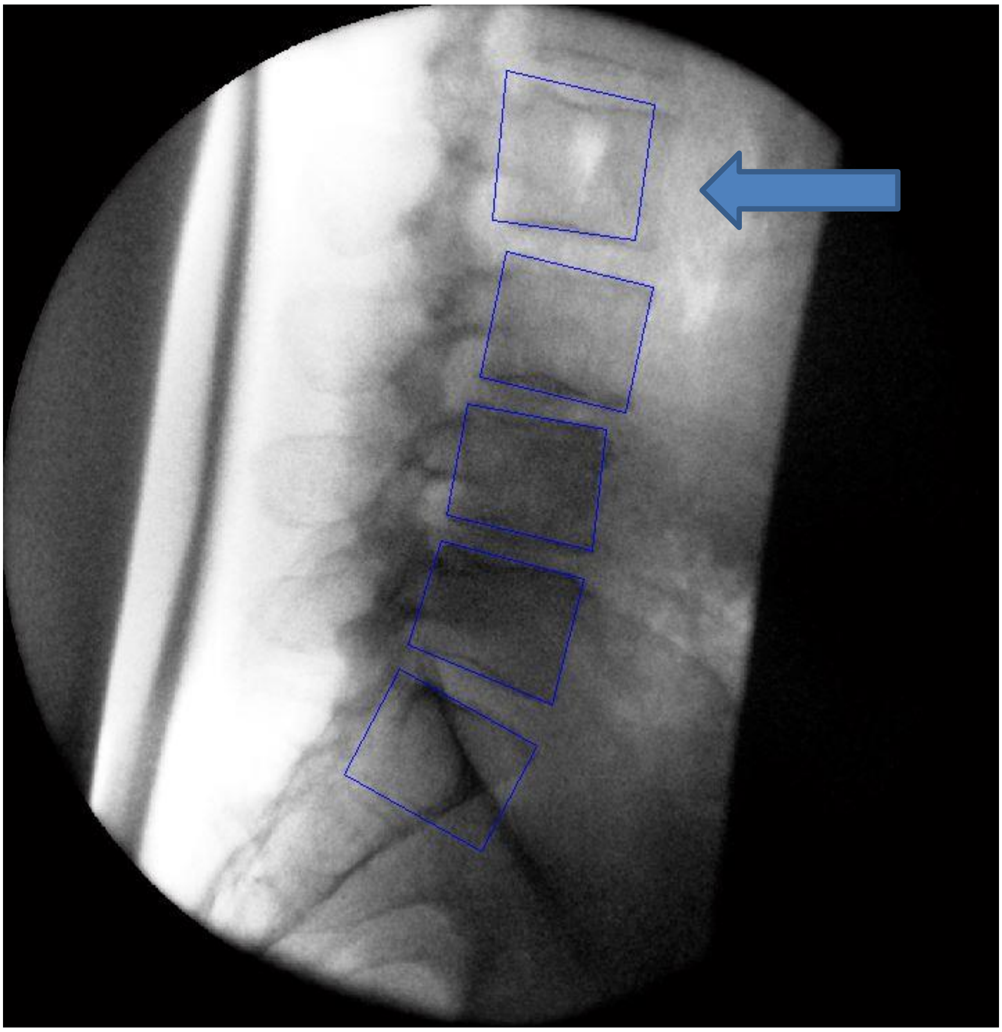


**Figure 23 A lateral lumbar spine fluoroscopic image from a sequence, with reference template shown.**
**This figure shows the reference template positions in the 130th image of a sequence. As indicated in Figure 24 the reference template for L2 is no longer tracking the vertebra (blue arrow).**

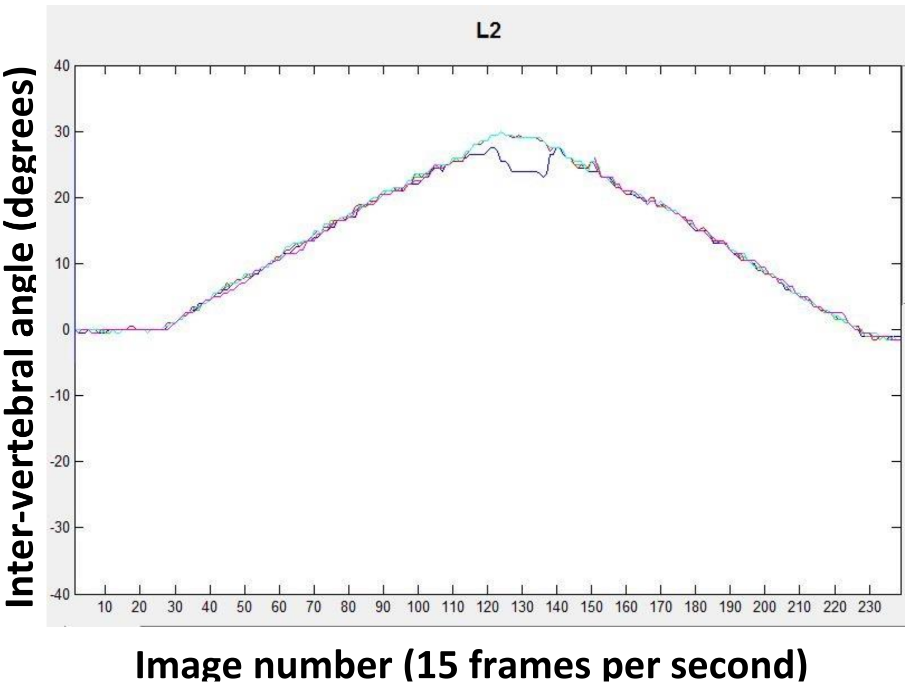



**Figure 24 Raw unedited vertebral (L2) angle output vs. image number.**
**In this example Test 'A' (dark blue) of the vertebra (L2) did not follow the vertebral body between frames 113 and 140. This is verified by viewing the template positions in the corresponding images (Figure 23)**

If the templates were not considered to have tracked they were replaced or removed. This was sometimes necessary if (as demonstrated by Figure 23) the greyscale of the pixels within the tracking template changed due to image artefacts such as bowel gas. After editing (Figure 25), each of the 5 template positions for each of the vertebra were then compared to those if the inferiorly adjacent vertebra to create a maximum of 25 inter/intra test and vertebra combinations. If only one or two tests for any given vertebra failed to track the vertebral bodies for a small distance, these portions of the results were removed and not replaced. A loss of 5 inter/intra test and vertebra combinations was caused per template removed. This part of the analysis was at the discretion of the operator.

Average inter-vertebral angular motion was smoothed by Tikhonov regularization to reduce inter image variation and would account for a maximum of 4 tests deemed not to track for short periods (Eilers 2003; Lubansky et al. 2006). Once all trackings were verified and the results were deemed accurate the operator could accept them then continue on to reading and analyzing the outputs.

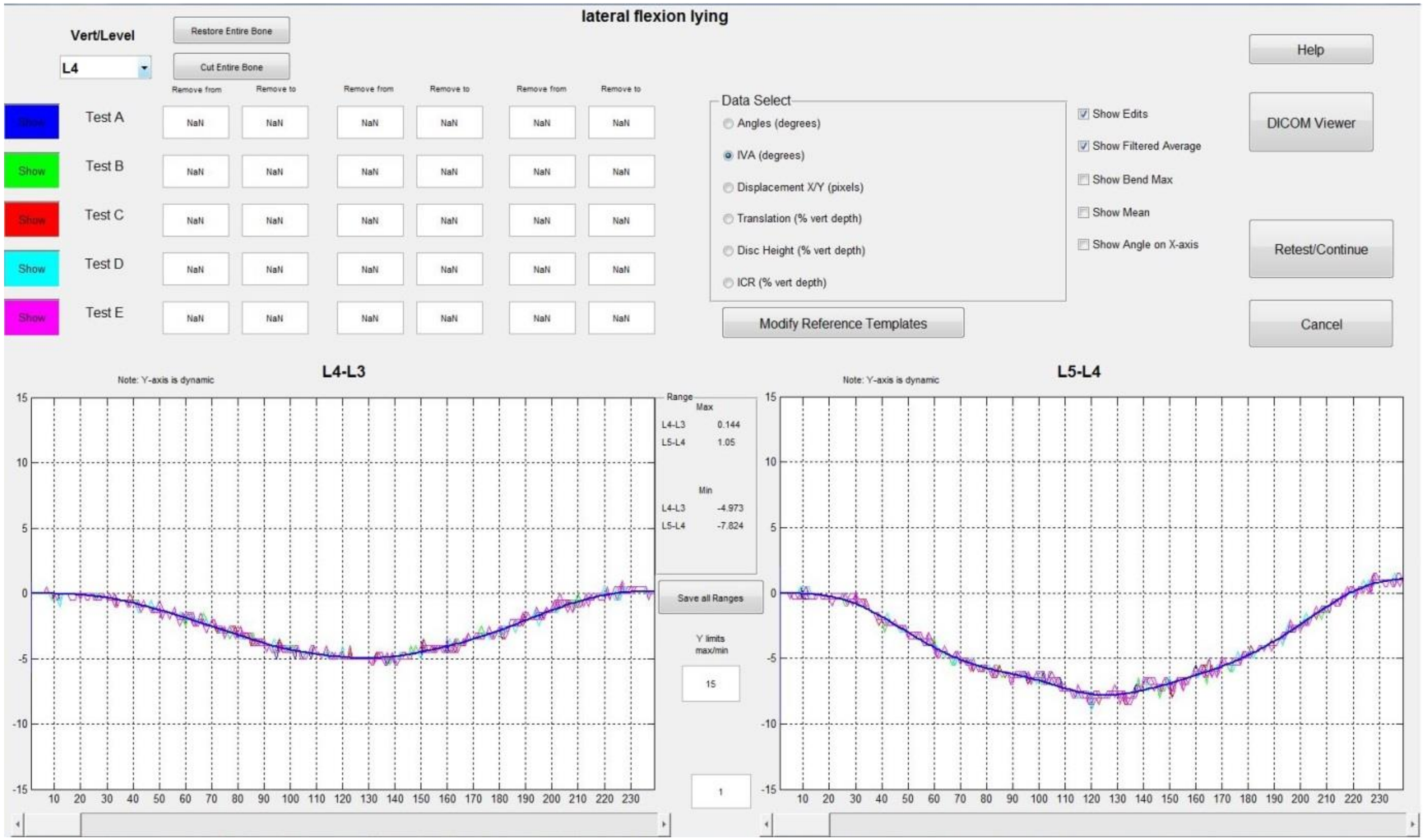



**Figure 25: Editing GUI.**

**The editing GUI allows for the replacement and/or removal erroneous trackings. Depicted in this figure the 25 inter/intra test and vertebra combinations for L3/L4 and L4/L5 are displayed along with smoothed average inter-vertebral.**

### 3.2.2.4 *Output measurements*

Each image sequence (per direction of movement and imaging view) contains over 200 images, making statistical analysis of the whole motion pattern made by each segment for each subject unfeasible. Therefore, the acquired vertebral motion was analysed for their maximum individual inter-vertebral angular range of motion (IV-ROM), their contributions to the overall L2-S1 angular motion and the rate at which each level attained its range. The latter is an expression of laxity as was discussed in section 2.7.1.1 of this thesis (Panjabi 1992b). These measures were collected from the Tikhonov regularization smoothed vertebral motion discussed in the previous section.

#### 3.2.2.4.1 *Range of motion*

The motion graphs were inspected visually and pattern differences noted, examples of which can be seen in Figure 26.Unlike previous techniques (discussed in section 1.3.1 page 5) which measure inter-vertebral motion, the QF method allows the investigator to find the maximum IV-ROM of each level individually rather than between 2 extreme static trunk positions (Figure 27).

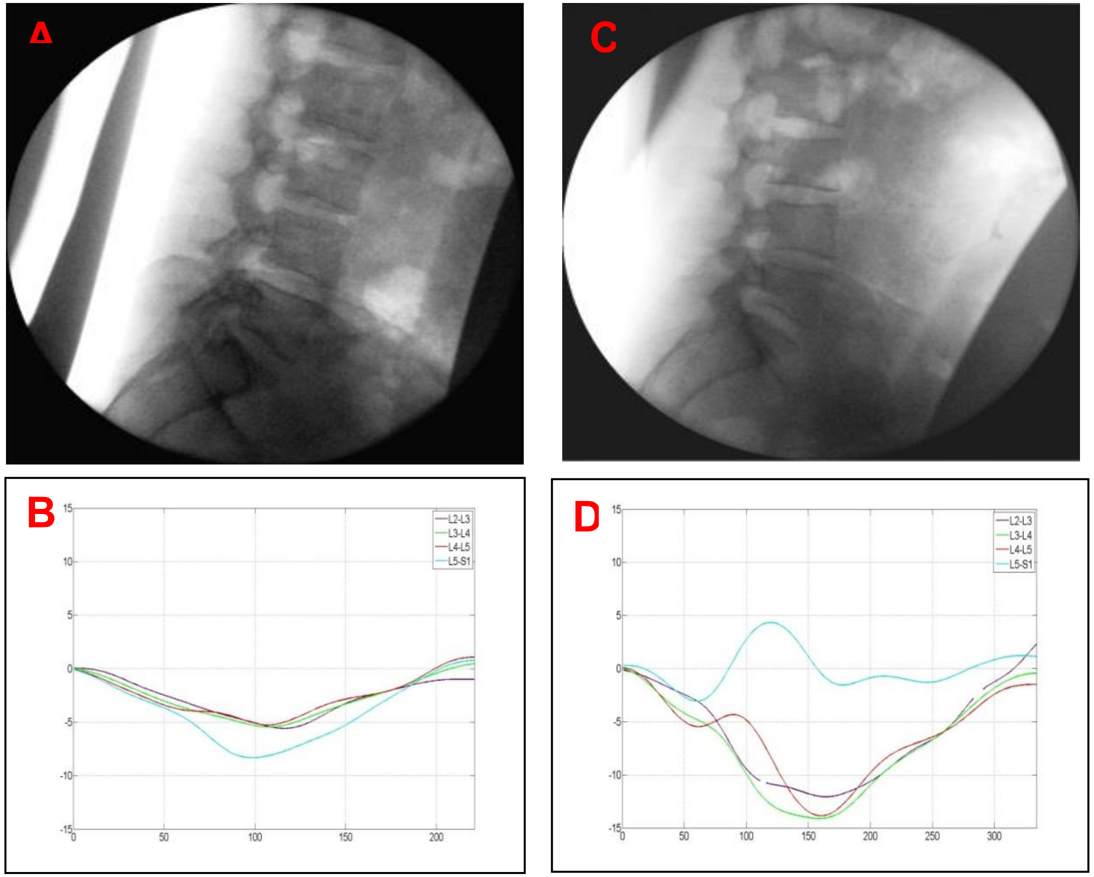



**Figure 26: Two sagittal images of a single participant undergoing flexion and an example of the motion graphs from their respective full image sequences while recumbent undergoing 40° of flexion (A&B) and 60° flexion while weight-bearing (C&D).**
**These motion graphs demonstrate greater variation in inter-vertebral motion in the lumbar spine while weight-bearing which is not in accordance with the greater trunk range.**

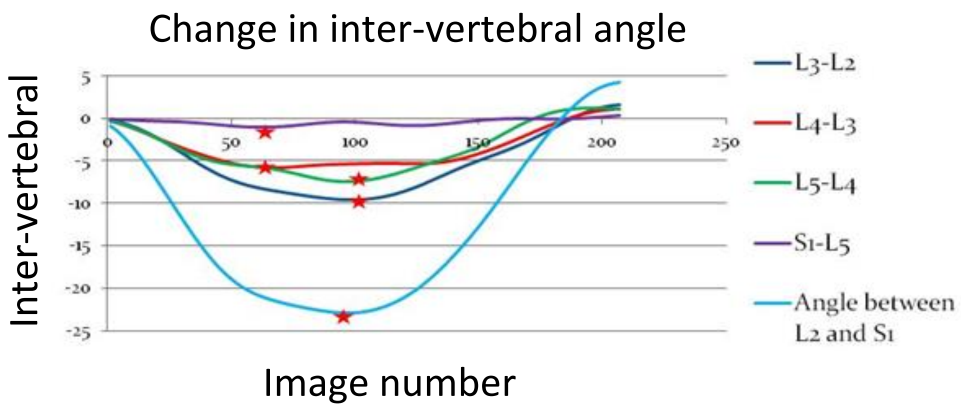



**Figure 27: An example of participant lumbar inter-vertebral angle changes over time (image number). Marked upon each graph is the point at which that vertebral pair reached its maximum Range of motion (IV-ROM)**

### *3.2.2.4.2 Initial attainment rate*

'Initial attainment rate' sometimes referred to as 'the laxity index' (Mellor et al. 2009) is a reflection of the restraint of a joint under load. Initial attainment rate has been used to express Panjabi's neutral zone (Panjabi 1992b), since inter- segmental forces cannot be directly measured *in vivo*. This measurement is achieved by comparing the motion of an inter-vertebral segment to that of the control platform during the first 10° of trunk motion during which the segment in question is moving (Mellor et al. 2009) and is defined as the gradient between the two (Figure 14 of section 2.7.1.1 page 57).

### *3.2.2.4.3 Statistical analysis*

The results per level and direction were tested for parametric properties across the population using a Shapiro-Wilk test (StatsDirect statistical software, version 2.7.7; StatsDirect Ltd). Since some of these results were found to be non-parametric, the statistical significance of the differences between weight-bearing and recumbent data in the same participants was determined using a Wilcoxons' rank sign test (Bland 1996; Hicks 1988), averages and variation were reported as medians and interquartile ranges.

### 3.2.3 Results

Ten healthy control participants were recruited into this preliminary study. All participants were male. Their ages ranged from 23 to 66 (Mean 46.8 SD 13.9) and all had a BMI of less than 30 (Mean 24.8 SD 2.5).

#### 3.2.3.1 *Inter-vertebral angular range of motion*

The inter-vertebral angular range of motion (IV-ROM) values per inter-segmental level was taken at the maximum outbound excursion as depicted in Figure 27. Despite these values not being taken at the end range of trunk motion, weight-bearing and recumbent IV-ROMs (Table 7 to Table 10) were similar to published data (Dvorak 1991).

**Table 7. Median rotational range for each intersegmental joint during flexion bending sequence**

| | L2-3 | L3-4 | L4-5 | L5-S1 |
|---|---|---|---|---|
| **Recumbent** | | | | |
| Population median (degrees) | 3.2 | 4.6 | 6.4 | 4.7 |
| Interquartile range | 0.9 | 1.1 | 2.6 | 0.6 |
| **Weight-bearing** | | | | |
| Population median (degrees) | 7.5 | 11.0 | 12.0 | 5.9 |
| Interquartile range | 2.8 | 2.9 | 5.7 | 4.0 |
| **Significance (Willcoxons' 2-sided p)** | 0.002 | 0.002 | 0.010 | 0.432 |

**Table 8. Median rotational range for each intersegmental joint during extension bending sequence**

| | L2-3 | L3-4 | L4-5 | L5-S1 |
|---|---|---|---|---|
| **Recumbent** | | | | |
| Population median (degrees) | 4.5 | 4.6 | 4.6 | 7.1 |
| Interquartile range | 0.9 | 1.4 | 3.0 | 4.5 |
| **Weight-bearing** | | | | |
| Population median (degrees) | 1.4 | 1.1 | 0.6 | 2.4 |
| Interquartile range | 1.1 | 1.0 | 2.0 | 2.5 |
| **Significance (Willcoxons' 2-sided p)** | 0.049 | 0.002 | 0.004 | 0.020 |

**Table 9. Median rotational range for each intersegmental joint during left side rotational bending**

| | L2-3 | L3-4 | L4-5 | L5-S1 |
|---|---|---|---|---|
| **Recumbent** | | | | |
| Population median (degrees) | 6.9 | 6.9 | 5.8 | 0.9 |
| Interquartile range | 1.4 | 2.0 | 0.9 | 1.2 |
| **Weight-bearing** | | | | |
| Population median (degrees) | 6.6 | 6.0 | 3.7 | 0.4 |
| Interquartile range | 1.9 | 1.4 | 1.9 | 1.5 |
| **Significance (Willcoxons' 2-sided p)** | 0.9999 | 0.2324 | 0.002 | 0.0273 |

**Table 10. Median rotational range for each intersegmental joint during right side rotational bending**

| | L2-3 | L3-4 | L4-5 | L5-S1 |
|---|---|---|---|---|
| **Recumbent** | 5.7 | 6.6 | 6.6 | 0.7 |
| Population median (degrees) | 2.5 | 0.8 | 1.9 | 2.4 |
| Interquartile range | | | | |
| **Weight-bearing** | | | | |
| Population median (degrees) | 6.8 | 5.9 | 4.7 | -0.2 |
| Interquartile range | 2.1 | 2.1 | 1.7 | 1.6 |
| **Significance (Willcoxons' 2-sided p)** | 0.1934 | 0.4316 | 0.0059 | 0.1309 |

#### 3.2.3.1.1 *Flexion and extension (sagittal plane motion)*

The main finding for these studies was that, as reflected in the example (Figure 26), weight-bearing IV- ROMs had greater variability than recumbent ones, as reflected in their Interquartile ranges (Figure 28). It should also be noted that the global trunk range (the range over which the participants' whole body is moved) was 60° in flexion and 20° in extension from the neutral position for weight-bearing and 40° in each direction for recumbent motion. This was because in the recumbent protocol for flexion-extension participants were required to bend their hips and knees to angles of around 120 degrees to achieve stability on the table, with the effect of causing a slight flexion of the spine and flattening of the lumbar lordotic curve. From this position, the participants underwent 40 degree flexion and 40 degree extension arcs. This gave overall 80 degree arcs in each orientation, but led to considerable differences in the outbound ranges of rotation per level as shown in Figure 28. This prevents comparison of recumbent and weight-bearing sequences for maximum IV-ROM. However, calculating the IV-ROM as a proportion of L2-S1 ROM can compensate for this (see section 3.2.3.2).

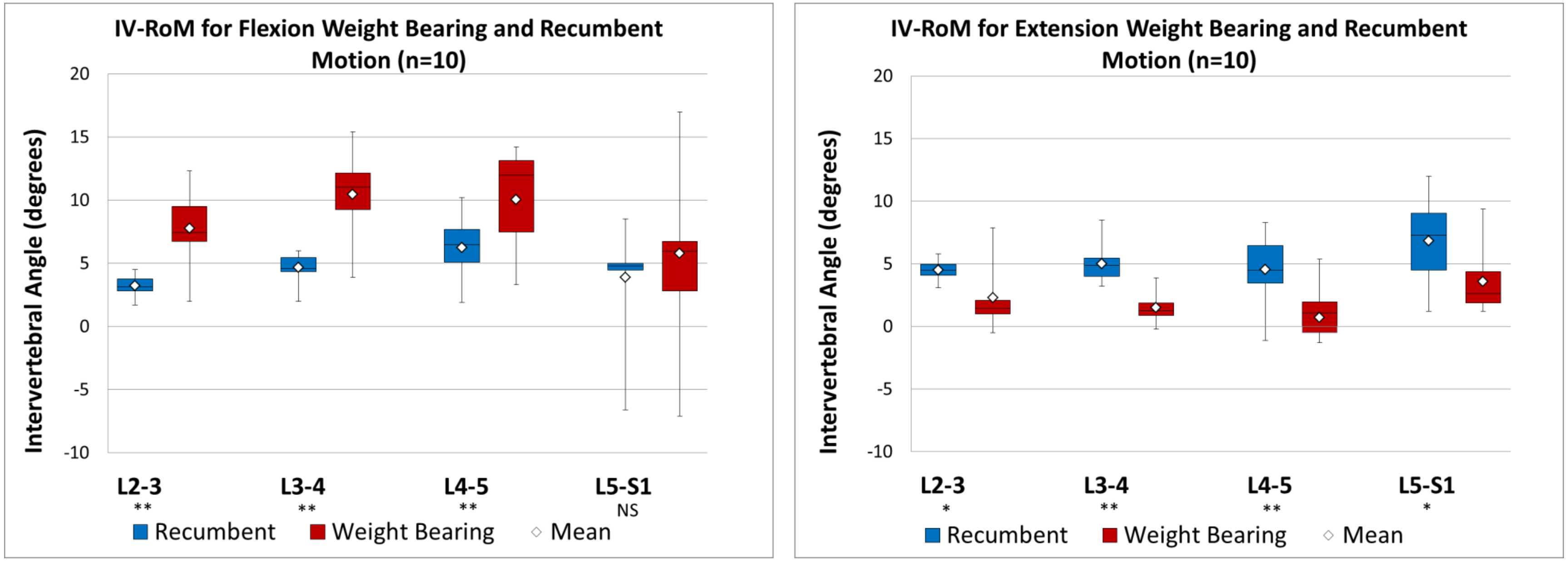



**Figure 28: Box plot comparison between angular ranges of motion of weight-bearing and recumbent protocols within; a) flexion motion (left) and b) extension motion (right).**
**Explanations of the box plot graphs can be found in Appendix A.I "*Explanation of box plots*" page 209**
**These results are given in full in Table 32 and Table 33 of A.II page 212.**
**Whole body movement while weight-bearing was 60° in flexion and 20° in extension from the neutral position and 40° in each direction for recumbent motion. The 40° range in recumbent configurations is due participants need to bend their hips and knees at angles of approximately 120 degrees to achieve stability on the table, with the effect of causing a slight flexion of the spine and flattening of the lumbar lordotic curve.**

NS=p>0.05, * = 0.01<p<0.05, **= 0.001<p0.01, ***= p<0.001

#### 3.2.3.1.2 *Side-bending (coronal plane motion)*

Due to the symmetrical nature of the 40 degree lateral flexion movements to the left and right, weight-bearing and recumbent IV-ROMs were similar for all levels and in both directions, with no significant differences between them, except at L4-5, where recumbent motion generated higher ranges for both directions and at L5-S1 during left side-bending where the median range was never greater than 1 degree (see Table 7,Table 10 & Figure 29).

The interquartile ranges for all levels and directions were generally smaller in side-bending than in flexion and extension.

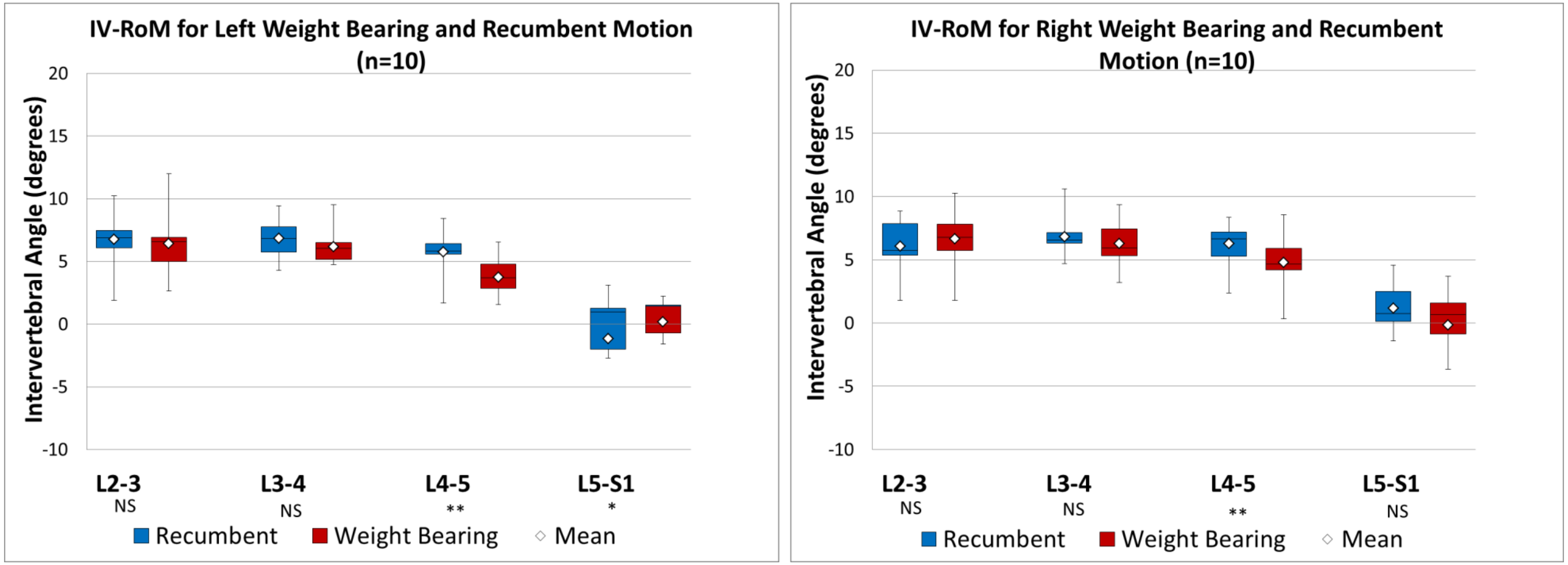



**Figure 29: Box plot comparison between angular ranges of motion of weight-bearing and recumbent protocols with in; a) left motion (left) and b) right motion (right).**
**These results are given in full in Table 30 and Table 31 of A.II page 211.**
**Explanations of the box plot graphs can be found in Appendix A.I "*Explanation of box plots*" page 209**

NS=p>0.05, * = 0.01<p<0.05, **= 0.001<p0.01, ***= p<0.001

### 3.2.3.2 *Coronal and sagittal IV-ROM expressed as a proportion of the L2-S1 range (proportional IV-ROM)*

In order to compare weight-bearing and recumbent motion while controlling for global range of motion, the IV-ROMs were expressed as proportions of L2-S1 range. For both flexion and extension, individual proportional segmental contributions to L2-S1 motion were again more variable (higher Interquartile ranges) than those segmental contributions in left and right motion (Figure 30 & Figure 31). There were also significantly greater contributions in weight-bearing than recumbent motion at L2-3 & L3-4 in extension and significantly less at L4-5 in flexion (Figure 30).

For side-bending, L2-3 and L3-4 contributed most to the motion in both configurations and especially in weight-bearing (Figure 31). However, variability (Interquartile ranges) and segmental contributions to motion were similar between the two orientations.

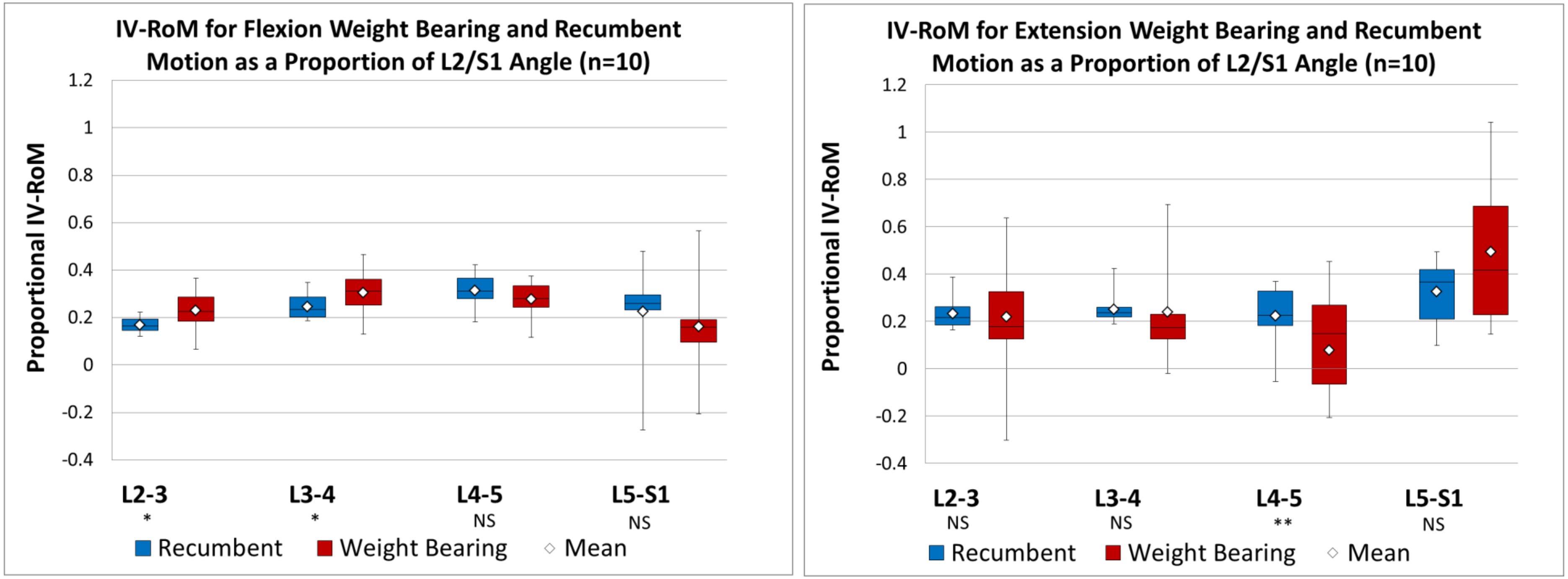



**Figure 30: Box plot comparison between proportional angular ranges of motion of weight-bearing and recumbent protocols in; a) flexion motion (left) and b) extension motion (right).**
**Explanations of the box plot graphs can be found in Appendix A.I “*Explanation of box plots*” page 209**

NS=p>0.05, * = 0.01<p<0.05, **= 0.001<p0.01, ***= p<0.001

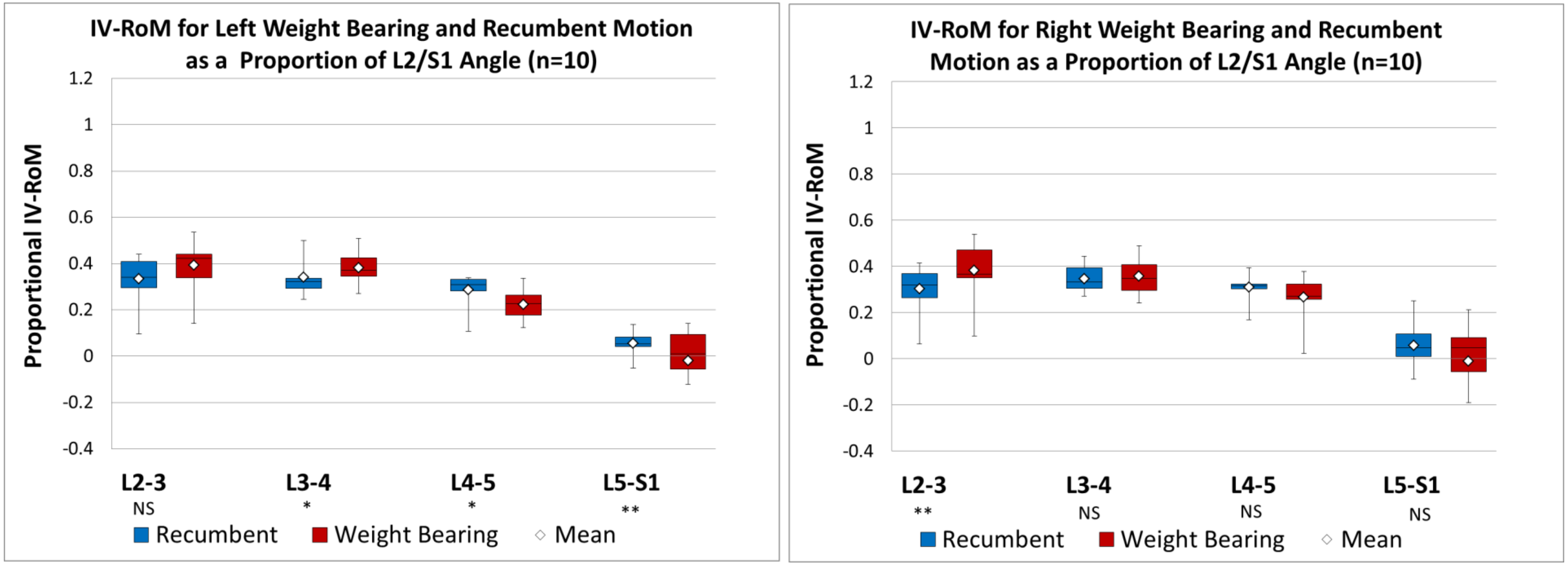



**Figure 31: Box plot comparison between proportional angular ranges of motion of weight-bearing and recumbent protocols in; a) left motion (left) and b) right motion (right) motion.**
**Explanations of the box plot graphs can be found in Appendix A.I "*Explanation of box plots*" page 209**

NS=p>0.05, * = 0.01<p<0.05, **= 0.001<p0.01, ***= p<0.001

#### 3.2.3.3 *Initial attainment rate (laxity)*

To determine the 'laxity, or degree to which a joint initially resists motion, the rate at which trunk motion is initially attained by each inter-vertebral joint in the form of rotation is calculated as described in section 2.7.1.1 and shown in Figure 14 of section 2.7.1.1. Since initial attainment rate is only measured for the first 10 degrees of trunk bending in which the inter-vertebral segment moves, unlike range of motion, it is not affected by total range of motion and as such a comparison can be drawn directly between weight-bearing and recumbent configurations.

The attainment rate was significantly greater during weight-bearing motion in flexion at L2-3 & L3-4 and in recumbent extension at L2-3 (described in Figure 32 and detailed in full of Table 34 and Table 35). By contrast, in side-bending, attainment rates were significantly greater in the recumbent position, at L3-L4 and L4-L5 (described in Figure 33 and detailed in full of Table 36 and Table 37).

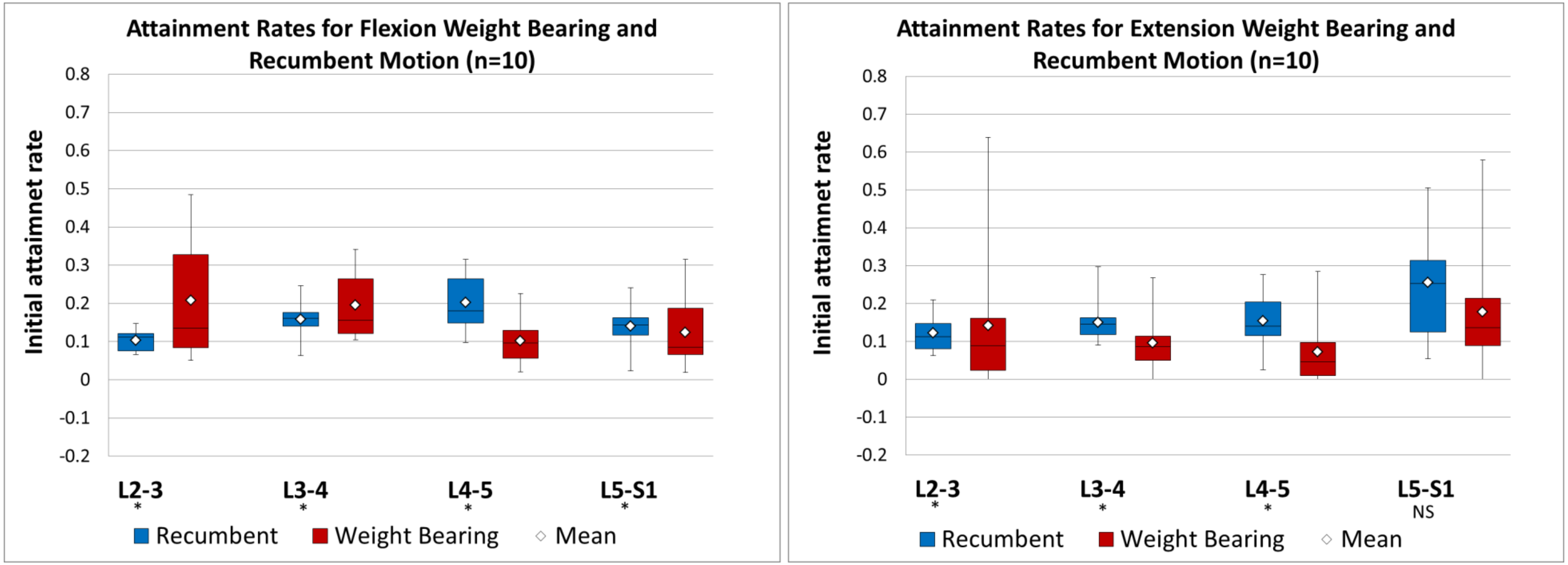



**Figure 32: Box plot comparison between attainment rates from weight-bearing and recumbent protocols in; a) extension motion (left) and b) flexion motion (right).**

**Explanations of the box plot graphs can be found in Appendix A.I "*Explanation of box plots*" page 209**

NS=p>0.05, * = 0.01<p<0.05, **= 0.001<p0.01, ***= p<0.001

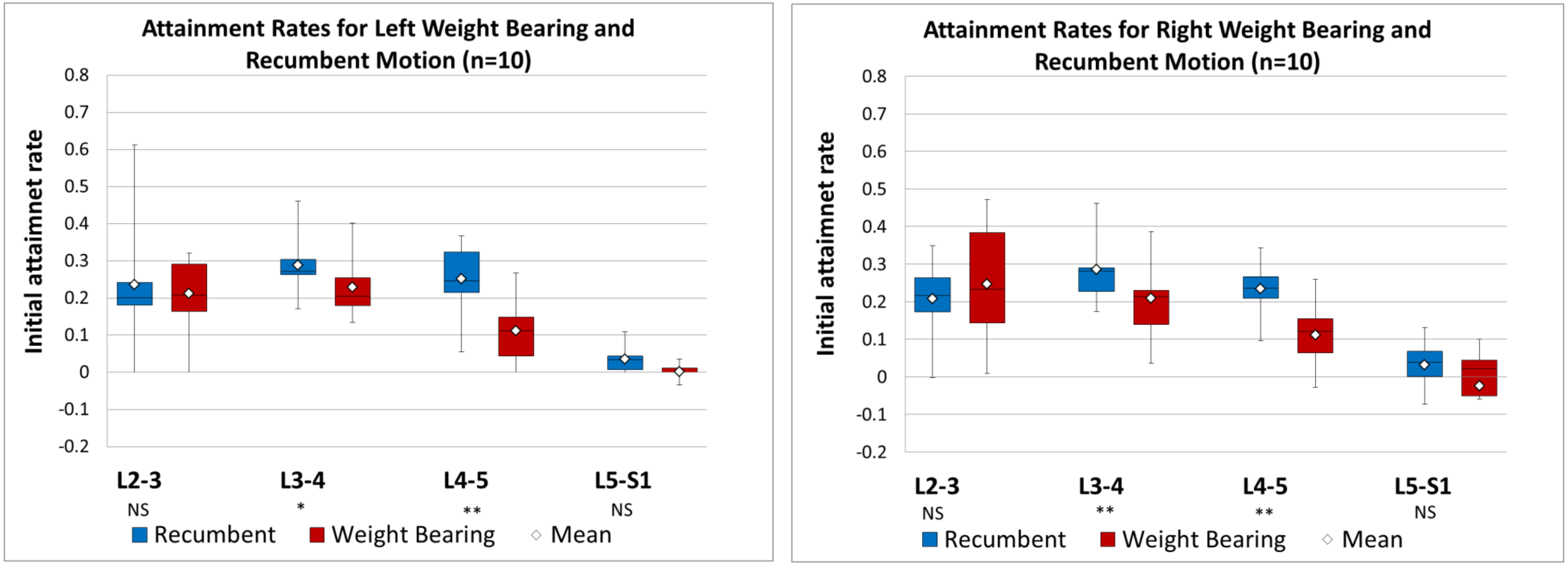



**Figure 33: Box plot comparison between attainment rates of weight-bearing and recumbent protocols in; a) left side-bending motion (left) and b) right side-bending motion (right).**
**Explanations of the box plot graphs can be found in Appendix A.I "*Explanation of box plots*" page 209**

NS=p>0.05, * = 0.01<p<0.05, **= 0.001<p0.01, ***= p<0.001

### 3.2.4 Discussion

As far as we know, this is the first direct comparison of weight-bearing and non-weight-bearing inter-vertebral kinematics in living subjects. The results suggest that there appear to be potentially important differences in inter-vertebral motion patterns in recumbent and weight-bearing postures and in the coronal and sagittal planes. If an analysis of greater participant numbers bears these differences out, it will enable investigators to make informed choices about optimal acquisition and analysis protocols for future research and clinical uses of QF.

### 3.2.5 Overview

For side-bending (Figure 34b), L2-3 and L3-4 contributed most to the overall left to right motion in both configurations, with recumbent contributing more at L4-L5. In full flexion-extension (Figure 34a), L5-S1 contributed more than any other level for both configurations, but weight-bearing contributed significantly more at L3-L4. These findings were also reflected in individual direction, proportional ranges and in attainment rates. However, variability was higher in flexion-extension in weight-bearing.

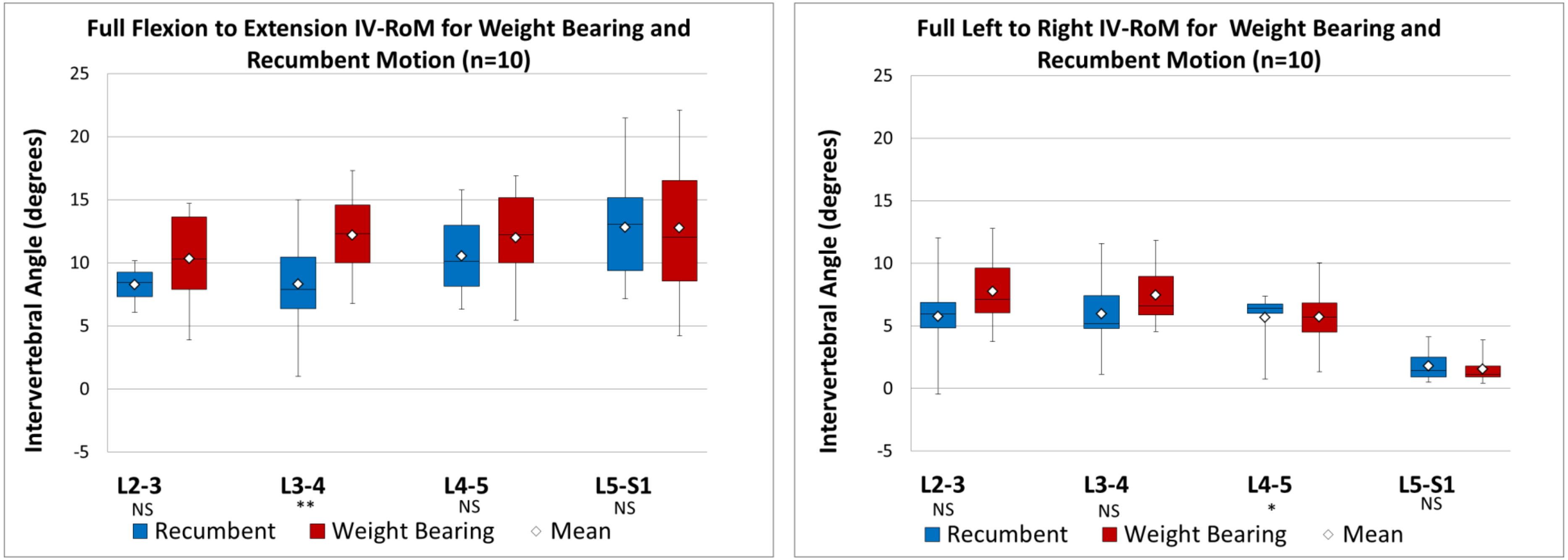



**Figure 34: Box plot comparison between mean overall angular ranges of motion of weight-bearing and recumbent protocols in a) flexion to Extension (left) motion and b) left to right (right) motion.**
**Explanations of the box plot graphs can be found in Appendix A.I "*Explanation of box plots*" page 209**

NS=p>0.05, * = 0.01<p<0.05, **= 0.001<p0.01, ***= p<0.001

For purposes of comparing cohorts and for minimising extraneous noise when examining relationships between these data and other factors, it would be desirable to have data with a substantial range of values and as little inter-subject variability as possible.

For flexion motion, it appears that proportional range of outward IV-ROM is greater in weight-bearing at L3-L4 than in passive recumbent motion (Figure 30a). It is also more variable at L5-S1 during weight-bearing extension (Figure 30b). Both of these features could work against the detection of differences between populations. Recumbent flexion and extension ranges were, by contrast, both similar and less variable in both orientations. However, both recumbent and weight-bearing full flexion to extension ranges were again highly variable.

In side-bending, the raw maximum outward inter-vertebral ranges were similar in both orientations as well as being less variable than flexion and extension (Figure 29a, b). However, the low range at L5-S1 in both orientations would tend to exclude it as a useful measure to compare populations. Full left to right ranges showed similar features (Figure 34b).

Proportional ranges gave similar results for all levels, directions and orientations. However, the low range for weight-bearing L3-4 extension and the high L5-S1 variability (Figure 8) would discourage its use for making comparisons, whereas passive recumbent proportional range inter-vertebral motion patterns have been found to discriminate healthy controls from patients with chronic, nonspecific low back pain in a parallel study to this one (Mellor et al 2014).

Previous research which has investigated lateral flexion of the lumbar spine found measurement to be problematical due to the effects of axial rotation (coupled motion) that accompanies coronal plane motion (Scholten 1985). Under weight-bearing conditions this coupled axial motion has been reported as an approximate 1° for every 4° to 5° of lateral flexion (Pearcy 1984). However, coupled axial and lateral rotation does not affect the degree of coronal plane  rotation itself and has been demonstrated to only marginally reduce the accuracy in previous studies which have utilised these QF imaging techniques (Breen et al. 2006).

Initial attainment rate results (Figure 32 & Figure 33) reflected similar features to the IV- ROM and proportional range results. However, initial attainment rate was low at L4-5 in all weight-bearing sequences and practically non-existent at L5-S1 in recumbent side-bending (Figure 33a, b).

On the basis of measurement characteristics, and leaving low L5-S1 IV- ROM aside, passive recumbent side-bending motion appears to be the most suitable for comparing cohorts and exploring correlations. This would test the passive structures of the inter-vertebral segments and therefore the hypothesis that changes in these in amputees could account for differences from healthy controls in terms of lumbar biomechanics. However, the literature provides little information from *in vivo* passive motion kinematic studies to support or refute this rationale apart from the work of Mellor et al (2014) and Willen and Danielson (2001).

Finally, passive recumbent sequences would reduce variability and noise from the effects of load bearing and participant behaviour on all parameters.

#### 3.2.5.1 *Rationale for choice of lumbar spine imaging protocol*

##### 3.2.5.1.1 *Coronal or sagittal*

As discussed in section 2.6 “Methods for assessing socket fit” (page 38), the issues which arise in unilateral amputee gait which are thought to have an impact on the spine are primarily those of symmetry between the healthy limb and the amputated limb. It would therefore follow logically, that measurements in the coronal plane would be better suited to identify any differences between the spinal kinematics of amputees and healthy controls. The precedent for which can be found within the literature (Hendershot 2012). Hendershot’s (2012) comparison of the stiffness of the lumbar spines of amputees and controls during bending found greater left-right differences in spinal stiffness in amputees than controls. As the present study will also investigate restriction of inter-vertebral movements, but using kinematics instead of force parameters, it was decided to also carry out the recumbent passive motion image acquisition in the coronal plane, comparing left to right in terms of a number of variables.

##### *3.2.5.1.2 Recumbent or weight-bearing*

The most common in vivo kinematic imaging of the lumbar spine is performed in flexion-extension and in the upright position. However, these preliminary studies showed that weight-bearing motion patterns are more variable in appearance than recumbent ones (Figure 26). In addition to the above data, subjective viewing of motion graphs suggest that variations between subjects are also greater in weight-bearing in terms of: start and return phase lengths, outward phase attainment rates, narrowed peak phase, return to below start phase, shifted outward phase and upper lumbar share of motion. These variations are likely to be due, in a good part, to differences between individuals in terms of loading and voluntary muscle contraction (Cort et al. 2013), which would represent ‘noise’ when trying to discriminate on the basis of the effects of a single factor such as amputation. Therefore, a decision was made to use passive recumbent image acquisition in the main study.

### 3.2.5.2 *Rationale for choice of variables*

Paramount among the variables for measurement at inter-vertebral level is angular range of motion in each direction both at segmental and L2-S1 levels. QF measurement of this has been found to be highly repeatable and accurate (Breen 2006). Initial attainment rate might also be expected to be more asymmetrical as with gait in amputees and has been shown to be more substantial in recumbent coronal plane studies (see above). Therefore, initial attainment rate will also be measured in the coronal plane.

QF also displays continuous rotational motion patterns (Figure 27), which when expressed as proportions of the total motion of all levels (e.g.L2-S1) (Figure 31), controls for variations in overall trunk motion during imaging. These patterns have been shown to be more variable in people with chronic, non-specific low back pain than in healthy controls (Mellor 2014). Left-right differences in coronal plane motion pattern variation will therefore also be compared between amputees and controls.

## 3.2.6 Conclusion

The above results support a rationale for selection of a spinal image acquisition method for comparison with prosthesis data consisting of coronal recumbent motion, measuring IV-ROM, initial attainment rate and symmetry. The selection of the protocol for recording images of the spine in motion depends on the relevance of the measurements it makes possible for comparing amputee and control kinematics. Also of importance is X-ray dose limitation and although coronal and sagittal and weight-bearing and recumbent recording are all possible, to keep the effective dose of ionising radiation received by a participant 'as low as reasonably achievable' (ALARA), a reduction of imaging to one plane and one orientation would be desirable. With the ALARA principle in mind it has been decided to keep measurements of the lower-limb amputees (LLA) spines to a manageable and useful amount by imaging in only one plane and orientation. The calculated mean effective dose for imaging of the spine in previouse studies was found to be 0.429mSv with the upper third quartile receiving 0.580mSv (Table 40 of appendix A.III.1.)

## 3.3 Study 2: Limb-socket imaging protocol

### 3.3.1 Background

Socket design often focuses on how weight is distributed to the residual limb when body weight is applied. However, it is also important to take into account the suspension of the socket from the residual limb when loading is removed or reversed during the swing phase of gait (causing torsional forces) as discussed in Section 2.4.3 (Gholizadeh et al. 2011). Decreased amounts of vertical tibial translation (pistoning/telescoping) have been directly correlated with successful, comfortable prosthetic fittings. Manufacturers have also developed innovative ways to reduce pistoning of the soft tissue (i.e. skin, muscle and fat) by creating new suspension techniques and socket liners to counteract the slip of the prosthesis out of the socket (Gholizadeh et al. 2011).

#### 3.3.1.1 *Pistoning and telescoping*

As discussed in Section 2.6.2 of the literature review, the vertical translation of the residual limb inside a prosthetic socket during gait is traditionally measured by surface markers on the skin of the limb and on the prosthesis (Gholizadeh 2012; Gholizadeh et al. 2011).  However, this does not account for the movement of the distal bone structures through soft tissue and prosthesis. To achieve this, evaluation of residual limb motion has been performed with various prosthetic sockets and liner interfaces in multiple studies which utilised radiographic techniques to measure the distal movement of the tibia in the socket.  In general, these found that the distal bone displacement measured between two static positions can vary from 2 to 36mm (Table 6 of section 2.6.2). The variation of this has been primarily linked to suspension type and socket build style. (Commean et al. 1997a; Grevsten and Erikson 1975; Grevsten and Eriksson 1974; Lilja et al. 1993; Narita et al. 1997; Soderberg et al. 2003; Tanner and Berke 2001).

#### 3.3.1.2 *Radiographic distortion*

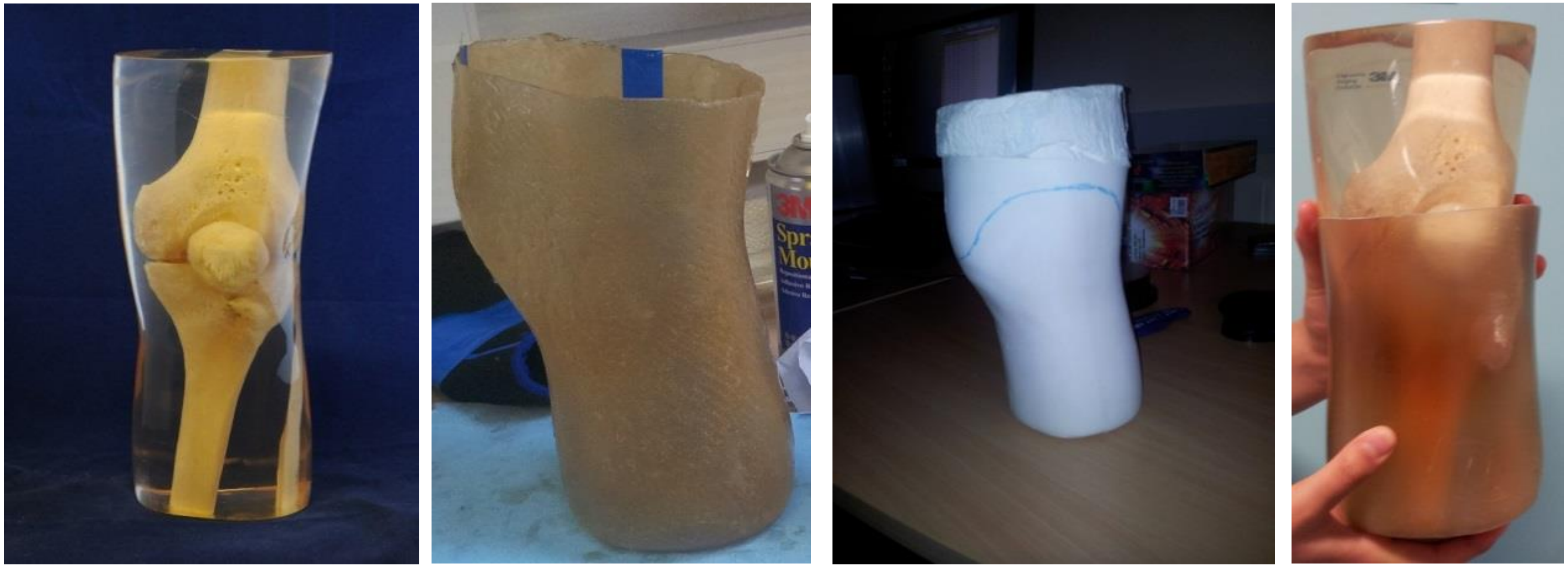
Plain radiographs can display the displacement of the distal bone structures within the prosthesis using radiopaque markers on the surface to provide a reference value for distances.  However, account has to be taken of magnification and projection errors when using plain radiographs both in terms of the bony structures and external markers. Fluoroscopy, like plain radiographs, utilises X-rays to produce its images and as such is able to visualise the position of radio-opaque structures (i.e. bones) in motion but suffers from the same intrinsic errors (Frobin 1997). In this study the magnification effects of rotating a prosthetic socket containing a radiographic phantom were examined, with the objective to optimise the acquisition of video fluoroscopic images of below knee residual limbs in motion.

### 3.3.2 Aim

The purpose of this second study was to inform the development of a fluoroscopic imaging protocol for the evaluation of the residual limb and socket kinematics of lower limb amputees (LLA) when body weight is applied as it would be in under normal walking conditions. This was done by constructing an *in vitro* mannequin of a limb-prosthesis interface and assessing its imaging properties for suitability in terms of the measurement precision that would be possible for assessing the limb-prosthesis kinematics in amputees.

### 3.3.3 Methods

A fiberglass approximation of a trans-tibial socket was custom made to fit a radiological knee phantom (manufactured by 3M, Figure 35a): A reusable negative mold of the radiological phantom was made using fiberglass (Figure 35b).This negative mold was made watertight and filled with plaster of Paris to make a positive cast. (Figure 35c) Additional padding was added to the positive cast to compensate for narrowing at the distal end and a fiberglass prosthetic socket was built (Figure 35d, overleaf)



**(a)** **(b)** **(c)** **(d)**

**Figure 35: Building of a prosthetic socket to contain a radiological phantom.**

(a) radiological phantom of a human knee and surrounding bones
(b) reusable fiberglass negative cast of phantom limb.
(c) single use positive plaster of Paris mold for development of socket
(d) radiological phantom in fiberglass socket

Spherical radiopaque metal markers of known diameter (4.4mm as measured using a GemRed Electronic Digital Caliper) were attached to the socket to act as a guide for image distortion and to create a measure for out of plane rotation.  Using these markers as a reference system, dimensions and movements of the residual limb anatomy within the socket measured in radiographic images can be described in terms of millimetres (Figure 36 & Figure 37).

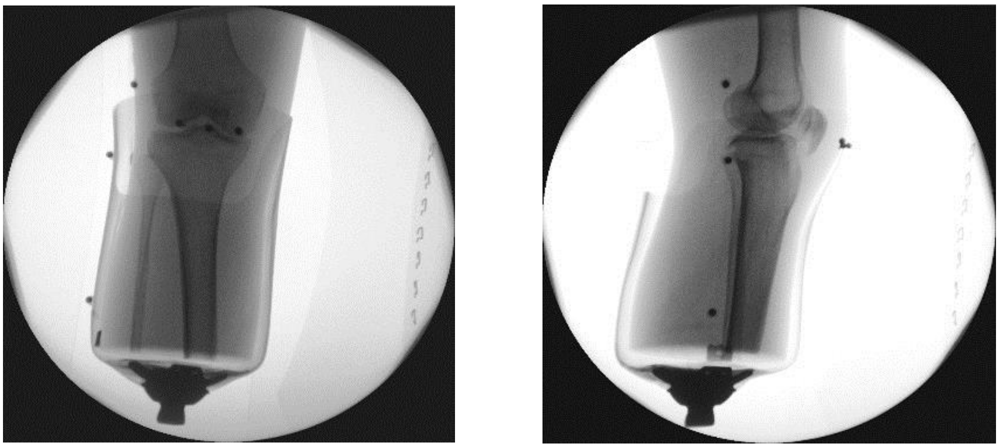
**(a)** **(b)**

**Figure 36; Radiological phantom in fiberglass socket positioned for fluoroscopic scout images.**

a) **phantom supine within the socket,**
b) **phantom lying facing right within the socket.**

The phantom was placed on a radiolucent X-ray table and images were acquired using modern c-arm fluoroscope (Siemens Arcadis Avantic, Siemens, GMBH, Germany).  The phantom was imaged in the anterior-posterior projection (supine) to obtain coronal plane images (Figure 36a) and in the lateral projection for sagittal plane images (Figure 36b).  The fluoroscope was set to acquire single frames at 53 kV and 1 mA.

A secondary effect of rotating the phantom and socket through 90 degrees to obtain images in both coronal and sagittal planes was a change in the positions of the radiopaque markers, effectively moving them 50mm closer to the x-ray source.  The images obtained (Figure 37) were inspected for quality in terms of visibility of anatomical markers and magnification distortion due to the decrease in marker distance from the X-ray source.



(a) (b)

**Figure 37; Scout images of radiological phantom within a custom made socket**

a) **phantom supine within the socket (anterior-posterior projection)**
b) **phantom lying facing right within the socket (lateral projection)**

The degree of distortion was determined by first, manually measuring the diameters of each marker within the radiographic images (in terms of pixels) using “ImageJ v 1.45s” (an open source software in the public domain http://rsb.info.nih.gov/ij/ ). To validate the repeatability of these measures, each marker diameter was determined 10 times for either image. The mean difference, standard deviation and standard error of measurement (SEM) were calculated between measurements of the marker in each image.

### 3.3.4 Results

The images acquired (Figure 37 a & b) showed good quality and definition of all borders and the radiopaque markers were clearly visible. However, it was observed that in a lateral image (Figure 37 b) the phantom's fibula superimposes on the tibia making it difficult to define their respective borders.

For the 10 measures of diameter of the marker in each image the mean difference in measurement when the phantom and socket were rotated through 90° was 2.43 pixels (SEM 0.56). Since the markers have been previously measured consistently to be 4.4mm in diameter, an estimate of these errors in terms millimetres can be acquired. This difference in measurement can be equated to 0.6mm (SD 0.19mm) which is negligible. Table 11 shows the mean diameters in pixels across these 10 readings and the mean difference between the measured diameters in the sagittal and coronal planes.

**Table 11. Effect of 90$^{o}$ rotation of the limb on metal bead image distortion**

| Diameter (pixels) | | | |
|---|---|---|---|
| | Sagittal | Coronal | Difference |
| **Mean** | 19.11 | 16.69 | 2.43 |
| **SD** | 0.47 | 0.67 | 0.80 |

### 3.3.5 Discussion

The majority of previous radiological studies of residual limb telescoping (discussed in section 2.6.2) recorded their measurements in the sagittal plane. However, for the purposes of this study the super-positioning of the fibula and tibia in the sagittal plane was considered to cause difficulty for repeatedly identifying anatomical markers for displacement measurements. Furthermore, it was the intention of the author to use the same techniques as outlined in section 3.2.2.3 to track the tibial displacement in order to quantify the quantity and quality of the limb movement under different loading protocols. A super positioning of the fibula and tibia would be a confounding factor for the tracking software due to the changes in the objects' apparent shapes and densities as one moves almost independently of the other.

The radiopaque external markers, attached to the participant's socket have been demonstrated here to be repeatedly measureable with a standard deviation of up to 0.67 pixels (equivalent to 0.18mm SD) in any given image and a magnification error to be as small 0.6mm (SD 0.19mm) when the distance to the x-ray source is reduced by 5cm. Furthermore, within the in vivo protocol which this study is designed to inform, the participant will not be required or encouraged to change this distance with their prosthetic and the differences in marker sizes due to distortion when the limb is positioned and repositioned will still be negligible.

Furthermore, as imaging during a gait simulation was required for this study, the intact limb image would obstruct the prosthetic one if sagittal plane images were attempted.

### 3.3.6 Conclusion

This study was designed to develop an imaging protocol for measuring the proximo-distal motion of the residual tibia within the soft tissues of the residual limb and subsequently the socket (the ‘telescoping’ or ‘pistoning’ of the residual limb) and estimating errors which may arise in these measurements.

In sagittal images, the fibula is seen to overlap the tibia during automated tracking sequences. Such super-positioning may cause degradation of results, consequently, future studies would be better served by acquiring images in the coronal plane, where the tibia and fibula are less likely to superimpose. This is consistent with the (coronal plane) imaging technique chosen for the lumbar spine in section 3.2 “*Study 1: Lumbar spine imaging and analysis protocol*”. The addition of radiopaque external markers, attached to the participant’s socket, will allow for a reference values by which to measure tibial displacement in the proximo-distal direction in terms of millimetres, with sub millimetre accuracy and accounting for magnification effects due to participant positioning.

Further work to automatically register the marker locations and apparent sizes throughout the fluoroscopic image sequence would increase the accuracy and repeatability of this measurement technique as well as reducing the errors of reported measurements by giving a reference frame for each image of a sequence.

## 3.4 STUDY 3: Validation of a lumbar spine stability assessment

A version of the following study has been accepted for publication by an open access BioMed Central journal (Breen et al. 2015).

### 3.4.1 Background

Lateral flexion instability, considered to be a cause of chronic low back pain, has been implicated in post-discectomy kinematics and in the spine kinematics of lower limb amputees (Goel 1986; Hendershot et al. 2013; Tibrewal 1985). These have characterised segmental stability as the intrinsic resistance of spine specimens to initial bending moments by quantifying the dynamic neutral zone. Yet, its measurement and characterisation have been largely limited to in vitro laboratory studies, preventing the measurement of inter-vertebral laxity in patient assessment. Many laboratory studies have explored segmental stability in terms of the ability of the inter-vertebral linkages to withstand initial bending moments, expressed as the size of the zone of displacement when these moments are minimal. This is known as the Neutral Zone (NZ) (Cannella 2008; Crawford 1998; Panjabi 1992b; Thompson 2003) and is discussed in detail in Section 2.7.1.1. However, these measurements have traditionally been impossible to obtain in vivo without invasive procedures, preventing the measurement of inter-vertebral robustness in patient assessment.

QF has been used *in vivo* to study lumbar inter-vertebral motion patients and healthy controls (Mellor 2009). An early version of this technology used weight-bearing cineradiography and manual image registration to measure sagittal inter-vertebral angular motion as trunk motion progressed and claimed to be a surrogate for the NZ (Kanayama 1996). Later studies using fluoroscopy described this parameter as “the slope of the inter-vertebral flexion-extension (IVFE) curve” and “the inter-vertebral attainment rate” (Teyhen et al. 2007; Wong 2006; Wong 2004). Although most studies have concentrated on flexion-extension motion, lateral flexion has also been linked to segmental instability (Kirkaldy-Willis 1982; Miles 1961).

The QF studies used the ratios of the intersegmental/global bending gradients in the first $10^o$ of standardised trunk lateral flexion to express the initial attainment rates (Mellor 2009)(Figure 14 of section 2.7.1.1 of this thesis).

Both the initial attainment rate and the NZ are expressions of inter-vertebral laxity and if a relationship is found to exist between them, it would provide evidence of the criterion validity of the former and demonstrate that this *in vivo* assessment of intrinsic lumbar segmental resistance might be used as a relatively non-invasive diagnostic tool in the living spine. This study therefore sought to explore this using a multi-segmented porcine lumbar spine with segments L1 to L5. The bending moments, inter-vertebral motion and global motion were recorded together with QF, using the same procedures as in lateral flexion QF studies of patients and research participants (Section 3.2.2.3).

## 3.4.2 Methods

### 3.4.2.1 *Apparatus*

A fresh 5-segment porcine lumbar spine (L1 to L5) was prepared as recommended for the biomechanical testing of vertebral specimens (Wilke et al. 1998) The porcine spine is considered to be a reasonable substitute for the human spine in biomechanical studies (Busscher et al. 2010; Tai 2008). This is because of its comparable anatomy, geometry and the size of the vertebrae (Bozkus et al. 2005). The paraspinal muscles were completely excised and all ligamentous components, including the interspinous ligament were preserved (Tai 2008). Following the recommendations of Wilke et al 1998 regarding the standardization of *in vitro* stability testing, the preparation, storage and testing conditions were carefully maintained so to reduce possible alterations to the mechanisms of the porcine spine during the experiment. The specimen was preserved wrapped in saline-soaked gauze, to keep it moist, covered in cling film and frozen for storage. It was thawed over 12 hours before testing, mounted in a horizontal testing frame with the L1 and L5 vertebrae secured by metal halos and circumferential bolts. The same robotic horizontal motion platform used to provide controlled passive motion in patients receiving quantitative fluoroscopy examinations was used for testing (Atlas Clinical Ltd.) Figure 38. L1 was attached to the movable segment of the platform and L5 to the fixed segment.

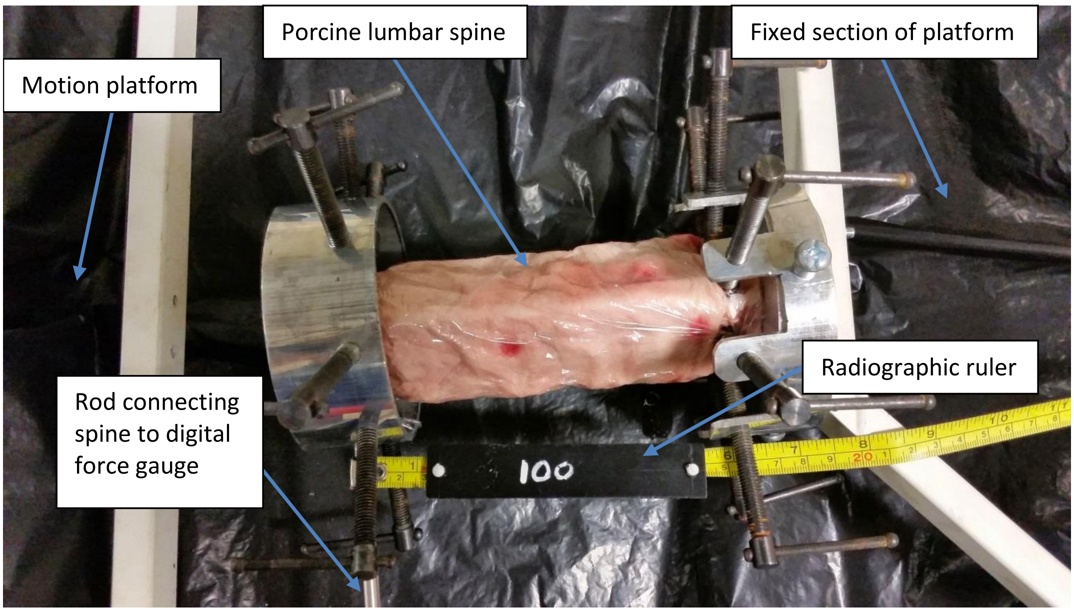



**Figure 38. Porcine lumbar spine testing apparatus and motion platform seen from above**

A digital force guage (Omega Engineering Ltd DFG35-10, range 50N, resolution 0.05N, sampled at 125Hz) was rigidly connected to the movable part of the motion platform holding the superior vertebral segment. The motion of the connecting rod forced the specimen through a $40^{o}$ arc, as applied in participant protocols detailed in Section 3.2.2.2 (Breen et al. 2012), simultaneously transmitting continuous force data from the rod to a laptop computer. The force data were co-ordinated with the digital time stamp output of the motion platform's motor, which moved the specimen at a uniform velocity of $6^{o}$ per second and at a standardised ramp-up speed over the first second of the motion.

### 3.4.2.2 *Data collection*

Fluoroscopic sequences of left and right lateral flexion were recorded the same rate (15 frames per second over 15 seconds) and using the same equipment as was used in the preliminary study detailed in section 3.2. The primary beam of the fluoroscope was centered on the disc space between the L3 and L4 vertebrae of the specimen. The image field included all 5 segments in all frames so that each vertebra could be tracked and the fluoroscope incorporated automatic distortion correction. Before recording the motion, a calibration image was acquired using a radiographic ruler comprising of two metallic beads of known diameter (4.4mm) set 100mm apart into a plastic bar and placed adjacent to the porcine spine and perpendicular to the primary-ray beam in the image field. A single fluoroscopic image was acquired so that this could be used as a scaling factor to calculate the distances between objects in the image sequences.

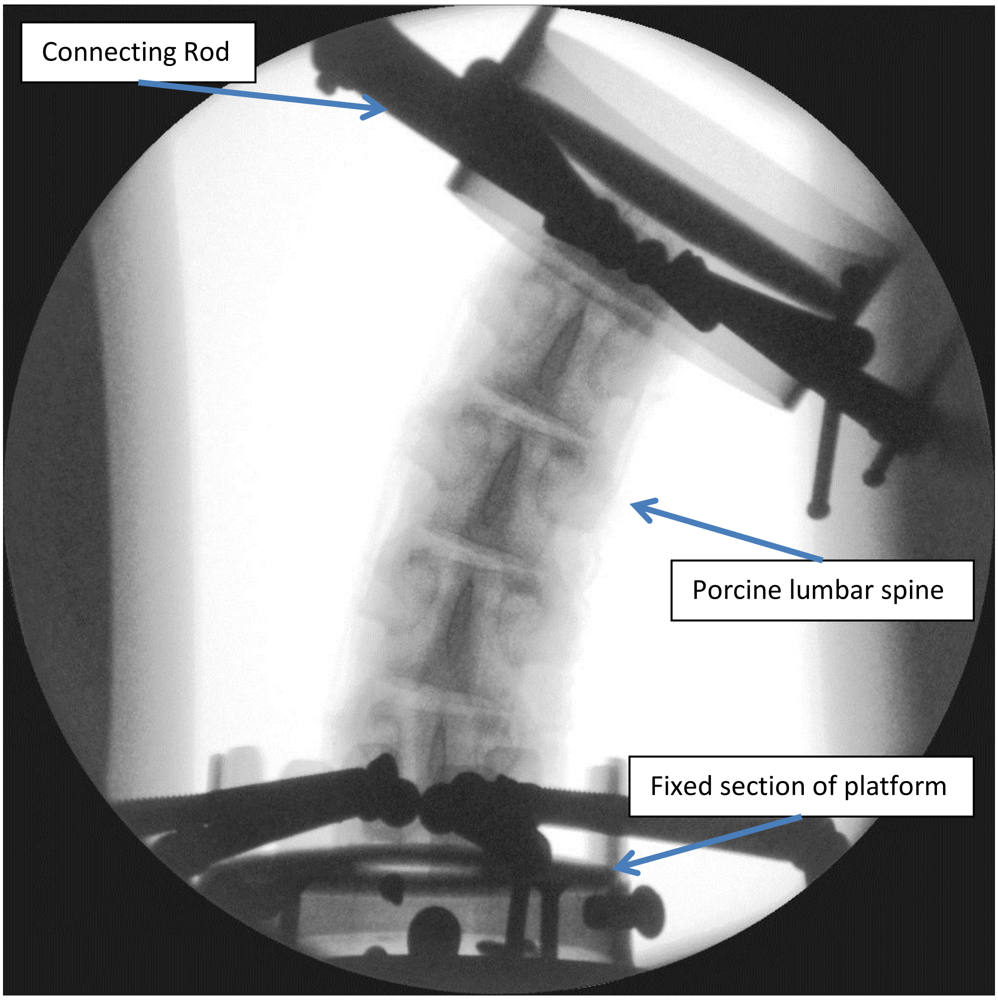



**Figure 39. Example of image acquired of porcine spine under motion (Left lateral flexion)**

As in the protocol for patient recordings (shown in section 3.2.2.2), the spine was preconditioned by performing four consecutive out and return lateral flexion sequences increasing from $10^{o}$ up to $40^{o}$ to replicate this. Ten consecutive recordings were then made of $40^o$ left lateral flexion sequences. The spine was then replaced in a 'neutral' position where the force applied by the motion platform was as close to zero as possible. The same procedure was followed for right lateral flexion, however, due to the configuration of the apparatus only a maximum of $30^o$ was achievable for right lateral flexion.

#### 3.4.2.3 *Image analysis*

Outlines of the vertebral body borders of the first image were marked using the computer's cursor in the first of each sequence of images in a manner identical to the patient mark-up protocol (3.2.2.3.2). The positions each of the vertebrae in each of the fluoroscopic images were calculated, producing continuous tracking of each vertebral body image throughout the sequences (Breen et al. 2006). Trackings were verified visually by a trained operator and the means of the positions of each vertebral section were generated as an output (as in section 3.2.2.3.3).

The changing inter-vertebral angles of the specimen were co-ordinated with the timing and position of the motion platform. The inter-vertebral angles of the specimen when the motion platform reached $10^o$, the moments applied at each inter-vertebral joint and the motion platform rotation were recorded dynamically. The positions of the point of load application/measurement and the individual joint centres were derived from the trackings of each vertebra in each image frame. Since the centres of rotation between vertebrae are not generally to be found in the joint centre and due to the elasticity of the inter-vertebral joint, these distances varied slightly during motion and were incorporated into the continuous calculation of moments as detailed below. Forces and moments could not be measured directly at each joint, therefore estimation of forces and moments of forces were derived from the kinematics and inertial properties of the spine by applying the process of inverse dynamics. Modelling the spine as a series of free bending rods of negligible thickness and with uniform mass distribution, an estimation of forces and moments was derived based on D'Alembert's principle (Fig 3). One can write the Newton-Euler equations as:

**Equation 1**

$$\sum \mathbf{F} = m_i \mathbf{a}_i \Leftrightarrow (-\mathbf{F}_{i-1}) + \mathbf{F}_i + m_i \mathbf{g} = m_i \mathbf{a}_i$$

**Equation 2**

$$\sum \mathbf{M} = I_i \boldsymbol{\alpha}_i \Leftrightarrow (-\mathbf{M}_{i-1}) + \mathbf{r}_{i-1} \times (-\mathbf{F}_{i-1}) + \mathbf{M}_i + \mathbf{r}_i \times \mathbf{F}_i = I_i \boldsymbol{\alpha}_i$$

These equations are used routinely in biomechanical models to examine joint reaction forces and moments within a kinematic chain by examining motion segments individually (free body diagrams). They are also presented in text books e.g. (Winter 2009) and in the peer reviewed literature e.g. (Dupac and Marghitu 2006). The input parameters are defined as follows:

$\mathbf{F}_{app}$ is the applied force, $\mathbf{F}_i$ is the reaction force and $\mathbf{r}_i$ is the distance from the segment centre of mass to $\mathbf{F}_i$. Since the geometrical centre is considered to be the centre of mass, $-\mathbf{r}_i$ is the distance from the segment centre of mass to $\mathbf{F}_{app}$. $m_i$ is the mass of segment $i$ assumed to be one 5th of the multi-segmental porcine spine (comprised of five vertebrae), g is gravity vector, $\boldsymbol{\alpha}_i$ is the angular acceleration, calculated as the second derivative of the change in angular position of each motion segment over time, $I_i$ is the moment of inertia and $\times$ represents the vector (cross) product. Since gravity is acting perpendicular to the plane of measurement it can be ignored as in Figure 40. $\mathbf{a}_i$ is the acceleration of the centre of mass of the segment. The acceleration vector of the centre of each segment is defined as the second derivative with respect to time of the change in position, that is,

**Equations 3 & 4**

$$\boldsymbol{a}_{xi} = \frac{\boldsymbol{d^2 x_i}}{\boldsymbol{dt^2}} \; ; \; \boldsymbol{a}_{yi} = \frac{\boldsymbol{d^2 y_i}}{\boldsymbol{dt^2}} \; ;$$

From Equation 1 and Equation 2 one can calculate each reaction force $(\mathbf{F}_{\mathrm{i}})$ and joint moment $(\mathbf{M}_{\mathrm{i}})$ acting on each individual motion segments of the kinematics chain (Dupac and Marghitu 2006; Winter 2009).

The applied force $\mathbf{F}_{app}$ (as seen in Figure 40) is measurable in its uniaxial form directly from the force transducer. Since the force was applied in the normal direction to the L1 vertebra and maintained throughout the motion, the direction of applied force at any given moment is measureable directly from the image data. This allows $\mathbf{F}_{app}$ to be converted to a biaxial vector force measure.

**Equations 5 & 6**

$$F_{app_y} = F_{app} \times \sin\theta\,; \quad F_{app_x} = F_{app} \times \cos\theta$$

where $\theta$ is the angle between the direction of $\mathbf{F}_{app}$ and the x-axis of the image field. Inertia (I) was calculated about the centre of the vertebra model as a uniform rigid rod as:

**Equation 7**

$$I = \frac{1}{3} m r_i^{\,2}$$

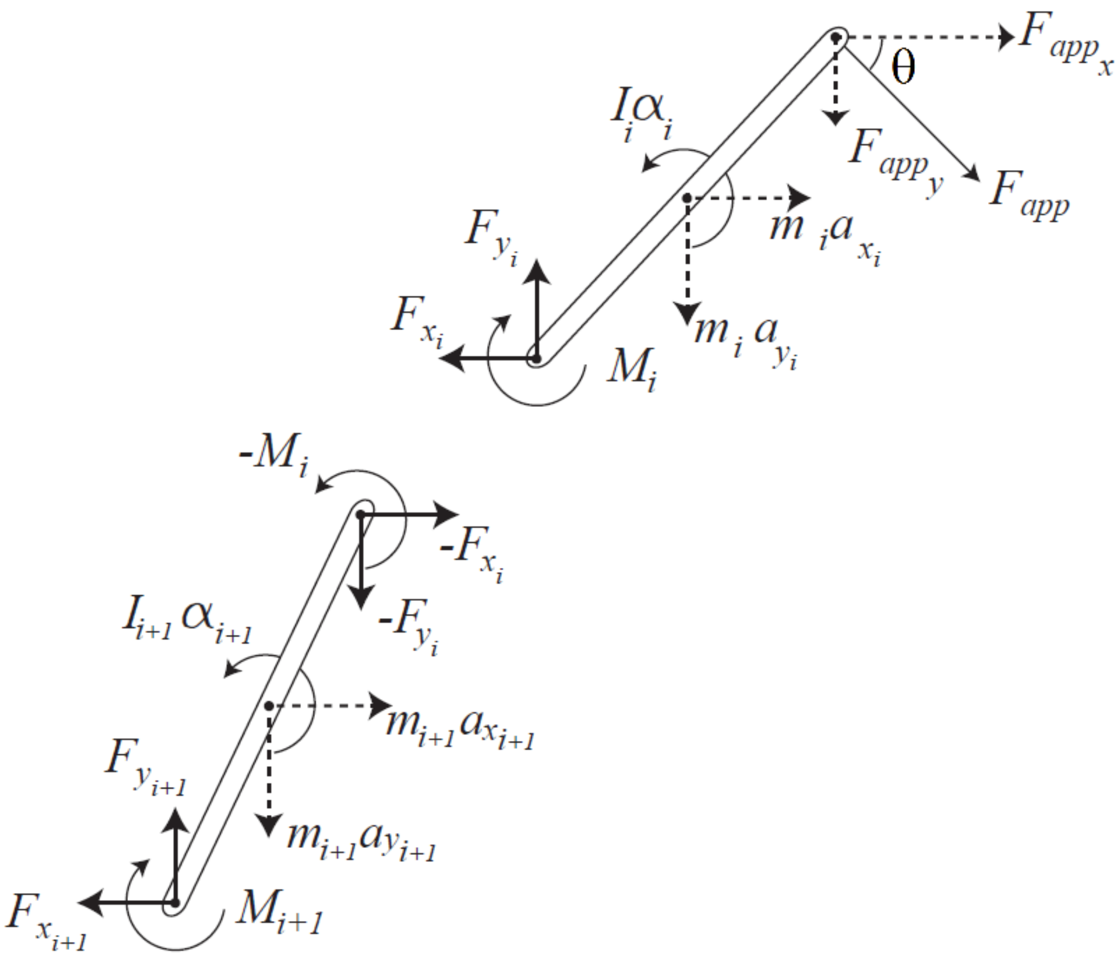



**Figure 40. A mechanical model of two successive vertebrae, modelled as having negligible thickness and uniform mass distribution.**
**The figure shows action and reaction forces, net moments of force, and all linear and angular accelerations. Gravitational forces are ignored as they are not applicable in the plane of motion.**

Initial attainment rate was calculated as previously discussed in section 3.2.2.4.2. If the motion segment did not rotate by at least 2.5° over this part of the motion (being twice the inter-observer error of the measurement of rotational deformation with this method) (Breen 2012), the segment was considered stiff and the initial attainment rate was not calculated.

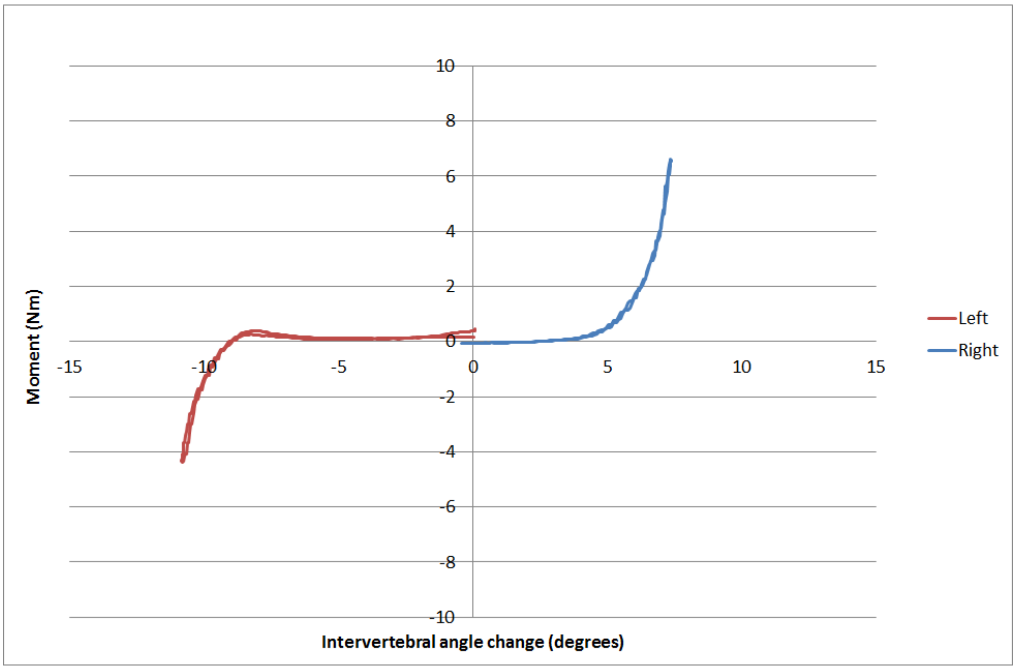



**Figure 41. Example of a force deformation curve from an L3-4 motion segment undergoing left and right lateral flexion.**

The dynamic NZ was taken to be the inter-vertebral angle at the end of the region confined by a slope of +0.05 Nm/degree (Thompson 2003). Samples of the force-deformation curves for all levels and directions in the specimen were examined to confirm that this was a reasonable assumption for this experiment.

### 3.4.2.4 *Statistical analysis*

All data were tested for normality using the Shapiro-Wilk test. The inter-vertebral angle at $10^{o}$ of platform motion, the dynamic NZs and the initial attainment rates were calculated for each inter-vertebral level and direction. Correlations between the dynamic NZs and the initial attainment rates in each segment were determined for the pooled data (n=52) and for left and right separately using the Spearman rank correlation coefficient for non-normally distributed data. The cut-off for statistical significance was set at a *P* value of 0.05.

### 3.4.3 Results

The median (interquartile range) range of motion for the whole spine (L1-5) for each direction, as measured on the fluoroscopic images were: left 33.0°(1.5) and right 28.6°(0.8), which represented 82% and 95% of platform motion respectively. The initial attainment rates for left and right lateral flexion and the pooled data are shown in Table 12. It is assumed that the motion from the platform which was not taken up between the levels L1-5 was lost to movement in the system linkages, especially in left motion.

These are comparable to previously published in vivo values for healthy controls (Mellor 2009) as well as those reported in this study (section 3.2.3.3). However, inter-vertebral deformation at $10^{o}$ of motion platform angle did not reach the required $2.5^{o}$ required for initial attainment rates to be reported at L1-2 and L4-5 for left bending. This may be a feature of the present method or a peculiarity of the specimen used. Further studies with multiple specimens would determine this.

The levels of nonparametric correlation between initial attainment rate and dynamic NZ (Figure 42) were substantial and highly significant for left and combined left-right and moderate for right alone (Landis 1977) (Table 13).

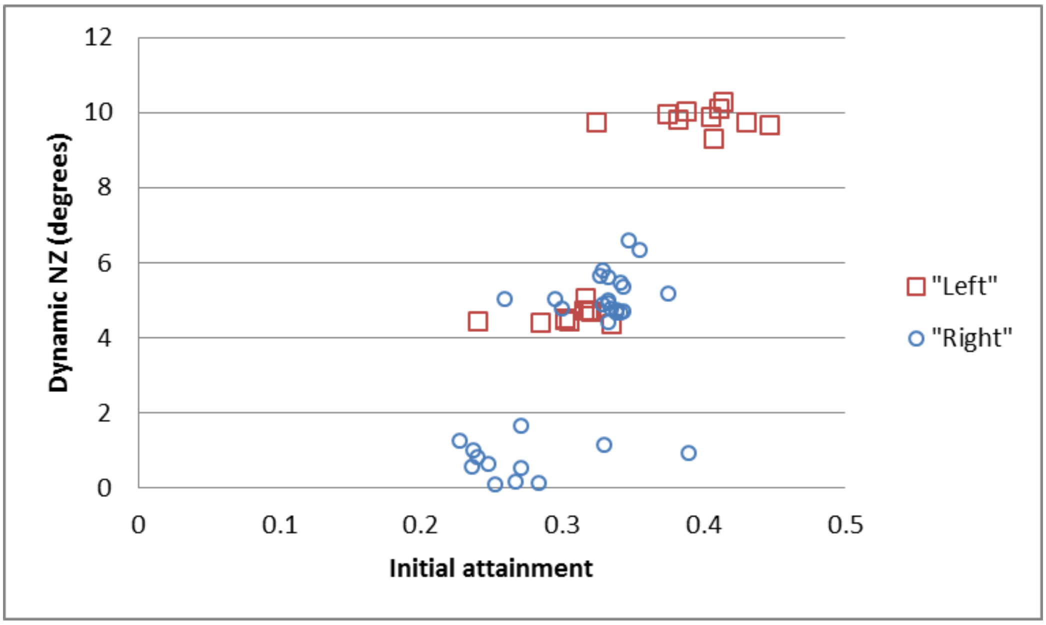



**Figure 42. Scatter plot of dynamic NZ (degrees) against initial attainment for left and right lateral flexion**

**Table 12. Median segmental initial attainment rates for left and right lateral flexion**

| | Left | | | | | Right | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Median | Upper Quartile | Lower Quartile | N | | Median | Upper Quartile | Lower Quartile | N |
| **L1-2** | - | - | - | 0 | **L1-2** | 0.204 | 0.351 | 0.271 | 7 |
| **L2-3** | 0.310 | 0.319 | 0.302 | 10 | **L2-3** | 0.331 | 0.342 | 0.300 | 10 |
| **L3-4** | 0.406 | 0.413 | 0.383 | 10 | **L3-4** | 0.339 | 0.344 | 0.333 | 10 |
| **L4-5** | - | - | - | 0 | **L4-5** | 0.239 | 0.248 | 0.236 | 6 |

**Table 13. Correlations between initial attainment rate and dynamic NZ for pooled levels (L1-2 to L 4-5)**

| | Rho* | 2-sided p | N |
|---|---|---|---|
| **Left and Right** | 0.72 | 0.0001 | 52 |
| **Right** | 0.55 | 0.0012 | 32 |
| **Left** | 0.75 | 0.0002 | 20 |

***Spearman's rank correlation**

### 3.4.4 Discussion

#### 3.4.4.1 *Main result*

These results are similar to previously published *in vivo* values for healthy human controls (Mellor 2009) and suggest that there is a relationship between the initial attainment rate and the dynamic NZ  The range of upper quartiles for initial attainment rate (0.204-0.413) were comparable to the upper reference ranges found in vivo (0.290-0.429) (Mellor 2009).  However, initial attainment rate and the dynamic NZ are not usually perfectly coincident because they do not measure the same thing; NZ reflects resistance to a pure moment and attainment rate the inter-vertebral motion velocity compared to trunk motion. Since both measures are expressions of inter-vertebral laxity and a substantial and highly significant (Rho = 0.72, P= 0.0001) correlation between pooled initial attainment rate and NZ was found to exist between them, this study has provided evidence of the criterion validity of the former and has demonstrated that Initial Attainment rate as an *in vivo* assessment of intrinsic lumbar segmental resistance has a use as a relatively non-invasive diagnostic tool in the living spine. However, it is recognized that this reflects only the concurrent validity and not the predictive validity of the measure and is therefore only the extent to which one variable is related to another.

It is not suggested that the NZ can be calculated from the initial attainment rate, but merely that they are linked in a way that would allow the order of NZ length to be determined from a set of specimens or patients/volunteers based on initial attainment rate results. The lack of the Initial Attainment rate's ability to explicitly predict NZ size is a limitation of this study but nevertheless does not detract from its usefulness of assessing inter-vertebral laxity.

In this experiment, they both appear to reflect the intrinsic restraining properties of the inter-vertebral linkages, although the differences need further explanation. In addition, the 10° cut-off used historically to define initial attainment was arbitrary.  A better justified calculation may be provided by considering the subsequent work of Smit et al (Smit et al. 2011).

#### 3.4.4.2 *Learning points as an exploratory study*

The data collected in this study formed into separate clusterings of the pooled data as can be seen in Figure 42. These four clusters are a reflection of the fact that the data were primarily gathered from repeated measures of two levels, each in two directions. While the clusters of repeated measures are less desirable than if the data were more widely dispersed, it does not invalidate the relationship. Further studies in larger samples across multiple specimens would be required to avoid such clustering.

Some of the motion of the frame (40°) was not transferred to the vertebral segments, as 6.5° (left) and 1.5° (right) respectively were lost. This may be due to the use of retaining bolt heads into the bone, calling for a better fixation method. This may have affected the correlations. In addition, two of the segments (L1-2 and L4-5 left) did not reach the required 2.5° required for initial attainment rate to be reported (Table 12). This is likely to be a prevailing feature of multi-segmental examinations, especially if segmental levels are not challenged. Future experimental setups should ensure that equal ranges of the motion platform are obtained.

In calculating the point of inter-vertebral motion from which initial attainment rate measurement begins, fluctuations can occur. If these are prominent, the initial attainment rate value may alter and the method chosen for smoothing to obtain an average value, as well as the ramp-up speed, could affect initial attainment rate values. An international forum on the use of QF suggested this preferred smoothing function but that these values should be kept under review (Breen et al. 2012; Eilers 2003; Lubansky et al. 2006).

Another question might be why there was not symmetry in the measurement results. The dynamic NZs were generally of a greater order for left lateral flexion, (median left = 7.17°, median right = 4.70°) but over a higher range (range left = 5.90°, range right = 6.49°). This might be the result of lower ranges of right global bending during pre-conditioning and repeated motion and/or alternatively, greater laxity at L3-4 in left lateral flexion (representing the upper cluster in Figure 42) as a physiological variant. Further studies using multiple specimens and symmetrical testing should clarify this.

#### 3.4.4.3 *Relevance to clinical studies*

In patient and volunteer research studies, the presence of a greater volume of soft tissue between the motion frame and the segment will add noise to the calculation of the initial attainment rate. It might be expected that laxity would be associated with a greater overall range of the segment, but may also be affected by the soft tissue mass. The extent of this might be explored *in vivo* by comparing the initial attainment rates to the overall segmental ranges obtained using QF and to body-mass index.

An additional major challenge in passive system spine kinematics research lies in the complexity of upright motion. This adds the influence of unaccounted variations arising from muscle motor control and body segment mass. However, it also extends the scope of the kind of stability parameters that can be considered.

#### 3.4.4.4 *Suggestions for further work*

The present studies were limited to lateral flexion, where in some circumstances stability may be important. However, the greatest interest in stability, especially for purposes of surgical decisions, focuses on the sagittal plane, where translation is the main kinematic measure used in estimating stability (Kanemura 2009). Studies of the correlation between this and initial attainment rate in the sagittal plane would further inform the use of initial attainment rate in the assessment of patients for segmental laxity.

### 3.4.5 Conclusion

The ability to measure inter-vertebral laxity *in vivo* with QF is a step forward in the assessment of chronic back pain where mechanics is thought to be important. This study used the passive recumbent QF protocol in a multi-segmental porcine model for assessing the intrinsic inter-vertebral responses to a minimal bending moment. It found there to be good correlation between the initial attainment rate and the dynamic NZ, thereby opening the possibility to measure passive system inter-vertebral laxity in clinical studies. However, this was an exploratory study based on repeated measurements in a single specimen, albeit a multilevel one. Therefore, the results, although likely to be important, should be treated with caution. Further, multi-specimen *in vitro* studies are now warranted.

## 3.5 Summary and conclusion of initial studies

This Chapter reported preparatory work to support a methodology for QF studies, using minimal radiation exposure, to compare *in vivo* inter-vertebral lumbar spine kinematics in amputee and control cohorts and with limb-socket movements in an amputee population. This required the development and optimisation of methods for lumbar spine QF image acquisition and analysis and a critical choice of variables to be used for making these comparisons. An imaging protocol for optimising the QF measurement of limb-socket displacements during simulated gait was also developed, together with options for the incorporation of load data during weight transfer. The results supported a decision to use coronal plane imaging for the evaluation of both spine and limb-prosthesis motion. They also supported the use of passive recumbent IV-ROM and initial attainment rate as the preferred variables for measuring spine kinematics. Initial attainment rate required validation as an expression of inter-vertebral instability and this was done with a cadaveric experiment.

It is assumed in the literature that due to the compensation mechanisms in the hip and spine to overcome the loss of limb, passive structures of the spine may be at risk as a result of increased cyclic loading over time (Yoder et al. 2015). However, while this is agreed upon throughout the literature, all studies discovered in the course of this thesis have measured spine kinematics while LLA participants undergo active weight-bearing tasks. The limitation of these studies is their lack of ability to distinguish between responses from active versus passive tissues (Hendershot and Wolf 2015).

The results of the preliminary studies presented in this chapter support the use of passive recumbent motion protocols for the investigation of spine kinematics among amputees and the relevance of measuring the restraining properties of the passive structures. Such an investigation would be novel and a unique contribution to knowledge.

# Chapter 4: Protocol design and implementation of methodology

## 4.1 Research study hypothesis

The hypothesis that this protocol was designed to investigate is that the greater the displacement of the limb/socket interface during gait simulation the greater the asymmetry in the inter-vertebral motion will be.

## 4.2 Research protocol rationale

In Chapter 2 it was concluded from the literature that most studies related to the biomechanics of amputees have either investigated telescoping of the residual limb within the prosthetic socket (Gholizadeh et al. 2011) or LLDs and their effects on global spine mechanics and relationships to back pain (Friberg 1983a, 1984; Kulkarni et al. 2005). However, none have yet accommodated dynamic LLD mechanics, where the limb must be considered as changing in length during gait rather than remaining the same length. This leads to the further question of whether there is a relationship between dynamic LLD and mechanisms that may promote low back pain in lower limb amputees. Studies have attempted to investigate this in terms of the mechanics of the spine (Gurney 2002; Hoikka et al. 1989; Lee and Turner-Smith 2003).

The mechanical differences found in the literature between amputees and healthy controls, using medical imaging techniques, postural assessment and motion capture data, have all been observed under weight-bearing conditions (either sitting or standing), when most back pain occurs (Hendershot et al. 2013; Hendershot and Nussbaum 2013; Hendershot and Wolf 2015). However, it is not known whether the mechanical changes observed result from impairment of neuro-muscular control or of the function of the inter-vertebral passive restraining elements due to repeated asymmetrical loading during gait.

QF has been demonstrated to be reliable for measuring the motion of vertebrae in vivo and should therefore provide insight into these issues in amputees. Chapter 3 presented a recording methodology for this. The imaging technique described was designed to apply a range of imaging parameters that can be used to investigate relationships between the kinematics of the spine and that of the residual limb/prosthesis interface. For this, the passive recumbent QF protocol can be utilised to determine whether any greater asymmetry of inter-vertebral motion in amputees is due to the passive holding elements of the spine. This study also posed the question of what effect dynamic limb length discrepancy from telescoping of the residual limb has on these elements.

## 4.3 Research protocol

Twelve male below knee amputees and 12 healthy male controls of similar age and body mass index were recruited and received passive recumbent coronal QF imaging of their lumbar spines. This was followed immediately by anterior-posterior QF imaging of their limb-socket interfaces during three different forms of simulated gait. Differences between amputee and control spine kinematics and relationships between limb-socket motion and inter-vertebral kinematics in amputees were investigated.

### 4.3.1 Limb-prosthesis interface

For the limb prosthesis interface, a new coronal plane QF imaging protocol was developed to be used during static load in and simulated gait. The intention was to assess the motion of the residual limb within the socket using the participant’s usual prosthesis. Participants applied load (degrees of body weight) during weight transfer from foot to foot in a simulation of normal walking gait. Displacement was measured against radiographic markers of known size. To control for tibial displacement under different loads that were dependent on body weight, the load applied through the participants’ feet were measured using force plates. The protocol design was derived from previous studies discussed in section 2.6 “Methods for assessing socket fit” of the literature review. In particular, the use of weights attached to the prosthetic to simulate the swing phase of gait (see Figure 6 of Section 2.4.3) was inspired by studies such as (Gholizadeh 2012; Gholizadeh et al. 2011).

Unlike Gholizadeh who measured the 'pistoning' between the liner and socket in 6 static loading configurations: full-weight-bearing on the prosthetic limb, double limb support, non-weight-bearing on the prosthetic limb, and three static vertical loading conditions (30 N, 60 N, and 90 N) (Gholizadeh 2012), this current study endeavors to investigate the dynamic motion of the tibia inside the residual limb and socket similar to Tucker et al. (2012).

The Integrated Research Application System (IRAS) used to obtain National Health Service (NHS) Research Ethics Committee (REC) approval requires an in-depth assessment of all aspects of the research, including its justification and implementation. This protocol received favourable approval from the NRES Committee South West – Frenchay, Health Research Authority, NRES reference 13/SW/0248 in November 2013 (Appendix A.IV "National research ethics approval of research protocol letter – gained 15/11/2013"). An amendment to allow for participants to consent to the transfer of patient details from NHS recruitment sites was approved in May 2014 (Appendix A.V "National research ethics approval of amendment letter – gained 08/05/2014")

### 4.3.2 Rationale for inclusion and exclusion criteria

The age range of participants was restricted within this population and was chosen to optimise bone maturity and density (Bogduk 2012) and to be representative of a population with mature amputation (United National Institute for Prosthetics & Orthotics Development 2013). Participant gender was limited to males to control for gender related effects. Male participants were chosen also as it was considered logistically more suitable for study recruitment. In addition, radiosensitive tissues such as gonads can be shielded from radiation more effectively in males (The location of female participant ovaries are impossible to accurately identify for shielding under these circumstances and may be directly in the field of view in spinal imaging protocols unlike their male counterparts). Participants with a BMI over 30 were excluded due to the greater chance of failed tracking of vertebral images due to image degradation as well as higher radiation dose due to the volume of muscle and fat in the image field.

These studies were limited to trans-tibial amputees. Although back pain is more prevalent in trans–femoral amputees (Table 3 of Section 2.2) and it might be assumed that there would be a greater likelihood of mechanical impairments compared to a population with intact limbs. Due to the proximity of trans–femoral amputation to the gonads and the increased thickness of the soft tissue around the femur when compared to the residual tibia which would affect image quality, trans-tibial amputees were chosen for inclusion in this study. The full inclusion/exclusion criteria are as follows;

#### 4.3.2.1 *Inclusion criteria.*

- Male
- Unilateral Trans-tibial amputation
- Aged 25 to 60
- Able to understand written information
- Willing to participate and able to freely give informed consent.
- Mature amputation (>12 months since surgery)

#### 4.3.2.2 *Exclusion criteria.*

- A BMI greater than 30
- Poor understanding of English rendering the participant unable to understand the information given
- Subjects were excluded if they have had spinal surgery, a fracture, a dislocation, or any structural defects of the spine
- Having treatment for osteoporosis
- Recent abdominal or pelvic surgery
- Severe scoliosis
- Any radiation exposure in the past year or exposure in the past 2 years with a dose of greater than 8mSv (defined as CT scan of chest, abdomen or pelvis or Interventional procedures under radiological control i.e. angiography)

- Current involvement as a participant in any other research study which requires ionising radiation, including any other current QF study

## 4.4 Study population and recruitment

A convenience sample of 12 participants per group was thought to be large enough to give a statistical representation of the overall population for this exploratory study (Julious 2005). Therefore, national research ethics service approval was sought for 15 participants, to allow for missing or unusable data (Appendix A.IV, A.V & A.VI).

Recruitment to the study was performed by raising awareness in prosthetist clinics at Dorset Orthopaedic (Ringwood) and The Limb Centre (Royal Bournemouth & Christchurch Hospital) using posters and information leaflets for attendees and visitors with directions to further information available on the website www.aecc.ac.uk/research-at-aecc/imrci/trans-tibial-study, provided on recruitment literature as tiny URL and QR code links. A PowerPoint presentation was given to prosthetics staff and made available to the clinic staff to increase their interest in the study as well as to persuade them to draw it to the attention of potential candidates. Awareness was also promoted by contacting the amputee charity organisations; 'Limb Power' and 'Douglas Bader Foundation'. These agreed to put electronic copies of the poster on their respective web sites and social network pages.

Participants could volunteer by contacting the author directly or by filling in a "Consent to Transfer Details" form and returning it to their prosthetist, who in turn passed it on to the author. All identifying details (name, address, telephone number) were stored on hard copy in a locked filing cabinet.

Interested patients were then contacted by the author and a pre-study questionnaire was completed before recruitment. This allowed age, gender, body-mass index and level of amputation to be determined after which a suitable appointment for those eligible was arranged for them to attend the AECC clinic X-ray department.

Twenty-two participants were identified or contacted the author independently. Seventeen met the study's inclusion/exclusion criteria, and 13 of them agreed to be recruited to the study. One of them failed to attend on 2 separate occasions and data collection was concluded with 12 amputee participants in total.

## 4.5 Procedure

### 4.5.1 Data Collection

On arrival, the author reviewed the information leaflet, answering any questions the participant may have had. Once they were happy to proceed, a written consent form was signed and a copy given to the participant

Amputee participants were then given a short questionnaire which asked about their usage of their prosthesis, secondary medical conditions, back pain history and the locations of any chronic pain (Appendix A.XII). These data were used to identify any unexpected but potentially confounding factors. All participants were then asked to change into radiolucent clothing (an x-ray gown or sportswear) before entering the room where the imaging equipment was assembled and the protocol they were about to undertake was explained to them.

Following image acquisition participants were given information on how to keep up-to-date with developments in the study and were released. Radiation dosage factors imaging factors (kVp/time and Dose Area Product (DAP)) were then recorded (the results of which are summarized in Section 5.2.3 “Radiation dose received”).

### 4.5.2 Equipment

Lumbar spine fluoroscopic data were collected using a Siemens Arcadis Avantic VC10A portable C-arm fluoroscope (CE0123) and horizontal motion platform (Atlas Clinical Ltd declared conformity under MDD93/42/EEC) (see Figure 18 page 67). Limb-prosthesis data collection was achieved using an elevated wooden horizontal platform resting on a cast iron pipework frame and fitted with two force measuring panels as described below in section 4.5.4.1 and Figure 43.

### 4.5.3 Lumbar spine data acquisition

The spine image acquisition protocol was taken directly from the parts of the "*Recumbent protocol*" used in the preliminary investigations leading up to this study (described in section 3.2.2.2.1) in which participants were imaged in the coronal view while supine.

The design of this study intentionally had the participants perform the recumbent lumbar spine data acquisition section of this protocol prior to the residual limb data acquisition. The reasoning for this was based on the findings of section 2.6.3 of the literature review. It was discussed in section 2.6.3 that even short periods of activity (i.e. walking 200m) can cause short term inflammation of the residual limb (Zachariah et al. 2004). However, since it was also reported that 95% of this volume change was found to happen within the first 8 minutes of rest after walking, this protocol determined to standardise the recumbent tasks, which takes approximately 10-15 minutes, prior to the weight-bearing tasks to allow any volume change to stabilise. Changes in shape and both increases and decreases in the volume of the residuum affect the quality of the socket fit over the course of a day (Sanders et al. 2005) and it could possibly alter the results of this study if the volume of the residuum was changing during the residual limb data acquisition.

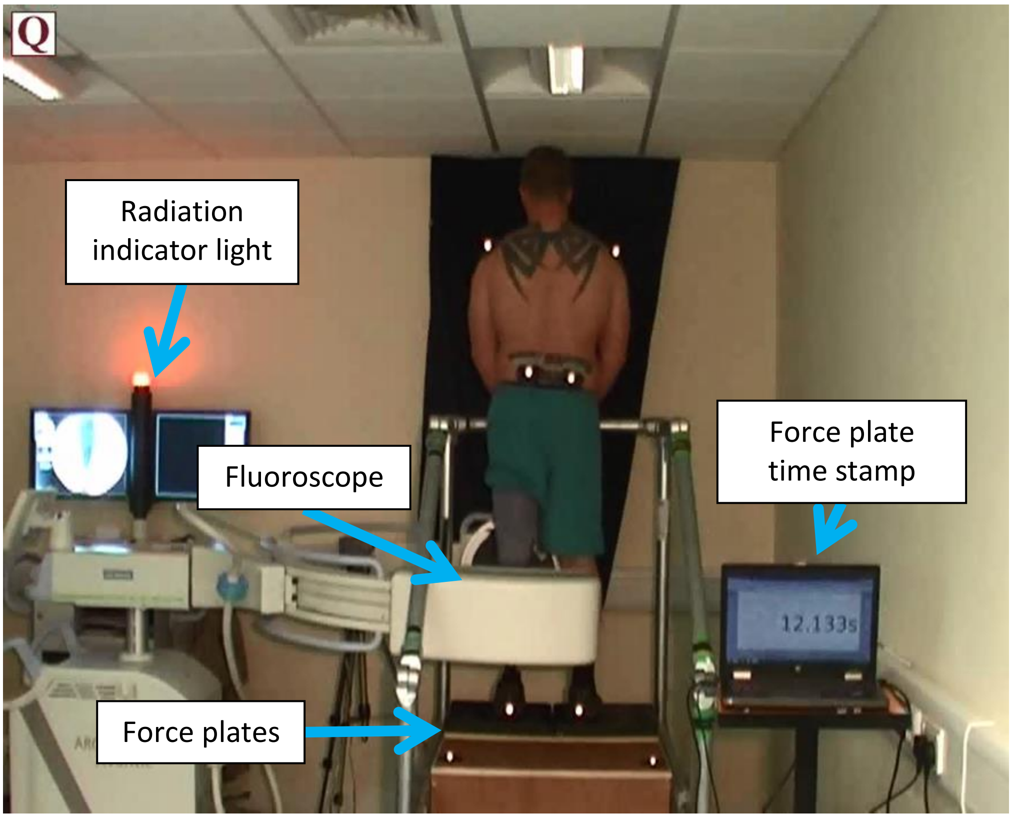



**Figure 43: Depicting the stance of a unilateral trans-tibial amputee volunteer during residual limb imaging procedure.**
**In this image the positions of the force plates and fluoroscope are shown. Also visible is the time stamp from the force plate measurement system (PASCO scientific Capstone application v1.1.4) and 'radiation indicator light' of the fluoroscope. The platform which the participant stands on, and houses the force plates, raises the participants up to the minimal height of the fluoroscope and allows images of the residual limb to be taken in the coronal plane while under the participants own body weight.**

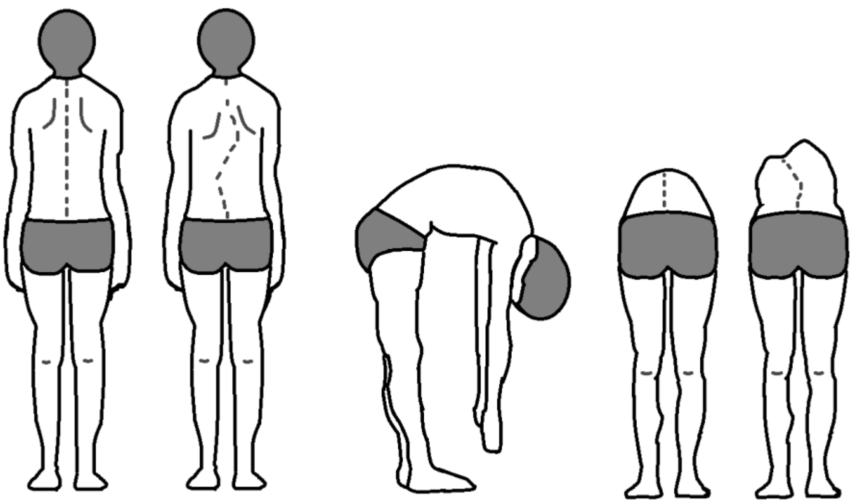


**Figure 44: Adams test.**
**The participants' bend forward from the waist with their hands hanging in front of them as though they were attempting to touch their toes, the examiner stands behind the participant and looks along the spine to determine any axial rotation.**

### 4.5.4 Residual limb data acquisition

Once the amputee lumbar spine data had been acquired, participants were asked to sit up on the motion platform and remain seated for a few moments to ensure that they did not become unsteady when leaving it. Each participant was asked to stand and remove their gown so that additional information could be collected regarding possible limb length discrepancies and evidence of scoliosis. For this, the participants were asked to stand with their weight equally distributed between their each leg and a chiropractor, experienced in palpation and spinal examination, measured the distances from the most superior-lateral palpable point on the greater trochanters of the femurs to the floor using a standard measuring tape (Gurney 2002).

For the assessment for scoliosis, the Adams test was used as it is considered to be a useful, non-invasive clinical test for scoliosis and more sensitive than using a scoliometer (Simpson and Gemmell 2006). Participants were asked to stand with their feet approximately 6 inches apart and bend forward from the waist with their hands hanging in front of them as though they were attempting to touch their toes and until the spine was in the horizontal plane. The examiner stood behind the participant and looked along the spine to determine any axial rotation as evidenced by more prominent muscle on one side of the flexed lumbar spine (a graphic of the Adams test can be seen in Figure 44 above).

Scoliosis, if severe, would also be observed on the initial images taken during lumbar imaging (see 4.5.3). This would exclude the participant from further study. However, this was never observed.

#### 4.5.4.1 *Contemporaneous limb-prosthesis imaging and surface motion recording*

Reflective surface markers were then positioned on the participant's shoulders, pelvis and ankles using non-allergenic tape. (lateral border of the acromion, posterior superior iliac spine and posterior aspect of calcaneum respectively). Additional markers were placed on the base of the equipment to give a horizontal reference for horizontal; as shown in Figure 43. The surface motion recordings were not directly relevent to the study hypothesis and were collected for completeness should the need for surface motion information arise.

The participant was then asked to mount a raised platform with handrails are available (Figure 43).

The platform was built to raise the participant to a level at which images of the limb-prosthesis interface could be acquired by the fluoroscope at its minimum height setting with the participant standing. The design was generated with stability in mind, with handrails available for the participant if needed.

The platform was built to house two multi-directional force plates on which the participant would stand. To ensure that the two plates were calibrated the participant was first asked to stand with both feet on the left hand platform, then on the right hand platform. They were then asked to place one foot on each platform an equal distance apart in a comfortable stance with their body centred over the gap between the two plates as though they were about to start walking forward.

A radio-opaque ruler made from metal beads of known diameter (4.4mm) at 20mm intervals along ridged plastic was placed on the lateral aspect of the socket, so as not to obscure the segments in the images to be tracked (Figure 45 & Figure 46). This was to provide a standard reading of distance in the fluoroscopic images by relating the apparent size of these beads (in pixels) to their known dimensions. The pixel to millimetre ratio in the image was calculated and later used quantify tibial motion within the socket while accounting for magnification effects (Breen et al. 2014)

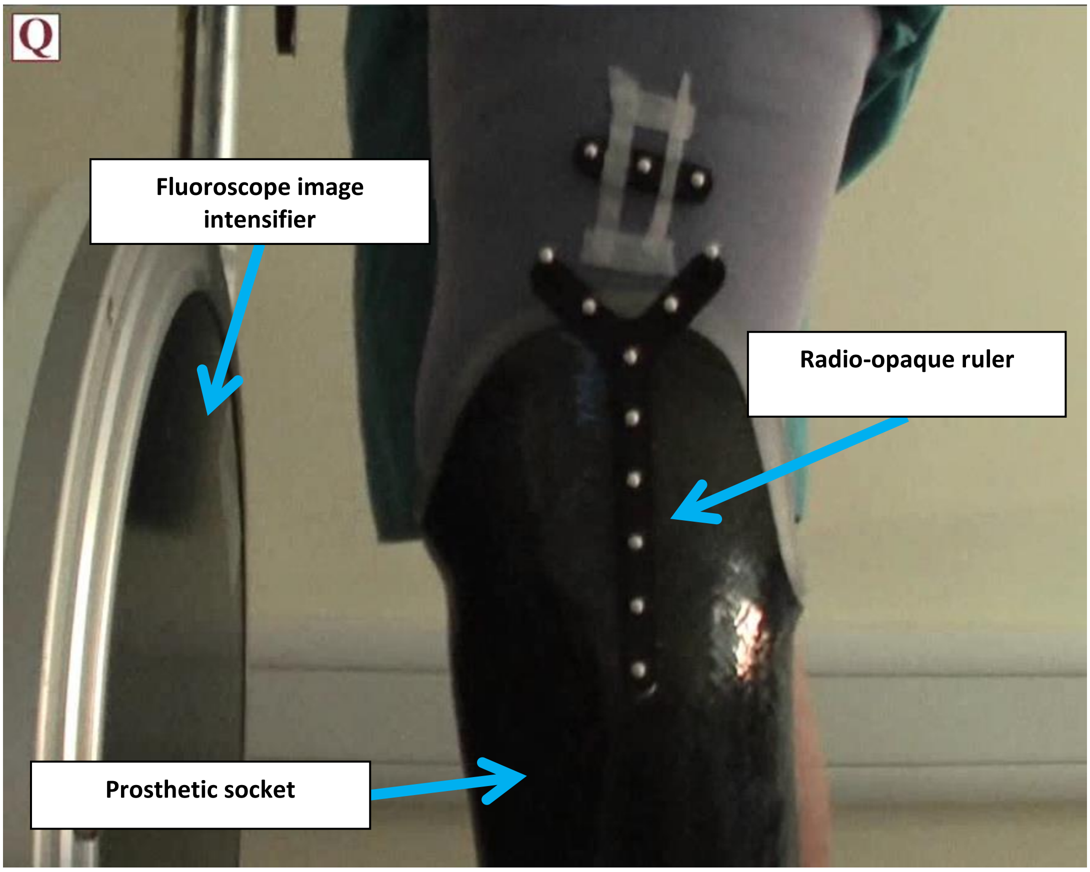



**Figure 45: A radio-opaque ruler positioned on the lateral aspect of the participants prosthetic socket.**
**The radio-opaque ruler was made from metal beads of known diameter (4.4mm) set at 20mm intervals along a ridged plastic board. The ruler was placed on the lateral aspect of the socket, so as not to obscure the segments in the images to be tracked. A fluoroscopic image of acquired at the same time as the image above can be seen in Figure 46.**

### 4.5.4.2 *Fluoroscopic image recording*

Before the image acquisition started participants were asked to rock their weight slightly from foot to foot to ensure their comfort with the motion. The image intensifier was positioned as close as possible to the participant’s amputated limb ensuring that the base of the prosthetic socket will not leave the image field at any time. The data recording was in three parts:

1. Rocking, 2. Rocking under 50N distraction, 3. Static body weight hold.

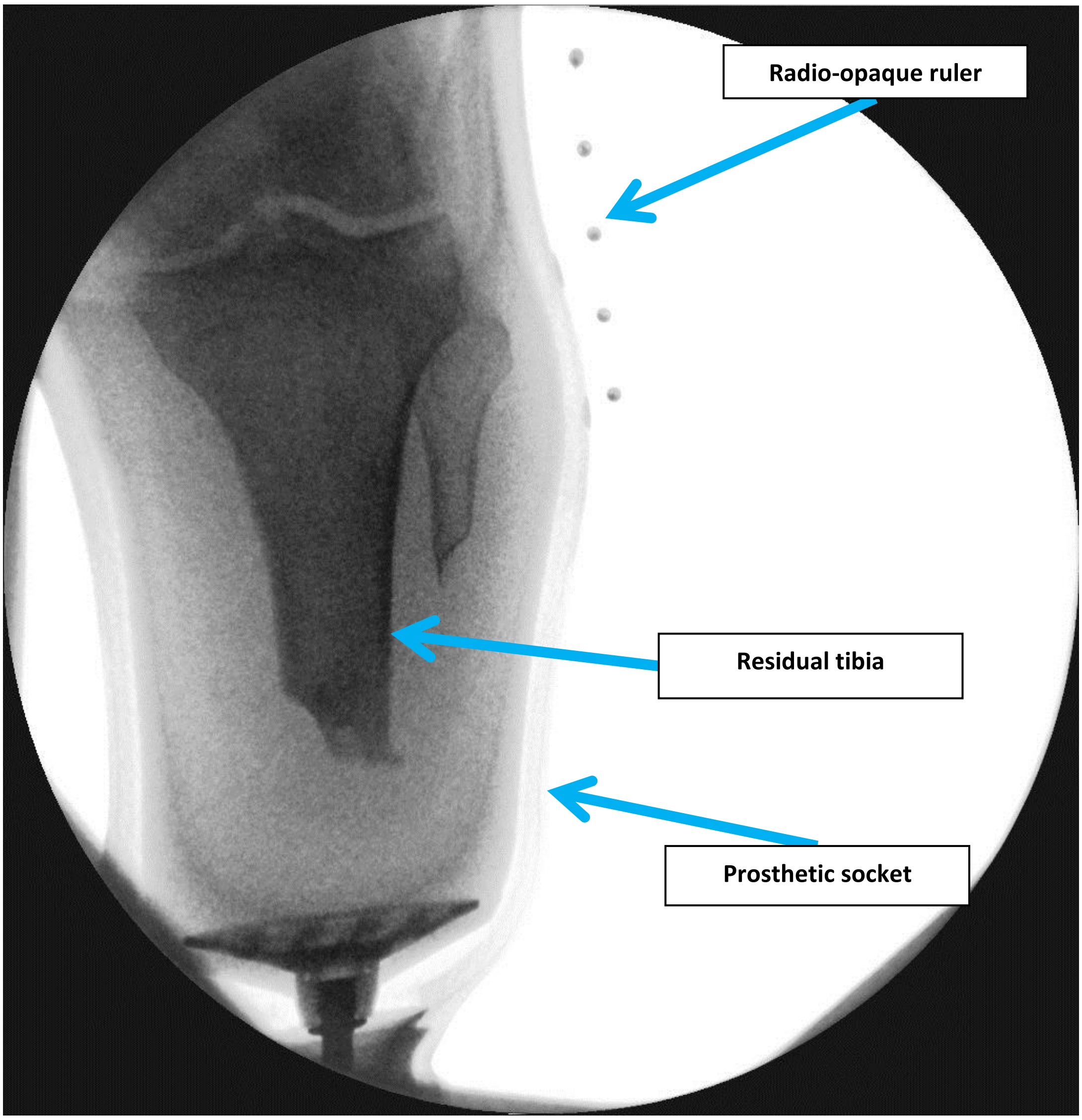



**Figure 46: Fluoroscopic image of tibia in socket with radiopaque ruler.**
**An image of the positioning of the ruler on the lateral aspects of the prosthetic socket can be seen in Figure 45.**

#### 4.5.4.2.1 *Rocking*

After initial tests it was determined that a 2 second gait cycle was required for patient comfort and in order that fluoroscopic image tracking could follow the tibia. A metronome was set to sound at each second and participants were asked to rock from foot to foot in time with it. Once the participant was moving comfortably (often within a few cycles) the fluoroscopic recording was started. Each image sequence recording lasted approximately 10 seconds so that 5 gait cycles could be acquired. The metronome guidance was configured so that each cycle of rocking from foot to foot (weight applied, removed and prepared to be reapplied, weight applied) took approximately 2 seconds for a full cycle as a simulation for a normal gait cycle. Images were acquired in the anterior-posterior (AP) view of the limb/prosthesis interface (Figure 46).

#### 4.5.4.2.2 *Rocking under 50N distraction*

This procedure was then repeated with the addition of a 5kg mass (2 x 2.5kg running weights) attached to the base of the prosthetic limb (around the ankle) to simulate the centrifugal force applied during the normal walking swing phase (Narita et al. 1997). Before starting the metronome the participants were asked if they would like to trial a few steps to become accustomed used to the new weight. All participants were comfortable with the addition.

#### 4.5.4.2.3 *Static body weight hold*

The additional weight was then removed and the participant asked to put their weight on to their healthy limb. After a countdown (assisted by the metronome) the participant slowly moved all of their body weight onto their prosthetic limb and held it there for 10 seconds.

### 4.5.4.3 *Data synchronisation*

During each of these sequences the weight distribution, measured by the force plates, was recorded contemporaneously with high frame-rate video, filmed from a posterior aspect. This was to later be synchronised to the motion acquired from the images of the limb/prosthesis interface. The high frame-rate video was recorded directly to a laptop hard drive using the 'Quintic video analysis software system' (Quintic Consultancy, Coventry, UK http://www.quintic.com/) which can later be reviewed as individual image frames. This synchronisation was guided by the known sample rate of each of the measurement tools (Fluoroscopy 15Hz, weight distribution 1000Hz, video capture 50Hz) and visual time markers which were inherent in the video capture system. In Figure 43, a computer screen displays the number "12.133s". This is the current time stamp of the weight distribution measurement system which could be linked with the video frame number by post processing to create a mutual time frame for synchronisation. This process allowed matching of the start of the fluoroscopy capture, by recording the time when the exposure indicator light turned on.

After these data sets had been saved, the fluoroscope was removed and the participant descended from the platform. The radiographic and reflective markers were removed and the participant replaced their gown. They were then asked to change back into their own clothing after which they could review their own fluoroscopy images if they wished before leaving, which many participants found interesting and novel.

## 4.6 Fluoroscopic data analysis

All fluoroscopic sequences were reviewed by the author and a chiropractor with training in X-ray interpretation for incidental findings of which none reportable were found. Data from the fluoroscopic sequences were separated into individual sequential frames (15 frames per second). The first image of the sequences was extracted and template tracking algorithms manually placed around each individual traceable structure in the field of view.

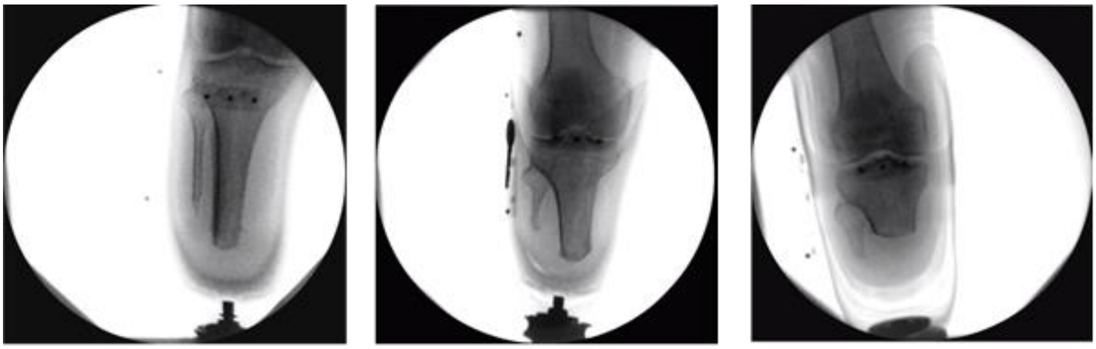


**Figure 47: An example of the variation in residual tibia lengths and shapes within this studies population**

The method by which data were analysed from fluoroscopic images of the lumbar spine is as detailed in Chapter 3.2.2.3. However, the nature of the fluoroscopic images of the limb socket interfaces meant that some alterations to this methodology were required.

It is apparent and not surprising that residual tibia shape, socket shape and suspension style varied greatly across the population (Figure 47). To account for these variations a method of standardising tibial displacement was developed.

Tracking templates were placed around the tibia and metallic base of the prosthetic socket. Four point reference templates were then overlaid on these templates as a simplified representation of the tibia and prosthesis base. For the tibia, these four points were the medial and lateral corners of the tibial plateau and the most medial and lateral aspects at the distal end of the residual tibia (Figure 48 below). Assuming that the socket is a rigid body, the inferior marker can be any structure which is visible throughout the motion sequence. Examples are the distal locking pin or the markers placed on the prosthesis socket. However, the reference template was always placed distally of the tibia.

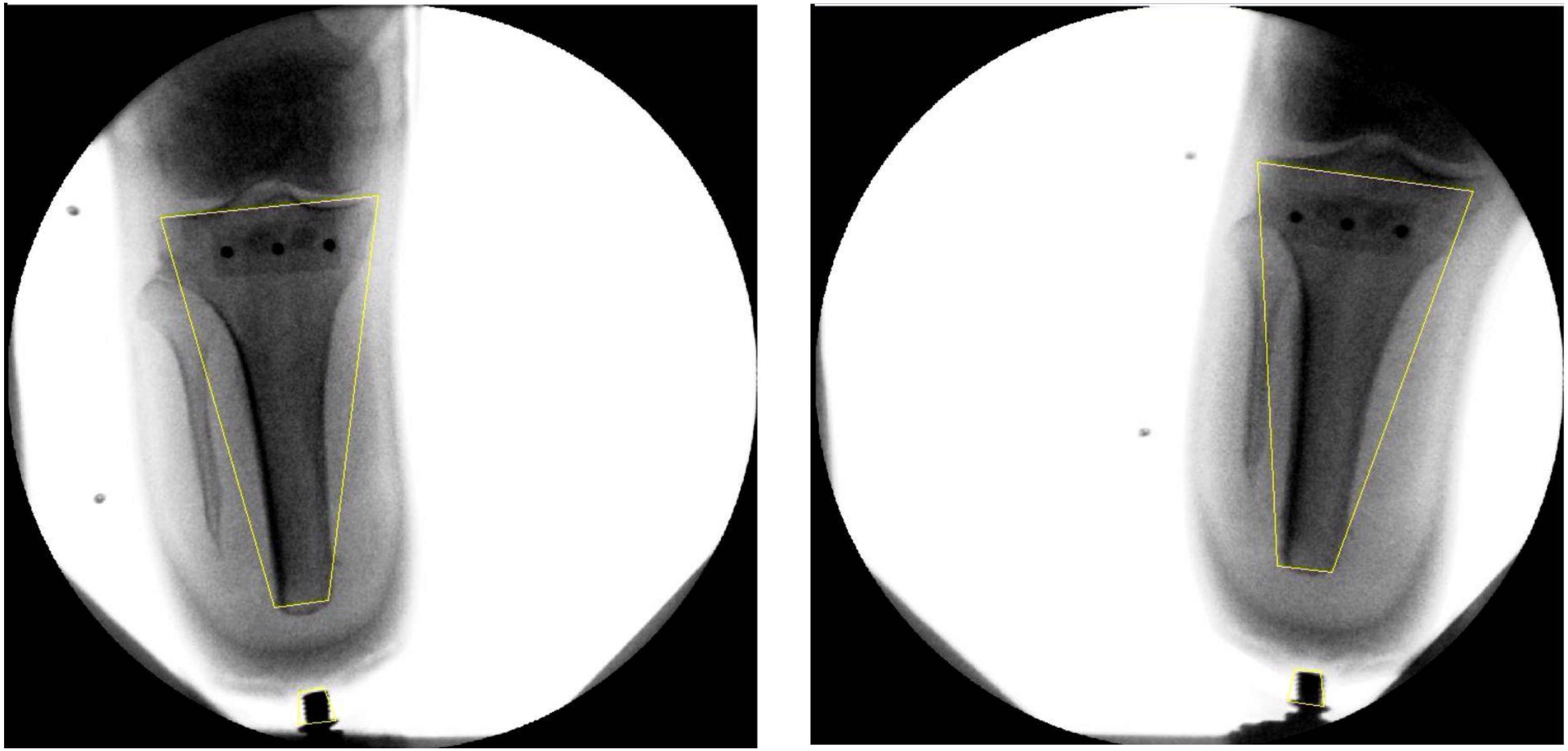


**Figure 48: Examples of automated tracking of tibia and distal locking pin showing the four point reference templates successful tracking of tibial rotation and displacement under compression due to body weight applied (left) and traction due to weight of the prosthesis (right).**

As with the lumbar spine protocol outlined in Section 3.2.2.3, each template was individually placed 5 times and averaged to reduce operator error and increase precision. The templates automatically calculated the x-y co-ordinates and degree of rotation of each structure in subsequent images and produced a graphical output of motion over time (An example of which can be seen in Figure 49).

As was the case in section 3.2.2.3.3 “Data extraction and tracking verification”, template positions were visually checked for quality assurance and any template that did not follow the structure was discarded. If all five templates did not follow the tracked structure, all the tracking data would be discarded and the participant removed from the study.  However, this eventuality never arose.

In addition to using this measurement protocol to track both the spine and prosthetic/limb interface, to account for magnification errors in the x-ray images of the limb prosthesis interface, the methods described in Section 3.3.3 (Preliminary study 2) was used to give pixel to millimeter ratios for accurate measurement of the movement of the residual limb within the socket.

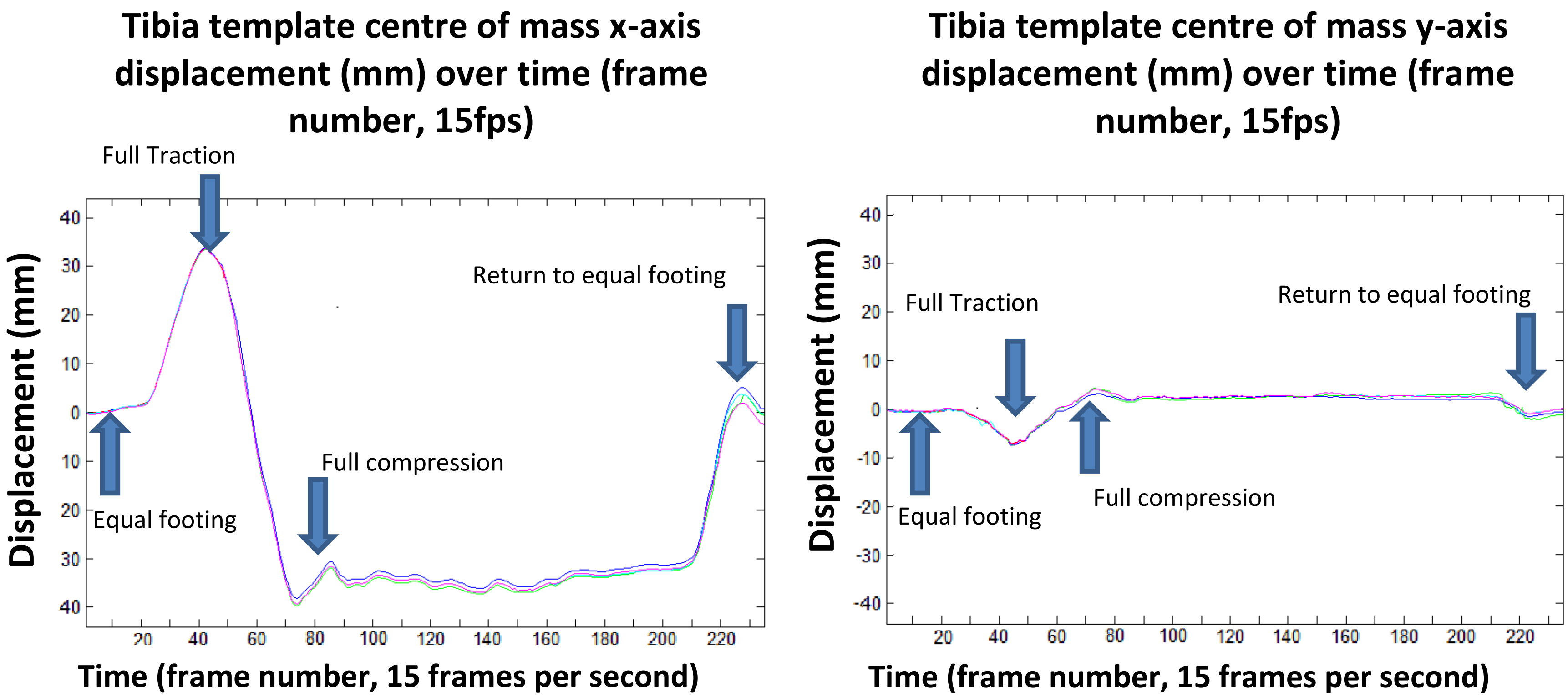



**Figure 49: An example of a graphical representation of tibial motion over time.**
**In these two graphs the change in position (mm) of the centre of mass (CoM) of tibial template is plotted over time (frame number, when images are recorded at 15 frames per second (fps)). The left hand graph shows the templates change in the horizontal direction (image x-axis) and the right hand image shows the templates change in the vertical direction (image y-axis). As in Figure 24 of section 3.2.2.3.3 each line represents an individual tracking test (total of 5).**

### 4.6.1 Radiation dosage

Radiation protection in the UK is based on the linear no threshold (LNT) model which is in turn based on the assumption that damage from ionising radiation (including x-rays) is directly proportional to the dose received. However, the evidence for this assumption is controversial and it is acknowledged that this model may lead to an over-estimation of the risks at low doses (<100mSv) (Kai 2009). Nevertheless, The LNT model was adhered to in this protocol of study by maintaining the ALARA (As Low as Reasonably Achievable) principle. The risks from radiation dose, as well as other potential risks of taking part in the study were fully explained to all participants beforehand. Participants had the right to refuse or withdraw at any stage, without prejudice.

This risks associated with the levels of radiation dosage received during this study are at the lower end of the ICRP category $II_b$ which is defined as "intermediate" (ICRP 2007). All exposures were recorded as per the Ionising Radiation (Medical Exposure) Regulations 2000 (The Stationery Office 2000) and were undertaken by the author who holds a Radiation Protection Supervisor certificate.

This study was designed using the guidance issued by NRES 'Approval for research involving ionising radiation' (NHS 2008). Keeping ionising radiation dose ‘as low as reasonably achievable’ (ALARA) was at the forefront of the design this investigation. All fluoroscopic image recording for these investigations were at 15 frames per second. Each data collection sequence (neutral-left-neutral or neutral-right-neutral) of the spine took approximately 15 seconds and the sequences of the residual limb took 30 seconds in total. The average radiation dose was expected to be 0.429 mSv based on a mean dose across a population of participants who had undergone the spinal imaging protocol plus a study of a radiological phantom (cadaveric leg encased in resin) (Appendix A.III.1 page 216). ICRP states that the risk of fatal cancer in a population receiving 1 mSv is 5 in 100,000 (1 in 20,000) or 0.005%. As such the expected dose 0.429mSv equates to an additional cancer risk of 2.15:100,000 (1:46,600) or 0.00215% in addition to the natural lifetime cancer risk of 50% (Ahmad et al. 2015; Belavy et al. 2013).

The radiation dose is comparable with the annual dose from natural sources in the United Kingdom. The risk is much less than the natural annual cancer risk.

# Chapter 5: Participant characteristics

## 5.1 Chapter overview

In this chapter participant characteristics, including the differences between amputee participants and healthy controls, age and BMI, are presented. Sex of participants has been removed since all participants were male.

Age, height and weight data were collected for both groups using the pre study forms (Appendix A.X page 238). Amputee group-specific data were collected using the questionnaire (Appendix A.XII page 240) and the data collection methods as detailed in Section 4.5.

## 5.2 Results

Twelve male below knee amputees and 12 healthy male controls of similar age and body mass index were recruited and received passive recumbent coronal QF imaging of their lumbar spines. The control population differed slightly from that reported in Chapter 3 (Section 3.2.3 page 81) where the number of participants analysed was 10. From the initial control population 2 participants (ages 65 and 66) were replaced with four additional controls (aged 35, 46, 49 & 58). This was to reduce the average age of the control population in terms of participant numbers and increase the sample population size to match that of the recruited below knee amputee population (Table 14). Tables of full characteristics for the original preliminary study control group, main study control group and the unilateral trans-tibial amputee group can be found in Appendix A.XIII page 242.

**Table 14. Population characteristics**

| | Controls | Amputees | Significance* (p) |
|---|---|---|---|
| **Mean age in years (SD)** | 44 years 5 months (11 years 2 months) | 44 years 7 months (10 years 1 month) | 0.850 |
| **Mean body mass index (SD)** | 24.9 (2.5) | 28.2 (3.4) | 0.015 |

* 2-sided unpaired t-test

Shapiro-Wilk tests demonstrated that there was no evidence of non-normality for the distribution of age or BMI in both amputees and control population groups. There were no significant differences between amputees and controls for age (2-sided unpaired t-test $P>0.1$), however, the amputees in this population had a slightly higher average BMI. This was statistically significant at the 5% level (2-sided unpaired t-test).

Highest BMI recorded in this study was 30.7 and among the amputee group, this equates to 32.6 when adjusted for limb loss, assumed to account for 5.9% body weight discrepancy (Yang et al. 1991). This raises the question; Is BMI a useful criterion for exclusion of participants into these studies? In terms of image quality at least.

### 5.2.2 Amputee specific characteristics

Among amputees, the time since amputation ranged from 2.3 to 29.3 years and their leg length differences ranged from 0.4 to 13 cm (mean 4.3cm, 3.4 SD). Seven amputees had a shorter intact leg and 5 were shorter toward the amputated side. The length of the prosthetic limb can be altered at the patients' discretion for reasons of comfort. Discussed in Sections 2.4.1, 2.4.3 & 2.6, the literature suggests that, in most cases, the prosthesis should be 2cm shorter than the contralateral limb to allow for the loss of ankle control during the forward swing phase. However, in this population limb length discrepancy was likely to be normally distributed (as evidenced by a Shapiro-Wilk test).

**Table 15. Amputee-specific characteristics**

| | |
|---|---|
| **Time since amputation (years)** | Max 29.33, Min 2.25, Median 12.7 (20.9 IQR) |
| **Limb length difference (cm)** | Max 13, Min 0.4, Mean 5 (5.4 SD) |
| **Side of shorter leg (intact/amputated)** | 7 intact, 5 amputated |
| **Scoliosis concave/convex to amputation** | 2 convex, 6 concave, 4 none |
| **Scoliosis concave/convex to shorter limb** | 1 convex, 7 concave, 4 none |

Eight amputees had a notable scoliosis. Two of these were convex to the side of amputation and six concave to it. However, only slight curvatures of the spine were ever observed and these did not impact the imaging of the spine as a significant curvature would. The curvatures observed seemed to be independent of the side of amputation and of the shorter limb when weight was equally distributed. However, with this population size a statistical analysis would be impracticable.

### 5.2.2.1 *Results from amputee questionnaire*

Eight of the twelve participants had an amputation of the right lower leg. Three reported having back pain in the last year and two reported having back pain in the last month. One had an artificial hip joint in the ipsilateral hip and another reported having arthritis in the contralateral hip.

A table of the full results of the amputee group questionnaire can be found in Appendix A.XIII.

#### 5.2.2.2 *Suspension styles*

Suspension styles used by amputees varied widely among this population. It was determined early on in the recruitment for this study that, for the purposes of this study, suspension styles among participants would not be controlled for. The reasoning behind this is that this study was designed to investigate the relationship between residual limb telescoping and spine kinematics. It is assumed that the passive properties of the spine would be altered due to prolonged exposure to asymmetric gait and poor limb control which are by-products of poor socket fit. To assess the movement of the participant's residual limb under a new or different suspension system would be confounding to this study's hypothesis (found in section 1.3.3, page 8).

- 4 Participants used a pin lock gel liner
- 3 used a gel liner in conjunction with an elasticated supracondylar sleeve
- 2 used vacuum suspension with a gel liner
- 1 used an elasticated supracondylar sleeve with a cloth liner (residual limb sock)
- 1 used a leather supracondylar strap system with a cloth liner
- 1 used a gel liner with a prosthetic socket that had a supracondylar supra-patellar brim

These suspension types are discussed in section 2.5.1.3 of the literature review and full details can be found in Table 44 & Table 45 along with the participant's characteristics in Appendix A.XIII.

### 5.2.3 Radiation dose received

Doses received by the control population during passive recumbent QF protocols are reported below in

Table 16. These doses are slightly higher than doses reported from previous studies (mean 0.429mSv appendix A.III.1 vs mean 0.5mSv

Table 16). This is most likely due to previous study's data including females as height and weight have been shown to be a contributing factor to dose during QF procedures (Mellor et al. 2014a).

**Table 16. Mean and upper 3rd quartile absorbed and effective doses among healthy control population (n=12)**

| Total Absorbed Dose $cGy.Cm^2$ | | Total Effective Dose mSv | |
|---|---|---|---|
| Mean | Upper third quartile | Mean | Upper third quartile |
| 225.56 | 272.79 | 0.50 | 0.60 |

Among the amputee population the average dose received was slightly higher than that of the control group (Table 17). Despite the amputee population performing additional tasks in front of a fluoroscope, the maximum radiation dose received by any participant during the residual limb image acquisition protocols alone was 0.0000097mSv. Therefore, the most likely cause for the higher average dose received by a participant is due to the significantly higher average BMI among amputee participants ($p<0.05$, Table 14). As stated above height and weight, from which BMI is calculated, has been shown to correlate strongly, positively and significantly with absorbed dose during QF procedures (Mellor et al. 2014a).

**Table 17. Mean and upper 3rd quartile absorbed and effective doses among amputee population (n=12)**

| Total Absorbed Dose cGy.Cm$^2$ | | Total Effective Dose mSv | |
|---|---|---|---|
| Mean | Upper third quartile | Mean | Upper third quartile |
| 237.95 | 328.36 | 0.52 | 0.72 |

## 5.3 Limitations

It is a failing of this study's design that LLD and scoliosis were not measured among the control population. Therefore no comparison was made with amputees. It was assumed that since these were healthy controls with no history of back pain in the previous year, that such a comparison would not be of interest and only relations of variables within the amputee population were needed. However, without testing for LLD and scoliosis these factors cannot be discounted as possibly confounding when comparing spine kinematic variables. Nonetheless, inspection of the initial fluoroscopic spinal images revealed little or no curvature in any of them.

## 5.4 Conclusion

It was important to ensure that both the amputee and healthy control population groups had similar characteristics to limit the influence of variables that may affect their biomechanics, such as gender, age (Wong et al. 2004) and BMI. These results show that the two groups were similar thus these variables are unlikely to confound subsequent analyses.

In the following chapters further comparisons of these two populations will be drawn in terms of lumbar spine symmetry and comparative lumbar spine stability (Chapters 6 and 7).

# Chapter 6: Spinal symmetry in unilateral below knee amputees and controls

## 6.1 Background

In Chapter 2 the literature suggests that there is a high prevalence of back pain among LLAs and the widely held belief that altered locomotion due to LLA is a major contributor to changes in amputee posture and trunk control is discussed (Sections 2.2 and 2.4). These phenomena are attributed primarily to asymmetry of amputee gait (Section 2.4.3), which is considered to transmit to the lumbar spine through compensatory processes such as “hip-hiking”. Such processes have been thought to put additional mechanical demands on the spine itself (Granata and Marras 1995). What effect this might have on the functional integrity of the spine at inter-vertebral levels and whether or when it may eventually result in any kind of impairment or become a source of back pain is however, not known. However, it is acknowledged that these alterations in body movement create high demands on the spine structure and have been linked to LBP and spinal instability (Section 2.6.2).

From the initial studies described in Chapter 3, the spine kinematics in a normative population were assessed. It was determined that during controlled spinal motion, there is greater inter-subject variability in lumbar inter-vertebral range of motion among the normative population during weight-bearing compared with passive recumbent bending. This is likely to be due, in a good part, to differences among individuals in terms of spinal loading, alignment and muscle contraction during motion. Arising from co-ordination and behaviour these would represent additional ‘noise’ when trying to discriminate on the basis of the effects of amputation.

Previous active weight-bearing studies have also observed asymmetries in the stiffness and range of global motion of amputee spines (Hendershot et al. 2011; Hendershot et al. 2013; Lee and Turner-Smith 2003). Hendershot et al. suggests that trunk muscle activity is increased among unilateral amputees compared to the normative population. This has been attributed to compensatory mechanisms to overcome reduced passive holding elements contributions to joint stiffness (Ahn et al. 2006; Sanchez-Zuriaga et al. 2015). If the asymmetries of spinal motion in amputees are not wholly due to the neuro-muscular control but also to passive (disc & ligament) element stiffness at segmental levels, a weight-bearing protocol that is limited to the measurement of global motion and where the participant controls their own movement would be unable to discriminate between these.

The most reliable descriptor of positional data produced by QF is the rotation of each vertebra expressed as the angle between the two vertebral bodies (Breen et al. 2006), either adjacent vertebra or the two which borders a section of spine (i.e. L2 and S1). Moreover, as shown in Section 3.4, a passive recumbent QF protocol is able to assess the response of inter-vertebral tissues to a minimal bending moment, allowing us to assess their passive holding elements' contributions to joint stiffness as referred to by Hendershot et al. (2013 & 2014). Joint stiffness or laxity of an intersegmental joint is measureable from its initial attainment rate, which was shown to have good correlation with the dynamic Neutral Zone (Section 3.4).

## 6.2 Aim

This chapter was aimed at ascertaining if there are differences in symmetry between the passive spines of a sample population of male unilateral below knee amputees compared to a healthy control population of males of similar age range and BMI in terms of range of motion and inter-vertebral laxity (initial attainment rate). Any differences observed between these two groups would be as a result of differences in the flexibility of the spine passive inter-vertebral restraining elements and not of active trunk behaviors.

## 6.3 Methods

The data analysed in this chapter compared the spinal kinematics of 12 male unilateral trans-tibial amputees (TTAs), collected by the methods described in Chapter 4 (4.3), against that of 12 healthy male controls of similar age and BMI (Table 14 of Chapter 5 (section 5.2) & Table 43 in Appendix A.XIII "Detailed participant characteristics" page 242). The rationale for this sample size is detailed in Chapter 4 (Section 4.4 "Study population and recruitment" page 126) (Julious 2005). Both cohorts underwent the same protocol for passive, recumbent lateral flexion during fluoroscopic imaging. Video fluoroscopic images were enhanced and analysed using the bespoke techniques described in 3.2.2.3.

To assess the symmetry of lumbar motion in these two population groups, a comparison was made of both inter-vertebral range of rotation and laxity between cohorts. Comparisons were also made between the ipsilateral and contralateral sides in amputees (in respect to side of amputation) and left to right in controls. This was assessed at the inter-vertebral level (inter-vertebral range of motion, IV-ROM), as the lumbar spine range as a whole (L2-S1 ROM) and, to account for variances in ROM due to anatomical differences, IV-ROM as a proportion of L2-S1 ROM.

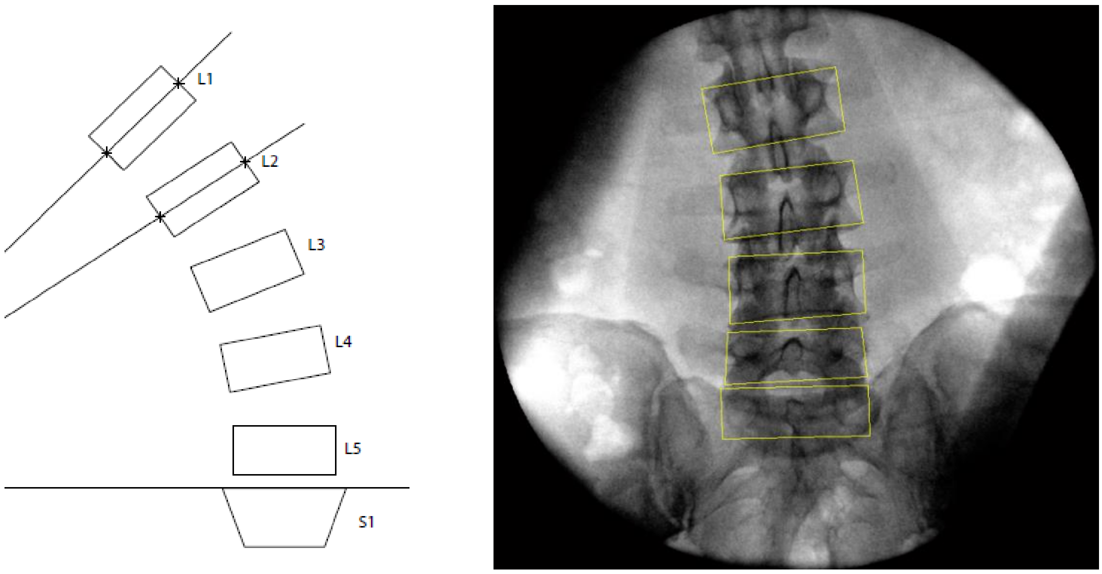



**Figure 50: Measurement of inter-vertebral angle. L1 to L5 angles are measured as the mid line of though the vertebral body. The sacrum (S1) angle is taken as the superior aspect of the sacrum due to lack of repeatability in identifying the inferior aspects**

The laxity (initial attainment rate) of each inter-segmental joint and its overall ROM (furthest left to furthest right bending) were also compared.

It was noted early on that, when comparing outward range of coronal plane rotation of L2-S1, as was done in Chapter 3.2.3.1, the position of the spine was not the same at the start of both sequences. Visual inspection of the motion pattern differences between vertebrae showed that, in most cases, before starting the bending sequences to the left, the angle between L2 and S1 was slightly to the right with the opposite being true for the right bending sequence (an example of which is shown in Figure 51). This is most likely to be due to the warm up procedure.

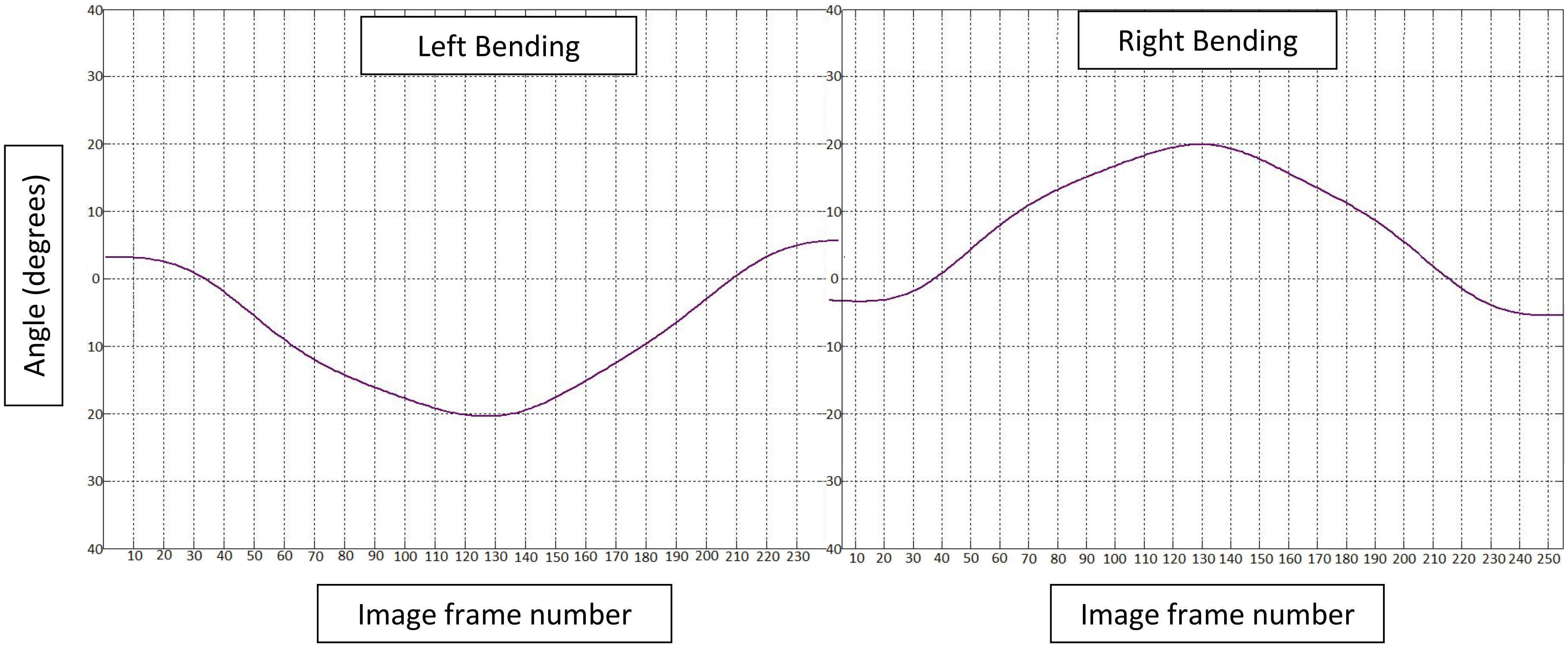



**Figure 51: Motion graph depicting the angle between the second lumbar (L2) and the Sacrum (S1) for left and right bending sequences, with differences in starting positions.**

A warm up procedure was designed to acclimatise the participant to the movement and ascertain their overall comfortable trunk range (as detailed in Sections 3.2.2.2.1 & 4.5.3). Within this procedure the participant was taken though the range of motion in increments, cycling from a neutral position out to 10° and back to neutral, this was repeated for 20°, 30° and 40°.

It was apparent from the difference in start position of the spine at the beginning of each imaging sequence that this procedure stressed the lumbar spine to its maximum range of motion before reaching the goal of 40°. The motion of the participant after the lumbar spine had reached its end range must therefore have been accommodated by other parts of the body. Possible locations for this additional motion include areas which are not within the image field, such as the thoracic spine or axial/transverse rotation which is not detectable with these methods. Moreover, we have assumed that there is some degree of slippage of the participant on the motion platform. It is for this reason that as the platform returns to its original position the participant might not have fully followed its outward path and was pushed slightly beyond the a neutral position during the return path. Thus the start positions may be different at the beginning of each bending sequence (Figure 51) and that the maximum angles between vertebrae are their maximum ROM. In light of this, the results given below are the maximum ROM of each vertebral pair from an assumed neutral position, where each adjacent vertebral pair started parallel to one another (i.e. inter-vertebral angle of 0°).

## 6.4 Results

### 6.4.1 Loss of data

In 5 of the 12 control subjects we were unable to confidently identify the positions of the first lumbar vertebrae (L1) throughout the image sequence, this was due to visual loss of L1 out of image field or soft tissue artefacts (bowel gas) obscuring the vertebra in a large number of images. For this reason the second Lumbar (L2) was used to represent the superior limits of the lumbar spine in all participants.

### 6.4.2 Statistical analysis

Shapiro-Wilk tests were used to detect non-normality in the distribution of data sets. Due to a number of samples used being considered “unlikely to be from a normal distribution” a 2-sided Wilcoxon's signed ranks test was used to compare inter-vertebral ranges and initial attainment rate values under different conditions within population groups and a 2-sided Mann-Whitney U test to compare them under the same conditions between population groups. All tests were performed using StatsDirect statistical Software V2.5.2

### 6.4.3 Asymmetry of initial positioning

The trend of participants to not have a straight spine following warm up and at the beginning of an image sequence was thought not to be a systematic error. The reason for this assumption was that the differences in vertebral position from parallel were not consistent within or across participants. Seven participants were found to have more off centre spinal alignment during right motion warm up, 2 during left motion warm up and 3 being equally stiff on both sides (within 1.5 degrees). This can also be expressed, in terms of amputated side, as 4 Ipsilateral to amputation, 5 contralateral to amputation and 3 with a difference within 1.5 degrees. Moreover, in terms of direction of scoliosis as determined by the Adams test, 4 participants were found to have more off centre spinal in the same direction as curvature of spine, 4 away from the curvature of spine and 4 who did not have any detectable scoliosis. The greatest asymmetry in start position among participants without detectable scoliosis was 1.5 degrees.

### 6.4.4 Range of motion

No statistically significant differences were found when comparing amputee inter-vertebral ranges of motion in bending ipsilateral and contralateral to the amputation (Table 18 & Figure 19). There was however, notable asymmetry at the L4-L5 level within the *control* population when comparing left to right in terms of range of motion ($p<0.01$) (Table 18). This was reinforced when comparing proportional ranges L4-L5 ($p<0.01$) and L3-L4 ($p<0.05$) and (Table 19).

**Table 18. Differences in coronal plane passive ranges of rotation of vertebral pairs from a parallel position. Displayed graphicaly in Figure 59 to Figure 64 of A.XIV "Inter-vertebral symmetry among amputees and a control population"**

| | Amputee | | | | Control | | | |
|---|---|---|---|---|---|---|---|---|
| | Ipsilateral (Median) | Contralateral (Median) | Median diff. | p* | Left (Median) | Right (Median) | Median diff. | p* |
| **L2-L3** | 5.0 | 6.7 | -0.4 | 0.569 | 5.8 | 5.8 | -0.6 | 0.677 |
| **L3-L4** | 5.3 | 5.0 | 0.4 | 0.339 | 5.3 | 6.3 | -1.4 | 0.052 |
| **L4-L5** | 4.8 | 6.6 | -1.2 | 0.233 | 6.2 | 4.5 | 1.9 | 0.003* |
| **L5-S1** | 2.7 | 1.2 | 0.5 | 0.569 | 2.6 | 1.4 | 1.2 | 0.077 |
| | | | | | | | | |
| **L2-S1** | 18.5 | 18.7 | 0.0 | 0.970 | 19.9 | 17.9 | 1.9 | 0.110 |

*2-sided Wilcoxon's signed ranks test

**Table 19. Differences in proportional range of rotation of vertebral pair from parallel position Displayed graphicaly in Figure 63 & Figure 64 Figure 59 of A.XIV.**

| | Amputee | | | | Control | | | |
|---|---|---|---|---|---|---|---|---|
| | Ipsilateral (Median) | Contralateral (Median) | Median diff. | p* | Left (Median) | Right (Median) | Median diff. | p* |
| **L2-L3** | 0.3 | 0.3 | 0.0 | 0.791 | 0.3 | 0.4 | 0.0 | 0.266 |
| **L3-L4** | 0.3 | 0.3 | 0.0 | 0.569 | 0.3 | 0.4 | -0.1 | 0.016* |
| **L4-L5** | 0.3 | 0.3 | -0.1 | 0.151 | 0.3 | 0.3 | 0.1 | 0.009* |
| **L5-S1** | 0.2 | 0.2 | 0.0 | 0.970 | 0.1 | 0.1 | 0.1 | 0.233 |

*2-sided Wilcoxon's signed ranks test

The amputee population's inter-vertebral motion data were also analyzed in terms of bending left and right. This however, did not reveal any statistically significant differences either (Table 20).

**Table 20. Differences in range of rotation (left to right among amputees) of vertebral pair from parallel position**

| | Left (Median) | Right (Median) | Median diff. | p* |
|---|---|---|---|---|
| **L2-L3** | 6.7 | 5.5 | 0.6 | 0.301 |
| **L3-L4** | 6.6 | 4.8 | 0.8 | 0.339 |
| **L4-L5** | 5.9 | 4.8 | 0.0 | 0.970 |
| **L5-S1** | 3.0 | 1.7 | 0.8 | 0.301 |

*2-sided Wilcoxon's signed ranks test

Finally, no differences were found in overall inter-vertebral, proportional or global lateral bending range between cohorts (Table 21 & Table 23 )

**Table 21. Differences in left-right IV-ROM**

| | Amputee (Median) | Control (Median) | Median diff. | p* |
|---|---|---|---|---|
| **L2-L3** | 11.5 | 11.8 | -0.1 | 0.932 |
| **L3-L4** | 10.8 | 11.8 | -0.9 | 0.551 |
| **L4-L5** | 9.6 | 10.9 | -0.4 | 0.755 |
| **L5-S1** | 3.4 | 2.6 | 1.1 | 0.178 |
| | | | | |
| **L2-S1** | 39.0 | 37.0 | 0.5 | 0.843 |

***2-sided Mann-Whitney U test**

It may be thought that a useful measure of asymmetry could be demonstrated as the difference between the left and right rotation sides divided by the average of the two sides. Such an index has been previously used by researchers when measuring gait symmetry among amputees in terms of ground reaction force differences between limbs using the absolute symmetry index (ASI) (Nolan and Lees 2000):

**Equation 8**

$$ASI = \frac{(L - R)}{0.5(L + R)}$$

where L is left motion and R is right motion. For the amputee group, asymmetry was calculated in the same way using:

**Equation 9**

$$ASI = \frac{(I - C)}{0.5(I + C)}$$

where $I$ is the motion ipsilateral to the amputation and $C$ is the motion contralateral to the amputation.

The results displayed in Table 22 below suggest significant differences in terms of symmetry at L3-L4 and L4-L5. However it is notable that it is the control group which has the greater asymmetry at these levels. This asymmetry among the control group was previously demonstrated to be significant in Table 19 when investigating differences in proportional range of rotation.

**Table 22. Comparison of coronal plane absolute symmetry index (ASI) in passive inter-vertebral ranges of rotation from a parallel position**

| | Amputee (Median) Ipsilateral vs Contralateral Asymmetry | Control (Median) Left vs Right Asymmetry | Median difference | p* |
|---|---|---|---|---|
| **L2-L3** | -0.12 | 0.09 | 0.10 | 0.755 |
| **L3-L4** | 0.06 | -0.25 | 0.34 | 0.028* |
| **L4-L5** | -0.12 | 0.39 | -0.51 | 0.008* |
| **L5-S1** | 0.86 | 0.42 | -0.20 | 0.843 |
| | | | | |
| **L2-S1** | -0.02 | 0.12 | -0.10 | 0.410 |

*2-sided Mann-Whitney U test

**Table 23. Differences in left-right IV-ROM as a proportion of L2-S1 ROM**

| | Amputee (Median) | Control (Median) | Median diff. | p* |
|---|---|---|---|---|
| **L2-L3** | 0.344 | 0.355 | -0.005 | 0.887 |
| **L3-L4** | 0.350 | 0.298 | 0.027 | 0.089 |
| **L4-L5** | 0.283 | 0.328 | -0.074 | 0.378 |
| **L5-S1** | -0.069 | -0.116 | -0.016 | 0.178 |

***2-sided Mann-Whitney U test**

However, although the average ranges of motion do not differ greatly between cohorts, the variability of the results is uniformly greater among amputees. This is most prominent at the L3-L4 level and between L2 and S1 where the amputee population is shown to have interquartile ranges >1.5 times that of the control populations (Table 24).

**Table 24. Variability in Overall IV-ROM**

| | Amputee (Median) | Interquartile Range | Control (Median) | Interquartile Range |
|---|---|---|---|---|
| **L2-L3** | 11.5 | 5.11 | 11.8 | 4.01 |
| **L3-L4** | 10.8 | 6.193 | 11.8 | 4.03 |
| **L4-L5** | 9.6 | 3.71 | 10.9 | 2.97 |
| **L5-S1** | 3.4 | 2.85 | 2.6 | 2.75 |
| | | | | |
| **L2-S1** | 39.0 | 12.62 | 37.0 | 7.63 |

### 6.4.5 Laxity

As with IV-ROM there were no significant differences between left and right or ipsilateral and contralateral attainment rates when analysed separately (Table 25). This was also true when pooling left and right data with the exception of L5-S1 (Table 26). When pooling data across bending directions it becomes obvious that control attainment rates were higher than those of amputees with the exception of L5-S1 which was significantly less at the 1% level (Table 26 & Figure 52). The variability of this data when pooled, demonstrates that both groups have similar variability, except at L3-4 where the interquartile range of the amputees was twice that of the control group (Table 27).

These differences (average 0.03) are 3% of the attainment rate scale (0-1), suggesting that amputees may have greater restraint and damping in the mid-lumbar spine and significantly less restraint at L5-S1 while side-bending, even though this does not affect the inter-vertebral ranges themselves.

**Table 25. Symmetry of attainment rate at each level per direction of bending**

| | Amputee | | | | Control | | | |
|---|---|---|---|---|---|---|---|---|
| | Ipsilateral (Median) | Contralateral (Median) | Median diff. | p* | Left (Median) | Right (Median) | Median diff. | p* |
| **L2-L3** | 0.190 | 0.184 | 0.008 | 0.519 | 0.196 | 0.211 | 0.010 | 0.380 |
| **L3-L4** | 0.245 | 0.221 | -0.001 | 0.970 | 0.275 | 0.244 | 0.012 | 0.470 |
| **L4-L5** | 0.216 | 0.212 | 0.005 | 0.677 | 0.235 | 0.233 | 0.009 | 0.470 |
| **L5-S1** | 0.060 | 0.056 | 0.007 | 0.339 | 0.033 | 0.019 | 0.009 | 0.677 |

***2-sided Wilcoxon's signed ranks test**

**Table 26. A comparison of attainment rates across population irrespective of direction of motion**

| | Amputee (Median) | Control (Median) | Median diff. | p* |
|---|---|---|---|---|
| **L2-L3** | 0.181 | 0.205 | -0.016 | 0.328 |
| **L3-L4** | 0.223 | 0.264 | -0.045 | 0.067 |
| **L4-L5** | 0.221 | 0.233 | -0.011 | 0.529 |
| **L5-S1** | 0.064 | 0.031 | 0.039 | 0.010 |

*2-sided Mann-Whitney U test

**Table 27. Variability in pooled attainment rate per level**

| | Amputee (Median) | Interquartile Range | Control (Median) | Interquartile Range |
|---|---|---|---|---|
| **L2-L3** | 0.181 | 0.074 | 0.205 | 0.079 |
| **L3-L4** | 0.223 | 0.115 | 0.264 | 0.058 |
| **L4-L5** | 0.221 | 0.089 | 0.233 | 0.081 |
| **L5-S1** | 0.064 | 0.067 | 0.031 | 0.048 |

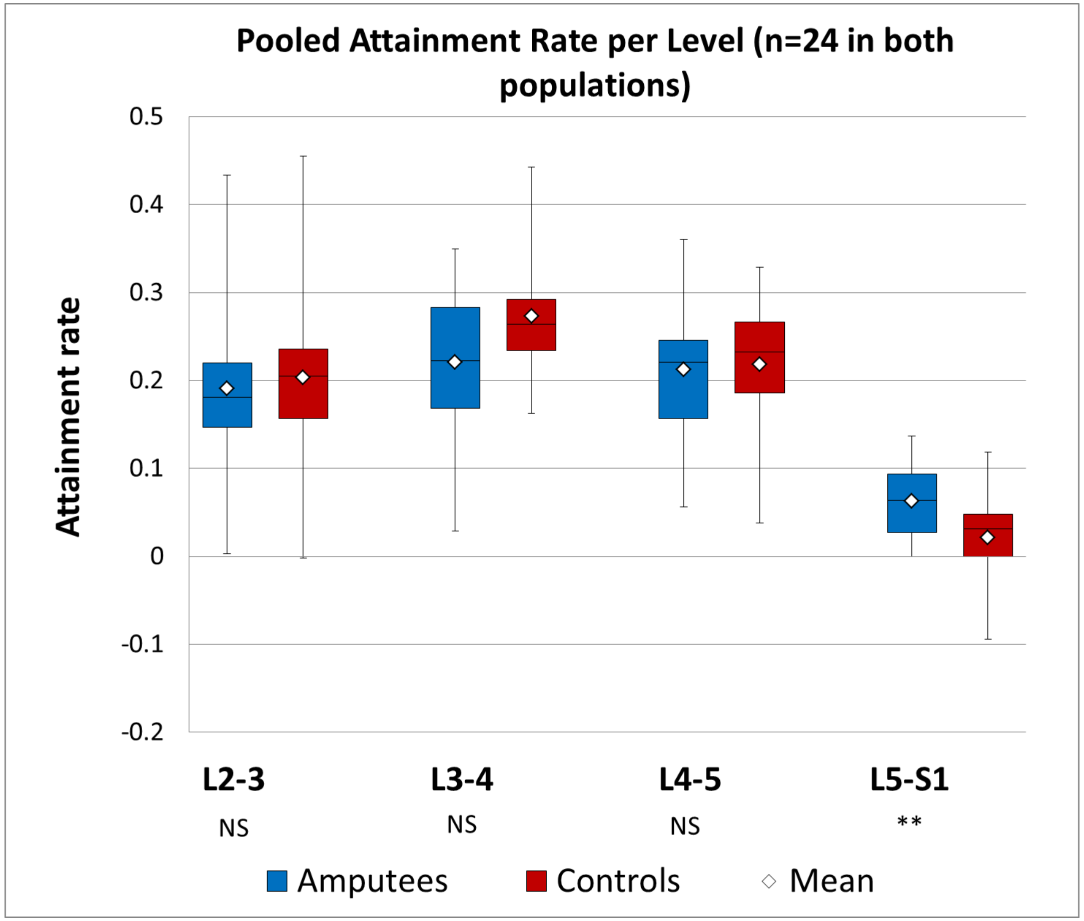



**Figure 52: Box plot comparison of the pooled attainment rates per level & participant between amputee and control populations**

NS=p>0.05, **=p<0.01, 2-sided Mann-Whitney U tests found a significant difference attainment rates at L5-S1 at the 1% level

## 6.5 Discussion

While the small sample size of this population does limit the power to detect significant differences in range of motion in this studies results, the sample size is comparable to previous active motion studies conducted by Hendershot (2013), Lee (2003) and Rueda et al. (2013) who included 4 to 20 trans-tibial amputees and found global spine asymmetries in terms of stiffness and range of motion during weight-bearing tasks (Hendershot et al. 2011; Hendershot et al. 2013; Lee and Turner-Smith 2003; Rueda et al. 2013).

This study found no significant asymmetry among the amputee population and no significant difference in range of motion between the amputee and control populations. Which directly contradicts Hendershots findings who found a lower trunk stiffness in a neutral weight-bearing posture among participants with LLA (Hendershot et al. 2013).

The significant difference between control and amputee initial attainment rates at L5-S1 when pooling data across bending directions deserves further investigation. It has been suggested that unilateral trans-femoral amputees use a more active medio-lateral trunk movement strategy during ambulation than uninjured controls, generating significantly larger positive phases of medio-lateral joint power at L5-S1 ($p<0.001$) in the coronal plane (Hendershot and Wolf 2015). While no studies could be found which investigate this among unilateral trans-tibial amputee populations, Hendershot's study in conjunction with the findings of this Chapter suggest that a similar process may be taking place, causing long term changes to the passive systems of the spine.

In a personal communication, Hendershot queries whether the level of amputation would have had an effect on the passive contributions to motion resistance, since half of his 2013 study's population (4 of eight) were unilateral trans-femoral amputees compared to the 12 unilateral trans-tibial amputees in this study. Moreover, Hendershot acknowledges that some of his earlier work assessing "passive" properties of the spine while weight-bearing were likely to have been confounded, to some extent, by low levels of muscle activity (even during 'quiet standing') and the protocol as contained in this current study is likely to isolate these "passive" properties better.

## 6.6 Conclusion

The hypothesis of this study that there would be differences in symmetry between the passive spines of amputees compared to a healthy control population fails. Therefore, we must conclude that differences between subjects with below knee amputations and controls' groups lumbar spine range of motion is likely to be determined by factors relating to motor control and co-ordination which are not applicable during passive recumbent motion protocols. However, there were nonsignificant trends toward greater variability of IV-ROM and attainment rates in amputees at the mid-lumbar spine (L3-4) as well as a significantly higher attainment rate at the L5-S1 level when data were pooled between directions ($p<0.01$). This deserves investigation as it may have to do with amputation and the active limb length discrepancies caused by telescoping of the residual limb.

# Chapter 7: Interactions between inter-vertebral levels and directions among male unilateral below knee amputees & a comparable control population

## 7.1 Background:

In Chapter 6, no significant asymmetry was found among a trans-tibial amputee population and no significant difference in range of motion between the amputee and control populations was detectible. This suggests that during passive motion protocols, spinal symmetry is unchanged by amputation which is contrary to Hendershots et al's. findings in amputees under weight-bearing conditions (Hendershot et al. 2013) . However, in this study, there were nonsignificant trends toward greater variability of IV-ROM and initial attainment rates in amputees in the mid-lumbar spine (L3-4) as well as a significantly higher initial attainment rate at the L5-S1 level when data were pooled between directions ($p<0.01$).

Maintaining spinal stability requires efficient and synergistic responses from passive structures at the segmental level as well as muscle contraction during active motion. This chapter investigates the interactions between the ranges of side-bending motion and attainment rates across and between the levels of the lumbar spine. If inter-vertebral motion involves no compensation between levels, then all levels would be independent of each other and no correlations would be found between them. However, if motion is symmetrical, left and right ranges would be associated due to these compensations and interdependence.

## 7.2 Aim

Chapter 6 (6.4.4) suggests that there may be more interactions between and within levels to compensate for the greater gait asymmetry brought about by telescoping of the residual limb within the socket. It was therefore the aim of this study to investigate the degree of interactions in terms of inter-vertebral motion range and initial attainment rates within and between levels in male unilateral below knee amputees and investigate how this compares to a similar control population.

## 7.3 Methods

As noted in Section 6.4.2 of Chapter 6 these data could not all be considered to be normally distributed. To assess the strength of correlations between levels a Spearmans Rho was used as a nonparametric measure of statistical dependence between each pair of variables using SPSS (IBM Corp. Released 2012. IBM SPSS Statistics for windows Version 21.0 Armonk, NY: IBM Corp.). Correlations were calculated within and between inter-vertebral levels and bending directions, for inter-vertebral range and attainment rate, left and right among controls and Ipsilateral and contralateral to amputation among amputees. Fisher's exact tests were then used to test if the proportions of levels/directions that correlated significantly, or trended towards significance, were significantly different. Statistically trending towards significance was based on $0.05<p<0.01$ and for the purposes of this study, all correlations of significance <0.10 were also included. An arbitrary significance of cut off <0.10 was chosen in order to have a consistent criterion to evaluate correlated variables.

The Fisher's exact test has been considered valid for sample sizes such as those given here and more accurate than the chi-square test or G–test of independence when the expected numbers are small (Bland 1996) page 231).

## 7.4 Results

### 7.4.1 Inter-vertebral Range of Motion from start of imaging sequence

Among the control group a number of strong and significant (p<0.05) positive correlations were found between the same inter-vertebral level ROM in the opposing bending direction (range 0.699 to 0.743) (with the exception of L3-L4 for which no statistically significant correlation (p=0.183) was found). In addition to this, a moderately strong negative correlation was found between two different levels, namely L2-L3 in left bending and L5-S1 in right bending and between L2-L3 in right bending and L3-L4 in right bending (this data can be seen in full in Table 46 & Table 47 of Appendix A.XV "IV-ROM from start of motion median ranges” page 252).

Strong and significant (p<0.05) positive correlations were also found among the amputee group at each level in the opposing bending direction, *including* L3-L4 which correlated very strongly (Rho = .902) and highly significantly (2-tailed significance p>0.001). Five further levels were found to correlate between levels and directions, 4 negatively and 1 (L4-L5 ipsilateral to L3-L4 contralateral) positively. These data can be seen in full in Table 48 to Table 50 of Appendix A.XVI "Correlations of IV-ROM from start of motion, both within and between levels and within and between bending directions” page 253 to 255. However, although a higher proportion of amputees had between level inter direction correlations (5 vs 2), a Fisher exact test revealed that this was not significant (two sided mid-P = 0.2565).

### 7.4.2 Attainment rate

Among the control population, strong positive correlations were consistently found for each inter-vertebral level in its opposite bending direction as expected (Rho ranging from 0.638 to 0.888, p<0.05). Furthermore, L2-L3 correlated substantially negatively (Range -0.552 to -0.667) with L5-S1 both within and across bending directions. These correlations were significant at the 5% level with the exception of between L2-L3 left and L5-S1 right bending which trended towards but did not quite reach significance (p=0.063). While correlations were apparent between other levels, these were not statistically significant at the 10% level (Table 51 of Appendix A.XVII page 256) and two correlations between levels were counted for controls.

Among the below knee amputee population, appreciably stronger positive correlations were consistently found for each inter-vertebral level in its opposite bending direction (Range 0.778 to 0.962). Moreover, 6 levels (not including L2-L3 to L5-S1) correlated moderately to strongly negatively (-0.545 to -0.811) and a further 5 correlated positively with different levels (0.510 to 0.748). Of these 11 levels, 6 were significant at the 5% level and 5 at the 10% level (Table 52 of Appendix A.XVII 256). A Fisher's exact test revealed that a significantly higher proportion of amputees had correlations in attainment rate between levels than controls (2-sided $p < 0.04$) (Table 53 of Appendix A.XVII 258).

## 7.5 Discussion

There was greater evidence of interdependence between levels and directions in terms of attainment rate in amputees than controls. However, this was only a trend in terms of IV-ROM. This is taken as evidence of changes in restraint and damping of passive inter-vertebral holding elements, supporting Hendershot’s (2013 & 2014) contention that there are more asymmetries of spinal motion in amputees (Hendershot et al. 2013; Hendershot and Nussbaum 2014). This seems to be more pronounced near the neutral position, as evidenced by its effects on attainment rate, suggesting that varying robustness of inter-vertebral restraint by the passive structure may be a feature in the lumbar spines of mature below knee amputees. This may be related to the degree of telescoping of the residual limb within the socket (discussed in Chapter 8).

# Chapter 8: Limb telescoping (ranges) static vs dynamic LLD

## 8.1 Background

Limiting the degree to which the residual limb is able to move out of the prosthetic socket during ambulation is the primary objective of a retention method, examples of which are discussed in Section 2.5.1.3 of the literature review. This operates in conjunction with a complimentary socket design (Section 2.5.1.2) that has the objective of distributing body weight when the prosthesis is loaded to the residuum, limiting the amount of distal movement.

Many studies have attempted to determine the vertical displacement of the residual limb in the prosthetic socket, coining the term ‘pistoning’ to describe this motion (Gholizadeh 2012; Gholizadeh et al. 2011). The majority of the studies discovered in the course of this research have utilised measurements external to the socket, with a few measuring soft tissue movement within the socket, while a few studies have measured the movement of the residual bones within the soft tissue and socket (Table 6 of Chapter 2.6 page 42).

As discussed in Chapter 1 and Section 2.6.2, the term ‘pistoning’ is used to describe movement of the whole residuum in and out of the socket, while ‘telescoping’ will be used to describe the manner in which the bones themselves move in comparison to the socket. The term ‘pistoning’ evokes an image of the distraction of the limb from the socket, when in fact, due to popularity of pin lock and suction suspension systems, an elongation (like that of a telescope) of the limb is taking place.

While there is limited information regarding the assessment of telescoping using fluoroscopic video, previous studies have demonstrated the reliability and accuracy of these techniques to be high. With repeatability measures of less than 1mm both within and between observers using fluoroscopy (Board et al. 2001) and being demonstrated to be suitable for use with measures of force applied to the prosthesis (both traction and compression) (Tucker et al. 2008), prospects for using this method for the  measurement of telescoping are good.

## 8.2 Aim

The aim of this study was to explore the measurement of telescoping of the residual limb within the prosthetic socket using QF. A protocol for image acquisition was devised, which is detailed in Section 4.5.4. The protocol used allows both visualisation and measurement of the changes in leg length of an amputee at different phases of loading as well as changes in alignment of the tibia.

## 8.3 Methods

### 8.3.1 Visualisation

The use of video fluoroscopy of residual limb movement yields two valuable outputs, the subjective and the objective. Firstly, the visualisation of these sequences reveals the variability in how the residual limb behaves during motion. In some participant sequences it became apparent that in conjunction with a small amount of telescoping, the alignment between the tibia and the socket altered as weight was applied and removed. The tibia and fibula moved distally, parallel to the socket wall, until it reached a point where it was forced by the shape of the socket to adduct, translating and rotating in the coronal plane (Bowker et al. 1992).

There may also be gross movements as demonstrated in Figure 53, where the amount of telescoping is so large that it is apparent that the socket suspension system is failing and the whole residuum is indeed ‘pistoning’.

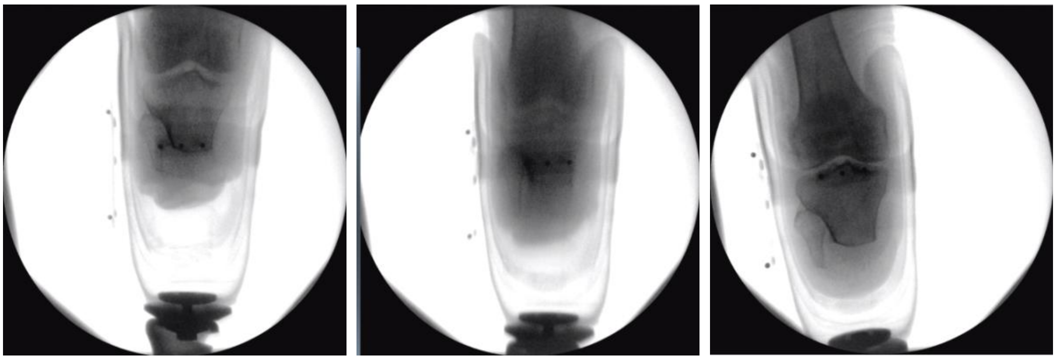


**Figure 53: Example of gross telescoping of the residual limb as weight is applied and removed. This figure shows examples of full traction, transition and full weight-bearing (left to right accordingly)**

### 8.3.2 Development of the quantification method

The methods by which the residual tibia and prosthetic socket were tracked was derived from those techniques used to track the vertebrae of the lumbar spine detailed in sections 3.2.2.3 to 3.2.2.4 of this thesis. The fluoroscopic image sequences of the residual limb in motion were enhanced (3.2.2.3.1), the initial positions of the residual tibia and base of the prosthesis were registered using a 'tracking template' to outline the object of interest and a 'reference template' to create a simplified model of these objects shape (3.2.2.3.2). Depiction of the average 'reference templates' used can be seen in Figure 54. The positions of each of the 'reference templates' in each of the following images after automatic tracking were verified using the same techniques as detailed in section 3.2.2.3.3.

The benefit of this methodology is its ability to quantify the telescoping of the residual limb within the socket and these methods were generated to provide standardisation of the measurements. This depends on the distribution of residual tibia shapes, socket shapes, suspension types and alignment of the residual tibia to the prosthesis shaft across the sample population.

However, there were some complications within this quantification process. The software used was developed in house and while routinely used to track inter-vertebral motion was applied here to measure the motion of the tibia. While identification of the tibial outline and anatomical landmarks were found to be satisfactory, tracking of the tibia often failed as it moved though the image field at speed (i.e. shifting weight). An example of this can be seen above in Figure 53.

In the full loading and full traction positions, where the limb is momentarily motionless, the tibia was readily identifiable. However, between these two positions, when the tibia is moving at speed, motion blur reduces the likelihood of successful image tracking. To account for these difficulties, manual or discrete identification of tibia positions were necessary at extremes of motion. To achieve this, the operator manually replaced the original templates in a corrected position before continuing automated tracking. This allowed the relative sizes and shapes of the reference templates to be maintained and to give consistent results.

Visual inspection of the templates overlaid on the fluoroscopy images were used for quality assurance of tracking as described in Sections 4.6. Additional quality assurance procedures included inspection for image distortion, magnification and out of plane rotation of the prosthesis. Since the reference template was of fixed size, if the shape of the tracked objects changed, the template would no longer fit. Image distortions such as pin cushion effect were not observed, since this is automatically corrected by the image interface of the Siemens Arcadis Avantic fluoroscope used. Magnification errors did not seem to arise, probably because the protocol ensured that motion was in the same plane as the imaging.

An example of out of plane rotation can be seen in the right hand image of Figure 47(of section 4.6 on page 135), where the proximal-medial corner of the tibia template does not quite meet the tibial plateau. This is the most striking example of out of plane rotation in the population. However, the error was thought to be negligible to the findings since it did not affect the tracking or the distances measured in the (proximo-distal) direction of interest. Tucker et al. (2008), using a similar video fluoroscopy protocol, found their inter-rater reliability to have a mean ICC of 0.99 with 95% confidence intervals (Low-High) between 0.98-0.99.

#### 8.3.2.1 *Compensating for coronal alignment change*

Although the literature does not elaborate on tibial angulation in the coronal plane, when reporting limb prosthesis kinematics derived from a number of radiological methods (discussed in Section 2.6 pages 38 to 50 of this thesis) in these studies, it became apparent that this may be an important factor in determining the range of telescoping. Furthermore, while not explicitly defined, previously conducted studies using sagittal or oblique imaging views have required adaptations to overcome the angular alignment change between the prosthesis and tibia as the tibia as it descends into the socket and soft tissue (Bocobo et al. 1998; Grevsten and Eriksson 1974; Narita et al. 1997; Tucker et al. 2012). In the course of this investigation it became apparent that such a method was needed and that it must be applicable across a range of tibia shapes and socket/suspension style combinations.

As can be seen Figure 46 in section 4.6.1 of this thesis (page 133), as well as tibia shape differences, the angle of the tibia with respect to the base of the socket was also variable among amputees in these studies. Furthermore, as the participant added or removed weight from the socket the angular alignment could change as suspected from the literature review of Section 2.6.1 of page 38 of this thesis.

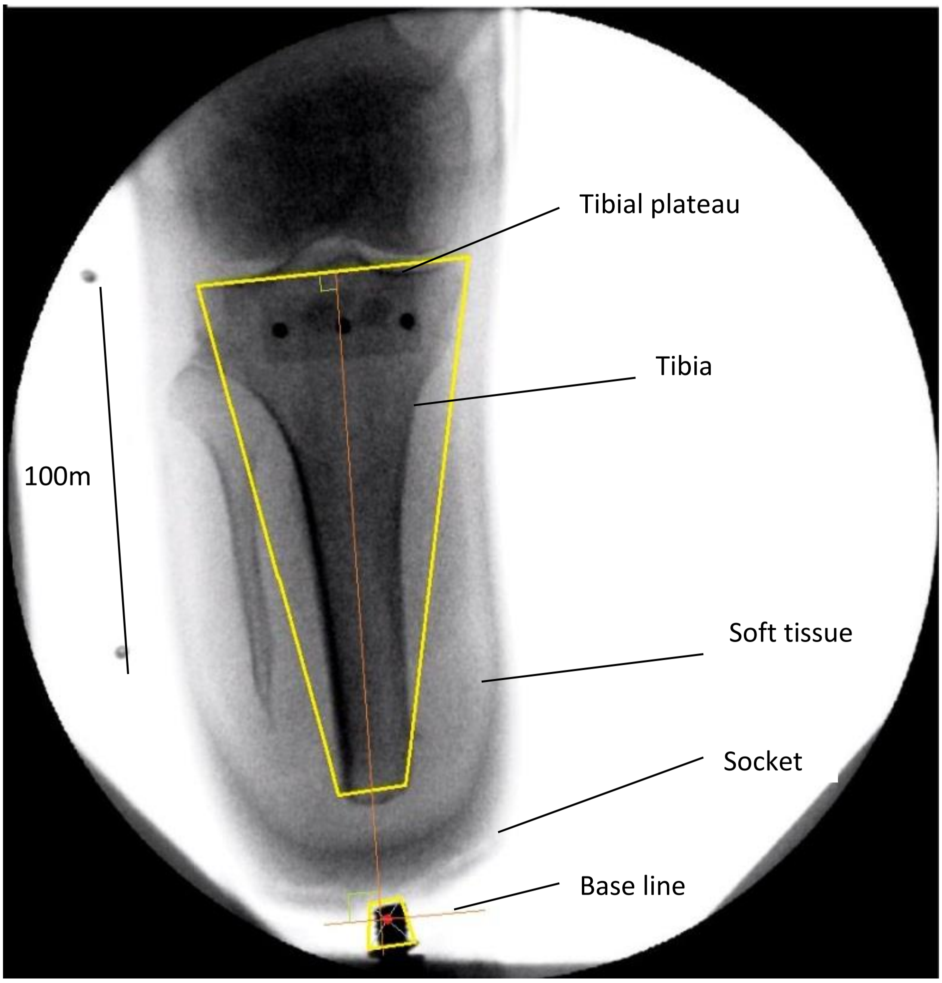



**Figure 54: Depiction of proximo-distal line through tibia, defined in the coronal plane as passing through the centre of the tibia perpendicular to the tibial plateau. A 100mm scale was included in all images for standardization**

To standardise this motion and in an attempt to account for coronal plane rotation variations in the alignment of the residual limb and socket, a method for measuring the proximo-distal motion of the tibia was derived from similar radiographic techniques which imaged the residual limb in the sagittal plane (Grevsten and Erikson 1975; Narita et al. 1997). As depicted in Figure 54, the proximo-distal direction was defined in the coronal plane as passing through the centre of the tibia, represented by a line running from the centre of the tibial plateau, perpendicular to it and extended to the bottom of the prosthetic socket. This was used to compensate for asymmetries at the distal end of the tibia due to the surgical techniques used or to post-surgical bone growth. To account for angular changes, the socket base was identified as a line, perpendicular to the proximo-distal direction and passing through the centre of the prosthesis base marker. Proximo-distal telescoping was defined as the change in length of the proximo-distal line, from tibial plateau to the socket base line, as shown in Figure 54.

### 8.3.3 Synchronisation with force data

The distribution of weight between the prosthetic foot and the contralateral foot were recorded using two 2-axis force platforms (PS-2142, PASCO scientific) using the methods described in Figure 43 of Section 4.5.4.1 (page 129) of this thesis. Data from these force platforms were collected through a PASCO 'SPARKlink' sensor interface (PS-2009A) and passed on to a laptop computer via USB to be sampled at 1000Hz using the PASCO scientific Capstone application (v1.1.4). As well as recording force distribution, the Capstone application is a versatile GUI which can be altered to suit the needs of the user. In this study and as portrayed in Figure 43 Section 4.5.4.1, this GUI was used to display the time stamp of data collection so that it could be synchronised with fluoroscopic data by the methods described in Section 4.5.4.1.

The 'normal' reaction forces (perpendicular to horizontal) were normalised as the percentage of the participant's body weight. Traction forces were calculated from the differences between the forces measured by the two force platforms with regard to the participant's body weight before weights were added to the prosthesis. Once data were synchronised, force data were sampled at 15Hz to match the sample rate of the fluoroscope images. An example of this can be seen in Figure 55 below where the participant rocked from foot to foot 5 times over a ten second period (150 image frames). This data were then used to describe the proximal displacement of the tibia as a function of the amputee's body weight applied to the residual limb as depicted in Figure 56 below.

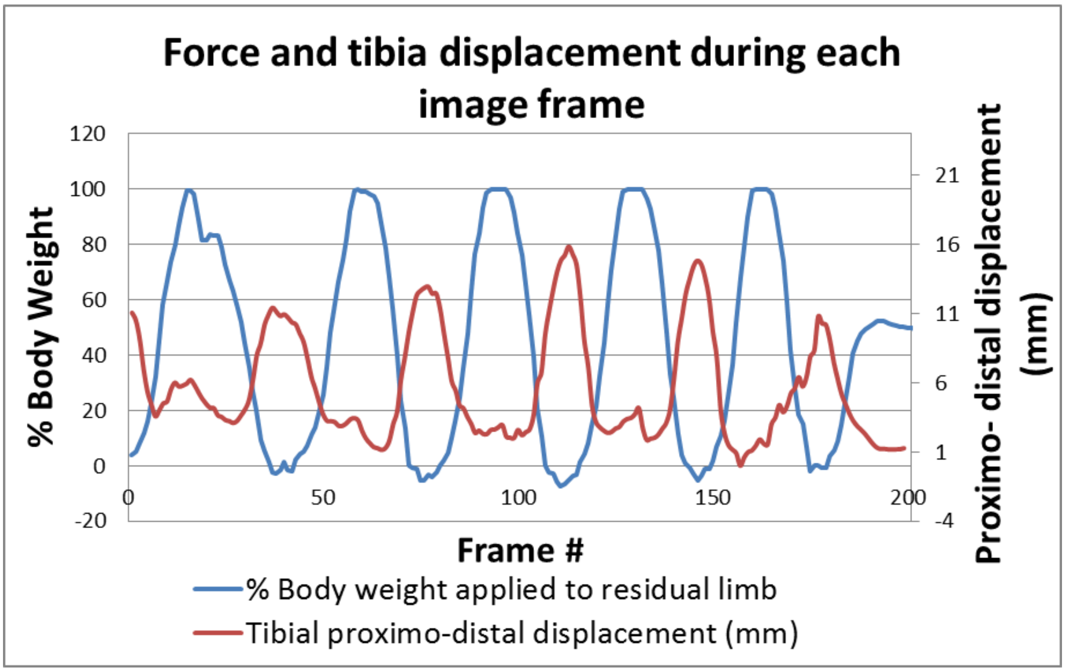



**Figure 55: Recordings of participant #1's force distribution and tibial displacement over time while wearing a 5kg mass to simulate traction forces during the swing phase of gait.**
**The data presented above depict an example of the normal force (% Body weight) applied to the residual limb and contemporaneous displacement of the residual tibia in the proximal distal direction (mm)**

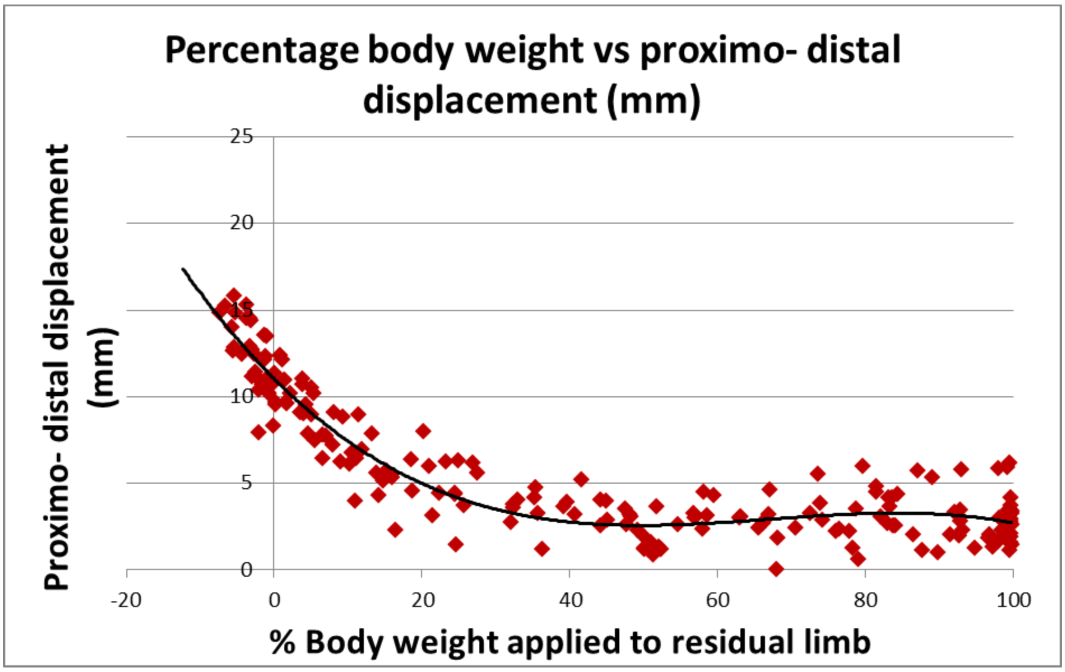



**Figure 56: Recordings of participant #1's tibial displacement as a function of weight applied to the prosthetic limb while wearing a 5kg mass to simulate traction forces during the swing phase of gait.**
**A 3rd order polynomial trend line is displayed on the graph to show the average displacement of the tibia as a function of force applied to the residual limb. The data in this figure are derived from that in Figure 55 above**

## 8.4 Results

As noted in Chapter 5 and summarised in Table 28 below, four participants had pin lock suspension, three used Gel liners in conjunction with an elastic (Supracondylar) sleeve, two had vacuum/suction suspension, one used an elastic sleeve alone without any other suspension system, one used a leather supracondylar strap alone and the final participant used a gel liner with a prosthetic socket that had a supracondylar supra-patellar brim.

**Table 28. A Summary of suspension styles used within the trans-tibial amputee population**

| Retention system | Number of users | Median degree of telescoping (millimetres) | Range (min – max) |
|---|---|---|---|
| Pin lock & gel liner | 4 | 16.3 | 11.8 - 18.7 |
| Supracondylar sleeve & gel liner | 3 | 29.2 | 21.3 - 32.5 |
| Suction & gel liner | 2 | 18.1 | 14.9 - 21.3 |
| Supracondylar sleeve & cloth liner | 1 | 46.5 | N/A |
| Supracondylar strap & cloth liner | 1 | 25.4 | N/A |
| Gel liner & supracondylar supra-patellar brim | 1 | 17.1 | N/A |

Across the population median range of telescoping was 20mm (9.9mm IQR). This varied greatly across the population, with proximo-distal movement of the tibia ranging between 47mm (a supracondylar sleeve suspension) and 12mm (pin lock suspension). This variability is likely to be due to the efficacy of the suspension method used. However, since suspension type, length of residuum, surgical method, cause of amputation and socket style were not controlled for, determining which factors influenced vertical displacement was not possible.

## 8.5 Discussion

### 8.5.1 Compression and distraction load

The findings of this study are very similar to those of Tucker et al. (2012) (Table 6 on page 42 of Section 2.6), with most displacement taking place during initial loading (0% to 20% of body weight) (Figure 57). Tucker et al. 2012, found an initial displacement of approximately 12.5mm during initial loading with approximately 7 mm of displacement taking place thereafter. They further report the variability of the total displacements measured to be in the order of 1.6mm SD, however, the results of this chapter were much more variable (Table 28 & Figure 57). This variability may be accounted for by the lack of homogeneity in the sample population in terms of surgical technique, suspension systems used and prosthesis build, unlike previous studies which concentrated on only one or two systems (Section 2.6)

In addition, this study found that the traction loads used to simulate those that would be incurred during normal gait caused further elongation of the limb. This can be concluded because LLD measures were taken at 50% body weight (Chapter 4) by which time (as visualised by Figure 57) the majority (if not all) of distal displacement of the residual tibia had taken place.

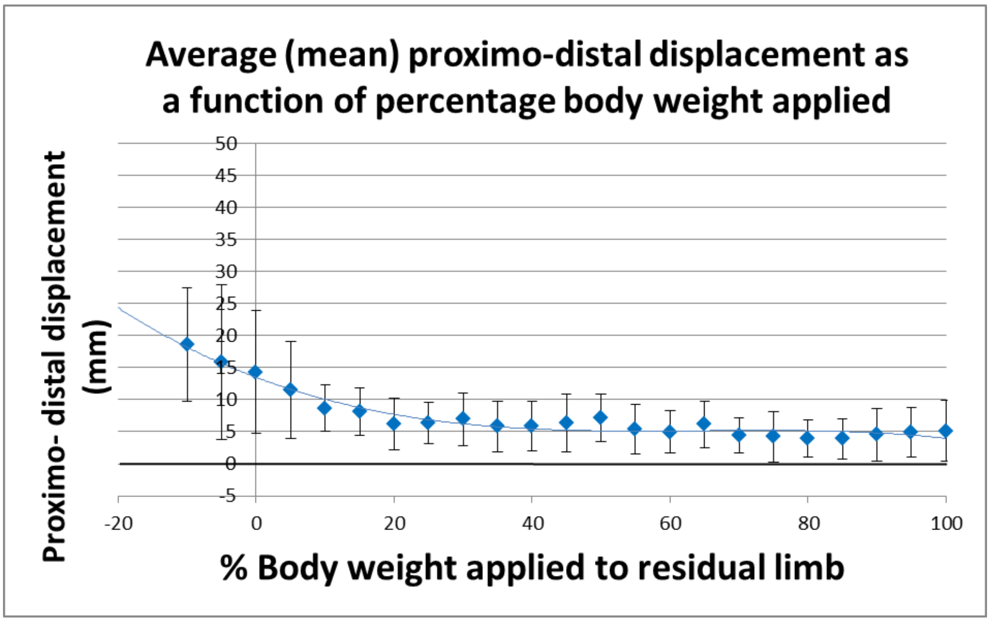



**Figure 57: Average (mean) proximo-distal displacement across the population as a function of body weight applied at 5% intervals to the prosthetic limb. (n=12)**
**A 3rd order polynomial is displayed on the graph as a trend line.**

### 8.5.2 Static LLD

During the measurement of LLD the participants were asked to stand with their feet shoulders width apart and their weight equally distributed (Section 4.5.4). The median LLD measured across the population was +4mm (78.8mm IQR) (ipsilateral limb longer than contralateral limb). The full dataset can be found in Table 44 of Appendix A.XIII. Assuming full compression of the residual limb at 50% body weight, the full range of telescoping could be added to these measures to find the dynamic LLD during a simulated swing phase of gait. The median LLD under these traction loads was +29mm (61.0mm IQR) (ipsilateral limb longer than contralateral limb).

### 8.5.3 Bayoneting

Bayoneting (discussed briefly in sections 2.5.1) is the distal displacement of the residual bones into or through the soft tissue of the residual limb. For this reason it is a focus of amputation surgery, prosthetic socket design and prosthesis management to create a stable environment to ensure that this does take place. In the design of this study it was assumed, due to the findings of a study by (Madsen et al. 2000), that during sustained weight transfer, if there was poro-viscosity in the system and when  the participant held the weight on the amputated limb, the tibia would descend more. If seen, this would provide evidence for bayoneting of the bone through soft tissue which could lead to secondary morbidity; however, this was not the case. The tibia remained in almost the same place when loaded >90% of body weight for 10 seconds, altered only in accordance to the direction of load applied and did not descend further. This is shown in Figure 57 where the greatest variability of tibial displacement occurred when between -10 and 40% of body weight was applied. This suggests that at least with socket weight distribution design the patellar tendon bears the majority of body load rather than the distal end of the limb.

## 8.6 Limitations

While not providing any additional information regarding proximo-distal pistoning of the tibia, the static stance protocol was the least susceptible to image blurring due to the slow speed of movement during initial weight transfer. This higher image quality allowed the prosthesis and tibia to be tracked the most consistently. However, it seems that most of the motion took place when between 40% of body weight was applied and when 5kg (plus the weight of the prosthetic) distracted the limb from the prosthesis. It is a limitation of this study that this period of the motion is also the fastest and least likely to track due to image blurring. However, this was overcome by the methods described in Section 8.3.2 of this chapter.

## 8.7 Further work

Within this study a relatively small sample was used. While acceptable for an exploratory study a larger population would be more representable. Further studies could usefully focus on the traction and initial application of body weight phases of movement.

A more controlled recording protocol which applies compression and traction loads at set velocities may be beneficial. In the protocol of Madsen et al. the participants were in a sitting position when loads were applied passively by a controller. This would allow more standardised investigations of telescoping of the residual limb as a function of force applied to the prosthesis. Furthermore, if a more standardised force application system were utilised, a rate of motion could be applied that would not confound the image tracking process as readily.

Using modified protocols, these measurement techniques could be used to inform finite element models which could provide a greater understanding of the force distribution and sheer stresses applied to the residual limb during compression and traction.

Finally, the heterogeneity of the amputee population group with respect to age, prosthesis and suspension style used and time since amputation may limit the generalisability of this study’s results. Further studies should take these factors into consideration during recruitment.

## 8.8 Conclusion

This chapter presented a methodology for measuring proximo-distal movement of the residual limb-socket interface and its results in 12 unilateral trans-tibial amputees focusing on the telescoping motion of the residual tibia. Results revealed that the range of such motion varied considerably with the prosthetic suspension method. While reasonably representable of loading patterns during actual gait, this required a trade off against controlled data recording.

# Chapter 9: Correlations of spine and limb data

## 9.1 Background

The research protocol hypothesis proposed in Chapter 4 was that the greater the displacement of the limb/socket interface during gait simulation the greater the asymmetry in the inter-vertebral motion will be.  In Chapter 6 we discovered no significant difference in range or symmetry between amputees and controls during passive side-bending lumbar spine motion, but greater variability in amputees specifically at L3-L4 and between L2 and S1. However, initial attainment rate trended non-significantly to be higher in controls. In Chapter 7 it was reported that amputees had greater evidence of interdependence between spinal levels and directions in terms of attainment rate than controls, but not of range of motion.

In Chapter 8 we found that the average telescoping among this population was 20mm (9.9mm IQR), which altered the average LLD.  During equal footing the ipsilateral limb was, as a median across the population, 4mm longer than the contralateral limb. During simulated swing phase of gait, telescoping of the residual limb causes the LLD increase to a median of 29mm. From Section 2.4.1 of the literature review, it was established that static LLDs as small as 15mm have been correlated with back pain (Friberg 1983a) and that LLDs have been shown to cause kinematic changes in the spine (Lee and Turner-Smith 2003). Until now no studies have investigated the effects of a dynamic LLD on the spine

## 9.2 Aim

In this chapter the aim was to determine if there were any correlations between the motion characteristics measured in the spine and the telescoping range of the residual limb.

## 9.3 Methods

As previously mentioned in section 6.4.2 many of the samples collected were not from normal distributions. For this reason the non-parametric correlations of these kinematic parameters were analysed and  Spearman's rank correlation (ρ), coefficients were employed, as in Chapter 7, to determine the statistical dependence between the residual limb kinematics as described in Chapter 8 and these spinal kinematic variables previously analysed in Chapters 6 & 7 (SPSS, IBM Corp. Released 2012. IBM SPSS Statistics for windows Version 21.0 Armonk, NY: IBM Corp.).

Correlations were calculated between the spine range of motion and attainment rate and the proximo-distal range of displacement of the tibia. The tibial ranges of displacement were taken from each of the 3 test configurations (rocking from foot to foot, rocking with 5kg mass on prosthetic limb, and static weight-bearing hold) as well as the mean range of the 3 tests and the total range across the 3 tests. Correlations between telescoping and amputee age, BMI and time since amputation surgery were also calculated.

## 9.4 Results

With the exception of the ***L2 to S1 rotation range asymmetry,*** the ***Total range of distraction*** incorporated all the measurements for each of the limb telescoping protocols. ***Rocking with the 5kg weight*** and ***Total range of distraction*** correlated negatively and significantly ($p<0.05$) with 6 and 7 of the spine kinematic measures respectively. All correlations were below -0.587***. L2 to S1 range asymmetry*** correlated only with ***Static body weight hold***. These results are detailed in Table 29 below.

**Table 29. Values for the spinal kinematic measures that significantly correlated with residual tibia displacement**

| | | Rocking with the 0kg weight | Rocking with the 5kg weight | Static body weight hold | Mean range of distraction | Total range of distraction |
|---|---|---|---|---|---|---|
| **Ipsilateral range of rotation between L2 and S1** | *ρ* | -0.238 | **-0.643** | -0.573 | -0.524 | **-0.608** |
| | **p** | 0.457 | ***0.024** | 0.051 | 0.080 | ***0.036** |
| **Contralateral range of rotation between L2 and S1** | *ρ* | -0.273 | -0.545 | -0.399 | -0.510 | **-0.587** |
| | **p** | 0.391 | 0.067 | 0.199 | 0.090 | ***0.045** |
| **L2 to S1 rotation range asymmetry** | *ρ* | -0.098 | -0.497 | **-0.713** | -0.490 | -0.343 |
| | **p** | 0.762 | 0.101 | ****0.009** | 0.106 | 0.276 |
| **Maximum L2 to S1 angle during contralateral bending** | *ρ* | -0.343 | **-0.713** | **-0.650** | **-0.671** | **-0.699** |
| | **p** | 0.276 | ****0.009** | ***0.022** | ***0.017** | ***0.011** |
| **Ipsilateral range of rotation of L3-L4** | *ρ* | -0.413 | **-0.685** | -0.406 | -0.566 | **-0.685** |
| | **p** | 0.183 | ***0.014** | 0.191 | 0.055 | ***0.014** |
| **Contralateral range of rotation of L3-L4** | *ρ* | -0.385 | **-0.685** | -0.427 | -0.524 | **-0.657** |
| | **p** | 0.217 | ***0.014** | 0.167 | 0.080 | ***0.020** |
| **Laxity of L3-L4 in Ipsilateral direction** | *ρ* | -0.503 | **-0.741** | -0.399 | **-0.587** | **-0.643** |
| | **p** | 0.095 | ****0.006** | 0.199 | ***0.045** | ***0.024** |
| **Laxity of L3-L4 in Contralateral direction** | *ρ* | **-0.629** | **-0.699** | -0.497 | **-0.685** | **-0.657** |
| | **p** | ***0.028** | ****0.011** | 0.101 | ***0.014** | ***0.020** |

**Spearman's rho (*ρ*), 2-tailed significance (p) * p<0.05, ** p<0.01**

## 9.5 Discussion

The assumptions inherent in this thesis include the suggestion that since most back pain is considered to have mechanical components, that lower-limb amputees have a higher prevalence of it, and that there are different intervertebral stresses in such people during gait, that these stresses should manifest themselves as kinematic variants that should be measurable using QF technology. In addition, as suggested in Section 1.1, prolonged exposure to gait asymmetries from repeated use of a lower limb prosthesis might be linked to lower back mechanical problems.

The measurements reported in Chapters 5, 6 & 7, showed no relationships with any of the telescoping or spine kinematic variables detailed in Table 29 and Age, BMI or time since amputation surgery (min 2.3 max 29.3 years).

However, the results presented in subsequent chapters constitute evidence that passive system intervertebral mechanics is not only different in trans-tibial amputees, but that this is in some ways proportional to the degree of tibia-socket telescoping attributable to body-weight transfer. Not only is this new knowledge of mechanical interactions in amputees, but the method for continuous measurement of limb-socket motion is of itself also entirely novel and is therefore a further contribution to knowledge.

It is apparent from Table 24 in Chapter 6 (section 6.4.4, page 159) that variability (the interquartile range) of IV-RoM is uniformly greater among the amputee population than the control population. Of particular note, is that the interquartile range is more than 150% greater among amputees at the L3-4 level and across the whole lumbar spine (L2-S1). This alone seems to give a greater opportunity for the significant correlations discovered above. It would be beneficial to perform this type of study with greater population size to find out if this tendency is maintained.

It was previously reported in the literature that these effects may spring from the increased lumbar spine movements and metabolic energy costs – leading to fatigue and injury (Hendershot 2015, Wiellberg 2012) and that these effects  might be detected by coronal plane lumbar spine studies (Hendershot 2012). However, far from being associated with reduced restraint, (Goel 1986, Hendershot 2013, Tribrewel 1985), residual tibia displacement was extensively associated with increased restraint of both range of motion and laxity. This was especially true in terms of the total range of distraction of the tibia. This chapters results suggest that greater amounts of telescoping of the limb within the socket is associated with an increased stiffness and reduced range of passive side-bending motion in the lumbar spine of mature amputees.

Whether these effects are directly related to back pain prevalence or not remains to be shown.  However, Chapter 7 showed that a significantly higher proportion of amputees than controls had between-level interactions in terms of restraint.  This is the first study to have done this in amputees and is therefore unique.  A different study of intervertebral motion pattern variations found that these were higher in patients with back pain than controls (Mellor 2014).

The results suggest that microstructural change may have occurred in the discs, ligaments and resting muscles –leading to greater restraint at specific levels and directions.  Such changes have also been proposed in amputees as associated with increased trunk muscle effort to overcome them, and consequently pain generation (Aho 2006, Sanches-Zurago 2015).  This therefore provides new support for a hypothesis for pain generation in trans-tibial amputees.

## 9.6 Conclusion

Large and significant negative correlations in between kinematics (L2-S1 and L3-4 ROM and laxity) and degree of telescoping suggest greater restraint and damping in mature amputees who wear high telescoping prosthetics.

Telescoping of the limb-prosthesis interface interacts with the intrinsic holding elements between vertebrae in the lumbar spine to alter their restraining properties over time compared to controls. This greater interaction (chapter 7) and the attendant variability of motion sharing (chapter 6) may be an underlying mechanism in the production of both compensation to the gait forces and at other times low back pain in amputees. A likely pathway between the two variable sets may be gait asymmetries in amputees brought about by the telescoping of the limb-prosthesis interface generating greater abduction of the spine to control for an active LLD.

# Chapter 10: Thesis Summary and Discussion

## 10.1 Summary

Limb length discrepancy has been demonstrated to have a measurable effect on the spine in terms of coronal plane motion and posture (Gurney 2002; Hendershot and Wolf 2015; Lee and Turner-Smith 2003). This study adds to this knowledge by demonstrating that amputees suffer these effects not only due to LLD but also to dynamic LLD (telescoping), which adds further complications to amputee gait, and by establishing a method for measuring dynamic LLD in the limb-prosthesis interface.

During the swing phase of gait, traction forces, caused by the weight of the prosthetic and its swing, distract the socket away from the residual limb, only to be forced back into position on heel contact. This constant elongation and reduction of limb length must be continually compensated for during gait and has been demonstrated to cause a more active medio-lateral trunk movement strategy to be adopted in unilateral trans-femoral amputees (Hendershot and Wolf 2015) . This in turn may contribute to higher metabolic energy expenditures and mechanical strains in the low back (Hendershot and Wolf 2015). This has been attributed to compensatory mechanisms to overcome reduced passive holding elements contributions to joint stiffness (Ahn et al. 2006; Sanchez-Zuriaga et al. 2015).  This thesis explored these relationships in trans-tibial amputees at the level of the passive intervertebral control structures using QF (Panjabi 1992b). This is the first study to do this.

Preliminary studies within this thesis demonstrated that QF has the ability to measure inter-vertebral laxity, represented by the initial attainment rate of inter-vertebral motion. This was shown to be a valid method for assessing the intrinsic inter-vertebral resistance to minimal bending moments. This represents an important contribution to the validation of the initial attainment rate as an expression of laxity in vivo, although confirmatory studies will be required. Subject to these studies and for the first time, QF is used to represent the dynamic neutral zone in *in vivo* studies of the mechanics of the lumbar spine.

The preliminary studies in this thesis also investigated the potential use of QF for measuring interactions between the residual limb and prosthetic socket, in order to quantify the vertical displacement of the tibia within the prosthesis in the coronal plane. This is the first time this has been done.

It allowed a protocol to be developed which used QF in both the spine and residual limb in experimental set-ups that included the addition of weights to the prosthesis to simulate gait. This enabled the measurement of telescoping motion under differing loading conditions, mimicking those that take place during walking or running with a prosthesis. These methods are new and innovative and constitute an additional contribution to knowledge.

The research collected kinematic data from 12 trans-tibial amputees (TTAs) in order to determine the statistical relationship between spine and residual limb kinematics in the coronal plane in terms of inter-vertebral range of motion (IV-ROM) and laxity. The intervertebral kinematics of amputees were compared to that of 12 healthy controls of similar age and BMI who underwent the same spinal imaging protocols. This is the first time such a comparison has been made.

In Chapter 6 it was found that there were no significant differences in passive inter-vertebral range of motion symmetry of amputees and controls, tending to disprove the main study hypothesis (Section 4.1 page 122) that the presence of a unilateral trans-tibial amputation has an effect on passive spinal symmetry, as suggested by Hendershot et al. (2013). This finding is novel and was unexpected. However, there was greater variability of the symmetry in amputees than that of controls, especially at L3-4. In addition, laxity trended non-significantly to be higher in controls and lower in amputees. The exception was L5-S1 where it was found that amputees had higher laxity. All of these findings confirm or disprove a number of theories about the effect of trans-tibial amputation on intervertebral restraint by the passive holding structures. Furthermore, this study introduces for the first time, the concept of greater interaction between levels rather than a difference between cohorts overall motion symmetry or range of motion.

To investigate this in terms of the increased variability of IV-ROM and laxity in amputees, Chapter 7 explored the degree of correlation of these within and between segmental levels as a measure of level interdependence. It was discovered that there was more interdependence in passive inter-vertebral motion between and across levels in BKAs than controls in terms of laxity, but not range of motion. These changes in restraint and damping of passive inter-vertebral holding elements were therefore associated with the presence of an amputated lower limb. This is a new and unexpected result.

In an effort to determine the statistical dependence between spine and residual limb kinematics in amputees a protocol for the measurement of proximo-distal telescoping of the residual tibia was then developed. In Chapter 8 it was discovered that telescoping of the residual tibia was highly variable across the population and would be likely to relate to the prosthesis retention system, although confirming this was outside the scope of this research. However, such assumptions are supported by the literature (Ali et al. 2014; Board et al. 2001; Gholizadeh 2012). It was also found that telescoping occurred mainly when between when 0% and 40% of body weight load was applied, and during the negative loads designed to simulate the swing phase of gait. This carries an important message for the manufacturers of prostheses and those who fit them, which is the necessity to consider the degree of telescoping over this range of body weight, as it may affect a potential pain producing mechanism in the spine.

Finally, in chapter 9, the relationships between residual limb telescoping and IV-ROM and laxity in the spine were explored. Significant negative correlations were found between the degree of tibial telescoping and the range of passive lumbar spine motion, especially at L3-4. Laxity also exhibited this inverse relationship, but only at L3-4. This constitutes new knowledge as a result of these investigations.

It was also found that residual limb telescoping during static hold negatively affected global (L2-S1) passive motion symmetry. As static hold had negative but less significant correlations with ranges of motion and laxity, it might be speculated that this has more to do with the loading phase of the simulated gait. This highlights for prosthesis manufacturers and fitters the importance of the loading phase of gait and suggests the need for focus group discussions among prosthetists to identify key issues for preventing back pain incidence.

## 10.2 Conclusion

### 10.2.1 Limitations

The hypothesis that the lumbar inter-vertebral motion is affected by lower limb amputation was supported by these studies. The relatively small sample size, while suitable for an exploratory study, and the heterogeneity of the amputee population group with respect to age, prosthesis socket, suspension type and time since amputation may limit the generalisability of the results. However, the wide range in the motion variables studied enabled them to be correlated.

### 10.2.2 Implications for low back pain

This study advances the field of biomechanics, by demonstrating that amputees suffer biomechanical effects to the passive properties of their spine with a direct correlation to the degree of dynamic LLD occurring as a result of lower limb prosthesis use and by establishing a method for measuring dynamic LLD in the limb-prosthesis interface itself. Furthermore this study advances the validation of the initial attainment rate as an expression of laxity in vivo, although confirmatory studies will be required. The higher interdependence of segmental motion among persons with unilateral LLA, suggests an association between altered spine kinematics and repeated exposure to altered and asymmetric gait following LLA. The negative relationship between spine and residual limb telescoping supports this, especially at L3-4. These findings therefore begin to identify how changes in movement patterns following LLA can lead to structural and functional alterations to the passive spinal elements. This may cause an increase in trunk muscle activity demands to overcome this stiffness leading to higher metabolic energy expenditure. Taken together, these changes may lead to an increased risk of LBP.

### 10.2.3 Further work

Further work is needed to investigate possible mechanisms for the observed alterations in trunk mechanics among persons with LLA.

This would be aided by replication of this study within a larger sample population in conjunction with further development of the limb-prosthesis data analysis. A comparison of lumbar segmental kinematic interdependence in amputees with and without LBP could be used to discriminate the relevance of this phenomenon and confirm that the spines of mature amputees at risk of LBP are inherently stiffer and require greater energy expenditure.

Further studies could also usefully explore the effects of such highlighted interdependence on muscular activity, control, co-ordination and proprioception. It would be particularly interesting to find out whether these effects are associated with imposed or diminished dissociation of muscle groups during co-ordinated spinal tasks (Cresswell et al. 1992).

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# Appendix

## A.I Explanation of box plots

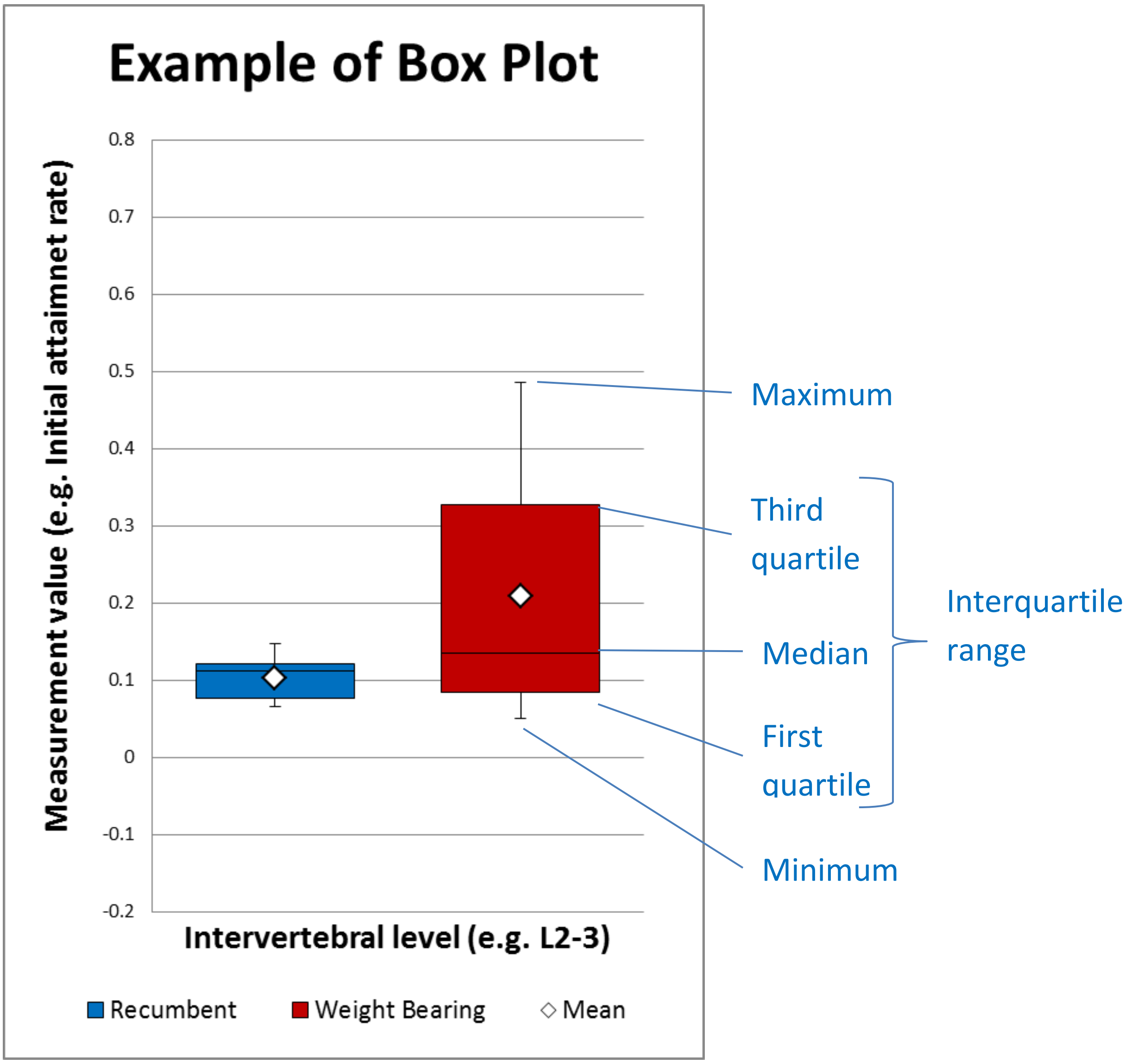


**Figure 58 Example of a box plot.**
**In this example the attainment rates are shown for the L2-3 intersegmental joint during flexion motion while undergoing weight-bearing and recumbent motion protocols (n=10)**

Due to the non-parametric nature of a large proportion of data presented, the average and variance of data has been presented as medians and interquartile ranges. A convenient way of depicting this data is as a “box plot”, an example of which can be seen above in Figure 58. A box plot (also known as a “box and whisker diagram”) is a standardized way of displaying the distribution of data. In a simple box plot, like that in the figure above, the central rectangle encompasses the first quartile and third quartile (the *interquartile range* or *IQR*). A line inside the rectangle shows the median and "whiskers" above and below the box show the locations of the minimum and maximum values of the data set.

## A.II Preliminary study healthy control range and rate of motion tables, average (median) and variance (interquartile range)

**Table 30. Median range for each intersegmental joints contribution to the angle between L2 & S1 during left side rotational bending**

| | | L2-3 | L3-4 | L4-5 | L5-S1 |
|---|---|---|---|---|---|
| **Recumbent** | **Population median (degrees)** | 0.34 | 0.32 | 0.309 | 0.053 |
| | **Interquartile range** | 0.11 | 0.04 | 0.051 | 0.041 |
| **Weight-bearing** | **Population median (degrees)** | 0.42 | 0.37 | 0.228 | -0.047 |
| | **Interquartile range** | 0.10 | 0.07 | 0.087 | 0.095 |
| **Significance (Willcoxons' 2-sided p)** | | 0.131 | 0.027 | 0.049 | 0.006 |

**Table 31. Median range for each intersegmental joints contribution to the angle between L2 & S1 during right side rotational bending**

| | | L2-3 | L3-4 | L4-5 | L5-S1 |
|---|---|---|---|---|---|
| **Recumbent** | **Population median (degrees)** | 0.319 | 0.331 | 0.316 | 0.048 |
| | **Interquartile range** | 0.104 | 0.087 | 0.020 | 0.098 |
| **Weight-bearing** | **Population median (degrees)** | 0.365 | 0.348 | 0.271 | -0.009 |
| | **Interquartile range** | 0.120 | 0.110 | 0.065 | 0.092 |
| **Significance (Willcoxons' 2-sided p)** | | 0.002 | 0.770 | 0.084 | 0.160 |

**Table 32. Median range for each intersegmental joints contribution to the angle between L2 & S1 during flexion**

| | | L2-3 | L3-4 | L4-5 | L5-S1 |
|---|---|---|---|---|---|
| **Recumbent** | **Population median (degrees)** | 0.164 | 0.234 | 0.311 | 0.260 |
| | **Interquartile range** | 0.047 | 0.084 | 0.087 | 0.064 |
| **Weight-bearing** | **Population median (degrees)** | 0.225 | 0.311 | 0.280 | 0.159 |
| | **Interquartile range** | 0.102 | 0.109 | 0.089 | 0.095 |
| **Significance (Willcoxons' 2-sided p)** | | 0.027 | 0.049 | 0.084 | 0.106 |

**Table 33. Median range for each intersegmental joints contribution to the angle between L2 & S1 during extension**

| | | L2-3 | L3-4 | L4-5 | L5-S1 |
|---|---|---|---|---|---|
| **Recumbent** | **Population median (degrees)** | 0.216 | 0.237 | 0.226 | 0.366 |
| | **Interquartile range** | 0.078 | 0.040 | 0.145 | 0.209 |
| **Weight-bearing** | **Population median (degrees)** | 0.177 | 0.174 | 0.083 | 0.417 |
| | **Interquartile range** | 0.199 | 0.106 | 0.268 | 0.460 |
| **Significance (Willcoxons' 2-sided p)** | | 0.846 | 0.625 | 0.010 | 0.232 |

**Table 34. Median attainment rate for each intersegmental joint during flexion**

| | | L2-3 | L3-4 | L4-5 | L5-S1 |
|---|---|---|---|---|---|
| **Recumbent** | **Population median (degrees)** | 0.112 | 0.161 | 0.181 | 0.143 |
| | **Interquartile range** | 0.045 | 0.035 | 0.115 | 0.045 |
| **Weight-bearing** | **Population median (degrees)** | 0.135 | 0.156 | 0.096 | 0.086 |
| | **Interquartile range** | 0.244 | 0.143 | 0.073 | 0.121 |
| **Significance (Willcoxons' 2-sided p)** | | 0.018 | 0.030 | 0.047 | 0.032 |

**Table 35. Median attainment rate for each intersegmental joint during extension**

| | | L2-3 | L3-4 | L4-5 | L5-S1 |
|---|---|---|---|---|---|
| **Recumbent** | **Population median (degrees)** | 0.113 | 0.146 | 0.140 | 0.253 |
| | **Interquartile range** | 0.066 | 0.045 | 0.089 | 0.190 |
| **Weight-bearing** | **Population median (degrees)** | 0.089 | 0.086 | 0.046 | 0.137 |
| | **Interquartile range** | 0.138 | 0.063 | 0.088 | 0.125 |
| **Significance (Willcoxons' 2-sided p)** | | 0.032 | 0.037 | 0.046 | 0.102 |

**Table 36. Median attainment rate for each intersegmental joint during left side rotational bending**

| | | L2-3 | L3-4 | L4-5 | L5-S1 |
|---|---|---|---|---|---|
| **Recumbent** | **Population median (degrees)** | 0.201 | 0.272 | 0.246 | 0.035 |
| | **Interquartile range** | 0.062 | 0.041 | 0.109 | 0.037 |
| **Weight-bearing** | **Population median (degrees)** | 0.233 | 0.213 | 0.121 | -0.028 |
| | **Interquartile range** | 0.241 | 0.091 | 0.091 | 0.045 |
| **Significance (Willcoxons' 2-sided p)** | | 0.734 | 0.037 | 0.002 | 0.055 |

**Table 37. Median attainment rate for each intersegmental joint during right side rotational bending**

| | | L2-3 | L3-4 | L4-5 | L5-S1 |
|---|---|---|---|---|---|
| **Recumbent** | **Population median (degrees)** | 0.216 | 0.282 | 0.236 | 0.039 |
| | **Interquartile range** | 0.090 | 0.063 | 0.058 | 0.066 |
| **Weight-bearing** | **Population median (degrees)** | 0.233 | 0.213 | 0.121 | -0.028 |
| | **Interquartile range** | 0.241 | 0.091 | 0.091 | 0.045 |
| **Significance (Willcoxons' 2-sided p)** | | 0.432 | 0.006 | 0.004 | 0.084 |

**Table 38. Median range for each intersegmental joint overall motion form left to right side rotational bending**

| | | L2-3 | L3-4 | L4-5 | L5-S1 |
|---|---|---|---|---|---|
| **Recumbent** | **Population median (degrees)** | 6.0 | 5.2 | 6.4 | 1.4 |
| | **Interquartile range** | 2.0 | 2.6 | 0.7 | 1.5 |
| **Weight-bearing** | **Population median (degrees)** | 7.1 | 6.6 | 5.7 | 1.1 |
| | **Interquartile range** | 3.6 | 3.1 | 2.3 | 0.9 |
| **Significance (Willcoxons' 2-sided p)** | | 0.322 | 0.625 | 0.027 | 0.322 |

**Table 39. Median range for each intersegmental joint overall motion form flexion to extension**

| | | L2-3 | L3-4 | L4-5 | L5-S1 |
|---|---|---|---|---|---|
| **Recumbent** | **Population median (degrees)** | 8.5 | 7.9 | 10.2 | 13.1 |
| | **Interquartile range** | 1.9 | 4.1 | 4.8 | 5.8 |
| **Weight-bearing** | **Population median (degrees)** | 10.3 | 12.3 | 12.3 | 12.1 |
| | **Interquartile range** | 5.8 | 4.6 | 5.2 | 8.0 |
| **Significance (Willcoxons' 2-sided p)** | | 0.131 | 0.006 | 0.432 | 1.000 |

## A.III Ethical considerations

The safety, dignity and wellbeing of the participants was paramount in these studies. All participants were given a minimum of 1 week to consider whether they want to take part in the research and all fluoroscopic images were assessed by the CI and a chiropractor.

### A.III.1 Radiation dosage

This study has been designed using the guidance issued by NRES 'Approval for research involving ionising radiation' (COREC and NHS R&D Forum 2006) and keeping ionising radiation dose ‘as low as reasonably achievable’ (ALARA) is always at the forefront of the design an investigation like this. The current radiation dosages, determined from people who have had the passive recumbent spinal investigation since February 2009, are shown in Table 17.

**Table 40. Mean and upper 3rd quartile absorbed and effective doses obtained for the current QF system**

| Total Absorbed Dose $cGy.Cm^2$ | | Total Effective Dose mSv | |
|---|---|---|---|
| Mean | Upper third quartile | Mean | Upper third quartile |
| 191.43 | 266.95 | 0.429 | 0.580 |

These dosages compare favorably with those approved in previous ethical applications to conduct spine studies of healthy control participants. These are summarised in Table 41

**Table 41. History of NHS ethical applications for QF studies of healthy participants**

| Investigator and Year | Purpose of study | Type of screening | Participants | Effective dose (mSv) | Outcome |
|---|---|---|---|---|---|
| **Thompson 1993** | Validate a surface goniometer for measuring vertebral motion | One flexion-extension sitting | | Not known | approved |
| **(Breen and Allen 1996)** | Exploratory study of normal motion and intra-subject reliability | Flexion-extension and side-bending lying repeated after 20 mins | 30 male healthy volunteers aged 18-40 | AP + LAT<br>1.8 (mean)<br>(repeated) | approved |
| **(Mellor 2009)** | Comparison of mechanics of healthy controls and chronic back pain patients | Flexion-extension and side-bending lying not repeated | 40 male and female healthy volunteers and 40 chronic back pain patients aged 21-51 | AP+ LAT<br>1.5 (max) | approved |
| **Breen 2010** | Establish reliability and normative reference levels for mechanics using standard protocols | Flexion-extension or side-bending lying and standing (repeated after 6 weeks in a subgroup of participants) | 268 male and female healthy volunteers aged 20-70<br>with a subgroup of 108 for repeated study | Reference study<br>AP 1.16 (max)<br>LAT 0.74 (max)<br><br>Reliability study (repeated)<br>AP 2.32 (max)<br>LAT 1.47 (max) | approved |

# A.IV National research ethics approval of research protocol letter – gained 15/11/2013

**NHS**
**Health Research Authority**
**NRES Committee South West - Frenchay**
Bristol Research Ethics Committee Centre
Level 3, Block B
Whitefriars
Lewins Mead,
Bristol
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Telephone: 01173421392

15 November 2013

Mr Alexander C Breen
Post Graduate Researcher at Bournemouth University/ Medical physicist (Specialist OSMIA) at AECC)
13-15 Parkwood Road
Bournemouth
BH5 2DF

Dear Mr Breen

| | |
|---|---|
| **Study title:** | **A quantitative fluoroscopic study of the relationships between lumbar inter-vertebral and residual limb/socket kinematics in the coronal plane in adult male unilateral amputees.** |
| **REC reference:** | **13/SW/0248** |
| **Protocol number:** | **n/a** |
| **IRAS project ID:** | **132938** |

Thank you for your letter of 25 September 2013, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered at the meeting of the Committee held on 25 October 2013. A list of the members who were present at the meeting is attached.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator Miss Lidia Gonzalez, nrescommittee.southwest-frenchay@nhs.net.

**Confirmation of ethical opinion**

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Research Ethics Committee established by the Health Research Authority

**Ethical review of research sites**

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

**Approved documents**

The final list of documents reviewed and approved by the Committee is as follows:

| *Document* | *Version* | *Date* |
|---|---|---|
| Other: Amputee Volunteer Information Sheet | 1.4 | 29 September 2013 |
| REC application | | 11 October 2013 |
| Participant Consent Form | 1.0 | 01 July 2013 |
| Evidence of insurance or indemnity | | 21 August 2013 |
| Response to Request for Further Information | | 25 September 2013 |
| Participant Consent Form: Consent for transfer of personal details | 1 | 01 July 2013 |
| Letter of invitation to participant | | |
| Summary/Synopsis | 1 | 14 August 2013 |
| Questionnaire | 1.1 | 09 August 2013 |
| Advertisement | 1.2 | 09 August 2013 |
| Other: CV Supervisor | | |
| Other: Pre-study participant form | 1.2 | 09 August 2013 |
| Other: Covering e-mail to participant | | |
| Covering Letter | | 20 August 2013 |
| Protocol | 1.7 | 12 August 2013 |
| Investigator CV | | 20 August 2013 |

**Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

**After ethical review**

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favorable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

| 13/SW/0248 | Please quote this number on all correspondence |
|---|---|

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

Yours sincerely

p.p. Lidia Glen

**Dr Robert Beetham**
**Chair**

Email:nrescommittee.southwest-frenchay@nhs.net

| | |
|---|---|
| *Enclosures:* | *List of names and professions of members who were present at the meeting and those who submitted written comments* |
| | "After ethical review – guidance of researchers" |
| *Copy to:* | *Haymo Thiel, Anglo-European College of Chiropractic* |

**NRES Committee South West - Frenchay**

**Attendance at Committee meeting on 25 October 2013**

**Committee Members:**

| *Name* | *Profession* | *Present* |
|---|---|---|
| Dr Robert Beetham | Retired Consultant Clinical Biochemist | Yes |

**Also in attendance:**

| *Name* | *Position (or reason for attending)* |
|---|---|
| Miss Lidia Gonzalez | REC Admin Assistant |

# A.V National research ethics approval of amendment letter – gained 08/05/2014

The amendment sought was to include a "Consent to transfer of personal details" form, to allow participant identification at NHS sites.

**NHS**
**Health Research Authority**

**NRES Committee South West - Frenchay**
Bristol Research Ethics Committee Centre
Level 3, Block B
Whitefriars
Lewins Mead,
Bristol BS1 2NT
nrescommittee.southwest-frenchay@nhs.net

08 May 2014

Mr Alexander C Breen
Post Graduate Researcher
Bournemouth University/ Medical physicist (Specialist OSMIA) at AECC)
13-15 Parkwood Road
Bournemouth
BH5 2DF

Dear Mr Breen

| | |
|---|---|
| **Study title:** | **A quantitative fluoroscopic study of the relationships between lumbar inter-vertebral and residual limb/socket kinematics in the coronal plane in adult male unilateral amputees.** |
| **REC reference:** | **13/SW/0248** |
| **Protocol number:** | **n/a** |
| **Amendment number:** | **1, 25/04/2014** |
| **Amendment date:** | **25 April 2014** |
| **IRAS project ID:** | **132938** |

The above amendment was reviewed in May 2014 by the Sub-Committee in correspondence.

**Ethical opinion**

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

**Approved documents**

The documents reviewed and approved at the meeting were:

| Document | Version | Date |
|---|---|---|
| Protocol | 1.8 | 22 April 2014 |
| Notice of Substantial Amendment (non-CTIMPs) | | 25 April 2014 |
| Participant Information Sheet: Amputee Volunteer - Alex A5 | 1.5 | 25 April 2014 |
| Participant Consent Form: for Transfer of Personal Details: Alex Breen - Amputee | 1.3 | 26 April 2014 |

**Membership of the Committee**

The members of the Committee who took part in the review are listed on the attached sheet.

**R&D approval**

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

**Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

| | |
|---|---|
| **13/SW/0248:** | **Please quote this number on all correspondence** |

Yours sincerely

p.p.

**Mr Peter Jones**
**Chair**

E-mail: nrescommittee.southwest-frenchay@nhs.net

*Enclosures:* *List of names and professions of members who took part in the review*

*Copy to:* .
*Haymo Thiel, Anglo-European College of Chiropractic*

**NRES Committee South West - Frenchay**

**Attendance at Sub-Committee of the REC meeting in May 2014**

| *Name* | *Profession* | *Capacity* |
|---|---|---|
| Mr Paul Allen | Consultant Oral Surgeon | Expert |
| Mr Peter Jones | Retired Head teacher | Lay Plus |

**Also in attendance:**

| *Name* | *Position (or reason for attending)* |
|---|---|
| Miss Lidia  Gonzalez | REC Admin Assistant |

# A.VI Research and Development approval letter – gained 29/05/2014

The Royal Bournemouth and Christchurch Hospitals NHS
NHS Foundation Trust

The Royal Bournemouth Hospital
Castle Lane East
Bournemouth
Dorset
United Kingdom
BH7 7DW

Tel: 01202 303626
www.rbch.nhs.uk

Mr Alexander Breen
Medical Physicist
Institute for Musculoskeletal Research and clinical Implementation
Anglo-European College of Chiropractic
13-15 Parkwood Road
Bournemouth
BH5 2DF

29/05/2014

Dear Mr Breen,

| | |
|---|---|
| Reference: | **A quantitive fluoroscopic study of the relationships between lumbar inter-vertebral and residual limb/socket kinematics in the coromal plane in adult male unilateral amputees** |
| REC reference: | **12/SW/0248** |
| IRAS Project ID: | **132938** |

I am pleased to inform you that this project has now received approvals from all parties and that you now have formal permission to start.

Please see the Terms and Conditions for undertaking research at the Trust at: http://dorsetresearch.org/docs/drc/TC_for_research_within_DRC.pdf.

The recruitment target is 15 patients by 01/10/2014. You should note that this study is subject to external performance management of the recruitment rate.

Please let me know when you officially start and I would be grateful for a progress report annually.

Good luck with the study,

Caroline Jamieson-Leadbitter
Acting Head of Research

CC: Claire Myint, Consultant in Rehab Medicine, Orthotics dept, RBH

# A.VII Volunteer information sheet

ANGLO-EUROPEAN COLLEGE OF CHIROPRACTIC

IMRCI Institute for Musculoskeletal Research & Clinical Implementation

## Participant Information Sheet

An investigation of spine and leg movement in amputees

I would like to invite you take part in my PhD research study. Before you decide, it is important that you to understand why the research is being done and what it involves.

**My contact details are at the end of this information and I would be happy to answer any questions you may have.**

**1. What is the purpose of this study?**

This study aims to improve our understanding of how the low back (lumbar spine) moves in below-knee amputees and the relationship between this movement and the motion happening between your leg and your prosthesis. It is thought that the lumbar spine bones (vertebrae) might move differently depending on how well the leg is secured within the socket. Until now there has been no way of investigating this theory as previous research has not been able to reliably measure real time movement of the spine or the leg under the body surface. A new technology which utilises video x-rays (fluoroscopy) will be used in this study to measure the motions between the of bones in real time as you move, making this investigation possible for the first time.

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IMRCI Institute for Musculoskeletal Research & Clinical Implementation

**2. Why have I received this information leaflet?**

You have received this leaflet because you are male, aged between 20 and 65 years and you replied to an email or advertisement asking for volunteers with a single below-knee amputation who would be willing to take part in a research study. This leaflet will explain the research in further detail. I**t is entirely your decision whether or not you decide to join the study. You are free to refuse to participate, or withdraw at any time during the study without giving a reason.**

**3. What will happen if I decide to participate?**

If you decide to take part, your name, age, height, weight, address and telephone number will be stored on a password-protected computer. You will be invited to attend the x-ray department at the AECC in Bournemouth at a time convenient to you. Travel expenses of up to £10 will be reimbursed but I regret that funding does not run to an amount greater than this. At the time of your visit I will go through this information leaflet with you and explain the video x-ray examination. If you are happy to proceed you will be asked to sign two consent forms, one of which will be for you to keep.

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IMRCI Institute for Musculoskeletal Research & Clinical Implementation

The motion x-ray assessment of your low back

You will be shown to a changing room and asked to change into a gown and shorts (provided) ready for the video x-rays of your lower spine during bending and your leg while standing.

To do this, I will use a new method called OSMIA (Objective Spinal Motion Imaging Assessment), which uses a specially designed table and low dose video x-rays. The table is hinged in the middle and the upper half moves slowly from side to side whilst you lie on it.

You will first be asked to lie on your back on the table with your knees bent. The upper half of the table will swing from left to right/right to left and video x-rays will be taken showing the movement of your lower back as you bend from side to side. Before I take the x-rays I will demonstrate the movement of the table with you to find the range of bending that you are comfortable with. Previous studies have shown that patients who have had or needed back surgery do not feel pain when doing this bending as the movement is 'passive', which means the movement is generated by the table rather than by you. You will be provided with a button that, if pressed, will stop the table immediately should you begin to feel pain or discomfort. Please visit http://www.aecc.ac.uk/research/imrci/osmia.aspx if you would like to observe a video of the low back procedure taking place.

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IMRCI Institute for Musculoskeletal Research & Clinical Implementation

The motion x-ray and video analysis of your leg

I will then ask you to disrobe to the waist and I will attach some reflective markers to your skin (shoulders and hips) and one to the back of each for your shoes and some further markers which will show up on the x-rays of your prosthesis socket. I will then ask you to stand on a platform, which has handrails provided for your comfort, and instruct you to shift your weight from one side to the other. With the use of a high frame rate camera I will track your body's movement and measure your weight distribution between your feet when standing on electric scales.

The video x-ray image acquisition of the residual limb will be twofold;

Firstly, you will be asked to rock from one side to the other 5 times over a 5 second period with guidance, as a simulation for a normal walking speed. This will be repeated with the addition of a small weight (similar to the type used by distance runners in training) attached above the ankle of the prosthetic limb to replicate the forces applied as you walk. Secondly, you will be asked to put as much of your body weight as you feel comfortable (preferably all of it) onto your amputated limb and hold it there for 10 seconds. **The whole procedure will take no more than 1 hour.**

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**4. What are the risks and benefits of participating?**

This examination uses radiation from x-rays. Therefore it is important you understand the risks and benefits of taking part. The radiation dose from the examination is less than the amount of naturally occurring background radiation you would receive in the UK over a 2 month period. Experts agree that it is very difficult to determine the risk of inducing cancer from such low doses, however it is estimated that there is a 3 in 100 000 increased chance of getting a fatal cancer from this examination. This is in addition to the 1 in 3 natural lifetime risk of you contracting cancer throughout your lifespan. You may wish to consider this risk in relation to some more familiar events as in the table below. There is no direct benefit to you from the radiation dose; however the risk is considered to be minimal.

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| Some familiar risks | Chance they will happen |
|---|---|
| Getting three balls in the UK national lottery | 1 in 11 |
| Needing emergency treatment in the next year after being injured by a can, bottle, or jar | 1 in 100 |
| Death by an accident at home | 1 in 7100 |
| Getting five balls in the UK national lottery | 1 in 11 098 |
| Death by an accident at work | 1 in 40 000 |
| Death playing soccer | 1 in 50 000 |
| Death by murder | 1 in 100 000 |
| Being hit in your home by a crashing aeroplane | 1 in 250 000 |

Sedgwick, P. and A. Hall (2003). "Teaching medical students and doctors how to communicate risk." BMJ **327**(7417): 694-695.

There is also a risk that an 'incidental' finding will be seen on your video x-ray. An incidental finding is defined as one that is unrelated to your back pain and is discovered unintentionally. To date more than 100 patients have undergone this examination and there have been no significant incidental findings. All video x-rays will be reviewed by a chiropractor at the AECC and in the event of an incidental finding you will be referred, if

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necessary, to the appropriate specialist in consultation with your GP. If this is necessary you will be informed and asked to give permission before any action is taken. Such detection has the benefit of starting treatment early but in a small number of cases may have implications for future employment and insurance.

There may be no overall benefit to you from taking part in this study but the information I receive may help improve the diagnosis of amputees who develop low back pain. After the video x-ray examination you will have the option of watching the movement of your spine and prosthesis on a TV screen which many previous research participants have found fascinating.

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**5. Will my taking part in this study be kept confidential?**

Ethical practice will be followed with respect to any information obtained from you in this study. Your details will be kept on a password-protected computer until all participants have been recruited. After this, all identifying details will be destroyed and all data collected will be anonymised. Consequently, you will not be able to withdraw your data from the study once it has been collected. This does not affect your right to withdraw from the study prior to, or during data collection. Your anonymised data will also be retained indefinitely for use in further ethically approved research studies.

**6. What if there is a problem?**

If you have a concern about any aspect of the study you should speak to me in the first instance and I will do my best to answer your questions. If you remain unhappy and wish to complain formally you can do this by contacting Dr Osborne (contact details at the end of this information sheet) at the AECC.

In the event that something does go wrong and you are harmed during the research due to someone's negligence, you may have grounds for legal action for compensation against the AECC but you may have to pay your own legal costs.

**7. What will happen to the results of this study?**

The results from this study will be collated and presented to Bournemouth University for the award of Doctor of Philosophy (PhD). They will also be presented at international meetings and published in international journals and on the AECC website (www.aecc.ac.uk). You are welcome to keep up to date with the study's progress by periodically checking the website, or contacting me at any time; my details are at the end of this leaflet.

**8. Who is funding the research?**

It is being supported and sponsored by Bournemouth University and the Anglo-European College of Chiropractic.

**9. Who has reviewed the study?**

This research has been reviewed by my academic supervisors; Dr Dupac, Dr Noroozi and Dr Osborne and advisor Professor Breen. Additionally, a National Research Ethics Committee have reviewed and given a favourable opinion on this study.

**10. Further information and contact details**

***Chief Investigator***
Mr Alexander Breen
Medical Physicist (Quantitative Fluoroscopy Specialist)
Anglo-European College of Chiropractic.
13-15 Parkwood Road
Bournemouth BH5 2Df
Tel: 01202 436200
Email: alexbreen@aecc.ac.uk

***Director of Clinic***
Dr Neil Osborne
Anglo-European College of Chiropractic.
13-15 Parkwood Road
Bournemouth BH5 2Df
Tel: 01202 436200
Email: nosborne@aecc.ac.uk

Version: 1.4

29/09/2013

# A.VIII Consent for Transfer of Personal Details

ANGLO-EUROPEAN COLLEGE OF CHIROPRACTIC

IMRCI Institute for Musculoskeletal Research & Clinical Implementation

## Consent for Transfer of Personal Details

You may be eligible to take part in a research study being undertaken by Mr Alexander Breen, Research Physicist.

The study will take place here at the Anglo-European College of Chiropractic (AECC) and involves comparing the motion in the lumbar spine and the residual limb movement within the socket in **volunteers with unilateral trans-tibial amputation** using low dose video x-rays.

If you would like to know more about this it is necessary to pass on your personal details (name, address, telephone number) to Mr Alexander Breen to allow him to contact you and explain the study further. For this we need your consent.

Please read and tick the 4 statements below, if you understand them please then complete your personal details at the bottom of this form along with your signature and today's date and return to your clinician.

| | Please Tick |
|---|---|
| 1. I understand that I may be eligible to take part in a research study comparing the motion in the lumbar spine and the residual limb movement within the socket. | ☐ |
| 2. I understand this consent is for the transfer of my personal details only and does not mean I have agreed to take part in the research. | ☐ |
| 3. I consent for my Name, Address and Telephone number to be given to Mr Alexander Breen so that he can contact me to provide further information about the study. | ☐ |
| 4. I understand that if I do not want not to take part in the research then my details will be destroyed. This will not affect my current or future healthcare provided by AECC. | ☐ |

**Name:** ……………………………………………………………………….

**Telephone Number:** ……………………………………………………

**Address:** ……………………………………………………………………

……………………………………………………………………………………

……………………………………………………………………………………

……………………………………………………………………………………

**Signature** ……………………………. **Date** ………………….

## Instructions to clinician.

Please return this form to Mr Alexander Breen. AECC. 13-15 Parkwood Road, Bournemouth, BH5 2DF If you have any questions about this form or the research please contact Alex on 01202 436369 or email: alexbreen@aecc.ac.uk

Consent for personal details transfer. V1. 01.07.13

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# A.IX Consent form

Consent for all. V1.1 17.09.13

ANGLO-EUROPEAN COLLEGE OF CHIROPRACTIC

IMRCI Institute for Musculoskeletal Research & Clinical Implementation

## CONSENT FORM

**Title:** A quantitative fluoroscopic study of the relationships between lumbar inter-vertebral and residual limb/socket kinematics in the coronal plane in adult male unilateral amputees.

**Name of researcher:** Mr Alexander Breen

**Patient identification number for this trial: …………………**

**Please initial**

1. I confirm that I have read and understood the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that all data will be anonymised and may be used in future ethically approved research studies. ☐
4. I agree to take part in the above study. ☐

| Name of Patient | Date | Signature |
|---|---|---|
| -------------------------------- | -------------------- | ------------------------ |
| Name of person taking consent | Date | Signature |
| -------------------------------- | -------------------- | ----------------------- |

BU Bournemouth University

Consent form for participants. V1. 01.07.13

# A.X Pre-study form

**Pre-study participant form. V1.2 09.08.2013**

| |
|---|
| Office use only: |
| Participant ID _______________ Eligibility ____________________ |

**Exploring the spine and lower limb kinematics of trans-tibial amputees**

Your name________________________ ______________________________
Last First

Telephone (home)________________(mobile)_________________ Sex(M/F)____

Email_______________________________________ Date of Birth______________
Day/month/year

Height (m)_________________Weight (kg)______________

Date of amputation DD/MM/YYYY (please approximate if unsure) ____/____/______

GP name ______________________________Surgery _____________________

| | | |
|---|---|---|
| 1. Do you have a single amputation of one leg below the knee? | Y | N |
| 2. Have you had abdominal or pelvic surgery in the past year? | Y | N |
| 3. Have you ever had low back surgery? | Y | N |
| 4. Have you had a CT scan of your chest, abdomen or pelvis, Interventional procedures under radiological control (such as angiography) in the past 2 years or quantitative Fluoroscopy procedure in the past 1 year? | Y | N |
| 5. Are you a participating in any other research study at the moment which utilises ionising radiation? | Y | N |

**PLEASE USE ENCLOSED ENVELOPE POST THIS FORM TO:**
**Mr Alexander Breen**
**AECC,**
**13-15 Parkwood Road,**
**Bournemouth BH5 2DF**
**Tel: 01202 436275**
**Email: alexbreen@aecc.ac.uk**
**And I will email you and let you know of your eligibility**

A.XI Volunteer recruitment poster

Exploring the spine and lower limb kinematics of trans-tibial amputees. Version 1.2 09/08/2013

ANGLO-EUROPEAN COLLEGE OF CHIROPRACTIC

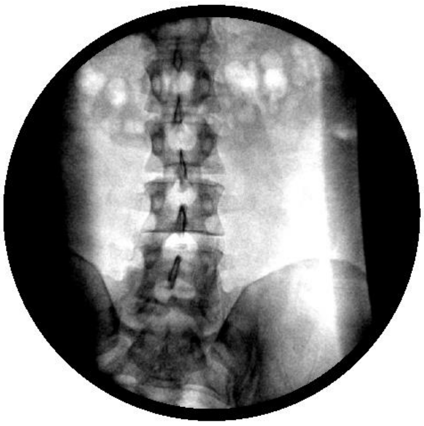
IMRCI Institute for Musculoskeletal Research & Clinical Implementation

# Unilateral Trans-Tibial Amputee Volunteers Needed

**Do you have a single amputation below the knee?**

**Are you Male, aged 25-60 years?**

**Volunteers are needed to be part of a new study of the lower spine and below knee prosthesis motion.**



To find out more contact:
Alexander Breen in **IMRCI**
Tel: 01202 436369, Email: alexbreen@aecc.ac.uk
On-line at www.aecc.ac.uk/research/imrci/osmia.aspx
or scan this QR code

Bournemouth University

# A.XII Participant questionnaire

Participant questionnaire V1.1 09/08/2013

## Exploring the spine and lower limb kinematics of trans-tibial amputees

Date (DD/MM/YYYY) ___/___/______ Participant identifier (office use only) ________________

1. Have you had low back pain that prevented normal activity for at least 1 day in the past **year**? Y N
2. Have you had low back pain that prevented normal activity for at least 1 day in the past **month**? Y N
3. How many days a week do you wear your prosthesis? _________ Days
4. How many hours a day do you wear your prosthesis? _________ Hours
5. Do you have any other diseases or disabilities listed below? (Please tick all that apply)

☐ Diabetes mellitus

☐ Sensation disorders of the legs (neuropathy)

☐ Cardiovascular diseases
  a. ☐ high blood pressure,
  b. ☐ cardiac insufficiency,
  c. ☐ coronary vessel diseases,
  d. ☐ other: ____________________________________________

☐ Circulatory disturbances of the legs

☐ Artificial hip joint: Where? ☐ amputated leg
  i. ☐ sound leg
  ii. ☐ both legs

☐ Hip problems: Where? ☐ amputated leg
  iii. ☐ sound leg
  iv. ☐ both legs

☐ Paralysis (if yes, what kind? [e. g. hemiplegia after a stroke]):
______________________________________________________________________
______________________________________________________________________

**Please Turn Over**

5 (Continued).

☐ Other amputations (if yes, what kind?)

______________________________________________________________________

______________________________________________________________________

______________________________________________________________________

☐Other diseases or disabilities (if yes, what kind?

______________________________________________________________________

______________________________________________________________________

______________________________________________________________________

6. On the drawings please indicate the level of your amputation by shading in the amputated limb

7. On the drawings please indicate where you are experiencing pain (if any) or any other symptoms by drawing the appropriate symbol(s) on the diagrams that most accurately reflect the type of discomfort you have been feeling.

   Numbness ===

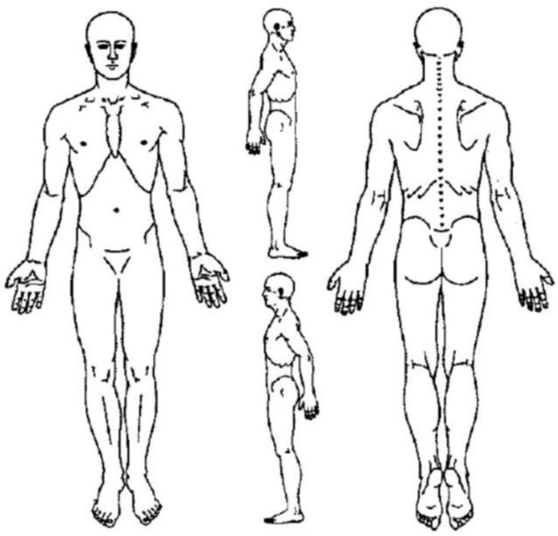
   Tingling OOO

   Dull Pain VVV

   Sharp pain ///

   Burning XXX

   Stiffness ###



| |
|---|
| Chief investigator to sign below once content has been acknowledged:<br><br>…………………………………….. |

## A.XIII Detailed participant characteristics

All participants were male to exclude gender bias and abided by the inclusion/exclusion criteria of their study (Section 3.2.2.1 for control population and Section 4.3.2 for amputee population)

**Table 42. Preliminary control population demographics for data analysed in Chapter 3**

| Participant Identifier | Age | BMI |
|---|---|---|
| **NS022** | 25 | 23 |
| **RS035** | 31 | 22 |
| **NS010** | 32 | 23 |
| **NS027** | 39 | 26 |
| **NS017** | 46 | 30 |
| **NS019** | 51 | 24 |
| **RS004** | 54 | 22 |
| **NS004** | 59 | 26 |
| **NS007** | 65 | 27 |
| **RS008** | 66 | 27 |

**Table 43. Control population demographics for comparison to amputee participants**

| Participant Identifier | Age | BMI |
|---|---|---|
| **NS022** | 25 | 23 |
| **RS035** | 31 | 22 |
| **NS010** | 32 | 23 |
| **NS027** | 39 | 26 |
| **NS017** | 46 | 30 |
| **NS019** | 51 | 24 |
| **RS004** | 54 | 22 |
| **NS004** | 59 | 26 |
| **RS049** | 35 | 28 |
| **RS048** | 46 | 25 |
| **RS069** | 49 | 23 |
| **RS045** | 58 | 27 |

**Table 44. Amputee population demographics**

| Participant Identifier | Age | BMI | Time since amputation | Leg length (cm) Left | Leg length (cm) Right | Side of amputation | LLD* (cm) | Level of scoliosis | Suspension style |
|---|---|---|---|---|---|---|---|---|---|
| **AS01** | 59 | 29.7 | 5.4 | 80.2 | 80.6 | Right | 0.4 | Slight right | Pin lock & gel liner |
| **AS02** | 49 | 21.0 | 29.3 | 93 | 80 | Right | -13.0 | Slight right | Pin lock & gel liner |
| **AS03** | 57 | 25.0 | 19.9 | 100 | 95 | Right | -5.0 | Slight right | Supracondylar sleeve & cloth liner |
| **AS04** | 48 | 31.3 | 2.3 | 93 | 93.5 | Right | 0.5 | None | Supracondylar sleeve & gel liner |
| **AS05** | 51 | 26.6 | 26.1 | 99 | 94 | Left | 5.0 | Slight right | Supracondylar sleeve & gel liner |
| **AS07** | 45 | 28.4 | 27.3 | 100.5 | 95 | Left | 5.5 | None | Pin lock & gel liner |
| **AS08** | 42 | 32.6 | 3.8 | 92 | 94 | Right | 2.0 | None | Suction & gel liner |
| **AS09** | 34 | 28.1 | 2.8 | 93 | 99 | Left | -6.0 | Slight left | Supracondylar sleeve & gel liner |
| **AS10** | 27 | 29.1 | 24.8 | 93 | 99 | Right | 6.0 | None | Gel liner (long residual limb) |
| **AS11** | 36 | 24.8 | 5.1 | 100 | 94.5 | Right | -5.5 | Slight right | Suction + gel liner |
| **AS12** | 34 | 29.2 | 4.4 | 84.5 | 85 | Left | -0.5 | Very slight Left | Pin lock + gel liner |
| **AS13** | 53 | 32.5 | 24.8 | 82 | 84 | Right | 2.0 | Slight left | Supracondylar strap & cloth liner |

* Limb length discrepancy (LLD) is given as positive if the ipsilateral limb is longer than the contralateral limb.

**Table 45. Results of amputee questionnaire**

| | |
|---|---|
| Right amputee | 8/12 |
| Low back pain in the previous year | 3/12 |
| Low back pain in the previous month | 2/12 |
| Usage of prosthesis (days per week) | 7 (0 IQR)** |
| Usage of prosthesis (hours per day) | 13.4 (3.5 SD)* |
| | |
| **Other diseases** | |
| Diabetes mellitus | 1/12 |
| Sensation disorders of the legs | 1/12 |
| **Cardiovascular diseases** | |
| High blood pressure | 1/12 |
| Cardiac insufficiency | 0/12 |
| Coronary vessel diseases | 0/12 |
| Other | 2/12 |
| | |
| Circulatory disturbances of the legs | 0/12 |
| | |
| Artificial hip joint: amputated leg | 1/12 |
| Artificial hip joint: Sound leg | 0/12 |
| Artificial hip joint: both legs | 0/12 |
| | |
| Hip problems: amputated leg | 0/12 |
| Hip problems: Sound leg | 1/12 |
| Hip problems: both legs | 0/12 |
| | |
| Paralysis | 0/12 |
| | |
| Other amputations | 1/12 |
| | |
| Other diseases or disabilities | 4/12 |

* normally distributed

** non-normally distributed

SD = Standard deviation, given alongside mean

IQR = Interquartile range, given alongside median

Further explanations of the questionnaire results are given bellow.

Of the two participants who reported cardiovascular diseases other than those listed; one reported having high cholesterol and the other atrial fibrillation.

One participant reported having had toes 4&5 of the contralateral limb foot amputated

Four participants reported having ‘other diseases or disabilities’, these were:

- Arthritis in Contra hip
- chronic obstructive airways disease
- Retinopathy - registered blind & Chronic Kidney Disease - stage 3
- Damage Vertebrae L3-L5 (note: inspection of fluoroscopy sequences and motion analysis graphs did not reveal anything abnormal)

A.XIV Inter-vertebral symmetry among amputees and a control population

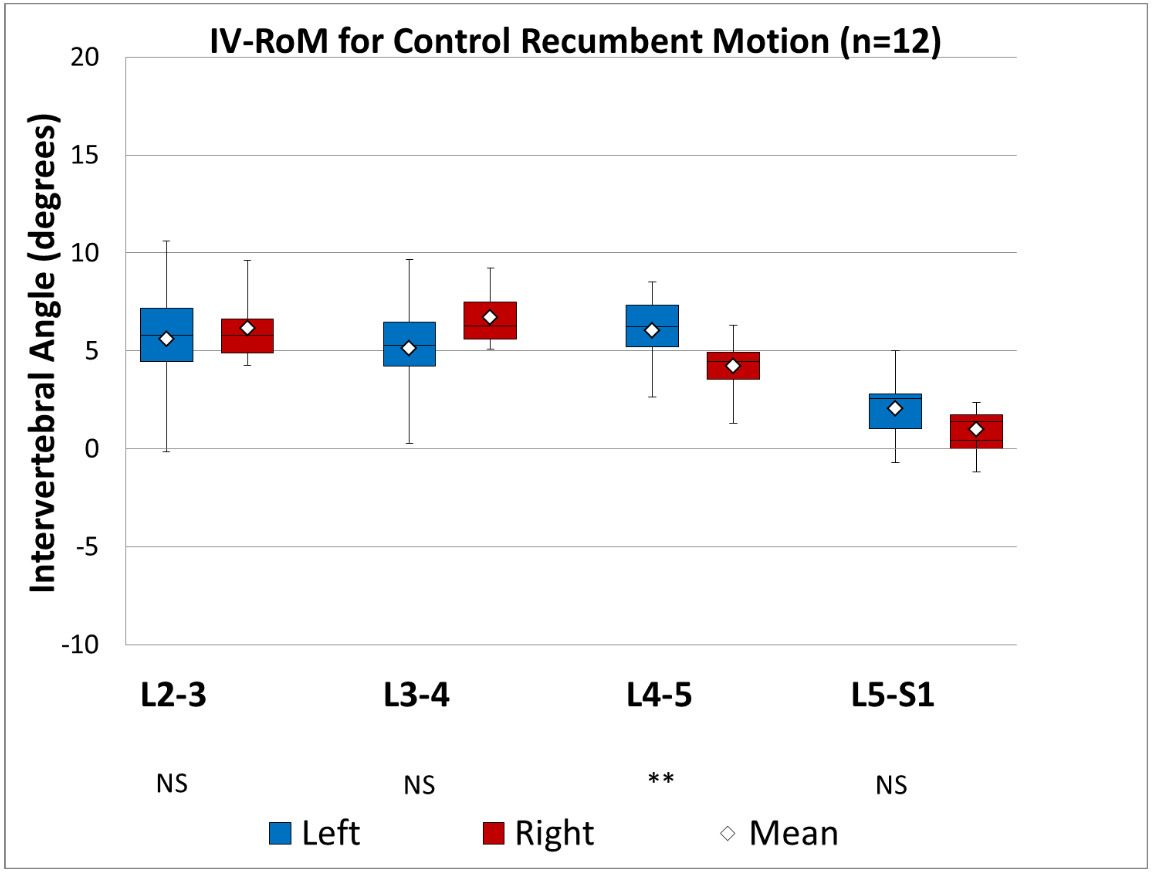



**Figure 59: Box plot comparison between angular ranges of motion during left and right bending recumbent protocols**
**Explanations of the box plot graphs can be found in Appendix A.I “*Explanation of box plots*” page 209**

NS=p>0.05, * = 0.01<p<0.05, **= 0.001<p0.01, ***= p<0.001

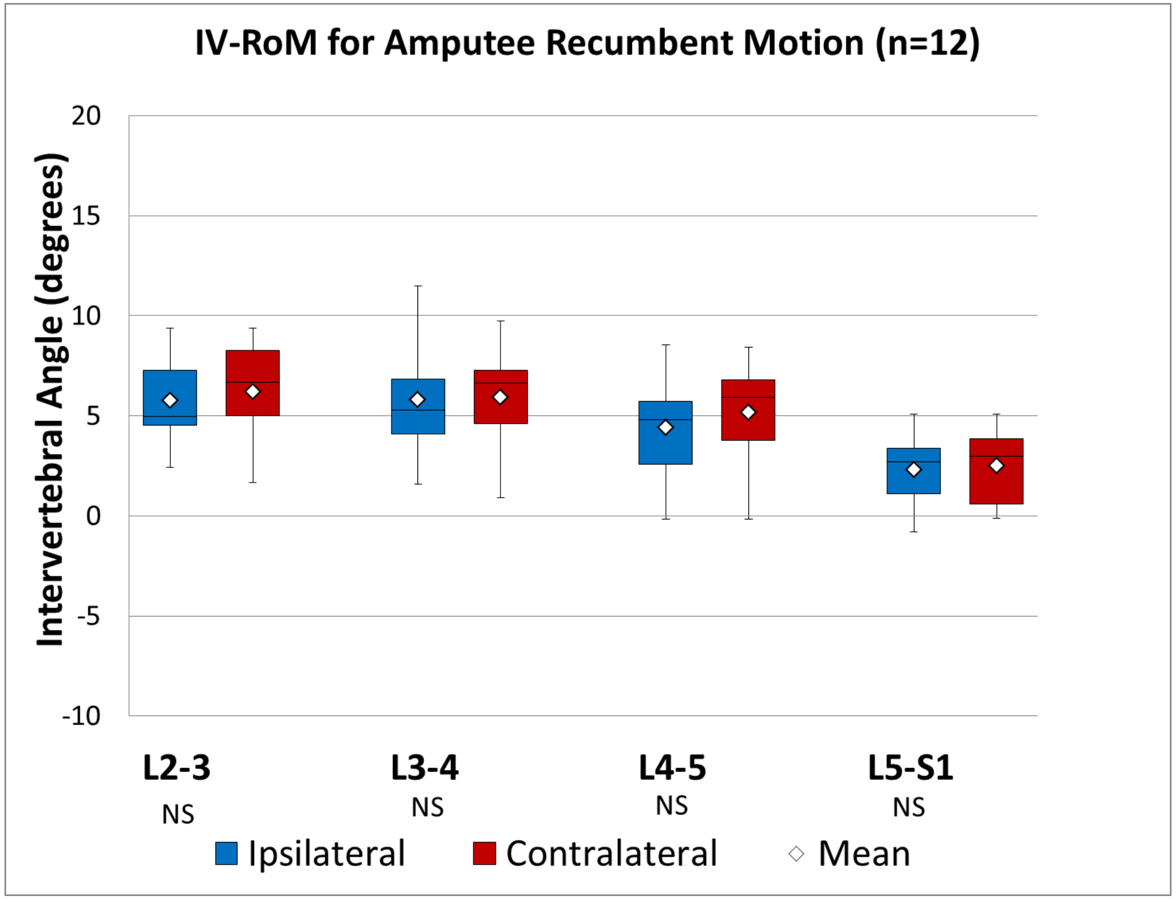



**Figure 60: Box plot comparison between angular ranges of motion during recumbent protocols while bending ipsilaterally and contralaterally to amputation**

NS=p>0.05, * = 0.01<p<0.05, **= 0.001<p0.01, ***= p<0.001

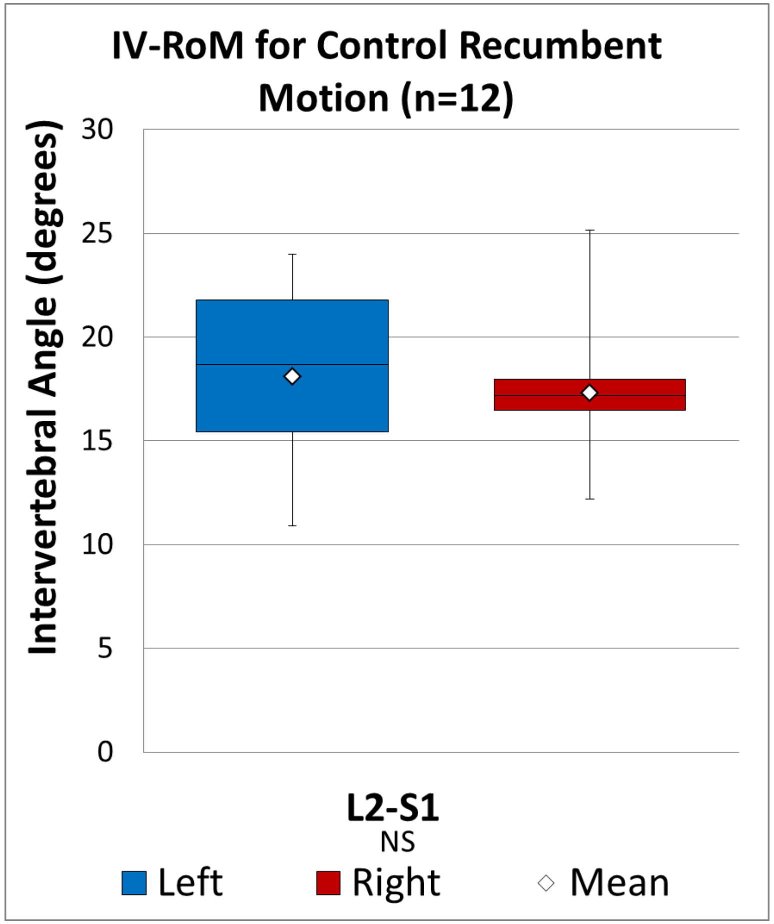



**Figure 61: Box plot comparison between the angular range of the lumbar spine (L2-S1) during recumbent protocols while bending left and right NS=p>0.05**
**Explanations of the box plot graphs can be found in Appendix A.I "*Explanation of box plots*" page 209**

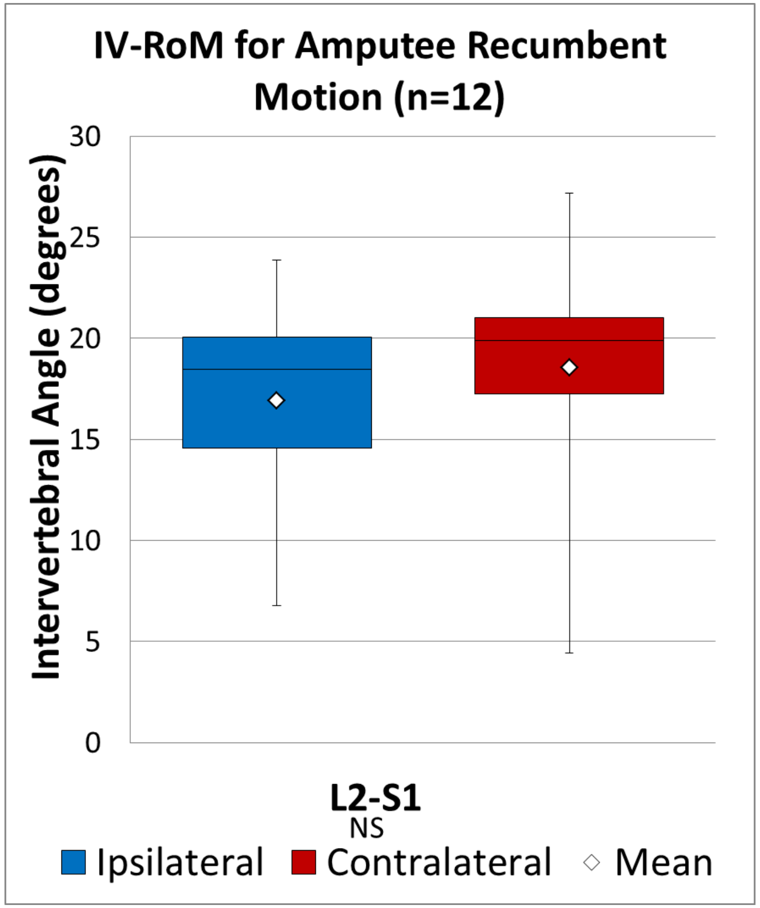



**Figure 62: Box plot comparison between the angular range of the lumbar spine (L2-S1) during recumbent protocols while bending ipsilaterally and contralaterally to amputation**
**NS=p>0.05**

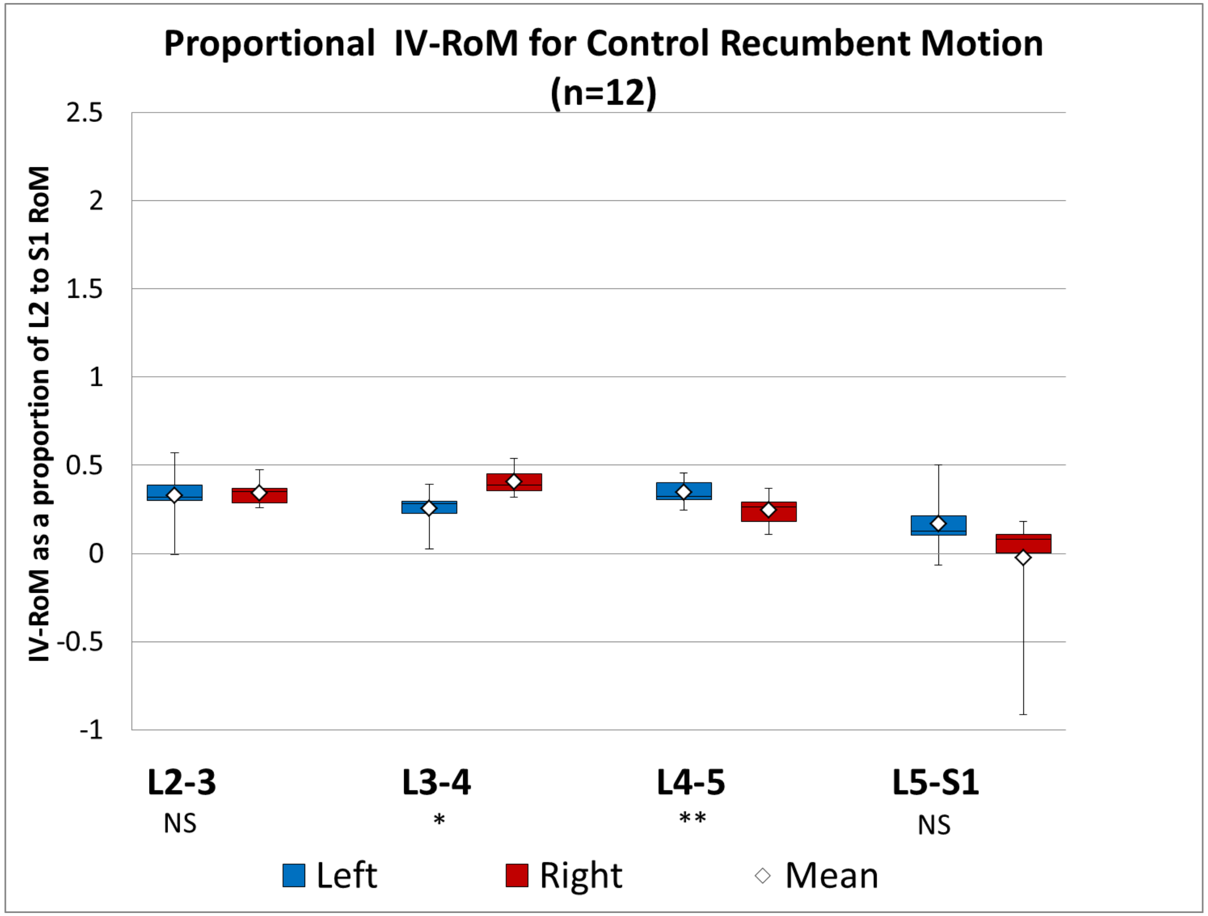



**Figure 63: Box plot comparison between ranges of motion at the inter-vertebral level as a proportion of the whole lumbar spine (L2-S1) during left and right bending recumbent protocols**
**Explanations of the box plot graphs can be found in Appendix A.I "*Explanation of box plots*" page 209**

NS=p>0.05, * = 0.01<p<0.05, **= 0.001<p0.01, ***= p<0.001

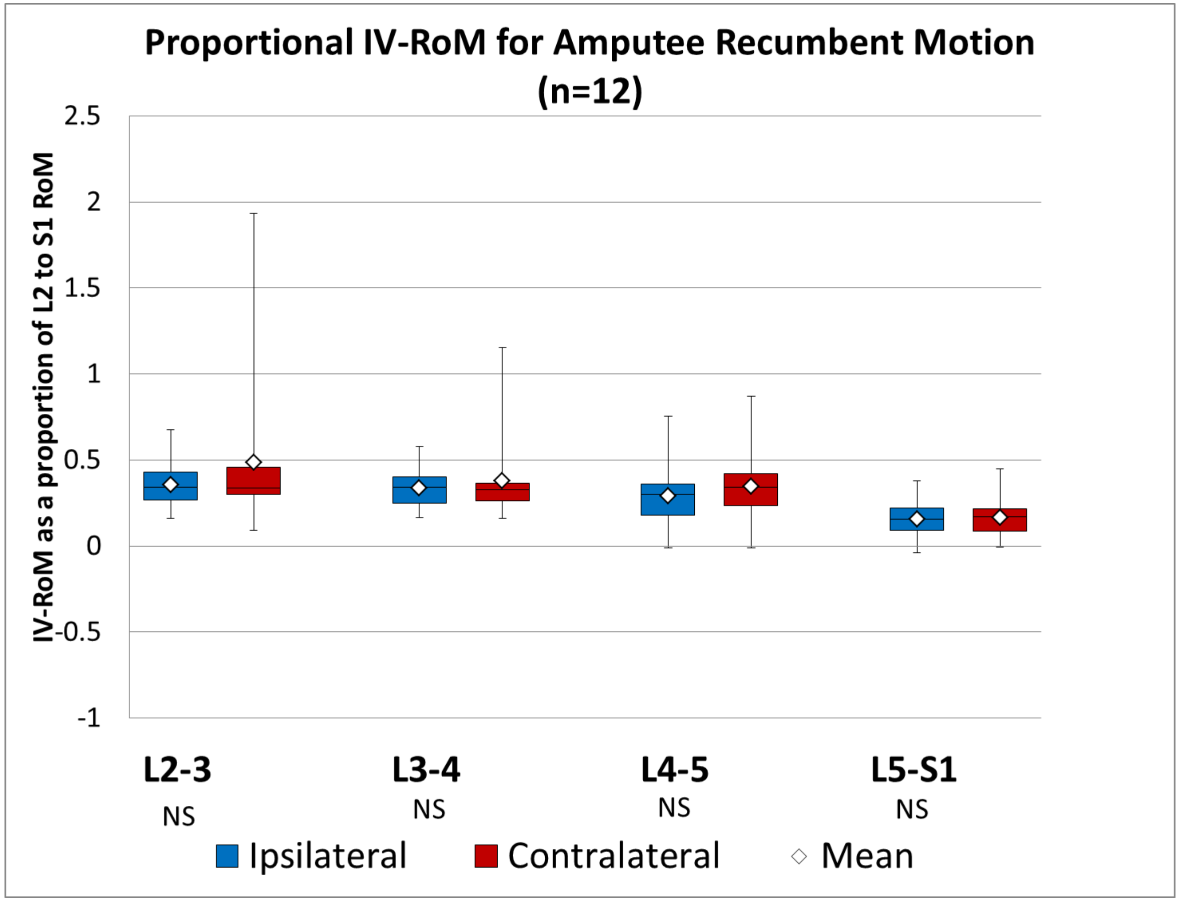



**Figure 64: Box plot comparison between ranges of motion at the inter-vertebral level as a proportion of the whole lumbar spine (L2-S1) while bending ipsilaterally and contralaterally to amputation during recumbent protocols**
**Explanations of the box plot graphs can be found in Appendix A.I "*Explanation of box plots*" page 209**

NS=p>0.05, * = 0.01<p<0.05, **= 0.001<p0.01, ***= p<0.001

## A.XV IV-ROM from start of motion median ranges

**Table 46. Differences in coronal plane IV-ROM from the start of motion between directions of movement**

| | Amputee | | | | Control | | | |
|---|---|---|---|---|---|---|---|---|
| | Ipsilateral (Median) | Contralateral (Median) | Median diff. | p* | Left (Median) | Right (Median) | Median diff. | p* |
| **L2-L3** | 6.0 | 7.1 | -0.4 | 0.380 | 6.9 | 5.7 | 0.9 | 0.009* |
| **L3-L4** | 6.2 | 6.5 | 0.1 | 0.910 | 7.3 | 6.6 | 0.3 | 0.519 |
| **L4-L5** | 6.7 | 6.8 | -0.8 | 0.064 | 6.1 | 6.4 | -0.2 | 0.569 |
| **L5-S1** | 1.6 | 1.5 | 0.2 | 0.519 | 1.0 | 0.6 | 0.0 | 0.970 |
| | | | | | | | | |
| **L2-S1** | 18.5 | 18.7 | 0.0 | 0.970 | 19.9 | 17.9 | 1.9 | 0.110 |

*2-sided Wilcoxon's signed ranks test

**Table 47. Differences in amputee coronal plane IV-ROM from the start of motion between directions of movement**

| | Left (Median) | Right (Median) | Median diff. | p* |
|---|---|---|---|---|
| **L2-L3** | 7.1 | 6.0 | 0.4 | 0.380 |
| **L3-L4** | 6.5 | 6.3 | 0.3 | 0.470 |
| **L4-L5** | 6.5 | 6.8 | 0.1 | 0.850 |
| **L5-S1** | 1.6 | 1.4 | 0.2 | 0.519 |
| ***2-sided Wilcoxon's signed ranks test** | | | | |

# A.XVI Correlations of IV-ROM from start of motion, both within and between levels and within and between bending directions

**Table 48. Spearman's rho correlations of IV-ROM within and between levels among the amputee population while moving ipsilaterally and contralaterally to amputation (n=12 for all cases)**

| | | | **Amputee ipsilateral motion** | | | | **Amputee contralateral motion** | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | **L2-L3** | **L3-L4** | **L4-L5** | **L5-S1** | **L2-L3** | **L3-L4** | **L4-L5** | **L5-S1** |
| **Amputee ipsilateral motion** | **L2-L3** | Correlation Coefficient | | .483 | -.028 | .420 | .755 | 0.259 | -.357 | .161 |
| | | *Sig. (2-tailed)* | | *.112* | *.931* | *.175* | *0.005***** | *.417* | *.255* | *.618* |
| | **L3-L4** | Correlation Coefficient | >>> | | .483 | -.035 | .434 | 0.902 | .273 | -.189 |
| | | *Sig. (2-tailed)* | >>> | | *.112* | *.914* | *.159* | *0.000****** | *.391* | *.557* |
| | **L4-L5** | Correlation Coefficient | >>> | >>> | | -.692 | -.035 | .531 | .566 | -.615 |
| | | *Sig. (2-tailed)* | >>> | >>> | | *0.013** | *.914* | *0.075~* | *0.055~* | *0.033** |
| | **L5-S1** | Correlation Coefficient | >>> | >>> | >>> | | .490 | -.266 | -.587 | .811 |
| | | *Sig. (2-tailed)* | >>> | >>> | >>> | | *.106* | *.404* | *0.045** | *0.001** |
| **Amputee contralateral motion** | **L2-L3** | Correlation Coefficient | >>> | >>> | >>> | >>> | | .294 | -.294 | .294 |
| | | *Sig. (2-tailed)* | >>> | >>> | >>> | >>> | | *.354* | *.354* | *.354* |
| | **L3-L4** | Correlation Coefficient | >>> | >>> | >>> | >>> | >>> | | .378 | -.280 |
| | | *Sig. (2-tailed)* | >>> | >>> | >>> | >>> | >>> | | *.226* | *.379* |
| | **L4-L5** | Correlation Coefficient | >>> | >>> | >>> | >>> | >>> | >>> | | -.678 |
| | | *Sig. (2-tailed)* | >>> | >>> | >>> | >>> | >>> | >>> | | *0.015** |
| | **L5-S1** | Correlation Coefficient | >>> | >>> | >>> | >>> | >>> | >>> | >>> | |
| | | *Sig. (2-tailed)* | >>> | >>> | >>> | >>> | >>> | >>> | >>> | |

***** = Correlation is significant at the 0.001 level (2-tailed).**
**** = Correlation is significant at the 0.01 level (2-tailed).**
*** = Correlation is significant at the 0.05 level (2-tailed).**
**~ = Correlation is significant at the 0.10 level (2-tailed).**

**= positive, significant correlation**
**= negative, significant correlation**
**= significant correlation at the same inter-vertebral level**

Table 49. Spearman's rho correlations of IV-ROM within and between levels among the amputee population while moving left and right (n=12 for all cases)

| | | | **Amputee left motion** | | | | **Amputee right motion** | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | **L2-L3** | **L3-L4** | **L4-L5** | **L5-S1** | **L2-L3** | **L3-L4** | **L4-L5** | **L5-S1** |
| **Amputee left motion** | **L2-L3** | Correlation Coefficient | | -.343 | .294 | -.503 | .762 | .420 | -.056 | .357 |
| | | *Sig. (2-tailed)* | | .276 | .354 | 0.095~ | 0.004** | .175 | -.863 | -.255 |
| | **L3-L4** | Correlation Coefficient | >>> | | -.420 | .042 | .301 | .881 | .371 | -.189 |
| | | *Sig. (2-tailed)* | >>> | | .175 | .897 | .342 | 0.000*** | .236 | .557 |
| | **L4-L5** | Correlation Coefficient | >>> | >>> | | .678 | -.294 | .399 | .629 | -.755 |
| | | *Sig. (2-tailed)* | >>> | >>> | | 0.015* | -.354 | .199 | 0.028* | 0.005** |
| | **L5-S1** | Correlation Coefficient | >>> | >>> | >>> | | -.112 | -.259 | -.552 | .867 |
| | | *Sig. (2-tailed)* | >>> | >>> | >>> | | .729 | -.417 | 0.063~ | 0.000*** |
| **Amputee right motion** | **L2-L3** | Correlation Coefficient | >>> | >>> | >>> | >>> | | -.469 | -.049 | -.133 |
| | | *Sig. (2-tailed)* | >>> | >>> | >>> | >>> | | .124 | .880 | -.681 |
| | **L3-L4** | Correlation Coefficient | >>> | >>> | >>> | >>> | >>> | | -.538 | -.322 |
| | | *Sig. (2-tailed)* | >>> | >>> | >>> | >>> | >>> | | 0.071~ | .308 |
| | **L4-L5** | Correlation Coefficient | >>> | >>> | >>> | >>> | >>> | >>> | | .720 |
| | | *Sig. (2-tailed)* | >>> | >>> | >>> | >>> | >>> | >>> | | 0.008** |
| | **L5-S1** | Correlation Coefficient | >>> | >>> | >>> | >>> | >>> | >>> | >>> | |
| | | *Sig. (2-tailed)* | >>> | >>> | >>> | >>> | >>> | >>> | >>> | |

***** = Correlation is significant at the 0.001 level (2-tailed).**
**** = Correlation is significant at the 0.01 level (2-tailed).**
*** = Correlation is significant at the 0.05 level (2-tailed).**
**~ = Correlation is significant at the 0.10 level (2-tailed).**

**= positive, significant correlation**
**= negative, significant correlation**
**= significant correlation at the same inter-vertebral level**

Table 50. Spearman's rho correlations of IV-ROM within and between levels among the control population while moving left and right (n=12 for all cases)

| | | | **Control left motion** | | | | **Control right motion** | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | **L2-L3** | **L3-L4** | **L4-L5** | **L5-S1** | **L2-L3** | **L3-L4** | **L4-L5** | **L5-S1** |
| **Control left motion** | **L2-L3** | Correlation Coefficient | | .210 | -.035 | .322 | .727 | .427 | .280 | -.573 |
| | | *Sig. (2-tailed)* | | *.513* | *.914* | *.308* | *0.007*** | *.167* | *.379* | *0.051~* |
| | **L3-L4** | Correlation Coefficient | >>> | | .000 | .231 | .091 | .413 | -.231 | .014 |
| | | *Sig. (2-tailed)* | >>> | | *1.000* | *.471* | *.779* | *.183* | *.471* | *.966* |
| | **L4-L5** | Correlation Coefficient | >>> | >>> | | -.140 | .182 | .420 | .699 | .154 |
| | | *Sig. (2-tailed)* | >>> | >>> | | *.665* | *.572* | *.175* | *0.011** | *.633* |
| | **L5-S1** | Correlation Coefficient | >>> | >>> | >>> | | -.273 | -.098 | -.315 | .734 |
| | | *Sig. (2-tailed)* | >>> | >>> | >>> | | *.391* | *.762* | *.319* | *0.007*** |
| **Control right motion** | **L2-L3** | Correlation Coefficient | >>> | >>> | >>> | >>> | | -.510 | -.119 | .497 |
| | | *Sig. (2-tailed)* | >>> | >>> | >>> | >>> | | *0.090~* | *.713* | *.101* |
| | **L3-L4** | Correlation Coefficient | >>> | >>> | >>> | >>> | >>> | | -.322 | .336 |
| | | *Sig. (2-tailed)* | >>> | >>> | >>> | >>> | >>> | | *.308* | *.286* |
| | **L4-L5** | Correlation Coefficient | >>> | >>> | >>> | >>> | >>> | >>> | | .196 |
| | | *Sig. (2-tailed)* | >>> | >>> | >>> | >>> | >>> | >>> | | *.542* |
| | **L5-S1** | Correlation Coefficient | >>> | >>> | >>> | >>> | >>> | >>> | >>> | |
| | | *Sig. (2-tailed)* | >>> | >>> | >>> | >>> | >>> | >>> | >>> | |

***** = Correlation is significant at the 0.001 level (2-tailed).**
**** = Correlation is significant at the 0.01 level (2-tailed).**
*** = Correlation is significant at the 0.05 level (2-tailed).**
**~ = Correlation is significant at the 0.10 level (2-tailed).**

**= positive, significant correlation**
**= negative, significant correlation**
**= significant correlation at the same inter-vertebral level**

# A.XVII Correlations of attainment rate, both within and between levels and within and between bending directions

**Table 51. Spearman's rho correlations of attainment rate within and between levels among the control population while moving left and right (n=12 for all cases)**

| | | | Control left motion | | | | Control right motion | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | L2-L3 | L3-L4 | L4-L5 | L5-S1 | L2-L3 | L3-L4 | L4-L5 | L5-S1 |
| **Control left motion** | **L2-L3** | Correlation Coefficient | | .238 | .182 | -.580* | .888** | .224 | .196 | -.552~ |
| | | *Sig. (2-tailed)* | | .457 | .572 | .048 | .000 | .484 | .542 | .063 |
| | **L3-L4** | Correlation Coefficient | >>> | | -.420 | -.058 | .315 | .790** | -.392 | -.357 |
| | | *Sig. (2-tailed)* | >>> | | .175 | .858 | .319 | .002 | .208 | .255 |
| | **L4-L5** | Correlation Coefficient | >>> | >>> | | .029 | .308 | -.140 | .748** | .049 |
| | | *Sig. (2-tailed)* | >>> | >>> | | .929 | .331 | .665 | .005 | .880 |
| | **L5-S1** | Correlation Coefficient | >>> | >>> | >>> | | -.667* | -.312 | .297 | .638* |
| | | *Sig. (2-tailed)* | >>> | >>> | >>> | | .018 | .324 | .348 | .026 |
| **Control right motion** | **L2-L3** | Correlation Coefficient | >>> | >>> | >>> | >>> | | .378 | .070 | -.636* |
| | | *Sig. (2-tailed)* | >>> | >>> | >>> | >>> | | .226 | .829 | .026 |
| | **L3-L4** | Correlation Coefficient | >>> | >>> | >>> | >>> | >>> | | -.196 | -.392 |
| | | *Sig. (2-tailed)* | >>> | >>> | >>> | >>> | >>> | | .542 | .208 |
| | **L4-L5** | Correlation Coefficient | >>> | >>> | >>> | >>> | >>> | >>> | | .217 |
| | | *Sig. (2-tailed)* | >>> | >>> | >>> | >>> | >>> | >>> | | .499 |
| | **L5-S1** | Correlation Coefficient | >>> | >>> | >>> | >>> | >>> | >>> | >>> | |
| | | *Sig. (2-tailed)* | >>> | >>> | >>> | >>> | >>> | >>> | >>> | |

***** = Correlation is significant at the 0.001 level (2-tailed).**
**** = Correlation is significant at the 0.01 level (2-tailed).**
*** = Correlation is significant at the 0.05 level (2-tailed).**
**~ = Correlation is significant at the 0.10 level (2-tailed).**

**= positive, significant correlation**
**= negative, significant correlation**
**= significant correlation at the same inter-vertebral level**

**Table 52. Spearman's rho correlations of attainment rate within and between levels among the amputee population while moving ipsilaterally and contralaterally to amputation (n=12 for all cases)**

| | | | Amputee ipsilateral motion | | | | Amputee contralateral motion | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | **L2-L3** | **L3-L4** | **L4-L5** | **L5-S1** | **L2-L3** | **L3-L4** | **L4-L5** | **L5-S1** |
| **Amputee ipsilateral motion** | **L2-L3** | Correlation Coefficient | | -.210 | -.643* | .476 | .923** | -.154 | -.657* | .515~ |
| | | *Sig. (2-tailed)* | | .513 | .024 | .118 | .000 | .633 | .020 | .087 |
| | **L3-L4** | Correlation Coefficient | >>> | | .748** | -.378 | -.427 | .860** | .510~ | -.455 |
| | | *Sig. (2-tailed)* | >>> | | .005 | .226 | .167 | .000 | .090 | .137 |
| | **L4-L5** | Correlation Coefficient | >>> | >>> | | -.545~ | -.706* | .552~ | .755** | -.662* |
| | | *Sig. (2-tailed)* | >>> | >>> | | .067 | .010 | .063 | .005 | .019 |
| | **L5-S1** | Correlation Coefficient | >>> | >>> | >>> | | .455 | -.098 | -.238 | .900** |
| | | *Sig. (2-tailed)* | >>> | >>> | >>> | | .138 | .762 | .457 | .000 |
| **Amputee contralateral motion** | **L2-L3** | Correlation Coefficient | >>> | >>> | >>> | >>> | | -.392 | -.811** | .567~ |
| | | *Sig. (2-tailed)* | >>> | >>> | >>> | >>> | | .208 | .001 | .054 |
| | **L3-L4** | Correlation Coefficient | >>> | >>> | >>> | >>> | >>> | | .497 | -.270 |
| | | *Sig. (2-tailed)* | >>> | >>> | >>> | >>> | >>> | | .101 | .397 |
| | **L4-L5** | Correlation Coefficient | >>> | >>> | >>> | >>> | >>> | >>> | | -.438 |
| | | *Sig. (2-tailed)* | >>> | >>> | >>> | >>> | >>> | >>> | | .155 |
| | **L5-S1** | Correlation Coefficient | >>> | >>> | >>> | >>> | >>> | >>> | >>> | |
| | | *Sig. (2-tailed)* | >>> | >>> | >>> | >>> | >>> | >>> | >>> | |

***** = Correlation is significant at the 0.001 level (2-tailed).**
**** = Correlation is significant at the 0.01 level (2-tailed).**
*** = Correlation is significant at the 0.05 level (2-tailed).**

**= positive, significant correlation**
**= negative, significant correlation**
**= significant correlation at the same inter-vertebral level**

**Table 53. Spearman's rho correlations of attainment rate within and between levels among the amputee population while moving left and right (n=12 for all cases)**

| | | | Amputee left motion | | | | Amputee right motion | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | L2-L3 | L3-L4 | L4-L5 | L5-S1 | L2-L3 | L3-L4 | L4-L5 | L5-S1 |
| **Amputee left motion** | **L2-L3** | Correlation Coefficient | | -.392 | -.811** | .567~ | .972** | -.413 | -.797** | .503~ |
| | | *Sig. (2-tailed)* | | .208 | .001 | .054 | .000 | .183 | .002 | .095 |
| | **L3-L4** | Correlation Coefficient | >>> | | .497 | -.270 | -.308 | .944** | .678* | -.196 |
| | | *Sig. (2-tailed)* | >>> | | .101 | .397 | .331 | .000 | .015 | .542 |
| | **L4-L5** | Correlation Coefficient | >>> | >>> | | -.438 | -.825** | .510~ | .867** | -.259 |
| | | *Sig. (2-tailed)* | >>> | >>> | | .155 | .001 | .090 | .000 | .417 |
| | **L5-S1** | Correlation Coefficient | >>> | >>> | >>> | | .483 | -.305 | -.613* | .921** |
| | | *Sig. (2-tailed)* | >>> | >>> | >>> | | .111 | .336 | .034 | .000 |
| **Amputee right motion** | **L2-L3** | Correlation Coefficient | >>> | >>> | >>> | >>> | | -.301 | -.741** | .420 |
| | | *Sig. (2-tailed)* | >>> | >>> | >>> | >>> | | .342 | .006 | .175 |
| | **L3-L4** | Correlation Coefficient | >>> | >>> | >>> | >>> | >>> | | .713** | -.287 |
| | | *Sig. (2-tailed)* | >>> | >>> | >>> | >>> | >>> | | .009 | .366 |
| | **L4-L5** | Correlation Coefficient | >>> | >>> | >>> | >>> | >>> | >>> | | -.483 |
| | | *Sig. (2-tailed)* | >>> | >>> | >>> | >>> | >>> | >>> | | .112 |
| | **L5-S1** | Correlation Coefficient | >>> | >>> | >>> | >>> | >>> | >>> | >>> | |
| | | *Sig. (2-tailed)* | >>> | >>> | >>> | >>> | >>> | >>> | >>> | |

***** = Correlation is significant at the 0.001 level (2-tailed).**
**** = Correlation is significant at the 0.01 level (2-tailed).**
*** = Correlation is significant at the 0.05 level (2-tailed).**

**= positive, significant correlation**
**= negative, significant correlation**
**= significant correlation at the same inter-vertebral level**

**Table 54. Fisher's exact test of the significance of the association between the presence of a unilateral below knee amputation and the number of correlations significant at the 10% level between inter-vertebral levels attainment rate**

| Amputee | Control | Total | Correlation |
|---|---|---|---|
| **11** | 4 | 15 | **p<0.1** |
| **13** | 20 | 33 | **p>0.1** |
| **24** | 24 | 48 | **Total** |