

SUPPORTED TREADMILL WALKING FOR LOW BACK PAIN PATIENTS: A BIOMECHANICAL RANDOMISED CONTROLLED TRIAL

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Bioengineering Unit University of Strathclyde October 2011 Glasgow

DECLARATION

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ABSTRACT

Background: Low back pain (LBP) is one of the commonest health conditions in industrialized societies affecting people of all ages. Despite the numerous conservative, surgical and alternative therapies, there is not an effective and widely accepted therapy for this disease. Thus, there is a need for high quality randomized controlled trials to investigate potential therapies and shed light on the mechanism of LBP.

Aims: The purposes of this thesis were twofold. The first aim was to develop and validate a technique for the measurement of the spinal range of motion (ROM) which can be used in clinical settings. The second and main aim was to investigate the effects of partial body weight supported treadmill walking on people with LBP (biomechanical effects and pain status) and compare these with asymptomatic people.

Methods: The test-retest reliability and the validity of Polhemus Liberty were concurrently examined with Vicon system on two spinal movement simulation rigs and on ten healthy volunteers. Nineteen LBP patients and twenty one healthy volunteers took part in the randomized control trial which aimed to assess the biomechanical effects and pain levels of 40% body weight supported treadmill walking.

Results: Polhemus Liberty is a valid and reliable system for the measurement of the spinal ROM. However, with the proposed sensor attachment technique the accurate measurement of spinal axial rotation is limited to $\pm 80^{\circ}$. 40% body weight supported treadmill walking does not cause any significant changes when compared to conventional walking in spinal length and spinal ROM in LBP patients or asymptomatic people. However, it prevents further pain exacerbations and reduces peak spinal frequencies related to the walking frequency in LBP patients.

Conclusions: This study showed that Polhemus is a valid and reliable system for multisegmental spinal ROM measurements when it is operated under certain conditions. Supported treadmill walking it is unlikely to cause any significant changes in the spinal length, ROM or clinical condition of LBP patients, but it could prevent pain exacerbations during walking exercise on a treadmill. LBP patients have significantly less spinal ROM than asymptomatic people.

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CHAPTER 1 INTRODUCTION TO THE STUDY

1.1 BACKGROUND

The human spine is a complex structure which plays a crucial role in maintaining the upright position of the human body and also in the protection of the spinal cord which is part of the central nervous system. The normal functioning of the spine is a prerequisite for physiological function and activities of daily living.

Due to the complexity of spine structure, the etiology of potential problems is often not easily defined and commonly therapeutic interventions cannot be clearly indicated. In addition, there is a gap in knowledge regarding the underlying mechanisms of many spinal problems and that constitutes an additional difficulty in the decision making process and the selection of appropriate treatments.

A common spinal problem in industrialized societies worldwide is low back pain (LBP) which has major biological, social, psychological, and financial implications. Low back pain may be the result of an injury or dysfunction of different structures such as: muscles, fascias, nerve roots, intervertebral discs, vertebras, ligaments etc. In addition social and psychological factors frequently play a crucial role in the development and maintenance of LBP. Usually, a combination of injuries and psychosocial factors may coexist and this is another feature which makes diagnosis and subsequent treatment ambiguous.

Although the majority of the low back pain problems resolve within the first weeks after the onset, a considerable percentage progress to chronic pain which continues to affect the normal everyday living of those affected for long periods of time (Croft *et al.*, 1998; Dunn & Croft, 2004). However, there is no clear evidence for the etiology of who will become chronic and who will not.

For the treatment of this disease numerous strategies consisting of conservative and invasive techniques exist and are employed by different health professionals such as, spinal surgeons, physiotherapists, manual therapists, osteopaths, alternative therapists etc. Despite the matrix of available therapies in the health care community there is little consensus or sound scientific evidence to support the use of any of these interventions.

Typically, due to uncertain diagnosis the treatments for LBP are focused on alleviating the symptoms instead of targeting the underlying cause of pain. The most common conservative treatment approaches include general exercise therapy (Hayden et al., 2005; Van Middelkoop et al., 2010) or more targeted interventions such as spinal manipulation aiming to increase the mobility of hypo-mobile spinal regions (Rubinstein et al., 2011; Walker et al., 2011). Similarly, other specific conventional interventions such as core stability exercises aim to activate and strengthen the abdominal and back muscles in order to stabilize hyper-mobile regions and treat or prevent recurrences of LBP (Akuthota et al., 2008). Other conservative treatments involve the use of massage therapy and transcutaneous electrical nerve stimulation (Visintin et al.), low level laser therapy, back school, education, behavior treatment, traction, back supports, heat/cold therapy, multidisciplinary approaches, etc (Van Middelkoop et al., 2011). Pharmacological interventions involve the use of non-steroid anti-inflammatory drugs (NSAIDs), muscle relaxants, antidepressant and opioids (Kuijpers et al., 2011). Minimally invasive treatments involve epidural and facet joint corticosteroid injections, spinal nerve blocking procedures as well as acupuncture (Yuan et al., 2008; Datta et al., 2009; Staal et al., 2009; Lewis & Abdi, 2010). More invasive treatments involve surgical techniques such as microdiscectomy, spinal fusion, laminectomy as well as total disc replacement (Freeman & Davenport, 2006; Chou et al., 2009; Van Den Eerenbeemt et al., 2010). Usually, more invasive interventions are reserved for the treatment of disc and vertebrae pathologies whereas less invasive and conservative interventions are used in non specific LBP.

None of the aforementioned invasive or conservative interventions for LBP are widely accepted or supported from sound evidence. The majority of high quality systematic reviews which attempted to investigate those issues are inconclusive or report some indications for particular interventions based on poor quality data. Thus, there is a clear need for high quality randomized control studies to shed light on whether current clinical practice is effective or not and propose specific interventions for different types

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of LBP. Regarding the management of non-specific LBP, a recent review summarizing international guidelines reported that LBP patients should remain active and avoid bed rest (Koes *et al.*, 2010). The simplest and most natural activity to remain active is walking. However, the potential therapeutic effects of walking have not yet been proved in LBP. A recent review reported low to moderate quality evidence indicating that overground walking does not have positive effects in the LBP management and poor evidence for the effectiveness of treadmill walking (Hendrick *et al.*, 2010). Due to the poor quality of the available evidence, these authors recommended that walking should be encouraged and also suggested further research to clarify the potential benefits of walking in the management of LBP (Hendrick *et al.*, 2010). Therefore, the current study aims to investigate the biomechanical effects and potential benefits of partial under arm supported and conventional treadmill walking in LBP patients.

The body weight supported treadmill walking technique has been extensively used in the rehabilitation of various neurological conditions. The terms body weight support (BWS) and body weight unloading (BWU) are used interchangeably in the literature to refer to the same walking condition. In this document both terms will be used as well as the term "experimental walking".

In addition, there is a lack of three dimensional, portable and economic motion analysis techniques which can be used in a clinical setting for the assessment and monitoring of the human spinal motion. The systems used to date in the clinical settings are commonly limited in measuring only one segment and in one dimension. Thus, the development of a valid and reliable technique for this purpose constitutes a secondary objective for this study.

Therefore, in this thesis, a study approaching from a biomechanical perspective this very common health condition (LBP) will be presented. The current document consists of seven chapters starting with the introduction chapter, which includes the aim and objectives for this study, and continues with a literature review of relevant topics, in chapter two. Chapter three and four are two methods chapters. Chapter three includes the methodology used as well as the findings and discussion of the validation process of Polhemus Liberty, which was one of the measuring tools in the main study. Chapter four describes the methods used in the main study (randomized controlled trial for the effects of partial unloading treadmill walking in LBP patients). In chapters five and six the findings and the discussion of the main study are presented respectively. The thesis ends up with chapter seven which includes the conclusions and recommendations. A flowchart of the thesis structure is presented below in Figure 1.1.



Figure 1.1 Flowchart of thesis chapter structure.

1.2 PROJECT AIM AND OBJECTIVES

The aims of this thesis were:

To develop a spinal range of motion measurement technique and establish its validity and reliability.

To investigate the relationships between spinal length, shape, range of motion and reported pain status in LBP patients during under-arm supported treadmill walking; and to comment on any potential therapeutic value.

The research aim of the main study was broken down into eight more specific research objectives:

- 1. To investigate the effect of 40% of BWU during 30 minutes of treadmill walking, on the spinal length and shape of patients with LBP.
- 2. To compare the spinal shape and length between LBP patients and healthy people in two different walking conditions (with and without BWU).
- 3. To compare the influence of supported and normal treadmill walking on the range of motion of patients with LBP.
- 4. To investigate the potential pain relieving effects of BWU on patients with LBP and to compare with the control walking condition (without BWU).
- 5. To investigate if pain status changes over time during treadmill walking, with and without BWU.
- 6. To compare the spinal kinematic and gait parameters of the LBP patients with those of healthy people and also during different walking conditions.
- 7. To associate the spinal length, shape, range of motion and reported pain status with quality of life and disability status.
- 8. To provide valuable evidence for further research in the rehabilitation of LBP patients.

CHAPTER 2 LITERATURE REVIEW

2.1 INTRODUCTION

Low Back Pain (LBP) is a condition affecting people not only in modern societies, but it is rather well recognized and described throughout the centuries. The first known text about back pain is the Edwin Smith papyrus which dates back to 1,500 B.C. (Allan & Waddell, 1989). This old Egyptian writing it is incomplete and ends suddenly while describing an acute LBP case. Although it is further described by others (Galen, Hippocrates, Freud), low back pain became an epidemic after Word War II (Allan & Waddell, 1989). Since then, low back pain gained great interest from the research community resulting in thousands of publications on this topic. A simple search with the keyword "Low Back Pain" in a database (PubMed) results in more than 18,000 hints. Despite the extensive historical reference and the modern publicity, LBP remains an ambiguous health condition.

The following chapter presents the literature review on fundamental topics of this thesis. This review focuses on five main topics. Initially, Low Back Pain as an entity will be discussed, with special focus on its socioeconomic impact, natural course and the state of art in terms of therapeutic interventions. Secondly, key aspects of pain and spinal anatomy will be presented, covering issues of: pain definitions and physiology, spine anatomy, mechanical properties of underlying tissues, pathophysiology. In the next two sections, the kinematics and biomechanics of the spine will be explored. Each section ends up with key points for this thesis and the final section is a summary of the chapter in lay terms.

2.2 CHARACTERISTICS OF LBP

2.2.1 Epidemiology & Cost of LBP

Low back pain is a common condition, especially in western societies, which affects both adults and children (Dunn & Croft, 2004; Jones & Macfarlane, 2005; Kent

& Keating, 2005). Approximately one in four adults seeks care in a six month period (Kent & Keating, 2005). Authors use different definitions for LBP and also cost estimation techniques. This makes comparison among epidemiological and cost estimation studies difficult. However, some data for frequency (prevalence) and economic impact will be presented. Prevalence is the proportion of individuals in a known population who have the disease at a given time and lifetime prevalence is the percentage of people who can recall symptoms of a disease at sometime in their life, irrespective if they have it or not now.

In a study conducted in fifteen primary centers in Asia, Africa, Europe and America, it was found that Back Pain is the commonest cause for persistent pain with 47.8% prevalence (Gureje *et al.*, 1998). In this study, persistent pain was defined as pain present for six months or more during the previous year (Table 2.1).

Table 2.1 Anatomical site of pain (based on Gureje et al. 1998)	
Anatomical site	People reported pain (%)
Back pain	47.8
Headache	45.2
Joint pain	41.7
Arm or leg pain	34.3
Chest pain	28.9
Abdominal pain	24.9
Pain elsewhere	11.7

Approximately one-fourth of all adults in the US reported LBP in a three months recall period (Lawrence *et al.*, 2008), with reported annual prevalence of 59% and lifetime prevalence between 65% to 80% (Lawrence *et al.*, 1998; Manchikanti, 2000; Lawrence *et al.*, 2008). A US national study, across all states, reported 31% prevalence during a three months period (Strine & Hootman, 2007). The annual prevalence in the UK was found to be between 36% to 37% (Maniadakis & Gray, 2000). According to a questionnaire study in a Grampian area in UK, back pain was the major cause of chronic

pain with the highest prevalence (16%) (Elliott *et al.*, 1999). In a cross-sectional population based study of 4501 individuals in the Manchester area, one month prevalence of LBP was 35% to 37% with peak prevalence occurring in those aged 45 to 59 years old (Papageorgiou *et al.*, 1995). Similar figures regarding age distribution of LBP prevalence where also described for the USA population (Deyo & Tsui-Wu, 1987).

A common problem which is often combined or confused with LBP is sciatica. A recent study which reviewed the literature regarding this issue, reported considerable variation between studies with sciatica prevalence varying between 1.2% and 43% (Konstantinou & Dunn, 2008). However, this variation was due to different definitions for sciatica and studies involving clinical assessment yielded much lower prevalence compared to self-reported ones. This last point indicates the need for research to work in a framework of clear definitions which are widely accepted and used. Without this framework we are forced to question the credibility of self-reported evidence.

Economic impact on society

The economic burden of low back pain is a very serious issue, especially nowadays with the global economic recession, and the growing need for the national health systems to decrease their expenses. The cost estimation of LBP varies considerably among studies due to different cost estimation techniques used. Interestingly, the evidence indicates a poor relationship between clinical and economic outcomes (Maetzel & Li, 2002). This is obviously due to the limited understanding about LBP and the ineffective interventions employed by the health care services to treat this condition. In 1998 estimates of the overall cost for treatment, employment, and informal care costs, in the UK varied between $\pounds 6.6$ to $\pounds 12.3$ billion (Maniadakis & Gray, 2000). A study taking into account cost estimates from different countries (Table 2.2), reported that the largest proportion of direct costs were for physical therapy (17%), impatient services (17%), pharmacy (13%) and primary care (13%).

				Total cost	Direct Costs		Indirect Cost	
Country	Year	Population	Curre			%		%
			-ncy					
Australia	2001	19.357.954	AUD	9,2 billion	1 billion	11	8,2 billion	89
Belgium	1999	10,182,034	€	1,18 billion	187 million	16	993 million	84
Japan	1994	124,712,000	Yen	6 billion	2,7 billion	45	3,3 billion	55
Jersey	1994	82,000	£				1,3 million	
Korea	1997	45,948,811	Won		349 billion			
Netherlands	1991	15,022,393	\$				4,6 billion	
Netherlands	2002	16,067,754	€	6,4 billion	4,2 billion	66	2,2 billion	34
Sweden	1994	8,730,290	SEK	25 billion	832 million	3	24,2 billion	97
Sweden	1994 –	8,778,461	€	3,34 billion	234 million	7	3,1 billion	93
	5							
Sweden	2001	8,909,128	€	1,86 billion	297 million	16	1,56 billion	84
UK	1998	58,970,119	£	12,3 billion	1,6 billion	13	10,7 billion	87
USA	1995	260,713,585	\$				13,9 billion	
USA	1996	263,814,032	\$		14,7 billion			
USA	1996	263,814,032	\$				18,5 billion	
USA	1996	263,814,032	\$				28,2 billion	
USA	1996	263,814,032	\$		12,2 billion			
USA	1998	270,311,756	\$		90,6 billion			
USA	2002	280,562,489	\$				19,8 billion	
USA	2004	293,027,571	\$				7,4 billion	

Table 2.2 National estimates of total, direct or indirect cost for LBP (Dagenais et al 2008).

The majority of the indirect costs were due to absence from work according to the same study (Dagenais *et al.*, 2008). Specifically, for medication usage in 2001 in Pittsburg health system, half the patients with a primary diagnosis of mechanical LBP used analgesics, with an overall cost of \$1.4 million and men showed a 52% higher usage than women (Vogt *et al.*, 2005). The total cost for LBP in USA for a three months period was \$34 million (Strine & Hootman, 2007). Similarly, the total cost for LBP in Sweden in 2001 was €1.8 billion, with 84% of this estimation to attributed to the indirect costs due to lost productivity (Ekman *et al.*, 2005). The same authors reported that the cost had been quite stable for a period of 10-15 years. Although you could argue that these numbers are inflated, due to the inclusion of the indirect costs, it is still a significant amount of lost resources which obviously have an impact on societies. LBP is therefore of clinical, social and economic importance.

2.2.2 Health, Illness and Disability

According to the World Health Organization (WHO), "health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" (World Health Organization, 1946).

In 1980 the WHO published the International Classification of Impairments, Disabilities and Handicaps (ICIDH) as a classification system regarding the consequences of a disease. This system provided a conceptual framework for disability which was described in three dimensions (impairment, disability and handicap) (WHO, 1980):

- **Impairment**: "Any temporary or permanent loss or abnormality of a body structure or function, whether physiological or psychological. An impairment is a disturbance affecting functions that are essentially mental (memory, consciousness) or sensory, internal organs (heart, kidney), the head, the trunk or the limbs".
- **Disability**: "A restriction or inability to perform an activity in the manner or within the range considered normal for a human being, mostly resulting from impairment".
- *Handicap*: "This is the result of an impairment or disability that limits or prevents the fulfillment of one or several roles regarded as normal, depending on age, sex and social and cultural factors".

However, this system was later revised and replaced by the (ICIDH-2) and the International Classification of Functioning, Disability and Health (ICF) (WHO, 2001). For example, in the ICF classification system the Handicap concept has been replaced by Participation which can have a negative dimension as participation restriction. The handicap concept was a social construct by definition and there was a difficulty in establishing international standards among different societies, cultures and languages. The ICF is based on the Biopsychosocial model (Figure 2.1) which is now widely accepted as the framework for disability and rehabilitation (Waddell & Burton, 2004). This is an individual-centered model which takes into account the person, their health condition and also their social context (Waddell & Burton, 2004).





The ICF describes functioning and disability as a dynamic interaction between the person's health status and contextual factors (Waddell & Burton, 2004) (Figure 2.2). The ICF classification consists of two parts, each of which has two components:

Part I. Functioning and Disability

- 1) Body Functions and Structures (impairments)
- 2) Activities and Participation (limitations and restrictions)

Part II. Contextual factors

- 3) Environmental Factors
- 4) Personal Factors



Figure 2.2 Interactions between ICF components adopted by WHO 2001.

Thus, there are complex relationships among model parameters and by definition this model does not assume only sequential or cause and effect relationships, like earlier models. For better understanding some common definitions from the revised ICF model are given below (WHO, 2001):

- *Well-being*: "is a general term encompassing the total universe of human life domains, including physical, mental and social aspects that make up what can be called a "good life". Health domains are a subset of domains that make up the total universe of human life".
- *Health condition*: "is an umbrella term for disease (acute or chronic), disorder, injury or trauma. A health condition may also include other circumstances such as pregnancy, ageing, stress, congenital anomaly, or genetic predisposition".
- *Functioning*: "is an umbrella term for body functions, body structures, activities and participation. It denotes the positive aspects of the interaction between an individual (with a health condition) and that individual's contextual factors (environmental and personal factors)".
- **Disability:** "is an umbrella term for impairments, activity limitations and participation restrictions. It denotes the negative aspects of the interaction between an individual (with a health condition) and that individual's contextual factors (environmental and personal factors)".
- **Body functions**: "are the physiological functions of body systems, including psychological functions. "Body" refers to the human organism as a whole, and thus includes the brain. Hence, mental (or psychological) functions are subsumed under body functions. The standard for these functions is considered to be the statistical norm for humans".
- *Body structures*: "are the structural or anatomical parts of the body such as organs, limbs and their components classified according to body systems. The standard for these structures is considered to be the statistical norm for humans".
- *Impairment*: "is a loss or abnormality in body structure or physiological function (including mental functions). Abnormality here is used strictly to refer to a significant variation from established statistical norms (i.e. as a deviation from a population mean within measured standard norms) and should be used only in this sense".
- *Activity*: "is the execution of a task or action by an individual. It represents the individual perspective of functioning".
- Activity limitations: "are difficulties an individual may have in executing activities. An activity limitation may range from a slight to a severe deviation in terms of quality or quantity in executing the activity in a manner or to the extent that is expected of people without the health condition".
- *Participation*: "is a person's involvement in a life situation. It represents the societal perspective of functioning".

- **Participation restrictions:** "are problems an individual may experience in involvement in life situations. The presence of a participation restriction is determined by comparing an individual's participation to that which is expected of an individual without disability in that culture or society".
- *Contextual factors*: "are the factors that together constitute the complete context of an individual's life and in particular the background against which health states are classified in ICF. There are two components of contextual factors: Environmental Factors and Personal Factors".
- *Environmental factors*: "constitute a component of ICF, and refer to all aspects of the external or extrinsic world that form the context of an individual's life and, as such, have an impact on that person's functioning. Environmental factors include the physical world and its features, the human-made physical world, other people in different relationships and roles, attitudes and values, social systems and services, and policies, rules and laws".
- *Personal factors*: "are contextual factors that relate to the individual such as age, gender, social status, life experiences and so on, which are not currently classified in ICF but which users may incorporate in their applications of the classification".

Other useful definitions include those for Disease and Illness which imply different concepts. Disease is related to pathology and medical diagnosis which may or may not lead to physical or mental impairment. Essentially, the presence of disease does not necessarily result to symptoms, disability or illness (Waddell & Burton, 2004). The concept of illness refers to the impact of a health condition on activities or participation, well being and quality of life and not purely the presence of symptoms, medical diagnosis or disease (WHO, 2003). Illness it is a social phenomenon which involves the individual, other people and the society (Waddell & Burton, 2004).

The usefulness of such classification systems is not only limited in classifying an individual's condition or providing a theoretical framework but also in clinical diagnosis, rehabilitation process, rehabilitation outcome measurement, effective research results communication and a range of other important parameters.

2.2.3 Definition of LBP

LBP is typically defined as "pain and discomfort, localized below the costal margin and above the inferior gluteal folds, with or without leg pain" (Manek &

Macgregor, 2005; Van Tulder *et al.*, 2006). In reality, there are numerous different definitions used in the literature.

A great issue in LBP epidemiological studies is the lack of a standardized way of defining back pain prevalence (Rossignol *et al.*, 2009). The lack of common language between studies makes the evidence difficult to summarize and consequently less than ideal for researchers and healthcare providers. Two international consensus LBP expert groups have recently addressed this issue. The first study used 51 articles reporting results of back pain population based studies and used them to identify elements that could be included in a definition of low back pain prevalence (Dionne *et al.*, 2008). Based on 7 elements (site of pain, measure time frame, symptoms, symptoms duration, frequency of symptoms, severity of LBP, and excluded symptoms) they identified 77 different definitions. One important recommendation was that questions on severity and duration are not considered to provide valid information, when examined in the time frame of a year, and suggested the use of a 'four week' time frame for LBP definitions. In a similar study the consensus group, based on five elements (pathology, symptoms, functional limitations, use of care services, participation) identified 132 definitions of LBP (Griffith *et al.*, 2007).

Taking into account the above findings it can be assumed that there is a need to use a common and more specific definition for low back pain. This can enhance the sensitivity of identifying appropriate participants for research studies and consequently make the findings comparable and easy to summarize.

2.2.4 Classification of LBP

Similarly to the definition of LBP, there is no clear and consistent classification system which is widely used. This has serious implications to research and clinical practice since the heterogeneity among studies makes the comparison of the evidence very difficult, if not impossible and hence it can not be used to target intervention to subgroups that respond to that intervention. Low back pain can be classified according to its chronicity or its underlying pathology.

Literature review

Considering the underlying pathology, LBP can be classified as specific or nonspecific. Specific LBP has identifiable causes such as spinal fractures, infection, cauda equina syndrome, discogenic problems, etc., which can be diagnosed and treated appropriately (Manek & Macgregor, 2005). Non-specific LBP is defined as pain not attributed to recognizable known pathology (Van Tulder et al., 2006). Non-specific LBP accounts for the 90% of cases (Manek & Macgregor, 2005). Recurrent low back pain is defined as a new LBP episode following a 6 months symptom free period and not an exacerbation of chronic low back pain (Van Tulder et al., 2006). An earlier classification known as the "diagnostic triangle", divided low back pain into three categories: a) specific spinal pathology, b) nerve root/radicular pain, c) nonspecific low back pain (Waddell, 1987). However, the "non-specific" is still a very vague term which obscures multiple conditions with different etiologies (Leboeuf-Yde et al., 1997). This fact commonly lead to the situation where the LBP disorder is being treated without considering the underlying mechanism of pain (O' Sullivan, 2005). In order for a classification system to be clinically useful it should be able to identify the underlying pathology which in turn can inform targeted interventions (O' Sullivan, 2005). For this reason, it has been indicated the need for the development of clinically meaningful subcategories which can speed up the identification of causal mechanisms (Leboeuf-Yde et al., 1997) and treatment options.

Recently a classification system has been proposed by O'Sullivan (2005) suggests three broad subgroups of CLBP disorders based on the Biopsychosocial model for LBP. The first subgroup consists of disorders where high levels of pain and disability and movement and/or motor impairments represent a secondary and adaptive pathological process. The second subgroup is when the cause of pain is not due to pathologicalorganic etiology but is from the forebrain following psychological and/or social reasons. The last proposed subgroup is due to abnormal movement or control impairments which are associated with faulty adapting strategies resulting in pain, chronic abnormal tissue loading, disability and distress. The above categories are further divided into smaller groups according to the characteristics of each of the three main groups. However, the proposed classification needs further consideration and validation in order to be broadly used.

Relatively to the duration of pain, LBP is classified as (Van Tulder *et al.*, 2006; Balague *et al.*, 2007):

Acute LBP (ALBP):< 6 weeks</th>Sub-Acute LBP (SALBP):6-12 weeksChronic LBP (CLBP):> 12 weeks

This classification it is rather arbitrarily and it is not based on any scientific evidence. It is a crude categorization system which aims to distinguish chronically different levels of low back pain without providing any information for the cause of pain.

2.2.5 Association between LBP and Disability

A historical review for LBP has reported that although LBP is known in humanity for thousands of years, was always considered as a rheumatic disease and it was only the 19th century that LBP has been identified as a result of spinal trauma (Allan & Waddell, 1989). That promoted the new orthopaedic principle of therapeutic rest which was escalated after the mid 20th century with the improved social support (Allan & Waddell, 1989). However, these changes in understanding and management of low back pain during the 19th and 20th century strengthened the development of chronic disability due to back pain. For this reason, the belief that much LBP disability is iatrogenic is reinforced (Allan & Waddell, 1989). Today it is accepted that psychological and social factors are important determinants for the development of LBP disability and that fear of pain it is rather more disabling than the pain itself (Waddell, 1996). This notion is further supported by a review which reported strong evidence about the role of psychological distress/depressive mood in the progression from acute to chronic LBP (Pincus *et al.*, 2002). However, the role of fear/anxiety and cognitive factors are not completely clear and require further consideration (Pincus *et al.*, 2002). An earlier study examined the relationship among chronic LBP, impairment and disability, and found a weak relationship (Figure 2.3) (Waddell *et al.*, 1993). In this study, severity of pain accounted only for 10% of variance in impairment and disability. This means that other factors are contributing in large degree to the development of chronic disabling low back pain. Additionally, fear avoidance beliefs correlated strongly with the self reported disability in activities of daily living (ADL) and absence from work (Waddell *et al.*, 1993).



Figure 2.3 The relationship among pain, impairment and disability (Waddell et al. 1993).

The fact that there is a weak direct relationship between pain and disability and stronger relationship between disability in ADL and fear avoidance beliefs, led the authors to the development of a Biopsychosocial model of low back pain disability (Waddell *et al.*, 1993). In this model the social environment, illness behavior, psychological distress, attitudes and beliefs and pain all play a central role in the development of LBP disability. The relationship among these factors may be the key in understanding the nature of LBP disability (Waddell *et al.*, 1993). Possible causal pathways between low back pain and disability are shown in Figure 2.4.



Figure 2.4 Cognitive, behavioral and affective pathways postulated between LBP and disability (Waddell *et al.*, 1993).

The multidimensional nature of chronic LBP is described by many studies (Pincus *et al.*, 2002; Mitchell *et al.*, 2008). Thus, the assessment and rehabilitation of low back pain should not only focus on the physiological signs and symptoms but also on the psychosocial aspects of LBP.

2.2.6 Natural course of LBP

There is confusion regarding the long term course of LBP due to the variation in definitions and the outcome measures used (Hestbaek *et al.*, 2003; Manek & Macgregor, 2005). Some patients fully recover, some have recurrent episodes and others continue to experience pain for years (Dunn & Croft, 2004). It has been suggested that the majority of acute LBP disorders resolve within a 4 weeks period and only 10-40% become chronic (Croft *et al.*, 1998). However, Hestbaek *et al.* 2003 reported that there is no evidence supporting the suggestion that 90% of patients recover within a month's time. According to them a 42% to 75% of patients continue to experience pain after 12 months and a 44% to 78% of them had relapses of pain. Additionally, the absence from work due to LBP relapse ranged between 26% to 37% (Hestbaek *et al.*, 2003). In terms of severity, the occurrence of benign LBP tends to decrease with age, after an observed peak in sixth decade of life, but the severe persistent LBP is increasing with age (Dionne *et al.*, 2006).

A recent cohort study revealed that only one third of patients with chronic LBP recovered within a period of twelve months (Menezes Costa *et al.*, 2009). The prognosis was poor for people who took sick leave, had high disability scores or pain intensity at

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onset, lower educational levels, as well as those thought to be at increased risk for persistent LBP. Interestingly, it has been suggested that symptom duration is an important determinant for the prognosis of LPB (Dunn & Croft, 2006). Patients with symptom duration more than three years needed significantly longer time to improve than those with shorter duration. This finding is not that surprising though, because it is well know that presence of chronic back pain is usually related with more complicated pathologies including psychological and social factors. On the other hand, people with acute low back pain improve rapidly within a few weeks but recurrence episodes are very common (Pengel *et al.*, 2003). According to Pengel *et al.* (2003) 82% of those with acute LBP returned to work within one month, but 73% of those patients had at least one recurrence episode over a 12 months period.

It has been assumed that early identification of patients who are likely to develop chronic LBP with function restriction is of great importance because an effective prevention needs appropriate patient allocation to health care services (Hilfiker *et al.*, 2007). However, it has been found that current predictive instruments have moderate ability to predict or explain function related outcomes (Hilfiker *et al.*, 2007). A recent study reported that the prognosis of chronic LBP is mostly determined by changes in pain intensity and disability status in the first three months of the disease (Heymans *et al.*, 2010). Thus, a no clinically relevant change in those parameters in the first months of the disease can possibly imply higher risk for chronic LBP development. Recently, a 9-item tool with good reliability and validity has been developed in order to classify patients into three subcategories (low, medium, and high risk) for targeted primary care management (Hill *et al.*, 2008). However, more high quality research is needed to prove if such tools can have benefits in the LBP prognosis prediction and consequently in the effective management of this condition.

2.2.7 Risk factors of LBP

In the literature, many factors have been mentioned as potential risk factors for the development of LBP. Some of these factors are: spinal loading, whole body vibration,

smoking, low educational level, heredity, obesity, health status, physical activity, lifestyle, social and work related factors, etc.

Daily spinal mechanical loading may be a risk factor for the development of LBP: long-term and intensive spinal loading especially in a flexed position, has been strongly associated with acute LBP (Bakker et al., 2007 -a), with persistent low back pain occurring in 60% of the same cohort after six months (Bakker et al., 2007 -b). However, the same authors reported that spinal mechanical loading was not a prognostic factor for the development of persistent and chronic LBP, but smoking and ageing were. This finding may indicate that spinal mechanical load could be a cause for acute LBP pain, but in order for this pain to progress into chronic LBP other factors (smoking, ageing, etc.) are mainly responsible. However, a cause and effect relationship cannot be established from these studies and thus these results can be perceived only as indications. A recent literature review, included 18 studies of good quality, reported strong evidence supporting that sports, exercises, sitting and prolonged walking or standing are not associated with the development of LBP (Bakker et al., 2009). Additionally, they found conflicting evidence regarding activities involving: whole body vibration, leisure time (repairing, gardening), working in positions with bent/twist trunk, and heavy physical work. A prospective cohort study of 180 patients reported that disabling LBP occurred to the one third of the study population and was more common among those with previous history of LBP, in older ages and in women (Thomas et al., 1999). The risk for the development of LBP has been found to be twice as high for people with previous history of LBP (Hestback et al., 2003). Factors associated with the development of persistent pain included: psychological distress, poor self reported health, low levels of physical activity, smoking, dissatisfaction with work, duration of symptoms, as well as restriction of spinal mobility (Thomas et al., 1999). These findings are further supported by another study which indicates the overall health status and psychological factors as important predictors for the development of LBP (Kopec et al., 2003). Although, the findings from the above studies are very logical and interesting, the representativeness of such studies is questioned due to particular biases such as:
selection bias, small sample sizes, and drop outs during the follow up procedure in their cohort studies.

Heritability is one factor that is also theorized by many researchers to be a strong predictor for the development of LBP. However, a study included 300 twin male pairs reported that the majority of the variance in back pain was unexplained and only moderate heritability estimates for LBP were found (Battie *et al.*, 2007).

Occupation is also strongly associated with the presence of LBP (Luoma *et al.*, 2000). The prevalence for sciatic pain found to be significantly higher in machine drivers who exposed to whole body vibration and also the prevalence for localized LBP was higher in carpenters, where their work involves physical work in various positions (Luoma *et al.*, 2000).

Despite the major research effort of various professions over last 30 years, there is not much progress in terms of identifying the causality, controlling the problem and minimizing the risk for LBP (Marras, 2005). One reason for this fact, according to Marras (2005), is the lack of communication between disciplines and the need to view LBP causality as a combination of factors and not from any single perspective applying to a particular discipline. In this respect, The National Research Council (2001), (a US non-profit organization which aims to promote the acquisition and dissemination of knowledge in matters involving health, science, technology and engineering) has suggested a conceptual model of how various factors may play a role in the development of musculoskeletal disorders such as work-related back pain and how different disciplines may be interrelated (Figure 2.5).



Figure 2.5 A conceptual model for the role of various factors in the development of LBP (National Research Council, 2001).

The right dotted box symbolizes the interaction between different processes within the person such as biomechanical load-tolerance relationship and how individual factors and adaptations may interfere in this relationship. The left box indicates the workplace and how this influences the persons in terms of triggering sequences of events resulting to injury and back pain. The arrows symbolize the different disciplines (biomechanics, medicine, epidemiology, psychology, etc.) attempted to explain this relationship (National Research Council, 2001).

A review exploring the relationship between physical factors and other risk factors for the development of LBP concluded that there is always a biomechanical explanation associated with these factors, which is often is falsely attributed to genetic or psychological reasons (Marras, 2005). This means that there is a lack of understanding for certain variables of LBP. Thus, this conceptual model may be a good way to view collectively the interaction between risk factors and understand the causality of LBP in the workplace.

2.2.8 Conservative vs. surgical treatment for LBP

Invasive interventions (lumbar fusion, discectomy) are often employed for the treatment of CLBP or acute low back pain due to disc pathology. However, no difference has been found in the prognosis of low back patients between surgical interventions and conservative exercises for the treatment of chronic low back pain (Brox et al., 2003; Fairbank et al., 2005; Brox et al., 2006). Although surgical treatment seems to be more effective for mechanical etiology (e.g. disc prolapse), it is unclear if it has positive or negative impact on the course of the underlying disc disease (Gibson & Waddell, 2007). A study observing the natural history of massive lumbar disc herniations reported that the vast majority of them substantially resolved without developing further complications such as cauda equina syndrome (Cribb et al., 2007). Thus, it may be preferable to choose a non-invasive scheme as a treatment of LBP in order to avoid undesirable adverse effects. Brox et al. (2003) found that the early complication rates after surgery with lumbar fusion were 18%. For this reason, it was suggested that surgical treatment is advisable only for patients with severe and debilitating symptoms (Lee, 2003). Moreover, Rivero-Arias et al. (2005) reported that surgical treatment might not be a cost effective solution as it is approximately twice as expensive as a conservative treatment regime (Rivero-Arias et al., 2005).

2.2.9 Exercise and LBP

Despite the availability of a wide variety of interventions for the treatment of LBP, their effectiveness is not clearly documented and the need for better quality randomized control trials is evident (Van Tulder *et al.*, 1997b). Specifically, it has been reported that exercise therapy is not more effective than other conservative treatment or no treatment at all for acute LBP (Van Tulder *et al.*, 1997b; Hayden *et al.*, 2005). This finding is not surprising since the majority of acute LBP cases are caused by injuries and improve within a few weeks of onset. Thus, the symptoms of acute LBP cease along with the healing process and in most cases there is no need for further interventions apart from analgesics during the initial stages of the condition. Additionally, a recent Cochrane review reported that there is some evidence of moderate quality supporting the statement

that post-treatment exercise programs can prevent recurrence of LBP but conflicting evidence for exercise as a treatment of LBP (Choi *et al.*, 2010). Two other systematic reviews suggested that exercise therapy is slightly more effective in reducing pain levels and improving the function in patients suffering from Chronic LBP (Van Tulder *et al.*, 1997b; Hayden *et al.*, 2005). However, all these studies failed to identify which of the exercise regimens was more effective compared to others due to contradictory evidence and only Hayden *et al.* 2005 suggested evidence in favor of graded activity programs for sub-acute LBP patients, since it seems to improve absenteeism outcomes.

Cochrane systematic reviews are studies with high credibility and they are respected by the community of health sciences. The above reviews suggested positive, but not sound, outcomes of exercise especially on patients with sub-acute and chronic LBP. Despite the fact that the majority of the evidence included in those reviews was not of high quality, their results encourage the use of exercise in the intervention regimens of people with LBP. Nonetheless, the positive effects of aerobic exercise on the psychological and general health status of people is well documented elsewhere and does not need further reference in this document. Thus, since chronic LBP is nowadays accepted as a biopsychosocial entity and not only as a medical or biomechanical problem, exercise will only have benefits to provide when it is undertaken with expert advice.

2.2.10 Key points

- LBP has significant socioeconomic impact on societies worldwide
- There is a need for the development and use of a definition and classification system which can be widely and confidently used by researchers.
- LBP is a multidimensional condition where social, psychological, environmental and other factors are playing an important role.
- There is no clear relationship between LBP and disability.
- The natural course of LBP has a varied trajectory. However, it seems that the majority of people recover within a short period after onset.

- Loading, physical work, general health status, previous history of back pain, physiological distress etc. may be risk factors for LBP.
- Conservative interventions are preferable for the treatment of LBP patients without delimitating symptoms.
- Exercise therapy may be a beneficial option for the intervention regimes of subacute and chronic LBP patients.

2.3 PAIN: A SUMMARY

Pain is a complex concept which is not fully understood and for this reason is the subject of investigation for many scientific studies. Also, it is a very common experience which affects people throughout their lives (Strong *et al.*, 2002).

2.3.1 Definition of pain

A definition of pain was devised by the International Association for the Study of Pain (IASP) which refered to pain as an "unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage". Pain is a highly subjective experience and it is said that every person learns the application of this word through experiences related of injury in early life (IASP, 1986). The above definition underlines aptly the physiologic as well as the psychological components of pain.

2.3.2 Pain classification

Pain can be categorized according to its duration and its causality. Thus, it is classified as acute or chronic and nociceptive or neuropathic pain respectively. Along with the classification, some commonly used definitions in the study of pain will be presented below, as described by IASP (1986, p. S220).

Nociceptor: "a receptor preferentially sensitive to a noxious stimulus or to a stimulus which would become noxious if prolonged".

Noxious stimulus: "a stimulus which is damaging to the normal tissue".

<u>Analgesia</u>: "absence of pain in response to stimulation which would normally be painful".

Nociceptive pain caused by the activation of nociceptive sensory axons by noxious stimuli and is normally finite, localized and decreases with healing or the removal of the noxious stimuli (Chong & Bajwa, 2003). It is associated with tissue damage and arises from mechanical, chemical, or thermal stimulation of nociceptors. The nociceptors responsible for the detection of such tissue damage are the $A\delta$ and C nerve fibers (Loeser & Melzack, 1999). If the pain persists after the removal of the noxious stimuli and without other evident pathophysiological cause, it is likely to be due to psychological reasons (IASP, 1986).

Neuropathic pain is described as "pain initiated or caused by a primary lesion or dysfunction of the nervous system" (Merskey & Bogduk, 1994). Neuropathic pain is less localized than nociceptive pain and it can occur in areas where there is no tissue damage. The patient usually describes symptoms like shooting, burning, aching etc. (Chong & Bajwa, 2003). Regarding the definition of neuropathic pain, Chong and Bajwa (2003) suggested that although this definition has high sensitivity it lacks specificity since not all patients with nerve damage experience neuropathic pain. Potential causes of neuropathic and nociceptive pain are shown in Figure 2.6.



Figure 2.6 Nociceptive & neuropathic pain (Nicholson, 2003).

Although chronic pain is less understood and characterized than acute pain, it is usually described as persistent pain which lasts more than three months which is the expected time for tissue healing after injury (Strong *et al.*, 2002; Nicholson, 2003).

Acute pain is typically caused by tissue damage and the activation of nociceptive mechanism at the site of injury (Loeser & Melzack, 1999). Most people with acute pain seek medical care although in most cases the pain stops long before the healing process has been completed. For this type of pain, medical interventions are helpful in order to reduce pain levels and speed up the healing process (Loeser & Melzack, 1999).

Chronic pain, such as chronic low back pain, is usually activated by an injury or other tissue damage but may be maintained by other factors irrelevant to the cause of pain (Loeser & Melzack, 1999). It is commonly associated with significant suffering and with behavioural and psychological changes (Strong *et al.*, 2002). The vast majority of people suffering from chronic pain seek medical help but usually fail to receive an effective treatment because the most treatments provide only temporary pain relief without being able to resolve the underlying pathological condition (Loeser & Melzack, 1999). Regarding the distinction between acute and chronic pain, Loeser and Melzack (1999, p. 1609) mentioned that:

"It is not the duration of pain that distinguishes acute from chronic pain but, more importantly, the inability of the body to restore its physiological functions to normal homoeostatic levels".

The identification of the underlying pathology and the effective treatment of chronic pain is a big challenge for the medical and allied health professions. Conditions such as chronic low back pain account for a respectable percentage of those suffering from chronic pain. It is recognized that a better understanding of the pathophysiological mechanisms of such conditions is required. However, taking into account the subjectivity and the multidimensional nature of this experience, this task has a high degree of difficulty both for researchers and clinicians.

2.3.3 Pain pathophysiology

It is very important to understand the function and the processes involved in the production and modulation of pain. In this subsection some basic information will be mentioned regarding the mechanism of reception, transmission, modulation or maintainace of pain.

A receptor is a specialized part of the nervous tissue which is very sensitive to particular changes in its environment (Strong *et al.*, 2002). As mentioned before, the nociceptor is a receptor which responds to a tissue damaging (or potentially damaging) stimuli. The term nociceptor has its roots from the latin word nocere which means to injure (Strong *et al.*, 2002). Different terminology is frequently used for the description of visceral and muscle or joint nerves. Table (2.3) presents the classification of mammalian nerve fibers most commonly used today.

Fiber	Function	Group	Function	Average	Average						
type				fibre	conduction						
				diameter	velocity						
				(µm)	(m/s)						
Αα	Primary muscle spindle	Ι	Primary muscle spindle	15	95						
	afferents, motor fibers		afferents								
	to motor neurons										
Αβ	Cutaneous touch and	II	Afferents from tendon	8	50						
	pressure afferents		organs, cutaneous								
			mechanoreceptors								
Αγ	Motor fibers to muscle	-		6	20						
	spindles										
Αδ	Cutaneous temperature	III	Deep pressure	3	15						
	and pain afferents		receptors in muscle								
В	Sympathetic	-	-	3	7						
	pregagliotic fibres										
С	Cutaneous pain	IV	Unmyelinated nerve	0.5	1						
	afferents		fibres								
	(unmyelinated);										
	sympathetic										
	postgangliotic fibres										

Table 2.3 Classification of nerve fibers (Strong et al. 2002).

In a noxious stimulus the $A\delta$ and C fibers in the peripheral nerves are activated. $A\delta$ nociceptors are small diameter fibers covered with a thin myelin layer with conduction velocity of 5-30 m/s. The activation of these fibers usually results in sensations of

localized sharp and pricking pain (Strong *et al.*, 2002). In contrast, *C* fibers are slow conducting (0.5-2 m/s) unmyelinated structures carrying diffuse, dull, and persistent pain sensations (Strong *et al.*, 2002).

Nociceptors do not exist in the articular cartilage, synovial membranes, lung parenchyma, visceral pleura, pericardium and brain or spinal cord tissues (Millan, 1999; Strong *et al.*, 2002). In muscles, they are located in connective tissue and the wall of arterioles, whereas in joints they are located in the joint capsule, ligaments, bone, periosteum, articular fat pads, and around blood vessels (Millan, 1999; Strong *et al.*, 2002).

These receptors are also called free nerve endings because they are not equipped with special corpuscular end organs (Schaible & Ritcher, 2004). The majority of these receptors are polymodal responding to various stimuli such as mechanical, chemical, and noxious thermal (Schaible & Ritcher, 2004). If the noxious stimulus is sufficiently high, action potentials are triggered and transmitted by the axon to the dorsal horn of the spinal cord and the brainstem (Schaible & Ritcher, 2004). However, apart from their afferent activity, nociceptors show efferent functions as well. This happens by releasing neuropeptides from their sensory ending inducing activities such as vasodilatation, plasma extravasation, attraction of macrophages, etc (Schaible & Ritcher, 2004). The central endings of the primary afferent fibers (nociceptors) activate synaptically the dorsal horn neurons which are organized in different laminae (Schaible & Ritcher, 2004; D'mello & Dickenson, 2008). The $A\delta$ and C fibers terminate in laminae I-II and a small number of their fibers reach deep laminae, whereas $A\beta$ fibers terminate in laminae III-VI (D'mello & Dickenson, 2008). From there, the ascending axons in the spinothalamic tract stimulate the thalamocortical system which is responsible for the conscious pain sensation (Schaible & Ritcher, 2004). The pain sensation has two main components: the sensory discriminative aspect (involves characteristics of pain such as location, duration and intensity) and the affective aspect of pain (emotional) (Schaible & Ritcher, 2004; D'mello & Dickenson, 2008). The sensory aspect of pain is produced in the lateral thalamocortical system consisting of the relay nuclei and the areas in the postcentral gyrus. The affective component of pain is produced in the medial thalamocortical system

comprised of the relay nuclei in the central and medial thalamus, the anterior cingulate cortex (ACC), the insula and the prefrontal cortex (Figure 2.7) (Schaible & Ritcher, 2004).



Figure 2.7 Schematic representation of nociceptive system (Schaible & Ritcher, 2004).

The mechanism for the development of persistent pain is quite complex involving a series of changes such as primary and secondary hyperalgesia, peripheral and central sensitization in which the neurotransmitters play an important role (Nicholson, 2003). An important neurotransmitter found throughout the nervous system and utilized by the majority of nociceptors, regardless of their size, is glutamate (D'mello & Dickenson, 2008). Peripheral sensitization has been shown to occur after inflammation due to activation of intracellular signaling pathways such as different types of protein kinase (D'mello & Dickenson, 2008). Central sensitization is a pathological condition in where an increased excitability of the spinal cord neurons is observed due to pathologically increased input (Schaible & Ritcher, 2004). In most cases the central sensitization disappears with the decrease of the nociceptive peripheral input. In other cases though, a mechanism which causes persistent increase of synaptic efficacy is triggered and such process could be responsible for the generation of persistent pain (Schaible & Ritcher, 2004).

Relatively to low back pain, the above mechanisms could partially explain the generation of acute and chronic pain. In acute pain, the symptoms disappear after the healing process, and the nociceptive input is radically decreased. However, in chronic LBP, mechanisms such as central sensitization involving increased nociceptive input in the central nervous system or dysfunctions of the limbic system can play an important role and do not resolve.

2.3.4 Pain Assessment

As mentioned earlier, pain is a highly subjective experience which is quite difficult to quantify. In pain assessment many factors should be taken into account, such as cognitive or other impairment and also the tools used should be validated in the specific patient group (Breivik et al., 2008). The commonest and most reliable way of measuring pain is by using Visual Analogue Scales (VAS). This pain assessment tool has been shown to be superior to other pain assessment scales in terms of being able to detect reliably meaningful differences in pain intensity (Breivik et al., 2008). Measuring pain levels is a useful way to assess intervention outcomes. However, there is a limited understanding of the association between pain intensity and disability. It has been suggested that for pain caused by low back injuries, the relationship between pain and disability is not linear (Turner et al., 2004). Also, when pain level is 1-4 (in a 0-10 rating scale) a decrease of one point corresponds to clinically meaningful improvement in functioning, but for more severe pain (5-10) a two point decrease is needed in order to reflect clinically meaningful improvement in functioning (Turner et al., 2004). It should also be mentioned that factors like: age, pain site and chronicity, medication usage and multiple pain locations also play an important role in disability (Scudds & Robertson, 2000).

2.3.5 Key Points

• Pain is a subjective experience which has both discriminative and affective components.

- The pain is classified according to its origin as neuropathic and nociceptive, and in terms of its duration as acute and chronic.
- $A\delta$ and C nerve fibres are mainly responsible for the reception and transmission of peripheral noxious stimuli to higher centres.
- Pathological persistent excitability of nociceptors can lead to central sensitisation which can result in chronic pain.
- Musculoskeletal pain can be successfully assessed with Visual Analogue Scales.

2.4 THE SPINE

The vertebral column (Fig. 2.8) consists of a series of bones called vertebrae making up approximately the 2/5ths of the total height of the human body. In early age the total number of vertebrae is 33. However, several vertebrae in the coccygeal and sacral region fuse and thus the adult spine contains 26 bones: 7 cervical, 12 thoracic, 5 lumbar, 1 sacrum (consists of five fused vertebrae), and 1 coccyx (consists of four fused vertebrae) (Tortora & Derrickson, 2009).



Figure 2.8 The human spine (Tortora & Derrickson 2009).

When the vertebral column is viewed from the side (sagittal plane), it forms four normal curves. These curves increase the strength of the whole structure and protect it from injuries. They also help in maintenance of balance required for moving in the upright position and in absorbing the shocks created by heel strike during walking. Various pathological conditions may exaggerate the normal curves or create a lateral deviation of the column resulting in abnormal curves. Three common abnormal curves are: kyphosis, lordosis and scoliosis (Tortora & Derrickson, 2009).

2.4.1 The Vertebral Body

Vertebrae form different regions of the spinal column vary in shape, size and mechanical properties. A vertebra consists of an anterior disc-shaped part, the vertebral body, which is the main weight bearing part of the vertebrae. The posterior part is formed by a bony ring, known as the neural arch, consisting of two laminae and two pedicles from which arise seven processes (Figure 2.9) (White & Panjabi, 1990; Tortora & Derrickson, 2009).



Figure 2.9 The vertebral body (Tortora & Derrickson 2009).

The vertebral or neural arch along with the vertebral body, form the vertebral foramen. The vertebral foramen of all vertebrae form the spinal canal which encloses the

spinal cord, blood vessels, areolar connective and adipose tissues. The notches of the adjacent vertebrae create openings called the intervertebral foramen enabling the spinal nerves and blood vessels to leave or enter the canal (Palastanga *et al.*, 2006; Tortora & Derrickson, 2009). The intervertebral foramen are of particular importance since any decrease in the opening (commonly due to intervertebral disc herniation) can cause compression of the spinal nerves and blood vessels which results in serious pain, locally and in the lower limbs, which is commonly followed by neurological signs (burning, numbness, sharp pain, etc).

It has been shown that vertebral strength decreases with age (Bell *et al.*, 1967). A small loss of osseous tissue creates significant loss of bone strength, for example, a 25% decrease of osseous tissue causes more than 50% decrease in vertebra strength (Bell *et al.*, 1967).

2.4.2 Facet Joints

The facet joints, also called zygoapophyseal joints, are paired synovial joints which link the vertebral arches of adjacent vertebrae (Cavanaugh et al., 1996). Their role is to support and stabilize the spine and also to prevent injury by restricting excessive motion (Cohen & Raja, 2007). They can support approximately twice body weight in young people but their strength decreases with age (Cyron & Hutton, 1981). In the standing position about 16% of the load is carried by the facet joints (Adams & Hutton, 1980). This explains why sitting in unsupported positions increases significantly the loads on the intervertebral discs, which was reported by other investigations (Nachemson & Morris, 1964). The zygoapophyseal joints can carry significant amount of spinal loads when the spine is hyper extended (Cavanaugh et al., 1996). In unsupported sitting positions the lumbar kyphosis increased, leaving the facet joints open, and thus the load is fully carried by the intervertebral discs. Asymmetric facet joint loading, due to intervertebral disc narrowing, may be a potential risk factor for the development of disc degeneration and back pain (Adams & Hutton, 1980). The prevalence of facet joint disorders in people with low back pain varies between 15-45%, with older patients showing higher prevalence (Manchikanti et al., 2004; Cohen & Raja,

2007; Manchikanti *et al.*, 2008). Lumbar facet joints are extensively innervated with free and encapsulated nerve endings existing in the joint capsule, including nerves containing neuropeptides such as substance P and neuropeptide Y, which are important pain modulators (Cavanaugh *et al.*, 1996; Cohen & Raja, 2007). Tissue damage or inflammation in the zygoapophyseal joints is likely to cause the release of specific chemicals which irritate the nerve endings and result in low back pain symptoms (Cavanaugh *et al.*, 1996).

The movement pattern of the spine is mainly dependent on the shape and orientation of the facet joints (Figure 2.10) (White & Panjabi, 1990).



Figure 2.10 3D orientation of facet joints (cervical, thoracic, lumbar) (2.10-A) and in respect to the sagittal plane (2.10-B) (White & Panjabi, 1990).

The orientation of lumbar facet joints is almost perpendicular to the transverse plane, with an angle of approximately 18° (White & Panjabi, 1990). This type of facet articulation allow greater ROM in the sagittal plane (i.e. forward flexion) and less movement in transverse and coronal planes (i.e. axial rotation, side flexions). Thus, although lumbar facets provide substantial resistance in axial rotation, they cannot resist effectively large shear forces produced during forward flexion (Cohen & Raja, 2007). It has been reported that the capsular ligaments of facet joints are arranged in such way as

to provide maximum resistance to flexion (Cyron & Hutton, 1981). The angle of facets in respect to the sagittal plane gradually increases from the L1-L2 to L5-S1 (Fig. 2.10-B) (White & Panjabi, 1990). In reality the facet joints demonstrate significant variability in terms of orientation and shape.

2.4.3 Intervertebral Disc

The intervertebral disc (Figure 2.11) is an important anatomic structure which constitutes 20-30% of the total height of the spinal column and consists of three main parts: the annulus fibrosus (AF), the nucleus pulposus (NP), and the vertebral end-plates (White & Panjabi, 1990). These structures are mainly formed of water, collagen and aggrecan (large aggregating proteoglycans), with the highest proportion of water and aggrecan in the nucleus and lowest in the outer annulus and endplate. The collagen shows an opposite profile (Sivan *et al.*, 2006). The disc is an active and living structure, constantly functioning and serves as articulation between the vertebrae and as a natural shock absorber (Coventry *et al.*, 1945). It transmits, modifies and evenly distributes the forces applied on the spine and without the discs the spinal column would be rigid and could not meet the delicate needs of the body (Coventry *et al.*, 1945).



Figure 2.11 Scematic representation of intervertebral disc. A) midsaggital cross-section anatomical regions. B) 3D view showing annulus fibrosus lamellar structure (Smith *et al.*, 2011).

Annulus Fibrosus

The annulus fibrosus is a structure which encapsulates the nucleus and made off fibrocartilaginous material (Jensen, 1980). The human lumbar discs contain type II collagen in 50–65% of total collagen proportion (Eyre & Mui, 1977). No significant variations exist in the relative proportions of types I and II collagens in the lumbar

annuli fibrosi of individuals aged 5, 16, 59 and 66 years (Eyre & Mui, 1977). Also, the water content of the annulus stays relatively unchanged throughout adulthood (Twomey & Taylor, 1985; Sivan *et al.*, 2006). Annulus fibers are more numerous and thicker at the anterior aspect than the posterior and the fibers of the posterior annulus are also attached to the posterior longitudinal ligament (Coventry *et al.*, 1945; Jensen, 1980). The longitudinal ligament becomes thinner in the lumbar area, reducing significantly the mechanical support so making the lumbar discs open to injuries. The disc fibers have varying orientation and cross obliquely to each other at an angle of $\pm 30^{\circ}$ relative to the disc. However, posterior and posterolateral fibers have a more parallel orientation than the anterior fibers (Jensen, 1980). This differential orientation of the disc fibers makes the disc capable of resisting multiaxial loading conditions. The parallel orientation of the posterior annulus is another factor which makes the posterior annulus vulnerable to injuries.

Cartilaginous end-plate

The plates are composed of hyaline cartilage with its cells to arranged horizontally (Coventry *et al.*, 1945). They form the physical boundary between the other two components of the disc and the vertebral bodies. The end-plates play an important role in disc nutrition and possible dysfunction of this structure may cause disc degeneration.

Nucleus Pulposus

The nucleus pulposus is a flattened bean shape formation located in the centre of the disc, it is under constant pressure and formed of a loose and translucent network of fibrous strands which lie in a mucoprotein gel (Calvé & Galland, 1930; White & Panjabi, 1990). The water content varies between 70-90% (White & Panjabi, 1990) and decreases by approximately 6% in older adults (Twomey & Taylor, 1985).

It has been found that more than 85% of the collagen in the human nucleus pulposus at various ages was type II (Eyre & Mui, 1977). The lumbar nucleus occupies 30-50% of the total disc cross-section area and lies at the junction of the middle and posterior thirds of the disc (White & Panjabi, 1990). The nucleus is more distinctive than the annulus in the young and becomes less so in older adults (Coventry *et al.*, 1945).

2.4.4 Disc Innervation

The lumbar intervertebral discs are innervated by a number of nerves. The posterior and posterolateral aspects of the disc and the posterior longitudinal ligaments are supplied by the sinuvertebral nerves (Bogduk et al., 1981). These nerves are formed by the combination of the ventral primary rami and the grey rami communicantes. Some rami communicantes embedded in the connective tissue of the disc deep to the origin of psoas after crossing the intervertebral disc and recurrent branches of the communicantes, with sympathetic origin, innervate the anterior longitudinal ligament and the anterior aspects of the discs (Bogduk et al., 1981). In healthy discs, free nerve endings have been found in the outer few millimeters of the annulus fibrosus, where this region of annulus is rich in collagen and exhibits tensile properties with little or no compressive stresses (Adams, 2004). The inner annulus and nucleus are exhibit high hydrostatic pressures and this may be a reason why nerve fibres and blood vessel do not grow in those structures (Adams, 2004). Nerve and capillary ingrowth has been observed in degenerated discs where the hydrostatic pressures are not high and this is a possible reason for the development of chronic low back pain (Freemont et al., 1997). However, others support that vascular invasion deeper than the periphery it is not a distinct feature of degenerated discs (Nerlich et al., 2007). In vivo studies, have suggested that discogenic low back pain is conveyed non-segmentally by visceral sympathetic afferents primarily through the L2 nerve roots (Nakamura et al., 1996).

2.4.5 Disc Nutrition & Mechanical Properties

The intervertebral disc is an organic viscous elastic structure able to withstand high loads without disintegration (Virgin, 1951). The information regarding the mechanical behavior of the intervertebral disc under loading is currently obtained by cadaveric studies and in-vivo intradiscal measurements. Regarding the biomechanical testing on cadaveric specimens, the big question is: can these data approximate the mechanical properties of the living tissue? Also, it is still unknown what effect the fixation has on the mechanical properties of cadaveric specimens. On the other hand, in-vivo intradiscal measurements should also be interpreted cautiously since it is a highly invasive procedure, which definitely has an impact on the normal lumbar kinematics and consequently the forces distribution.

It has been suggested that the central region of a lumbar intervertebral disc (nucleus, inner annulus) behaves like a pressurized fluid (Adams et al., 1996). The collagen and proteoglycan synthesis in the disc cells is directly affected by the hydrostatic pressure (Hutton et al., 1999). Also, proteoglycan content has found to be decreased with age and degeneration (Rodriguez et al., 2011). It is well known that the intervertebral discs are the largest avascular structures in the body and their survival depends on the barely sufficient supply of nutrients (Adams, 2004). Although it is not completely clarified, it is believed that outer annulus is supplied by nutrients from the blood vessels existing in the structures around the annulus (Horner & Urban, 2001). The inner annulus and the nucleus receive nutrients by diffusion through the cartilaginous end plates (Horner & Urban, 2001). Endplate cartilage degeneration increases with age and produces significant alterations in diffusion (Rajasekaran et al., 2004). Today there is evidence from histological studies indicating decrease of the blood vessels in the endplates, starting in the second decade of life, resulting in tissue breakdown which is initiated in the nucleus pulposus (Boos et al., 2002). However, the behavior of the end plates with age and degeneration is unclear due to the conflicting results. Earlier studies suggest that end plate porosity and permeability decrease with age and degeneration (Nachemson et al., 1970) whereas current studies suggest the opposite (Rodriguez et al., 2011). Also, it has been shown that glycation stiffens the annular mechanical behavior (Wagner et al., 2006). Conversely, cell culture studies have found that a decrease in the oxygen supply significantly reduces the metabolic rate and that glucose deprivation is fatal for the disc cells (Horner & Urban, 2001). This is probably the reason why factors causing decrease in nutrient supply (smoking, etc.) can be risk factors for the development of disc degeneration. Additionally, disc cell density relies on nutrient supply which has an inverse relationship to disc thickness (Horner & Urban, 2001). A recent study found that the cell density in nucleus pulposus, endplate, and annulus fibrosus decreased significantly from 0 to 16 years of age without significant changes to be observed thereafter (Liebscher et al., 2011). Interestingly, the highest compressive

forces are observed in the annulus, except from the outer 2-4 mm which exhibit a tensile skin behavior (Adams *et al.*, 1996). In vitro testing revealed that the annulus is the most important structure which determines the compressive behavior of the disc (Markolf & Morris, 1974).

Nachemson was the first to measure in vivo intervertebral disc pressures with a needle like transducer inserted in the disc (Nachemson & Morris, 1964). In these studies, Nachemson and his colleagues measured disc pressures in static positions (Fig. 2.12-A) and during dynamic exercises (Fig. 2.12-B).



Figure 2.12 Disc pressures (100% = 70 kPa) in the third lumbar disc during certain postures (A) and during exercising (B) (Nachemson, 1975; Nachemson, 1976).

The static measurements included: sitting and standing positions, reclining, holding weights of 9.1 and 22.7 kilograms, performing Valsava maneuver, etc. (Nachemson & Morris, 1964). The dynamic measurements included commonly used

movements and therapeutic exercises such as: standing, active back hyperextension in prone, bilateral straight leg raise, sit-up with knees bent, both knees to chest, back hyperextension, and supine lying with legs elevated (Nachemson & Elfström, 1970). It should be noted that the values shown in Figure 2.12 are not absolute values of pressure but represent percentages of pressure when compared to the standing position. The measured pressure during upright standing in L3 disc was approximately 70 kPa and this value was the reference point to relate the pressures from other postures showed in Figure 2.12. In static measurements the pressure in the sitting position was 30% higher than standing and was further increasing with leaning forwards or holding weights. In absolute values the loads on the discs in the seated positions varied between 100-175 kg and in standing position between 90-120 kg (Nachemson & Morris, 1964). They also measured significant tensile loads (60-80 kg/cm²) in the posterior aspect of the annulus in normal discs. The Valsava maneuver also increased the pressure in the disc, which varied across subjects. This finding rejects earlier speculation suggesting that an increase in the intra-abdominal pressure can reduce the loads on the discs (Bartelink, 1957). Interestingly, the disc pressures observed when the subjects were under general anesthesia were about 1.5 kg/cm² which indicates a constant pressure of the discs (Nachemson & Morris, 1964). In active exercises the highest loads observed were in straight leg rising, active back hyperextension, and sit-up exercise with knees flexed. This data may explain the increase of pain levels in patients with LBP when adapting specific positions or doing certain exercises (Nachemson & Morris, 1964). This study provides also valuable information for people constructing exercise programs targeting healthy or patient populations.

The results of these pioneer studies where further verified by more contemporary evidence (Sato *et al.*, 1999; Wilke *et al.*, 1999). Sato reported that the intradiscal pressure in degenerated discs was significantly reduced compared to normal discs (Sato *et al.*, 1999). This is probably the result of the load transferring from the intervertebral disc to the facet joints due to the collapsing of the degenerated discs and particularly the posterior annulus (Adams *et al.*, 1996).

2.4.6 Disc degeneration & low back pain

Similar to all living tissues, intervertebral discs sustain the effects of ageing and degeneration. Battie and Videman (2006) have defined disc degeneration as:

"a product of lifelong degradation with synchronized remodeling of discs and neighboring vertebrae, including simultaneous adaptation of the disc structures to changes in physical loading and responses to the occasional injury".

Identifiable structural changes of the lumbar intervertebral discs are likely to begin in adolescence (Videman & Nurminen, 2004). The etiology of disc degeneration is multifactorial. Although many factors are responsible for degeneration, the initiation of the degenerative process remains unclear (Hadjipavlou *et al.*, 2008). However, evidence indicates that it is an age related process, largely influenced by genetic and mechanical factors (Hadjipavlou *et al.*, 2008). It has been observed that minor damage to the vertebral end-plates results in progressive structural changes to the adjacent intervertebral discs (Adams *et al.*, 2000). This confirms the notion that the body acts as a kinetic chain where structural changes at one point lead to adaptation from adjacent segments. This can result in anomalous distribution of the forces on the disc surfaces and the mechanical initiation of disc degeneration. The degree of degeneration is classified into five grades (Figure 2.13), with IV and V grades to be considered as degenerated (Pfirrmann *et al.*, 2001; Hangai *et al.*, 2008).



Figure 2.13 MRI images of discs classified from I to V (Hangai et al. 2008).

Despite the numerous qualitative methods of evaluating disc degeneration, the comparison between studies is difficult due to the variability of assessment methods and

many times due to the lack of precision and reliability of the measurement methods (Battie & Videman, 2006).

Although the discs are targeted by various therapeutic interventions, the association between the degenerative changes and pain production remains unclear (Battie et al., 2004). An earlier review concluded no causal relationship between radiographic findings and non specific LBP (Van Tulder et al., 1997a). However, although the degenerative changes increase with age, the possibility of identifying the specific cause of LBP with radiographs is very low (<1%) (Van Den Boscha *et al.*, 2004). Conversely, other studies reported that disc narrowing is more strongly associated with LBP than other radiographic features, especially when narrowing is observed on two or more levels (Pye et al., 2004; De Schepper et al., 2010). This is further supported by a classic twin study involving 300 monozygotic and dizygotic male twin pairs, where disc narrowing was also the most strongly associated factor with pain history (Battie et al., 2007). Moreover, spinal stenosis has also been strongly associated with the presence of LBP (Kalichman et al., 2010). Additionally, an MRI study, examined 164 male participants from different occupations, reported that signs of disc degeneration was associated with LBP and also that sciatic pain was associated with posterior disc bulges (Luoma et al., 2000). In addition, annular tears are also highly associated with the history of frequent low back pain (Videman & Nurminen, 2004).

A retrospective study showed that in patients below 45 years of age no abnormalities revealed by the 65% of radiographs, but the degenerative changes increased with age to approximately 71% in patients aged 65 – 74 years (Van Den Boscha *et al.*, 2004). Osteophytes are the most common radiographic finding, with men showing the greatest frequency, but disc narrowing was more common in women (Shao *et al.*, 2002; De Schepper *et al.*, 2010). Also the degeneration effects are more prominent at the L4/L5 than the L2/L3 level, with the posterior annulus more affected than the anterior (Adams *et al.*, 1996). In a community based study disc narrowing was one of the commonest radiological findings (63.9%), along with facet joint osteoarthritis (64.5%) and spondylolysis (11.5%) (Kalichman *et al.*, 2010).

Other studies have underlined the significance of heredity in disc degeneration since it explains approximately 74% of the variance in adult populations (Battie *et al.*, 2004). However, only a minority of the genetic influences on back pain were due to genetic influences affecting disc degeneration, and this highlights the complexity of back pain (Battie *et al.*, 2007).

2.4.7 Muscles & Tendons

The trunk muscles are targeted by many therapeutic interventions dealing with low back pain, especially the abdominal and the spinal extensor muscles. The spinal muscles and their neuromuscular control are necessary for the stability of the spine and the movement generation (White & Panjabi, 1990). According to their position the muscles which directly control the spinal movements are categorised as *postvertebral* and *prevertebral* (Fig. 2.14) (White & Panjabi, 1990). The postvertebral muscles are further categorised into deep, intermediate and superficial muscles. The **deep muscles** consist of short muscles connecting adjacent spinal processes (musculi interspinales), adjacent transverse processes (musculi intertransversarii), and those connecting the inferior transverse processes with the adjacent laminae above (musculi rotatores). The **intermediate muscles** connect the transverse processes with the spinous processes of adjacent vertebrae. According to their region the intermediate muscles are the multifidus (lumbosacral region), semispinalis thoracis (thorax), semispinalis cervisis, and semispinalis capitis. The **superficial muscles**, which are called the erector spinae, consisting of the iliocostalis, the longissimus and the spinalis (White & Panjabi, 1990).



Posterior view Figure 2.14 The spinal muscles (Tortora & Derrickson 2009).

The psoas muscle which is located in anterior aspect of the lumbar spine is also directly controlling the lumbar spine movements. This muscle although thought to be primarily a hip extensor, is now recognized as an important stabilizer of the lumbar spine which extends the lumbar spine increasing the lumbar lordosis (Herkowitz *et al.*,

1992). The contribution of this muscle to the flexion extension of the lumbar spine is weak and its fibers are distributed in such way that extend the upper lumbar segments and flex the lower (Bogduk, 2005). However, since the psoas fibers act very close to lumbar vertebrae line of rotation can only exert small moments but rather massive axial compression loads (Bogduk, 2005). It has been estimated that in activities such as sit-ups the two psoas muscles are expected to exert on the L5-S1 disc a compressive load equal to 100 Kg (Bogduk, 2005). Tide psoas muscles can possibly cause LBP due to the constant exertion of compressive loads on the lumbar discs (Akuthota et al., 2008). The prevertebral muscles consisting of the four abdominal muscles, the rectus abdominis which is primary acting as trunk flexor, and the three obliquely oriented abdominal muscles (from superficial to deeper) the external oblique, internal oblique, and tranversalis abdominis. Additionally, other important muscles, which indirectly affecting the spinal movements, are the gluteal muscles (gluteus maximus, gluteus medius and gluteus minimus) and the posterior musculature of the thigh i.e. hamstrings (Herkowitz et al., 1992). These muscles along with the abdominal muscles are the major factors controlling the lumbar tilt and the lumbosacral rhythm.

Apart from the musculature, the human spine is also surrounded by a complicated network of ligaments. These uniaxial structures are most effective in resisting tensile forces along the orientation of their fibers (White & Panjabi, 1990). The main function of the ligaments are to maintain spinal motion within physiologic limits, help keep fixed postures with minimal muscle energy expenditure, protect the spinal cord and provide stability to the spine along with the muscles (White & Panjabi, 1990). The main ligaments of the spine are the anterior and posterior longitudinal ligaments, the intertransverse ligaments, the capsular ligaments, the ligamenta flava, the interspinous ligaments and the supraspinous ligament. Of particular interest is the posterior longitudinal ligament which runs over the posterior aspects of all the vertebral bodies. This ligament is thicker in the thoracic region and becomes thinner in lumbar spine (reducing the mechanical support to lumbar intervertebral discs) allowing mechanical predisposition for lumbar disc injuries.

Many studies have investigated the functional and structural changes of the spinal muscles in people with low back pain. A recent study reviewing evidence regarding this issue reported that people with chronic LBP show significant atrophy in Type II muscle fibers, a conversion of fibers from Type I to Type II and increased fatigability of paraspinal muscles (Demoulin et al., 2007). The paraspinal muscles of healthy people contain a high proportion of slow-twitch fibers (Type I) which are responsible for posture maintenance. It has been shown that fatigue of lumbar extensor muscles increases the response time after a sudden perturbation in healthy people (Herrmann et al., 2006). Patients with subacute and chronic LBP demonstrate muscle EMG activation imbalances during a symmetrical trunk extension task which is suggested to reflect the physiological impairments associated with their condition (Oddsson & De Luca, 2003). Also, patients with chronic LBP have increased lumbar EMG activity in the swing phase during walking where normally the lumbar muscles are silent, and decreased peak activity during the double support phase where typically the lumbar muscles are active (Arendt-Nielsen et al., 1995). These changes correlated significantly with pain intensity and probably indicate that motor performance during gait is modulated by musculoskeletal pain (Arendt-Nielsen et al., 1995). Additionally, LBP patients show decreased normal walking speed and a disturbed coordination pattern between thorax and pelvis in higher speeds, coinciding with increased stability of movement coordination perhaps due to muscle guarding (Selles et al., 2001). The muscle guarding hypothesis is also supported by a recent study reported increased EMG activity of erector spinae and rectus abdominis during walking in patients with CLBP (Van Der Hulst et al., 2010b). Disturbed lumbar spine and hip coordination (during sit-to-stand and stand-to-sit) has also been found in patients with subacute LBP (Shum et al., 2005; Shum et al., 2007).

These studies suggested structural and functional muscle changes in people suffering from LBP. However, these studies have several limitations and cannot establish a cause and effect relationship. Thus, it is unknown if the structural changes and activation imbalances precede LBP or vice versa.

2.4.8 Key points

- Facet joint orientation determines the movement pattern of each spinal segment.
- Facet joint degeneration is directly associated with intervertebral disc degeneration and is a possible source of low back pain.
- Intervertebral disc narrowing is the most common radiographic finding which is significantly associated with the presence of low back pain.
- Upright standing position creates less intradiscal pressures than the seated unsupported and flexed positions, mainly because the load is shared between the discs and facet joints during the standing position.
- Structural and functional changes have been observed on trunk muscles of people with LBP.

2.5 KINEMATICS OF THE SPINE

Kinematics is the study of motion regardless of the forces that causes the motion (Robertson *et al.*, 2004; Winter, 2005). The study of kinematics includes linear and angular displacements, velocities and accelerations (Winter, 2005).

2.5.1 Definitions

Since in the course of this thesis some terms and definitions will be continuously used, it worth mentioning some of them in order to avoid confusion. These definitions are described by White and Panjabi (1990).

<u>Rotation</u>: an object is said to be in rotation when the movement of all its particles along some straight line show zero velocity relative to a reference point. Rotation is an angular displacement of an object about an axis which can be located inside or outside the rotating object.

<u>Translation</u>: a body is said to be in translation when all its particles at a given time have the same direction of movement relative to a reference point.

<u>Range of Motion (ROM)</u>: The difference between two points in the course of a physiologic movement is described as the range of motion.

<u>Degrees of Freedom (DOF)</u>: one degree of freedom in motion of a rigid body is described as the translation back and forth along a straight line or the rotation back and forth about a specific axis. The human spine allows three-dimensional movement which means that has six degrees of freedom (able to rotate about and translate along all three orthogonal axes).

<u>Coupling</u>: this term refers to the movement of an object, translation or rotation, along or about an axis while at the same time there is a rotation or translation about another axis.

2.5.2 Coordinate Systems

In order to conduct 3-D analysis of a moving body there is a need of defining a system of axes which is called a coordinate system. The method most commonly used for defining a position in 3-D space is the Cartesian coordinate system (Robertson *et al.*, 2004). These axes are by nature orthogonal (90° to each other) following the right hand rule. Normally, a global coordinate system (GCS) is defined and one or more local coordinate systems (LCS). The GCS is commonly named with uppercase letters **XYZ** and the LCS with lowercase letters **xyz** (Figure 2.15).



Figure 2.15 Schematic representation of global and local coordinate systems.

A common mnemonic way of defining the positive and negative rotation of an axes system is the right-hand rule. According to this rule, when curving the fingers of the right hand around the axis of rotation, with the fingers indicating the direction of rotation and then comparing the direction of the thumb relatively to the reference axis, the sign of the particular angle of rotation can be determined. If the thumb points in the direction of a positive axis, the angle is positive if not the angle is negative.

In motion analysis with optical motion capture systems, i.e. Vicon, Qualisys, etc., the global coordinate system is fixed to the laboratory and clusters of markers on the moving body or segment form the LCS. When using optical motion analysis systems, in order to establish a LCS the use of a cluster of three or more reflective markers is required. However, for motion recording with electromagnetic motion devices i.e. Polhemus Liberty, 3space Isotrak, Fastrak, etc., the source (emitting low frequency magnetic field) plays the role of the GCS and the sensors that of the LCS. The axes convention used in the Bioengineering Unit gait laboratory (University of Strathclyde), and partially used in this thesis is the one shown in Figure 2.16.



Figure 2.16 Anatomical planes and axes of movement, adapted and modified by (Winter, 2005).

According to this convention, \mathbf{X} is forward/backward, \mathbf{Y} is the left/right direction (medial-lateral) and \mathbf{Z} is the gravitational axis (up-down). The combination of these axes forms the planes, for example the $\mathbf{X}\mathbf{Y}$ axes form the transverse or axial plane, the $\mathbf{X}\mathbf{Z}$ axes form the sagittal or anterior-posterior plane, and the $\mathbf{Y}\mathbf{Z}$ axes form the frontal or coronal plane.

2.5.3 Joint Angles

There are several methods used to describe the relative orientation between two reference systems or body segments. The most common method is the Euler/Cardan angles. The so called projection angles are formed by the projections of the vectors of the LCS on the orthogonal planes of the GCS (Davis et al., 1991; Cole et al., 1993; Robertson et al., 2004). Although the three unit vectors (x', y', z') of the LCS can determine nine projection angles, only three of them are independent of each other which correspond to three rotational DOF. However, these angles are not communicative and must be performed in a specific sequence. Twelve rotational sequences can be used in total, with the first rotation about an axis of the GCS (X, Y, Z) a second rotation about a floating axis (an axis which is dependant and changes according to the orientations of the first and third axes) and the third is about an axis fixed in the LCS (x,y,z) (Robertson et al., 2004). The difference between the Euler and Cardan angles is that six out of twelve rotation sequences have a terminal rotation axis identical to the first rotation axis (i.e. Xyx) and defined as Euler angles. The other six rotation sequences have different terminal rotation from the first rotation axis (i.e. Z y x) and referred to as Cardan angles. So, both Euler and Cardan angles describe the relative orientation between two coordinate systems as a sequence of ordered rotations from the initial position of the GCS, which has been also defined as sequence dependency (Cole et al., 1993; Robertson et al., 2004).

In biomechanics the Cardan sequence of rotations is more commonly used and xyz is one commonly used Cardan rotation sequence (Cole *et al.*, 1993; Robertson *et al.*, 2004; Winter, 2005). The relative orientation of two coordinate systems, for an xyz rotation, is defined by a 3x3 rotation matrix [R], which includes a set of three

independent angles under an ordered sequence of rotation (α , β , γ). The angle α is designated for the first rotation, β for the second rotation and γ for the third rotation (Robertson *et al.*, 2004). Thus, for a xyz sequence the rotation matrix [R] can be described as:

$$[R] = [R_Z] [R_Y] [R_X]$$

Where

$$\begin{bmatrix} R_{X} \end{bmatrix} = \begin{bmatrix} 1 & 0 & 0 \\ 0 & \cos \alpha & \sin \alpha \\ 0 & -\sin \alpha & \cos \alpha \end{bmatrix}$$
$$\begin{bmatrix} R_{Y} \end{bmatrix} = \begin{bmatrix} \cos \beta & 0 & -\sin \beta \\ 0 & 1 & 0 \\ \sin \beta & 0 & \cos \beta \end{bmatrix}$$
$$\begin{bmatrix} R_{Z} \end{bmatrix} = \begin{bmatrix} \cos \gamma & \sin \gamma & 0 \\ -\sin \gamma & \cos \gamma & 0 \\ 0 & 0 & 1 \end{bmatrix}$$

The above rotation matrices can be expressed as successive rotations with the combined rotation matrix below:

$$[R] = \begin{bmatrix} \cos\beta\cos\gamma & \cos\gamma\sin\beta + \sin\gamma\cos\alpha & \sin\gamma\sin\alpha - \cos\gamma\sin\beta\cos\alpha \\ -\sin\gamma\cos\beta & \cos\alpha\cos\gamma - \sin\alpha\sin\beta\sin\gamma & \sin\gamma\sin\beta\cos\alpha + \cos\gamma\sin\alpha \\ \sin\beta & -\cos\beta\sin\alpha & \cos\alpha\cos\beta \end{bmatrix}$$

Due to inconsistencies in the usage of joint coordinate systems to determine the relative orientation of two segments, Cole et al. (1993) have suggested a standard method. Those authors found substantial differences in the representation of joint orientation between different sets of body fixed axes of the joint coordinate system. The usual procedure is to define a fixed axis in the proximal segment, a second fixed axis in the distal segment and have a floating axis defined by the two fixed axes. In the

literature, these joint axes have been referred to as \hat{e}_1 , \hat{e}_3 and \hat{e}_2 respectively (Cole *et al.*, 1993). Therefore, this proposal suggests a sequence of rotation where the first (fixed) axis is defined as \hat{e}_1 and describes the flexion-extension axis of the proximal segment, the second (floating) axis as \hat{e}_2 for the ad-abduction axis and the third (fixed) \hat{e}_3 as the long axis of the distal segment describing the axial rotation. This standardized method can describe orientation components of a joint which are consistent with their anatomical definitions, regardless of the definition used for the adjacent segment coordinate systems (Cole *et al.*, 1993).

2.5.4 Lumbar Kinematics

Kinematics of the human spine and especially the lumbar section is of great interest both for researchers and clinicians. Lumbar range of motion is often used as an outcome measure in LBP clinical trials or in monitoring patient progress after clinical interventions. There is strong evidence suggesting that lumbar range of motion is decreasing with age (Bible *et al.*, 2008; Intolo *et al.*, 2009).

In the literature, there are a number of studies using different methodologies in order to assess the spinal ROM. This is the probably the reason for the large variation in the reported lumbar ROM values according to Taylor and Twomey (1980). The commonest methods used to explore the lumbar ROM include: a) radiographic, b) cadaveric, c) direct in vivo measurement of the spinal ROM, d) Photographic techniques and e) theoretical mathematical modeling studies (Twomey, 1979; Taylor & Twomey, 1980). Measurement techniques such as flexicurves and skin distraction (Burton, 1986; Einkauf *et al.*, 1987; Fitzgerald *et al.*, 1991) are quite simple to use but they can only measure movement in one dimension. Cadaveric studies may provide a false approximation of the lumbar ROM because structures like muscles and ligaments have been removed and may not reflect those obtained in the living where body weight, abdominal pressure and muscle action differentiate the condition (Twomey, 1979). Radiographic techniques (Schuit *et al.*, 1997) can provide accurate measures, mainly in two dimensions but they are inappropriate for follow up studies due to the exposure to radiation and the expenses required. On the other hand photographic techniques are quite

difficult to use but can provide information only for the sagittal plane, require significant processing time and the accuracy of the measurements is questioned (Pearcy, 1986). However, measurements with electromagnetic tracking systems (Hindle *et al.*, 1990; Russel *et al.*, 1993; Van Herp *et al.*, 2000) seem to be more appropriate for clinical and research environments. These systems can provide real-time information and are very valid and reliable when the appropriate precautions are taken (i.e. firm attachment of systems' source and sensor, use them away from big metallic objects to avoid interference). Although technology has been advanced in the last few years, there is still a need for further developments in the current measurement methods and for spinal ROM employ new technologies (Lee, 2002).

A summary of lumbar range of motion across studies using different methodologies and study populations is described in Table 2.4. The values presented from each study are the weighted values among participant groups of different gender and age. The weighted means were calculated by multiplying the values in degrees in each participant group by the number of participants in this group. Then the summations of all group products were divided by the total number of participants in each study (see equation below).



Where A,B,C = Values in degrees for a particular movement a, b, c = the number of participants in each group

The difficulty in summarizing data presented in different studies lies on the variability of methods utilized by different authors to present their data. This is evident

in Table 2.4 in which due to missing information, it was not always possible to obtain both mean values and ranges of ROM values.

In a cadaveric study of 200 fresh lumbar segments the range of motion in six gross spinal movements was reported (Twomey, 1979). The results of this cadaveric study suggested an inverse relationship between age and lumbar ROM. This is an important finding which is reported by the majority of the studies investigating the effect of ageing on lumbar ROM. However, the ROM values differ considerably when compared with those obtained by in vivo studies using different methodologies.

Study Characteristics				Flexion- Extension (°)		Right – Left Axial Rotation (°)		Right-Left Side Rotation (°)					
Study	System used	Age (y)	Sample size	Inclusion criteria	Flex.	Ext.	Exc.	Right	Left	Exc.	Right	Left	Exc.
((Twomey, 1979)	Cadaveric study	1day- 97years	200 (M&F)	≤24 hours of death	35 24-45	13 9-23	48	19 14-28	19 14-28	38	15 12-23	15 12-23	30
(Fitzgerald <i>et al.</i> , 1991)	Skin distraction , Gonio- meter	20-82	172 (168M,4F)	No back pain the last three months		29 10-44					27 15 -40	28 15-41	55
(Einkauf <i>et al.</i> , 1987)	Skin distraction , Gonio- meter	20-84	109F	No LBP history, No LBP for the last three months		24 36-18					29 24-36	27 20-33	56
(Hindle <i>et al.</i> , 1990)	Isotrack 3space	20-50+	80(40M, 40F)	No back surgery, no LBP last 6 months	70	23	93	14	14	29	26	26	52
(Russel <i>et al.</i> , 1993)	Isotrak 3space	20-69	200 (100M, 100F)	No spinal problems , no LBP for the last three months	67 58-75	21 15-28	88			31 26-36			47 39-57
(Vachalathiti et al., 1995)	Expert Vision, Motion analysis	20-60+	100 (46M 54F)	No history of serious spinal or hip joint trauma	42 33-48			21 20-23	22 22-23	43	29 24-32	32 29-35	61
(Schuit <i>et al.</i> , 1997)	X-rays	20-48	13 (9F, 4M)	No LBP history, No LBP the past 6 months	60.6	20.1	80.7				30.6	31.9	62.5
(Van Herp <i>et al.</i> , 2000)	Isotrak 3space	20-60+	100 (50M, 50F)	No disability due to LBP, No LBP for 6 months	56 51-59	23 37-15	79	13 11-19	14 11-19	27	26 26-15	26 26-15	52
(Troke <i>et al.</i> , 2001)	CA6000 SMA	16-90	405 (196- 209)	No LBP History last 12 months or pain last 6 months	72-40	29-6		7	7	14	28-15	29-16	

Table 2.4 Lumbar range of motion measurements (weighted mean + range)
This difference obviously accounts to the physiological and biomechanical differentiation between the living and cadaveric tissue and of course due to the completely different testing conditions. The same authors, in a later study compared these results with those obtained by 437 living subjects of different age ranges and both sexes (Taylor & Twomey, 1980). Although they found a good agreement between the values obtained by cadavers and living people, the accuracy of the measurement tools used and thus the validity of the results is questioned. Particularly, a significant difference with the other studies (Table 2.4) is observed in the measurements for the sagittal and coronal planes (Flexion-Extension, Left-Right side bending). In contrast, measurements from the transverse plane (axial rotation) match better with the other studies. This fact may indicate that the measurement tools used by those authors (spondylometer, rotameter) may lack accuracy in greater ROMs.

One could assume that the lumbar ROM values obtained by studies using x-rays would be more accurate and can form a sound base for comparison with other studies used different measurement tools. However, to the author's knowledge, such studies (Dvorák et al., 1991, Pearcy et al., 1985, Schuit et al., 1997) are not very common, can lack accuracy and have very small sample sizes which make them unrepresentative. Thus, any attempt for using these studies to act as the baseline for comparisons is difficult. However, due to the absence of high quality radiographic three dimensional studies, these studies can offer a better estimate of the pragmatic lumbar ROM.

On the other hand, in-vivo studies using three-dimensional tools like 3space Isotrak seem to provide more consistent results. This is obvious in Table 2.4. when comparing the results reported by (Hindle *et al.*, 1990; Russel *et al.*, 1993; Van Herp *et al.*, 2000). These studies have adequate sample sizes and their results show high agreement in the majority of the movements measured. Interestingly, these studies also show better agreement with the radiographic study reported by Schuit et al. 1997 and this is an extra supportive fact regarding the accuracy of these measurements. This is a very important finding since three-dimensional electromagnetic motion capture systems like 3space Isotrak are user friendly systems with known measurement accuracy (Pearcy & Hindle, 1989).

2.5.5 Key points

- Cardan/Euler method is most commonly used to describe the relative orientation of two coordinate systems or body segments.
- Lumbar range of motion is decreasing with age.
- Electromagnetic motion capture systems appear to be a useful method for the measurement of the spinal ROM.

2.6 BIOMECHANICS OF LBP

2.6.1 Supported treadmill walking for LBP

Body Weight Unloading (BWU) during treadmill walking has been used particularly in the rehabilitation of neurological patients (Toole et al. 2005, Wirz et al. 2005, Dobkin et al. 2006) and also for orthopaedic patients (Mangione et al. 1996), as well as in patients with gait impairments as a gait retraining tool (Finch et al. 1991, Vistivin et al. 1998). However, to the author's knowledge, only one study has used this technique for people suffering from low back pain. In this study, Joffe et al. (2002) tested BWU during treadmill walking on 6 subacute LBP patients and observed a significant improvement in pain scores between the baseline and post intervention condition and for this reason they suggested more investigations in this field (Joffe *et al.*, 2002). Interestingly, the majority of their patients were diagnosed with lumbar disc space narrowing, which has been previously reported to be significantly associated with low back pain. However, the small sample size and the absence of control group does not allow generalizations and firm conclusions from this study, since any improvements found can result form the natural course of back pain. Also, in this study, the BWU was applied with a harness fitted around the waist and the thighs and thus the lumbar unloading produced was less than optimal. Thus the benefit may have arisen from a reduction in the transient shock vibrations in the musculoskeletal system after a heel strike. A different study compared the effects of treadmill walking with BWU and cycling when added to an exercise program for patients with lumbar spinal stenosis (Pua et al., 2007). They found an improvement in both groups, but no difference between

cycling and treadmill walking with BWU. However, due to several limitations, (drop outs, absence of control group, interventions were part of an exercise program and not a sole intervention) the significance of these results were markedly decreased and consequently no firm conclusions can be drawn for the effectiveness of BWU for spinal stenosis back pain. A recent study suggested that 40% under-arm BWU during treadmill walking decreases the compressive loads on the spine resulting in spinal elongation and also attenuates the magnitude of the transient shock waves, caused by the heel strike during walking (Pollock *et al.*, 2008).

Apart from the possible pain relieving effects of BWU treadmill training, there may be other benefits from this approach, for instance the aerobic and psychological improvement of the patients (Sculo *et al.*, 2001). Thomas et al. (2007) showed that older women, after a 12 week under-arm BWU treadmill training program (40% of body weight), had significantly reduced their walking energy cost per unit distance and also significantly increased their walking speed and their mechanical power output (Thomas, 2007).

Considering the gap in the literature regarding the effectiveness of supported treadmill walking for LBP and the potential benefits suggested by Pollock et al. (2008), it is sensible to suggest a well design randomized control trial to investigate this issue.

2.6.2 Spinal Shrinkage-Elongation

Many studies have shown that the spinal height is subjected to diurnal changes. This is the result of mechanical pressure applied on the intervertebral discs, especially the nucleus pulposus which consists of 80-90% water, during upright standing. The degree of height variation of the human spine depends on the external loading (Tyrrell *et al.*, 1985; Kanlayanaphotporn *et al.*, 2003) and possibly the activities performed throughout the day. Height variation has been studied with stadiomerty and Magnetic Resonance Imaging techniques (MRI). Along with height loss, an increase of disc bulge which is more apparent in the anterior part of the lower discs has been reported (Park, 1997). In young adults, the mean diurnal variation was found to be 19.3 mm (1.1% of total height), with the 54% of the height loss to occur in the first hour after waking up

(Tyrrell et al., 1985). External loading increases the rate of shrinkage and 70% of the height loss is regained during the first half of the night rest (Tyrrell et al., 1985). Additionally, with a period of 20-25 minutes of loading with an external load of 15% of the body weight, older people (with and without chronic LBP) showed less height loss than the younger ones, although older male participants had longer recovery periods (Kanlayanaphotporn *et al.*, 2003). Another study reported an increased height recovery (2-3 mm), after a loading task, due to 10 minutes back hyperextension (Kourtis et al., 2004). Others found no difference between two recovery positions (hyperextension in prone position, flexion in supine position) with a height recovery of about 3.1mm (Owens et al., 2009). However, the two latter studies lack credibility due to small sample size and absence of control group. Moreover, no difference has been found in the vertical spinal creep of young asymptomatic subjects over different times during the day (morning, midday, evening) (Puntumetakul et al., 2009). Contrarily, another study (Healey et al., 2008) found significantly less height loss, after a loaded walking task and greater recovery in asymptomatic people, in the afternoon compared to the morning. A similar pattern to the asymptomatic group was found, by the same authors, in a group of chronic LBP patients, but without any significant difference between the morning and afternoon sessions. Additionally, no difference was found between pregnant and non pregnant women, with and without LBP, in terms of stature recovery after a loading task (Rodacki et al., 2003; Fowler et al., 2005). Contrarily, chronic LBP patients exhibit higher EMG paraspinal activity and delayed stature recovery, irrespectively of the recovery position (Healey et al., 2005).

In respect to the effect of age on stature loss and the ability to recover the height, studies have reported small or no differences among different ages (Kanlayanaphotporn *et al.*, 2003; Reilly & Freeman, 2006). Also, it was supported that irrespective of age, the spine is less responsive with the increase of activity duration and that healthy older people subjected to spinal loading are not necessarily at risk unless the load exceeds their capabilities (Reilly & Freeman, 2006).

Walking causes spinal mechanical loading dependant on the walking speed and body mass (Callaghan *et al.*, 1999). However, spinal loading during walking is below the force levels created during many other rehabilitation activities and thus the use of walking in general rehabilitation regimes for LBP is sensible (Callaghan et al., 1999). In contrast, loaded walking (delivered with a standard mail bag and with a load equal to 17.5% of total body weight) can produce a stature loss of approximately double that observed in normal walking and an increased forward lean ($\leq 6^{\circ}$) and lateral bending of the spine ($\leq 12^{\circ}$) (Fowler *et al.*, 2006). The long-term application of such loads can possibly result in intervertebral disc degeneration due to abnormal walking pattern and abnormal disc loading. Additionally, the loads and the spinal shrinkage are greater while working in a standing position compared to a sitting one (4.16mm and 1.73 mm of height loss respectively, after 6.5 hours of work) (Leivseth & Drerup, 1997). On the contrary, deep water running cause significantly less spinal loading and shrinkage when compared to shallow water or treadmill running (Dowzer et al., 1998). This is obviously due to the buoyancy effects which provide an extra support to the body and probably decrease the ground reaction forces. Swimming and water exercises are widely used for rehabilitation purposes because for the majority of people they constitute a very familiar and pleasant environment. However, a recent study found no difference in stature loss between water and overground training, although they reported a facilitation of stature recovery in the water based condition (Camilotti et al., 2009).

Interestingly, a study aiming to reduce the loads on the spine, by means of underarm BWU treadmill walking, showed significant increase in the total spinal length (\approx 18 mm) of young healthy males (Pollock *et al.*, 2008). Similarly, Rodacki et al. (2005) suggested a positive relationship between body mass and stature change. They tested healthy obese and non-obese individuals during a 30 minutes walking task, both in unloaded (i.e. normal walking) and loaded condition (with external weight of 10% body mass) (Rodacki *et al.*, 2005). After every walking task a 30 minute period of standing recovery was given. They found that in both groups the stature loss was greater in the loaded compared to the unloaded condition. However, the obese individuals showed greater stature loss in both task conditions and also an inability to recover the stature loss after the walking task regardless of the loading condition. The non-obese subjects regained approximately 76% of their initial height in contrast to the obese individuals who on average continued to loose height during the standing recovery period. Regarding the recovery position, the gravity inverted position has been found to be most effective for spinal recovery but is difficult to achieve without specialized equipment (Healey *et al.*, 2005).

It can be assumed that the evidence regarding the involvement of LBP in stature loss and recovery are conflicting. Nevertheless, spinal loading has definitely an important effect on stature loss, with the age factor to play a less important role.

2.6.3 LBP and Vibration

Whole Body Vibration (WBV) is described by many authors as a risk factor for the development of LBP. A literature review of epidemiologic studies published between 1986-1997 concluded that professions with extensive exposure in WBV have increased risk for LBP disorders (Bovenzi & Hulshof, 1999). Earlier reviews on this subject raise the same concerns regarding exposure to WBV and indicate the need for further research (Seidel & Heide, 1986; Wikstrom et al., 1994). Nevertheless, the LBP due to WBV occupational exposure in Britain is less that that associated with lifting at work (Palmer et al., 2003). How can the exposure to vibration can become a cause for the development of LBP? The combination of exposure to vibration and loading may explain partially this association since the lumbar and lower thoracic vertebras are subjected to the largest compressive and shear forces (Verver et al., 2003). Studies examining the rheological and biological behavior of porcine intervertebral discs under vibration reported an exponential increase of dissipated energy with frequency increase and suppression of the proteoglycan synthesis in the nucleus pulposus (Ishihara et al., 1992). For long term exposures, these effects can lead to intervertebral disc degeneration as a result of matrix integrity disruption due to the decrease of proteoglycan content in the nucleus pulposus (Ishihara et al., 1992). Conversely, an in vivo human study revealed no significant differences, in terms of average water content, disc height, viscoelastic behavior and compressive strength of lumbar vertebras between long-term exposed to WBV group and age matched non exposed subjects (Drerup et al., 1999). A recent in vitro porcine model study reported significant increases of herniation occurrences in the specimens, as

compared to the control ones, subjected to flexion/extension repetitive tasks under 1400N applied compression in a 5Hz frequency (Gregory & Callaghan, 2011).

Human in vivo studies using accelerometers have been assessed the transmissibility of the vibratory input through the spine. A study replicating industrial vibration environments in different vibration frequencies found that the greater vibration transmissibility occurs in frequencies around 5Hz (Wilder et al., 1982). The same authors reported decreased EMG signals suggesting a fatigue of the spinal musculature after an exposure to vibration of more than 30 minutes. Another study, measured lumbar vertebra vibration frequencies directly with pin-attached transducers, suggested that in the unsupported sitting position frequencies between four and five Hz should be avoided (Panjabi et al., 1986). In addition, it has been shown that after three hours of exposure to vehicle WBV (2Hz), the participants shrunk by 2.2 mm less than the non exposed group (Hampel & Chang, 1999). Moreover, the same authors reported an increase in height after the first hour in the WBV exposed group by 1.1 mm, and this coincides with the finding of another study which showed an increase in height by 1.8mm after one hour of 4Hz WBV exposure during driving environment simulation (Bonney & Corlett, 2003). However, the use of accelerometers for the study of vibration activity on the human spine has been questioned since concepts like accelerometer artifacts and the linearity of human dynamic responses have not yet been adequately addressed (Sandover, 1988). Thus, if we combine the suggested biological effects, certain frequencies and the muscular response to long term vibration exposure, we can assume a possible association between vibration and the development of LBP. Additionally, it has been found that LBP patients have about 20% less vibration attenuation capacity when compared with other groups (healthy, menicectomized, painful knee) (Voloshin & Wosk, 1982). This is very important since the decrease of the shock resulting from the heel contact during walking has been found to be beneficial for patients with chronic low back pain (Wosk & Voloshin, 1985).

Over the last few years there has been an increasing use of vibrating systems within the routine exercise training regimes. Such systems are unlikely to cause any significant improvement in the performance of athletes or well trained young people (Cardinale & Wakeling, 2005). However, it has been shown that weight-bearing exercise in conjunction with WBV improves significantly the lumbosacral proprioception of healthy people (Fontana *et al.*, 2005). This may have some implications to LBP patients since they have impaired lumbopelvic proprioception (O'sullivan *et al.*, 2003), even though, vibrating systems may not be the most appropriate for LBP patients. Doubtless, these systems should be treated with caution until the neurophysiological mechanisms involved are completely understood (Cardinale & Wakeling, 2005).

In summary, these results might have implications in the treatment of LBP, because both compressive loads and vibration caused from walking can be considered as aggravators of LBP (Voloshin & Wosk, 1982). Moreover, vibrations in frequencies around 5Hz have the greatest transmissibility in the human body (Wilder *et al.*, 1982) and therefore it is suggested that these be avoided especially in unsupported sitting positions (Panjabi *et al.*, 1986). Thus, the potential control of compressive loads and vibrations, in combination with the benefits of aerobic exercise may have positive impact in the treatment of LBP.

2.6.4 Treadmill vs. Overground walking

Gait analysis is a major component in biomechanical studies which provides useful information for the gait pattern of the study population. Thus, it is worth reviewing the biomechanical and physiological characteristics of treadmill walking and also to compare these with over-ground walking. Many studies have considered the differences between overground and treadmill walking in terms of temporal, kinematic, kinetic, muscle activation and metabolic parameters.

In most gait laboratories over-ground data capture is limited to 1-2 gait cycles due to space and camera restrictions. This is not a problem in treadmill gait analysis which provides a controlled setting where the capture volume and the number of cameras can be significantly reduced and multiple gait cycles can be analyzed (Matsas *et al.*, 2000; Riley *et al.*, 2007). However, because treadmill walking is initially an unfamiliar experience it is suggested that, in order to obtain reliable data, a treadmill familiarization period is required (Taylor *et al.*, 1996; Matsas *et al.*, 2000; Wass *et al.*, 2005). This is

very useful since treadmill walking it is not an automated task and requires continuous attention (Regnaux *et al.*, 2006). For healthy unimpaired adults this familiarization time was suggested to be 4 min for the joint kinematics (Taylor *et al.*, 1996; Matsas *et al.*, 2000) and 6 min for the temporal-spatial parameters (Matsas *et al.*, 2000). However, this time is significantly increased for healthy older adults and rises to 14 min (Wass *et al.*, 2005). Longer familiarization times, especially for older adults may result in fatigue and thus multiple familiarization sessions were suggested (Wass *et al.*, 2005). This difference in familiarization time in older people may be explained by the age related changes affecting postural control (Woollacott & Shumway-Cook, 2002). This information is very important for the validity of treadmill gait assessments.

In terms of the temporal characteristics of gait, Riley et al. (2007) found no significant differences between overground and treadmill walking apart from a slightly larger stride length in overground walking which was attributed to the greater walking speed. Lee and Hidler (2007) reported shorter swing and stance times on treadmill walking which was partially confirmed by Alton et al. (1998) who also suggested shorted stance times but higher cadences on treadmill walking (Alton et al., 1998; Lee & Hidler, 2007). In another study comparing overground and treadmill walking (Murray et al., 1985) at different speeds (slow, normal, fast), the authors found no significant differences but they reported a trend at all speeds for shorter step lengths, faster cadences, shorter swing phases, and longer double support periods during treadmill walking. A similar study, comparing the two walking modalities during very slow (0.20m/s, 0.30m/s) and normal walking speeds, reported shorter stride lengths and slower cadences during normal walking (Nymark et al., 2005). No differences in the temporal-spatial parameters, between the walking conditions, were found by another study and only the double support time was significantly higher in treadmill walking (Parvataneni et al., 2009).

Regarding the kinematic differences of overground and treadmill walking the literature is consistent reporting small or insignificant differences. For example, Riley et al. (2007) for the sagittal knee and hip kinematics, reported statistical significant decreases in peak flexions and extensions in the treadmill walking, but with absolute

differences of about 1.5° which cannot be considered important. This finding is in agreement with other studies which also found a significant increase of hip flexion (Alton *et al.*, 1998; Parvataneni *et al.*, 2009) and knee extension (Parvataneni *et al.*, 2009) of the same magnitude during treadmill walking. Similarly, Lee and Hidler (2007) found no significant differences apart from a decrease in knee ROM of approximately 2° in treadmill walking. This is further supported by another study (Nymark *et al.*, 2005) which also reported no difference between treadmill and overground walking during different speeds. Other researchers (Murray *et al.*, 1985) found a decrease in hip extension and dorsiflexion in stance phase of approximately 3° , during differences, between treadmill and overground walking, cannot be considered as important and can be easily attributed to the normal gait variability.

In the same way, overground and treadmill walking produce similar walking patterns and have small or no kinetic differences. Regarding the ground reaction forces (GRF), some studies report lower vertical forces of approximately 5% during push-off on treadmill walking (Parvataneni et al., 2009, White et al., 1998), others reported decreased GRF maxima in all directions (AP, ML, V) (Riley *et al.*, 2007) and others no statistical significant differences in all GRF during treadmill walking (Lee & Hidler, 2007). Some differences in GRF may explained from the variations in the treadmill belt speed during the heel contact (Savelberg *et al.*, 1998) or due to different force plates used each time between treadmill and overground walking (Lee & Hidler, 2007). Likewise, in terms of joint moments and powers, although studies report significant diecreases during treadmill walking, these cannot be regarded as important since the absolute difference is small (Lee & Hidler, 2007; Riley *et al.*, 2007).

Although overground and treadmill walking appear to be biomechanically similar, the average heart rate (Murray *et al.*, 1985; Parvataneni *et al.*, 2009) and the oxygen consumption (Parvataneni *et al.*, 2009) seem to be significantly higher during treadmill walking. However, in terms of muscle activity, only small changes were observed between treadmill and overground walking (Murray *et al.*, 1985; Nymark *et al.*, 2005; Lee & Hidler, 2007). Although insignificant, Murrey et al. 1985 showed that the average

EMG activity of the lower limb muscles was greater in treadmill walking at different speeds. Contrarily, other studies showed a more variable EMG activity. Specifically, the Tibialis Anterior showed a slight increase in EMG at initial contact and a decrease throughout stance during treadmill walking (Murray *et al.*, 1985; Nymark *et al.*, 2005; Lee & Hidler, 2007). Rectus Femoris and Gastrocnemious, exhibited decreased EMG activity during treadmill walking in early to midstance which was increasing significantly in late stance and swing phases (Murray *et al.*, 1985; Nymark *et al.*, 2005; Lee & Hidler, 2007). However, EMG measurements should be interpreted with caution, due to the fact that there is a big variability among studies in terms of treadmill familiarization times of the participants and EMG application sites, which can result in various muscle activation patterns.

In summary, it can be assumed that treadmill and overground walking do not differ markedly and can be interchangeably used for gait retraining or other rehabilitation purposes.

2.6.5 LBP and spinal ROM

Not many studies have explored the effect of LBP on patient spinal ROM, although ROM measurements is one of the most common methods used by the physiotherapists to assess the disability level of their patients (Battié *et al.*, 1994). In contrast, there are numerous studies in the literature reporting lumbar range of motion measurements of healthy participants. Nevertheless, the sensitivity of ROM measurements as an outcome measure has been challenged (Mcgregor *et al.*, 1995), with others reporting poor correlation between lumbar flexion and disability (Sullivan *et al.*, 2000). On the contrary, a strong relationship was found between segmental movements and pain in chronic low back pain patients (Dickey *et al.*, 2002). However, the latter study used percutaneous screws in order to identify three-dimensional movements of the vertebras and this may be a factor which complicates the movements and the reported pain levels. Mcgregor *et al.* (1995) reported no differences between LBP patients and the control group in lumbar back ROM, except for lumbar flexion, while the velocity of all movements was significantly decreased. Likewise, in another study the flexibility in

flexion and extension was reduced, by 25% and the velocity in flexion by 50%, in the LBP group when compared to the control group (Marras & Wongsam, 1986). The latter study suggested that the reduced back ROM may be due to protective muscle guarding in order that the moments and the forces are reduced. This is a common theory suggested by many authors. In addition, a study examining the lumbar spinal movements during gait in patients with mild LBP reported smooth and symmetric walking patterns, without evident lumbar motion abnormalities (Rowe & White, 1996). However, in this study apart from the small sample size, the patient pain levels were very low ($\bar{x} = 8\%$) and it is known that pain levels below five (in a 0-10 VAS scale) do not imply severe decrease in functioning (Turner *et al.*, 2004). Therefore, patients with higher pain levels may reveal altered gait and lumbar kinematics. Further, people being at risk of developing LBP, like heavy laborers, although they demonstrate a gradual decrease of the lumbar ROM with age, they do not appear to have less lumbar mobility than the normal population (Hasten *et al.*, 1996).

Regarding the usefulness of low back ROM as an outcome measurement for the monitoring of LBP patients, some authors suggested it should not be used (Sullivan et al., 1994; Mcgregor et al., 1995) and the motion velocity should be used instead (Mcgregor et al., 1995). However, such statements exceed the scientific validity of those studies due to methodological drawbacks and also due to the high degree of variability in lumbar ROM measurements, where some measuring tools (i.e. inclinometers) may be problematic in detecting impairment (Sullivan et al., 1994). Additionally, the relationship between spinal range of motion and disability it is not completely defined, especially for chronic low back patients where a patient could have normal range of motion while appearing severely disabled. On the other hand, the use of motion pattern, particularly the velocity, as an outcome measure is not judged to be an objective measure. Decreased motion velocity could be the result of pain sensitization and fear of re-injury, and it is highly affected by subjective factors like mood, fear, motivation, and thus it is difficult to be used as objective parameter in repeated measures. Whereas ROM measures, when used with adequate tools and instruction, can be a far more objective measure of the functional status of the spine. Finally, although it appears that lumbar

motion of mild LBP patients do not changes markedly during gait (Rowe & White, 1996) or during gross movements on the coronal and transverse planes, significant reductions were found in lumbar sagittal motion and especially the flexion (Marras & Wongsam, 1986; Mcgregor *et al.*, 1995). Lumbar flexion is one movement which demonstrates the highest ROM. This may be an indication that in movements with high ROM, the moments created at the motion extremes, aggravate the pain and thus these ranges are avoided by the patients or a protective muscle guarding mechanism may subconsciously be activated and automatically restrict the excess ROM.

2.6.6 Key points

- There is a gap in the literature regarding the effects of supported treadmill walking on LBP Patients.
- Using 40% under-arm BWU treadmill walking it is possible to elongate significantly the spine and attenuate the transient shocks created by the heel strike during walking, and these can have beneficial implications on LBP patients.
- Spinal loading is an important factor in stature loss and recovery.
- Exposure to certain vibration frequencies may be a risk factor or aggravator of LBP, which can possibly contribute to disc degeneration.
- No clinically important differences exist between treadmill and overground walking in terms of: kinematic, kinetic, temporal-spatial and muscle activation parameters.
- Movements with greater ROM seem to be affected more in patients suffering from low back pain, particularly forward flexion.

2.7 LITERATURE SUMMARY

This literature clearly showed that LBP constitutes an important socioeconomic problem which is not well understood. Factors like spinal mechanical loading and spinal vibrations may play an important role in the development or aggravation of LBP. Also, structures like intervertebral discs and facet joints are common origins of LBP and significantly affected by mechanical loading and vibrations. Aerobic exercise may be useful, as part of a conservative therapy regime for LBP patients and there is evidence to suggest that walking on a treadmill with under arm BWU may have beneficial effects on spinal shape, loading, range of motion and pain levels of LBP patients.

Hence, in this study, we propose to examine scientifically the use of under-arm BWU treadmill walking with patients with LBP. Conventionally, the BWU is applied with a harness around the waist and the thighs with the intention to reduce the ground reaction forces in the lower limbs (Joffe *et al.*, 2002). However, in this study we will use under-arm BWU (Thomas, 2007; Pollock *et al.*, 2008) with an unloading equivalent to 40% of body weight as has been suggested by Pollock *et al.* (2008). We hypothesize that the decrease in the compressive spinal loads during walking produced by the under arm BWU in LBP participants will result in spinal elongation, improved spinal shape, improved spinal range of motion and analgesic effects, when compared to non-BWU walking of similar time duration.

CHAPTER 3 METHODS: POLHEMUS VALIDATION 3.1 INTRODUCTION

This chapter presents the validation process of the Polhemus Liberty which was used as measurement tool in the main study of this thesis, described in Chapter 4. The chapter begins with a short background followed by the methods used throughout the course of the validation process and the presentation of the results. The chapter ends with a brief discussion of the findings and with the relevant conclusions.

3.2 BACKGROUND

Non-invasive techniques for the assessment of the spinal Range of Motion (ROM) are frequently used in biomechanical and clinical studies to identify motion deviations, make diagnosis, plan the appropriate treatment and also monitor patient progress. Over the last years there has been increasing discussion regarding the dangers of exposure to radiation from repeated radiographic assessments of the progression of the spinal curvature especially in spinal pathologies such as scoliosis, in both adults and childern (Doody *et al.*, 2000; Kleinerman, 2006). Thus, the need to use alternative technologies is of great importance. Many different non invasive techniques are available at the moment for the evaluation of the spinal curvature and range of motion. However, the validity and reliability of surface spine measurements is frequently questioned due to the systematic and random errors produced by the systems and the users.

Three dimensional motion analysis systems like Vicon are widely accepted as very accurate and valid. However, Vicon like systems are very expensive, not portable, require significant expertise to operate and consequently are very difficult to use in a clinical setting. On the other hand, the Polhemus Liberty is a 6 Degree of Freedom motion capture device, which records positional and angular data, and it is also inexpensive compared to Vicon and more importantly is portable. It is assumed that the Polhemus device will be ideal for the evaluation of spinal range of motion and possibly

under certain conditions can be used for the three dimensional reconstruction of the spinal curvature.

To our knowledge there is no other study in the literature describing the validity of the Polhemus Liberty for the measurement of spinal ROM in humans. Earlier versions of this system have been tested and recommended for kinesiologic research (An *et al.*, 1988) and have been used for the measurement of the lumbar range of motion (Hindle *et al.*, 1990; Russel *et al.*, 1993; Rowe & White, 1996; Van Herp *et al.*, 2000). Van Herp *et al.* (2000) used the 3Space Isotrak to measure the ROM of the lumbar spine in 100 healthy participants. They measured the spinal ROM in six gross movements (forward flexion, extension, lateral bending to the left/right, and axial rotation to the right/left) and compared their findings with published data from electrogoniometry and 3D radiography studies. They found that their ROM values as well as those from electrogoniometry studies where in excess of the values reported from 3D radiography studies. However, their values showed a greater level of agreement with X-ray data than the data from electrogoniometry studies.

The 3Space Isotrak device comprises of a source generating a low frequency electromagnetic field and one sensor which determines the position relative to the source and can measure only one body segment at a time. The Liberty device is a more advanced version which can take up to eight sensors. This fact allows greater freedom for measuring multiple body segments simultaneously. The findings of Van Herp *et al.* (2000) interestingly showed that these devices can better approximate the actual ROM of the spine than other measuring systems. However, to date, there are no studies in the literature to have examined the validity of the Liberty or of the older version with a criterion measure. Thus, the main aim of this study is to establish the concurrent validity of Polhemus Liberty for the measurement of spinal ROM with the Vicon. Concurrent validity is established when the performance of a measuring instrument is compared against an independent standard, when measuring the same entity at the same time (Sim & Wright, 2000). We expect that the spinal ROM measurements with the Polhemus Liberty to have a high level of agreement with an established criterion measure like the Vicon system.

3.2.1 Aims

The aim of this study is to:

"Establish the concurrent validity of the Polhemus Liberty with the Vicon for the measurement of spinal Range of Motion on healthy volunteers".

Secondary aims:

- Test the accuracy of Polhemus measurements on custom made rigs simulating spinal segments.
- Examine the test-retest reliability of repeated Polhemus measurements of gross spinal movements.
- Address possible operational problems e.g. method of sensor attachment. This
 pilot study is the first part of a larger study which will measure spinal parameters
 of low back pain patients. This study is expected to provide useful feedback
 regarding the feasibility of the suggested protocol in terms of producing sensible
 data under repeated measures. Although the most operational parameters (i.e.
 method of attachment of Polhemus source/sensors) have been addressed,
 pragmatic measurement such as this can also reveal methodological/operational
 problems.

3.3 METHODS

3.3.1 Introduction

The testing process of the Polhemus was a two step procedure. At first the accuracy of the system was tested on custom made spinal segment simulation rigs with inter-segmental plastic goniometers. Thus, angles could simultaneously measured by the goniometers, the Polhemus liberty and the Vicon system. The next step was to compare

simultaneous Polhemus and Vicon measures on healthy volunteers who perform gross spinal movements. Finally, repeated Polhemus measures were compared from the same healthy volunteers when performed the same movements on two different occasions.

Measurement tools:

- Polhemus Liberty: electromagnetic motion tracking system
- An eight camera motion analysis (Vicon 620, Oxford, UK) system was used at 120Hz. Vicon has extensively used in research, especially for gait analysis, and its accuracy and validity is widely accepted.

Setting:

The study was conducted in the "Biomechanics 3" laboratory at the Bioengineering Unit of the University of Strathclyde.

3.3.2 Polhemus Liberty Description

Polhemus Liberty (Figure 3.1) (Colchester, U.S.A.) is six degrees of freedom electromagnetic motion capture system which consists of a station, a source and up to eight lightweight wired sensors. Other models of Polhemus Liberty can host more than eight sensors with the option to be wireless.



Figure 3.1 Polhemus Liberty

The source emits a low-frequency magnetic field and the system can determine the position and orientation of the sensors in space. Thus, the source is the reference for the position and orientation measurements of the sensors.

Unlike earlier models, Polhemus Liberty has a more user-friendly computer interface, with the option of RS-232, USB, as well as external synchronization port. The Polhemus screen display (Figure 3.2) shows the number of active sensors, a real time graphic representation of the each sensor in space and also live streaming of position and orientation data.

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Figure 3.2 Polhemus Screen display

When the synchronisation mode is activated a visual feedback appeared as a numerical flag in the left hand side of the data stream. Figure 3.3 presents in which order the streaming data appear in the screen display. This order is also the same when the data are exported in ASCII files.

	Position in cm			Euler orientation in degrees		
Sensor number	X	Y	Z	Yaw (Z)	Pitch (Y)	Roll (X)
1	7.5	-22.8	-1.79	128.6	9.6	-105.3
2	17.1	13.5	1.5	-57.4	8.8	-43.5
3	7.2	5.1	-24.9	-88	50	84.7

Polhemus Validation

Figure 3.3 Polhemus data output

The output data of the system sensors are angles (degrees) and positions (cm) and not only XYZ spatial coordinates (i.e. Vicon markers) and that is something which makes it simpler to use and also reducing significantly the processing time required. Each Polhemus sensor has 6DOF and therefore can define a segment by its own whereas with Vicon there is a need for at least three noncollinear markers to do so. The orientation angles use the Euler sequence of Yaw, Pitch and Roll. These terms are used by the aircraft industry with yaw corresponding to a left-right rotation of a plane in flight, pitch is a nose up-down movement and roll the rotation about the airplane's long axis. According to this sequence the rotation about Z-axis is followed by rotation about Y-axis which in turn followed by rotation about X-axis. The system gives an option between degrees or radians for the orientation angles and cm or inches for position data. There is also an option for the update rate between 120 and 240 Hz. Sensor wires are ten meters long allowing a variety of different dynamic activities. Numerous other options are also provided like: alignment (defines a reference frame to which all position and orientation output data is referred and created a new origin for the X, Y, Z sensor measurements), boresight (this command causes the sensor to be electronically aligned in orientation and optionally in position with the user system coordinates) and hemisphere function (sensors can only operate in one hemisphere at a time relative to the source and it is necessary to tell the Liberty which side of the source they will be on) (Liberty user manual, 2005). The alignment and boresight options were not used in these series of testing in order to avoid potential mathematical correction artefacts.

The Polhemus manual reports a static accuracy for orientation of 0.15° Root Mean Squared within a distance of up to 0.90 m between the source and the sensor and a

angular resolution of 0.004° RMS. Accuracy of an instrument refers to the agreement between the values being measured and a true and correct value (reference value). Precision of an instrument refers to the repeatability of the values being measured. The terms precision, resolution and stability are commonly used interchangeably, although precision and resolution do not imply the same thing. Precision is measured by estimating the variability of a series of measurement usually by calculating the standard deviation (SD) or the root RMS.

3.3.3 Rigid Body Rotation Validation

Two rigs were designed to provide a rigid and measurable environment where segment angles are known and thus can be directly compared with those obtained concurrently by the Polhemus and Vicon systems. As the Polhemus is known to be metal sensitive, no metal was used in the construction of these rigs. The rigs were made from polyethylene material and their segments joined together with plastic screws. In each joint plastic goniometers were incorporated along with a wooden stool (its parts were glued together without using metallic screws) which was formed the base for those rigs (Figure 3.4).



Figure 3.4 a) axial rotation & lateral flexion rigs

The height of each segment was 20 cm with the intention to simulate the lumbar, lower thoracic and upper thoracic spinal segments. The bottom part was 10 cm high and was playing the role of the sacral segment.

In addition, four custom made reflective marker triads were also developed from polyethylene (base), carbon-fibre (rods) and wooden materials (markers covered with reflective material) (Figure 3.5).



Figure 3.5 Vicon triads used to establish local coordinate systems in Polhemus validation.

These triads were mounted on the Polhemus source and on each one of the three sensors in order to establish four local Vicon coordinate systems (Figure 3.6).



Figure 3.6 a) Polhemus sensor, b) Vicon trial mounted on Polhemus sensor.

Polhemus source/sensors with the Vicon triads were in turn attached on the rig segments with double sided adhesive tape (Figure 3.7).



Figure 3.7 a) axial rotation rig & b) lateral flexion rig testing configuration.

A Vicon bodybuilder (V3.6) code was written (Appendix 1), assigning the source mounted triad as the reference coordinate system and thus relative angles were calculated between the source's mounted triad and sensor mounted triads.

In addition, all testing was conducted away from large metallic objects, including the lab's force plates. Vicon cameras were positioned in a circular manner covering the testing area from different angles. The same camera configuration was used for the testing on healthy participants described in next section (Figure 3.8).



Figure 3.8 Polhemus interface & Vicon camera configuration.

Polhemus and Vicon were synchronised in order to collect their data in phase. The systems were synchronised through the sync Polhemus mode (through a mini-din 8 pin connector) and a wired start switch of the Vicon system (Figure 3.8). The sync flag of the Polhemus system appears as an ace in the screen display. However, when the Vicon system was switched on, the sync flag was changing to zero. This indicator in the Polhemus output data was used from a Matlab code (Appendix 2), during data processing, to identify and compare the concurrent Polhemus and Vicon measurements.

For each rotation axis (X, Y, Z) the rig segments were moved manually, altogether or separately, in a range of $\pm 90^{\circ}$ at 10° increments. It should be mentioned here that since no identifiable stops were on the plastic goniometers, in each 10° increment, a small random error in measurements could be introduced by the user.

The Polhemus source and sensors were attached on the rigs (and on volunteers) in such way that the axes configuration was: X axis, lateral the Y axis vertical and the Z axis anterior-posterior (Figure 3.9a).



Figure 3.9 a) Polhemus and b) Vicon axes system conventions.

Vicon lab axes system convention was different and the X axis represented the anterior-posterior line of progression, the Y axis was the lateral and the Z axis was the vertical axis across the longitudinal axis of the body (Figure 3.9b). No attempt was made to align the axis convention of the two systems. This different axes convention did not cause any confusion or problem since coupling or other complicated activities were not in the scope of this study. Using the right hand rule, the positive rotations in each reference system could be identified. In addition, all sensors were recording angles in

respect to the source and no effort was made to obtain relative angles between different sensors. Thus, regarding the segmental spinal angles obtained by the healthy volunteers, the lower sensor was recording lumbar angles, the middle one trunk angles and the top one angles from the whole spine which included the lumbar, thoracic and cervical segments (Figure 3.10).



Figure 3.10 Schematic representation of segments defined by the Polhemus source/sensors.

3.3.4 Validation on Healthy Participants

Attachment of source and sensor

One major drawback of non-invasive systems is the accurate identification of anatomic landmarks and the firm attachment of the measuring devices on the participants (Hindle *et al.*, 1990).

Polhemus Validation

Regarding the identification of the anatomic landmarks, it has been shown that experience plays an important role in the accurate location of those points and that lumbar L5 spinous process is one of the most difficult palpable points (Billis *et al.*, 2003). Physiotherapists who have further trained in manipulative techniques show enhanced skills in palpation of lumbar vertebras (Downey *et al.*, 1999). Others have been reported poorer inter-rater reliability than intra-rater reliability and suggested the landmark identification in studies should be performed by a single rater (Moriguchi *et al.*, 2009). This is also supported by another study which was further reported no effect of age, sex and BMI in the accuracy of lumbar vertebrae identification by experienced manipulative physiotherapists (Harlick *et al.*, 2007). However, the effect of inter-rater variability it is not applicable in this study since only one rater was responsible for the spinal process identification. It is recognised though that the poor landmark location can be a potential source for bias in this study.

For the anatomic landmark location in this study a method previously described by (Burton, 1986) was used. According to this method, the Tuffier's line was identified (a horizontal line joining the superior aspect of the iliac crests) and in its bisection we locate the L4 spinous process. It has been reported that there are significant differences in the anatomic location of the Tuffier's line between women and men. In men, this line more often intersects the L4 body or its inferior endplate whereas in women intersects the body of L5 or its superior endplate (Snider *et al.*, 2008). Additionally, the level of Tuffier's line is not associated with weight or BMI and can vary between L4 and L5 vertebral bodies in both sexes (Snider *et al.*, 2008). Having, identified L4 spinous process, counting upwards the processes of L3, L2, L1, and T12 are also identified. Particularly for the T12 vertebra, an extra measure was taken to reassure the correct identification. Apart form the fact that this vertebra was identified by counting up the spinous processes from L5, the 12th rib was also palpated to verify the correctness of the location. Occipital bone and T1 spinous processes are prominent in the majority of the people and thus no specific method for their identification was needed.

Once the relevant spinal processes have been identified, the Polhemus source and sensors were attached on the participants using hypoallergenic tape and elastic straps with adjustable buckles (Figure 3.11). The Polhemus source was attached with plastic screws on a polyethylene plate. The surface of the plate attached on the skin was soft padded. An elastic band was attached at the sides of the plate in specially made gaps. Similarly, the sensors were attached on miniature carbon-fibre plates with double sided tape. Double sided hypoallergenic tape was also used to secure the source/sensor plates.



Figure 3.11 a)Polhemus source-sensor & Vicon triad placement b) anatomical position

3.3.5 Sample Size & Recruitment

A convenient sample of ten healthy male participants took part in this study. The participants were recruited from staff and students at the Bioengineering Unit of the University of Strathclyde. The study protocol was reviewed and granted ethical approval by the departmental ethical committee (Appendix 3). Study participants were approached by Mr. Konstantinos Kaliarntas. The study was explained verbally and also an information sheet was provided. If the volunteers met the inclusion criteria (Table 3.1) and agreed to participate, a signed consent form was requested. All participants were given a copy of the signed consent form.

	Criteria			
	Inclusion	Exclusion		
Age (years)	18-35			
Sex (♂♀)	Men	Women*		
Obesity (BMI)	BMI≤30	$BMI \geq 30^{**}$		
Pain	Normal functioning, no pain	Any pain		
Other diseases		Any disease affecting normal movement		

Table 3.1 Participant inclusion-exclusion criteria.

* Participants needed to be topless during the testing, **Due to soft tissue artifact and difficulty to locate anatomic landmarks

3.3.6 Experimental Procedure

Volunteers attended the laboratory twice (one week apart) and the overall duration of the study for each participant was approximately two hours. On the first arrival to the laboratory the participants were given enough time to read the information sheet and receive further information for the experimental procedure. Also, their biometric characteristics (i.e. weight, height) were recorded. All Participants were topless and had to wear a pair of shorts which were provided.

The Polhemus sensors with the mounted Vicon triads were attached over the spinous processes of C7, T12 and on the back of the head (occipital bone) and the Polhemus source was attached over the sacrum (Figure 3.11). In addition, more single Vicon reflective markers (14mm) (Figure 3.12) were attached on each spinous process only for identification and training purposes since identification of all spinous processes was involved in the protocol of the main study of this thesis.



Figure 3.12 Vicon retro-reflective marker

The participants were standing in the middle of the laboratory. From the standing anatomical position (Figure 3.11b) they were asked to perform six gross movements of the upper body: forward flexion, extension (leaning back), lateral bending to the right, lateral bending to the left, axial rotation to the right, axial rotation to the left. Each of these movements was repeated three times. These movements are illustrated in detail in the next chapter (Section 4.4).

The movements were described in detail verbally and demonstrated by the investigator and then were practiced by the volunteer before the formal measurements. All participants were instructed to perform the movements at a slow and steady pace and also to hold the end of ROM position for a second.

At the second session, Polhemus source/sensors and mounted Vicon marker triads were attached over the same anatomical positions. The same six gross spinal movements were performed by the participants. The scope of the second session was to determine the test-retest reliability. The range of motion (during six gross movements), of the thoracic and the lumbar spine, was compared between the two sessions in order to determine the level of agreement between the Liberty measurements when applied by the same rater.

3.3.7 Data Analysis

The rig testing results were plotted in graphs and the association between reference angles and Polhemus angle is examined. Each graph includes the regression equation and the R^2 values for each comparison. In addition, a visual comparison can be made between Polhemus and Vicon measures.

For the testing on the healthy participants, an average of the three measurements (of both Polhemus and Vicon) of each spinal movement was calculated. Intra-class Correlation Coefficient (ICC) was used to evaluate the level of association between the Polhemus Liberty and Vicon data for all the six gross spinal movements. The reliability of the Liberty measures between the two trials (on separate days) were also examined using ICC. This was achieved by comparing the measurements of the spinal range of motion (lumbar and thoracic segments), during the six gross spinal movements of the two sessions performed by the Liberty system. In addition to ICC, another method described by Bland and Altman (1986) was also used assessing the agreement between the two systems and Polhemus repeated measures. This method gives a visual feedback of the degree of difference between paired measures, the mean difference between of the two samples and the 95% limits of agreements. The limits of agreement correspond to \pm two standard deviations from the mean difference $(\overline{d} \pm 2SD)$. These limits are only estimates and should not be confused with measures of precision of an estimate such as standard errors or confidence intervals. However, confidence intervals can be calculated for these limits of agreement. It has been suggested that differences within the limits of $\overline{d} \pm 2SD$ are not clinically important (Bland & Altman, 1986). For all figures presented below the difference is given for the Polhemus value minus the Vicon value, such that a positive mean difference demonstrates higher values obtained by the Polhemus.

3.4 RESULTS

In this section the results from the rig testing as well as the healthy volunteers testing are presented. Regarding the rig testing each figure presents the pure rotation about a main axis of the Polhemus along with the cross-talk effects of the secondary Polhemus axes. Also, direct visual comparison of the main axis with the Vicon angles can be made. Each figure includes the regression equation and the R^2 values between the Polhemus values and the reference angles (goniometer). R squared value is a statistic measure which gives information about the goodness to fit of the regression model. An

 R^2 value of 1 indicates that the regression line is perfectly aligned with the data. Also, in the regression equation, the relationship between the measured angles (Polhemus) and the reference angles (goniometer) is linear when the slope is close to 1 and the intercept as close to 0.

3.4.1 Rig Testing

Rotation about X Polhemus axis (forward flexion – backward extension)

Figures 3.13 - 3.15 show the performance of the Polhemus in rotations about X axis, across all three segments. In those figures it can be observed a linear relationship between Polhemus and reference angles in all three segments. Additionally, no significant cross-talk effects are observed in the secondary Polhemus axes. The three segments represent the lower, middle and upper rig segments respectively.

X Axis (segment 1)



Reference Angles (Gonio)

Figure 3.13 Rotations about X axis of first rig segment, forward-backward (regression & R² value for Polhemus).



Reference Angles (Gonio)

Figure 3.14 Rotations about X axis of second rig segment, forward-backward (regression & R² value for Polhemus).



Figure 3.15 Rotations about X axis of third rig segment, forward-backward (regression & R² value for Polhemus).

Rotation about Y Polhemus axis (right-left axial rotation)

Figures 3.16 - 3.18 also present the performance of Y Polhemus axis across all three measured segments and the cross-talk effects of the secondary Polhemus axes. The Y axis rotations can be visually compared with those of the Vicon system. The regression equation and the R^2 values reveal a linear relationship between the Polhemus values and the reference (goniometer) angles. However, significant cross-talk effects are observed in the secondary Polhemus axes beyond 70° of rotation.



Y Axis (segment 1)

Figure 3.16 Rotations about Y axis of first rig segment, axial rotation (regression & R² value for Polhemus).



Figure 3.17 Rotations about Y axis of second rig segment, axial rotation (regression & R² value for Polhemus).



Reference Angles (Gomo)

Figure 3.18 Rotations about Y axis of third rig segment, axial rotation (regression & R² value for Polhemus).

Rotation about Z Polhemus axis (right – left lateral flexion)

Similarly to the two previous subsections, Figures 3.19 - 3.21 present the response of Polhemus in rotations about Y axis. In these figures, a linear relationship between the Polhemus angles and reference angles is observed without significant cross-talk effects.





Figure 3.19 Rotations about Z axis of first rig segment, right-left (regression & R² value for Polhemus).



Z Axis (segment 2)

Reference Angles (Gonio)

Figure 3.20 Rotations about Z axis of second rig segment, right-left (regression & R² value for Polhemus).



Figure 3.21 Rotations about Z axis of third rig segment, right-left (regression & R² value for Polhemus).

In Appendix 4, Tables 1 - 9 show the angles about all three Polhemus axes, across three measurements and the errors across each measurement. No significant errors can be observed in X and Z Polhemus angles throughout the -90° to 90° rotation range. However, in Y axis, the errors are significantly increased in rotations beyond $\pm 80^{\circ}$, along with a significant increase in the cross-talk effects of the other axes showed in Figures 3.16 - 3.18.

3.4.2 Healthy Participants Testing

Participant characteristics

A convenient sample of ten healthy male participants was used for the purpose of this validation study (Age: 26.6 ± 1.5 years, height: 178 ± 9 cm, and mass: 80 ± 10 Kg). No participant reported any LBP incident for at least one year previous to the assessment or history of low back pain.

In the graphs below are presented results of the concurrent validity and test-retest reliability of the lumbar and trunk sensors. The head mounted sensor (which recorded angles from the whole spine (Fig. 3.10)) data showed similar trends to the thoracic one. Only major movements (forward flexion, left-right lateral flexion) are presented in all sections below due to significant marker occlusions in the majority of the Vicon data in the other movements (backward extension, right-left axial rotation).

Lumbar Segment: Concurrent Validity

For the lumbar forward flexion movement, the two systems showed highly correlated values (ICC = 0.96). There was a non significant mean difference of -1.45° favoring higher values in for the Vicon with quite narrow limits of agreement (-5.71° to 2.81°). All differences were within the limits of agreement (Figure 3.22).


Figure 3.22 Agreement and difference between Vicon & Polhemus during the concurrent measurement of lumbar forward flexion.

Similarly, a high correlation was also found in the lumbar lateral flexion to the right (ICC = 0.96). Also the systematic bias was again quite small (-1.46) favoring again higher values for the Vicon. In addition, the limits of agreement were again narrow (-4.06 to 1.14) enclosing all paired differences (Figure 3.23).



Figure 3.23 Agreement and difference between Vicon & Polhemus during the concurrent measurement of lumbar right flexion.

A high correlation was also found in lumbar lateral flexion to the left (ICC = 0.93). The systematic bias was not significant (-1.09°) indicating higher values for Vicon system. The limits of agreement were between -4.69° to 2.51° (Figure 3.24).



Figure 3.24 Agreement and difference between Vicon & Polhemus during the concurrent measurement of lumbar left flexion.

The Polhemus values showed a high agreement and correlation with the Vicon values. Also, the systematic bias was around 1.5° indicating constantly higher mean values for the Vicon system. All limits of agreement were quite narrow and acceptable.

Lumbar Segment: Test-retest Reliability

This section presents the reliability of the Polhemus measures in the lumbar segment. In Figure 3.25, the correlation and the agreement of Polhemus measures for the lumbar forward flexion is illustrated. Although the Intraclass correlation coefficient indicates a good correlation between Polhemus measures (ICC = 0.75), the Bland and Altman's plot revealed some substantial individual differences of up to 10° . The systematic bias between Polhemus measures is very small (0.13°) with quite wide limits of agreement (-14.07° to 14.33°) indicating some large random differences.



Figure 3.25 Agreement and difference between lumbar forward flexion angles obtained by Polhemus on two different occasions.

For the lateral flexion to the right (Figure 3.26), the systematic bias was zero and the limits of agreement (-3.8° to 3.8°) revealed small random differences between measures. Additionally, there was a high correlation between measures (ICC = 0.94) further supporting the assumption of agreement.



Figure 3.26 Agreement and difference between lumbar right flexion angles obtained by Polhemus on two different occasions.

Likewise, the Polhemus measures for the lateral bending to the left were also showed good reliability (Figure 3.27). The correlation analysis showed a very strong relationship between Polhemus measures (ICC = 0.95). The systematic bias was very



small (- 0.2°) along with narrow limits of agreement (- 3° to 2.6°) indicating small random differences.

Figure 3.27 Agreement and difference between **lumbar** left flexion angles obtained by Polhemus on two different occasions.

In total, the Polhemus repeated measures for lumbar spine movements showed a very high reliability for the right and left lateral flexion movements and moderate reliability for forward flexion movement.

Trunk segment: Concurrent Validity

Regarding the trunk forward flexion, there was a high correlation between Polhemus and Vicon systems (ICC = 0.97). The systematic bias was 0.4° indicating a very small mean difference between Polhemus and Vicon measurements. Considering that the mean trunk forward flexion was 75.2°, the limits of agreement for the differences (-4.8° to 5.6°) were narrow indicating high level of agreement (Figure 3.28).



Figure 3.28 Agreement and difference between Vicon & Polhemus during the concurrent measurement of trunk forward flexion.

Similarly, the systematic bias for the trunk lateral flexion to the right was 0.1° followed by narrow limits of agreement (-3.9° to 3.7°) and supporting a significant agreement of the two systems for this gross movement (Figure 3.29). The correlation coefficient was also highly significant (0.94).



Figure 3.29 Agreement and difference between Vicon & Polhemus during the concurrent measurement of trunk right flexion.

For the trunk lateral flexion to the left the agreement and correlation was even higher (Figure 3.30). The Intraclass Correlation Coefficient indicated a significantly



high correlation (0.99). The mean difference was zero and the limits of agreement were $(-1.13^{\circ} \text{ to } 1.13^{\circ})$ pointing out a high agreement between the two systems.

Figure 3.30 Agreement and difference between Vicon & Polhemus during the concurrent measurement of trunk left flexion.

In a similar manner with the lumbar segment, the Polhemus measurements showed high agreement with Vicon for all movements examined. This fact indicates that Polhemus can produce valid measurements of range of motion for the particular segment.

Trunk Segment: Test-retest Reliability

Regarding the reliability of Polhemus repeated measures Figure 3.31 shows the agreement level of trunk forward flexion measured by Polhemus on different days. The mean difference between measurements was quite small (-2.4°) indicating higher values for the second Polhemus measurement. However, due to the very wide limits of agreement (-22.8° to 18°) and considering the mean trunk forward flexion being approximately 75.2° (Table 3.2), this lack of agreement cannot be considered as acceptable. Correlation analysis also revealed a moderate correlation between Polhemus repeated measures (ICC = 0.55).



Figure 3.31 Difference between trunk forward flexion angles obtained by Polhemus on two different occasions.

The reliability analysis for the trunk lateral flexion to the right also showed lack of agreement between Polhemus measures (Figure 3.32). Although the systematic bias was again small (-2.8°) indicating again higher values for the second Polhemus measurement, the limits of agreement (-18° to 12.4°) are quite wide reveling large

random differences. These differences are not acceptable especially if we consider that the mean trunk lateral right flexion is approximately 45.2° (Table 3.2). The Intraclass correlation coefficient was also revealed a poor agreement between the two measurements (ICC = -0.32).



Figure 3.32 Difference between trunk lateral flexion (right) angles obtained by Polhemus on two different occasions.

In a same way as above, Polhemus measurements for the trunk flexion to the left also showed poor agreement (Figure 3.33). Although the systematic bias was again small (1.4°), the limits of agreement (-18.8° to 16°) showed again large random differences. The Intraclass correlation coefficient was also indicated a poor correlation between Polhemus measures (ICC = -0.13).



Figure 3.33 Difference between trunk lateral flexion (left) angles obtained by Polhemus on two different occasions.

In total, the Polhemus repeated measures for the trunk segment showed moderate to poor reliability.

In order to verify the accuracy of Polhemus sensor placement and explain any possible variation in repeated measures, the distance of the source and sensor was compared between the two measurements for the lumbar and the trunk segments respectively (Figures 3.34 - 3.35).



Figure 3.34 Repeatability of sensor placement in lumbar segment (distance source-sensor).

Regarding the lumbar segment, reliability analysis yielded a strong correlation (ICC = .81) between group measures which indicates a consisted anatomic landmark identification and Polhemus sensor placement. The mean difference between group measurements was .29 cm and the paired samples t-test indicated not statistically significant differences (p = .51).



Figure 3.35 Repeatability of sensor placement in trunk segment (distance source-sensor).

Similarly, for the trunk segment, the reliability analysis again showed strong correlation between group values (ICC = .77). The mean difference was 0.1 cm which again was not statistically significant (p = .84). These results indicate a consistent anatomic landmark location and sensor attachment for both lumbar and trunk segments.

In addition, an extra measure was taken to explain variability between Polhemus repeated measures. Since the standardization of the anatomical starting position is difficult, a different starting position could yield significant differences between repeated measures. Thus, the difference in orientation of the spinal segments between the two measurements was compared with the difference in ROM.

In the lumbar segment, the between measures difference in starting position orientation values and the difference in ROM values yielded a moderate correlation (ICC = .65). Additionally, the mean difference between group values was $.5^{\circ}$ and not

statistically significant (p = .8). Regarding the trunk segment a strong correlation in the same values was also found (ICC = .72), with a mean difference of 1.6° which again was not statistically significant (p = .43).

This analysis showed that the difference in repeated measures presented above was primarily due to differences in starting position and secondary due to inaccurate sensor attachment or difference in performance of participants between different days. This is particularly important for the sagittal plane and not as much for the transverse and coronal planes.

In Table 3.2, mean ROM values of the ten healthy participants, across all six gross spinal movements are presented.

Table 3.2 Segmental ROM (degrees) measured by Polhemus in the six gross movements (means \pm SD, N = 10).

Movements	Lumbar (°)	Trunk (°)	Total (°)	
Forward Flexion	53.5 ± 8.7	75.2 ± 11.1	101.7 ± 13.6	
Backward extension	14.4 ± 5.5	44.6 ± 18	60 ± 21	
Lateral bending right	22.2 ± 5.9	45.2 ± 4.8	65.4 ± 16.3	
Lateral bending left	21.1 ± 4.1	47.7 ± 7.2	68.8 ± 14	
Axial rotation right	7.7 ± 3	34.8 ± 6.9		
Axial rotation left	7.3 ± 2.7	31.2 ± 4.8		

3.5 DISCUSSION

The assumptions of validity and reliability are closely related and are two main requirements for a trustworthy tool. Some authors use the assumption of validity as an overarching term which also contains the assumption of reliability. The term validity relates to the accuracy (correctness) of the inferences drawn from the measurements, whereas reliability deals with the reproducibility of such measurements (Sim & Arnell, 1993). Although reliability does not presuppose validity, a high degree of validity

Polhemus Validation

presupposes a high degree of reliability (Sim & Wright, 2000). Invalidity leads to distorted inferences due to systematic error (bias), whereas lack of reliability is mainly due to random error and leads to indistinct inferences (Sim & Wright, 2000). Criterion related validity is probably the most objective method to establish the measurement trustworthiness of a tool. It is important to understand that in research there are no universally valid and reliable tools but only for specific applications. This supports the notion of checking these two important assumptions before using a tool for a specific purpose and thus any differences in findings can be attributed to the manipulation of study parameters and not to systematic or random errors.

In clinical and research environment there is often the need of replacing an old measurement technique or instrument with a new one or use them interchangeably. Other reasons for replacing a technique with another are: user-friendliness, cost, level of expertise required for its use and portability. However, measurements of a new instrument have to be compared with a criterion measure in order to establish its measurement accuracy and reproducibility and hence its validity.

The accuracy testing of this instrument was conducted in two steps: a) validation on specifically made rigs simulating spinal segmental movements and b) validation on healthy participants with concurrent Vicon measurements. The reliability was tested by comparing repeated Polhemus measures (captured on different days) of the same spinal movements from the same healthy participants. Thus in more technical terms, this study tested the concurrent validity of the Polhemus with the Vicon and goniometers and also its test-retest reliability over repeated measures.

The first step, in section 3.4.1, of the Polhemus validation on the rigs showed repeatably no significant variation of the Polhemus performance in different segments. Thus, according to those results, different Polhemus sensors showed accurate performance irrespective of the distance form the Polhemus source, with a maximum distance specified in this study of up to 0.70 m. As mentioned before the operation range (distance between source and sensors) recommended by the manufactures is up to 0.90 m, although operation is allowable up to 1.8 m with reduced accuracy. Thus, the 0.70 m maximum separation distance used here is well in the recommended operation range.

However, the rotations about Y axis showed significant deviation from the reference angles (goniometer) in rotations beyond $\pm 80^{\circ}$ along with significant cross-talk effects. The Y axis was assigned to measure the axial rotation angles on the participants testing. Because this value is in excess of normal spinal motion in the lumbar and thoracic spine, this deviation could not have an effect in the measurements of those segments. However, due to the fact that the cervical spine can show axial rotations near or above 90° (relatively to the pelvis), Polhemus is inappropriate to measure these angles, with the current source-sensor configuration which is described in the methods section. Thus, for the cervical segment the axial rotation angles were not measured. The X (Figures 3.13 – 3.15) and Z (Figures 3.19 -3.21) axes showed a linear relationship with reference angles and minimal cross talk effects in ranges even in excess of $\pm 90^{\circ}$.

Regarding the deviation beyond the 80° of rotation about Y axis, it was observed that when the angles were approaching the 90°, the angles were actually reversed and started decreasing at 10° increments. A different deviation was observed in the secondary (X & Z) rotation axes in where the angles were actually flipping by 90°. However, the cross-talk effects were not of significance in this study since it is not in the scope of this study to measure coupling movements. The effect observed in the rotation about the Y axis is due to a well known problem which the Euler angles are suffering from and is known as gimbal lock. Since there was a pure rotation about Y axis, when the rotation became close to 90°, the other two axes of rotation became aligned with one another, making it impossible to distinguish them from one another. In this case a degree of freedom is lost and the commonest way to avoid this problem is to restrict the one of the angles to $\pm 90^{\circ}$. This is a technique which is also used by other systems utilizing Euler angles such as Vicon. In Appendix 4 are presented the Polhemus values from all three segment and movements, during three subsequent measurement at the same day. Mean values of the three measurements and mean errors are also presented. The mean values are those compared with the reference angles and Vicon mean angles in the result section. From both the tables in Appendix 4 and the accuracy analysis presented in the results section it is evident that the useful operating range of the Polhemus, about the Y axis, is limited up to $\pm 80^{\circ}$.

Polhemus Validation

After the rig validation of the Polhemus, the system was further tested on healthy participants. The validity of the measurements was compared against simultaneous Vicon measures and the repeatability of the Polhemus measures were compared against repeated Polhemus measures of the same subjects and movements, one week apart. In order to test the agreement between Polhemus and Vicon concurrent measures and also between Polhemus repeated measures, apart form the relevant Intraclass Correlation Coefficient (ICC) it was decided to utilize the limits of agreement method described by Bland and Altman (1986). This was because a high correlation does not necessarily mean that two measurement methods agree (Bland & Altman, 1986). It has been agreed that a plot of difference against subject mean is very informative, whereas a crude comparison of group means or a simple product moment correlation coefficient (r), is unsatisfactory (Lee et al., 1989; Bland & Altman, 1990). Classic correlation coefficient such as Pearson's measures the strength of association between two entities and not the agreement between them. This means that there is a perfect agreement when measurement data points are aligned with the equality line, but we can also have a perfect correlation if these points lie along any straight line (Bland & Altman, 1986). However, ICC is also a more appropriate statistic to assess agreement than simple correlation coefficients due to the fact that ICC it is calculated utilizing variance estimates derived from analysis of variance and represents a ratio of the variance of interest over the sum of the variance of interest plus error (Sim & Wright, 2000). Intraclass correlation coefficient is a dimensionless measure which cannot provide information regarding the magnitude of the measurements error. This can be estimated with the confidence intervals of the mean difference between two measures. The agreement in Bland and Altman's (1986) method is summarized by two measures: bias and 95% limits of agreement, which indicate the systematic and random differences in measurements (Sim & Wright, 2000).

For the lumbar segment, the values obtained simultaneously from the Polhemus and the Vicon systems showed a high level of agreement (Figures 3.22- 3.24). As was observed in Bland and Altman's figures, the systematic error (mean difference), and the paired differences were small and the limits of agreement were quite narrow for all three

gross movements (forward flexion, right and left lateral flexion). The mean difference was about 1.5° with Vicon system to exhibit higher mean difference for all three movements. These results indicate that Polhemus measurements have adequate group accuracy and can be confidently used for the measurement of the lumbar range of motion between groups. Regarding the observed paired differences, some systematic error in the concurrent measurements may have introduced from the rater during the data processing. For example, Polhemus data were filtered with a built in Polhemus filter whereas Vicon data filtered with 4th order low pass Butterworth filter.

Similarly, the same measurements obtained from the trunk segment also showed a high level of agreement. The Intraclass Correlation Coefficient values indicated almost perfect correlation between Polhemus and Vicon measurements for all movements (Figures 3.28-3.30). The systematic error for the trunk segment was even smaller than the one observed in the lumbar segment, for all three movements. Taking into account the mean values for the trunk movements reported in Table 3.2, the paired differences between Polhemus and Vicon systems and the limits of agreement cannot be considered large. Thus, again here, these results suggest that the Polhemus liberty can produce accurate measurements for the ROM of the trunk segment. Additionally, these results indicate that multiple sensors can be confidently used simultaneously without the accuracy of the measurements to be compromised. Provided that the sensors operate within the distance recommended by the manufacturer from the source, it seems that separation distance does not play an important role in the accuracy of measurements.

Regarding the test-retest reliability of the lumbar Polhemus measurements, the ICC results indicated moderate reliability for the lumbar forward flexion (ICC = 0.75) and almost perfect reliability for the right (ICC = 0.94) and left (ICC = 0.95) lateral flexions (Figures 3.25 - 3.27). For the right and left lumbar lateral flexion, the systematic bias and the paired Polhemus differences were very small, followed by very narrow limits of agreement. However, for the forward flexion values, although the systematic bias was very small (0.1°), some paired Polhemus differences were quite large (10°) indicating some large random differences. This discrepancy between Polhemus measures is probably due to differences in the segment orientation in the starting position and not as

much due to unreliable sensor attachment or variant participant performance between different days. This is supported by the reliability analysis of sensor attachment between different days which was quite high and showed almost perfect agreement (ICC = .81). For this analysis the distance between the Polhemus source and sensor was compared between the two measurement days. On the other hand, the comparison between starting position segment orientation differences and ROM measurement differences in the lumbar segment were also moderately correlated (ICC = .65) (Figure 3.34). Also the mean difference (between starting position and ROM differences) was very small (.5°) and not statistically significant (p = .8). This is particularly relevant for the sagittal plane measurements (flexion-extension) in where the spine orientation is quite difficult to be standardized. Thus, it is assumed that these relatively large paired differences were primarily due to variations in participant starting position and secondary due to performance variation or due to errors in the sensor attachment method.

The test-retest reliability of the trunk Polhemus measurements was very low for all three movements (Figures 3.31-3.33). The ICC values indicated poor correlation between Polhemus repeated trunk measures. Although, the systematic error was relatively small (< 3°) for all three movements, the random errors observed were quite large and were considered unacceptable. All three mean differences were negative indicating higher angles for the second Polhemus session measurements. The sensor attachment for this segment was again proved to be very reliable since the Polhemus source-sensor distance between different days showed strong agreement (ICC = .77). Especially for the trunk segment it is less likely to misplace the trunk mounted sensor during its attachment because the C7 spinal process (where the thoracic sensor was attached) is very prominent and easily palpable. In addition, the between measures difference in starting position orientation values and the difference in ROM values yielded a strong agreement (ICC = 0.72). These findings indicate that the large variability between different trunk Polhemus measures are mostly explained by the variability in starting position and less likely to be due to unreliable source-sensor attachment or variability in individual performance between different days. However, the variability observed does not entirely explained by the variations in starting position.

Polhemus Validation

Thus, the possibility of performance variability in spinal range of motion during different days, especially for the trunk segment, can not be excluded. This is supported by the fact that in the trunk segment, the coronal gross movements (right/left side flexion), which theoretically are not prone to errors arising from individual inconsistent starting position, were also showed large variability over repeated measures. It is also speculated that participants were more familiarized and relaxed with the measurement procedure and performed better in the second session. No error could have arisen from interference with metallic objects since all measurements were obtained away from large metallic surfaces and under similar conditions. It is speculated that the difference in repeated measures found in this study should be the result of a combination of three factors: a) variability in performance between different days b) inconsistency in starting position and c) failure to identify reliably anatomic landmarks. This is evident from the data which consistently showed a large random error and a very small systematic error indicating a variant source of error. Therefore, although those three factors are highly subjective, they have to be controlled strictly for reliable ROM measurements with Polhemus Liberty.

In respect to the operational problems when using the system for the measurement of the spinal ROM, which was a secondary objective of this study, two major drawbacks were identified. One was related to the attachment method of the lumbar sensors and the other to the individual variability in performance during the gross spinal movements.

The attachment method was mostly problematic during the axial rotation movements of the lumbar segment. Due to the lumbar anatomy, the firm attachment of the sensor in this segment was difficult, especially in people with developed musculature. For this reason, the measurement of the pragmatic axial rotation with surface sensor is considered of low quality according to the author. This is because during the lumbar axial rotation there is a large skin sliding on the underlying lower back soft tissues. Sometimes skin sliding creates a paradox effect where the sensor is rotating towards the opposite direction than the direction of the movement. According to this observation, the lumbar axial rotation was the least accurate measurement and the one which was poorly estimating the true lumbar axial rotation.

Polhemus Validation

Regarding the individual performance during the gross spinal movements, it was observed that participants usually had difficulty in identifying accurately the end of their spinal range of motion. This is very important observation which can have a considerable effect in the outcome of repeated spinal ROM measurements. It is considered necessary for the participants to understand very well what they are asked to do and also to perform a comprehensive training session before the formal measurements. It is expected that the biological variation between different measurement days has not played an important role in the outcome of those measurements. This is because the participants used in this study were relatively young (mean age: 26.6 years) and without any known history of spinal pathology or low back pain. In addition, the experiment took place in the same laboratory with controlled and fixed conditions i.e. room temperature. Therefore, it is quite unlikely for the specific target group the variations, found in the between days measurements, to be attributed to biological variation. This could be the case in older and diseased populations.

3.6 CONCLUSIONS

In this section the main findings discussed previously will be underlined. The conclusions are linked directly to the aim and objectives stated earlier in this chapter.

From the rig testing it was showed that Polhemus Liberty is a very accurate system for the measurement of the spinal range of motion across different segments simultaneously. However, the operation range in rotations about the Y axis is limited to $\pm 80^{\circ}$ due to the increased errors beyond this range, caused by loss of one DOF due to gimbal lock effect. Separation distance and number of sensors used each time do not seem to affect the performance and accuracy of this system. The level of accuracy of this system is in excess of what is required for the proposed measurements.

Polhemus liberty was also proved to be a valid system for the simultaneous ROM measurements across different spinal segments on groups of healthy individuals. Concurrent gross spinal measurements of Polhemus and Vicon showed a high level of agreement. Thus, based on the findings of this study, the Polhemus Liberty can be confidently used for the measurement of the spinal ROM in groups.

The test-retest reliability proved to be adequate for the lumbar segment measurements and poor for the trunk segment. Intra-individual variability in starting position and performance (especial for the measurements in the sagittal plane) during repeated measures is likely to play an important role in the test-retest reliability of spinal measurements with Polhemus on individuals.

Lumbar axial rotation was found to be the least accurate measure compared to the true value due to difficulties in the sensor attachment and paradoxical axial rotation movement.

Participants have to familiarize very well with the procedure and the system, by performing several training movement trials, before the formal spinal measurements in order to provide accurate and pragmatic ROM values.

3.7 SUMMARY

In the current chapter the validation process of the Polhemus liberty was described. The chapter included its own short background information, methods, results, discussion and conclusions. It was showed that the Polhemus Liberty was an accurate, valid, and under some conditions a reliable tool for the simultaneous ROM assessment of multiple spinal segments.

In the following chapter, Chapter 4, the methods used for the supported treadmill walking for LBP patient's trial is described.

CHAPTER 4 METHODS: SUPPORTED TREADMILL WALKING STUDY

4.1 INTRODUCTION

Following the Polhemus Validation study in Chapter 3, this chapter will describe the methods used to test the main objective of this thesis. This objective was to examine the effects of supported and normal treadmill walking on LBP patients in terms of: spinal length, spinal shape, spinal vibration activity, pain status, and gait and compare them with those of healthy participants.

This is an explanatory research using an experimental design of a Randomized Control Laboratory study. The following diagram (Figure 4.1) presents an outline of the methods used to achieve the objectives of this study.



Figure 4.1 Methods chapter outline

4.2 STUDY PARTICIPANTS

4.2.1 Sample size

The main objective in this study was to see whether there is a change in spinal length between LBP patients and healthy volunteers when 40% BWU is applied. This was the main hypothesis and tested at a power of 0.8 along with a significance level of 0.05 and using spinal length as the primary outcome measure. Due to the absence of relevant spinal elongation data, the primary sample size calculation was executed based on information from other studies used different methodologies. After exercise-induced spinal shrinkage, Fowler et al. (2005) reported that women with back pain recovered only half their lost height within 20 minutes, but healthy volunteers recovered all of their lost height. A loss of proteoglycan from the discs and/or an increase in paraspinal activity may account for this effect. Consequently, we hypothesize that those with back pain will not have their spine elongated to the same extent as healthy people when subjected to BWU. However, since the elongation is forced, due to the BWU apparatus, we expect the difference between the groups to be smaller than that found by Fowler et al. (2005). Since 40% unloading increases spinal length by $\sim 2\%$ in 30 minutes in young healthy volunteers (Pollock et al., 2008), we estimate that LBP sufferers will elongate by $\sim 1.5\%$. As we are to measure spinal length statically, we expect the standard deviation to be less than that of Pollock et al. (2008). Conservatively, we expect the standard deviation to be the same for each group and to be approximately 0.67% of spinal length. Therefore, using an independent t-test, an effect size of 0.75, together with a power of 0.8 and $\alpha = 0.05$, gives a sample size in each group to be 28 (Cohen, 1988). Allowing for drop out, we aimed to recruit 32 into each group.

4.2.2 Ethics

For the accomplishment of this project ethical approval was sought and obtained from the National Health System (NHS) as well as from the University of Strathclyde ethical committee and research and development (R&D) department. Appendices 5 & 6 contain the relevant documentation from the NHS ethics and R&D approvals.

4.2.3 Participant Recruitment

A specialist physiotherapist was responsible for the identification of suitable LBP patients for this study. A screening questionnaire (Appendix 7) was used during the recruitment process to make sure each participant met the study criteria and to record the details of those excluded (Table 4.1). Suitable LBP patients were identified from three primary care sites (Milngavie Clinic, Maryhill Health Centre, Woodside Health Centre) by Ms Susan Smith who informed them of the study and if interested asked them to consider their participation in the study. The research project was discussed and explained to the patient and a copy of the patient information sheet and consent form was provided (Appendix 7). The patients were given enough time (minimum 48 hours) to consider volunteering and also to ask for clarification of any aspect of the project they were unsure about. If they were willing to participate they were informed about the research team and provided with their contact details.

Healthy volunteers (controls) were recruited from University of Strathclyde students and staff. An invitational e-mail was circulated to the staff of the University of Strathclyde and a supplementary invitation was published through the departmental website. All the responders were approached by a member of the research team and screened with a questionnaire (Appendix 8). Further information about the study was given and an information sheet along with a consent form was provided (Appendix 8). If they consented and met the inclusion criteria (Table 4.1) then they were considered for inclusion in the study. They were again given enough time to consider their participation in the study (minimum 48 hours).

	LBP patients		Healthy participants	
Criteria	Inclusion	Exclusion	Inclusion	Exclusion
Age (years)	25-65		25-65	
Sex $(\mathcal{A}_{+}^{\mathbb{Q}})$	Men	Women*	Men	Women*
Obesity (BMI)	BMI≤30	BMI \geq 30**	$BMI \leq 30$	$BMI \ge 30**$
Pain	3-6 months presence of low back pain	LBP history, chronic pain, pain in other sites		Any pain
Other diseases		Neurological, cardiovascular, lower limb problems, other spinal problems		Any disease affecting normal movement

 Table 4.1 Participant inclusion-exclusion criteria.

* Participants needed to be topless during the testing, **Due to soft tissue artifact and difficulty to locate anatomic landmarks

4.2.4 Setting

The study was commenced in the Neuro-Biomechanics Laboratory, Strathclyde Institute of Pharmacy and Biological Sciences (SIPBS), on Jordanhill Campus, University of Strathclyde. However, due to operational issues, the testing was transferred to the Biomechanics 1 & 2 laboratories in Bioengineering Unit, on main campus of University of Strathclyde. All the equipment used remained the same between the two sites.

4.3 TOOLS & MATERIALS

4.3.1 Motion Analysis Systems

A six camera motion analysis (Vicon, Oxford, UK) system was used at 100Hz to measure the spinal length and shape as well as temporal-spatial gait parameters. Additionally, a digital camera was incorporated and synchronized with Vicon system to record all testing activities. A six-degrees-of-freedom Polhemus Liberty electromagnetic motion tracking systems operating at 120 Hz was used to measure spinal range of

motion. The Polhemus Liberty has been described in detail in Chapter 3. Both of these systems are commercially available three dimensional motion capture systems produced for human movement applications and with widely accepted accuracy, validity and reliability.

The Vicon cameras were positioned in a semicircular manner approximately 2-3 meters behind the treadmill. These cameras were set in this configuration in order to capture as accurately as possible VICON marker movements positioned on different body segments (spine, pelvis, and lower limbs).

4.3.2 Disability & Pain Assessment Scales

The disability level, the general health status and the pain level of the patients was assessed with the Oswestry Disability Index (ODI), the SF-12v2, and the Visual Analogue Scales (VAS) respectively. The ODI is widely used for LBP disability assessment and for the purposes of this study the version 2 proposed by (Fairbank & Pynsent, 2000) was used. This scale is of know validity and reliability, performs better than other assessment tools and thus its use is strongly supported by many authors (Fairbank & Pynsent, 2000; Roland & Fairbank, 2000; Davidson & Keating, 2002). The benefit of this scale is its user-friendliness and also that it is provided free of charge. It consists of ten sections; each of them contains 6 items, covering different aspects of everyday functioning (Appendix 9). The items of each section are scored from 0 to 6 and the total score ads up to fifty which is then converted to a score from 0-100%. It has been suggested that for repeated measures, a minimum detectable change (with 90% confidence) is 10% and less that this may be attributable to error (Davidson & Keating, 2002).

Similarly, the SF- $12_v 2^{\text{(B)}}$ is an assessment tool containing twelve items measuring and providing total scores for both physical and emotional functioning (Appendix 10). Both components of this scale have been examined and showed adequate reliability and validity (Luo *et al.*, 2003; Cheak-Zamora *et al.*, 2009). A licence to use this scale was purchased from the QualityMetric Health OutcomesTM, USA. In this study both scales

have not used for repeated measures but only for the initial assessment of each patient during the first session.

The Visual Analog Scale is one of the most accurate tools known to date for the measurement of a subjective feeling such as pain. Special mention about VAS has been made in Section 2.3.4 of Chapter 2.

4.3.3 Treadmill & BWU System

A commercially available pneumatic device was used to apply BWU (Pneu-Lift, Pneumex, USA) combined with a modified harness (described by Thomas et al. 2007) which was applied at the upper body of the subject, under the armpits (Figure 4.2). This device was able to provide an upward force of up to 640 N and was equipped with a pressure indicator and a pressure adjustment switch for accurate unloading adjustments.



Figure 4.2 BWU system & treadmill

The treadmill used was also a commercially available item (HP Cosmos Stellar 4, Germany) able to provide inclination and speed adjustments and was equipped with an emergency stop button.

4.4 TESTING PROTOCOL

Each participant attended the laboratory on two occasions, in the one session they received treadmill walking with BWU and in the other treadmill walking without BWU. The sequence of these two conditions was randomly allocated using a computerized stratified block randomization procedure with blocks of four. Two different randomization tables were created, one for the patients and one for the healthy volunteers. For this purpose an online engine was used (www.randomization.com). When each new participant entered the laboratory for the first time, he was assigned with the next available sequential number of the randomization table. Following randomization the participants received 30 minutes of horizontal rest on a plinth in order to control for physiological daily height loss and allow spinal hydration. During this time additional information for the procedure was given and also, for the patients, their disability, and pain status were assessed with the Oswestry Disability Index (ODI), the SF-12 questionnaire and the pain Visual Analogue Scale (VAS) respectively. Additional biometric measurements (leg lengths, ankle-knee widths, height, weight) where also obtained during this time. An outline of the experimental procedure is presented in Figure 4.3.



Figure 4.3 Experimental procedure diagram

After the 30 minutes of resting time, three sensors and the source (Figure 4.4) of the Polhemus Liberty device were mounted on the following locations: head, over spinal process of Thoracic 1 & 12 (T1 & T12) and the liberty source was mounted over the sacrum and held in place using elasticized straps or hypoallergenic tape (Figure 4.4). The anatomic landmarks were identified by palpation following the protocol described

in Chapter 3. These landmarks were marked on skin with a cosmetic pencil in order to minimize the systematic error, arising by source/sensor misplacing in within session repeated measures, and speed up the reattachment process.



Figure 4.4 Polhemus Liberty sensors & source placement

Before and after the walking session the range of motion of the spine was assessed in all three planes (from the anatomic standing position: forward flexion, extension, axial rotation to the left/right, lateral bending left/right) (Figures 4.5-4.7).



Figure 4.5 Gross spinal movements in the sagittal plane (forward-backward).



Figure 4.6 Gross spinal movements in the coronal plane (left-right bending).



Figure 4.7 Gross spinal moments in the transverse plane (left-right axial rotation).

Thereafter, 14mm diameter, hemispherical, retro-reflective markers (Figure 3.12) were mounted using hypoallergenic double sided tape (toupee tape) along the patient's spine (one over every spinous process) in the longitudinal axis (T1-L5) as well as over other relevant anatomic landmarks (acromion, pelvis, legs, etc). Overall, 37 reflective markers were attached: 17 across T1-L5 spinal processes, 12 on the legs and 4 on the pelvis (VICON Plug-in Gait marker configuration), 2 on the acromions and 2 over the epicondyles.

Volunteers were asked to walk on the treadmill with or without 40% under-arm BWU for half an hour. The subjects were topless and wore their own trainers. Every 5 minutes the treadmill was stopped for static assessments of the spine with the VICON

motion analysis system. These static assessments were performed without the application of BWU. The whole session therefore involved 7 static measurements at each of the following times: 0, 5, 10, 15, 20, 25 and 30 minutes. In addition, pain status was assessed after every static assessment of the spine with the VAS. Six dynamic measurements of 30 seconds were also captured during each of the six walking intervals. After approximately a week, the same procedure with or without BWU was repeated for every participant.

The participants were free to stop at any time and withdraw from the experiment if they felt an unbearable increase in their pain status or for any other reason. Moreover, they walked at their own pace without any verbal or other external encouragement. The normal walking speed was self-selected for each participant, on the treadmill without BWU, before the initiation of the first walking session and this speed was only adjusted when appropriate during the two sessions of treadmill walking. Normal walking speed was defined as the speed which each participant believed was closest to his normal overground walking.

The duration of the study for each participant was approximately three hours, ninety minutes for each session (10 minutes introduction, 30 minutes laying on a plinth, 10 minutes marker/sensors attachment, 10 minutes assessment, 30 minutes walking with or without BWU on the treadmill).

4.5 DATA PROCESSING

4.5.1 Spinal ROM Analysis

For the analysis of the spinal ROM data, the protocol described in chapter 2 was followed. In order to calculate the total angular displacement of each spinal section, measured by the Polhemus Liberty, the average of the three repetitions was calculated (Figure 4.8).



Figure 4.8 Points used for calculation of spinal angles (baseline, peaks).

The equation below shows how the angles of each spinal movement were calculated:

$$\mathbf{A} = |\mathbf{B}| + \overline{\mathbf{X}} \{\mathbf{P}_1, \mathbf{P}_2, \mathbf{P}_3\}$$

Where, A= spinal angle

B= average of the 100 baseline frames

 $\overline{\mathbf{X}}$ = average of three peak values

All three repetitions were recorded as one trial in each movement. Polhemus liberty has a built in option where the starting position can be electronically aligned and the baseline appear to start from zero. However, this option was not chosen so as to simplify the procedure and avoid any electronic artefacts. In order to standardise the baseline condition, the first 100 frames (F) were averaged and the absolute mean was obtained. Then, the absolute mean of the three peaks values (P_1,P_2,P_3) was calculated. The absolute difference between the baseline and the mean peak value was used as the angle of movement.

4.5.2 Vicon Data Residual Analysis

Raw kinematic data usually contain additive noise which results in random errors in the differentiated data. For this reason, the raw data have to be smoothed using digital filtering techniques. However, this is not always a straight forward procedure and for best results an appropriate filter with an optimal cut-off frequency should be chosen by the user. It has been suggested that for human movement data the Butterworth type filters should be preferred (Winter, 2005). Also, in order to find the optimal cut-off frequency for a given signal a residual analysis should be performed (Winter, 2005). With this procedure it is possible to assess the deviation between the filtered and unfiltered data over a series of different cut-off frequencies (Nagano *et al.*, 2003). When choosing a cut-off frequency the compromise is always a balance between the amount of noise allowed and the degree of signal distortion (Winter, 2005). A theoretical approach of the residuals between filtered and unfiltered signal as a function of the filter cut-off frequency is presented in Figure 4.9 (Winter, 2005).



Figure 4.9 Residuals between filtered & unfiltered signal as a function of filter cut-off frequency (adapted form Winter, 2005).

For *N* samples of signal points, the residual at any cut-off frequency is calculated with the following equation (where X_i = raw data, \hat{X}_i = filtered data):

$$R(f_c) = \sqrt{\frac{1}{N} \sum_{i=1}^{N} (X_i - \hat{X}_i)^2}$$

For the purposes of this project, a 4th order zero-phase shift Butterworth filter was used. This filter was a VICON plug-in Butterworth filter which was developed in the Bioengineering Unit since it is not provided in the standard Vicon version. A residual analysis was performed on each coordinate (XYZ) over a range of reflective markers positioned on different anatomic landmarks (1st thoracic (TH1), 1st lumbar (LU1), heel (LHEE), knee (RKNE)) in order to obtain the optimal cut-off frequency. It has been suggested that for walking data the optimal cut-off frequency should be at around 6Hz (Winter, 2005). In the current study the noise content of the trajectories was found to be minimal. This is obvious in figure 4.10 where representative raw data appear to be smooth without any major deviations. The same graph indicates that higher cut-off frequencies should be used since lower frequencies (i.e. 3Hz) seem to slightly distort the signal.



Figure 4.10 Trajectory filtered with Butterworth filter over a range of cut-off frequencies.
The low noise content is further verified by the residual analysis of the XYZ coordinates of various Vicon markers (Figure 4.11). In Figure 4.11 the residual shows that all markers in vertical displacement (Z) show power up to 7 Hz, while this is limited to 4Hz in the horizontal (X and Y) displacements. This low noise content of the raw data can be easily explained by the fact that the walking trials took place on a treadmill where the Vicon cameras had to cover much smaller volume than overground walking and also the quite large size Vicon markers were used (14 mm) in this study which made them easily visible. In addition, only the location of single markers was used and hence combined errors found in three dimensional axis systems, using multiple markers, was not present in the data.



Figure 4.11 Comparison of the effect of different cut-off frequencies on XYZ marker coordinates.

The RMS residual of all markers in all coordinates at frequencies >5Hz was less than 0.01 mm. Thus, in order to cover the variability of the whole dataset and also to provide an optimal filter, with minimal signal distortion, a cut-off frequency of 7Hz were chosen for all the trajectories apart from those used to identify the frequency response (spine markers (TH1-LU5) of the dynamic trials) of the spine during walking. For those trajectories a cut-off frequency of 10Hz was chosen.

4.5.3 Spinal Elongation Analysis

The spinal length was calculated from the reflective markers attached to each spinal process of the thoracic and the lumbar segments (Figure 4.12). Change in spinal length was calculated relative to the baseline measurement.



Figure 4.12 VICON marker placement on each spinal process of thoracic & lumbar segments.

The XYZ coordinates of the spinal markers (TH1- LU5) were imported in Matlab (Figure 4.13). By applying the Pythagoras's theorem in three dimensions the length between 2 markers could be determined.



Figure 4.13 Spinal coordinates in 3D space.

From 17 markers, 16 segments were created. Thus the total length of the spine was found by adding the distances among those 16 segments.

If A is point (spinal process) defined by a Vicon marker,

Then,
$$A = \sqrt{(X^2 + Y^2 + Z^2)}$$

Thus, the difference between two points (A_1-A_2) is expressed by the following equation.

$$(A_1 - A_2) = \sqrt{(X_1 - X_2)^2 + (Y_1 - Y_2)^2 + (Z_1 - Z_2)^2}$$

And total length

=>
$$T_L = \sum ((A_1 - A_2) + (A_2 - A_3)....+ (A_{16} - A_{17}))$$

In addition, the total spinal length was also estimated by calculating the absolute difference between the TH1-LU5 markers. This calculation does not take into account the spinal curvature and was conducted as an alternative method for verification reasons.

The participants were asked to standstill during the recording of the static trials used for the spinal length estimation over time. The accuracy and reliability of this method was tested in a rigid surface imitating human spine with mean measurement error below 0.01 mm for both within and between different day's measurements (Appendix 12, Figure 1). However, because it is difficult to standardise a standing position without an external support some error could be induced in the measurements.

4.5.4 Posture Analysis

Apart from the change in the spinal length of the study participants, another important parameter was the change in posture during walking. A number of Vicon markers were used in order to divide the spine into different segments which were considered as rigid bodies and allowed segmental analysis (Figure 4.14, Primal Pictures Ltd, 2008). The Vicon axes system convention shown in Figure 4.14 and used in this analysis was different than the one described in chapters two and three. This was because in the main study, a different Vicon system was used (6 camera Vicon 612) than the one used for the Polhemus validation study (8 camera Vicon 612).



Figure 4.14 Marker configuration for identification of spinal segment angles.

Three segments defined in total: upper thoracic (UT) T1-T6, lower thoracic (LT) T7-T12, and lumbar (LU) L1-L5. With this marker configuration, five local coordinate systems were established in the spine and relative angles were calculated. Thus, five sets of angles were obtained (three spinal segments, pelvis and the orientation of the trunk as total) and each of these angles representing the relative angles between adjacent segments. The lumbar angles were given by the orientation between the pelvis and the lumbar local coordinate systems (LCS), the lower thoracic angles between the lumbar and lower thoracic LCS, the upper thoracic between the lower and upper thoracic LCS,

and the trunk orientation as a total was estimated by the relative orientation between the thorax LCS and pelvis LCS. The pelvis segment was defined by three real markers (right-left anterior superior iliac spines (RASIS, LASIS) and the 5th lumbar (L5)) and one virtual point created in the mid-distance between the RASIS and LASIS (Figure 4.14). In this coordinate system the X axis was aligned with the first defining line and the Z axis was perpendicular to the plane between the first and second defining lines. The Y axis was perpendicular to the plane created by the X and Z axes. The trunk segment was defined by a similar marker configuration consisting of three real markers (left-right acromions (LA, RA) and the 1st thoracic marker (T1) and one virtual marker established in the mid-distance between the two acromion markers. In order to establish the coordinate systems in the three spinal segments, the virtual markers were used to define the second defining line. Since the virtual markers were primarily used by the reference coordinate systems (pelvis, trunk) the rotation about Z axis could not be obtained. Thus, for the three spinal segment only rotations about X and Y axes (sideforward/backward flexions) were calculated and rotations about all three axes for the pelvis and trunk segments.

4.5.5 Spinal Vibration Analysis

For the analysis of spinal vibration during walking, Fourier analysis of the dynamic data was carried out to identify the frequencies of peak vibration activity in both participant groups. Dynamic trials of 10 seconds were captured by the VICON and used to identify the frequency response of the spine. The data across all the participants were imported and analysed in Matlab (The MathworksTM, R2008b). Particularly the dynamic trials at the baseline and 30th walking minutes (from each participant) were chosen for the analysis. Each dynamic trial was containing the change in spinal length over a ten seconds walking period (Figure 4.15). This is the raw signal in the time domain which then examined in the frequency domain (Figure 4.16) to identify peak patterns and magnitudes during different walking conditions. This choice was made under the assumption that the spine and the surrounding tissues would be preconditioned after 30 minutes of walking and probably show different response from the initial

walking sessions and thus the overall as well as the difference in spinal frequency response over time was examined. The frequency response of the lumbar and the thoracic sections were studied separately.



Figure 4.15 Relationship between stepping frequency and spinal response.

The power spectral densities of the spine during normal and supported walking were identified and the differences will be presented in next chapter both statistically and graphically (Figure 4.16).



Figure 4.16 Typical spine frequency response

In particular, the power spectral density (PSD) of each participant's dynamic trial was determined to identify the frequency response of the lumbar and thoracic spine

respectively. The peak frequency responses were then pooled (separately for each participant group, spinal segment, sampling period and walking condition) and t-tests were used (in 1 Hz increments) to compare peak frequency responses in different walking conditions.

4.5.6 Gait Analysis

The temporal-spatial parameters of the participants were recorded with the Vicon system using the Plug-in-Gait marker configuration. Key gait events like heel strike and toe-off were identified manually since no synchronised foot switches were used. These events where identified by the synchronised digital camera and marked in the Vicon workstation with the relative function (Figure 4.17).



Figure 4.17 Vicon workstation (Plug-in-Gait & Gait cycle event identification tool).

Lower limb angles (pelvis, hip, knee, and ankle) were calculated automatically by the relevant VICON pipeline function based again on the Plug-in-Gait marker set. The main temporospatial parameters of particular interest are the: cadence (step/min), stride length (cm), swing and stance time (s). The temporospatial parameters as well as the angular displacements of the lower limbs were examined for all participants and for both walking conditions. The gait differences between walking conditions and participant groups will be examined statistically and presented in the next chapter.

4.6 STATISTICAL ANALYSIS

Descriptive statistics were calculated and the characteristics of the study population will be described. Data across all sampling periods, for each participant group, were pooled and analyzed collectively and for both walking conditions. Spinal data were analyzed both as a whole and segmentally (lumbar, thoracic). Repeated measures ANOVA was used to examine potential differences between the experimental conditions (with and without BWU) and between groups (control, LBP patients). Statistical significance was considered when p < 0.05. The dependent variables which were examined for differences over time, between groups and between different walking conditions are: a) spinal elongation, b) range of motion, c) reported pain, and d) peak vibration activity. Post hoc tests of these dependent variables were performed with respect to time, contrasting with the initial condition.

In addition, correlation analysis was performed to examine the relationships among the **reported** pain status and disability level with the **measured** spinal elongation, spinal shape, range of motion, peak vibration activity and gait temporal-spatial parameters. The data were analyzed with the SPSS v18 (Statistical Package for the Social Sciences).

4.7 SUMMARY

In Chapter 4, the methods used for the accomplishment of the body weight support treadmill walking study were described. Main themes of this chapter were the participant selection and recruitment, the testing protocol as well as the data processing and the statistical analysis of the findings.

In the next chapter, results chapter 5, the findings of this study will be presented.

CHAPTER 5 RESULTS

5.1 INTRODUCTION

The current chapter presents the results of the biomechanical study described in Chapter 4. The results categorized in three sections according to chronological order of the outcome measures during the RCT. Thus, according to this order three measurement categories were identified:

- i. Those obtained before and after the 30 minute walking session (dynamic).
- ii. Those obtained between the 5 minute walking intervals (static).
- iii. Those obtained during the 5 minutes walking intervals (dynamic).

Figure 5.1 illustrates the outcome measures falling in the above categories.



Figure 5.1 Results presentation diagram

In order to assist the reader and for better understanding of this chapter, the results of an individual will be presented as a case study. The collective results of all participants will follow the case study and will be presented in a similar manner.

5.2 PARTICIPANT CASE STUDY

For the purpose of this case study, the first participant from the patient group was chosen. The following table (5.1) contains biometric characteristics as well as the disability scores of this participant.

	Patient 1
Age	50
Height (m)	1.71
Mass (kg)	87
BMI	29.75
Walking speed (km/h)	3.2
ODI score*	20%
SF-12 (PCS)**	39%
SF-12 (MSC)***	32%

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ant	2.1	1 artici	pant chi	aracterist.	ivo

*Oswestry Disability Index, **Physical component score, ***Mental Component Score

This patient was overweight according to his Body Mass Index (BMI, overweight = 25-29.9) and reported minimal disability (ODI score 0-20%). In addition, both SF-12 components were below average suggesting that LBP had a significant effect on his quality of life.

5.2.1 Before & After Walking Measurements

The main variable measured before and after each walking session was the spinal range of motion during six dynamic gross spinal movements (Figure 5.2).



Figure 5.2 Schematic representation of gross spinal movements

The values of the lumbar movements are presented in Table 5.2 both as single or combined (excursions) movements in each of the three planes of movement.

Lumbar Movements (°)	C	ontrol Wa	lking	Supported Walking			
	Before	After	ΔROM	Before	After	ΔROM	
Forward Flexion	46.1	45.6	-0.5	34.3	34	-0.3	
Backward extension	18.4	16.4	-2	8.9	9.4	0.5	
Forward-Backward							
(excursion)	64.6	62.1	-2.5	43.2	43.4	0.2	
Lateral bending right	14.4	16.2	1.8	14.7	14.3	-0.4	
Lateral bending left	12.9	12	-0.9	11.4	11.1	-0.3	
Lateral bending (excursion)	27.3	28.2	0.9	26.1	25.4	-0.7	
Axial rotation right	3	2.8	-0.2	3.8	4.2	0.4	
Axial rotation left	5.4	4.4	-1	3	4.4	1.4	
Axial rotation							
(excursion)	8.4	7.2	-1.2	6.8	8.6	1.8	

Table 5.2 Lumbar ROM in six gross movements before & after control and experimental treadmill walking.

No large differences in the lumbar angles in those six movements can be observed after each walking session. However, a significant difference exists in the forward flexion of lumbar spine between the two measurement days indicating differences in performance between different days.

Similarly, Table 5.3 presents the angular displacements of the thoracic segment, in respect to the pelvis, during the same gross movements.

Trunk Movements (°)	Co	ontrol Wa	lking	Supported Walking				
	Before	After	ΔROM	Before	After	ΔROM		
Forward Flexion	40.3	42.3	2	30.3	21.9	-8.4		
Backward extension	44.6	47.2	2.6	59.5	24.3	-35.2		
Forward-Backward								
(excursion)	84.9	89.5	4.6	89.8	46.2	-43.6		
Lateral bending right	57	52	-5	55.3	55	-0.3		
Lateral bending left	49.2	44.6	-4.6	46.6	46.8	0.2		
Lateral bending (excursion)	106.2	96.6	-9.4	101.9	101.8	-0.1		
Axial rotation right	35.9	44.9	9	41.8	41	-7		
Axial rotation left	29.2	31.7	2.5	12.9	20	7.1		
Axial rotation								
(excursion)	65.1	76.6	11.5	54.7	61	6.3		

Table 5.3 Trunk ROM in six gross movements before & after control and supported treadmill walking.

Differently to the lumbar segment, the majority of the movements in the trunk segment exhibited large changes in respect to pre-walking measurements.

In Table 5.4 the whole spine angle values, in respect to the pelvis, in the four gross spinal movements of this patient are presented.

	Co	ontrol Wal	king	Supported Walking				
Total Spine								
Movements (°)	Before	After	ΔROM	Before	After	ΔROM		
Forward Flexion	59	55.2	-3.8	41.4	40.1	-1.3		
Backward extension	41.6	37.7	-3.9	47.9	42.4	-5.5		
Forward-Backward								
(excursion)	100.6	92.9	-7.7	89.3	82.5	-6.8		
Lateral bending right	66.8	66.4	- 0.4	36.9	51.2	14.3		
Lateral bending left	70.4	69.2	-1.2	48.1	58.1	10		
Lateral bending								
(excursion)	137.2	135.6	-1.6	85	109.3	24.3		

Table 5.4 Total ROM in six gross movements before & after control and supported treadmill walking.

Similarly to the trunk segment, large differences between the pre and post walking measurements, in both walking conditions, were also found in some of the gross movements of the total spine segment.

5.2.2 Between walking intervals measures

The variables measured statically between the walking intervals of each walking session, were the self-reported pain level and the measured spinal length.

Figure 5.3 shows the change over time in the pain level of the individual during the control and supported walking. For illustration purposes a continuous figure used, instead of an interval one, although reported pain is not a continuous variable.



Figure 5.3 Self-reported pain scores measured with VAS

The particular LBP patient showed a decrease in pain over time during the supported walking and no change during the control walking. However, the pain level at baseline was significantly higher at the day of the experimental walking.

Figure 5.4 illustrates the variation of the spinal length during the supported and control walking.



Figure 5.4 Total spinal length change over time

It is clear that the spinal length is significantly increased, by approximately 1.5% of the total length, during the supported treadmill walking. No large change is observed in the spinal length during the control treadmill walking. The increase of the spinal length during the supported walking can be probably associated with the reduction in the reported pain levels (Figure 5.3).

5.2.3 During walking sessions measurements

The outcome measures presented in this section are the frequency response of the spine during walking, the segmental spinal motion analysis as well as the gait characteristics during supported and control treadmill walking.

Figure 5.5 below demonstrates the frequency response of the lumbar spine at baseline and at 30 minutes of supported and control treadmill walking.



Figure 5.5 Frequency response of the lumbar spine (1-3, 3-6 Hz) at a) baseline and b) 30 minutes of treadmill supported and control walking.

Power spectral densities (PSD) in both walking conditions and measurement times show similar patterns. In Figure 5.5 it is evident that during control walking the power spectral densities are higher especially in frequencies below 1 Hz. This frequency is related to the periodic stepping frequency during gait. Significantly lower peaks, than those in frequencies between 1-3 Hz, are observed at the higher frequencies between 3 to 6 Hz which again are higher in control that those in supported walking.

In a same manner, Figure 5.6 shows the power spectral densities of the thoracic segment during both walking conditions.



Figure 5.6 Frequency response of the thoracic spine (1-3, 3-6 Hz) at a) baseline and b) 30 minutes of treadmill supported and control walking.

Peaks observed in the thoracic segment show different patterns than the lumbar segment indicating significantly decreased power spectral densities. No obvious variation exists between measurements (baseline, 30 minutes).

Gait characteristics and spinal kinematics

Table 5.5 illustrates the temporal-spatial and kinematic differences between control and supported walking of the individual.

Variable	Cor	itrol	Supported			
Variable	Left	Right	Left	Right		
Cadence (step/min)	100	103	95	96		
Stride time (s)	1.2	1.16	1.27	1.25		
Step time (s)	0.63	0.57	0.62	0.63		
Foot off (% cycle)	66.7	68.1	66.1	65.6		
Opposite foot off (% cycle)	16.7	16.4	15.7	15.2		
Opposite foot contact (% cycle)	47.5	50.9	51.2	49.6		
Single support (% cycle)	30.8	30.5	35.4	34.4		
Double support (% cycle)	35.8	33.6	30.7	31.2		
Est. Stride length (m)	1.06	1.03	1.13	1.11		

Table 5.5 Temporospatial gait variables.

The main observation from the temporospatial gait characteristics is that the estimated stride length and the single support time are increased while the cadence and the double support time are decreased in the supported walking when compared to the control treadmill walking.

In Table 5.6 below basic lower body kinematics are presented. Those include pelvic rotations about all three axes and hip and knee angles about one major axis.

tubic cito Lower body kinematics during warking								
Angle (°)	LBP patient							
	Supported	Control						
Pelvic tilt	3.5	3.4						
Pelvic obliquity	3.34	3.1						
Pelvic axial	6.7	4.86						
Knee flexion (right)	54	60						
Knee flexion (left)	54	60						
Hip excursion (right)	37	33						
Hip excursion (left)	37	32						

Table 5.6 Lower body kinematics during walking

Form the data presented in Table 5.6, it seems that the knee flexion angles are decreased during the supported walking while the hip excursion angles are increased. The last variable examined in this section is the segmental spinal movement in relation to the adjacent segments. The spine was separated into three segments (upper thoracic,

lower thoracic, lumbar). Additionally, angles of the whole trunk in relation to the pelvis were also calculated. The angular displacements of three spinal segments and the whole trunk are summarized in Table 5.7.

Angle (°)	LBP pa	tient
	Experimental	Control
Lumbar sagittal	1.52	2
Lumbar coronal	3.66	3.58
Lower thoracic sagittal	1.1	1
Lower thoracic coronal	5.1	1.65
Upper thoracic sagittal	1.7	0.6
Upper thoracic coronal	1.67	1.58
Trunk sagittal plane	3.2	2.2
Trunk coronal plane	5.95	5.57
Trunk transverse plane	5.65	5.89

 Table 5.7 Spinal kinematics during walking

The majority of the spinal angles did not exhibited large differences between different walking conditions. Trunk movement patterns of the particular patient are illustrated in Figure 5.7.



Figure 5.7 Trunk movement patterns during control walking (patient 1, mean ± SD of 10 gait cycles).

5.3 LBP PATIENT & HEALTHY PARTICIPANT RESULTS

5.3.1 Participant characteristics

In this section the main characteristics of the participants recruited for this study are presented. A total of 19 low back pain patients and 21 healthy individuals recruited in the trial between April 2009 and September 2010. Basic biometric parameters as well as disability mean scores of the patients are illustrated in Table 5.8.

	Patients $(N = 19)$	Healthy $(N=21)$	$\overline{\mathbf{X}}$ dif	$p = .05^*$
Age	47.2 (9.4)	37.6 (7.9)	9.6	<.01
Height (m)	1.74 (0.05)	1.78 (0.06)	.04	.01
Mass (kg)	80.5 (13.3)	77.5 (10.8)	3	.4
BMI	26.7 (4.1)	24.3 (2.6)	2.4	.03
Walking speed (km/h)	3.34 (0.84)	3.74 (0.57)	.4	.09
Pain (weeks)	14.5 (8.2)	-	-	-
ODI score *	21.7 (12)	-	-	-
SF-12 (PCS)**	40.1 (7.9)	-	-	-
SF-12 (MCS)***	48.7 (11.3)	-	-	-

 Table 5.8 LBP patients & control participants characteristics (mean ± standard deviation)

*Independent samples t-test, *Oswestry Disability Index, **Physical Component Summary, ***Mental Component Summary

Patient mean pain duration was 14.5 (8.2) weeks. Eleven patients (57.9%) reported that their pain was due to injury and remaining eight (42.1%) could not recall a specific reason. Additionally, ten patients (52%) reported having at least one low back pain episode in the past.

Regarding the recruitment process, 40 patients were approached in total by the clinician (Ms Susan Smith) (Figure 5.8).



Figure 5.8 Patient recruitment process.

From the total of forty patients approached, only two were refused participation in the study. However, nine further patients were excluded due to various reasons (1 for heart problems, 3 obese, 5 with LBP symptoms completely resolved). Additionally, nine of those consented at the clinic, when contacted by the author refused to participate due to time, family and work related issues. Details from each participant's biometric, disability and social characteristics are presented in Appendix 11.

5.3.2 Disability profile of LBP patients

Disability status of all LBP patients was assessed with the Oswestry Disability Index (ODI) and the SF-12 Health Survey. Those questionnaires were administered before the first walking session.



Oswestry Disability Index

Figure 5.9 Oswestry Disability Index Scores of LBP patients (*N* = 19).

The mean Oswestry disability score for all 19 patients was 21.7% which indicated a minimal to moderate mean disability score. Specifically, nine patients produced a disability score between 0-20% (minimal disability), nine patients had scores between 20-40% (moderate disability) and only one patient showed a score between 40-60% (severe disability) (for scoring system see Appendix 9). Patients 4, 11 and 14 reported no pain in the Visual Analogue Scales (VAS) and this seems to reflect in their disability scores, at least in patients 11 and 14 (Figure 5.9).



SF-12 Health Survey

Figure 5.10 SF-12_{V2} Health Survey scores for both Physical Component Summary (PCS) and Mental Component Summary (MCS) scores (N = 19).

The mean score of the Physical Component Summary (PCS) score was 40.1 (\pm 7.9) and for the Mental Component Summary (MCS) mean score was 48.7 (\pm 11.3). In SF-12 the PCS and MCS scores are computed using the scores of the twelve questions with a range from 0-100. Differently to the ODI, higher scores in PCS and MCS indicate better health. A score of 0 indicates the lowest level of health and the 100 the highest level of health measured by the scales. In total, fourteen out of nineteen patients scored higher MCS scores than their PCS scores. Again here SF-12 ratings of patients 11 and 14 were among the highest in the group (Figure 5.10). Patient 4 while reports no pain in VAS, his ODI scores indicate moderate disability and below average quality of life scores.

5.4 BEFORE AND AFTER WALKING SESSION MEASUREMENTS5.4.1 Spinal Range of Motion

The differences in mean ROM values were analysed within and between groups of LBP patients and healthy participants. All ROM data were plotted in histograms in order to examine their normality. Additionally, the distribution was further tested with

Kolmogorov-Smirnov tests. None of the samples were significantly skewed which allowed the use of parametric tests.

Specifically, a one-way repeated measures analysis of variance design (ANOVA) was used. The ANOVA examines the hypothesis that the means (three or more) of a sample are equal. In this design, there was one Within-Subjects factor which consisted of four levels (supported walking (1st, 2nd measurement), control walking (1st, 2nd measurement)) and a between Subjects-Factor which was the participants group (patients, healthy). The assumptions of homogeneity and sphericity were checked in order to choose the appropriate test to examine the variances across sample means. When the assumption of sphericity was violated, the degrees of freedom were corrected by using the Greenhouse-Geiser test values. Equally, when the assumption of homogeneity was violated, in one variable, the whole data set of the specific variable was transformed in order for the accuracy of the F-test to be maintained.

Specifically, for the analysis of variance design used in this study the null hypothesis (H_0) was:

$$\mathbf{H}_{0} = \mathbf{P}\overline{\mathbf{X}}_{S1} = \mathbf{P}\overline{\mathbf{X}}_{S2} = \mathbf{P}\overline{\mathbf{X}}_{C1} = \mathbf{P}\overline{\mathbf{X}}_{C2} = \mathbf{H}\overline{\mathbf{X}}_{S1} = \mathbf{H}\overline{\mathbf{X}}_{S2} = \mathbf{H}\overline{\mathbf{X}}_{C1} = \mathbf{H}\overline{\mathbf{X}}_{C2}$$

Where, \overline{X} = mean of each sample (2 groups * 2 walking conditions * 2 measurements = 8 means)

P= patients group, H = healthy participant group, $_{s}$ = supported walking, $_{c}$ = control walking

The alternative hypothesis (H_1) for this design is accepted when two or more means differ.

Tables 5.9 to 5.11 present the descriptive statistics for all six gross movements from the lumbar, thoracic and cervical segments respectively. In these tables, simple paired t-tests were conducted to compare each pair of ROM measurements for each of the walking sessions. Similarly, Tables 5.12 to 5.14 illustrate the ANOVA results for every gross movement of each spinal segment. Appendix 11 includes individual ROM values for both participant groups and about all spinal gross movements.

	LPB Patients								Healthy Volunteers							
Lumbar Movements (°)	C	Control Walking (N =19)Supported Walking (N =19)			C	Control WalkingSupported W(N =21)(N =22)				l Walki =21)	ng					
	Before	After	Xdif	р.	Before	After	Xdif	р.	Before	After	Xdif	р.	Before	After	Xdif	р.
Forward Flexion	40.5	40.1	4	.66	41.2	38.3	-2.9	.02	53.2	51.7	-1.5	.1	51.2	49.8	-1.4	.12
Backward extension	10.4	11.2	.8	.29	10.5	11.6	1.1	.23	14.4	14	-0.4	.5	13.2	13.3	.1	.8
Forward-Backward (excursion)	50.9	51.3	0.4	.76	51.7	49.9	-1.8	.31	67.6	65.7	-1.9	.11	64.4	63.1	-1.3	.37
Lateral bending right	14.8	14.6	-2	.78	14.3	13.9	-0.4	.44	19.5	19.6	0.1	.9	18.4	18.1	3	.6
Lateral bending left	14.2	14.8	.6	.3	15.1	14.8	-0.3	.6	19.4	19.8	0.4	.4	18	17.3	7	.2
Lateral bending (excursion)	29	29.4	0.4	.68	29.4	28.7	-0.7	.43	38.9	39.4	0.5	.25	36.4	35.4	-1	.94
Axial rotation right	6.7	6.4	3	.67	7.3	7.2	-0.1	.8	6.8	6.6	-0.2	.6	6.8	6.5	3	.5
Axial rotation left	8.9	7.5	-1.4	.009	9.4	9.6	-0.2	.7	8	8.2	0.2	.8	8.2	7.8	4	.5
Axial rotation (excursion)	15.6	13.9	-1.7	.002	16.7	15.8	-0.7	.71	14.8	14.8	0	.93	15	14.3	7	.26

Table 5.9 Lumbar segment ROM's during six gross movements (mean, mean difference (\overline{X} *dif*), statistical significance (p < 0.05))

p < 0.05 (paired samples t-test)

	LPB Patients								Healthy Volunteers							
Trunk Movements (°)	Control WalkingSupported V(N =19)(N =19)			l Walk =19)	ing	Control Walking (N =21)				Su	Supported Walking (N =21)					
	Before	After	Xdif	р.	Before	After	Xdif	р.	Before	After	Xdif	р.	Befor	e After	Xdif	р.
Forward Flexion	51.4	49.4	-2	.35	49.9	46.6	-3.3	.13	63.2	64.5	1.3	.53	64.7	65.5	.8	.66
Backward extension	29.1	29.7	.6	.79	32.9	30.6	-2.3	.32	32.9	32.4	5	.75	35.1	32.5	-2.6	.11
Forward-Backward (excursion)	80.5	79.1	-0.6	.63	82.8	77.2	-5.6	.09	96.1	96.9	.8	.80	99.8	98	-1.8	.50
Lateral bending right	42.3	40.6	-1.7	.10	41	41.1	0.1	.88	46.4	46.2	2	.66	46.3	45.1	-1.2	.16
Lateral bending left	43.4	41.8	-1.6	.14	43.3	43.5	0.2	.86	45.8	46.8	1	.28	45.5	46.6	1.1	.36
Lateral bending (excursion)	85.7	82.4	-3.3	.07	84.3	84.6	0.3	.81	92.2	93	.8	.60	91.8	91.7	1	.34
Axial rotation right	37	38.4	1.4	.43	41.4	37.5	-3.9	.08	41.8	41.7	1	.92	40.6	42.8	2.2	.19
Axial rotation left	39	37.9	-1.2	.55	37.7	35.5	-2.2	.12	38	39.8	1.8	.24	38.5	38.3	2	.90
Axial rotation (excursion)	76	76.3	0.3	.93	79.1	73	-6.1	.04	79.8	81.4	1.7	.40	79.1	81.1	2	.34

	—	-
Table 5.10 Trunk segment ROM's during	six gross movements (mean, mean difference (X	<i>Kdif</i>), statistical significance $(p < 0.05)$

p < 0.05 (paired samples t-test)

	LPB Patients									Healthy Volunteers						
Total Spine Movements (°)	Control Walking (N =19)				Supported Walking (N =19)			Control Walking (N =21)				Supported Walking (N =21)				
	Before	After	Xdif	р.	Before	After	$\overline{\mathbf{X}}$ dif	р.	Before	After	Xdif	р.	Before	e After	Xdif	р.
Forward Flexion	53.9	56	2.1	.28	52.2	49.9	-2.3	.36	68.1	69	.9	.77	67.4	69.9	2.5	.27
Backward extension	59	60.5	1.5	.57	60.4	61.3	.9	.73	76.7	77.8	1.1	.60	75.6	73.5	-2.1	.40
Forward-Backward (excursion)	112.9	116.5	3.6	.36	112.6	111.2	-1.4	.70	144.8	146.8	2	.50	143	143.4	0.4	.90
Lateral bending right	59.2	57.8	-1.4	.53	57.1	57.3	.2	.95	75.8	73.9	-1.9	.41	74.6	74.5	1	.91
Lateral bending left	61.2	60.2	-1	.66	59.7	58.4	-1.3	.54	73	76	3	.19	70.9	73.2	2.3	.24
Lateral bending (excursion)	120.4	118	-2.4	.48	116.8	115.7	-1.1	.74	148.8	149.9	1.1	.74	145.5	147.7	2.2	.19

Table 5.11 Total spine ROM's during six gross movements (mean, mean difference (\overline{X} *dif*), statistical significance (p < 0.05))

p < 0.05 (paired samples t-test)

Table 5.9 contains the mean values of the lumbar segment along with a statistical comparison of the mean angular difference of every gross movement in each walking condition. Two statistically significant differences were observed in this table, one indicating a decrease (-2.9°, p = .02) of the forward flexion movement in the LBP patients group during the supported walking. The second one it is also shows a significant decrease (-1.4°, p = .002) of the left axial rotation in the LBP patient group during the control walking session. In addition, in this table it can be observed an important deviation between groups ROM mean values in forward-backward and left-right lateral bending movements, with healthy volunteers to exhibit greater values.

In the trunk segment (Table 5.10), there is only one statistically significant decrease (-6.1°, p = .04) in the total axial rotation (excursion) of the LBP patient group during the supported treadmill walking session. Again here, the healthy participant group has higher ROM mean values than those of the LBP patient group.

In the total spine (Table 5.11), no statistically significant difference is observed in the mean ROM values. However, the mean ROM values of the healthy group were again greater than those of the LBP patients group.

It is worth mentioning that in Tables 5.12 to 5.14, under the headings of "Sphericity" and "Homogeneity", the words Yes/No appeared for each of the variables. When the word "Yes" is indicated the assumptions of sphericity or homogeneity are maintained, otherwise they are violated.

Table 3.12 Main Airo VA values for Six gross movements of the futiloar spine.	Table 5.12 Main ANOVA	A values for six gross	s movements of the lumbar spine) .
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LUMBAR	Sphericity	Homogeneity	Deg. of	F-Ratio	p-value
			Freedom		
Forward flexion	No	Yes			
Test of within			1.9, 72	2.1	.13
subject effects					
Interaction			1.9, 72	1	.36
Test of Between					
groups effects			1, 37	8.4	.006
Extension	No	Yes			
Test of within			2.4, 87.5	.47	.67
subject effects					
Interaction			2.4, 87.5	.99	.39
Test of Between					
groups effects			1.36	2.5	.13
Lateral bending	No	No			
Right					
Test of within			19.2, 8.7	2.2	.12
subject effects					
Interaction			4.8, 8.7	.55	.57
Test of Between			,		_
groups effects			1, 36	10.5	(.003)
Lateral Bending	No	No			
left					
Test of within			1.9, 69	1.5	.23
subject effects			,		
Interaction			1.9, 69	2.5	.09
Test of Between			,		
groups effects			1, 36	8.9	.005
Axial Rotation	Yes	Yes			
right					
Test of within			3, 105	1	.38
subject effects			,		
Interaction			3, 105	1	.39
Test of Between			1,35	.18	.68
groups effects			,		
Axial Rotation	No	Yes			
Left					
Test of within			2.1, 73	2.7	.07
subject effects			,		
Interaction			2.1, 73	3.6	.03
Test of Between			,		
groups effects			1, 34	0.8	.37

 Table 5.13 Main ANOVA values for six gross movements of the trunk segment.

TRUNK	Sphericity	Homogeneity	Deg. of	F-Ratio	p-value
	1 0	0 1	Freedom		r · · · · · ·
Forward flexion	No	No			
Test of within			2.4, 90	.10	.93
subject effects					
Interaction			2.4, 90	.91	.42
Test of Between					
groups effects			1, 37	11.9	.001
Extension	Yes	Yes			
Test of within			3, 111	3.2	.025
subject effects					
Interaction			3, 111	.34	.80
Test of Between					
groups effects			1, 37	.74	.39
Lateral bending	Yes	Yes			
Right					
Test of within			3, 108	.87	.46
subject effects					
Interaction			3, 108	.54	.66
Test of Between					\sim
groups effects			1, 36	4.4	.043
Lateral Bending	No	Yes			
left					
Test of within			2.2, 80.8	.19	.85
subject effects					
Interaction			2.2, 80.8	.97	.39
Test of Between					
groups effects			1, 36	2.4	.13
Axial Rotation	No	Yes			
right				71	(0)
Test of within			2.2, 80.2	.51	.62
subject effects				2	1.4
Interaction			2.2, 80.2	2	.14
Test of Between			1 27	1.6	22
groups effects	NT.	NT	1, 37	1.0	.22
Axial Rotation	No	No			
Lett			16 506	0	(001)
subject offects			1.0, 39.0	9	.001
Subject effects			16 50 6	60	51
Tast of Potwart			1.0, 39.0	.02	.31
rest of Between			1 26	26	55
groups effects			1, 30	.30	.55

TOTAL SPINE	Sphericity	Homogeneity	Deg. of	F-Ratio	p-value
			Freedom		-
Forward flexion	No	Yes			
Test of within			1.6, 59.2	.34	.66
subject effects					
Interaction			1.6, 59.2	.33	.67
Test of Between					
groups effects			1, 37	6.3	.017
Extension	Yes	Yes			
Test of within			3, 111	.35	.79
subject effects					
Interaction			3, 111	1.3	.26
Test of Between					\sim
groups effects			1, 37	13	(.001)
Lateral bending	Yes	Yes			
Right					
Test of within			3, 108	.44	.73
subject effects					
Interaction			3, 108	.019	.99
Test of Between					\sim
groups effects			1, 36	18	.000
Lateral Bending	Yes	Yes			
left					
Test of within			3, 108	1	.36
subject effects					
Interaction			3, 108	.90	.44
Test of Between					
groups effects			1, 36	15.6	(.000)

Table 5.14 Main ANOVA values for six gross movements of the total spine.

The results from the ANOVA models presented in the Tables 5.12 to 5.14 are confirming the findings of the descriptive data presented in Tables 5.9 to 5.11.

For the lumbar segment, Table 5.12, there was a significant effect in the between subject factors for the forward flexion, right lateral bending and left lateral bending indicating that the ROM of these gross movements were significantly different between participant groups and yield large effect sizes (r = 0.43, r = 0.48, and r = 0.45 respectively). Additionally, in the lumbar segment, a significant interaction effect was found between the walking sessions and participant groups in left axial rotation gross movement. However, this interaction yielded a small effect (r = 0.22). No further

significant main effects (within subject effects), between subject effects or their interaction was found in this segment indicating equality of variances for the rest of the variables.

For the trunk segment, Table 5.13, there was a significant effect in the between subject factors of the forward flexion and right lateral bending variables indicating a significant differences between the participant groups in the ROM of those gross movements. Both effects yield medium to large effect sizes, r = 0.49 for the forward flexion and r = 0.33 for the right lateral bending. Additionally, there was a significant interaction between walking sessions and participant groups in the backward bending variable (extension) which, however, yield a small effect (r = 0.17). Also, there was a significant main effect indicating significant differences between walking sessions in the left axial rotation variable which had a medium effect size (r = 0.37).

Finally, for the total spine segment, Table 5.14, there was a significant between subject's effect in the flexion/extension and right/left lateral bending movements indicating significant ROM differences between participant groups. All these differences illustrated large effect sizes (r = 0.38, r = 0.51 and r = 0.58, r = 0.55).

5.5 BETWEEN WALKING PERIODS MEASUREMENTS

5.5.1 Spinal elongation

This section presents the spinal length analysis during the supported and control treadmill walking conditions. At first, the total spinal length of the two groups was compared for both walking conditions and afterwards the segmental length (lumbar, thoracic) was explored in a similar manner. For the statistical analysis a mixed repeated measures ANOVA design was used to examine differences in spinal length among participant groups, walking conditions and time. This design consisted of two *repeated measures variables*: **walking condition** (with two levels because each volunteer participated in both supported and control walking) and **time** (with seven levels, as there were seven subsequent measurements). Also, there was a *between-group variable*, the **participant group** consisting of patients and healthy individuals (Table 5.15).

Table 5.15 Representation of repeated measures and between group variables.																
Walking	Supported								Control							
Time (min)	0	5	10	15	20	25	30	0	5	10	15	20	25	30		
		1								1						
Patients (N=19)		:								:						
		19								19						
		1								1						
Healthy (N=21)		:								:						
		21								21						

The null hypothesis (H_0) in this section was that no differences will exist in the spinal length between participant groups, walking conditions and over time or their interaction:

$$\mathbf{H}_{0} = \overline{\mathbf{X}} \mathbf{P}_{C1-7} = \overline{\mathbf{X}} \mathbf{P}_{S1-7} = \overline{\mathbf{X}} \mathbf{H}_{C1-7} = \overline{\mathbf{X}} \mathbf{H}_{S1-7} = \mathbf{0}$$

Where \overline{X} is the mean length, P and H are the patient and the healthy participant groups respectively and S and C represent the supported and control walking conditions respectively. Also, numbers 1-7 symbolize the seven levels of repeated measures in each session.

The alternative hypothesis, in a narrative form, states that at least two means either between or within the groups (time periods) will be different.

The total variation in this repeated measures design is schematically presented in Figure 5.11.



Figure 5.11 Schematic representation of variation in the repeated measures design using one within subject factor.

Descriptive analysis, using Kolmogorov-Smirnov tests and histograms, revealed normally distributed data which enabled the use of parametric tests. The assumption of homogeneity of variance was maintained for all data. This assumption means that all the samples used were from populations with equal variances (Sim & Wright, 2000; Field, 2005). It is particularly important for designs with between-group factors. SPSS software provides the Levene's test which examined the homogeneity of all samples used in the analysis. However, the assumption of sphericity was violated for both the time $\chi^2(20) = 35.4$, p = .02 and its interaction with the walking condition $\chi^2(20) = 32.3$, p= .04. This assumption is of importance in repeated measures designs. Sphericity or circularity refers to the equality of variances of the differences between measurement levels in repeated measures ANOVA designs (Field, 2005). Therefore degrees of freedom were corrected using Greenhouse-Geisser estimates of sphericity ($\varepsilon = .73$ for the main effect of time and $\varepsilon = .77$ for the interaction between time and walking condition).

In Figure 5.12 the variation of the total spinal length during the supported walking is illustrated. For both participant groups a decrease in spinal length throughout the walking session it is observed.



1





Figure 5.12 Percentage change in total spinal length over time during supported walking (mean \pm standard error, patients N = 19, healthy participants N = 21).

The greatest decrease in length is observed during the first five minutes of walking. This decrease is almost the double in the controls group at the fifth minute and approximates the 1% of the total spinal length (≈ 4.5 mm).

Similarly, Figure 5.13 presents the variation of total spinal length during the control walking condition in both participant groups.



Control Walking

Figure 5.13 Percentage change in total spinal length over time during control walking (mean \pm standard error, patients N = 19, healthy participants N = 21)
The total spinal length variation over time showed similar trajectory even with the alternative length calculation method (Appendix 12). In the alternative method the total spinal length was estimated by the absolute distance between the first thoracic (TH1) and fifth lumbar (LU5) Vicon retroreflective markers. The results presented above were based on the main calculation method which considered the spinal curvature and consists of the sum of the 16 spinal segments lengths defined by the Vicon markers (Section 4.5.3).

The length variation during the control walking shows a similar pattern with the supported walking. Again here, the shrinkage in the healthy group is greater than the one observed in the patients group, but in total is less (0.5%) than the one observed in the supported walking condition illustrated in Figure 5.12.

The test of between subject effects was not significant indicating no significant differences in variation of spinal length between LBP patients and healthy individuals F(1, 38) = .53, p = .47.

Also, there was no significant main effect of different **walking conditions** on the spinal length, F(1, 38) = .04, p = .83.

Equally, all the interaction effects among time, participant groups and walking conditions were non significant.

However, there was a significant main effect of **time** on the spinal length, F(4.4, 166) = 3.9, p = 0.03. Contrasts revealed that the spinal length changed significantly on 5^{th} minute F(1, 38) = 17, p = <.01, r = .55, 10^{th} minute of walking F(1, 38) = 11.1, p = <.01, r = .47 and at the 30th minute of walking F(1, 38) = 6.9, p = .01, r = .39, as these compared to the baseline (0 minutes). The effect sizes of these differences (r) indicate medium to large effects. Effect size is very important measure because constitutes an objective measure of the importance of the effect (Field, 2005). An effect size of r = .50 (large effect) accounts for 25% of the variance (Cohen, 1988).

In the Figure 5.14 it is presented the variation of lumbar length of patients and healthy individuals in both the supported and control walking conditions. It has to be mentioned that the lumbar length change over time it is expressed as a percentage change in relation to the total spinal length.



Figure 5.14 Patient (N=19) and healthy participant (N = 21) lumbar length change over time during a) supported and b) control walking (mean± standard error).

The same mixed ANOVA model described above was also used for the segmental analysis. The assumptions of normality, homogeneity, and sphericity were again checked. Levene's test revealed that the data were homogenous across all subsets. Additionally, Kolmogorov-Smirnov tests and histograms indicated that lumbar data were also normally distributed and thus no transformation or correction needed for these assumptions. The assumption of sphericity was met for the interaction between the walking condition and time and was violated for the main effect of time $\chi^2(20) = 37.4$, *p*

= .01. Thus, the Greenhouse-Geisser correction was used only for the degrees of freedom for time variable ($\varepsilon = .72$).

There was no significant effect of participant group indicating that changes of lumbar length were in general the same between participant groups, F(1, 38) = .31, p = .58.

Similarly, all the interactions effects among time, walking conditions and group of participants were not statistically significant.

However, there was a significant main effect of time on the lumbar spinal length, F(4.3, 165) = 3.5, p = < .01. Planned contrasts revealed that significant lumbar length changes happened at the 5th minute of walking F(1, 38) = 10.5, p < .01, r = .46, at the 10th minute of walking F(1, 38) = 5.6, p = .02, r = .36 and after the completion of the walking session at the 30th minute F(1, 38) = 7.3, p = .01, r = .40. Interestingly, the significant changes in lumbar length occurred at those times also observed in the total spine length analysis. The effects sizes of those changes are again medium to large.

Figure 5.15 below illustrates the length variation of the thoracic spine during supported and control walking in both LBP patients and healthy people. During supported walking both participant groups showed similar pattern of length variation. The maximum difference is observed in 5th minute and is a decrease of about .3% (\approx 1.4 mm) of the total spinal length. In control walking those patterns are different. While the patients showed a slight increase in length, the healthy group shows a constant decrease of approximately .4% of the total length. However, in both walking conditions the standard errors of those measurements are quite large.



Figure 5.15 Patient (N=19) and healthy participant (N = 21) thoracic length change over time during a) supported and b) control walking (mean± standard error).

For the statistical analysis of the thoracic spine data the ANOVA model described in the total spine length analysis was used. Data were normally distributed and the assumption of homogeneity was met for all variables. However, the results of Mauchly's sphericity test showed that sphericity was violated for the main effect of time $\chi^2(20) =$ 52.4, p < .01, as well as the interaction between time and walking condition $\chi^2(20) =$ 36.6, p = .01. Thus, the degrees of freedom were corrected using Greenhouse-Geisser estimates of sphericity ($\epsilon = .67$ for the main effect of time, $\epsilon = .74$ for the interaction between time and walking condition).

Again here, there was no significant effect of the participant group on the spinal length, F(1, 38) = 2.1, p = .15.

Additionally, there was no significant main effect of the walking condition on the spinal length, F(1, 38) = .02, p = .89

Differently to total spine and the lumbar spine length analysis, no significant main effect of time on thoracic spinal length was observed, F(4, 153) = 2.1, p = .08.

Also, there was no significant effect in all interactions among time, walking conditions and participant groups.

5.5.2 Effects of supported & control treadmill walking on pain

The pain values, as these were reported by the patients in visual analogue scales (VAS), were analysed between and within each walking condition. This analysis contains the VAS values from only sixteen out of the nineteen patients. Three patients, although were complaining for sore backs, reported no pain during the walking sessions.

All data were plotted in histograms to examine the data distribution. Additionally, normality tests were conducted in order to further verify the normality of the data and make an informed decision for the statistical analysis. The majority of data appeared to be normally distributed, with some being slightly positive skewed. However, some sub-datasets (especially from the supported walking session) were deviating significantly from normality. For this reason a logarithmic transformation was applied to the whole dataset.

A repeated measures ANOVA was used to test the variance of the means over time, between groups and their interaction. Additionally, planned pairwise contrasts were also conducted. When significant differences were found effect sizes (r) were calculated for both main effects and their contrasts.

The null hypothesis (H₀) tested in the analysis of pain variance was:

$$\mathbf{H}_0 = \overline{\mathbf{X}} S_{1-7} = \overline{\mathbf{X}} C_{1-7}$$

Where

 \overline{X} = mean of each group, S = Supported walking condition, C = control walking condition, and 1-7 = the seven levels of repeated measures in each walking session (baseline to 30minutes).

The alternative hypothesis (H_1) , in a narrative form, for this design is accepted when two or more means (within or between groups) are different.

Figure 5.16 illustrates the trajectory of pain over 30 minutes of walking for both treadmill walking conditions. Pain is illustrated as a continuous variable only for purposes of presentation.



Figure 5.16 LBP Pain status change over time during supported & control treadmill walking (N=16, mean \pm standard error).

Mauchly's test indicated that the assumption of sphericity was violated for both the main effect **time** $\chi^2(20) = 113.6$, p < .01 and its **interaction** with the walking conditions $\chi^2(20) = 48.3$, p < .01. Sphericity was not an issue for the walking condition variable because that was consisting of two levels. In order for sphericity to be an issue, at least three conditions are needed (Field, 2005). Therefore, the Greenhouse-Geisser correction was used as an adjustment of this sphericity violation ($\varepsilon = .23$ for the main effect of time and .47 for the interaction). All effects are reported as significant at p < .05.

There was not a significant main effect of type of walking on ratings of pain, F(1, 15) = 3.1, p = .098.

Also, there was not a significant main effect of time on the ratings of pain, F(1.3, 20.5) = .27, p = .68.

However, there was a significant interaction between different walking conditions and time, F(2.8, 42) = 5, p < .01. This indicates that time had different effect on pain ratings depending on which walking condition was used. To break down this interaction, contrasts were performed comparing both walking conditions to their baseline which was the baseline pain evaluation with the subsequent ones (5, 10, 15, 20, 25, and 30 minute). These contrasts revealed that the two walking groups interacted differently in pain ratings over time, at 25th minute F(1, 15) = 7.2, p = .01, r = .57 and at 30th minute F(1, 15) = 9.4, p < .01, r = .62. These contrasts yield large effects.

5.6 DURING WALKING SESSION MEASUREMENTS

5.6.1 Spinal frequency response

In this section the analysis of frequency response is presented. Low back pain patient and healthy participant data are presented separately. Each graph presents contrasts between the supported and control walking conditions in the thoracic and lumbar spinal segments. Figures 5.17-18 show an example of each participant's lumbar spine length response, during the baseline measurement, over 10 seconds of the control walking treadmill condition. These are the raw signals in the time domain which then examined in the frequency domain to identify peak patterns and magnitudes during different walking conditions. The raw data in the time domain from both participant groups (patients, healthy), walking conditions (control, supported), sampling periods, (baseline, 30 minutes) and spinal segments (lumbar, thoracic) are presented in Appendix 13.



Figure 5.17 Variation in spinal length during control treadmill walking (patients).



Figure 5.18 Variation in spinal length during control treadmill walking (healthy).

LBP patient's frequency analysis

Figure 5.19 illustrates the frequency response of the lumbar spine at the baseline and 30th minute of supported and control treadmill walking in the LBP patient group.



Figure 5.19 Mean power spectral densities (PSD) (N=19, LBP patients) of the lumbar segment at a) baseline and b) 30th minute of supported and control walking (p < .05).

Frequency analysis indicated similar patterns of lumbar frequency response in LPB patients between the baseline and the 30th minute of walking, with control treadmill walking to show higher peaks in frequencies between 1-3 Hz. However, those peaks were not significantly higher than those observed in the supported walking. In frequencies between 3-6 Hz lumbar spine exhibited statistically higher PSD (power spectral density) during the supported walking. Significance values shown in each graph

refer to the statistical comparison of PSD values between different walking conditions. Thus, these p-values refer to the frequency ranges shown in each figure and not specifically to individual peaks.

In a similar way, Figure 5.20 presents the frequency response of the thoracic spine at the baseline and 30th minute of supported and control treadmill walking in the LBP patient group.



Figure 5.20 Mean power spectral densities (PSD) (N=19, LBP patients) of the thoracic segment at a) baseline and b) 30th minute of supported and control walking (p < .05).

The frequency response of the thoracic segment was similar to the lumbar segment in terms of PSD magnitudes and frequency patterns. Higher PSD magnitudes were again observed in frequencies between 1-3 Hz.

Healthy participant's frequency analysis

For the healthy volunteers group, Figure 5.21 illustrates the frequency response of the lumbar spine at the baseline and 30^{th} minute of supported and control treadmill walking.



Figure 5.21 Mean power spectral densities (PSD) (N=21, Healthy volunteers) of the lumbar segment at a) baseline and b) 30th minute of during supported and control walking (p < .05).

The lumbar frequency response in the healthy participant group showed higher PSD magnitudes in frequencies between 1-3Hz. A different PSD pattern observed between measurement times in frequencies between 1-3 Hz. At the baseline measurement, the supported walking condition exhibited higher peaks, whereas in the measurement at the 30th minute those peaks were higher in the control walking condition. This indicates possibly an effect of time in the lumbar frequency response. Figure 5.22 shows the frequency response of the thoracic spine at the baseline and 30th minute of supported and control treadmill walking in the healthy participants group.



Figure 5.22 Mean power spectral densities (PSD) (N=21, Healthy volunteers) of the thoracic segment at a) baseline and b) 30th minute of supported and control walking (p < .05).

The frequency response of the thoracic segment of the healthy participants showed again higher PSD values in frequencies between 1-3 Hz, in both walking conditions. Supported walking showed no change in peak pattern and magnitude over time.

However, in control walking the peaks observed were significantly reduced at the 30th minute of walking.

In total, the frequency analysis showed a variant PSD pattern among participant groups and spinal segments, especially in the supported walking condition. The control walking condition showed a more consistent pattern of peaks at frequencies between 0.5-1 Hz, 1.5-2 Hz and 3-4 Hz.

5.6.2 Temporospatial gait parameters

In this section the temporal/spatial gait characteristics of the study participants at the 30th minute of walking (for both walking conditions) are presented. Gait events identified visually through the synchronised digital video in the Vicon Workstation. The procedure is described in detail in section 4.5.6 of methods chapter. Tables 5.16 and 5.17 illustrate the LBP patients and healthy individual data respectively. Both tables contain temporospatial characteristics of both legs and for both treadmill walking conditions. Tables present descriptive statistics as well statistical comparisons.

All data appeared to be normally distributed and this allowed the use of parametric tests. No statistically significant differences found between right and left leg for both participant groups and walking conditions, revealing a symmetric gait pattern. For this reason, Tables 5.16 & 517 present statistical comparisons only between left leg values of control and supported walking conditions.

From patient data it is evident that the external support provided by the harness decreased significantly the double support time (p = .02) and increased the single support time (p = .01). At the same time the opposite foot off parameter decreased significantly (p = .03). These three parameters are interdependent and unavoidably affect each other. Interestingly, no significant differences were observed in the cadence and stride length.

Variable	Con	trol	Supp	t-test	
v allable	Left	Right	Left	Right	p<.05*
Cadence (step/min)	99.7 (10.3)	100.1 (10.8)	97.8(12.4)	97.7 (13)	.33
Stride time (s)	1.21 (0.13)	1.21 (0.13)	1.25(0.16)	1.25(0.16)	.23
Step time (s)	0.60 (0.07)	0.6 (0.06)	0.62(0.08)	0.63(0.09)	.50
Foot off (% cycle)	62.1 (2.3)	62.1 (2.3)	63.7(4.3)	63.6 (2.7)	.08
Opposite foot off (% cycle)	15.1 (2.2)	14.7 (2.5)	13.9 (4.2)	13.2 (3.6)	.03
Opposite foot contact (% cycle)	50.2 (2)	49.9 (1.8)	50.4 (2.1)	49.3 (1.9)	.69
Single support (% cycle)	32.2 (2.7)	32.8 (2.5)	36.4 (4)	36 (4.5)	.01
Double support (% cycle)	30 (4.6)	29.4 (4)	27.5 (7.7)	27.7 (7)	.02
Est. Stride length (m)	1.1 (0.22)	1.1 (0.22)	1.14(0.25)	1.14(0.24)	.22

Table 5.16 Temporospatial parameters of LBP patients (N = 19, means & SD)

*Paired Samples t-test (for differences between left legs of different walking conditions)

The majority of the temporospatial parameters of the healthy participants group indicated statistically significant differences between control and supported walking conditions. Apart from the single and double support parameters, which showed a similar change to this observed in the LBP patient group, healthy individuals seem to significantly alter their cadence and stride length in the supported walking condition (Table 5.17).

Table 5.17 Temporospatial parameters of healthy participants (N = 21, means & SD)

Variable	Cont	rol	Suppo	t-test	
Variable	Left	Right	Left	Right	p<.05*
Cadence (step/min)	98.4 (6.7)	98.3 (6.5)	95.5 (8.4)	95.4 (8.9)	.01
Stride time (s)	1.22 (0.08)	1.22 (0.09)	1.27 (0.14)	1.27(0.13)	.01
Step time (s)	0.61 (0.05)	0.61 (0.04)	0.63 (0.06)	0.64(0.07)	.005
Foot off (% cycle)	65.4 (1.8)	64.7(1.7)	61.8 (1.7)	61.4 (2.1)	.000
Opposite foot off (% cycle)	15.1 (1.4)	14.8 (1.6)	12.5 (1.7)	11.8 (2.3)	.000
Opposite foot contact (% cycle)	50.5 (1.4)	49.9 (1.5)	50.4 (1.4)	49.6 (1.7)	.75
Single support (% cycle)	35.5 (1.7)	35 (1.9)	37.8 (1.9)	37.8 (1.9)	.000
Double support (% cycle)	29.9 (2.7)	29.7 (2.7)	23.9 (3.2)	23.6 (3.4)	.000
Est. Stride length (m)	1.26 (0.15)	1.26 (0.16)	1.3 (0.13)	1.3 (0.13)	.01

*Paired Samples t-test (for differences between left legs of different walking conditions)

These changes indicate that apart from the decreased double support time, healthy individuals during the supported walking decreased significantly their stepping frequency and increased their stride length.

5.6.3 Lower body & spine kinematics

The kinematics of the lower body and the spine presented in this section are from the last walking interval of every walking session $(30^{th} \text{ walking minute})$. In Table 5.18, the three major angles of the spinal curvature as well as the rotations of the trunk as a whole are presented.

Angle (*)	LBP patients		Healthy			
	$(N=19, \overline{X}\pm SD)$			$(N=19, \overline{X}\pm SD)$		
	Supported	Control	<i>p</i> < .05	Supported	Control	<i>p</i> < .05
Lumbar sagittal	1.93 (0.5)	2.33 (0.8)	.1	2.4 (0.9)	2.8 (1)	.15
Lumbar coronal	3.66 (1.2)	4.4 (1.6)	.16	3.64 (1.3)	4.5 (2)	.02
Lower thoracic sagittal	1.89 (0.7)	1.9 (1)	.1	2 (0.7)	2 (0.7)	.1
Lower thoracic coronal	5.2 (2.1)	3.8 (1.7)	.02	3.37 (1.3)	5.1 (2.7)	.01
Upper thoracic sagittal	1.3 (0.5)	1 (0.4)	.07	1.2 (0.4)	1 (0.6)	.3
Upper thoracic coronal	2.1 (0.7)	3.3 (2)	.02	1.72 (0.6)	3.2 (1.4)	.00
Trunk sagittal plane	4.1 (1.3)	3.8 (1.9)	.65	3.96 (1.5)	3.8 (1.3)	.9
Trunk coronal plane	6.2 (2.2)	8.7 (3.7)	.01	5.5 (2.2)	10.9 (3.3)	.00
Trunk transverse plane	6 (2.6)	9 (5.3)	.02	7.6 (5.4)	10.5 (4.3)	.02

Table 5.18 Kinematic characteristics of spinal segments of LBP patients and healthy volunteers.

In the above table it is evident that for both groups the spinal excursions in the coronal plane (lateral) are greater than those observed in the sagittal plane (forward-backward). Also, it is observed a significant decrease of the excursions, for both groups and all spinal levels, in the coronal plane during the supported walking indicating that the under arm harness restricts significantly the range of motion in this plane. Interestingly, the lumbar excursion in the coronal plane of the LBP patient group was not significantly different between walking conditions and probably indicating that the lumbar excursions in this plane were already decreased in this group.

Differences in the lower body kinematics were observed between the walking conditions as well as between groups. The kinematics of the pelvis and knee and hip joints of all participants are summarized in table 5.19.

Angle (°)	LBP patients			Healthy		
	$(N=19, \overline{X}\pm SD)$			$(N=19, \overline{X} \pm SD)$		
	Supported	Control	<i>p</i> < .05	Supported	Control	<i>p</i> < .05
Pelvic tilt	3.24 (0.9)	2.77 (0.9)	.16	3.13 (0.94)	3.28 (1.1)	.59
Pelvic obliquity	4.97 (1.6)	4.78 (1.7)	.62	4.42 (1.57)	6.15 (2.5)	.003
Pelvic axial	5.23 (2.1)	7.34 (3.5)	.055	5.11 (1.7)	7.34 (2.7)	.006
Knee flexion (right)	56.2 (7.3)	61.5 (7.5)	.00	59 (5.1)	62.3 (6.8)	.03
Knee flexion (left)	55.8 (7)	59.7 (7.5)	.01	58.7(5.8)	61.8 (6.4)	.02
Hip excursion (right)	39.5 (5.6)	35 (5.5)	.02	39.2 (4.2)	38 (4.6)	.53
Hip excursion (left)	40 (5.4)	36.2 (5.4)	.01	40.4 (3.7)	38.9 (4.9)	.34

Table 5.19 Kinematic characteristics of pelvis and lower limbs of LBP patients & healthy volunteers.

It is worth mentioning that no asymmetries were observed between the right and left leg kinematics in both participant groups. Pelvis axial rotation and obliquity were significantly reduced during the supported walking in the healthy participants group. This effect was not observed in the LBP patient group and that probably points out that those movements were already limited in this group. Knee flexion angles in both legs were also significantly reduced during supported treadmill walking in both participant groups. Additionally, the hip excursion angles were significantly increased during supported walking in LBP patients while no effect was observed in the healthy participants group.

5.7 KEY POINTS

- LBP patients group was on average 10 years older than the healthy volunteers group.
- No significant effects of supported or control treadmill walking were observed in spinal ROM.
- Healthy volunteers exhibited greater ROM's than the LBP patients in the majority of gross spinal movements and across different segments.

- No significant difference was found between the walking conditions and participant groups in terms of spinal length change.
- Spinal height decreased significantly over time in both participant groups.
- In both groups, the lumbar spine was mostly responsible for the spinal shrinkage observed.
- A significant interaction of pain levels with time was found in the control walking condition, indicating a significant increase of pain levels during the control treadmill walking.
- No consistent trends were found, across participant groups and walking conditions, in the power spectral density magnitudes of the lumbar and the thoracic spine, during the baseline and 30th minute measurements.
- Power spectral densities were significantly higher in frequencies between 1-3 Hz and lower in frequencies between 3-6 Hz.
- An indication of the impact of the heel strike during walking is confirmed by the consistent trend of power spectral density spikes observed in frequencies between 0.6 0.7 Hz, which coincide with the stepping frequency of the participants.
- Double support and single support gait parameters are significantly altered during supported walking.
- Lateral and axial spinal rotations are significantly decreased by the harness during the supported walking whereas forward/backward rotations seem to remain unaffected.
- Knee flexion angles are significantly reduced in both groups during the supported walking and hip excursions are significantly increased only in the LBP group.
- Trunk axial rotation and lateral flexion angles are significantly reduced by the harness in supported walking, in both participant groups.

5.8 SUMMARY

In the results chapter, Chapter 5, the findings from the randomized controlled trial were presented. Descriptive characteristics of the sample population as well as the main outcome variables were described in detail and along with the statistical analysis will form the basis for a constructive discussion.

In the following chapter, Chapter 6, a comprehensive discussion of the results will be attempted in conjunction to the literature review presented in Chapter 2. Based on the statistical analysis, a critical interpretation of the findings will be performed and possible implications will be mentioned.

CHAPTER 6 DISCUSSION

6.1 INTRODUCTION

The current chapter discusses the results presented in Chapter 5 in relation to the literature presented in Chapter 2. Conclusions will be reached relating to the importance of the findings and how these fit in the broader field of spine and low back pain related literature. All findings will be discussed in a critical manner and special attention will be given to the limitations of this study.

6.2 CASE STUDY DISCUSSION

The LBP participant was randomly selected for presentation to show an individual set of data before presenting the data from all participants. It is recognized that individual data are not typical or representative of the whole dataset due to individual variation.

This patient was 50 years old, which is close to the patient group average, and from his biometric characteristics was classified as overweight. Moreover, his Oswestry Disability Index (ODI) score indicates minimal disability. The SF-12 PCS and MCS scores were significantly below the average score (based on U.S. general population norms), especially the mental component summary score, demonstrating a significant impact of LBP in the functioning for this patient.

No large differences were found in the lumbar range of motion values after each walking session for all six gross movements (Table 5.2). However, there was a large difference ($\approx 20^{\circ}$) in the lumbar flexion between the two testing days. This difference is well reflected in the data and can be explained from the reported pain levels (Figure 5.4). It can be clearly seen that at the day of experimental walking, when lumbar ROM in forward flexion appears to be significantly reduced, the patient pain levels are significantly higher than the day of the control walking at baseline. This can possibly support an association between pain levels and lumbar ROM particularly in movements which exhibit greater trajectories. This confirms previous findings suggesting that lumbar forward flexion is significantly affected by LBP (Marras & Wongsam, 1986;

Mcgregor *et al.*, 1995). This difference is quite large and thus cannot be solely attributed to differences in starting position or performance between spinal ROM measures which have been found to be sources of error (Chapter 3).

In contrast to the lumbar ROM, thoracic ROM showed significant variation within experimental and control walking days. Additionally, the ROM of the cervical spine segment showed significant variation in ROM both within and between the two walking conditions. Range of Motion from the thoracic and cervical segments exhibited greater trajectories than the lumbar segment. It is assumed that the measurements from those segments are highly dependant on individual performance and difficult to measure accurately and consistently. A small deviation in individual performance (i.e. failure to reach the "end of range of motion" consistently) can result in more than 10° difference between repeated measures. In addition, regarding the ROM measures in the sagittal plane, an inconsistent starting position could be an additional source of error.

Regarding the reported pain levels of this patient, there was a significant difference at baseline between the two sessions. The experimental walking had a significant effect on pain levels as these were decreased by approximately 10% in the VAS at the 30^{th} minute of walking, whereas pain levels during control walking remained unchanged. However, during the control walking condition, the baseline pain levels were very low (< 10% in VAS) and this may be a critical factor which differentiated significantly the walking conditions. However, it is considered important that the pain status did not increase during the experimental walking (Figure 5.3).

Spinal length also showed a significant interaction with time. During the experimental walking the total spinal length was gradually increased throughout the session with a total increase of approximately 1.5% of total length at the 30^{th} minute (Figure 5.4). However, during the control walking condition the total spinal length decreased with a value of approximately 0.5% at the 5^{th} minute of walking, which was regained by the end of the session. The data of this patient showed similar trends to those reported by Pollock *et al.* (2008).

Frequency analysis revealed different power spectral densities (PSD) between experimental and control walking conditions. This was the case for both the thoracic and

lumbar segments as well as in lower (1-3Hz) and higher frequency domains (3-6Hz). Specifically, in lumbar spine, peaks were observed at around 1Hz and were significantly higher in the control walking condition than the experimental one. This is probably due to the decreased heel strike impact as a result of the body weight unloading system. No large differences were observed over time in the measurements indicating a similar response of the underlying tissues over time. Peaks observed in the thoracic segment were generally less powerful than those observed in lumbar segment demonstrating that the shock created by the heel strike is mostly absorbed by the lumbar spine and thus it is transmitted less powerfully to the thoracic segment. Peaks observed in the thoracic segment were more powerful in the experimental walking condition in frequencies between 1-3Hz than those of the control walking. However, this was reversed in higher frequencies (between 3-6Hz), where control walking exhibit greater PSD.

6.3 PARTICIPANT CHARACTERISTICS

An effort was made to achieve equally sized and sufficiently powered groups of LBP patient and Healthy participant. Thus, a total of 19 LBP patients and 21 healthy participants were recruited (Table 5.8).

The patient mean pain duration was 14.5 (\pm 8.2) weeks with a large standard deviation which was clearly below the lower pain duration limit of 12 weeks set in the recruitment inclusion criteria. Pain data were not normally distributed. Ten patients (52.6%) had experienced at least one episode of low back pain in the past. Initially, both pain duration and history of LBP were two criteria initially set with strict limits in order to recruit a homogenous sample. The vast majority of LBP patients attending the primary care NHS sites, where recruitment was undertaken, were either patients with chronic LBP, aged (> 65) or had multiple other health issues. This compromised the feasibility of the study and therefore we adopted a more pragmatic approach with less strict criteria. Thus, the upper age limit was set at 65 years (instead of 50) and the LBP chronicity could range between acute to chronic LBP instead of recruiting only patients with sub-acute LBP. It is recognised that this is a limitation of this study which can significantly affect the results and their interpretation.

A further implication of this change was it undermined the attempt to match the LBP patients and the healthy participants in terms of age. There was a statistically significant (p < .01) mean difference of ten years between the two groups, with the patient group being older (Patients = 47.2, Healthy = 37.6 years). Comparing the biometric characteristics, patients had significantly greater (p = .03) mean Body Mass Index (BMI) than the healthy participants. The mean patient BMI was 26.7 whereas for the healthy group was 24.3. BMI value ranges from 18.5 to 24.9 are considered normal while BMI values range from 25 to 29.9 are categorised as overweight. It is well known that BMI calculation is based only on participant height and weight without considering other biometric measurements. It is a crude categorization system which cannot predict health and commonly used to assess the degree of deviation from what is considered normal for a particular height. No statistical significant difference was found in the mean body weight of the two groups (p = .4) and the self selected walking speed (p = .09). Therefore the patient group was on average ten years older and overweight than the healthy group.

Regarding the disability status the patients were assessed with the Oswestry Disability Index (ODI_v2) and the SF-12_v2 (Appendices 9-10). ODI is a scale which consists of ten sections focused on physical activities. It has been suggested that the ODI when used for repeated measures performs better in patients with more serious disabilities (Fairbank & Pynsent, 2000; Roland & Fairbank, 2000). This is an issue for the sensitivity of this scale to detect significant differences over time. However, this was not a problem for this study since both ODI and SF-12 scales were used only for baseline cross-sectional measurements. The scores obtained by the ODI indicated that the vast majority of this patient sample had minimal to moderate disability (Figure 5.9).

On the other hand patients were also assessed with the SF- 12_v2 scale which is a generic health-related quality of life measure. This scale is a shortened version of the 36item survey (SF-36) and it is summarised by two subscales, the physical component summary (PCS) and the mental component summary (MCS). SF-12 scoring system uses specific algorithms determined from 1998 U.S. general population norms. The mean PCS score (40.1%, CI = ± 7.9) of all patients was lower that the MCS score (48.7%, CI $= \pm 5$) with 14 out of 19 patients to report higher MCS scores (Figure 5.10). It is worth mentioning that higher scores in both components indicate better functioning. This is a valuable finding because it is known that LBP is a multidimensional problem in where psychological and mental issues are of great importance. The higher scores in the MCS it is probably an indicator that the aetiology of LBP in this group was mainly due to organic rather than psychological dysfunction. Altogether, both mean MCS and PCS scores of the SF-12 were below the normal. However, since the 95% confidence interval of the MCS mean (± 5) crosses the normal score, this group can characterised as not significantly different from normal in terms of mental health but significantly below normal in terms of physical health (CI = \pm 7.9). The PCS and MCS scores were related to the ODI score and revealed a significant correlation (p < .01, r = -.6) with PCS and not significant correlation with the MCS. This indicates an agreement of the two scales which is further confirming the impact of LBP in the physical health of those patients. Pain is an important variable which affects significantly the reported disability and quality of life scores. This is evident from the two out of three patients who had no pain and reported amongst the lowest disability scores and highest quality of life status scores. Due to the limited number of patients no age specific analysis of the SF-12 scores was conducted.

Even though the two groups were slightly different sizes, this did not have a significant effect on the between groups variability and thus direct comparisons were allowed. However, the fact that the study failed to recruit the estimated (by the sample size calculation) participant numbers in both groups (n =28), may have an effect on the power of the study. An underpowered study it is prone to Type II error, which is the inability to detect significant changes when these exist and thus unable to reject a false null hypothesis. Although the probability of a Type I error is controlled by the researcher, with the decision of an acceptable risk ($\alpha = 0.05$) to reject a true null hypothesis ('false positive' result), the probability of committing a Type II error (finding a 'false negative result') is controlled by the sample size (Sim & Wright, 2000).

6.4 ROM ANALYSIS DISCUSSION

To the author's knowledge, the current study is the first which has attempted to measure spinal ROM across different spinal segments. The in vivo studies in the literature have been measured the ROM of only the lumbar segment (Burton, 1986; Pearcy & Hindle, 1989; Hindle *et al.*, 1990; Fitzgerald *et al.*, 1991; Vachalathiti *et al.*, 1995; Van Herp *et al.*, 2000; Troke *et al.*, 2001). The measurement tool used in this study was the Polhemus Liberty (electromagnetic motion capture system) which was suggested to be valid and reliable for this type of measurements and especially for the lumbar ROM (Kaliarntas *et al.*, 2009). Extended reference to this system has been made in Chapter 3.

The findings of this study suggest that the ROM of the LBP patients group was significantly lower than the healthy participant group (Tables 5.9-5.11, Tables 5.12-5.13). This fact was true for the majority of the gross movements and spinal segments. This can be partially explained by the fact that the LBP patients group was on average about ten years older than the healthy participant group. Earlier studies have been reported a clear trend that the spinal range of motion is decreasing with age (Van Herp *et al.*, 2000; Troke *et al.*, 2005; Bible *et al.*, 2008; Intolo *et al.*, 2009). Additionally, it has also been reported that a strong predictor for the lumbar range of motion was the BMI index (Bible *et al.*, 2008), which again was significantly higher in the LBP patient group (Table 5.8). However, these differences cannot be attributed only to the age or BMI since other studies have also reported decreased lumbar ROM in LBP patients (Pearcy *et al.*, 1985; Mcgregor *et al.*, 1995) and the size of the differences are greater than the predicted effects of age and obesity.

Data from this study (Table 5.9) indicate that the lumbar segment of healthy adults exhibits approximately: 53° of flexion, 14° of extension, 19° of right and left lateral bending respectively, 7° of axial rotation to the right and 8° of axial rotation to the left. These values were in close agreement with those reported by the radiographic study of Pearcy *et al.* (1985). However, these values are on average 5° lower, across all movements, than the weighted values obtained by electromagnetic motion systems and

presented in Table 2.4 (Hindle *et al.*, 1990; Russel *et al.*, 1993; Van Herp *et al.*, 2000). The greatest discrepancy of about 15° was with the Hindle et al. (1990) and Russel et al. (1993) studies and was observed in the forward flexion movement.

Regarding the LBP patient ROM values for the lumbar spine, the forward flexion and the right/left bending movements where statistically significantly lower than the healthy participants group. The highest mean difference was observed in the forward flexion and was approximately 13° lower in the LBP patient group. However, axial rotations and the backward extension were not significantly decreased in the LBP patient group and this probably indicates that the movements which exhibit greater ROM are affected more in patients with LBP. This notion is partially supported by earlier studies reporting significantly decreased forward flexion values but unaffected side bending and axial rotations (Marras & Wongsam, 1986; Mcgregor *et al.*, 1995). A possible assertion could be that movements with higher ROM can probably increase significantly the moments created in the lumbar spine. This can in turn increase the pressure on the surrounding structures with the end result the exacerbation of pain. Thus, a subconscious mechanism may be activated which inhibits greater spinal trajectories as a protective response.

In relation to the effectiveness of the supported treadmill walking as a rehabilitation technique for LBP data shows that the experimental treadmill walking cannot significantly alter the lumbar ROM in patients with LBP over one session. Thus, this form of exercise may either be ineffective for improving the mobility of the lower back or it requires more than one session in order to produce any effect. However, a design with subsequent training sessions was not in the scope of this study. No direct comparisons, for the effect of supported treadmill walking on lumbar ROM, can be made with other studies since, to the author's knowledge, no other study has examined this parameter before. Two previous studies found in the literature and used a variation of this training technique for patients with LBP did not report spinal ROM measurements (Joffe *et al.*, 2002; Pua *et al.*, 2007).

Apart from the effects of experimental and control treadmill walking in the lumbar ROM, Table 5.9 indicates a close agreement of Polhemus repeated measures within a session or between different sessions. This finding further verifies the validity and reliability of Polhemus measures, reported in Chapter 3, and thus its use for the measurement of the lumbar range of motion it is further supported.

Similarly, the trunk ROM values in the majority of the gross movements (Table 5.10), were again higher in the healthy participants group than those observed in the LBP patients group. However, only the forward flexion and the lateral bending to the right were statistically different. Some statistically significant differences were also observed within the groups (Table 5.13), but they cannot be characterised as clinically significant since they are not large and also produced small to medium effect sizes. They do however give further evidence of the accuracy of the measures themselves. Interestingly, the values observed in the forward flexion of the trunk segment were only about 10° higher that those observed in the lumbar segment, in both participant groups. This indicates that the lumbar segment is mostly responsible for the forward flexion because the orientation of lumbar facet joints is almost perpendicular to the transverse plane allowing greater mobility in the sagittal plane (White & Panjabi, 1990). It is worth mentioning that this is the first study reporting three dimensional in vivo trunk ROM (with respect to the pelvis) and the mean values presented in Table 5.10 can possible form a normative database. However, it should be recognised that those values are from a relatively small group of individuals with a wide age range. Studies with more participants across different age categories can be possible provide more detailed information regarding the trunk movement of healthy people and low back pain patients.

Similar to the lumbar and trunk segments, the total spine of the LBP patient group exhibited significantly lower ROM values (Table 5.14) than the healthy participant group. However, it should be noted that the forward flexion values of both groups are a poor approximation of the true total spine forward flexion. This is due to the fact that although the whole trunk flexes forwards during the forward flexion, the head moves backwards as automatic response for balance maintainace. However, the backward extension and the lateral bending measurements were reliable and indicate significantly higher rotations than the lower segments in both participant groups. It should also be reminded that total spine axial rotation values are not shown in Table 5.11 because Polhemus measurements were restricted up to 80° about this axis, due to gimbal lock effects, and the majority of the participants had values in excess of the 80° limit.

In total, the main outcome of this section is that LBP patients have significantly lower spinal ROM in most of the gross movements and across different segments and also that a single session of 40% of body weight supported treadmill walking is unlikely to improve the spinal mobility of people with LBP in a clinical meaningful way. It seems that movements which exhibit greater ROM, such as the forward flexion, are affected more in absolute terms from the LBP than those with lower ROM.

6.5 SPINAL LENGTH ANALYSIS DISCUSSION

The spinal length was one of the main variables and was considered as the most critical outcome variable in this study. For this reason the sample size calculation was based on that variable.

One of the main findings is that no statistically significant difference observed in the spinal length variation between low back pain (LBP) patients and healthy individuals. This was the case for the total spinal analysis (F(1, 38) = .53, p = .47) as well as for the segmental analysis which looked separately at the lumbar (F(1, 38) = .31,p = .58) and the thoracic (F(1, 38) = 2.1, p = .15) segments. Although statistically insignificant, Figures 5.12 and 5.13 illustrate that healthy individuals lost almost double the spinal length lost by LBP patients, in both walking conditions. Similar patterns were also found with the alternative spinal length calculation method (based on the absolute difference between 1st thoracic and 5th lumbar markers) which did not take into account the spinal curvature (Appendix 12, Figures 2 & 3). This is an indication that the LBP patient spines were already compressed and thus had less room for further stature loses. This may be due to the increased paraspinal muscle activity which has been reported to exist in chronic LBP patients (Healey et al., 2005). Similarly, no significant main effects were found between walking conditions in both the segmental and total spinal analysis. This was indicative that the control and experimental treadmill walking conditions caused similar decreases on the participants' spinal lengths.

Discussion

Another important finding is that the spinal length decreased significantly over time in both walking conditions. Interestingly, the lumbar segment mostly accounted for the significant length decrease observed in the total spinal length. This assumption is based on the fact that the lumbar segment interacted significantly with time (F(4.3, 165)) = 3.5, p = < .01) whereas the thoracic segment did not (F(4, 153) = 2.1, p = .08). This further supports the assumption mentioned above regarding the effects of the increased paraspinal muscle activity. It has been suggested that the compressive loads exerted by the psoas muscles on the lumbar spine during simple activities can be equal to 100 Kg (Bogduk, 2005). Thus, continuous activation of those muscles can have massive compressive effects on the intervertebral discs. The insignificant time effect in thoracic spine is due to the large standard errors observed in the thoracic segment analysis. Differently to the current study, Pollock et al. (2008) who also used 40% of body weight unloading, delivered with an underarm harness similar to the current study, reported a significant interaction between time and walking condition. Particularly for the lumbar spine they reported an increase of approximately 2% at the 60th minute of the supported walking condition. However, during the 30th minute of the supported walking condition the lumbar spine showed a decrease similar to the one observed in the current study. This is an important finding which probably indicates that in order to produce a significant elongation effect in the lumbar spine, a decompression of more than a half hour may be needed.

The significant spinal length increase observed in the Pollock *et al.* (2008) study may be due to the differences in participant groups. They used a small sample of eight young (22 ± 3.9 years) asymptomatic participants whereas in the current study the participants were far older and particularly the patients group was on average ten years older than the healthy group (patients 47±9, healthy 37.7±7.8 years). This can itself be a factor of height variability between the groups because their spinal biomechanical properties can vary considerably. In Pollock *et al.* (2008) it is assumed that the participant's intervertebral discs were healthy and hydrated and it is highly unlikely their spines had any degeneration effects. In addition, the fact that in the current study the patient group was quite small (n = 19) and more diverse, in terms of age and presence of pain, may account for the difference in the results. It has been suggested that LBP patients with different characteristics (age and pain chronicity) show different trajectories in spinal height loss and recovery and therefore should not be combined in the analysis (Kanlayanaphotporn *et al.*, 2003). Thus, a categorization and analysis of patient data according to different age groups and pain levels would be more appropriate. However, the power of this study did not allow further subgroup analysis and this constitutes a limitation of the current study.

In total, this study suggests that half an hour of 40% of body weight supported treadmill walking does not increase the spinal length of either healthy middle-aged adults or patients with low back pain. In addition, treadmill walking (both supported and control) causes significant spinal shrinkage which is more prominent in the lumbar segment and in the control treadmill walking condition.

6.6 PAIN ANALYSIS DISCUSSION

Pain was also one of the main outcome variables in this study and the target variable for most therapeutic interventions. In Figure 5.16 it is evident that mean pain scores interacted differently with time in each walking condition. This was further verified by the statistical analysis where a statistically significant interaction between walking condition and time was found (F(2.8, 42) = 5, p <.01). Further analysis revealed that this interaction was statistically significant for the 25th and 30th minute of control walking. This interaction was corresponded to a mean pain increase of approximately one VAS point at 30th minute of control walking and such change has been suggested to be clinical meaningful in mild low back pain (mild = 1 - 4 VAS score) (Turner *et al.*, 2004). No significant main effects were found for the walking condition and time variables suggesting that no significant differences existed in these variables.

Few studies have investigated the effects of supported walking on low back pain. To the authors knowledge there is one study in the literature investigated this issue on LBP patients (Joffe *et al.*, 2002), two other studies on patients with lumbar spinal stenosis (Fritz et al., 1997; Pua et al., 2007) and a recent case study investigated this concept on a patient with lumbar disc herniation (Moore et al., 2010). These studies have used different techniques and percentages of body weight support. Joffe et al. (2002) was the only study which has examined the effects of supported walking on acute and subacute LBP patients. However, this was combined with an exercise program, did not have a control group and used only six participants. Thus, although improvements in pain levels were reported, no assumptions about the effectiveness of body weight supported treadmill walking can be made. It has been reported that the majority of LBP patients recover in the first four weeks after onset (Croft et al., 1998). Hence, without control data it is difficult to say if these are improvements or if the intervention was harmful and delayed recovery. Pua et al. (2007) used an unloading of up to 40% of body weight for six weeks and they did not report significant improvement in patient pain levels. However, no firm conclusions can be drawn from this study since the supported walking was used as an adjunct to a general rehabilitation program. Similarly, in the case study of Fritz et al. (1997), although there was a significant reduction of pain levels in both patients after a six week program involving supported treadmill walking and physical therapy, again no firm conclusions can be drawn. In the last study mentioned (Moore et al., 2010), despite of the fact that it was a description of an acute disc herniation case, the authors did not reported any quantifiable pain outcomes.

The current study is the first study with a randomized controlled design to investigate the effects of supported treadmill walking on pain levels of LBP patients. The findings of this study showed that patient pain levels increased significantly with time in the control walking condition, with maximum increase at the end of the half hour session. Also, the size of the effect observed in the control walking was large. Conversely, in experimental walking condition (supported) no significant pain increase was observed. This is a very important result which supports the use of body weight supported treadmill walking as a method of exercise for low back patients, without the fear of exacerbating the existing pain. A study with follow up sessions is needed to investigate if there is a therapeutic or long lasting pain relief effect. In general, decompression of the spine achieved via conventional spinal traction has been reported to have no significant effects in the treatment of LBP (Macario & Pergolizzi, 2006; Clarke *et al.*, 2007; Schimmel *et al.*, 2009). Thus, the usefulness of supported walking may be limited to prevention of further pain exacerbation rather that for treating the condition.

6.7 SPINAL VIBRATION RESPONSE DISCUSSION

Following Newton's third law of motion, during walking the ground exerts an equal and opposite force to the one applied by the heel. This force is transmitted through the heel to the body and attenuated along its path through different structures (i.e. intervertebral disc) of the musculoskeletal system (Wosk & Voloshin, 1985). Due to the fact that walking is a dynamic periodic activity, shock waves created by the heel strike have characteristic frequencies and different magnitudes. It has been found that conventional treadmill walking has a similar kinetic profile with overground walking, although small decreases in the ground reaction forces can be observed during treadmill walking (Riley *et al.*, 2007). No study has investigated the effect of different percentages of body weight support treadmill walking on the ground reaction force profile. However, it is speculated that ground reaction forces will reduce in proportion with the body weight percentage unloaded.

In this study the length change of the spine during walking was analyzed in the frequency domain. This analysis intended to identify any potential spinal frequency response differences between the supported and control treadmill walking. It has been suggested that the shock waves generated during the heel strike, and transmitted up to the whole musculoskeletal system, can be a cause for LBP aggravation (Voloshin & Wosk, 1982; Wosk & Voloshin, 1985).

The exposure in repetitive impulsive loading has been associated by many authors with fatigue damage of viscoelastic structures, such as intervertebral discs, resulting in degeneration and pain (Panjabi *et al.*, 1986). There is a consensus in the literature regarding which frequencies are considered harmful. It has been shown that frequencies in the 4 - 6Hz range exhibit greater transmissibility (Wilder *et al.*, 1982) in the human musculoskeletal system and thus should be avoided (Panjabi *et al.*, 1986; Pope *et al.*,

1998). These frequencies are commonly created by industrial machinery and the chronic exposure to them has been associated with the occurrence of low back pain (Bovenzi & Hulshof, 1999). In these conditions, apart from the usual sitting position adopted by the users, the multiaxial nature of the vibration exposure may be the critical factor for the development of LBP and not the frequency itself. Another important factor may be the increased dissipated energy and suppression in proteoglycan synthesis in the nucleus pulposus, under vibration loading, which can lead to disruption of matrix integrity under chronic exposure (Ishihara *et al.*, 1992). It has been also shown that after exposure to whole body vibration, the muscles are fatigued and the discs compressed (Pope *et al.*, 1998). Disc compression can be further exaggerated in the sitting position since it is known that the intradiscal pressure is increased in that position (Nachemson & Elfström, 1970; Nachemson, 1975; Nachemson, 1976).

In the current study the frequency response of the segmental spinal length change during walking was examined for both walking conditions and participant groups. The main finding was that predominant peaks were observed in frequencies between 0.5 - 1Hz, 1.5 - 2 Hz and also between 3 - 4 Hz. Similar frequency patterns were observed in a previous study (Pollock et al., 2008), although this study reported consistently higher peaks in favour of the control walking condition. In the current study a more variant response was observed among walking conditions, participant groups and measurement times. A common trend was observed in both participant groups, indicating predominant higher peaks in frequencies between 0.5 - 1 Hz during the control walking condition (for both spinal segments), with the exception of the lumbar segment of healthy participants (Figure 5.19). This is associated with the mean stepping frequency during gait which was found to be between 0.6-0.64 Hz for both participant groups (Tables 5.16 - 5.17). This finding indicates that heel strike has a significant impact in the spine especially during the control walking condition. This impact can be considerably increased in more strenuous activities such as running. Also, no consistent differences were observed between participant groups in the magnitude of the peaks and this contradicts a previous study suggesting that low back pain patients have decreased shock attenuation capacity (Voloshin & Wosk, 1982). Moreover, no consistent or large differences existed in the

peak magnitudes over time and between different spinal segments (for 0.5-1Hz frequencies which are associated with the heel strike), indicating that shock magnitude does not significantly attenuate over time or along its trajectory through different segments.

Consistent peaks were also found in ranges between 1.5 - 2 Hz probably indicating a delayed response of tissues to heel strike. In particular, for the lumbar segment of the LBP patients these frequencies were lower during the experimental walking than the control walking condition (Figure 5.17). Similarly, in the healthy participant's lumbar segment, these peaks were either equal to the control walking condition or lower (Figure 5.19). This again indicates that the experimental treadmill walking reduced the magnitude of the lumbar peaks observed in these frequencies.

In both participant groups and walking conditions, spinal resonant frequencies which were associated with the stepping frequency during gait (0.5-2 Hz) showed significantly higher magnitudes than higher resonant frequencies (3-6 Hz) which have been suggested to be associated with LBP development. However, frequencies between 3-6 Hz are not of particular interest in this study because it is unlikely for normal walking to produce such significant magnitudes which could lead into the development or exaggeration of LBP. These frequencies could be a risk factor when created by commercial machinery in where the frequency magnitudes and the exposure duration, as well as the posture adopted during exposure, are probably the critical factors for the development of LBP.

Frequencies created by normal walking are not likely to cause disc degeneration and low back pain development. However, since the shock created by heel strike during gait has been characterized as aggravator of existing LBP, possible benefits from its reduction may arise. Thus, the findings of this study indicate that experimental walking (supported) can attenuate the shock created by the heel strike during walking and thus can possibly be a preventive factor for pain exacerbations. However, due to the fact that the dynamic spinal measures were based on surface retro-reflective markers, it is recognized that a degree of error due to soft tissue artifact (STA) during dynamic measurements has been unavoidably introduced. In the literature two main sources of error have identified in measurements utilizing skin mounted markers. The first is anatomic landmark misplacement and the second the soft tissue artifact (Della Croce et al., 2005; Leardini et al., 2005). In this study the first has been addressed with the best possible approach by standardizing the method of marker placement, although certain objectivity exists with possibilities of error. It has been also reported that STA has a frequency content similar to that of the underlying bone movement, it is not reproducible among participants and it is task dependent (Leardini *et al.*, 2005). Due to the similarity in the frequency content with the actual bone movement, it is difficult to distinguish STA by means of any filtering technique (Leardini et al., 2005). However, it is expected that the frequencies of interest in this study (1-6 Hz) cannot be masked to a great extend by STA and also filtering techniques are mostly concerned about frequencies well above this range. In addition, STA is of more importance in measurements used in inverse dynamics, where soft tissue artifact can affect the calculations. Periodic spine change in length (shown in appendix 13) is indicative of motion phenomena, whereas measurement error is associated with random noise (Pollock et al., 2008). Therefore, if STA was a major contributing factor in the spinal frequency response we would not see any difference in the frequency spectra between supported and control walking. On the other hand, it is unknown of how much the skin elasticity was altered during the supported walking and if this contributed in the different frequency response found between the walking conditions. Thus, with the method used, we can not be completely sure what the true frequency response of the spinal column was and if the mechanical stresses created during walking are truly attenuated by the experimental condition. However it seems likely and plausible.

6.8 GAIT CHARACTERISTICS AND SPINAL KINEMATICS DISCUSSION

In this section, the results from the gait analysis and the spinal kinematics of the study participants will be discussed. For the purposes of this analysis, data from the ultimate walking interval were chosen because they were considered more consistent and relevant. This decision was based on literature recommendations regarding the optimal familiarization time required for reliable kinematic measurements, although there was no evidence referring specifically to LBP patients. Considering that the optimal familiarization time for older unimpaired adults was suggested to be 14 minutes (Wass *et al.*, 2005), we decided to use the measurements obtained between the $25 - 30^{\text{th}}$ minute in order to maximize the familiarization time of all participants.

Regarding the temporospatial and kinematic differences between treadmill and overground walking, the majority of the studies in the literature reported small and insignificant differences (Murray *et al.*, 1985; Nymark *et al.*, 2005; Riley *et al.*, 2007; Parvataneni *et al.*, 2009). The most common difference reported by the researchers was shorter double support time and higher cadences during the treadmill walking.

In the present study, the majority of the temporospatial parameters (cadence, stride time, step time, foot off, opposite foot contact, estimated stride length) in the LPB patient group were not altered significantly during the supported treadmill walking (Table 5.16). However, the double support was significantly shorter (p = .02) and the single support significantly longer (p = .01) during the experimental walking. The same effect in the double/single support gait parameters was also observed in the healthy participant group, with the exception that the rest of the temporospatial parameters were also significantly changed in this group (Table 5.17). This effect in the gait support times may be a direct result of the 40% upward force and the harness which was restricting the body motion along the progression line. Also, it may be an indirect effect caused by the neuro-musculoskeletal system adaptations due to the decreased demand for balance maintenance. These results agree with an earlier study which also reported decreased double support and increased single support times during supported treadmill walking (Finch et al., 1991). The muscle activation patterns can change during the body weight supported treadmill walking. It has been found that the combination of different levels of body weight support and stride frequencies affect differently the muscle coordination patterns (Klarner et al., 2010). In higher body weight support conditions (>40%) the electromyographic muscle intensities were significantly decreased and in order to be increased a higher stride intensity was required (Klarner et al., 2010). It has also been reported that, during supported walking, muscles required for the weight

acceptance and push-off showed decreased activation whereas those activated in the swing phase had increased activity (Finch *et al.*, 1991).

Some changes were also observed in the kinematics of the pelvis and the lower limbs (Table 5.19). It was interesting to see that LBP patients altered significantly the kinematics of the hip and knee joints as a compensatory mechanism for the altered walking environment (experimental walking), while their pelvis kinematics remained unchanged. The decrease in hip and knee angles was also reported by others and was attributed to the restriction of the movement in the vertical direction from the harness (Finch et al., 1991). In contrast, the asymptomatic participants decreased significantly their pelvic movements during the experimental walking suggesting a different response to the altered walking environment. Possibly pelvis motion was also already decreased in the LBP patients group, probably due to movement inhibition created by muscle guarding, as protective mechanism for pain exaggerations. This inhibition may have been further increased by the use of treadmill, since treadmill walking constitutes an unfamiliar experience for many people (Wass et al., 2005). The decrease in knee flexion during experimental walking is an indicative for the decreased vertical movement of the centre of mass. It was previously theorized that the decrease of centre of mass vertical amplitude it is an inherent determinant of gait to maximize efficiency (Saunders et al., 1953). Although this assumption has been heavily criticized over the last years, in this study the decrease of body motion in vertical direction it is also indicates a reduction of heel strike impact during walking. This further confirms the findings from the frequency analysis.

Regarding the spinal motion both groups exhibited similar movement patterns in the majority of the spinal segments measured (Table 5.18). Due to the methods utilized to measure segmental spinal motion during treadmill walking, it was only possible to obtain segmental angles about the coronal (side flexion) and sagittal (flexion-extension) planes. Thus, in both groups, the segmental movements in the coronal plane decreased significantly during the experimental walking session, while the sagittal segmental angles remained unchanged. The only exception was the LBP patients' lumbar excursion in the coronal plane which did not yield a statistically significant difference between the
two walking conditions, indicating again decreased lumbar mobility due to a protective muscle guarding. It has been suggested that LBP- related fear decreases significantly the peak angular velocity and acceleration of the spine (Thomas et al., 2008). The lumbar angular amplitudes found in the present study are in agreement with those reported by a study which measured lumbar motion, with an electromagnetic motion capture system, in mild LBP patients during overground walking (Rowe & White, 1996). The overall impression from the spinal kinematic analysis during walking is that the under-arm harness although allows normal spinal movements in the sagittal plane it reduces significantly the motion in the coronal plane. It has been suggested that the spine acceleration decreases significantly in all three axes during supported treadmill walking (Aaslund & Moe-Nilssen, 2008). Also, the sagittal angles of movement of the whole trunk ($\approx 4^{\circ}$) were similar for both groups and walking conditions and are in close agreement with those reported by other studies (Syczewska et al., 1999). However, the side (coronal) and axial (transverse) trunk excursions are the ones which showed the larger values and also those which decreased significantly during the supported treadmill walking in both participant groups. It is expected that different harnesses would not exhibit any differences in the motion reduction in the vertical direction, given that equal body weight unloading is provided. However, under-arm and conventional harnesses would probably affect differently the kinematics of pelvis and spine.

The spinal angles of LBP patients and healthy participants during walking did not exhibited large differences across different spinal segments or the trunk as a whole. Small differences can be attributed to the ten years (on average) age difference between the two groups. It is well known that spinal flexibility reduces with age (Intolo *et al.*, 2009). In addition, the findings of this study support the use of the methods, described in Section 4.5.4, for the estimation of the segmental spinal motion during walking. This assumption is based on the fact that similar values were reported by studies employed similar methods (Syczewska *et al.*, 1999) or others using electromagnetic motion capture systems (Rowe & White, 1996). Also, although some differences were documented between the two walking conditions in the kinematics of the spine, pelvis and lower limbs, as well as in the temporospatial gait parameters, no gait asymmetries or other

kinematic malfunctions were observed. From this respect, the harness supported treadmill walking can be used for gait rehabilitation or other purposes.

6.9 PROJECT LIMITATIONS

Although during the design of this study all the possible measures to reduce the systematic and random errors were taken, a number of factors could have affected the results.

One major limitation of this study was the lower than estimated sample size. With an a priori sample size calculation, based on the spinal length as a primary outcome, it was estimated that an adequate sample size would be constituted by 28 participants in each group (28 LBP patients, 28 healthy volunteers). However, due to poor recruitment rate of appropriate LBP participants, there were finally recruited only 19 LBP patients and 21 healthy volunteers. The fact that the study was undersized may have reduced the power of the study to detect existing meaningful differences and thus there is an increased probability for a type II error (fail to reject a true null hypothesis). However, from the primary analysis the results showed clear trends without dramatic changes when compared to the final dataset. Thus, we assume that it is unlikely that a few more participants would have been changed radically the final outcome of this study. In addition, no sample size calculation was conducted for the other variables examined in this study. In relation to the unequal sample size in the two groups it is assumed that the power of the study was not affected significantly because the differences between the two samples were too small to differentiate their variances.

A further limitation was the variability of the LBP chronicity. The LBP patient group was a heterogeneous group consisted mainly of sub-acute and chronic LPB patients. It is well known that chronic LBP patients may have a complex pathologic background which makes their diagnosis, rehabilitation and interpretation of their results difficult. Also, considering that the sample size was relatively small and the participants were recruited from only three primary care sites, this trial should not be characterized as completely representative or generalisable.

Another important limitation of this study was the measurement method utilized for the estimation of the spinal length and the spinal vibration response during walking. This method was based on surface retro-reflective markers as described in an earlier chapter. In particular for the spinal length variable, the major limitation was the absence of a tightly controlled measuring posture like the one used in stadiometry studies (Rodacki et al., 2003; Rodacki et al., 2005). Thus, the reliability of the measurement was depended on the individual posture adopted each time and thus could be highly subjective. However, apart from the difficulty in the standardization of the measuring position, this technique proved highly accurate (error < 0.01mm) from measurements taken on a rigid surface with known dimensions (Appendix 12, Figure 1). Also, all the possible measures were taken by the researcher in order to encourage the participants to maintain the same posture during all static measurements. Similarly, for the spinal frequency response estimation it is not clear whether the measured frequencies reflect the spinal response and/or that of the overlaying soft tissues. It has been shown, that in areas with increased musculature such as the thigh, when the muscles are loose the resonant frequencies are significantly lower than when the muscles are actively tightened (Karlsson & Tranberg, 1999). Thus, markers attached on loose tissues may produce significant oscillations during walking which are not necessarily representing the behavior of the underlying rigid structures. This is particularly important when measurements are obtained from overweight participants. In this study, some participants were categorized as overweight according to their BMI and thus a possible bias in the frequency response measurement may have been introduced.

The use of under-arm harness it is also a possible limitation for this study. The idea for the use of this type of harness was to apply traction in the lower back, as a result of the upwards pulling force, and thus to reduce the mechanical stresses on the lumbar structures. This effect cannot be achieved with the usual parachute type harness, used in other studies (Joffe *et al.*, 2002; Pua *et al.*, 2007), because the pulling force is applied to the pelvis so compressing the lumbar section. However, the under arm harness has some inhered drawbacks. The first of all is that the application of force under the armpit is a somewhat unpleasant experience, especially when used continuously. This is particularly

significant when used for people with increased body mass where the amount of the unloading force required is greater. The main reason is due to the fact that through the armpit they pass some very sensitive structures such as the axillar artery, nerves and lymphatic glands. Under pressure these structures are compressed with the end result of decreased blood circulation and neural conduction in the arms. In addition, the shoulder joints are the most unstable joints in the body and apart from the muscles they are only connected to the body by the sternoclavicular joint. Thus, the muscles supporting the shoulder joint require a significant effort in order to withstand the 40% of body weight unloading force. These muscles cannot resist continuously this load and participants often end up with over-abducted arms. This position exerts pressure on the neck which causes additional unpleasant sensations in the neck muscles. This was a common complain by the study participants of both groups. Discomfort, fatigue and dyspnea are some common symptoms that participants have reported when using conventional supported treadmill training with a 15% of body weight (Mackay-Lyons *et al.*, 2001).

Under arm body weight unloading treadmill walking cannot be characterized as an optimal rehabilitation solution for LBP patients. This is due to the fact that contemporary LBP rehabilitation regimens for non specific LBP aim to encourage independent activity and change the behavior of patients and not provide solutions which depend on heavy machinery. This is because LBP is a complex problem and its approach with a medical or biomechanical model alone would constitute less than ideal practice. A biopsychosocial approach, especially for the non specific LBP, which has proposed a couple of decades back (Waddell, 1987) is probably the preferred healthcare approach. The proposed system is difficult to incorporate into everyday practice since it requires regular attendance to a training center or clinical site. On the other hand to provide a weight bearing harness at a local leisure centre would allow LBP patients to exercise and keep fit with less pain than is currently possible.

6.10 OVERALL DISCUSSION

This project achieved its primary aim to evaluate the effects of supported treadmill walking in LBP patients and healthy individuals using a number of different variables. Despite the various limitations outlined above, it is suggested that all the objectives set at the beginning of this research were met successfully.

Although it is not possible to establish cause and effect relationships between the outcomes of this study, several explanations of how the study findings may be related will be attempted. One of the major findings in this study was that 30 minutes of 40% of body weight supported treadmill walking has statistically significant effects over time on the reported pain status of LBP patients. This effect indicated that LBP increased over time during conventional treadmill walking while it remained unchanged during the experimental walking. However, what was the critical factor for this effect? Was it the reduction of the forces created during the heel strike or the decompression of the lumbar spine? The answer for this question is not straight forward since the evidence does not clearly support either of the two hypotheses. Regarding the decompression of spine, the findings of this study suggest an opposite outcome from what was expected. The spine, especially the lumbar segment, was found to be compressed significantly over time, even in the supported walking condition. This is probably the effect from the increased muscle activity. It has been found that the typical intervertebral disc pressures during walking are between 0.53 - 0.63 MPa whereas when performing the Valsava maneuver from the standing position the actual disc pressures can go up to 0.92 MPa (Wilke et al., 1999). It is also known that patients with low back pain have significantly increased activity of the erector spinae and the rectus abdominis muscle during walking (Arendt-Nielsen et al., 1995; Van Der Hulst et al., 2010a; Van Der Hulst et al., 2010b). However, no relation was reported between erector spinae activity and disability and pain scores (Van Der Hulst et al., 2010a). The findings of Wilke et al (1999) suggest that the contraction of the abdominal and back muscles can exert much higher pressures on the intervertebral discs than the everyday normal activities such as walking. Thus, a possible speculation regarding the decrease of the spinal height in this study is that the

proposed training position was an unfamiliar and sometimes uncomfortable for the participants. This eventually increased further the muscle activity, as a compensatory mechanism for this new and unfamiliar walking condition, which in turn increased the compression forces on the discs, regardless of the significant 40% of body weight unloading force. In both walking conditions, a dramatic decrease was observed in the lumbar length (Figures 5.12-514) during the first 5-10 minutes and this can be further associated with the increased muscular activity. When the participants became more familiar with the walking environment and probably relaxed, the length started to be regained also indicating the loss is reversible and probably not therefore due to viscoelastic compression or the expulsion of fluid from the disc. However, this is an arbitrarily assumption which needs further investigation by electromyography measurements in order to be proved. It has been reported that individuals with chronic LBP exhibit higher EMG activity and delayed stature recovery after a loaded task (Healey et al., 2005). The 30 minutes of horizontal resting time before each walking session it is not expected to have contributed significantly in the observed spinal height variation. No robust evidence exists regarding the required time for the recovery of spinal diurnal changes. An earlier study suggested that 54% of diurnal loss in stature occur within an hour after rising and the 70% is regained within approximately four hours after lying down in young adults (Tyrrell et al., 1985).

Thus, the important factor may be the decrease in the ground reaction forces during walking and not the spinal decompression itself. This is partially supported by the fact that conventional spinal decompression achieved through traction has been found to be ineffective for the treatment of LBP (Macario & Pergolizzi, 2006; Schimmel *et al.*, 2009), especially when used as a single treatment (Clarke *et al.*, 2007). In addition, another study using a parachute type harness (and thus not being able to elongate the spine) reported a modicum of pain relief (Joffe *et al.*, 2002) which is an additional reason to suggest that spine elongation is probably irrelevant to pain relief. On the other hand though, limited evidence exists for the value of the ground reaction force reduction during walking. An earlier study has been reported a reduction by about 40% of the impulsive forces with the use of insoles (Wosk & Voloshin, 1985). However, recent

high quality reviews suggest that interventions designed to reduce the repetitive impulsive impact in the spine (such as the use of insoles or back support) are also ineffective for the prevention or treatment of LBP (Sahar *et al.*, 2008; Van Duijvenbode *et al.*, 2008). Thus, no firm conclusions can be made for the value of the ground reaction forces reduction for the treatment of LBP. However, the decrease in the walking related spinal peak frequencies and the non exacerbation of pain found in this study, during the supported walking, may suggest a potential benefit for LBP patients.

The significant pain increase observed in the control walking condition does not seem to cause significant changes in the spinal ROM values. It has been suggested that spine kinematic measurements of flexion and extension are not valid estimates of disability in patients with chronic and subacute LBP (Poitras *et al.*, 2000). Also, a poor correlation between lumbar flexion and disability has been also reported (Sullivan *et al.*, 2000). Similarly, in this study, weak correlations were found between reported pain status, disability status and measured spinal range of motion. Thus, the main finding regarding this variable is limited to the observation that LBP patients have significantly decreased spinal range of motion than healthy participants especially in movements which exhibit greater angulations. However, since the sensitivity and the usefulness of spinal ROM is a useful measurement which can predict disability and also monitor progress in LBP patients.

6.11 SUMMARY

This chapter presented the discussion of the findings of the main study presented in chapter 5. The main effects of the application of 40% of body weight supported treadmill walking in LBP patients were the ability to undertake a period of 30 minutes walking activity without elevating pain levels and a reduction in the vibration response of the spine caused by heel strike. These benefits were achieved at the price of arm shoulder and neck discomfort. Methodological drawbacks and study limitations were also discussed but are unlikely to have influenced significantly these conclusions.

The current findings could add in the greater LBP literature regarding means to maintain or improve fitness levels of LBP patients without exacerbating LBP. It is well known that fear avoidance attitudes contribute vastly in the development of a sick behavior, resulting to fitness reduction, which could be the critical factor for the transition from an acute LBP incident to a chronic and complicated condition. Therefore, for mechanical LBP, methods to reduce the heel impact during walking as well as advice regarding the optimal exercising time while being on pain may be critical.

In the following chapter, the objectives stated in chapter one will be linked with the findings of this research and the overall conclusions will be drawn. In addition, based on the conclusions, further recommendations for future studies will be attempted.

CHAPTER 7 CONCLUSIONS & RECOMMENDATIONS 7.1 INTRODUCTION

This chapter summarizes the findings of this project in relation to the aims and objectives stated in Chapter 1. In relation to those findings the author aims to make some recommendations for further research and clinical practice.

7.2 CONCLUSIONS

The overall conclusion of this project is that the main aim of the study was successfully fulfilled. All the objectives of the main research question were investigated thoroughly and the conclusion for each or them will be stated below.

This study was successful in developing a multi-segment spinal ROM measuring technique which was validated and can be confidently used for clinical and research purposes. Chapter 3 is dedicated to the development and testing methods of the Polhemus Liberty. To the author's knowledge this is the first study reported ROM data in more than one spinal segment from asymptomatic individuals and people with LBP. Thus, Polhemus Liberty is a valid and reliable system with accuracy levels in excess of those required for gross spinal measurements. However, special attention should be given to the sensors attachment and participant training and instruction before and during movement performance. In addition, regarding the movements in the sagittal plane, the poor repeatability of the starting position can be a source of error in repeated measures. These were identified as the greatest sources of error since inconsistent participant performance, poor reliability of sensor attachment and inconsistent starting position especially in the sagittal plane can introduce quite large random errors.

Supported treadmill walking did not alter significantly the spinal range of motion in LBP patients when used in a single session. Multiple sessions may be needed for a potential improvement. Spinal movements which exhibit greater ROM, such as forward flexion, are mostly affected in low back pain patients.

Regarding the spinal elongation, the findings of this study indicate that 30 minutes of 40% body weight supported treadmill walking does not cause any significant

lengthening of the spine, in both healthy people and LBP patients. Conversely, the spinal length decreased significantly over time and the lumbar spine was mainly responsible for this decrease. Since no statistically significant difference existed in spinal length between walking conditions, but on the other hand there was a significant pain increase during the control walking condition, the spinal compression may not be a critical factor for the pain exacerbation observed in the control walking condition.

Although not statistically significant, the healthy participant group showed greater decrease in spinal length than the LBP group, in both walking conditions. This was probably an indication that the spines of LBP patients were already more compressed (possibly due to muscle guarding) than these of healthy participants. This fact allowed greater spinal length variability in the healthy participants group.

Low back pain levels were gradually increased over time during the control treadmill walking. On the contrary, although supported treadmill walking did not resolve LBP symptoms, the findings of this study indicate that it can prevent further pain exacerbations. Thus, this training regime may be of benefit to LBP patients because they can maintain or even improve their physical fitness while preventing pain exacerbations during treadmill walking. In terms of the walking duration it can be concluded that people with LBP can walk relatively safely for up to 10 minutes. After this time they may be at an increased risk of significant pain increase, which can be avoided using supported walking.

The reduction of ground reaction forces during walking may be a key factor for the prevention of pain exacerbations in people with LBP. The frequency spectra of values related to stepping frequency (1-2 Hz) were reduced during the supported walking condition. This may be a contributing factor for the non increase of the reported low back pain levels during this supported walking condition. Frequencies between 4-6Hz produced by industrial machinery, and have been reported to be risk factors for the development or exacerbation of LBP, may not be of interest in normal walking because their power appeared to be insignificant.

Under-arm supported treadmill walking alters significantly the temporospatial and kinematic parameters of lower limbs. In addition, the lateral and the axial rotations of the spine during walking where mostly limited by the under-arm harness.

The use of the under-arm harness for partial body weight unloading walking proved to be problematic in practice. The design of a new upper-body harness attached to the trunk or the use of the conventional parachute type harness is recommended instead.

The body weight supported treadmill walking concept may not be of benefit for the treatment of non-specific low back pain which constitutes the vast majority of LBP cases. Further high quality randomized controlled trials with more than one session of supported walking and large sample sizes are needed in order to verify its clinical efficacy and cost effectiveness.

To sum up, due to methodological limitations discussed in earlier section, no categorical conclusions can be drawn from this study. However these findings can provide some useful information for future research and for clinical practice. Further research is needed to explore any associations among spinal elongation, ROM, disability and pain levels in LBP patients.

7.3 RECOMMENDATIONS FOR FURTHER RESEARCH

The concept of decompression of the lumbar spine it is frequently used by various treatment techniques, especially those provided by osteopaths, chiropractors and manual therapists. The current study proposed an alternative technique for applying spinal decompression without being able to measure any significant spinal elongation or pain relief at the end of a single 30 minute session of walking in mild to moderate LBP.

The effects of supported treadmill walking should be further investigated. A study incorporating electromyography is needed to provide further information regarding the function of the abdominal and back muscles during conventional and supported treadmill walking. A possible over-activation of those muscles may not be desirable since it can introduce significant spinal compression. Furthermore, the association between spinal compression and low back pain should also be further investigated.

Due to reasons discussed above, supported treadmill waking it is highly unlikely to provide any significant pain relief or constitute a primary therapy regime for LBP. However, because this study did not have a follow up design, a study with subsequent sessions may be more appropriate to investigate potential pain relief effects. Also, a more user friendly harness should be designed, although it is recognized that it is quite difficult to design an effective upper body harness. Thus, probably the conventional type of harness should be used instead.

There is a need for further high quality randomized controlled trials to investigate in depth the mechanical effects on the spine of conventional and body weight unloaded walking. The need for high quality research studies is emphasized by the strong controversy in the literature regarding the effectiveness of spinal traction, back support, use of foot shock absorbers, exercises, manipulative techniques etc. This is often obvious in Cochrane reviews where little or poor quality of evidence exist in order to support assumptions.

There is also a need to develop a rigid categorization system of low back pain. The inclusion in research studies of heterogeneous LBP patient groups is often leads to inconclusive results.

Regarding the clinical implication of these findings it can be suggested that the reduction of ground reaction forces may have benefits for patients with LBP. From the pain trajectory an indication can be also drawn about the safe walking time for a low back pain patient. In addition, the usefulness of traction techniques usually utilized in clinical practice is questioned. In conjunction to the conventional LBP treatment, it is probably advisable for the patients to use means to reduce the impact of heel strike during walking. In addition, prolonged activities while being on pain should be possibly avoided.

The main benefit of under arm body weight supported walking would appear to be the ability for LBP patients to undertake exercise without exacerbating pain and hence to help maintain their physical fitness and prevent secondary deconditioning of the body due to the limitations of activity caused by LBP. To this end, if a suitable and pain free upper body harness and weight support system could be introduced to local leisure centres, then this could allow people with LBP to exercise regularly and maintain fitness without exacerbating their pain.

7.4 PUBLICATIONS

7.4.1 Current Publications (Conference Proceedings)

So far, findings from this project have been published in the proceedings of four

international conferences:

- 1. Kaliarntas K.T, Ugbolue, U.C., Riches, P.E., Rowe, P.J., (2009) Proceedings of the XXII Congress of the International Society of Biomechanics. *Concurrent validity and test-retest reliability of the Polhemus Liberty for the measurement of spinal range of motion*. July 5-9, University of Cape Town, South Africa
- 2. Kaliarntas, K.T., Riches, P.E., Ugbolue, U.C., Rowe, P.J. (2010) Proceedings of the 17th Congress of the European Society of Biomechanics. *Effects of supported and normal treadmill walking on healthy middle-aged spines*. July 5-8, University of Edinburgh, UK
- 3. Kaliarntas, K.T., Riches, P.E, Ugbolue C.U., Rowe, P.J. (2010) Proceedings of the 7th Interdisciplinary World Congress on Low Back & Pelvic Pain. *Effects of supported and normal treadmill walking on Low Back Pain Patients*. November 9-12, Los Angeles, USA
- 4. Kaliarntas, K.T., Riches, P.E, Ugbolue C.U., Rowe, P.J. (2011) Proceedings of the XXIII Congress of the International Society of Biomechanics. *Gait and trunk movement patterns of low back pain patients and healthy volunteers during supported and conventional treadmill walking*. July 3-7, Brussels, Belgium

7.4.2 Future Publications (Journal Articles)

Two publications are currently prepared for submission in relevant journals such as Gait & Posture and Spine.

The one paper will consist of results presented in chapter 3 and is related to the validity and reliability testing of the Polhemus Liberty. The other paper will be the outcome of the main study regarding the supported treadmill walking randomised control trial.

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APPENDICES

APPENDIX 1: VICON BODYBUILDER CODE

{*Start of macro section*}

{*=====*}

macro SUBSTITUTE4(p1,p2,p3,p4)
{*Replaces any point missing from set of four fixed in a segment*}

s234 = [p3,p2-p3,p3-p4] p1V = Average(p1/s234)*s234 s341 = [p4,p3-p4,p4-p1] p2V = Average(p2/s341)*s341 s412 = [p1,p4-p1,p1-p2] p3V = Average(p3/s412)*s412 s123 = [p2,p1-p2,p2-p3] p4V = Average(p4/s123)*s123

p1 = p1 ? p1V p2 = p2 ? p2V p3 = p3 ? p3V p4 = p4 ? p4V endmacro

macro SEGVIS(Segment)
{*outputs a visual representation of the segment to be viewed in the Workspace*}
{*0(Segment) is the origin of the segment*}

```
ORIGIN#Segment=0(Segment)
XAXIS#Segment=0(Segment)+(1(Segment)*10)
YAXIS#Segment=0(Segment)+(2(Segment)*10)
ZAXIS#Segment=0(Segment)+(3(Segment)*10)
OUTPUT(ORIGIN#Segment,XAXIS#Segment,YAXIS#Segment,ZAXIS#Segment)
endmacro
```

macro POINTER(Anatomy,Segment)

{*Calculates the position of the end of the pointer for calibration in the technical frame it belongs to*}

{*1st determine the "point" in the Global system and outputs it as point#Calib. Then converts the point into*}

{*the appropriate technical reference frame and stores it as parameter \$%#point#Calib*}

unitPointer=((POI1-POI2)/DIST(POI1,POI2)) Anatomy#Calib=POI1+123*unitPointer OUTPUT(Anatomy#Calib) PARAM(Anatomy#Calib) %#Anatomy#Calib=Anatomy#Calib/Segment PARAM(%#Anatomy#Calib)

endmacro

macro ColeJCS(seg1,seg2,joint)

{* Procedure to calculate the rotations about defined embedded axes using the joint co-ordinate system.

References: Cole,G.K. et al (1993). Application of the Joint Co-ordinate System to Three-dimensional Joint Attitude and Movement Representation : A Standardization Proposal. Journal of Biomechanical Engineering. November 1993 : Vol 112 : pp 344-349

aEone,aEtwo,aEthree =unit vector describing the attitude of the 1st,2nd and 3rd axis of the joint co-ordinate system between the reference segment (seg1) and the target segment (seg2), relative to an inertial reference system.

If the axes of a body segment co-ordinate system are identified as an axis of Flexion, a Longitudinal axis and a Third axis, then Fone, Lone, Tone are unit vectors that describe the attitude of the Flexion, Longitudinal and Third axes respectively, in an inertial reference system.

Input: 'seg1', 'seg2' describing the axes of the co-ordinate systems embedded in each segment.

Fone, Lone, Tone describe the flexion, longitudinal and third co-ordinate axes of the proximal segment.

Ftwo, Ltwo, Ttwo describe the flexion, longitudinal and third co-ordinate axes of the distal segment.

'joint' is the name given to the joint at which the specified segments interact.

Output: Angles of rotation about axes aEone,aEtwo,aEthree, flexion, abduction and rotation respectively. Counterclockwise rotations are chosen as positive*}

Fone=3(seg1) Lone=2(seg1) Tone=1(seg1) Ftwo=3(seg2) Ltwo=2(seg2) Ttwo=1(seg2)

{*Defines e1 and e3*} aEone=Fone aEthree=Ltwo

{*Calculate the Vector or Cross Product between the Vectors*} Va={2(aEthree)*3(aEone)-3(aEthree)*2(aEone),3(aEthree)*1(aEone)-1(aEthree)*3(aEone),1(aEthree)*2(aEone)-2(aEthree)*1(aEone)} $\{ \text{*Calculate the Scalar or Dot Product between the Vectors*} \} \\ DPone=(1(Va)*1(Ttwo))+(2(Va)*2(Ttwo))+(3(Va)*3(Ttwo)) \\ DPtwo=(1(Vc)*1(Ftwo))+(2(Vc)*2(Ftwo))+(3(Vc)*3(Ftwo)) \\ \end{tabular}$

{*Calculates A (AA) and then e2*} IF DPone < 0 AND DPtwo > 0 THEN AA=-1 ELSE AA=1 ENDIF aEtwo=(Va/Vb)*AA

```
{*Calculate the value of r.*}
Rone={2(Fone)*3(aEtwo)-3(Fone)*2(aEtwo),3(Fone)*1(aEtwo)-
1(Fone)*3(aEtwo),1(Fone)*2(aEtwo)-2(Fone)*1(aEtwo)}
Rtwo=DIST(Rone,{0,0,0})
r=Rone/Rtwo
```

```
IF aEtwoLonedp >= 0 THEN aEtwoLonesign=1 ENDIF
IF aEtwoLonedp < 0 THEN aEtwoLonesign=-1 ENDIF
IF FoneLtwodp >= 0 THEN FoneLtwosign=-1 ENDIF
IF aEtwoFtwodp >= 0 THEN aEtwoFtwosign=-1 ENDIF
IF aEtwoFtwodp < 0 THEN aEtwoFtwosign=-1 ENDIF
```

```
joint#Flex=(acos(aEtwoTonedp))*(aEtwoLonesign)
joint#Abd=(acos(rLtwodp))*(FoneLtwosign)
joint#Rot=(acos(aEtwoTtwodp))*(aEtwoFtwosign)
joint#JCSAngles=<joint#Flex,joint#Abd,joint#Rot>
```

```
{*For later calculations of moments*}
{*x axis will be the floating axis*}
joint#JCS=[0(Seg1),aEtwo,aEone,xyz]
XAXISjcs#joint=aEtwo
```

ENDMACRO

```
macro PROJECTION(line, segment, joint)
{* Calculates flexion/extension and abduction/adduction angles using technique of:
Cheng P.L., Pearcy M. (1998) A 3D Definition for the Flexion/Extension and
Abduction/Adduction Angles.
Proc. 4th International Symposium on the 3D Analysis of Human Movement, July2nd-
2th, Chattanooga, USA.*}
{* input is the unit vector of the distal segment as "line" *}
%line=(line+0(segment))/segment
RotZ=acos(SQRT((2(%line)*2(%line))+(3(%line)*3(%line))))
RotX=acos(SQRT((1(%line)*1(%line))+(2(%line)*2(%line))))
If 1(%line) > 0 Then RotZ=-RotZ Else RotZ=RotZ EndIf
If 3(%line) > 0 Then RotX=-RotX Else RotX=RotX EndIf
RotZ2=acos(SORT(1-1(\%line)*1(\%line)))
RotX2=acos(SQRT(1-3(%line)*3(%line)))
joint#ProjAngles=<RotX,0,RotZ>
joint#ProjAngles2=<RotX2,0,RotZ2>
output(joint#ProjAngles)
endmacro
{*Macro for Dot Product*}
MACRO DotProduct (One,Two,DotProd)
       DotProd = (1(One)*1(Two)+2(One)*2(Two)+3(One)*3(Two))
ENDMACRO
{* Macro to do a cross product *}
MACRO CrossProduct (First, Second, Result)
       Result = { First(2)*Second(3)-First(3)*Second(2),
      First(3)*Second(1)-First(1)*Second(3),
      First(1)*Second(2)-First(2)*Second(1)}
ENDMACRO
{*End of macro section*}
{* define segments *}
{* SEGMENTS: Sacral, Lumbar, Thoracic, Cervical*}
STRMID=(STR1+STR3)/2
SSEG=[STRMID,STR1-STR3,STRMID-STR2,YXZ]
```

```
HDTRMID=(HDTR1+HDTR3)/2
HDSEG=[HDTRMID,HDTR1-HDTR3,HDTRMID-HDTR2,YXZ]
```

```
{*page87:segment definition-origin*}
{*LLSEG=LLSEG+LLTRMID*}
```

ULTRMID=(ULTR1+ULTR3)/2 ULSEG=[ULTRMID,ULTR1-ULTR3,ULTRMID-ULTR2,YXZ]

CTRMID=(CTR1+CTR3)/2 CSEG=[CTRMID,CTR1-CTR3,CTRMID-CTR2,YXZ]

{*CSEG=CSEG+CTRMID*}

SEGVIS(HDSEG) {*head triad*} SEGVIS(CSEG) {*thoracic triad*} SEGVIS(ULSEG) {*lumbar triad*} SEGVIS(SSEG) {*sacral triad*}

{*OUTPUT FOR VIRTUAL POINTS (these are the origins)*}

{*OUTPUT(STRMID,HDTRMID,ULTRMID,CRTMID)*}

{*calculate joint angles, sequence - flexion, side bending, axial rotaion*} {* Euler angles application of rule 1 & rule 2 (page 101 in manual)*}

HDSEGAngles= -<SSEG,HDSEG,XYZ>

CSEGAngles= -<SSEG,CSEG,XYZ>

ULSEGAngles= -<SSEG,ULSEG,XYZ>

SSEGAngles= -<SSEG,1,XYZ>

{*OUTPUT angles for plotting and saving*}

OUTPUT(HDSEGAngles,CSEGAngles,ULSEGAngles,SSEGAngles)

APPENDIX 2: *MATLAB CODE FOR DATA PROCESSING*

%% CODE TO ANALYSE THE POLHEMUS SPINAL MOTION DATA

```
clc; clear all
% GETS DATA
 [Filename, pathname, filterindex ] = uigetfile('*.txt', 'Select data
file', 'multiselect', 'on');
[rr cc]=size(Filename);
for ii=1:cc
filename=Filename:
f=filename(1:end-4);f=[f '_1.xls'];f=fullfile(pathname, f);
F=fullfile(pathname, filename);
a=importdata(F);
[r c]=size(a);
b=a(:,c);
idl=find(b==0);
id2=id1+1;
id3=id2+1;
s1=a(id1,1:end-1);
s2=a(id2,1:end-1);
s3=a(id3,1:end-1);
xlswrite(f,a,'Sheet1');
xlswrite(f,s1,'sensor1');
xlswrite(f,s2,'sensor2');
xlswrite(f,s3,'sensor3');
maxS1xyz=max(s1(:,5:7));maxS2xyz=max(s2(:,5:7));maxS3xyz=max(s3(:,5:7));
minS1xyz=min(s1(:,5:7));minS2xyz=min(s2(:,5:7));minS3xyz=min(s3(:,5:7));
rS1xyz=range(s1(:,5:7));rS2xyz=range(s2(:,5:7));rS3xyz=range(s3(:,5:7));
maxxyz=[maxS1xyz, maxS2xyz, maxS3xyz];
minxyz=[minS1xyz, minS2xyz, minS3xyz];
rxyz=[rS1xyz, rS2xyz, rS3xyz];
   maxmin=[maxxyz, 0, minxyz, 0, rxyz];
xlswrite(f,maxmin,'sheet3');
% Interpolation
% xo is the xdata that you have collected and want to sinterpolate -
          in this application xo will be time
2
% yo is the ydata that you have collected and want to interpolate -
2
         in this application yo will be angle
% xi is the x value that you want to have after interpolation -
00
          in this case xi will be time and will have 101 points starting
at
          zero and ending at the last time point.
[rs cs]=size(s1);
tend=rs/120; %number of points divided by sampling frequency
xo=(0:tend/(rs-1):tend);
xi=(0:(tend/100):tend);
k=1;
    for j=5:7;
    yos1=s1(:,j);yos2=s2(:,j);yos3=s3(:,j);
    yisl=interpl(xo,yosl,xi,'spline')';
```

```
yis2=interp1(xo,yos2,xi,'spline')';
    yis3=interp1(xo,yos3,xi,'spline')';
    %Plots collected xo & yo data in black and interpolated data (xi,
yi) as red crosses.
    % figure, plot (xo,yos1)
% hold on, plot (xi, yis1, 'r+')
% title('Interpolated Data')
    % xlabel('Time')
    % ylabel('Angle')
    % axis('tight')
    is1(:,k)=yis1;
    is2(:,k)=yis2;
    is3(:,k)=yis3;
    k=k+1;
    end
 is123=[is1 is2 is3];
 xlswrite(f,is123,'Sheet2');
end
display('COMPLETED');
```

APPENDIX 3: DEPARTMENTAL ETHICAL APPROVAL



BIOENGINEERING ETHICS COMMITTEE

NAME: KONSTANTINOS KALIARNTAS

PROJECT TITLE:

"CONSCURRENT JANDITT AND INTRA-RATTER RELIABILITY OF THE POLHERUS LIBERTY EXECTRONALAUETIC NOTIONS TRACKING SYSTEM FOR THE MEASURENEST OF SPINAL RANGE OF MOTION IN HEALTHY ADJULTS"

given.

On behalf of the Committee, may I take this opportunity to wish you every success with the project.

Yours sincerely

Date:

Chairman of Ethics Committee: Secretary of Ethics Committee: Secretary of Ethics Committee: 2/07/08

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APPENDIX 4: POLHEMUS RIG ANGLES & ERRORS

Reference		Measured angle				Error			
Angle °		(d	egrees)			(de	grees)		
	1^{st}	2nd	3 rd	Mean	1^{st}	2nd	3^{rd}	Mean	
90	91.3	91.6	91.5	91.5	1.3	1.6	1.5	1.5	
80	79.5	79.6	79.7	79.6	0.5	0.4	0.3	0.4	
70	69.7	69.8	69.6	69.7	0.3	0.2	0.4	0.3	
60	59.6	59.6	59.9	59.7	0.4	0.4	0.03	0.3	
50	49.8	49.7	49.3	49.6	0.2	0.3	0.7	0.4	
40	39.9	39.3	39.7	39.6	0.1	0.7	0.3	0.4	
30	29.8	29.7	29.5	29.7	0.2	0.3	0.5	0.3	
20	19.9	20.2	19.9	19.9	0.1	0.2	0.1	0.1	
10	10.1	9.8	9.9	9.91	0.1	0.2	0.1	0.1	
0	0	0	0	0	0	0	0	0	
-10	9.6	10.1	9.9	9.9	0.4	0.1	0.1	0.2	
-20	19.6	19.6	19.6	19.6	0.4	0.4	0.4	0.4	
-30	29.6	29.4	29.3	29.5	0.4	0.6	0.7	0.5	
-40	39.2	39.2	39.1	39.2	0.8	0.8	0.9	0.8	
-50	49	48.9	49	48.9	1	1.1	1	1.1	
-60	58.9	58.8	58.7	58.8	1.1	1.2	1.3	1.2	
-70	69.2	68.8	68.6	68.9	0.8	1.2	1.4	1.1	
-80	79.3	79.5	79.6	79.5	0.7	0.5	0.4	0.5	
-90	92	91.7	91.1	91.5	2	1.7	1.1	1.5	
				Mean	0.57	0.6	0.6	0.6	
				Max	2	1.7	1.5	1.5	

 Table 1. Rotation about X axis, (Forward-backward) segment 1.

Reference		Meas	ured angle			Ε	rror	
Angle °		(d	legrees)			(de	grees)	
	1^{st}	2nd	3 rd	Mean	1 st	2nd	3 rd	Mean
90	90.9	91.2	91.1	91	0.9	1	1.1	1
80	79.3	79.4	79.5	79.4	0.7	0.6	0.5	0.6
70	69.7	69.8	69.6	69.7	0.3	0.2	0.4	0.3
60	59.4	59.7	60.1	59.7	0.6	0.3	0.1	0.3
50	49.9	49.9	49.5	49.7	0.1	0.1	0.5	0.3
40	40	39.5	39.9	39.7	0	0.5	0.1	0.3
30	30	29.9	29.7	29.7	0	0.1	0.3	0.3
20	20	20.3	20	20.1	0	0.3	0	0.1
10	10.1	9.9	10	10	0.1	0.1	0	0.1
0	0	0	0	0	0	0	0	0
-10	9.7	10.2	10	9.9	0.3	0.2	0	0.1
-20	19.8	19.8	19.8	19.8	0.2	0.2	0.2	0.2
-30	29.9	29.7	29.6	29.8	0.1	0.3	0.4	0.2
-40	39.6	39.6	39.6	39.6	0.4	0.4	0.4	0.4
-50	49.5	49.5	49.5	49.5	0.5	0.5	0.5	0.5
-60	59.5	59.4	59.3	59.4	0.5	0.6	0.7	0.6
-70	69.6	69.1	68.9	69.2	0.4	0.9	1.1	0.8
-80	78.9	79.1	79.2	79	1.1	0.9	0.8	1
-90	89.7	89.5	89.1	89.4	0.3	0.5	0.9	0.6
				Mean	0.3	0.4	0.4	0.4
				max	1.1	1.2	1.1	1

Table 1. Rotation about X axis, (Forward-backward) segment 2.

Table 3. Rotation about X axis, (Forward-backward) segment 3.

Reference		Measured angle				Error			
Angle °		(d	egrees)			(de	grees)		
	1 st	2nd	3 rd	Mean	1 st	2nd	3 rd	Mean	
90	92	92.4	92.3	92.3	2	2.4	2.3	2.3	
80	80.2	80.3	80.5	80.3	0.2	0.3	0.5	0.3	
70	70.3	70.4	70.3	70.3	0.3	0.4	0.3	0.3	
60	60.2	60.2	60.6	60.3	0.2	0.2	0.6	0.3	
50	50	50.3	49.9	50	0	0.3	0.1	0.2	
40	40.4	39.9	40.2	40.2	0.4	0.1	0.2	0.2	
30	30.3	30.1	29.9	30.1	0.3	0.1	0.1	0.1	
20	20.3	20.6	20.2	20.4	0.3	0.6	0.2	0.4	
10	10.3	10.3	10.3	10.3	0.3	0.3	0.3	0.3	
0	0	0	0	0	0	0	0	0	
-10	9.9	10.3	10.1	10.1	0.1	0.3	0.1	0.2	
-20	20	20	20	20	0	0	0	0	
-30	30.3	30.1	30	30.1	0.3	0.1	0	0.1	
-40	40.1	40.3	40.2	40.2	0.1	0.3	0.2	0.2	
-50	50.3	50.2	50.4	50.3	0.3	0.2	0.4	0.3	
-60	60.5	60.2	60.4	60.4	0.5	0.2	0.4	0.4	
-70	71.6	70.5	70.8	70.1	1.6	0.5	0.8	0.1	
-80	80.8	81	81	80.9	0.8	1	1	0.9	
-90	91.8	91.3	90.7	91.2	1.8	1.3	0.7	1.2	
				Mean	0.5	0.5	0.4	0.5	
				Max	2	2.4	2.3	2.3	

Reference Angle °		Measured angle (degrees)				Error (degrees)			
	1^{st}	2nd	3 rd	Mean	1^{st}	2nd	3 rd	Mean	
120	58.7	58.2	58.4	58.4	61.3	61.8	61.6	61.6	
110	69.3	68.9	69	69	40.7	41.1	41	41	
100	78.7	78.9	78.6	78.7	21.3	21.1	21.4	21.3	
90	85.9	85.8	85.8	85.8	4.1	4.2	4.2	4.2	
80	79	79	79.2	79	1	1	0.8	1	
70	69.1	69.3	69.5	69.3	0.9	0.7	0.5	0.7	
60	59.1	59.4	59.1	59.2	0.9	0.6	0.9	0.8	
50	49.6	49.6	49.6	49.6	0.4	0.4	0.4	0.4	
40	39.6	39.7	39.6	39.6	0.4	0.3	0.4	0.4	
30	29.8	29.8	29.7	29.7	0.2	0.2	0.3	0.3	
20	19.8	19.5	19.6	19.6	0.2	0.5	0.4	0.4	
10	10.3	10	9.9	10	0.3	0	0.1	0.1	
0	0	0	0	0	0	0	0	0	
-10	9.8	10	10.1	10	0.2	0	0.1	0	
-20	19.7	19.6	19.8	19.7	0.3	0.4	0.2	0.2	
-30	29.6	29.7	29.7	29.7	0.4	0.3	0.3	0.3	
-40	39.8	39.8	39.5	39.7	0.2	0.2	0.5	0.2	
-50	50	50	49.8	49.9	0	0	0.2	0.1	
-60	59.3	59.5	59.6	59.5	0.7	0.5	0.4	0.5	
-70	69.8	69.8	69.7	69.7	0.2	0.2	0.3	0.3	
-80	79.8	79.8	79.7	79.8	0.2	0.2	0.3	0.2	
-90	89.7	89.8	89.8	89.8	0.3	0.2	0.2	0.2	
100	80.4	80.4	80.3	80.3	19.6	19.6	19.7	19.6	
110	69.9	70.4	70.1	70.1	40.1	39.6	19.9	39.7	
120	60.4	60.7	60.3	60.5	59.6	59.3	59.7	59.4	
				Mean					
				Max					

 Table 4. Rotation about Y axis, (Left-right axial rotation) segment 1.

Reference Angle °		Measured angle (degrees)				Error (degrees)			
	1^{st}	2nd	3 rd	Mean	1 st	2nd	3 rd	Mean	
120	59.3	58.9	59.1	59.1	60.7	61.1	60.9	60.9	
110	69.9	69.5	69.7	69.7	40.1	40.5	40.3	40.3	
100	79.1	79.3	79	79.1	20.9	20.7	21	20.9	
90	85.8	85.7	85.7	85.7	4.2	4.3	4.3	4.3	
80	78.9	79	79	79	1.1	1	1	1	
70	69.1	69.3	69.4	69.3	0.9	0.7	0.6	0.7	
60	59.1	59.5	59.1	59.3	0.9	0.5	0.9	0.7	
50	49.6	49.6	49.6	49.6	0.4	0.4	0.4	0.4	
40	39.6	39.7	39.6	39.6	0.4	0.3	0.4	0.4	
30	29.8	29.7	29.7	29.7	0.2	0.3	0.3	0.3	
20	19.8	19.5	19.6	19.6	0.2	0.5	0.4	0.4	
10	10.2	10	9.9	10.1	0.2	0	0.1	0.1	
0	0	0	0	0	0	0	0	0	
-10	9.8	10	-10.1	-9.9	0.2	0	0.1	0.1	
-20	19.6	19.6	-19.8	-19.7	0.4	0.4	0.2	0.3	
-30	29.6	29.7	-29.7	-29.7	0.4	0.3	0.3	0.3	
-40	39.7	39.8	-39.4	-39.6	0.3	0.2	0.6	0.4	
-50	49.9	49.9	-49.8	-49.9	0.1	0.1	0.2	0.1	
-60	59.8	59.5	-59.5	-59.4	0.2	0.5	0.5	0.6	
-70	69.7	69.7	-69.5	-69.6	0.3	0.3	0.5	0.4	
-80	79.6	79.6	-79.5	-79.5	0.4	0.4	0.5	0.5	
-90	87.6	87.4	-87.4	-87.5	2.4	2.6	2.6	2.5	
100	79.2	79.1	-79	-79.1	20.8	20.9	21	20.9	
110	68.8	69.3	-69	-69	41.2	40.7	41	41	
120	59.3	59.4	-59.3	-59	60.7	60.6	60.7	60.6	
				Mean					
				Max					

Table 5. Rotation about Y axis, (Left-right axial rotation) segment 2.

Appendix 4

Reference		Measu	red angle			Ε	rror	
Angle °		(de	grees)			(de	grees)	
	1 st	2nd	3 rd	Mean	1 st	2nd	3 rd	Mean
120	56.1	55.7	55.9	55.9	63.9	64.3	64.1	64.1
110	66.7	66.4	66.5	66.5	43.3	43.6	43.5	43.5
100	76.2	76.4	76.1	76.3	23.8	23.6	23.9	23.7
90	84.5	84.5	84.5	84.5	5.5	5.5	5.5	5.5
80	78.7	78.8	78.9	78.8	1.3	1.2	1.1	1.2
70	68.9	69.1	69.2	69	1.1	0.9	0.8	1
60	58.9	59.2	58.9	59	1.1	0.8	1.1	1
50	49.4	49.4	49.3	49.4	0.6	0.6	0.7	0.6
40	39.4	39.5	39.5	39.5	0.6	0.5	0.5	0.5
30	29.6	29.6	29.5	29.6	0.4	0.4	0.5	0.4
20	19.8	19.4	19.5	19.6	0.2	0.6	0.5	0.4
10	10.2	10	9.8	10	0.2	0	0.2	0
0	0	0	0	0	0	0	0	0
-10	-9.8	-10	-10.1	-9.9	-0.2	0	0.1	0.1
-20	-19.6	-19.6	-19.8	-19.7	-0.4	0.4	0.2	0.3
-30	-29.6	-29.7	-29.7	-29.7	-0.4	0.3	0.3	0.3
-40	-39.8	-39.8	-39.5	-39.7	-0.2	0.2	0.5	0.3
-50	-49.9	-50	-49.7	-49.9	-0.1	0	0.3	0.1
-60	-59.1	-59.4	-59.4	-59.3	-0.9	0.6	0.6	0.7
-70	-69.5	-69.5	-69.4	-69.5	-0.5	0.5	0.6	0.5
-80	-79.5	-79.5	-79.4	-79.5	-0.5	0.5	0.6	0.5
-90	-88.7	-88.6	-88.6	-88.7	-1.3	1.4	1.4	1.3
100	-83	-82.9	-82.8	-82.9	-17	17.1	17.2	17.1
110	-72.5	-73.1	-72.9	-72.8	-37.5	36.9	37.1	37.12
120	-63.1	-63.4	-63	-63.2	-56.9	56.6	57	56.8
				Mean				
				Max				

Table 6. Rotation about Y axis, (Left-right axial rotation) segment 3.

Reference		Measured angle				Error			
Angle °		(de	grees)		(degrees)				
	1 st	2nd	3 rd	Mean	1 st	2nd	3 rd	Mean	
90	88.9	88.6	88.8	88.8	1.1	1.4	1.2	1.2	
80	78.7	79	78.9	78.8	1.3	1	1.1	1.2	
70	68.9	68.9	68.6	68.8	1.1	1.1	1.4	1.2	
60	59.2	59.4	59.5	59.4	0.8	0.6	0.5	0.6	
50	50.7	49.8	49.6	50	0.7	0.2	0.4	0.4	
40	40	40	40	40		0	0	0	
30	29.9	29.8	30.1	30.2	0.1	0.2	0.1	0.2	
20	19.6	20.2	20	19.9	0.4	0.2	0	0.1	
10	9.9	9.9	10.3	10.	0.1	0.1	0.3	0.2	
0	0	0	0	0	0	0	0	0	
-10	-9.8	-9.4	-9.8	-9.6	0.2	0.6	0.2	0.4	
-20	-19.7	-19.6	-19.4	-19.5	0.3	0.4	0.6	0.5	
-30	-29.4	-29.6	-29.7	-29.6	0.6	0.34	0.3	0.4	
-40	-39.5	-39.4	-39.4	-39.5	0.5	0.6	0.6	0.5	
-50	-49.1	-49.8	-49.4	-49.4	0.9	0.2	0.6	0.6	
-60	-59.3	-58.9	-59.2	-59.2	0.7	1.1	0.8	0.8	
-70	-69.1	-69	-69.2	-69.1	0.9	1	0.8	0.9	
-80	-79	-79	-78.9	-79	1	1	1.1	1	
-90	-88.8	-89.4	-89.6	-89.2	1.2	0.6	0.4	0.8	
				Mean	0.6	0.6	0.6	0.6	
				Max	1.3	1.4	1.4	1.2	

Table 7. Rotation about Z axis, (Left-right lateral flexion) segment 1.

Reference Angle °		Measu (de	red angle grees)	0	Error (degrees)			
	1 st	2nd	3 rd	Mean	1 st	2nd	3 rd	Mean
90	89	88.8	89	89	1	1.2	1	1
80	78.8	79.1	79	79	1.2	0.9	1	1
70	68.9	68.9	68.7	68.8	1.1	1.1	1.3	1.2
60	59.2	59.3	59.4	59.3	0.8	0.7	0.6	0.7
50	50.6	49.8	49.6	50	0.6	0.2	0.4	0.4
40	40	40	40	40	0	0	0	0
30	29.9	29.8	30.1	30.1	0.1	0.2	0.1	0.3
20	19.6	20.2	20	20	0.4	0.2	0	0.2
10	9.9	9.9	10.2	10	0.1	0.2	0.2	0.2
0	0	0	0	0	0	0	0	0
-10	-9.7	-9.4	-9.7	-9.6	0.3	0.6	0.3	0.4
-20	-19.7	-19.6	-19.4	-19.5	0.3	0.4	0.6	0.5
-30	-29.4	-29.6	-29.7	-29.6	0.6	0.4	0.3	0.4
-40	-39.5	-39.4	-39.4	-39.5	0.5	0.6	0.6	0.5
-50	-49.2	-49.8	-49.4	-49.4	0.8	0.2	0.6	0.56
-60	-59.3	-59	-59.3	-59.2	0.7	1	0.7	0.8
-70	-69.1	-69.1	-69.3	-69.2	0.9	0.9	0.7	0.8
-80	-79.1	-79	-79	-79	0.9	1	1	1
-90	-88.9	-89.6	-89.7	-89.4	1.1	0.4	0.3	0.6
				Mean	0.6	0.5	0.5	0.5
				Max	1.2	1.2	1.3	1.2

Table 8. Rotation about Z axis, (Left-right lateral flexion) segment 2.

Table 9. Rotation about Z axis, (Left-right lateral flexion) segment 3.

Reference	Measured angle				Error			
Angle °		(de	grees)		(degrees)			
	1^{st}	2nd	3 rd	Mean	1 st	2nd	3 rd	Mean
90	90.1	89.7	89.9	89.9	0.1	0.3	0.1	0.1
80	79.8	80.3	80	80	0.2	0.3	0	0.2
70	69.6	70.1	69.1	69.6	0.4	0.1	0.9	0.5
60	59.8	59.9	60.3	60	0.2	0.1	0.3	0.2
50	51.4	51.1	50	50.8	1.4	1.1	0	0.8
40	40.5	40.6	40.7	40.6	0.5	0.6	0.7	0.6
30	30.4	30.2	31.1	30.6	0.4	0.2	1.1	0.6
20	19.9	19.6	20.6	20	0.1	0.4	0.6	0.4
10	9.5	10.3	10.9	10.2	0.5	0.3	0.9	0.6
0	0	0	0	0	0	0	0	0
-10	-10	-9.3	-9.56	-9.6	0	0.7	0.4	0.4
-20	-19.9	-19.7	-19.9	-19.8	0.1	0.3	0.1	0.2
-30	-30	-30.3	-30.4	-30.2	0	0.3	0.4	0.2
-40	-40.5	-40.4	-40.3	-40.4	0.4	0.4	0.3	0.4
-50	-50.4	-51	-50.6	-50.7	0.4	1	0.6	0.7
-60	-61	-60.7	-61	-60.9	1	0.7	1	0.9
-70	-71.3	-71.3	-71.5	-71.4	1.3	1.3	1.5	1.4
-80	-82.1	-82.1	-81.9	-82.	2.1	2.1	1.9	2
-90	-92.6	-93.4	-93.5	-93.2	2.6	3.4	3.5	3.2
				Mean	0.6	0.7	0.8	0.7
				Max	2.6	3.4	3.5	3.2

APPENDIX 5: RESEARCH & DEVELOPMENT APPROVAL

Acute Services Division

Coordinator/administrator: Emma Cuthbertson Telephone Number: 0141 211 8551 Fax Number: 0141 211 2811 E-Mail: <u>Emma.Cuthbertson@ggc.scot.nhs.uk</u>

23 March 2009

Professor Philip Rowe Head of HealthQuest University of Strathclyde Bioengineering Unit Wolfson Centre 106 Rottenrow Glasgow G4 0NW

NHS

Greater Glasgow and Clyde

R&D Management Office Western Infirmary Tennent Institute 1st Floor, 38 Church Street Glasgow, G11 6NT

R&D Management Approval

Dear Professor Rowe

Project Title: Under arm body weight unloading during treadmill walking for low back pain patients Chief Investigator: Professor Philip Rowe R&D Reference: PN08PY451 Professor patients of details wereign 6, deted 16th May 2009

Protocol no (including version and date): version 6, dated 16th May 2008

I am pleased to confirm that Greater Glasgow & Clyde Health Board is now able to grant Management Approval for the above study.

As a condition of this approval the following information is required during the lifespan of the project:

- SAES/SUSARS If the study is a **Clinical Trial** as defined by the Medicines for Human Use Clinical Trial Regulations, 2004 (CTIMP only)
- Recruitment Numbers on a quarterly basis (not required for commercial trials)
- Any change of Staff working on the project named on the ethics form
- Change of CI
- 5. Amendments Protocol/CRF etc
- 6. Notification of when the Trial / study has ended
- 7. Final Report
- 8. Copies of Publications & Abstracts

Please add this approval to your study file as this letter may be subject to audit and monitoring.

Yours sincerely

1.

2.

3.

Professor Chris Packard Director of Research and Development

cc Mr Konstantinos Kaliarntas, University of Strathclyde

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APPENDIX 6: NHS ETHICAL APPROVAL

Acute Services Division



Greater Glasgow and Clyde

West Glasgow Ethics Committee 1 Western Infirmary Dumbarton Road Glasgow G11 6NT

> Telephone: 0141-211-6238 Facsimile: 0141-211-1920

08 May 2008

Professor Philip J Rowe Head of HealthQuest "function for living" research programme University of Strathclyde Bioengineering Unit, Wolfson Centre 106 Rottenrow Glasgow G4 0NW

Dear Professor Rowe

Full title of study:

REC reference number:

Under-Arm Body Weight Unloading during treadmill walking for Low Back Pain Patients 08/S0703/53

The Research Ethics Committee reviewed the above application at the meeting held on 06 May 2008. Thank you for attending to discuss the study.

Ethical opinion

The Committee seek undernoted clarifications/amendments to both the study design and participant information sheet.

The Committee raised the following points and were assured by Prof Rowe that the Committee suggestions would be carried out.

a. Consent forms will be passed to physiotherapist to give out to potential participants b. The Committee asked that soft matting be placed at the sides and rear of the treadmill to prevent any injuries. Prof Rowe explained that the type of harness participants would be wearing this type of injury should not be an issue.

Study Design

a. Insurance policy has now lapsed. Copy of new insurance certificate required by the Committee

b. Question A39 The Committee are of the opinion that participants should contact the researchers

c.Questions A3 and A10 length of time for the study to be clarified

Patient Information Sheet

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a. Invitation letter Section 2 2nd paragraph typo should "our b. Delete all references to "analgesic" and insert "pain reliev c. Page 2 Section 2 typo should read "lie" not "lav"	r" not "out" ving"	
d. Page 3 Section 1 typo should read "weight"		
f. Delete all references to "extending your back" and insert f. Page 3 Section 2 paragraph 2 delete "We hope that " and g. Page 3 Section 2 paragraph 2 delete "we would remind on h. Page 3 Section 2 paragraph typo should read "complaint i. LBP Information sheet Section 1 4th sentence delete "this	"leaning bac l insert "Whet of your right" "	k" her or not" e"
The above amendments to come back to the Secretary for	checking and	filing
The members of the Committee present gave a favourable research on the basis described in the application form, pro documentation, subject to the conditions specified below.	ethical opinio tocol and sup	n of the above oporting
Ethical review of research sites		
The favourable opinion applies to the research sites listed o Confirmation of approval for other sites listed in the applicat local assessors have confirmed they have no objection.	on the attache ion will be iss	ed form. sued as soon as
Conditions of the favourable opinion		
The favourable opinion is subject to the following conditions the study.	being met p	rior to the start of
Management permission or approval must be obtained from the start of the study at the site concerned.	each host o	rganisation prior to
Management permission at NHS sites ("R&D approval") sho relevant care organisation(s) in accordance with NHS resea Guidance on applying for NHS permission is available in the Application System or at <u>http://www.rdforum.nhs.uk</u> .	ould be obtair rch governar Integrated F	ned from the nce arrangements. Research
Approved documents		
The documents reviewed and approved at the meeting were	e:	
Decument	Version	Date
Document	5.5	31 March 2008
Application		26 March 2008
Application Investigator CV	5	06 March 2008
Application Investigator CV Protocol	0	00 1101011 2000
Application Investigator CV Protocol Covering Letter		10 March 2008
Application Investigator CV Protocol Covering Letter Summary/Synopsis	2	10 March 2008 06 March 2008
Application Investigator CV Protocol Covering Letter Summary/Synopsis Compensation Arrangements	2	10 March 2008 06 March 2008 06 March 2008 02 August 2007
Application Investigator CV Protocol Covering Letter Summary/Synopsis Compensation Arrangements Questionnaire: non-validated scereening for healthy participants	2	10 March 2008 10 March 2008 06 March 2008 02 August 2007 06 March 2008
Application Investigator CV Protocol Covering Letter Summary/Synopsis Compensation Arrangements Questionnaire: non-validated screening for healthy participants Questionnaire: non-validated screening for LBP patients	2 2 2 2 2	10 March 2008 10 March 2008 06 March 2008 02 August 2007 06 March 2008 19 March 2008
Application Investigator CV Protocol Covering Letter Summary/Synopsis Compensation Arrangements Questionnaire: non-validated screeening for healthy participants Questionnaire: non-validated screening for LBP patients Questionnaire: validated Visual analogue scale	2 2 2	10 March 2008 10 March 2008 06 March 2008 02 August 2007 06 March 2008 19 March 2008 31 March 2008
Application Investigator CV Protocol Covering Letter Summary/Synopsis Compensation Arrangements Questionnaire: non-validated screening for healthy participants Questionnaire: validated Visual analogue scale Questionnaire: validated SF-12	2 2 2 2	10 March 2008 10 March 2008 06 March 2008 02 August 2007 06 March 2008 19 March 2008 31 March 2008 31 March 2008
Application Investigator CV Protocol Covering Letter Summary/Synopsis Compensation Arrangements Questionnaire: non-validated screening for healthy participants Questionnaire: validated Visual analogue scale Questionnaire: validated SF-12 Questionnaire: Oswestry disability Index	2 2 2 2 2	10 March 2008 10 March 2008 06 March 2008 02 August 2007 06 March 2008 19 March 2008 31 March 2008
Application Investigator CV Protocol Covering Letter Summary/Synopsis Compensation Arrangements Questionnaire: non-validated screening for healthy participants Questionnaire: non-validated screening for LBP patients Questionnaire: validated Visual analogue scale Questionnaire: validated SF-12 Questionnaire: Oswestry disability Index Advertisement	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	10 March 2008 10 March 2008 06 March 2008 02 August 2007 06 March 2008 19 March 2008 31 March 2008

Pag

50703/53

Participant Information Sheet: healthy participants	2	06 March 2008
Participant Information Sheet: LBP patients	2	06 March 2008
Participant Consent Form: healthy participants	2	06 March 2008
Participant Consent Form: LBP Patients	2	06 March 2008
CV for research student	2	31 March 2008
CV for PI Summary	2	31 March 2008
CV for PI Summary	2	11 March 2008
letter from sponsor		17 March 2008

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Website > After Review

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.

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

- Notifying substantial amendments
- 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.

1

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

08/S0703/53	Please quote this number on all correspondence

0703/53		Page 4
With the Committee's	best wishes for the success of this project	
Yours sincerely		
PP Andrea Torrie, Mana	YCMNUV ger - West Glasgow LREC's	
Email: andrea.torrie@	ggc.scot.nhs.uk	
Enclosures:	List of names and professions of members who were present at the meeting and those who submitted written comments "After ethical review – guidance for researchers" [SL-AR1 for CTIMPs, SL-AR2 for other studies] Site approval form (SF1)	
Copy to:	LLB Louise McKean	

Acute Services Division

Western Infirmary Dumbarton Road Glasgow G11 6NT



Telephone : 0141 211 6238 and Clyde Fax : 0141 211 1920

Date : 5th June 2008 Our Ref : AHT/SAJ Enquires to : Andrea Torrie Extension : As above Direct Line : As above

Email: andrea.torrie@ggc.scot.nhs.uk

Prof P J Rowe University of Strathclyde Bioengineering Unit Wolfson Centre 106 Rottenrow Glasgow G4 0NW

Dear Prof Rowe

Project : 08/S0703/53 Body Weight Unloading for patients with Low back Pain

I should like to acknowledge the content of letter dated 27^{th} May 2008 from you enclosing *a* copies of the amendments and amended documents required by the Committee at the meeting on 6^{th} May 2008 :-

1. Research protocol Version 6 16.05.08

2. Information Sheet for LBP Patients Version 3 16.05.08

3. Invitation Letter Version 3 16.05.08

These will be held on file

Yours sincerely,

Andre & Some

Andrea Torrie, Manager West Glasgow LRECs

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APPENDIX 7: *RECRUITMENT QUESTIONNAIRE, INFORMATION SHEET AND CONSENT FORM FOR LBP PATIENTS.*

Study title	Under-Arm Body Weight Unloading during treadmill walking for Low Back Pain patients	
Principle	Prof. Philip Rowe, Tel: 0141 548 3032, e-mail: philip.rowe@strath.ac.uk	
Investigator	Bioengineering Unit, University of Strathclyde, 106 Rottenrow, Glasgow, G4 0NW, Scotland, United Kingdom	
Secondary Investigators	Mr Konstantinos Kaliarntas PT, MSc Tel: 07783008813, e-mail: <u>konstantinos.kaliarntas@strath.ac.uk</u> Dr Philip Riches, Tel: 0141 548 5703, e-mail: <u>Philip.riches@strath.ac.uk</u> Dr. Ukadike Chris Ugbolue, Tel: 01415483228, e-mail: <u>u.c.ugbolue@strath.ac.uk</u> Bioengineering Unit, University of Strathclyde, 106 Rottenrow, Glasgow, G4 0NW. Scotland. United Kingdom	

Participant Number:

Name:	Phone:	
Address:	E-mail:	

(ring the answer that applies and strike through the one that does not)		
Are you between 30-65 years old?	YES	NO
Do you suffer from Low Back Pain LBP the last 3 to 6 months?	YES	NO
Do you have a history of (LBP)?	YES	NO
Do you have scoliosis, Kyphosis or Lordosis (a spinal curvature)?	YES	NO
Do you have any diagnosed heart condition?	YES	NO
Do you have High or Low blood pressure?	YES	NO
Do you have Angina?	YES	NO
Have you had a heart attack?	YES	NO
Do you have any of the following symptoms: Sciatica, numbness and hypersensitivity of the skin in your legs, tingling and weakness of the leg muscles?	YES	NO
Do you have any neurological problems? e.g. Multiple Sclerosis	YES	NO
Do you have any diagnosed muscular pathologies?	YES	NO
Have you been diagnosed with Rheumatoid Arthritis?	YES	NO
Do you have any dermatitis or skin condition?	YES	NO
Do you suffer from any skin allergies?	YES	NO
Apart from your LBP, do you have any pain anywhere else at the moment?	YES	NO
Have you had a recent (within last year) injury to your spine, legs or feet (e.g. fractures) which cause you pain or movement restriction?	YES	NO
Apart from your LBP, are you generally fit and well?	YES	NO

If you have answered "yes" to any of the questions apart from first, second and the last questions, you will be asked for detailed explanation and you might be excluded from this research.

Participant's signature: Inves	stigators' signature:
Participants Name (Block Letters):	Investigators' Name (Block Letters):
Date:	Date:
Screening Questionnaire for LBP Participan	nts 15/09/2009 – Version 3



Bioengineering Unit, University of Strathclyde

PARTICIPANT INFORMATION SHEET (LBP Patients)

Study title	Under-Arm Body Weight Unloading during treadmill walking for Low Back Pain patients	
Principle Investigator	Prof. Philip Rowe, Tel: 0141 548 3032, e-mail: <u>philip.rowe@strath.ac.uk</u> Bicengineering Unit, University of Strathclyde, 106 Rottenrow, Glasgow, G4 0NW, Scotland, United Kingdom	
Secondary Investigators	Mr Konstanti nos Kaliarntas PT, MSc Tel: 07783008813, e-mail: konstantinos.kaliarntas@strath.ac.uk Dr Philip Riches, Tel: 0141 548 5703, e-mail: Philip.riches@strath.ac.uk Dr. Ukadike Chris Ugbolue, Tel: 01415483228, e-mail: u.c.ugbolue@strath.ac.uk Bicengineering Unit, University of Strathclyde, 106 Rottenrow, Glasgow, G4 0NW, Scotland, United Kingdom	

What is the research for?

We would like to invite you to take part in a research study that has been approved by the Glasgow West Research Ethics Committee. This study is being conducted as part fulfilment of a PhD thesis. Before you decide if you wish to participate, we would like you to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. If you have any questions regarding the study please ask at any time. You can talk to others about the study if you wish. The present study will investigate if supported treadmill walking using an under arm support system to help lift you up provides a more mobile spine and pain relief to people suffering from Low Back Pain (LBP). You are eligible to participate in this study because you were referred to a primary care clinic with LBP and you have the characteristics we are interested to study. In total 32 people with LBP and 32 people without LBP will take part in this study. Participation in this study is voluntary. We will describe the study and go through this information sheet, which we will then give to you. We will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. This will not affect the relationship between you and the university research team or the standard nature of care you receive from the NHS.

What will happen?

The proposed study will take place in the Biomechanics 1 Laboratory, in Bioengineering Unit of the University of Strathclyde. A University car will take you to and from the Bioengineering Unit or should you prefer it you can make your own way there by car or public transport and we will reimburse your travel costs. You will be asked to attend the laboratory twice within 10 days. Each test session will last 90 minutes. This study has been designed to investigate the pain relieving effects of supported walking (Body Weight Unloading, BWU) and also to compare the spinal characteristics of LBP patients with healthy people. BWU is a technique with which a percentage of your body weight is supported via a harness which passes under your arms. On your arrival in the laboratory you will be asked to lie down on a plinth for 30 minutes. While waiting on the plinth you will be given two assessment forms to fill out, this won't take more than 15 minutes. The remaining time you can discuss anything you want with the research team or read a magazine. Thereafter, in one of the two sessions, you will be asked to walk for 30 minutes on a treadmill with BWU and at other session just to walk on the treadmill for 30 minutes.

Information Sheet For LBP Patients 15/09/2009 - Version 4

Page 1

order of walking on the treadmill with and without BWU will be random. A system of infrared cameras and an electromagnetic motion tracking system will be used to record your spinal motion while walking and standing, along with a digital camera incorporated in the infrared cameras system.

What do I need to do?

If you decide to participate in this study, you will be asked to bring your own trainers and to wear shorts which we will provide. While walking on the treadmill we would like you to be topless in order to record your spinal motion. To do this we will attach using double sided medical grade sticky tape some small light weight reflective markers. This will be attached along your spine, at your shoulders and pelvis, and over the sole of your shoes. These reflective markers can be seen by the infrared cameras which follows them and this is how your spinal motion is recorded while you walk. Also, we will attach three small light weight sensors of to your skin, again with hypoallergenic tape and a source to your pelvis using an elasticated strap. These sensors will record the movement occurring in you spine as you walk. Before the walking session and after it we will assess your spinal motion using these sensors while you do 6 everyday movement's e.g. bending forward, leaning back etc. During the walking task you will be asked to stop every five minutes for a few seconds so that we can measure your standing posture. You will also be asked to report your pain status by ticking a line on some specially designed forms. The walking speed will be determined by you and it will be your normal walking speed. You should report any discomfort or change in your pain status and you can withdraw at any time if you feel any discomfort or without having any reason. The treatment you receive for your back pain will remain the same before the first session, between the two sessions and after the second session,

Are there any dangers?

The dangers with this study are thought to be minor. As with all activity there is a slight risk of falling. However, this is minimal because you will not asked to do something over your abilities and also a member of the research team will be close to you at all times. Additionally, it is possible that you may have an itching sensation over the areas where we will attach the markers but there is less likely because we will use hypoallergenic tape in order to avoid this effect and this has not been a problem in our previous studies. Discomfort or pain increase during walking is a possibility, for this reason a researcher will be in close proximity at all times to discuss what you are feeling and consider the continuation of treadmill walking. In order to ensure and maximise your safety throughout the study, an emergency phone line will be available and a trained person to provide first aid will be in the building at all the times. All researchers will have undertaken suitable training to ensure the protocol used is safely administered. Insurance cover is in place from the University of Strathclyde which is the sponsor of this research. The information we get from your participation in this study may help advance the intervention given to future patients. However, a single session of BWU treadmill walking is unlikely to cause any lasting benefit to you.

Whether or not you consent to participate in the study you should know that the participation is completely voluntary and you can withdraw at any time during the experiment without giving a reason. Your relationship with the university research team and the NHS will not be affected. All aspects of the study will remain confidential within the research group and all data will be anonymous in any reports. In case you wish to make any complaint about the way you have been approached or treated in the course of research, you can contact Ms Louise McKean, a representative of the University of Strathclyde, on 0141548 4364. For further information on the study please feel free to contact the research team using the contact details provided in the box above (page 1).

Thank you

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Participant Number				
Bioengineering Unit, University of Strathclyde				
INFORMED CONSENT SHEET				
Study title	Under-Arm Body Weight Unloading during treadmill			
	walking for Low Back Pain patients			
Principle	Prof. Philip Rowe, Tel: 0141 548 3032, e-mail: philip.rowe@strath.ac.uk			
Investigator	Bicengineering Unit, University of Strathclyde, 106 Rottenrow,			
ganos	Glasgow, G4 0NW, Scotland, United Kingdom			
Secondary	Mr Konstantinos Kaliarntas PT, MSc tel: 07783008813.			
Investigators	e-mail: konstantinos kaliamtas@strath.ac.uk			
investigators	Dr Philip Riches tel: 0141 548 5703 e-mail:			
	Philip riches@strath as uk			
	Dr Ukadike Chris Ugbolne tel: 01415483228 e-mail:			
	in a usbalue (detroth as uk			
	Discrete Lie Lie Lie of Southland 106 Better			
Bicengineering Unit, University of Strathclyde, 106 Rottenrow, Glasgow, G4 0NW, Scotland, United Kingdom				

To be completed by the participant:

Please circle "yes" or "no" to each of the following sentences:

1. I have read and understood the information sheet/letter explaining this study	Yes	No			
I have had the opportunity to ask questions and discuss this study	Yes	No			
3. I have received satisfactory answers to all my questions	Yes	No			
4. I have received enough information about this study	Yes	No			
5. I understand that I can ask any further questions I may have at any time during the study (if I decide to participate)	Yes	No			
6. I understand that my participation in this study is entirely voluntary and that I may withdraw from the study at any time, without giving any reason, should I choose to do so	Yes	No			
7. I understand that if I do decide to withdraw from the study that this will not affect my future relationship with Strathclyde University or the research team nor will it effect any treatment I may be receiving or may be offered from the NHS.	Yes	No			
8. I understand that information may be collected about me by the investigators, and that the results of the study may be published, but that my identity will be protected at all times					
I agree to my GP being informed of my participation in the study	Yes	No			
I agree to my spinal motion be recorded with a digital camera.	Yes	No			
11. I hereby freely consent to take part in this study	Yes	No			
Signed:					
Researcher's signature:Name in Block Letters:	Researcher's signature:Name in Block Letters:				
Date:					

Consent Form for LBP Participants 15/09/2009 - Version 3

APPENDIX 8: RECRUITMENT QUESTIONNAIRE, INFORMATION SHEET &CONSENT FORM FOR HEALTHY VOLUNTEERS

Study title	Under-Arm Body Weight Unloading during treadmill walking for Low				
Distal	Back Pain patients Prof. Philip Rowe, Tel: 0141 548 3032, e-mail: philip rowe@strath.ac.uk				
Investigator	Pior, Philip Kowe, Ter: 0141 54	Bioengineering Unit, University of Strathclyde, 106 Rottenrow, Glasgow,			
investigator	G4 0NW, Scotland, United Kin	gdom	row, Giasgow,		
Secondary Investigators	Mr Konstantinos Kaliarntas PT,	MSc Tel: 07783008813,			
	e-mail: konstantinos.kaliarntas@strath.ac.uk				
	Dr Philip Riches, Tel: 0141 548 5703, e-mail: Philip.riches@strath.ac.uk				
	Dr. Ukadike Chris Ugbolue, T-b 01415482228 a maile a sa	the loss of the second			
	Bioengineering Unit University	of Strathchyde 106 Rotten	row Glasgow		
	G4 0NW, Scotland, United Kin	gdom	row, Glasgow,		
			Particinant Nur	ober:	
Name:		Phone:	unicipalit i tui		
		E 11			
Address:		E-mair:			
PAR	TICIPANT RECRUITMENT QUES	TIONS (healthy participan	ts)		
(ring the answer that a	pplies and strike through the or	e that does not)			
Are you between 30-65 y	ears old?		YES	NO	
Do you have a history of	Low Back Pain (LBP)?		YES	NO	
Do you have scoliosis, Ky	phosis or Lordosis (a spinal curv	ature)?	YES	NO	
Do you have any diagnos	ed heart condition?		YES	NO	
Do you have High or Low blood pressure?		YES	NO		
Do you have Angina?			YES	NO	
Have you had a heart atta	ck?		YES	NO	
Do you have any neurolo	gical problems? e.g. Multiple Scl	erosis	YES	NO	
Do you have any diagnos	ed muscular pathologies?		YES	NO	
Have you been diagnosed	with Rheumatoid Arthritis?		YES	NO	
Do you have any dermati	tis or skin condition?		YES	NO	
Do you suffer from any s	kin allergies?		YES	NO	
Do you have any pain any	where at the moment?		YES	NO	
Have you had a recent (w fractures) which cause yo	ithin last year) injury to your spin u pain or movement restriction?	ne, legs or feet (e.g.	YES	NO	
Are you generally fit and	well?		YES	NO	
rite you generally in and	won .		110	110	
f you have answered "ye isked for detailed explanat	s" to any of the questions apart i ion and you might be excluded fi	from first and the last qu rom this research.	estions, you v	vill be	
arucipan s signature:	mvesuga	ora signaure:			
Participants Name (Block	Letters):In	vestigators' Name (Block	Letters):		
Date:		Date:	•••••		

Study title	Bioengineering Unit, University of Strathclyde Bioengineering Unit, University of Strathclyde PARTICIPANT INFORMATION SHEET (Healthy Volunteers)
Study tine	Back Pain patients
Principle	Prof. Philip Rowe, Tel: 0141 548 3032, e-mail: philip.rowe@strath.ac.uk
Investigator	Bicengineering Unit, University of Strathclyde, 106 Rottenrow, Glasgow, G4 0NW, Scotland, United Kingdom
Secondary Investigators	Mr Konstantinos Kaliarntas PT, MSc Tel: 07783008813, e-mail: <u>konstantinos.kaliarntas@strath.ac.uk</u> Dr Philip Riches, Tel: 0141 548 5703, e-mail: <u>Philip.riches@strath.ac.uk</u> Dr. Ukadike Chris Ugbolue, Tel: 01415483228, e-mail: <u>u.c.ugbolue@strath.ac.uk</u> Bicengineering Unit, University of Strathclyde, 106 Rottenrow, Glasgow, G4 0NW, Scotland, United Kingdom

What is the research for?

We would like to invite you to take part in a research study that has been approved by the Glasgow West Research Ethics Committee. This study is being conducted as part fulfilment of a PhD thesis. Before you decide if you wish to participate, we would like you to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. If you have any questions regarding the study please ask at any time. You can talk to others about the study if you wish.

The present study will investigate if supported treadmill walking using an under arm support system to help lift you up provides a more mobile spine and pain relief to people suffering from Low Back Pain (LBP). In total 32 people with LBP and 32 people without LBP will take part in this study. We understand that you are considering participating in the study as a health volunteer who does not have back pain. By comparing you to those with LBP we will be able to identify how LBP affects the spine during walking.

Participation in this study is voluntary. We will describe the study and go through this information sheet, which we will then give to you. We will then ask you to sign a consent form to show you have agreed to take part. Once you agreed to participate, you are free to withdraw at any time without giving a reason. This will not affect the relationship between you and the university research team.

What will happen?

The proposed study will take place in the Biomechanics 1 Laboratory, in Bioengineering Unit of the University of Strathclyde. A University car will take you to and from the Bioengineering Unit or should you prefer it you can make your own way there by car or public transport and we will reimburse your travel costs. You will be asked to attend the laboratory twice within 10 days. Each test session will last 90 minutes. This study has been designed to investigate the analgesic effects of supported walking (Body Weight Unloading, BWU) and also to compare the spinal characteristics of LBP patients with healthy people. BWU is a technique with which a percentage of your body weight is supported via a harness which passes under your arms. On your arrival in the laboratory you will be asked to lay down on a plinth for 30 minutes. While waiting on the plinth you will be given two assessment forms to fill out, this won't take

Information Sheet for Healthy Participants 15/09/2009 - Version 3

Page 1

more than 15 minutes. The remaining time you can discuss anything you want with the research team or read a magazine. Thereafter, in one of the two sessions, you will be asked to walk for 30 minutes on a treadmill with BWU and at other session just to walk on the treadmill for 30 minutes. The order of walking on the treadmill with and without BWU will be random. A system of infrared cameras and an electromagnetic motion tracking system will be used to record your spinal motion while walking and standing, along with a digital camera incorporated in the infrared cameras system.

What do I need to do?

If you decide to participate in this study, you will be asked to bring your own trainers and to wear shorts which we will provide. While walking on the treadmill we would like you to be topless in order to record your spinal motion. To do this we will attach using double sided medical grade sticky tape some small light weight reflective markers. This will be attached along your spine, at your shoulders and pelvis, and over the sole of your shoes. These reflective markers can be seen by the infrared cameras which follows them and this is how your spinal motion is recorded while you walk. Also, we will attach three small light weight sensors of to your skin, again with hypoallergenic tape and a source to your pelvis using an elasticated strap. These sensors will record the movement occurring in you spine as you walk. Before the walking session and after it we will assess your spinal motion using these sensors while you do 6 everyday movement's e.g. bending forward, extending your back etc. During the walking task you will be asked to stop every five minutes for a few seconds so that we can measure your standing posture. You will also be asked to report your pain status by ticking a line on some specially designed forms. The walking speed will be determined by you and it will be your normal walking speed. You should report any discomfort or change in your pain status and you can withdraw at any time if you feel any discomfort or without having any reason.

Are there any dangers?

The dangers with this study are thought to be minor. As with all activity there is a slight risk of falling. However, this is minimal because you will not asked to do something over your abilities and also a member of the research team will be close to you at all times. Additionally, it is possible that you may have an itching sensation over the areas where we will attach the markers but this is less likely because we will use hypoallergenic tape in order to avoid this effect and this has not been a problem in our previous studies. Discomfort or pain increase during walking is a possibility, for this reason a researcher will be in close proximity at all times to discuss what you are feeling and consider the continuation of treadmill walking. In order to ensure and maximise your safety throughout the study, an emergency phone line will be available and a trained person to provide first aid will be in the building at all the times. All researchers will have undertaken suitable training to ensure the protocol used is safely administered. Insurance cover is in place from the University of Strathclyde which is the sponsor of this research. The information we get from your participation in this study may help advance the intervention given to future patients.

We hope that you consent to participate in the study, and we would remind you of your right to withdraw at any time during the experiment without giving a reason. Your relationship with the university research team will not be affected. All aspects of the study will remain confidential within the research group and all data will be anonymous in any reports. In case you wish to make any complain about the way you have been approached or treated in the course of research, you can contact Ms Louise McKean, a representative of the University of Strathclyde, on 0141548 4364. For further information on the study please feel free to contact the research team using the contact details provided in the box above (page 1).

Thank you

Information Sheet for Healthy Participants 15/09/2009 - Version 3

Page 2

	Participant Number		
	Bioengineering Unit, University of Strathclyde		
	INFORMED CONSENT SHEET		
Study title Under-Arm Body Weight Unloading during treadmill walking for Low Back Pain patients			
Principle Investigator	Prof. Philip Rowe, Tel: 0141 548 3032, e-mail: <u>philip.rowe@strath.ac.uk</u> Bicengineering Unit, University of Strathclyde, 106 Rottenrow, Glasgow, G4 0NW, Scotland, United Kingdom		
Se condary Investigators	Mr Konstantinos Kaliarntas PT, MSc tel: 07783008813, e-mail: <u>konstantinos.kaliarntas@strath.ac.uk</u> Dr Philip Riches, tel: 0141 548 5703, e-mail: <u>Philip.riches@strath.ac.uk</u> Dr. Ukadike Chris Ugbolue, tel: 01415483228, e-mail: <u>u.c.ugbolue@strath.ac.uk</u> Bicengineering Unit, University of Strathclyde, 106 Rottenrow, Glasgow, G4 0NW, Scotland, United Kingdom		

To be completed by the participant:

Please circle "yes" or "no" to each of the following sentences:

1. I have read and understood the information sheet/letter explaining this study	Yes	No
2. I have had the opportunity to ask questions and discuss this study	Yes	No
3. I have received satisfactory answers to all my questions	Yes	No
4. I have received enough information about this study	Yes	No
5. I understand that I can ask any further questions I may have at any time during the study (if I decide to participate)	Yes	No
6. I understand that my participation in this study is entirely voluntary and that I may withdraw from the study at any time, without giving any reason, should I choose to do so		No
 I understand that if I do decide to withdraw from the study that this will not affect my future relationship with Strathchyde University or the research team. 	Yes	No
8. I understand that information may be collected about me by the investigators, and that the results of the study may be published, but that my identity will be protected at all times		No
9. I agree to my spinal motion be recorded with a digital camera.	Yes	No
10. I hereby freely consent to take part in this study	Yes	No

Signed:..... Name in Block Letters:.....

Date:....

I confirm that I have explained the nature of the study to the above named person and have given them opportunity to ask me any questions they may have regarding this research.

Date:....

Consent Form for Healthy Participants 15/09/2009 - Version 3

APPENDIX 9: OSWESTRY DISABILITY INDEX

Oswestry Disability Questionnaire

Could you please complete this questionnaire? It is designed to give us information as to how back or (leg) trouble has affected your ability to manage in everyday life. Please answer every section. Mark one box only in each section that most closely describes you today.

Section1: Pain intensity

- I have no pain at the moment
- The pain is very mild at the moment
- The pain is moderate at the moment
 The pain is fairly severe at the moment
- The pain is very sever at the moment
- The pain is the worst imaginable at the moment

Personal care: (washing, dressing, etc.)

- I can look after myself normally without causing extra pain.
 I can look after myself normally but it is very painful.
 It is painful to look after myself and I am slow and careful.

- I need some help but manage most of my personal care.
- I need help every day in most aspects of self care.
 I do not get dressed, wash with difficulty and stay in bed.

Section 3: Lifting

- I can lift heavy weights without extra pain.
- □ I can lift heavy weights but it gives extra pain. □ Pain prevents me from lifting heavy weights off the floor but I can manage if they are conveniently positioned, e.g. on a table.
- Pain prevents me from lifting heavy weights but I can manage light to medium weights if they are conveniently positioned.
- I can lift only very light weights.
- I cannot lift or carry anything at all.

Section 4 - Walking

- Pain does not prevent me walking any distance.
- Pain prevents me walking more than one mile.
- Pain prevents me walking more than a quarter of a mile.
- Pain prevents me walking more than 100 yards.
- I can only walk using a stick or crutches.
- I am in bed most of the time and have to crawl to the toilet.

Section 5 - Sitting

- I can sit in any chair as long as I like.
- I can sit in my favourite chair as long as I like.
- Pain prevents me from sitting for more than 1 hour.
 Pain prevents me from sitting for more than half an hour.
- Pain prevents me from sitting for more than 10 minutes.
- Pain prevents me from sitting at all.

Section 6: Standing

- I can stand as long as I want without extra pain.
- I can stand as long as I want but it gives me extra pain.
 Pain prevents me from standing for more than 1 hour.
 Pain prevents me from standing for more than half an
- hour.
- Pain prevents me from standing for more than 10 minutes
- Pain prevents me from standing at all.

Section 7 - Sleeping

- My sleep is never disturbed by pain.
- My sleep is occasionally disturbed by pain.
- Because of pain I have less than 6 hours sleep.
- Because of pain I have less than 4 hours sleep.
- Because of pain I have less than 2 hours sleep. Pain prevents me from sleeping at all.
- Section 8 Sex life (if applicable)
- □ My sex life is normal and causes no extra pain.
- My sex life is normal but causes some extra pain.
- My sex life is nearly normal but is very painful.
- My sex life is severely restricted by pain.
 My sex life is nearly absent because of pain.
- Pain prevents any sex life at all.

Section 9 - Social life

- My social life is normal and causes me no extra pain.
- My social life is normal but increases the degree of pain.
 Pain has no significant effect on my social life apart from
- limiting my more energetic interests, e.g. sport, etc. Pain has restricted my social life and I do not go out as ofton
- Pain has restricted social life to my home.
- I have no social life because of pain.

Section 10 - Travelling

- I can travel anywhere without pain.
- I can travel anywhere but it gives extra pain.

- Pain is bad but I manage journeys over two hours.
 Pain restricts me to journeys of less than one hour.
 Pain restricts me to short necessary journeys under 30 minutes.
- Pain prevents me from travelling except to receive treatment.

ODI Version 2,0 (Fairbank & Pynsent 2000)

Score: / x 100 = %

Scoring: For each section the total possible score is 5: if the first statement is marked the section score = 0, if the last statement is marked it = 5. If all ten sections are completed the score is calculated as follows: Example: $\frac{16}{100}$ (total scored)

50 (total possible score) x 100 = 32%

If one section is missed or not applicable the score is calculated: <u>16</u> (total scored)

 $\overline{45}$ (total possible score) x 100 = 35.5%

Minimum Detectable Change (90% confidence): 10%points (Change of less than this may be attributable to error in the measurement)

Source: Fairbank JCT & Pynsent, PB (2000) The Oswestry Disability Index. *Spine*, 25(22):2940-2953. Davidson M & Keating J (2001) A comparison of five low back disability questionnaires: reliability and responsiveness. Physical Therapy 2002;82:8-24.

*Note: Distances of 1mile, ½ mile and 100 yards have been replaced by metric distances in the Walking section.

ODI Scoring:

- **0% to 20% (minimal disability)**: Patients can cope with most activities of daily living. No treatment may be indicated except for suggestions on lifting, posture, physical fitness and diet. Patients with sedentary occupations (ex. secretaries) may experience more problems than others.
- 21%-40% (moderate disability): Patients may experience more pain and problems with sitting, lifting and standing. Travel and social life are more difficult. Patients may be off work. Personal care, sleeping and sexual activity may not be grossly affected. Conservative treatment may be sufficient.
- **41%-60%** (severe disability): Pain is a primary problem for these patients, but they may also be experiencing significant problems in travel, personal care, social life, sexual activity and sleep. A detailed evaluation is appropriate.
- **61%-80%** (**crippled**): Back pain has an impact on all aspects of daily living and work. Active treatment is required.
- **81%-100%:** These patients may be bed bound or exaggerating their symptoms. Careful evaluation is recommended.
APPENDIX 10: SF-12_{V2} HEALTHY SURVEY









7. During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or</u> <u>emotional problems</u> interfered with your social activities (like visiting with friends, relatives, etc.)?



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APPENDIX 11: *INDIVIDUAL CHARACTERISTICS & SPINAL EXCURSIONS*

Patient ID	Age	Height	Mass	BMI	SF12	SF12	ODI	Pain duration	Cause	Working status	
	_	(cm)	(kg)		(PCS)	(MCS)		(weeks)			
1	50	171	87	30	39	32	20	9	Injury	Bakery worker	
2	41	174	81	27	40	42	30	7	Injury	Office worker	
3	39.4	181	70	21	41	34	30	12	Injury	Army	
4	44.7	167	56	20	38	44	24	12	Injury	Technician	
5	51.5	172	78	26	44	46	38	24	C/R*	Businessman	
6	47	174	71	23	48	55	6	24	C/R	Salesman	
7	41.3	174	80	26	35	58	14	8	Injury	Builder	
8	50.7	180	99	30	41	46	20	3	Injury	Office worker	
9	46.2	185	90	26	37	58	26	8	Injury	Farmer	
10	44.6	176	111	36	41	49	24	24	Injury	Technician	
11	60	171	61	21	50	59	6	8	Injury	Office worker	
12	48	167	89	32	21	55	46	24	Injury	Plumber/teacher	
13	59	171	65	22	40	63	18	24	C/R	Pensioner	
14	40.9	169	88	31	36	64	4	6	C/R	Truck driver	
15	59.5	174	72	24	52	34	12	24	C/R	Painter	
16	31.4	183	93	28	55	54	4	24	C/R	Software engineer	
17	58	168	79	28	40	63	32	8	Injury	S/market worker	
18	26	176	81	26	29	42	22	20	C/R	Office worker	
19	57	166	79	29	35	28	36	6	C/R	Factory worker	

*Cannot recall

Patient ID	Age	Height (cm)	Mass (kg)	L	umbar Excurs	ion	Т	Frunk Excursion	Total Spine excursions		
			(U)	Sagittal	Coronal	Transverse	Sagittal	Coronal	Transverse	Sagittal	Coronal
				C			0			0	
1	50	171	87	53.36648	26.81357	7.810546	77.63912	101.7608	64.40842	91.31687	116.7646
2	41	174	81	44.37304	23.2596	10.41196	75.984	79.51759	61.02735	101.5627	95.50718
3	39.4	181	70	64.45823	29.22729	13.61699	96.03817	76.13483	73.98068	123.6546	115.6627
4	44.7	167	56	32.71716	35.00675	9.808045	84.21394	81.13289	55.12731	124.1162	123.8668
5	51.5	172	78	48.07253	20.77216	17.17993	82.40691	95.34326	96.34601	137.5994	122.16
6	47	174	71	65.11168	30.41987	4.587152	84.12379	84.16325	72.77032	90.89145	133.9867
7	41.3	174	80	48.93334	34.75262	9.92873	66.95653	73.66369	71.69095	96.31094	128.5673
8	50.7	180	99	49.53689	29.22673	23.67969	98.14124	89.46326	84.01779	119.9188	134.0356
9	46.2	185	90	39.26231	25.34944	23.56159	92.188	84.17216	85.29206	121.9377	121.2563
10	44.6	176	111	36.95133	27.32971	27.5777	77.14116	95.00906	112.6759	111.8948	147.0507
11	60	171	61	62.25283	40.65504	13.49686	92.89631	107.0663	97.46809	159.8779	160.1005
12	48	167	89	37.18306	20.85394	20.44245	67.91224	72.58996	71.13683	105.1242	94.56351
13	59	171	65	70.31919	32.73616	10.69197	106.0694	92.0497	72.01175	128.3949	125.1367
14	40.9	169	88	61.25699	29.62011	14.48177	89.2505	73.76604	57.0394	119.8858	96.961
15	59.5	174	72	57.27201	27.38226	25.10191	74.43501	78.65576	98.49222	133.4341	126.5816
16	31.4	183	93	80.93384	41.53781	12.91289	101.2675	105.3378	84.38313	131.0373	117.6256
17	58	168	79	25.03147	24.94112	14.01386	42.35419	61.51996	54.95781	89.69412	80.87095
18	26	176	81	39.03778	27.99735	14.19407	50.46962	71.85902	70.96109	82.15713	112.8003
19	57	166	79	41.02746	25.21993	11.43784	45.05532	72.15824	60.02657	67.76688	80.89069

Healthy	Healthy Age		Mass	Lumbar Excursion				Trunk Excursio	Total Spine Excursions		
ID		(cm)	(kg)	Sagittal	Coronal	Transverse	Sagittal	Coronal	Transverse	Sagittal	Coronal
1	34	1.81	75	63.91817	41.64104	16.29542	79.46557	96.2272	76.97473	151.564	160.4028
2	39	1.79	83	85.19828	47.65218	21.40754	100.0465	85.76871	81.43506	146.9077	169.0792
3	38.6	1.75	74	71.11429	36.61511	13.12208	110.3353	89.75847	87.19275	177.2841	135.6033
4	32.6	1.76	84	72.32407	40.33353	9.963063	91.04792	103.6543	55.38689	136.9654	181.951
5	29.1	1.75	79	85.25336	48.82457	12.24823	113.4323	100.5134	87.40324	184.7556	177.1833
6	39	1.72	65	63.59431	40.27367	9.498991	106.7518	93.06212	70.46091	170.835	148.5107
7	29.5	1.75	80	69.633	32.86084	11.02374	102.6836	87.51241	103.0313	149.6507	153.3869
8	33	1.81	90	44.48193	22.63294	10.97345	92.27597	84.56929	83.71769	141.0949	127.9603
9	30.6	1.76	63	63.31336	39.90205	11.45123	91.2246	84.20903	75.26563	185.6431	142.7852
10	31.5	1.71	66	54.30076	44.54598	10.85266	90.2388	102.8097	71.01267	156.7403	161.0278
11	33	1.73	72	53.96807	27.64098	13.58578	108.0213	99.10208	87.32097	160.822	158.7088
12	32.6	1.81	72.5	71.10349	43.29607	13.52674	93.46953	109.3775	66.67086	113.5642	148.2229
13	50	1.72	66	77.9541	41.48583	10.03718	116.9668	95.14321	86.48934	144.0239	129.6093
14	38.5	1.87	79	62.64533	39.52999	11.65283	101.0081	103.9104	88.84299	143.0502	143.4333
15	44.5	1.91	115	58.6589	19.91443	24.22559	80.35983	83.48312	87.31334	124.9929	157.2038
16	34	1.9	79	84.87761	46.13254	26.445	100.6905	95.8956	90.71234	116.7099	140.2594
17	45	1.82	77	68.08219	39.75386	23.31358	90.56551	91.14332	80.58414	123.4936	111.7944
18	60	1.69	77	33.01504	33.24175	11.907	80.28635	76.84969	78.84101	86.64475	98.85154
19	46.5	1.86	76	52.57004	28.33006	15.94667	107.0192	79.14299	57.44132	138.8201	155.0441
20	40	1.78	78	59.85315	27.19968	15.08308	92.28513	77.30653	86.42879	114.4912	129.9531
21	30	1.79	78	73.9236	44.52782	17.87634	104.9444	92.39993	85.53954	167.0146	161.4808

 Table 3. Healthy Volunteers biometric characteristics and spinal excursions.

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APPENDIX 12: SPINAL LENGTH & MEASUREMENT ACCURACY



Figure 1. Accuracy of length calculation technique, tested on a rigid body under the same experimental conditions used for the estimation of the human spinal length.



Figure 2. Spinal length of LBP patients and healthy individuals during supported walking (mean± standard error).



Figure 3. Spinal length of LBP patients and healthy individuals during control walking (mean± standard error).

APPENDIX 13: RAW DYNAMIC SPINAL LENGTH CHANGE DATA

The figures of the raw dynamic spine data presented in the same order as they appear in the results chapter (5.6.1).

LBP Patients [Lumbar Segment baseline measurement]





LBP Patients [Lumbar Segment, measurement at 30th minute]





LBP Patients [Thoracic Segment, baseline measurement]





LBP Patients [Thoracic Segment, measurement at 30th minute]





Healthy Participants [Lumbar Segment, baseline measurement]





Healthy Participants [Lumbar Segment, measurement at 30th minute]





Healthy Participants [Thoracic Segment, baseline measurement]



Healthy Participants [Thoracic Segment, measurement at 30th minute]

