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# **Assessment and Rehabilitation of Chronic Low Back Pain**

Research exercise submitted by

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in fulfilment of the requirements of the degree of

Doctor of Philosophy

University of Glasgow  
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## DECLARATION

This thesis is my own work but it was part of a larger study on the evaluation of low back pain for which I was the Research Physiotherapist. The four year study produced six papers, three of which directly resulted from this thesis and are reprinted in the Appendix (12, 13, 14).

Newton M, Waddell G. (1991) Reliability and validity of clinical measurement of the lumbar spine in patients with chronic low back pain. *Physiotherapy* 77:796-800 (Appendix 12)

Waddell G, Allen D B, Newton M (1991) Clinical Evaluation of Disability in Back Pain in Ed Frymoyer J W The Adult Spine: Principles and Practice. Raven Press, Ltd., New York.

Waddell G, Somerville D, Henderson I, Newton M (1992) Objective clinical evaluation of physical impairment in chronic low back pain. *Spine* 17:617-628.

Newton M, Waddell G (1993) Trunk strength testing with iso-machines Part 1: Review of a decade of scientific evidence. *Spine* 18:801-811.(Appendix 13)

Newton M, Thow M, Henderson I, Waddell G (1993) Trunk strength testing with iso-machines Part 2: Experimental evaluation of the Cybex 11 back testing system in normal subjects and patients with chronic low back pain. *Spine* 18:812-824.(Appendix 14)

Waddell G, Newton M, Henderson I, Somerville D, Main C J (1993) A fear-avoidance beliefs questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low back pain and disability. *Pain* 52:157-168.

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## SUMMARY

This thesis presents a set of studies which investigated chronic low back pain. The specific aim of this thesis was to develop reliable methods for the assessment and rehabilitation of chronic low back pain. The two assessment methods tested were a broad based clinical evaluation and an isokinetic assessment of trunk muscle strength. The rehabilitation regime was based on a system of isokinetic exercise. The thesis is presented in three parts: clinical assessment, isokinetic assessment and isokinetic rehabilitation.

The first part of the thesis describes the reliability and validity studies of the clinical methods for measuring trunk mobility, trunk muscle strength, spinal shape and palpation. A total of 27 physical tests were studied using 70 patients and 10 normal subjects. Twenty-three of these tests were found to be reliable and were incorporated into the isokinetic assessment study.

The second part of the study reports the standardisation and reliability studies for the isokinetic assessment of trunk muscle strength in 70 normal subjects and 120 patients with chronic low back pain. The patients received a full clinical assessment, including the 23 physical tests, and completed a battery of psychometric questionnaires. To assess test-retest reliability and learning effects, subgroups of 21 normal subjects and 20 patients repeated the isokinetic protocol on four occasions. In the reliability study of patients the questionnaires were administered before and after the isokinetic tests to measure the potential behavioural effect resulting from the isokinetic testing.

The results showed that the main isokinetic measures were reliable for both normal subjects and patients. There was a significant learning effect from test 1 to test 2 in



both normal subjects and patients. The magnitude of this learning effect was greater in patients than normal subjects.

The normal subjects were followed up by a postal questionnaire in a two year prospective study to predict future back pain using the isokinetic measures. None of the measures used showed any significant differences between those subjects who developed back pain and those who did not.

The third part of the thesis describes studies to develop a rehabilitation programme for patients with chronic low back pain using the isokinetic machines, both as a means of monitoring progress and as an exercise regime. The first study of 26 patients indicated that the programme was safe and effective, but also revealed a major problem with adherence to a six week exercise programme. The second study investigated the problem of adherence and examined the time course of response to isokinetic exercise by repeating the tests at three weeks and six weeks. In this study 52 patients completed a clinical examination and the psychometric questionnaires at the clinic.

The results demonstrated that identification of patients who complied with the programme was not possible from clinical, psychometric or isokinetic measures. There was a significant improvement in isokinetic and psychometric measures from test 1 to test 2 and a further significant improvement from test 2 to test 3, but no improvement from test 3 to test 4. This indicated that improvement can occur with isokinetic testing and isokinetic treatment for three weeks but no further improvement occurs by continuing the treatment for a further three weeks. The magnitude of the improvement was similar for both testing and treatment indicating the effect of isokinetic testing was similar to effect of isokinetic treatment. Isometric lifting and

isokinetic lifting did not demonstrate a significant improvement suggesting that isokinetic exercise does not improve lifting capacity. Range of movement measurements showed limited improvement indicating that an isokinetic exercise programme did not improve lumbar mobility. Isokinetic exercise has potential benefits for the rehabilitation of patients with chronic low back pain but further research is necessary.

## **CHAPTER 1**

### **Background**

#### **1.1 Introduction**

The management of low back pain is the single most common reason for all visits to physiotherapy out-patient departments thus it should be a top priority in research (Jette *et al* 1994). The problem of chronic low back pain has now reached epidemic proportions in Great Britain and most of the western world (Waddell 1987a, Spitzer *et al* 1987). Sick certification due to low back pain has increased by 104 % in the last decade and is showing no signs of decreasing (Klaber Moffet *et al* 1995). There are enormous costs in human and economic terms. Individuals suffer pain, disability, loss of earnings and fear of becoming a back cripple while the economy of the nation is weakened by sickness absence from work, early retirement and demands on the social services. As back pain is a condition that has afflicted humans throughout recorded history (Allen and Waddell 1989), the current epidemic in industrial cultures appears to be due to changes in the response to pain mediated through the complex interaction of physiological, psychological, and social factors. In other cultures, such as Australian Aboriginal, back pain is not publicly acknowledged because of cultural beliefs (Honeyman and Jacobs 1996). In developing countries such as the Middle East and South East Asia there is very little low back disability, at least until Western medicine is introduced (Waddell 1992).

#### **1.2 Natural History**

Low back pain is a common occurrence with approximately 80% of the population suffering from it at some time in their life time. It should be a benign self - limiting

condition and indeed 90% of sufferers recover within 6 weeks of the onset with or without treatment although repeated episodes are common (Von Korff *et al* 1993). However, 5% go on to develop chronic low back pain or disability due to low back pain and this 5% accounts for 60% of the costs associated with low back pain. The longer the low back pain persists the less likely the patient is to return to work, or even to a normal life-style (Waddell 1987a).

### **1.3 Risk Factors**

Cigarette smoking, alcohol drinking and lack of exercise have been suggested as risk factors in low back pain (Kelsey *et al* 1984, Deyo and Bass 1989). Smoking could interfere with the blood flow to the intervertebral disc, ligaments and nerve root, leaving them more vulnerable to injury (Frymoyer *et al* 1983, Holm and Nachamson 1985). There is evidence that people who drink alcohol have more episodes of back pain than teetotallers (Vallfors 1985). Similarly fire-fighters who were unfit had more episodes than those who were fit (Cady *et al* 1979). It is however, possible that these are life-style factors that simply are a part of other factors that could be the true cause. Two work related factors have been implicated; exposure to vibration (Pope *et al* 1991) and heavy lifting (Frymoyer *et al* 1983, Kelsey *et al* 1984). Knowledge of risk factors could help prevent back pain. Although the ultimate goal should be to prevent back pain the reality of this is questionable given the fact that back pain is such a common place occurrence (Bigos and Battie 1987, Waddell 1987a). In the meantime it is essential to identify the potential chronic group as early as possible and offer an adequate rehabilitation programme before disability becomes a problem.

## 1.4 Diagnosis

There have been numerous suggested causes of low back pain over the years; disc degeneration, lumbosacral strain, sacro-iliac disorders, facet joint disorders, fibrositis, myofascial syndrome and coccydynia and a host of others. There is no scientific evidence for any of these being the cause of low back pain. It has been suggested that they are little better than medical fads (Deyo 1991a). The danger is that the patient will be given a nominal diagnosis, which is just a convenient label to put on the symptoms, but leads the patient to believe they have 'degeneration', 'arthritis', or a 'slipped disc' and makes them fear for worst. Terms used by the physician and the therapist should be carefully considered (Deyo *et al* 1994)

## 1.5 Assessment

The major problem with chronic low back pain is lack of a diagnosis (Deyo *et al* 1994). Only about 15% are given an accurate diagnosis the rest are described as mechanical back pain. In most instances it is not possible to identify the tissues which are causing the pain. The clinician has to rely on the patients report of severity of symptoms and physical examination of the patient. This physical assessment of the patient must be reliable if it is to be clinically useful (Waddell *et al* 1982). There is a considerable body of published research on the reliability of various aspects of a physical examination but very little on a complete physical assessment using patients as the subjects (for complete review see Chapter 2). Measurement of performance provides a baseline against which functional improvement can be measured. Availability of objective measures is essential to help guide the clinical decision making and to feed back to the patient in a consistent manner (Mayer *et al* 1985a).

## **1.6 Trunk Muscle Strength**

Functional deficits are rarely a problem in the acute stages of low back pain but as inactivity increases functional deficits become more apparent. Decreased trunk muscle strength has been reported as a possible factor in assessing functional capacity of the lumbar spine but measurement of this is difficult because muscle bulk cannot be measured and there is no contralateral side to compare for normality. Recent research from North America suggests that an isokinetic method of measuring trunk muscle strength is reliable (Mayer *et al* 1985a). (For a complete literature review see Chapter 4).

## **1.7 Pain**

Pain has been described as one of the most pressing issues of our time (Turk *et al* 1983). No medical symptom is more ubiquitous and most patients who attend a physiotherapy department have a main complaint of pain. Pain varies in intensity, quality, duration and meaning. This thesis dealt with chronic pain, i.e. present most of the time, with varying intensity (Turk *et al* 1983). Alleviating pain has resulted in extraordinary treatments in the past such as blistering, bleeding, cupping, cutting, purging, poisoning and no less bizarre treatments in the present such as heating, freezing, needling and transcutaneous nerve stimulation (Turk *et al* 1983). The subjective experience of pain is to try to escape from the cause or to seek relief. This desire can make pain a powerful factor in the sufferer's life producing fear of any behaviour that causes pain. The definition of pain proposed by the International Association for the Study of Pain "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such",

conveys the multidimensional and subjective nature of pain (Mersky 1979). Pain experience itself is private and perceived only by the individual (Klaber Moffet and Richardson 1995). The only way clinicians can gain some understanding of pain is by obtaining pain reports from the patient.

## **1.8 Rehabilitation**

Traditional treatment does not appear to be working as the problem of disability due to low back pain is increasing dramatically (Spitzer *et al* 1987, Waddell 1987a). The uncertainty of diagnosis is reflected in the multiplicity of treatments used in low back pain. General Practitioners are most likely to prescribe rest, medication and perhaps advice. The philosophy underlying the treatment of other musculoskeletal injuries, i.e. early activity at an appropriate point in the healing process aimed at restoration of function, has not been embraced in the treatment of low back pain (Mayer and Gatchel 1988).

The treatment by physiotherapists has been mainly passive, pain relieving treatment such as electrotherapy, massage and manual therapy. These passive treatments are still widely used throughout the western world although there is no scientific evidence that they are of any lasting benefit (Evans and Richards 1996, Koes *et al* 1991a, Spitzer *et al* 1987). There is some evidence that manipulation can speed up the recovery in the acute stage within two to four weeks of onset (Koes *et al* 1991a). Although there is no evidence that these treatments do any direct harm there is a danger that inappropriate or prolonged treatment could increase disability (Nachemson 1983).

More recently patients with low back pain have been encouraged to take a more active part in the management of their back pain by using a 'self help' treatment first

advocated by a New Zealand physiotherapist (McKenzie 1981). This approach only considers passive treatment when 'self help' measures have failed to make any improvement. To date there is little research to support this regime for chronic low back pain although there is some evidence for its usefulness in acute pain (Stankovic and Johnell 1990). However in a recent survey of physical therapists attitudes and treatment preferences 85% of therapists perceived the McKenzie method as moderately to very effective and 48% rated it as the most useful approach (Battie *et al* 1994).

Back schools also embrace the 'self help' philosophy but research does not support their use for patients with chronic low back pain (Keijsers *et al* 1991, Koes *et al* 1994). Back schools are basically an educational programme delivered to the patient as weekly lessons. If back schools have any benefit it is at the acute stage of low back pain (Linton and Kamwendo 1987).

However, there is a growing body of research which supports an active exercise approach to the rehabilitation of chronic low back pain (Nachemson 1983, Waddell 1987a). Current knowledge suggests that exercise has the potential to benefit all the structures in the spine (Twomey & Taylor 1994). North America and Scandinavia are tackling the problem of rehabilitation and producing most of the published research. Very few centres in Great Britain appear to be using an active exercise approach to the rehabilitation of chronic low back pain with only one published study (Frost *et al* 1995). (For complete review of the literature see Chapter 6.)

In order to plan treatment, monitor progress and determine outcomes in rehabilitation programmes reliable methods of objective measurement must be available. The



research from North America suggests that isokinetic equipment allows a reliable method of measuring trunk muscle strength (Mayer *et al* 1985a). However, this equipment has not been tested in a British setting. In addition there is no literature to support the use of isokinetic exercise as a method of rehabilitation for patients with chronic low back pain.

## **1.9 Thesis aims**

The aims of the thesis were:

1. To develop an objective clinical evaluation of physical impairment in chronic low back pain.
2. To standardise isokinetic assessment of trunk muscle strength in normal subjects and patients with chronic low back pain.
3. To develop and provide preliminary evaluation of an isokinetic exercise programme in the treatment of patients with chronic low back pain.

The thesis is presented in three parts:

Part 1 - Describes reliability studies of clinical methods for measuring patients with low back pain

Part 2 - Reports the standardisation and reliability studies of the isokinetic back testing system

Part 3 - Describes studies to develop a rehabilitation programme for patients with chronic low back pain using the isokinetic machines as a method of exercise and as a means of monitoring progress

# **PART 1**

## **OBJECTIVE MEASUREMENT OF LOW BACK PAIN**

## **CHAPTER 2**

### **Literature review of objective measurement**

#### **2.1 Introduction**

Patients with low back pain make up about 60% of the referrals to a physiotherapy department. In a recent report by the Clinical Standards Advisory Group (1994), physiotherapy was identified as playing a key role in the management of simple back pain and in order to assess the severity of the condition, plan treatment and monitor progress it is necessary to provide objective measurement of spinal function (Rothstein 1985). This also enables effective communication between therapists and between therapists and doctors, provided the measurements are valid and reliable. A review of the literature revealed a confusing variety of methods for measuring function of the lumbar spine.

The main focus of this literature review was concerned with the currently available objective methods for measuring lumbar mobility. These include fingers to floor, skin distraction or modified Schober method, flexirule, kyphometer, and the inclinometer method. The review considered reliability studies and comparison studies of the different methods for measuring lumbar mobility. Although some of the studies include flexion, extension and lateral flexion, the latter two measurements were also reviewed separately. Other aspects of the objective examination of the lumbar spine, including spinal shape, straight leg raising, palpation and trunk muscle strength were briefly reviewed.

## 2.2 Spinal flexion

### 2.2.1 Fingers to the floor

The earliest and still the commonest way of measuring lumbar flexion is fingers to the floor. The subject is asked to bend forward as far as he can go keeping his knees straight and the distance from fingertips to floor is measured using an inch tape. This method is not generally considered valid, depending as it does on a combination of spinal movement, hip movement and hamstring extensibility. It has been described by Moll and Wright (1976) as notoriously misleading. Although some reliability studies have suggested that the method is reliable, Biering-Sorensen (1984), Frost *et al* (1982), Matyas and Bach (1985), others did not find the method reliable Gill *et al* (1988), Merritt *et al* (1986). Matyas and Bach (1985) reviewed unpublished data from studies done by post-graduate physiotherapy students which revealed a high degree of reliability for the method. Although Matyas and Bach agreed that it may not be a good measure of specific spinal mobility they felt that it was a good way of monitoring gross movement and pain progress and should not be overlooked as a simple and reliable clinical method of measuring function.

### 2.2.2 Skin Distraction Method

The skin distraction method was originally developed by Schober in 1937 and adapted by Macrae and Wright in 1969 in an attempt to improve its accuracy. In Schober's original method the subject stood erect, the skin was marked at the lumbosacral junction and another mark was made 10 centimetres higher. The subject then bent forward as far as possible and the increased distance between the marks was used as a measure of lumbar flexion. As the accurate identification of the lumbosacral

junction is difficult the skin marks could be placed incorrectly. Macrae and Wright modified the method by using the dimples of Venus as a surface marker approximating to the lumbosacral junction and introducing a third mark 5 centimetres below the lumbosacral mark. Their radiological validation of the two methods showed a considerable improvement in the accuracy ( $r=0.97$ ) compared with the original method ( $r=0.90$ ). Normal values for spinal mobility were determined and can be used to assess the significance of measurements in patients with back problems. The authors claimed advantages of this method are that it is simple, does not harm the patient, and has low intra-observer and inter-observer error.

Biering-Sorensen (1984) and Million *et al* (1981) found the method to be reliable on studies of patients with low back pain. Waddell *et al.* (1982) demonstrated a 91% agreement on the measurement of limited flexion i.e. if  $>$  or  $<$  5 centimetres, using the skin distraction method of measuring, but this is a very crude judgement of reliability. Gill *et al* (1988) and Merritt *et al.* (1986) looked at normal subjects and again demonstrated good reliability. The value of the method is however disputed in two studies (Reynolds 1975 and Portek *et al.* 1983) who found poor reliability during studies of healthy subjects and patients with back pain. In the Reynolds study neither of the examiners had previous experience of the method which could explain the poor results, as inadequate training of observers has been suggested as a source of poor reliability (Nelson *et al* 1979). Portek *et al* (1983) reported difficulty in establishing a neutral upright position which could explain their poor results. The method is still widely used as a simple convenient method of measuring specific lumbar flexion in routine clinical examinations.

### 2.2.3 Flexirule

The flexirule is essentially a draughtsman's flexible curve which can be moulded to the shape of the lumbar spine. The contour is then drawn on a sheet of paper, tangents drawn at fixed points, and the resulting angle is measured and recorded. The reliability of this method of measuring lumbar mobility in normal subjects has been studied by Burton (1986) who reported an intra-observer variation of 9% and an inter-observer variation of 15%. The validity of the method was checked by comparing a radiographic measurement with a flexicurve measurement of the same subject which showed a difference of only one degree between the two measurements. However measurements on one subject are not considered sufficient for a validation procedure. Hart and Rose (1986) also reported good reliability results from normal subjects, the correlation coefficient for intra tester being 0.97. A good intra-tester reliability result was also found by Lovell *et al* (1989) when they compared twenty normal subjects and twenty subjects with back pain. However the inter-tester results were poor, with correlation coefficients of 0.41 for subjects without back pain and 0.50 for subjects with back pain. Although the flexicurve appears to be reliable for the same tester it does not seem to be reliable for different testers and it is only useful in the hands of an experienced examiner. Indeed Burton (1986) himself states that the 9% reliability result must be considered the limit of accuracy as the observer was well practised in the method. This does not appear to be a method which will be widely applicable in a clinical setting.

### 2.2.4 Kyphometer

As the name suggests the kyphometer was originally used to measure kyphosis. It is basically a protractor with two double parallel arms. It was introduced by Debrunner

in 1972 and has been used by Ohlen (1989) in a study of spinal sagittal configuration and mobility. The first part of the study looked at the reliability of the kyphometer as a measurement tool for 21 healthy volunteers. Each subject was examined four times by the examiners who were blind to each others results. A random sample of ten of these subjects were also examined by the same examiner ten times within the space to three weeks. Instructions to the subjects and starting positions were carefully standardised and the measurements were taken from S1/2 to T11/12. The results indicated high reliability for lumbar flexion  $r=0.93$ . However there are few studies using the method of measurement and as the kyphometer is reported as rather cumbersome to use (Salisbury and Porter 1987) it is doubtful if it will become the method of choice for clinicians.

#### 2.2.5 Inclinometer

Recent studies show the possibility of using an inclinometer as a method for measuring lumbar mobility. The inclinometer can be a simple builder's tool or a commercial model manufactured for clinical use. This method was first used by Loebl (1967) and offers the opportunity to separate the components of the compound motion of hip and spine. The method has been described as reliable by various authors: Reynolds (1975), Mayer *et al* (1984) and Mellin (1986a). However, Portek *et al* (1983), did not find the method convincingly reliably, but had a problem with defining the starting position (see skin distraction).

The study done by Mayer *et al* (1984) was divided into two parts. One part used 12 normal adults and compared two different inclinometer methods to measure lumbar flexion and extension. The results were reported as "no difference" between the



methods. The other part of the study used 12 patients with back problems to compare the same two inclinometer methods with a radiological method to confirm their validity. The results were reported as showing no statistically significant difference between the methods.

A further reliability study using the inclinometer method of measurement (Keeley *et al* 1986) looked at patients with chronic low back pain who were enrolled in a functional restoration programme using normal adults as a control group. The subjects were divided into two groups. Group 1 (11 normal subjects and 9 patients) were measured for flexion, extension, and straight leg raising by one examiner after another and the results were compared, allowing a learning curve to occur. This was described as non-blind. Group 2 (20 normal subjects and 23 patients) were measured one after the other but the results were not compared and described as blind. Ink marks were made on the sacrum and at T12/L1 as reference points for the measurements, thus eliminating a source of error from the study. The results for group 1 showed that inter-tester reliability was good ( $r=0.90$ ) for all movements, whereas group 2 showed a definite decrease of reliability for pelvic measurement. The results for intra-tester reliability for both groups were good for all movements ( $r=0.90$ ). However all subjects (1 normal subject and 7 patients) classified as showing sub-optimal effort, i.e. more than 15% discrepancy between straight leg raising and hip flexion plus extension, were excluded from the study and the correlations given were based solely on the remaining 19 normal subjects and 16 patients. This completely invalidates the study as a test of reproducibility. The subjects were also instructed to "warm up" by flexing and extending 5 times. This has not previously been described in the literature, but as a warm up appears to improve performance (Roberts *et al*

1988) it could reduce measurement error and should be included in future studies. This study also suggested that allowing a learning curve to occur could improve inter-tester reliability, a finding was also reported by Nelson *et al* (1979) and Waddell *et al* (1982).

Mellin (1986a) evaluated the Myrin inclinometer by measuring 25 healthy adults. Flexion was measured with the subject in the sitting position, lateral flexion in standing and extension in the crawling position. Intra-tester reproducibility was tested by measuring ten subjects on ten consecutive days and one subject ten times. Intertester reproducibility was evaluated from the results of two testers measuring 15 subjects on consecutive days. The results showed good reliability for flexion and extension ( $r=0.97$ ,  $r=0.89$ ) but poor reliability for lateral flexion. The results for flexion and extension agree with the studies by Mayer *et al* (1984) and Keeley *et al* (1986).

#### 2.2.6 Radiological Measurement

Macrae and Wright (1969) in their study of the skin distraction method x-rayed 12 subjects in order to check the validity of the method. They placed lead markers on the skin marks at the lumbosacral junction, 10 centimetres above and 5 centimetres below. Lateral x-rays were then taken in standing and in full flexion. They found that clinical identification of lumbosacral junction was subject to a 2 centimetre error which seriously affected the Schober method of up to 15 centimetres but only 5 with the modified method. They confirmed that there was a linear relationship between lumbar flexion and skin distraction of 0.90 for the Schober method and 0.97 for the modified method.

Mayer *et al* (1984) also found the inclinometer method of measuring lumbar flexion to be valid. As part of a study to compare two methods of measuring lumbar mobility 12 subjects were x-rayed standing and in full flexion and extension. The x-rays were measured by a radiologist who drew lines parallel to the superior surface of SI and the inferior surface of T12, dropped perpendicular lines from these and measured the angle of inclination at the intersection. Results are only given for total lumbar movement and showed no significant difference between the inclinometer and x-ray measurements. However Portek *et al* (1983) found little correlation between the radiographic technique and the clinical techniques of skin distraction and inclinometer. They maintained that external measurement techniques only gave indices of lumbar movement. However the measurements were taken at different times in different positions and the radiological measurements were taken with the hips fixed to prevent hip flexion.

Burton (1986) compared x-ray measurement with the flexicurve method for measuring lumbar movement on one subject. The flexicurve was taped to the skin and lead markers were put in position while the subject was in a flexed position. This eliminated skin distraction occurring as the subject moved into flexion. The results showed only one degree difference between the two measurements. However Stokes *et al* (1987) found a poor correlation between flexirule measurements and radiographic measurements.

## 2.3 Extension

Measurement of extension has recently become more important with the incorporation of an extension regime into treatment and prevention routines used by physiotherapists for patients with back pain (MacKenzie 1981).

### 2.3.1 Plumb line

One method of measuring lumbar extension was the plumb line method used by Moll *et al* (1972a). Skin marks were made on the lateral aspect of the trunk as a horizontal line drawn through xiphisternum and the highest point of the iliac crest. A plumb line was constructed and suspended over the lower mark. The subject was instructed to bend backwards without support, with hands on head and without taking a deep breath (apparently a deep breath caused an appreciable elevation of the upper skin mark). The distance the plumb line marker moved was marked on the flank and measured in centimetres. Although a reliability study and a radiographic study revealed the method to be reasonably accurate and valid, the instability of the method plus the limitations mentioned by the authors i.e. problems with obese patients, difficulty assuming the starting position and lack of confidence about bending back, make this method unsuitable for clinical use. Merritt *et al* (1986) found good inter and intra reliability whereas Reynolds (1975) found the method to be inaccurate and complicated.

### 2.3.2 Skin attraction

Moll and Wright (1976) suggested a modified Schober method as a way of measuring lumbar extension. The skin was marked as for their flexion method and the subject was asked to bend backwards as far as possible. The new distance between the skin

marks was measured and subtracted from the starting distance of 15 centimetres. Beattie *et al* (1987) tested the reliability of this method by examining 100 subjects with low back pain and 100 without low back pain. and found intra-tester and inter-tester reliability was high. The authors suggested further studies using several examiners and larger samples were needed.

Another method of measuring lumbar extension using a tape measure was described by Maihafer and Echternach (1987) where the subject was asked to stand facing a wall with their toes and pelvis touching it's surface. The examiner measured the distance from the wall to the subjects supra sternal notch. The subject was then asked to bend backwards and the distance was remeasured. Again the position seems unsteady and awkward and although the reliability was high the sample population was small and homogeneous.

Frost *et al* (1982) found poor inter and intra rater reliability using a tape measure to measure lumbar extension and suggested that there was such a limited amount of excursion in extension that any minor error strongly affected the accuracy of the measurement.

### 2.3.3 Inclinometer

Measuring lumbar extension using an inclinometer has been found to be reliable by Keeley *et al* (1986) and Mellin (1986a). Unfortunately Keeley's study had major flaws as discussed in the flexion section and Mellin only looked at normal subjects and measured these in the crawling position which is unlikely to be used in a clinical setting. Poor reliability was found by Merrit *et al.* (1986) whereas Gill *et al.* (1988)

found good reliability using the inclinometer in normal subjects.

The problem with the studies on measuring lumbar extension is the variety of positions in which it is measured; free standing, standing facing a wall, cobra position and lying using arms to push into extension. Currently it does not seem to have been measured in a clinical setting probably due to the difficulties already mentioned.

## **2.4 Lateral Flexion**

Moll *et al* (1972b) described a skin attraction method using the same skin marks the as for extension but marked in the lateral aspect of the trunk (see 2.3.2). The problems with this method are similar to the problems with measurement of extension (see 2.3.2). Merrit *et al.* (1986) found the method reliable whereas Reynolds (1975) found it inaccurate and complicated. However the latter author found using an inclinometer resulted in reasonable reliability. This result was confirmed by Mellin (1986a) using the same technique. Mellin (1986b) also found good reliability using an inch tape to measure the distance the finger tip moved down the leg. When Lankhorst (1982), tried to compare three methods of measuring lateral flexion in an attempt to determine the best method, he found no one method better than another. Reynolds (1975) suggested that the difficulty with the measurement of lateral flexion could be due to poor technique, subject variability or poor examiner technique.

## **2.5 Comparison Studies**

Reynolds (1975) studied three methods for measuring lumbar mobility. The methods were kyphometer, skin distraction method and inclinometer. The measurements were taken with subjects, who were a mixture of healthy adults and patients with

ankylosing spondylitis, in a standing position.. Intra-observer error was calculated from the results of one observer on a single subject on ten occasions. The author suggested that the skin distraction method was the least reliable and the most difficult to use and the inclinometer was the most versatile.

Portek *et al* (1983) also did a comparison study of skin distraction and the inclinometer for measuring lumbar flexion and extension in twenty healthy adult males. The results showed a statistically significant difference between the two observers' measurements for the skin distraction method similar to that reported by Reynolds. The method was said to be difficult to reproduce because of the mobility of the skin over the bony landmarks, resulting in the marks moving relative to one another during attempts to measure distraction. The results of the inclinometer measurements indicated that the method was reproducible by different observers but it should be carefully monitored as the statistical analysis gives an indication of the average difference between observers, but masks individual differences in the measured value of up to 40%.

In a later comparison study Merritt *et al* (1986) looked at three methods of measuring lumbar movement in 50 healthy adults; fingertips to floor, skin distraction and inclinometer. Flexion, extension and lateral flexion were measured in the standing position for fingertips to floor and skin distraction methods. Flexion was measured in sitting and extension in lying for the inclinometer method. Skin marks were left on to aid reproducibility thus contaminating the results. The results showed poor reliability for fingertips to floor method (76% variation) but good reliability for all the other measurements except extension measured by the inclinometer. The authors found

skin distraction to be the preferred method for measuring lumbar mobility.

Gill *et al* (1988). compared the same three methods of measuring lumbar flexion and extension with an added photometric measure. Ten healthy adults were examined by one examiner for intra-examiner reliability. Ink marks were again made on the skin to ensure accurate placement when repeating the measurements. The results demonstrated good reliability for all measures except fingertip to floor and flexion measured by the inclinometer method but recommended the skin distraction method as the most repeatable method.

Salisbury and Porter (1987) compared five different methods of measuring lumbar sagittal mobility, kyphometer, inclinometer, flexicurve, skin distraction and ultrasound. Seventeen young asymptomatic subjects were measured for flexion in sitting and extension in lying for the four external methods and nine volunteers from this number had ultrasound measurements taken. The vertebral levels were compared by ultrasound and direct palpation on 34 occasions and was unsuccessful only once. The results showed skin distraction to be the least reliable method and to have the poorest correlation with the other methods. The inclinometer, kyphometer and flexicurve all correlated well with each other and had similar levels of reliability. As the flexicurve had the poorest level of reliability and the kyphometer was felt to be heavy to use, the authors judged the inclinometer to be the best instrument to measure sagittal mobility of the lumbar spine.

## **2.6 Straight Leg Raising**

This is a widely used test for both diagnosis and evaluation of treatment progress. The test is performed with the patient in the supine position with both legs straight.



One leg is passively raised by the examiner keeping the knee straight and controlling for hip rotation as suggested by Brieg and Troup (1979). The end point of the movement is reproduction of pain felt in the back or leg. Some studies suggested the end point should be the limit of tolerance of pain and others used the end point when the contra lateral leg begins to lift off the bed (Mayer *et al* 1984). Most of the studies used an inclinometer to measure the angle the leg is raised from the bed (Million 1981, Matyas and Bach 1985, Keeley *et al* 1986, McCombe *et al* 1989) and found the method to be reliable. Million (1982) found a within session test retest reliability of 0.97 using 19 patients with low back pain as subjects. Matyas and Bach (1985) recorded a similar result using 20 patients as subjects and McCombe *et al* (1989) found inter-tester reliability to be 0.68 again using patients as subjects. Nelson *et al* (1979) found poor reliability using a goniometer for measurement whereas Waddell *et al* (1982) found a 77% agreement between examiners.

In a study done by Kostaljanetz *et al.* (1988) in which 55 patients with unilateral sciatica were measured with a goniometer the results showed a high degree of variation. The patients were examined by three different examiners during the course of a day with a period of a few hours between each examination thus allowing diurnal variation to contaminate the trial. The author suggested that the poor reliability results could be due to the fluctuating symptoms, analgesic levels, or changing activity levels as none of these variables were controlled.

Porter and Trailescu (1990) found good reliability during a study to measure diurnal changes using an oil-filled precision goniometer. The intra-observer repeatability for 60 paired measurements from six patients with nerve root signs was 1.2 degrees.

Eight of the 30 patients who were examined for diurnal changes showed less than 10 degrees change while the remaining 20 had 10 degrees or more improvement. Five of the patients who showed the least diurnal change went on to have discectomy and four had complete annular tears, leading the authors to suggest that a recumbancy test, comparing straight leg raising after a period in contrasting postures, might be a useful supplement to the usual single test.

The literature suggested the test for straight leg raising was reliable providing it is carefully performed and the end point is clearly defined. From the evidence reviewed it would appear that an inclinometer was the most reliable method for this measurement.

## **2.7 Palpation**

Despite the emphasis placed on the findings from palpation in a clinical examination of the lumbar spine by manual therapists (Maitland 1986, Grieve 1983), they appear to have been accepted without testing (Matyas and Bach 1985). In medical studies soft tissue palpation has been found to be one of the most unreliable parts of the examination (Nelson *et al* 1979 Waddell *et al* 1982, McCombe *et al* 1989). McCombe *et al.* (1989) also found bony palpation to be only potentially reliable confirming a previous study by Gonnella *et al.* (1982) when the inter-observer results of vertebral palpation by physiotherapists were reported as disappointing and thought provoking. A review of the literature covering methods of osteopathic palpation (Alley 1983) found these to be unreliable. Similarly a study of clinical tests of the sacroiliac joint (Potter and Rothstein 1983) revealed none of these tests to be reliable, as confirmed in later studies by Carmicheal (1987) and Hertzog *et al* (1989). In a

further study, Boline *et al.* (1988) examined the lumbar spines of 23 symptomatic and 27 asymptomatic subjects for intra-rater reliability of intervertebral motion and paraspinal pain and found that statistical data revealed weak to no reliability.

The main problem is that palpation of movement is a highly subjective method of analysis depending on examiner skill, experience and interpretation. Indeed McKenzie (1981) thinks palpatory findings should be rejected on two counts:

1. Inability to demonstrate inter-tester reliability
2. Widespread incidence of tropism causes palpatory findings to be unreliable, constantly suspect and open to misinterpretation

Further research remains to be done before palpatory findings can be used in a clinical examination with confidence that they are reliable.

## **2.8 Spinal Shape**

The clinical significance of spinal shape or postural malalignment is unclear (Bullock-Saxton 1988) and there are no normal standards to help determine abnormality. Spinal list, pelvic tilt, lumbar lordosis and thoracic kyphosis can all be measured in a clinical setting.

### **2.8.1 TrunkList**

There is very little literature in measuring spinal list clinically. One radiographic study looked at the significance of lumbosacral list and low back pain (Porter and Miller 1986) and found trunk list to be associated with disc protrusion and poor

prognosis for conservative management.

### 2.8.2 Pelvic tilt

Simultaneous palpation of both iliac crests of a standing subject has been used to determine pelvic tilt. Although this method is easy to perform, intra-tester and inter-tester reliability has been shown to be lacking (Clarke 1972, Mann *et al* 1984). In a study to test the reliability of three leg length checks used by chiropractors Venn *et al* (1983) found poor agreement between operators and low correlation between their findings and x-ray measurements. However the leg length checks were done in lying and the x-rays in standing which could have contributed to the poor correlation between the two measurements.

A study of pelvic tilt was found to be reliable using a crest tester (Niosh 1988). Previously Biering-Sorensen (1984) used a similar device to measure leg length discrepancy in standing and found a 44% coefficient of variation on repeated measurements

### 2.8.3 Kyphosis and lordosis

Measurement of lumbar lordosis and thoracic kyphosis was found to be reliable using a kyphometer (Ohlen 1989) but few studies were done using other methods of measuring. Ohlen found increased lordosis was significantly related to incidence of back pain in young female gymnasts. On the other hand Hansson *et al* (1985) compared the amount of lumbar lordosis, measured by x-ray, in normal subjects and patients and found that the shape of lumbar lordosis was unimportant for the occurrence of either acute or chronic low back pain.

## 2.9 Trunk Muscle Strength

The earliest method of measuring trunk muscle strength was manual muscle testing. The force with which the patient resisted the tester was recorded as normal, fair or poor. As perception of force by the tester was a mental integration of force and time, inaccuracies resulted e.g. a weak contraction held for a long period could be perceived as stronger than a strong contraction held for a short period. This was therefore a largely subjective test of questionable reliability when performed by different individuals (Nicholas et al 1978).

Methods of measuring trunk muscle strength in the clinical environment usually involved variations of a sit-up and prone extension.

The test for extension strength was measured with the patient in prone lying with their hands clasped behind their back. The patient was asked to lift their head and shoulders off the bed and hold for a count of five. Endurance was measured by asking the patient to hold an unsupported extended position for as long as possible (up to a maximum of 240 seconds).

To measure flexion the patient lay supine with the knees bent and the feet held by the examiner. The patient then lifted his head and shoulders off the bed and touched his knees with his fingers and holds for a count of five. The other test for flexion strength was again with the patient supine and lifting both straight legs off the bed, holding for a count of five.

Biering-Sorensen (1984) found a modified version of these tests to be reliable with a 7% variation between repeated tests while Nordin *et al* (1987) found a 10% variation

over 10 tests. Smidt *et al.* (1987) examined the validity of the two clinical tests for flexion and one test for extension by comparing them with the more objective tests of trunk strength using an instrument method, Kin Com Trunk Testing Unit. The subjects were normal men and women and patients with low back pain. Most subjects, including patients, were able to perform the sit-up and prone extension, which indicated that these tests were poor discriminators as tests of strength capability among subjects.

The value of trunk muscle strength testing in the management of low back pain is questionable as is the use of clinical strength tests (Nachemson and Lindh 1969). Berkson *et al* (1977) found in a study of normal subjects and subjects with back pain that for some activity related strength tests, patients were as good as normal subjects. Biering-Sorensen (1984) reported the tests to be of marginal significance in predicting either occurrence or recurrence of back pain over one year.

## **2.10 Conclusion to review of the literature**

From the results of the literature review it would appear that the most reliable method of measuring lumbar mobility is the inclinometer method. The advantage of the inclinometer is that it can measure flexion, extension, lateral flexion and straight leg raising. However fingers to floor and skin distraction should not be overlooked as quick easy ways of measuring movement, provided their disadvantages are allowed for.

On the whole reliability studies were flawed. The following are some general criticisms.

1. Use of normal subjects which means that the results cannot be applied to patient groups. Normal subjects are relatively easy to measure and are readily available for research projects. However they are less likely to have limited movement or to vary as much as patient groups. Reliability must be measured for the particular group of patients.
2. Lack of explanation and standardisation of starting positions which makes repetition of the study difficult.
3. Use of skin marking which allows the following examiner to overcome the problem of identifying landmarks (i.e. contamination).
4. Omission of an inter-observer reliability study which is more important than intra-observer reliability.
5. Use of examiners who are involved in the development of a particular instrument or who are not typical users (i.e. researchers rather than routine clinicians).
6. Use of differing methods of statistical analysis which makes direct comparison of results difficult.

Future studies of clinical methods for measuring spinal mobility should carefully standardise starting and finishing positions and instructions to patients. They should use the relevant patient group and examiners who will possibly be using the measurements in the future.

## **CHAPTER 3**

### **Reliability studies of objective measurement**

#### **3.1 Introduction**

To date few studies have included a broad based clinical assessment of objective signs in chronic low back pain using the relevant patient group, in a clinical setting. The current study was an inter-tester reliability study of a broad spectrum of currently used methods for the clinical examination of patients with low back pain. The examiners were an Orthopaedic Consultant and a Research Physiotherapist who had no previous knowledge of the techniques to be used except fingers to the floor.

#### **3.2 Aims of the study**

This study formed part of a larger study to develop an objective clinical assessment of patients with chronic low back pain. The aims of the study were:

- 1 To determine the reliability of the various components of an objective physical examination of the lumbar spine: lumbar mobility, straight leg raising, spinal shape, palpation for tenderness, trunk muscle strength and pelvic tilt
- 2 To determine the optimal level of the skin markings used to measure lumbar mobility
- 3 To determine the accuracy of the skin markings and the validity of the method for measuring lumbar flexion
- 4 To select the best method for measuring lumbar mobility. The main emphasis was on the reliability and validity of the inclinometer method as this appeared from the



literature review to have the most theoretical advantages and to be the most suitable for routine clinical use. Reliability of the fingers to floor method was also assessed as it is still the method in widest use by physiotherapists. The kyphometer was evaluated to compare it to the inclinometer.

### **3.3 Materials and methods**

#### **3.3.1 Subjects**

A total of 70 patients with low back pain and 10 normal subjects were studied. The subjects were aged between 20 and 55 years which is the common age range for patients with low back pain. The patients had all been referred with low back pain to an orthopaedic out-patient department.

#### **3.3.2. Instruments**

The inclinometer used was a hand held computerised inclinometer (EDI-320) manufactured by Cybex Inc., Ronkonkoma, NY. The kyphometer used was a Debrunner's kyphometer manufactured by Portek AG, Postfach 2016, Bern, Switzerland.

#### **3.3.3 Measurements**

The measurements taken were flexion, extension, lateral flexion, kyphosis, lordosis and straight leg raising for the inclinometer, flexion, kyphosis and lordosis for the kyphometer and flexion for fingers to floor. Other measurements considered were loss of lordosis, lumbar list, sacral angle, and pelvic tilt. Palpation for tenderness, trunk muscle strength, passive hip flexion, passive knee flexion, hip abduction and

flexion strength were also examined.

### 3.3.4 Design

Four sequential studies were carried out to allow refinement of the examination technique. The results of each study were analysed before moving on to the next study. This allowed modifications to be made, if necessary. Reliability statistics were calculated separately for continuous and categorical variables. Intraclass correlation coefficients for continuous variables were based one-way analysis of variance (Baumgartner 1989). Categorical data were assessed by percentage agreement and kappa statistics for the concordance of nominal data (Fleiss *et al* 1969).

## **3.4 Study 1**

The purpose of this study was to determine the inter-observer reliability of objective physical examination of the lumbar spine and to assess the validity of the method of measuring lumbar flexion. This study was conducted by the Orthopaedic Surgeon and the Research Physiotherapist. Twenty subjects were measured by the Orthopaedic Consultant followed by the Research Physiotherapist who was blind to the first examiners findings. The skin markings were carefully removed to ensure the study was not contaminated. The methods of measuring lumbar mobility were the inclinometer method and fingers to floor.

### 3.4.1 Procedure

The patient was asked to stand straight with hands at their sides and looking straight ahead. Skin marks were made on the sacrum at the level of the dimples of Venus and the lumbar spine palpated up to the level of T12 and L1.

Loss of lordosis was measured by stringing the tape measure from the apex of the thoracic convexity to the apex of the sacral convexity in the mid line. The distance from the tape to the apex of the lumbar concavity was estimated.

List was measured by dropping the tape measure as a plumb line from the apex of the thoracic convexity and the distance from the tape to the natal cleft was estimated.

The sacral angle was measured by setting the inclinometer on reference mode, obtaining zero for the inclinometer on the wall and placing the inclinometer head centred on the sacral mark (Fig 1).

Lordosis was measured by placing the inclinometer on the sacrum and (Fig 1) then on T12/L1 (Fig 2).

Flexion was measured using the inclinometer on the compound mode. The first recording was made at the sacrum (Fig 1) and the second at T12/L1 (Fig 2). The patient was then asked to bend forward with both hands reaching as far as possible to the floor. In this position a reading was made at T12/L1 (Fig 3) and the sacrum (Fig 4). Patient then returned to the upright position.

While the patient was fully flexed the distance from the finger tips to the floor was measured in centimetres and recorded.

Extension was measured with the inclinometer in the compound mode. The first recording was made at the sacrum and the second at T12/L1. The patient was asked to bend back as far as he could go (the operator supported his shoulder with one hand) and the third and fourth recordings were made at T12/L1 and the sacrum.

Lateral flexion required the inclinometer to be set to the reference mode and

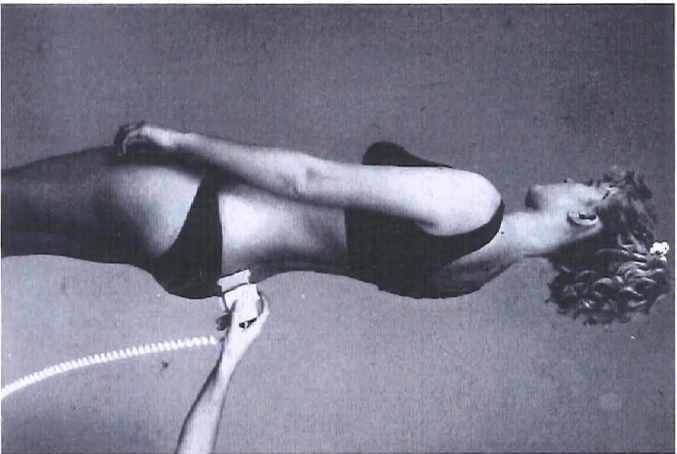


Figure 1

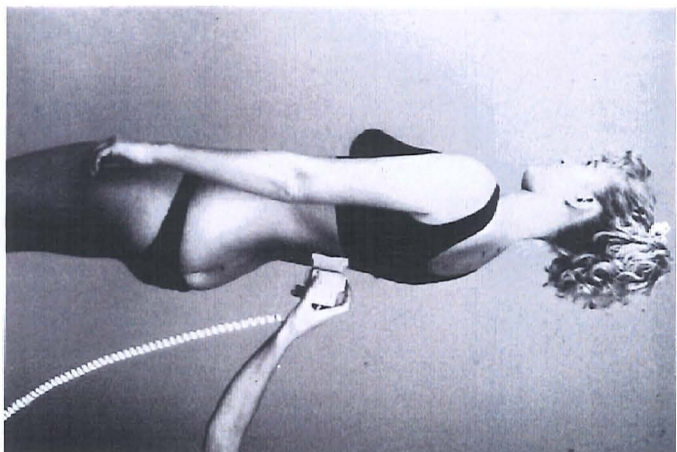


Figure 2

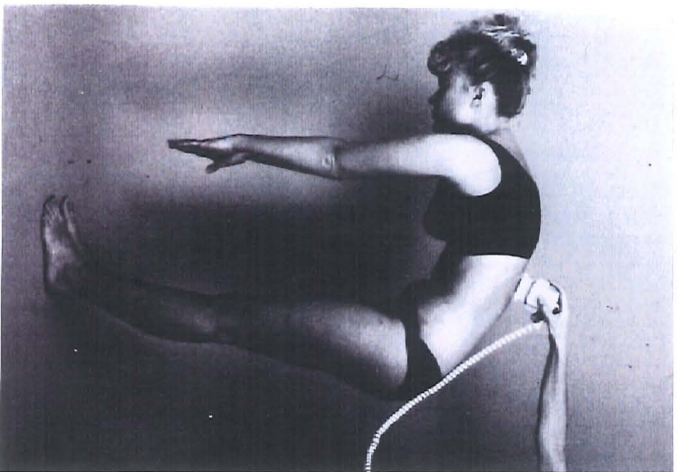


Figure 3



Figure 4

positioned on the upper thoracic spine between the shoulder blades. The patients were asked to lean over as far as possible to the left keeping their feet flat on the ground (the operator again supported his shoulder). The reading on the inclinometer was noted and the patient then bent over in the opposite direction and the reading recorded.

Tenderness was palpated with the patient lying in a relaxed prone position on the couch. The operator palpated for

1. spine tenderness over the spinous process (or interspinous ligament within one centimetre of the mid-line)
2. paraspinal tenderness over the lumbar paraspinal muscles (more than one centimetre from the mid-line)
3. muscle tenderness over the gluteal muscles and their attachments beneath the iliac crest

Trunk muscle strength was measured using one test for extension and two tests for flexion .

For extension the patients lay prone and clasped their hands behind their backs. They were then asked to lift their head and shoulders off the couch and hold the position for five seconds.

The first flexion test was a bilateral active straight leg raise and the patients were asked to move to the supine position and lift both legs off the bed and hold for five seconds.

The second flexion test was a sit-up for which the patients remained supine and bent both knees to 45° keeping feet flat on the couch. The patients were asked to lift their head and shoulders, touch their knees with their fingertips and hold for five seconds.

Straight leg raising was measured with the inclinometer on reference mode and positioned on the tibial crest just below the tibial tubercle. The leg was raised to the limit of tolerance and the angle noted. The measurement was repeated on the other leg.

The patients finally went to the radiography department where lateral and flexion x-rays were taken.

#### 3.4.2 Results

The reliability was good for some of the measures but poor for others especially sacral angle and loss of lordosis (Table 3.1). Reliability of lateral flexion was poor. Only total extension could be measured reliably as separate pelvic and lumbar extension were not reliable. There was poor correlation between the clinical measurements and the x-ray measurements lumbar flexion 0.47, pelvic flexion 0.54, and total flexion 0.67.

#### 3.4.3 Discussion

There were several problems which contributed to the poor reliability results. The main problem was lack of a standardised starting position. Observation during measuring revealed that the patient did not always return to the same starting position. It is important to standardise the starting position (Youdas *et al* 1991) as reliable measurement of movement depends on achieving a consistent erect position (Ohlen

1989).

Another problem was a possible warm up effect. It has been suggested in the literature that it improves performance (Roberts *et al* 1988) and has been included in other studies (Keeley *et al* 1986).

Two specific movements showed poor reliability, extension and lateral flexion. The results of the extension studies examined in the literature were equivocal as some reported poor results (Reynolds 1975, Merrit *et al* 1986) but others reported good results (Keeley *et al* 1986, Mellin 1986, Gill *et al* 1988). Although all these studies used the inclinometer method of measuring extension, different positions e.g. standing, lying and cobra position were used. There appears to be no standardised way of measuring extension.

The poor results for lateral flexion confirmed the results from the literature which suggested that lateral flexion was difficult to measure reliably (Reynolds 1975). It was also possible that the technique used to measure lateral flexion was faulty.

The poor results for the validity of the lumbar measurements could have been due to the clinical measurements being taken at a different time from the x-ray measurements although Portek *et al* (1983) has reported that clinical measurements, which are affected by factors such as thoracic movement, hip flexibility and skin extensibility, only gave indices of back movement which did not reflect the true intervertebral movements. However Mayer *et al* (1984) found the inclinometer method of measuring lumbar mobility to be valid.

Loss of lordosis and sacral angle were considered too unreliable to merit further

development.

The conclusions from Study 1 were that subsequent studies should attempt to improve the reliability for all movements by including a warm up before the examination and using a standardised erect starting position. The technique for measuring lateral flexion should use different landmarks and a longer bar on the inclinometer. The validity should be reassessed by taking the clinical measurements at the same time as the x-rays.

The measurements for the subsequent studies were taken in the following standardised way.

Anatomical landmarks were identified with the patient in prone lying. S2 was found by palpating the inferior border of the posterior superior iliac spines. Then, by counting up the spinous processes and checking that the iliac crests approximated to L4/5, the junction of T12/L1 and T9 were identified. T2 was identified by counting down from the prominent C7. Midline skin marks were made at S2 and T12/L1, T9 and T2 with a ball-point pen.

The patient then performed a warm-up of flexion/extension twice, rotation twice, lateral flexion twice and one more flexion/extension.

The starting position was with the patient in bare feet with heels together and knees straight, looking straight ahead at a point on the wall at eye height, hands hanging loosely at sides.



### **3.5 Study 2.**

The purpose of this study was to compare the inclinometer with the kyphometer method of measuring lordosis, kyphosis and lumbar flexion and to compare the use of different landmarks for measuring. This study was done by the Research Physiotherapist. The subjects were 10 healthy volunteers with no back pain. The age range was 21 to 52 years.

#### **3.5.1 Procedure**

Skin marks were made and the subject was asked to take up the standardised starting position. Lordosis and kyphosis were measured first by the inclinometer followed by the kyphometer. The inclinometer was set on the reference mode and a zero reading set on T12/L1. The inclinometer was then moved to S2 where the reading was noted and then T2 where the reading was again noted. The process was repeated for the measurements at T11/12.

The kyphometer measurements were taken by placing the inferior foot of the kyphometer on S2 and the superior foot on T12/L1 for lordosis and on T12/L1 and T2 for kyphosis. The readings were recorded and the measurements repeated using T11/12 in place of T12/L1. The subject was then asked to bend forward as far as he could go and flexion was measured at T12/L1 followed by T12/L1.

#### **3.5.2 Results**

The results of this study showed a high correlation between measurements using the two different instruments. There was a mean difference of only 3 degrees between the two different landmarks used for measuring lumbar lordosis and kyphosis.

### 3.5.3 Discussion

These results confirmed those of Salisbury and Porter (1987) showing a high correlation between measurements taken by an inclinometer and a kyphometer. The kyphometer was found to be cumbersome to use but, as it was new to the operator, the following study retained it. As the difference between the two different landmarks was not significant it was decided to use the more common T12/L1 level in subsequent studies.

## **3.6 Study 3**

The purpose of this study was to determine the accuracy of the skin markings used to identify the lumbar vertebrae and to reassess the validity of the methods for measuring lumbar lordosis and flexion. This study was conducted by the Research Physiotherapist using 10 patients.

### 3.6.1 Procedure

The clinical measurements were taken by the Research Physiotherapist in the radiography department at the same time as the x-ray. The spine was marked as before and metal markers were taped to the spine. The patient then had an antero/posterior x-ray taken to determine if the metal markers correctly identified the landmarks after which the metal markers were removed. The patient was then positioned ready for a lateral x-ray. Lumbar lordosis was measured in this position by the inclinometer and kyphometer followed by a lateral x-ray. The patient was then asked to bend forward as far as possible and the angle of flexion was measured by both instruments followed by a repeat lateral x-ray in the flexed position.

The angle of inclination was measured on the x-rays by drawing lines parallel to the upper vertebral end plate of S1 and the lower vertebral end plate of T12. A vertical plumb line was drawn and the angle of inclination at the intersection of the lines was measured.

### 3.6.2 Results

The results showed a reasonable correlation between the clinical measurements and the x-ray measurements and between the two different methods of measurement. Correlation between the inclinometer and x-ray was lumbar flexion 0.76, pelvic flexion 0.90 and total flexion 0.91. The corresponding correlation for kyphometer and x-ray was lumbar flexion 0.68. The correlation between the inclinometer and the kyphometer was 0.92. The skin markings were subject to an error of four centimetres.

### 3.6.3 Discussion

The results indicated that the skin markings were accurate enough to be used in further studies confirming the results of previous authors (Salisbury and Porter 1987, Mayer *et al* 1984, Macrae and Wright 1969). The kyphometer was still found to be cumbersome to use confirming the findings of Salisbury and Porter (1987), who reported it as heavy to use and difficult to place. No further evaluation of the kyphometer will be made.

## **3.7 Study 4**

The purpose of this study was to determine the inter-observer reliability of the inclinometer method of measuring lumbar mobility, to determine the inter-observer reliability of objective physical examination of the lumbar spine, to determine the

inter-observer reliability of three methods of measuring pelvic tilt.

### 3.7.1 Procedure

Forty subjects were measured during a routine clinical examination by the Orthopaedic Consultant and then independently by the Research Physiotherapist as in Study 1. The measurements taken were pelvic tilt, list, lordosis, kyphosis, lumbar flexion, extension, lateral flexion, straight leg raising. Passive knee flexion, passive hip flexion, trunk muscle strength, hip flexion and abduction strength and palpation for tenderness were also examined.

**Pelvic tilt (Method 1)** The examiner palpated both iliac crests simultaneously by placing the straight index finger of each hand on the two crests and estimated by eye if they were level. If one side was down by more than one centimetre it was recorded as left or right.

**Pelvic tilt (Method 2)** The examiner sat or knelt in front of the patient. The anterior superior iliac spines were palpated by placing the thumbs beneath the spines and sliding them up until they came into contact with the inferior slopes of the spines. The thumbs remained below the spines and it was estimated by eye if one was higher than the other. The lower level was recorded if it was estimated as more than one centimetre different.

**Pelvic tilt (Method 3)** The examiner sat or knelt behind the patient. The bars of a crest tester were spread an equal distance from the middle and placed on either side of the patient's trunk. The examiner then palpated for the patients iliac crests and slid the bars over the crests making sure that they were below any rolls of tissue. The bars

were then pressed down firmly on the crests and the bubble was observed. If none of the bubble remained visible between the marks the lower level was recorded.

Measurement of lumbar lordosis, kyphosis flexion, extension and straight leg raising have previously been described.

Lateral flexion was measured using a longer bar on the inclinometer. The first reading was obtained with the bar lined up between the spinous processes at T9 and T12 and the measurement was taken as before.

Passive knee flexion was examined with the patient lying prone. The knee was passively flexed to 90 degrees or whatever lesser amount the patient could tolerate. The thigh was not lifted off the couch and the hip was not extended. The examiner recorded if this was less than 90 degrees (-) or full (+).

Passive hip flexion was examined while the patient lay supine and the examiner passively flexed the hip to 90 degrees allowing the knee to flex at the same time to avoid a straight leg raise effect. The result was recorded as for passive knee flexion.

Hip flexion strength was measured while the patient was supine and the examiner passively flexed the hip to 90 degrees. The patient was asked to hold the position while the examiner attempted to extend the hip. The result was recorded as either normal (+) or reduced (-).

Hip abduction strength was measured with the patient lying in the lateral position with the hip and knee of the upper leg extended. The examiner checked that the pelvis was lying vertically and steadied the patient with a hand on their pelvis. The patient was asked to lift the upper leg up straight about six inches and hold that position. The

examiner pressed down on the lower thigh and estimated the strength. The result was recorded as normal (+), weak (-) or absent (0).

### 3.7.2 Results

All tests reached satisfactory reliability except pelvic tilt which was unreliable for all three methods (Table 3.2).

### 3.7.3 Discussion

No method of measuring pelvic tilt was found to be reliable in this study. A previous study also reported poor reliability for method 1 (Mann *et al* 1984). Although the crest tester method was found to be reliable by one group of researchers (NIOSH 1988) and by Bieren-Sorensen (1984) this study did not confirm these findings. Other methods of measuring leg length were reported as unreliable. There is also an unresolved issue of what constitutes a clinically significant leg length difference (Beattie *et al* 1990).

The good reliability for the other measurements confirms previous studies. Fingers to floor was a reliable method of measuring lumbar function but it has to be acknowledged it is not a valid method of measuring specific lumbar flexion. However good reliability has been reported by several authors and as Matyas and Bach (1985) have pointed out it should not be overlooked as a method of measuring mobility.

The kyphometer was a valid and reliable method of measuring lumbar flexion which confirms the findings of Ohlen (1989) and Salisbury and Porter (1987) but it was awkward to use therefore is unlikely to become the method of choice in a busy

clinical setting.

The inclinometer was a valid and reliable method of measuring lumbar flexion which confirms the results of Reynolds (1975) Keeley *et al* (1986), and Mellin (1986a) although Merrit *et al* (1986) and Gill *et al* (1988) did not find the method convincingly reliable for all measures. As it was easy to use and versatile it could be recommended for use in a clinical setting.

Although total extension was reliable it was not possible to separate pelvic and lumbar extension. Extension is a movement which is less frequently performed than flexion and has a comparatively small excursion which could account for the difficulty in measuring the movement reliably.

This study highlighted the necessity of using a carefully standardised technique of measurement to obtain reliable measurements. It has been argued that a carefully standardised technique is not routinely used in a busy clinical setting and therefore the results cannot be generalised into clinical practise (Rothstein 1985). However as no single protocol has been recommended for measurement of lumbar range of movement it was necessary to suggest a standardised method of measurement. These measurements allow physiotherapists to evaluate each programme of intervention with a patient and should be distinguished from clinical impressions or opinions which physiotherapists hold about their patients(Rothstein 1985).

### **3.8 Conclusions from the four studies**

These studies have shown the inclinometer to be a reliable and valid method of measuring lumbar mobility and it will be the method of measuring lumbar mobility in

subsequent studies. The studies have highlighted the necessity of using a carefully standardised technique of measurement which will also be used in subsequent studies.

This was one of a few inter-observer reliability studies incorporating the complete examination of the patient with low back pain conducted in a clinical setting by clinical personnel who were not involved in the development of any of the instruments. The studies took place in a normal busy out-patient department and the examination could be done as a routine examination for patients with low back pain.

### **3.9 Limitations of the studies**

The reliability was only measured between two examiners who were not blind to the measurements. The measurements were taken by one examiner immediately followed by the other which would increase the reliability. In reality measurements could be taken days or weeks apart and probably at a different time of day. Further studies using several examiners with a greater time scale between measurements should be done.



Table 3 1: Inter-observer reproducibility of clinical examination of objective assessment

		Correlation Coefficient	p<
Sacral angle		0.56	0.01
Lumbar lordosis in cms		0.54	0.01
Lumbar lordosis		0.91	0.001
Lumbar list in cms		0.80	0.001
Thoracic kyphosis		0.84	0.001
Lumbar list		0.95	0.001
Flexion	lumbar	0.91	0.001
	pelvic	0.93	0.001
	total	0.97	0.001
Fingers to ground		0.97	0.001
Extension	lumbar	0.66	0.001
	pelvic	0.41	ns
	total	0.60	0.01
Lateral flexion		0.73	0.001
Straight leg raising	left	0.89	0.001
	right	0.76	0.001

		% agreement	kappa	p<
Tenderness	lumbar	85	0.66	0.010
	paravertebral	89	0.78	0.001
	buttock	80	0.23	ns
Prone extension		84	0.58	0.001
Bilateral active SLR		92	0.75	0.001
Sit-up		88	0.70	0.001

Table 3.2: Inter-observer reproducibility of clinical examination of objective assessment

		Correlation Coefficient	p<
Lumbar lordosis		0.95	0.001
Thoracic kyphosis		0.84	0.001
Lumbar list		0.95	0.001
Flexion	lumbar	0.91	0.001
	pelvic	0.93	0.001
	total	0.97	0.001
Extension		0.77	0.001
Lateral flexion		0.88	0.001
Straight leg raising	left	0.93	0.001
	right	0.9	0.001

		% agreement	kappa	p<
Tenderness	lumbar	80	0.60	0.010
	paravertebral	90	0.80	0.001
	buttock	80	0.51	0.010
Passive knee flexion		95	0.64	0.001
reproduction of pain		91	0.57	0.001
Passive hip flexion		100	1.00	0.001
reproduction of pain		93	0.71	0.001
Hip flexion strength		93	0.63	0.001
reproduction of pain		93	0.72	0.001
Hip abduction strength		90	0.61	0.001
reproduction of pain		92	0.56	0.001
Prone extension		95	0.77	0.001
Bilateral active SLR		95	0.77	0.001
Sit-up		85	0.48	0.050

## **PART 2**

### **EVALUATION OF ISOKINETIC SYSTEM**

## **CHAPTER 4**

### **Literature review of trunk muscle strength testing**

#### **4.1 Introduction**

Quantitative trunk muscle testing was rare 10 years ago. There has been a surge of interest due in part to the need to objectively assess function but also because of the availability of new technology. The danger is that technology has moved ahead of science and need (Andersson 1992).

The use of sophisticated computerised machines for measuring trunk muscle strength has become very popular in the USA with various claims being made by the manufacturers as to the validity, reliability and clinical application of these machines. However there are many sources of potential error and variability which may affect their clinical application (Rothstein 1987). Before using these devices as testing instruments in clinical research or as rehabilitation instruments it was necessary to establish their reliability, validity and clinical utility. This review covered ways of measuring trunk muscle strength using instruments.

Trunk muscle strength testing can be divided into static which is isometric testing and dynamic which can be isokinetic or isoinertial. Isokinetic machines measure force or torque throughout a range of movement at various constant pre-set velocities. Isoinertial measures torque at pre-set loads with a varying velocity. The main focus of the review was the isokinetic method, but isometric and isoinertial methods were reviewed to complete the picture of trunk muscle strength testing. Lifting was reviewed separately as it involves the whole body and not just the trunk muscles. The

limiting muscle group in a lifting test may not be the trunk muscles but the leg muscles or even the arm muscles.

Lift testing was originally isometric the disadvantage being that lifting is a dynamic activity. Isokinetic and isoinertial systems are now available. An alternative to these is a psychophysical approach which is a submaximal strength test. The idea behind it is that there is a relationship between the perceived strength and the actual strength based on the subjects perception of what they are capable of lifting.

## **4.2 Isometric**

The studies of isometric strength testing used cable tensiometers (Alston *et al* 1966), and strain gauge dynamometers for testing (Troup and Chapman 1969, Nachemson and Lindh 1969). Caldwell *et al* recognised in 1974 that there was disparity and confusion in strength testing. This led to the standardisation of one procedure, static isometric muscle testing, when guidelines for testing were suggested. Three studies by a group of researchers in Chicago used strain gauge dynamometers for isometric strength testing to compare normal subjects with patients suffering from low back pain. In the first, Berkson *et al* (1977) compared the subjects ability to exert forces in different directions when different body postures were prescribed and found that as a rule patients were either unable to take up a given position, or their performance was close to normal. The positions which a significant number of patients could not assume were those involving substantial trunk twisting or a combination of bending and twisting. McNeill *et al* (1980) compared the trunk strength of normal subjects with that of patients with chronic low back pain. Addison and Schultz (1980) compared the trunk strength of normal subjects with that of patients with chronic low

back pain seeking hospital admission and compared them with the previous two groups. The conclusions drawn were that patients with low back pain were weaker than normal subjects, but patients seeking admission to hospital, compared with those attending an out-patient clinic, showed no statistical difference in mean strength.

In a recent isometric study Graves *et al* (1990) measured lumbar extension strength through a full range of motion using a commercially manufactured device, MedX (Ocala, FL) which tests this movement in a sitting position. The results demonstrated good reliability ( $r=0.90$ ), but the most interesting result was that one pre-trial test was required to obtain the most accurate and reliable results. Unfortunately the authors did not report what the percentage change was from test 1 to test 2. A percentage change has been reported in a study of the strength of wrist flexors (Kroll 1963) when an 8 to 15% increase was recorded from test 1 to test 2. The author suggested the increase was due to a motor learning effect, a physiological response to the initial test, or a combination of both of these. This learning effect is important and suggests a second test should be used as a baseline for testing.

#### **4.3 Isokinetic**

Isokinetic testing is rapidly expanding in North America as commercially manufactured machines are readily available and aggressively promoted. There are various types of equipment marketed for measuring isokinetic performance. The main focus of this review was the Cybex 11 Back Testing System, but reference will be made to other machines where necessary.

Some of the studies were descriptive using normal subjects, but most of the studies compared normal subjects with low back pain patients in an attempt to use trunk

muscle strength to discriminate between these two groups. Four reliability studies of isokinetic devices were identified in the literature (Mayer *et al* 1985a, Smidt *et al* 1989, Delitto *et al* 1989, and Grabiner *et al* 1990) but only one was a reliability study on the Cybex 11 system (Mayer *et al* 1985a)

The early studies used a Cybex dynamometer with attachments to enable it to be used as a back testing machine for isokinetic torque measurements in flexion and extension. The subjects were tested in lying or sitting positions. As the manufacturers developed commercially available devices descriptive studies were reported using the prototype of these back testing devices.

Hasue *et al* (1980) examined 100 normal subjects and 26 patients with low back pain. Patients who could not perform the required movements were excluded from the study. Hasue reported lower levels of strength for abdominal muscles compared to extensor muscles and decreasing strength with age. Results for patients were said to be lower than normal subjects, but inconclusive, because of the small numbers and wide individual differences. Another study performed in the lying position was reported by Suzuki and Endo (1983) who tested 90 male patients with low back pain and 50 healthy male subjects. Patients were divided into two groups; those with acute and those with chronic pain. The results suggested that patients with low back pain had weaker trunk muscles than the normal controls, but there was no statistical difference between the two types of patients. The authors suggested that this could indicate that subjects with weak muscles are prone to back pain. In 1984 Langrana *et al* reported a study of testing in a sitting position using 50 normal males, 26 normal females and 10 patients (7 males and 3 females) with low back pain.. An attempt at reproducibility was described as "four subjects performed strength tests on different

days". No details were given or results reported it was simply stated that "the isokinetic extension characteristic is closely reproduced". The results suggested that isokinetic torque production was lower in patients than it was in normal subjects but only 8 patients were tested (2 were unable to perform the isokinetic test) making the results inconclusive. Thorstensson reported two studies in 1982; the first (Thorstensson and Nilsson, 1982) examined the effect of body position on trunk muscle strength, while the second (Thorstensson and Arvidson, 1982) investigated the potential deficits in trunk muscle strength in 15 young male subjects (military recruits), 7 with low back pain and 8 in the control group. The tests were performed in lying with 2 different pivot positions used. Only small differences were found between the groups and as the numbers were small and the patient group were very young (age 19-20) and demonstrated no loss of lumbar mobility on examination, these results must also be regarded as inconclusive.

Descriptive studies of the prototype Cybex 11 were reported by Davies and Gould (1982) and Thomson *et al* (1984). However the former used college athletes as their subjects (average age 20) making the results only applicable to that particular group. Thomson *et al* (1984) tested 44 healthy adults aged 19 to 72. The movements tested were flexion/extension at isokinetic speeds of 30, 60, 90, and 120 degrees/second, Although the subjects were reported to have repeated the test over 3 days no reliability figure was stated.

#### 4.3.1 Reliability Studies

The first reliability study identified in the literature was by Smidt *et al* (1983) using an Iowa Trunk Dynamometer. The purpose of the study was to describe the method of



testing, to determine the reliability of the method and to compare trunk muscle strength and endurance between normal subjects and patients with chronic low back pain. Twenty four normal subjects and patients with chronic low back pain were tested in sitting. Only four normal subjects were tested and retested one week later for reliability with an average change reported as 13% for flexion and 21% for extension. However the small numbers mean the results were inconclusive and led the authors to suggest that longitudinal studies involving treatment effects should be done with the understanding that the interday reliability is "less than desirable". The study also found that women were on average 50% weaker than men and patients were 47% to 80% weaker than normal subjects. Women demonstrated more endurance than normal subjects however only those patients able to perform the test (10 out of 14) were included in the results which must be considered inconclusive. The author suggested that the women demonstrated more endurance as their initial effort was less than that of the men. This is supported by lower recorded heart rates for the women during initial stages of testing.

The only reliability studies of the Cybex 11 back testing system, as currently manufactured, which could be identified were those reported by Smith *et al* (1985), followed and Mayer *et al* (1985a). These two studies form the major justification for the Cybex back testing system, together with the study of the Liftask (Kishino *et al* 1985) which will be reviewed later. Smith and co-workers tested both extension-flexion and rotation to determine the reliability of the method for measuring trunk strength, to describe preliminary relationships between trunk muscle groups, and to determine the efficacy of adjusting torque values to body weight as compared to lean body weight. One hundred twenty-five normal subjects were tested for extension-

flexion and 67 normal subjects were tested for rotation. The subjects answered an advertisement for research participants but it was not stated whether they were remunerated or not. For the reliability study subjects were tested and retested within 7-14 days, 15 for the extension-flexion and 10 for the rotation. The subjects were tested at speeds of 30, 60, 120 degrees/second for extension-flexion and rotation with the addition of 150 degrees/ second for rotation. The reliability study was poorly reported as it was not clear whether the test was repeated by the same tester or a different tester. The assumption was that the tester was the same, making it an intra-tester reliability study. The results were calculated using a Pearson product-moment correlation coefficient and were stated to range from 0.74 to 0.96 for trunk extension, 0.76 to 0.77 for trunk flexion, 0.77 to 0.90 for right rotation, and 0.83 to 0.93 for left rotation. Although it was stated that test-retest differences may be attributable to 'learning', no scores were given, it was simply reported that "torques produced during the second tests were slightly greater than those produced during the first test".

The authors also reported that the reproducibility of the first three repetitions for each speed was high for both devices. They suggested that this data would be helpful for evaluation of patient effort as considerable variation (greater than 10-20%) between repetitions suggest a less than maximal effort by the patient.

This suggestion has since been disputed by Hazard *et al* (1988) who concluded that clinical observation of subjects using the extension-flexion and lifting devices was more accurate than analysing curve variability. They also reported that it was possible for highly motivated subjects to produce variable curves and inexperienced subjects to inadvertently produce consistent curves while exerting submaximal effort. It has also been disputed by Mandell *et al* (1993) who found normal subjects and back injured

subjects both had mean values of 8-18%. Back injured subjects had lower mean values for extension than the normal subjects and almost the same for flexion. Reid *et al* (1991) showed that variable curves in low back pain patients were associated with lower isokinetic performance.

The data reported by Smith *et al* (1985) for trunk extension-flexion and rotation indicated that males were stronger than females. Torque output decreased as speed increased especially in extension and rotation. The ratios of trunk extension to flexion ranged from 1:1 to 2.7:1 for males and females regardless of age or test speed. Left to right rotation ratios were 1:1 for both sexes at all speeds.

The second study by the same group of researchers (Mayer *et al* 1985a) tested 286 patients with low back pain and compared them with the previously described normal subjects with the intention of showing the degree of alteration in trunk strength patterns produced by lumbar dysfunction. The study only tested extension-flexion and not rotation. Unfortunately the test protocol did not appear to be standardised, indeed there is some confusion as to what the protocol was. In the first study range of movement stops were set at 0-80 degrees of trunk flexion. In the second study extension-flexion stops were set at 0-45 degrees for the controls and patients who could manage this range, and 0-30 degrees for patients with less range. The authors went on to state "in order to make testing comfortable for chronic low back pain patients some compromises had to be made in the testing protocols for both patients and normal subjects". If testing is standardised the same protocol must be used for both patients and controls. To confound the issue patients who could not achieve the limited range were not tested, but no numbers were reported for this group. Results for male patients were compared to normal male subjects from the previous study said

to be "tested under the same protocol". Unless the normal subjects were retested for the second study this was not the case and the results were not comparable. Testing speeds were reported as 30, 60, 120 degrees/second on "most" subjects. The results in general showed patient values for both flexors and extensors were markedly decreased compared with normal subjects and there was greater variability in the range. These decreases were greater in female patients. Extensor strength appeared to be affected more than flexor strength.

The substantial flaws identified in this study weaken the reported results and the lack of standardisation of the test protocol made it difficult to repeat.

Smidt *et al* (1989) studied seven normal subjects using a Kin Kom (Chattecx Corp., Chattanooga, TN) with a back attachment. The authors found none of the measured variables demonstrated a significant variation on retesting 3 days later. They also found flexion/extension ratios to be good ( $r=0.70-0.90$ ).

A later reliability study was reported by Delitto *et al* (1989) using a Lido (Loredan Biomedical Inc., Davis, CA) isokinetic device which works on the same principle as the Cybex 11. The main purpose of their study was to document the relationship between isokinetic extension-flexion, peak torque and body weight. The subjects were 61 healthy volunteers who were remunerated 25 dollars at the completion of testing. The test speeds used in this study were 60, 120, 180 degrees/second through a range of 100 degrees (10 degrees extension to 90 degrees flexion). All subjects were tested 3 times at one and two week intervals after the initial test. Intra-tester reliability was determined using intraclass correlation coefficients (ICC). Acceptable ICC scores ( $>0.70$ ) were reported ranging from 0.74 to 0.87 for all speeds except the

highest (180 degrees/second). The authors report that this speed was dropped because of the unacceptable reliability coefficient of  $<0.70$  and because they had doubts concerning the functional utility of a test performed at this speed. There was a relationship between peak torque for flexion and body weight of 0.66-0.70, but only 0.27-0.39 for extension.

Although this study appears to support the use of body weight ratios Delitto (1990) subsequently concluded that there was no rational basis for forming peak torque to body weight ratios in females. In males body weight only accounted for a small proportion of the variance in peak torque (0.20-0.25) and the peak torque/body weight ratio range was so large that it was clinically insensitive for detecting trunk extensor weakness. The demographic description of the subjects, procedure and analysis of results were all clearly reported. However body weight was reported as being obtained verbally from the subject which is an inaccurate way of determining body weight (personal experience revealed up to a 14lb difference between reported body weight and measured body weight). There was no percentage change reported from test 1 to test 2 and no raw data reported making it impossible to determine if a learning effect occurred.

Delitto *et al* (1991) published further results from this same group of subjects. In this later report they gave results for three speeds of 60, 120, and 180 degrees/second. Peak torque was reported as percentage body weight and further measures of work and peak torque extension-flexion ratios were reported. The ratios were found to be unreliable in both males and females at all speeds. Average work was reported as the most reliable measure with no significant upward trend on the test-retest scores. There was a significant upward trend in mean test-retest peak torque scores in males at

60 and 120 degrees/second and females at all speeds. The authors rejected the term "learning effect" and chose instead to call this upward trend an "artifactual effect". It was stated that the percentage increase was not clinically significant in high scores but would be significant in low scores. As patients with low back pain tend to have lower scores the results of this reliability study cannot be applied to a patient population.

The most recent reliability study (Grabiner *et al* 1990) tested eight healthy men and 10 men with low back pain using a newly marketed machine, the Biodex dynamometer (Biodex Corp., Shirley, NY 11967). The testing protocol consisted of two sets of five reciprocal trunk extension-flexion cycles at speeds of 60, 120, and 180 degrees/second with a five minute rest between each set. The range of motion was reported as 100 degrees. The results from both groups demonstrated correlation coefficients ranging from 0.72 to 0.99 which reflects a moderate to strong relationship between the two tests. As a group the low back pain patients demonstrated a universal performance improvement at the retest (>20%). Therefore the authors suggested that test-retest protocol be considered as a minimum requirement in clinical and industrial testing environments. The observed changes were interpreted as indicating that motor learning may occur above and beyond that which is associated with a series of practise trials. Unfortunately it is reported that only patients capable of achieving the described protocol were included in the statistical analysis, with no numbers given, weakening the stated result.

#### **4.4 Isoinertial**

Isoinertial testing represents the latest technology in trunk strength testing. A computerised isoinertial testing device (B-200, Isotechnologies, Hillsborough, NC)

has recently appeared on the market and was briefly reviewed. This machine is fundamentally different both in theory and practice (Deutch 1989). It uses computer controlled hydraulic pumps which provide resistance in each axis. Measurements of position, torque and velocity in sagittal, coronal and transverse planes are stored in computers to be analysed in a variety of modes. The subject stands on a platform with the pelvis stabilised and a shoulder harness arrangement holding the upper trunk. The resistance has to be set low enough for the weakest muscle group to overcome it.

Seeds *et al* (1987) reported torque and range of motion data for 160 asymptomatic subjects. They noted that graphs presenting secondary axes torque and range of motion data coincided with the patterns for the extension-flexion axis and were reproducible. They called this effect "cross talk" and suggested that it might be an indication of patient effort as the effect became less consistent with controlled or guarded effort. In a follow-on study, Seeds *et al* (1988) presented torque and range of motion data for patients with low back pain. Comparison of results between the two studies revealed significant differences in all parameters of normal and low back pain subjects. They reported reduced "crosstalk" for patients again suggesting this effect could be an indicator of effort. Levene *et al* (1989) also reported this "crosstalk" effect during a study to gather normative data from 300 normal subjects but the authors did not suggest it could be an indication of effort.

Reliability of the isostation B200 was studied by Parnianpour *et al* (1989) who found good reliability for the torque readings but poor reliability for velocity. Spalski *et al* (1992) found highly consistent readings in 92 patients with low back pain when they were re-tested within the same test session. However when 16 normal subjects were re-tested at weekly intervals on 4 occasions the results were less satisfactory. In a

review of the isoinertial literature Gomez *et al* (1991) concluded that most of the normative data bases previously reported had not adequately accounted for the wide variation that could be expected in any "normal" population and that further research was needed to establish test-retest reliability and to investigate the patient population.

## **4.5 Lifting**

The literature on lifting was reviewed separately as it does not measure trunk strength directly but to a certain extent relies on trunk muscle performance.

### 4.5.1 Isometric lifting

Isometric strength testing in specific lifting positions has been suggested as a screening method for reduction of occupational back injuries in the USA (Chaffin 1975) but this has been disputed by Battie *et al* (1989a) who did not find that testing was effective in identifying individuals at risk for industrial back problems. Marras *et al* (1984) compared isometric and isokinetic testing and considered, on theoretical grounds, that isokinetic testing was a more realistic procedure for the evaluation of tasks related to manual lifting and that ergonomics based entirely on isometric lifting capabilities could be misleading. Kroemer (1985) also demonstrated that isoinertial lifting gave a low coefficient of variation (3.5-6.9%) compared with isometric (13.2-13.7%) suggesting that dynamic lifting is less variable than static lifting.

Another concern with isometric testing is the safety of the procedure. Hansson *et al* (1984) found compressive loads of 5,000 to 11,000 newtons on the L3 vertebral body during squat and torso lifting with isometric testing. Battie *et al* (1989a) reported



three injuries during testing of 495 subjects and subsequently abandoned isometric testing due to safety concerns.

#### 4.5.2 Isokinetic lifting

The Cybex 11 isokinetic lifting device was first reported by Kishino *et al* (1985). The purpose of the study was to collect the first normative data on isokinetic lifting strength and compare normal subjects with low back pain patients. The normal subjects were 23 men and 42 women randomly selected from the local community. The patients were 43 men and 25 women with chronic back pain who were being assessed for admission to a rehabilitation programme. The test protocol was three lifts at each of three speeds; 18, 30, and 36 inches/second. The results indicated that patients could lift considerably less than controls across the speed spectrum.

A further study (Timm 1988) tested 2688 normal subjects aged 10 to 79 years. The purpose of the study was to describe the system and to establish a normative database for future reference. Testing consisted of four lifting repetitions at speeds of 6, 12, 18, 24, and 36 inches/second. The results were reported as means and standard deviations for sex and age in decades and demonstrated a general trend of decreasing magnitude across the test velocity spectrum for the parameters of peak force, average force and total work.

In the only published study of reliability of isokinetic lifting Porterfield *et al* (1987) reported readings within 1% when re-tested on different days but no figures were given.

#### 4.5.3 Isoinertial lifting

Isoinertial or isodynamic testing is a dynamic measure of maximum weight moved through a range. It was first reported by Snook *et al* (1978) using a very simple test of filling boxes with bricks or lead shot. Mayer *et al* (1988) have developed this test into a progressive isoinertial lifting evaluation (PILE). A constant load lift ergometer (Liftest) was described by Kroemer (1985) who reported low coefficient of variation of 3.5-6.9 indicating good reliability with this equipment.

#### **4.6 Summary of review of literature**

There was reasonable evidence that isokinetic and isoinertial measurements of extension-flexion up to 120 degrees/second, and isokinetic lifting provided reliable measures for torque and force respectively. There was limited and conflicting evidence for rotation or lateral flexion at any speed or for the reliability of computed ratios. Smidt *et al* (1989) claimed extension-flexion ratios were reliable but endurance ratios were not whereas Delitto *et al* (1990) found extension-flexion ratios to be unreliable. As can be seen from the reports the studies suffered from small numbers and inadequate reporting of data.

The machines were frequently reset to the same position for retesting hence eliminating a source of variability in patient positioning. Grabiner *et al* (1991) showed that a change in axis alignment could produce a 20% variation in peak torque and Stokes (1987) used a computer simulation to demonstrate that incorrect axis position could result in non-isokinetic measurement. Moreover Stokes (1987) maintained that the theoretically ideal axis position was L3 which differs from that

recommended by the manufacturers (Cybex 1989). Most studies have used L5/S1 alignment.

#### 4.6.1 Validity

Validity is the ability of a test to measure what it claims to measure. There was no direct evidence that isokinetic measures were measuring actual trunk muscle strength. The indirect evidence was considered. The calibration procedure makes use of the principle that a weight on an input arm set at a specific predetermined distance will generate a known amount of torque as it falls about the axis of rotation. The calibration is carried out at a low velocity of 12 °/second. Smidt *et al* (1989) found the calibration method for the Cybex 11 to be highly reliable. Calibration of the other machines is purely isometric and Parnianpour *et al* (1989) found the method to be reliable for the Isostation 200. Bembien *et al* (1988) noted that the velocity settings on the Cybex 11 dynamometer were highly accurate. These studies merely described the mechanical properties of the measuring device and did not directly address the problem of validity of the measurements.

To say a measurement is valid means nothing as a measurement is only valid for some specific purpose (Rothstein 1987). All dynamic measures of trunk strength were reduced in patients with low back pain compared with normal subjects which appears to give validity to the measures, but there was no data on the relationship between the measures and pain, disability or physical impairment.

A fundamental limitation of isokinetic testing is that the machine only records torque if the subject is able to move at the pre-selected speed. Therefore a recording of zero does not mean that the subject has no muscle activity merely that they cannot or will

not move at the selected speed. This unmeasured amount of torque is omitted from all recordings and the recorded isokinetic torque is not proportional to actual muscle force.

#### 4.6.2 Learning

A learning effect has been documented in isometric and isokinetic testing of peripheral joints (Giles *et al* 1990) and isometric testing of trunk extension (Graves *et al* 1990). Smith *et al* (1985) emphasised the need for a general warm up and a trial run of the movements before testing. They also noted that torque produced on the second test were slightly greater and concluded that some of the test-retest differences might be attributed to "learning". There was evidence that a learning effect takes place between test one and test two.

#### 4.6.3 Normalisation for Sex, Body Weight and Age

There was evidence that males demonstrated higher performance in all strength measures than females, both in normal subjects and patients with low back pain. All reports agreed that males and females should be analysed separately.

There was conflicting evidence on the relationship between strength measures and weight and very limited, weak evidence of a relationship with age.

#### 4.6.4 Normal Subjects Versus Patients

All studies reported that patients with low back pain performed less well than normal subjects. However the problem with discriminating between patients and normal subjects was the wide range of recordings in both groups, with these ranges invariable

overlapping resulting in no convincing evidence that isokinetic measures can discriminate among individuals.

#### **4.7 General criticisms**

A number of general criticisms emerged from this review of the literature.

1. Test protocols were not standardised or clearly described and in some cases not adhered to
2. Standardised instructions to subjects were not reported or not given
3. Small number of subjects in studies, especially reliability studies
4. Lack of reliability studies on patients
5. No inter-tester reliability studies
6. Inadequate statistical analysis particularly in the use of mean values, with no information on the range, and simple correlation statistics instead of reliability statistics
7. Number of subjects completing the test were not reported
8. Percentage increase for test-retest not reported making it impossible to determine if a learning effect had taken place
9. Payment of money to subjects which could influence results

#### **4.8 Conclusion**

Isokinetic machines have the potential to contribute to the assessment of patients with low back pain. However, it was obvious from the review of the literature that

additional work was needed to define and improve levels of reliability, to obtain normative data, and to obtain data in relevant patient populations. The general lack of standardisation and incomplete reporting of results hampers comparisons of studies conducted by different researchers and makes interpretation of results unclear. It also makes studies difficult to reproduce in order to confirm or contest results.

## **CHAPTER 5**

### **Isokinetic Standardisation Study**

The purpose of the study was an experimental standardisation and evaluation of the Cybex 11 Back Testing System in normal subjects and patients with chronic low back pain. This study was designed to fill the gaps in the literature by completing a reliability study on patients with low back pain and also examining the relationship between clinical findings and isokinetic results

#### **5.1 Overall strategy and study design**

Overall the study collected isokinetic data from 70 normal subjects and 120 patients. Sub-groups of 21 normal subjects and 20 patients repeated the complete assessment on four occasions to determine intra-tester reliability, inter-tester reliability and learning effect. The equipment, measurements and testing procedure were the same throughout the study and are described first. A pilot study is then described as observations made during this study altered the design of the main study. Thereafter the study is described separately for normal subjects and patients, as the procedure and design are different for the two groups. Finally a follow-up study of the normal subjects is described. The study was conducted by an Orthopaedic Consultant and a Clinical Assistant who identified the patients, and a Research Physiotherapist and a physiotherapy lecturer who conducted the testing.

### **5.1.1 Aims of the study**

The specific aims of the study were

1. To develop a test protocol suitable for all normal subjects and patients
2. To relate the isokinetic scores to sex, body weight and age
3. To assess the learning effect in normal subjects and patients
4. To test the reliability in normal subjects and patients
5. To assess the consistency of effort by repeated isokinetic movements
6. To determine the relationship between different isokinetic measures
7. To determine the relationship between isokinetic measures and clinical measures
8. To assess the ability of isokinetic measures to discriminate between normal subjects and patients
9. To determine if isokinetic measures predicted future back trouble

### **5.2 Materials and method**

All subjects, both normal subjects and patients, were 20-55 years old, with English as their native language. The age range was chosen as the common age range for patients with low back pain. The subjects needed English as their native language in order to complete the questionnaires. All subjects had a resting heart rate of less than 100 beats per minute and resting blood pressure of less than 160/100. No subject was pregnant. Height of the subjects was within 5 ft. and 6ft. 6 ins. These were all limitations of the manufactures for practical or safety reasons. Characteristics of the subjects are shown in Table 5.1.



### 5.2.1 Normal Subjects

Seventy normal subjects (35 males, 35 females) were tested on torso rotation, extension-flexion and lift task. The subjects were volunteers chosen from hospital personnel (excluding physiotherapists), friends, and patients attending the hospital with minor musculoskeletal problems. An attempt was made to obtain a wide variety of active and inactive subjects but no attempt was made to classify the activity levels.

The selection criteria was

1. No back pain at present
2. No clinical history of back pain in past year
3. Never off work with back pain for more than one month
4. No previous back surgery

The subjects were stratified according to sex and age in five year age bands from 20 to 55 years. All subjects were personally asked by the Research Physiotherapist to take part in the study. The purpose of the study and the nature of the testing was explained to them and they were advised to wear comfortable clothing for the test.

### 5.2.2 Patients

The patients were 125 patients attending a routine orthopaedic clinic or a tertiary referral problem back clinic with low back pain. They were identified by the Orthopaedic Consultant or the Clinical Assistant as suitable for inclusion into the study. The selection criteria was patients suffering from low back pain with or without referred leg pain. The patients were excluded if they demonstrated the following:

1. Nerve root pain as current main complaint with active nerve root signs or current motor or sensory loss
2. Spinal pathology such as tumour, infection or inflammatory disease
3. Previous spinal surgery or chemonucleolysis < six months
4. Spinal fracture, fracture dislocation or osteoporotic wedge fracture
5. Structural spinal deformity e.g. kyphosis or structural scoliosis

The general health exclusions were the following

1. History of primary psychiatric illness or alcohol abuse
2. Myocardial infarction
3. Cerebrovascular disease or peripheral vascular disease
4. Current respiratory problems
5. Long term use of systemic steroids
6. Systemic neurological disease or convulsions
7. Trunk or eye surgery in the past six months

### 5.2.3 Equipment

The Cybex 11 Back Testing, Rehabilitation and Screening System (Cybex Division of Lumex, Inc. 2100 Smithtown Ave. Ronkonkoma, NY 11779) was used to measure trunk muscle strength. This system consists of three pieces of apparatus Torso Rotation (Fig 5), Extension-Flexion (Fig 6) and Liftask (Fig 7). The machines were calibrated according to the manufacturers instructions. The Fitron Cycle-Ergometer (Cybex Division of Lumex, Inc. 2100 Smithtown Av. Ronkonkoma, NY 11779-0903) was used to test aerobic fitness and the Sport Tester PE 3000 (Hakamaantie 18, SF-9044 Kempele, Finland) was used to monitor resting heart rate and exercise heart rate. The sports tester had previously been tested for accuracy by the cardiac technicians.

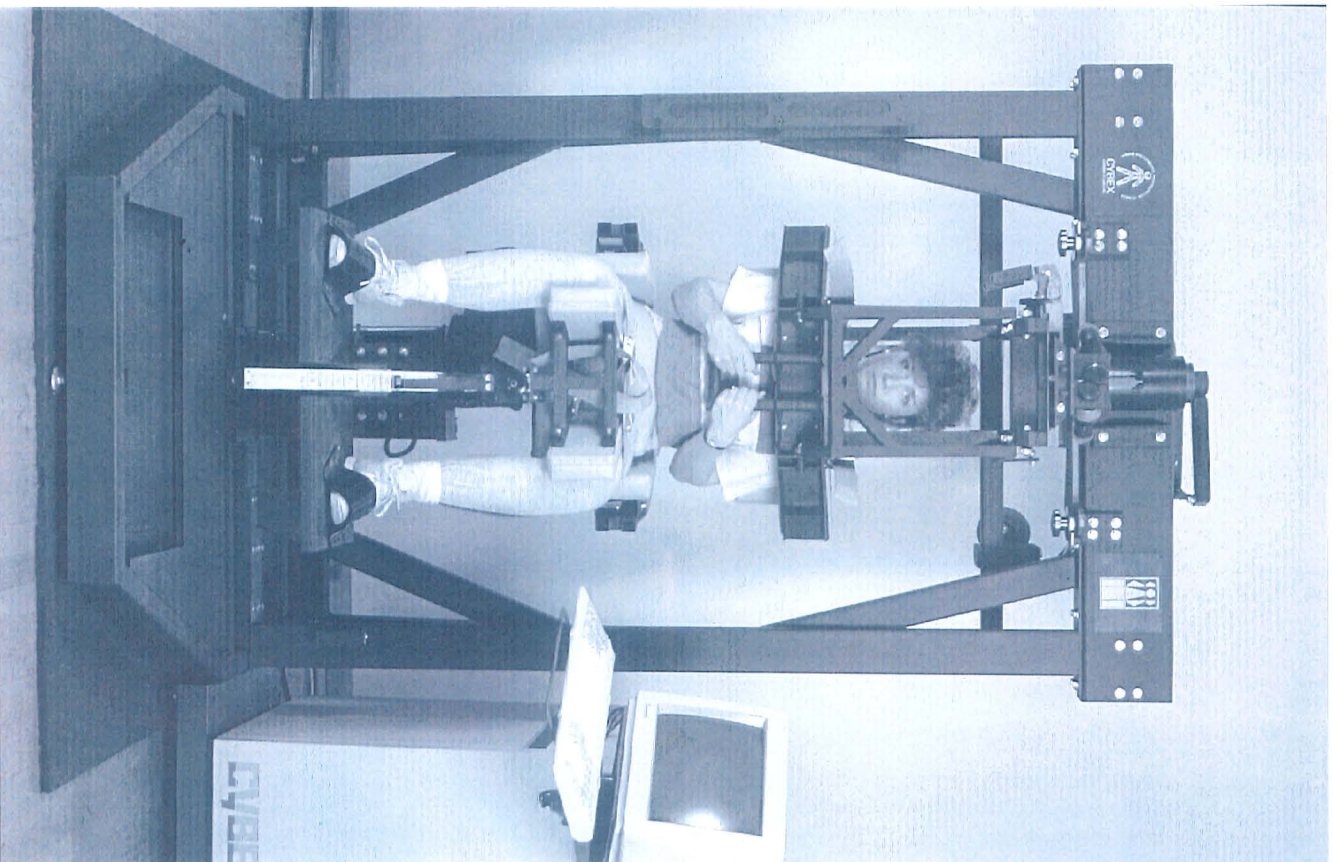
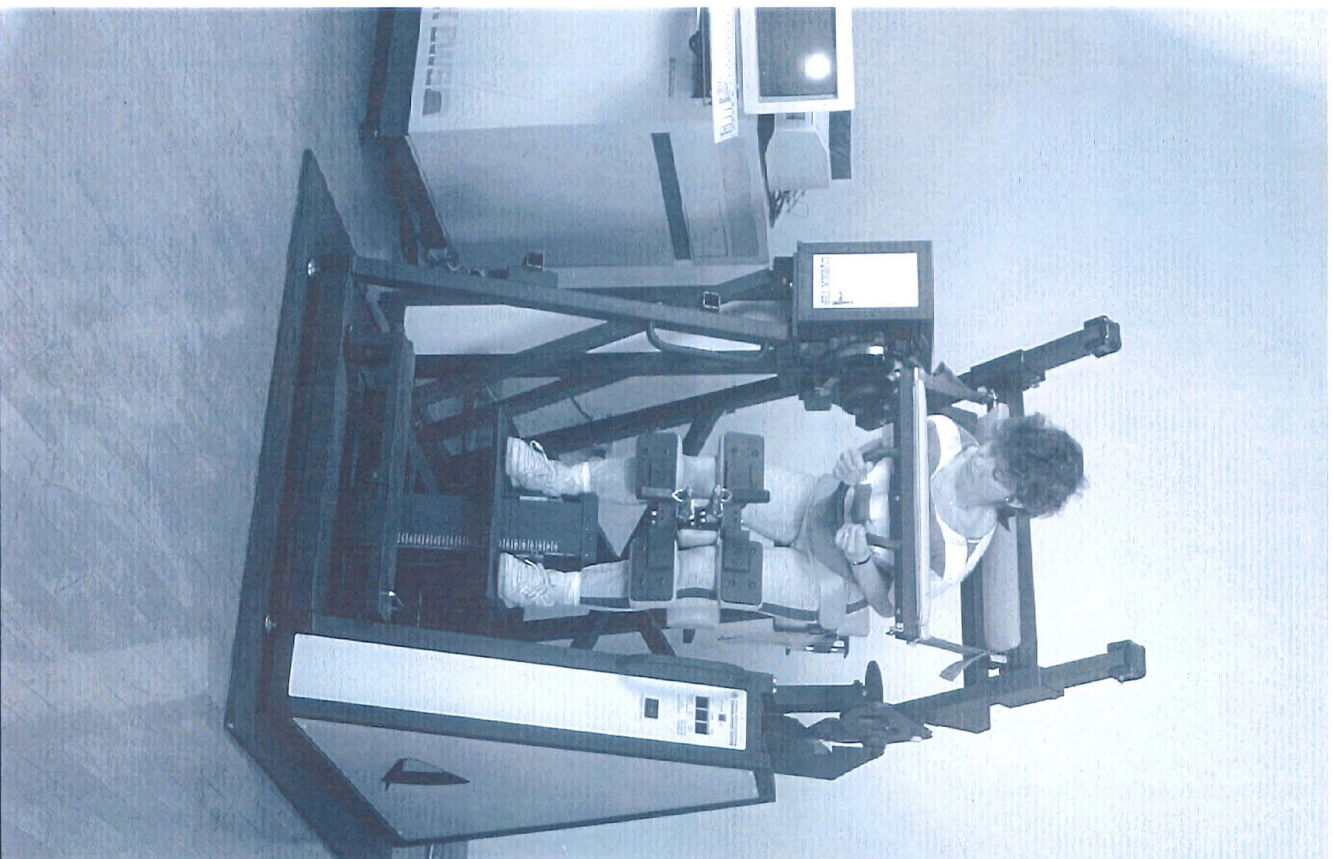


Fig 5



**Fig 6**





Fig 7

#### 5.2.4 Measurements

The measurements taken were height in inches, weight in pounds, resting heart rate in beats per minute, exercise heart rate and estimated Max VO<sub>2</sub>. Isokinetic measurements for extension-flexion and rotation were peak torque in foot-pounds and for lift task peak force in pounds. From the basic isokinetic measures of peak torque or peak force, the Cybex software derived average power from the torque curve in extension-flexion and rotation and average power and total work from the force curve in lift task. A number of ratios were calculated: extension-flexion ratios; left right ratios; fatigue ratios; recovery ratios. The Cybex software also calculated an average points variance as a measure of 'consistency of effort' within each set of test repetitions. This study also calculated a total isokinetic score as the sum of the main isokinetic variables expressed as a ratio of the corresponding normal mean. To give equal weight to each of rotation, extension-flexion and lift task, the lift task variables were each multiplied by three. Males and females were computed separately normal means. Isometric and psychophysical measures of lifting were also taken. Psychophysical lift tests are based on the association between perceived strength and actual strength.

#### 5.2.5 Procedure

On arrival subjects were asked to sign a consent form explaining the purpose of the study and how the machines worked (Normal Subjects Appendix 1, Patients Appendix 2 ). Height, weight and resting heart rate were measured and recorded.

Subjects performed an exercise tolerance test on a Fitron ergonomic bicycle using a standard progressive bicycle ergometer test adapted from Pollock *et al* (1984) This

served as a warm up prior to isokinetic testing as suggested in the manual and provided the physiological measurements of exercise heart rate, and estimated max vo2 which is a score estimated from the heart rate obtained during the exercise tolerance test. Heart rate was monitored with the sports tester.

The standard test protocol was developed during the pilot study as being achievable by most of the patients. The subjects performed the test protocol (detailed in Appendix 3) in the following order:

1. Sub-maximal exercise tolerance test on the Fitron ergometer bicycle
2. Torso rotation
3. Extension-flexion
4. Liftask
5. Isometric lifts
  - a) Psychophysical lift at waist height
  - b) Maximum isometric lift at waist height
  - c) Psychophysical lift at knee height.
  - d) Maximum isometric lift at knee height.

The results of the fitness test and the isometric lifting were recorded on a separate form (Appendix 4).



### Torso rotation (Fig 5)

The subject sat in the unit to stabilise the pelvis. The feet were secured in the foot plates which were adjusted to 90 degrees hip and knee flexion. Seat height was adjusted to rest the shoulders against the posterior shoulder pad. Axis of rotation was aligned with the greater trochanter. A chest pad connected to the overhead assembly was lowered and secured across the chest and shoulders, the subject lightly held a handle to stabilise the position. A belt was secured across the pelvis and a device to hold the hips in abduction was positioned between the knees and secured with thigh straps. Range limiting stops were set at 45 degrees to the left and right. As the concept of isokinetic exercise was new to the subjects they were allowed four trial repetitions at each of the test speeds to get the feeling of isokinetic exercise. The test then proceeded as follows. Each speed allowed four trial repetitions followed by the four test repetitions. The subject was encouraged to proceed with factual instructions as follows: "get the feeling of the speed during the first four repetitions then for the next four go as hard and as fast as you can. I will give the command Go! when I want you to try as hard as you can." The subject was not given further verbal encouragement and could not see the screen to obtain feedback. No emotional appeals were made to encourage the subject to try harder (Caldwell *et al* 1974). If the subject could not achieve the selected speed the test was terminated at that point and the results recorded as zero. The results were stored in file and printed at a later time.

### Trunk extension-flexion (Fig 6)

The subject stood in adjustable footplates with the pelvis resting on a sacral pad. The axis of rotation was aligned with S1/L5 articulation by adjusting the height of the foot

plates. An adjustable padded bar behind the popliteal fossa held the knees in 15 degrees of flexion. The knees were secured in position by pads at the distal end of the femur and upper end of the tibia. A pelvic strap held the pelvis in place. A padded chest pad was positioned below the level of the sternal notch and secured to the posterior scapula pad at the frame. The extension stop was set at 0 degrees and the flexion stop at 60 degrees. The test was conducted in the same manner as the test for rotation.

#### Liftask (Fig 7)

The subject was asked to stand in position on the platform of the lift task machine. Waist and knee heights were measured in inches and recorded. The operator demonstrated the method of lifting and the subject was allowed to try both speeds before the test began. The test proceeded in the same manner as the previous tests. The subjects were not corrected if they did not lift according to the demonstration.

#### Isometric lifting

An adjustable platform was positioned at waist height. The subject then performed the psychophysical and isometric lifts. The instructions for the psychophysical lift (Troup *et al*1987) were to "select a comfortable level of force which you could hold steady for two minutes. Tell me when you have achieved the force and hold it steady." The operator checked that the force was held steady for four seconds and recorded the reading. The instructions for the maximal lift were "increase the force gradually to as much as you possibly can and hold for a count of four seconds". The operator again recorded the reading. The platform was moved to knee height and the

tests were repeated. The subject then exercised on the bicycle as a cool down to prevent pooling of blood in the lower limbs, to help prevent muscle soreness and to allow a psychological winding down to occur.

### **5.3 Pilot Study**

The pilot study of 25 normal subjects and 20 patients who satisfied the selection criteria was used to develop the standard assessment protocol used throughout the study for both normal subjects and patients. On the basis of the pilot study changes in the study design were decided.

In general the pilot study was unremarkable. However one important observation was made which affected the design of the main study. Originally the study intended to conduct a reliability study on the patients only as it was recognised that reliability studies must be done on the appropriate patient population (Rothstein 1985). Although normal subjects are relatively easy to measure and are often available as subjects for reliability studies the data resulting from studies of normal subjects cannot necessarily be extrapolated to prove reliability in patient groups.

However it was noticed during the pilot study that normal subjects and patients were having different reactions to the isokinetic testing. The normal subjects reported feeling tired and having worked hard after the test whereas several patients expressed surprise at being able to accomplish the test and admitted to 'feeling a little easier' after the test. It was possible that some patients had been accommodating their back pain without being aware of it. This is similar to phenomenon described as 'fear avoidance' by Troup *et al* (1987). As a significant proportion of patients reported this therapeutic effect from a single isokinetic assessment session it was necessary to take it into

consideration as a possible influence on the results of a reliability study on patients. A reliability study of normal subjects would allow a comparison to be made between patients and normal subjects. The hypothesis was that the patients would show a greater learning effect than the normal subjects subjects and that this effect would be due to behavioural reasons. Thus normal subjects were used for the first reliability study, and patients were used for the second reliability study allowing an exploration of the cognitive process underlying the behavioural change.

#### **5.4 Study of Normal Subjects**

The study of normal subjects consisted of a standardisation study and a reliability study. Seventy normal subjects, 35 males and 35 females, were tested for the standardisation study.

##### **5.4.1 Reliability Study Normal Subjects**

The purpose of this study was to determine the reliability of the Cybex back assessment unit on normal subjects. The study was conducted by the Research Physiotherapist and a physiotherapy lecturer.

Twenty six of the normal subjects from the standardisation study were tested four times. There were equal numbers of men and women. Twenty one subjects completed the study as four subjects were unable to complete the study. One subject dropped out of the study due to an unrelated injury and the other three subjects due to a minor upper respiratory tract infection epidemic.

#### 5.4.2 Study Design

The design of the study allowed intra-tester and inter-tester reliability to be measured. Intra-tester reliability is the degree to which one observer can replicate the measurements he obtains. Inter-tester reliability is the degree to which different testers can obtain measurements which agree. The design also allowed the learning effect over four consecutive tests to be measured. The subjects were asked to attend four testing sessions on alternate days at the same time if possible. The tests were carried out by two testers who alternated as first tester to eliminate tester effect in the learning curve. To eliminate the diurnal effect the subjects were tested at approximately the same time each test day and under the same conditions. Each subject was tested on alternate days for two reasons:

- 1) to eliminate the training stimulus caused by muscle contraction. This stimulus is fully effective for twenty four hours and thereafter fades from day to day to become ineffective after seven days (Muller 1968)
- 2) to eliminate muscle pain which could last from one hour to twenty four hours after strenuous exercise (Pollock *et al* 1984)

One problem which is difficult to overcome is that of motivation. It is recognised that measurement of maximum strength is a psychological as well as a technical problem (Muller 1968). Maximum strength can only be obtained if the subject is willing to make a maximum effort and this was encouraged by the standardised verbal instructions reported in the test procedure.

The full test protocol was conducted in exactly the same way as described previously. Verbal encouragement by both testers during the testing procedure was limited to the

previously described instructions. Each subject completed the four tests within two weeks.

## **5.5 Study of Patients**

The purpose of this study was to collect isometric and isokinetic data on patients with chronic low back pain. In addition a full history and clinical examination was carried out by a medical examiner. Pain was assessed by anatomic pattern, time pattern, severity on a visual analogue scale (Waddell 1987b) and the short form McGill Pain Questionnaire (Melzak 1987). Objective physical impairment was assessed by clinical examination (Waddell *et al* 1992). Disability was assessed in activities of daily living (Waddell and Main 1984) and work loss. Psychological distress was measured by the Distress and Risk Assessment Method (Main *et al* 1992) based on the Modified Somatic Perception Questionnaire (Main 1983) and a modified Zung Depressive Inventory (Zung 1965). A comprehensive assessment of illness behaviour (Waddell and Richardson 1991) included overt pain behaviour (Keefe and Block 1982) and behavioural or nonorganic signs (Waddell *et al* 1980). The clinical and psychometric data were compared with the isokinetic and isometric data. The study was conducted by the Orthopaedic Consultant and a Clinical Assistant who identified the patients and performed the clinical examination and the Research Physiotherapist who conducted the isokinetic testing.

The subjects were 125 patients selected by one of the medical examiners as meeting the selection criteria. Five of the subjects agreeing to participate in the study failed to attend for isokinetic testing.

## Procedure

The Research Physiotherapist was present at the clinic and interviewed each patient to explain the purpose of the study, the nature of the exercise, and to ask the patient to sign a consent form. The patient was given an appointment to attend the physiotherapy department at a time suitable to them (evening appointments were given if necessary) and any potential problems with transport were sorted out (occasionally a taxi fare was paid). The patient was advised to wear comfortable clothing or to bring this with them.

The standard test protocol was carried out in exactly the same way as for the normal subjects.

### 5. 5.1 Reliability Study: Patients

The purpose of this study was threefold:

1. to determine intra-tester reliability in patients
2. to determine learning effect in patients
3. to determine the change in patient behaviour

The secondary purpose of this study was to investigate the possible behavioural changes which were observed during the pilot study. It is possible that the machine was not so much measuring actual muscle strength as measuring what the patient was willing to do with his muscles. As the frequency and intensity of the previous reliability study was chosen to have no physiological effect any change in performance scores in patients could be said to be due to a change in behaviour. In

order to measure this suggested change in behaviour the patients completed the following questionnaires:

Short form McGill Pain Questionnaire (Melzak 1987)

Roland & Morris Disability Questionnaire (Roland & Morris 1983)

Fear Avoidance Beliefs Questionnaire (Waddell et al 1993)

Modified Somatic Perception Questionnaire (Main 1983)

Zung Depressive Inventory (Zung 1965)

The subjects were 21 patients from the main patient isokinetic study who were asked to attend for testing four times. The selection criteria was the same criteria as the main study with the following additions; the subjects were working or off sick with a job open, the subjects lived within reasonable travelling distance of the hospital, the subjects were judged to be co-operative patients. One subject dropped out as he refused to fill in the repeated questionnaires.

Each patient was tested four times by the same tester. The questionnaires were administered by the Research Physiotherapist three times over the course of the four isokinetic tests:

1. before the first isokinetic test
2. before the second isokinetic test
3. after the fourth isokinetic test but not immediately after testing as the feeling of either exercise induced euphoria or fatigue after exercising could influence the



answers to the questions. The patient was given a review appointment to complete the final questionnaire and to discuss the results of the tests. The four tests were completed within two weeks.

## **5.6 Follow-up Study**

The 70 normal subjects were followed up by postal questionnaire after 26-32 months to determine if isokinetic measures predicted future episodes of back pain. They were asked "Have you had any pain or other trouble with the lower part of your back" since the time of the initial assessment, as in Biering-Sorensen (1984). If the answer was affirmative, supplementary questions were asked about medical consultation and work loss for back pain.

## **5.7 Results**

### **5.7.1 Test Protocol**

Normal subjects No subject was unable to complete the single isokinetic assessment. All the normal subjects were able to achieve results for the full test except one female who was unable to produce an extension-flexion reading at 150 degrees/second (Table 5.2).

Patients. No subject was unable to complete the single isokinetic assessment. However several patients were unable to achieve extension-flexion at 150 degrees/second which was dropped from the results. The female tertiary referral had difficulty with all speeds with several failing to record on any of the isokinetic variables. Several patients were also unable to complete the cardiovascular fitness test (Table 5.2). Patients who failed to achieve their targeted heart rate were recorded as missing for Max  $\text{VO}_2$  as it was not possible to calculate this figure. Patients who failed to produce a reading on any of the isokinetic machines were recorded as zero.

### **5.7.2 Safety**

No injuries or exacerbation of back pain occurred during the testing procedure. Several patients reported that back pain limited their performance but no patient refused to attempt the required exercise due to back pain. Several normal subjects reported muscular discomfort for 24 hours of the test but no subject was unable to complete the reliability study due to this discomfort.

### **5.7.3 Variables related to sex**

All the main isokinetic, isometric and fitness variables are significantly different in males and females, in both normal subjects and patients: weight, max vo<sub>2</sub>, peak torque, peak torque/body weight, power, power/body weight, psychophysical lift force, maximum isometric lift force, isokinetic lift force using unpaired t tests (Appendix 11).

### **5.7.4 Variables related to weight males and females analysed separately**

When males and females are analysed separately only normal males showed a significant correlation between weight and peak torque and power in both rotation and extension-flexion. Body weight accounted for 20-40% of the variance for extension-flexion and rotation. Even in normal males however there was no significant correlation between body weight and Liftask, maximum isometric lifting, or psychophysical lifting. Normal females showed few correlations between isokinetic measures and body weight. Neither male or female patients showed any significant correlations between any of the isokinetic measures and body weight. (Table 5.2). All the isokinetic measures are reported raw.

### **5.7.5 Variables related to age**

None of the isokinetic variables were related to age within the age range 20 to 55 years in either normal subjects or patients using Pearson product-moment correlation coefficients.

### **5.7.6 Average points variance (APV)**

This is a computed measure of the amount of variation between the curves of each isokinetic run. The APV is based on the difference between the highest of the four curves and the mean of the four curves at each degree of movement, averaged and presented as a percentage. There is no published work on this APV. It is suggested that a APV of greater than 15% demonstrates lack of effort.

Normal subjects All the measures of APV in this study had a mean APV of >15% in normal subjects with the exception of the slow speed on extension-flexion and Liftask most of which just reached this level. However 45-80% of normal subjects had >15% APV with the exception of flexion and extension at 60 degrees/sec and extension at 90 degrees/sec.

Patients All the measures of APV for the 120 patients had a mean APV of 20-34% and 40-90% of patients had APV of >15%. There was no consistent or significant pattern in APVs between males and females or between GP and problem patients so all 120 patients were analysed together. Follow-up t-tests confirmed that there was a highly significant increase in APVs in all measures in patients compared with normal subjects.

### **5.7.7 Learning**

There was a significant increase from Test 1 to Test 2 on extension-flexion and rotation but not liftask for all speeds in both normal subjects and patients. There was no further significant increase from Tests 2-4 (Table 5.3, 5.4).

There was no significant change and in particular no improvement in APV between any of the Tests 1-4.

### **5.7.8 Reliability**

Test retest reliability was assessed by Intra-class Correlation Coefficients (ICCs) based on ANOVA and calculated according to the formula  $R = (MSs - MSw)/MSs$  where  $R = ICC$

$MSs$  = mean square between subjects

$MSw$  = mean square within subjects

as described by Baumgartner (1989). An acceptable level of reliability is  $ICC > 0.80$ .

In view of the learning effect between Test 1 and Test 2 the reliability statistics were calculated on tests 2-4.

Normal subjects are reported in Table 5.3 and patients in Table 5.4. All the main isokinetic variables were highly reliable ( $ICC > 0.80$ ) for both normal subjects and patients. Isometric and psychophysical lifting were reliable for patients but only isometric lifting was reliable for normal subjects. The reliability of the psychophysical lifting was poor especially for one tester. The cardiovascular fitness test was highly reliable. Intra-tester and inter-tester reliability of normal subjects were equally good. Intra-tester reliability was good for both patients and normal subjects.

The results of the derived isokinetic variables are reported in Table 5.5. None of these variables reach acceptable reliability levels in either normal subjects or patients but one reached an acceptable level in patients alone.

None of the APVs of the various isokinetic tests were reliable for normal subjects and only two exceeded reliability levels in patients. However as it could be argued that a high APV is a measure of inconsistency a high APV could itself be unreliable. The

APVs were therefore analysed by a Chi squared test to see if they remained above or below the cut off of 15%. Normal subjects revealed two of the APVs showed significant agreement as to whether they were above or below the cut-off on test-retest. Patients revealed that two different APVs reached comparable levels of significance.

### **5.7.9 Relationship between different isokinetic measures**

The correlation between the various isokinetic measures was analysed using Pearson product-moment correlation coefficients. Males and females were analysed separately in both normal subjects and patients.

In extension-flexion and rotation the computed measures of average power correlated at least 0.93 and generally 0.97-0.99 with peak torque at the corresponding speed in both normal subjects and patients. In liftask both average power and total work correlated highly (generally 0.95 or more) with peak force. These correlations were so high that further analysis was limited to peak torque and peak force as the computed measures were in fact no different from the basic measures.

The correlations between peak torque for extension-flexion and rotation and peak force for liftask at the various speeds were also high 0.60-0.90 in male and female normal subjects and patients. They tended to be higher between the different speeds for each machine and lower between each of these dimensions. However from the correlation matrix there was clearly a large amount of variance in common (35-80%) Principal components analysis extracted a single factor accounting for 82% of the total variance in normal subjects and 85% in patients. All of the isokinetic measures loaded 0.89-0.94 on this factor. When males and females were analysed separately there remained a single major factor accounting for 69-77% of the total variance in both normal subjects and in patients.

All individual isokinetic measures correlated significantly with the total isokinetic score, 0.82-0.91 in males and 0.81-0.89 in females. The total isokinetic score correlated more than 0.99 with a computed isokinetic score based on the factor loading in males and females separately.

Correlations between lift task, isometric measures and both maximal isometric and psychophysical lift strengths were 0.47-0.62 in males and females separately in both normal subjects and patients.

Correlations between extension-flexion and rotation and both maximum isometric and psychophysical lift strength were 0.32-0.62 in males and 0.38-0.68 in females.

Seven of the APV measures correlated with their corresponding peak torque in normal subjects and ten in patients. The correlations were all negative indicating that the poorer the isokinetic performance the higher the APV.

#### **5.7.10 Normal values and discrimination between normal subjects and patients with low back pain**

Values for normal subjects and patients for the main isokinetic variables are shown separately for males and females in Tables 5.6 and 5.7. Normal females achieved 60% of the performance of normal males. Ninety five percent confidence intervals for the means averaged  $\pm 10\%$  and  $11\%$  in normal males and females respectively, compared with  $13\%$  and  $15\%$  in primary referral male and female patient. In tertiary referral patients, however due to small numbers, wide individual variation and numbers failing to record, 95% confidence interval the means averaged  $\pm 36\%$  in males and  $64\%$  in females.

The wide variation in normal subjects is illustrated in the standard deviation averaging  $25\%$  of the mean in males and  $32\%$  in females.

There was a similarly wide range in computed ratios. In rotation mean left/right torques approximated 1:1 in normal subjects and patients. Mean extension/flexion ratios were approximately 1;1 at all speeds normal females and in normal males at higher speeds although males at lower speeds was closer to 1.1:1. The extension/flexion ratios fell in patients. However these ratios only apply to the means. There was an extremely wide range in all the ratios from 1:10 to 10:1. Individually 25% of patients had a ratio of greater than 2:1, 10-50% of normal subjects and 25-60% of patients had positive fatigue ratios while 40% of both normal subjects and patients had negative recovery ratios.

Values for patients for the main isokinetic variables are also shown separately for males and females in Table 5.6 and 5.7. The primary and tertiary referrals are presented separately. The primary referral male patient achieved an average of 74% of the value for normal male subjects compared with 57% in the females but tertiary referral males only achieved 66% for males and 23% in females. There was a corresponding increase in range with the SD averaging 43% and 57% in primary and tertiary referral males respectively, 50% and 116% for primary and tertiary referral females.

Analysis of variance and unpaired t-tests revealed a highly significant difference in the mean values of all the isokinetic variables between normal subjects and primary and tertiary referrals in both males and females. The differences between primary referrals and tertiary referrals were not significant.

Taking the generally accepted normal range of any test as being mean  $+2 \times \text{SD}$ , only 25 of normal subjects fell below the lower limit of normal the isokinetic measures, that is 2% false positive. However, this cut off produced 80% false negative in patients; i.e. a specificity of 89% but sensitivity of only 20%. Such a cut off is clearly not clinically useful.

More effect discrimination was achieved by taking the lower limit of normal as mean + 1xSD (Tables 5.6 5.7). For the main isokinetic measures in males this achieved an average specificity of 84% (false positive rate in normal subjects of 16% but a mean sensitivity of only 44% (false negative 56%) in primary referral and 61% (false negative 39%) in tertiary referral. In females the corresponding average figures were specificity 85% (false positive 15%) and sensitivity of 63% (false positive 37%) in primary referral patients. The total isokinetic score produced better discrimination than any of the single isokinetic variable specificity male 89%, female 86% sensitivity in primary referrals, male 53%, female 75%; sensitivity in tertiary referrals, male 67%. Discrimination in tertiary referral females could not be analysed because of the large proportion who failed to produce isokinetic readings (Table 5.2).

Formal discriminant analysis showed that different isokinetic measures best discriminated patients from normal subjects in males or in females. In males the significant discriminators, in order of entry to the discriminant equation: extension 60 degrees/sec, flexion 90 degrees/sec, right rotation 60 degrees/sec, right rotation 150 degrees/sec, left rotation 150 degrees/sec, and extension 120 degrees/sec. In females the corresponding equation included: Liftask 36 inches/sec, right rotation 60 degrees/sec, extension 120 degrees/sec, extension 60 degrees/sec, extension 60 degrees/sec, and flexion 60 degrees/sec. However equations could be constructed with several different combinations of isokinetic measures.

Table 5.8 shows the ability of isokinetic measures to discriminate individual patient from normal subjects. This is the best possible discrimination based on discriminant analysis using the above combination of isokinetic measures in formal discriminant equations. Discriminant analysis using only the total isokinetic score achieved 64% accuracy in males and 81% in females. Extension-flexion measures alone achieved a similar 64% accuracy in males and 80% in females. In Table 8 it can be seen that discrimination based on isokinetic measures had comparable accuracy to a



combination of isometric and psychophysical measures and was only slightly more accurate than clinical observation of physical impairment. The isokinetic measures had comparable 70-80% specificity and 85-98% sensitivity, whereas clinical observations had better 94% specificity but poorer 69-73% sensitivity.

#### **5.7.11 Relationship Between Isokinetic and Clinical Measures**

None of the individual isokinetic measures, total isokinetic score, maximum isometric lifting, psychophysical lifting, or cardiovascular fitness correlated significantly with total duration of symptoms or the duration of the present episode. Isokinetic performance on all the main isokinetic measures was significantly lower in patients with a chronic pattern of pain compared with patients with recurrent pattern of pain.

Table 5.9 shows the significant correlations between a selected number of representative isokinetic measures and the main clinical measures. Males and females are shown separately. Females showed few significant correlations whereas males showed more and stronger correlations. The correlations between the isokinetic measures and clinical evaluation of physical impairment were weak approximately 10% of the variation in common. Correlations between the isokinetic measures and severity of pain, whether assessed by the pain scale or the McGill pain questionnaire, were even weaker. Some of the isokinetic measures showed a moderate correlation with disability activities of daily living but none was stronger than clinical evaluation of physical impairment. The strongest correlation was between most of the isokinetic measures and work loss, which in males was generally in the range  $r = 0.51-0.68$ , some of which were slightly higher than the correlation between clinical evaluation of physical impairment and work loss. Weak correlations were also seen between the isokinetic measures and psychological distress, overt pain behaviour, and behavioural signs. Most of the isokinetic measures showed a weak but significant correlation with behavioural signs in females.

When the relationship between the isokinetic measures and the clinical measures was investigated further by regression analysis of disability in activities of daily living and work loss, few of the relationships met the more stringent statistical requirements. Regression analysis was only possible in males. In these analysis extension 90 degrees/ sec was consistently the strongest individual isokinetic measure and none of the other isokinetic measures added significantly. Extension 90 degrees/ sec alone was approximately equal to the total isokinetic score. The total isokinetic score explained 13.8% of the variance of disability in activities of daily living, but in contrast clinical evaluation of physical impairment explained 20.8%. The total isokinetic score explained 38.9% of the variance of work loss in the past year which was more powerful than the 32.4% explained by the clinical evaluation of physical impairment. The total isokinetic score still explained an additional 19.5% of the variance of work loss in the past year when entered into the regression equation after allowing for clinical evaluation of physical impairment. None of the maximum isometric or psychophysical lift strengths entered significantly into the regression equations.

Many APVs showed significant correlations of 0.31-0.53 with the Modified Somatic Perception Questionnaire and a few showed significant correlations with the Zung Depression Questionnaire in males though none reached significant levels in females. A number of extension and rotation APVs showed significant correlations of 0.32-0.39 with the behavioural signs in males though only the APV of extension 120 degrees/sec reached significance in females.

#### **5.7.12 Physiological Variables**

Resting heart rate was significantly lower in male and female normal subjects compared with patients ( $p < 0.01$ ). Max  $\text{VO}_2$  was significantly higher in male normal subjects compared with patients ( $p=0.05$ ) and female normal subjects compared with patients ( $p=0.01$ )

### **5.7.13 Questionnaires**

The results of the paired t-tests for the questionnaires completed during the patient reliability study can be seen in Table 5.10 and show a progressive change especially in patients beliefs.

### **5.7.14 Follow-up of normal subjects**

Sixty-six of the 70 normal subjects (94%) were followed up for 26-32 months (mean 30.2 +/- SD 1.4). Fifteen of the 66 reported low back trouble having developed since the time of their isokinetic assessment.

The results of the t tests showed none of the individual isokinetic measures, total isokinetic score, maximum isometric lifting, physophysical lifting or cardiovascular fitness showed any significant differences between those subjects in whom low back pain did or did not develop.

## **5.8 Discussion**

### **5.8.1 Isokinetic variables related to weight**

When males and females were analysed together it appeared that all the isokinetic variables were related to weight. However the isokinetic variables were also related to sex indicating a major interaction between weight and sex. When males and females were analysed separately only normal males showed a correlation between isokinetic variables and weight. Body weight accounted for 20-40% of the variance for rotation and extension-flexion. This agrees with the findings of Delitto *et al* (1990) who concluded that there was no basis to form a peak torque to body weight ratio in females; in males body weight only accounted for 20 25 of the variance of the peak torque and the peak torque/ body weight ratio was still so large that it was clinically insensitive for detecting trunk extensor weakness. Jerome *et al* (1991) in the only report of Cybex 11 found that 0.5-0.7 of the variance of all extension-flexion

body weight was the most powerful. unfortunately they did not initially make an allowance for sex. The results of the current study supports the theoretical argument by Mayhew and Rothstein (1985) against the practice of reporting isokinetic measures as a ratio to body weight. There was no significant correlation in either male or female patients between isokinetic variables and weight. Previous literature reports results which have been adjusted for body weight in normal subjects. The results of this study do not support this practice.

### **5.8.2 Isokinetic variables related to age**

None of the isokinetic variables were related to age. There is disagreement in the literature about age at which any fall in performance begins. Langrana and Lee (1984) noted it after age 30 years, Hasue *et al* (1980) noted it after 40, Gomez *et al* (1991) after 40 in men but 50 in women. Smith *et al* (1985) found no difference between the age groups 18-29 and 30-40 years. In general any effect of age is small. In the only study large enough to draw any firm conclusion Timm (1988) reported Cybex Liftask measures in 2688 normal subjects. Both men and women showed a consistent fall in peak torque at the common test speeds of approximately 30% between the third and sixth decades. However lifting depends on other muscle groups and not only trunk muscle.

### **5.8.3 Average points variance (APV)**

The degree of effort on the part of the subject can affect the validity of the measurement. If the subject does not understand the concept of maximum effort an objective qualitative measurement of maximum physical capacity is unlikely to be obtained.

The results of the current study do not support the use of APV scores as a measure of consistency of effort. It was originally suggested in the literature (Mayer *et al* 1985a) that a high variation (>15%) indicated a lack of consistent effort on the part of the

subject, although this suggestion was later disputed by Hazard *et al* (1988). It is argued that it is difficult to produce consistent curves with submaximal effort. Inconsistent curves could therefore be used as a means of identifying those patients deliberately attempting to falsify results. This information has been used in American legal context as demonstrating "malingering". The literature review revealed only three papers providing data on curve inconsistency in isokinetic trunk muscle testing (Mayer *et al* 1985a, Hazard *et al* 1988, Mandell *et al* 1993). The two former studies dealt only with subjective assessment of curve consistency as they were carried out before the development of the current software measuring average points variance. Mayer dealt only with extension-flexion and Hazard with extension-flexion and lift task but not rotation. Mayer maintained that an APV result of >15% indicated lack of effort by the subject. The results of the study by Hazard *et al* cast considerable doubt on this suggestion. Apparently it was possible for highly motivated subjects to produce inconsistent curves and inexperienced subjects to inadvertently produce consistent curves. They found that "clinical observation" of the subject during testing was a more accurate method of assessing effort than examination of curve variability. They concluded that "clinical judgement is further demanded in evaluating isokinetic performance because we have no data or experience to suggest that specific patterns of variable curves correlate exclusively with depression, fear of injury, malingering, or other causes of submaximal efforts, with the possible exception of pain itself". Mandell *et al* (1993) has also challenged the use of the measure after finding subjects with back injury demonstrated lower or similar scores to subjects with no back pain. The authors conclusion on average points variance was "The imprecise definition and use of this measure can clearly have significant negative consequences if incorrectly applied in medicolegal evaluations." Mayer (1988) has since refuted his original suggestion and stated in a recent publication that "accuracy has been assumed by the manufacturers with only preliminary evidence."

Literature relating to isoinertial testing reported a phenomenon called "crosstalk" which Seeds *et al* (1988) suggested might be an indication of subject effort but this was not supported by Levene *et al* (1989). In a review of the isoinertial literature Gomez *et al* (1991) concluded "the range of variability found in the normal population should serve as a reminder that production of maximal exertion is multifactorial and that inconsistency is not synonymous with insincerity of effort." Robinson *et al* (1991) have shown that 20 normal subjects could consistently reproduce a 50% submaximal isometric trunk exertion at seven different positions. There was no difference in test-retest reliability and therapists could not tell the difference between maximal and sub-maximal effort.

The literature reporting isokinetic testing of limbs has also challenged the interpretation of isokinetic data to distinguish malingerers from injured patients. Nicholas *et al* (1989) studied young but non-athletic able-bodied subjects and were surprised to find endurance ratios (range 4-171%) were well above the average (50%) published for similarly aged athletic populations. They concluded that before isokinetic testing is considered as a possible way to distinguish malingerers normal values for an aged-matched non-athletic population should be clearly defined.

The reasons and sources of individual variation during muscle testing are a complex combination of physiological and psychological factors and to date no reliable method of detecting malingerers has been reported.

#### **5.8.4 Learning**

Learning is described as a change in the internal state of a person that results from practice or experience and must be inferred from the observation of that person's performance (Magill 1985). Motor learning is said to have taken place when a characteristic pattern of performance is seen on serial testing. The performance must improve, persist at the improved level and show decreasing variability over time

(Magill 1985). The learning effect demonstrated in the current study was in agreement with previous reports. It was documented in isometric testing (Kroll 1963) and isokinetic testing of peripheral joints (Mawdsley and Knapik 1982, Giles *et al* 1990 ) and isometric testing of the trunk (Graves *et al* 1990). In one of the early reliability studies on the isokinetic machines Smidt *et al* (1983) reported an average increase of 13-21 %. In a later study by Smidt *et al* (1989) the test results from the second test were used as a baseline and it was stated that "this pretest training is believed to be critical if reliable measures are to be obtained". Delitto *et al* (1991) demonstrated a 5-15% increase over 3 trials on the same day with the greatest increase between test 1 and test 2. Kahanovitz *et al* (1987), in a randomised controlled trial of the effect of electrical stimulation or exercise on isokinetic back muscle strength in normal subjects, noted a non significant change in the control group and attributed it to a "learning process" from participating in the test battery.

A greater learning effect for patients than normal subjects has been reported (Grabiner *et al* 1990) with normal subjects showing a 0-8% increase and patients with low back pain showing a 17-28% increase. This indicated that they were learning something about their pain as well as learning the technique. Estlander *et al* (1991) have reported a learning effect for isokinetic lifting of 9% for normal and 17% for patients which supports the results of the current study of 5% for normal subjects and 10% for patients.

The much greater increase in learning for the patients suggests that there may not only be learning of the test technique but also learning about their back pain. This suggestion that a therapeutic effect is taking place is supported by the results of the questionnaires which were administered before and after the isokinetic tests for the reliability study. The steady improvement in the questionnaires suggests that the patients are changing their cognitive beliefs about their back pain.

The learning effect was greater for the movements of rotation and extension. These findings may simply reflect the relatively unpractised nature of extension and rotation compared with the more frequent movements of flexion and lifting but there is no evidence from the literature to support this suggestion.

In light of the learning effect it is recommended that isokinetic performance is assessed on the second test. This is particularly important when the test is used as a baseline to monitor progress or the effect of treatment. Few of the reported studies have met this stringent requirement. In view of the greater learning effect in patients, the difference between patients and normal subjects and the ability of isokinetic performance to discriminate between them would be overestimated.

#### **5.8.5 Reliability**

This study clearly demonstrated good inter-tester and intra-tester reliability for all the main isokinetic measures in normal subjects and good intra-tester reliability for patients. It also demonstrated good reliability results for isometric and psychophysical lifting in patients but good reliability for isometric lifting only in normal subjects. The results for reliability are consistent with the previous results reported in the literature. The reported ICCs for this study were in fact higher than the ICCs reported by Delitto (1989). The low reliability for the psychophysical lifting in normal subjects could have been related to the instructions as it was observed during the study that the normal subjects appeared to have a problem understanding the concept of a 'comfortable lift' whereas the patients did not have the same problem. The psychophysical lift requires the subjects to make a judgement on a certain amount of force which they can sustain over a set period.

Only one of the ratios reached acceptable level of reliability in patients and none in normal subjects and patients. There is limited evidence in the literature for reliability of ratios. There is strong theoretical argument that ratios are so error ridden that they



should not be used to make clinical judgements (Rothstein *et al* 1987) as the zero level on an isokinetic scale does not mean that the subject has no muscle strength. The scale is an interval scale and as such cannot be used to form ratios. Winter *et al* (1981) found endurance tests errors in work measurement exceeding 500% and errors in torque exceeding 79%. Delitto *et al* (1991) found extension-flexion ratios were unreliable with test-retest errors approaching 50% of mean scores. On the other hand Smidt *et al* (1989) did find extension-flexion ratio reliable but not endurance ratios. Osternig (1986) stated whilst agonist antagonist relationships are considered to be important factors in performance screening these relationships are not static and have been found to vary throughout the arc of motion and are affected by speed of movement.

#### **5.8.6 Relationship Between Different Isokinetic Measures**

All the different isokinetic measures were highly related to each other which supports the argument by Jerome *et al* (1991) that all isokinetic measures are simply different measures of a single dimension of isokinetic performance. There was no evidence from this study to support the suggestion that different isokinetic measures are measures of different biological characteristics such as strength or power (Mayhew and Rothstein 1985). These results suggest that there is no justification in the additional expense of an extra machine to measure trunk muscle strength when one is sufficient.

### 5.8.7 Discrimination between normal subjects and patients

The results of this study agree with the previously published literature that patients with low back pain perform less well than normal subjects (Hasue 1980, Mayer *et al* 1985a, Gomez *et al* 1991). The magnitude of the difference was greater for females than males with tertiary referral females showing the biggest difference. The primary referral females recorded 57% of the value for normal females whereas tertiary referrals only achieved 23%. The primary referral males achieved 74% of the corresponding values for normal males compared with tertiary referrals achievement of 66%. The variables also discriminated between GP patients and problem patients in females. Male patients also demonstrated a constant tendency to lower levels than problem patients but it did not reach statistical significance.

However the main problem with attempting to compare normal subjects with patients experiencing low back pain was the wide range of scores for individual subjects. This wide range which is illustrated by the SD averaging 25% of the mean in males and 32% of the mean in females agrees with the previous literature. In fact the range for normal subjects was so wide it was difficult to set a lower limit of normal. This wide range for normal subjects plus an even greater range for patients means isokinetic scores are poor discriminators for individuals. This suggests that isokinetic testing would be of no value for screening purposes.

In one of the early studies of trunk muscle strength Nachemson and Lindh (1969) noted that "pain during the performance of the tests was found to be a probable strength reducing factor. Beimborn and Morrissey (1987) reached the same conclusion in their review of trunk muscle performance: "Comparing trunk muscle strength in normal subjects and patients is difficult because of the influence of pain itself on the force producing capacity of the individual patient. Pain can greatly hinder maximal effort and, as a result, testing of patients with low back pain may actually be tests of their pain level or tolerance".

Mayer *et al* (1985a) also noted that in patients with low back pain, reduced performance could be caused by pain leading to muscle inhibition or guarding, to fear of injury which might be intensified by psychological factors or to conscious lack of effort. Hirsch *et al* (1991) listed possible explanations for patients performing poorly or inconsistently as : failure to understand the degree of effort required, anxiety related to the test situation, depression, pain, fear avoidance, or unconscious.

#### **5.8.8 Physiological variables**

The high reliability for these measures was not surprising as fitness measures are unlikely to change over the course of two weeks with a testing sequence not designed to increase fitness.

The lower resting heart rate and the higher Max VO<sub>2</sub> reported suggest that the normal subjects tested were fitter than the patients tested. The normal subjects represented a cross section of the population and not only fit active subjects.

The role of aerobic fitness in the prevention and recovery from low back pain is currently receiving attention and will be discussed more fully in chapter 7.

The method of assessing aerobic capacity in patients with low back pain requires attention. In the current study 6% of male and 25% of female patients were unable to achieve their predetermined target heart rate as they were unable or unwilling to pedal the bicycle hard enough to increase their heart rate sufficiently. Problems associated with exercise testing using a bicycle ergometer have not been mentioned in the literature which suggests they have not occurred or have been ignored. Mayer *et al* (1985a) and Hazard *et al* (1989) both used the same protocol as the current study but failed to report any patient not reaching the required heart rate. In a review of aerobic testing for patients with chronic low back pain Battie (1991) suggested using a treadmill as a mode of testing. This method was used on 3020 employees aged 21-67

years when 16% of subjects stopped before the test was complete. It does not appear that the treadmill test was more appropriate.

### **5.8.9 Follow-up of Normal Subjects**

The results of the follow-up study failed to show isokinetic measures predicting low back pain. Although the follow-up study was based on a small sample the negative results agree with the only previous longitudinal study of isokinetic measures (Mostardi *et al* 1992) which studied a small (171), high risk group of nurses and found isokinetic lifting failed to identify the 16 nurses who reported work related back pain during the subsequent two year follow-up. The results also confirm the results of the prospective study of cardiovascular fitness (Battie *et al* 1989b) and a study of isometric lifting strength (Battie *et al* 1989a). In the former study isometric lifting strength did not predict low back pain in 2,178 workers during a four year follow-up.

### **5.9 Conclusions**

The Cybex 11 Back Testing System is safe and suitable for all normal subjects, male and female primary referral patients and most male tertiary referral patients with chronic low back pain but of limited value in female tertiary referral patients. Males and females should be analysed separately but there is no need to adjust for body weight.

The main isokinetic measures were reliable. However there was a learning effect from Test 1 to Test 2 therefore isokinetic performance should be assessed from the second test session. The derived ratios were unreliable and should not be used to detect individual muscle weakness or to plan individual treatment. The measurement of average points variance was unreliable therefore it cannot be used to distinguish maximal or sub-maximal effort or diagnose malingering.

There was a high correlation between peak torque in extension-flexion and rotation and peak force in liftask and between the isokinetic measures at different speeds. Therefore all isokinetic measures appeared to be of a single dimension of isokinetic performance. Derived measures of power and work were so highly correlated with the corresponding peak torque and peak force that they have no independent validity. There was no evidence that these derived measures or different speeds measure any different biological characteristics such as power or strength. There was no evidence that rotation or liftask add any clinically useful information to extension-flexion alone.

There were significant differences in the mean values of all the isokinetic measures between normal subjects and patients. However the ranges were so wide and overlapping that the discrimination of individuals was limited and little better than either isometric measures or clinical evaluation of physical impairment. As there was also no evidence that isokinetic measures in normal subjects predicted future low back trouble isokinetic performance appears to have no value for pre employment screening.

Isokinetic performance had a limited relationship to pain, clinical evaluation of physical impairment or disability in activities of daily living. There was no evidence that isokinetic performance provides a valid method of measuring actual trunk muscle strength.

Patients showed a greater learning effect than normal subjects. In addition patients showed an improvement in disability and fear avoidance beliefs indicating that patients were learning about their back pain as well as learning how to use the machines suggesting that the machines had potential as rehabilitation tools.

Table 5.1: Characteristics of normal subjects and patients

	Normal Subjects		Primary Referrals		Tertiary Referrals	
Number	70		94		26	
Sex (male, female)	35m	35f	47m	47f	12m	14f
Age (years +/- SD)	37.9 $\pm$ 10.4		35.3 $\pm$ 9.9		34.5 $\pm$ 8.7	
Height (inches)						
male	69.9 $\pm$ 2.7		69.5 $\pm$ 2.2		70 $\pm$ 3.5	
female	63.9 $\pm$ 2.6		64.2 $\pm$ 2.8		63.4 $\pm$ 2	
Weight (lbs)						
male	165.8 $\pm$ 22.5		168.4 $\pm$ 25.1		178.9 $\pm$ 29.3	
female	132.8 $\pm$ 15.8		143.2 $\pm$ 22.7		132.6 $\pm$ 18.2	
Low back pain (LBP) alone	-		53		11	
Low back pain + referred thigh pain	-		41		15	
Total duration (months)	-		83.5 $\pm$ 84.7		76.3 $\pm$ 54.4	
Present attack (months)	-		14 $\pm$ 25.5		30.9 $\pm$ 28.9	
Recurrent	-		32		2	
Chronic	-		64		24	
Working	-		42		0	
Off sick, job open	-		17		2	
Lost job not working	-		16		24	

TABLE 5.2 : Tests performed, proportion of normal subjects and patients failing to record, and relation to body weight

		% failing to record						Relationship to body weight (r)			
		normal subjects		patients				normal subjects		patients	
				primary		tertiary					
				male	female	male	female				
Tests performed	velocity o/sec	male 35	female 35	male 47	female 47	male 12	female 14	male 35	female 35	male 59	female 61
TEF extension	60	—	—	2	4	—	21	.55**	—	—	—
	90	—	—	2	4	—	36	.39*	—	—	—
	120	—	—	4	6	8	64	—	.42*	—	—
	150	—	3	15	32	33	93	—	—	—	—
flexion	60	—	—	2	4	—	21	.70**	.46*	—	.36*
	90	—	—	2	4	—	29	.63**	.43*	—	—
	120	—	—	4	4	—	50	.63**	—	—	—
	150	—	—	9	19	8	71	.51**	—	—	—
TR left	60	—	—	2	4	—	14	.50*	—	—	—
	120	—	—	2	4	—	29	.53*	—	—	—
	150	—	—	2	6	—	29	.51*	—	—	—
right	60	—	—	2	4	—	14	.47*	—	—	—
	120	—	—	2	4	—	14	.43*	—	—	—
	150	—	—	2	6	—	29	—	.41*	—	—
LIFTASK											
	18 "/sec	—	—	2	—	—	21	—	—	—	—
	36 "/sec	—	—	2	—	—	21	—	—	—	—
Isokinetic total score	—	—	2	—	—	7	.49*	.40*	—	—	—
Max isometric lifting											
	knee	—	—	—	—	—	—	—	—	—	—
	waist	—	—	—	—	—	—	—	—	—	—
Psychophysical lifting											
	knee	—	—	—	—	—	—	—	—	—	—
	waist	—	—	—	—	—	—	—	—	—	—
Cardiovascular fitness	—	—	6	15	—	36	—	—	—	—	—

Pearson correlation coefficients (r)

significant correlations only \*p &lt; .01 \*\*p &lt; .001

TABLE5.3: Test - retest reliability and "learning" of main isokinetic variables in normal subjects (n=21).

Tests performed		velocity o/sec	Test Sessions				Reliability tests 2-4 (ICC)			"Learning" % increase tests 1-2
			(means)				inter- observer	intra-observer		
			1	2	3	4		observer 1	observer 2	
TEF extension	60	122.6	142.9	139.5	148.5	.94	.98	.97	16***	
	90	116.9	132.4	130.0	136.0	.94	.94	.96	13*	
	120	98.8	113.4	123.1	119.6	.94	.91	.85	15*	
flexion	60	112.7	115.8	112.5	115.8	.95	.94	.98	3	
	90	105.6	111.9	108.9	113.3	.95	.96	.98	6	
	120	101.3	103.4	105.6	107.3	.97	.95	.95	2	
TR left	60	68.5	78.0	76.8	78.1	.95	.98	.97	14**	
	120	61.4	69.5	71.4	70.0	.95	.90	.95	13**	
	150	62.1	68.2	69.4	68.7	.98	.96	.97	10**	
right	60	69.1	76.5	74.6	74.2	.93	.92	.98	11*	
	120	61.6	71.3	67.6	68.7	.90	.84	.97	16**	
	150	62.7	66.3	66.1	70.0	.95	.92	.94	6	
LIFTASK										
	18 "/sec	140.6	148.0	145.2	144.7	.98	.93	.98	5	
	36 "/sec	126.7	127.0	129.6	123.6	.98	.87	.97	0	
Isokinetic total score		17.5	19.0	19.0	19.1	.98	.97	.98	8	
Max isometric lifting										
	knee	150.2	160.3	155.4	160.5	.96	.94	.92	7	
	waist	98.1	105.0	108.8	106.6	.83	.94	.81	7	
Psychophysical lifting										
	knee	95.0	99.2	93.8	94.2	.89	.87	.51	4	
	waist	68.9	70.1	70.3	70.7	.88	.89	.54	5	
Cardiovascular fitness		2.72	2.74	2.86	2.89	.88	.76	.99	1	

TEF & TR measures peak torque in ft lbs. Lifting measures peak force in lbs.

ICC Intra class correlation coefficients.

Paired t-test \*p <.05 \*\*p <.01 \*\*\*p <.001



TABLE 5.4: Test - retest reliability and "learning" of main isokinetic variables in patients (n=20)

Tests performed	velocity o/sec	Test Sessions (means)				Reliability (ICC) tests 2-4	"Learning" % increase tests 1-2
		1	2	3	4		
TEF							
extension	60	93.5	122.0	124.9	123.8	.98	30***
	90	88.3	100.9	108.9	106.5	.97	14*
	120	63.4	81.7	88.4	84.7	.98	28***
flexion	60	103.2	114.1	113.7	113.6	.98	10**
	90	96.9	104.0	104.1	106.0	.98	7
	120	83.0	88.7	92.3	100.5	.98	6
TR							
left	60	48.8	67.2	65.5	62.3	.98	37***
	120	49.5	59.4	60.8	56.9	.98	20**
	150	48.4	58.1	55.9	57.8	.98	19**
right	60	45.1	61.9	61.8	58.2	.98	37**
	120	45.4	56.0	56.4	58.6	.98	23*
	150	45.5	55.8	55.4	56.1	.97	22*
LIFTASK							
	18 "/sec	113.7	125.1	136.7	133.0	.98	10
	36 "/sec	100.3	102.0	114.1	115.7	.97	1
Isokinetic total score		12.3	14.3	15.0	14.9	.98	9
Max isometric lifting							
	knee	95.0	102.3	112.5	114.8	.96	8
	waist	77.1	84.8	83.1	84.4	.99	10*
Psychophysical lifting							
	knee	50.1	50.0	56.5	56.9	.96	0
	waist	43.8	44.2	46.8	47.1	.98	1
Cardiovascular fitness		2.45	2.50	2.50	2.50	1.00	2

TEF & TR measures peak torque in ft lbs. Lifting measures peak force in lbs.

ICC Intra class correlation coefficients.

Paired t-test \*p < .05 \*\*p < .01 \*\*\*p < .001

Table 5.5: Test-retest reliability of isokintetic ratios and APVs in normal subjects and patients

Tests performed	Test-retest reliability (ICC)		
	velocity o/sec	Normal subjects	Patients
Ratios			
TEF flexion/extension ratio	60	0.88	0.72
	90	0.91	0.50
	120	0.77	0.76
TR left/right ratio	60	0.35	0.35
	120	0.63	0.17
	150	0.78	0.90
TEF extension fatigue ratio	120	0.66	0.76
flexion fatigue ratio	120	0.59	0.67
TR fatigue ratio 1	150	0.75	0.76
fatigue ratio 2	150	0.88	0.56
recovery ratio	150	0.31	0.49

Table 5.5B: Average points variance (APV)

Tests performed	Test-retest reliability (ICC)		
	velocity o/sec	Normal subjects	Patients
TEF extension	60	0.66	0.87
	90	0.75	0.90
	120	0.35	0.72
flexion	60	0.65	0.84
	90	0.33	0.82
	120	0.25	0.81
TR left	60	0.50	0.83
	120	0.78	0.97
	150	0.58	0.64
right	60	0.66	0.84
	120	0.56	0.89
	150	0.63	0.68
Liftask	18	0.79	0.32
	36	0.71	0.62

Intra-class correlation coefficients (ICC)  
based on tests 2 - 4

Table 5.6: Results of isokinetic tests in male normal subjects and patients

Tests performed	velocity o/sec	Results of isokinetic tests*									false +ve  %	false -ve primary referrals  %	false -ve tertiary referrals  %
		normal subjects  35			patients								
					primary referrals  47			tertiary referrals  14					
TEF													
extension	60	175	±	52	115	±	51	104	±	57	20	47	33
	90	166	±	52	107	±	54	95	±	61	20	45	33
	120	146	±	52	87	±	49	80	±	56	17	45	33
	60	157	±	35	132	±	47	125	±	53	17	72	42
	90	152	±	35	131	±	44	120	±	56	11	77	68
	120	146	±	34	114	±	45	114	±	55	14	62	58
TR													
left	60	94	±	31	66	±	29	51	±	31	11	55	33
	120	87	±	29	63	±	30	55	±	36	20	55	42
	150	85	±	29	64	±	28	59	±	38	17	62	42
right	60	94	±	26	64	±	27	49	±	35	17	45	25
	120	88	±	28	61	±	29	53	±	39	14	55	33
	150	87	±	27	64	±	29	53	±	37	14	58	33
LIFTASK													
	18 "/sec	186	±	41	148	±	58	137	±	63	14	55	42
	36 "/sec	164	±	44	127	±	56	109	±	74	11	55	33
ISOKINETIC													
TOTAL SCORE		18.0	±	4.2	13.4	±	5.1	11.9	±	6.0	11	47	33
Max isometric lifting													
	knee	194	±	48	139	±	62	90	±	90	11	40	8
	waist	121	±	35	107	±	43	81	±	38	11	66	50
Psychophysical lifting													
	knee	108	±	41	74	±	38	49	±	28	14	53	17
	waist	73	±	36	60	±	30	43	±	21	11	79	58
Cardiovascular fitness		3.0	+	0.7	2.7	+	0.6	2.6	+	0.7	3	79	58

\*TEF & TR measures peak torque in ft lbs. Lifting measures peak force in lbs (mean +/-SD).

False positive and negative rates based on cut-offs of normal mean - 1 x SD.

Table 5.7: Results of isokinetic tests in female normal subjects and patients

Tests performed	velocity o/sec	Results of isokinetic tests*									false +ve	false -ve	false -ve
		normal subjects 35			patients							primary referrals	tertiary referrals
					primary referrals 47			tertiary referrals 14					
TEF													
extension	60	95	+	31	60	+	25	27	+	27	9	45	7
	90	93	+	32	50	+	30	14	+	17	11	34	7
	120	77	+	35	33	+	26	7	+	19	8	30	7
	60	93	+	23	68	+	26	30	+	31	14	55	14
	90	90	+	25	58	+	30	19	+	26	14	45	7
	120	80	+	27	49	+	33	14	+	25	11	43	7
TR													
left	60	50	+	19	27	+	14	18	+	21	20	38	21
	120	52	+	19	28	+	14	11	+	11	17	34	7
	150	52	+	17	28	+	15	11	+	11	14	34	0
right	60	51	+	19	26	+	13	13	+	10	17	30	7
	120	52	+	19	27	+	13	13	+	11	23	34	7
	150	54	+	18	29	+	14	11	+	12	17	43	7
LIFTASK													
	18 "/sec	118	+	31	74	+	28	38	+	34	20	30	14
	36 "/sec	111	+	32	58	+	26	25	+	25	17	25	7
ISOKINETIC													
TOTAL SCORE		18.0	+	5.0	10.2	+	4.0	4.4	+	3.7	14	25	7
Max isometric lifting													
	knee	127	+	40	59	+	27	25	+	17	11	17	0
	waist	79	+	26	47	+	20	31	+	16	20	34	7
Psychophysical lifting													
	knee	75	+	29	34	+	17	15	+	11	14	19	7
	waist	51	+	20	26	+	11	18	+	8	17	28	7
Cardiovascular fitness		2.5	+	0.7	2.1	+	0.5	2.0	+	0.6	14	65	67

\*TEF & TR measures peak torque in ft lbs. Lifting measures peak force in lbs (mean +/-SD). False positive and negative rates based on cut-offs of normal mean - 1 x SD.

Table 5.8: A comparison of the ability of isokinetic measures, isometric measurements, and clinical observations of physical impairment to discriminate individual patients from normal subjects.

		Male		Female	
		Normal Subjects	Patients	Normal Subjects	Patients
Predicted on the basis of isokinetic measures	normal subjects	27	9	28	7
	patients	8	50	6	55
	Accuracy	82%		86%	
Predicted on the basis of isometric and psychophysical measures	normal subjects	27	13	29	6
	patients	8	46	6	55
	Accuracy	78%		88%	
Predicted on the basis of clinical observation of physical impairment	normal subjects	33	18	33	16
	patients	2	41	2	38
	Accuracy	79%		80%	

Table 5.9: Correlation between isokinetic variables and the main clinical variables

Isokinetic Measures	Physical Impairment	Pain Scale	Disability	Work loss in past year	MSPQ	Depressive symptoms	Overt pain behavior	Behavioral signs
Male								
TR left 150	0.37	-	-	0.60*	0.36	0.31	0.34	0.38
TEF ext 90	0.36	0.35	.44*	0.68*	0.45*	0.43*	0.40*	0.46*
TEF flex 90	0.37	0.37	.47*	0.58*	0.34	0.33	0.45*	0.52*
Liftask 36	-	0.32	0.39	0.51*	-	-	-	-
Isokinetic total score	0.37	-	0.38	0.63*	0.33	0.33	0.34	0.40*
Max isometric	-	-	-	0.43	-	-	-	-
Psychophysical	-	-	-	0.39	-	-	-	-
MaxVO2	-	-	-	-	-	-	-	-
Physical impairment		-	+0.47*	+0.58*	+0.37*	-	+0.46*	0.54*
Female								
TR left 150	0.36	-	-	-	-	-	-	-
TEF ext 90	0.33	-	-	-	-	-	-	0.34
TEF flex 90	-	-	-	0.47*	-	-	-	0.39
Liftask 36	0.43*	-	0.3	0.35	-	-	0.32	0.42*
Isokinetic total score	0.41*	-	-	0.38	-	-	0.34	0.45*
Max isometric	-	-	-	0.38	-	-	-	-
Psychophysical	-	-	-	-	-	-	-	-
MaxVO2	-	-	-	-	-	-	-	-
Physical impairment		-	-	-	-	-	-	-

Pearson correlation coefficients

significant correlations only shown ( $p < 0.01$ ) \* $p < 0.001$

all correlations negative unless stated +ve

Table 5.10: Means & standard deviation for psychometric measures 20 patients completing reliability study

	before test 1	before test 2	after test 4
Mc Gill Pain Scale	48.7 ± 22.5	45.9 ± 23.1	36.5 ± 20.8**
Roland & Morris Disability	9.4 ± 5.0	8.9 ± 4.9	7.1 ± 5.1*
Fear Avoidance Beliefs Physical	17.2 ± 5.6	14.0 ± 5.1*	10.3 ± 5.4***
Fear Avoidance Beliefs Work	17.5 ± 5.3	17.1 ± 5.0	13.6 ± 6.0*
Modified Somatic Perception Q.	4.1 ± 4.2	4.6 ± 4.5	3.8 ± 3.7
Zung	16.8 ± 10.2	15.6 ± 8.3	13.5 ± 7.9

Paired t-test \* p < .05 \*\* p < .01 \*\*\* p < .001

## **PART 3**

### **DEVELOPMENT AND EVALUATION OF AN ISOKINETIC SPINAL REHABILITATION PROGRAMME**



## CHAPTER 6

### Literature review of exercise approach to management of chronic low back pain

#### 6.1 Introduction

Rehabilitation of patients with chronic low back pain is currently very topical as the problem appears to be increasing, suggesting that previous methods of rehabilitation have been unsuccessful (Waddell 1992).

There is evidence to suggest that both general and specific trunk deconditioning occurs in patients with chronic low back pain. The patient may also develop mental passivity, dependence and depression (Mayer *et al* 1985b). The patient's actual or perceived level of deconditioning affects the way they react to any subsequent episode of back pain or attempt at rehabilitation. It is therefore important to quantify the level of deconditioning that has taken place in the trunk and to be able to monitor any change over the course of a rehabilitation programme. It has been suggested in the literature that isokinetic machines have been successful for these purposes (Mayer *et al* 1985b, Hazard *et al* 1989). A number of isokinetic machines are now being marketed as rehabilitation tools, but their effectiveness has not been widely tested.

The aim of Part 3 of the of the thesis was to develop a new rehabilitation programme for chronic low back pain using the isokinetic machines both as treatment devices and as a method of monitoring progress during treatment. To date no such programme has been described. The isokinetic machines have been used to monitor the progress of other rehabilitation methods in several studies (Mayer *et al* 1985b,

Hazard *et al* 1989). Personal visits to centres in North America with isokinetic machines only identified one centre using them as part of a rehabilitation programme. It is not clear why isokinetic machines are not being used more widely for this purpose but one possible reason is the time consuming aspect of setting up and supervising the patient while using the machines. This proved to be one of the main disadvantages identified in the previous standardisation study using the same machines (see chapter 5). The other treatment centres visited were using strengthening machines which were less sophisticated but easier and quicker to use.

## **6.2 Isokinetic exercise**

The manual for the isokinetic machines (Cybex 1989) states that “clinical researchers have demonstrated that chronic low back pain patients who were rehabilitated using Cybex Back Systems exhibited significant improvement in objective physical measures,” but offer no references to substantiate this claim. One study did report the use of an isoinertial machine as an addition to a comprehensive rehabilitation programme (Sachs *et al* 1994). In this study patients were randomly allocated into three groups: a standard work tolerance programme, a standard work tolerance programme plus exercise on an isoinertial machine, and a control group. All subjects were assessed on the isostation before and three weeks after the exercise programme. The results failed to find any benefit from the addition of the isoinertial exercise. As the isoinertial exercise only consisted of 15 minutes additional to a six hour programme of various exercises it is hardly surprising that no additional benefits were reported. Timm (1991) also reported the use of isokinetic exercise as part of a rehabilitation programme for low back pain. The subjects in this prospective study

were divided into four groups, each taking part in a different rehabilitation programme one of which included isokinetics. The results appear impressive (100% return to work), but the trial was neither randomised nor controlled and the isokinetic exercise was "specific to the rehabilitation requirements of each subject" making it impossible to reproduce the study. The same researcher has reported a case study (Timm 1987) using isokinetic exercise along with cardiovascular exercise, cold modalities and a home exercise programme. The patient had chronic low back pain and had undergone triple back surgery. After a month of the programme he was free of back pain for the first time in three years. After a further month he had resumed all desired activities and maintained this improvement at a six week follow up assessment. Unfortunately it is not possible to single out isokinetic exercise as the cause of the improvement as he was receiving other treatment at the same time. Risch *et al* (1993) conducted a controlled trial using dynamic variable resistance with machine designed to test and rehabilitate lumbar extensors (Medx Ocala Florida). The results showed a significant improvement in isometric strength and a significant reduction in pain for the treatment group compared to the control group. However the improvements were not related to changes in activity or psychological distress.

### **6.3 General exercise**

Although there is limited literature on isokinetic exercise there is more written on an active exercise approach to rehabilitation of chronic low back pain. This literature was reviewed to provide a theoretical background for the use of exercise as a method of rehabilitation.

Exercise has been used in the rehabilitation of spinal problems since the 19th century when Delpeche described a programme of treatment for patients with spinal deformities such as scoliosis (Peltier 1983). This programme included patients climbing up rope ladders and swinging from a trapeze. However there was no mention of the programme being used for chronic low back pain as this was not seen as a problem at that time.

In 1983 Jackson and Brown reviewed the literature and found no rationale for exercise treatment to improve the mechanical stability of hypermobile joints, control pain, improve posture or decrease mechanical stress, but did find evidence that exercise could improve fitness, strength and flexibility, and decrease stress and depression. Deyo (1983) reported poor methodology and inconclusive results from a review of six studies of exercise regimens. A recent blinded review of 23 papers by Koes *et al* (1991b) also suggested that the role of specific back exercises was inconclusive. Various types of specific exercise regimes (e.g. Williams flexion exercises and McKenzie extension exercises) have been advocated for the treatment of low back pain during the past few years with each enthusiast for their type of treatment maintaining it is the best, making the situation contradictory and confusing. One author found no difference between flexion and extension exercises (Elnaggar *et al* 1991). Other leading authors in the field suggest that theoretical evidence is growing in favour of an active exercise approach rather than any specific exercise (Nachemson 1983, Waddell 1992).

Exercise is in fact emerging as a key element in recent promotions for national health recommendations (Dargie and Grant 1991). Several of the targeted diseases have 'life-style' elements amenable to change by exercise. As the literature is reporting similar

'life-style' elements which may correlate with low back pain (Battie *et al* 1989b, Deyo and Bass 1989, Bortz 1984) it is feasible that exercise will be beneficial in the treatment of low back pain. The musculoskeletal system responds well to movement at all ages and adversely to immobility (Bortz 1984, Twomey and Taylor 1994). Exercise physiology studies report the benefits of exercise such as increased nutrition to ligaments and discs, increased muscle strength, increased aerobic capacity (Astrand 1987, Twomey and Taylor 1994). The Psychology literature also suggests several benefits of exercise such as reduced anxiety and depression (Folkins and Sime 1981, Morgan 1985) and a tranquillising effect (De Vries 1981). De Vries suggests that the mechanism for this tranquillising effect is reduced tension due to rhythmic exercise such as walking, jogging or cycling. Although mechanisms for the psychological benefits of exercise are likely to operate in a synergist way (Biddle and Mutrie 1991) the most important psychological aspect could be the sense of mastery and control. The sense of control must be perceived as personal rather than attributed to external factors such as therapist's encouragement or medication which can undermine the patients sense of control (Dolce *et al* 1986). Patients who attribute their improvement to their own efforts are less likely to relapse. Unfortunately the current status of the physical activity undertaken by the adult population in Great Britain is low. The Allied Dunbar National Fitness Survey (1992) found that 70% of adults in all age groups were under an acceptable level of activity that would have health benefits. In addition 80% of adults believed themselves to be fit and the majority of subjects incorrectly thought they did enough exercise to keep healthy.

The role of aerobic fitness in prevention of low back pain and improving recovery from the symptoms is receiving attention (Battie 1991). It has been suggested in the

literature that fit patients experienced less back pain than unfit patients (Cady *et al* 1979). Cady *et al* discovered an inverse relationship between the level of fitness and subsequent incidence of low back pain in 1652 fire-fighters. Those with high levels of fitness were 10 times less likely to develop back pain than those with low levels of fitness. This suggestion has largely gone unchallenged although Battie *et al* (1989b) could not identify a composite score that would predict back pain using aerobic capacity, isometric strength, and flexibility measures in a study of back pain complaints in aircraft manufacturing workers. While the problem of cardiovascular fitness may not affect the risk of having an episode of back pain it may affect the response to the problem and especially the vital issue of recovery.

Although the role of fitness in the prevention of chronic low back pain is still equivocal there is evidence to suggest that patients with this symptom have become less fit. In a study attempting to identify "healthy backs" Hultman (1987) found that men who had not experienced low back pain took part in physical activity during their leisure time and did low intensity training to maintain their levels of fitness. McQuade *et al* (1988) found physical fitness, especially strength, accounted for 23% of the physical dysfunction in patients with chronic low back pain. Karvanoman *et al* (1980) in a study of young men in military service found that those with a history of lumbago performed poorly during a 12 minute run. This suggests there is a place for aerobic type of exercises in the rehabilitation of chronic low back pain and these are currently a component of several programmes.

#### **6.4 Trials of therapeutic exercise.**

An early trial of vigorous exercise by White (1966) did not demonstrate good results but this study only included problem patients, who were not representative of those with chronic low back pain. The author commented that continuing with unsuccessful treatment for more than 6 weeks is harmful and leads to low morale. Catchlove and

Cohen (1982) reported that 60% of patients returned to work following a rehabilitation programme which included a directive to return to work as a component part. This was the first time that such a directive had been employed. The results were impressive as the patients were Workers Compensation patients whom the previous study by White (1966) had reported a low return to work rate of only 20-30%. Return to work has been suggested as an important factor in reducing chronicity (Nachemson 1983).

Non-randomised controlled trials of an intensive comprehensive programme, guided by objective measurement using isokinetic trunk strength measurements, have reported extremely good results. Mayer *et al* (1985b) in a trial of patients with chronic low back pain reported an 87% return to work for the treatment group compared with a 40% return for the controls. Hazard *et al* (1989) replicated the programme and reported a comparable 81% and 40% return to work for the two groups. However these studies were not randomised and there was a danger that they were commercially orientated, as they were currently being marketed in North America as an 'innovative' approach to the management of chronic low back pain known as Functional Restoration. This is a three week residential programme employing multidisciplinary staff and as such expensive to run. Reservations as to the validity of the studies have been expressed by Teasell and Harth (1996) and comparable approaches to rehabilitation have proved less successful. Ohland and Tveiten (1991), in a different cultural setting with a similar programme, reported a 23% return to work. Mitchell and Carmen (1994) in the only randomised study found return to work rate for the treated group and the control group was the same. However in the latter study management of the control group was left in the hands of

the primary care provider and the facilities available in the community. These were reported to include physiotherapy, work hardening, back schools, and active exercise using a sports medicine approach. As several, or indeed all, of the control group could have been participating in an equally intensive programme as the functional restoration programme, it is not surprising that the return to work rates were similar.

Other randomised trials of an intensive approach to treatment included subjects who were at work but identified as potential chronic low back pain sufferers. The first trial (Linton *et al* 1989) was of workers suffering from recurrent back pain who undertook a daily eight hour programme of exercise and education. The results showed a significant decrease in the patients' ratings of pain, anxiety and fatigue. The second trial (Harkappa *et al* 1989) compared in-patient and out-patient programmes. The results showed a decrease in pain in both groups when compared with a control group. Although multidisciplinary programmes have reported good results the role of each intervention again remains unclear and the value of these programmes has recently been questioned (Linssen & Spinhoven 1992).

An attempt to evaluate the behavioural component of these programmes was the purpose of a trial by Turner *et al* (1990) who compared a combined behavioural/exercise regime with exercise alone. Ninety-six chronic low back pain patients were randomly allocated to a programme of combined exercise/behavioural therapy, behavioural therapy alone, or exercise alone. The combination programme gave better results suggesting that the behavioural part of the programme was beneficial. Sachs *et al* (1990) studied a less intensive programme in a work situation with no psychological input. The results were similar to the more intensive programmes. This indicated that perhaps it was not necessary to run an expensive



programme to achieve the same results and a psychological input was not necessary. Indeed in a trial reported by Deyo *et al* (1990) there was improved pain relief and greater levels of activity after an exercise programme of only 1/2 hour daily lasting for 4 weeks. This was a controlled trial comparing active and sham transcutaneous nerve stimulation both alone and combined with exercise for patients with chronic low back. Unfortunately two months after the active intervention most of the patients had discontinued the exercise and the initial improvements had been lost. The effect of supervision was investigated in a work situation by Reilly *et al* (1989) who reported better compliance with the supervised group suggesting that self-supervised exercises may have a lower compliance rate than supervised exercises.

Rehabilitation programmes based in work sites have reported benefits from a variety of exercise programmes. Kellett *et al* (1991) reported less episodes of back pain and less time off work after exercising for an hour twice a week. This year long trial was a randomly allocated 111 workers with recurrent low back pain to an exercise group or a no treatment group. This was an inexpensive, easily organised exercise programme within the possibilities of most work places. Other 'in house' treatment programmes for workers have reported good results. Dehlin *et al* (1981) reported no change in low back symptoms but an improved psychological perception of their work in a group of Nursing Aides with recurrent low back pain who took part in rehabilitation programme. Donchin *et al* (1990) also studied workers in a controlled trial comparing callisthenics exercise and a back school. The callisthenics exercise was administered in groups for 45 minutes, biweekly for three months and was more effective than the back school in reducing the number of recurrent low back pain episodes.

In a Danish study Manniche *et al* (1988) precisely described three simple exercises to rehabilitate patients with chronic low back pain. The 105 patients were randomly allocated to three groups; a group exercising for 90 minutes, a group exercising for 45 minutes and a placebo group. The exercises took place three times a week for 12 weeks. The authors reported a statistically significant favourable result for the intensive group over the other groups both at completion of treatment and at 3 month follow up. They suggested that the 12 weeks duration was necessary as several patients were no better at four weeks. They also suggested that an exercise regime should be a life time commitment. Hansen *et al* (1993) used the same three exercises when they studied 150 men and women with chronic or subacute low back pain employed by Scandinavian Airlines System. This was a randomised double blind trial of three groups; intensive exercises, standardised physiotherapy, and placebo controls. All groups, including the placebo group, were allocated one hour, twice a week for four weeks of treatment. The surprising result of this trial was that the females improved with the intensive exercise whereas the males improved with the standard physiotherapy. Unfortunately these results cannot be directly compared with the results of the previous trial in which males and females were not reported separately. However Manniche and co-workers also maintained that four weeks not long enough for the exercise programme to take effect as several patients were worse at that stage in their study, but later went on to improve.

A recent British study (Frost *et al* 1995) randomly allocated patients with chronic low back pain to a fitness programme and a control group. Both groups were taught home exercises and attended a back school. The treatment group also attended eight exercises classes over a four week period. This group showed a significant

improvement in disability, pain, self efficacy and walking distance over the control group. The authors suggested that the programme would be easy to run and would not require any expensive equipment.

Although this literature review was not concerned with treatment of acute low back pain, one reference was reviewed as it was seen as a land mark report on the use of exercise for low back pain. Fordyce *et al* (1986) studied the effects of an exercise approach to acute low back pain using exercise quotas, while not allowing the patient to use pain as their guide. This is an issue which was not addressed in the studies in general, but is fundamental to the rehabilitation of chronic low back pain. Its importance is that Fordyce and his co-workers found that pain contingent management (rest until the pain goes away) prolonged the symptoms report and activity limitations. A randomised controlled trial (Lindstrom *et al* 1992) used this exercise quota approach when comparing routine care only with routine care plus an activity programme in a study of workers with sub-acute low back pain and found the graded activity programme returned subjects to work more quickly, and significantly reduced long term sick leave relative to routine care.

## **6.5 Conclusion**

These published studies suggest that an exercise approach is beneficial for patients with chronic low back pain. However the literature raised several issues which should be considered in planning future trials. The optimum amount of exercise was impossible to interpret as treatment intensity ranged from 1½ hour to eight hours, its frequency from biweekly to daily and its duration from three weeks to one year with one group of authors (Manniche *et al* 1988) suggesting four weeks was too short.

Several treatment programmes were multidisciplinary and included a behavioural and/or a psychological input. Supervision of programmes was reported and suggested as a means of ensuring adherence but unsupervised programmes were also used. In several programmes exercises were done in groups, involving the elusive "group effect". Wagstaff (1982) has suggested that group participation can lead to better compliance as patients who are fearful and perhaps unmotivated will learn, accept, and carry out instructions if they see a patient similar to them doing this i.e. modelling themselves on another patient. This observational learning is one of the main modes of acquisition of new patterns of behaviour (Klaver Moffet and Richardson 1995). Return to work has been reported as part of the treatment programme and as an outcome measure.

## **CHAPTER 7**

### **Isokinetic rehabilitation studies**

#### **7.1 Introduction**

This chapter describes the development and initial evaluation of a rehabilitation programme for patients with low back pain using isokinetic machines. As no previous studies using isokinetic exercise had previously been reported an initial pilot study was done to investigate potential problems with this mode of exercise. This study examined the tolerance of the patients to an isokinetic exercise programme and the compliance to six weeks duration. Based on the results of the first study, the second study examined the problem of adherence to the exercise programme and the time course of response to the exercise.

The studies tried to address the issues raised in the literature review, but there were several restrictions which were impossible to overcome. The main disadvantage of the isokinetic machines revealed in the standardisation study was the time of one hour it took to set up and test a single patient. This means a single operator can only test or treat a limited number of patients in one day, as only one patient at a time can exercise on the machine.

The studies were conducted by the Research Physiotherapist who administered the questionnaires, tested and treated the patients. While it is recognised that the person testing should be blind to the treatment (Bloch 1987, Deyo 1993), it was not possible to achieve this in these studies. However the researcher was blind to the clinical and psychometric assessment and tried to be as impartial as possible. The instructions used

in the standardisation study were strictly adhered to during the testing sessions and an equal amount of time was spent with each patient.

The exercise programme was the same for both studies and was based on an understanding of the functional anatomy of the lumbar spine, science of soft tissue healing, exercise science, the adaptive changes of the musculoskeletal and cardiovascular tissues as a result of deconditioning, and the influence of the central nervous system on motor behaviour. Bohannon (1990) reviewed studies of normal subjects and from these suggested guidelines for patients:

- intensity should be as close as possible to the patient's maximum capacity
- frequency should be more than twice a week
- duration should be several weeks (normal subjects at least 6 weeks)

The focus of the programme was active restoration of function to enable the patient to take responsibility for his own rehabilitation. Pain was not dealt with by any passive treatment and care was taken not to reinforce pain behaviour. There was no additional formal psychological component to the programme. The exercises were supervised but were not performed in groups thereby excluding a 'group effect'.

## **7.2 Isokinetic rehabilitation study 1**

It is unlikely that an individual will adhere to a type of exercise which is uncomfortable, not enjoyable because of duration or intensity, or is inconvenient in terms of its frequency (Dishman 1982). The first study was planned with the following aims

- 1 to determine the amount of exercise patients could tolerate in one exercise session
- 2 to report any incidence of muscle pain severe enough to stop the patient exercising
- 3 to determine the compliance of patients attending a 6 week exercise programme

#### 7.2.1 Subjects

The patients had to satisfy the selection criteria used for the isokinetic standardisation study and also live within travelling distance of the hospital and be willing to travel regularly for treatment. The patients were identified by the Orthopaedic Consultant or one of his team during a routine out-patient clinic. They were selected in two groups due to time restraints over a holiday period but the intention was to analyse them all together.

#### 7.2.2 Assessment

The patients completed a consent form to take part in an exercise programme (Appendix 10). The isokinetic assessment protocol was a modified version of the main isokinetic protocol. The tests were conducted in exactly the same way as in the standardisation study. The patients also completed the questionnaires used in the reliability study; Short-form McGill Pain Questionnaire, Roland & Morris Disability Questionnaire, Fear Avoidance Beliefs Questionnaire, Modified Somatic Perception Questionnaire (MSPQ), Zung Depressive Inventory. The work status of the patients was also recorded. The patients then completed a six week exercise programme and the assessment was repeated.

### 7.2.3 Exercise programme

The exercise protocol consisted of 5 sets of 10 repetitions over 3 velocities; 60, 90, 120 degrees/second. The order of sets increased in velocity from 60 degrees/second through 90 degrees/second to a maximum velocity of 120 degrees/second. Thereafter velocity decreased back to 90 degrees /second and ended with the lowest velocity of 60 degrees/second. Progression was made by increasing the number of repetitions by two/week up to 20.

The exercise programme was based on quotas. The patient was asked to complete a set amount of exercise during each session and encouraged to keep to the quota. The patients were also given visual feedback while they were executing the exercises. The monitor displays the exercise screen which graphically presents the torque scores in the form of a bar graph. Marker bars display the peak torque which the patient can attempt to reach with each repetition.

The amount of time the patients exercised on the machines was approximately 40 minutes, three times a week for six weeks.

### 7.2.4 Results

No patient dropped out of the study due to back pain caused by the isokinetic exercise. However 36% of the patients failed to complete the study. All 10 patients in the first group completed the 6 weeks programme except one who missed the final assessment due to an unrelated illness. From the second group five of the 16 patients failed to attend for their first appointment. One patient broke her leg, two patients could not find a baby sitter, and two failed to attend despite a repeat appointment being sent therefore



no reason could be given. A further three patients dropped during the treatment programme. Again baby sitting problems were given as the reason for one patient, one had various unrelated illnesses and one could not be contacted.

The results for the remaining 17 patients were analysed together. The results from the isokinetic scores showed a significant increase from pre to post treatment (Table 7.1) for most of the measures. The overall percent change was 40%. The results of the questionnaires also showed a significant improvement for McGill Pain Scale, Roland and Morris Disability Questionnaire and Fear Avoidance Beliefs Questionnaire (Table 7.1). The results for return to work showed that five of the six patients who were off work, with their job open, returned to work. None of the six patients who had lost their jobs returned to work but one started retraining for another job. The nine patients who were at work remained at work.

#### 7.2.5 Discussion

The overall improvement for the self assessment questionnaires in particular the McGill Pain Scale, Roland & Morris Disability Scale and Fear Avoidance Beliefs suggested that cognitive and behavioural factors played an important role in the rehabilitation process. It also suggested that cognitive and behavioural changes can take place without overt psychological therapeutic interventions as these were not used in the programme. These results agree with those reported by Sachs *et al* (1990).

The mean percentage increase of 40% on the isokinetic scores must be compared with the 20% increase from test 1 to test 2 in the reliability study leaving a 20% increase for the exercise programme.

The major problem identified was the high dropout rate at the beginning of the study. Although one of the aims of the study was to investigate the compliance to a six week programme it was expected to be the length of the programme which might be a potential problem. The number of patients who failed to attend for their first appointment was surprisingly high considering only five out of 125 patients failed to attend during the standardisation study. The number of patients dropping out during the programme was also unexpected as only one patient out of 20 dropped out of the reliability study and that was because he refused to repeat the questionnaires. It does however highlight the question of compliance and of patient selection. It is possible that as no patient dropped out of the first group that inadvertent careful selection of the patients was the reason. It could be argued that selecting patients who are most likely to benefit from an expensive rehabilitation programme makes sound economic sense. However these patients are not representative of the whole population of those with chronic low back pain, threatening generalisation of the results. The solution would be an attempt to improve and measure compliance as suggested by Deyo *et al* (1991). Compliance has been described as a neglected area in research into low back pain (Turk and Rudy 1990) and failure to document and report dropouts has been a major criticism of previous trials (Deyo 1983).

It is reasonable to assume that the length of the study could have contributed to the dropout rate. The patients were told at the beginning of the programme that it would last for six weeks whereas the patients in the reliability study were only asked to attend for two weeks.

Another problem revealed by the pilot study was the use of 'return to work' as an outcome measure. If the patient is off sick with their job still open then 'return to

work' is a good hard outcome measure and defines the transition from the sick role to an active social position. However it is unrealistic to expect a rehabilitation programme to affect the work status of patients who have lost their job as return to work is a complicated social and economic problem (Mayer et al 1985b)

There are several factors influencing return to work. From the medical point of view return to work indicates a relative freedom from disabling symptoms and dysfunction. The medical practitioner may not be able or willing to initiate the return to work and may wait for the patient to indicate that he is ready to go back to work. The patient, on the other hand, is waiting to be instructed to return to work. The situation could result where both the doctor and the patient were waiting for the other to make the decision, prolonging the absence. Obviously different doctors will approach the problem in different ways depending on their understanding of the patient. The doctors could also have varying knowledge of the physical requirements of the patients job and perhaps have a misconception of how arduous and demanding it is. The reluctance to send the patient back to work could have the effect of confirming in the patients mind that there is something seriously wrong.. In addition the patient may have a job which requires a clearance by the company doctor for return to work. The employer may then be reluctant to take the employee back until they have been declared fully fit.

One encouraging result was that no patient dropped out because of increased back pain resulting from use of the isokinetic machines. In fact several patients commented that they felt secure exercising within the constraints of the machine.

### 7.2.6 Conclusion

The isokinetic programme appeared to be suitable, safe and successful for patients with chronic low back pain. However there was a major problem with compliance which will be investigated in the following study. As the length of the programme was a possible cause of patients dropping out, it will be necessary to determine the optimum length of treatment to gain maximum benefits and make the programme as cost effective as possible. In addition continuing with unnecessary treatment after a plateau is neither cost effective nor useful to the patient (Deyo 1993).

## **7.3 Isokinetic rehabilitation study 2**

### 7.3.1 Aims of the study

1. To investigate the problem of compliance
2. To determine the time course of response to isokinetic treatment
  - a) to determine how much clinical improvement occurs with isokinetic assessment alone compared with isokinetic treatment
  - b) to compare the relative effectiveness of a 3 or 6 week treatment programme

### 7.3.2 Study design

A full clinical examination was conducted including the range of movement measurements of flexion, extension, lateral flexion and straight leg raising. To help identify dropouts the initial assessment included questions on smoking, downtime (the amount of time a patient spends resting during the day) and social class. Convenience was measured by questions about distance to travel, type of transport used and time spent travelling. The self report questionnaires were completed at the clinic allowing this data to be available if the patient failed to attend for their first treatment appointment. In order to compare isokinetic test effect with isokinetic treatment effect testing was done on two initial visits, after three weeks treatment and six weeks treatment.

An attempt to improve compliance was made by giving patients appointments at convenient times, including evenings. Patients were also given feedback on their progress.

### 7.3.3 Subjects

The subjects were 52 patients who satisfied the selection criteria for the standardisation study (ch 5.2.2). The subjects had to live within a 25 mile radius of the hospital and be willing to travel on a regular basis for treatment, their characteristics are shown in Table 7 2

### 7.3.4 Method

The subjects were given a full clinical examination by either the Orthopaedic Consultant or the Clinical Assistant. If suitable for inclusion the patients were invited

to take part in the research the nature and purpose of which was explained by the examiner. The subjects completed the self report questionnaires at the clinic. They were given a convenient appointment by the Research Physiotherapist who also explained the nature and purpose of the programme. A telephone number was requested to enable contact to be made if the patient failed to attend.

An isokinetic assessment was made on each of the first two visits before treatment was started. The second assessment was taken as the baseline measure for treatment effect. On arrival at the third visit the clinical measurements and the questionnaires were repeated before the treatment started. The complete isokinetic, clinical and psychometric measures were repeated again at the end of three weeks and six weeks treatment.

### 7.3.5 Results

#### 7.3.5.1 Compliance

Thirteen of the 52 patients dropped out of the study thus compliance was improved but remained low enough to allow analysis of the results. Two patients failed to attend for their initial appointment and could not be contacted. A further 11 dropped out during treatment. One had various unrelated illnesses, one was advised not to attend until his compensation claim was settled, one was self employed and could not afford the time, one sought help elsewhere as she was not satisfied with the diagnosis she was given, one left the vicinity for work, one was a single parent with no child minder, two left home as they were in the process of a divorce and the others could not be contacted.

The results from t-tests and chi-squared tests failed to identify dropouts from characteristics (Table 7.2), work variables (Table 7.3), social variables (Table 7.4), physical variables (Table 7.6), or self report variables (Table 7.7). The only significant effect was for initial medical examiner  $p=0.01$ . (Table 7.2). There was a tendency for the dropouts to have higher resting heart rate and lower Max  $VO_2$  than the subjects who completed the study. There was no difference in Roland and Morris Disability Score and no difference in downtime between the subjects who completed and those who did not. There was also a tendency for the dropouts to have lower isokinetic scores than the subjects who completed the study.

The 39 patients who completed the study were analysed together. The means and standard deviations for the isokinetic variables, self report questionnaires and range of movement variables for the 4 tests are shown in Tables 7.6, 7.7 and 7.8.

#### 7.3.5.2 Effect of isokinetic testing

The results demonstrated a significant increase from test 1 to test 2 for all the main isokinetic measures except rotation at 150 degrees/second and extension at 120 degrees/second. There was no significant increase for the isometric or psychophysical measures.

The results for the self report questionnaires demonstrated a significant test effect for Roland and Morris, McGill Scale and Fear Avoidance Beliefs.

The results for the range of movement variables demonstrated no testing effect. In fact lumbar flexion decreased significantly while all other measures either decreased slightly or stayed the same.

#### 7.3.5.3 The effect of 3 weeks treatment with isokinetic exercise

From test 2 to test 3 all isokinetic measures improved significantly except Liftask.

There was no significant improvement in isometric or psychophysical measures.

The self report questionnaires for Roland and Morris, McGill Scale and Fear Avoidance Beliefs again improved significantly. The Zung depression score showed a significant decrease but the MSPQ decreased very little.

The range of movement measures which demonstrated a significant improvement were total extension and straight leg raising with no other measure changing over the 3 weeks of treatment.

The fitness measure of resting heart rate and Max  $\text{VO}_2$  showed a significant improvement over the three weeks of treatment.

#### 7.3.5.4 The effect of 6 weeks treatment with isokinetic exercise

There was limited improvement for the isokinetic measures after a further 3 weeks treatment. From test 3 to test 4 the only isokinetic measure to show a significant improvement was isokinetic flexion at 120 degrees/second and 150 degrees/second.

No range of movement measure improved except lumbar flexion which increased significantly. Max  $\text{VO}_2$  showed a significant improvement but not resting heart rate. No self report measure improved significantly.

At the end of the programme seven of the 13 patients (53%) who were off sick had returned to work. One patient had started a university course and another had returned to nursing training. Unfortunately two further patients lost their jobs. One



was made redundant from the cleansing department and the other either resigned or lost his job as a postman.

### 7.3.6 Discussion

#### 7.3.6.1 Compliance

The study failed to identify potential dropouts from the initial demographic, work, social, psychological or physical variables. The only variable to identify dropouts was the initial medical examiner. This examiner effect was unexpected as no such effect has been reported in the literature. In addition the same physiotherapist followed the explanation by the two doctors with a further explanation. It is reasonable to assume this could have diluted the effect of the different examiners. However it does highlight the doctor/patient relationship and the part it plays in compliance to prescribed treatment.

It has been suggested that maximum adherence to a treatment depends on a fit between the recommended treatment and the patients perception of the problem and his understanding of how it can be treated (Turk and Rudy 1990). If the patients expectation of a consultation with an orthopaedic specialist was a 'cure' for his back pain then to be told that there is no surgical solution to his problem could be disappointing. To be further told that no identifiable cause for his low back pain is evident could add to the problem especially if the patient refuses to believe the specialist. One of the dropouts did in fact admit to seeking a further opinion elsewhere as she was not satisfied with the explanation given. Other patients reported anger or dismay at the result of the consultation.

Deyo and Diehl (1986) have reported that the source of patient dissatisfaction when seeking care for low back pain was the failure to receive an adequate explanation of the symptoms. Cherkin *et al* (1991a) identified a negative attitude held by physicians to patients with low back pain and implemented an education programme for primary care physicians aimed at improving the physicians perceptions of their back pain related confidence, knowledge and skills, in an attempt to improve their effectiveness with patients satisfaction with the outcome of a consultation for back pain. In a follow up study of acute and chronic patients (Cherkin *et al* 1991b) found no improvement in patient satisfaction with the consultation even although there was an increased number of doctors who thought their patients were satisfied with the consultation. The programme improved the confidence of the physicians but did not improve their negative attitude.

Failure to communicate effectively has also been suggested as a reason for non compliance with prescribed treatment. Obstacles to communication between the medical profession and the layman can be larger than necessary either by lack of empathy or deliberate use of medical terminology to preserve dominance. In the past the model patient was required to be uncritical, submissive and appreciative of care. In a non hospital setting this would lay the person open to a charge of naive idiocy (Fitzpatrick *et al* 1988). Patients can appear to collude with this by not questioning the examining doctor but may simply be afraid to ask questions. One patient in the current study went home and looked up degeneration in the dictionary and was then convinced he was going to end up in a wheelchair.

Satisfaction with the consultation, with communication and in general with the medical care received are all correlated with patient compliance (Fitzpatrick *et al*

1988). Patients were more satisfied when the doctors indulged in friendly talk, if the patient was allowed to talk at least as much as the doctor and if the patient felt they had been able to express their concerns and they had been understood (Fitzpatrick *et al* 1988).

Physician/patient communication has been reported by Deyo and Deihl (1986) as lacking in therapeutic content. As the communication between the patient and the doctor in the current study was not standardised in any way it is impossible to determine if the two medical examiners were giving the same explanation or even if the one examiner was giving the same explanation to each patient. Lacroix *et al* (1989) reported patients indulged in self diagnosis and may develop naive theories about their condition that may then guide their compliance with treatment regimes. It is important for patients to understand what is wrong with them and how treatment will help. An effective communicator is able to persuade by virtue of credibility, likeability, enthusiasm, and trustworthiness (Fitzpatrick *et al* 1988). The credibility of the medical examiner could be taken as present. The patient was attending a back clinic and would therefore assume the attending doctors to be experts. Trustworthiness is taken as implied as most patients trust the medical profession. Enthusiasm was evident in at least one of the examiners who had the high attendance rate. The most likely stumbling block could be likeability as it is difficult to build up a rapport in the space of a short consultation (Fitzpatrick *et al* 1988, Roland *et al* 1986).

The characteristics of the message which makes for persuasion is more complex. In the medical setting the message is likely to be one sided with the recipient having little or no opportunity to contribute. Many medical exhortations are crudely stated and baldly repeated, making it possible the audience will reject the advice and dislike the

source. A more gradual approach which recognises that life style change are difficult and require a change of attitude on the patients part is more likely to be well received. It is recognised that a brief interview cannot be relied on as the sole agent of change but what happens during that interview can affect the patients attitude to the suggested treatment.

If compliance is to be active involvement based on understanding time has to be taken to talk to the patient bearing in mind that anxiety and fear alter the way a person listens and remembers.

#### Dropout rate

Although the dropout rate was reduced it remained at 25% which is slightly higher than other authors have reported. The lowest rate of 7% was reported by Hazard *et al* (1989, 1991) for a three week intensive rehabilitation programme. A similar low rate (10%) for the same programme was reported by Mayer (1985) although it is not clear who are included in the dropouts. Both Manniche *et al* (1988) and Deyo *et al* (1990) reported a 14% dropout rate, the former during a three month trial of intensive exercise and the latter during a six week trial of stretching exercise. However when Hansen *et al* (1993) compared the same intensive exercises with physiotherapy they found an overall rate of 12% but a higher rate of 21% from the intensive exercise group. Turner *et al* (1990) reported a dropout rate of 20 % for the exercise and a higher drop out rate for the behavioural group indicating that it was not the exercise per se which caused the patients to drop out. Kellet *et al* (1991) reported a high dropout rate of 23% overall but 36% from the exercise programme during a controlled trial of workers exercising for an hour twice a week. However as the study lasted 18

months a higher dropout rate might have been expected as rates of compliance drop as time passes (Sluijs and Knibbe 1991).

Several authors reported patients not taking up the offer once randomisation had taken place but did not include the numbers in the dropout rate. For example Hansen *et al* (1993) reported 180 patients randomised of which 11 did not take up the offer and 19 dropped out of treatment. The authors reported no significant difference for pain levels between the 19 dropouts and the 150 patients who completed the treatment. However the authors also report significantly higher median pain level at the time of entry to the study for patients who completed the treatments than those who were randomised and did not complete (n=30). It is not clear whether the patients who were randomised but did not take up the offer of a place actually refused the place or failed to attend the first appointment. In fact patients who are randomised and then fail to take up the place should be considered dropouts.

Oldridge and Streiner (1990) suggested a difference between avoidable and unavoidable dropouts should be considered. The unavoidable dropouts were described as having medical problems, moved away, or achieved their objective early and the avoidable as having psychosocial problems, job inconvenience, fatigued, or unable to contact. The designation of what constitutes a dropout should be agreed between researchers and clearly stated at the start of the study.

#### Reasons for dropping out

The patients who could be contacted were asked why they no longer wished to attend. Although it is recognised that simply asking people why they discontinue with the programme without due attention to the validity or reliability of their answers is an

inadequate approach (Dishman 1982). Knowing the reasons for dropping out may help to design compliance enhancing strategies in the future.

The reasons given for dropping out in the current study were social reasons such as inconvenience, transport and leaving home or unrelated medical problems. This compares with the reasons given by the patients in the few studies which reported reasons. Hansen *et al* (1993) reported social reasons for dropping out of a trial comparing intensive exercises, standardised physiotherapy and a control group. However Hansen also reported patients dropping out because of aggravated pain. Aggravated pain was also reported by Manniche *et al* (1988) in a trial of the same intensive exercises. Pain was also reported in a study of normal subjects (Smidt 1989) when 18 % dropped out because they developed back pain during a trail of isokinetic exercise. No patient reported that they dropped out of the current study because of aggravated pain.

Hansen *et al* (1993) reported a dropout rate of 12% overall but a 21% dropout for the dynamic programme suggesting the exercise was too much for some patients. No patient in the current study reported the exercise as too difficult. One patient had to reduce the amount of exercise for two sessions but this was due to an unrelated fall. Dishman (1982) suggested perceived excessive exercise as a reason for dropping out. It has been previously reported that patients with low back pain perceive their level of exercise on a treadmill to be greater than that perceived by normal subjects (Dolce *et al* 1986).

However not all researchers were interested in identifying dropouts or attempting to improve the dropout rate. Mayer *et al* (1985b) stated they were "only interested in

demonstrating the efficacy of the programme among those who were willing to complete.” They maintained that dropout was “always to due to the patients recognition that secondary gain aspects of their back pain would be threatened by getting well, not by physical incapacity.”

### Identification of dropouts

This study could not identify dropouts from demographic, work, social psychological or physical variables. Only three other studies tried to compare dropouts with subjects who completed the study (Hazard *et al* 1989, Deyo *et al* 1990 and Hansen *et al* 1993). One was an intensive rehabilitation programme (Hazard *et al* 1989) which found no significant difference between the groups for initial personal attributes, self assessment of pain, disability and depression, and physical capacity measures. Deyo *et al* (1990) found patients who dropped out and those who completed an exercise trial were similar with regard to most base line demographic, historical, physical and functional measures. Hansen *et al* (1993) found no difference between pain levels in patients who dropped out and those who completed the treatment. These results are consistent with the findings of the current study.

It has been suggested that patients who have a higher disability associated with disease are more inclined to adhere to a treatment programme (Dishman 1982). The current study could not confirm that suggestion as disability measured by the Roland and Morris Questionnaire demonstrated no difference (12.2 v 12.9) and the amount of downtime was slightly higher for the patients who completed compared to the patients who dropped out. The downtime ranged from 0 to 14 hours with two patients recording 14 hours. Surprisingly these two patients remained in the study.

Deyo (1991) suggests that patients who drop out tend to be at either end of a spectrum, either they recover quickly or they perceive less than dramatic improvement. He suggests that patients who have received multiple treatment in the past are used to assessing quickly if it will work.

Deyo *et al* (1990) suggested that the dropouts demonstrated a shorter duration of pain (24 v 60 months) but a greater severity than those who completed. Although the current study did not show a statistically significant difference between the two groups the drop outs did have a shorter duration (93 v 118 months) and a higher pain score (64.8 v 57.2) than those who completed. The dropouts tended to have greater psychopathology as indicated in higher pain scores (64.8 v 57.2) and anxiety (MSPQ 7.3 V 4.4) and depression (Zung 27.2 v 21.5) scores. Hazard *et al* (1991) also found this trend when they attempted to distinguish patients who would benefit from a functional restoration programme. They concluded however that no single factor was accurate in predicting outcome to determine treatment prescription. The current study confirms this finding as no single patient characteristic distinguished which patient would dropout.

#### 7.3.6.2 The effect of isokinetic testing

The significant learning effect from test 1 to test 2 demonstrated by the isokinetic measures support the learning effect first reported in the reliability study (Chapter 5.7.7). The discussion of the learning effects has largely been done in Chapter 5.8.4 where the conclusion was that the learning effect could be due to cognitive changes but no studies had directly evaluated these changes.



The cognitive improvements in the current study support the improvements in the reliability study where they were first investigated. These changes in the cognitive measures suggested that a therapeutic effect is taking place i.e. the patient feels better simply by being tested. The change in cognitive measures due to testing demonstrated in these studies cannot be compared with any other study as none were identified in the literature. However one group of researchers have suggested that “the evaluative process brings about change in and of itself” (Matheson *et al* 1993). In a study on measures of self perception one of the unexpected finding was that patients consistently improved in self perception over a brief period with a functional capacity evaluation as the primary intervention. The author believed that work capacity evaluations are both an evaluative and a developmental process. One study did provide an anecdotal report of a therapeutic test effect (McQuade *et al* 1988) during fitness testing of patients with chronic low back pain. The fitness tests included a submaximal exercise tolerance test using a bicycle ergometer, isometric strength tests for hip extension, and trunk strength tests. Flexion was measured by a timed partial sit-up and extension by a timed prone back extension. Flexibility of the trunk and hamstrings was measured by a sit and reach test. The authors stated “It is interesting to note that although we expected the patients to have symptom magnification immediately to 24 hours after the tests, this did not happen. On the contrary, many of the subjects reported feeling better following the exercise tests.” This is exactly the same response as reported by the patients in the current study.

#### 7.3.6.3 The effect of 3 weeks treatment with isokinetic exercise

After 3 weeks all isokinetic measures showed a significant improvement except lifting. The improvement was of the same magnitude as the test effect suggesting that

the two effects were similar. This was an unexpected result as it had been expected that isokinetic treatment would result in greater increases in trunk muscle performance than isokinetic testing. As the learning effect in the reliability study only occurred from test 1 to test 2 and no further improvement in isokinetic measures occurred from test 2 through test 4 it was expected that a treatment effect would occur and be greater than the test effect.

The patients were allowed visual feedback (described in 7.2.3) during the exercise sessions in order to motivate them whereas the patients in the reliability study did not receive any feedback. However Peacock *et al* (1981) has suggested that feedback should be a combination of visual and verbal for best effects whereas Cairns and Passino (1977) studied the effects of verbal reinforcement separate from and in combination with visual feedback and found that verbal reinforcement was a significant factor in increasing daily walking and exercise tolerance.

An equal test and treatment effect has been suggested by Estlander *et al* (1992) who found that the performance of the patients on an isokinetic testing session increased as much from the first to the second measurement, during 4 weeks pre-treatment, as it did from the second to the last measurement, during 4 weeks of intensive physical training. Trunk flexion and extension strength and lifting capacity all demonstrated a significant improvement ( $p > 0.05-0.001$ ) The authors suggested that reduced fear of pain after one successful performance probably influenced the results.

Cooke *et al* (1992) and Smidt *et al* ((1989) maintained that the speed and magnitude of the changes in trunk strength measures cannot be explained by any known training effect on muscle physiology and they suggested that the simplest explanation for

improvement is because of psychological or behavioural factors. These cognitive changes were demonstrated in the current study.

The current study demonstrated a clear psychological effect with no formal psychological input which supports the study by Sachs *et al* (1990) who suggested no specific behavioural component was necessary in a treatment programme for patients with low back pain. There was no attempt to directly influence the patients thoughts about his pain, other than to respond in a positive manner to reports of 'feeling better.' Cognitive measures improved without a specific cognitive intervention, suggesting that behaviour and attitudes can be altered by physical exercise. It is possible that exercise is a behavioural technique. Klaber Moffet and Richardson (1995) have suggested that carrying out exercises may assist the patient in the cognitive process of encoding and help an individual to modify their attitudes to physical activity.

The range of movement measurement of lumbar flexion demonstrated a significant decrease in from test 1 to test 2 which was hard to explain. It could have been the result of patient variation but such a large variation was unlikely. The patients could have been feeling stiff after the exercise or they could have been trying particularly hard for the examining doctor and not made the same effort for the physiotherapist. Another possible explanation was that the standardised method of measuring was not strictly adhered to by the two different medical examiners. One of the examiners was involved in the reliability study and could have been more aware of the standardised method (Chapter 3.4.3) whereas the other was not involved in this study. Other variables were that the measurements were taken at different times of the day from test 1 to test 2 while these from test 2 through test 4 were all taken by the Research Physiotherapist at the same time of day. This does highlight the problems of Outcome

Measures in studies where these measurements should be taken by an independent assessor who is confident that the method and their own technique are both reliable.

The other measurements stayed the same or decreased slightly which is what was expected. The measurements of total extension and straight leg raising showed a significant increase from test 2 to test 3 and lumbar flexion increased significantly from test 3 to test 4. Mayer *et al* (1985b) found improvement in isokinetic measurements was accompanied by improvement in range of movement. Hazard *et al* (1989) also reported that range of movement measurements, isokinetic lifting and cycling all changed with isokinetic extension but proportionally greater than isokinetic flexion. The current study did not find range of movement measurements, isokinetic lifting or isometric lifting improved with the other isokinetic measurements. However as no lifting or flexibility training was included in the programme this is perhaps not surprising. Astrand (1992) maintains training must be specific. None the less the result for range of movement measurements was disappointing as it was expected that they would have shown a more consistent improvement. The use of range of movement as an outcome measure is questionable in a study that does not include flexibility training.

Mayer *et al* (1985b) reported that isokinetic lifting reached normal values after the rehabilitation programme. The current study did not replicate that result and indeed it demonstrated no improvement at all for three weeks of treatment. However, the Mayer study was of intensive exercise with job related tasks included. The current study did not include any lifting related tasks in the exercise programme, but it was thought that lifting would improve with a programme of exercise aimed at

strengthening trunk extensor and flexor muscles. However lifting is a complex combination of trunk strength, limb strength and motivation.

#### 6.3.6.4 The effect of 6 weeks treatment with isokinetic exercise

The Max VO<sub>2</sub> changed from test 3 to test 4. Although the programme did not include aerobic exercise the patients exercised on the bicycle ergometer as a warm up and isokinetic exercise was shown to increase heart rate when monitored with the sports tester. These two factors could account for the increase in Max VO<sub>2</sub> after the six weeks. The change in fitness level could also be due to patients being generally more active and not due to the isokinetic exercise.

The only isokinetic measures to improve at this time were flexion at 120 and 150 degrees/second which were the speeds patients found difficult to achieve. Reduced fear of pain is the most likely explanation for improvement at this higher speed.

There are several possible explanations as to why patients failed to demonstrate continued improvement with a further three weeks of exercise. It is possible that patients were becoming bored with the isokinetic exercise and it had lost its novelty value. Perhaps they no longer saw it as a challenge to master the machine. The lack of improvement suggests that no actual muscle training was taking place as this would have been expected to continue after three weeks. However exercise must be rigorous enough to have an effect on muscle training. Trunk strength increases were reported by Rissanen *et al* (1995) in the first study which suggested that training with maximal or submaximal effort may reverse the selective atrophy of type 2 fibres in the multifidus muscle in men. The trunk extension strength also increased in women, but

the authors suggested that they may need a longer training period than men to achieve significant structural changes in their back muscles.

The functional integration of rehabilitation of the trunk muscles using isokinetic exercise has not been demonstrated in the current study. One finding to suggest this was the lack of improvement in lift testing. Apart from the initial learning effect lifting remained virtually unchanged throughout the study. Isometric scores and lumbar mobility also showed little change throughout the study. These results suggest that isokinetic exercise does not improve general trunk flexibility or lifting capacity.

Return to work should still be used as an outcome measure although Deyo et al (1994) have suggested that it is hazardous to judge the effectiveness of therapy on this outcome alone. For patients who have no employment an alternative choice of an outcome goal which is appropriate for the patient could be used. Having assessed a patient it is established practise for a physiotherapist to draw up a problem list. The physiotherapist then negotiates joint timed goals for the physiotherapy intervention. These goals may be measured by recognised measurement tools or the attainment of a goal may be used as outcome measure. The goals are related to activity such as playing golf, hillwalking or some aspect of housework. Return to this designated activity could then be used as the outcome measure instead of return to work.

The difficulty in trying to relate the findings of the current study with other studies is that they have used different isokinetic machines for testing, and different test and treatment protocols. Indeed it is difficult to compare any one study with another other than the Mayer *et al* (1985b) study which was basically replicated by Hazard *et al* (1989). Mayor's group have severely criticised other authors who maintain they have

replicated the functional restoration studies study but found different results (Gatchel *et al* 1992).

#### 7.3.7 Suggested reasons for improvement other than the treatment

Natural recovery It has been suggested as a reason for improvement other than the treatment (Deyo 1993). However as the patients with chronic low back pain are in a stable condition (Philips and Grant 1991) past the stage of natural recovery and unlikely to change without intervention it is reasonable to assume that this reason could be rejected.

Increased self esteem This could be due to the feeling of mastery of the machine. Self esteem was not measured in the current study but several patients remarked that they felt good about themselves One patient stated "I was totally fed up off with myself before I started this exercise. Now I am going to go back to nursing." It is also possible that the patients simply started doing more because they felt better.

Placebo effect of a novel treatment The isokinetic machines were undoubtedly explained in terms of a new method of assessing and treating low back pain. In addition the appearance of the machines and their obvious high technology could have reinforced this effect. The machines were publicised on television at the start of the research and this could have influenced patients. However it might have been expected that this would have increased the uptake of the programme and decreased the dropout rate. As this was not the case it is reasonable to assume that the patients did not improve because of the novelty of the machines.

Placebo effect of attention from a physiotherapist As each patient had the undivided attention of the physiotherapist for the duration of the programme it would be difficult to separate any placebo effect this might have had. There is strong evidence to suggest that a therapist who shows concern and support, is friendly and reassuring and conveys expertise and trustworthiness may evoke a strong placebo effect (Grant 1995). This placebo effect tends to be dismissed rather than considered in its own right. Wall (1992) suggested that the placebo response could be due to a decrease in anxiety on the part of the patient or a cognitive readjustment of appropriate behaviour. He also suggested that the myths should be dispelled that placebo responders have nothing wrong with them or have a personality defect.

This placebo effect was demonstrated during a trial of the effectiveness of manual therapy, physiotherapy and treatment by a general practitioner for non-specific back and neck complaints (Koes *et al* 1992). The results indicated that there was no difference between the manual therapy group and the physiotherapy group, but there was a difference between the two groups and the placebo group. However the patients in the placebo group also responded remarkably well, leading the authors to conclude that a large part of the effect for the treatment groups was a placebo effect.

Grant (1995) has suggested physiotherapists use the placebo effect to maximise the benefit of physiotherapeutic intervention and that physiotherapy by the very nature of its sympathetic and tactile emphasis of work has a unique opportunity to enhance and maximise a positive effect.



#### **7.4. Conclusions from isokinetic exercise studies 1 and 2**

The two studies of isokinetic exercise have been shown to give both physical and psychological benefits to the patient with chronic low back pain. The patients reported less pain, less disability, less depression, and less fear of activity and work. The objective measurement of trunk muscle performance improved after testing and after three weeks treatment but no further benefit were evident after six weeks treatment. However the benefits were limited to the performance on the machines used for the rehabilitation programme and did not transfer to the objective measurements of lumbar mobility, isokinetic lifting or isometric lifting. The results of this study cannot be widely applied due to the lack of availability of isokinetic machines. In addition the improvements cannot be said to be due to the isokinetic testing or exercise with certainty as there was no control group.

There are several drawbacks to the use of isokinetic machines, the main one being cost. Their initial purchasing price is high and it is unlikely that health providers will be willing to bear the cost unless the benefits can be clearly demonstrated. This adds to the pressure on physiotherapists to evaluate the benefits of new methods of treatment before a purchaser of health care is willing to buy the service. The machine has to be serviced and calibrated regularly with the requirements of an experienced operator adding to the costs. Finally it is time consuming to set the patient up in the machines and they have to be supervised during exercise.

#### **7.5. Limitations of the study**

The most significant limitation of the study was the one group pretest-posttest design without a control group (Cook and Campbell 1979). This design has been criticised

because of the temporal effects occurring between test administrations. These effects are considered uncontrolled because no Control Group was used for comparison with the Experimental Group, leaving history and maturation factors unmeasured. However, since this novel method of treatment has not been reported previously it was considered necessary to establish the potential benefits and problems of isokinetic exercise before a controlled trial was attempted.

Uncontrolled trials are likely to generate enthusiasm and suggest a treatment effect which could be due to other reasons as discussed in 7.3.6 5. However the results of this study is unlikely to do that as the test effect was the same as the treatment effect therefore this would need further investigation before any final conclusions could be drawn.

Another limitation of the study was the lack of follow up of patients to determine if the benefits were maintained. Generally a follow up at one year would have been required to allow for the fluctuating nature of low back pain.

The study population was limited to those patients attending a single Orthopaedic Consultant's out-patient department. Thus it is hazardous to generalise the results to patients from all orthopaedic practices (Deyo 1993), or primary care patients who are not referred for a specialist opinion. The characteristics of patients attending an out-patient clinic as opposed to patients attending a general practitioner could be different. The patients would have waited at least three months for their appointment with a variety of hopes and anxieties affecting them and the danger that during this period they become disabled through lack of advice and activity due to fear of making their problem worse. Referral patterns to hospitals are complex and the reasons are not

well documented it is therefore difficult to determine current practise in the United Kingdom (Fertig *et al* 1993). The method of recruitment of patients in to a study has been found to strongly influence prognostic characteristics and outcomes of clinical trials (Deyo *et al* 1988).

Table 7.1: Means and standard deviation for 17 patients who completed exercise study1. Isokinetic and psychometric variables

isokinetic variable	°/sec	Pre-exercise	Post-exercise	T value	P-value
Rotation Left					
Peak Torque	60	49.35 ± 33.01	66.24 ± 41.44	-2.67	0.008
	120	41.18 ± 30.20	62.47 ± 40.78	-2.92	0.005
	150	44.00 ± 28.79	57.94 ± 38.86	-2.37	0.015
Rotation Right					
Peak Torque	60	47.29 ± 31.19	68.06 ± 42.76	-3.40	0.002
	120	41.06 ± 26.87	62.47 ± 40.07	-3.55	0.001
	150	45.36 ± 25.97	61.18 ± 36.60	-2.91	0.005
Extension					
Peak Torque	60	85.82 ± 60.89	111.12 ± 54.45	-2.13	0.024
	90	74.71 ± 59.57	104.06 ± 59.57	-2.31	0.017
	120	51.94 ± 52.98	81.59 ± 59.41	-2.30	0.015
	150	29.00 ± 36.93	52.53 ± 51.58	-2.37	0.015
Flexion					
Peak Torque	60	95.47 ± 45.79	107.82 ± 39.49	-1.04	0.150
	90	82.47 ± 49.06	99.35 ± 46.52	-1.32	0.100
	120	66.94 ± 48.47	88.94 ± 52.79	-1.65	0.050
	150	37.53 ± 45.52	67.82 ± 55.77	-2.68	0.008
Psychometric variables					
McGill pain scale		43.47 ± 22.46	33.94 ± 23.57	1.98	0.032
Roland & Morris		11.82 ± 7.35	7.82 ± 4.98	3.46	0.001
FABQ phys		14.59 ± 4.46	10.29 ± 7.0	2.58	0.005
FABQwork		16.45 ± 5.50	12.78 ± 6.54	2.68	0.005
MSPQ		5.71 ± 4.63	4.12 ± 4.57	1.49	0.075
Zung		18.12 ± 11.54	14.94 ± 9.48	1.23	0.118

FABQ Fear Avoidance Beliefs Questionnaire

MSPQ Modified Somatic Perception Questionnaire

Table 7.2: Characteristics of patients completing the study versus those dropping out

	Completing study		Dropping out	p Value
Number	39		13	
Sex (male, female)	26m	13f	8m 5f	NS
Age (years +/- SD)	35.2	$\pm$ 8.4	35.2 $\pm$ 8.4	NS
Height (inches)	67.7	$\pm$ 3.4	67.2 $\pm$ 4.3	NS
Weight (lbs)	160.1	$\pm$ 25.1	165.0 $\pm$ 32.0	NS
Low back pain (LBP) alone	12		5	NS
Low back pain + referred thigh pain	17		8	NS
Total duration (months)	118.0	90.0	93.1 $\pm$ 101.	NS
Present attack (months)	12.4	14.5	19.8 $\pm$ 18.3	NS
Recurrent	14		2	NS
Chronic	25		11	NS
Source GP	30		11	NS
Tertiary	9		2	NS
Examiner one	20		1	
two	19		12	0.01

Table 7.3 Work characteristics of patients completing the study versus those dropping out

	completing study	dropping out	p value
working	16	3	NS
off sick	10	3	NS
lost job	9	6	NS
housewife	4	1	NS
Time off			
now	166.3 ± 243	242.0 ± 291	NS
past year	137.3 ± 149	186.0 ± 156	NS
Cause off			
back pain	5	10	NS
other	4	4	NS
Full time	33	8	NS
Part time	2	3	NS
Work type			NS
light	13	4	
sitting	5	0	
driving	4	0	
heavy	14	7	

NS = differences significant at  $p > .05$  using t-tests for continuous variables and chi-square for discrete variables

Table 7.4: Social characteristics of patients completing the study versus those dropping out

Social class	Completing study	Dropping out	p value
11	10	2	NS
111(NM)	6	1	
111(M)	10	2	
1V	5	3	
V	6	4	
Married	26	3	NS
Single	10	3	NS
Smoker	23	3	NS
Non smoker	16	10	NS
Distance to home (miles)	6.4	6.6	NS
Transport			
private	26	7	NS
public	13	6	NS
Time to travel (minutes)	20.9	22.7	NS
Down time (hours)	1.5	1.0	NS
Max vo2	22.5	22.5	NS
RHR (bpm)	82.4	82.4	NS

NS = differences significant at  $p > .05$  using t-test for continuous variables and chi-square for discrete variables

RHR=resting heart rate bpm=beats per minute

Table 7.5: Physical and psychological characteristics of patients completing the study versus those dropping out

	Completing	Dropping out	p - value
MaxVO <sub>2</sub>	23.4 ± 5.2	25.0 ± 7.0	NS
Isokinetic total score	9.3 ± 6.3	7.4 ± 8.0	NS
Lumbar flexion	50.2 ± 13.6	48.3 ± 14.4	NS
Total flexion	87.7 ± 26.4	85.6 ± 24.2	NS
Total extension	20.8 ± 10.1	19.3 ± 9.8	NS
Pain scale	57.2 ± 23.5	64.8 ± 22.1	NS
Roland & Morris	12.2 ± 6.2	12.9 ± 5.9	NS
FABQ physical	17.1 ± 5.6	18.9 ± 3.6	NS
FABQ work	22.1 ± 14.6	29.5 ± 11.1	NS
MSPQ	4.4 ± 4.6	7.3 ± 5.2	NS
Zung	21.5 ± 11.1	27.2 ± 9.7	NS

FABQ Fear Avoidance Beliefs Questionnaire

MSPQ Modified Somatic Perception Questionnaire



Table 7.6(a): Means and standard deviation of Isokinetic Variables for 39 subjects who completed exercise study 2

		1	2	3	4
RHR		82.44 $\pm$ 10.16	81.92 $\pm$ 9.32	77.59 $\pm$ 8.40	76.69 $\pm$ 8.45
Max VO <sub>2</sub>		23.36 $\pm$ 5.22	22.9 $\pm$ 6.59	23.06 $\pm$ 4.30	26.38 $\pm$ 3.97
Max 1		97.72 $\pm$ 71.00	105.77 $\pm$ 76.48	106.41 $\pm$ 68.20	109.77 $\pm$ 65.30
Max 2		93.74 $\pm$ 64.80	96.95 $\pm$ 66.32	101.82 $\pm$ 67.47	103.61 $\pm$ 68.85
PP 1		53.12 $\pm$ 42.29	57.38 $\pm$ 46.61	58.23 $\pm$ 39.10	60.36 $\pm$ 39.21
PP2		44.08 $\pm$ 29.38	61.82 $\pm$ 70.90	56.67 $\pm$ 42.09	56.36 $\pm$ 37.74
Rot L	60	41.15 $\pm$ 33.89	54.41 $\pm$ 38.36	67.90 $\pm$ 37.79	70.08 $\pm$ 38.92
	120	38.87 $\pm$ 34.57	46.77 $\pm$ 36.76	62.72 $\pm$ 38.53	65.08 $\pm$ 38.55
	150	38.64 $\pm$ 33.81	42.97 $\pm$ 34.52	61.51 $\pm$ 37.43	62.28 $\pm$ 38.65
Rot R	60	41.56 $\pm$ 35.23	55.38 $\pm$ 37.54	70.72 $\pm$ 41.34	73.77 $\pm$ 40.09
	120	38.46 $\pm$ 32.96	45.82 $\pm$ 33.40	65.61 $\pm$ 37.47	69.72 $\pm$ 40.06
	150	41.23 $\pm$ 35.27	48.08 $\pm$ 36.72	61.23 $\pm$ 34.58	64.56 $\pm$ 38.37
Ext	60	83.59 $\pm$ 72.67	101.54 $\pm$ 79.01	125.97 $\pm$ 78.84	129.23 $\pm$ 69.00
	120	50.72 $\pm$ 67.84	63.21 $\pm$ 71.63	92.23 $\pm$ 80.10	102.10 $\pm$ 76.43
	150	40.01 $\pm$ 54.56	52.74 $\pm$ 66.96	74.80 $\pm$ 83.00	77.59 $\pm$ 75.95
Flex	60	95.08 $\pm$ 73.16	108.15 $\pm$ 74.36	120.77 $\pm$ 62.55	126.08 $\pm$ 61.12
	120	59.46 $\pm$ 74.16	78.13 $\pm$ 74.70	98.54 $\pm$ 66.48	109.92 $\pm$ 63.35
	150	54.56 $\pm$ 67.57	66.85 $\pm$ 72.08	81.74 $\pm$ 66.35	94.92 $\pm$ 67.57
LT	18	122.21 $\pm$ 78.21	138.74 $\pm$ 77.48	136.41 $\pm$ 74.01	141.44 $\pm$ 72.80
	36	83.85 $\pm$ 69.37	103.95 $\pm$ 77.38	109.13 $\pm$ 71.26	113.79 $\pm$ 68.81
Total Iso score		9.37 $\pm$ 6.31	11.4 $\pm$ 6.82	13.82 $\pm$ 6.70	14.51 $\pm$ 6.33
		TEST 1- 2 = 21%		TEST 2- 3 = 21%	TEST 3- 4 = 5%

Table 7.6(b): T values and p values for isokinetic variables

Tests Values		1-2		2-3		3-4	
		t	p	t	p	t	p
RHR		0.82	0.417	4.98	0.000	1.18	0.245
Max vo <sub>2</sub>		-1.19	0.246	-2.67	0.012	-3.31	0.002
Max Isometric lifting	knee	-1.65	0.106	-0.11	0.913	-0.84	0.405
		-0.87	0.389	-1.04	0.304	-0.65	0.522
Psychophysical Lifting	knee	-1.30	0.201	-0.20	0.840	-0.75	0.455
	waist	-1.69	0.099	0.46	0.651	0.10	0.925
Rotation L1	60	-4.33	0.000	-4.18	0.000	-0.76	0.450
	120	-3.51	0.001	-4.77	0.000	-0.87	0.391
	150	-1.98	0.055	-6.38	0.000	-0.29	0.774
Rotation R	60	-4.25	0.000	-4.54	0.000	-1.00	0.323
	120	-3.15	0.003	-6.32	0.000	-1.50	0.143
	150	-3.21	0.003	-3.91	0.000	-1.17	0.250
Extension	60	-5.58	0.000	-3.28	0.002	-0.57	0.572
	120	-2.63	0.012	-4.30	0.000	-1.79	0.081
	150	-2.74	0.009	-3.50	0.001	-0.50	0.622
Flexion	60	-3.91	0.000	-2.03	0.050	-1.27	0.213
	120	-3.66	0.001	-3.85	0.000	-2.44	0.019
	150	-3.54	0.001	-2.48	0.018	-2.57	0.014
Liftask	18	-2.90	0.006	0.41	0.681	-1.15	0.259
	36	-2.99	0.005	-1.02	0.312	-0.88	0.382

Table 7.7: Means and standard deviations of psychometric variables for 39 patients completing exercise study 2

	test 1	test 2	test 3	test 4
Mc Gill scale	57.2 ± 23.4	49.9 ± 24.1	37.6 ± 24.8	36.6 ± 28.6
Roland & Morris	12.2 ± 6.2	10.4 ± 6.4	8.5 ± 5.5	8.0 ± 5.9
FAB Physical	17.1 ± 5.6	14.8 ± 5.4	12.2 ± 6.6	12.5 ± 5.8
FAB Work	22.1 ± 14.6	19.8 ± 13.5	16.6 ± 13.9	16.7 ± 14.6
MSPQ	4.4 ± 4.7	4.7 ± 4.7	4.0 ± 4.0	4.2 ± 5.6
Zung	21.5 ± 11.1	19.8 ± 8.4	16.4 ± 8.3	16.8 ± 9.5

p Values

	Test 1-2	Test 2-3	Test 3-4
Mc Gill scale	0.007	0.001	0.717
Roland & Morris	0.002	0.002	0.283
FAB Physical	0.012	0.002	0.742
FAB Work	0.009	0.006	0.808
MCSQ	0.491	0.178	0.699
Zung	0.061	0.000	0.653

Table 7.8 Means and standard deviation of range of movement variables for 39 subjects who completed the study

Variable		test 1	test 2	test 3	test 4
Flexion	lumbar	50.2 ± 13.6	43.9 ± 13.3	43.4 ± 13.4	47.4 ± 13.3
	pelvic	37.5 ± 20.2	37.4 ± 20.5	42.6 ± 17.5	42.8 ± 18.0
	total	87.7 ± 26.4	82.1 ± 26.4	86.4 ± 25.6	89.6 ± 20.3
Total extension		20.8 ± 10.1	21.4 ± 9.1	24.3 ± 8.1	24.3 ± 7.9
Lateral flexion	left	26.0 ± 5.9	25.6 ± 8.9	25.3 ± 5.5	26.4 ± 5.5
	right	26.3 ± 7.0	25.9 ± 5.9	26.0 ± 6.1	26.1 ± 5.9
Straight Leg Raising	left	70.8 ± 13.7	69.7 ± 12.0	71.5 ± 11.8	72.6 ± 11.4
	right	69.5 ± 15.0	68.0 ± 14.3	70.1 ± 14.2	70.7 ± 12.0

p values

		test 1-2	test 2-3	test 3-4
Flexion	lumbar	0.000	0.647	0.008
	total	0.160	0.324	1.00
	pelvic	1.00	0.262	0.421
Total extension		0.083	0.044	0.510
Lateral flexion	left	0.516	0.728	0.132
	right	0.681	0.908	0.897
Straight Leg Raising	left	0.052	0.018	0.881
	right	0.098	0.013	0.759

## CONCLUSIONS AND FUTURE RESEARCH

## **CHAPTER 8**

### **Conclusions and future studies**

#### **8.1 General conclusions of the thesis**

**8.1.1 Part 1** The first part of the study set out to establish a reliable, valid method of assessment for objective measurements of low back pain and this was successfully done. The development of such an assessment is important in order to plan treatment and evaluate outcomes. The results from the study contributes to the physiotherapy research on the reliability and validity of clinical measurement tools.

**8.1.2 Part 2** This thesis also aimed to evaluate the reliability of an isokinetic assessment of trunk muscle strength as an objective measure. This was also successfully achieved and is the most comprehensive evaluation to date, serving as a basis for others wishing to build on the results of the isokinetic research. It was clearly important to establish an independent evaluation of the reliability of a novel method of measurement and treatment which had previously been introduced and heavily promoted by the manufacturers of the equipment.

One important aspect of this part of the thesis was the unreliability of the measure used for assessment of effort. It was not possible to detect malingerers using this measure. This was an important finding because the machine is being marketed as a medicolegal tool to help settle legal cases. The results of this research have challenged the concept of using isokinetic measurement as a tool in legal cases and make a significant contribution to the knowledge in this field.

Another important aspect of the research was the follow up study. The negative result of this study means it was not possible to predict the development of low back pain using isokinetic measures, therefore they should not be used in pre-employment strength testing.

**8.1.3 Part 3** This was the first study of isokinetic exercise as the sole method of trunk conditioning and provides a starting position for future research. The study showed that the machines have potential as rehabilitation tools but they have several disadvantages which have been discussed in Chapter 7. Although the main measurements were reliable, the use of these machine needs further research before they can be recommended as a cost effective means of rehabilitation for patients with chronic low back pain.

An interesting aspect of the investigation was the concept of a therapeutic effect of testing which was observed in the pilot study, and investigated in the reliability study and the rehabilitation study. As this has not been investigated previously this was seen as major contribution to the knowledge in this field.

The doctor/patient relationship was highlighted as the only identifiable factor in the compliance of patients to the exercise programme.

## **8.2. Future Research**

In order to plan clinical trials the safety and effectiveness of any intervention must be known and any potential bias or confounding factors must be recognised. This study has supplied the data to justify a more rigorous pursuit of isokinetic exercise as a method of rehabilitation. The study has supplied data on compliance with an

isokinetic exercise programme, the effect of isokinetic testing, as well as the time course of response to exercise, outcome measures, and potential medical examiner bias.

Future studies of back pain should investigate the therapeutic effect of testing in relation to free standing exercise. Any study should compare the cognitive improvements for isokinetic testing with dynamic exercise testing such as the tests used by McQuade *et al* (1988) which included a submaximal exercise tolerance test using a bicycle ergometer, timed prone extension and partial sit-up for muscle strength, and sit and reach for flexibility of the lumbar spine.

Future studies should include a comparison of isokinetic exercise with another form of exercise, such as those exercises studied by Manniche *et al* (1988) which have been shown to be effective. An alternative would be to devise exercises to mimic the isokinetic exercises. These could be a prone extension exercise, a flexion exercise and a rotation exercise. This would determine whether the cognitive benefits are specific to isokinetic exercise or if free standing exercise have the same cognitive benefits.

A randomised, double blind, controlled trial would provide the strongest evidence for treatment effectiveness (Hoffman *et al* 1994). There have been problems reported with controlled trials (Turk *et al* 1990) such as the therapist effect on the treatment group and the control group seeking other treatment outside. The problems with treatment which involves so called life style changes is that people change their behaviour as soon as the trial starts and even if they are not in the treatment group (Haynes and Dantes 1987). The control treatment in the trial should be as similar as



possible to the active treatment to allow for the therapist effect, and care should be taken to identify alternative treatments sought by the control the group.

A follow-up period of at least a year to allow for the recurrent nature of low back pain would be necessary for benefits of treatment to be clearly demonstrated. Follow up could be a particular problem due to non compliance and a postal questionnaire may need to be followed by a telephone reminder or a personal visit. The use of telephone interviews has been shown to be a cost effective method of both obtaining high rates of follow-up and high quality data (Von Korff 1994). Hoffman *et al* (1994) suggested that attrition rates of more than 15% would present a problem. If the attrition rate is higher than this a worst case analysis, which assumes that all patients lost to follow-up have not improved, should be used to safeguard against misinterpretation of the results.

As the costs of chronic low back pain to society are huge and the majority of these costs are associated with primary care (Klaber Moffat *et al* 1995) a study of an exercise programme based in a primary care setting would make a significant contribution to the future management of these patients. The programme reported by Frost *et al* (1995) could be replicated in the out-patient clinics in health centres in the community. If accommodation was a problem, the use of leisure centres could be investigated as a venue for exercise classes with the added advantage that the patients would be introduced to these centres and be encouraged to take up regular exercise.

The doctor/patient relationship and the significance this makes to the compliance of the patient with an exercise programme is a difficult area. As there is limited evidence that attempts to change behaviour of physicians by continuing medical education are

successful (Cherkin *et al* 1991), a more fruitful approach would be to attempt to change doctors attitude to patients with low back early in the process of medical education. This would require innovative methods of undergraduate education with communication skills and exposure to patients introduced early in the programme. Undergraduates would follow a programme which inculcated appropriate attitudes towards patients.

While not a finding of the current research study but emerging from the literature and anecdotal evidence from patients it has become clear that the management of the first episode of back pain is vitally important. The issue of advice to rest and fear of pain has been reported by patients as having a profound effect on how they managed their back pain subsequently. Patients were reporting up to 14 hours of rest over a 24 hour period. Many patients were aggrieved at the advice given to them. Comments such as "if only someone had told me", "I was frightened I would make it worse" and "I looked up degeneration in the dictionary and thought I was going to end up in a wheelchair" were reported to the investigator. No matter what course of treatment is recommended the issue of fear should be identified and addressed in order to dispel irrational fears and help to prevent the condition becoming chronic. Results from a recent trial (Klenerman *et al* 1995) suggested that the outcome in terms of future back pain can be correctly classified in 66% of cases from fear avoidance variables alone.

It is now considered possible that early intervention could reduce chronicity and this should be the main aim of primary care. In a recent study it was shown that patients who received physiotherapy early rated their management as above average and resulted in fewer hospital referrals Hackett *et al* (1993). The natural history of back pain is still poorly understood and further research in primary care could contribute to

the understanding of the development of chronicity in particular the problem of adherence to suggested treatment should be investigated.

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## APPENDIX 1

### THE CYBEX BACK SYSTEM: NORMAL VOLUNTEERS

This equipment will give us better information about the physical condition of your back.

It is entirely up to you if you wish to take part in the study but we will be very grateful for your help. We hope that these measurements will give information which will help us to understand how the spine is affected by backache and to improve the treatment of patients with backache. To do this we also need to see what the measurements should be like in normal people. That is why we need your help.

There are three separate pieces of equipment which measure, bending, turning and lifting. The equipment will support and protect you during these movements. The amount and speed of movement can be set to suit you. All movements are under your own control and you will be able to stop at any time you wish. You are free to withdraw at any time during the study. The equipment has been thoroughly testing in America and shown to be safe. You should not take part if you are pregnant or think that you might be pregnant.

Thank you for your help.

#### Consent

I, ..... of .....  
give my consent to the research procedures described above, the nature, purpose and  
possible consequence of which have been described to me by  
.....

Signed ..... Date .....

Witness .....

## APPENDIX 2

### THE CYBEX BACK SYSTEM Patients

This equipment will give us better information about the physical condition of your back while you are exercising. There are three separate pieces of equipment for bending, turning and lifting. The equipment will support and protect you during these movements. The amount and speed of movement can be set to suit you. All movements are under your own control and you will be able to stop at any time you wish. The equipment has been thoroughly tested in America and shown to be safe.

It is entirely up to you if you wish to take part in the study but we will be very grateful for your help. These exercises are the start of your treatment and the measurements will help us to plan your further rehabilitation. The studies will also help us to develop treatment which will benefit future patients. If you do take part in the study we will let your family doctor know about the research and about your treatment. If you do not wish to take part in the study your medical care will not be affected in any way. You are free to withdraw at any time during the study. You should not take part if you are pregnant or think that you might be pregnant.

Thank you for your help.

### Consent

I, ..... of .....  
give my consent to the research procedures described above, the nature, purpose and possible consequence of which have been described to me by

.....

Signed ..... Date .....

Witness .....



## **APPENDIX 3**

### **STANDARDISED TEST PROTOCOL**

#### **Cardiovascular Fitness Test**

Sub-maximal cardiovascular fitness test which also functions as a warm-up for isokinetic testing.

5 minutes rest: explanation of the isokinetic equipment and testing.

#### **Trunk rotation**

45° left and right

4 x 60°/sec \*

40 secs rest

4 x 120°/sec \*

40 secs rest

10 x 150/sec (\*4 x 150°/sec)

1 min rest

10 x 150°/sec

This provides Torque Sets \* at 60, 120 and 150°/sec, Work Fatigue Protocol and Work Recovery Protocol.

### **Trunk Extension - Flexion (TEF)**

4 x 60°/sec

40 secs rest

4 x 90°/sec \*

40 secs rest

4 x 150°/sec (4 x 120°/sec)

40 secs rest

10 x 120°/sec

This gives Torque Sets at 60°, 90°, 120° and 150°/sec and a Work Fatigue Protocol.

### **Lift task**

In all life tests patients chose their own positions which they find comfortable and use whatever lifting technique they find most effective.

### **Isometric**

Two forms of isometric lift are tested - psychophysical and maximal, and both are tests eg at knee and waist levels. The order is psychophysical and then maximal isometric at knee height and then psychophysical and maximal isometric at waist height.

### **Isokinetic**

Lift floor to knuckle height (measure erect relaxed knuckle height and record)

3 x 18°/sec

30 secs rest

3 x 36°/sec

Cool down on isokinetic bicycle

## APPENDIX 4

NAME: .....

AGE: .....

HEIGHT: .....

WEIGHT: .....

SEAT                      HEIGHT:

.....

Resting Heart Rate .....

Maximum Heart Rate .....

Target Heart Rate .....

Exercise Heart Rate .....

	<u>3 mins</u>	<u>3 mins</u>	<u>3 mins</u>
KGM/min	_____	_____	_____
Heart Rate	_____	_____	_____

Predicted Max  $\text{VO}_2$  .....

Fitness .....

### Isometric Lift

Tibial Tubercle      1) .....cms

Waist Height        2) .....cms

Phychophysical      1) .....      2) .....

Max                    1) .....      2) .....

Comments:

## APPENDIX 5

Please tick which of these words describes your pain. Put the tick in the box which gives the intensity of that particular quality of your pain.

	<u>NONE</u>	<u>MILD</u>	<u>MODERATE</u>	<u>SEVERE</u>
THROBBING	0)	1)	2)	3)
SHOOTING	0)	1)	2)	3)
STABBING	0)	1)	2)	3)
SHARP	0)	1)	2)	3)
CRAMPING	0)	1)	2)	3)
GNAWING	0)	1)	2)	3)
HOT-BURNING	0)	1)	2)	3)
ACHING	0)	1)	2)	3)
HEAVY	0)	1)	2)	3)
TENDER	0)	1)	2)	3)
SPLITTING	0)	1)	2)	3)
TIRING-EXHAUSTING	0)	1)	2)	3)
SICKENING	0)	1)	2)	3)
FEARFUL	0)	1)	2)	3)
PUNISHING-CRUEL	0)	1)	2)	3)

---

Please put a mark on the scale to show how bad your usual pain has been these days.

NO PAIN ----- WORST  
POSSIBLE  
PAIN

---

How bad is your pain now?

- |   |               |       |
|---|---------------|-------|
| 0 | NO PAIN       | _____ |
| 1 | MILD          | _____ |
| 2 | DISCOMFORTING | _____ |
| 3 | DISTRESSING   | _____ |
| 4 | HORRIBLE      | _____ |
| 5 | EXCRUCIATING  | _____ |

## APPENDIX 6

When your back hurts you may find it difficult to do some of the things you normally do.

These are some of the sentences that people use to describe themselves when they have back pain. When you read them, you may find that some stand out because they describe you today. As you read the list, think of yourself today. When you read a sentence that describes you today, circle **YES**. If that sentence does not describe you today, circle **NO**. **Remember, only answer YES if you are sure the sentence describes you today.**

1. I stay at home most of the day because of my back.....YES / NO
2. I change position frequently to try and get my back comfortable.....YES / NO
3. I walk more slowly than usual because of my back.....YES / NO
4. Because of my back, I am not doing any of the jobs that I usually do around the house.....YES / NO
5. Because of my back, I use a handrail to get upstairs.....YES / NO
6. Because of my back, I lie down to rest more often.....YES / NO
7. Because of my back, I have to hold on to something to get out of an easy chair..YES / NO
8. Because of my back, I try to get other people to do things for me.....YES / NO
9. I get dressed more slowly than usual because of my back.....YES / NO
10. I only stand up for short periods of time because of my back.....YES / NO
11. Because of my back, I try not to bend or kneel down.....YES / NO
12. I find it difficult to get out of a chair because of my back.....YES / NO
13. My back is painful almost all the time.....YES / NO
14. I find it difficult to turn over in bed because of my back.....YES / NO
15. My appetite is not very good because of my back pain.....YES / NO
16. I have trouble putting on my socks/stockings because of the pain in my back.....YES / NO
17. I only walk short distances because of the pain in my back.....YES / NO
18. I sleep less well because of the pain in my back.....YES / NO

19. Because of the pain in my back, I get dressed with help from someone else.....YES / NO
20. I sit down for most of the day because of my back.....YES / NO
21. I avoid heavy jobs around the house because of my back.....YES / NO
22. Because of my back pain, I am more irritable & bad tempered with people  
than usual.....YES / NO
23. Because of my back, I go upstairs more slowly than usual.....YES / NO
24. I stay in bed most of the time because of my back.....YES / NO

## APPENDIX 7

Here are some of the things which other patients have told us about their pain. For each statement, please circle any number ranging from 0 to 6 to say how much physical activities such as bending, lifting, walking or driving affect, or would affect your back pain.

	completely disagree				unsure			completely agree
1. My pain was caused by physical activity .....	0	1	2	3	4	5	6	
2. Physical activity makes my pain worse .....	0	1	2	3	4	5	6	
3. Physical activity might harm my back .....	0	1	2	3	4	5	6	
4. I should not do physical activities which (might) make my pain worse.....	0	1	2	3	4	5	6	
5. I cannot do physical activities which (might) make my pain worse.....	0	1	2	3	4	5	6	

The following statements are about how your normal work affects your back pain.

	completely disagree				unsure			completely agree
6. My pain was caused by my work or by an accident at work.....	0	1	2	3	4	5	6	
7. My work aggravated my pain.....	0	1	2	3	4	5	6	
8. I have a claim for compensation for my pain.	0	1	2	3	4	5	6	
9. My work is too heavy for me.....	0	1	2	3	4	5	6	
10. My work makes / would make my pain worse	0	1	2	3	4	5	6	
11. My work might harm my back.....	0	1	2	3	4	5	6	
12. I should not do normal work with my present pain.....	0	1	2	3	4	5	6	
13. I cannot do my normal work with my present pain.....	0	1	2	3	4	5	6	
14. I cannot do my normal work till my pain is treated.....	0	1	2	3	4	5	6	
15. I do not think I will be back to my normal work within 3 months.....	0	1	2	3	4	5	6	
16. I do not think that I will ever be able to go back to that work.....	0	1	2	3	4	5	6	

## APPENDIX 8

Please describe how you felt during the **past week** by placing a tick in the appropriate box.  
Please answer all questions. Do not think too long before answering.

1. Heart rate increasing
2. Feeling hot all over
3. Sweating all over
4. Sweating in a particular part of the body
5. Pulse in the neck
6. Pounding in the head
7. Dizziness
8. Blurring of vision
9. Feeling faint
10. Everything appearing unreal
11. Nausea
12. Butterflies in stomach
13. Pain or ache in the stomach
14. Stomach churning
15. Desire to pass water
16. Mouth becoming dry
17. Difficulty swallowing
18. Muscles in neck aching
19. Legs feel weak
20. Muscles twitching or jumping
21. Tense feeling across forehead
22. Tense feeling in jaw muscles



## APPENDIX 9

Please indicate for each of these questions which answer best describes how you have been feeling recently.

1. I feel downhearted and sad.
2. Morning is when I feel best
3. I have crying spells or feel like it.
4. I have trouble getting to sleep at night.
5. I feel that nobody cares.
6. I eat as much as I used to.
7. I still enjoy sex.
8. I notice that I am losing weight.
9. I have trouble with constipation.
10. My heart beats faster than usual.
11. I get tired for no reason.
12. My mind is as clear as it used to be.
13. I tend to wake up too early.
14. I find it easy to do the things I used to.
15. I am restless and can't keep still.
16. I feel hopeful about the future.
17. I am more irritable than usual.
18. I find it easy to make a decision.
19. I feel quite guilty.
20. I feel that I am useful and needed.
21. My life is pretty full.
22. I feel that others would be better off  
if I were dead.
23. I still enjoy the things I used to.

## APPENDIX 10

### THE CYBEX BACK SYSTEM Exercise programme

This equipment gives us better information about the physical condition of your back while you are exercising. There are three separate pieces of equipment for bending, turning and lifting. The equipment will support and protect you during these movements. The amount and speed of movement can be set to suit you. All movements are under your own control and you will be able to stop at any time you wish. The equipment has been thoroughly tested in America and shown to be safe.

It is entirely up to you if you wish to take part in the study but we will be very grateful for your help. These exercises are the start of your treatment and the measurements will help us to plan your further rehabilitation. The studies will also help us to develop treatment which will benefit future patients. If you do take part in the study we will let your family doctor know about the research and about your treatment. If you do not wish to take part in the study your medical care will not be affected in any way. You are free to withdraw at any time during the study. You should not take part if you are pregnant or think that you might be pregnant.

Thank you for your help.

#### Consent

I, ..... of .....  
give my consent to the research procedures described above, the nature, purpose and  
possible consequence of which have been described to me by  
.....

Signed ..... Date .....

Witness .....

## APPENDIX 11

TABLE 1

## Isokinetic variables related to sex in normals

VARIABLE		FEMALE			MALE			T VALUE	P
WEIGHT		132.8	±	15.8	165.8	±	22.5	-7.11	0.000
MAX VO2		2.5	±	0.7	2.9	±	0.7	-2.67	0.000
PSYCH PHYS									
LIFT	knee	754.0	±	28.5	107.7	±	41.2	-3.82	0.003
	waist	51.1	±	20.1	72.5	±	36.1	-3.07	0.000
ISOMETRIC									
LIFT	knee	127.7	±	40.2	193.8	±	47.8	-6.26	0.000
	waist	78.9	±	26.3	121.4	±	33.4	-5.70	0.000
ROT LEFT									
Peak torque	40	50.3	±	19.1	93.5	±	31.4	-6.96	0.000
	60	52.4	±	19.8	56.5	±	21.5	-5.75	0.000
	150	52.0	±	16.8	84.6	±	28.5	-5.83	0.000
Peak torque/ body weight	60	37.5	±	13.5	55.0	±	16.4	-4.89	0.000
	120	38.8	±	13.3	51.2	±	14.8	-3.68	0.000
	150	38.6	±	11.7	50.4	±	14.5	-3.76	0.000
Average power	60	45.1	±	17.9	85.5	±	28.1	-7.17	0.000
	120	85.3	±	35.8	152.4	±	51.1	-6.36	0.000
	150	101.9	±	41.0	183.7	±	74.0	-5.72	0.000
Average power/ body weight	60	33.5	±	13.7	50.8	±	14.0	-5.41	0.000
	120	63.5	±	24.6	92.2	±	26.7	-4.69	0.000
	150	75.8	±	28.3	111.0	±	35.4	-4.60	0.000
ROT. RIGHT									
Peak torque	60	51.2	±	18.9	93.5	±	26.2	-7.75	0.000
	120	53.4	±	18.9	87.9	±	27.9	-6.23	0.000
	150	54.1	±	18.4	87.3	±	26.9	-6.03	0.000
Peak torque/ body weight	60	38.1	±	13.0	55.7	±	13.1	-5.64	0.000
	120	39.0	±	13.4	52.6	±	14.5	-4.05	0.000
	150		±			±		-3.51	0.000
Average power	60	46.2	±	18.1	86.8	±	25.7	-7.65	0.000
	120	85.5	±	34.9	155.1	±	52.4	-6.55	0.000
	150	103.6	±	41.5	187.1	±	67.9	-6.20	0.000
Average power/ body weight	60	34.3	±	12.6	51.6	±	12.8	-5.70	0.000
	120	63.8	±	24.1	92.5	±	27.1	-4.69	0.000
	150	7.3	±	2.9	10.6	±	3.9	-4.02	0.000
TEF EXT									
Peak torque	60	98.4	±	15.8	99.5	±	16.1	-7.90	0.000
	90	92.9	±	32.0	166.2	±	51.9	-7.12	0.000
	120	76.8	±	34.7	145.9	±	52.3	-6.52	0.000
	150	49.9	±	32.8	120.5	±	57.0	-6.35	0.000
Peak torque/ body weight	60	70.5	±	20.7	104.3	±	25.9	-6.02	0.000
	90	69.1	±	21.5	99.6	±	28.7	-5.03	0.000

## APPENDIX 11

	120	57.1	±	24.7	86.9	±	29.3	-4.61	0.000
	150	37.2	±	23.7	73.3	±	34.3	-5.12	0.000
<b>VARIABLE</b>	<b>FEMALE</b>				<b>MALE</b>			<b>T VALUE</b>	<b>P</b>
Average power	60	96.0	±	33.4	177.4	±	48.4	-8.20	0.000
	90	135.0	±	50.8	240.8	±	72.2	-7.10	0.000
	120	153.2	±	69.2	279.5	±	97.1	-6.26	0.000
	150	127.1	±	84.8	283.4	±	135.6	-5.78	0.000
Average power/ body weight	60	71.7	±	22.9	105.9	±	23.9	-6.12	0.000
	90	101.5	±	34.1	144.8	±	40.8	-4.83	0.000
	120	116.1	±	48.9	167.8	±	54.7	-4.17	0.000
	150	94.6	±	60.0	170.3	±	79.5	-4.50	0.000
<b>TEF FLEX</b>									
Peak torque	60	93.2	±	23.4	156.7	±	35.0	-8.93	0.000
	90	90.2	±	25.2	151.8	±	35.2	-8.40	0.000
	120	79.9	±	26.5	145.6	±	33.5	-9.10	0.000
	150	60.3	±	30.0	131.7	±	41.4	-8.28	0.000
Peak torque/ body weight	60	70.3	±	16.4	94.3	±	14.3	-6.49	0.000
	90	67.4	±	17.2	90.8	±	16.4	-5.84	0.000
	120	59.5	±	18.8	8.7	±	15.8	-6.60	0.000
	150	45.2	±	22.1	79.3	±	24.1	-6.18	0.000
Average power	60	92.9	±	26.7	162.8	±	37.2	-9.02	0.000
	90	130.0	±	39.1	227.7	±	56.1	-8.46	0.000
	120	155.5	±	56.1	281.4	±	79.4	-7.66	0.000
	150	141.4	±	67.6	304.7	±	106.1	-7.68	0.000
Average power/ body weight	60	68.3	±	19.6	97.2	±	16.0	-6.77	0.000
	90	95.2	±	32.6	136.3	±	26.7	-5.77	0.000
	120	119.4	±	42.5	174.9	±	42.9	-5.44	0.000
	150	105.5	±	56.4	184.0	±	58.0	-5.74	0.000
<b>LIFT TASK</b>									
Peak force	18	118.1	±	30.6	186.2	±	10.5	-7.94	0.000
	36	110.9	±	32.0	163.8	±	44.0	-5.76	0.000
Peak force/ body weight	18	88.8	±	21.5	112.4	±	23.9	-4.35	0.000
	36	83.1	±	27.9	98.5	±	27.1	-2.61	0.000
Average power	18	184.5	±	48.3	303.4	±	77.1	-7.73	0.000
	36	319.5	±	90.4	495.7	±	169.1	-5.44	0.000
Average power/ body weight	18	138.9	±	33.2	183.4	±	44.1	-4.77	0.000
	36	240.9	±	62.7	308.4	±	89.0	-3.67	0.000
Total work	18	224.5	±	58.7	369.4	±	94.2	-7.72	0.000
	36	193.8	±	54.8	305.3	±	93.8	-6.08	0.000
Total work/ body weight	18	169.5	±	40.0	223.3	±	54.0	-4.74	0.000
	36	143.9	±	38.1	187.2	±	54.4	-3.68	0.000

## APPENDIX 11

TABLE 2

## Isokinetic variables related to sex in patients

VARIABLE		FEMALE			MALE			T VALUE	P
WEIGHT		140.7	±	22.0	170.6	±	26.1	-6.76	0.000
MAX VO2		2.1	±	0.4	2.7	±	0.6	-5.95	0.000
PSYCH PHYS									
LIFT	knee	29.2	±	17.9	69.1	±	37.3	-7.42	0.003
	waist	24.3	±	11.2	56.9	±	28.9	-8.09	0.000
ISOMETRIC									
LIFT	knee	51.1	±	29.1	129.2	±	61.1	-8.89	0.000
	waist	43.2	±	20.5	101.7	±	42.3	-9.61	0.000
ROT LEFT									
Peak torque	40	25.2	±	16.3	63.0	±	29.6	-8.61	0.000
	60	24.0	±	15.1	61.6	±	31.5	-8.31	0.006
	150	24.2	±	15.7	62.6	±	29.7	-8.82	0.006
Peak torque/ body weight	60	16.9	±	10.7	37.6	±	18.7	-7.40	0.000
	120	16.8	±	11.2	36.5	±	19.1	-6.90	0.006
	150	17.0	±	11.8	37.0	±	17.8	-7.23	0.000
Average power	60	20.7	±	14.5	58.5	±	29.7	-8.83	0.000
	120	33.3	±	25.4	111.7	±	61.1	-9.12	0.006
	150	37.7	±	31.2	134.7	±	74.3	-9.27	0.006
Average power/ body weight	60	14.3	±	10.4	35.1	±	18.8	-7.46	0.000
	120	23.5	±	18.7	66.6	±	36.9	-8.04	0.006
	150	26.9	±	23.6	80.1	±	44.5	-8.14	0.000
ROT. RIGHT									
Peak torque	60	23.0	±	13.6	61.1	±	29.4	-9.04	0.000
	120	24.1	±	13.5	59.6	±	31.3	-8.02	0.000
	150	25.1	±	15.8	61.9	±	30.5	-8.25	0.000
Peak torque/ body weight	60	15.9	±	9.7	36.3	±	17.9	-7.71	0.000
	120	16.9	±	10.0	35.1	±	18.6	-6.66	0.000
	150	18.5	±	12.1	36.8	±	17.8	-6.74	0.000
Average power	60	18.6	±	12.7	55.6	±	28.6	-9.11	0.000
	120	30.9	±	22.1	105.5	±	62.2	-8.69	0.000
	150	34.2	±	30.3	133.9	±	76.2	-9.36	0.000
Average power/ body weight	60	12.7	±	8.9	33.2	±	17.6	-7.97	0.000
	120	21.4	±	16.0	62.2	±	37.0	-7.80	0.000
	150	2.1	±	2.2	7.5	±	4.3	-8.66	0.000
TEF EXT									
Peak torque	60	52.4	±	28.9	112.4	±	51.8	-7.79	0.000
	90	41.5	±	31.0	104.8	±	55.5	-7.67	0.000
	120	26.8	±	26.4	85.6	±	49.8	-8.05	0.000
	150	11.3	±	18.3	45.1	±	46.8	-5.19	0.000
Peak torque/ body weight	60	36.9	±	21.5	67.1	±	31.5	-6.12	0.000

# APPENDIX 11

	90	29.1	±	23.4	62.9	±	34.0	-6.32	0.000
	120	18.0	±	19.4	51.1	±	29.8	-7.18	0.000
	150	8.1	±	14.5	28.7	±	28.9	-4.92	0.000
<b>VARIABLE</b>	<b>FEMALE</b>				<b>MALE</b>			<b>T VALUE</b>	<b>P</b>
Average power	60	46.3	±	28.7	109.0	±	55.3	-7.76	0.000
	90	53.1	±	44.1	143.6	±	83.5	-7.39	0.000
	120	46.9	±	49.3	159.9	±	102.8	-7.62	0.000
	150	25.7	±	42.3	104.0	±	117.1	-4.84	0.000
Average power/ body weight	60	32.6	±	21.6	65.6	±	33.7	-6.38	0.000
	90	36.9	±	32.6	86.6	±	51.1	-6.34	0.000
	120	33.4	±	37.8	95.6	±	61.3	-6.67	0.000
	150	18.7	±	33.4	61.5	±	65.9	-4.64	0.000
<b>TEF FLEX</b>									
Peak torque	60	59.2	±	31.4	130.4	±	47.9	-9.60	0.000
	90	49.0	±	33.1	128.9	±	46.1	-10.87	0.000
	120	41.0	±	34.5	113.9	±	48.1	-9.51	0.000
	150	19.6	±	22.3	77.6	±	54.8	-7.55	0.000
Peak torque/ body weight	60	41.3	±	21.9	77.4	±	27.9	-7.86	0.000
	90	34.0	±	23.1	76.6	±	27.4	-9.19	0.000
	120	27.4	±	20.9	67.3	±	27.7	-8.89	0.000
	150	15.9	±	22.0	46.2	±	31.9	-6.04	0.000
Average power	60	48.5	±	28.2	123.0	±	53.7	-9.47	0.000
	90	55.7	±	43.7	171.8	±	75.4	-10.24	0.000
	120	66.4	±	55.4	206.1	±	102.5	-9.24	0.000
	150	43.0	±	50.1	172.2	±	133.5	-6.97	0.000
Average power/ body weight	60	53.2	±	19.7	71.8	±	30.6	-8.21	0.000
	90	38.6	±	30.2	100.9	±	42.4	-9.25	0.000
	120	46.2	±	38.7	121.5	±	59.7	-8.18	0.000
	150	28.0	±	34.1	97.2	±	75.0	-6.48	0.000
<b>LIFT TASK</b>									
Peak force	18	65.4	±	32.9	146.1	±	59.0	-9.21	0.000
	36	50.1	±	29.0	122.9	±	60.1	-8.40	0.000
Peak force/ body weight	18	46.2	±	23.3	87.3	±	37.6	-7.15	0.000
	36	35.3	±	21.2	73.0	±	36.0	-6.97	0.000
Average power	18	97.3	±	50.9	216.3	±	98.0	-8.30	0.000
	36	136.0	±	83.2	340.9	±	193.3	-7.50	0.000
Average power/ body weight	18	69.0	±	36.8	130.4	±	60.9	-6.67	0.000
	36	96.9	±	61.3	207.9	±	111.7	-6.71	0.000
Total work	18	119.4	±	63.1	264.7	±	118.8	-8.32	0.000
	36	81.1	±	50.1	212.7	±	114.0	-8.14	0.000
Total work/ body weight	18	82.4	±	45.5	160.2	±	76.1	-6.77	0.000
	36	58.4	±	37.3	126.4	±	67.4	-6.80	0.000