

A Reliability Study of a New Back Strain Monitor Based on Clinical Trials

A thesis submitted in fulfillment of the requirements for the degree of
Doctor of Philosophy

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Declaration

I certify that except where due acknowledgement has been made, the work is that of the author alone; the work has not been submitted previously, in whole or in part, to qualify for any other academic award; the content of the thesis is the result of work which has been carried out since the official commencement date of the approved research program; and, any editorial work, paid or unpaid, carried out by a third party is acknowledged.

Andrew James Ronchi

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Abstract

Movements of the lower back are a contributing factor for developing low back pain. Various techniques have been developed and tested for the measurement of lower back movement but most have been too expensive, too cumbersome and have been unable to measure movements over a prolonged period. The thesis investigates the development, the reliability and the validity of a new device (the Back Strain Monitor) to be used to measure lower back movement during a day's activity.

After a review of potential devices, three transducers to measure back movement were selected for laboratory testing. The first transducer, the conductive silicone polymer, performed poorly displaying an electrical drift as the polymer underwent repeated stretching. The second, the inductive coil technique, performed well in the laboratory trials with a CV of 0.54% for maximum linear stretch measurements. However, issues relating to electrical drift and electrical lag led to large variation of the baseline readings (CV = 82%). The third transducer, the accelerometer method, performed very well during the laboratory trials displaying a CV of 0.12% for the range of movement.

Two of the three sensors (the inductive coil and the accelerometer method) were developed to the level of stand-alone prototypes, capable of being tested within a clinical trial setting. The first clinical trial involved three testers applying the inductive coil prototype to 15 subjects to assess its measurement properties. The inductive coil performed with moderate inter tester reliability (ICC (2,1) = 0.65). There was limited evidence of validity for the inductive coil technique as it showed poor to average correlation with the three comparator techniques (ICC (2,1) values from 0.47 to 0.75).

The second clinical trial applied the accelerometer method to 23 subjects with three testers. There was very good inter tester reliability ($ICC(2,1) \geq 0.86$) and test re-test reliability ($ICC(2,1) \geq 0.89$). The accelerometer method also displayed a high level of agreement ($ICC(2,1) \geq 0.88$) with the main recognized comparator technique (the double inclinometer) providing evidence of criterion validity.

The accelerometer method provided a reliable option for measuring movements of the lower back. There was evidence of criterion validity and a preliminary case study demonstrated that the movement data collected over 8 hours was able to alter back postures via biofeedback. The accelerometer method displays advantages over other methods in that there is the potential to measure three dimensional movement at a high sampling rate and for extended periods of time. The device may provide a new management tool to assist health practitioners in the treatment of low back pain.

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Acronyms and Abbreviations

AccM	Accelerometer Method
ADL	Activity of Daily Living
AHP	Allied Health Practitioners
ANOVA	Analysis of Variance
ATB	Accelerometer Transducer Boards
BEACH	Bettering the Evaluation and Care of Health
BMI	Body Mass Index
BMS	Between Subject Mean Squared Result
BSM	Back Strain Monitor
CPU	Central Processing Unit
CSP	Conductive Silicone Polymer
CT	Computerised Tomography
DI	Double Inclinometer
EMG	Electro-Myographic Activity
EMI	Electro-Magnetic Interference
EMS	Error Mean Squared
EPC	Enhanced Primary Care
FRP	Flexion-Relaxation Phenomenon
GPs	General Practitioners
IC	Inductive Coil
ICC	Interclass Correlation Coefficient
iMEMS	Integrated Micro Electro-Mechanical System
ITR	Inter-tester Reliability
IVD	Intervertebral Disc
JMS	Mean Squared Result for Judges

L1	First Lumbar Vertebrae
L5S1	Lumbo-Sacral Junction
LBA	Lower Back Activity
LBD	Lower back disorders
LBP	Low Back Pain
LBT	Low Back Trouble
LMM	Lumbar Motion Monitor
MD	Measuring Device (of the BSM)
MDE	Measuring Device for Electrical Muscle Activity
MDM	Measuring Device for Movement
MEMS	Micro Electro-Mechanical System
MHT	Manual Handling Tasks
MMS	Modified-Modified Schober
MRI	Magnetic Resonance Imaging
MVA	Motor Vehicle Accident
NIOSH	National Institute for Occupational Safety and Health
NOHSC	National Occupational Health and Safety Commission
NSAI	Non Steroidal Anti-Inflammatory
NSLBP	Non Specific Low Back Pain
OH&S	Occupational Health and Safety
PCB	Printed Circuit Board
PP	Patient Profile
PSIS	Posterior Superior Iliac Spine
PS	Psycho-Social
RCT	Randomised Controlled Trial
RFD	Recording Feedback Device
ROM	Range of Movement

R&VT	Reliability and Validity Trial
RWL	Recommended Weight Limit
S1	First Sacral Spinous Process
SEM	Standard Error of Measurement
sEMG	Surface Electro-Myographic Activity
SLBP	Specific Low Back Pain
T12/L1	Thoraco-Lumbar Junction
TAC	Transport Accident Commission
THP	Treating Health Practitioner
TRTR	Test Re-Test Reliability
VAS	Visual Analogue Scale
VWA	Victorian Workcover Authority
WBV	Whole Body Vibration
WT	Wand Technique

Glossary of Terms

B Tracker – is a device that measures the angular changes between the spine and the pelvis, via a triaxial goniometer (see Figure 3.2). A harness is worn around the thorax and another around the pelvis (level of the belt line), to anchor the device to the lower and upper measurement regions.

Central Processing Unit (CPU) – a computer chip with the power to receive, analyse and control the workings and functions of the PCB.

Controlled setting – for this study is defined as an indoor setting, where all subject movements are performed with feet in a stationary position and there are minimal external influences from the environment. (ie. minimal EMI, no wind, minimal noise, minimal electrical interference and minimal distractions).

Dimples of Venus – dimples at either side of the lower aspect of the lumbar spine, at the level of the PSIS. These represent the vertebral level of the lumbo-sacral junction.

Hysteresis – the term relates to when a tissue or substance is placed under physical or mechanical tension such that the tissue is stretched to beyond its limit and when the load or tension is released, the tissue may retract but not to its original length or state.

Irritability – a physiotherapy and medical term that describes how sensitive or irritable a person's condition is. For example, a highly irritable condition may be easily aggravated by one or two movements that would normally not cause pain but due to the level of irritability, the patient may experience a significant increase in pain from a relatively minor activity.

Lumbar Motion Monitor – This monitoring device for the lower back was developed by Dr. William Marras. The device is an exo-skeleton which is worn on the back, from the thoracic spine to the lumbar spine (see Figure 3.1). The device has been validated to give reliable measurements of lumbar spine movement in three dimensions.

Mechanical Pain – From a physiotherapy perspective, the word *mechanical* relates to pain or symptoms that arise from a particular movement or action and follow a somewhat definable pattern. In contrast, *Inflammatory* pain and symptoms do not necessarily follow an action or movement and often do not follow a pattern that relates to activity.

Non Specific Low Back Pain (NSLBP) – this phrase relates to LBP that can not be definitively linked to a known cause or event and in such cases it is difficult to achieve a specific diagnosis based on pathology.

Patient Profile – a rating system that is being developed to score or rate individual characteristics of a person, based on the likelihood of those characteristics contributing to LBP. The score from multiple characteristics are combined via a risk algorithm to rate a person's probability of developing LBP. This process has not been validated and is discussed only as a concept during this thesis.

Posterior Superior Iliac Spine (PSIS) – a bony landmark at the base of the lumbar spine, used to identify the level of S1. The PSIS is a bony prominence on the most medial aspect of the ilium, close to the superior margin of the sacro iliac joint (see Figure 7.6, Line A)

Specific Low Back Pain (SLBP) – relates to LBP with an identified and specific diagnosis. SLBP may be a disc prolapse noted on MRI scan or a spondylolithesis diagnosed via CT scan. SLBP is well defined and often has an objective measure supporting the diagnosis.

Publication and Presentation

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Chapter 1. Introduction

1.1 Problem statement

Lower back disorders (LBD) in occupational settings have been considered the most significant musculoskeletal disorder in both cost and prevalence (Fathallah, Marras et al. 1998; Kerr 2001). Low back pain (LBP) affects 60-80% of people during their lifetime (Riihimaki 1991) and is the major cause of disability for people under the age of 45 years (Magnusson, Bishop et al. 1998). The cost of LBP in Australia is estimated to be \$9.17 billion dollars per year (Walker 2003) and \$100-200 billion per year in the United States (Katz 2006), accounting for up to 50% of direct compensation costs (Kerr 2001). With such significant disability and costs associated with LBP, health practitioners have a difficult job managing this condition. There are limited treatment choices available for the management of LBP, with general practitioners relying on medication, advice and the occasional referral to other health practitioners. There appears to be no readily available tool to aid health practitioners or workers, in returning patients safely to the work force.

The challenge in dealing with the causes of LBP is that they are multi-factorial and complex (Morlock, Bonin et al. 2000). There is evidence that postures and movements performed by the lumbar spine contribute to lower back injuries (Riihimaki 1991; Adams and Dolan 1995; Fathallah, Marras et al. 1998; Hoogendoorn, Bongers et al. 2000), as do the loads placed on the spine (Burton, Tillotson et al. 1996; Fathallah, Marras et al. 1998; Hoogendoorn, Bongers et al. 2000). It has been proposed that to measure these complex loads within a normal work setting is most important (Cholewicki, Crisco lii et al. 1996).

A measurement of the lower back movements with a high degree of reliability and validity presents itself as a very difficult task. The human spine moves in a three dimensional space, often combining movements from different planes. Different body types, significant

variations in normal ranges of movement for different people and small ranges of movement in some planes of movement provide additional challenges for any measuring instrument.

There are numerous techniques available for measuring movements of the lower back. Many of these techniques are either very basic and lack validity or they are labour intensive and time consuming to perform. Other options are quite complex and cumbersome and they are not easy for the health practitioners to apply.

Many studies present methods for estimation of loads and forces acting on the lower back but these studies are usually conducted in laboratory settings. Limited options are available to measure movement in real time, for prolonged periods and with the potential to estimate loads acting on the lumbar spine.

1.2 Thesis aim

The aim of this thesis is to first introduce a new device (Back Strain Monitor) for measuring and analyzing movements of the lower back and second to determine the reliability and validity of the device via clinical trials.

1.3 Thesis contribution

The thesis provides the following major contributions:

1. A new device for measuring the three-dimensional movements of the lumbar spine called the Back Strain Monitor (BSM) is introduced.
2. Development stages of the BSM are presented including laboratory experiments testing different concepts and options which lead to the final prototype of the device.
3. During the development process of the BSM, a number of different options for measuring and analyzing lower back movement were examined and tested in

laboratory conditions. Two viable measurement options, the Inductive Coil technique and the Accelerometer method, were identified and tested in laboratory settings and clinical trials.

4. Analysis of the results provided by clinical trials indicates that the accelerometer method provided a high level of reliability and evidence of validity.

1.4 Major conclusions

Based on the results of laboratory test and clinical experiments, it was concluded that the accelerometer method represents a reliable and valid option as a method for measuring lower back movements. The accelerometer method showed a high degree of reliability in both a laboratory setting and within a controlled clinical setting. It can be concluded that the accelerometer method provides a better option for the measurement and analysis of lower back movements than other methods reviewed in this study.

1.5 Thesis outline

The thesis is organized in the following way:

Chapter 2 discusses low back pain (LBP) and the complexities associated with diagnosing a specific type of LBP. Who is affected by LBP and how frequently does it occur? What is the financial impact of LBP on society and on industry and importantly, what are the risk factors associated with developing LBP?

Chapter 3 discusses multiple techniques for capturing and measuring the lower back movement. The advantages and drawbacks of each method are presented. Following this, the management of LBP is discussed. The varied roles of the doctor, allied health practitioners, the patient, the government and the insurance companies is reviewed in the context of this challenging and costly condition. The current management of back pain is

varied from profession to profession, with a recent study suggesting that there is little consensus among 'clinicians' when identifying subgroups within the category of non-specific low back pain (NSLBP; (Kent and Keating 2005).

A new concept of a back strain monitor (BSM) is introduced in Chapter 4. The development stages of the essential requirements of the BSM are described in detail. Seven different measurement techniques are evaluated and the three strongest candidates are identified and prototypes for each are produced. A conductive silicone transducer, an inductive coil sensor and a technique using accelerometers are tested within a laboratory setting. The review of the different methods considered for the movement sensor helps to understand the development process leading to the current version of the BSM device.

Chapter 5 describes the construction and functionality of the current version of the BSM device. The focus of the chapter is on the accelerometers although the gyroscope, EMG sensors and the Recording Feedback Device (RFD) are also briefly described. Possible formats for the output data are presented. There is also a brief description of further developments of the BSM, which include the Patient Profile and the Numerical Algorithm that will process the sensor's data and calculate an overall risk score for the low back pain.

Chapter 6 describes the design of the experiments that tested the reliability and validity of the inductive coil technique for measuring lower back movement in a clinical setting. Three testers were involved in the trial that reviewed the inter-tester reliability of the inductive coil technique in conjunction with three well recognised methods for measuring lower back movement. Fifteen subjects wore the inductive coil and performed basic lumbar spine movements in a controlled setting. The results from the inductive coil measuring technique were compared to the results from the other three methods, to assess the validity of the inductive coil technique.

Chapter 7 describes the design of the trials that tested the reliability and validity of the Accelerometer method (AccM) for measuring lower back movement in a clinical setting. Three testers were involved in the trial that reviewed the inter-tester reliability (ITR) and the test re-test reliability (TRTR) of the accelerometer method in conjunction with two methods for measuring lower back movement. Twenty-three subjects wore the accelerometer method transducer and performed basic lumbar spine movements in a controlled setting. Twenty-two of the twenty-three subjects repeated the trial with one of the testers, five weeks later, to test the TRTR of the method. The results from the accelerometer method were compared to the results from the double inclinometer technique, to assess the validity of the accelerometer method.

Chapter 8 provides an overview of the thesis. The extent of the LBP problem is summarized with a suggestion that current management for LBP is inadequate. The importance of posture and awareness of movement patterns is reinforced, as is how biofeedback may be able to guide patients on movement patterns to efficiently recover from LBP. The different transducer options for measuring lower back movement are briefly discussed with justification presented as to why two prototypes were developed to a clinical trial stage. The clinical trials for the inductive coil and the accelerometer method are reviewed and the results are used to plan for future development for the BSM concept.

Appendix I contains a full list of risk factors for the low back pain identified during the literature review discussed in Chapter 2. Appendix II shows the full protocol for the inductive coil trial described in Chapter 6, and Appendix III contains full protocol for the Accelerometer trial described in Chapter 7.

Chapter 2. Epidemiology and risk factors for low back pain

This chapter discusses low back pain (LBP). What is LBP and what are the complexities associated with diagnosing a specific type of LBP. Who does it affect, how frequently does it occur, what is the cost and what are the risk factors associated with developing LBP?

2.1 Introduction

Low back pain continues to be a common, costly and disabling condition. Low back pain (LBP) affects between 60% and 80% of the population during their lifetime (Riihimaki 1991; Magnusson, Bishop et al. 1998) and is the most frequent cause of activity limitation in the US and Australia for people under the age of 45 years (Bigos, Bowyer et al. 1994). Back pain occurs in every nationality, gender and age group. Twelve months post lower back injury, between 62% and 72% of patients still have back pain and 16% have not been able to return to work (Henschke, Maher et al. 2008; Kent and Keating 2008). The direct and indirect cost of low back pain in Australia in 2001 was AUD\$9.17 billion (Walker 2003) and as high as USD\$100–200 billion US p.a. in 2005 (Katz 2006). Once a lower back injury has occurred, the recurrence rate is 60% within the first 12 months (Kent and Keating 2008) whilst treatment costs have increased 131% in New South Wales over the past 10 years (Richards 2003). It has been suggested that LBP is so common within human cultures that we may not ever be able to prevent LBP (Frank, Brooker et al. 1996). The epidemiology of LBP covers a number of categories and will be discussed under the following headings:

- What is LBP and what are the difficulties associated with diagnosing LBP?
- What is the frequency and the duration of LBP?
- What is the cost of LBP?
- Who is affected by LBP?
- What are the risk factors for low back pain?

An electronic search was conducted using the following databases: Proquest, Medline and CINAHL, up until August 2008. The search terms for articles related to the epidemiology of low back pain included Low Back Pain “OR” LBP “OR” Lumbar “AND” epidemiology “OR” cost “OR” incidence. More than 230 articles were found between the three databases with over half of these being peer reviewed articles. Priority was given to the more recent peer reviewed articles.

2.2 The difficulty with diagnosing low back pain

Low back pain is often non-specific in nature and it can be difficult to achieve an accurate diagnosis of the cause. Certainly there are many cases of acute disc prolapse causing neural compression that may require surgery. These cases are usually well diagnosed, with a definite intervention to reduce pressure on neural tissues. A fracture in the lower back region may also be well diagnosed and defined through a detailed subjective history and imaging via X-ray, computed tomography (CT) scan or magnetic resonance imaging (MRI). These cases, where a specific pathological diagnosis can be made, have been recently classified in the literature as specific low back pain (SLBP). Specific low back pain accounts for approximately 20% of LBP in primary care (Kent and Keating 2008).

The remaining 80% of LBP falls within the category of non-specific low back pain (NSLBP) (Dillingham 1995; O’Sullivan 2000; Woolf and Pfleger 2003; Kent and Keating 2008). This type of LBP cannot be definitively linked to a known cause or event and in such cases it is difficult to achieve a specific diagnosis based on pathology. Studies have shown there is little correlation between medical imaging results and the level of pain experienced by a patient (Kent and Keating 2004; Ahmed and Modic 2007). For example there are often imaging findings in asymptomatic patients, reducing the confidence in imaging as a stand-alone diagnostic tool (Kent and Keating 2004). Whilst imaging techniques have vastly improved in clarity and are often important in the SLBP cases, imaging is often of little

benefit in NSLBP (Woolf and Henshall 2000). It has been concluded that there is no physical benefit gained via an X-ray of the lumbar spine and there is only a slight psychological benefit (Woolf and Henshall 2000).

The opinion of general practitioners is that X-rays of the lower back are of minor benefit and rarely helpful (Lovett 2003). The decision to prescribe an X-ray was often to satisfy an inquisitive patient more than provide a diagnosis for the LBP. This suggests that the patient is often seeking further information about their LBP and the imaging provides a form of visual feedback and comfort that there is no sinister pathology causing their LBP.

Recent literature suggests that the patterns observed in the behaviour of patients experiencing pain may be more informative than diagnostic imaging in classifying people with LBP (Kent and Keating 2004). A journal paper from the same authors (Kent and Keating 2004) surveyed 200 clinicians from different health care professions (physiotherapy, chiropractic, general practice and osteopaths). Five patho-anatomical subgroups for LBP were defined. The five subgroups included facet joint syndrome, contained disc lesion, instability, sacroiliac joint pain and postural pain (Kent and Keating 2005). These subgroups did not give a definitive diagnosis but indicated that there are subgroups of LBP sufferers who experience similar symptoms, pain patterns and movement disorders. For example, a patient suffering from a contained disc lesion may be aggravated by sitting for long periods or repeated bending forward (Maitland 1987; Carr 1989; Pynt, Higgs et al. 2001). This mechanical pain behaviour is defined by cause and effect, meaning that the patient's symptoms are aggravated by specific movements or postures.

The phrase 'mechanical pain' behaviour relates to pain or discomfort caused by the positions and postures adopted during activities of daily living (ADLs). Bogduk and Twomey defined mechanical LBP as the pathological conditions that involve only minor structural

abnormalities (Bogduk and Twomey 1987). Maitland *et al.* described functional movements of the spine that can demonstrate the disability or disorder that is contributing to LBP (Maitland, Brewerton *et al.* 1986). Mechanical pain has also been described as pain associated with movement (Lewis, Hewitt *et al.* 2005). If mechanical pain is associated with positions of the spine, measurement of the lower back movements are important for understanding LBP. The analysis of the movement patterns cannot only help to understand the causes and mechanisms of the LBP, but also allows the option of providing a warning, and corrective biofeedback information to the patient.

The concept of performing certain movements to prevent LBP or assist in the recovery of LBP is not new, but few studies have shown significant effect. Prone extension exercises have been studied to assess whether that type of exercise has a preventative role for LBP (Larsen, Weidick *et al.* 2002). The 10 month study followed 249 military recruits in a prospective randomised controlled trial. The intervention group performed passive lumbar extension exercises on a daily basis whereas the control group had no intervention. The results showed significantly fewer recruits reported LBP in the prone extension group (33%) compared to the control group (51%). There were also fewer visits to the military doctor for the intervention group (9% versus 25%).

A study by Magnusson (2008) reviewed the efficacy of postural biofeedback in facilitating chronic LBP sufferers to improve their movement patterns and improve functional ability (Magnusson 2008). The study involved 47 subjects and compared normal physiotherapy treatment (as the control group) with an intervention group receiving postural biofeedback and physiotherapy. The biofeedback was provided in three forms (visual, auditory and report based) and aimed to facilitate movement patterns that had been avoided due to chronic learned pain behaviour. Fifteen-minute training sessions were performed twice a week over a 5-week intervention period. Outcome measures (visual analogue scale, short

form 36 and range of movement) were performed before and after the training session, 6 weeks after the program and 6 months after the program. The paper reported good treatment effect for chronic LBP participants receiving postural biofeedback.

In another paper (Snook, Webster et al. 1998), the effect of controlling lumbar spine flexion during the morning hours was assessed to determine whether there was an effect on chronic NSLBP. The 18-month random controlled trial (RCT) followed 85 subjects with persistent or recurring LBP. The intervention involved instruction on how to avoid early morning lumbar flexion whereas the control group were given sham exercises to perform. Significant reductions in pain, disability, impairment and medication usage were observed.

The above three studies demonstrated that movement patterns have an effect on the development of temporary or ongoing LBP. The first study (Larsen, Weidick et al. 2002) looked at a preventative model aimed at reducing the onset of LBP, the second study (Magnusson 2008) used a facilitative model aimed at encouraging movements into positions that had been avoided, and the third study (Snook, Webster et al. 1998) used a restrictive based model aimed at avoiding certain postures associated with higher risk of LBP. All three studies showed an impact on LBP through adjusting movement parameters for the subjects.

In general the effects of movement patterns on LBP are poorly understood. The difficulty of understanding is increased by the lack of measuring tools for lower back movements in real time and in real life settings.

Possibly the emphasis in management of LBP should identify the movement disorders and pain provoking activities and guide the patient to optimise their recovery. This may be performed via facilitating movement patterns that have been avoided due to pain or by

protective biofeedback that avoids the more provocative positions which may increase the risk of developing LBP. In order to manage these complex decisions, we must first be able to reliably and validly measure and quantify movement patterns of the lumbar spine and record these over extended periods of time.

Whether the pain is coming from a sprained iliolumbar ligament or disc lesion may be less relevant than guiding the patient to move into positions and postures that will increase their rate of recovery, optimise their potential for normal movement patterns and reduce the chance of recurrence.

There is some consensus as to which movement patterns increase the risk of LBP (Marras *et al.* 1993; Hoogendoorn, Bongers *et al.* 2000; Mazloun *et al.* 2006; Bio *et al.* 2007) and these factors are explored later in this chapter. In order to manage LBP more effectively it may be more helpful to have less emphasis on diagnosis and more emphasis on learning optimal movement patterns, and to put steps in place to guide people to move within safe limits.

In order to provide instantaneous postural biofeedback, we first need to measure movements accurately. Ideally this would be able to be done within a real life setting. Second, there needs to be professional acceptance as to which movement patterns are desirable and which are provocative for the different subgroups of NSLBP. Third, a protocol is needed to guide different workers in different industries as to what are safe limits of movement. This protocol has already partially been formed through the NIOSH lifting equation (Waters and Putz-Anderson 1998) and other such instruments used to guide workers. The issue with these strategies is that they are complex and poorly understood by the average worker and clinician. The implementation of these systems is expensive, time consuming and complex.

The aim of this thesis is to assess a device that may be capable of measuring movements of the lower back. If these measurements are shown to be reliable and valid, the device would be able to analyse the movement data in real time and provide biofeedback to the wearer as to which movement patterns are to be avoided or facilitated. The biofeedback decisions and feedback options are not within the scope of this thesis. The emphasis of this thesis is to develop a reliable and valid measuring tool for movements of the lower back.

2.3 The frequency and duration of low back pain

The frequency of LBP is most often reported using one of the following measures: a point prevalence percentage, LBP within a 12-month period or the lifetime frequency of LBP. At an international level, LBP has very similar occurrences across many developed countries.

Low back pain is a prevalent condition observed in many countries. In the US it has been reported that 28% of the population have disabling LBP during their lifetime and 8% of the entire work force will be disabled by LBP in any given year (Manchikanti 2000). The yearly prevalence of LBP in the US is stated at between 15% and 20% whereas in Europe, the figure is 25–40% (van der Beek and Frings-Dresen 1998). In Sweden, the point prevalence for LBP is 15–30% of the population with the lifetime prevalence of between 60% and 70% (Ekman, Johnell et al. 2005). In Australia the point prevalence of LBP was estimated by Walker (2003) to be 25.5% (Walker 2003) with a 12-month prevalence of 67.6% and a lifetime prevalence of 79.2%. In the Netherlands the point prevalence of LBP is between 3% and 44% with a lifetime prevalence of 58-84% (Woolf and Pfleger 2003). Woolf and Pfleger also reported that a new episode of LBP is twice as likely if the patient has a history of LBP. From an international perspective, LBP continues to be a common and disabling condition having similar frequency distribution across different nations and time periods.

A significant proportion of LBP episodes are of short duration and resolve with minimal intervention. It is stated that 80–90% of LBP will resolve within six weeks (Manchikanti 2000) and that 44.3% of people suffering from LBP will seek professional help (Walker, Muller et al. 2004). Whilst there is often a rapid improvement in lumbar spine symptoms for many patients, 12 months following the onset of LBP, 62% will still experience pain and 16% of those patients initially off work due to LBP will continue to be off work (Kent and Keating 2005). Once LBP is experienced, chronic or persistent LBP has been reported as affecting 5-10% of people (Shekelle, Martin Markovich et al. 1995) whereas other authors suggest this figure is as high as 28% (Miedema, Chorus et al. 1998). In Australia, one in ten adults have experienced LBP to a level requiring time away from normal occupational duties and the mean time away from normal activities is suggested to be 1.6 months (Walker 2003). In 13.4% of 3000 Australian subjects questioned, LBP lasted for 6 months and 37.7% confirmed they had experienced LBP on most days over a two week period (Walker, Muller et al. 2004).

Another approach to reviewing the duration of LBP is to assess the number of days of absence per patient per year. A 1992 report found that LBP resulted in nine days off work per patient per year in the US where as the problem was more significant in other countries. There were an average of 10 days per year in West Germany, 20 days per year in Canada, 25 days in the Netherlands, 30 days in Great Britain and 40 days in Sweden (Nachemson 1992).

Although 80–90% of people with LBP have symptoms that resolve within 6 weeks, the high recurrence rate of LBP causes the real disability and cost for this condition. Unfortunately, symptoms often recur with acute flare ups affecting 20–44% of patients in the first 12 months and up to 85% during their lifetime (Woolf and Pfleger 2003). Other authors suggest the 12-month recurrence rate to be as high as 60% (Kent and Keating 2005). The

recurrent episodes increase the chance of the lower back symptoms becoming chronic, not allowing the patient to return to their normal occupational and recreational activities (Manchikanti 2000).

2.4 The cost of low back pain

The total cost of LBP includes the direct costs and indirect costs. The direct costs are the diagnostic, treatment, medication or intervention costs associated with managing and treating LBP. The indirect costs are less tangible and more difficult to quantify. They include the cost of days off work, staff replacement, staff training and compensation payments.

Low back pain is the most significant occupational health issue contributing to 20-30% of compensation claims and up to 50% of compensation costs (Kerr 2001). In the US the direct costs associated with LBP in 1990 were calculated to be \$24.3 billion (Frymoyer and Cats-Baril 1991) whilst the total costs of LBP have been reported as high as \$100–200 billion (Katz 2006). In the Netherlands in 1991, the direct costs of LBP were estimated to be \$367 million with the indirect costs being \$4.6 billion (van Tulder, Koes et al. 1995) showing the total cost for LBP in the Netherlands as being close to \$5 billion p.a. In Germany, the direct costs associated with LBP in 1994 were DM 10 billion and the indirect costs were DM 24 billion, equating to a total figure of DM 34 billion (Bolten, Kempel-Waibel et al. 1998). In the UK the direct costs associated with LBP were calculated to be GBP 1.6 billion with the indirect costs as high as GBP 10.7 billion (Maniadakis and Gray 2000). The overall cost of LBP in Sweden is stated as being Euro 1.86 billion in 2001 with direct costs accounting for Euro 308 million and indirect costs Euro 1.55 billion (Ekman, Johnell et al. 2005). Other reports have suggested even higher figures for LBP in Sweden of Euro 3.2 billion Euro (SBU-Report 1991).

In Australia, LBP is reported to cost AUD 9.17 billion per year with AUD 1.02 billion related to direct costs and AUD 8.15 billion related to indirect costs (Walker 2003). The direct treatment costs associated with treating low back pain in Australia are presented in Table 2.1. The statistics indicate AUD 835 million is spent on healthcare providers, whilst AUD 92 million is spent on public hospitals and AUD 85 million on private hospitals. There is AUD 67 million spent on imaging and AUD 0.5 million spent on pathology. There is an adjustment made for double counting of selected health providers, with the total direct costs being AUD 1.02 billion.

Low back pain continues to pose a significant financial problem for many of the most technologically advanced countries in the world. The rate of lower back injury, the costs incurred and the recurrence rate are not well controlled. The rate of increase in lumbar spine fusions within the UK has risen 77% between 1996 and 2001. In the same five-year period, hip replacement and knee arthroscopy increased only 13-14% (Deyo, Nachemson et al. 2004).

The Australian federal government has shown significant concern in regard to the increasing number of people on the disability support pension, mostly due to musculoskeletal back pain. The former Federal Treasurer Peter Costello recently said, "We have seen a fairly significant increase in people on disability pensions. We have now got around 700,000 people on disability support pension. And the most common cause is musculoskeletal pain, back pain. Now, it is hard to think that there are so many more disabled people with bad backs in our society today than there were say 10 years ago or 20 years ago. But we have seen this real increase Ray, this very, very substantial increase in people that are disabled" (Hadley 2005).

Table 2-1 Low back pain (LBP) management costs for individual healthcare providers in Australia, 2001 (Walker 2003)

Cost Description or service	Proportion with low back pain (%)	Cost per visit (AUD)	Total Cost of LBP (in AUD millions)
Chiropractor	19.6	32.81	182.932
Physiotherapist	13.4	36.90	131.512
General Practitioner	22.4	28.75	117.602
Masseur	14.8	30.00	109.350
Prescription Drugs	13.3	10.00	66.285
Medical Specialist	4.7	67.75	51.219
Accupuncture	3.7	27.86	45.885
Osteopathy	2.7	49.40	35.346
Over the counter drugs	9.5	10.90	26.928
Other Providers	3.2	30.00	15.390
Psychologist	1.1	83.47	15,100
Naturopath	2.6	43.20	14.580
Occupational Therapist	0.7	49.80	14.118
Social Worker	0.5	50.00	5.535
Private Nursing Care	0.6	24.00	2.333
Dietetics	0.4	47.40	1.343
Total			835

These costs and trends indicate that the current interventions for managing LBP are not effective enough.

2.5 Who is affected by low back pain?

The incidence of LBP is partially age dependent, with the greatest injury occurrence between 35 and 45 years old for occupational related LBP (Manchikanti 2000; (VWA 2004)Figure 2.1). It has been postulated that this may be due to the fact that slightly degenerative discs within the lumbar spine are at the highest risk of prolapse in subjects aged between 40 and 50 years (Adams and Hutton 1982) but the site or region of the structure causing the LBP is not the focus of this thesis.

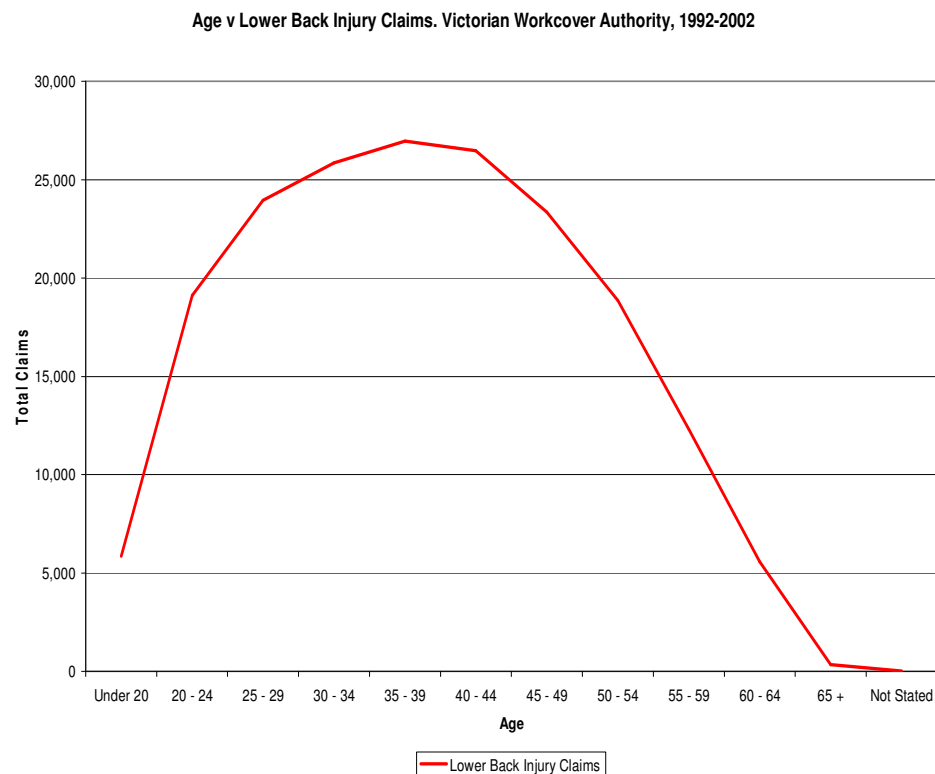


Figure 2.1 Age versus incidence for lumbar spine injuries (VWA 2004)

In the Netherlands, the highest incidence of LBP is seen in patients between the ages of 25 and 64 years (Woolf and Pfleger 2003) and in Australia the mean age for the onset of LBP is 28.4 years based on a questionnaire filled out by 3000 subjects (Walker, Muller et al. 2004).

The industry or occupation in which a person works influences the development of LBP. Certain industries, such as nursing and steel fixing, have a high incidence of lower back injuries (Smedley, Egger et al. 1995; Kumar 2007). Table 2.2 shows the 18 different industry codes used by the National Occupational Health and Safety Commission (NOHSC).

Table 2-2 National Occupational Health and Safety Commission figures for work related lower back claims 2001–2004 (NOHSC Database 2005)

Industry	Av Claims per year	Industry Population	Back Claims per Year	% Chance of Claim for LBP
Agri, Forestry & Fishing	7,298	195,140	1,359	0.70
Mining	3,222	79,347	725	0.91
Manufacturing	48,553	980,874	10,176	1.04
Elec, Gas & Water	1,470	69,976	346	0.49
Construction	19,057	451,582	4,227	0.94
Wholesale Trade	10,353	384,861	2,749	0.71
Retail Trade	24,779	1,238,963	6,607	0.53
Accom & Restaurants	10,385	449,578	2,266	0.5
Transport & Storage	17,608	352,856	4,308	1.22
Communication	3,150	145,138	734	0.51
Finance & Insurance	2,977	323,560	467	0.14
Property & Business	15,939	1,008,813	3,342	0.33
Government & Defence	9,667	414,871	2,174	0.52
Education	12,103	657,772	2,344	0.36
Health & Community	25,698	892,283	7,940	0.89
Cultural & Recreational	4,728	217,869	940	0.43
Personal & Other	9,213	300,098	1,724	0.57
Not Stated	9			
Total	226,198	8,163,580	52,424	10.81

Table 2.2 indicates that five industries (bold) with the highest percentage of lower back injuries per person, contribute to 46% (5% of 10.81%) of the lower back injuries across all the 18 occupational sectors. They are mining, manufacturing, construction, transport and health and community. These sectors are not specific enough to show the occurrence rates of LBP within a subgroup such as nursing because the statistics for nurses are included within the occupational sector of health and community services. In the same way roof tilers

and steel fixers have a very high incidence of LBP, but these figures are included within the building and construction sector, which also includes building supervisors, engineers and architects.

A number of research papers have specifically reviewed LBP within the nursing sector suggesting that the incidence of LBP is between 1.8 and 4.3 times higher than the average incidence (Venning *et al.* 1987; Lagerstrom *et al.* 1998; Hofmann *et al.* 2002). In a separate study, via a questionnaire of 47 nurses, 74% of LBP was attributed to overexertion with strenuous activities and via a separate question 70% of LBP occurred whilst transferring patients (Vieira 2007).

Studies involving steel workers have shown a high incidence of work related LBP (Kumar 2007). The incidence of LBP within the steel industry was reported as 53% within the previous year and 25% within the previous week (Masset and Malchaire 1994). A separate study stated that close to 70% of steel industry workers reported having occupational related LBP (Udo and Yoshinaga 2001).

Although LBP affects people of all ages and occupations, a higher proportion of LBP sufferers are middle aged workers who are performing tasks in occupational sectors that have a higher proportion of manual handling, whether that be patients or industrial equipment. It may be the workers within these occupational groups that are the most appropriate workers to assess from a movement and posture perspective.

2.6 Risk factors for low back pain

There is much discussion in the literature as to the cause of pain in the lower lumbar spine. Some experts believe psychosocial factors play a large role in the development of LBP (Burton, Tillotson *et al.* 1996; Boos, Semmer *et al.* 2000) whilst other authors suggest

sustained postures (Pynt, Higgs *et al.* 2001) or particular movement patterns (Hoogendoorn, Bongers *et al.* 2000) increase the risk of LBP.

Movement patterns of individuals are difficult to quantify, especially when they can involve three-dimensional (3D) movement, differing velocities/accelerations and other parameters such as vibration and complex/combined movement patterns.

The causes of LBP are numerous and varied. To investigate the risk factors for low back pain, a search strategy was designed to review current literature. The search was undertaken in August 2008 within the following recognised databases: Proquest (from 1971), Medline (CSA) (only peer reviewed from 1966), CINAHL (EBSCO) (from 1982) and PsycINFO. The search involved the specific phrases 'low back pain' or 'LBP' and 'risk factors'. A total of 1149 papers were reviewed with 194 papers from Proquest (50 retrieved), 524 papers from Medline (127 retrieved), 364 papers from CINAHL (44 retrieved) and 67 from PsycINFO (26 retrieved).

The inclusion criteria included retrospective and prospective studies that reviewed the relationship between LBP and risk factors for developing first time low back pain. Studies focusing on chronicity of LBP were not included. Papers searching for any LBP risk factors and papers attempting to identify specific LBP risk factors were included. Only papers reported in English, performed on living human subjects and those with an n value greater than 10 were included. No (n=1) case studies were included. Literature reviews were included. Papers focusing on generalised musculoskeletal studies (not specific to LBP) and papers focusing on LBP during or after pregnancy were not included.

Screening of the titles and abstracts led to a total of 247 papers being retrieved and after removing duplicate papers, 204 papers remained. Of the 204 papers, 106 met the inclusion

criteria and were included for the final review. The analysis of the papers involved grouping the risk factors into themes in a table format to display the most commonly cited risk factors for the development of LBP. The odds ratio for LBP was often reported within the studies. This represents the additional chance of a particular risk factor influencing the development of LBP, based on statistical probability.

There were 278 risk factors identified within the 106 studies and a full tabled list is in Appendix I. The majority of the papers were questionnaire-based studies of significantly sized cohorts from various countries and nationalities. Table 2.3 represents the most commonly identified risk factors grouped into themes. For example, flexion of the lumbar spine was described as 'prolonged flexion' in one paper and 'flexion angle' in another paper. It is acknowledged that these are potentially very different movements and may have profoundly different effects on the spine but there needs to be a way to group the different factors from different papers/authors.

Four of the five most commonly cited risk factors for LBP (in this review) relate to movement or posture of the lumbar spine. The four mechanical or movement based factors (lifting, flexion, rotation/lateral flexion and sitting) are all potentially measureable and modifiable parameters based on optimising movement patterns with biofeedback.

Table 2-3 The cited themes for risk factors associated with low back pain

Identified Risk Factor theme	Years of Publication	No. of papers	Papers with Odds Ratio
Lifting as a risk factor	1994-2007	35	10
Flexion as a risk factor	1995-2007	20	10
Rotation/lateral flexion as a risk factor	1995-2007	16	7
Previous LBP is a risk factor	1997-2007	10	0
Sitting as a risk factor	1993-2008	10	2
Low social support as a risk factor	1998-2004	9	1
Psychological distress as a risk factor	1999-2007	8	2
Smoking as a risk factor	1999-2008	8	2
Driving as a risk factor	1999-2006	7	3
Low job satisfaction support as a risk factor	2002-2006	7	4
Positioning patients in bed as a risk factor	1997-2007	7	2
Depression as a risk factor	2000-2006	5	0
High BMI/Obesity as a risk factor	1999-2004	5	1
Whole body vibration as a risk factor	1996-2003	5	3
Age as a risk factor	2001-2004	2	1

There are other significant risk factors that are not mechanical by nature and add another layer of complexity to the management of LBP. Depression, lack of social support and psychological distress rank highly on the list of identified risk factors and have become an important part of managing patients with LBP, for any health care practitioner. Whether these factors affect the actual onset of low back pain at a mechanical level or whether they have a greater impact on the coping mechanism for LBP remains unclear. One strong theme from the literature review is that psychological factors certainly have a significant impact on the development of chronicity of LBP.

2.6.1 Mechanical factors in low back pain

The four most commonly cited mechanical risk factors: sagittal flexion, lifting, prolonged sitting and rotation and lateral bending will be briefly discussed in the context of being able to modify these parameters in an attempt to reduce the incidence LBP or to improve rehabilitation times once LBP has occurred.

Sagittal Flexion

Some movement patterns are essential for daily activity. To reach into the bottom of a top loading washing machine or to lift a sleeping child from a car seat requires a significant degree of lumbar spine flexion. At other times, flexed postures of the lumbar spine are adopted for potentially long periods of time, with little awareness from the person that this flexed position is a potentially imposing position for the lower back (Jackson, Solomonow *et al.* 2001). One hypothesis is that these assumed positions (whether that position involved flexion, lateral flexion, rotation or a combination of these) over prolonged periods of time adversely stress the fundamental support structures of the lumbar spine.

Cadaver studies have shown that posterior lumbar spine structures, such as the intervertebral disc, are most loaded in lumbar flexion (Shiraz-Adl 1989). The stress strain curve in Figure 2.2 illustrates that all tissue will stretch or 'creep' with sustained mechanical tension, to a certain point after which it may not be able to return to its original length. If this tension increases causing continued micro-failure of the collagen fibres, macro-failure may occur at levels of greater than 5% elongation (Bogduk and Twomey 1987).

One possible explanation for the lack of conscious appreciation of this tissue degradation is that certain areas of the intervertebral disc have been described as being aneural (Alleva and Hudgins 2001; Huang and Sandhu 2004; Frelinghuysen *et al.* 2005). Whilst the outer layers of the annulus fibrosis are innervated by the sinuvertebral nerve, the inner third to two thirds of the annulus (as well as the nucleus pulposus) do not have a nerve supply. This area of the disc is not able to provide sensory input as to the stresses and strains occurring within the fibre layers. This is a highly selective argument but provides an example and a theory as to why there may be a lack of conscious appreciation of potentially provocative postures. This argument may also suggest that there is merit in monitoring movements of the lumbar spine and providing biofeedback about the potentially provocative postures. By

measuring these postures and positions, more will hopefully be learnt about the movement patterns that place the lumbar spine at most risk.

Another complexity when studying risk factors or movement patterns of the lumbar spine is the lack of standardisation of terminology and measurement parameters. Table 2.4 displays the 21 papers from the literature review that describe flexion of the lumbar spine as a risk factor for LBP.

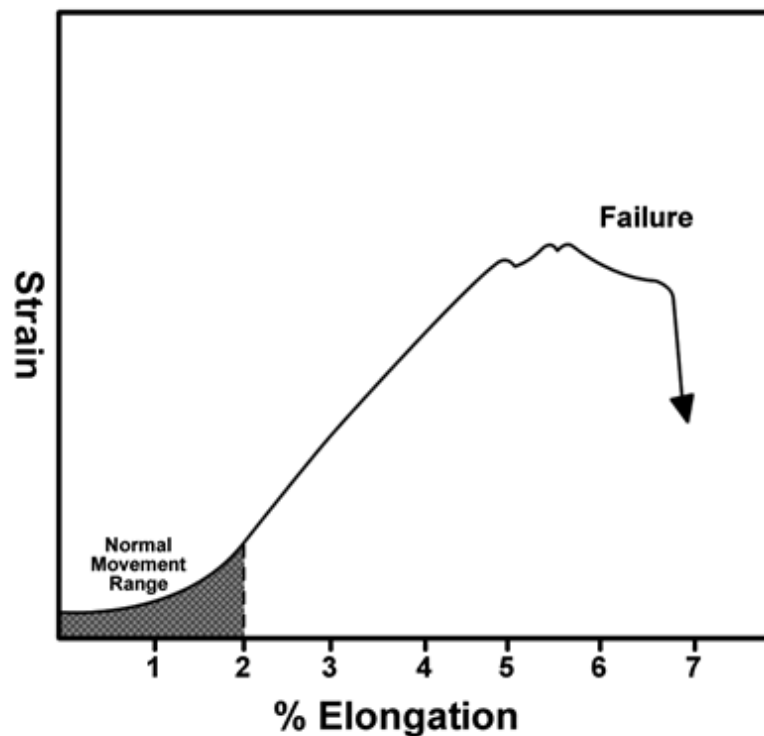


Figure 2.2 Stress strain curve showing clinical range, micro failure and macro failure
(based on (Bogduk and Twomey 1987), (Nordin, Frankel *et al.* 1980) and (Noyes 1977)).

Table 2-4 Papers citing flexion of the lumbar spine as a risk factor for low back pain

	Flexion as a specific risk factor	Author	No. in Study	Odds Ratio
1	Prolonged flexion	Bakker	200	
2	Sitting with forward flexion	Bridger	246	
3	Frequent bending	Canadian Task	na	
4	Prolonged forward and lateral fl of Cx	Christensen	281	
5	Flexion > 60 degrees for > 5% work time	Hoogendoorn	861	1.5
6	Flexion >30 degrees for 10-15% time	Hoogendoorn	732	2.03
7	Flexion and Rotation	Hoogendoorn	1192	1.8
8	Trunk flexion>45 degrees(105 vs 30min)	Jansen	523	3.18
9	Flexion and rotation	Jin	16	2 to 8.5
10	Forward bending positions	Josephson	269	
11	Flexion angle	Keyserling	600	
12	Frequent flexion and rotation	Lotters	na	1.68
13	Trunk sagittal angle	Marras	403 jobs	
14	Flexion in combination with lat fl and rot	Milosevljevic	12	
15	>12 flexion or rotation movements per hr	Nieuwenhuysse	278	3
16	Frequent flexion and rotation	Picavet	22,415	
17	Flexion and rotation	Sun	477	
18	Sustained flexion of 90 degrees	van Vuuren	109	2.16
19	Flexion and rotation	van Vuuren	366	2.81
20	Flexed postures	Yip	144	2.7
21	Duration of stooping at work	Friedrich	255	

Each of the descriptions for flexion as a risk factor, is defined differently. 'Prolonged flexion' and 'frequent bending' can be substantially different activities and therefore place very different pressures and strains on the lumbar spine. The immediate questions that come to mind are; How long is prolonged flexion for? How often does someone need to bend before the movement is classified as frequent bending? There is no standardised protocol for measuring movement parameters of the lumbar spine in real time and in the work setting. Currently, video assessment, subject questionnaires and clinical goniometer measurements provide the basis for a significant proportion of the lower back research performed. More complex 3D devices have been used but the associated costs, set up time, software expertise and availability mean that only few studies utilise these systems. The options for measuring devices for the lumbar spine are described in Chapter 3. One of the aims of this project is to provide real time 3D measurement of lumbar spine movement at a low cost and with a discrete device.

Although there are attempts to isolate movements of the lumbar spine into the three anatomical planes of movement, humans are functional creatures and most ADLs involve movements that are combination of two or three planes of movement. An additional theme that became evident during the risk factor literature review was that the Odds Ratio (also known as the estimated relative risk) with a 95% confidence interval (CI) was far greater for combined movements than for isolated movements and individual factors.

From Table 2.5, it is evident that of the risk factors with the highest odds ratio, eight of the eleven, are mechanical movement patterns that involve a combination of activities or combined movements.

Table 2-5 The risk factors with the highest odds ratio

Activity Performed	Author	No. in Study	Odds Ratio
Trunk flexion>45 degrees(105 vs 30min)	Jansen	523	3.18
Flexion and rotation	Jin	16	2 to 8.5
>12 flexion or rotation movements per hr	Nieuwenhuysse	278	3
Lifting tasks combined with driving	Lilia	231	7.3
Frequent lifting and driving	Lilia	231	10.4
>3 yrs in job lifting>25kg once an hour	Nieuwenhuysse	278	3.7
Lifting	van Vuuren	109	4.61
Lifting heavy objects	van Vuuren	366	5.58
Sitting with WBV and awkward postures	Lis	25 papers	4 to 9
Low job satisfaction	Tam	38	4.18
Flexion and rotation	Jin	16	2 to 8.5

This further emphasises the need to be able to concurrently collect multiple data parameters, in multiple dimensions of movement and over extended periods of time. For maximum effect, the real time analysis of the movement parameters would allow instantaneous biofeedback if provocative movement patterns were identified.

Lifting as a Risk Factor for low back pain

The amount of weight lifted and the type of lifting (manual handling tasks [MHT]) have been shown to be a risk factor for the development of LBP. In the risk factor literature review, 28 separate studies identified 35 lifting-associated risk factors. Table 2.6 displays the 35 factors in conjunction with the number of participants within each study and the odds ratio, when available.

Table 2-6 Lifting as a risk factor for low back pain

	Description of Activity	Author	No. in Study	Odds Ratio
1	Lifting > 10Kg	Alcouffe	7129	
2	Static loads	Bagirova	260	
3	Loading in flexed positions	Bakker	200	
4	Frequent lifting	Byrns	270	
5	Lifting > 10Kg	Canadian Task	na	
6	Lifting heavy objects	Chiou	3159	
7	Lifting previous 5 years	Friedrich	255	
8	Lifting heavy objects	Harkness	1186	
9	Lifting heavy objects	Harreby	1389	
10	Lifting > 25kg, > 15 times per day	Hoogendoorn	861	1.6
11	Lifting >25kg, > 15 times per day	Hoogendoorn	732	2.18
12	Heavy loads	Hoogendoorn	1192	1.4
13	Heavy loads	Kerr	316	
14	Velocity of lift	Keyserling	600	
15	Frequency of lift	Keyserling	600	
16	Assymetry of lift	Keyserling	600	
17	Frequent lifting	Lee	1562	
18	Lifting heavy objects	Lee	3159	
19	Lifting tasks combined with driving	Lilia	231	7.3
20	Frequent lifting and driving	Lilia	231	10.4
21	Lifting/pushing/pulling objects > 25lbs	Macfarlane	1412	
22	Lifting heavy objects	Magnusson	365	
23	Frequent lifting	Magnusson	365	
24	Liftig/forceful movement	Marras	57	
25	Frequent lifting	Marras	403 jobs	
26	Lifting heavy objects	Matsui	3042	
27	Lifting load	Mazloun	103	
28	Lifting	Mohseni-Bandpe	1226	
29	>3 yrs in job lifting>25kg once an hour	Nieuwenhuys	278	3.7
30	Lifting > 10 kg at work	Palmer	22,194	1.3 to 1.7
31	Carrying heavy loads	Tubach	3164	
32	Lifting	van Vuuren	109	4.61
33	Lifting heavy objects	van Vuuren	366	5.58
34	Poor lifting technique	Wrigley	149	
35	Laying large sandstone pavers	Latza	571	2.6

Some authors suggest there is ample evidence for a strong link between lifting physical load and LBP (Burdorf 1999). When the human lumbar spine is lifting a load, large muscle forces act on the lumbar spine and are responsible for significant compressive and shear loads, especially at the lower lumbar segments. These active compressive forces may be partially responsible for LBP when the lifting loads, especially whilst in a flexed position (Wilder, Aleksiev et al. 1996). Many questions remain but it seems there is some consensus that the load and frequency of lifting play a role in the development of LBP.

Prolonged Sitting

There is continuing debate regarding sitting as a risk factor for LBP. Whilst a number of authors suggest a link between prolonged sitting and LBP (Alcouffe, Manillier et al. 1999; Pynt, Higgs et al. 2001; Leclerc, Tubach et al. 2003; Tubach, Beautrais et al. 2004; Waters, Genaidy et al. 2005; Toshihiko, Yuichi et al. 2006; Okunribido, Shimbles et al. 2007) another suggests, via a literature review of 35 papers, that there is no specific link between sitting and LBP (Hartvigsen, Leboeuf-Yde et al. 2000).

Other authors have examined the intradiscal pressure whilst sitting and found high pressures in the lumbar discs whilst seated, especially in slouched positions (Nachemson and Morris 1964; Nachemson 1976; Nachemson 1981; Sato *et al.* 1999; Wilke *et al.* 1999). The ideal sitting position has also been studied by Pynt (2001) who suggests that a 'lordosed seated posture' is the optimal seated position, with frequent breaks to allow the lumbar spine to maintain good postural health and prevent LBP (Pynt, Higgs et al. 2001). Whether the increase in intradiscal pressure correlates with an increased the risk of LBP whilst sitting, remains a question.

Based on the literature review performed for this thesis, there were certainly more articles and papers describing prolonged sitting as a risk factor (10 papers) than those stating there

is no link (one paper). Table 2.7 presents a summary of the papers that site sitting or driving as a risk factor for the development of LBP. This seems especially true when sitting is combined with a driving occupation or when sitting is combined with asymmetrical movements or sustained postures. The subtle changes occurring within the posture of the lumbar lordosis whilst sitting are difficult to view via video camera and subjects may be unaware of their posture or seating positions if asked within a questionnaire. A device that is able to perform real time monitoring of the lumbar posture whilst sitting for prolonged periods, maybe able to assist in understanding if there is a link between sitting and LBP.

Table 2-7 Driving and sitting as a risk factor for low back pain

	Description of Activity	Author	No. in Study	Odds Ratio
	Driving as a specific risk factor			
1	Driving for long periods	Alcouffe	7129	
2	Driving > 2hours per day (sciatica only)	Leclerc	841	2
3	Driving several days of > 2hours(sciatica only)	Leclerc	841	2.7
4	Driving a bus	Okunribido	64	
5	Driving	Tubach	3164	
6	Driving for long periods	Toshihiko	551	
7	Being a forklift driver	Waters		2.13
	Sitting as a specific risk factor			
1	Sitting, WBV and Awkard postures	Angela Maria	na	
2	Sitting posture	Auvinen	5999	
3	Sitting with forward flexion	Bridger	246	
4	Sitting in non neutral posture	Burdorf	275	
5	Sitting posture	Chiou	3159	
6	Poor sitting habits	Lee	3159	
7	Sitting with WBV and awkward postures	Lis	25 papers	4-9.0
8	Sitting looking down for > 20 hours in a month	Nyland	250	
9	Sitting > 3 hours	Omokhodion	840	
10	Sitting for prolonged periods	van Vuuren	366	2.33
	Sitting is not a specific risk factor			
1	Sitting is not a risk factor	Hartvigsen	35 papers	

Rotation and lateral bending movements

Rotation (twisting) and lateral bending movements of the lumbar spine are difficult to measure. Video techniques that can give an indication of flexion range of movement (ROM),

have less reliability with the more subtle and often combined movements of rotation and lateral flexion. Both rotation and lateral flexion have been discussed as provocative movements that increase the risk of developing LBP. Table 2.8 presents the papers from the literature review that suggest rotation and/or lateral flexion as risk factors for LBP. One theory that may explain this link is discussed by Shirazi in a paper from 1989. The paper described that when rotation and lateral flexion occur together, there is a marked increase in the strain on the intervertebral disc fibres (Shiraz-Adl 1989) due to the orientation of the fibres of the annulus fibrosis.

Table 2-8 Rotation and/or lateral flexion as a risk factor for low back pain

	Rotation/lateral flexion as a risk factor	Author	Subjects	Odds Ratio
1	Lateral bending	Adams	403	
2	Prolonged forward and lateral fl of Cx	Christensen	281	
3	Rotation 30 degrees for > 10% work time	Hoogendoorn	861	1.3
4	Trunk Rotation >30 degrees for 5-10%time	Hoogendoorn	732	2.12
5	Flexion and Rotation	Hoogendoorn	1192	1.8
6	Trunk axial rotation	Jang	21	
7	Flexion and rotation	Jin	16	2 to 8.5
8	Frequent flexion and rotation	Lotters	na	1.68
9	Lateral bending velocity	Marras	403 jobs	
10	Rotation velocity	Marras	403 jobs	
11	Flexion in combination with lat fl and rot	Milosevljevic	12	
12	Rotation of spine	Miranda	2077	
13	>12 flexion or rotation movements per hour	Nieuwenhuyse	278	3
14	Frequent flexion and rotation	Picavet	22,415	
15	Flexion and rotation	Sun	477	
16	Flexion and rotation	van Vuuren	366	2.81

Many authors have suggested that flexion movements in combination with rotation and/or lateral flexion movements, further increase the incidence of LBP (Punnett, Fine et al. 1991; van Dieën 1996; Fathallah, Marras et al. 1998; Hoogendoorn, Bongers et al. 2000). The combined effect of axial torque, compression loading and anatomical flexion place the posterior and the postero-lateral aspect of the intervertebral disc in a vulnerable position (Shiraz-Adl 1989; Fathallah, Marras et al. 1998).

2.6.2 Other risk factors in low back pain

As illustrated in Table 2.3, there are many cited risk factors for LBP. In total, 18 factors were cited two or more times whilst another 16 factors were only cited once. There is an additional mechanical factor that was not identified in this literature review yet has been discussed and reviewed by other papers.

Sudden or unexpected movements have been shown to relate to a higher incidence of LBP (Magora 1973; Wilder, Aleksiev et al. 1996; Fathallah, Marras et al. 1998). There is greater muscle force production in unexpected movements than during planned or expected movements. In one study, the mean muscle force was more than twice as large for sudden or unexpected movements as it was for planned or expected movements (Wilder, Aleksiev et al. 1996). From a study design perspective, it is difficult to simulate a sudden or unexpected movement and from an ethical perspective, it is difficult to examine this risk factor without unduly placing a subject at risk of LBP.

2.7 Using biofeedback to modify movement patterns

The previously discussed risk factors provide evidence of an increased risk of LBP. Whether the source of LBP relates to an intervertebral disc, a facet joint or another pain sensitive structure, the movements and postures a person performs may be important when analysing the aetiology of lumbar spine injuries. The ability to measure and record lower back parameters, over extended periods of time, may assist clinicians build a clearer picture of what may be accepted as normal and abnormal movement patterns for the spine. It may be valuable to measure and record movements and loads acting at the lumbar spine in order to better manage LBP.

Once reliable and valid data about lumbar spine movements and loads is able to be recorded, biofeedback can be introduced in order to guide the movement patterns. This

guidance of movement patterns may be used to restrict certain provocative movement patterns or to facilitate desired movement patterns. The parameters around the dosages and thresholds of the biofeedback are another realm in themselves but early work has shown positive results. Recently, two separate studies have shown postural biofeedback is able to train subjects and guide their movement patterns. Wong, using a Smart Garment (fitted with accelerometers and a gyroscope), trained five healthy subjects to maintain a more upright posture over four days whilst performing ADLs (Wong and Wong 2008). The second study used a Back Tracker device (see Figure 3.2) to monitor posture and retrain subjects with chronic LBP. The training sessions were of 15 minute duration and were performed ten times over a five-week period. Positive outcomes were gained based on pain scales and the SF36 short form (Magnusson 2008).

The studies to date show that there is potential for postural biofeedback to become an effective tool for clinicians in guiding and correcting patient's movements.

Developments of LBP measurement methods and devices provide continued challenges. This thesis introduces a new device for measurement and monitoring of lower back movement called the Back Strain Monitor (BSM).

Chapter 3. Measuring methods and the management of low back pain

Many different measuring techniques for capturing lower back movement have been suggested. This chapter discusses multiple techniques, evaluating the positives and negatives of each. Following this, the management of LBP is discussed. The role of the doctor, allied health practitioners, the patient, the government and the insurance companies is reviewed in the context of this challenging and costly condition.

3.1 Introduction

The three-dimensional movement pattern of the multi-segmented structure has fascinated academics and professionals involved in medicine, engineering, physics, applied mathematics, biomechanics, radiology and other forms of imaging and movement analysis. This chapter describes some of the commercially available techniques and methods for assessing and quantifying the movements and deviations within the human lumbar spine.

3.2 Existing methods of measuring lumbar spine movement

There have been many different methods reported through the years, which have looked at ways of measuring lower back movement. A literature search was performed in order to identify measurement techniques that have specifically assessed the lumbar spine range of motion, with evidence of either reliability or validity.

The search was undertaken in September 2008 and additions to the search were added as other methods or devices were identified through additional searches, industry knowledge and discussion with peers. Medline (from 1966) and CINAHL (from 1982) databases were searched. The search involved the specific phrases 'low back' or 'lumbar' or 'spine' AND 'measure' or 'movement' or 'analyse' AND 'device' or 'method' or 'technique'. A total of 743

papers were reviewed with 483 papers from Medline (58 retrieved) and 260 papers from CINAHL (12 retrieved).

The inclusion criteria incorporated techniques, methods or devices that were clinically tested on subjects with and without LBP. Only papers reported in English, performed on living human subjects and those with a sample size greater than 10 were included. No ($n=1$) case studies were included. Literature reviews were included.

Screening of the titles and abstracts led to a total of 70 papers being retrieved of which 24 met the inclusion criteria and were included for the final review. Ten lower back measuring devices were identified from the 24 articles reviewed. The positive and negative aspects of each device, method or technique are noted.

3.2.1 Biplanar radiography (X-ray)

The Biplanar radiographic technique evolved from the simple plan X-ray. Two separate X-ray machines are set such that the object being X-rayed is able to be viewed from the frontal plane and the lateral plane. The technique has been shown to be accurate to within a root mean square (RMS) error of less than 1.5° (Pearcy and Whittle 1982; Portek I 1983). Recent studies have even suggested that the biplanar technique is more accurate than MRI in identifying early signs of disc degeneration (Benneker, Heini et al. 2005).

Positives

Gives a real image of the shape and contours of the spine in real time.

- Patient is assessed in a standing position meaning that the spine is under load and in a functional position.
- Accurate technique, considered to be the gold standard for lumbar spine measurement.

Negatives

- Radiation dose
- Possible refraction depending on the size of the patient, distance from the X-ray machine and distance to the film.
- Expensive
- Unable to judge movement without being done via fluoroscopy (a moving x-ray), that further increases the radiation levels.

3.2.2 Inclinator and the double inclinometer technique

An inclinometer measures angular displacement in relation to the line of gravity. The inclinometer technique has been shown to be more accurate for measuring lumbar spine motion when used as the double inclinometer (DI) technique. The DI technique utilises one inclinometer placed at the upper aspect of the lumbar spine (T12/L1) and a second inclinometer placed at the lower lumbar spine (S1 at the level of the posterior superior iliac spine [PSIS] see glossary). This method takes angular measurement of the lower lumbar spine in relation to gravity and subtracts that measure from the angular measurements of the upper lumbar spine in relation to gravity. The difference between the two measurements represents the angular position of the lumbar spine.

Positives

- Separates hip and lumbar spine movements.
- Measures degrees of movement (directly comparable to X-ray).
- Able to measure flexion, extension and lateral flexion.
- Inexpensive and able to be used easily within a clinical setting.
- Evidence of inter-tester reliability (Newton and Waddell 1991).
- Evidence of intra-tester reliability (Keeley, Mayer et al. 1986; Beattie, Rothstein et al. 1987; Gauvin, Riddle et al. 1990; Paquet, Malouin et al. 1991).
- Evidence of its validity as a measure of lumbar spine motion (Reynolds 1975; Moll 1976; Portek I 1983; Mayer, Tencer et al. 1984; Merritt, McLean et al. 1986; Newton and Waddell 1991).

Negatives

- Time consuming.
- Increased margin for error through human measurement and calculations.
- Human interpretation of landmarks and angles when placing the inclinometer.

3.2.3 Flexicurve

A draftsman's flexible ruler was adapted to follow the contour of the lumbar spine, from S2 to T12. This flexible 30 cm ruler was used to measure the change in contours of the spine during flexion and extension.

Positives

- Easy to mould to the lumbar spine.
- Contour drawn on paper to obtain angle measurement.
- Positively correlated with goniometer (0.94) (Salisbury and Porter 1987).
- Shows evidence of intra-tester reliability (Burton 1986) (Hart and Rose 1986) (Lovell, Rothstein et al. 1989).

Negatives

- Laborious and time consuming.
- Errors with estimations of tangents.
- No inter-tester of reliability (Lovell, Rothstein et al. 1989).

3.2.4 Kyphometer

A protractor with two parallel arms, placed on the upper and lower sections of the lumbar spine.

Positives

- Simple to use.
- Correlated well with goniometer technique (0.99) and flexicurve (0.93) (Salisbury and Porter 1987).
- Inexpensive and can be used within a clinical setting.
- Evidence of inter-tester reliability (ÖHIÉN, Spangfort et al. 1989) (Newton and Waddell 1991).

Negatives

- Not readily available.
- Unable to be used through range in real time.

3.2.5 Lumbar motion monitor: Marras (1993)

A three-dimensional exoskeleton, which enables movement analysis in the anatomical planes of flexion, lateral flexion and rotation.

Positives

- Evidence of inter- and intra-tester reliability (Marras, Fathallah et al. 1992; Gill and Callaghan 1996).
- Data recorded electronically for easy data tabulation and statistical analysis.
- Assesses lumbar spine movement through range.
- Assesses 3D movement

Negatives

- Large, cumbersome and not able to be worn whilst seated.
- Expensive (USD \$30,000+ plus custom software).
- Need designated computer terminal and expert training to use the device.



Figure 3.1 The Lumbar Motion Monitor (LMM) (Marras *et al.* 2000)

(reproduced with permission from Spine journal, © Lippincott Williams & Wilkins)

3.2.6 Back Tracker: developed by Iso Technologies (Hillsborough, NC)

The device measures angular changes between the spine and the pelvis, via a triaxial goniometer. A harness is worn around the thorax and another around the pelvis (level of the belt line), to anchor the device to the lower and upper measurement regions. The measurement regions are joined by a long upright pole extending from the pelvis to the fixation point at the level of the mid thoracic spine. As the lumbar spine moves, the pole will rotate, tilt forward or tilt sideways. These movements are registered by the triaxial goniometer located at the pelvic end of the pole.



Figure 3.2 Back Tracker in use (Magnusson 2008)

(reproduced with permission from Spine journal, © Lippincott Williams & Wilkins)

Positives

- Multiple measurements are recorded through range of movement.
- Potential applications within industry.
- Evidence of reliability but only one paper identified (Barr 1988).

Negatives

- Unable to sit with the device being worn.
- Expensive and quite cumbersome.
- Could potentially catch on various other structures, especially if working in an area with leads or hanging machinery.

3.2.7 Finger to floor

Method whereby subject flexes forward with hands reaching toward the ground and a measurement is taken from the fingertips to the ground.

Positives

- Quick, simple and easily performed within a clinical sitting.
- Easily reproducible and evidence of reliability from an inter-tester perspective (Frost *et al.* 1982; Gill *et al.* 1988; Newton and Waddell 1991).

Negatives

- Not valid as a measure of spinal movement (Moll 1976; Newton and Waddell 1991).
- Results not comparable from one subject to another.
- Not able to record movements through the range of motion, but only at the end range of flexion.

3.2.8 The Schober Method (Modified Schober and Modified-Modified Schober)

This method involves marking two landmarks on the lumbar spine, one at the lumbo-sacral junction and the other 150 mm above this point. The subject is then asked to flex forward as far as comfortable and a new measurement is made between the lower and upper lines on the lumbar spine.

The difference between the 150 mm starting point and the end-measured point is deemed as the number of millimetres the lumbar spine has flexed.

Positives

- Easy, quick, simple, inexpensive and able to be used in a clinical setting.
- Has evidence of inter- and intra-tester reliability (Million, Nilsen *et al.* 1981; Waddell, Main *et al.* 1982; Biering-Sorensen 1984; Merritt, McLean *et al.* 1986; Gill, Krag *et al.* 1988).
- Has demonstrated evidence of validity for the measurement of lumbar spine movement (Rae 1984).

Negatives

- Shown not to correlate to goniometer, kyphometer, flexicurve (Salisbury and Porter 1987).

- Unable to achieve recordings of multiple measurements through the range of lumbar spine movement.
- Variations with finding landmarks on the human lumbar spine.

3.2.9 Lumbar Spine and Pelvic Skin Rigs (Wands)

Rigid plastic wands that project perpendicular to the spine at the lumbo-sacral junction and at the thoraco-lumbar junction (Whittle and Levine 1997).

Positives

- Easy to use within a clinical setting.
- Inexpensive if camera laboratory available.
- Shown to be reliable for gait and static lumbar lordosis (ICC 0.90) (Whittle and Levine 1997).

Negatives

- Laboratory level camera set up is required.
- Laborious to derive angles from video captured images.
- Validity has not been assessed.

3.2.10 Spinal sensor

A posture device that adheres to the lumbar spine and monitors the degree of lumbar lordosis. The device has wireless communication with a docking biofeedback instrument, allowing the subject to receive feedback in relation to less than optimal postures.

Positives

- Self-calibrating.
- Relatively inexpensive.
- Wireless and rechargeable.

Negatives

- Does not allow the lumbar spine to move through full range of movement.
- It remains unclear if the device is able to measure rotation of the lumbar spine.
- Measurement properties not established.

3.2.11 Video and Laser Measurement Techniques

Video and laser recording techniques are well established methods for assessing low back movement. The systems utilize multiple cameras that are strategically orientated to capture a subject's movement. Opto-reflective markers are placed on the subject in pre-determined positions. For the lumbar spine, reliable results have been found by using 'wands' that protrude perpendicular to the spine with reflective markers placed on these wands (Whittle and Levine 1997). Currently available video assessment systems include the Vicon system, the OptiTrack and the Peak system.

Positives

- Accurate (to within 1° or 1mm depending on the application).
- Established technology.
- Able to be used on all parts of the body, not just the lumbar spine.
- Able to be used through full range of motion.

Negatives

- Large set up cost.
- Need laboratory infrastructure and dedicated technician.
- Require 'wands' or 'sticks' protruding from the lumbar spine (potentially increases margin for error because markers are not where the movement is occurring).

3.2.12 Smart Textiles

A relatively new field of work involves using 'Smart Textiles' to sense movement of the body. Various sensors are placed within the woven fabric of clothing to sense movement. Dunne in a 2008 paper describes using plastic optic fibres to sense movement of the lower back (Dunne, Walsh et al. 2008). Lymberis in 2007 describes using a 'Strain Fibre Sensor' based on piezo-resistive yarns (Lymberis and Dittmar 2007). These techniques are currently laboratory based prototypes that are not available for commercial application.

3.2.13 Conclusions

As can be seen from the above list of methods for measuring lumbar spine movement, there have been many attempts to find a simple, reliable and valid measuring tool for the lower lumbar spine. As yet there is no stand out method for the reliable and valid measure of the lumbar spine in all settings. The Lumbar Motion Monitor has the greatest number of publications and academic scrutiny and has been revised in 2001 to be a more mobile unit.

3.3 Objectives used while building a measuring device for the lumbar spine

The objectives used for building a measuring device for the lower lumbar spine can be summarized by the following list of requirements:

- Inexpensive and readily available to all practitioners wishing to use it.
- Evidence of reliability both from an inter-tester and intra-tester perspective.
- Required to correlate well with existing reliable and valid measures of lumbar spine movement.
- Able to provide measurements in the three dimensions of lumbar spine movement.
- Required to measure multiple points through the full range of movements, at a high sampling rate (eg: >5 samples per second).
- Record movements of the lumbar spine and analyse this movement data in real time to make decisions as to whether the subject is moving in a safe or unsafe way.
- Be comfortable to wear, discrete and not impede normal movements of someone wearing the device.
- Be able to be worn for 8–12 hours and provide preprogrammed biofeedback to the wearer.

3.4 Current management of low back pain

Low back pain is a very difficult condition to manage. The focus in low back pain management for the past two decades has been in reducing the chronicity of LBP. That is the prevalence and duration of LBP. The overwhelming theme has been to keep patients active, don't allow them to stay in bed or allow their general fitness and strength to fade (Kankaanpää, Taimela et al. 1999; Mannion, Muntener et al. 1999; Koes, van Tulder et al. 2001; Mannion, Junge et al. 2001; Hagen, Hilde et al. 2002; Hagen, Jamtvedt et al. 2005). There have also been a significant number of studies attempting to identify people at risk of becoming chronic LBP sufferers (Murphy and Cornish 1984; Kleenerman, Slade et al. 1995; Miedema, Chorus et al. 1998; Seferlis, Nemeth et al. 2000; Pincus, Burton et al. 2002; Fayad, Lefevre-Colau et al. 2004). These studies have provided health practitioners with the skills to encourage their patients to stay active and to identify the patients at risk of developing chronic pain symptoms (Kleenerman, Slade et al. 1995).

From the patient's perspective, it is difficult to follow medical advice to stay active when the LBP being experienced is at a high level or causing significant dysfunction to the person's normal ADLs. How is a patient, who has experienced low back pain for the first time, going to rapidly capture these complex themes, internalize the impact of this potentially serious condition and trust a health practitioner who is telling them to continue activity in spite of pain being experienced?

Evidence shows that particular movements of the lower spine are related to an increase in risk of LBP (see Chapter 2). It is important to be able to quantify movement and measure the physical activities of people in relation to their spine. Once these parameters can be reliably measured, the additional knowledge and quantification of movement patterns may assist in the understanding and the improved the management of LBP.

A guidance device or real time motion analysis system may help both the health professional and the patient to understand the movements being performed by the person experiencing LBP. The device is planned to record movements of the lower back, in real time, analyse the data and distribute biofeedback in the form of vibration, audible tone or visual score/graph/symbol on a handheld screen. Once the movement patterns are understood, biofeedback settings can be set in an attempt to guide the patient to those postures and movements deemed acceptable, or those encouraged by the health practitioner. At times the biofeedback settings may encourage the patient to move whereas at other times, depending on pain severity and level of dysfunction, the biofeedback may be restrictive or warn the subject to avoid certain movement patterns and postures.

To review the usefulness of a new device for measuring and managing lower back movement and injuries, it is important to look at the current management of back pain. There are four main groups identified in the treatment and management of back pain and these include general practitioners (GPs) and doctors, allied health practitioners (AHP, i.e.; physiotherapists, chiropractors, osteopaths and naturopaths), patients who suffer back pain, and those who fund the management of LBP (government, employer groups, insurance companies, unions and Occupational Health & Safety [OH&S] workers). Each of these groups will be briefly discussed in the context of managing LBP.

3.4.1 General practitioners

Low back pain makes up approximately 5% of a doctor's case load (Jensen 2004) with general practitioners (GPs) still being the first person consulted for the majority of the Australian public when they experience LBP (Walker, Muller et al. 2004).

There are four stages of LBP management for a GP: the assessment, treatment, referral to other health practitioners or specialists, and the review of the patient.

Assessment of the low back pain

The assessment will usually involve a history or subjective assessment followed by a physical examination or an objective assessment. This assessment process is explained in detail in Jensen's 2004 article (Jensen 2004). A thorough lower back assessment may take between 20 and 30 minutes to administer. This becomes a problem for the Australian GP who spends an average of 13 minutes per consultation with each patient (BEACH 2006).

Imaging forms another dimension to the doctor's assessment process, whether that be via an X-ray, CT scan or MRI scan. Each of these imaging tools have their particular application, although recent studies suggest X-rays may be of limited value in managing low back pain. The X-ray may satisfy an aspect of the patient's concerns and GP's curiosity yet X-rays have been reported in a UK paper to be of no physical benefit to the patient and only a minor psychological benefit (Woolf and Henshall 2000). X-rays have also been shown to have minimal clinical correlation with patient's symptoms (Lohman, Tallroth et al. 2006). Whilst CT scans and MRI scans have improved the imaging quality of bone and soft tissue structures, some authors still believe they are of limited benefit in the diagnosing disc related conditions of LBP (Malik and Joseph 2007).

Treatment of the low back pain

Treatment for LBP by GP's involves a combination of medication, advice/exercise prescription and occasionally manipulation or mobilization. It is reported in the 2005/2006 Beach study that 71% of GP consults prescribe medication, with the most commonly prescribed medication being non-steroidal anti-inflammatories (NSAI) (BEACH 2007). However, NSAIs have been linked to an increased risk of stroke and heart problems, if taken for prolonged periods (Aneja and Farkouh 2008). There has also been a worldwide recall for a well known and widely used NSAI, VIOXX (Hawker, Katz et al. 2006).

Advice to remain active and exercise prescription is possibly the safest and most important tool for the GP in the management of LBP but this can be difficult in a brief and often complex appointment session for a patient experiencing LBP. Understanding the movement patterns and daily activities that are potentially responsible for the LBP is a time consuming task. Once these provocative movement patterns are identified, educating the patient as to how to avoid these activities and how to promote the advantageous postures and exercises will take further time. A tool or device that could automatically acquire personalized movement data may be of benefit in streamlining the information flow between the patient and the medical practitioner. The same tool may also be beneficial in providing biofeedback in relation to the desired movement patterns outside the clinical confines.

Manipulation and mobilization are specific skills utilized by physiotherapists, chiropractors and some GPs. The necessary skills for both manipulation and mobilization lie outside the normal medical training and are only taught in extracurricular training courses. This requires the GP to have a special interest in LBP and only a small number of GPs undergo this additional training.

Referral

If the patient's LBP is not settling with medication and the GP's advice, referral to a specialist or allied health practitioner is considered yet a referral only occurs 8% of the time (BEACH 2007). Of those patients referred, 68% are referred to specialists and 24% are referred to allied health practitioners (BEACH 2006). Of those referred to allied health practitioners, 10% are to physiotherapists, the highest single group, suggesting that 0.19% of GP consultations are referred to physiotherapists (BEACH 2006). These statistics demonstrate that the majority of patients seen by a GP will remain in the care of the GP. With GPs being the number one care giver for people suffering from LBP (see Table 2.1)

and 71% of patients visiting doctors being prescribed medication, the majority of patients are likely to be prescribed medication, imaging and advice only.

Review consultation

Low back pain rarely requires a single visit to a GP. Repeat consultations are to monitor progress, repeat subjective and objective assessments, review medication and pain levels and advise on return to work or sporting activities. If progress is satisfactory, management is likely to follow a very similar pathway. If no change in the LBP is evident or the condition has worsened, imaging, referral or a change in treatment strategy is likely.

Low back pain continues to be a challenge for GPs and any health practitioner treating or managing the condition. Two of the GP's main management tools for treating low back pain are NSAIs and X-rays. With NSAIs having been shown to have increasing side effects and the obvious radiation issues and the lack of physical benefit associated with X-ray, doctors may benefit from an objective tool for managing LBP. If the measuring tool/device were to have no side effects and could educate both the GP and their patients about the movements and the stresses occurring within the lumbar spine, a new device may have a place in the GP's management of LBP.

3.4.2 Allied health practitioners

The large majority of LBP patients treated by allied health practitioners in Australia are not publicly funded. A small cohort of chronic LBP patients are allowed five sessions per year (Medicare-based Enhanced Primary Care [EPC] program), spread across a number of AHPs but the majority of LBP patients will not receive funding through the EPC program. Funding for treatment with an AHP may be available through private health insurance, Work Cover (State based compensation for work related injuries), TAC (State based Transport

Accident Commission) and the Department of Veterans Affairs (Federal funding for returned service people).

The AHPs who manage LBP include physiotherapists, chiropractors, osteopaths, naturopaths and myotherapists/masseurs (see Table 2.1). There are other small boutique therapies but these are the main five who care for people with back pain. As a group, these AHPs offer advice, education, mobilising techniques, manipulation, massage, rehabilitation and exercise programs. There have been recent attempts to identify sub groups of patients within the definition of non-specific low back pain (NSLBP) (Kent and Keating 2004; O'Sullivan 2005; Dankaerts, O'Sullivan et al. 2006). The concept of sub grouping aims to classify LBP subjects into the movement patterns that aggravate their pain. For example, there may be a 'flexion group' that by definition, experience an increase in LBP with flexion related activities. This movement or posture related theme of treatment has been developing for a number of years (McKenzie and MacKenzie 1997) but there is now an attempt to put a framework around the definitions of the different types of sub groups. There may be less emphasis on diagnosing the anatomical structure responsible for the pain and more emphasis on teaching the patient to move in a way that facilitates healing and optimal functioning of the painful area. This theme of LBP management may be well supported by a measuring device that is also able to guide the way a patient moves, with those desired movement patterns guided by the therapist.

3.4.3 Patients with low back pain

For the patient who is experiencing LBP, managing the condition and the pain becomes a difficult decision. Should they see their GP, a physiotherapist, a chiropractor or be treated by an osteopath? Patients may find it quite difficult to decide on which profession will be able to manage their condition for optimal recovery.

Patients seek objective information about their lower back and the cause of their back pain. Limited consultation time in general practice (10–15 minutes) often leaves a patient wanting more information. Allied health practitioners using a ‘hands on’ approach can only spare a small component of the consultation time for education and advice, as the patient often expects and demands the ‘touch based’ therapy. The patients will often seek answers from the internet, family and friends and ‘current affair’ programs, although much of this information is uneducated, not individualized for that patient and is not based on any professional opinion or objective measure.

This thesis proposes that the quality of, and access to, objective information about the lower back, for patients suffering LBP, does not meet the needs of the patients. In focus groups conducted in 2003, patients were most interested in further information in relation to their movement patterns performed during a days’ activities (Lovett 2003). Patients are interested in an objective measure of their back movement and the pressures placed on their back, allowing them to see a graphical representation of the movements they perform. The biofeedback settings, adjusted by the therapist, may provide a guide or suggestion as to which movement patterns may be best to avoid. The concept of a score or objective goal, has the potential to ‘create a sense of control’ (Brasher 2006) and understanding about their movement patterns. In a similar way, the heart rate monitors worn by some footballers and many recreational athletes, provide an example of the interest people have in their own bodily functions. The cholesterol threshold of 5.5 is another example of a guide or tangible number for the public to aim for, a goal.

By measuring and quantifying lower back movements and by providing an option of biofeedback, patients may become empowered by this new information, controlling their movement patterns through a new option for rehabilitation.

3.4.4 Funding the management of low back pain

For the groups who fund the management of LBP (government, employer groups, insurance companies, unions and OH&S workers), treatment is fragmented and the associated costs of managing LBP are difficult to manage. There are many different suppliers offering different treatment options for treatment of LBP. Treatment costs in Australia have risen 131% in the last decade (Richards 2003) and the incidence of lumbar spine surgery has increased 77% in the US in the past 5 years (Deyo, Nachemson et al. 2004). In Australia, the government is particularly concerned about this significant increase in LBP management costs (Hadley 2005).

Within industry, back pain management certainly has many challenges. Injury prevention strategies have become common place in the work place over the past decade and have included the no lift policy with nurses, the customized trolley for the 44 gallon drums, back braces used at hardware stores for all employees and weight restrictions put on most products handled by employees and labourers (e.g. concrete bag going from 40 kg to 20 kg, paint tins going from 20 L to 10-15 L). These prevention strategies have been put in place in an attempt to reduce the incidence and recurrence of low back pain. There is still no measurement system that is readily available for measuring what movements are performed whilst at work. Before you can manage a problem effectively, the first step is to be able to measure the problem.

The Victorian Workcover Authority (VWA) has produced 'Safe Handling Guidelines' that aim to provide a guide as to what type of movement patterns are recommended in the work place. For the average employer these guidelines are time consuming to read, difficult to understand and interpret and even more difficult to educate the workers as to the requirements of the 'safe handling guidelines'. The VWA guidelines suggest that the lumbar spine should not be in positions of greater than 20 degrees of flexion for prolonged periods.

The average employer and employee are not going to understand when the lumbar spine is at 20 degrees flexion if asked in a static position. It is even more difficult to understand when the worker is mobile, performing their normal daily activities. There is currently no objective guide, within industry, for what 20° of the lumbar spine is.

The industry appreciates that guidelines are necessary but it is most difficult for both the employer and the employee to follow these guidelines when there is no objective measuring tool quantifying the movements they currently perform. If the movements were able to be quantified, the same measuring tool could potentially give biofeedback as to when particular movements were outside the guidelines provided by the industry.

3.5 Conclusions

There is currently no simple, cost effective, readily available measuring tool for the lower back. There is significant evidence that spinal posture and movement patterns are risk factors for LBP (Table 2.3) and have an impact on the chronicity of LBP (Magnusson 2008). If a device were to be designed such that it was reliable, gave a valid measure of lower back movements in three dimensions, was cost effective to use and was readily available to the people who manage LBP, this may be able to assist in the management of LBP. Chapter 4 describes the Back Strain Monitor concept and the early stage planning of this new measuring device.

Chapter 4. Development stages of the new Back Strain Monitor

This Chapter introduces the concept of a Back Strain Monitor (BSM) and then focuses on the development stages of the essential part of the BSM called the measuring device (MD). The measuring device contains sensors for measuring movement of the lower back.

Seven different measurement techniques are evaluated and the three strongest candidates, conductive silicone, inductive coil and the accelerometers, are selected and tested within a laboratory setting.

The review of the different methods considered for the movement sensor, helped to inform the development process that led to the current version of the BSM device.

4.1 The rationale for a back strain monitor

To improve the management of LBP, it may be important to be able to measure multiple factors that could influence the development of LBP. The literature review of causative factors for the development of low back pain, (see Chapter 2) outlined a number of identified causes or risk factors that may contribute to the development of low back pain. These can be broadly split into biomechanical factors, psycho-social factors and individual risk factors (see Table 4.1).

The biomechanical factors affecting the lumbar spine relate to the activity a person does, the movement they perform and the forces acting on the spine. Biomechanical factors are regularly referred to as a causative factor for the development of low back pain (Adams and Dolan 1995; Bernard 1997; Fathallah *et al.* 1998a,b; Hoogendoorn, Bongers *et al.* 2000; Morlock *et al.* 2000; McLean *et al.* 2001; Punnett and Wegman 2004). Biomechanical factors include factors such as lower back activity or lower back movement. Lower back activity is complex, multi-factorial and historically difficult to measure. The measurement of

lower back activity is a key requirement of the Back Strain Monitor (BSM, discussed in detail in Section 4.3), yet for a new device to be viable, the device needs to be comfortable to wear for prolonged periods and affordable for health practitioners to access.

Table 4-1 Summary of risk factors for developing low back pain

Biomechanical Factors	Psycho-social Factors	Individual Factors
Heavy physical work	Work dissatisfaction	Age
Manual materials handling	Work support	Gender
Static postures		Socio-economic status
Prolonged standing & sitting		Genetic profile
Frequent trunk flexion		Previous low back disorders
Lateral flexion and rotation		Posture
Repetitive work		Anthropometry
Vibration		Strength & Fitness
		Spinal mobility
		Smoking
		Body weight

Table adapted from 'Biomechanics in Ergonomics', (Kumar 2007)

The phrase lower back activity (LBA) encompasses movement in three dimensions, body orientation in relation to gravity, muscle activity, vibration acting on the spine, speed and acceleration of movement and forces acting externally on the spine (eg: lifting a heavy object). Measuring these factors will provide the basic data building blocks for the lower back measuring device.

4.2 Which low back pain risk factors should be measured?

The mechanical load or strain on the lower back is difficult to measure. Marras in 2006 used an EMG-assisted biomechanical model to estimate spinal loading (Marras, Parakkat et al.

2006). In 1998 Fathallah used electrogoniometers, electro-myogram and a force plate to estimate loads acting on the lumbar spine (Fathallah, Marras et al. 1998). In 1998 Sparto used an electro-myogram model to estimate torque and spinal loading (Sparto and Parnianpour 1998). To estimate the amount of 'strain' the lower back is experiencing at any time, multiple factors needed to be considered. Early in the development of the BSM concept, three priority factors were identified. Two of these factors were mechanical factors (movement performed by the lumbar spine and lumbar spine muscle activity) with the third factor being psycho-social influences.

The first mechanical factor to be measured, based on the analysis table in Chapter 2 (Table 2.3), was flexion range of movement. Lumbar flexion has been identified as a specific biomechanical risk factor for the development of work-related back pain in 21 journal papers within the literature review outlined in Chapter 2 (see Table 2.4). If the anatomical movements of lateral flexion and lumbar spine rotation could be measured by the same transducer, this could be of added benefit. The development of the measuring transducer to accurately quantify the movements of the lumbar spine was a priority of this study.

The second mechanical factor to be measured by the BSM device was electro-myographic (EMG) activity of the muscles of the lumbar spine. Electro-myographic analysis has the potential to provide an indication of the load acting on the lumbar spine. The literature regarding the reliability of sEMG for quantifying muscle activity and deriving load assumptions in relation to the lumbar spine is debated within the literature (Dankaerts, O'Sullivan et al. 2004). Electro-myographic activity may be the more difficult parameter to measure reliably and was thus chosen second in the BSM development process. Although inherent in the BSM concept, sEMG is not specifically analysed as part of this thesis. Both the movement analysis and sEMG analysis were classified as assessment tools for the biomechanical risk factors for the development of LBP.

The third priority factor was not a mechanical factor but related to the pre-existing psycho-social and individual factors, that may predispose a person to developing LBP (see Table 4.1). The aim for the third priority was to formulate a patient profile (PP) that was derived by scoring the psycho-social factors and individual factors through a proposed scoring table. The table would allow for each factor to be rated and a formula is planned to combine these factors to give an overall 'risk' score.

The psycho-social factors and individual factors used in calculating the PP included factors such as the patient having a history of the low back pain, the patient's occupation and the age of the patient. Although planned to be a part of the BSM system, the PP table and scoring system are outside the scope of this thesis.

4.3 General concept of the Back Strain Monitor

The Back Strain Monitor (BSM) is an electronic and programmable device developed in conjunction with this thesis. The device is designed to be used by patients presenting with low back pain or potentially to assess whether a patient is at risk of developing low back pain. The aim of the device is to monitor movement, measure muscle activity, and to provide real-time biofeedback to the patient about potentially provocative postures and movements of their lumbar spine. Real-time biofeedback potentially allows the patient to correct the body posture or to stop the physical activity that may carry a higher risk of injury. The biofeedback may stimulate the neuromuscular programming needed for behavioural change related to postural patterns. There is some preliminary evidence that biofeedback is able to assist change in postures and movements, leading to improved recovery from LBP (Magnusson 2008).

The current form of the device has been derived through a number of intermediate versions. The intermediate versions were initially tested within a laboratory setting and later, clinically

tested. Based on the results of these reliability trials, new improved versions of the device were developed. The current version of the Back Strain Monitor (BSM) has been developed through the knowledge and experience acquired during the laboratory and reliability trials.

The development plan required that the BSM device record the three priority factors (Movement, EMG and the Patient Profile) and combine the data from the three factors via a specifically developed algorithm. The aim of the algorithm was to determine the load experienced by the lower back and the overall risk of low back pain.

The BSM device consists of two parts (see Figure 4.1): the Measuring Device (MD) and the Recording Feedback Device (RFD). The Measuring Device is the transducer component that collects raw real-time movement and muscle activity data from the patients via sensors placed on the patient's body. The Recording Feedback Device is an electronic, programmable device that uses a numerical algorithm to extract and process information from the sensors, and from the patient profile stored in the memory. By combining these different data outputs from the sensors, a LBP risk score is calculated. When the risk score exceeds certain threshold value, a real-time biofeedback signal (sound or vibration) is activated to inform the patient of the excessive load or high risk activity that their low back may be experiencing.

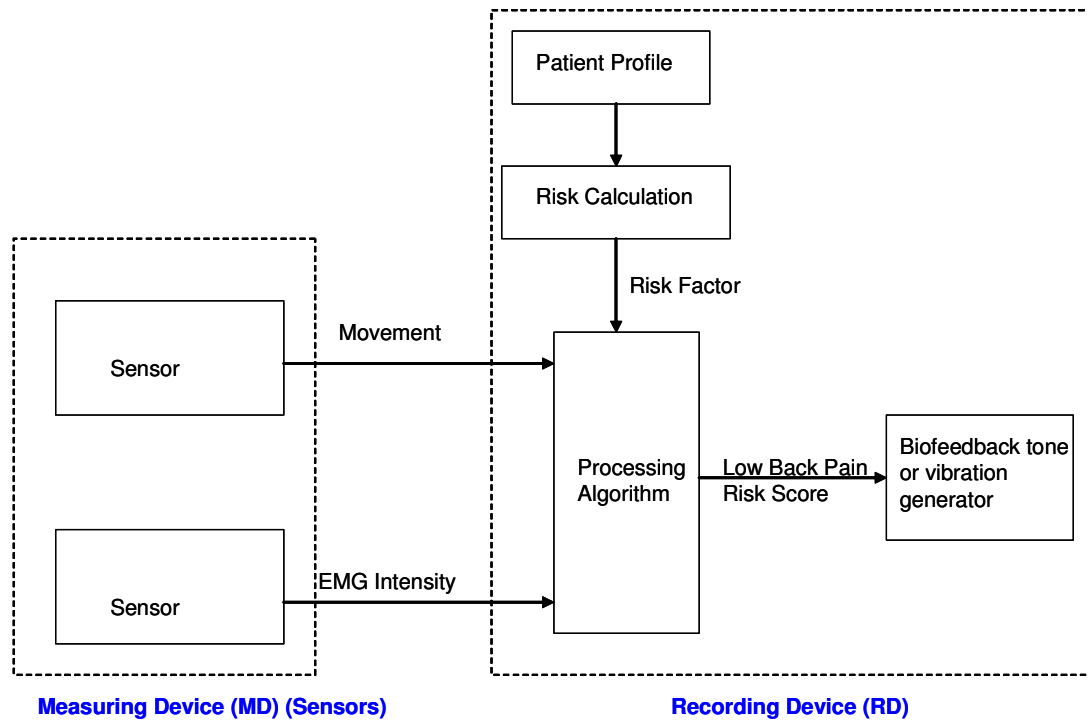


Figure 4.1 The general concept of the Back Strain Monitor

4.4 Development of the Back Strain Monitor Measuring Device (the movement sensor)

An aim of this thesis was to find a new way to measure movement of the lumbar spine. The most important single movement (based on a review of the literature performed in Chapter 2, Table 2.3), was that of lumbar spine flexion. This posed the question; can a reliable method be found to measure sagittal-plane flexion of the lumbar spine? If so, can this measurement method be adapted to also measure lateral flexion and rotation movements of the lumbar spine?

The initial concept for measuring lower back movement revolved around measuring skin stretch of the lower back as a person flexed forward. Various potential techniques similar to the Schober method (see Chapter 3) for skin distraction (Schober 1937) were reviewed. These methods measured the skin distraction or skin stretch as the lumbar spine flexed forward. These techniques worked as linear transducers, measuring elongation along a

predetermined path. Magnetic tape measures (Ball 1999) and electronic verniers (de Bruin, Verheij et al. 2006) were the early considerations. An electro-goniometer, used to measure body movement (Polak 1998) was also considered. These methods were reported to be reliable measuring instruments, with the vernier measuring increments of as little as one micron. Electronic engineers were consulted in order to gauge the likely costs and timeframes to modify these measurement transducers for lower back movement measurement. The base model transducers were all above one hundred dollars (AUD \$100) per unit and these methods proved to be too costly to be modified to measure lower back movement.

A literature search was carried out (see Chapter 3) to identify other products capable of measuring lower back movements, accurately and in real time. The identified transducers/methods were either linear, manual methods that were slow and could not automatically record movements, or they were cumbersome and conspicuous (e.g. Lumbar Motion Monitor and the Back Tracker). The BSM device was planned so as to be inconspicuous and comfortable to wear. The literature review did not identify a discrete transducer (sensor) that was readily available to measure lower back movement in real time and in three dimensions.

A review of potential measuring methods was undertaken, to determine whether a suitable method could be found and developed into the BSM transducer for measuring lower back movement. The review involved workshops with two electronic engineers and two physiotherapists, using a combination of professional experience, industry knowledge and electronic searches. Seven potential transducer methods were identified for measuring lower back movement.

4.4.1 Review of potential methods for sensing movement of the lumbar spine

Each of the seven transducer methods are briefly described below, with a more detailed description of the three highest ranking transducer methods, later in the Chapter.

The seven reviewed transducer methods were as follows:

1. Gravity angle measurement via accelerometers (Baten 1996)

Accelerometers sense acceleration, and angular position is able to be calculated from the acceleration reading. The plan was initially for two, 2 dimensional accelerometers to be placed at the top of the lumbar spine and two, 2 dimensional accelerometers to be placed at the lower section of the lumbar spine. It was anticipated that angular rotational movements of the upper section of the lumbar spine and the lower section of the lumbar spine could be derived from the accelerometers. The difference between the angular outputs of these two groups of accelerometers would provide the resultant change in lumbar spine movement.

2. Inductive coil (Cimmino, Klein et al. 1990)

The identified inductive coil technique involved a double helix conductive core inserted into a flexible elastomer body. The inductive coil converted dimensional changes (stretching or compression) of the double helix coil into electrical current (or voltage) variations to provide data output. The current (or voltage) changes were proportional to the amount the coil was stretched.

3. Flexible conductive silicone (Marmaropoulos and Van Heerden 2002)

The flexible conductive silicone contains an electrically conductive element such as carbon or silver. The silicone is impregnated with the conductive element during extrusion, allowing the silicone to conduct an electrical charge. When the silicone is stretched, the orientation of the conductive elements is modified, changing the electrical properties of the conductive

silicone and thus changing the electrical resistance. The change in electrical resistance is potentially proportional to the change in length of the conductive silicone. It is proposed that a formula linking the length of the silicone to the electrical resistance of the silicone be defined through prototype building and reliability experiments.

4. Strain gauge (Steffen, Rubin et al. 1997)

The type of strain gauge reviewed involved the attachment of a spring to a load cell whereby the force within the spring is proportional to elongation or compression of the spring. The spring acts an electrical conductor that is able to be stretched or compressed within its elastic limit. Stretching the strain gauge will increase the electrical resistance whereas compressing the strain gauge will decrease the electrical resistance. By measuring the change in electrical resistance the stress within the system is able to be estimated.

5. Optical fibre (Mikasa, Sakuragi et al. 2004)

A flexible piece of optic fibre is used to transmit a pulse of light. The time for the pulse of light to travel the length of the optic fibre is measured and the change in the optic fibre length is calculated.

6. A linear resistor (M.W.Cresswell 1991)

This transducer involves a silicone and brush assembly with a resistor development stretched between two fixed points. A sliding brush reads the resistance as it moves along the resistance wire.

7. Magnetic strip encoder (Schmitt 2004)

A metal ribbon has magnetic signals encoded upon it at 1 mm increments. A sliding magnetic sensor moves along the metal ribbon, reading the position of the sensor in relation to the length of the metal ribbon. At any time (t), the sensor knows its position along the

metal strip by way of the encoded magnetic signals, relative to the starting position and the pre-determined length of the metal ribbon.

A review was undertaken, critically assessing the suitability of the seven identified transducers to record movement of the lumbar spine.

A matrix was developed, ranking the seven different measuring techniques by way of a weighted scoring system. A simple 1, 2 or 3 ranking (with a higher ranking more favourable) was given to each transducer for each of eleven criteria important to the reliability, timeframe and cost of the BSM prototype development. The criteria were: thermal resistance, noise immunity, physical robustness, physical wear, skin movement tracking, cost, hysteresis, resolution, electronic drift, physical resistance and tolerance to moisture.

The aim was to determine the most suitable techniques for measuring lumbar spine movement. The principal investigator conducted a literature review of the different potential methods to gain a high level understanding of each method. Workshops were conducted with both hardware and software engineers to produce a rating score for each of the measuring methods, based on each of the criteria within the selection matrix. As can be seen from Table 4.2, the accelerometer method, the conductive silicone and the inductive coil were ranked higher than the other transducers. The accelerometer method scored 0.86 from a possible 1.0, whilst the inductive coil scored 0.73 and the conductive silicone scored 0.70.

Table 4-2 The matrix used to evaluate the transducers'

Transducer	Accelerometer	Inductive Coil	Conductive Silicone	Strain Gauge	Optical Fibre	Linear Resistor	Magnetic encoder
Thermal resistance	3	2	2	2	2	2	2
Noise Immunity	3	1	1	2	2	1	2
Physical Robustness	3	2	3	1	2	2	1
Physical Wear	3	3	2	2	3	1	1
Skin Tracking	na	2	3	na	1	2	2
Cost	1	3	2	2	1	2	1
Hysteresis	na	2	2	2	na	3	na
Resolution	3	2	2	2	2	1	1
Electronic drift	na	2	2	2	na	2	na
Physical Resistance	na	3	2	2	2	2	3
Tolerance to Moisture	2	2	2	2	2	2	2
Score	18/21	24/33	23/33	19/30	17/27	20/33	15/27
Ratio	0.86	0.73	0.70	0.63	0.63	0.61	0.56

na, not applicable

The matrix selection identified the accelerometers, inductive coil and the conductive silicone as the most suitable transducers with the highest score rating. These three methods were investigated more thoroughly through the building of bench prototypes to examine the reliability, timeframe involved and expenditure for the different transducers.

The BSM concept development, prototype design, laboratory analysis and clinical trial statistical analysis was performed by Andrew Ronchi, with the assistance of Daniel Ronchi. Each of the prototypes had technical input from specialists in who were working in the relevant technical domain. The conductive silicone used in 'Conductive Silicone Polymer' prototype was developed in conjunction with ABAR Rubber, Melbourne, Australia. The 'Inductive Coil' prototype was developed in conjunction with RMIT University Melbourne, Australia. The 'Accelerometer Transducer Board' prototype was developed in conjunction with Total Electronic Solutions, Melbourne, Australia. The prototype testing described within this chapter was performed within a laboratory setting. Phase 1 clinical testing involving human subjects, is described later in Chapters 6 and 7.

4.5 Reliability analysis

The statistical measure used to assess the reliability of measurements provided by tested devices was given by the coefficient of variation (CV) defined as

$$CV = \frac{std(x)}{mean(x)} \quad (4.1)$$

Where $std(x)$ is the standard deviation of measurements x , and $mean(x)$ is the mean value of measurements x (Hopkins 2000). A series of N measurements can be accepted as having an acceptable reliability if the CV value is less than 10% (Atkinson 1998) although this does depend on the type of measurement being assessed. For the purpose of assessing the comparative reliability of three different measurement techniques, all to be used for measuring lower back movement, the CV of less than 10% was deemed acceptable.

Note that in Eq. (4.1), when the $mean(x)$ approaches zero, the CV value increases rapidly to infinity. For that reason, the CV parameter should not be used as a reliability measure for measurements that have the mean value close to zero.

4.6 Flexible conductive silicone polymer sensor

A conductive silicone polymer was the initial technique chosen for consideration as a measurement method for the lower back. The conductive silicone was incorporated into the BSM concept, as displayed in the diagram in Figure 4.2.

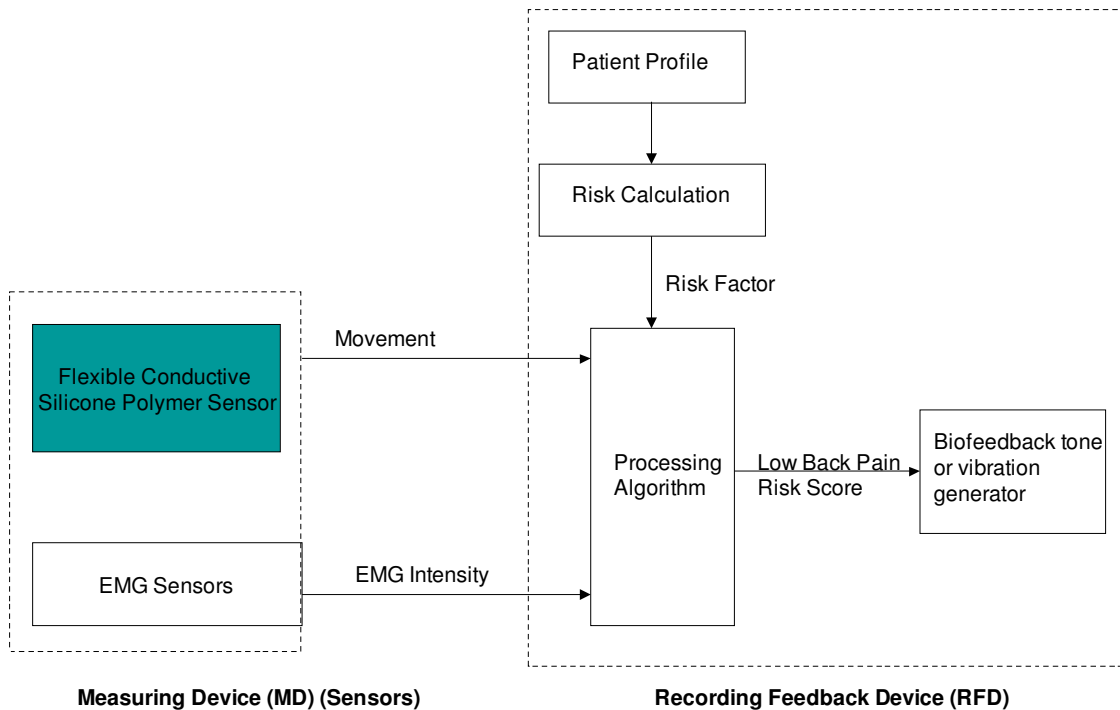


Figure 4.2 The first version of the Back Strain Monitor

The flexible conductive silicone changes its electrical properties as it is stretched. This concept evolved through the awareness that conductive silicone is used as a flexible contact point under the keys on a computer keyboard. The silicone is produced with a conductive element (carbon or silver) throughout the silicone compound. To build a suitable transducer, the conductive silicone needed to be extremely flexible, to allow the silicone to mimic the stretching of the skin on the lower back. From the Modified-Modified Schober (MMS) method that analyses skin stretch of the lower back, it is known that 150 mm of skin between L1 and S1 on the lumbar spine, can stretch as much as 90 mm on a person with a highly flexible lumbar spine, resulting in a total length of 240 mm for the MMS measurement. This equates to a 60% increase in length. Not only does the conductive silicone need to stretch to an additional 60% of its length, but there can only be 50 g of physical tension or resistance at the contact/attachment points at the skin of the lower back.

Silicone is graded in 'Shores' as a measure of its flexibility. More flexible silicones have a lower 'Shore' value. More rigid silicones have a higher 'Shore' value. The manufacturers

(One Stop Plastics, Melbourne, Australia) identified a potential problem with using the more flexible silicones, that is the more flexible the silicone, the more unstable and degradable it becomes when stretched.

Initial bench testing of a variety of conductive silicones aimed to examine whether the flexibility was high enough to allow a 60% stretch with a physical resistance of only 50 g. The conductive silicones available were too rigid at the sample size of 10 mm wide and 2 mm thick. Different widths were tested until the flexibility matched the required resistance of 50 g tension at the attachment point. The sample developed for testing was 2 mm wide and 2 mm thick, yet the sample would break with a load that stretched the silicone to more than 60%. To reinforce the conductive silicone component, a more flexible clear silicone of '30 Shore A' was used, with good results produced in early testing. Figure 4.3 shows the final conductive silicone prototype used for testing. The thin, black conductive silicone runs through the centre of the more flexible, clear silicone.



Figure 4.3 The Conductive Silicone Transducers

4.6.1 Repeatability testing of the conductive silicone

Introduction

Laboratory-based trials were conducted in order to test the performance of the silicone polymer in three ways. First, to assess whether the conductivity of the silicone is continuous

whilst being stretched. Second, to assess whether the electrical resistance for the baseline reading (the resting position of the CSP) remained constant after a repeated stretching, and third, to assess whether the change in electrical resistance between the baseline reading and the maximum stretch position remained constant after repeated stretching.

Method

The experimental set-up for the conductive silicone prototype (CSP) involved attaching the CSP to a fixation device on the lab bench such that the baseline (resting) length was 150 mm. A current was passed through the CSP via a multi-meter connected to either end of the CSP. The length of the CSP could be increased from the baseline position (150 mm) to the maximum stretch position at a length of 250 mm. The electrical resistance corresponding to the baseline CSP length of 150 mm and the maximum stretch of 250 mm were registered using the multi-meter readings. The CSP was stretched 212 times.

Analysis

The statistical analysis used to evaluate the CSP reliability was coefficient of variation (CV), with an acceptable level for reliability analysis of 10% (Atkinson 1998).

Question 1: *Is there a continuous conductivity whilst the CSP is being stretched?*

The aim of this part of the experiment was to record the current through the CSP and to observe if there was a continuous current flow whilst the CSP was stretched from 150 mm to 250 mm.

Test Results: The conductivity of the CSP was constant during the 212 stretch cycles performed (see Table 4.3), with no periods of electrical 'drop out'.

Table 4-3 Number of 'drop outs' or lack of conductivity within the conductive silicone polymer

Number of stretches	Number of outliers	Number of zero readings	% Drop outs (Non- conductivity)
212	0	0	0

Conclusion: The CSP performed well, showing continuous conductivity during 212 stretches from 150 mm to 250 mm.

Question 2: *Does the CSP electrical resistance for the baseline position (150 mm) remaining constant between the repeated stretches?*

The aim of this part of the test was to establish if the coefficient of variation for the baseline readings (between stretches) had a $CV < 10\%$ to ensure the electrical resistance was relatively constant.

Test Results: The CSP was stretched 212 times from 150 mm to 250 mm (total stretch equal to 100 mm). After each stretch, the CSP baseline electrical resistance was measured. Figure 4.4 shows the graph of the CSP resistance for the baseline (150 mm) in Ohms versus the number of stretches for the total 212 stretches.

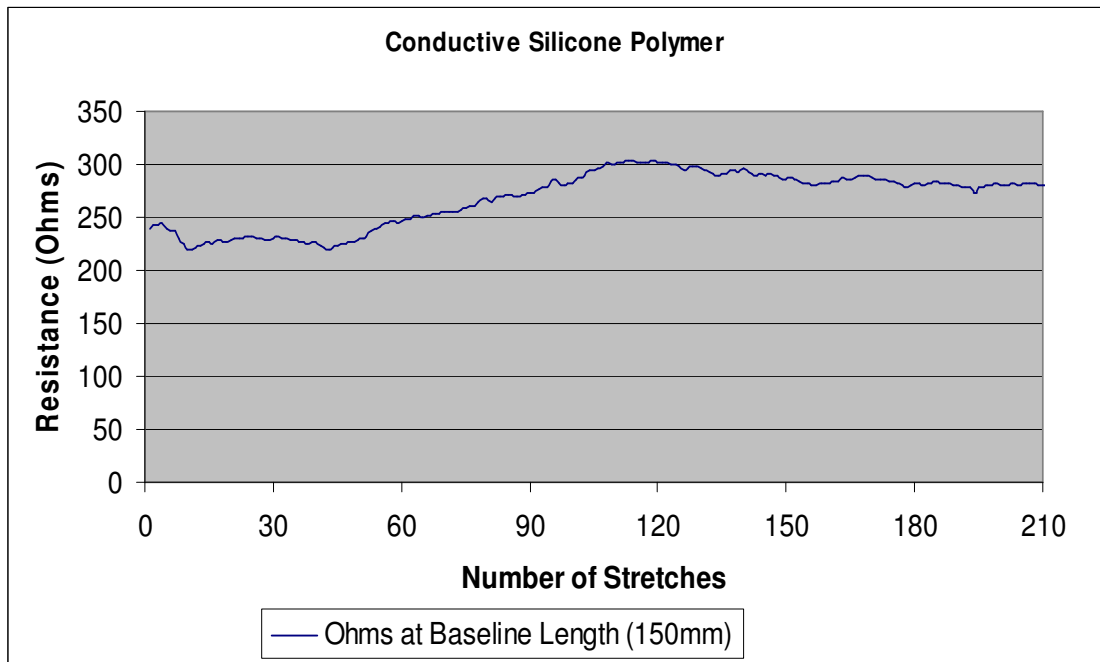


Figure 4.4 The electrical resistance (Ohms) of the baseline readings of the conductive silicone polymer

The coefficient of variation (CV) for the 212 stretches was 9.8%, which lies within the tolerance level of 10%.

Conclusion: The electrical resistance of the CSP for the baseline position (150 mm) of the CSP remained relatively constant during a repetitive stretching process. The CV was within the desired levels.

Question 3: *Did the difference between the CSP resistance for the baseline position (150 mm) and the CSP resistance for the maximum-stretch position (250 mm) remain constant during repeated stretching process?*

The aim of this part of the test was to establish if the coefficient of variation for the changes in the difference between the baseline and the maximum stretch electrical resistance remained within the 10% tolerance level during a repeated stretching process.

Test Results: As the CSP was stretched 212 times from 150 mm to 250 mm (stretch of 100 mm), the CSP electrical resistance at baseline (150 mm) was recorded from the multi-meter. A separate recording of electrical resistance was repeated at the maximum stretch point (250 mm).

During the first 15 stretches, the change in CSP electrical resistance varied between 50 and 63 Ohms. The coefficient of variation for the first 15 stretches was 7.9%, which was within the tolerance level of 10%. Figure 4.5 shows the graph of the change in electrical resistance as the CSP is stretched from 150 mm to 250 mm, for the first 15 stretches.

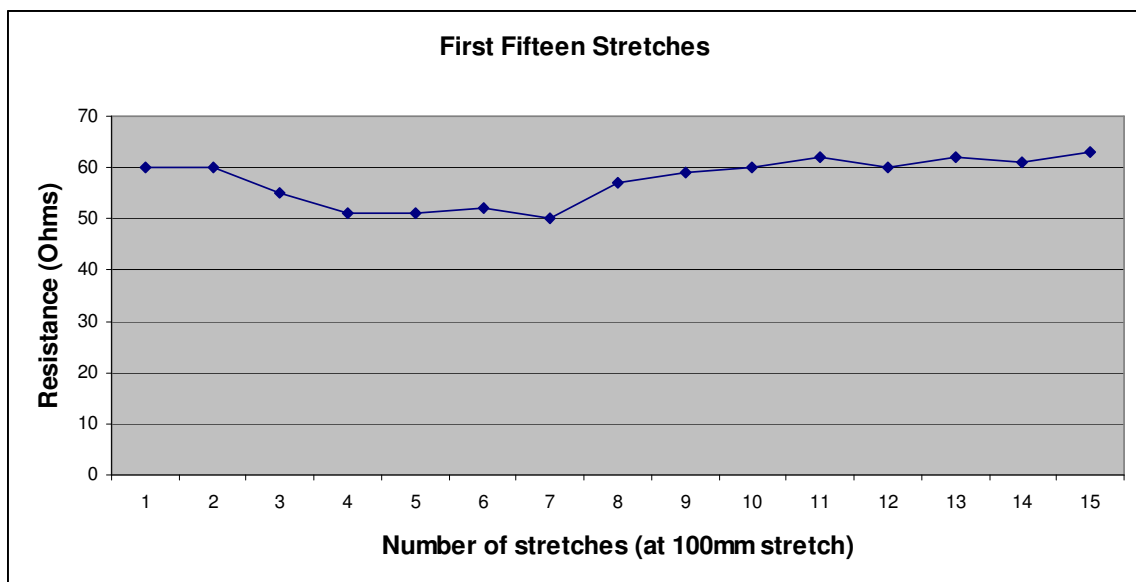


Figure 4.5 The change in resistance (Ohms) versus the number of stretches

As the number of stretches increased from 15 to 212, however, the electrical resistance of the maximum stretch of the CSP started to increase steeply with the number of stretches (see Figure 4.6). For the stretch cycles from 15 to 212, the coefficient of variation (CV) was 49%, well above the tolerance level of 10%.

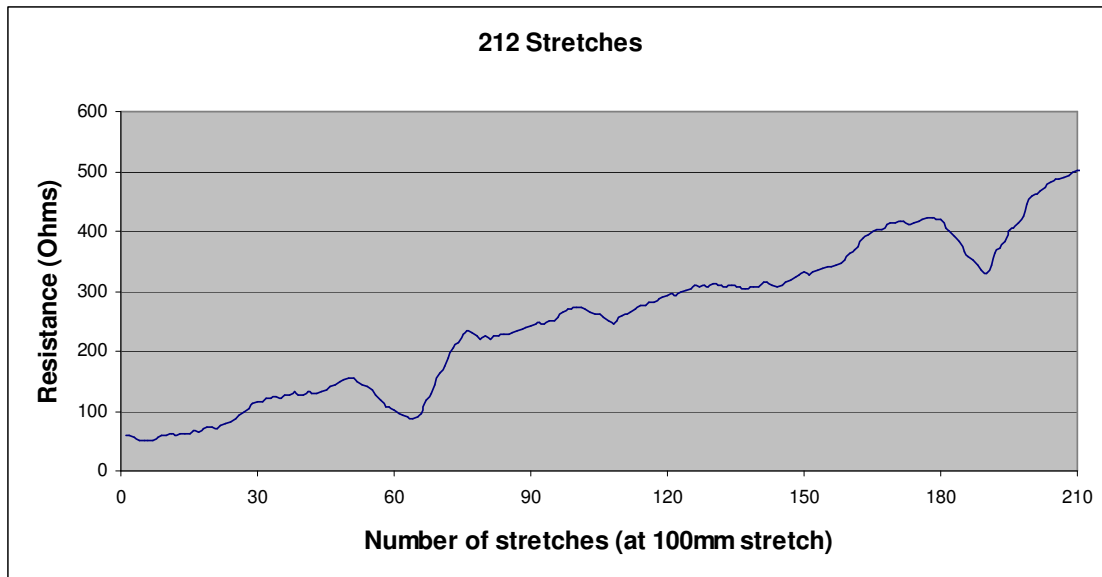


Figure 4.6 The change in resistance (Ohms) versus the number of stretches

Figure 4.7 shows the graph of the CSP resistance for the baseline (150 mm) in Ohms versus the number of stretches (blue line), and the graph of the CSP resistance for the maximum stretch (250 mm) in Ohms versus the number of stretches (pink line).

During the first 15 stretches, the difference between the baseline and the maximum stretch resistance is relatively constant, but after the first 15 stretches the difference between the baseline and the maximum stretch point increase in a non-linear way.

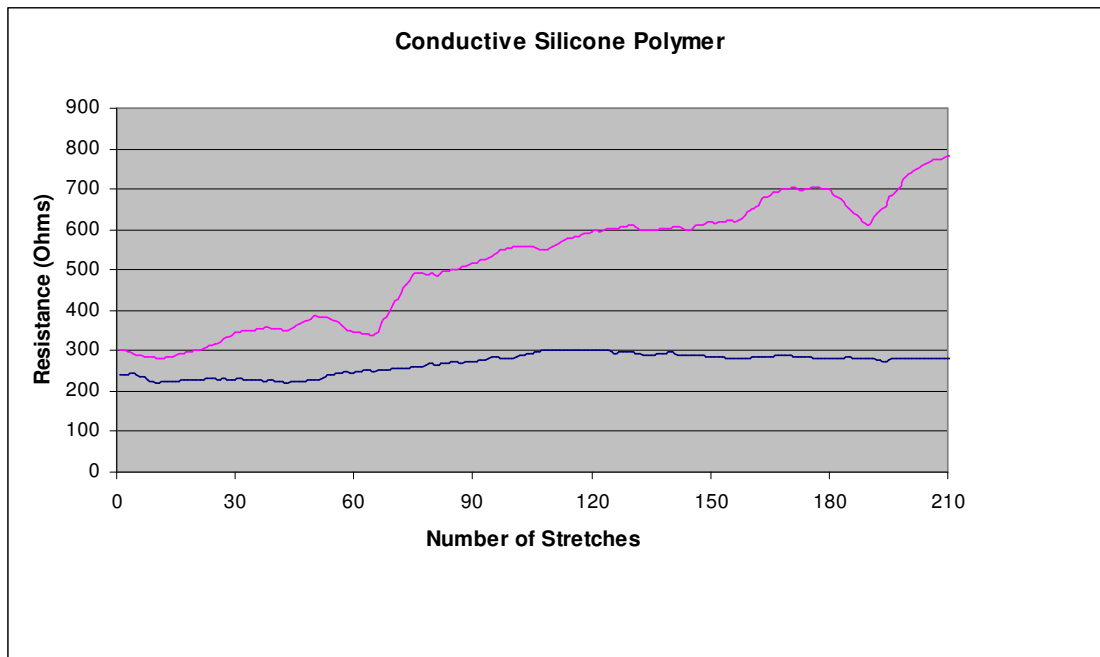


Figure 4.7 The change in resistance (Ohms) versus the number of stretches

(the blue line represents the electrical resistance for the baseline (150 mm CSP length), the pink line represents the electrical resistance for the maximum stretch (250 mm CSP length))

It was considered impractical to determine a mathematical formula relating the baseline resistance to the number of stretches due to the highly unstable nature of the readings when the number of stretches was greater than 15.

Conclusion: The difference between the CSP resistance for the baseline position (150 mm) and the CSP resistance for the maximum-stretch position (250 mm) increased in a nonlinear way during a repeated stretching process. This provides evidence that the electrical resistance readings from the CSP did not provide a reliable measure of longitudinal stretch and may not be appropriate for measuring repeated lower back movements.

Discussion

The laboratory tests concluded that the CSP did not provide a reliable measure of repeated lower back movements and therefore it was not suitable as a movement sensor for the BSM device.

Other drawbacks of the conductive silicone included: high development costs, complex chemical pathways for silicone production and the degradation of the stretching silicone compound in early laboratory trials.

In the laboratory trials there was evidence of conductive silicone degradation. As the silicone was stretched hundreds of times, the physical bonding of the silicone began to show signs of fatigue, possibly leading to the increase in electrical resistance seen during the laboratory trials. With further analysis and research, it became evident that adding carbon black or other conducting elements to silicone, changed the properties of the polymer and the elastic and electrical properties. This caused a large increase in the modulus of elasticity and a decrease in percentage elongation at break point (Skotheim, Elsenbaumer et al. 1997). The silicone itself became plastic, undergoing hysteresis (Bogduk and Twomey 1987) and could not return to its normal length.

There was also an electrical lag that existed when a current was passed through the stretching conductive silicone. This meant that the electrical resistance of the conductive silicone would change with the increasing length but would not revert back to the existing resistance, without a time lag. The time lag for the initial readings was 2-3 seconds, yet by stretch number 130, the time lag was as high as 28 seconds. This response time meant that particular movements would be missed if the CSP prototype was used to assess lower back movements in real time.

There was potential to improve the conductive silicone concept but the projected costs would be too high due to the complexity of developing a purpose-specific silicone. For these reasons, the CSP did not undergo clinical trials on human subjects.

4.7 The Inductive Coil sensor

The second BSM prototype involved an inductive coil technique. The coil was anticipated to be used as a measurement method for lower back movement. At an initial review that involved simple tests within a laboratory setting, the coil showed no sign of degradation with repeated stretching and no obvious electrical lag. Early investigation of the inductive coil concept highlighted low component cost, rapid turnaround time and concept simplicity.

The inductive coil (see Figure 4.8) was incorporated into the BSM concept, potentially replacing the conductive silicone (see Figure 4.3).

The inductive coil measurement system uses a rule of electrical physics, that is, when a conductive coil is stretched, the change in inductance of the coil (with a current running through it) is proportional to its length (Hughes 2002). An example of this type of transducer can be seen in the Rubbery Ruler.

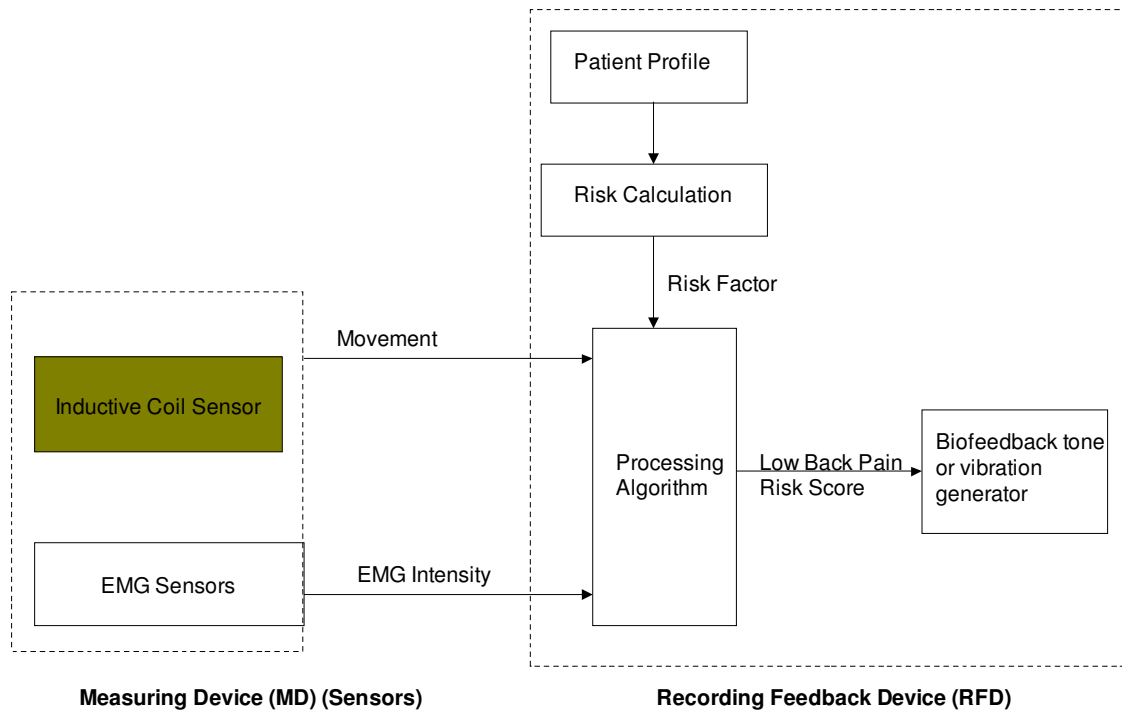


Figure 4.8 The second version of the Back Strain Monitor

4.7.1 Rubbery Ruler device

Cimmino (1990) pioneered a device based on the inductive coil, called the 'Rubbery Ruler' or Flexor, (see Figure 4.9). (Cimmino, Klein et al. 1990)

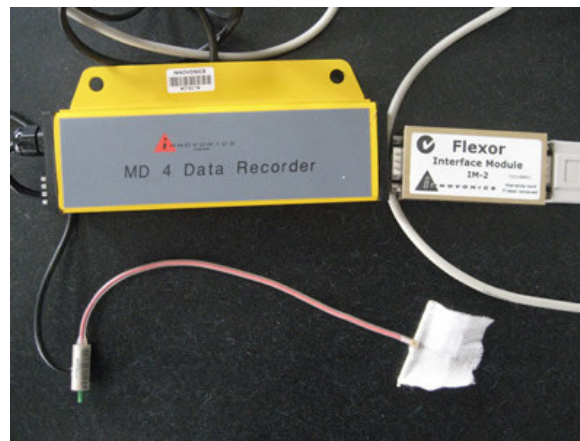


Figure 4.9 The 'Rubbery Ruler' device (also called the 'Flexor')

The Rubbery Ruler used a double helical coil of copper embedded in silicone to monitor displacement as the coil was stretched. The transducer is highly sensitive (to 0.1%), allows

a large range of elongation (more than twice its length) and is non-invasive (Cimmino, Klein et al. 1990).

The Rubbery Ruler is a transducer with a slim sensor, an elastomer body and double helix conductive core. It converts dimensional changes (stretching or compression) of the double helix coil into electrical current (or voltage) variations to provide data output. The current (or voltage) changes are in proportion to the magnitude of stretching or compression. The Rubbery Ruler is lightweight, flexible and durable ranging in length from centimetres to tens of metres.

The Rubbery Ruler is a relatively expensive device (>AUD \$1,500), and comes with its own data processing software. The BSM concept needed a low price movement transducer, to allow for the costs associated with other potential transducers (EMG) and the Recording Feedback Device (RFD). The aim was to keep the manufacturing cost for the entire BSM device, including software and hardware, at a relatively low level (<AUD \$1,000). The complexity of the double helical coil of the Rubbery Ruler allowed very high measurement accuracy that was not necessarily needed for the BSM device, therefore a simpler transducer version was discussed and planned. Concept drawings for a new inductive coil prototype were developed, involving a single helical coil.

4.7.2 The design of the Inductive Coil

The inductive coil was required to elongate to track the skin stretch and curvature of the lower lumbar spine. The intention was to measure the change in stretch of the inductive coil via the change in inductance as the coil was stretched (see circuit diagram in Figure 4.10). The change in length of the coil, in a similar way to the Modified-Modified Schober (MMS) method (see Chapters 3 and 5), would represent the amount of lumbar spine flexion. As with the MMS method, the final measurement would be in millimetres.

The mapping of the voltage change in mV onto the corresponding change of the coil length in millimetres was done during the coil calibration process. This information was then used by the BSM processing algorithm to transform the readings in volts to metres.

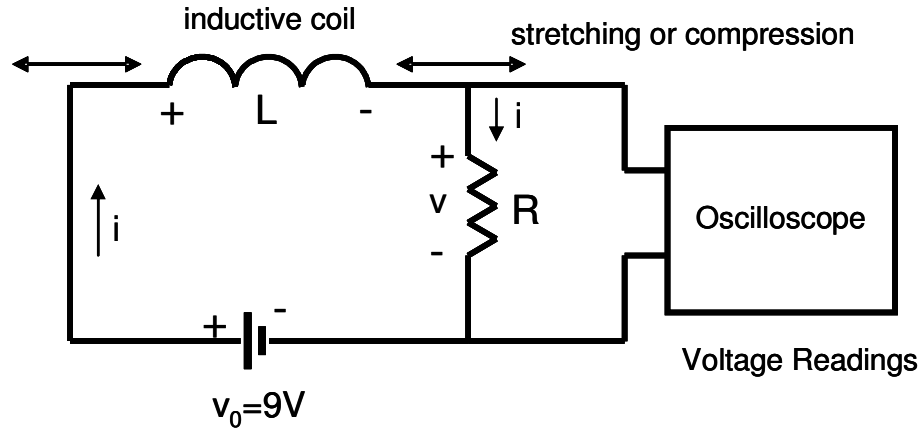


Figure 4.10 The inductive coil circuit

4.7.3 Laboratory calibration of the Inductive Coil

The calibration of the inductive coil uses the rule of electrical physics which states that the length of an inductive coil is proportional to the radius of that coil and the change of inductance. The relationship between a cylindrical coil length l and the corresponding inductance change L is given by the following formula:

$$l = \frac{\mu_0 \mu_r N^2 A}{L} \quad (4.2)$$

or

$$L = \frac{l}{\mu_0 \mu_r N^2 A} \quad (4.3)$$

where:

l - coil length (m)

μ_0 - permeability of free space = $4\pi \times 10^{-7}$ H/m

μ_r - relative permeability of core material

N - number of turns

A - area of cross-section of the coil (m²)

L - inductance in Henries (H)

In the calibration process (Eq. 4.3), a constant voltage $v_0 = 9$ V was connected across the coil and a load resistor R to generate a current flow $i(t)$ through the coil. As the coil length changed by l , an inductance change L was generated (see Eq. 4.2). The corresponding voltage change $v(t)$ across the known load resistor R, was measured. The relationship between the measured voltage $v(t)$ and the corresponding coil length was given by a differential equation, which can be derived from Eq. 4.3. Using the Kirchhoff Voltage Law, we have:

$$-v_0 + L \frac{di(t)}{dt} + Ri(t) = 0 \quad (4.4)$$

The voltage $v(t)$ across the resistor R is given as:

$$v(t) = Ri(t) \quad (4.5)$$

Replacing Eq. (4.5) into Eq. (4.4), we have

$$-v_0 + L \frac{di(t)}{dt} + v(t) = 0 \quad (4.6)$$

or

$$\frac{L}{R} \frac{dv(t)}{dt} + v(t) = v_0 \quad (4.7)$$

Replacing Eq. (4.3) into Eq. (4.7), we can obtain an explicit relationship between the voltage change $v(t)$ in Volts and the corresponding coil length l change in metres:

$$\frac{l}{R\mu_o\mu_rN^2A} \frac{dv(t)}{dt} + v(t) = v_0 \quad (4.8)$$

or

$$l = R\mu_o\mu_rN^2A \left(v - v_0 / \frac{dv(t)}{dt} \right) \quad (4.9)$$

Where:

v_0 – applied voltage (V)

$i(t)$ – current (A)

L – inductance in Henries (H)

R – load resistance

As the term $R\mu_o\mu_rN^2A$ in (4.10) represents a constant coefficient, it can be written as:

$$l = \gamma \left(v - v_0 / \frac{dv(t)}{dt} \right) \quad (4.10)$$

where $\gamma = R\mu_o\mu_rN^2A$

The appropriate value of γ was determined experimentally during the calibration process.

The BSM software package displayed the coil length and the inductance/voltage reading on a computer screen. The algorithm automatically converted the voltage readings in Volts into corresponding coil length changes in millimetres.

The calibration process was performed in laboratory conditions; the coil was placed on the stretching rig such that the initial length of the coil was 150 mm and the corresponding voltage reading was registered. Once a stable length measurement for the coil was

obtained ($150 \text{ mm} \pm 2 \text{ mm}$), the coil was physically stretched, on the testing rig, to 250 mm. The software displayed the new voltage reading for the new coil length. Depending on temperature and how long the circuit had been turned on, the calibration parameters would be modified until the 250 mm reading was accurate to within 2 mm. Once calibrated, the coil would be stretched to the 250 mm marker five more times to ensure the calibration was stable.

4.7.4 Inductive Coil tests

To assess whether the inductive coil could reliably measure longitudinal stretch, three laboratory-based experiments were performed. The first experiment assessed various coils for their physical tension whilst being stretched. This would ensure the coil was able to elongate without significant deformation/stretching of the skin that it would be attached to. The second experiment reviewed the coil durability, both from a mechanical perspective and an electrical perspective. The third experiment assessed the laboratory-based reliability of the Inductive coil technique for measuring linear displacement.

The inductive coil was tested using knowledge derived from performing the MMS method described in Chapter 3. In the MMS method for measuring lower back movement, the lumbar spine measurements are based on a change in length between the upper and lower aspect of the lumbar spine. Body landmarks are used to identify the lower point S1 and the upper point L1, 150 mm towards the head, from the lower point.

Experiment 1: Physical tension at the coil attachments points

Introduction

The aim was to find an inductive coil with 50 g or less of physical tension at the attachment points to the skin, when the coil was stretched to twice its length. The physical tension at the attachment points of the coil to the skin could potentially distort the normal skin

movement and contour. For the Inductive coil to be an ideal transducer, there should be no more than 50 g of physical tension on the skin when the coil is stretched to twice its length. This was verified by testing the amount of tension needed to deform the skin of the lower back by greater than 2 mm.

Method

Four different coils were identified and tested for physical tension whilst being stretched. The coil tension was measured using a Salter scale (Super Samson 5 g to 500 g, Salter Australia, Springvale, Australia). The coil was attached to the Samson scale at one end (Point A) with the stretch zone of the coil lined up with the 0 mm reading on a ruler fixed to the bench (Figure 4.11). The other end of the coil (Point B) was lightly stretched parallel to the ruler until it reached the 150 mm mark on the ruler. This was the starting point for the stretch cycle and the Samson scale was calibrated to zero at this point. The coil was manually stretched until the free end of the coil reached the 300 mm mark on the ruler (Point C) (see Figure 4.12). A reading of the grams of tension was taken from the Samson scale at this point and recorded.

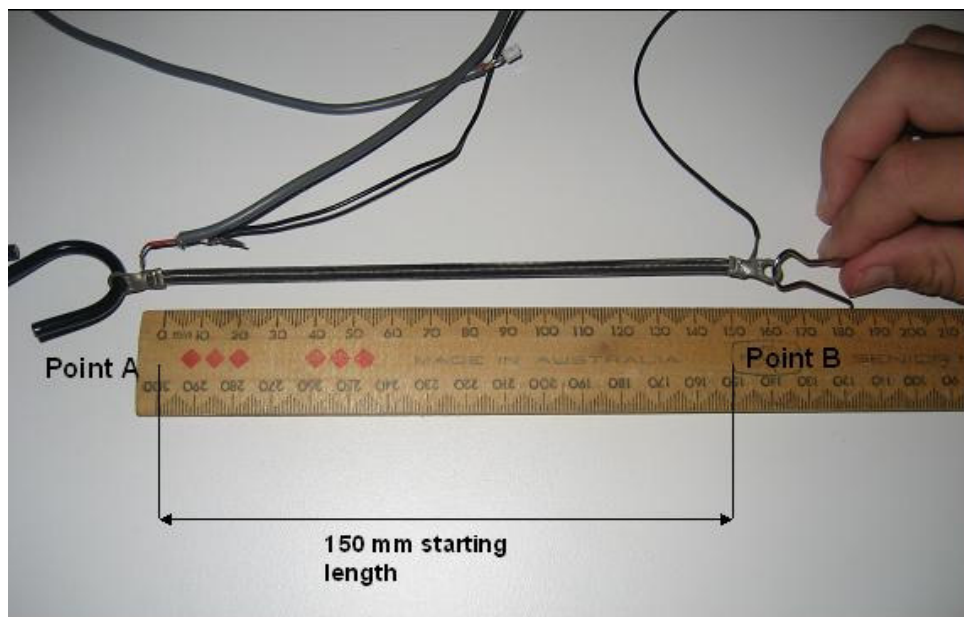


Figure 4.11 The starting point for the Inductive Coil tension test

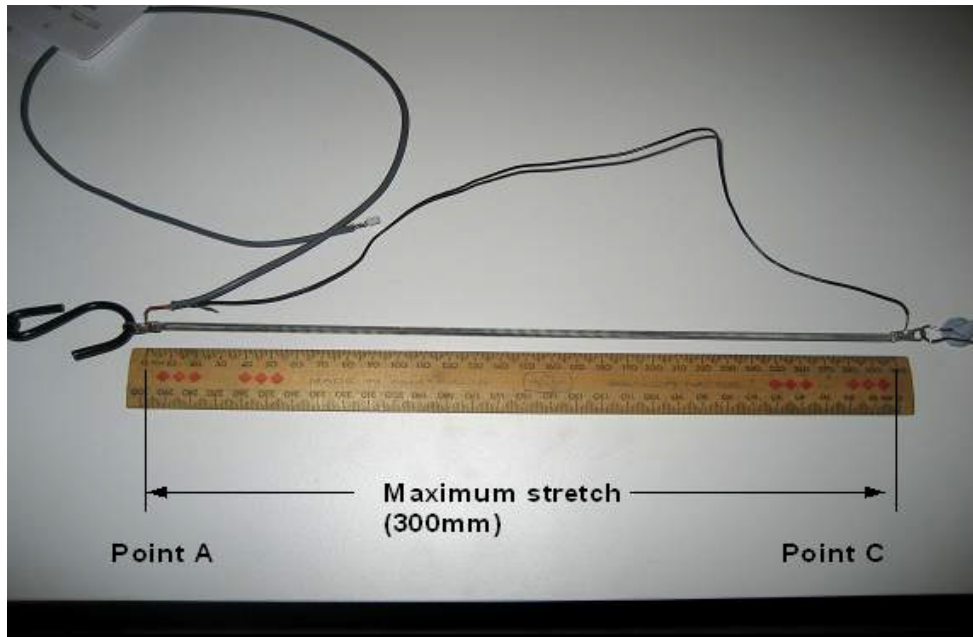


Figure 4.12 The maximum stretch position for the Inductive Coil tension test

Analysis

Visual observation was used to determine the amount of physical tension on the Samson scale when the coil was stretched to twice its length.

Results

The four coils tested are set out in the Table 4.4, showing the diameters of the coil and the gauge of the wire. The amount of physical tension (in grams) needed to stretch the coil to twice its length is displayed. From the table it can be seen that the greater the gauge of the coil wire, the larger the physical tension required to stretch the coil.

Table 4-4 Tension testing on four coils with differing dimensions

Coil Description	Coil Diameter	Coil Gauge	Grams of physical resistance at twice the coil's length
Tungsten Steel	4.0 mm	0.25 mm	35 grams
Tungsten Steel	4.0 mm	0.32 mm	50 grams
Tungsten Steel	5.0 mm	0.40 mm	60 grams
Tungsten Steel	6.0 mm	0.45 mm	65 grams

Conclusion

The coil that satisfied the above criteria was a tungsten spring coil measuring 150 mm in length, 4.0 mm in diameter with 0.25 mm gauge wire.

Experiment 2: Coil durability test

Introduction

Experiment 2 was composed of two parts. The first part reviewed the mechanical durability of the inductive coil. The second part assessed the electrical durability of the inductive coil.

For the inductive coil to be an effective transducer, the coil was required to be able to stretch more than 1,500 times (to simulate a person's movements over a period of 8 hours) without showing signs of mechanical wear or electrical inconsistency. The coil also needed to be able to stretch from 150 mm to 250 mm (100 mm) to allow for the extent of skin distraction in the lumbar spine. The 100 mm of skin distraction is greater than the maximum MMS measurements of the lumbar spine (Williams, Binkley et al. 1993).

Method

In preparation for the durability test, the coil had to be stretched to the maximum allowable length (300 mm) and sprayed with an insulating paint in order to avoid conduction between loops of the coil whilst the coil was at rest or being compressed.

A conducting wire was soldered to either end of the coil, to transfer the low level current through the coil. The conducting wire was arranged in an 's' bend pattern so the wire could elongate to allow the full stretch of the coil, with no tension on the conducting wire. (see Figure 4.13).

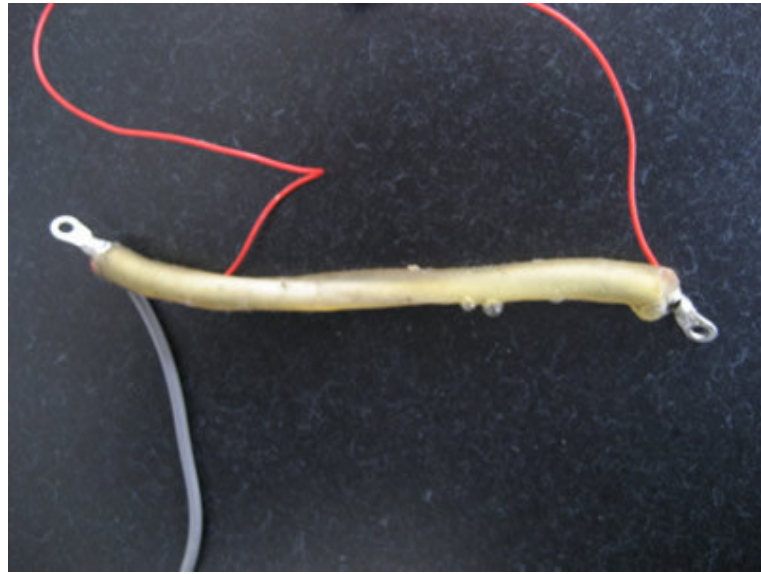


Figure 4.13 The Inductive Coil used for the trial (embedded in an elastomeric gel)

To achieve an accurate recording of inductance, shielding between the coil and the circuitry of the device was necessary. There was a thin layer of copper shielding, placed over the printed circuit board (PCB) of the data logging device (a recording unit for data that isolated the prototype from mains power).

Testing rig

For the purpose of testing mechanical and electrical durability, a testing rig was constructed (see Figure 4.14) involving a straight arm attached to a circular wheel, run by a small, low voltage motor. The end of the straight arm moved between 150 mm and 250 mm from a fixed point. One end of the coil was attached to the end of the straight arm and the other end attached to the fixed point. This movement stretched the coil from the starting length of 150 mm to 250 mm.

The testing rig allowed the coil to be stretched 1200 times per hour (one stretch every 3 seconds). Table 4.5 contains a list of eight time-intervals during which the tests were performed. The time-intervals include four run periods and four rest periods performed over a total of 2 hours, 41 minutes and 18 seconds.

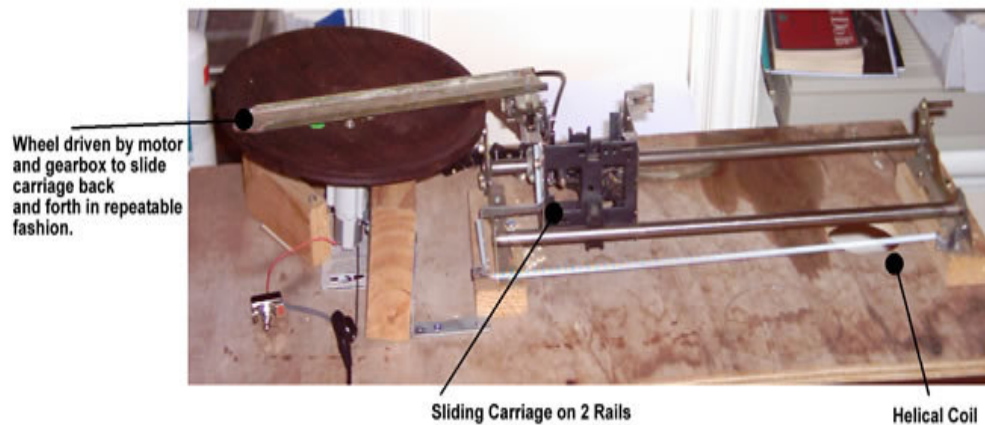


Figure 4.14 The 'testing rig' for stretching the Inductive Coil

The inductive coil device was turned on for the entire duration, whereas the 'testing rig' was turned on and off to instigate the 'run' time and the 'rest' time. During the 'run' period, recordings of coil conductivity and length were taken.

Mechanical durability analysis

Based on the results from the repeated stretching, the mechanical durability was assessed in two ways. First, by the durability of the soldered ends of the inductive coil and second, by testing the amount of mechanical hysteresis in the coil after repeated stretching (coil-length repeatability testing).

Question 1: *Is the solder attachment between the electrical wire and the coil maintaining a solid mechanical connection during and after a large number of repeated stretches?*

Analysis

The strength of the coil connection was manually tested after each of the four runs by physically viewing and applying longitudinal tension to the soldered wire attachment to the coil.

Result

The solder attachment between the Inductive coil and electrical wire was intact with no physical or visual sign of fatigue after repeated stretching.

Conclusion

The solder attachment was adequate to withstand the repeated mechanical durability testing.

Table 4-5 Recordings for the coil durability test using the test rig

Run / Rest Name	Duration Hrs: Min: Sec	No. of Recordings (at 17 samples per sec)	Stretches of Coil (at 1 stretch every 3 seconds)
Run 1	0:09:02	9,517	180
Rest 1	0:03:54	4,121	0
Run 2	0:15:47	16,651	315
Rest 2	0:12:21	13,039	0
Run 3	0:18:58	20,001	380
Rest 3	1:00:17	63,607	0
Run 4	0:27:03	28,528	540
Rest 4	0:13:49	12,423	0
Total	2:41:18	167,887	1415

Question 2: Does the physical length of the coil change after the repeated stretching is complete? That is, does the coil return to the original starting (baseline) length of 150 mm after repeated stretching?

Analysis

The coil baseline length was measured as 150 mm, prior to the repeated stretching. The four run cycles had a total of 1415 repeated stretches (see Table 4.5). After each run cycle,

the length of the coil was measured using the same ruler as was used for the initial measurements. The measurement increments of the ruler were 1 mm and CV was used to analyse the results.

Result

From the recordings of coil length, the CV of the coil length (including the initial coil length) varied by only 1mm on two of the measurements. The CV was 0.4%.

Conclusion

The inductive coil showed no significant signs of hysteresis from the four run cycles.

Electrical durability analysis

The aim of the electrical durability analysis was to find out if there was continuous conductivity in the inductive coil during the stretch testing and if there were consistent voltage readings across the coil as the coil stretched from the baseline length of 150 mm to the required length of 250 mm.

Method

The data for the electrical durability test was taken from Run 4, Table 4.5. There were 540 stretch cycles over 27 minutes with 28,528 recording samples. Figure 4.15 presents a graph of the stretch cycles.

Question 1: *Is there continuous conductivity whilst the coil is being stretched?*

Analysis

A visual review of the excel data spreadsheet was performed to identify any missing data fields or drop outs that may indicate a lack of electrical conductivity.

Result

There were no missing data fields in the spreadsheet.

Conclusion

It was found that there was continuous electrical conductivity in the coil, with no electrical drop outs or missed data fields.

Question 2: *Is there consistent displacement recordings from the coil (mVolts converted to mm) as the coil is stretched from the baseline length of 150mm to 250mm length?*

Analysis

The CV was used to analyse the variance in coil displacement measurements during the repeated stretch in Run 4. A trend line was generated for the data set of 28,528 samples.

Results

It can be observed in Figure 4.15 that during the first 5700 recordings (108 stretches) the voltage readings for the baseline and for the maximum stretch were relatively constant; however after the first 5700 recordings a downward bias was observed. There was a steady decrease in both, the baseline and the maximum stretch readings.

The CV for the entire data set was 5.6% for the 27 minutes of repeated stretching. The voltage difference between the baseline and the maximum stretch reading remained approximately constant.

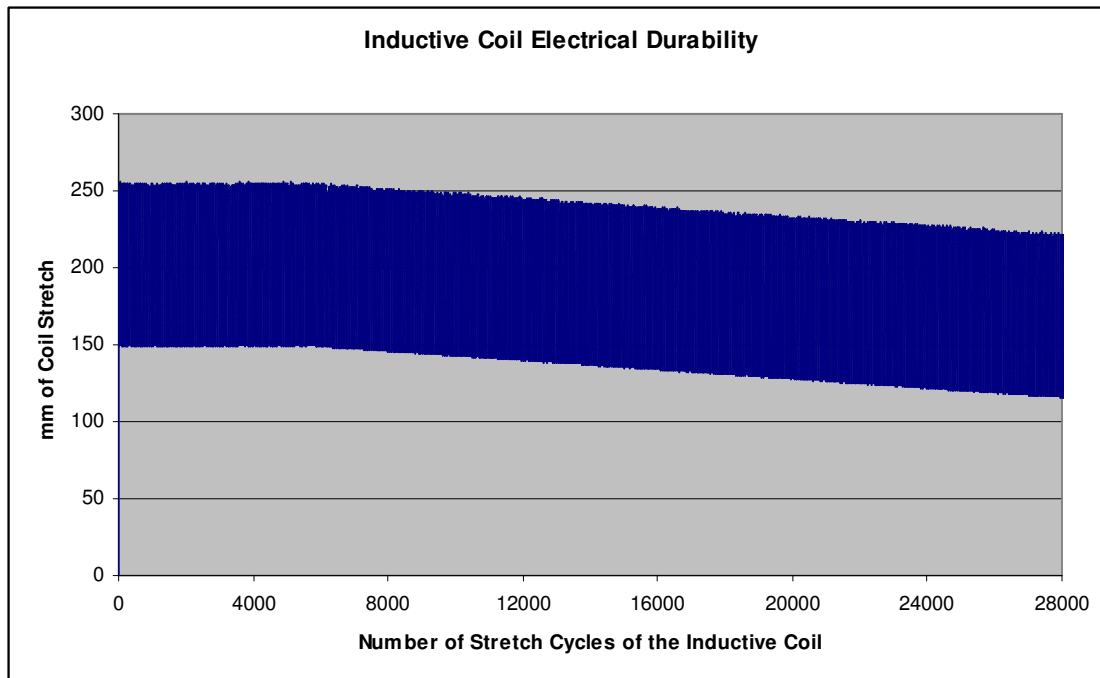


Figure 4.15 The coil durability test showing the coil measurements during the repeated stretching

Conclusion

The consistency and stability of the electrical readings was satisfactory for a relatively short period of time (less than 30 minutes). A CV of 5.6% in 27 minutes, for a device that was to be used for 15- to 30-minute recording sessions, may be acceptable yet the BSM device was planned to be used for 12 to 24 hours. Due to the drift, the current form of the inductive coil was found to be not suitable for long term (> 30 minute) applications. A system compensating for the drift in voltage reading was needed to make the coil more suitable as a movement sensor for the BSM applications.

The drift observed during the electrical durability testing was thought to be related to excessive heat build-up in a component on the printed circuit board, thus affecting the readings of the coil. Changes were made to the circuit that did minimize the drift, yet it was not possible to eliminate it completely. During the clinical trials (see Chapter 6), the circuit had to be turned off between subjects, to minimise the amount of heat build-up.

Experiment 3: Pre-clinical trial electrical reliability test

Introduction

Prior to the clinical trials, the electrical reliability of the improved coil circuit was tested in the laboratory conditions to verify that the software and minor hardware modifications made to the prototype were adequate to conduct the clinical trials.

Method

The stretching rate for the test rig was still at one stretch every three seconds and the sampling rate, for voltage recordings, was increased from 17 samples per second to 44 samples per second. A new formula had also been incorporated into the software in an attempt to rectify the drift experienced in the electrical durability experiment.

The coil was stretched by using the testing rig (see Figure 4.14). Eighteen repetitions were completed, stretching the coil between 150 mm and 250 mm. The initial voltage at the baseline length of coil was set to zero. It was observed (see Figure 4.16) that the baseline readings were not reaching the zero value before the next stretching cycle. However, the readings for the maximum stretch were relatively constant. These results suggested there was an electrical lag in the inductance readings from the coil, in a response to a change in the length of the coil. The electrical lag most likely related to the capacitance remaining within the circuit. The capacitance was able to dissipate when there was a delay between stretch cycles but became more evident when the stretch cycles were more frequent (parasitic capacitance).

Analysis

The coefficient of variation (CV) was used to determine the reliability of the upper stretch limit and the baseline reading of the coil for the eighteen stretch cycles. The 2401 voltage

readings (samples) were examined to determine the maximum and minimum values for each stretch cycle.

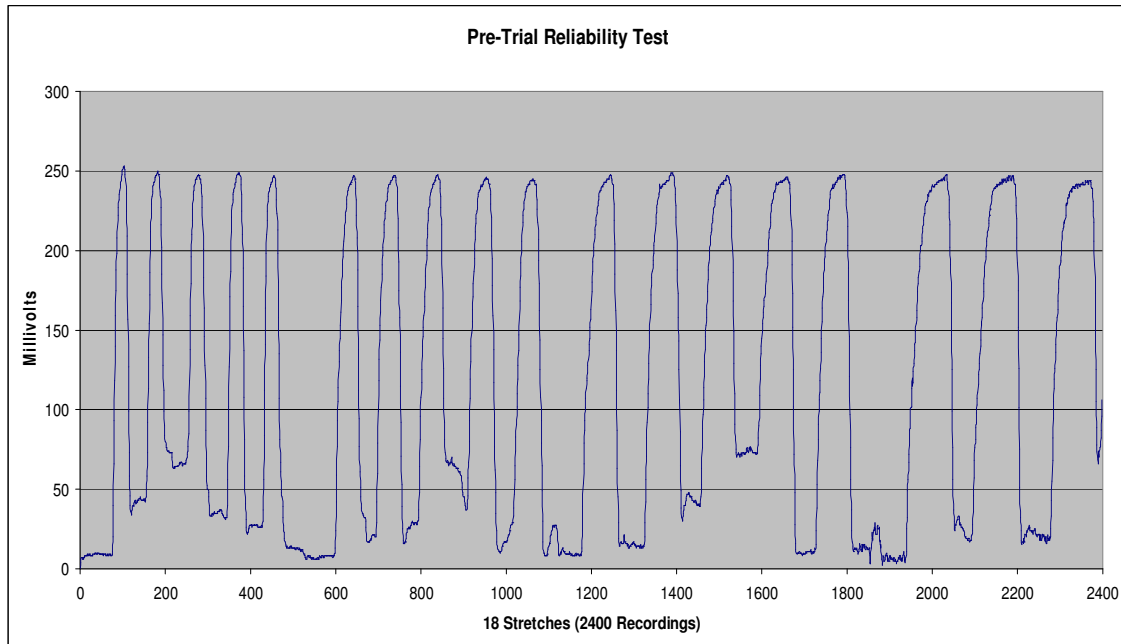


Figure 4.16 Results of the pre-clinical trial reliability test; voltage in mV against the sample number

Results

The maximum and minimum voltage readings for each stretching cycle are illustrated in Figure 4.17. Whilst the voltage readings for the maximum stretch were stable, the baseline readings varied considerably.

The coefficient of variation for the maximum stretch had an acceptably small value of 0.54% (mean = 247.17 ± 1.34). The CV for the baseline on the other hand, had a large value of 81.9% (mean = 23.72 ± 19.44).

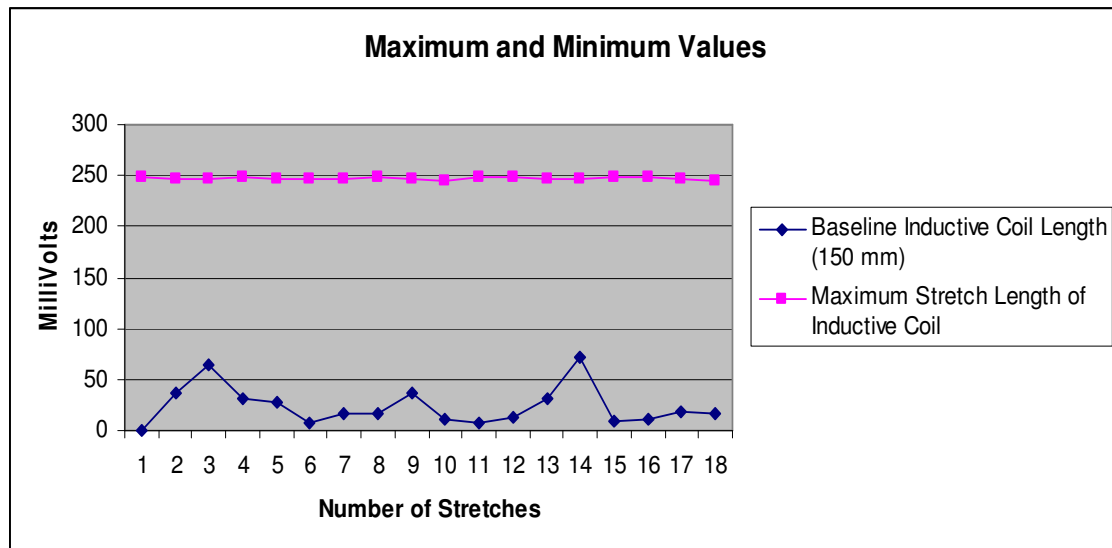


Figure 4.17 The pre-clinical trial reliability test

(Voltage readings in mV for the baseline (blue) and for the maximum stretch (pink) values against the number of stretches)

Conclusion

The recordings for the shorter run of stretches certainly proved more accurate for the upper stretch limit. The reliability for the upper limit stretch reading of the inductive coil was excellent for the eighteen cycles, showing a CV of only 0.54%. The baseline or resting length measurement exposed a different problem. There was a CV of 81.9% which was considerably higher than expected and the upper limit CV.

It was concluded that, although the implemented circuit changes and shortening of the test time improved the reliability of the voltage readings for short duration testing, there was an electrical 'lag' issue with the inductive coil prototype at the baseline point.

Inductive Coil discussion

The inductive coil prototype proved to be a more reliable measuring transducer for the lower back, than the conductive silicone. As seen in Inductive Coil Experiment 1 (4.7.4), a coil was identified that, when stretched to twice its length, placed minimal tension on the attachment points to the skin when stretched. The coil was also durable from a physical

perspective showing no signs of deformation with repeated stretching in Inductive Coil Experiment 2 (4.7.4).

From an electrical perspective, the current flow was continuous yet the electrical resistance reading drifted with repeated stretching or when the device was turned on for longer periods of time, potentially due to overheating of the electrical circuit. To overcome this, the device would need to be turned off between each trial to improve reliability.

Reliability of the inductive coil was examined for a smaller number of stretches, to avoid overheating and to mimic the number of stretches that would be performed in the clinical trials on human subjects. Inductive Coil Experiment 3 (4.7.4) showed the device to have excellent reliability for the upper limit of stretch (CV 0.54%) yet the baseline limit showed considerable variation (CV 81.9%), which could be reduced by further software-based compensation.

In general, it was decided that the inductive coil electrical and mechanical reliability was adequate during laboratory experiments and the inductive coil would be an appropriate transducer for clinical trials. The reliability of the inductive coil prototype was tested during clinical trials that are described in Chapter 6.

4.8 Accelerometer sensors

The review of potential methods for sensing movement of the lumbar spine (see Section 4.4.1) revealed that the method with the highest score (0.86), involved the use of accelerometers. The accelerometers were considered another transducer option for the BSM, potentially allowing inertial forces acting on the upper and lower aspects of the lumbar spine to be quantified. The third version of the BSM, utilizing accelerometers as the movement sensor, is illustrated in Figure 4.18.

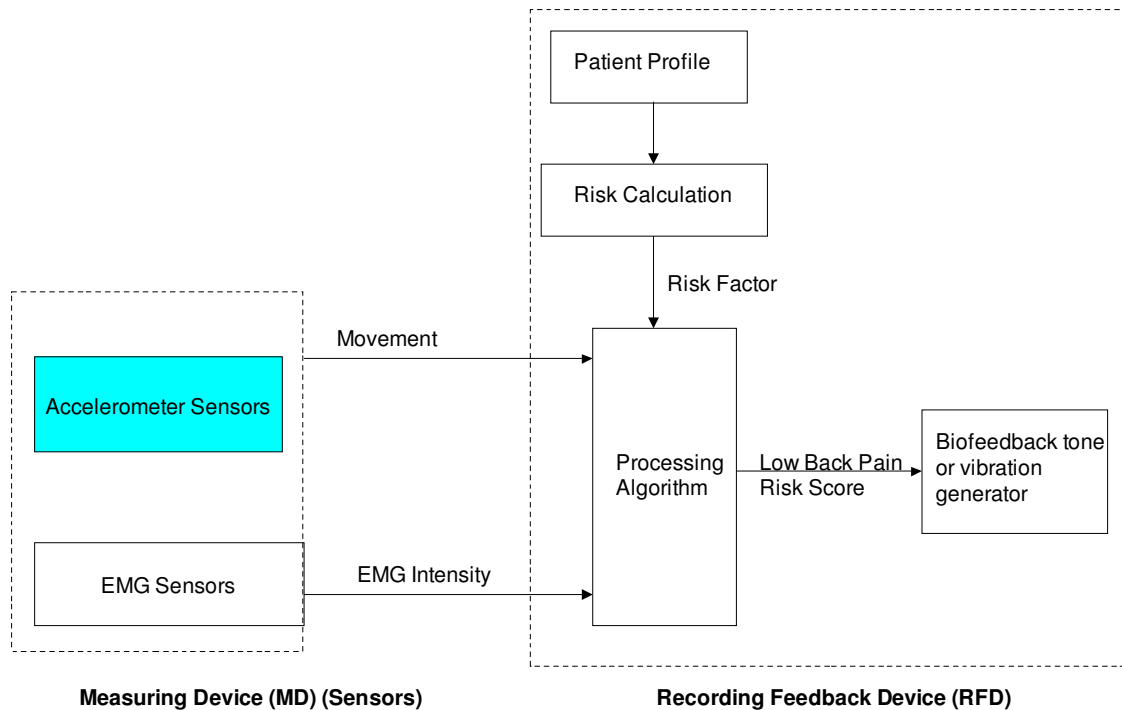


Figure 4.18 The third version of the Back Strain Monitor

The accelerometers measure change in acceleration of a small mass mounted within a tiny accelerometer chip (2 mm x 3 mm x 4 mm) and placed on a printed circuit board (PCB). As the board, and thus the accelerometer, moves from one position to another, the mass experiences acceleration at the start of the movement and deceleration as the movement finishes. The idea was to derive angular measurements of the lumbar spine movement from the accelerometers' readings, as a solution from simultaneous and trigonometric equations.

Accelerometers have a high degree of precision and reliability, having applications in the automotive industry and display linearity with an error smaller than 1% (Marek 2003).

The application of accelerometers opens an opportunity to measure a wider range of the lumbar spine movement including the flexion, extension, right and left lateral flexion, as well as the rotational movements.

Laboratory prototypes of accelerometers were developed by Total Electronic Solutions (Bayswater, Australia), using two, two-dimensional accelerometer chips in an attempt to derive positional changes in three dimensions of movement (see Figure 4.19). The reliability of the accelerometer board was tested in the laboratory conditions, before the technique could be used to measure movement of the lower back.

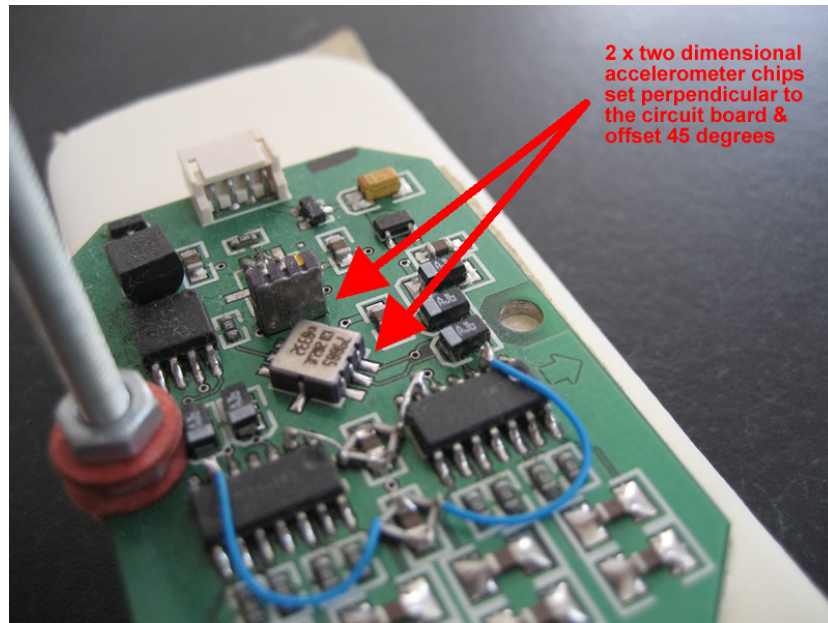


Figure 4.19 The accelerometer printed circuit board with the accelerometer chip highlighted

4.8.1 Laboratory test of accelerometers

Introduction

The laboratory tests investigating the usefulness of accelerometers for the BSM were focused on establishing whether the accelerometers could provide a reliable technique for the measurement of four types of lower back movement: flexion, extension, left lateral flexion and right lateral flexion.

The aim of this experiment was to measure the consistency of the accelerometers' readings during four different movements, simulating four different movements of the lower back.

Method

Initially, the accelerometer PCB was placed on the tripod at the fixed initial position. During the experiment the board was subjected to four different movements. The accelerometers' readings were taken at the initial position, at the maximum positions for each movement and after each return to the initial position.

The consistency of the accelerometers' readings was assessed by calculating the coefficient of variation (CV) between readings. The accuracy of the accelerometer measurements was analysed by calculating the variation between the known measure (the tripod set) and the mean difference of the accelerometer measurement.

The accelerometer board was mounted on a tripod, with a three dimensional rotating platform, allowing the chosen movement to be performed, whilst the other planes of movement remained locked.

The tripod was set with maximum base width and the accelerometer board was mounted to the camera platform with a 90 degree bracket. The alignment of the accelerometer board as adjusted till the platform was vertical (set to a plumb line – see pink string line behind the tripod in Figure 4.20).

The level of the accelerometer board was set via a spirit level (see Figure 4.21) to ensure an accurate starting platform for testing of the accelerometer.

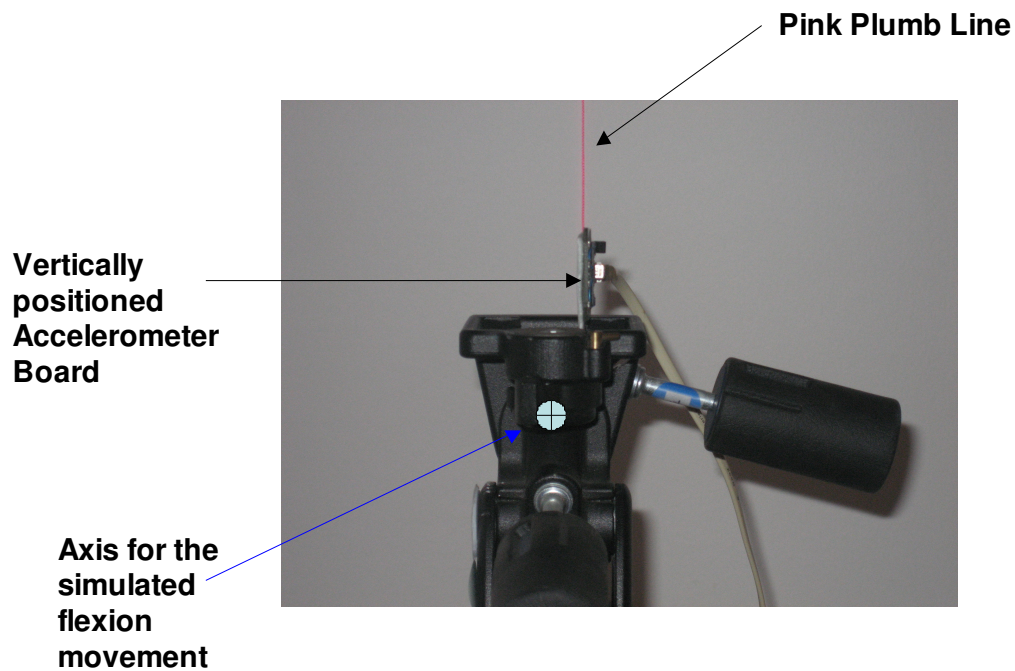


Figure 4.20 Vertical alignment of the accelerometer board using a plumb line

Experimental procedure

The experiment was designed to test the consistency of the accelerometer's readings during four different types of movement (flexion, extension, left lateral flexion and right lateral flexion).

These movements occurred in two separate planes of movement. The forward bending (flexion) and the backward bending (extension) of the spine take place on the sagittal plane of movement (see Figure 4.22). Sideways tilting (lateral flexion) to the left and right side of the body occur on the coronal plane of movement (see Figure 4.22).

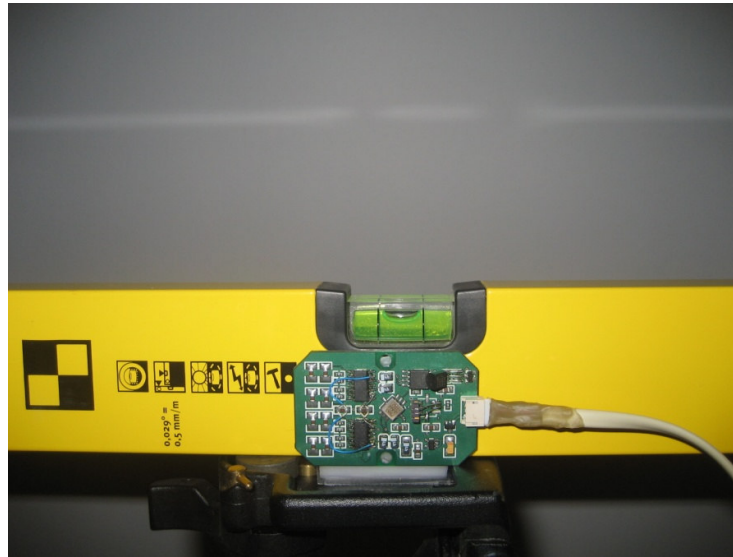


Figure 4.21 Horizontal alignment of the accelerometer board using a spirit level

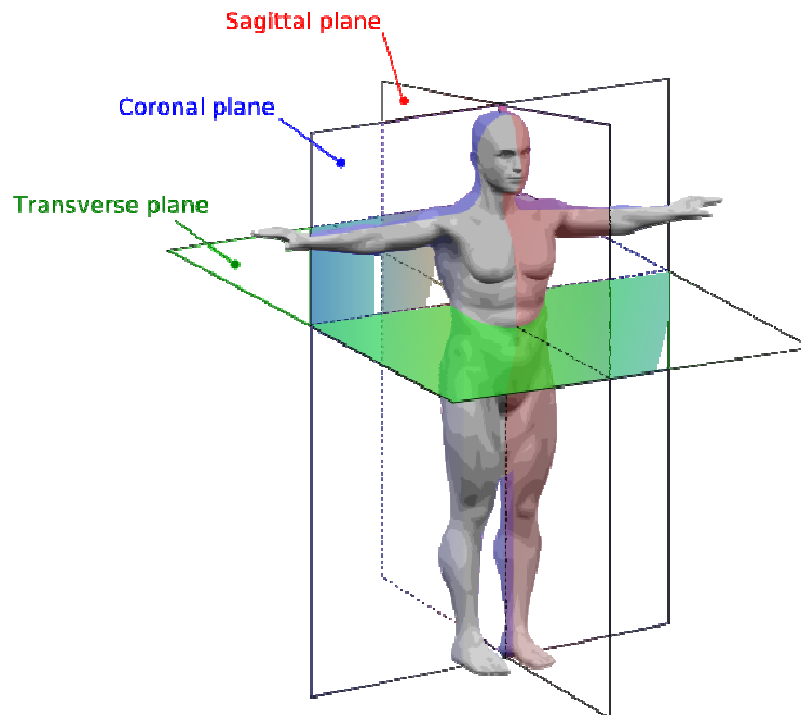


Figure 4.22 The three anatomical planes of movement
(Permission granted, CC-BY-SA, © Yassine Mrabet (2008))

Movement One: Flexion

The tripod allowed the accelerometer board to tilt/rotate forward by +90 degrees until a preset bumper was reached (see Figure 4.23). This bumper determined the 90-degree point for the flexion/forward bending movement. The readings of the accelerometer position were

automatically and continually recorded by the BSM. The accelerometer board was returned to the vertical starting point. This movement was labelled as movement number one, and was repeated ten times.

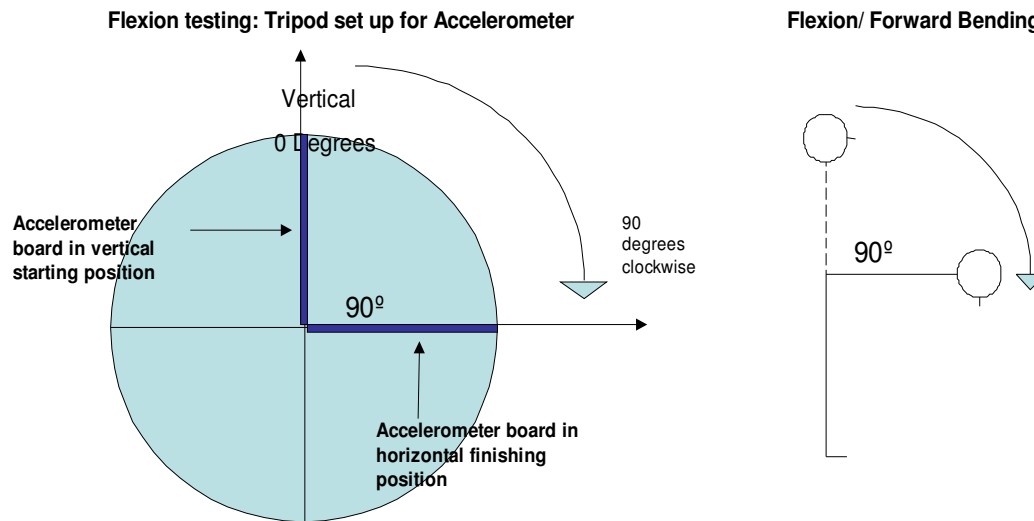


Figure 4.23 Movement 1: Flexion movement to test the accelerometer board

Movement Two: Extension

Next, the accelerometer board was rotated backward (extension) from the vertical position of 0 degrees to the position of -30 degrees in an anti-clockwise direction (see Figure 4.24). Readings were automatically taken by the BSM and the accelerometer was returned to the starting position. This movement was labeled as movement number two, and was repeated ten times.

Following the first two movements, the tripod set up was adapted to allow lateral flexion (sideways tilting) to be tested. The total range of movement that the tripod set up allowed (in the coronal plane) was 60 degrees (including, +30 degrees (clockwise) to -30 degrees (anti-clockwise)). This range of movement closely matched the expected maximum range of movement for lateral flexion of the lumbar spine from previously reported trials on human subjects (Bogduk and Twomey 1987).

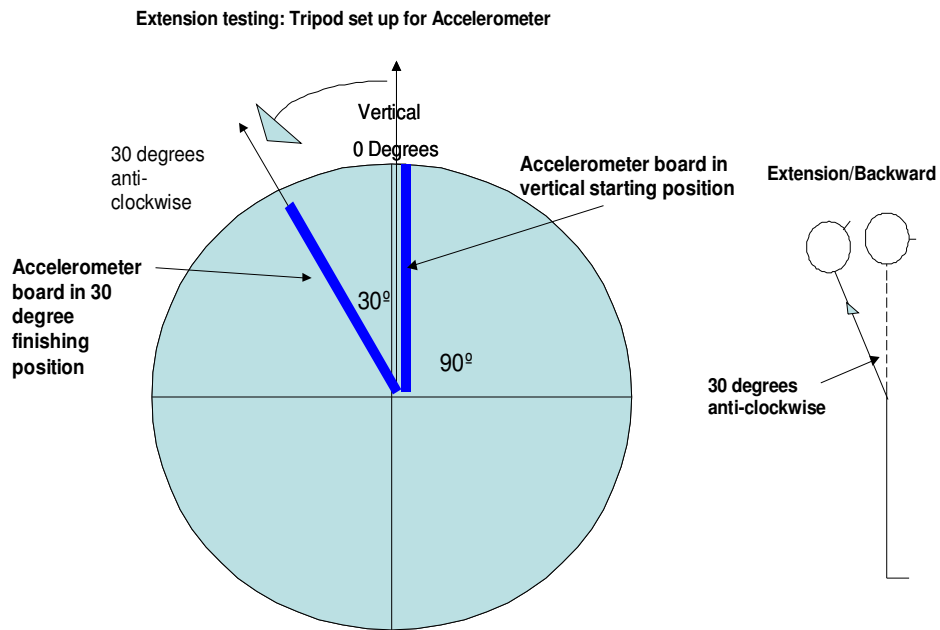


Figure 4.24 Movement 2: Extension movement to test the accelerometer board

Movement Three: Right lateral flexion

The accelerometer board was rotated/tilted from the vertical starting position, +30 degrees in a clockwise direction (right lateral flexion) until the board reached the pre-determined bumper (see Figure 4.25). Readings were automatically taken by the BSM, and the accelerometer was returned to the starting position. This movement was labeled as movement number three and was repeated ten times.

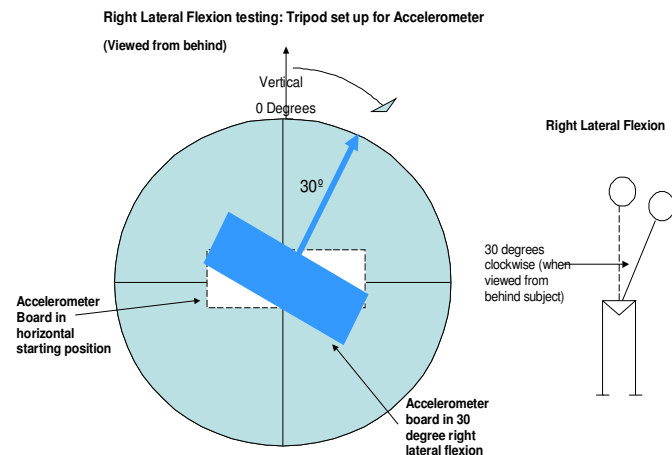


Figure 4.25 Movement 3: Right lateral flexion movement to test the accelerometer board

Movement Four: Left lateral flexion

The accelerometer board was then rotated/tilted from the vertical starting position, -30 degrees in an anti-clockwise direction (left lateral flexion) until the board reached the pre-determined bumper (see Figure 4.26). Readings were automatically taken by the device and the accelerometer was returned to the starting position. This movement was labeled as movement number four and was repeated ten times.

The axial rotation movement of the accelerometer board was not tested during these laboratory tests. In the preliminary trials, measurement errors become evident during rotational movements. Software modifications or use of a gyroscope for the measurement of the rotational movements were considered (see Chapter 5).

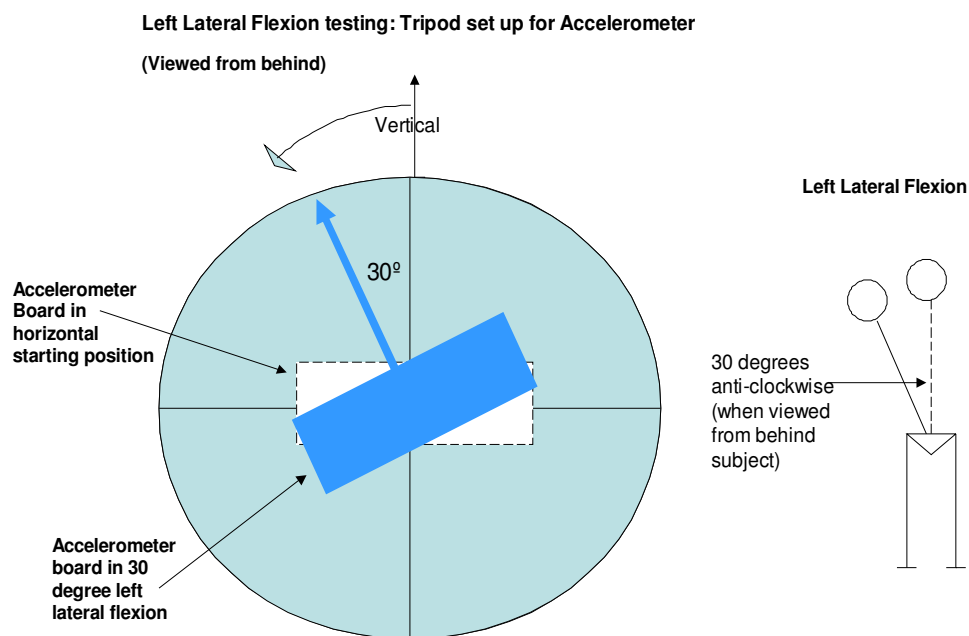


Figure 4.26 Movement 4: Left lateral flexion movement to test the accelerometer board

Analysis

The four different movements (flexion, extension, right lateral flexion and left lateral flexion) were analysed separately using the coefficient of variation (CV) to assess the consistency of accelerometer's readings for each type of movement. As with the previous transducers

(CSP and inductive coil), the readings were accepted as consistent when the corresponding CV value was below 10%.

Results

The results are listed in Table 4.6 through to Table 4.9.

The results suggested that the accelerometer boards provide very consistent with the flexion movement having a CV of 1.2% (see Table 4.6) and the extension having a CV of 2.2% (see Table 4.7).

The accelerometers' readings for the entire range of movement in the case of the lateral flexion movements, also showed high consistency with the right lateral flexion having a CV of 2.4% (see Table 4.8) and the left lateral flexion having a CV of 3.1% (see Table 4.9). The CV values in Table 4.6 through to Table 4.9 for the starting position are marked as N/A. The mean value of readings at the starting position was <0.6 which is close to zero, and the CV is not an appropriate statistical method when the mean value approaches zero (Armstrong, Shen et al. 2007).

The accuracy measure for the accelerometer measurements is calculated by subtracting the known tripod reading from the mean accelerometer reading. For flexion, the mean difference was 0.10° (Table 4.6). For extension the mean difference was 0.11° (Table 4.7). For right lateral flexion the mean difference was 0.47° (Table 4.8) and for left lateral flexion the mean difference was 0.19° (Table 4.9). All mean differences were within one degree.

Table 4-6 Results for the flexion movements

Flexion (clockwise)			
Range of movement	Reading at the starting position	Reading at the finishing position	Range of readings
0 to +90 degrees	0.0	89.9	89.9
0 to +90 degrees	0.3	90.2	89.9
0 to +90 degrees	0.6	90.7	90.1
0 to +90 degrees	0.2	90.6	90.4
0 to +90 degrees	0.7	89.2	88.5
0 to +90 degrees	1.1	88.7	87.6
0 to +90 degrees	0.3	88.9	88.6
0 to +90 degrees	0.2	90.8	90.6
0 to +90 degrees	0.5	91.4	90.9
0 to +90 degrees	0.6	90.6	90.0
Standard Deviation	0.32	0.90	1.06
Mean	0.45	90.10	89.65
Coefficient of Variation	N/A	1.0%	1.2%

Table 4-7 Results for the extension movements

Extension (anti-clockwise)			
Range of movement	Reading at the starting position	Reading at the finishing position	Range of readings
0 to -30 degrees	0.1	-30.5	-30.6
0 to -30 degrees	1.5	-30.1	-31.6
0 to -30 degrees	0.3	-29.3	-29.6
0 to -30 degrees	0.0	-29.4	-29.4
0 to -30 degrees	0.6	-29.7	-30.3
0 to -30 degrees	0.3	-30.2	-30.5
0 to -30 degrees	0.4	-30.6	-31.0
0 to -30 degrees	0.4	-30.7	-31.1
0 to -30 degrees	0.9	-29.4	-30.3
0 to -30 degrees	1.2	-29.0	-30.2
Standard Deviation	0.49	0.61	0.67
Mean	0.57	-29.89	-30.46
Coefficient of Variation	N/A	2.0%	2.2%

Table 4-8 Results for the right lateral flexion movements

Right Lateral Flexion (clockwise)			
Range of movement	Reading at the starting position	Reading at the finishing position	Range of readings
0 to +30 degrees	0.0	28.9	28.9
0 to +30 degrees	0.6	29.4	28.8
0 to +30 degrees	0.4	29.7	29.3
0 to +30 degrees	0.8	28.8	28.0
0 to +30 degrees	0.1	30.1	30.0
0 to +30 degrees	0.7	30.0	29.3
0 to +30 degrees	0.7	29.3	28.6
0 to +30 degrees	1.0	29.1	28.1
0 to +30 degrees	0.3	29.7	29.4
0 to +30 degrees	0.2	30.3	30.1
Standard Deviation	0.33	0.51	0.71
Mean	0.48	29.53	29.05
Coefficient of Variation	N/A	1.7%	2.4%

Table 4-9 Results for the left lateral flexion movements

Left Lateral Flexion (anti-clockwise)			
Range of movement	Reading at the starting position	Reading at the finishing position	Range of readings
0 to -30 degrees	0.1	-28.8	-28.9
0 to -30 degrees	0.7	-28.9	-29.6
0 to -30 degrees	0.3	-29.7	-30.0
0 to -30 degrees	1.3	-30.3	-31.6
0 to -30 degrees	-0.3	-30.6	-30.3
0 to -30 degrees	-0.2	-29.4	-29.2
0 to -30 degrees	0.1	-28.9	-29.0
0 to -30 degrees	0.6	-29.4	-30.0
0 to -30 degrees	0.4	-30.9	-31.3
0 to -30 degrees	-0.4	-31.2	-30.8
Standard Deviation	0.52	0.88	0.94
Mean	0.26	-29.81	-30.07
Coefficient of Variation	N/A	3.0%	3.1%

Discussion

The ability to derive angular changes of the upper and lower aspect of the lumbar spine is a very useful aspect of the BSM. The angular measurements are preferable in comparison to the linear measurements of the skin stretch recorded by the inductive coil and CSP.

Angular measurements are more commonly used within clinical practice and provide a more natural physical interpretation. Angular measurements can be combined together as a vector of measurement values representing 3-dimensional movement parameters. These vectors can be stored in memory and further processed by the BSM device.

The accelerometer board technique has been shown to have a high degree of reliability within laboratory conditions. The accuracy of the accelerometer readings is also high showing less than one degree mean difference between the accelerometer readings and the tripod known measurements.

The measurements of the flexion movement showed least variability and the highest degree of accuracy. This is important because the flexion movement has been shown to be an important contributing factor in the development of LBP (see Chapter 3).

The next stage of the BSM development and testing involved placing the inductive coil (Chapter 6) and accelerometer boards (Chapter 7) on the lower back of human subjects to examine whether it is possible to derive reliable measurements of movements of the lower back in clinical conditions. Prior to the clinical trial chapters, the final form of the BSM device is presented in Chapter 5.

Chapter 5. The current version of the new Back Strain Monitor

This Chapter describes how the current version of the Back Strain Monitor (BSM) device is built and how it works. The focus of the Chapter is on the accelerometers yet the gyroscope, EMG sensors and the Recording Feedback Device are also briefly described. Finally, formats of the data outputs are presented.

There is also a brief description of further developments of the BSM, which includes the Patient Profile and the Numerical Algorithm that will process the sensor's data and calculate an overall risk score for the low back pain.

5.1 Description of the current Back Strain Monitor device

The current BSM device incorporates the Measuring Device (MD) and the Recording Feedback Device (RFD).

The Measuring Device (MD) consists of three different types of sensors: accelerometers, gyroscopes and EMG sensors. In the new version described here, there are two accelerometers, two gyroscopes and two EMG sensors. One three-dimensional (3D) accelerometer (replacing the need for two, 2D accelerometers) and one gyroscope are on the same PCB of transducers called the Measuring Device for Movement (MDM). There is an MDM at both the upper and lower aspects of the lumbar spine (see Figure 5.1 and 5.3). The EMG sensors are individual, portable and wireless with no lead attachments. The EMG sensors are called the Measuring Device for EMG (MDE) and these are positioned on the left and right erector spinal muscle group of the lower back (see Figure 5.1 and 5.3).

The three types of sensors provide the raw measurement data that includes angular movement data from the accelerometers, rotational movement data from the gyroscope and muscle activity (EMG) signals from the EMG sensors.

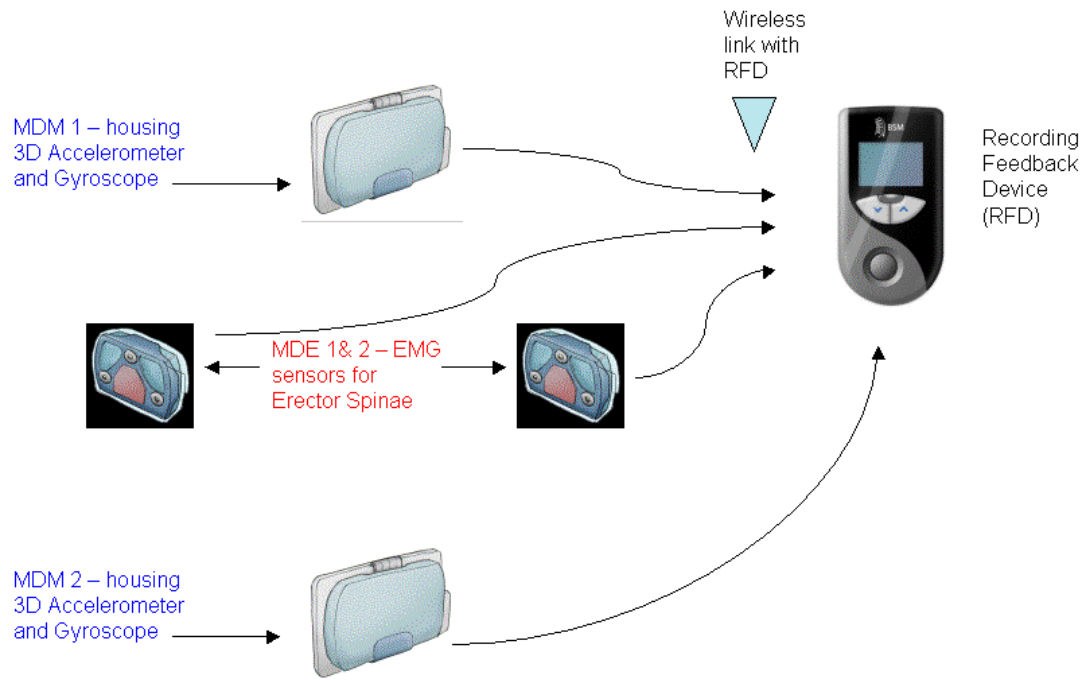


Figure 5.1 The Back Strain Monitor (BSM) device with sensors and the Recording Feedback Device (RFD)

The sensors provide input data to the processing unit of the Recording Feedback Device (RFD). The processing unit or RFD uses a set of patient's data parameters called the Patient Profile (PP), resulting from the clinical interviews with the patient, and determines the risk factor for each patient (see Figure 5.2).

The patient's risk factor together with the raw data from the sensors are processed using a numerical algorithm build into the RFD. The algorithm determines the low back pain risk score for a particular person. If the resultant score is above a pre-determined threshold (based on the PP), real time biofeedback is activated in the form of an audible tone or vibration informing the patient that they are performing movements outside recommended levels. The data recorded by the BSM can also be stored in the memory for later analysis or processing if required.

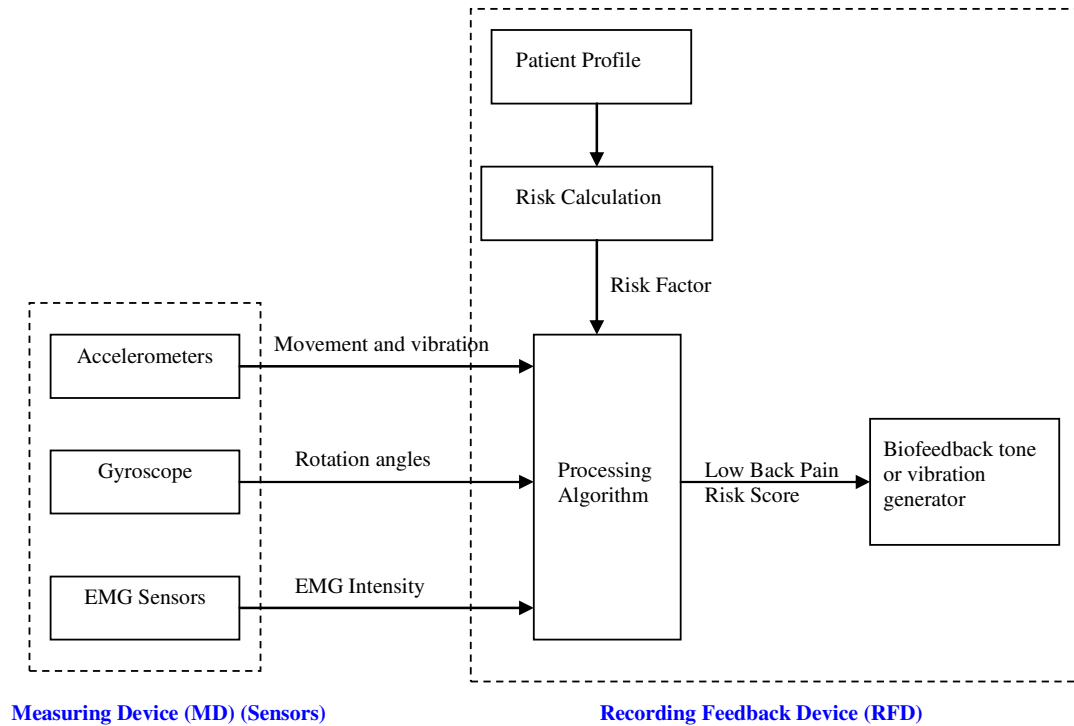


Figure 5.2 Functional flowchart of the Back Strain Monitor (BSM)

5.2 The Measuring Device (Back Strain Monitor Sensors)

The BSM Measuring Device includes three types of sensors: accelerometers, gyroscopes and EMG sensors.

The Measuring Device contains a number of transducers (sensors), whose function it is to measure different parameters characterising movement of the lower back region.

The Measuring Device for Movement (MDM) and the Measuring Device for Electromyographic muscle activity (MDE) are attached to the skin on the lumbar spine of a patient as illustrated in Figure 5.3, using a biocompatible and therapeutically tested adhesive foam.

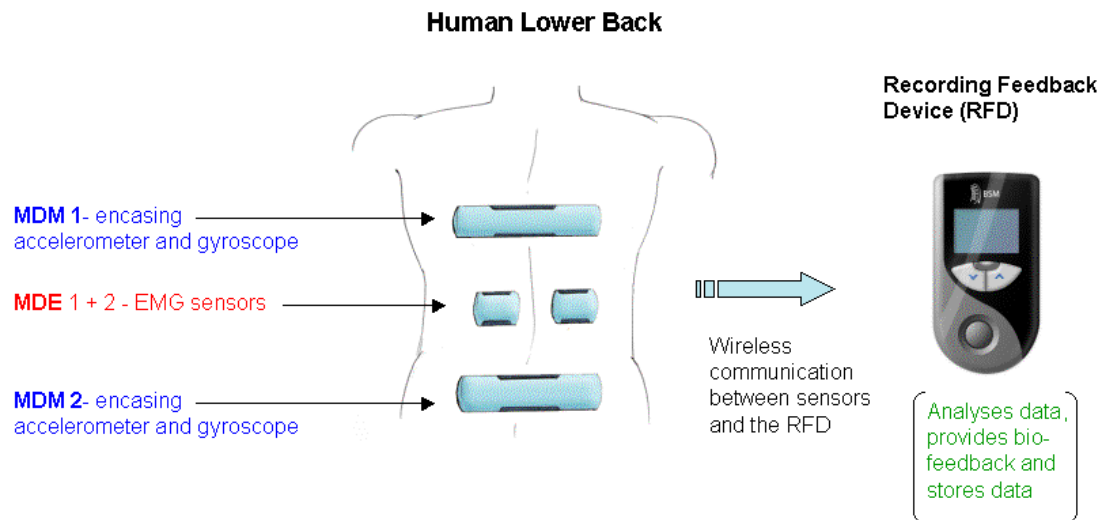


Figure 5.3 Placement of the Back Strain Monitor sensors

The accelerometers and the gyroscope (MDM) provide information about the movement of the lumbar spine about three planes of movement (see Figure 5.4). Using anatomical terminology, flexion and extension movements of the lumbar spine are performed in the sagittal plane. Side bending or lateral flexion occurs in the coronal plane and rotation occurs in the transverse or horizontal plane. From a biomechanical perspective, movements are defined in relation to three imaginary axes, drawn through the body and labelled X, Y and Z (Bogduk and Twomey 1991). Flexion is a rotation around the X axis, lateral flexion is rotation around the Z axis and rotation of the lumbar spine or twisting is rotation around the Y axis.

The description for the accelerometer assessment of movement uses the X, Y and Z axes within the formulas used to derive range of movement of the lumbar spine.

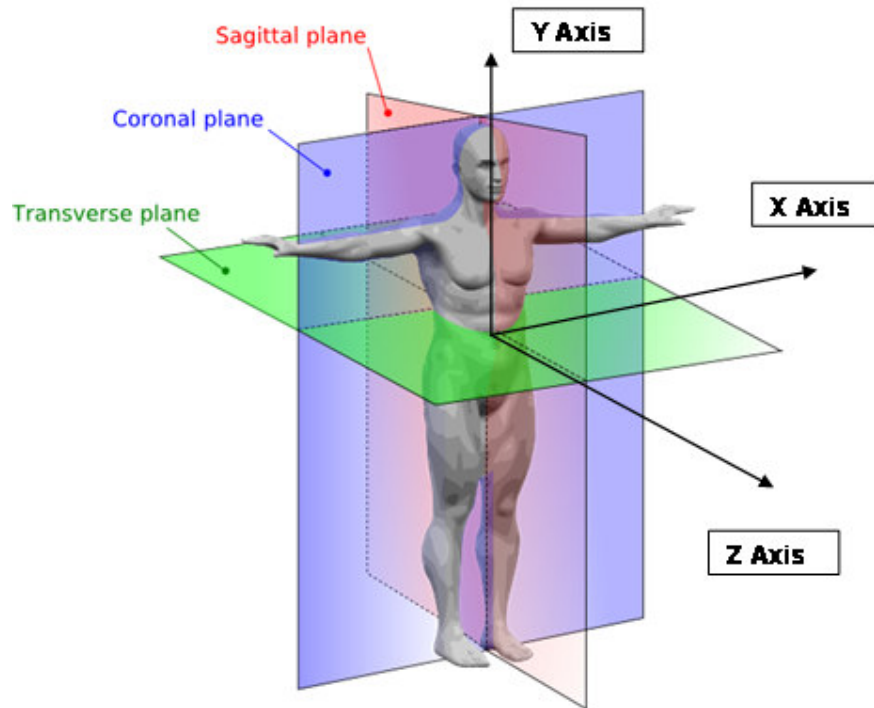


Figure 5.4 Anatomical planes of movement with reference to the three axes (X, Y, Z)

Adapted from Mrabet (2008) (Permission granted, CC-BY-SA, © Yassine Mrabet (2008))

The accelerometers also provide information about:

- Body orientation (lying vs standing vs sitting)
- Vibration (Measured in G forces by the accelerometers from raw data)
- Data on velocity/acceleration of a movement.

The EMG sensors (MDE) capture muscle activity data, which gives an indication of how well the support structures of the spine are working and an indication of when these muscles may be overworked. Each of the sensors is discussed in more detail in the following sections.

5.2.1 Accelerometers

There is one 3D accelerometer chip on each of the two MDM boards, the upper MDM board (MDM 1) and the lower MDM board (MDM 2) (see Figure 5.1 and Figure 5.3). In the earlier

accelerometer laboratory trial described in Chapter 4, two two-dimensional (2D) accelerometers were used for each MDM board. The 2D accelerometers were superseded in the current BSM prototype, by the 3D accelerometers.

Each MDM has a 3D accelerometer mounted on a small PCB measuring 38 mm x 90 mm. One 3D accelerometer is mounted on MDM 1 and is located at the upper end of the lumbar spine (at the level of the first lumbar spinous process – L1). The second accelerometer is mounted on MDM 2 (an identical PCB to MDM 1) and is located at the lower end of the lumbar spine (the first sacral spinous process – S1) (see Figure 5.3). The distance between the two MDMs is 150 mm, measured with a flexible tape measure along the skin of the lumbar spine (as in the Modified-Modified Schober method, see Chapter 3).

The accelerometer method works by calculating the change in angular position of the upper section of the lumbar spine (L1) and subtracting this value from the lower section of the lumbar spine (S1). The difference between the angular outputs of these two accelerometers provides the resultant change in lumbar spine movement, in the three anatomical planes of movement.

For example, when a subject flexes forward, the upper accelerometer (L1) rotates by 40° in a flexion/extension plane (sagittal plane) of movement from its starting position. During the same movement, the lower accelerometer (S1) rotates in the same plane by 10° resulting in $40^{\circ} - 10^{\circ} = 30^{\circ}$ of lumbar flexion range of movement. A more detailed example of the accelerometer calculation of lumbar spine movement is described in Section 5.2.1.3.

Calibration of the accelerometers

The accelerometers are devices designed to measure change in acceleration of a small mass mounted within a tiny accelerometer chip (2mm x 3mm x 4mm) on the PCB.

As the board, and thus the accelerometer, moves from one position to another, the mass experiences acceleration at the start of the movement and deceleration as the movement finishes.

The mass movement is generated by a force F , the value of which is given as a product of the mass m and the corresponding acceleration a .

$$F = ma \quad (5.1)$$

When the force is caused by gravitation, then the acceleration has a known constant value $g = 9.8 \text{ m/s}^2$. The corresponding force is called the gravitational force F_{grav} , and it is given as:

$$F_{\text{grav}} = mg \quad (5.2)$$

The accelerometer converts the force into an electrical signal with amplitude given in millivolts (mV) that is proportional to the force (or acceleration values). The mapping from the particular force (or acceleration) values to the corresponding voltage values is done during the calibration process.

Calculation of gain p and offset o

The calibration process assumes that the acceleration is a linear function of the measured voltage value v , and therefore, can be written as:

$$a = pv + o \quad (5.3)$$

Where the constant values of the gain p and the offset o are unknown and have to be determined during the calibration process.

Since there are two unknowns to be determined, two equations are needed to determine their values.

The first equation is given by the calibration setup in which the voltage v_a is measured when the mass acceleration is caused by the gravitational force, so the corresponding acceleration is known and is equal to $g = 9.8 \text{ m/s}^2$.

This gives the first equation as:

$$g = pv_a + o \quad (5.4)$$

The second equation is given by the calibration setup in which the voltage v_d is measured when the mass initially accelerated by gravity decelerates. The corresponding acceleration in this case is equal $g = -9.8 \text{ m/s}^2$. This gives the second equation as:

$$-g = pv_d + o \quad (5.5)$$

Solving the set of equations (5.4) and (5.5) for p and o, we have:

$$p = \frac{2g}{v_a - v_d} \quad (5.6)$$

and

$$o = g - v_a p \quad (5.7)$$

or

$$o = g - v_a \left(\frac{2g}{v_a - v_d} \right) \quad (5.8)$$

The values of p and o are calculated for each axis x , y and z . Thus the calibration process gives six constant values: p_x, o_x , p_y, o_y , and p_z, o_z .

There are two calibration constants for each channel and three channels per sensor. This means there are six sets of constants determined for each accelerometer during the calibration process.

From acceleration to the displacement angles

The linear displacement values x_0 , y_0 and z_0 corresponding to the voltages v_{x0} , v_{y0} and v_{z0} measured during the gravitational acceleration are calculated using Eq. (5.3).

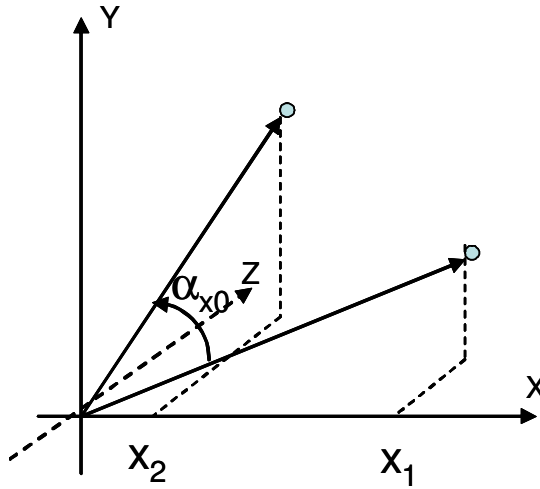


Figure 5.5 Linear displacement $x_0 = x_2 - x_1$ along the X-axis

As illustrated in Figure 5.5, the linear displacement along the X-axis is given as $x_0 = x_2 - x_1$.

Replacing the acceleration value along X-direction in Eq. (5.3) by a_{x0} , we have

$$a_{x0} = p_x v_{x0} + o_x \quad (5.9)$$

During the calibration process, the acceleration a_{x0} is:

$$a_{x0} = g = \frac{x_0}{(\Delta t)^2} \quad (5.10)$$

Assuming that the time interval corresponding to the calibration measurement is of unit value (i.e. $\Delta t=1$), Eq. (5.9) changes to:

$$x_0 = p_x v_{x0} + o_x \quad (5.11)$$

In a similar way, the displacement values along Y-axis and Z-axis can be determined using:

$$y_0 = p_y v_{y0} + o_y \quad (5.12)$$

and

$$z_0 = p_z v_{z0} + o_z \quad (5.13)$$

The linear displacement values x_0 , y_0 and z_0 are then used to determine the corresponding angular displacements α_{x0} , α_{y0} , and α_{z0} . This is done using the following formulas:

$$r_0 = \sqrt{x_0^2 + y_0^2 + z_0^2} \quad (5.14)$$

$$\alpha_{x0} = \tan^{-1} \left(\frac{x_0}{\sqrt{y_0^2 + z_0^2}} \right) \quad (5.15)$$

$$\alpha_{y0} = \tan^{-1} \left(\frac{y_0}{\sqrt{x_0^2 + z_0^2}} \right) \quad (5.16)$$

$$\alpha_{z0} = \tan^{-1} \left(\frac{z_0}{\sqrt{x_0^2 + y_0^2}} \right) \quad (5.17)$$

From the raw accelerometer data, vibration affecting the human lumbar spine can be calculated as well as the body orientation. The device will be able to estimate whether the subject is upright, lying prone or supine, or upside down. The velocity and the acceleration of the whole body, such as running speed, may be derived from the raw data although these calculations are beyond the scope of this thesis.

Calculation of the initial angles of the lumbar spine

To measure the movement of the spine, the starting position (or initial angle) needs to be known. These initial angles are determined during the accelerometer calibration process.

The starting position is chosen to be an erect standing position. The angles between the gravity axis and the X axis, the Z axis and the Y axis are measured at this position to provide the reference point (zero) for the further measurements of the lumbar spine movement. The calibration process is performed automatically by the BSM by pressing the calibration button.

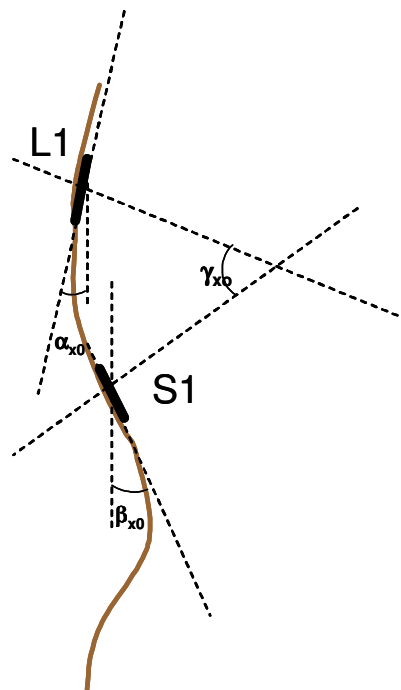


Figure 5.6 Calculation of the initial flexion angle flexion angle γ_{xo}

Figure 5.6 illustrates the calibration process for the initial flexion angle. In order to determine the starting position for the lumbar spine, in the flexion plane of movement (i.e.: rotation in the sagittal plane, occurring around the X axis), the accelerometers at L1 and S1 measure the initial angles (eg: Flexion angle at L1 = α_{x0} and flexion angle at S1 = β_{x0} respectively for the erect standing position). The initial flexion angle γ_{x0} is then determined as:

$$\gamma_{x0} = \alpha_{x0} - \beta_{x0} \quad (5.18)$$

The same measurements are done for the initial lateral flexion angle γ_{y0} and the initial rotation angle γ_{z0} . The values of the initial angles $\alpha_{x0}, \beta_{x0}, \alpha_{y0}, \beta_{y0}, \alpha_{z0}, \beta_{z0}$, are then derived from the measured acceleration values.

Measurements performed by accelerometers

The aim of using the accelerometers is to derive three angles of movement. These include an angle between the direction of gravity axis and the flexion plane of movement (X axis), an angle between the direction of gravity axis and the lateral flexion plane (Z axis) and an angle between the direction of gravity axis and the rotation plane (Y axis) (see Figure 5.4).

Determining the lumbar spine position

Once calibrated, the device is able to calculate the change in flexion angle by subtracting the top accelerometer flexion angle from the bottom accelerometer flexion angle. The result gives the new flexion angle of the lumbar spine with respect to the calibration value (zero).

This procedure is illustrated in Figure 5.7, where the flexion angle y is calculated.

Let us assume that α_{x0} and β_{x0} denote the flexion calibration position of the accelerometer L1 and S1 respectively, and $\alpha_x - \alpha_{x0}$ and $\beta_x - \beta_{x0}$ correspond to the flexion angle measured by accelerometer L1 and S1 respectively.

We can now derive the formula for the flexion angle γ_x .

According to Fig.5.7, The flexion angle γ_x is:

$$\gamma_x = 180^\circ - (\varepsilon + \varphi) \quad (5.19)$$

where

$$\varphi = (180^\circ - (90^\circ - (\beta_x - \beta_{x0}))) = 90^\circ + (\beta_x - \beta_{x0}) \quad (5.20)$$

$$\varepsilon = 90^\circ - (\alpha_x - \alpha_{x0}) \quad (5.21)$$

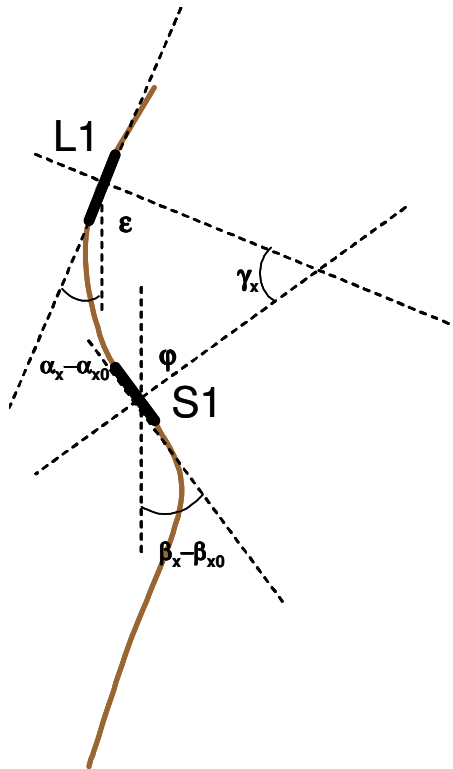


Figure 5.7 Calculation of the flexion angle γ_x

Replacing Eq.(5.3) and Eq.(5.4) into Eq.(5.2), we have

$$\gamma_x = 180^0 - (90^0 - (\alpha_x - \alpha_{x0}) + 90^0 + (\beta_x - \beta_{x0})) = (\alpha_x - \alpha_{x0}) - (\beta_x - \beta_{x0}) \quad (5.22)$$

or simply

$$\gamma_x = (\alpha_x - \alpha_{x0}) - (\beta_x - \beta_{x0}) \quad (5.23)$$

The (5.6) can be also written as:

$$\gamma_x = (\alpha_x - \beta_x) - \gamma_{x0} \quad (5.24)$$

where γ_{x0} is the initial flexion angle calculated during the calibration process using Eq.(5.1).

Equation 5.24 shows that the flexion angle movement is given as a difference between flexion angle measured by the accelerometer L1 and the flexion angle measured by the accelerometer S1.

Similar derivations can be done for the lateral flexion angle γ_y and the rotation angle γ_z .

These three angles γ_x , γ_y and γ_z , define the lumbar spine position at a given point in time.

Determining the lumbar spine movement

The lumbar spine movement is defined as a change of lumbar spine position within a given time interval t_2-t_1 , where $t_2>t_1$. Therefore the lumbar spine movement is measured as a difference in angular position calculated between t_1 and the angular position calculated at t_2 (see Figure 5.8 and 5.9).

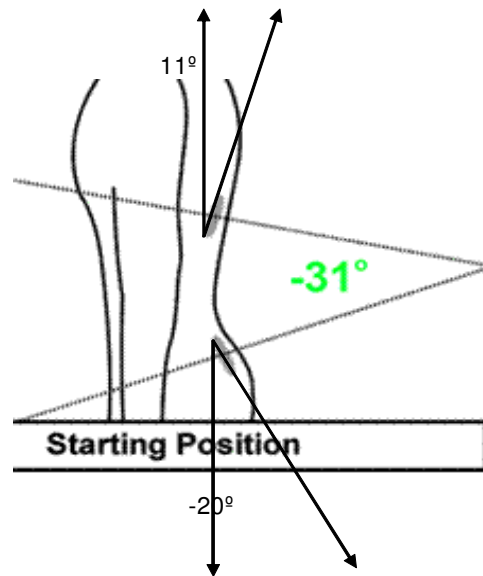


Figure 5.8 Calculation of the starting position for the lumbar spine (-31 degrees)

The patient then flexes forward to a comfortable finishing position. The top accelerometer angle is now -82° (rotating anti-clockwise from the vertical). The bottom accelerometer angle is now -69° (rotating anti-clockwise from the vertical). The resultant angle in a sagittal plane (for the finishing position) is $-69^\circ - (-82^\circ) = +13^\circ$.

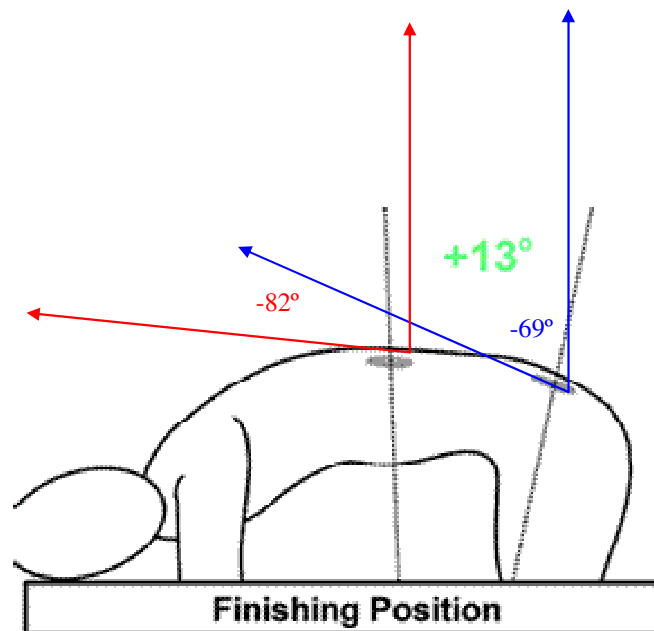


Figure 5.9 Calculation of the finishing position for the lumbar spine ($+13$ degrees)

The total range of the lumbar spine movement from the starting position to the finishing position is calculated as the angular difference between the two positions at an angular level. Mathematically this is represented as: $-31^{\circ} - (+13^{\circ}) = -44^{\circ}$ (anti-clockwise)(see Figure 5.10.). From a visual perspective, the range of movement seems far greater than 44 degrees. The subject looks to bend forward to approximately 90 degrees. Note that 44 degrees of movement occurs at the lumbar spine and the remaining movement occurs at the hip joints and in the thoracic spine. The accelerometers are able to gauge the relative angular change of position of the lumbar spine, between the approximate spinal levels of L1 to S1, without being influenced by hip and thoracic spine range of movement.

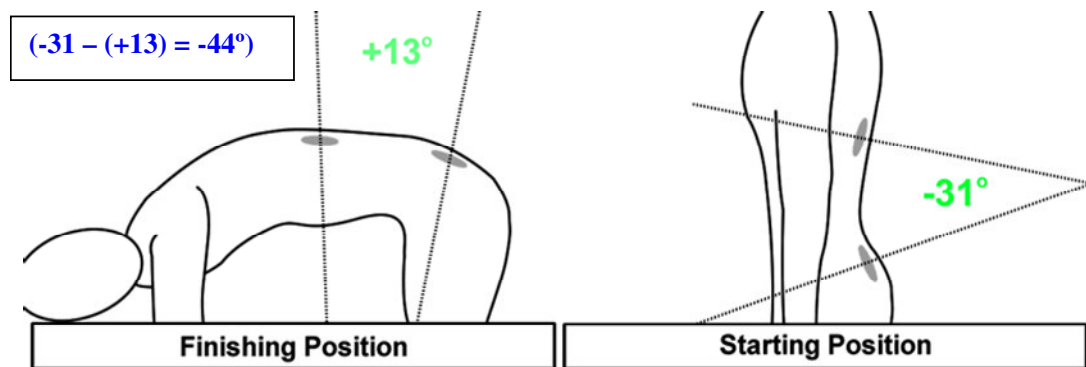


Figure 5.10 Lumbar spine flexion (in the sagittal plane) with the resultant range of movement equal to -44 degrees (anti-clockwise)

Clinical experiment to determine the optimal sampling rate for the accelerometer method

The frequency with which the movement data is registered by the BSM (sampling rate) is a very important factor determining the accuracy and the overall performance of the device. Too small a sampling rate means that some important developments in the data time series can be missed out. Too high a sampling rate provides a risk of redundant data, blocks wireless transmission, wastes storage space and increases processing time.

A small clinical study of lumbar spine movements was undertaken to enable the optimal sampling rate to be calculated for the accelerometer method, such that no significant

movements of the lumbar spine were missed in the data and no irrelevant data was recorded.

The study involved five subjects performing the movements of the lumbar spine, in the three anatomical planes (see Figure 4.22): the sagittal plane (flexion/extension), the coronal plane (left and right lateral flexion) and the transverse plane (rotation to the left and right). The movements were performed in a random sequence.

The number of lumbar spine movements that were performed over a ten-second period were recorded by video and counted by visual observation, checking results against the video. For a movement to be counted as a measurable, it had to simulate a normal activity of the lumbar spine. The participants were asked to make natural movements that they may perform during their normal ADLs. For example: reaching over a desk to gather a pen, picking up a tissue from the floor, moving an object along a bench and sitting down into a couch. Each time, the process of bending forward was counted as one movement, and the process of returning to an upright position, was counted as another movement. Thus, bending forward and returning to upright standing equated to two movements.

It was found that, the total number of movements within a ten-second period varied from as low as 16 to as high as 24, with a mean value of 20.6 and a standard deviation of ± 3.21 . The average number of movements per second was 2.06 with a standard deviation of ± 0.32 . The individual results for each subject along with the averaged values are presented in Table 5.1. The average value (2 movements per second) equates to a person being able to flex forward and return to an upright position within one second.

Based on the results of the clinical study, it was concluded that, a sampling rate less than or equal to one sample per second would be too small and may miss valuable data. For the

sampling rate to have a high probability of capturing all the important details of spine movement, it would have to be greater than one sample per second.

Figures 5.11, 5.12 and 5.13 show an example of the same movement data displayed at three different sampling rates: 1 sample/second, 2 samples/second and 5 samples/second respectively. In this example, the subject flexed forward two times during a 10 second period.

Table 5-1 The average number of movements of the lumbar spine in a ten second period

Subject	Total number of movements in a ten second period	Average number of movements per second
1	21	2.1
2	19	1.9
3	16	1.6
4	23	2.3
5	24	2.4
Mean	20.6	2.06
Standard Deviation	3.21	0.32

The graph in Figure 5.13, corresponding to the sampling rate of 5 samples/second, contains the greatest level of detail. Each large peak in Figure 5.13 represents a forward flexion movement. A comparison between the graphs shows that the lowest sampling rate (Figure 5.11 at 1 sample per second) misses the first flexion movement and the middle sampling rate (Figure 5.1 at 2 samples per second) showed two flexion movements of 23° and 19°. The third sampling rate (Figure 5.13 at 5 samples per second) clearly shows the two flexion movements to > 30°.

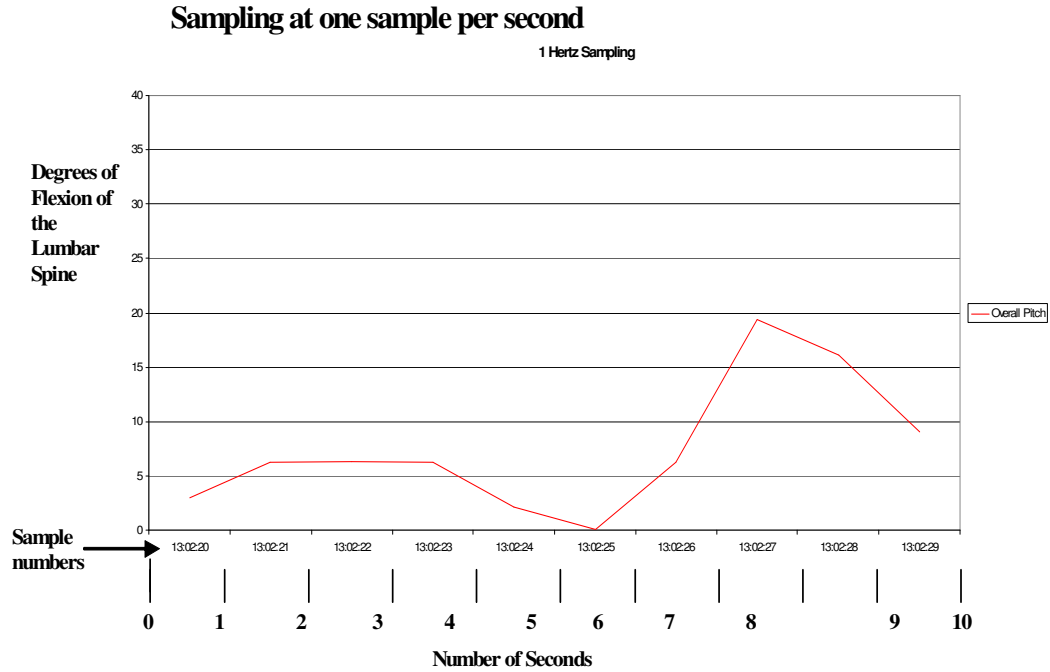


Figure 5.11 Sampling at one sample per second, showing degrees of flexion of the lumbar spine

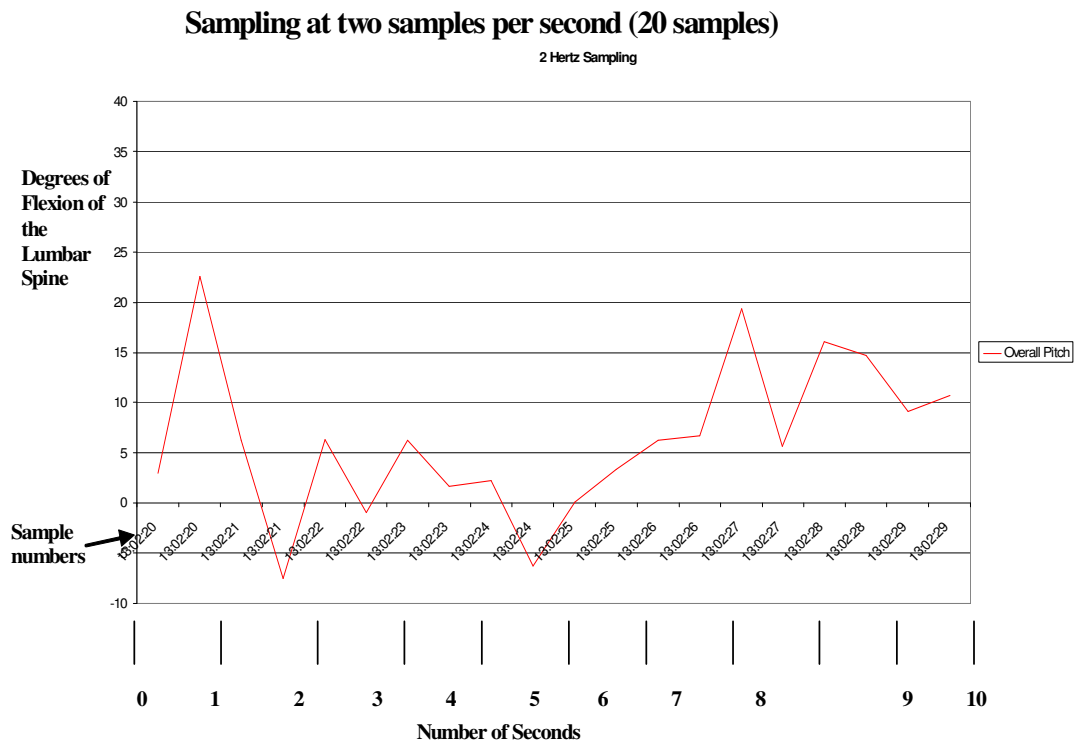


Figure 5.12 Sampling at two samples per second, showing degrees of flexion of the lumbar spine

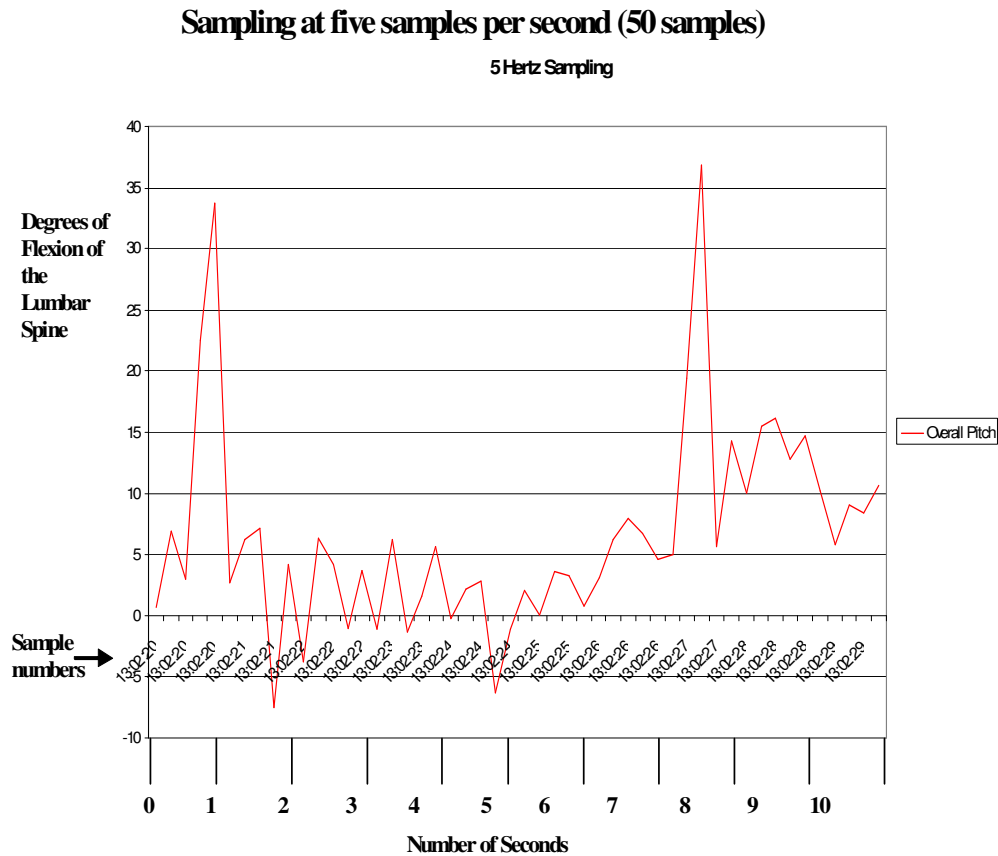


Figure 5.13 Sampling at five samples per second, showing degrees of flexion of the lumbar spine

For this reason, a sampling rate of 5 samples/second was chosen for the BSM device as the most appropriate rate, highly likely to capture the majority of movements with the minimum of data redundancy. The sampling rate for the BSM device can be adjusted via the device software, up to a maximum value of 20 samples/second.

5.2.2 The Gyroscope

The rotational or twisting movements (transverse plane) of the human lumbar spine are very difficult to measure due to the usually small ranges of rotation (between L1 and S1) and different starting positions of the spine when the spinal rotation occurs.

Initially the accelerometers were planned to be used to calculate rotation of the lumbar spine. However, preliminary laboratory trials showed that in certain positions the accelerometers experienced data dropouts, specifically when the transducer board was moving in a horizontal or transverse plane.

The error was due to the inability of the accelerometers to gather the rotational movement data when their alignment was perpendicular to the line of gravity. In order to overcome this error, a gyroscopic sensor was incorporated into the design of the Measuring Device for the movement (MDM) aspect of the BSM.

A gyroscope is a device used to detect and measure the rotation of an object on which it is installed. Gyroscopes have been previously used to acquire accurate measurements of human motion in the form of a pedometer (Lim, Brown et al. 2008). The rotation is measured as an angular velocity in radians/second. Different types of gyroscopes use different ways to detect rotational movement. The gyroscope used in the MDM part of the BSM detects the rotation of an object on which it is mounted by measuring the Coriolis effect on a vibrating part of the gyroscope. The device contains a surface-micromachined angular rate sensor known as MEMS (Micro Electro-Mechanical System) with integrated electronics (iMEMS) (see Figure 5.14). A detailed description of the iMEMS angular rate sensing gyroscope can be found in Geen and Krakauer (2003).

The iMEMS gyroscopes are small, have low power consumption, and better immunity to shock and vibration than other gyroscopes having comparable functionality. Figure 5.14 shows the gyroscope on its own PCB, mounted perpendicular to the main PCB of the MDM.

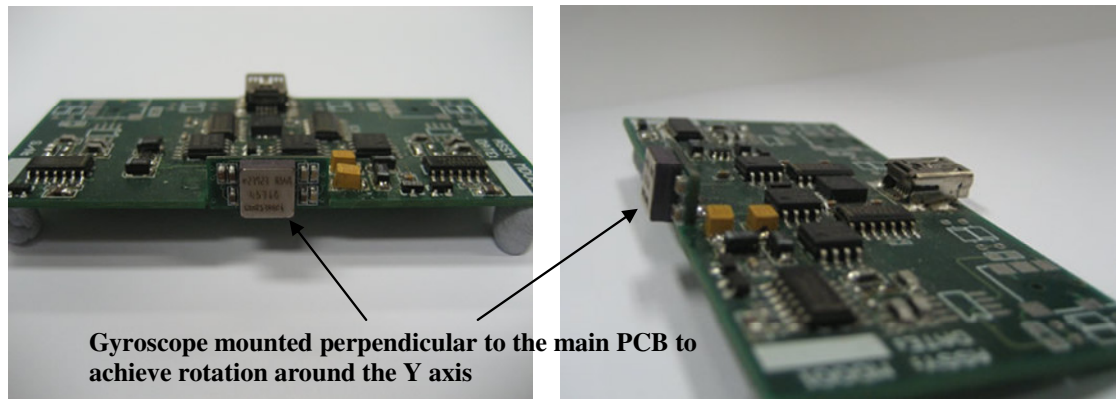


Figure 5.14 Showing the gyroscope on the new printed circuit board (PCB), mounted perpendicular to the main board

The gyroscope measures the angular velocity (or rate) as an angular change per unit of time in radians/second. The angular change can be then determined by time-integration of the angular rate.

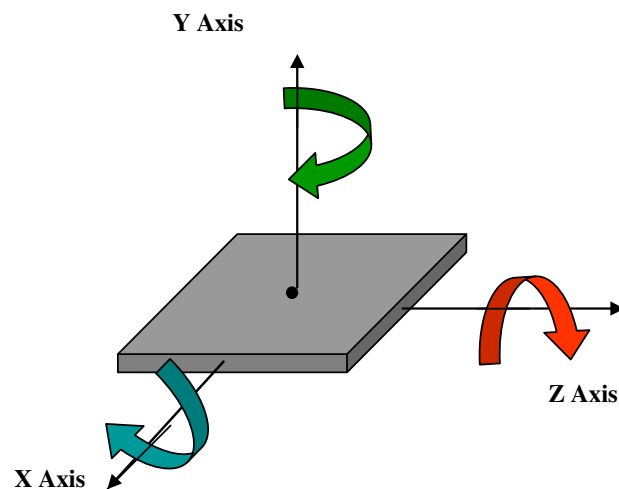


Figure 5.15 The gyroscopic axes of sensitivity

Depending on how a gyroscope is positioned, its primary axis of sensitivity can be one of the three axes of motion: X, Y and Z (see Fig. 5.15). The gyroscope used in the BSM device was set to enable a measurement around the Y axis (see Fig. 5.16 and Figure 5.17).

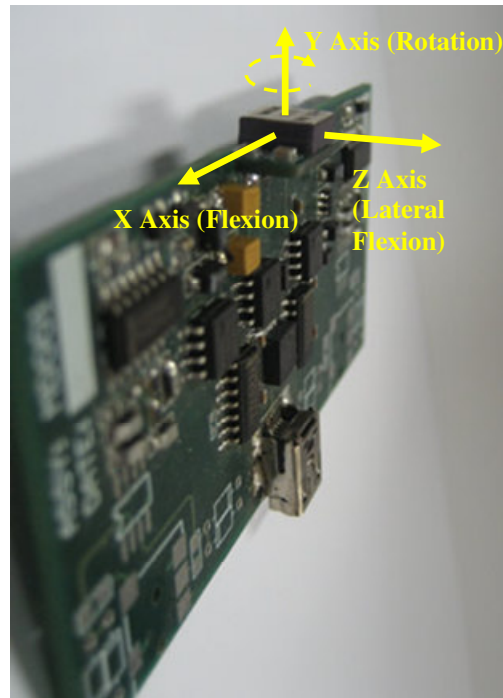


Figure 5.16 The gyroscope mounted on the printed circuit board of the Back Strain Monitor

For example, a gyroscope mounted to measure rotation around the y axis of an object rotating at 10 rpm (revolutions per minute) would measure a constant rotation of

$10 \times \frac{360^0}{60 \text{ seconds}}$ or 60 degrees/s. The gyroscope would output a voltage proportional to the

angular rate, as determined by its sensitivity, measured in millivolts per degree per second (mV/degree/s). The full-scale voltage determines how much angular rate can be measured, so in our example, a gyroscope would need to have a full-scale voltage corresponding to at least 60 degrees/s. Full-scale is limited by the available voltage swing divided by the sensitivity.

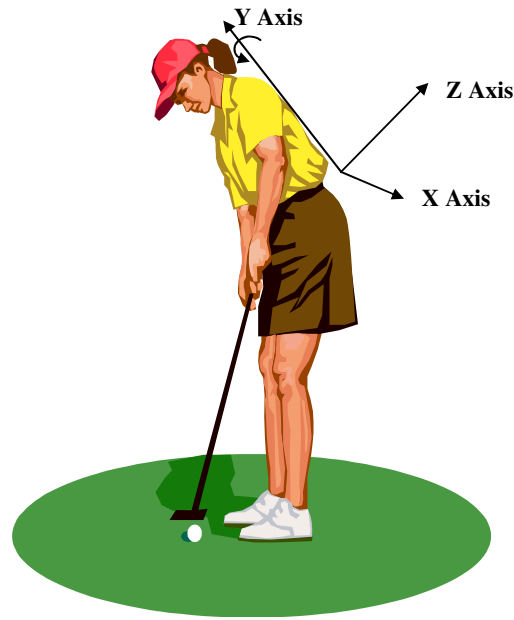


Figure 5.17 The orientation of the gyroscope axis setup to measure the rotational movement around the y axis

The lab based gyroscope trials aim to give the BSM a useful sensor for the rotational movement of the lower back, however the reliability and the validity studies of the gyroscope go beyond the scope of this thesis.

5.2.3 The Electro-myographic sensors

The third component of the Measuring Device of the BSM is a combination of two or more electro-myographic (EMG) activity sensors.

Surface electromyography (EMG) is a non-invasive method for evaluating and recording physiologic properties of muscles at rest and while contracting (Dankaerts, O'Sullivan et al. 2004). Electro-myographic sensors detect the **electrical potential** generated by muscle **cells** when these cells contract, and also when the cells are at rest.

The technique involves placing 3 or more electrodes on the skin. There are 'smart textile' projects that utilize more than ten EMG or ECG sensors knitted into clothing (Lymberis and

Dittmar 2007; Wiklund, Karlsson et al. 2007). For the lumbar spine, an adhesive electrode is preferable due to the changing contours of the lumbar spine and the large range of movement. The BSM device uses three small electrodes that are adhered to the skin overlying the chosen muscle group to receive the electrical activity (voltage) from the muscle fibres below. The two active electrodes are aligned with the muscles fibres. The third electrode is a reference electrode that acts as a baseline measure for the electrical activity. The source of the electrical activity is the muscle membrane potential of about -70mV. The EMG potentials typically range between less than 50 μ V and up to 20 or 30 mV, depending on the observed muscle.

The received EMG signal is periodic. Typical repetition rate of muscle unit firing is about 7–20 Hz, depending on the size of the muscle, previous axonal damage and other factors. The reason for including the EMG sensor as a transducer in the BSM device was to add another factor characterising the physiological state of the lower back. In combination with the linear and rotational movement parameters, the EMG data could provide a stronger and more reliable assessment of the pressures and loads occurring at the level of the lower lumbar spine.

Reliability of the EMG sensors

The reliability of the EMG technique has been questioned, especially when used for studying muscle activity over prolonged periods (Kumar 2007). A number of other EMG studies report a moderately high degree of reliability for EMG recordings of the muscles of the lumbar spine (Lehman 2002; Ng *et al.* 2003; Dankaerts *et al.* 2004).

It has been suggested (Lariviere, Arsenault et al. 2002), that an improvement of the EMG reliability can be achieved by placing two EMG sensors on the right side of the erector

spinae muscle group and two on the left side (at the vertebral level of L2 and L5) and averaging the EMG signal between the two levels.

The BSM uses customised EMG electrodes and a new wireless circuit design. The reliability and validity of the new circuit and the customised electrodes require thorough testing for the lumbar spine applications, however the reliability studies of the EMG circuitry and electrodes are beyond the scope of this thesis.

Which muscles should monitored by the EMG sensors?

As part of the current BSM device, the EMG sensors are primarily placed on the erector spinae muscle to give an indication of the activity level of the muscles supporting the vertebral segments of the lumbar spine.

Erector spinae muscle

The erector spinae muscle group has been frequently studied using EMG and there are a number of publications showing that reliable EMG readings can be obtained from these muscles (Elfving, Nemeth et al. 1999; Lehman 2002; O'Sullivan, Grahamslaw et al. 2002; Colloca and Hinrichs 2005; Pitcher, Behm et al. 2008).

The BSM also has the potential to concurrently measure muscle activity from other muscle groups, via the wireless EMG sensors. For example, valuable information could be gained by assessing the activity level of the deeper core muscles such as transversus abdominus, iliocostalis lumborum, multifidus or the oblique abdominal muscles. It should be noted that surface based electrodes (sEMG) may be of limited benefit in assessing the muscle activity of the deeper core muscles.

Transversus abdominus

Deficiencies in the active support of the core stabilising muscles (transversus abdominus) has been shown in subjects suffering from low back pain (Hodges and Richardson 1996). If the BSM EMG component were able to identify whether a subject had asymmetrical functioning of the deeper core muscles (transversus abdominus), this could potentially assist in the management of the low back pain. However, the BSM monitoring results of transversus abdominus had to be treated with caution since the transversus abdominus is a deep muscle and surface EMG is better suited to superficial muscles. One article suggests good validity and reliability from surface EMG on the transversus abdominus muscle (Marshall and Murphy 2003) although more conclusive reliability studies on transversus abdominus use needle electrodes into the transversus abdominus muscle belly (McMeeken, Beith et al. 2004).

Iliocostalis lumborum and multifidus

Reliable EMG results were recently reported to be obtained from the studies of the muscles iliocostalis lumborum and multifidus (Lehman 2002; Ng *et al.* 2003; Dankaerts *et al.* 2004), subject to quite specific landmarks for the positioning of the electrodes.

The importance of the multifidus muscle as a stabilizer of the lumbar spine has been well documented (MacDonald, Lorimer Moseley *et al.* 2006). Electro-myographic studies from the previous decade, examined EMG of the erector spinae, quadratus lumborum and latissimis dorsi (van Dieën 1996; Sparto and Parnianpour 1998) yet multifidus was not a muscle widely discussed in studies relating to surface EMG. It is not clear from the literature whether multifidus was not able to be accurately recorded by surface EMG or whether the importance of the multifidus muscle as a core stabiliser was not fully known. It seems that few studies saw the merit of recording multifidus activity and rather, examined the erector spinae muscle group.

The current BSM protocol for EMG monitors the erector spinae muscle group although there may be a number of muscles added to the protocol (potentially transversus abdominus and multifidus) once the reliability of monitoring the erector spinae muscle activity is established.

What kind of useful information can be derived from the EMG recordings?

Recording of the EMG muscle activities can provide two types of useful information supporting the assessment of the low back pain risk level. These include the amount of load or pressure on the spine and the timing of the muscle activation.

The amount of load or pressure on the spine

Whilst EMG measurements are not precise and only give an estimate of the magnitude of muscle activity, EMG has been shown to give a good indication of dynamic spinal loading (Sparto and Parnianpour 1998; Dolan, Kingma *et al.* 1999) and to be a useful tool for calculating cumulative load (Village, Frazer *et al.* 2005). The contraction of the erector spinae muscle group has an extension moment and compressive moment acting on the lumbar vertebrae. The distribution of forces acting on the lower lumbar vertebrae due to the erector spinae muscle group is illustrated in Figure 5.18.

Whether the contraction of the erector spinae muscle provides support for the stability of the lumbar vertebrae or whether the contraction adversely stresses the fundamental support structures of the lumbar spine, is a very difficult question.

The answer may partially lie in matching the magnitude, timing and cumulative effect of the muscle activity with the position of the lumbar spine in three dimensions.

When the lumbar spine is in a flexed position, the intervertebral disc fibre layers are under a high level of tension and high compressive forces act on the lumbar spine (Shirazi-Adl

1994). These significant forces acting on the lumbar spine, especially in flexed positions, can adversely affect the passive tissues of the lumbar spine if adequate muscle support is absent (Colloca and Hinrichs 2005).

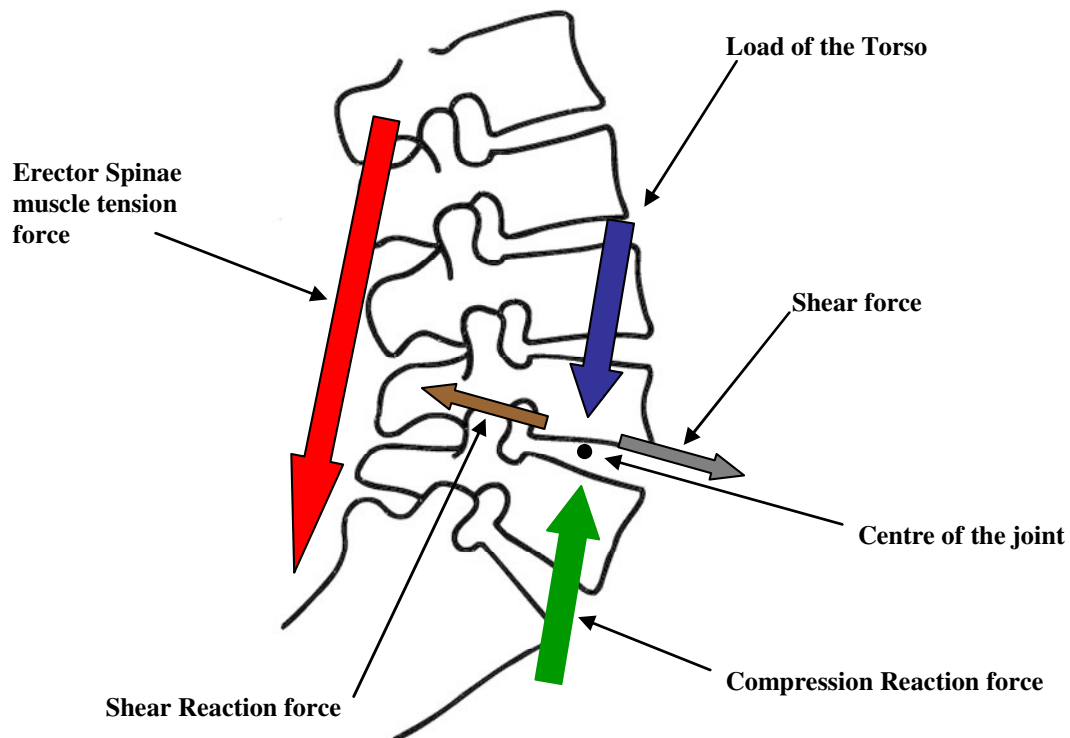


Figure 5.18 Forces acting on the lower lumbar vertebrae due to the erector spinae muscle
(Kumar 2007)

(image concept adapted from S. Kumar, Basic Biomechanics, 2007)

Conversely, if the lumbar spine is maintained in a neutral or slightly lordosed position and high compressive forces occur (eg lifting a heavy box whilst maintaining a straight lumbar spine), there is a more symmetrical loading of the passive support structures of the lumbar spine (Kiefer, Shirazi-Adl et al. 1997).

A combination of the three dimensional movement data synchronised in time with the EMG data, and a biomechanical model of loads acting on the lumbar spine may provide a comprehensive assessment of the low back pain risk (Snijders, Van Riel et al. 1987).

The timing of the muscle activation

The timing of muscle activation in the lumbar spine provides a potentially important insight into the risk of lumbar spine injury. Correct timing of the muscle activity is crucial to the normal functioning of the lumbar spine. In normal subjects, there is a pre-movement muscle activity of the core muscles prior to an activity causing the actual movement (Marshall and Murphy 2003).

The EMG studies of the baseball pitchers show the preparation activity of the core muscles and scapula muscles, prior to the initiation of the prime moving muscles (Hirashima, Kadota et al. 2002). In a similar way, the core muscles of the spine have a preparation phase for particular movements (Hodges, Cresswell et al. 2000). An analysis of the EMG data may be able to show, if the actual movement of the lumbar spine is occurring, prior to the pre-movement (or preparation activity) of the core stabilising muscles or after the preparation activity. If the movement of the lumbar spine is occurring, prior to the pre-movement then, an additional tension (or load) is being placed on the passive support structures of the lumbar spine, potentially increasing the probability of low back pain.

Another risk factor for lumbar spine pain, highlights the issue of timing of muscle activity. If a person slips and has to adjust their posture, or if a person accidentally drops something and lunges in an attempt to retrieve the object, the unexpected movement is a reflex action. This reflex activity involving the limb/s, occurs prior to the activity of the core stabilising muscles, not allowing for the preparation activity to occur (Gagnon, Plamondon et al. 1995; Sparto and Parnianpour 1998).

Poor timing of the activation of the lumbar spine muscles and the limited ability to predict movement (proprioception) has been shown in subjects suffering from chronic low back pain (Hodges and Richardson 1996). These factors are especially evident when lumbar

spine muscles are fatigued (Taimela, Kankaanpaa et al. 1999). An analysis of the EMG data from the BSM may be able to be used to identify deficient timing sequences and activity levels of the lumbar musculature in subjects with chronic back pain.

Custom design of the EMG electrode for the BSM

The BSM muscle activity sensors (MDE) contain arrays of electrodes placed on the sensor pads. Each array of electrodes contains two active electrodes placed 3 cm apart and a third reference electrode placed in a relatively equi-distant position from the two active electrodes (see Figure 5.19). This particular configuration of electrodes was suggested in studies by Mirka and Sparto (Mirka 1991; Sparto, Parnianpour et al. 1998).

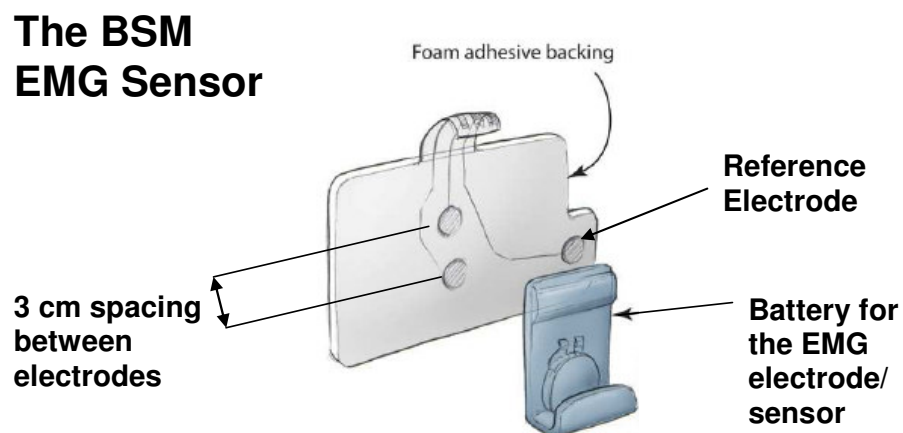


Figure 5.19 The array of electrodes on the EMG sensor pad

The EMG sensors include a disposable battery (see Figure 5.19 and Figure 5.20) to enable the EMG signal to be transmitted through a wireless communication channel to the Recording Feedback Device (RFD) unit. As illustrated in Figure 5.20, each sensor pad contains a low allergenic foam adhesive to adhere the electrode to the patient's skin.

Signal Processing for the EMG Circuit

Due to their low frequency and voltage (mV), surface EMG signals require amplification and filtering prior to digital conversion. A differential amplifier with a high CMRR (Common Mode Rejection Ratio) was required to reduce noise from the power supply. A high pass filter (minimum of 10Hz) was used to remove electrode DC offset and electrode movement interference. A low pass filter (500Hz) allowed harmonics to be included but was able to avoid signal aliasing. The signals from the analogue circuit were simulated on a PC using SIMetrix software package to assess amplification characteristics and frequency response.

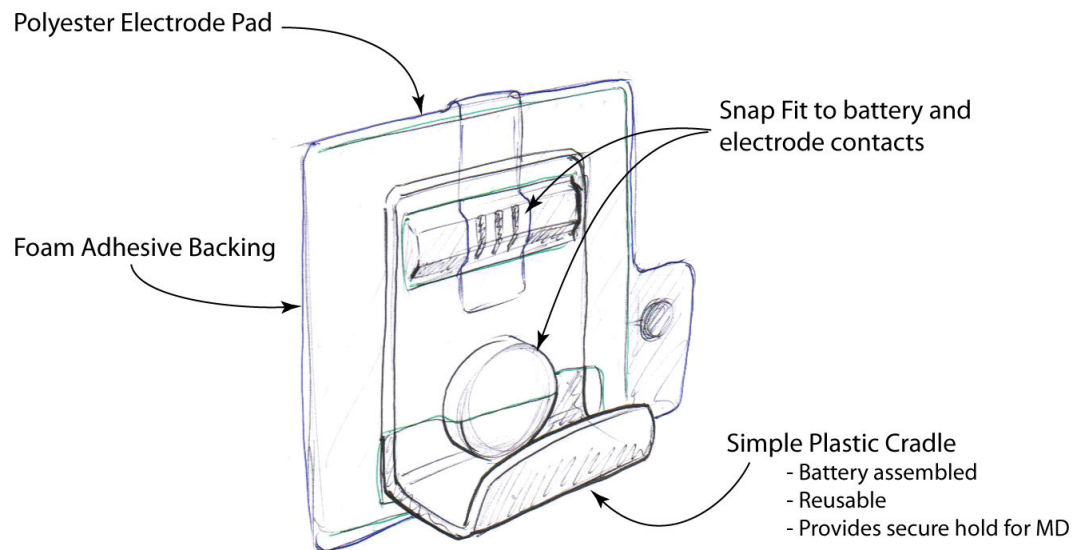


Figure 5.20 The components of the EMG sensors

Placement of the EMG sensors

The process of finding an optimal placement of the EMG sensors was based on the literature review and laboratory-based reliability trials. Previous EMG studies (Lariviere, Arsenault et al. 2002; Lehman 2002) showed good reliability when the electrodes for the erector spinae muscle were placed at L3.

In the laboratory trials, the BSM EMG circuit was tested using a repeatable EMG signal generated by a flexion of the lumbar spine. The time waveform of the EMG signal is

illustrated in Figure 5.21. The first peak, between the two vertical blue lines, represents eccentric muscle activity (620mV) of erector spinae during flexion of the lumbar spine. The trough between the two peaks (between the vertical blue line and red line) represents sustaining the flexed position. The second peak, between the two vertical red lines, represents concentric muscle activity (1000 mV) to return the lumbar spine to an upright position.

Note that there is a lack of muscle activity when the subject holds the flexed position. This is called the myoelectric silencing of the erector spinae or the lumbar erector spinae flexion-relaxation phenomenon (FRP). It has been suggested by Colloca and Hinrichs (2005) that a prolonged silencing may stress passive tissues of the lumbar spine (Colloca and Hinrichs 2005).

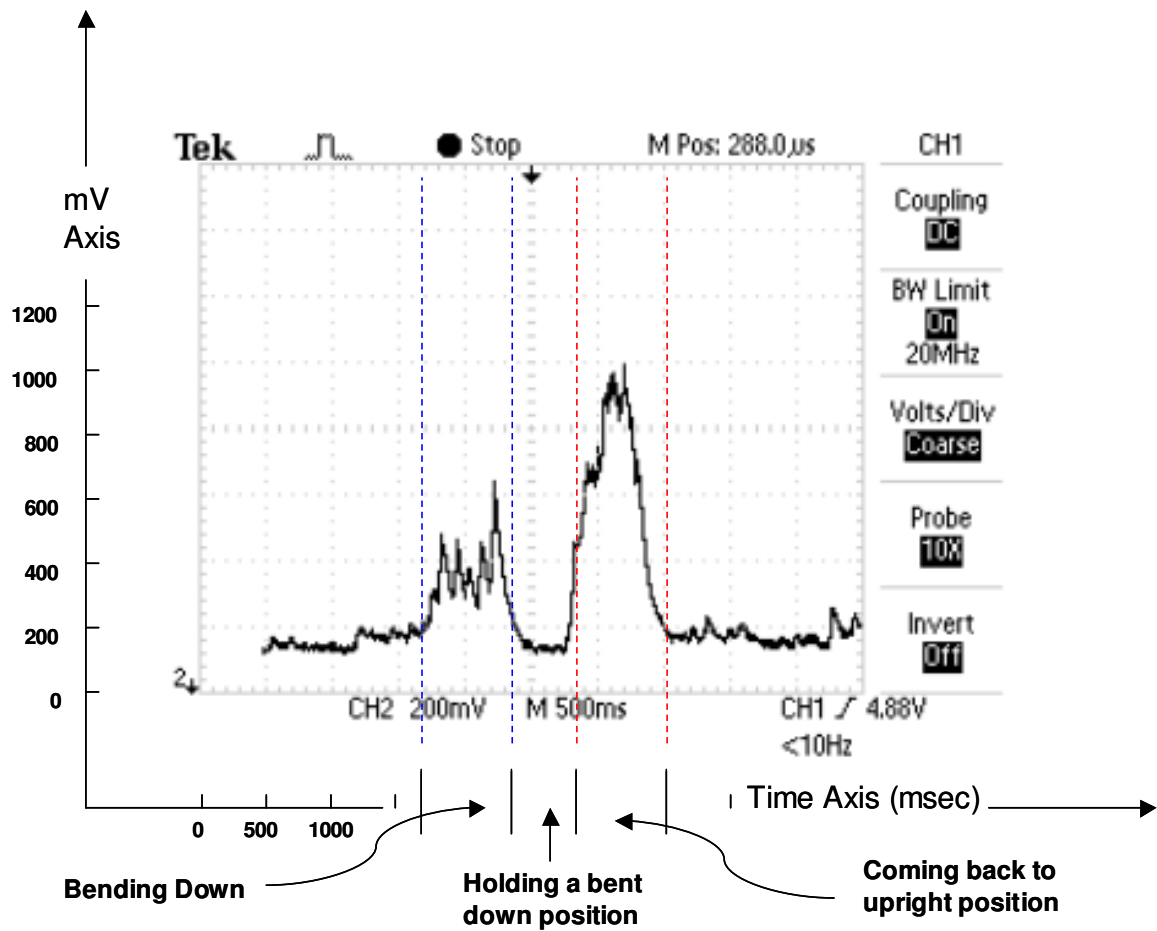


Figure 5.21 A time waveform of the EMG signal registered during a forward flexion of the lumbar spine

5.3 The Recording Feedback Device

The recording device of the previous version of the BSM was upgraded in the latest version to become the Recording Feedback Device (RFD), with the capacity to analyse data in real time and generate instant feedback (sound or vibration) to the person wearing the device. The concept of ambulatory monitoring is gathering momentum as a new and valuable area of health management (Jovanov 2005). Some authors have described miniature, lightweight sensors capable of wireless communication negating the need for awkward and potentially dangerous leads (Jovanov, Milenkovic et al. 2004). This would be the ideal scenario for the BSM concept where the sensors wirelessly communicate with the RFD.

The RFD has the memory capacity to store 24 hours of continuous recordings for off line downloading, processing and analysis. The biofeedback is provided instantly to the person wearing the device once a pre-determined threshold parameter is exceeded. The threshold parameter is currently calculated based on the time duration of the flexed position. The feedback is provided via vibration or an audible tone, or a combination of the two. Settings are adjustable to increase or decrease volume or turn off the biofeedback.



Figure 5.22 The Recording Feedback Device

The RFD unit is a battery powered (7Volt DC Lithium Ion battery) device the size of a mobile phone (see Figure 5.22). The input buttons allow modification of the threshold and device settings, using the visual display on the LCD screen. The screen has 128 x 64 pixels, allowing objects and figures to be displayed to visually communicate provocative movement patterns. The central processing unit (CPU) is a Texas Instruments MSP 430F149 Mixed Signal 16 bit Microcontroller (Texas Instruments, Dallas, Texas).

The BSM device uses a one wire communication circuit (or 'Daisy Chain Style') that allows additional sensors to be attached to the circuit in series. This feature may become valuable when extra information is required from additional EMG sensors or even additional accelerometers. For the reliability trial discussed in Chapter 7, the BSM sensors communicated with the RFD via one USB cable and a JAE (Japan Aviation Electronics) 10 pin connector. This allowed device charging, USB facilities and sensor connections through one plug. The PCB layout is double sided and double layered with a ribbon connector joining the boards. The dimensions of the device are 50 mm x 25 mm x 93 mm, with rounded ends and corners for user comfort (see Figure 5.23).

5.3.1 Setting bio-feedback thresholds of the Recording Feedback Device

The ultimate aim of the BSM is to provide accurate measurement of the lower back movements, allowing the identification of high risk movement patterns. Once identified, real-time feedback can be administered in an effort to modify the posture or movement patterns to improve recovery rate from painful episodes of LBP and to reduce the likelihood of further episodes of LBP.

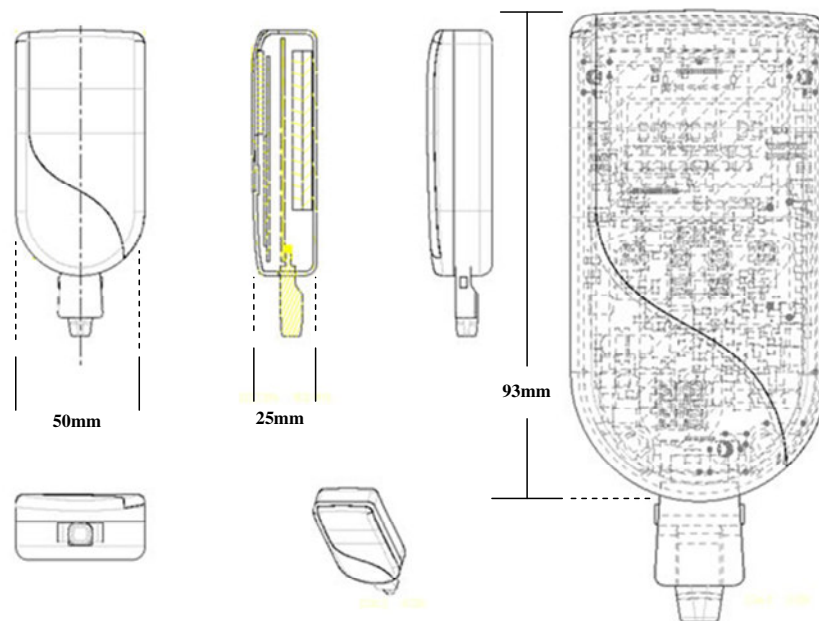


Figure 5.23 Dimensions and shape of the Recording Feedback Device (RFD)

The BSM threshold level determines when the patient will receive the biofeedback. The optimal threshold value for a given patient is determined and programmed into the RFD by the doctor or treating health practitioner (THP), prior to the device being fitted to the subject. The thresholds can be also adjusted by the subject during the course of the day.

In the current version of the BSM, the bio-feedback activation decision is based on the amount of lumbar spine flexion and the time spent in these flexed positions. If the subject wearing the BSM is in a flexed position exceeding the specified threshold level of flexion, and maintains this position for greater than the pre-determined time interval, then the biofeedback is activated.

Figure 5.24 shows the result of a test session for the BSM thresholds settings and biofeedback activation. The test was conducted with one person wearing the BSM device for 8 hours and 15 minutes. The person wearing the device performed a normal day's work

that included driving a car to various truck depots to inspect trucks that the firm may purchase.

During the first 2 hours the BSM device simply recorded movement data, giving no biofeedback to the wearer (during this time period, the biofeedback threshold was set to 50° , greater than the maximum ROM for most people, therefore the threshold level was not reached and no biofeedback was given).

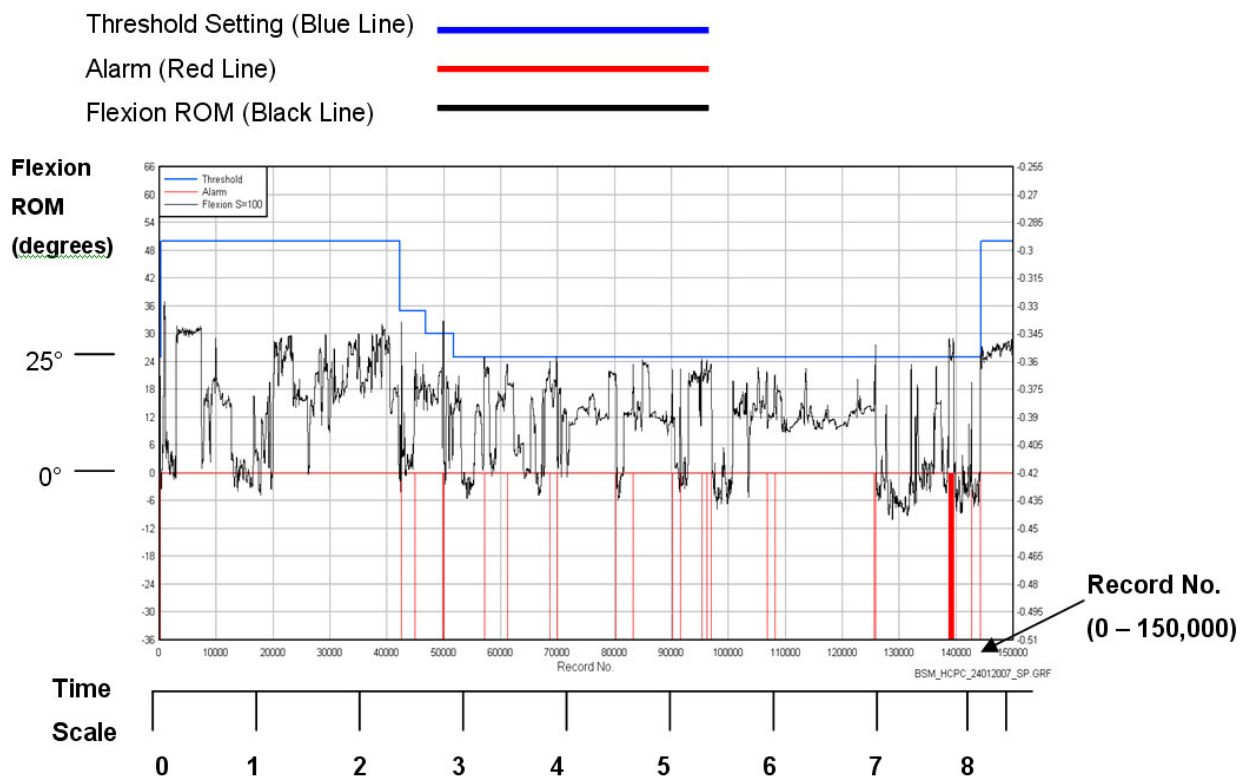


Figure 5.24 Data records showing the flexion time waveform for an 8 hour period
(Blue line – flexion threshold value, Red line – feedback activation)
(The data was recorded at the rate of 5 recordings per second)

At 2 hours and 15 minutes, the biofeedback threshold was reset such that every time the subject flexed their lumbar spine more than 25° , for a time period greater than or equal to 5 seconds, an audible beep and vibration warning was activated. The black line (Figure 5.24.) represents the time waveform of the flexion value (in degrees). The blue line

corresponds to the flexion threshold (in degrees) and the red lines show the moments when an alarm or feedback was triggered.

It can be observed in figure 5.24 that during the first 2 hours and 15 minutes, the biofeedback was not activated during the entire time. This scenario aims to allow the subject to move as they normally would. In this case, the subject frequently flexed their lumbar spine greater than 25°.

During the next 6 hours, flexion of the lumbar spine to > 25° resulted in the biofeedback being triggered. The time spent in a position of flexion greater than 30° is graphically represented by the histogram in figure 5.25. The red bar indicates the duration of time in > 30° flexion, the yellow bar represents the time spent between 20° and 30° and the green bar represents the time spent below 20° flexion.

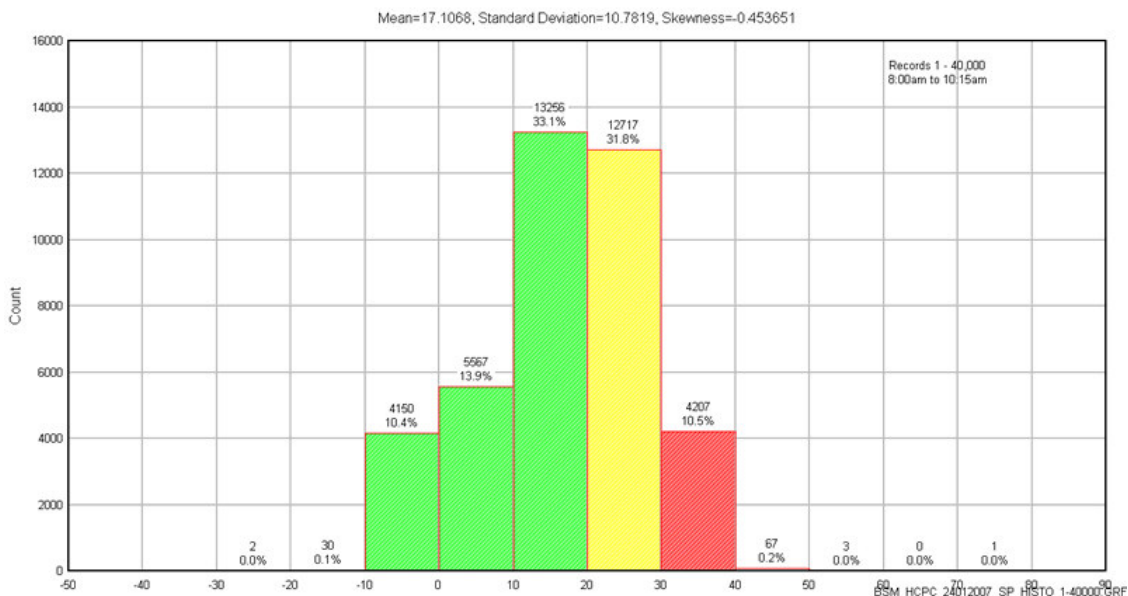


Figure 5.25 Distribution of the flexion values during the first 2 hrs 15mins

(40,000 recordings) of movements with no bio-feedback provided to the subject. The x axis is the degrees of lumbar spine flexion (in 10° increments) and the y axis is the number of samples/records from the device at 5 samples per second.

The Victorian Workcover Authority (VWA) states that positions greater than 20° flexion are to be avoided where possible, especially for prolonged periods (Authority 2005). As can be seen from the histogram (Figure. 5.25), without feedback (the first 2 hours, 15 minutes) the subject spent 31.8% of their time between 20° and 30° lumbar flexion, 10.5% of their time between 30° and 40° and 0.2% of their time between 40° and 50°. This equates to 42.5% of their time above the recommended amount of lumbar spine flexion.

As can be seen from the second histogram (Figure 5.26) when feedback was turned on (the remaining 6 hours) the subject spent 11.0% of their time between 20° and 30° lumbar flexion and 0.2% of their time between >30°. This equates to 11.2% of their time above the recommended amount of lumbar spine flexion.

From this example it can be seen that by recording lower back movement and providing biofeedback to modify that movement, significant postural changes are possible. Based on recommendations from the VWA, the BSM device was able to increase the amount of time spent in the recommended positions (i.e.: less than 20° of flexion of the lumbar spine).

Without biofeedback, the subject spent 42.5% of their time over the recommended level of safe bending. With biofeedback turned on, the subject spent 11.2% of their time over the recommended level of safe bending (see Table 5.2). This result shows the potential effectiveness of the biofeedback. Based on the biofeedback received from the BSM, the subject was able to modify their movement patterns to avoid positions carrying a higher risk of injury.

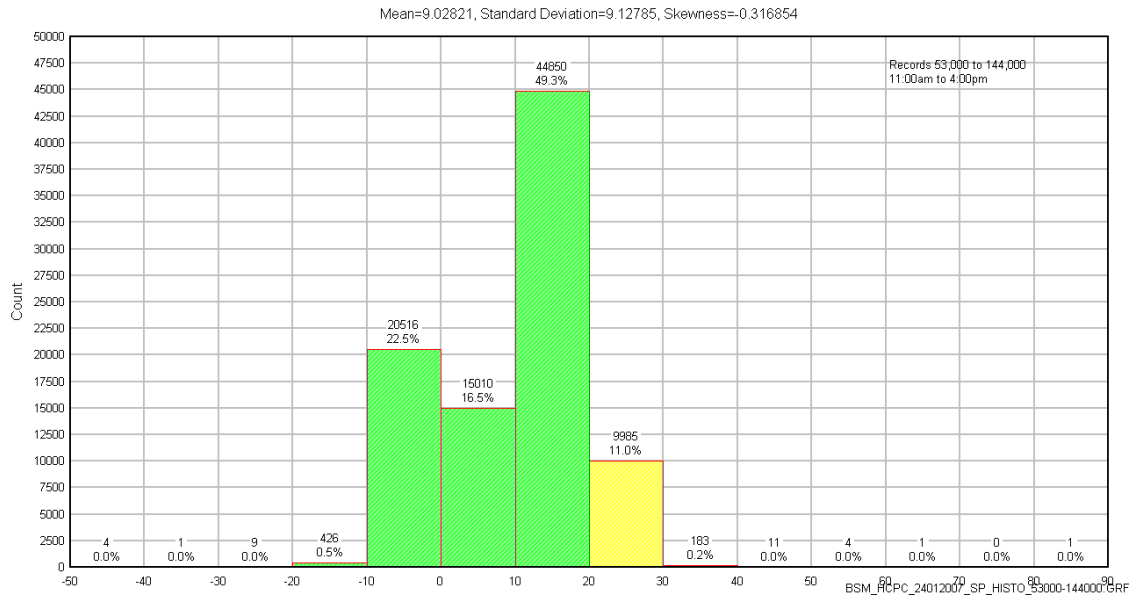


Figure 5.26 Distribution of the flexion values during the following 6hrs

(91,000 recordings) with bio-feedback provided to the subject. The x axis is the degrees of lumbar spine flexion (in 10° increments) and the y axis is the number of samples/records from the device at 5 samples per second.

Table 5-2 The subject's response to bio-feedback from the BSM device

	Time with BSM device on	Total number of flexion recordings	% of time between 30° and 40° Flexion	% of time in > 20° Flexion
Biofeedback off	2 h 15 min	40000	10.5 %	42.5 %
Biofeedback on	6 h	91000	0.2 %	11.2 %

Further clinical trials will have to be conducted to determine whether the bio-feedback and modified behaviour correspond to improved movement patterns in the longer term. How frequently should the biofeedback be provided to obtain maximum change in poor postures? Will improved movement patterns correspond to improved timeframes for the recovery from LBP? Will improved movement patterns reduce the chance of a recurrence of

low back pain? There are many questions that will require further research and investigation.

5.4 Data reports produced by the Back Strain Monitor

The BSM data provides a new approach to the monitoring of the lower back movements that occur during occupational or home activities.

Currently, the following ways of displaying the raw and the processed data from the BSM are used:

1. A graph showing the time waveform of the measured parameter
2. A histogram showing the distribution of the measured parameter values
3. A BSM Risk-Load Report of the measurement results.

The first type of report shows raw data in the form of measured parameter values plotted against time (time waveform) (see examples in Figure 5.24, Figure 5.28 and Figure 5.29). These types of reports allow detection and analysis of specific movements patterns matched to the times that those movements occurred.

The second type of report shows processed data in the form of a histogram, which displays the distribution of values in the recorded time waveform. The examples in Figure 5.25 and 5.26, show how many measurement values (count) fall into different ranges of the parameter values displayed on the horizontal axis. The histogram reports assist with assessment of the severity and frequency of movement patterns that are outside recommended levels.

It is envisaged that the third type of report (see example Figure 5.27) shows quantitative assessment of a parameter called the Risk-Load. The Risk-Load is derived from the raw measurements of flexion and EMG signals as follows.

$$Risk - Load(t) = (FROM + LFROM) \times (LEMG(t) + REMG(t)) \quad (5.25)$$

Where t denotes the time value, $FROM$ is the flexion range of movement in degrees, $LFROM$ is the lateral flexion range of movement in degrees, $LEMG$ is the electromyographic activity of the left erector spinae muscle group and $REMG$ is the electromyographic activity of the right erector spinae muscle group. The calculations are performed using the BSM processing algorithm. The algorithm is only in a very early stage of development.

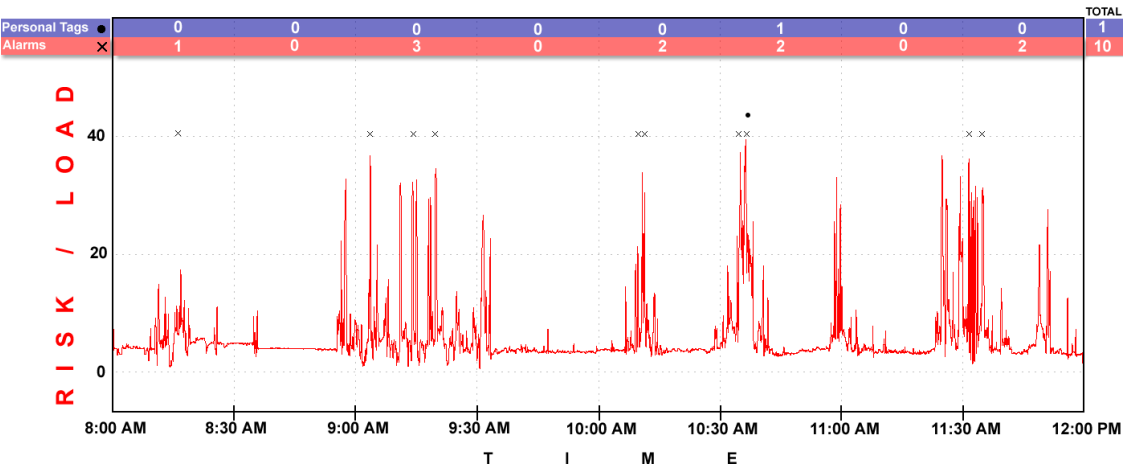


Figure 5.27 An example of the BSM Risk-Load report

Figure 5.27 shows an example of the Risk-Load report. The Risk-Load report may be used to determine the time events when the warning feedback should be activated. The purple bar along the top of the graph in Figure 5.27 shows 'Personal Tags'. The 'Personal Tags' mark an event or time when the patient experiences pain or a 'high risk' event. To generate the "Personal Tags", the patient needs to press a button on the RFD to note the event in the data field, that is displayed for later discussion or further analysis. The red bar marks the

‘Alarms’. These are the times when the biofeedback threshold has been reached and a beep and vibration warning have been delivered to the patient. The threshold in the example depicted in Figure 5.27 is based on the flexion range of movement (ROM) of the lumbar spine, as well as the estimated Risk-Load parameter.

Figure 5.28 shows the flexion ROM only of the corresponding four hour period of the data from Figure 5.27, with the feedback threshold level set at 40° (the black dotted line). The marked events are shown in the personal tags line and alarms line at the top of the graph. Figure 5.29 displays the EMG readings for the same four hour period. It is anticipated that practitioner’s feedback is required to identify a report format that suits their needs.

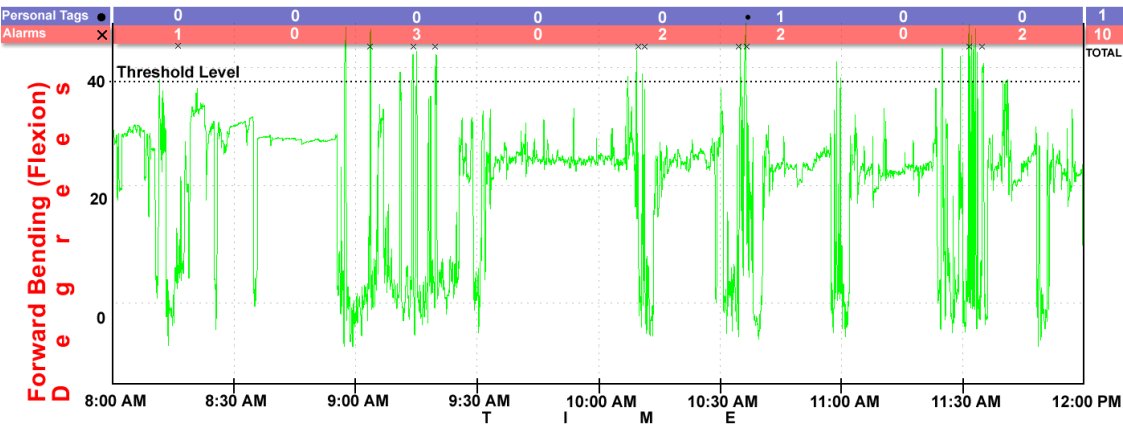


Figure 5.28 Four Hours of recording of BSM flexion data

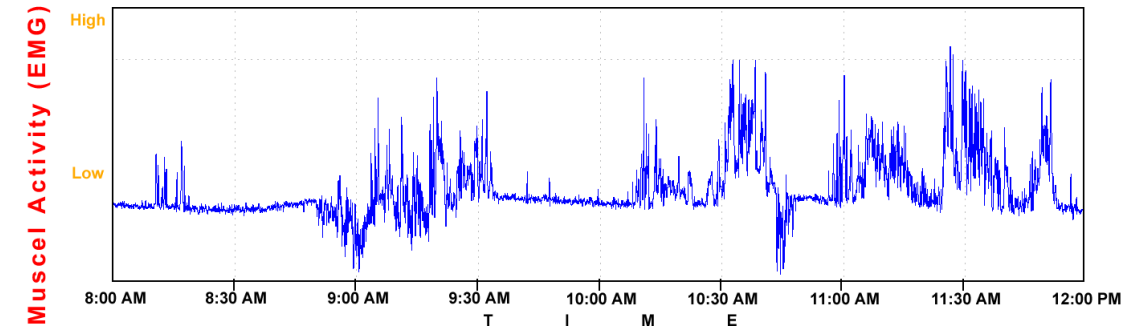


Figure 5.29 Four hours of recording of the BSM's EMG data

The BSM device has many components and data sets that require additional work and research in order to validate. The following two chapters discuss the clinical trials for the

early BSM device. Chapter 6 analyses the inductive coil via a clinical trial and Chapter 7 assesses the accelerometer method via a separate clinical trial. The focus of both clinical trials is to analyse the movement aspect of the different transducers.

Chapter 6. Clinical Study I for the Back Strain Monitor: The Inductive Coil technique

This Chapter describes the design of the experiments that tested the reliability and validity of the inductive coil technique for measuring lower back movement in a clinical setting. Three testers were involved in the trial that reviewed the inter-tester reliability of the inductive coil technique in conjunction with three well recognised methods for measuring lower back movement. The results from the inductive coil measuring technique were compared to the results from the other three methods, to assess the validity of the inductive coil technique.

6.1 Introduction

Two clinical reliability and validity studies were performed as a part of the development of the BSM device. The first clinical study tested the reliability and validity of the inductive coil applied in the BSM as a movement transducer (Chapter 6). The second clinical study tested the reliability and validity of accelerometers applied in the BSM as the movement transducers (Chapter 7).

The clinical trials performed as part of this thesis involved investigation of the reliability of two different measurement techniques for the lumbar spine on normal subjects, that is, subjects without low back pain. Subjects with low back pain have inconsistent movement patterns due to the nature of their low back pain. If a subject with low back pain is asked to 'bend forward as far as comfortable', this could produce a significantly different movement on each repetition depending on the level of pain the subject is experiencing. This is a potential error source when movements are inconsistent.

For the initial reliability study of a new device, it is preferable to have subjects who have normal low back movement so that their movement patterns will be more consistent. A

clinical trial on normal subjects is classified as a Phase 1 clinical trial and it is usual practice to investigate the reliability and stability of new devices and pharmaceuticals on normal subjects. The subjects in this type of Phase 1 clinical trial are used to test the 'on body' reliability of the measuring system. Subsequent trials (Phase 2 and 3 trials) will investigate the reliability of the device on subjects with low back pain and aim to investigate whether biofeedback is able to provide a treatment effect to subjects with low back pain.

This Chapter describes the clinical reliability and validity tests for the inductive coil technique. The reliability test included comparison between measurements obtained by different testers (inter-tester reliability) on the same day. The reliability of the inductive coil was tested in parallel with the reliability of three other methods including: the double inclinometer (DI) technique, the Modified-Modified Schober (MMS) method and the Wand technique (WT).

The validity tests, were done through a pairwise comparison between measurements obtained by the same tester using different techniques: the inductive coil technique, the Wand technique (Whittle and Levine 1997), the double inclinometer technique (Reynolds 1975; Mayer, Tencer et al. 1984) and the Modified-Modified Schober method (van Adrichem and van der Korst 1973; Williams, Binkley et al. 1993).

6.2 The Inductive Coil technique

6.2.1 The Inductive Coil device

The inductive coil device involved a datalogger, cable to the coil, software to calibrate the coil and the inductive coil itself (Figure 6.1). The background to the inductive coil is described in Section 4.7. The datalogger was powered by a 9 V battery and remained

isolated from mains power at all times. The inductive coil measured 150 mm at rest, had a diameter of 4.0 mm and was made of tungsten steel.

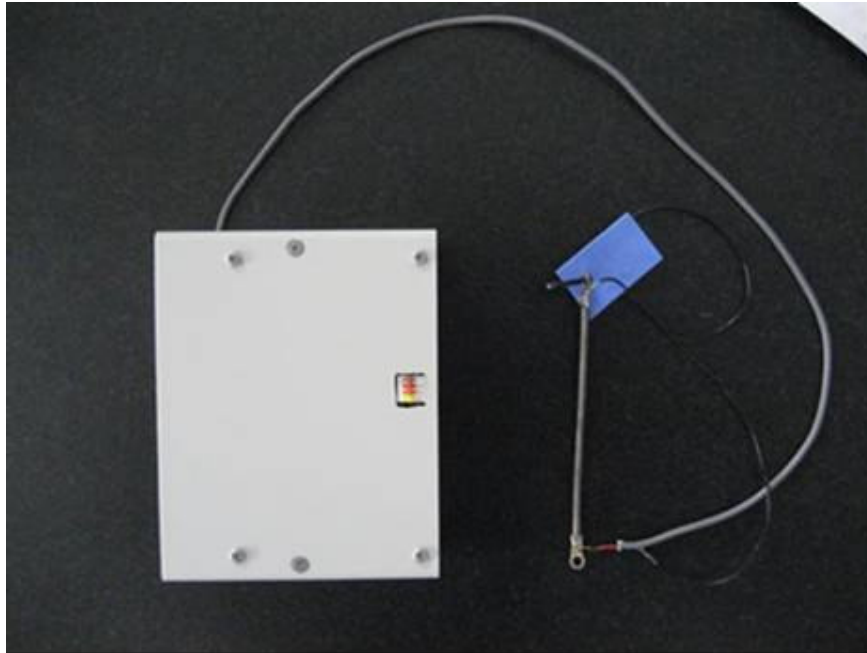


Figure 6.1 The Inductive Coil prototype: Datalogger, lead and the inductive coil

6.2.2 Attachment of the Inductive Coil to the subject

The coil was attached to 'stick-on cardboard rectangles' (30 mm x 48 mm), by way of a small hook. One piece of cardboard was placed at the thoracic lumbar junction (T12/L1) and the other at the lumbo-sacral junction (L5/S1). The coil ran vertically for 150 mm, being attached to the skin at either end of the coil (Figure 6.2).

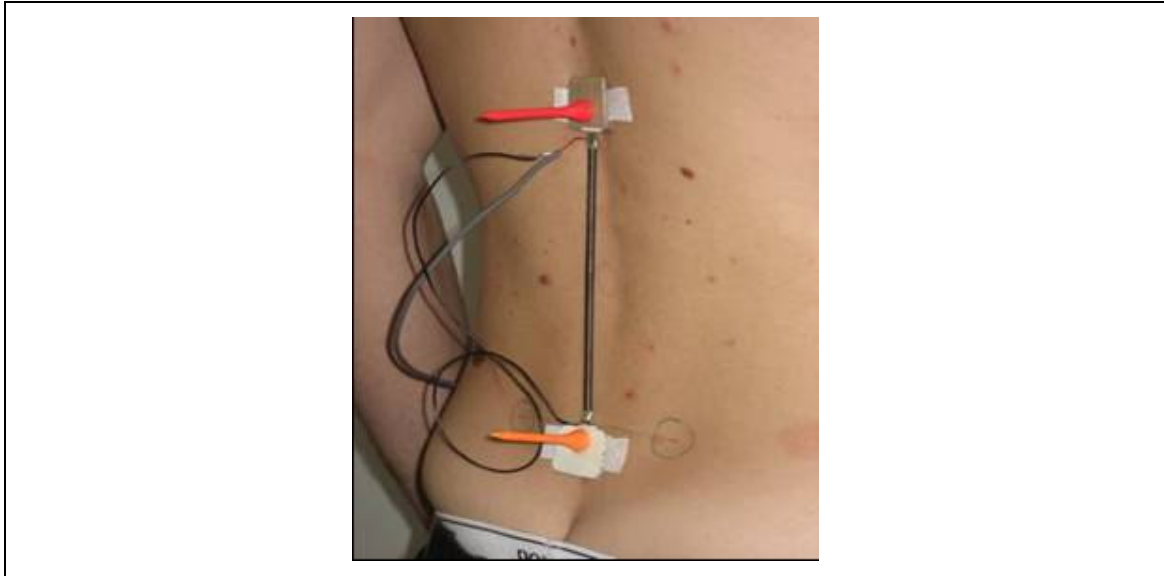


Figure 6.2 Coil attached to the lumbar spine

Coil calibration for clinical tests

The coil was initially calibrated under laboratory conditions (see Section 4.7) using a customised stretching rig. At the beginning of the clinical trials the laboratory calibration process was repeated to ensure the coil readings were re-calibrated for each subject. A separate and simplified calibration process was performed when the coil was mounted on the patient's back. This was done for each patient before the measurements were taken.

The calibration procedure involved recording the starting position data when the subject was in the erect standing position, after ensuring that the starting length of the coil was 150 mm (± 2 mm). The calibration button was pressed on the data logger, acknowledging the starting length for the coil. The button was pressed a second time when the subject bent forward to their fully flexed position and the coil was at its maximum stretch length (for that subject). The maximum flexed position was recorded with the tape measure to ensure the recorded range of the coil matched (within ± 2 mm) the recording from the tape measure.

6.3 Methods used in the Inductive Coil validity tests

6.3.1 The tests used to assess the validity of the Inductive Coil

The validity of the inductive coil measurements was tested by comparison with three established techniques for the measurement of the lumbar spine flexion. These methods were the double inclinometer (DI) technique, the Wand technique (WT) and the Modified-Modified Schober (MMS) method.

The DI technique has been shown to have good reliability in multiple studies (Keeley, Mayer et al. 1986; Beattie, Rothstein et al. 1987; Gauvin, Riddle et al. 1990; Paquet, Malouin et al. 1991; Saur, Ensink et al. 1996; Ng, Kippers et al. 2001). Inter-tester reliability for the DI technique has been documented (Newton and Waddell 1991). The technique has also been shown to be valid for measuring lower back movement (Reynolds 1975; Moll 1976; Portek I 1983; Mayer, Tencer et al. 1984; Merritt, McLean et al. 1986; Newton and Waddell 1991; Saur, Ensink et al. 1996). The DI technique was compared to radiograph measurements by Mayer (1984) on 12 subjects with chronic LBP (Mayer, Tencer et al. 1984). The results suggested that the DI technique was valid when compared to radiograph and that the technique was a useful tool for assessing range of movement (ROM) in patients with LBP. The DI technique is reliable for measuring flexion, extension and lateral flexion movements of the lumbar spine.

Angular changes occurring within the lumbar spine have also been calculated using fixed surface markers. The Wand technique (WT) was the second method chosen for measuring lumbar spine movement. The WT has been shown to be reliable for measuring the angular lordosis of the lumbar spine (Whittle and Levine 1997). Similar methods have been used to analyse lumbar spine and pelvic movement whilst walking. In Taylor's study, spinal rigs protruded from the lower back and pelvis and movements were captured via motion

analysis cameras. The changes in the angular movements of the lumbar spine and pelvis whilst walking on a treadmill were extrapolated from the rigs (Taylor, Goldie et al. 1999).

The third technique is the Modified-Modified Schober (MMS) method. This method does not calculate angular changes of the lumbar spine. The MMS uses a tape measure to record the amount of skin distraction occurring as the lower back flexes forward. The MMS method has demonstrated good inter-tester reliability (Waddell, Main et al. 1982; Biering-Sorensen 1984; Merritt, McLean et al. 1986; Gill, Krag et al. 1988; Hyytiainen, Salminen et al. 1991; Williams, Binkley et al. 1993) and has been shown to be a valid measure for lumbar spine flexion (Rae, Waddell et al. 1984). One limitation of the MMS method is that it is only able to measure flexion of the lumbar spine, not extension or lateral flexion movements.

The three comparative techniques are explained in more detail.

6.3.2 The Double Inclinator technique

The double inclinometer (DI) (Reynolds 1975; Mayer, Tencer et al. 1984) technique uses two gravity inclinometers to measure the angle of two aspects of the lumbar spine in relation to the line of gravity. The upper inclinometer is placed at the thoraco-lumbar junction (T12/L1) and the lower inclinometer is placed at the lumbo-sacral junction (L5/S1) (see Figure 6.4a,b).

The DI measuring technique (Reynolds 1975; Mayer, Tencer et al. 1984) requires two gravity goniometers which have swinging needles that are always aligned with the gravity line (see Figure 6.3). A goniometer is calibrated such that the swinging needle points to the goniometer's scale, showing the angle between the gravity line (swinging needle) and the base of the goniometer.

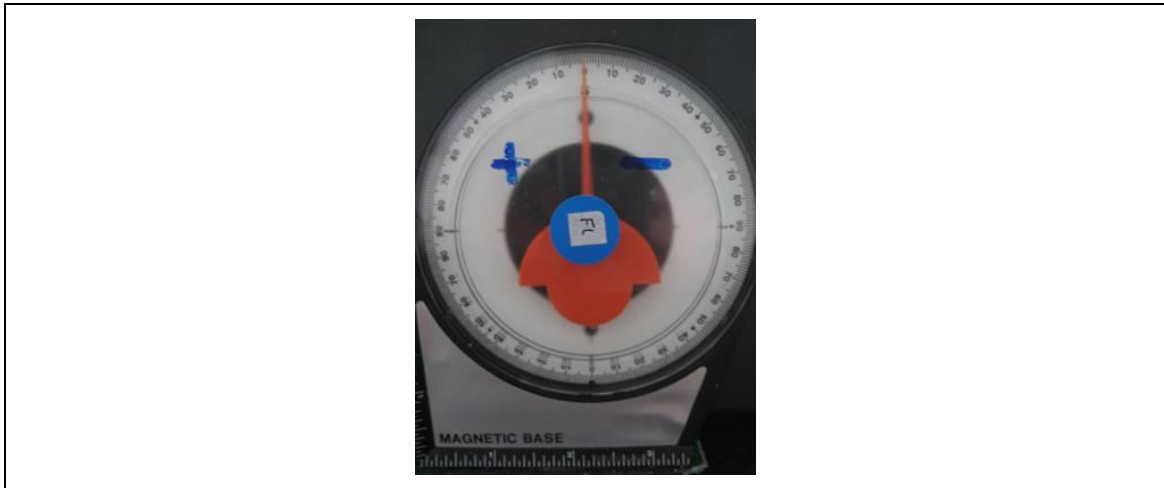


Figure 6.3 The Gravity Inclinometer used for the Double Inclinometer Technique

During a measurement, the base of the goniometer is aligned with the moving object. For this study the base of each goniometer was aligned with the 'Wands' protruding out from the spine (see Figure 6.4a,b). The wands allow a baseline (or reference) measurement for the DI technique.

The DI measurements are recorded with the subject in the starting position (erect standing, see Figure 6.4a) and repeated at the end of the range of flexion (see Figure 6.4b). The difference in degrees between the initial measurement and the final measurement represents the amount of an angular movement (flexion) performed by the lumbar spine.

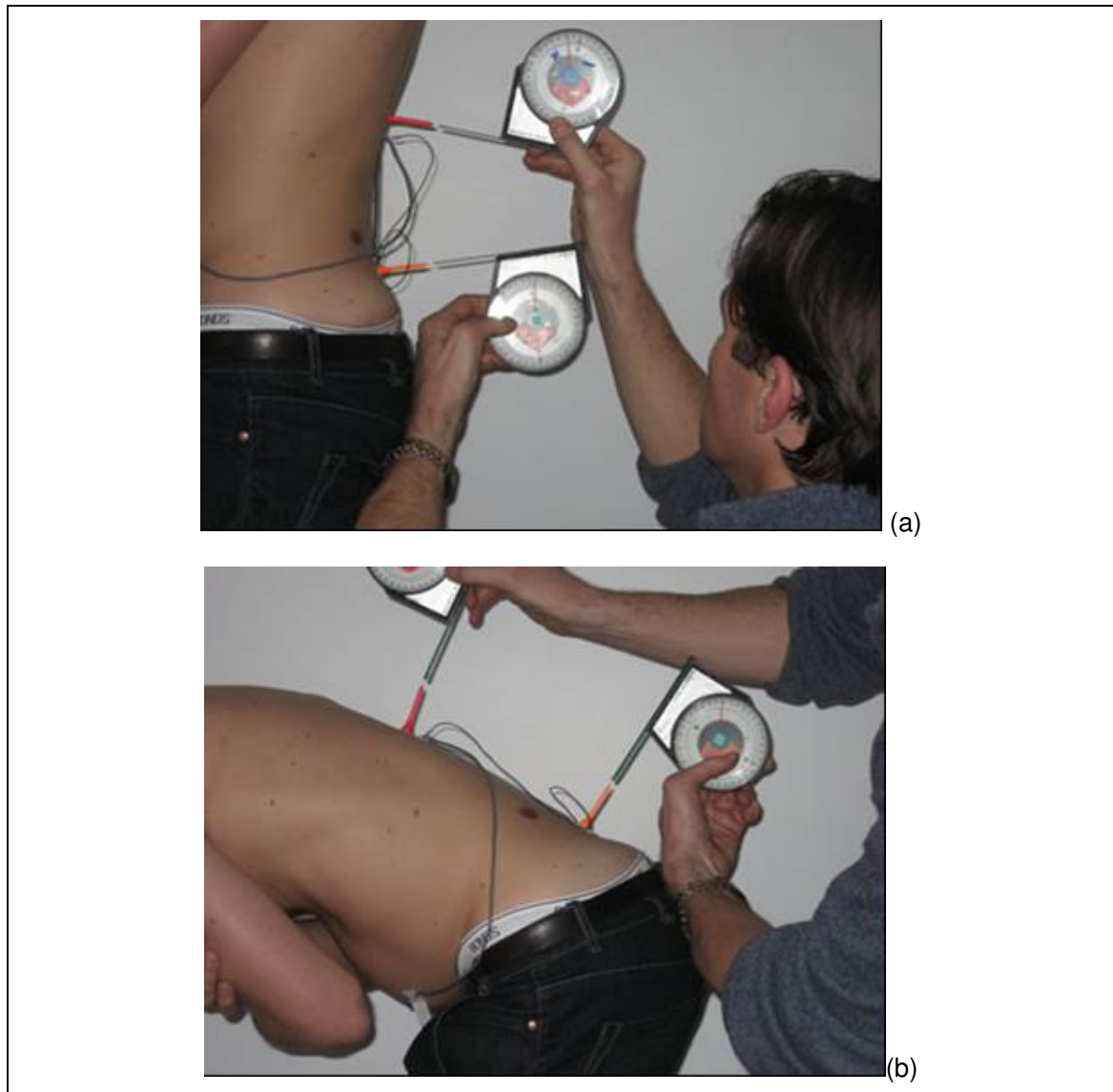


Figure 6.4 (a) Subject standing in the initial upright position, (b) Subject in the final position after flexing forward

(This picture shows the process of obtaining the lumbar spine movement measurements by simultaneous application of three methods: the IC, the DI and the WT)

6.3.3 The Wand technique

The 'Wand' technique (WT) was described by Whittle and Levine (1997) (Whittle and Levine 1997). The Wand technique uses small, flat cardboard templates adhered to the lumbar spine, with perpendicular 'wands' protruding from these templates (see Figure 6.5).

The wands used in this study were made of inverted, long golf tees, glued onto the cardboard rectangles, ensuring the golf tee was perpendicular to the cardboard. The rigid cardboard pieces measured 30 mm x 25 mm and the golf tee was 55 mm long.



Figure 6.5 Diagram of the Wands stuck onto cardboard pieces

The WT measurements of lumbar spine movement were recorded from a lateral aspect, via a video camera. The images of the subject in the initial standing upright position and in the final flexed forward position were printed out. Lines extending from the wands were drawn on the initial and final pictures (see Figure 6.6), the intersection angles (negative for lordosis and positive for flexion) were calculated for the initial and final position and subtracted from each other giving the final amount of the angular movement.

The benefit of the Wand technique was that it was possible to install the coil, the wands and the inclinometers on the patient's spine and take simultaneous measurements using three methods: IC, DI and WT. It can be observed in Figure 6.4, that such application of three methods could potentially provide a measurement error due to the possibility of misalignment between the inclinometers and the wands. Other arrangements were considered, however each alternative method had their own sources of potential error.

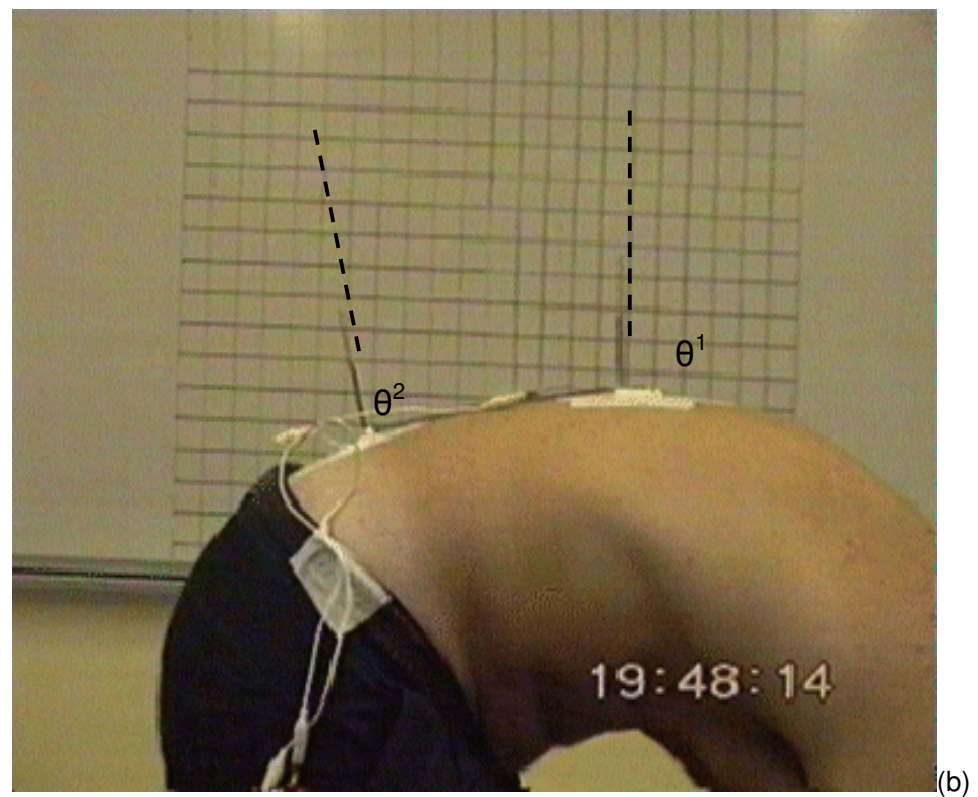
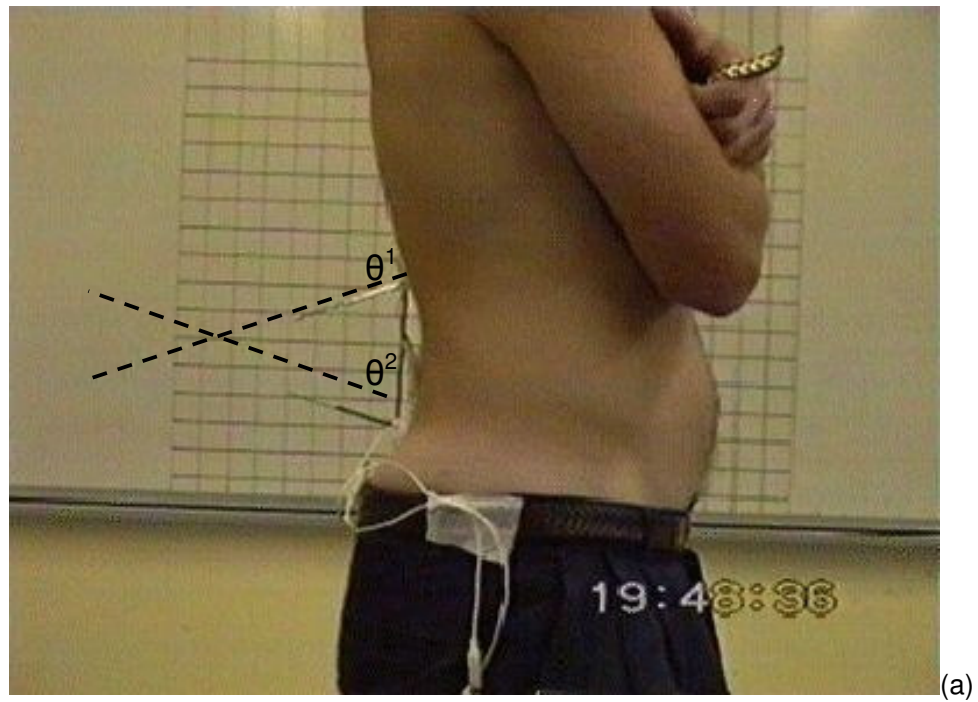


Figure 6.6 The Wand technique; (a) Subject standing in the initial upright position, (b) Subject in the final position after flexing forward. The angle of movement is calculated as a difference

$$\theta^1 - \theta^2$$

Unlike the inductive coil (IC), which provides the movement measurements in millimetres, the DI and the WT methods measure the lumbar spine movements via angular displacement, recorded in degrees of movement. A direct comparison between the IC and DI or WT was not possible because the methods use different scales to record their findings. Mapping formulas relating the DI and WT angles to the corresponding values of the IC method would need to be derived.

To enable a direct comparison of results, the Modified-Modified Schober (MMS) method, which provides results in millimetres, was included in the tests.

6.3.4 The Modified-Modified Schober method

The Modified-Modified Schober method (van Adrichem and van der Korst 1973; Williams, Binkley et al. 1993) is a version of the original Schober method, which uses a flexible tape measure to determine the change in the skin stretch when the lumbar spine flexes from a neutral position (erect standing) to a fully flexed position.

The original Schober method (Schober 1937) recommended a baseline measurement of 10 cm, marked vertically upward along the spine from the L5S1 landmark. This measurement was to approximately represent the length of the lumbar spine. Macrae (Macrae, 1969) modified the original Schober method by adding a further 5 cm measurement below the L5S1, producing a lumbar spine starting length of 150 mm.

Van Adrichem and van der Korst (1973) (van Adrichem and van der Korst 1973) used the 150 mm length but also used the posterior superior iliac spine (PSIS) as bony landmarks, due the ease of locating these as compared to the L5S1 landmark. Initially two points are marked at the positions of the two PSIS landmarks, and a horizontal line is drawn between these two PSIS points. At the intersection of this horizontal line and the midline of the spine,

a perpendicular line of length 150 mm is drawn upwards along the spine. A third marking is made at this upper point. These are the landmarks required for the Modified-Modified Schober (MMS) technique.

In this study the posterior superior iliac spine (PSIS) landmark was used as the primary bony landmark. Some authors have used the lumbo-sacral junction (L5S1) although a comprehensive research report in 1993, explained the merits of the PSIS landmark in preference to the L5S1 landmark (Williams, Binkley et al. 1993). The PSIS landmark is easier to locate, is more reproducible than the L5S1 landmark and provides a more stable reference point for the measurement of lumbar spine movement.

To perform the MMS measurements, the subject adopts an initial position of erect standing with feet spread shoulder-width apart. The tester circles the two PSIS landmark points and draws a horizontal line between them (see Figure 6.7a). At the intersection point with the spine, the tape is used to measure another point 150 mm upwards along the spine. A third point is marked 150 mm above the PSIS line (see Figure 6.7a). The subject is then requested to flex forward as far as comfortable and to stay at the point for 3 seconds. During the 3 seconds at the full flexion, the tester uses a soft flexible tape (see Figure 6.8) to measure the length of the stretched distance between the upper and lower marking. The difference between the initial length and the final length is the recorded flexion ROM of the lumbar spine.

Flexible tapes used during the measurements were known to stretch or deform after prolonged use. For that reason only new tapes were used and checked against a metal ruler after every ten measurements. Tapes that varied greater than visual 1 mm from the metal ruler were not used for the trial.

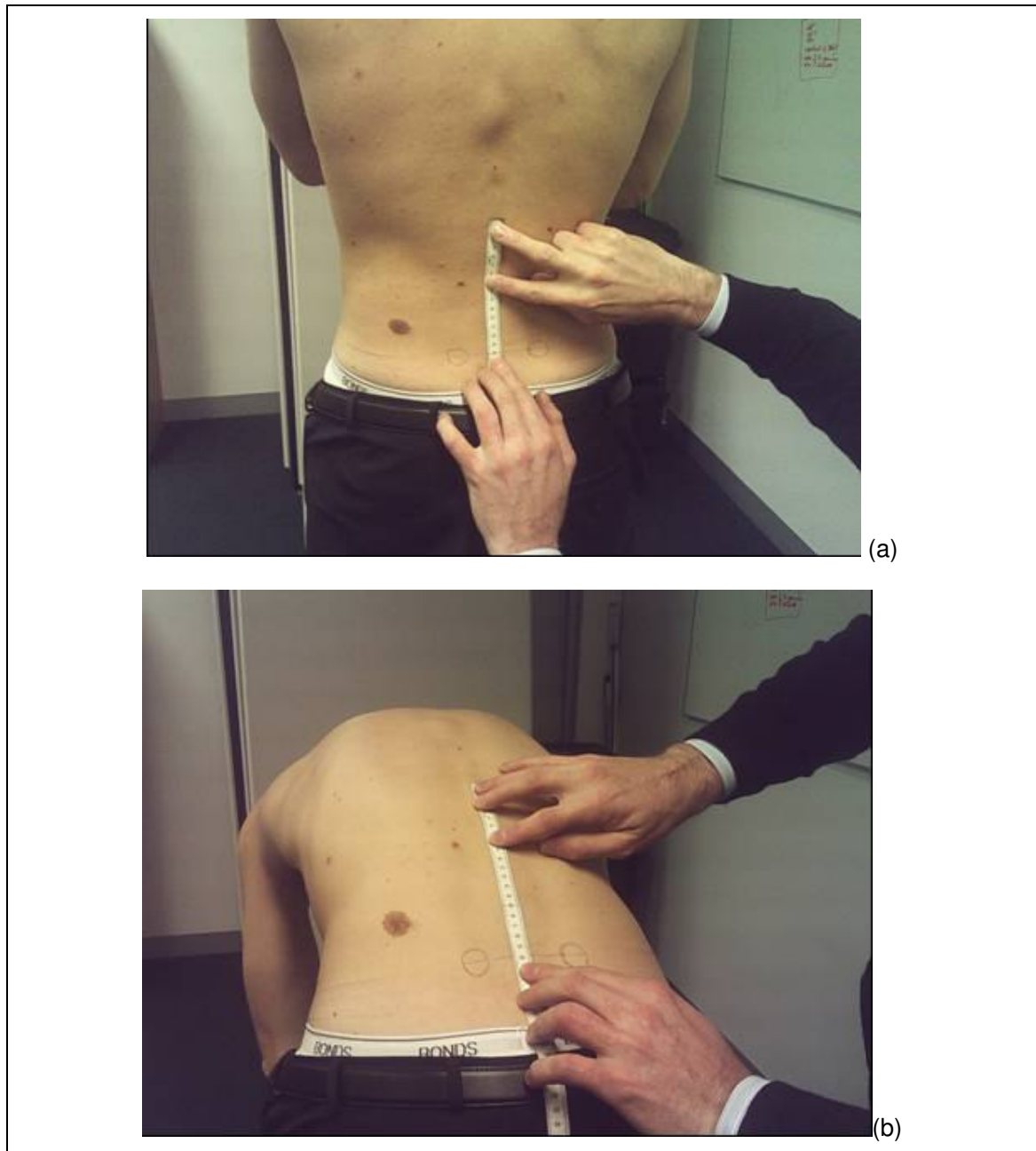


Figure 6.7 Application of the MMS method; (a) The baseline bony landmarks made during the initial upright standing position, (b) Measuring the stretch of the baseline due to the flexion

6.3.5 Testers (judges)

Three health practitioners; an Anaesthetist, a Sports Physician and a Manipulative Physiotherapist, took part in the inductive coil trial as testers. The clinician's experience ranged from 11 years to 20 years and each therapist had significant knowledge in relation to

the clinical assessment and the bony landmarks of the lumbar spine. Each clinician received a trial package one week before the trial that included a description of the inductive coil prototype, the trial protocol, an instruction sheet for the application of the device and a timetable for the trial day. The testers (or judges) were required to be at the trial location one hour before the trial began, to observe a demonstration of the inductive coil prototype and to use the device themselves, ensuring they were familiar with the functionality of the device.

6.3.6 Participants (subjects)

To be involved in the inductive coil trial, participants were required to be aged between 18 and 65 years and have had no significant low back pain within the previous 3 months. The participants were also ineligible for the trial if they were pregnant, if they were fitted with a pacemaker or if they had a history of spinal surgery. All participants were examined by a non-trial physiotherapist immediately before trial to ensure that each subject had full pain-free movement prior to commencing the trial and understood the requirements of the trial.

A sample of 15 subjects, who met the inclusion criteria was selected for testing. The sample included 11 males and 4 females. The participants' ages ranged from 23 to 59 years and were recruited on a voluntary basis. No payment was offered. The participants were spread across different occupational groups.

Each participant was given an identification number and the order in which the subjects were allocated to different testers was randomly selected and placed within a timetable for the trial day, to ensure that each subject was allocated to each measuring therapist, in random.

The order in which the movement tests were performed was not random. The inductive coil measurements and the WT measurements occurred simultaneously (managed by the inductive coil device and the video camera) whereas the MMS method and the DI technique were performed manually, with the MMS occurring first.

6.4 Procedure

The Human Research Ethics Sub Committee from RMIT University and the Faculty Human Ethics Committee from La Trobe University approved the trial. A written consent form was completed by each of the subjects. The trial took place at a physiotherapy centre in East Malvern, Melbourne.

6.4.1 The protocol

The protocol for the trial combined aspects from three relevant studies (van Adrichem and van der Korst 1973; Williams, Binkley et al. 1993; Whittle and Levine 1997). A copy of the protocol can be found in the Appendix II.

Bony landmarks

All participants were initially positioned in a comfortable erect standing position with feet shoulder-width apart (Youdas, Carey et al. 1991). Landmarks of the posterior superior iliac spine (PSIS) (Youdas, Carey et al. 1991) were identified and marked, in the shape of an olive with a removable pen marker, by a practitioner on the back of each participant. A horizontal line 'line A' (see Figure 6.7a) was then drawn through the centre of the two olives representing the lumbo-sacral junction and marking the lower attachment position for the coil to attach to the cardboard piece as described in Section 6.2.2.

A separate point, 150 mm above the first horizontal 'line A', was measured keeping the flexible tape measure pressed gently against the skin. A second horizontal line was drawn at this higher point and was labelled 'line B'. The line 'B' marked the position of the upper attachment for the coil.

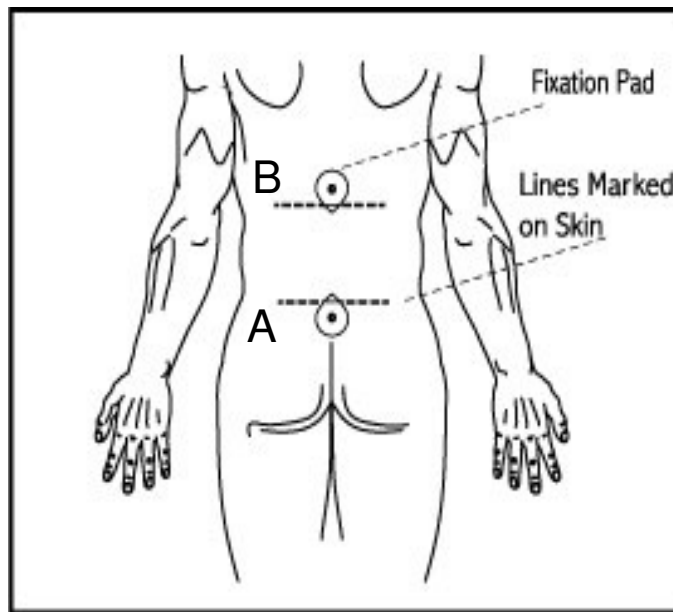


Figure 6.8 Bony landmarks used for the device fixation for the Inductive Coil Trial

Device fixation

The cardboard pieces, with wands attached, were then applied to the skin using a therapeutic, low allergenic, double sided wig tape from Burbec medical product company (Melbourne, Australia). The cardboard was adhered in a horizontal position, confirmed with a spirit level. The coil and lead were then attached to the cardboard pieces and the lead plugged into the device. The device was turned on and warm up movements were performed. Each subject was asked to flex forward, backward, tilt left and right and rotate left and right to ensure that they move correctly and this also accounted for the potential of warm up effect (Roberts, Liang et al. 1988). Following these movements, calibration of the coil was performed.

Subject starting position

Each subject, before commencing movements, was asked to ensure the following:

- Stand facing the door of the room with head and shoulders straight;
- Stand with feet shoulder-width apart;
- Stand with arms relaxed by side; and
- Stand with spine in an upright and erect stance.

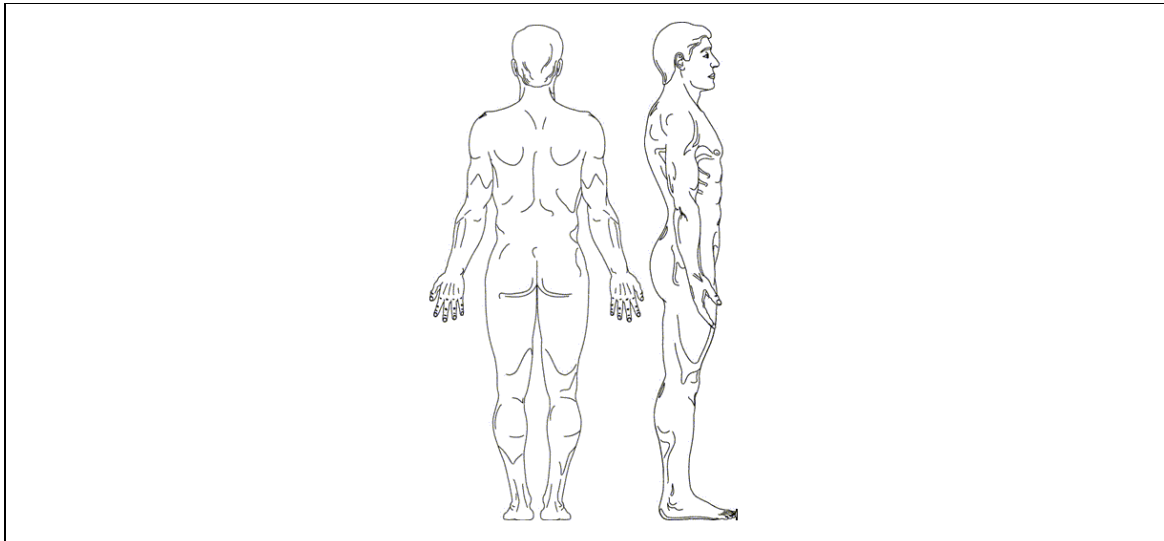


Figure 6.9 Subject starting position in erect standing

Calibration of the inductive coil device

Bench calibration was performed to match the coil length to a ruler, prior to the subjects arriving. Due to the electrical drift identified in the laboratory testing (see Chapter 4), the calibration needed to be performed every 30 minutes to reduce the potential drift from one subject to another and one tester to another. On-body calibration was also performed for each subject. The starting position was adopted by the subject and the calibration button on the device was pressed to mark the zero position/length of the coil.

The subject was asked to flex forward to their maximum comfortable position and to hold that position for three seconds. This allowed the inductance readings from the coil to stabilise and the calibration maximum button was pressed. The inductive coil reading was

matched to a MMS measurement to ensure the calibration procedure was successful. The inductive coil was now calibrated for full flexion ROM of the lumbar spine.

Movement to be performed

The following lumbar spine flexion movement was performed, with all described transducers (IC, WT, DI, and MMS) measuring the movement.

The participant was asked to flex their trunk forward in the sagittal plane, reaching their fingers toward the ground as far as they could comfortably reach. The distance from the finger tips to the ground was measured and a box at this same height was placed on the ground. The purpose of the box was to give the subject a marker to reach to, such that the movement amplitude was consistent. The subject was then asked to reach forward and touch the box lightly with their fingertips and hold the position for five seconds. This routine was repeated three times. The average of the three movements was calculated for each measurement technique and recorded.

At the starting position and the fully flexed position, a MMS reading and the DI readings were taken whilst the coil and the video were actively recording the movement. After the three flexion movements were performed, the device was removed and the skin markings cleaned off with a safe solvent, to avoid any bias from the next tester using the same landmarks. The subject was then assisted back to the waiting room to be allocated, in a random sequence, to the next practitioner.

6.5 Method

6.5.1 Statistical analysis

The desired qualities of a lumbar spine movement measurement based on the inductive coil were assessed in two ways. First, it was determined whether the method was reliable. Second, it was determined whether the method was valid.

The reliability was assessed as an amount of variability between different testers, and the validity was determined as an amount of agreement between different comparative methods.

The inter-tester (between testers) reliability (ITR) (Streiner and Norman 2003) was assessed using the intraclass correlation coefficient (ICC) (Shrout and Fleiss 1979).

Evidence of validity of the inductive coil technique was assessed by comparing the coil measurements to three other standard methods of the lower back movement measurements. These methods were: the double inclinometer (DI) technique, the Wand technique (WT), and the Modified-Modified Schober (MMS) method. The intraclass correlation coefficient (ICC) was again used to assess the agreement between these methods.

According to recommendations, an ICC between 0.8 and 1.0 represents a very reliable method or procedure, those between 0.6 and 0.79 represent moderate reliability or agreement and those lower than 0.6 show doubtful, or at least questionable, reliability or agreement (Durand, Malouin et al. 1991).

6.5.2 Measures of the inter-tester reliability.

The inter-rater reliability is the measurement of agreement among raters. It gives a score of how consistent the ratings are between different testers.

There are a number of statistical methods which can be used to determine the inter-rater reliability. Different statistics are appropriate for different types of measurement.

The most common methods are: joint-probability of agreement, Cohen's kappa and the related Fleiss' kappa, inter-rater correlation (Pearson's r or Spearman's ρ), concordance correlation coefficient and intra-class correlation.

Joint probability of agreement. The joint-probability of agreement is probably the most simple and least robust measure. It is the number of times each rating is assigned by each tester, and then divides this number by the total number of ratings.

Kappa statistics. The kappa statistics include: the Cohen's kappa (Cohen 1960), which works for two raters, and the Fleiss' kappa, an adaptation that works for any fixed number of raters. These methods provide an improvement upon the joint probability in that they take into account the amount of agreement that could be expected to occur through chance. They suffer from the same problem as the joint-probability in that they treat the data as nominal and assume the ratings have no natural ordering (Vincent 2002). If the data are continuous, some potentially valuable information within the measurements cannot be fully analysed.

Correlation coefficients. Either Pearson's r or Spearman's ρ are used to measure pairwise correlation between testers using a scale that is ordered. Pearson's r (Hayes 2005) assumes the rating scale is continuous; Spearman assumes only that it is ordinal. If more

than two raters are observed, an average level of agreement for the group can be calculated as the mean of the r (or ρ) values from each possible pair of raters. However neither coefficient takes into account systematic change between raters. For example, when rating on a scale from 1 to 5, Judge X might assign the following scores to four items: 1,2,1,3 and Judge Y might assign 2,3,2,4. Using either Spearman's or Pearson's method, the correlation coefficient would be 1, indicating perfect correlation; however the judges do not agree on any of the items.

Intra-class correlation coefficient. In this study the intra-class correlation coefficient (ICC) method was chosen as a measure of the inter-tester reliability (Keating and Matyas 1998). There are several types of the ICC. The range of the ICC may be between 0.0 and 1.0. The ICC will be high when there is little variation between the scores given to each item by the testers, e.g. if all testers give the same, or similar scores to each of the items. The ICC is an improvement over Pearson's r and Spearman's ρ , as it takes systematic change into account, along with the correlation between raters.

6.5.3 Choice of the intraclass correlation coefficients

There are several measures of ICC and they may yield different values for the same data set. The ICC coefficients were calculated using the SPSS statistical software package (SPSS Inc, Chicago, IL, USA).

The first decision that must be made in order to select an appropriate ICC is whether the data are to be treated via a one way or a two way analysis of variance (ANOVA) model.

If, for example, k ratings for each of the N participants have been produced by a subset of $j > k$ testers, there is no way to associate each of the k variables with a particular tester. In this situation the one way random effects model should be used, with each person

representing a level of the random person factor. There is then no way to separate variability due to specific tester, interactions of testers with persons, and measurement error. All of these sources of variability are combined in the within participants variability, which is treated as an error.

If there are k testers and each one rates all of the N participants then the variability among the testers is treated as a second source of systematic variability. Testers in this case become the second factor in a two way ANOVA model.

If the k testers are selected at random from a larger population, the tester factor is random, and the two way mixed ANOVA model is used.

The second decision to be made is whether the agreement between testers should be estimated in terms of consistency or in terms of absolute agreement.

If the one way model is selected, only measures of absolute agreement are available because consistency measures are not defined in this case.

If the two way model or the mixed model is selected, consistency or absolute agreement can be chosen.

The difference between consistency and absolute agreement measures is defined depending on the importance of the systematic variability due to testers.

If that variability between testers is considered irrelevant, it is not included in the denominator of the estimated ICCs, and measures of consistency are calculated.

If systematic differences among testers are considered relevant, tester variability contributes to the denominators of the ICC estimates, and measures of absolute agreement are calculated.

Summarising, there are five possible options when calculating the ICC

1. one way random model with measures of absolute agreement;
2. two way random model with measures of consistency;
3. two way random model with measures of absolute agreement;
4. two way mixed model with measures of consistency;
5. two way mixed model with measures of absolute agreement.

Each of the five possible combinations includes two different ICC estimates: one for the reliability of a single rating, and one for the reliability of the mean or sum of k ratings.

The choice depends on whether it is expected to rely on a single rating or a combination of k ratings.

Taking into consideration all the above factors, the following choices were made:

1. Determining the inter-tester reliability

In the case of the inter-tester reliability, there was a random sample of k testers and each tester judged N participants. The two-way random effect model (ANOVA) was chosen to be appropriate. The participants were deemed random and the testers were also deemed random. Taking into account these factors, the ICC(2,1) was found to be the most appropriate (Keating and Matyas 1998).

The value of the ICC (2,1) coefficient can be calculated as follows:

$$ICC(2,1) = \frac{BMS - EMS}{BMS + (k - 1)EMS + \frac{k(JMS - EMS)}{N}} \quad (6.1)$$

Where k is the number of testers, N is the number of participants, BMS is the between-subjects mean squared result, JMS is the mean squared result for judges (testers) and EMS is the error mean squared.

2. Determining the validity of the inductive coil technique

In the case of the inductive coil validity, the measurements of three separate methods (WT, DI and MMS techniques) were compared to the measurements of the inductive coil. The N participants were deemed random and their movements were rated by each of the sample of k testers who were randomly selected from a larger population. The two-way mixed effects model (ANOVA) was chosen to assess the agreement between two measurement methods for a specific tester. Taking into account these factors, the ICC(2,1) was again found to be the most appropriate (Keating and Matyas 1998).

The ICC (2,1) was calculated using the following formula:

$$ICC(2,1) = \frac{BMS - EMS}{BMS + (k - 1)EMS + \frac{k(JMS - EMS)}{N}} \quad (6.2)$$

Each of the variables used in the ICC (2,1) equation was taken from the ANOVA table.

A separate ANOVA table was produced for the analysis of each ICC value.

6.5.4 The standard error of measurement method

Correlation coefficients indicate the retest variance between different devices in terms of a ratio. Correlation coefficients do not display the magnitude of the differences between

results in retest trials (Keating and Matyas 1998). Keating (1998) suggests that to present data based on ICC values in isolation, potentially raises concerns about using that data to support optimum reliability.

To quantify data recording variation, alternative statistical options are available that record the size of the error in the actual measurement unit used. One form of this type of assessment is the standard error of measurement (SEM). The SEM is an average of the error that is presented in the initial unit of measurement (Atkinson 1998; Keating and Matyas 1998).

SEM values can be calculated using the following formula (Atkinson 1998; Streiner and Norman 2003):

$$SEM = SD\sqrt{1 - ICC} \quad (6.3)$$

Where SD is the standard deviation and ICC is the intra-class correlation coefficient

Keating (Keating and Matyas 1998) suggested that SEM can be also calculated as the square root of the EMS term, obtained from the ANOVA table. The Keating formula is given as:

$$SEM = \sqrt{EMS} \quad (6.4)$$

Both formulas (Eq. 6.3 and Eq. 6.4) gave the same results within two decimal points when analysing results produced in this study. Keating's formula from Eq. 6.4 was chosen to present the results of this study.

To determine a 95% confidence interval $CI_{95\%}$ for the SEM, the formula is:

$$CI_{95\%} = \pm 1.96 \sqrt{EMS} \quad (6.5)$$

6.6 Results and analysis

6.6.1 Flexion measurement results using the four measurement techniques

The raw measurement results of the reliability trial for the four measurement techniques are displayed in Table 6.1. Each data point represents an average value obtained for the same measurement repeated three times. For example, the first data point in Table 6.1 for Tester 1, Subject 1, is 60. The number 60 represents the average measurement value for a flexion movement performed three times by Subject 1 being tested by Tester 1.

Table 6-1 Results representing the flexion movement measurements using four measurement techniques

		Wand Flexion			Double Incln FI			MMS Flexion			Inductive Coil Flexion		
	Tester	T1	T2	T3	T1	T2	T3	T1	T2	T3	T1	T2	T3
Subj	Subj												
No.	Age	x°	x°	x°	x°	x°	x°	mm	mm	mm	mm	mm	mm
1	32	60	65	61	71	74	69	71	62	80	61	54	68
2	59	32	33	31	39	38	35	43	42	44	30	39	40
3	50	49	59	59	57	62	66	63	67	54	43	59	46
4	51	36	37	43	41	41	45	41	52	42	33	47	39
5	26	54	55	58	67	69	71	67	77	80	52	64	68
6	48	56	53	55	53	54	57	54	56	68	46	44	55
7	43	47	36	52	57	46	62	65	55	49	57	50	41
8	23	68	56	62	68	65	71	60	75	66	48	43	55
9	28	60	58	53	71	70	66	72	72	70	49	45	58
10	37	33	30	34	34	32	37	43	42	46	35	39	30
11	33	60	61	50	57	66	61	71	72	72	66	60	53
12	40	59	57	51	58	60	57	79	76	75	67	62	66
13	20	52	58	56	62	62	61	62	62	62	46	55	40
14	61	38	40	31	44	47	35	55	59	42	47	50	36
15	59	31	36	30	38	35	34	47	44	41	38	30	37

Results presented in Table 6.1 were used to generate the ANOVA analysis tables for the Wand technique (Table 6.2), Double Inclinomater technique (Table 6.3), MMS method (Table 6.4) and for the Inductive Coil technique (Table 6.5). The results from the ANOVA table were used to estimate the reliability of each method, using the ICC.

6.6.2 Reliability of the Wand technique

The values listed in Table 6.2 represent the ANOVA analysis results for the Wand technique.

Table 6-2 ANOVA results for the reliability of the Wand technique; N=15 (number of subjects), k=3 (number of measurement repeats)

	SS	df	MS	F	p-value	F-crit
Rows	5395.778	14	BMS =385.4127	19.45281	8.42E-11	2.063541
Columns	3.244444	2	JMS =1.622222	0.081878	0.921604	3.340386
Error	554.7556	28	EMS =19.8127			
Total	5953.778	44				

Replacing the BMS, EMS, JMS, k, and N values from Table 6.2 into the ICC(2,1) formula given by Eq. 6.2, we have

$$\begin{aligned}
 ICC(2,1) &= \frac{BMS - EMS}{BMS + (k - 1)EMS + \frac{k(JMS - EMS)}{N}} = \\
 &= \frac{385.4 - 19.8}{385.4 + (3 - 1)19.8 + \frac{3(1.6 - 19.8)}{15}} = 0.87
 \end{aligned}
 \tag{6.6}$$

Replacing the EMS value from Table 6.2 into the standard error of measurement (SEM) formula in Eq. 6.4, the following SEM and CI_{95%} values were calculated:

$$SEM = \sqrt{EMS} = \sqrt{19.8127} = 4.45^0
 \tag{6.7}$$

$$CI_{95\%} = 1.96 \pm \sqrt{EMS} = \pm 1.96 \cdot SEM = \pm 1.96 \cdot 4.45^0 = \pm 8.72^0 \quad (6.8)$$

These results can be interpreted such that if a flexion movement was performed and measured as 47° by the WT, there is a 95% chance that the measurement was within $\pm 8.72^\circ$ (the range being between 38.28° and 55.72°).

6.6.3 Reliability of the Double Inclinomater technique

The values listed in Table 6.3 represent the ANOVA analysis results for the double inclinometer technique.

Table 6-3 ANOVA results for the reliability of the double inclinometer technique; N=15 (number of subjects), k=3 (number of measurement repeats)

	SS	df	MS	F	p-value	F-crit
Rows	7219.561	14	BMS =515.6829	35.62123	4.11E-14	2.063541
Columns	3.574524	2	JMS =1.787262	0.123457	0.884338	3.340386
Error	405.3515	28	EMS =14.47684			
Total	7628.487	44				

Replacing the BMS, EMS, JMS, k, and N values from Table 6.3 into the ICC(2,1) formula given by Eq. 6.2, we have

$$\begin{aligned}
 ICC(2,1) &= \frac{BMS - EMS}{BMS + (k - 1)EMS + \frac{k(JMS - EMS)}{N}} = \\
 &= \frac{515.7 - 14.5}{515.7 + (3 - 1)14.5 + \frac{3(1.8 - 14.5)}{15}} = 0.92 \quad (6.9)
 \end{aligned}$$

Replacing the EMS value from Table 6.3 into the standard error of measurement (SEM) formula in Eq. 6.4, the following SEM and $CI_{95\%}$ values were calculated:

$$SEM = \sqrt{EMS} = \sqrt{14.48} = 3.81^0 \quad (6.10)$$

$$CI_{95\%} = 1.96 \pm \sqrt{EMS} = \pm 1.96 \cdot SEM = \pm 1.96 \cdot 3.81^0 = \pm 7.47^0 \quad (6.11)$$

These results can be interpreted such that if a flexion movement was performed and measured as 50° by the DI technique, there was a 95% chance that the measurement was within $\pm 7.47^\circ$ (the range being between 42.53° and 57.47°).

6.6.4 Reliability of the Modified-Modified Schober method

The values listed in Table 6.4 represent the ANOVA analysis results for the Modified-Modified Schober (MMS) Method.

Table 6-4 ANOVA results for the reliability of the Modified-Modified Schober Method; N=15 (number of subjects), k=3 (number of measurement repeats)

	SS	df	MS	F	p-value	F-crit
Rows	6131.2	14	BMS =437.9429	12.87565	1.09E-08	2.063541
Columns	20.00441	2	JMS =10.00221	0.294068	0.747499	3.340386
Error	952.3713	28	EMS =34.01326			
Total	7103.576	44				

Replacing the BMS, EMS, JMS, k, and N values from Table 6.4 into the ICC(2,1) formula given by Eq. 6.2, we have

$$\begin{aligned}
 ICC(2,1) &= \frac{BMS - EMS}{BMS + (k-1)EMS + \frac{k(JMS - EMS)}{N}} = \\
 &= \frac{437.9 - 34.0}{437.9 + (3-1)34.0 + \frac{3(10.0 - 34.0)}{15}} = 0.81
 \end{aligned}
 \tag{6.12}$$

Replacing the EMS value from Table 6.4 into the standard error of measurement (SEM) formula in Eq. 6.4, the following SEM and $CI_{95\%}$ values were calculated:

$$SEM = \sqrt{EMS} = \sqrt{14.48} = 5.83 \text{ mm} \tag{6.13}$$

$$CI_{95\%} = 1.96 \pm \sqrt{EMS} = \pm 1.96 \cdot SEM = \pm 1.96 \cdot 5.83 \text{ mm} = \pm 11.43 \text{ mm} \tag{6.14}$$

These results can be interpreted such that if a flexion movement was performed and measured as 60 mm by the MMS Method, there was a 95% chance that the measurement was within $\pm 11.43\text{mm}$ (the range being between 48.57mm and 71.43mm).

6.6.5 Reliability of the Inductive Coil technique

The values listed in Table 6.5 represent the ANOVA analysis results for the inductive coil technique.

Table 6-5 ANOVA results for the reliability of the inductive coil technique; N=15 (number of subjects), k=3 (number of measurement repeats)

	SS	df	MS	F	p-value	F-crit
Rows	4028.311	14	BMS =287.7365	6.28725	1.92E-05	2.063541
Columns	17.91111	2	JMS =8.955556	0.195685	0.823386	3.340386
Error	1281.422	28	EMS =45.76508			
Total	5327.644	44				

Replacing the BMS, EMS, JMS, k, and N values from Table 6.5 into the ICC(2,1) formula given by Eq. 6.2, we have

$$\begin{aligned} ICC(2,1) &= \frac{BMS - EMS}{BMS + (k - 1)EMS + \frac{k(JMS - EMS)}{N}} = \\ &= \frac{287.7 - 45.8}{287.7 + (3 - 1)45.8 + \frac{3(9.0 - 45.8)}{15}} = 0.65 \end{aligned} \quad (6.15)$$

Replacing the EMS value from Table 6.5 into the standard error of measurement (SEM) formula in Eq. 6.4, the following SEM value was calculated:

$$SEM = \sqrt{EMS} = \sqrt{45.77} = 6.76 \text{ mm} \quad (6.16)$$

$$CI_{of 95\%} = \pm 1.96 \times SEM = \pm 1.96 \times 6.76 \text{ mm} = \pm 13.23 \text{ mm} \quad (6.17)$$

These results can be interpreted such that if a flexion movement was performed and measured as 55 mm by the Inductive Coil technique, there was a 95% chance that the measurement was within ± 13.23 mm (the range being between 41.77 mm and 68.23 mm).

6.6.6 Summary of the reliability tests for the four flexion measurement techniques

Table 6.6 summarises the reliability test results for the four flexion measurement methods: WT, DI, MMS and the Inductive Coil technique.

Table 6-6 Intraclass correlation coefficient, standard error of measurement and 95% confidence interval for the Wand technique, Double Inclinator, Modified-Modified Schober method and Inductive Coil technique

Measurement Technique	Intraclass Correlation Coefficient (ICC(2,1))	Standard Error of Measurement	95% Confidence Interval
Wand technique Flexion	0.87	4.45°	±8.72°
Double Inclinator Flexion	0.93	3.81°	±7.47°
Modified- Modified Schober Method Flexion	0.81	5.83 mm	±11.43 mm
Inductive Coil Technique	0.65	6.76 mm	±13.23 mm

6.6.7 Validity of the Inductive Coil technique

The validity of the inductive coil technique was assessed through a pairwise comparison between the Double Inclinator technique, the Wand technique, and the Modified-Modified Schober method when tested by the same tester.

The intra-class correlation coefficient ICC (2,1) was used to assess the agreement between these techniques. The methods were compared, with N participants (deemed random) and rated by a sample of k testers randomly selected from a larger population (Keating and Matyas 1998). The ICC (2,1) values for the pairwise comparison between different flexion measurement techniques are listed in Table 6.7.

Table 6-7 Intra-class correlation coefficient ICC(2,1) for a pairwise comparison between different flexion measurement techniques

Compared Techniques	Tester number	ICC (2,1)
WT v. IC	1	0.75
WT v. IC	2	0.65
WT v. IC	3	0.72
DI v. IC	1	0.58
DI v. IC	2	0.59
DI v. IC	3	0.68
MMS v. IC	1	0.61
MMS v. IC	2	0.47
MMS v. IC	3	0.70
DI v. MMS	1	0.78
DI v. MMS	2	0.80
DI v. MMS	3	0.78
WT v. MMS	1	0.59
WT v. MMS	2	0.56
WT v. MMS	3	0.57
WT v. DI	1	0.83
WT v. DI	2	0.86
WT v. DI	3	0.84

DI, Double Inclinator; IC, Inductive Coil; MMS, Modified-Modified Schober; WT, Wand Technique

6.7 Discussion

The clinical reliability and validity trial for the inductive coil as a potential transducer for the BSM was conducted. The reliability of the inductive coil was tested in parallel with the reliability of three other methods including: the Wand technique (WT), the double

inclinometer (DI) technique, and the Modified-Modified Schober (MMS). The validity tests were done through a pairwise comparison between measurements obtained by the same tester using different techniques.

The inductive coil trial also allowed a greater understanding of the three other measuring techniques (WT, DI and MMS) for measuring lower back movement.

6.7.1 Discussion of the reliability of the Inductive Coil technique

The results presented in Table 6.7 indicate that, the inductive coil technique showed moderate inter-tester reliability in the current clinical trial. The ICC value of 0.65 is lower than the ICC values for reliability of the other three techniques tested. The inductive coil technique also displays the highest error value using the standard error of measurement (SEM). An SEM value of 6.76 mm with a 95% CI ± 13.23 mm. The amount of variance shown in the inductive coil results suggest the technique will not be suitable for the intended purpose of measuring lower back movement.

Note that the conditions for testing the inductive coil were controlled and quite favourable for achieving reliable results. Training for the testers was provided and the flexion movement was closely guided by testers. A flexion limit (the box that set the maximum comfortable flexion limit (see 6.4.1.5)) provided a stop marker to improve the reliability of the subject's movement and there was minimal external interference (emissions from electrical equipment). The potential sources of error for the inductive coil technique form part of this discussion.

The inductive coil's agreement with other measuring techniques also varied considerably. The coil measurements showed moderate correlation with the WT, with ICC's ranging from 0.65 to 0.75. The correlation was weaker between the coil and the DI technique (ICC's

between 0.58 and 0.68). The poorest correlation was between the coil and the MMS, varying from 0.47 to 0.70.

The inductive coil device was also turned off between each subject, to reduce the impact of the electrical drift seen in the laboratory trial. The inductive coil results were poorer than expected. The ICC value of 0.65 does correspond with moderate reliability by definition but the aim of the BSM device was to improve the current state of reliability for measuring lower back ROM.

The WT showed good reliability with an ICC value of 0.87. This figure is less than the ICC values reported by Whittle, who achieved ICC values for the WT of between 0.95 and 0.97 (Whittle and Levine 1997). The WT correlated well with the DI technique, showing ICC values of between 0.83 and 0.86 for the three testers. Both these techniques derive angular changes of the lumbar lordosis, whereas the MMS method and the inductive coil technique rely on skin distraction to gauge measurement of the lumbar spine. This distinction becomes important during the design and testing of the accelerometer method in Chapter 7.

The DI technique displayed the most reliable results of the four measurement techniques, with an inter-tester ICC of 0.93. This result is closely aligned with similar studies that have assessed the inter-tester reliability of the DI technique. Saur *et al.* in 1996 showed an ICC of 0.95 for DI measure of lumbar spine flexion (Saur, Ensink *et al.* 1996). Newton and Waddell in 1991 showed an ICC of 0.94 for the DI technique for measuring lumbar spine flexion (Newton and Waddell 1991). Burdett *et al.* in 1986 showed an ICC of 0.91 for lumbar spine flexion (Burdett, Brown *et al.* 1986). Other studies have noted significantly lower ICCs for lumbar spine flexion using the DI technique. Williams *et al.* in 1993 found an ICC of 0.60 using the DI technique (Williams, Binkley *et al.* 1993).

6.7.2 Discussion of the validity of the Inductive Coil technique

The two techniques that used angular change to measure lumbar spine movement (WT and DI) correlated well showing between 0.83 to 0.86 correlations for the three testers.

The measurements of most interest in this study were those comparing the MMS to the inductive coil, because both techniques record the movements of the lumbar spine in millimetres. Correlations ranged from 0.47 to 0.70 suggesting there was questionable correlation between the two techniques.

The validity of the DI technique has been supported by a number of studies. The concept of using angular measures to quantify ROM of the lumbar spine has been further supported by Mayer *et al.* (1984) who stated that there was no statistically significant difference between X-ray measurements and inclinometer measurements. Saur *et al.* (1996) also compared radiological measurements to inclinometer measurements in their 1996 paper in the 'Spine' journal. Their study reported high correlation between radiological techniques and inclinometer techniques, with an r value of 0.93 ($P < 0.001$).

In the current study, it is difficult to draw conclusions on the validity of the DI technique, due to the lack of reliability of the other measuring methods. The best result was seen between the DI technique and the WT (ICC 0.83 to 0.86). Results between the DI and the MMS showed moderate agreement (ICC 0.78 to 0.80) yet significantly less agreement was shown between the DI technique and the inductive coil (ICC 0.58 to 0.68).

The MMS method performed quite well showing good inter-tester reliability (ICC 0.81).

This result shows a higher degree of inter-tester reliability than the Williams *et al.* study of 1993 that showed an ICC for the MMS of 0.72 (Williams, Binkley *et al.* 1993). The Williams

et al. study, however, did not use a stop point for lumbar spine flexion. This may have improved the subject's ability to flex to the same point for each movement. In the Williams *et al.* study, movements were only performed once yet in this study, movements were performed three times and the average of the three movements was used in the statistical analysis. These factors may have increased the reliability of the MMS technique in this study, since averaging is a method to reduce unpredictable variability.

Within any clinical study, there are three potential sources of error during testing of reliability and validity (Streiner and Norman 2003). Errors can occur at the level of the equipment (the inductive coil in this case), at the level of the tester or at the level of the subject. For the purpose of this discussion, the error assessment will focus on the inductive coil technique.

The first source of error related to the equipment, that is the inductive coil. Errors occurring with the inductive coil device were identified as coming from three different factors. First, the coil fixation to the body, second, an electronic drift occurring within the inductive coil and third, an electrical lag with the inductive coil.

The first equipment error stemmed from the fact that the inductive coil was difficult to reliably fix to the subject. Fixation of the coil to the lines marked on the body (Line A and Line B) was such that the attachment of the coil to the adhesive cardboard platform could vary 1-2 mm depending on the attachment hook or link. This attachment was at either end of the coil and therefore potentially caused a variation of $\pm 2-4$ mm in the total measure of lumbar spine ROM. This provides a potential source of error in the fixation of the inductive coil.

The second equipment error related to the electronic drift occurring within the readings of the coil. The inductive coil, in preliminary experiments, tended to show electronic drift over

time. The longer the device was on, the further the coil measurements would drift. This was thought to be related to a component on the circuit overheating, thus affecting the readings of the coil. Changes were made to the circuit which did reduce the drift, yet the coil readings continued to drift, especially if the device was used continuously for greater than 30 minutes. In Section 4.7.4, an example was given where the resting millimetre reading from the inductive coil drifted 5.6% in 27 minutes. This was a concern leading up to the trials but was managed by turning off the circuit in between each subject. The electronic drift was a potential source of error for the inductive coil readings.

The third equipment error potentially stemmed from electronic lag of the inductive coil. The human spine has the ability to move quite quickly. When assessing movements of the spine, it is possible that a number of movements are made within one second. A simple clinical test of 'Rate of Lumbar Spine' movements was displayed in Chapter 5, Table 5.1. The results showed that the lumbar spine could perform just over two movements per second (2.06 per second with $SD \pm 0.32$). The hold time (3 seconds) at the full extent of the flexion movement should have allowed for this lag and the lag was less evident at full stretch/full flexion, than in the upright position. The lag error was more evident in the upright position (the starting position), that is, when the coil was not being stretched. This introduced a potential issue with the trial protocol. The time the subject stayed in an upright position, between movements, was not standardised in this trial. In order to reduce the effect of the lag, it may have been best to ensure the subjects remained in an upright position for a minimum of three seconds, to allow the inductance reading from the coil to stabilise.

Why did the electronic lag only occur at the baseline, or starting position, readings? When the coil was stretched to its maximum length (i.e., from 150 mm to 250 mm) and allowed to return to its starting position, the electronic recording of the coil length took 1-2 seconds to

reach the baseline starting position, this phenomena being called an 'electronic lag'. This meant that certain movements of the lumbar spine would be missed due to the electronic lag experienced by the coil. This 'lag' was only seen at the baseline readings, whereas the upper limit readings showed good reliability (see Figure 4.14). The reasoning behind why the lag affects the baseline limit and not the upper limit is not clear. One hypothesis is that at the upper limit (fully stretched), there is more spacing between the loops of the coil therefore potentially less interference, whereas when the coil in its resting position, the loops of the coil are in close proximity and although insulated from each other (insulating paint applied when coil on full stretch, see Chapter 4), there may still be some electrical interference.

The second source of error, using Streiner and Norman's categories, relate to errors at the level of the tester (Streiner and Norman 2003). Two separate tester errors are discussed that may have influenced the results of the trial.

The first tester error relates to the identification of bony landmarks on the human body, to mark the placement for the inductive coil and other measuring techniques. The testers used for the trial had significant experience in the management and assessment of low back pain but came from different backgrounds. There was an anaesthetist, a sports physician and a manipulative physiotherapist. During the training session for the inductive coil trial, it became obvious that each professional had their own technique for locating bony landmarks. It has also been shown in previous studies that there is significant variance between therapists when locating the landmarks (Panzer 1992). In order to minimise inter-tester variance when locating landmarks for the PSIS, a brief workshop was performed prior to the trial, to ensure compliance and consensus with the identification of the PSIS.

The second tester-related error potentially stemmed from the testers' instructions to the subject. The phrases and terminology used to instruct a subject on how to move can be a potential source of error. The phrase, 'Bend forward as far as you comfortably can' was used to describe the flexion movement of the lumbar spine. It was noted that one subject was unsure as to whether they should flex forward as far as they possibly could. The phrase 'possibly could' was quite different to 'comfortably can'. For this purpose, the tester was instructed to explain that the movement was not intended to put any strain on the subject at all and they needed to be able to comfortably hold the position for five seconds. The protocol stated quite specific instructions, or scripted phrases in an attempt to reduce errors relating to the instructions from the testers and the subjects interpretation of those instructions.

The third source of error occurred at the level of the subject. Two potential subject errors were noted.

The first subject-related error was the 'warm up' effect. In earlier trials, it had been observed that subjects would flex forward further on their repeated bends. There is a documented warm up effect that suggests that a subject performing a particular task, will be able to move further into range once the movement has been performed a number of times (Roberts, Liang et al. 1988; Youdas, Carey et al. 1991). In order to mitigate this potential for error, the subject was taken through a warm procedure as part of the protocol, involving hamstring stretches, lumbar rotations, lumbar flexion and extension. A further strategy involved setting a marker or stop point such that when a subject reached their hands forward, toward the ground as far as they comfortably could, a box was set at this height. This box gave the subject a definitive end point for their flexion ROM, encouraging them to repeat the same range and type of flexion movement. This procedure was repeated for the

lateral flexion movements but was more difficult to perform for extension of the lumbar spine.

The second subject-related error was that each individual subject could vary in the way they performed each movement. Subjects have different concentration levels and different awareness about how their body is moving in a three dimensional space and this could have contributed to error in the measurement. The described tasks are relatively simple daily movements of the spine yet even in the warm up procedure, the variation in the way subjects would move from one movement to another was quite noticeable. Subjects with poor concentration or lack of attention to detail varied their starting positions whereas other subjects were more attentive to the instructions from the testers.

The three standard measuring techniques (WT, DI and MMS) performed in a similar way to previous studies, showing similar ICC values for inter-tester reliability (Wand ICC 0.87, DI ICC 0.93 and MMS ICC 0.81). The validity between the DI technique and the Wand technique was certainly encouraging (with ICCs between 0.83 to 0.86), suggesting that the angular techniques may be more a more reliable method for measuring lower back movement than the skin distraction techniques (MMS and the inductive coil technique). The correlation between the MMS and the inductive coil technique ranged from 0.47 to 0.70 which was not enough to have confidence that the recording of the coil method was reliable and agreed with the MMS method.

The inductive coil technique provided positive early results in a laboratory based setting yet with continuous use, issues with reliability became evident. Modifications to the circuit and software assisted in reducing the electrical issues but the inductive coil device still needed to be turned off between each of the subjects. The electronic drift when the inductive coil was turned on for greater than 30 minutes and the electrical lag whilst the inductance levels

stabilized after stretching, were issues that were not easy to rectify. Coupled with the poorer than expected reliability and validity results, the inductive coil would need significant improvement before becoming a useful measuring transducer for the lower back.

The essence of the BSM device was to develop a new reliable, valid and easy to use measuring device for the lower back. The inductive coil technique proved to have moderate reliability for short duration testing but not for prolonged periods of assessment. There was merit in investigating the accelerometer technique more closely, especially in light of the positive results from the angular techniques within the inductive coil trial. Chapter 7 reviews the clinical trials for the accelerometer method. The background and laboratory testing of the accelerometer method are described in Chapters 4 and 5.

Chapter 7. Clinical Study II for the Back Strain Monitor: The Accelerometer Method

This Chapter describes clinical experiments conducted to test the reliability and validity of the Accelerometer Method. The Accelerometer Method allowed for the measuring of lower back movement in two dimensions. Three testers were involved in the trial that reviewed the inter-tester reliability of the Accelerometer Method, the Double Inclinator technique and the Modified-Modified Schober method. The results obtained from the Accelerometer method were compared with the results obtained from the Double Inclinator technique, to assess the criterion validity of the Accelerometer Method.

7.1 Introduction

The second clinical trial for reliability and validity of the BSM used the accelerometer transducers to measure movements of the lumbar spine.

The aim of the study was to assess whether the accelerometer method could reliably and validly measure the range of movement on human subjects. The accelerometer method was developed 18 months after the inductive coil technique resulting in the second clinical study being performed on a different set of subjects. In an ideal setting, the same subjects would be assessed using the inductive coil technique and the accelerometer method.

For reliability, the accelerometer method was assessed for inter-tester reliability (three testers on the same day) and for test re-test reliability (one tester on two different days). For validity, the accelerometer method (AccM) was assessed by comparing the accelerometer readings to two other reliable measuring methods: the double inclinometer (DI) technique (Mayer, Tencer et al. 1984), and the Modified-Modified Schober (MMS) technique (Williams, Binkley et al. 1993).

The DI and MMS techniques were described in detail in Chapter 6. In brief, the DI technique involves using two gravity inclinometers to measure the relative angle of the spine in relation to the line of gravity (or vertical). The DI technique measures the angular difference between the upper lumbar spine (L1), measured by one inclinometer, and the lower lumbar spine (S1), measured by a second inclinometer. One inclinometer reading is subtracted from the other inclinometer to calculate the position of the lumbar spine at that point in time.

The DI technique is the comparator that most closely mimics the accelerometer transducers. The accelerometers measure angular movement and the accelerometers are placed at the same bony landmarks as inclinometers used by the DI technique. For the purpose of the clinical trial, the DI technique is considered the 'Gold Standard' against which to gauge the accelerometer measurements. The DI technique is therefore the criterion measure for a clinical trial that aims to produce evidence of criterion validity for the AccM (Streiner and Norman 2003).

The DI technique has been shown to be reliable and valid. However, it does only provide a single measurement of the start and end of lumbar spine movement. The AccM aims to provide multiple measurements through the full range of movement at five recordings per second and for extended periods of time (up to 24 hours).

The MMS method uses a flexible tape measure to measure the change in skin stretch when the lumbar spine flexes from a neutral position to a fully flexed position. The landmarks are at the lumbo-sacral junction and the thoraco-lumbar junction and this method has been shown to have relatively high levels of inter-tester and test intra-tester reliability by various authors (Million, Nilsen et al. 1981; Waddell, Main et al. 1982; Biering-Sorensen 1984; Merritt, McLean et al. 1986; Gill, Krag et al. 1988), and in the previous Chapter (ICC = 0.81).

The clinical trial was performed within a controlled setting. A controlled setting for this study was defined as an indoor setting, where all subject movements are performed with their feet stationary and there are few external influences from the environment.

7.2 Method

7.2.1 Instrumentation: description of measurement techniques

The gravity inclinometers for the double inclinometer (DI) technique

The DI measuring technique (Reynolds 1975; Mayer, Tencer et al. 1984) requires two gravity inclinometers that have a swinging needle that always points vertically as the housing is rotated through space. The base of the inclinometer is aligned with the object being measured and the needle will point to the specific angle on the inclinometer housing, in reference to the vertical. (For a diagram of the gravity inclinometer, see Figure 6.1)

Tape measure

A soft, flexible tape measure (similar to one a seamstress may use) was required for the MMS technique. This needed to be calibrated against a ruler to ensure the metal end capping had been well placed when the tape was manufactured (see Figures 6.4 and 6.5).

The Accelerometer method (Back Strain Monitor)

The accelerometer method (AccM) involved two identical accelerometer transducer boards (ATBs) (Figure 7.1), EMG electrodes and a recording feedback device (RFD) (Figure 7.2) which acted as a data storage unit for the trial data. Whilst the EMG electrodes were used in the trial, the recordings and reliability of the EMG signals do not form part of this thesis.

The Accelerometer Transducer Boards

The ATBs were fitted with the two separate, two-dimensional (2D) accelerometers, positioned perpendicular to each other, with one offset at 45° to the other accelerometer and the main PCB (see Figure 4.19). The accelerometers measured acceleration of the ATBs,

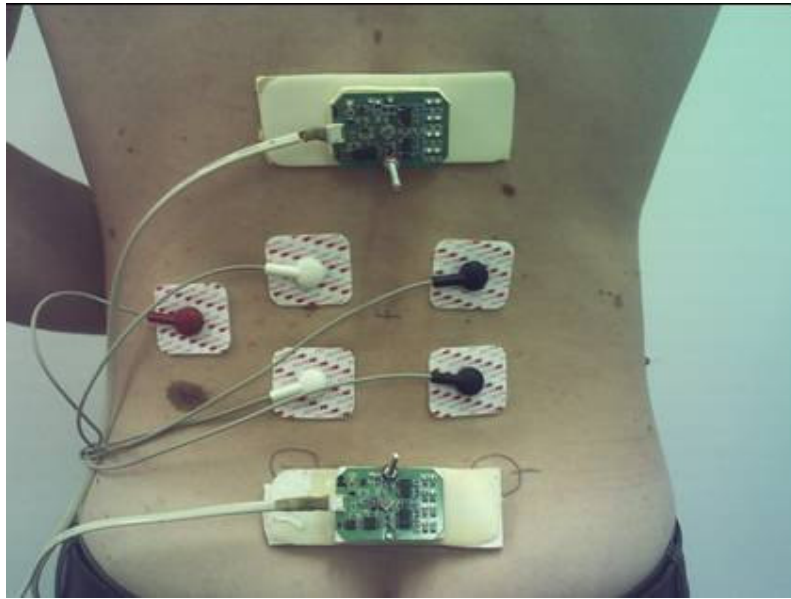


Figure 7.1 Diagram of the accelerometer prototype in place on the lumbar spine (accelerometer transducer boards and electro-myographic electrodes)

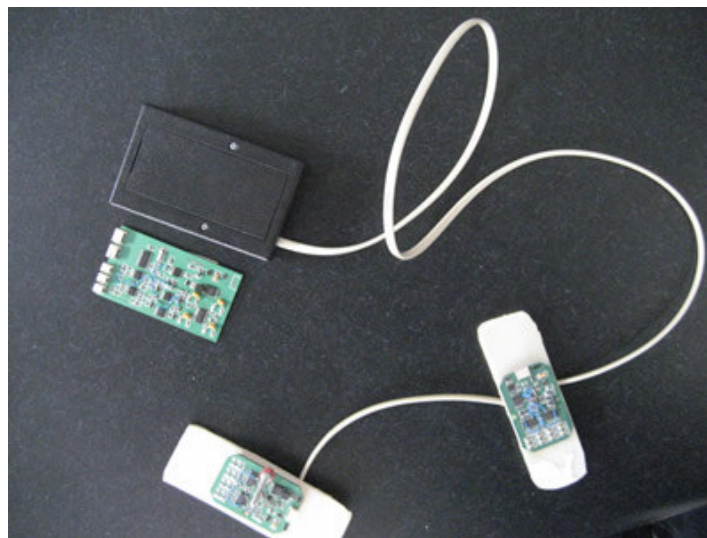


Figure 7.2 The accelerometer prototype used for the accelerometer trial showing the accelerometer transducer boards and the original recording feedback device

whilst the orientation of the accelerometers enabled three-dimensional trigonometry and simultaneous equations to calculate of the angular changes of the ATBs in relation to gravity (see Chapter 5).

The first ATB was placed at the level of the PSIS, on the first sacral spinous process (S1) and the second ATB was placed 150mm above this, close to the level of the first lumbar spinous process (L1), (see Figure 7.1). By subtracting one ATB angular position from the other ATB angular position, the lumbar lordosis (or starting position) was derived (Whittle and Levine 1997). The change in lumbar lordosis was calculated by sampling the different positions of the lumbar spine at regular intervals, and subtracting one position from another. Five samples a second were taken by the accelerometers allowing a continuous analysis of the change in position or posture of the lumbar spine.

The ATBs were mounted onto a thermoplastic board in order to extend the width of the fixation points. Although this reliability study only reviews two dimensions of movement (flexion/extension and lateral flexion movements), the accelerometer technique may have the capability to quantify axial rotation movements of the lumbar spine. During early laboratory testing, a smaller ATB was used with lateral dimensions of 52 mm. It became evident that rotation ROM of the lumbar spine caused significant contraction of the erector spinae musculature, leading to deviation of the small ATB, such that the ATB rotated in the opposite direction to the movement being performed. This only occurred at the upper ATB but would cause errors to any rotational measurements.

To overcome this issue, a wider thermoplastic base was used for the ATB (100 mm, see Figure 7.3) than the original 52 mm. The wider base plate for the ATB ensured the intended rotational motion was captured by the upper ATB. Double sided adhesive foam was used to adhere the ATB to the subject, protecting the skin from any sharp edges of the ATB.

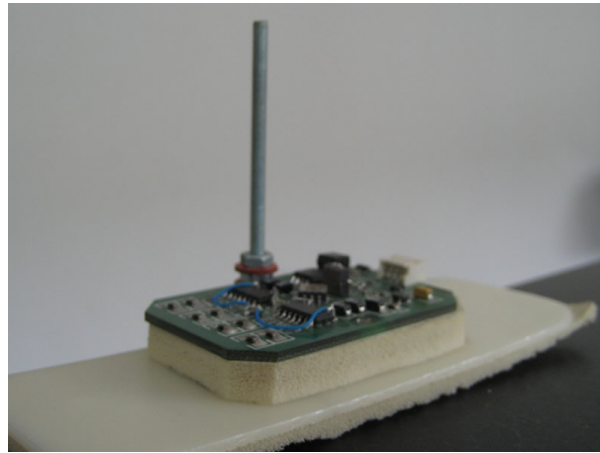


Figure 7.3 The accelerometer transducer board

The electro-myographic electrodes

To be able to record the muscle activity of the lumbar spine muscles, EMG electrodes were placed on the erector spinae muscle group at the level of L3 (Fathallah, Marras et al. 1998). The EMG electrodes used were 3M brand, 2560 Red Dot electrode (3M, Pymble, Australia). The placement and orientation of the electrodes matched the orientation described by Fathallah *et al.* (1998). The skin preparation and application of the EMG electrodes followed the manufacturer's instructions.

The Recording Feedback Device

The RFD consisted of a double layered printed circuit board, a 9V battery, the housing and the leads to the ATBs and to the EMG electrodes (further detail provided in Chapter 5). The RFD was capable of recording 24 hours of data. Each subject's data set was downloaded to the mainframe computer after each subject performed each trial. The feedback aspect of the device was not used for the purposes of this trial. The original version of the RFD is pictured in figure 7.2, and the current version is pictured in figure 7.4.



Figure 7.4 The current recording feedback device

7.2.2 Testers

Three health practitioners, a manipulative physiotherapist, a physiotherapist and an anaesthetist, were the testers for the accelerometer trial. The therapist's professional experience ranged from 10 years to 16 years and each therapist had significant experience with the assessment, treatment and management of lower back conditions. Each of the therapists received a trial package prior to the trials, to allow a more comprehensive understanding of the protocol and timetable for the trial. The package included a description of the device, a copy of the trial protocol, an instruction sheet in relation to the application of the device and a timetable for the trial day.

The testers were required to be at the trial location one hour before the trial began, to observe a demonstration of the accelerometer prototype to be used in the trial and to operate the prototype themselves. The comparator measuring devices (DI and MMS techniques) were demonstrated in the same way, to ensure each of the testers were familiar with each of the measuring techniques.

7.2.3 Subjects

The subjects for this study were a convenience sample of 23 volunteers who responded to an advertisement placed in the waiting room of two physiotherapy centres in Melbourne.

The centres were the Hoppers Crossing Physiotherapy Centre, Hoppers Crossing and the Bluff Road Physiotherapy Centre, Sandringham.

Before acceptance as a volunteer, each subject was questioned by a receptionist at the centre, who was not taking part in the trials. The subjects were not asked to take part in the study by their treating physiotherapist or any other health practitioner. Subjects were excluded from the study if they had had back pain in the previous 3 months, had a history of lower back surgery, were pregnant or had a cardiac pacemaker. For inclusion, the subjects were required to be between 20 and 65 years of age and were not able to have had recent surgery or have experienced a significant medical condition which affected their normal daily activity and/or movements of their lower back.

The subject sample was a different and independent sample from the subjects tested in Chapter 6. There were 17 males and 6 females and the subjects' age aged from 21 to 62 years, with a mean age of 40.4. The participants were spread across different occupational groups. All subjects read and signed an informed consent form prior to inclusion in the study. Each subject was given an identification number and the order in which the subjects were tested was randomly selected and placed on a timetable to ensure that on the trial day, subjects were allocated to testers in a random order.

7.3 Procedure for the accelerometer reliability trial

The Human Research Ethics Sub Committee from RMIT University referred the accelerometer trial ethics application to the main Human Research Ethics Committee at RMIT. Approval was gained from the RMIT and the La Trobe University Faculty Human Research Ethics Committees for the trial to proceed.

7.3.1 The accelerometer trial protocol

The protocol for the trial closely followed the protocol used for the inductive coil trial, described in Chapter 6, with the omission of the wand technique and the inductive coil technique and the inclusion of the accelerometer technique. The protocol for the accelerometer trial combines aspects of three relevant studies.

The first study is a research report by Williams *et al.* (1993), who compared the MMS technique to the DI technique. This research report also discusses the development of the MMS from the original Schober technique (Schober 1937) and describes a number of previous studies that utilise the DI technique for assessing reliability and validity of lumbar spine movement (Mayer *et al.* 1984; Keeley *et al.* 1986; Merritt *et al.* 1986; Gill *et al.* 1988).

In the second relevant study the Modified-Modified Schober (MMS) method was described for the first time (van Adrichem and van der Korst 1973). This study elaborates how the MMS method was derived from the original Schober method (Schober 1937). Van Adrichem and van der Korst report that the MMS method provides a reliable method for measuring lumbar spine movement.

The third relevant study for the development of the accelerometer trial and the trial protocol is by Mayer *et al.* (1984). In Mayer's study, the DI technique was compared to X-ray and no statistically significant difference was found between the two techniques. This study supported the concept of measuring angular changes at the upper and lower aspects of the lumbar spine to derive a measure of the movement taking place in the lumbar spine. Other authors have been critical of the Mayer article because the statistical analysis used means and standard deviations, not correlations (Williams, Binkley *et al.* 1993). This criticism is balanced by other authors who have reported that the DI is a valid technique for measuring

lumbar spine motion (Moll 1976; Portek I 1983; Merritt *et al.* 1986; Newton and Waddell 1991).

The protocol for the accelerometer trial was based on components from each of the above studies, as well as a specifically written procedure for the application of the accelerometers. A copy of the accelerometer trial protocol is attached in Appendix III.

Bony landmarks

All participants were initially positioned in a comfortable erect standing position with feet shoulder-width apart (Youdas, Carey *et al.* 1991). The posterior superior iliac spines (PSIS) (Hoppenfeld 1976; Magee 1987; Youdas, Carey *et al.* 1991) were identified and marked, in the shape of an olive with a removable pen marker, by each practitioner on the lower lumbar spine of each participant. A horizontal line 'line A' (see Figure 7.5) was then drawn through the centre of the two olives representing S1. This line marked the application point for the lower accelerometer transducer board (ATB) with its superior border sitting directly along 'line A'.

The second application point was identified by measuring 150 mm vertically above the horizontal 'line A' (towards the thoraco-lumbar (T12/L1) junction) whilst keeping the flexible tape measure pressed gently against the skin. Another horizontal line was drawn at this higher point and was labelled 'line B'. The line 'B' marked the application point for the upper accelerometer transducer board (ATB), where its inferior border was adhered directly along 'line B'.

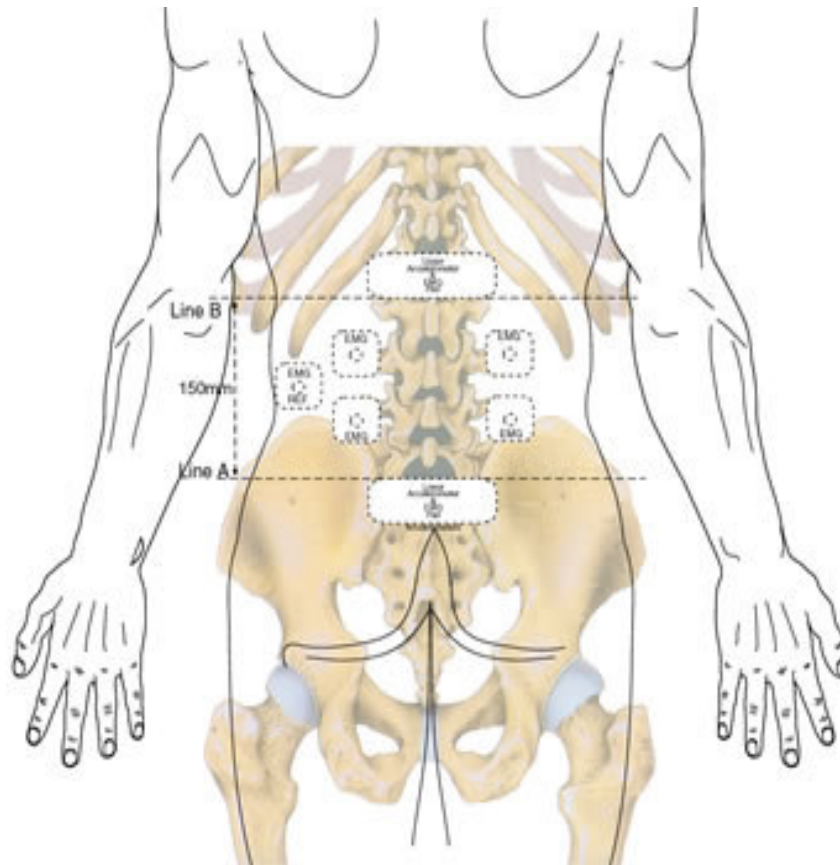


Figure 7.5 Diagram showing the placement of the transducer boards and electromyographic electrodes on the lumbar spine for the accelerometer trial

The EMG electrode placements were derived from those described by Fathallah *et al.* (1998a,b).

Device fixation

The skin of the lower lumbar spine was shaved, where necessary, and cleaned with alcohol based wipes to reduce the oil content of the skin and ensure minimum impedance between the skin and the EMG electrodes. The skin preparation also allowed adequate adhesion of the EMG electrodes and the ATBs to the skin.

The ATBs were applied to the skin using a therapeutic, low allergenic, double sided wig tape from Burbec P/L (Melbourne, Australia). The ATBs were placed centrally on 'line A' and 'line B' in accordance with the trial protocol. The ATBs needed to be horizontal and this

was confirmed with a spirit level. The EMG electrodes were placed in their respective positions in keeping with the protocol. The leads connecting the transducers (ATBs and EMG electrodes) to the RFD were checked to ensure adequate connection.

Calibration of the Accelerometer Transducer Boards

The subject was asked to stand in an erect position with hands by their side, feet shoulder-width apart and looking forward. Once the subject was in their 'calibration position' (identical to the starting position) and the tester checked conformity with the protocol, the RFD calibration button was pressed to give the accelerometers their zero reference point. For the three dimensions of movement, this zero position was the point where all measurements would be referenced from. The calibration process needed to be performed for each subject.

Warm up routine

A subject's maximum ROM of the lumbar spine can vary depending on the number of movements previously performed. In order to reduce the warm up effect, warm up movements were performed prior to measurements being taken. Each subject was asked to flex forward, backward, tilt left and right and rotate left and right (once in each direction) to ensure that were able to perform the required movements (Roberts, Liang et al. 1988).

Subject starting position

Each subject, before commencing movements, was asked to ensure the following:

- Stand facing the door of the room with head and shoulders straight;
- Stand with feet shoulder-width apart;
- Stand with arms relaxed by side; and
- Stand with spine in an upright and erect stance.

(for a diagram of the subject starting position see Figure 6.9)

Movements to be performed

The following movements were performed, with all described transducers measuring the movement.

1. Lumbar spine flexion

Starting posture: Standing (in starting position)

The participant was asked to 'flex your trunk forward, reaching your fingers toward the ground as far as you comfortably can'. It was explained to the subject that it was not a test or competition for their maximum amount of flexion, but more to bend to a level of flexion that they could comfortably hold for a five-second period.



Figure 7.6 Subject flexing forward to a box as their limit for flexion range of movement testing

The distance between the finger tips and the ground was measured with a tape measure and a box, matching this same height, was placed on the ground (see Figure 7.6). The

purpose of the box was to give the subject a marker to reach to such that the movements performed were consistent. The subject was then asked to reach forward and lightly touch the box with their fingertips and hold the position for five seconds. This routine was repeated three times. At the starting position and the fully flexed position, MMS readings were taken first, followed by the DI readings. The RFD automatically recorded all movements performed.

2. Lumbar spine extension

Starting posture: Standing (starting position)

The subject was asked to arch backward as far as they are comfortable, with their arms folded across their chest, and to hold this position for five seconds. Whilst holding this position the DI readings were taken and repeated when the subject returned to their starting standing position. The MMS method was not used for the lumbar extension movement. The extension movement was repeated three times. An extreme range of movement was discouraged as it was shown to become uncomfortable with the sustained hold. This was explained to the subject during the warm up movements.

3. Lumbar spine lateral flexion

Starting posture: Standing (starting position)

The subject was asked to laterally flex the lumbar spine, sliding their hand down the side of their thigh without allowing the trunk to deviate forward or backward. The movement was closely monitored during the warm up routine as well as during the testing, to ensure each subject understood the requirements of the lateral flexion movement.

It was noted in previous trials that significant variability existed when subjects performed the lateral flexion movements. This may be due to the scapula and shoulder complex being able to reach a variable amount. The testers' instructions to the subject and subject's understanding of these instructions and the lateral flexion movement, were crucial to the reliability of the lateral movement being performed.

At the maximum comfortable lateral flexion range of movement, a box placed on a small table was placed at that height to allow the subject to return to the same level of lateral flexion. The lateral flexion movement was performed three times to the right and three times to the left with a five second hold at the maximum range of movement.

The double inclinometer was used to record the range of lateral flexion to the right and left. The base of the inclinometer was placed in line with the top of the upper ATB whilst the second inclinometer was placed in line with the lower ATB. Readings were taken from both inclinometers and recorded on the subject's data sheet.

No Modified-Modified Schober (MMS) readings were taken for extension ROM or lateral flexion ROM as the MMS technique has not proven to be reliable for these movements.

After all appropriate movements were performed, the ATBs and the EMG electrodes were removed and the skin markings cleaned off with a safe solvent to reduce any potential bias from the next tester utilising the same landmarks. The subject's data sheet was checked by the trial co-ordinator, ensuring each subjects' details and each testers' details were correct and that all data fields were complete. The subject was then assisted back to the waiting room to be allocated, in a random sequence, to the next practitioner. Each subject was tested by the three testers within a one hour period, with each individual test taking between 15 and 20 minutes to perform.

7.4 Statistical analysis

The reliability of the accelerometer method relates to the consistency and reproducibility of the measurements from one tester to another tester (inter-tester reliability) and from the same tester using the accelerometer method on two separate days (test re-test reliability) (Thorndike and Hagen 1977). To obtain evidence of validity, the AccM measurements were compared to another measurement method with documented evidence of validity, in this case the DI technique.

The reliability and validity of the accelerometer method for measuring lower back movement is currently not known. Therefore, the first step was to establish the reliability of the accelerometer method, to determine how consistent do the device recordings need to be in order to be useful? (Keating and Matyas 1998) Definitions of reliability again follow Durand's recommendations (Durand, Malouin et al. 1991). An ICC between 0.80 and 1.0 represents a very reliable method or procedure, those between 0.60 and 0.79 represent moderate reliability and those lower than 0.60 show doubtful, or at least questionable, reliability.

In Chapter 4, the inductive coil showed reasonable reliability in the laboratory trials, with a CV of 5.6% due to an electronic drift. Expectations for the reliability of the inductive coil in the clinical trial were not high due to the inherent problems in the laboratory setting. Once the inductive coil was placed on the lumbar spine, it was anticipated that there would be significantly more error. In the clinical trial described in Chapter 6, the inductive coil results were further impeded by the electronic lag, leaving less than acceptable results for the inductive coil reliability (ICC range 0.47 – 0.70).

The accelerometer method showed very good results within the laboratory setting. There was a coefficient of variation of 1.0% for movements between 0° and 90°. The higher degree of consistency within a laboratory setting increased the expectations for the accelerometer

method within the accelerometer clinical trial. The DI technique has been shown to have an ICC as high as 0.95 (Saur, Ensink et al. 1996) with other studies reporting ICCs greater than 0.90 (Burdett, Brown et al. 1986; Newton and Waddell 1991). Within the previously described inductive coil trial, the DI technique had an ICC of 0.92. Whilst an ICC of above 0.80 constitutes good reliability based on Durand's definition (Durand, Malouin et al. 1991), the expectation for an acceptable ICC for the reliability of the accelerometer method within a controlled clinical trial setting is to be 0.90. There are also observations and lessons learnt from the inductive coil clinical trial, in relation to the landmark identification, tester education and instructions to the subject. Prior to the statistical analysis being performed, an average was taken for the three movements that each tester asked the subject to perform. This was done for the AccM, the DI technique and the MMS method.

The statistical analysis reviewed the accelerometer measurements in three ways. First, the inter-tester reliability (ITR) (Streiner and Norman 2003) of the accelerometers was examined to determine the variability between different raters or testers using the accelerometer method. Secondly, the intra-tester reliability or test re-test reliability (TRTR) was used to determine the variability between the same tester but on a different day (Streiner and Norman 2003). Thirdly, evidence of validity of the accelerometer method was assessed by comparing the accelerometer readings to other standard lower back measurements, the DI and MMS techniques. To acquire evidence of validity, by comparison with a 'gold standard' measurement, is to provide evidence of criterion validity (Streiner and Norman 2003).

In all three cases an intraclass correlation coefficient (ICC) method, as described by Shrout and Fleiss (Shrout and Fleiss 1979), was used to review the reliability and validity of the accelerometer method. Different forms of the ICC are used for the analysis depending on the design and the nature of the study. For the inter-tester reliability and the test re-test

reliability, ICC (2,1) was used (Keating and Matyas 1998). The ICC (2,1) has been previously used to account for variance in a test re-test reliability study (Taylor, Dodd *et al.* 2004). For the correlation between the accelerometer method and the DI and MMS techniques, ICC (2,1) was also used (Keating and Matyas 1998). The ICC (2,1) formula (see Eq. 6.1) and the reasoning behind the choice of each ICC method is described in detail in Section 6.5.2 and 6.5.3 (Keating and Matyas 1998).

7.4.1 The standard error of measurement method

The SEM method displays the size of the error in the actual measurement unit used (Keating and Matyas 1998). The SEM is used to compare the measurements taken by three different testers on the same day and is also used to compare the measurements taken by the same tester, on different days. The reasoning behind utilising the SEM method has been previously described in Section 6.5.4.

Another way of reviewing the SEM can be to view the data in a scatterplot (Keating and Matyas 1998; Hayes 2005). Hayes suggests that a visual approach can be useful because the variance of data points from the regression line is easily identified. If the measured scores are precisely the same, a straight line could be drawn through every point on a scatter-plot. If the opposite is true and there is significant variance in the scores, there will be a wide range of data points around the regression line.

The formula for the SEM has been previously described in Eq. (6.4). A scatter-plot was also used to examine the deviation of the measurement scores from the regression line, in order to view the standard error of measurement.

The formula to determine a 95% confidence interval $CI_{95\%}$ for the SEM is previously displayed in Eq. (6.5).

7.4.2 Prediction of variability (Pearson's r and r^2)

Whilst not chosen to be used for the main correlation coefficient for the reliability analysis, the Pearson's r can be used to derive the r^2 values. The r^2 values can be used as a measure of predictable variability between the DI technique and the AccM. Howell (1992) suggests that the r^2 value is extremely useful because it suggests that the variability in one measure (DI technique) that is directly predictable from the variability in another method (AccM) (Howell 1992). The r^2 value is used to compare the prediction of the variability of the DI technique from the variability of the AccM.

7.5 Results

7.5.1 Inter-tester reliability

The three testers' results were correlated against each other's results to determine the inter-tester reliability for the three different measurement techniques (the AccM, DI and the MMS), for each of the four movements tested. Tables 7.1 and 7.2 demonstrate the data set and ANOVA analysis for the movement of flexion only. The results of the other movements are summarised in Table 7.3.

An ANOVA table was produced to determine the variance between testers and the error limits. The inter-tester reliability, for the movement of flexion, was estimated for each of the measurement techniques. The ANOVA table used to calculate the ICC (2,1) for flexion ROM of the Accelerometer Method (AccM) is presented in Table 7.2.

Table 7-1 The data sets for the three measurement techniques for lumbar spine flexion

		Double Inclination Flexion			Accelerometer Flexion			MMS Flexion		
	Tester	T1	T2	T3	T1	T2	T3	T1	T2	T3
Subj	Subj									
No.	Age	x°	x°	x°	x°	x°	x°	mm	mm	mm
1	37	70	74	72	69	71	72	72	81	68
2	34	57	56	67	66	55	66	64	74	58
3	31	71	66	61	63	65	60	67	74	68
4	60	39	37	36	40	38	40	49	47	43
5	62	45	49	36	60	50	55	56	62	44
6	21	63	64	62	60	64	64	64	65	64
7	41	59	61	59	60	62	63	82	78	77
8	34	59	67	62	63	65	62	76	75	74
9	38	35	33	38	41	39	39	46	45	48
10	29	72	71	68	63	65	67	74	75	72
11	24	69	66	72	67	70	71	61	78	69
12	44	58	46	63	63	59	66	68	58	51
13	49	54	55	59	57	61	62	56	59	70
14	27	68	71	73	71	71	74	69	80	82
15	52	42	43	46	47	46	47	43	47	44
16	51	58	63	67	61	61	60	65	70	56
17	60	41	39	36	45	47	47	45	45	46
18	33	72	75	71	74	75	75	73	65	82
19	55	68	61	58	73	75	72	70	86	68
20	57	54	57	58	52	55	55	63	80	57
21	32	80	73	76	75	76	76	75	88	71
22	28	59	47	64	63	62	62	58	61	45
23	31	74	79	76	76	75	74	75	80	83

Table 7-2 ANOVA table for accelerometer method (AccM) for flexion of the lumbar spine

	SS	df	MS	F	p-value	F-crit
Rows	7485.333	22	BMS =340.2424	69.9554	1.91E-26	1.7889
Columns	13.42029	2	JMS =6.7101	1.2613	0.2933	3.2093
Error	234.0797	44	EMS =5.3200			
Total	7732.833	68				

There was a separate ANOVA table produced for each of the measurement techniques (AccM, DI and MMS) and for each movement direction (flexion, extension, left lateral flexion and right lateral flexion). From each of the ANOVA tables, ICC values were calculated. Table 7.3 summarises the ICC (2,1) calculations for inter-tester reliability.

Table 7-3 Results for the inter-tester reliability test for the AccM, DI and MMS

Type of movement	ICC for AccM	ICC for DI	ICC for MMS
Flexion	0.95	0.89	0.74
Extension	0.95	0.91	N/A
Left Lateral Flexion	0.89	0.85	N/A
Right Lateral Flexion	0.86	0.83	N/A

The ICC values for the AccM and the DI showed very good reliability for the four different movements whereas the MMS displayed moderate reliability for the one movement of flexion. The ICC values for the DI technique are slightly less than in the previously described inductive coil (Chapter 6) and previous studies (Burdett, Brown et al. 1986; Newton and Waddell 1991; Saur, Ensink et al. 1996), yet still within guidelines of good reliability (Durand, Malouin et al. 1991).

By using the SEM, the reliability results can be reviewed in the context of the original unit of measurement. The calculated ICC values from Table 7.3, the SEM values have been calculated for each of the three devices, for each of the four tested movements.

Table 7.4 presents the SEM values for the three devices. Note that the SEM value is represented in the unit of measurement, that being degrees of movement for the AccM and the DI whereas the MMS is represented in millimetres.

Table 7-4 Standard error of measurements and 95% confidence intervals for the inter-tester reliability of the three measuring techniques

Type of movement	SEM for AccM	95% CI (AccM)	SEM for DI	95% CI (DI)	SEM for MMS	95% CI (MMS)
Flexion	2.31°	±4.53°	4.24°	±8.31°	6.01 mm	±11.78 mm
Extension	1.56°	±3.06°	2.42°	±4.74°	N/A	
Left lateral flexion	1.95°	±3.82°	2.47°	±4.84°	N/A	
Right lateral flexion	2.39°	±4.68°	2.35°	±4.61°	N/A	

7.5.2 Intra-tester reliability (test re-test reliability)

The test re-test reliability involved the comparison of one tester's measurements on two separate days. Tester one repeated the measurements on 22 of the 23 subjects, five weeks after the first testing day. The three measuring techniques stayed constant, those being the AccM, DI and the MMS method. The same protocol was used, the same device, the same setting yet the order of subjects was randomized to avoid any potential memory effect. One subject was unable to attend the retest session.

The ANOVA table was calculated to assess the variance between the first test day and the second. A separate ANOVA was required for each of the test methods and each of the movements. A total of nine ANOVA tables were produced. The ANOVA table for the Accelerometer extension is displayed in Table 7.5. The results of the ANOVA table were used to calculate the ICC (2,1) for the accelerometer method for extension.

Table 7.6 summarises the ICC (2,1) calculations for test re-test reliability (TRTR) of the three measuring techniques.

Table 7-5 The ANOVA used to calculate the test re-test reliability for accelerometer extension

	SS	df	MS	F	p-value	F-crit
Rows	1787.159	21	BMS =85.1028	102.5228	1.15E-16	2.0842
Columns	0.5682	1	JMS =0.5682	0.6845	0.4173	4.3248
Error	17.4318	21	EMS =0.8301			
Total	1805.159	43				

Table 7-6 Test re-test reliability of the accelerometer method

Type of Movement	ICC for AccM	ICC for DI	ICC for MMS
Flexion	0.99	0.94	0.77
Extension	0.98	0.95	N/A
Left Lateral Flexion	0.89	0.88	N/A
Right Lateral Flexion	0.93	0.86	N/A

The SEM for accelerometer extension is calculated using Keating's formula (Keating and Matyas 1998). Using the EMS value from Table 7.5, the SEM value was calculated as follows:

$$SEM = \sqrt{EMS} = \sqrt{0.83} = 0.91^0 \quad (7.1)$$

The 95% confidence interval $CI_{95\%}$ from was then calculated. The results for the AccM TRTR are presented in Table 7.7.

Table 7-7 Standard error of measurement and 95% confidence intervals for the test re-test reliability

Type of movement	SEM for AccM	95% CI (AccM)	SEM for DI	95% CI (DI)	SEM for MMS	95% CI (MMS)
Flexion	0.91°	±1.78°	3.03°	±5.94°	4.54 mm	±8.90 mm
Extension	0.91°	±1.78°	1.80°	±3.53°	N/A	N/A
Left lateral Flexion	1.84°	±3.61°	2.16°	±4.23°	N/A	N/A
Right lateral flexion	1.56°	±3.01°	2.21°	±4.33°	N/A	N/A

The SEM values show that the measurement error for the test re-test results are less than the measurement error for the inter-tester results. The AccM method showed the least error when compared to the DI technique and the MMS method.

Figure 7.7 displays a scatterplot for the data set of test re-test values for the accelerometer method on Day 1 and Day 2.

7.5.3 Validity: comparisons of the Back Strain Monitor Accelerometer and Double Inclinator technique

The previous two sections of this chapter have focused on whether the AccM is repeatable between different testers and with the same tester on different days. This section statistically analyses the evidence of criterion validity of the accelerometer method, comparing the accelerometer method (AccM) to the double inclinometer technique (DI). The DI technique has been shown to be valid (Reynolds 1975; Moll 1976; Portek I 1983; Mayer *et al.* 1984; Merritt *et al.* 1986; Newton and Waddell 1991; Saur *et al.* 1996; Ng *et al.* 2001). The DI technique has also been shown to correlate well with X-ray (Mayer, Tencer *et al.* 1984; Saur, Ensink *et al.* 1996) (see Chapter 6 for more detail).

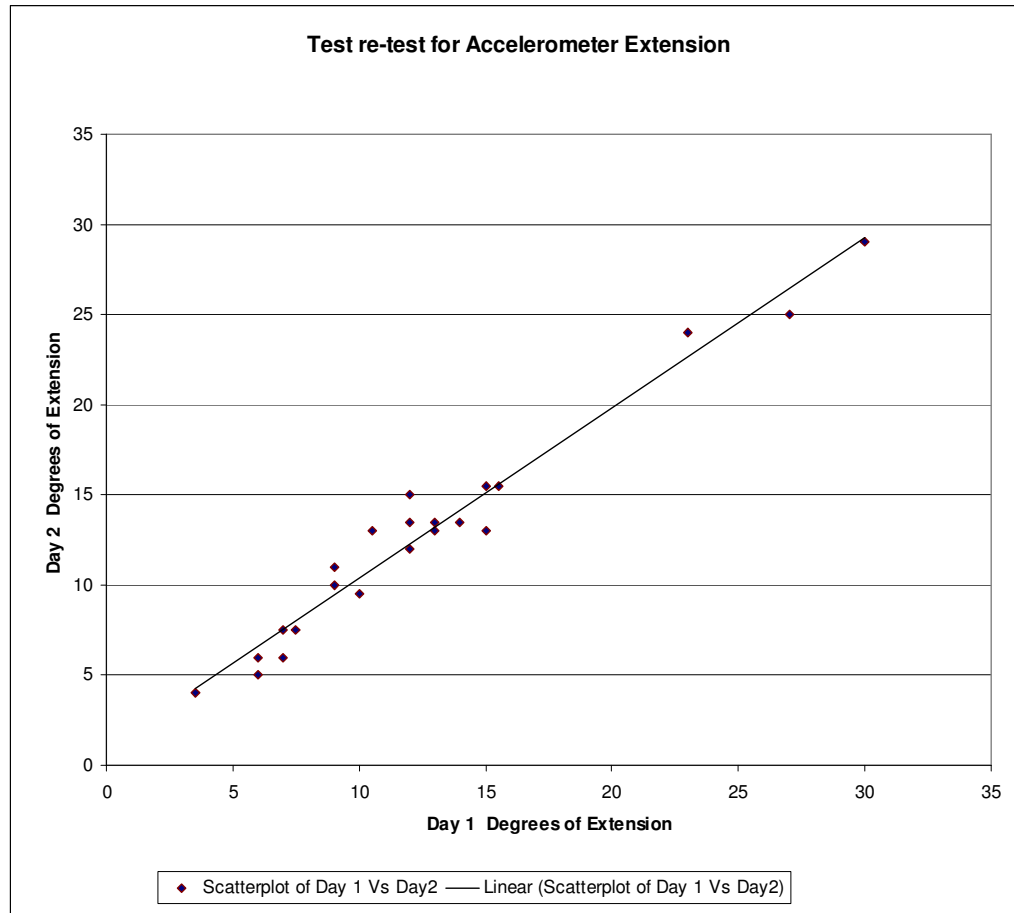


Figure 7.7 A scatterplot of test re-test values for the accelerometer method for the movement of extension (Day 1 & Day 2)

The intra-class correlation coefficient (ICC) was again used to compare the double inclinometer technique to the accelerometers within the BSM. As discussed previously, the type of ICC used for this application was ICC (2,1). The formula used to calculate the ICC(2,1) values is given in Eq. (6.1).

The variables used in the ICC (2,1) equation were taken from the ANOVA table. A separate ANOVA table was produced for the analysis of each ICC value.

Table 7.8 shows an example of the ANOVA table used to calculate the ICC (2,1) for the movement of Flexion performed by Tester 1. The results of the ICC calculations are presented in table 7.9.

Table 7-8 ANOVA table for Flexion – Tester 1

	SS	df	MS	F	p-value	F-crit
Rows	5434.419	22	BMS =247.019	17.8060	2.06E-09	2.0478
Columns	29.8736	1	JMS =29.8736	2.1534	0.1564	4.3010
Error	305.2022	22	EMS =13.8728			
Total	5769.494	45				

$$\begin{aligned} \text{ICC (2,1)} &= \frac{BMS - EMS}{BMS + (k - 1)EMS + \frac{k(JMS - EMS)}{N}} = \\ &= \frac{247.02 - 13.87}{247.02 + (2 - 1)13.87 + \frac{2(29.87 - 13.87)}{22}} = 0.8889 \end{aligned} \quad (7.2)$$

The ICC (2,1) values showed very good correlation between the AccM and DI techniques for measuring lower back movement.

The Pearson's r values were calculated to determine the r^2 values. The r^2 values can be used as a measure of predictable variability between the DI technique and the AccM.

Table 7-9 Validity of the accelerometer method: correlation of the accelerometer method to the double inclinometer for each tester performing each movement

Measurements tested	ICC (2,1)
Compare methods: Flexion-Tester 1	0.89
Compare methods: Flexion-Tester 2	0.88
Compare methods: Flexion-Tester 3	0.88
Compare methods: Extension-Tester 1	0.93
Compare methods: Extension- Tester 2	0.96
Compare methods: Extension-Tester 3	0.96
Compare methods: Left Lateral Flexion- Tester 1	0.82
Compare methods: Left Lateral Flexion- Tester 2	0.84
Compare methods: Left Lateral Flexion- Tester 3	0.84
Compare methods: Right Lateral Flexion- Tester 1	0.73
Compare methods: Right Lateral Flexion- Tester 2	0.65
Compare methods: Right Lateral Flexion- Tester 3	0.91

Table 7-10 Pearson's r values and r² values for the AccM correlated to the DI technique

Movement	Tester	r	r ²
Flexion	1	0.91	0.83
Flexion	2	0.90	0.82
Flexion	3	0.90	0.82
Extension	1	0.96	0.92
Extension	2	0.97	0.94
Extension	3	0.96	0.92
Left lateral flexion	1	0.86	0.74
Left lateral flexion	2	0.86	0.75
Left lateral flexion	3	0.90	0.80
Right lateral flexion	1	0.78	0.61
Right lateral flexion	2	0.67	0.45
Right lateral flexion	3	0.91	0.84

7.5.4 Comparison of the Accelerometer Method and Double Inclinometer technique

There are advantages and disadvantages of the accelerometer method and the inductive coil technique. Table 7.11 presents a comparative table of the two methods.

Table 7-11 Comparison of the two measurement methods

	Accelerometer Method	Inductive Coil Technique
Advantages	Capable of measuring 2-3 dimensional movement	Cost effective
	Able to sense velocity and acceleration of movement	Simple product
	Stable reference point (gravity)	Small adhesion area on skin
	Stable and reliable measurements	
	Able to sense vibration and impact	
Disadvantages	Expensive for hardware	One dimensional measurement
	Larger adhesion area on skin	Unstable measurements seen in the recordings (due to electrical drift and lag (parasitic capacitance))
	Complex algorithms to fine tune measurement results for combined movements	Finding a suitable insulating product to cover the coil yet allow it to have the flexibility to stretch to double its length
		Mechanical interference with coil such as when a subject is sitting and leaning back, compressing the coil against the back of a chair

7.6 Discussion

Both inter-tester reliability and retest reliability of the accelerometer method were assessed.

The criterion validity of the accelerometer method was analysed by comparing the

accelerometer readings to those of the DI technique. The DI technique measured angular movements of the lumbar spine, has been previously supported in the literature and displayed the highest degree of inter-tester reliability during the Inductive coil trial in Chapter 6.

7.6.1 Discussion of the reliability of the Accelerometer method

The inter-tester reliability (ITR) for the accelerometer method showed very good results with ICC (2,1) in the sagittal plane of 0.95, with 0.95 for flexion and 0.95 for extension (Table 7.3). Movements in a lateral (or coronal) plane were not as reliable as the sagittal-plane although still showing good reliability by Durand's definition (left lateral flexion 0.89 and right lateral flexion 0.86). Interestingly the ITR for the DI technique displayed slightly lower correlations in the accelerometer study (Flexion ICC DI = 0.89) than in the inductive coil study (Chapter 6, Flexion ICC DI = 0.93). The MMS also showed a lower ICC in the accelerometer trial (Flexion ICC MMS = 0.74) than in the inductive coil trial (Flexion ICC MMS = 0.81).

The SEM for the accelerometer method was relatively low when compared to the other techniques used in Chapter 6 and the DI technique and MMS method used in the accelerometer clinical trial. The SEM for the AccM was close to 2° for each of the four movements (Table 7.4) with the lowest value being 1.56° for the extension movement and the highest value being 2.39° for right lateral flexion. The SEM for the DI technique was close to double that of the AccM for movements in a sagittal plane (Table 7.4) but very similar for the lateral flexion movements. The SEM for the MMS was 6.01 mm (95% CI = ± 11.78 mm), similar to the SEM for MMS in the previous inductive coil trial (5.83 mm with a 95% CI = ± 11.43 mm, Table 6.6) and more difficult to correlate to the AccM due to the difference in measurement scales (MMS in millimetres and AccM in degrees of movement).

The accelerometer clinical trial showed evidence that the AccM may provide a more reliable method for measuring lower back movement than the existing methods of the DI technique and the MMS method. The ICC (2,1) values for the ITR were all above 0.85 showing good reliability between the three testers using the AccM (Table 7.3).

The test-retest reliability (TRTR) compared the same tester using the accelerometer method on two different days, five weeks apart. The TRTR showed very high levels of reliability with ICC (2,1) in the sagittal plane of 0.99 for flexion and 0.98 for extension (Table 7.6). Movements in a lateral (or coronal) plane were within guidelines of good reliability, although not as high as the reliability for movements in a sagittal-plane (left lateral flexion 0.89 and right lateral flexion 0.93). The MMS showed consistent ICC values across the three trials with an ICC for the TRTR of 0.77 (accelerometer trial ITR, Flexion ICC MMS = 0.74, and the inductive coil trial, Flexion ICC MMS = 0.81).

The higher ICC results for the TRTR for the AccM may suggest that the identification of the bony landmarks, used to place the accelerometers (Figure 7.5), is a very important aspect for the reliability when using the accelerometer technique. When the same tester applied the AccM on the same subjects, five weeks later, the results showed higher degrees of reliability than the reliability between testers on the same day. Each of the testers was given the same degree of training about landmark identification and each had significant experience with identifying bony landmarks on the lumbar spine. The same trial protocol was used for the ITR trial as was used for the TRTR trial. Refinement of the 'bony landmark identification' aspect of the protocol may be necessary to improve the ITR for the AccM.

The SEM for the TRTR using the accelerometer method was very low suggesting relatively low levels of error. Low SEM values across the four movements tested supported the high reliability of the AccM, when used by the same tester. The SEM values ranged from 0.91°

(95% CI = $\pm 1.78^\circ$) (for flexion and extension) to 1.84° (95% CI = $\pm 3.61^\circ$) (left lateral flexion), approximately half of the SEM levels for the ITR trial. The SEM values for the DI technique and the MMS method were also slightly lower (Table 7.7) for the TRTR trial than for the ITR trial, but not to the same degree as for the AccM method. The DI technique showed an SEM range from 1.8° (95% CI = $\pm 3.53^\circ$) (extension) to 3.03° (95% CI = $\pm 5.94^\circ$) (flexion) whereas the MMS showed an SEM of 4.54 mm (95% CI = ± 8.90 mm). The SEM values provide further evidence that the AccM, in a controlled setting, shows a high degree of reliability and low levels of error, when applied by the same tester. These results suggest that any changes observed in measurement values when using the AccM are unlikely to be due to measurement error and the measurement represents an actual change in the position of the lumbar spine.

7.6.2 Discussion of the validity of the Accelerometer method

The AccM showed evidence of validity through its high level of correlation and agreement with the DI technique. The ICC was performed for each of the testers' measurements when using the AccM compared to the DI technique (Table 7.9). The results displayed high agreement for lumbar spine flexion (ICC of 0.89 for tester 1, 0.88 for tester 2 and 0.88 for tester 3). The ICC values for lumbar spine extension showed higher values for all three testers (0.93 for tester 1 and 0.96 for tester 2 and tester 3). The movement of left lateral flexion also performed with a moderate to high degree of correlation between the AccM and the DI technique. The ICC values were between 0.82 and 0.84 for each of the testers (Table 7.9). The movement of right lateral flexion showed more variation than the other three movements. For tester 1, the correlation between the AccM and the DI technique displayed an ICC of 0.73 showing only moderate correlation. For tester 2 the ICC value was lower still at 0.65 showing a weaker correlation, but for tester 3, the ICC value was 0.91 showing a strong correlation. These results were quite different to the other three movements that had performed with a high degree of consistency among the three testers.

The r^2 values in Table 7.10 give an indication of predictable variability between the DI technique and the AccM (Howell 1992).

An r^2 value of 0.94 indicates that 94% of the variance of the DI technique measurement (Tester 2 Extension, see Table 7.10) was directly predictable from the AccM measurement. Whilst the sagittal movements performed well, there was less predictable variability in the lateral flexion movements. Left lateral flexion r^2 values ranged between 0.74 and 0.80 whereas for right lateral flexion the r^2 values ranged from between 0.45 to 0.84. Tester 2 for the movement of right lateral flexion displayed the poorest results with the r^2 value of 0.45, suggesting that only 45% of the variance of the DI technique measurement was directly predictable from the AccM measurement.

7.6.3 Sources of Error and Improvement Potentials

As was discussed in Section 6.7.3, there are three potential sources of error; at the level of the equipment, at the level of the tester or at the level of the subject (Streiner and Norman 2003).

The equipment used for this trial mainly related to the DI technique and the AccM. From the reliability analysis of the two methods, the AccM showed a higher degree of ITR and TRTR, as well as lower SEM values than for the DI technique. The first source of equipment error may relate to the accuracy of the goniometers. The goniometers used for the DI technique had a scale of one degree increments suggesting that this would be the absolute maximum level of accuracy for this device. The needle of the goniometer would occasionally catch whilst the housing was being rotated. This was a potential source of error, especially if the catching occurred close to the end of a movement and was not detectable by the tester.

The AccM reported angular measurements to multiple decimal places of a degree. The laboratory testing of the AccM in Section 4.8.1 showed a CV of between 1% (flexion) and 3% (left lateral flexion) for the AccM but no such testing was performed on the DI technique. The laboratory based testing of the goniometer would assist in defining the degree of error related to the goniometer.

The second equipment based error relates to the fixation of the equipment, when recording of measurements was being taken. The AccM adheres the sensors to the lower back whereas the DI technique needs the manual positioning of two goniometers, simultaneously, to obtain measurements. This is partly an equipment based error and partly a tester based error due to the alignment of the goniometer with the 'Wands' protruding from the lumbar spine.

Both of the potential equipment-based errors expose the DI technique to a higher error rate than the AccM. The results suggest that the DI technique may have contributed to more error than the AccM, yet further testing would be required to confirm this. One approach would be to laboratory test the DI technique to determine the degree of accuracy of the goniometers. A more attractive option would be to use an industrial type digital protractor that has been shown to be accurate to within 0.1° (Amasay and Karduna 2006). This may be a better comparator for the AccM.

Another option to further examine the validity of the AccM would be to perform video analysis of the movements from a lateral perspective (for sagittal movements) and from a frontal perspective (for coronal movements). These would need to be performed in time sync with the AccM measurements and manual calculations (via drawn angles) can be taken of the angular change of movement, once screen shot images are printed. This

technique has been previously used to analyse movements of the lumbar spine (Whittle and Levine 1997) and would allow through range analysis of movements of the lumbar spine.

The second source of error related to the testers. The potential for tester error has already been discussed in detail in Section 6.7.3 and the AccM clinical trial uses a very similar trial structure from the tester's perspective. A brief summary of the three potential tester-related errors is given.

First, the identification of the bony landmarks is critical for the placement of the AccM and the goniometers. Using appropriately qualified health practitioners with experience in finding bony landmarks should reduce errors related to bony landmarks. The additional training prior to the trial may also assist in forming some consensus about the bony landmarks that are open to interpretation and are more difficult to locate. Second, clear, concise and consistent instructions from the tester to the subject were necessary for repeatable movements from the subject. If these varied, even slightly, there was additional potential for error. Third, the goniometer reading required human interpretation of the range of movement. This was especially difficult because the needle of the goniometer was free to swing and would often take time to settle on a spot before a measurement could be taken.

The third source of error related to the subjects. The subject-related errors were also discussed in Section 6.7.3. Two subject errors were identified.

First, the potential for 'warm up effect' that could change the magnitude of movement as the subject repeated movements. This error was minimised by supplying a box to reach to at the end of each movement but there is still the potential for this error to occur. Second, the subject could vary the way a movement was performed. The human spine is a complex structure, able to move with many different permutations and combinations, not always

obvious to the subject performing the movements. An attempt was made to reduce this error by clear and uniform instructions from the tester to the subject and by the tester closely monitoring each movement performed by the subject. It was difficult to eradicate this type of potential error.

The AccM showed positive signs of being a worthwhile instrument for measuring lower back movement. The ITR was high between the three testers, giving confidence that the measurement method may be able to be used by various testers to give reliable results. The TRTR was very high, suggesting that when used by the same tester the AccM is a very reliable method of measuring lower back movement, in a controlled setting. There was reasonable evidence of validity when the AccM was compared to the DI technique, but further work is required to quantify how valid the AccM is when compared to a more accurate measurement tool. And there was uncertainty about how much of variability between the two devices was due to the AccM and how much was due to the DI technique.

Some significant advantages were seen for the AccM method. First, the ability of the AccM to automatically record measurements of lumbar spine movement, without the need for tester intervention. This saved time and potentially reduced tester related error. Second was the continuous recording of measurements (5 samples per second), not only at the start and the end of a movement (as with the DI technique). This allowed for 'through range measurements' for posture monitoring and also allowed for recordings to be taken over extended periods of time.

This trial was performed in a very controlled setting and with movements performed in only one plane of movement at a time. The real test environment for a measuring device for the lower back will need to cater for three-dimensional movement in an uncontrolled setting. An

alternative comparator device such as the LMM or Back Tracker may be required to validate the AccM in 3D and in an uncontrolled setting.

Chapter 8. Discussion and Conclusions

Low back pain provides a significant challenge to health practitioners, compensable bodies, governments and those experiencing LBP. With LBP affecting 60–80% of people during their lifetime (Riihimaki 1991) and being the major cause of disability for people under the age of 45 years (Magnusson, Bishop et al. 1998) new management methods are required to aid this problem. With AUD \$9.2 billion dollars per year being spent in Australia on LBP (Walker 2003) and between USD \$100-200 billion per year in the US (Katz 2006), it would be justified to commit significant resources to curbing this debilitating condition.

Medical practitioners currently have only limited treatment options for LBP with little evidence of effectiveness. Non steroidal anti-inflammatory medication and pain killers are their number one option yet a number of the NSAIs have been shown to have adverse side effects. Radiological investigation is also a common management choice but recent studies suggest that X-rays are of no physical benefit and provide only minor psychological and diagnostic benefit to the patient. There is no readily available tool to aid health practitioners or workers in how they should move or how to safely return to the work force after an episode of LBP.

The postures and movements performed by the lumbar spine contribute to lower back injuries (Riihimaki 1991; Adams and Dolan 1995; Fathallah, Marras et al. 1998; Hoogendoorn, Bongers et al. 2000), as do the loads placed on the spine (Burton, Tillotson et al. 1996; Fathallah, Marras et al. 1998; Hoogendoorn, Bongers et al. 2000). It is also acknowledged that to measure these complex loads within a normal work setting is most important (Cholewicki, Crisco lii et al. 1996). The literature review in Chapter 2 highlighted the movements and postures that are documented risk factors for LBP. A recent RCT has shown the benefits of postural biofeedback in improving recovery from LBP in a population

of chronic LBP patients (Magnusson 2008). The measurement system used was a cumbersome unit (see Figure 2.3) that could not be worn in a work environment and needed to be attached to a computer. New health sensor technology now allows for miniature sensors for ambulatory monitoring with wireless communication to a central base (Jovanov, Milenkovic et al. 2004).

The aim of this thesis was to introduce the Back Strain Monitor (BSM) and to determine its reliability and validity via clinical trials. The BSM is a new device which uses small sensors to provide real time measurement and analysis of low back movements and generates a warning feedback to the wearer when the movements are likely to cause harm. It is of relatively small size and weight and can be worn without causing any limitation to natural movements. The device is powered by a battery, it has built-in analysis software and data storage capabilities, and it does not need to be attached to an external computer.

The thesis provided the following major contributions:

1. A new device for measuring the three-dimensional movements of the lumbar spine called the Back Strain Monitor (BSM) was introduced. The BSM provided an implementation platform for different low back movement measurement methods.
2. Development stages of the BSM were presented including laboratory experiments testing different concepts and options which lead to the final prototype of the device.
3. During the development process of the BSM, a number of different options for measuring and analyzing the movement of the lower back were examined and tested in laboratory conditions. Two viable measurement options, the Inductive Coil technique and the Accelerometer method, were identified and tested in laboratory settings and clinical trials.
4. Analysis of the results provided by clinical trials indicates that the Accelerometer method provided a high level of reliability and evidence of validity.

Chapter 2 discussed the epidemiology of low back pain, its nature and the complexities associated with diagnosing a specific type of lower back disorder. The frequency of LBP was reviewed and documentation provided as to who is affected by LBP and the extraordinary costs associated with the management of LBP. A literature review was also presented and summarized to identify the risk factors associated with developing LBP.

Chapter 3 reviewed the existing, most commonly used measurement methods for lower back movements. Ten different measurement methods were reviewed and the advantages and drawbacks of each were listed. The majority of the reviewed techniques were not suitable for automatic measurement since they required the health practitioner to manually record results based on goniometer or tape measure readings. Only three methods were potentially suitable for an automated measurement system. These included the Lumbar Motion Monitor (LMM), Back Tracker and Spinal Sensa. Unfortunately, all these three methods shared the same major drawback which was that the patient was not able to move and work normally whilst wearing the device. The LMM and Back Tracker are too cumbersome, whilst the Spinal Sensa adheres to the lumbar spine such that normal flexion ROM is restricted.

Chapter 4 introduced the concept of the Back Strain Monitor (BSM) and the development stages of the essential part of the BSM called the measuring device (MD). Seven potential measurement techniques involving different types of movement sensors were reviewed and their suitability for the MD was assessed. The three most suitable methods were selected and used to build three different prototypes of the MD. These prototypes were tested in laboratory conditions.

Prototype one was a conductive silicone polymer (CSP) that changed electrical resistance as it was stretched. Early laboratory tests showed positive results yet after repeated

stretching, the silicone bonds degraded and electrical resistance increased in a non-uniform way. The CSP prototype was superseded by the inductive coil prototype, derived from a commercially available transducer called the 'Flexor'. Early laboratory tests showed the inductive coil to be a reliable transducer for linear stretch, with no sign of mechanical degradation or hysteresis on repeated stretching. However, once the testing sessions lasted for longer than 30 minutes, the readings from the coil began to drift. There was also an electrical lag seen as the coil returned from its stretched state. This led to significant variation in the baseline readings from the inductive coil ($CV = 82\%$) even though the full stretch measurements performed well ($CV = 0.54\%$). The inductive coil laboratory test results were only moderate and a third option using accelerometers was developed into a prototype.

The third prototype built used accelerometers and a gyroscope to sense movements of the lumbar spine. Early testing of the accelerometer components showed low power consumption, stable readings and minimal electrical drift. The accelerometer prototype was tested within a laboratory setting producing very little variation when tested with repeated movements ($CV = 0.12\%$ for flexion). The other significant advantage of the accelerometer method was that the accelerometers could sense motion in three dimensions. The first level accelerometer prototype was able to measure movements in the sagittal plane and the coronal plane but showed missing data sets and aberrant readings when measurements of lumbar spine rotation were attempted. For this reason the gyroscope was introduced into the prototype but a formal review of the rotation movement analysis and the gyroscope readings is beyond the scope of this thesis. The laboratory tests for the accelerometer focused on the movements in the sagittal plane (flexion and extension) and the coronal plane (left and right lateral flexion).

Chapter 5 described the current version of the Back Strain Monitor (BSM) device. The focus of the chapter was on the accelerometers although the gyroscope, EMG sensors and the recording feedback device (RFD) were also briefly described. The BSM device has been developed to measure the three-dimensional movements of the lumbar spine and muscle activity levels of the erector spinae muscles. Potential formats for the data outputs are presented in a graphical way. There was also a brief description of further potential developments of the BSM, which included a patient profile and a numerical algorithm that could process the sensor's data and calculate an overall risk score for the low back pain.

The clinical trials have been described in Chapters 6 and 7. The aim of the clinical trials was to examine the reliability and validity of the Inductive Coil transducer technique (Clinical Study I, Chapter 6) and of the Accelerometer method (Clinical Study II, Chapter 7).

Chapter 6 described experiments that tested the reliability and validity of the inductive coil technique for measuring lower back movement in a clinical setting. Fifteen subjects wore the inductive coil device and performed basic lumbar spine movements in a controlled setting. Only movements in one direction (flexion) were tested. The measurements were made by three testers. The reliability test included comparison of measurements obtained by different testers (inter-tester reliability) on the same day. The reliability of the inductive coil was tested in parallel with the reliability of three other methods including: the Double Inclinator (DI) technique, the Modified-Modified Schober (MMS) method and the Wand technique (WT). The amount of reliability was measured using the Interclass Correlation Coefficient (ICC(2,1)). The results showed the inductive coil to perform with the least degree of reliability (ICC (2,1) = 0.65) compared to the other three methods (ICC(2,1)=0.92, for DI, ICC(2,1)=0.81 for MMS, and ICC(2,1)=0.87 for WT) (see Table 6.6).

The validity tests were analysed via a pairwise comparison between measurements obtained by the same tester using four different techniques: the Inductive Coil technique, the Wand technique, the Double Inclinometer technique and the Modified-Modified Schober method. The amount of validity was measured using the Interclass Correlation Coefficient (ICC(2,1)). The results showed relatively low values of the ICC(2,1) for the inductive coil. Depending on the tester, the ICC values were ranging from 0.74 to 0.65 when compared with WT, from 0.67 to 0.58 when compared to DI, and from 0.70 to 0.47 when compared to MMS (see Table 6.7). The Inductive Coil technique also displayed the largest error measurement with an SEM of 6.76 mm (95% CI = ± 13.23 mm).

Based on these results, it was concluded that the inductive coil did not represent a reliable and valid option for measuring lower back movements.

Chapter 7 described the clinical experiments that tested the reliability and validity of the accelerometer method (AccM) for measuring movements of the lower back. Twenty-three subjects wore the accelerometer sensors and performed basic lumbar spine movements in a controlled setting. Unlike for the inductive coil, where only movement in one direction (flexion) was tested, in the case of accelerometers, four movements were tested: flexion, extension, left lateral flexion and right lateral flexion. The measurements were made by three testers. The reliability test included comparison between measurements obtained by different testers. The inter-tester reliability (ITR) was assessed for three testers on the same day whereas the test re-test reliability (TRTR) was assessed by one tester on two different days. The reliability of the accelerometer method was tested in parallel with the reliability of two other methods including: the DI technique and the MMS method. The amount of reliability was measured using ICC(2,1).

The inter-tester reliability (ITR) results showed that, the accelerometers performed with the highest degree of reliability (ICC (2,1) = 0.95 for flexion, 0.95 for extension, 0.89 for left lateral flexion, and 0.86 for right lateral flexion) compared to the DI technique (ICC (2,1) = 0.89 for flexion, 0.91 for extension, 0.85 for left lateral flexion, and 0.83 for right lateral flexion) and the MMS method (ICC (2,1) = 0.74 for F) (see Table 7. 3).

The SEM for the AccM was also relatively low for the ITR (eg, Flexion SEM for AccM = 2.3° , 95% CI = $\pm 4.53^{\circ}$) when compared with the previous results from the inductive coil clinical trial (Table 6.7) and the DI technique used in the AccM clinical trial (Table 7.4).

Consistently, the test re-test reliability results also showed that the accelerometers performed with the highest degree of reliability (ICC (2,1) = 0.99 for flexion, 0.98 for extension, 0.89 for left lateral flexion, and 0.93 for right lateral flexion) compared to the DI technique (ICC (2,1) = 0.94 for flexion, 0.95 for extension, 0.88 for left lateral flexion, and 0.86 for right lateral flexion) and the MMS method (ICC (2,1) = 0.77 for flexion) (see Table 7. 6).

The SEM for the AccM was quite low for the TRTR (eg, Flexion SEM for AccM = 0.91° , 95% CI = $\pm 1.78^{\circ}$) when compared with the DI technique used in the AccM clinical trial (Table 7.7).

The AccM showed evidence of a high degree of reliability in both a laboratory setting and within a controlled clinical setting. A high level of reliability was shown between different testers on the same day (ITR) and by the same tester on different days (TRTR).

Criterion validity assessment was performed via a comparison between measurements obtained by the same tester using two different techniques: the Accelerometer method and the Double Inclinator technique. Evidence of validity was measured using the Interclass Correlation Coefficient (ICC(2,1)). The results demonstrated a high level of agreement

between the two techniques with ICC values of 0.88 to 0.89 for flexion and 0.93 to 0.96 for extension, for all three testers. The ICC values for the movement of left lateral flexion were between 0.82 and 0.84 yet for the right lateral flexion there was less agreement with ICC values ranging from 0.65 to 0.91.

Pearson's r was used to calculate predictable variability between the two methods. The r^2 value was above 0.90 for movements in the sagittal plane yet less predictable for movements in the lateral plane where the r^2 values ranged from 0.67 to 0.91. The AccM displayed a moderate to high level of agreement with the DI technique.

Based on these results, it was concluded that the Accelerometer method represents a reliable and valid option as a method for measuring lower back movements. It showed a high degree of reliability in both a laboratory setting and within a controlled clinical setting. It can be concluded that the accelerometer method provides the better option as a spinal movement transducer for the proposed Back Strain Monitor.

8.1 Limitations of this research

To be able to measure and quantify movements of the lower back is a complex and multifactorial challenge. Whilst this study has aimed to answer a number of questions about the reliability and validity of the AccM, there are limitations associated with such a study.

The first limitation related to the reliability and validity of the double inclinometers used in both of the clinical trials. It should be noted that further research will be necessary to validate the Accelerometer technique against more accurate transducers than the goniometers used in the clinical trials.

The second limitation was that the AccM measured movements of the lumbar spine in two planes but was unable to reliably measure movements in a rotational plane. Rotation of the lower back needs an accurate transducer due to the small range of rotational movement occurring at the lumbar spine. A gyroscope has been incorporated into the MDM component of the new device but further testing is required to validate the gyroscopic measurements.

The third limitation relates to the EMG aspect of the BSM device. The reliability and validity of EMG was not studied during this thesis. The use of the EMG values recorded by the BSM system will require thorough testing and validation before this data can be used to estimate forces acting within and around the lumbar spine.

The final limitation is the studies described in this thesis were all performed in a controlled setting. Additional work will be required to analyse the reliability and validity of the AccM measurements during combined movements and in a real world, functional environment. Whilst further work is needed, the device provides the potential to collect new data in relation to lumbar spine movements and postures that are adopted during a full day's activity and record this data for retrospective analysis.

8.2 Future research directions

The AccM has displayed preliminary evidence of providing a reliable and valid method for measuring movements of the lumbar spine in two dimensions.

Further research is required to analyse the reliability and validity of the third dimension of movement, that being the rotational movement of the lumbar spine, measured by the gyroscope. Rotational movements of the lumbar spine provide a particular challenge because they often occur across gravity and there is only a small range of movement

occurring at the lumbar spine ($<10^\circ$). This requires the movement sensor to be very accurate.

The trials performed in this study were either laboratory based or within a controlled clinical environment, not in the real world or a fully functional setting. Further trials and research are required to validate the AccM within a functional setting. This may require a trial that compares movements recorded by the AccM (as part of the BSM device) to movements recorded by a recognized and validated measurement system such as the LMM. This type of trial would need to be performed in a semi-controlled environment, such as a production line or assembly line, where workers performed very similar movement patterns from one day to the next. There would also need to be a video analysis to validate that the type of movements and activities performed by the workers whilst wearing the two different devices were very similar to each other.

A further extension of this work would be to formally evaluate the case study presented in Chapter 5. This study presented data from a single case study in which a subject wore the BSM device for a day at work and received biofeedback when certain movement thresholds were reached. The results suggested that the subject responded well to the guidance from the biofeedback. It would be interesting to design an additional trial to investigate the construct validity of the AccM and the BSM device in being able to modify posture via biofeedback. A second step in this trial would be to investigate how long the improved posture patterns continued and whether they reduced the risk of LBP or improved recovery rates for existing LBP.

The AccM aims to provide one aspect of data for the BSM device, that being the movements of the lumbar spine. The other two aspects of the BSM are the sEMG measurements and the Patient Profile. These two aspects are outside the scope of this

thesis but are areas where future research is required. First, to substantiate that the sEMG signals are reliable. Second, to assess the merits of a patient profile to see whether it is able to differentiate people who are more likely to experience LBP from people who are not. Third, the data from the AccM, sEMG and the Patient Profile may be combined to form a risk score or rating system. These three areas of work will require significant resources and time but if coordinated in a strategic way, a new management system for LBP may be developed.

8.3 Final conclusion

This thesis has reviewed potential measurement options for analyzing lower back movements. Seven potential measurement methods were reviewed and three methods were chosen for which prototypes were built for laboratory testing. Two of the three prototypes performed with moderate reliability in the laboratory testing and further reliability testing was conducted through clinical trials. The inductive coil technique experienced issues with electrical drift and a lag that lead to reduced reliability in clinical trial testing.

The Accelerometer method was tested in a separate clinical trial with positive results for inter-tester reliability, test re-test reliability and the method demonstrated evidence of validity when compared to the double inclinometer technique. Further work is required to test the Accelerometer method against a more accurate comparator, through three dimensions of movement and within a functional, real world environment.

The Accelerometer method forms part of the new Back Strain Monitor (BSM) device that provides health practitioners with the ability to monitor a patient's movement patterns over extended periods of time. The device has the potential to provide a new tool for the management of LBP. It is hypothesized that postural biofeedback may become an important aspect in the management of LBP. The BSM device may become part of the monitoring and biofeedback process.

APPENDIX I

Full list of risk factors identified in the literature review

Risk Factors for LBP

Risk Factor for LBP	Author	Journal	Year
1 Lateral bending	Adams	Spine	1999
2 Long back	Adams	Spine	1999
3 Reduced lumbar lordosis	Adams	Spine	1999
4 Psychological distress	Adams	Spine	1999
5 Previous LBP	Adams	Spine	1999
6 Driving for long periods	Alcouffe	Occ and Envir medicine	1999
7 High BMI	Alcouffe	Occ and Envir medicine	1999
8 Uncomfortable work positions	Alcouffe	Occ and Envir medicine	1999
9 Lifting > 10Kg	Alcouffe	Occ and Envir medicine	1999
10 Long work hours	Andrusaitis	Clinics	2006
11 Sitting, WBV and Awkard postures	Angela Maria	European spine journal	2007
12 Psychological distress	Feyer	Occ and Envir medicine	2000
13 Previous LBP	Feyer	Occ and Envir medicine	2000
14 Not a risk - twin study	Ashraf	European spine journal	2008
15 High physical activity	Auvinen	Sacnd J of medicine	2008
16 Sitting posture	Auvinen	Sacnd J of medicine	2008
17 Static loads	Bagirova	Terapevticheskii arkhiv	2001
18 Physical overstrain	Bagirova	Terapevticheskii arkhiv	2001
19 Smoking and alcohol abuse	Bagirova	Terapevticheskii arkhiv	2001
20 Low physical activity	Bagirova	Terapevticheskii arkhiv	2001
21 Prolonged flexion	Bakker	European spine journal	2007
22 Loading in flexed positions	Bakker	European spine journal	2007
23 Depression	Bildt	Int J of Behav Medicine	2000
24 Occupational conditions	Bildt	Int J of Behav Medicine	2000
25 Sitting with forward flexion	Bridger	Aviation	2002
26 Sitting in non neutral posture	Burdorf	J of Occ Medicine	1993
27 Years as a nurse	Byrns	J Occ & Environ Hyg	2004
28 Frequent lifting	Byrns	J Occ & Environ Hyg	2004
29 Low social support	Byrns	J Occ & Environ Hyg	2004
30 Previous LBP	Canadian Task	Canadian med assc	2003
31 Lifting > 10Kg	Canadian Task	Canadian med assc	2003
32 Whole body vibration	Canadian Task	Canadian med assc	2003
33 Frequent bending	Canadian Task	Canadian med assc	2003
34 Depression	Carroll	Pain	2004
35 Lifting heavy objects	Chiou	Int J Nursing Studies	1994
36 Sitting posture	Chiou	Int J Nursing Studies	1994
37 Long work hours	Chiou	Int J Nursing Studies	1994
38 Psychological distress	Chris	Am J of Public Health	2001
39 Smoking	Chris	Am J of Public Health	2001
40 Prolonged forward and lateral fl of Cx	Christensen	Ergonomics	1995

41	Poor physical health	Croft	Spine	1999
42	Obesity	Croft	Spine	1999
43	High growth	Ehrmann	Am J of Epidemiology	2001
44	Smoking	Ehrmann	Am J of Epidemiology	2001
45	Working in cold environments	Dovrat	Am J of Epidemiology	2007
46	High manual handling	Elders	Occ and Envir medicine	2001
47	Previous LBP	Elders	Occ and Envir medicine	2001
48	Positioning patients in bed	Eriksen	Occ and Envir medicine	2004
49	Low social support	Eriksen	Occ and Envir medicine	2004
50	Heavy physical work and smoking	Eriksen	Occupational Medicine	1999
51	Depression/mental illness	Failde	Occupational Medicine	2000
52	Manual transfer of patients	Feng	BMC Musculoskel dis	2007
53	Perceived physical exertion	Feng	BMC Musculoskel dis	2007
54	Psychological demands	Feng	BMC Musculoskel dis	2007
55	Job design	Ferguson	Ergonomics	2004
56	Lifting previous 5 years	Friedrich	Int arc of occ env heal	2000
57	Duration of stooping at work	Friedrich	Int arc of occ env heal	2000
58	Increasing age	Friedrich	Int arc of occ env heal	2000
59	Abnormal illness behaviour	Friedrich	Int arc of occ env heal	2000
60	Personal factors	Gilkey	Colorado State Uni	2002
61	Workplace factors	Gilkey	Colorado State Uni	2002
62	Lifting heavy objects	Harkness	Rheumatology	2003
63	Pulling heavy weights	Harkness	Rheumatology	2003
64	Kneeling or squatting > 15min	Harkness	Rheumatology	2003
65	Stressful conditions	Harkness	Rheumatology	2003
66	Monotonous conditions	Harkness	Rheumatology	2003
67	Lifting heavy objects	Harreby	European spine journal	1999
68	Smoking	Harreby	European spine journal	1999
69	Female Adolescence	Harreby	European spine journal	1999
70	Heavy physical work	Hartvigsen	Spine	2001
71	Sitting is not a risk factor	Hartvigsen	Sacnd J of Pub Health	2000
72	Parents with high IQs	Hestbaek	BMC Musculoskel dis	2005
73	Previous LBP	Hestbaek	BMC Musculoskel dis	2005
74	Military physical activity	Hestbaek	BMC Musculoskel dis	2005
75	Smoking not linked to LBP	Hestbaek	BMC Musculoskel dis	2006
76	Exercise is protective	Hides	Spine	2001
77	Flexion > 60 degrees for > 5% work time	Hoogendoorn	Spine	2000
78	Rotation 30 degrees for > 10% work time	Hoogendoorn	Spine	2000
79	Lifting > 25kg, > 15 times per day	Hoogendoorn	Spine	2000
80	Low social support	Hoogendoorn	Scand J of Work	2001

81	Low supervisory support	Hoogendoorn	Scand J of Work	2001
82	Flexion >30 degrees for 10-15% time	Hoogendoorn	Occ and Envir medicine	2002
83	Flexion > 30 degrees for 15-20% time	Hoogendoorn	Occ and Envir medicine	2002
84	Flexion >30 degrees for >20% time	Hoogendoorn	Occ and Envir medicine	2002
85	Trunk Rotation >30 degrees for 5-10% time	Hoogendoorn	Occ and Envir medicine	2002
86	Lifting >25kg, > 15 times per day	Hoogendoorn	Occ and Envir medicine	2002
87	Low job satisfaction	Hoogendoorn	Occ and Envir medicine	2002
88	Flexion and Rotation	Hoogendoorn	Occ and Envir medicine	2002
89	Heavy loads	Hoogendoorn	Occ and Envir medicine	2002
90	Low social support	Hoogendoorn	Spine	2000
91	Low supervisory support	Hoogendoorn	Spine	2000
92	Weight of patients	Jang	Ergonomics	2007
93	Load moment about the spine	Jang	Ergonomics	2007
94	Trunk axial rotation	Jang	Ergonomics	2007
95	Trunk flexion >45 degrees (105min vs 30min)	Jansen	Occ and Envir medicine	2004
96	Flexion and rotation	Jin	Int J Occ and Envir Med	2000
97	Static postures	Jin	Int J Occ and Envir Med	2000
98	Whole body vibration	Jin	Int J Occ and Envir Med	2000
99	High intensity demands	Johnston	Am J of Indust Med	2003
100	Low job satisfaction	Johnston	Am J of Indust Med	2003
101	High job scheduling demands	Johnston	Am J of Indust Med	2003
102	Reduced lumbar flexion	Jones	British J Sports Med	2005
103	Reduced lateral flexion	Jones	British J Sports Med	2005
104	Reduced muscle endurance	Jones	British J Sports Med	2005
105	Reduced hip mobility	Jones	British J Sports Med	2005
106	Forward bending positions	Josephson	Scand J Work,Env,Heal	1998
107	High energetic work load	Josephson	Scand J Work,Env,Heal	1998
108	Perceived physical exertion	Josephson	Scand J Work,Env,Heal	1998
109	Low social support	Josephson	Scand J Work,Env,Heal	1998
110	Novice worker performing lifting tasks	Julia	Ergonomics	2007
111	Previous LBP	Julia	British Medical J	1997
112	Frequent patient transfer	Julia	British Medical J	1997
113	Stressful working conditions	Kaneda	J Nippon Medical Sch	2001
114	Postures at work	Kaneda	J Nippon Medical Sch	2001
115	Unstable body balance on scaffold	Kaneda	J Nippon Medical Sch	2001
116	Previous LBP	Kerr	Am J Public Health	2001
117	Low BMI	Kerr	Am J Public Health	2001
118	Poor workplace social support	Kerr	Am J Public Health	2001
119	Physically demanding job	Kerr	Am J Public Health	2001
120	Peak lumbar shear force	Kerr	Am J Public Health	2001

121	Heavy loads	Kerr	Am J Public Health	2001
123	Cumulative lumbar disc compression	Kerr	Am J Public Health	2001
124	Load moment about the spine	Keyserling	AIHAJ	2000
125	Velocity of lift	Keyserling	AIHAJ	2000
126	Frequency of lift	Keyserling	AIHAJ	2000
127	Assymetry of lift	Keyserling	AIHAJ	2000
128	Flexion angle	Keyserling	AIHAJ	2000
129	Leg length difference	Kovacs	Pain	2003
130	University graduate	Kovacs	Pain	2003
131	Female Adolescence	Kovacs	Pain	2003
132	Scoliosis	Kovacs	Pain	2003
133	Increased driving time	Krause	Am J Indust Medicine	2004
134	Physical workload	Krause	Am J Indust Medicine	2004
135	Physical workload	Krause	Am J Indust Medicine	2005
136	Intense work	Krause	Am J Indust Medicine	2005
137	Materials handling	Lotters	Scand J of Work	2003
138	Frequent flexion and rotation	Lotters	Scand J of Work	2003
139	Whole body vibration	Lotters	Scand J of Work	2003
140	Low job satisfaction	Lotters	Scand J of Work	2003
141	Laying large sandstone pavers	Latza	Occ and Envir medicine	2000
142	Obesity plays a part in chronicity of LBP	Leboeuf-Yde	Spine	1999
143	Height above 180cm	Leclerc	Occupational medicine	2003
144	Driving > 2hours per day (sciatica only)	Leclerc	Occupational medicine	2003
145	Driving several days of > 2hours(sciatica)	Leclerc	Occupational medicine	2003
146	Physical workload	Lee	The J of Rheumatology	2001
147	Frequent lifting	Lee	The J of Rheumatology	2001
148	Poor general health	Lee	The J of Rheumatology	2001
149	Lifting heavy objects	Lee	J of safety research	1994
150	Reduced work experience	Lee	J of safety research	1994
151	Increased age	Lee	J of safety research	1994
152	Poor sitting habits	Lee	J of safety research	1994
153	Lifting tasks combined with driving	Lilia	Work	2005
154	Frequent lifting and driving	Lilia	Work	2005
155	Sitting with WBV and awkward postures	Lis	European spine journal	2007
156	Lifting/pushing/pulling objects > 25lbs	Macfarlane	Spine	1997
157	Prolonged standing and walking	Macfarlane	Spine	1997
158	Lifting heavy objects	Magnusson	Spine	1996
159	Frequent lifting	Magnusson	Spine	1996
160	Whole body vibration	Magnusson	Spine	1996

161	Previous LBP	Marras	Ergonomics	2000
162	Unemployment/Household income	Marras	Ergonomics	2000
163	Age Smoking	Marras	Ergonomics	2000
164	Liftig/forceful movement	Marras	Ergonomics	2000
165	Whole body vibration	Marras	Ergonomics	2000
166	Awkward posture	Marras	Ergonomics	2000
167	Heavy physical work	Marras	Ergonomics	2000
168	Frequent lifting	Marras	Ergonomics	1995
169	Load moment about the spine	Marras	Ergonomics	1995
170	Lateral bending velocity	Marras	Ergonomics	1995
171	Rotation velocity	Marras	Ergonomics	1995
172	Trunk sagittal angle	Marras	Ergonomics	1995
173	Frontal plane imbalance	Masset	Spine	1998
174	Low body weight	Masset	Spine	1998
175	Perception of heavy lifting efforts	Masset	Spine	1998
176	Lifting heavy objects	Matsui	Spine	1997
177	Family history	Matsui	Spine	1997
178	Depression	Mayr	Lancet	2003
179	Lifting load	Mazloun	Industrial health	2006
180	Flexion in combination with lat fl and rot	Milosevljevic	Applied ergonomics	2007
181	Increased age	Miranda	Spine	2002
182	Mental stress	Miranda	Spine	2002
183	Smoking	Miranda	Spine	2002
184	Rotation of spine	Miranda	Spine	2002
185	Low job satisfication	Miranda	Spine	2002
186	Lifting	Mohseni-Bandpe	British journal of nursing	2006
187	School furniture	Murphy	Applied ergonomics	2007
188	Emotional problems	Murphy	Applied ergonomics	2007
189	Family history	Murphy	Applied ergonomics	2007
190	Previous LBP	Murphy	Applied ergonomics	2007
191	Tranferring patients	Muto	Industrial health	2006
192	Assisting feeding	Muto	Industrial health	2006
193	Assisting toileting	Muto	Industrial health	2006
194	Depression	Muto	Industrial health	2006
195	Job Stressors	Muto	Industrial health	2006
196	Long periods of sitting	Nieuwenhuyse	Occupational medicine	2004
197	>12 flexion or rotation movements per ho	Nieuwenhuyse	Occupational medicine	2004
198	>3 yrs in job lifting>25kg once an hour	Nieuwenhuyse	Occupational medicine	2004
200	Low psychological job demands	Nieuwenhuyse	Occupational medicine	2004

201	Low supervisory support	Nieuwenhuys	Occupational medicine	2004
202	Being a physio student for > 2 years	Nyland	BMC Musculoskeletal	2003
203	Sitting looking down for > 20 hours in a m	Nyland	BMC Musculoskeletal	2003
204	Treating patients	Nyland	BMC Musculoskeletal	2003
205	Driving a bus	Okunribido	Int J Ind Ergonomics	2006
206	Combination of 2+ of posture, MMH & Vit	Okunribido	Ergonomics	2008
207	Farmers	Omokhodion	Tropical doctor	2004
208	History of trauma	Omokhodion	Tropical doctor	2004
209	Low educational status	Omokhodion	Tropical doctor	2004
210	Smoking	Omokhodion	Occupational medicine	2003
211	Senior staff grade	Omokhodion	Occupational medicine	2003
212	Sitting > 3 hours	Omokhodion	Occupational medicine	2003
213	Lifting > 10 kg at work	Palmer	Occ & Env Medicine	2003
214	Age (45-59)	Park	Am J Indust Medicine	2001
215	Farmer with non agricultural job as main	Park	Am J Indust Medicine	2001
216	Awkward posture	Picavet	Preventative medicine	2000
217	Sustained postures or positions	Picavet	Preventative medicine	2000
218	Frequent flexion and rotation	Picavet	Preventative medicine	2000
219	Psychological distress	Power	Am J Public Health	2001
220	Heavy smokers	Power	Am J Public Health	2001
221	Gradual onset assc w psych symptoms	Smedley	Journal of Rheumatology	2005
222	Sudden onset assc w patient hand tasks	Smedley	Journal of Rheumatology	2005
223	Increased age	Stevenson	Spine	2001
224	Thoracic spine acceleration	Stevenson	Spine	2001
225	Medium frequency intercept EMG at L3	Stevenson	Spine	2001
226	Reduced Quad strength	Stevenson	Spine	2001
227	Reduced Quad endurance	Stevenson	Spine	2001
228	Self-assessment of poor physical fitness	Stevenson	Spine	2001
229	Low social support	Stevenson	Spine	2001
230	Mediations taken	Stevenson	Spine	2001
231	Flexion and rotation	Sun	Zhonghua lao dong wei	2007
232	Transferring patients	Sun	Zhonghua lao dong wei	2007
233	Physically demanding job	Sven	European spine journal	2006
234	Poor work conditions	Sven	European spine journal	2006
235	Bad weather	Sven	European spine journal	2006
236	Increased age	Tam	J of Occ Rehab	2006
237	Perceived effort	Tam	J of Occ Rehab	2006
238	Low job satisfaction	Tam	J of Occ Rehab	2006
239	Steering wheel adjustment	Tamrin	Industrial health	2007
240	Perception of exposure to vibration	Tamrin	Industrial health	2007

241 Central Obesity	Toda	Arch Int Med	2000
242 Driving	Tubach	J Clinical Epidemiology	2004
243 Carrying heavy loads	Tubach	J Clinical Epidemiology	2004
244 Previous LBP	Tubach	J Clinical Epidemiology	2004
245 Psychological distress	Tubach	J Clinical Epidemiology	2004
246 Driving for long periods	Toshihiko	Occupational Medicine	2006
247 Sustained flexion of 90 degrees	van Vuuren	J of Occ Rehab	2007
248 Manual handling	van Vuuren	J of Occ Rehab	2007
249 Lifting	van Vuuren	J of Occ Rehab	2007
250 Load carriage	van Vuuren	J of Occ Rehab	2007
251 Flexion and rotation	van Vuuren	Am J of Indust Med	2005
252 Lifting heavy objects	van Vuuren	Am J of Indust Med	2005
253 Load carriage	van Vuuren	Am J of Indust Med	2005
254 Sitting for prolonged periods	van Vuuren	Am J of Indust Med	2005
255 Kneeling or squatting	van Vuuren	Am J of Indust Med	2005
256 Uneven or slippery surfaces	van Vuuren	Am J of Indust Med	2005
257 Two or more other diseases	Ville	European spine journal	2008
258 Below average self perceived health	Ville	European spine journal	2008
259 Smoking	Ville	European spine journal	2008
260 Being a forklift driver	Waters	Am J Indust Medicine	2005
261 Emotional problems	Watson	Arch of dis in childhood	2003
262 Daytime tiredness	Watson	Arch of dis in childhood	2003
263 Headaches	Watson	Arch of dis in childhood	2003
264 Abdominal pain	Watson	Arch of dis in childhood	2003
265 Sore throat	Watson	Arch of dis in childhood	2003
266 Poor lifting technique	Wrigley	Clinical biomechanics	2005
267 New on ward	Yip	J of Advanced Nursing	2004
268 Flexed postures	Yip	J of Advanced Nursing	2004
269 Poor social support at work	Yip	J of Advanced Nursing	2004
270 Not enjoying work	Yip	J of Advanced Nursing	2001
271 Positioning patients in bed	Yip	J of Advanced Nursing	2001
272 Assisting patients with walking	Yip	J of Advanced Nursing	2001
273 Poor social support at work and low mood	Yip	Psych,Health & Med	2002
274 Stressful past 12 months	Yip	Health care women Int	2004
275 High psychological stress	Yip	Health care women Int	2004
276 Physical strain activities	Yip	Health care women Int	2004
277 Low hip to waist ratio	Yip	Health care women Int	2004

APPENDIX II

Clinical Trial Protocol for the Inductive Coil Trial

BSM

Experimental Trials

Protocol

May 2002

Description of the Experiment

1. General Description
2. Experiment Aim.
3. Preparation.
4. Collection of Data.
5. Analysing Collected Data.

1. General Description

The experiment is split into two stages:

Stage 1

Stage 1 will involve 20 subjects and 3 practitioners.

Each Practitioner will mark on each subject, the PSIS and another mark 150mm up from the PSIS's intersecting line, apply the BSM device, Calibrate the device and the subject will be asked to go through 4 movements. There is a specific protocol to follow in this procedure which is outlined below. Measurements will then be taken of the subject's full range of flexion using the BSM Device.

The process will be recorded by the BSM device and on video tape for later analysis.

Stage 2

Stage 2 involves 20 subjects and 1 practitioner.

Each subject will then have additional markers applied to their lower back, and be asked to go through a set of movements. These movements will be recorded by the BSM device, and by video cameras for later analysis.

2. Aim:

The aims of this experiment are:

- To establish the inter-tester reliability of using the PSIS as a landmark for reliable measurement of lower back movements.

- To verify the reliability of the BSM to measure skin stretch during lumbar movement based on the parameters defined below.
- To gain feedback from practitioners regarding the use of the device and the concept itself.

3. Preparation:

The Equipment

MD

Description:	Titanium Coil
Diameter:	4.00mm
Thickness of Wire:	0.25mm
Length:	150.00mm
Frequency:	100 KHz
Attachment types:	Approved electrodes (insulated) commonly used with EMG work.
Other:	Coil coated with lacquer to prevent current 'leak'.

RFD

Description:	Prototype Datalogger on breadboard. 2 potentiometers for calibration + 2 LED's for calibration. Power/Reset LED and switch. Start/stop recording switch and LED.
Input Type:	MilliVolts
DSP type:	Motorola 68HC11
Power:	6 volts DC.

Method

Blind Testing. Practitioners will not be aware of the purpose of the testing or the status of each subjects low back pain.

Subjects will be unaware of the purpose of the testing, as well as the desired results.

Subjects

- 20 subjects in total.
- Subjects are to be collected via private connections.
- The Population for the trials will have the following characteristics:

Category	Sample Population
Sex	10 male, 10 female
Age	> 60 =5 50-60 =5 20-30 =5 30-50 =5
Other	Subjects must have no history of back injury, defined as injury requiring days off work (normal daily activities).

- Each subject must complete:
 1. the PAI "BSM Questionnaire – Contributing Factors" Form
 2. The PAI Consent Form.

Practitioners / Testers

3 qualified Practitioners will conduct stage 1 of the trial with each subject.

Practitioners will be briefed on the protocol before beginning with subjects.

Subject Starting Position

Each subject before commencing each movement, should be asked to stand in “the starting position”. Please ask the subject to:

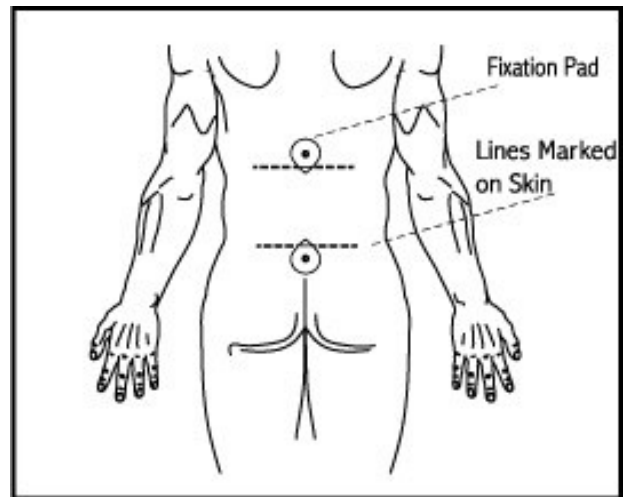
- ***“stand relaxed but upright with your feet shoulder-width apart and arms relaxed by your side”***

Please explain this starting position to each subject.

Landmarks Protocol

Both stages of the trials require locating of landmarks for the attachment of the MD unit. The marks on the lower back are to be located using the following procedure only:

1. Instruct the subject to stand in the “starting position”;
2. Mark the PSIS on the left and right sides such that each is the size of an olive;
3. Draw a small horizontal line across the middle of each PSIS ‘olive’;
4. Join these two horizontal marks with one extended horizontal line (Line “A”) stretching across the spine.
5. Measure with a soft measuring tape, 150mm up from line “A”, measuring with the tape pressed against the subjects skin, gently following the skin contours. Mark a small horizontal line here (Line “B”).
6. Get the subject to stand with feet shoulder-width apart and re-measure the distance in millimetres between the two lines;
7. Instruct the subject to bend forward as far as they feel comfortable, keeping their knees straight.
8. Whilst the subject is in their maximum flexed position, measure the new distance between line **A** and **B** in millimetres. Also mark the point on the subjects shins, where the tips of their fingers have reached. Record measurements on data sheet;
9. Instruct the subject to return to their original standing position.
10. Place a fixation pad (provided) such that the white line on the pad matches up with the line marked on the skin. Place each pad orientated such that the bulk of the pad is outside of the area to be measured (see diagram to the right).

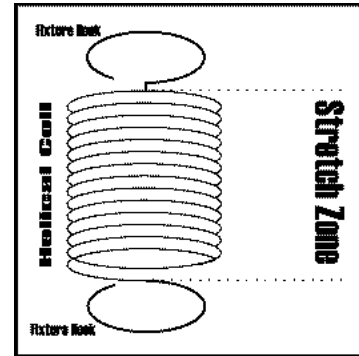


Stage 2 – BSM Recordings

Fixation to the skin

1. Instruct the subject to stand on the feet placement markers on the ground in area two;
2. Instruct the subject to stand in the ‘starting position’;
3. Apply the BSM Measuring unit (helical coil) to the lower back;

- 3.1. The stretch zone is as indicated in the diagram to the right. Clip the press-studs at both ends of the MD to the press-studs on the pads at the top and bottom of the stretch zone. Connect the wires from the device to the coil;
- 3.2. Secure the wires with a piece of tape to the subject's hip either on the skin or on a belt.
- 3.3. Check that the technician is ready to begin the test;
4. Instruct the patient to stand in the starting position;
5. Instruct the patient to bend forward as far as they comfortably can, hold for one second and then return to the starting position;
6. Repeat steps 4 and 5 five times.



4. Data Collection:

The BSM will be positioned at midline of L1 and S1 level. Data is to be collected by initiating movements where we believe the back is most active.

In summary, each subject will be performing two steps. Firstly, they will be asked to bend to their maximum range, and return to the starting position.

This will be repeated three times.

The subject will then be asked to perform a set of simple activities, mimicking everyday activities. These will be video taped as well as recorded by the BSM for later analysis.

Stage 2, Step 1

Setting

Ask the subject to place the feet on the placement markers on ground, and stand in the starting position, looking straight ahead.

Aim

The purpose of this station is to collect data regarding simple forward flexion of the spine, and compare this data to Schober method recordings. This will assist in verifying the relationship of skin stretch to lower back movement.

Actions to be Taken

The subject is standing in the starting position as outlined above.

The subject is asked to bend forward as far as comfortably possible at slow speed, whilst recordings are taken using the Schober method. When at full flexion the subject is asked to return to the starting position.

This step is repeated three times.

Stage 2, Step 2

Setting

At Station two there is an ordinary office desk set up with a computer, printer and chair.

A camera is placed recording the desk at right angles, on the left hand side.

The subject is asked to sit in the chair and perform a number of predetermined tasks.

Aim

The aim of this Step is to capture movement recordings for a very everyday task for many workers.

BSM recordings will later be compared with video analysis of the tasks.

Actions to be Taken

The subject is asked to begin with feet on the placement markers.

The subject is asked to take a seat in the chair at the desk.

The subject is asked to type "The quick brown fox jumped over the lazy dog" onto the keyboard.

The subject is asked to pick up the pile of paper off the floor and fill the printer tray.

The subject is asked to print the text to the printer.

The subject is asked to highlight the text using the mouse and delete it.

The Experiments Utility

The experiments will be conducted to determine the reliability of the BSM device when measuring the back strain of subjects.

5. Analysis of Collected Data

Subjects chosen are of three 'sizes' with no physical limitation in order to get accurate readings.

In order to get accurate readings the experiment is done in a controlled environment with all the positions and the movements predetermined. The position of the BSM on the skin of the lower back will be the same in all subjects.

Once the data is collected, a histogram for each subject is analysed using subjective practitioner questionnaire and also statistical methods.

Practitioner Analysis

Graphs will be created separately for movements recorded during each of the stations for each subject.

Practitioners will be shown graphs for each station mixed in random order and asked to predict which station the graphs depicts activity in.

The practitioner will be unaware of which station and which subject they are analysing.

Statistical Analysis

The Intraclass Correlation Coefficient (ICC) will be used to analyse the reliability of the coil technique. The reliability of the Schober method will also be calculated using the same method.

Classification

Project may be classified Minimal Risk:

Procedures taken to minimise risks involved –

Maintaining Confidentiality

All the forms and experimentation sheets will not have subject identification details, only specific details to identify the age and sex of the subject relevant to the experiment.

- The device is electrically safe and is not connected to mains electricity.

RMIT HUMAN RESEARCH ETHICS COMMITTEE
PLAIN LANGUAGE STATEMENT

FACULTY OF	Engineering
SCHOOL OF	Electrical and Computer Systems Engineering
Name of participant:	
Project Title:	Back Strain Monitor (BSM) Experimental Trials
Name(s) of investigators: (1)	Andrew J Ronchi
Phone:	0417-882267

Pro-Active Industries Pty Ltd (PAI) & RMIT University are conducting research into injuries of the lower back region. This research requires PAI to collect measurements of lower back movement from many different people.

The experiment involves subjects being fitted with a small device onto the skin of their lower back, and then being asked to go through a variety of everyday movements.

The collated results of these measurements will be used to create standardised ranges of movement for the lower back and to test the validity of an electronic measurement device. The results of this study may be published in a journal in Australia and/or overseas, and/or used to promote the commercial interests of PAI.

However, none of your personal details, including your name, will be connected with any of the published material. Only the measurements taken (sex, height, weight and age) will be included in the published results.

The experiments do not involve any dangerous substances, radiation or processes. There is no electrical current passed through the body, and the device is battery powered, not mains powered.

Please Note:

If you feel any discomfort or pain during the experiments, please return to a standing or lying position immediately and notify the practitioner of your pain/discomfort.

HREC Form No 2b

RMIT HUMAN RESEARCH ETHICS COMMITTEE

Prescribed Consent Form For Persons Participating In Research Projects Involving Interviews, Questionnaires or Disclosure of Personal Information

FACULTY OF Engineering

SCHOOL OF Electrical and Computer Systems Engineering

Name of participant: _____

Project Title: Back Strain Monitor (BSM) Experimental Trials

Name(s) of investigators: (1) Andrew J Ronchi Phone: 0417-882267

(2) _____ Phone: _____

1. I have received a statement explaining the interview/questionnaire/activities involved in this project.
2. I consent to participate in the above project, the particulars of which - including details of the interviews or questionnaires - have been explained to me.
3. I authorise the investigator or his or her assistant to interview me or administer a questionnaire.
4. I acknowledge that:
 - (a) Having read Plain Language Statement, I agree to the general purpose, methods and demands of the study.
 - (b) I have been informed that I am free to withdraw from the project at any time and to withdraw any unprocessed data previously supplied.
 - (c) The project is for the purpose of research and/or teaching. It may not be of direct benefit to me.
 - (d) The confidentiality of the information I provide will be safeguarded. However should information of a confidential nature need to be disclosed for moral, clinical or legal reasons, I will be given an opportunity to negotiate the terms of this disclosure.
 - (e) The security of the research data is assured during and after completion of the study. The data collected during the study may be published, and a report of the project outcomes will be provided to _____ (specify as appropriate). Any information which will identify me will not be used.

Participant's Consent

Name: _____

Date: _____

(Participant)

Name: _____

Date: _____

(Witness to signature)

Participants should be given a photocopy of this consent form after it has been signed.

Any complaints about your participation in this project may be directed to the Secretary, RMIT Human Research Ethics Committee, University Secretariat, RMIT, GPO Box 2476V, Melbourne, 3001. The telephone number is (03) 9925 1745.

Appendix III

Clinical Trial Protocol for the Accelerometer Trial

RMIT HUMAN RESEARCH ETHICS COMMITTEE

APPLICATION FOR APPROVAL OF A PROJECT INVOLVING HUMAN PARTICIPANTS

No handwritten applications can be accepted. This form is available from:

<http://www.rmit.edu.au/departments/secretariat/hrec.html>

Section A: Approvals and Declarations

Project title:

Determine the usefulness of a device for measuring lumbar spine movements and load within an industrial setting over prolonged periods of time.

A1. Complete this section if you are undertaking Research for a Degree Awarded by RMIT or another university. (Bachelor/Masters by Coursework/Masters by Research/PhD).

Investigator

Name:	Andrew J Ronchi		
Student No:	3029015		
Qualifications:	B.App.Sci(Physio)		
Department:	School of Electrical & Computer Systems Engineering		
Address:	7 Burke Road, Malvern East, Victoria, 3145		
Phone:	0417-882267	Email:	<u>Pro_act@ihug.com.au</u>
Degree	Doctor of Philosophy		
(for which research is undertaken)			

Supervisor

Name:	Dr Dinesh Kant Kumar
Qualifications:	PhD, BE Honour(Electrical)
Department:	School of Electrical & Computer Systems Engineering
Campus:	City

Phone: 03-9925-1954 Email: dinesh@rmit.edu.au

A1. Complete this section if your research is Not for Any Degree

Principal Investigator

Name:

Qualifications:

Department:

Campus:

Phone:

Email:

Other Investigators

Name:

Qualifications:

Department:

Campus:

Phone:

Email:

Section A2

Project title: Determine the usefulness of a device for measuring lumbar spine movement and load within an industrial setting over prolonged periods of time.

Name/s of persons associated with the conduct of the work described in this proposal (you may increase space to include all those involved):

Name: Mr. Phil Brasher Qualifications B.App.Sci (Physio)

:

Role: Research adviser and planner.

Name: Nick Taylor Qualifications PhD, BAppSc (Physio)

:

Role: Consultant

Name: Ms. Barbara Polus Qualifications Dr. Of Chiropractic

:

Role: 2nd Supervisor

Name: Dr Dinesh Kant Kumar Qualifications PhD, BE Honour(Electrical)

:

Role: Supervisor

Name: Mr Andrew Ronchi Qualifications B.App.Sci (Physio)

:

Role: Researcher / Applicant

Declaration by the Investigator(s):

I have read the current NH&MRC National Statement on Ethical Conduct in Research Involving Humans 1999, and accept responsibility for the conduct of the procedures detailed below in accordance with the principles contained in the Statement and any other condition laid down by the RMIT Human Research Ethics Committee.

Name: Andrew Ronchi **Date:** _____
(Signature of Principal Investigator)

Name: Phillip Brasher **Date:** _____
(Signature of other Investigators)

Name: Dr Dinesh K. Kumar **Date:** _____
(Signature of supervisor – if applicable)

Name: Dr Barbara Polus **Date:** _____
(Signature of supervisor – if applicable)

Dr Nick Taylor
Name: _____ **Date:** _____
(Signature of supervisor – if applicable)

Section A3

Project title: Determine the usefulness of a device for measuring lumbar spine movement and load within an industrial setting over prolonged periods of time.

Declaration by the Head of Department:

Statement on the adequacy of the project's experimental design:

The proposed project follows a logical pathway. The first aspect of the project analyses lumbar spine movement and load, comparing the new device measurements to pre-existing parameters which are well recognised by the medical profession. This analysis will be performed by way of experimental trials with a strict experimental protocol which has already been field tested. The correlation between the new device measurements and pre-existing data measurements will give valuable statistical data in relation to the reliability and validity of the device and the proposed measuring technique, within a controlled setting.

The second aspect of the project will involve a pilot study in which the device will be used within a real work setting. Subjects will perform normal daily work tasks whilst wearing the device as well as being video taped. The correlation between the device's recorded movement data and the video recording data, will give an idea of the reliability and validity of the device within a work setting.

Ethical issues that are to be addressed by the Human Ethics Committee:

- 1) Safety of subjects:
 - a) A low grade electrical device is to be used for the trials. To ensure there is no danger to subjects, the device is currently powered by a standard mains isolated powerpack, with additional 5KV isolation built into the circuitry itself (exceeding AS3000 commercial requirements).

- b) Subjects are advised that if they feel pain and/or discomfort during the test, they are to stop and discontinue the trials.
 - c) No heavy loads will be lifted during the course (i.e.: < 10Kg's) of the experiments.
- 2) Confidentiality of Data: The data collected from the subjects will not be linked to their name or date of birth. Only the subjects age may be used. No private information will be published unless we have written permission from each particular subject involved.

The project set out in the attached application, including the adequacy of its experimental design and compliance with recognised ethical standards, has the approval of the Department/Faculty.

Name:	<i>(Signature of Head of Department)</i>	Date:	22 nd AUGUST 2003
Department:	Electrical & Computer Systems Engineering	Extn:	9925 1971
Faculty:	Engineering	Campus:	City

Should substantive amendments to the proposal be sought by the HREC or its Faculty Sub Committee, these are to be endorsed below:

Amendments made at the date indicated:

Name:	<i>(Signature of Head of Department)</i>	Date:	
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Section A4

Faculty Human Research Sub-Committee Use Only

Date Application Received: _____

Faculty HRE Sub-Committee Register No _____

Recommended project risk classification (circle one): **Level 1** **Level 2** **Level 3**

☐

Approved by Faculty Sub-Committee:

Date: _____

Period of Approval:

From _____

to _____

Or

☐

Referred to RMIT HREC:

Date: _____

Comments/Provisos:

Name: _____

(Faculty HRE Sub-Committee Chair)

Date: _____

Date PI notified/sent to RMIT HREC: _____

Section A5

University Human Research Ethics Committee Use Only

AR Project: _____ RMIT HREC Register No: _____

Period of Approval: From _____ to: _____

Comments/Provisos:

Name: _____ **Date:** _____
(HREC Chair)

Date PI notified/sent to HREC Sub-Committee: _____

Investigators are advised to include with their application sufficient detail about the project, recruitment method and procedures for obtaining informed consent, to enable the Committee to make a proper assessment of the project. Having sufficient information assists the Committee to make a speedy decision.

Please supply details of your proposed project according to the headings given below -

Section B: Project particulars

B1. Title of Project:

Determine the usefulness of a device for measuring lumbar spine movements and load over prolonged periods of time: Experimental Trials

There will be two trials/tests over the duration of the project that need approval from the HREC. The first is outlined comprehensively below and the second is outlined briefly and will be submitted separately to the first, before February 2004.

B2. Project description: for HREC assessment of ethical issues.

TRIAL ONE – RELIABILITY TESTING

1. Aim:

Reliability testing in a controlled setting:

(1) The first aim of this experiment is to assess the test-retest reliability and the inter-tester reliability within a controlled setting (i.e.: one room) of the Back Strain Monitor (BSM) to measure skin stretch and angular change during lumbar movement.

(2) The second aim is to compare the BSM accelerometer readings to the inclinometer readings, as well as the video angular readings, to assess the degree of criterion validity of the BSM accelerometer readings.

(3) The third aim is to review whether the BSM device can reliably (test/re-test and inter-tester reliability) measure functional activity in a semi-controlled setting (i.e.: 10 chosen functional activities performed in one room with the BSM device worn and video recording of the activities).

(4)The Fourth: The 10 chosen activities will be ranked, in order of risk/pressure to the lumbar spine disc (Nachemson 1976), by 30 physiotherapists. From the data gathered by the BSM in the functional reliability study, estimates will be made of which activity is performed by reviewing the data only. These data estimates will be compared to the professional estimates to see whether there is criterion validity of the BSM data in being able to discriminate professional opinion in relation to risk to the lumbar spine disc.

2. Methods

The experiment will use a combination of the Modified-Modified Schober test, the double inclinometer technique, the BSM device and video analysis. The BSM measures two parameters at any one time. These are;

- (a) Angular changes via 4 accelerometers, with 2 at the upper lumbar spine and 2 at the lower lumbar spine (see 'landmarks' heading for more specific placement details). These angular recordings will be taken through range during flexion, lateral flexion and rotation movements. The readings will then be compared with the double inclinometer technique as described by Mayer, 1984. These measurements will give start and end range of movement for each of the described movements.
- (b) Muscle activity of the erector spinae/multifidus and biceps brachii via EMG recordings (Muscle activity will not be measured in these experiments).

Research questions: (numbered in sync with the above aims)

Controlled Setting:

1. Do the accelerometers, attached to the upper and lower lumbar spine, reliably (test/re-test and inter-tester reliability) measure the movements of the lumbar spine in all three planes (i.e.: flexion, lateral flexion and rotation)? Proposed statistical method for test/re-test will be ICC and estimates in the units of measurement based on the standard error of measurement (Keating,1998)
2. How do the readings from the accelerometers compare to the readings from the inclinometers and the angular readings taken from the video? What degree of criterion validity exists between these three measuring systems? The accelerometer readings, the inclinometer readings and the video angular readings will be compared by the determination

of the correlation coefficient and 95% confidence intervals derived from the standard error of estimate.

Functional Setting:

3. Can the combined data from the accelerometers and the EMG readings, reliably measure functional activity (as defined by 10 chosen functional activities with an increasing risk rating to injuring the lumbar spine)? Test/retest and inter-tester reliability will be assessed via ICC(2,1) (Shrout, 1979).

4. Ten different movements, representing differing loads/pressure on the lumbar spine, are ranked in order of estimated risk, by qualified physiotherapists (1= highest risk, 10= least risk). Can these movements be identified and differentiated from each other from the data alone (i.e.: the three types of data: the coil, the accelerometers and the EMG recordings)?

Testing Procedure:

Subjects will be briefly interviewed to establish whether they fulfil the inclusion criteria which states that subjects can not have had any back pain in the preceding three months and the subject has no history of spinal surgery to the lumbar, thoracic or cervical spine. There will be three testers; a Manipulative Physiotherapist (10yrs experience), a Sports Physician (15 yrs experience) and an Anaesthetist (15yrs experience). There will be 30 subjects to be assessed over an eight hour period on one day. A follow up testing day will be organised for four weeks later to gather the data for the test/retest reliability aspect which will involve one of the testers with the same 30 subjects.

Starting position will be with each subject standing with feet shoulder width apart in comfortable but erect standing (Youdas et al, 1991). The landmarks will be identified by Therapist 1 marking the PSIS's, with a removable pen marker, in the shape of an olive. A horizontal line 'Line A' is then drawn across the middle of the olive and joined with the corresponding line on the opposite side of the lumbosacral spine. This line represents the lumbosacral junction and is the lower attachment for the coil and for the lower accelerometer. Fifteen centimetres is then measured from this horizontal line upwards towards the thoracolumbar junction keeping a flexible tape measure pressed gently against the skin. This point is marked with another horizontal line 'Line B' and the distance between the two horizontal lines will be confirmed as 15cm's with the same flexible tape measure pressed gently against the skin on the central vertical line of the lumbar spine. This line 'B' is the upper

attachment for the coil and the marker for the upper accelerometer. The EMG electrodes positions are marked for the erector spinae group as described by Fathallah.F.A,1998, Spine.

Subjects will then be fitted with the BSM Device such that the Accelerometers are at either end of line A and B.

Movements within a **controlled setting** will be tested first. Each subject will be asked to flex forward, backward, tilt left and right and rotate left and right to ensure that they move correctly and this will also account for any warm up effect (Roberts *et al.* 1988).

The testing will then begin (see next section for detailed description of requirement of subjects).

Movements within a **functional setting** will then be tested. Subjects will be asked to go through 10 everyday activities with each movement being repeated three times.

The BSM will be removed and the subject will be free to leave.

The entire process is expected to take approximately 4 hours.

The subjects will be required to return four weeks later, for one hour only, for one tester to re-test his/her measurements to assess the test/re-test reliability.

3. Detailed Description of requirements of Subjects:

The movements being performed during the experiments are listed below. The first section relates to movements within a 'controlled setting' and the second part to movements within a more 'functional setting'.

Controlled setting:

NOTE

Each practitioner will explain to each subject to stop movements if they have any discomfort. The experiment will stop immediately for any such Subject.

Subject Starting Position (reliability testing in a controlled setting)

Each subject before commencing movements, should ensure the following:

- Stand facing the door of the lab with head and shoulders straight;
- Stand with feet shoulder width apart;
- Stand with arms relaxed by side; and
- Stand with legs and trunk in relaxed stance.

These following movements will be performed in a random sequence to avoid any potential bias.

1. Lumbar spine Flexion:

Starting posture: Standing as detailed above.

The subject is asked to flex trunk forward reaching their fingers toward the ground as far as they comfortably can. The distance from the finger tips to the ground is measured and a box at this same height is placed on the ground. This box gives the subject a marker to reach to such that the movements they perform are consistent. The subject is then asked to reach forward and touch the box with their fingertips and hold the position for five seconds. This routine is repeated three times. At the erect standing position and the fully flexed position, a Schober reading and the double inclinometer readings will be taken and the BSM will be recording continuously.

2. Lumbar spine extension:

Starting posture: as above

The subject is asked to arch backward as far as they are comfortable, with their arms folded across their chest, and to hold this position for five seconds. Whilst holding this position the double inclinometer readings are taken and repeated when the subject is in erect standing. The Schober method is not used here. This extension movement is repeated three times. An extreme range of movement is not desirable as it may become uncomfortable with the sustained hold. This will be explained to the subject during the warm up movements.

3. Lumbar spine Lateral Flexion:

Starting posture: Standing with erect trunk.

The subject is asked to laterally flex the lumbar spine, sliding their hand down the side of their leg without allowing the trunk to deviate forward or backward. This will be closely monitored during the warm up routine as well as during the testing. At the maximum comfortable lateral flexion, a box or marker will be placed at that height to allow the subject to return to the same level of lateral flexion. This lateral flexion movement is repeated three times to the right and three times to the left with a five second hold for each movements maximum range. The double inclinometer is again used to record the range of lateral flexion to the right and left.

No Schober readings are required here.

Thoraco-lumbar rotation:

Starting position is in a 60 degree squat to reduce rotation through the hips, knees and ankles. The video camera is set up above the subject and will record the movement of the markers sticking out from the accelerometer boards. The subject will be asked to rotate to the left and the right, as far as comfortable, ensuring their knees continue to point forward. The inclinometer and the Schober are not to be used here. The movements will be held at full comfortable rotation for two seconds and repeated two times. Recordings will be taken automatically by the video and the accelerometers.

Uncontrolled Setting:

With the BSM still attached and recording, the subjects will be asked to carry out ten different functional activities and repeat each activity twice, except movements one and two. These two movements will only be performed one time each as they are potentially provocative movements, especially if repeated more than once.

There will be no attempt to record Schober measurements or inclinometer measurements during these movements.

Each subject will be asked if they feel safe lifting each object and if it is something they would normally do. If they do not normally lift that particular weight, that lift will be left out of their functional movements.

The movements will be recorded via video, in time sync with the BSM readings, to allow later processing of what movements occurred at what exact time.

These movements will be performed in a random sequence in order to avoid any bias.

- (1) Bending forward fully and twisting fully to lift 20 Kg from ground level.
- (2) Bending forward fully and lifting 20 Kg from ground level.
- (3) Bending forward $\frac{3}{4}$ range flexion and lifting 15 Kg weight from 20cm high (i.e.: 1 step).
- (4) Bending forward $\frac{1}{2}$ range of movement and lifting 10 Kg from 40cm high (i.e.: 2 steps).
- (5) Bending forward $\frac{1}{2}$ range of movement and lifting 5 Kg from 60 cm high (i.e.: 3 steps).
- (6) Forward flexion to $\frac{1}{2}$ range of movement.
- (7) Forward flexion to $\frac{1}{4}$ range of movement.
- (8) Squat with lumbar spine remaining in lordosis.
- (9) Walking upright.
- (10) Lying down on side.

After all appropriate movements are performed, the BSM will be removed and the skin markings cleaned off with a safe solvent to reduce any bias from the next tester. The subject then moves to the next tester who has been allocated in a random sequence to reduce any potential bias.

B3. Proposed commencement of project

RELIABILITY TESTING – October 2003

B4. Proposed duration of project; proposed finish date.

The project will begin in October 2003 and end in February 2004.

The Clinical Tests will run for two days in total.

B5. Source of funding (internal and/or external)

External

B6. Project grant title; proposed duration of grant (where applicable)

Back Strain Monitor – AusIndustry Biotechnology Innovation Fund Grant No.2588

Grant duration (July '02 – February '04)

Section C: Details of participants

C1. Number, type, age range, and any special characteristics of participants.

RELIABILITY TESTING:

Number: 30

Sex: Male & Female

Age Range: 20 – 60 years old

Special Characteristics:

Subjects must not have suffered from an injury to the lower back in the past 3 months.

C2. Source of participants (attach written permission where appropriate)

Advertisements are being placed at RMIT city campus and at two Private Physiotherapy practices.

C3. Means by which participants are to be recruited

Flyer advertisements, practitioners asking suitable patients.

C4. Are any of the participants "vulnerable" or in a dependent relationship with any of the investigators, particularly those involved in recruiting for or conducting the project?

No.

Section D: Risk classification and estimation of potential risk to participants

D1. Please identify the risk classification for your project by assessing the level of risk to participants or (if any) to the researcher.

Risk Level 2 (MR)

D2. If you believe the project should be classified level 2 or level 1 please explain why you believe there are minimal risks to the participants.

Physical Risks: Subjects are not being required to perform any strenuous or dangerous tasks. The tasks being performed are well within everyday tasks for the average person and there is therefore very little risk involved in the project. All subjects and examiners will be briefed that if any discomfort is felt by any subject, then the experiment must stop immediately for that subject.

There is no electrical current passed through the body and extensive measures have been taken to isolate the equipment and the subject from mains power.

Other Risks: Subjects will not be placed under any stress to complete tasks. There will be no pressure on applicants. There is no risk of any mental or psychological ramifications from the trials. There is no nudity or compromising positions involved in the trials that may cause some subjects discomfort or humiliation.

OR

If you believe the project is classified level 3 please identify all potential risks to participants associated with the proposed research. Please explain how you intend to protect participants against or minimise these risks.

D3. Please explain how the potential benefits to the participant or contributions to the general body of knowledge outweigh the risks.

The risks involved are very minor. The benefits to the subjects are minimal.

The potential contribution to the body of knowledge will be significant.

D4. Contingency planning: first aid / debriefing

Mr Andrew Ronchi and Mr Phil Brasher, who are both Physiotherapists involved in the trials, have current First Aid certificates, as will other practitioners involved. A locality plan will also be placed in the lab, which will illustrate where the nearest first aid room is available, and list all relevant phone numbers for ambulance, nearest hospital and RMIT First Aid Room.

D5. Please complete this checklist by placing Y (Yes) or N (No) and give details of any other ethical issues that may be associated with this project.

Y/N

a	Is deception to be used?	
b	Does the data collection process involve access to personal or sensitive data without the prior consent of participants?	

c	Will participants have pictures taken of them eg: photographs, video recording, radiography?	
d	Will participants come into contact with any equipment which uses an electrical supply in any form eg: audiometer, biofeedback, electrical stimulation, etc?	
e	If interviews are to be conducted will they be tape-recorded or videotaped?	
f	Do you plan to use an interpreter?	
g	Will participants be asked to commit any acts which might diminish self-esteem or cause them to experience embarrassment or regret?	
h	Are any items to be taken internally (orally or intravenously)?	
i	Will any treatment be used with potentially unpleasant or harmful side effects?	
j	Does the research involve a fertilised human ovum?	
k	Does the research involve any stimuli, tasks, investigations or procedures which may be experienced by participants as stressful, noxious, aversive or unpleasant during or after the research procedures?	
l	Will the research involve the use of no-treatment or placebo control conditions?	
m	Will any samples of body fluid or body tissue be required specifically for the research, which would not be required in the case of ordinary treatment?	
n	Will participants be fingerprinted or DNA "fingerprinted"?	
o	Are the participants in any sort of dependent relationship to the investigator/s?	
p	Are participants asked to disclose information that may leave them feeling vulnerable or embarrassed?	
q	Are there in your opinion any other ethical issues involved in the research?	

Where you have placed 'Y' to any of the questions on the checklist, please give details and state what action you intend to take to ensure that no difficulties arise for your participants.

D5(C) Video Footage

Video footage will be taken of the subjects throughout the trials. This is an integral part of the analysis of the data once the trials have been completed. As stated in the subject consent form, PAI make a written assurance that this footage will not be used apart from

internally. It will not be used in any marketing or promotional materials, nor shown to any parties that are not a member of the trial team.

We think this adequately prevents any public viewing of the material and therefore any ramifications for the subjects. We have been sure to state that video footage will be taken right from the outset, to ensure all subjects are fully aware well before the trials commence.

D5(D) Electrical Equipment

The device being tested is an electrical device. Power isolation has been a major point of design of the prototype, both the power supply and the electrical circuit itself have power isolation to above AS3000 standards. This poses no threat of electrocution to the subjects. No electrical current is at any time passed through any part of the subject's person (eg: electrodes) and at no time will any equipment subjects come in contact with be connected to main power.

There is no risk of any harm coming to any subject through electrocution.

Details [except (a) and (b)] must be included in the plain language statement.

Section E: Informed consent

E1. Attach to the application your plain language statement & consent form.

See Attachment #1

E2. Dissemination of results

Included in PLS

E3. Participants under 18 years

N/A

E4 Persons subject to the Guardianship Act (Vic) (If applicable)

N/A

Section F: Research Involving Collection, Use Or Disclosure Of Information

We wish to acknowledge permission from the Department of Human Services, Vic on whose Common Application Form the questions in this section have been based.

Please note that if you propose to collect information about an individual from a source other than the individual, or to use or disclose information without the consent of the individual whose information it is, you will **also** have to complete the Special Privacy Module (Appendix ix) as well as the questions below.

Under statutory guidelines a HREC may approve some research where the public interest outweighs considerations of privacy, however a researcher must make a special case for such approval. The Special Privacy Module is the starting point for preparing such a case.

For a more detailed guidance and definitions for each of the question below, *see Notes to assist in completing the form, Section F.*

F1 Does this Section Has to be Completed?

Does the project involve the collection, use or disclosure of personal information, health information including genetic information, or sensitive information,? (*see Notes to assist in completing the form, Section F*)

☐ No – you do not have to answer any questions in this section. Go to Section G.

☒ Yes – you must answer questions in this section. Go to Question F2.

F2 Type of Activity Proposed

Are you seeking approval from this HREC for:

(a) collection of information?

☒ Yes – start at Question F3

☐ No – start at Question F4

(b) use of information?

☒ Yes ☐ No

(c) disclosure of information?

☐ Yes ☒ No

F3 Collection of Information

(a) Does the project involve collection of information **directly** from individuals about themselves?

☐ No – (i.e. -collected from a third party/existing records) You must fill out the Special Privacy Form 9 (See Appendix ix), as well as this form.

☒ Yes – answer the following questions:

(b) What type of information will be collected? (*Tick as many as apply*)

☒ personal information

☐ sensitive information

☒ health information

(c) Does the plain language statement explain the following:

The identity of the organisation collecting the information and how to contact it?

Yes ☒ No ☐

The purposes for which the information is being collected?

Yes ☒ No ☐

The period for which the records relating to the participant will be kept?

Yes ☒ No ☐

The steps taken to ensure confidentiality and secure storage of data?

Yes ☒ No ☐

The types of individuals or organisations to which your organisation usually discloses information of this kind?

Yes ☒ No ☐

How privacy will be protected in any publication of the information?

Yes ☒ No ☐

The fact that the individual may access that information?

Yes ☒ No ☐

Any law that requires the particular information to be collected/disclosed? (e.g. notifiable diseases or mandatory reporting obligations re child abuse)

Yes ☐ No ☐
Not
Applicable

☒

The consequences (if any) for the individual if all or part of the information is not provided? (eg any additional risks if a participant does not fully disclose his/her medical history)

Yes ☒ No ☐

Not
Applicable

☐

If you answered “No” to any of these questions, give the reasons why this information has not been included in the plain language statement.

F4 Use or Disclosure of Information About Individuals

- (a) Does the project involve the use or disclosure of identified or potentially identifiable information?

☒ No – go to Question F5.

☐ Yes, answer the following questions.

- (b) Does the project involve use or disclosure of information **without** the consent of the individual whose information it is?

☒ No - go to Question F5.

☐ Yes, You must fill out the Special Privacy Form, as well as this form. (See Appendix ix)

F5 General Issues

- (a) How many records will be collected, used or disclosed? Specify the information that will be collected, used or disclosed (*e.g. date of birth, medical history, number of convictions, etc*)

Number of records: 300 – 500 records

Type of information: Date of Birth, History of low back pain, Occupation.

- (b) For what period of time will the information be retained? How will the information be disposed of at the end of this period?

It is anticipated that the information will be retained for the required statutory period. It is unclear at this time whether a follow-up study will be required on some subjects. The information will be destroyed by shredding after the statutory period.

- (c) Describe the security arrangements for storage of the information. Where will the information be stored? Who will have access to the information?

Only the investigator will have access to the confidential data. Records relating to data collected and to personal information will be removed from each other by a coding system for names and records.

Once collation of the data is complete (2 weeks from conclusion), the information will be stored in two separate, locked filing cabinets at 7 Burke Rd, East Malvern 3145.

- (d) How will the privacy of individuals be respected in any publication arising from this project?

No information that would enable identification of an individual will be published. In any results, no information will link any name with date of birth or other personal information.

(e) Does the project involve trans-border (i.e. interstate or overseas) data flow?

☐ Yes ☒ No

If Yes, give details of how this will be carried out in accordance with relevant Privacy Principles (e.g. HPP 9, VIPP 9 or NPP 9).

(f) Does the project involve the adoption of unique identifiers assigned to individuals by other agencies or organisations?

☐ Yes ☒ No

If yes, give details of how this will be carried out in accordance with relevant Privacy Principles (e.g. HPP 7, VIPP 7 or NPP 7).

F6 Adverse Events

Are procedures in place to manage, monitor and report adverse and/or unforeseen events relating to the collection, use or disclosure of information?

☒ Yes ☐ No

Give details.

Both in the plain English statement and as part of the experimental protocol, subjects will be given the opportunity to ask questions or express concerns, about any part of the experiment they are not entirely comfortable with. Subjects will also be advised that if at any time during the course of the experiments they encounter any pain or discomfort, they are to cease the experiment immediately.

F7 Other Ethical Issues

Discuss any other ethical issues relevant to the collection, use or disclosure of information proposed in this project. Explain how these issues have been addressed.

Section G: Other issues

G1. Do you propose to pay participants? If so, how much and for what purpose.

A \$20 payment will be made to the subject in appreciation for the subject's time.

G2. Where will the project be conducted?

The project is to be completed at two private physiotherapy practices in Melbourne.

G3. Is this project being submitted to another Human Research Ethics Committee, or has it been previously submitted to a Human Research Ethics Committee?

No

G4. Are there any other issues of relevance?

No.

For any further detail about completion of this form, or for additional supporting material, please contact the Secretary of your Faculty HRE Sub Committee or the Secretary to the RMIT Human Research Ethics Committee C/o University Secretariat, (03) 9925 1745.
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HREC Form 2a**RMIT HUMAN RESEARCH ETHICS COMMITTEE**

Prescribed Consent Form For Persons Participating In Research Projects Involving Tests and/or Medical Procedures

FACULTY OF	Engineering
DEPARTMENT OF	Electrical & Computer Systems Engineering
Name of participant:	
Project Title:	Back Strain Monitor (BSM)
Name(s) of investigators: (1)	Andrew Ronchi Phone: 0417-882267

- 1) I have received a statement explaining the tests/procedures involved in this project.
- 2) I consent to participate in the above project, the particulars of which - including details of tests or procedures - have been explained to me.
- 3) I authorise the investigator or his or her assistant to use with me the tests or procedures referred to in 1 above.
- 4) I acknowledge that:
 - a) The possible effects of the tests or procedures have been explained to me to my satisfaction.
 - b) I have been informed that I am free to withdraw from the project at any time and to withdraw any unprocessed data previously supplied (unless follow-up is needed for safety).
 - c) The project is for the purpose of research and/or teaching. It may not be of direct benefit to me.
 - d) The privacy of the information I provide will be safeguarded. However should information of a private nature need to be disclosed for moral, clinical or legal reasons, I will be given an opportunity to negotiate the terms of this disclosure.
 - e) The security of the research data is assured during and after completion of the study. The data collected during the study may be published, and a report of the project outcomes will be provided to RMIT HREC. Any information which will identify me will not be used.

Participant's Consent

Name:	_____	Date:	_____
	(Participant)		
Name:	_____	Date:	_____
	(Witness to signature)		

Where participant is under 18 years of age:

I consent to the participation of _____ in the above project.

Signature: (1) _____ (2) _____ **Date:** _____
(Signatures of parents or guardians)

Name: _____ **Date:** _____
(Witness to signature)

Participants should be given a photocopy of this consent form after it has been signed.

Any complaints about your participation in this project may be directed to the Secretary, RMIT Human Research Ethics Committee, University Secretariat, RMIT, GPO Box 2476V, Melbourne, 3001. The telephone number is (03) 9925 1745.

Details of the complaints procedure are available from the above address.

HREC Form No 2b**RMIT HUMAN RESEARCH ETHICS COMMITTEE**

**Prescribed Consent Form For Persons Participating In Research Projects Involving
Interviews, Questionnaires or Disclosure of Personal Information**

FACULTY OF	Engineering	
DEPARTMENT OF	Electrical & Computer Systems Engineering	
Name of participant:		
Project Title:	Back Strain Monitor (BSM)	
Name(s) of	Andrew Ronchi	Phone: 0417-882267
investigators: (1)		
(2)		Phone:

1. I have received a statement explaining the interview/questionnaire involved in this project.

2. I consent to participate in the above project, the particulars of which - including details of the interviews or questionnaires - have been explained to me.

3. I authorise the investigator or his or her assistant to interview me or administer a questionnaire.

4. I acknowledge that:

Having read Plain Language Statement, I agree to the general purpose, methods and demands of the study.

I have been informed that I am free to withdraw from the project at any time and to withdraw any unprocessed data previously supplied.

The project is for the purpose of research and/or teaching. It may not be of direct benefit to me.

The privacy of the information I provide will be safeguarded. However should information of a private nature need to be disclosed for moral, clinical or legal reasons, I will be given an opportunity to negotiate the terms of this disclosure.

The security of the research data is assured during and after completion of the study. The data collected during the study may be published, and a report of the project outcomes will be provided to the RMIT HREC. Any information which will identify me will not be used.

Participant's Consent

Name:

Date:

(Participant)

Name:

Date:

(Witness to signature)

RMIT HUMAN RESEARCH ETHICS COMMITTEE

PLAIN LANGUAGE STATEMENT

FACULTY OF **Engineering**

SCHOOL OF **Electrical and Computer Systems Engineering**

Name of participant:

Project Title: Determine the usefulness of a device for measuring lumbar spine movement and load within an industrial setting over prolonged periods of time. title needs to be more descriptive

Name(s) of **Andrew J Ronchi** **Phone:** **0417-882267**
investigators: (1)

Andrew Ronchi is conducting research into injuries of the lower back region as part of his PhD. This research requires him to collect measurements of lower back movement from many different people.

The experiment involves subjects being fitted with a small device onto the skin of their lower back, and then being asked to go through a variety of everyday movements.

The collated results of these measurements will be used to create standardised ranges of movement for the lower back and to test the validity of an electronic measurement device. The results of this study may be published in a thesis, in journals in Australia and/or overseas, and perhaps used for the release of a commercial product.

However, none of your personal details, including your name, will be connected with any of the published material. Only the measurements taken, sex, height, weight and age may be included in the published results.

The confidential data will be stored separately from the data collected to help ensure your privacy is kept, and only the investigator himself will have access to both sources of information that would enable identification. The confidential information will be kept for the statutory period. If you would like to see the confidential information at any time, you can phone the investigator on the number above.

The experiments do not involve any dangerous substances, radiation or processes. There is no electrical current passed through the body, there is no invasive elements to the tests.

Please Note:

Be sure to indicate to the research team if you have had any prior back injuries and what the severity of those injuries is or was. This is essential to ensure your safety through the testing.

If you feel any discomfort or pain during the experiments, please return to a standing or lying position immediately and notify the practitioner of your pain/discomfort.

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