THE UNIVERSITY OF CALGARY

The Characterization Of Functional Tissue Compliances In The Human Lumbar Spine

by

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The undersigned certify that they have read, and recommend to the Faculty of Graduate Studies for acceptance, a thesis entitled "The Characterization of Functional Tissue Compliances in the Human Lumbar Spine" submitted by Gregory N. Kawchuk in partial fulfillment of the requirements for the degree of Master of Science.

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Abstract

Various health professions attempt to improve musculoskeletal status by altering tissue stiffness (TS). TS is assessed typically by palpation and less frequently by instrumentation. The instrument employed most commonly is the tissue compliance meter or TCM.

When tested, the TCM's Intraclass Correlation Coefficient (ICC), a reliability measure, was 0.005 while its deformation error was 1.28±0.57mm/49.1N. An new instrument was developed (tissue stiffness meter or TSM) to assess TS. The TSM's ICC was 0.99 while its deformation error was 0.008±0.01mm/30N. It was concluded that the TSM was accurate and reliable compared to the TCM.

The TSM was tested *in vivo* and it was concluded that it could detect within subject TS differences in the human lumbar spine at rest, compared to conditions of isometric contraction.

While future data derived from the TSM may be useful, direct clinical use of this TSM prototype is limited because of its size.

Preface

1] Chapters 3 and 5 of this thesis are respectively based on the following manuscripts:

Kawchuk GN, Herzog W. (1995) The reliability and accuracy of a standard method of tissue compliance assessment. *J Manipulative Physiol Ther.* **18**, 298-301.

Kawchuk GN, Herzog W. (1995) A new technique of tissue stiffness (compliance) assessment: its reliability, accuracy, and comparison to an existing method. Accepted for publication, *J Manipulative Physiol Ther.*

2] Parts of this thesis have been acknowledged by award. These awards include:

Kawchuk GN, Herzog W. The Centennial Award for Research Performed by a Clinician (1rst place) for the paper entitled, *A new method of assessing tissue stiffness (compliance)*. Presented at the 100 Centennial Celebration, Washington D.C., U.S.A., 1995

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The Foundation for Chiropractic Education and Research for their financial support.

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Dedication

To my family, Janet, Jonathan and Michael.

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List of Symbols and Abbreviations

A/D	Analog to Digital
BMI	Body Mass Index
cm	centimeters
cm^3	cubic centimeters
CS1	Control surface 1
CS2	Control surface 2
DC	Direct Current
D_{max}	Maximal deformation at an applied load
EMG	Electromyography
EQQ	Preconditioning stiffness trials
EXT	Unloaded stiffness trials
IBM	International Business Machines
ICC	Intraclass Correlation Coefficient
kHz	kiloHertz
kPa	kiloPascals
L3	Third lumbar vertebrae
LOAD	Loaded stiffness trials
LVDT	Linear Voltage Displacement Transducer
mm	millimeters
MRI	Magnetic Resonance Imaging
ms	milliseconds
MVC	Maximal Voluntary Contraction

N ..... Newtons

PA ..... Posteroanterior

PC ..... Personal Computer

PRE ..... Baseline stiffness trials

REST ..... Resting stiffness trials

RMS ..... Root Mean Square

s ..... seconds

$S_{1/3}$ ..... Stiffness at 1/3 D_{max}

SD ..... standard deviation

SE ..... standard error

S_{max} ..... Maximal stiffness at an applied load

SMT ..... Spinal Manipulative Therapy

TCM ..... Tissue Compliance Meter

TS ..... tissue stiffness

TSM ..... Tissue Stiffness Meter

Chapter 1

Introduction

Background

Research of the human musculoskeletal system typically falls into two categories: the study of biology and the study of mechanics. While each area has its inherent difficulties in terms of scientific investigation, the mechanical assessment is particularly challenging due to several unique factors. These factors include the relatively large size of the objects of interest, and the difficulty in removing or controlling confounding factors in these large, intricate systems. As a result, the study of the gross function of the human musculoskeletal system is a cumbersome and complex endeavor for the modern researcher.

An even more arduous task awaits the clinician assessing the musculoskeletal system. In comparison to the problems facing the researcher, a clinician faces several unique difficulties including: triage, cost control, patient satisfaction, and pressure to improve a patient's health. Perhaps the most basic problem for the clinician is a lack of tools, or investigative tests, that would improve the reliability and accuracy in the diagnosis of musculoskeletal pathology. While some tools are available (i.e. electromyography, force plate analysis), these tools are typically used in research settings and are not easily implemented in the clinic. Because of this, clinicians often resort to using their own hands as the primary tool of musculoskeletal assessment. This skill is termed palpation.

Palpation is thought to be a way in which certain features of a tissue may be detected. These features include, but are not limited to, the presence of edema, restriction of joint motion and

abnormalities in tissue stiffness (Maher and Latimer, 1992). To assess tissue stiffness, a clinician pushes his/her finger-tips into a tissue and then compares that sensation of stiffness to an impression obtained from an unaffected, contralateral structure. If this comparison is not available, the impression of the tissue stiffness is compared to a mental recollection of "normal" (Maitland, 1986). This assessment technique is given relatively high clinical importance as it is frequently used in decisions regarding a patient's diagnosis and treatment protocol (Magarey, 1985).

While commonly used, the procedure of stiffness assessment by palpation has been found to be both unreliable and inaccurate (Maher and Adams, 1994) making health care decisions based on this procedure highly questionable. This finding however, does not imply that the parameter of tissue stiffness itself is valueless. To understand if tissue stiffness has importance in the assessment of the musculoskeletal system, a way to assess tissue stiffness in a reliable and accurate manner must be found.

Attempts to remove the subjectivity inherent to palpatory stiffness assessment have been made in the past via the use of instrumentation (Ashman et al., 1994, Avramov et al., 1992, Childress and Steege, 1987, Ebara et al., 1992, Fischer 1987a, Graves et al., 1993, Krouskop et al., 1990, Kwiatkowski and Inigo, 1993, Lee and Svensson, 1990, Mak et al., 1994, Malinauskas et al., 1989 Owens 1988, Ylinen 1993). While several modern day instruments have been developed and are indeed used in clinical settings today, the majority of the above instruments (with the exception of Lee et al., 1990 and Ashman et al., 1994) have not had their reliability and accuracy reported. This lack of quantitative testing has been a considerable problem, as one instrument in particular, the manual tissue compliance meter developed by Fisher (TCM), has been used in the majority of the studies reviewed by the author that deal specifically with clinical aspects of tissue stiffness. As well, some of the above instruments are used invasively (Avramov et al., Ebara et al., 1992) while others are limited in the types of tissues that can be assessed (Ashman et al., 1994, Avramov et al., 1992, Ebara et al., 1992, Fischer 1987a, Graves et al., 1993, Krouskop et al., 1990, Kwiatkowski and Inigo, 1993, Lee and Svensson, 1990, Malinauskas et al., 1989; Ylinen 1993). Therefore, there are few tissue stiffness assessment instruments that have been tested for reliability and accuracy, and can be used non-invasively for tissues in various anatomical locations.

Statement of Problem

The measurement of tissue stiffness in a clinical setting is thought to provide insight into the status of the musculoskeletal system. When assessed by the customary method (palpation), tissue stiffness measures have been shown to be unreliable and inaccurate. To date, the development of non-invasive instrumentation for assessing tissue stiffness from multiple anatomical sites has not been shown to improve the reliability or accuracy of tissue stiffness measurements.

Statement of Purpose

The purpose of this thesis was 1) to develop an instrument that could reliably and accurately assess stiffness in non-biological test conditions, and 2) to determine if that instrument was capable of identifying a local, subject-induced, change in tissue stiffness.

Research Hypothesis

Significant, within subject differences exist between the posteroanterior tissue stiffness at the spinous process of the third lumbar vertebrae (L3) in the human spine at rest and during isometric contraction of the lumbar extensor muscles.

Chapter 2

Literature Review

The stiffness of a tissue can be defined as the first derivative of the tissue's force-deformation curve with respect to deformation. Additionally, the average stiffness of the same tissue can be defined as the ratio of a change in force and the corresponding change in deformation. Compliance is the inverse of stiffness. Therefore, to assess a tissue's stiffness or its compliance via instrumentation, a minimum of two variables need to be recorded: the applied load and the resulting deformation of the test tissue.

Historical methods of assessing tissue stiffness

The first record of an instrument being created to measure the resistance of soft tissues to an external force can be found in the early 20th century. Mangold (1922), devised an instrument where indentation of the skin was produced by a weighted lever with the resulting indentation measured by the movement of the lever with respect to an external reference scale. The creation of this instrument was most likely based on clinical need, as in 1922, no other instruments were readily available to assess changes in tissue stiffness. In fact, the first clinically relevant report relating to tissue stiffness appeared in 1931, when Lange attempted to quantify "myogelosis" or "muscle hardening". Gordon (1964) developed what was known as the myotonometer, which was thought to be the first commercially available instrument to assess "muscle firmness", or muscle tone. Ultimately, the myotonometer fell into disfavor as it was extremely bulky and difficult to apply in clinical circumstances. Brodin (1972), later developed a device similar to a fat caliper, which was the first device to use electronic sensors to determine the amount of tissue located between the pincers of the caliper.

Contemporary methods of assessing tissue stiffness

Since the device by Brodin, a number of other instruments have been developed which utilize modern electronic advancements. These types of devices generally fall into two categories: force application devices and reflective ultrasonic devices. Force application devices measure the applied force and the resultant deformation. Forces are applied by these devices by motors that drive an indentor into the tissue (Childress and Steege, 1987, Graves et al., 1993, Kwiatkowski and Inigo, 1993, ,Lee and Svensson, 1990, Mak et al., 1994, Owens 1988, Ylinen 1993), by lever systems (Latimer, personal comm., Lee and Svensson 1990), or by caliper/clamping methods (Avramov et al., 1992, Ebara et al., 1992). Measurement of the applied force typically occurs via an electronic force sensor placed at some point between the site of force generation and the tissue contact site. The amount of tissue deformation is measured either directly via calipers, radiologically, or indirectly by determining the amount of displacement occurring in the force application device. Ultrasonic devices typically consist of a device which vibrates the test tissue at a certain rate and a sensing device which measures the displacements of the tissues being vibrated at varying depths (Ashman et al., 1994, Krouskop et al., 1990, Malinauskas et al., 1989).

Other modern day devices used for tissue stiffness measurements are not dependent on electronics. As a result, such devices are easily employed and are thought to be more clinically prevalent. By far, the most prominent of these devices is the Tissue Compliance Meter, or TCM (Fischer 1981, Fischer 1987a) . This device consists of a cylindrical indentor that is placed in-line with a spring-based gauge that estimates the applied load. A collar surrounding the indentor is used to remain at the tissue level prior to indentation, thus acting as a reference point to determine deformation.

While tissue stiffness in research settings is measured using a variety of devices, the most wide-spread method of tissue stiffness assessment used clinically is manual palpation (Magarey 1985, Maitland 1986).

Tissue stiffness: applied research

In many studies, tissue stiffness measurements have been the primary investigative focus. These studies include methodologies where stiffness was measured invasively (*in vivo*). Avramov et al. (1992) described changes in afferent nerve signals correlated with stiffness measurements obtained

from dissected rabbit lumbar facet joints under varying load conditions. Ebara et al. (1992) assessed stiffness changes between vertebrae during surgery and concluded that pathological motion segments (those with degenerative diseases or herniated discs) have decreased stiffness compared to normal segments.

The largest number of studies in the field of tissue stiffness measurement utilize the TCM, a non-invasive instrument. Fischer, the inventor of the TCM, published a study in 1987 describing the clinical uses of the TCM. Vernon and Gitelman (1990), used the TCM in a case study to conclude that changes in the stiffness of muscles relating to tension-type headaches could be detected following spinal manipulative therapy (SMT). Mongini et al. (1993) attempted a similar study to Vernon's, and concluded that changes in tissue stiffness were insignificant in headache patients using medication for treatment. Sakai et al. (1995) documented stiffness alterations in the facial muscles of patients with cephalgia. Albright and Fischer (1990) documented changes in "muscle stiffness" in subjects before and after training in biofeedback imagery. Granges and Littlejohn (1993) used the TCM and concluded that stiffness measures could be used to identify subjects with fibromyalgia from control populations. Hogeweg et al. (1995) determined that subjects with juvenile chronic arthritis did not display significant changes in tissue stiffness when compared to other populations. Lawson and Sanders (1992a) observed that different SMT procedures did not alter spinal stiffness as detected by the TCM. Following this study, Lawson and Sanders (1992b) found an insignificant correlation in stiffness changes detected by the TCM and surface electromyography (EMG). Nansel et al. (1993) concluded that when using the TCM, alterations in lumbar spine stiffness were detectable when spinal manipulative procedures were induced in the cervical spine.

Other investigators have used different stiffness assessment instruments to address questions similar to those addressed with the TCM. Lee et al. (1993a) described the effects of spinal muscle contracture on spinal stiffness using a lever type force application device. Lee et al. (1993b) used the same device and determined that changes in thoracic spinal stiffness could not be detected following SMT delivered to asymptomatic subjects. Graves et al. (1993) used a solenoid driven force application device to describe the effect of cumulative percussive skin trauma. Kwiatkowski and Inigo (1993) employed 128 separate stepping motors, and force sensors, to create a system that was reported to customize seating cushions for wheelchair patients.

Finally, a group of researchers used stiffness measures to help above and below knee amputees have a more comfortable prosthesis. Mak et al. (1994) studied indentation properties of residual limb tissues in below knee amputees, and found that there were significant differences in tissue stiffness associated with sample location and muscle activity. From studies such as these, Reynolds and Lord (1992) and Todd and Thacker (1994) used finite element analysis to predict pressures at socket/tissue interfaces and to determine the changes required to optimize the fitting of above and below knee prostheses.

Reliability and accuracy of contemporary instruments.

Despite a large volume of research, there are few published reports regarding the accuracy or the reliability of instruments used to assess tissue stiffness. Accuracy and reliability have been tested for a force application device (this device is limited to testing large areas of tissue where the subject is prone) (Lee and Svensson, 1990) and an ultrasound device (Ashman et al., 1994). In other studies, quantification of the reliability of the TCM was attempted but the conclusions of these studies were limited due to various errors. In all of these studies (Fischer 1987c, Jansen et al., 1990, Lawson and Sanders, 1991, Sanders and Lawson, 1992, Waldorf et al., 1991), human subjects were used as criterion measures. This choice of criterion is inappropriate due to the inherent viscoelastic behavior of human tissue (Viidik 1968). Fischer (1987c) incorrectly concluded that the inter-examiner reliability of the TCM was acceptable because two separate Pearson's Correlation Coefficients generated from two separate groups of subjects by two separate examiners were similar. Inter-examiner reliability is correctly determined by having many examiners repeatedly test the same object/subject. Waldorf et al (1991) incorrectly computed inter-examiner reliability by comparing the data generated by three examiners in paired comparisons. The proper statistic to apply is this scenario is an Intraclass Correlation Coefficient which considers all examiners data at once.

The accuracy and reliability of direct palpation has been described in several reports. Maher and Latimer (1992) summarized a wide range of studies that investigated different palpation procedures from physiotherapy, allopathic medicine, and chiropractic: all palpation procedures were found to be unreliable. The procedures included assessment of bony anomalies, tissue texture, muscle tension, joint compliance, and range of motion. In his own study, Maher and Adams (1994)

specifically addressed the question of the reliability of palpatory assessments of the posteroanterior (PA) stiffness in the lumbar spine; it was found to be poor. While attempts have been made to improve clinicians palpatory reliability through training, the resulting improvements have been negligible (Lee et al., 1990).

The majority of clinical studies aimed at quantifying tissue stiffness have employed the TCM. With its unknown accuracy and reliability, the conclusions of studies using the TCM must be questioned.

Pre-conditioning of tissue

Biological tissues are typically visco-elastic, that is, have elastic-like properties which are dependent on the rate of loading. Where testing musculoskeletal tissues such as ligament, tendon, and muscle, the tissue of interest must be cyclically loaded so that the tissue reaches as steady-state with respect to changes in length for a given force (Viidik, 1968). This process is termed pre-conditioning. There are few clinical studies which describe pre-conditioning in their methodology. However, changes in stiffness attributed to experimental protocols could well be attributed to transient changes in stiffness while the tissue is reaching a steady-state behavior. In studies using the TCM, only Jansen et al. (1991) noted trends toward decreased stiffness over time. In Jansen's study, 26% of the subjects showed changes in stiffness with repeated measures, but no significant changes for the entire subject population was observed. Even if pre-conditioning is incorporated into a design, it is questionable if the TCM is sensitive enough to detect the small changes associated with pre-conditioning. In fact, Lawson and Sanders (1991) reported no change in stiffness in a 10 minute interval of repeated testing, Sanders and Lawson (1992) reported stability in 20 stiffness measurements taken over 10 minutes, and Waldorf et al. (1991) suggested that stiffness is stable for two successive measures, and for to measures taken 15 minutes and 2 weeks apart.

Many clinical researchers have neglected to incorporate tissue pre-conditioning into their studies, however, much work has been done on the subject of tissue pre-conditioning. Oomens et al., (1987) studied the *in vitro* indentation properties of 15 cm thick porcine skin and fat layers bound to a rigid plate. The protocol for this study used flat and cylindrical indentors to measure tissue creep with a static 8 N load. Oomens et al., (1987) concluded that a steady-state was reached within 10

minutes. Zeigert and Lewis (1978) measured soft tissue stiffness over the tibia and found site variation of up to 70% with individual variations of up to 300% when using a 22.4 N load applied for 5 minutes. It should be kept in mind, that at this anatomical location, the test tissue consists almost completely of epidermis, dermis and bone. With a lack of hypodermal tissues, such as fat and muscle, this is a site in the human body where one might expect little variance as a function of location. Reger et al. (1990) used pressure sensors and magnetic resonance imaging (MRI) measurements to demonstrate that when an applied load is given to the tissue over the ischium, the stiffness of the skin and underlying fat were greater than that of the underlying muscle. Not only does a tissue's composition potentially affect overall tissue stiffness, the activity of the tissue may drastically change the tissue's stiffness as well. Lee et al. (1993a) demonstrated that tissue stiffness in the lumbar spine changed with voluntary erector-spinae contractions. Krouskop et al. (1987) used an ultrasonic device to show that the Young's Modulus of a tissue (a measure of stiffness), could be increased 16 fold when muscle tissue directly below the test site was active.

Fatigue analysis

Later in this thesis, a methodology will be described where subjects exert maximum voluntary contractions of the lumbar spine muscles. As it is important that these contractions are reproducible, a short review on issues relating to spinal extension contractions and muscular fatigue is presented.

Prior investigators have used force/endurance relationships to show that the production of force from muscular contraction decreases as fatigue increases (Jorgensen and Nicolaisen, 1987, Seidel et al., 1987, van Dieen and Vrielink, 1993). The force-endurance may be used to estimate the time that a contraction of a specific relative force can be held before force levels diminish (Manenica 1986, van Dieen and Vrielink, 1994). During a maximal voluntary contraction of the extensors of the lumbar spine, the estimated time before fatigue, (defined as a drop in the force of the contraction) is approximately 15 s. In comparison, the estimated time before fatigue at 75% MVC is 50 s. When asking a subject to perform a muscle contraction, the contraction can be influenced by subject-centered factors such as motivation and the presence of pain (van Dieen and Vrielink, 1994). As well, individual physiological parameters, such as muscle fiber composition, available blood supply and the subject's sex, can influence the force output of a MVC (van Dieen and Vrielink, 1994). The prevention of fatigue in a test protocol, can be very difficult and great

attention must be paid to control the time and force of contraction, and any factors which may cause pain or alter the motivation of a subject.

Chapter 3

The Tissue Compliance Meter (TCM): Reliability and Accuracy

Introduction

Increasingly, subjective information derived from a health practitioner's hands is being augmented or replaced by objective measures obtained through instrumentation. This is especially true in professions that specialize in the assessment of the musculoskeletal system. Developed in the 1980's, the tissue compliance meter (TCM) is an instrument that has been used to quantify the compliance of tissues (Fischer, 1987b). Average compliance, the inverse of average stiffness, is a measure of the deformation that occurs when a defined force is applied to a surface. It is the summary representation of many individual factors such as muscle tone, edema, and skin elasticity.

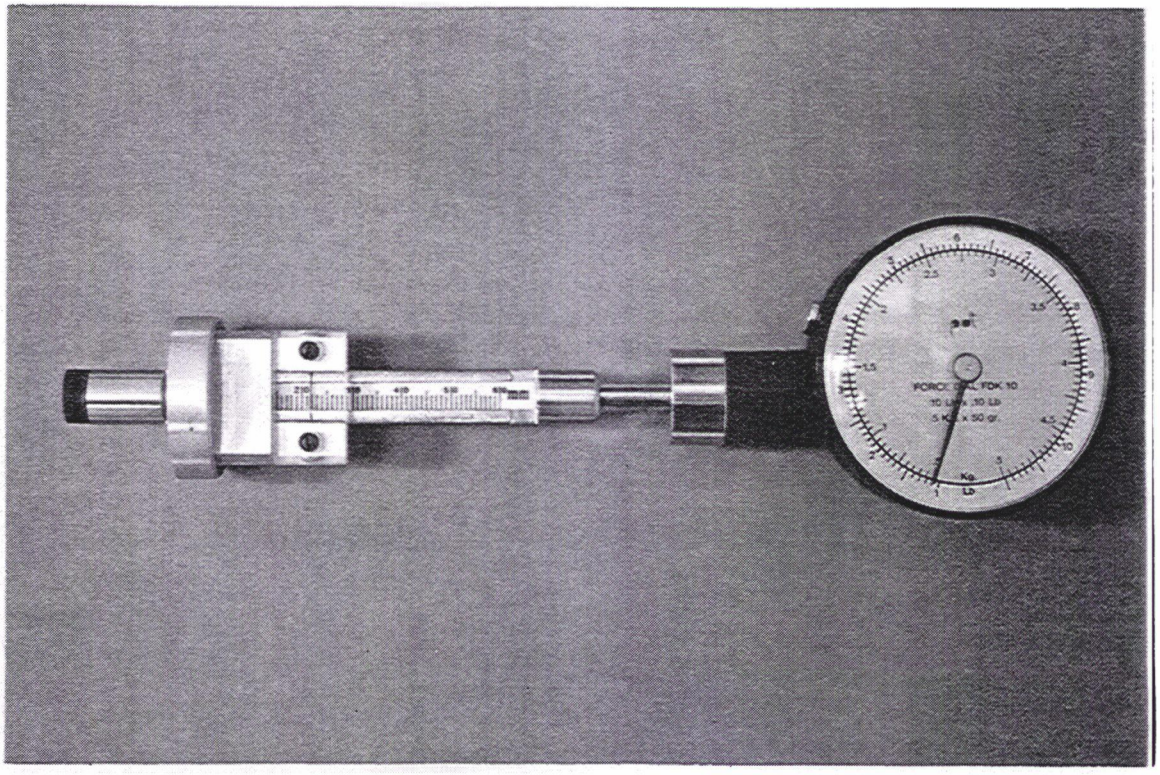
The TCM (Plate 1) consists of a cylindrical probe which is pressed into a tissue resulting in surface deformation. A collar surrounding the probe contacts the tissue residing at the original surface level as the probe is moved downward. This collar acts as a point of reference to determine how far the probe has moved downward into the tissue. The amount of force that is used to push the instrument into the tissue is recorded by a spring mechanism analog gauge. The result is a measurement which is termed compliance and can be expressed as millimeters of deformation per Newton of applied force (mm/N).

Since its inception, the TCM has been used in numerous investigations which have attempted to demonstrate a change in tissue compliance following some perturbation of an experimental system. Examples of these studies include: pre/post manipulative studies, comparison of pathological

populations to non-pathological populations, drug trials and most recently, a study characterizing individuals with juvenile chronic arthritis.

With the wide-spread use of the TCM, it would seem likely that preliminary studies have been done reporting the TCM's reliability and accuracy. Although such studies exist, they have suffered from limitations in analysis and a lack of a valid criterion measure (Fischer 1987c, Jansen et al., 1990, Lawson and Sanders, 1991, Sanders and Lawson 1992, Waldorf et al., 1991).

Plate 1. The Tissue Compliance Meter (TCM).



Purpose

The purpose of this study was to determine the reliability and accuracy of the TCM by using non-biological test surfaces of known properties.

Materials and Methods

Materials: Three foam surfaces were obtained from a single manufacturer, each having equal dimensions but different compression characteristics (foam A = 214 kPa, foam B = 331 kPa, and foam c = 428 kPa, where kPa represents the pressure required to completely compress a foam block of standardized dimensions). A fourth surface (a secure laboratory bench top) was used as a control surface and was assumed to be incompressible. The TCM was obtained from Pain Diagnostics (Great Neck, New York).

Methods: Each examiner was equally trained in the use of tissue compliance assessment and allowed practice measurements prior to the start of the experiment. Five separate input forces (2.0, 9.8, 19.6, 29.4, and 49.1 N) were applied on each of the test surfaces resulting in 20 unique surface/force combinations. Intervals of one minute were observed between trials. For all combinations of examiner/input force/test surface, ten trials were obtained in a random order by each of five examiners, yielding a total of 1000 separate measurements of surface compliance. Results were reported to one individual who recorded information from all five examiners. As the displacement scale of the TCM had a resolution of 1 mm, examiners were asked to report measures of displacement in increments of 0.5 mm, if the measurement fell between millimeter divisions. (e.g. 2.0, 2.5 and 3.0 mm).

Evaluation: Intra-examiner reliability of the TCM was assessed by examining the distribution of the standard deviations provided from the ten trials obtained for each examiner/input force/test combination. Inter-examiner reliability was assessed by using analysis of variance and intraclass correlation coefficients (ICC) (Shrout and Fleiss, 1979). Accuracy was judged by comparing deformations obtained from the TCM to a criterion measure (control surface) whose expected value of deformation was zero (i.e. a rigid surface).

Results

Regarding intra-examiner reliability, Figure 1 displays a box-plot describing the distribution of the standard deviations obtained from the ten trials recorded for each examiner/input force/test surface combination. The median of the distribution was 0.24 mm.

With respect to inter-examiner reliability, the ten trials recorded by all five examiners for a particular surface/force combination were assessed by analysis of variance. It was found that in 85% of the 20 surface/force combinations, at least one examiner's data significantly differed from the remaining four examiners ($p < 0.05$). An ICC was calculated for each surface/force combination, with the resultant distribution having a median value of 0.005 and a maximum value of 0.22 (Figure 2).

Regarding the error of the instrument, deformation values from all trials involving the control surface ranged from 0.00 to 2.00 mm. Deformation data from all examiners tended to increase in magnitude as the input force was increased, having a mean value (± SD) at 49.1 N of input force of 1.28 ± 0.57 mm (Figure 3).

Figure 1. Boxplot distribution of the standard deviations of ten trials collected from 100 unique examiner/input force/test surface groupings. The shaded box represents the range of the data's second and third quartiles (interquartile range, IQR) which is transected by a vertical line representing the median of the data. Dashed lines represent the IQR multiplied by 1.5. Values falling outside the range of the dashed lines are considered to be outliers and are represented by circles.

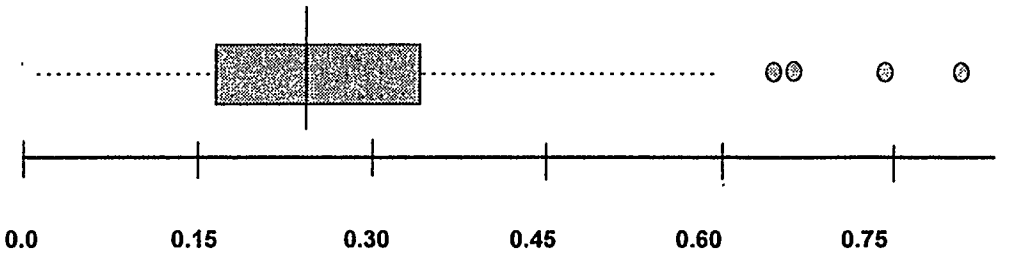


Figure 2. Boxplot distribution of the ICCs generated for 20 surface force groups. The shaded box represents the range of the data's second and third quartiles (interquartile range, IQR) which is transected by a vertical line representing the median of the data. Dashed lines represent the IQR multiplied by 1.5. Values falling outside the range of the dashed lines are considered to be outliers and are represented by circles.

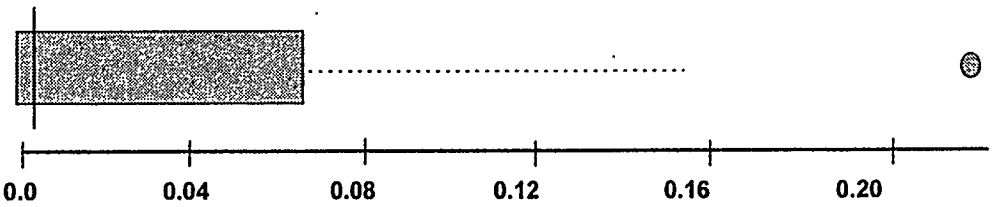
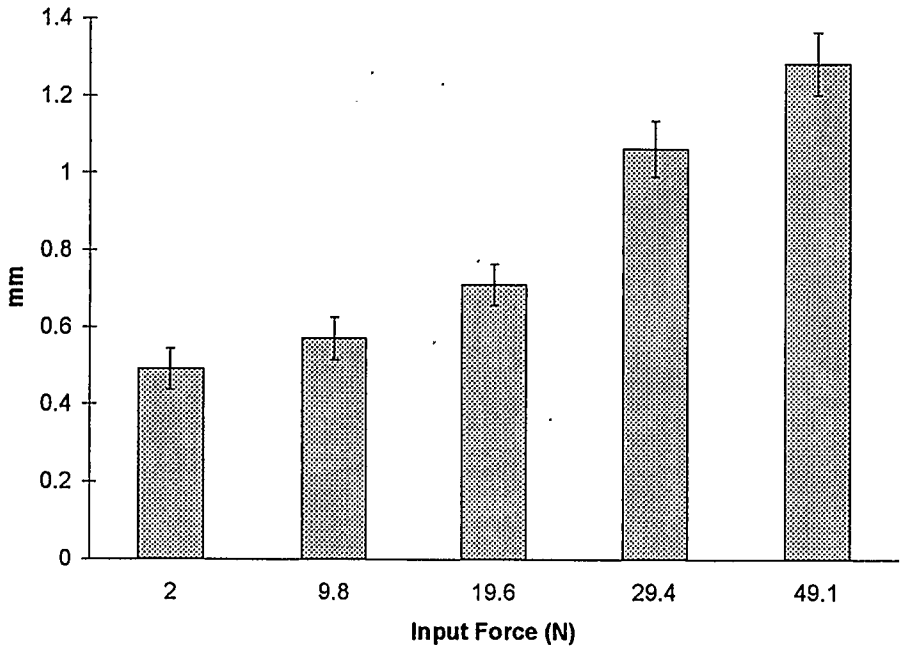


Figure 3. Mean deformations ± SE computed from data collected from a rigid surface by the TCM. Means were calculated by pooling each examiner's data (ten trials/examiner) for five different input forces.



Discussion

In previous studies, it was claimed that the TCM was reliable; a result that is in direct contradiction with the findings presented here. In one of these studies, two examiners were asked to obtain tissue compliance readings from two separate groups of patients (Fischer, 1987c). This methodology is not adequate for assessing the reliability of the TCM, as reliability can only be assessed when the same measure is performed several times by one person (intra-examiner reliability) or a series of people (inter-examiner reliability). The results obtained by Fischer cannot be used to determine the instrument's reliability as the measured compliances are likely to differ between different subjects. Also, using human tissue as a criterion measure may be inappropriate because of the known changes in the mechanical properties of musculoskeletal tissues with repeated measurements (Viidik, 1968). In another study, Waldorf et al. (1991) addressed the issue of inter-examiner reliability using the TCM, but his explanation of how inter-examiner reliability was calculated was incomplete. To evaluate reliability, Waldorf et al. (1991) compared the results of two out of three examiners. A comparison of the results from all three examiners using an ICC would have been an appropriate statistical approach. Also, Waldorf et al. (1991) arrived at their conclusions regarding TCM reliability from data collected on human subjects, as did Jansen et al., 1990, Lawson and Sanders (1991), and Sanders and Lawson (1992). To our knowledge, no experimental validation of the accuracy of the TCM has been performed.

Reliability: Based on the limitations of previous research regarding TCM reliability, there appears to be no evidence in the literature that the TCM is reliable or accurate. Therefore, the first task to be undertaken in judging the overall reliability of the TCM is to determine if any examiner who uses the instrument can generate consistent output (intra-examiner reliability). In order to assess intra-examiner reliability, it was assumed that the instrument behaved consistently in changing test conditions (surface/force combinations). Therefore, we would expect that for a given examiner, the measurement error, or the variance from the ten trials obtained from any surface/force combination, should not change significantly. In the boxplot shown in Figure 1, it can be seen that the distribution of the standard deviations of ten repeated measures for unique examiner/input force/test surface combinations is large, suggesting that the intra-examiner reliability of the TCM is poor.

It may be argued that if intra-examiner reliability is poor, then there is no purpose in assessing the inter-examiner reliability. Because our intra-examiner estimate is based on the appearance of a distribution, our conclusion of a "poor" intra-examiner reliability is subjective and may be questioned. As a result, the issue of inter-examiner reliability was explored. It was found that in 85% of the 20 surface/force combinations, at least one examiner's data differed significantly from the remaining four examiners. This result suggested that inter-examiner reliability was poor. When using intraclass correlation coefficients, a statistical test designed specifically for multiple judge/target scenarios (Shrout and Fleiss, 1979), a similar conclusion was reached. The 20 ICCs calculated for each surface/force combination showed very low correlations, the median value being 0.005 (where 0 indicates no reliability and a value of 1 indicates perfect reliability) (Figure 2).

Accuracy: Pertaining to the accuracy of the instrument, significant deformations were recorded with all five input forces when using the control surface (Figure 3). It can be seen that using the weight of the TCM alone (force = 2.0 N), several examiners recorded positive deformations (0.50 ± 0.38 mm). Although this result may be explained as a calibration error of the TCM, this explanation does not necessarily hold as it can be seen that with increasing input forces, deformation also increased. The mean deformation value at 49.1 N of input force was 1.28 ± 0.57 mm (Figure 3). This finding implies that the magnitude of the error in deformation is related to the test conditions and is not only a calibration error. In testing the TCM on the control surface, only the error produced by the rubber tip and the phenomenon of "tilting" were accounted for, while the phenomenon of "submarining" was not tested due to the characteristics of the test surface itself. In actuality, what was quantified in this study was not the accuracy of the TCM, but a "partial error" (1.28 ± 0.57 mm of deformation at 49.1 N of input force) consisting of two of the three identified sources of error in the TCM.

The absolute errors in deformation discussed above may not appear to be significant, but to date, all studies reviewed that used the TCM, have recorded changes in tissue deformations smaller than 2.0 mm. Therefore, using the deformation value corresponding to the input force of the TCM itself (0.50 ± 0.38 mm), and the maximum change in deformation found experimentally to date (~ 2.00 mm), the TCM produces a minimum error of 25%.

Explanations: The poor performance of the TCM in this study may be explained by two factors: instrument design and instrument application. Regarding instrument design, the TCM utilizes two analog scales (deformation and load) which require reading and reporting by the user (Plate 1). It can be assumed that the higher the resolution of the scales, the better the reporting by the user. In the case of the displacement scale, the resolution is 1 mm. When the TCM was applied to a test surface, the cross-hair of the displacement collar often fell between the scale's millimeter divisions causing the user to make a judgment as to the displacement value. An attempt to reduce this subjectivity was made by having each examiner report displacements in 0.5 mm intervals. The same problem regarding scale interpretation also existed in the gauge that measured load. The resolution given by the scale is 0.05 kg or 0.1 lbs.

The deformations obtained on the incompressible control surface were likely caused by another design feature: the rubber tip of the TCM that makes direct contact with the patient (Plate 1). When force is applied to the control surface via the TCM, compression of the rubber tip occurs which is registered on the TCM as a displacement. This deformation of the rubber tip therefore produces an over-estimation of the true surface deformation. Although it is possible that the control surface was not incompressible as assumed, it is safe to suppose that a 50 N force will not compress the control surface by more than a few micrometers, and clearly can not be responsible for the deformation values obtained using the TCM on this surface. It should be noted that the deformations recorded from the control surface were obtained with input forces that are considered to be clinically useful and have been employed previously in clinical studies (Fischer 1987b, Granges and Littlejohn, 1993, Hogeweg et al., 1995, Nansel et al., 1993, Lawson and Sanders, 1992a, Lawson and Sanders, 1992b, Mongini et al., 1993, Waldorf et al., 1991)

Besides instrument design, instrument application was also seen to be a source of poor TCM performance. It was observed that if the TCM was not applied perpendicularly to the tissue surface during measurement, the displacement collar was prematurely forced up the displacement probe giving a potentially false reading (Figure 4). Feedback from the examiners participating in this study indicated that although they were warned about this phenomenon and were trained in keeping the device perpendicular, it was difficult to maintain the instrument in the proper orientation during the measurements. Another source of error is associated with the way in which a tissue surface deforms when an input force is applied. Musculoskeletal tissues do not follow the outline of the

TCM probe, but involute in a curvilinear fashion (Figure 5). Because of this phenomenon, and the limits of the diameter of the displacement collar, the TCM actually measures deformation from below the original surface level of the tissue. This event was termed "submarining" and underestimates the true deformation of the tissue.

Figure 4. Over-estimation of tissue deformation caused by TCM tilting.

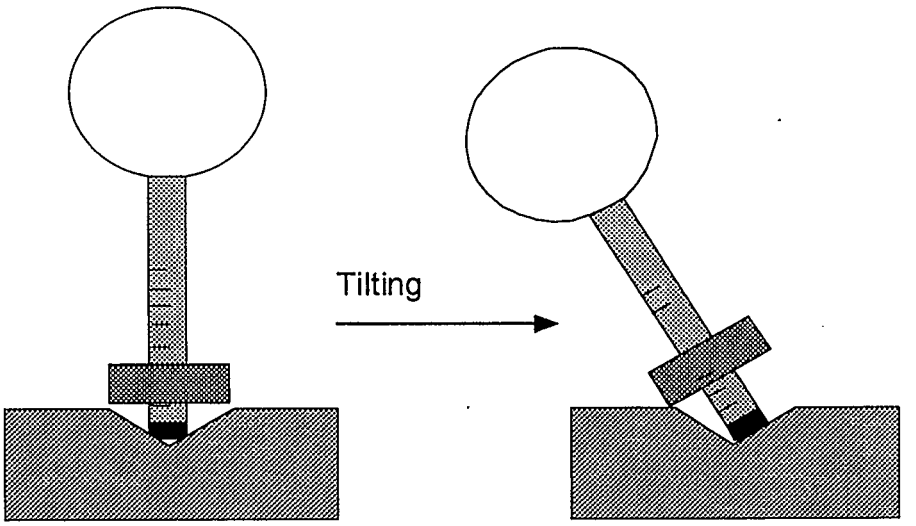
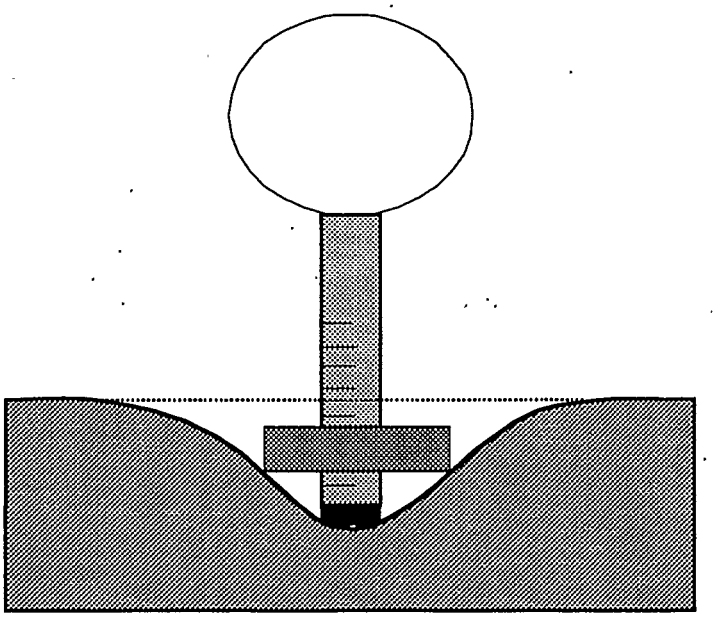


Figure 5. Under-estimation of tissue deformation caused by "submarining".



Conclusion

The TCM was found to have poor intra-examiner and inter-examiner reliability. The device was also shown to be inaccurate. The results of this study bring into question the conclusions of prior studies that have used the TCM to evaluate tissue compliance.

Chapter 4

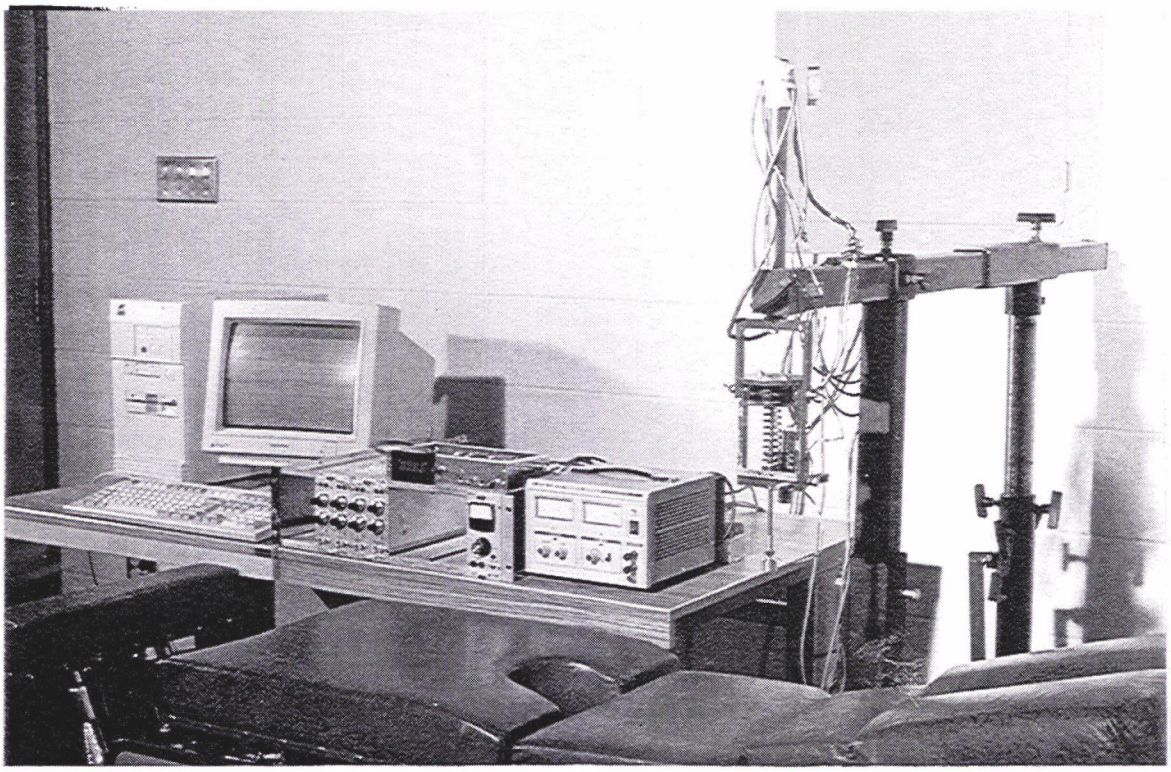
The Tissue Stiffness Meter (TSM): A Description

Technical Description

The tissue stiffness meter, or TSM, is an instrument that has been developed in the Human Performance Laboratory at the University of Calgary (Plate 2). The TSM applies forces to a target tissue and measures that force and the corresponding deformation. For the purpose of description, the TSM can be separated into three parts: the electronic components, the signal collection/control equipment, and the supporting framework.

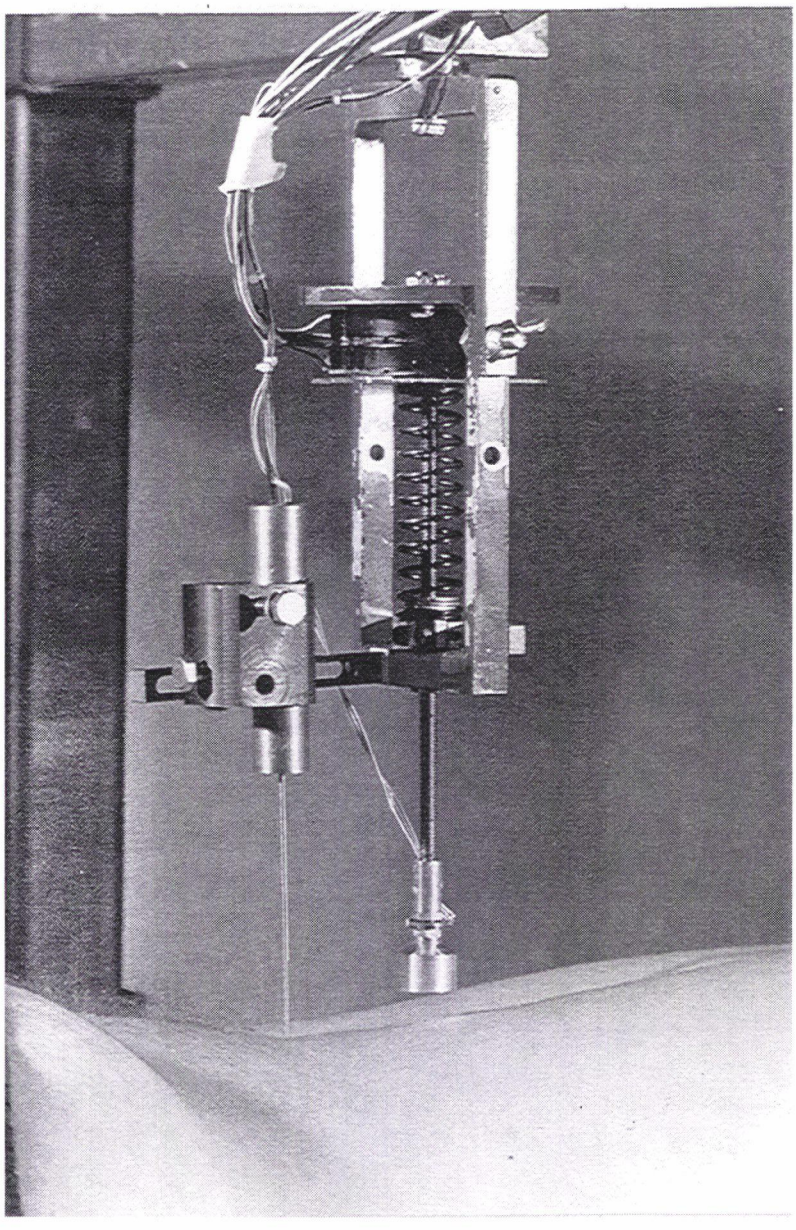
The electronic components of the TSM consist of a stepping motor with an associated drive spindle, a strain gauge, and a linear voltage displacement transducer (LVDT) (Plate 3). The stepping motor has a metallic drive spindle inserted through it, which when activated, moves the spindle in steps of 0.0254 millimeters either toward or away from the tissue of interest. The stepping motor is powered by a DC power supply (12 volts) and is controlled remotely by an integrated circuit board which can be used to set the rate of spindle movement, as well as activate and de-activate the stepping motor based on manual input or threshold signals from other electronic devices. The maximum force that can be delivered by the stepping motor is approximately 115 N at the commonly used rate. The maximum force can be increased to 225 N if the motor's speed is kept minimal. The strain gauge is attached in-series with the drive spindle and is powered by an amplifier that transmits a voltage which is proportional to the force applied at the spindle/tissue interface (maximum rating of +/- 225 N). At the end of the spindle, rigid indentor surfaces with different diameters or contact properties can be attached. The LVDT, powered by a 12 volt DC

Plate 2. The Tissue Stiffness Meter (TSM).



power supply, consists of a magnetic cylinder in which a ferrous rod passes through the cylinder's long axis. This rod is in constant contact with the test surface, and any displacement occurring in the contact surface parallel to the long axis of the cylinder will move the rod. The resultant displacement of the rod produces a change in voltage which is proportional to the displacement. The LVDT can record displacements of up to five cm in either direction from its center point. The signal collection system consists of an IBM compatible PC equipped with an analog to digital (A/D) converter that acquires signals from the electronic components named previously (Plate 3). The signals are collected on to the hard disk of the PC by CODAS software. The maximal sampling rate of the A/D board is 50 kHz. During data collection, five channels of data are typically collected: the applied force, the stepping motor displacement, the displacement of the LVDT rod, the current direction of the stepping motor, and a signal indicating the instant in time of surface contact.

Plate 3. Electronic components used in the TSM.



All of the electronic components of the TSM are housed in a rigid support framework that suspends the components over the tissue to be tested. This framework has been designed to allow the spindle to be easily positioned in three dimensional space, allowing for stiffness measurements to be taken at any spindle/tissue contact angle.

Assessing tissue stiffness via the TSM occurs as follows: by activating the stepping motor, the spindle is driven toward the test tissue at a pre-selected rate. As the spindle contacts the tissue surface, it touches a piece of thin metallic tape which is adhered to the target site. At the time of contact, a change in voltage is sent to the signal collection system on a dedicated channel. The spindle continues downward, increasing the force to the test tissue until a preset force threshold is reached. When the force threshold is attained, the stepping motor reverses direction causing the spindle to be lifted away from the tissue. The instant of reversal is recorded as a change in voltage on a separate input channel. The spindle of the stepping motor then returns to its exact starting location. During the entire procedure, the LVDT measures the displacement of a point on the tissue in the vicinity of the stiffness measurement.

Signal Processing

The signal obtained from the stepping motor is used to determine when the motor is on and when it is off. In the periods of time between steps when the motor is switched off, all other voltage signals are averaged for that period of time. Therefore, there is an average output created for each signal for each step that the stepping motor turns. Next, the signals corresponding to motor reversal and surface contact are used to determine the instant of spindle-target contact and the instant of the occurrence of the peak force. When these instants in time have been determined, the stepping motor, strain gauge, and LVDT signals between these instants are isolated. An estimate of the relative displacement of the target point and the point contacted by the LVDT can then be calculated by subtracting the displacement recorded by the LVDT from that recorded by the stepping motor.

Chapter 5

The Tissue Stiffness Meter (TSM): Reliability and Accuracy

Introduction

Stiffness is defined as the first derivative of a force-deformation curve (with respect to deformation), while average stiffness is defined as the force applied to a tissue divided by the magnitude of the resulting deformation. Health care professionals often use palpation (feeling with the hands) to subjectively assess the stiffness of musculoskeletal tissues, as stiffness is thought to reflect the status of the human musculoskeletal system. It has been demonstrated, however, that palpation as a measure of tissue stiffness, is neither reliable nor accurate. In recent years, attempts have been made to objectively quantify tissue stiffness or inversely, tissue compliance, by using instrumentation. The most widely used instrument is a manual, hand-held device, known as the tissue compliance meter (TCM). This device has been used in the majority of studies exploring tissue stiffness to date, however, it has been shown in Chapter 3 that the TCM is unreliable and inaccurate. If reliably and accurately assessed, tissue stiffness may indeed provide useful information regarding the human musculoskeletal system. To this end, a new device has been developed to solve many of the problems plaguing previous efforts to measure tissue stiffness via instrumentation. This new device has been termed the tissue stiffness meter, or TSM, and a full description of it can be found in Chapter 4.

Purpose

The goal of this study was to determine the reliability and accuracy of the TSM, and to compare results to those obtained previously using the TCM.

Materials and Methods

Materials: The stiffness of five test surfaces were assessed with the TSM. Three of the test surfaces consisted of foam pieces of similar dimension but of different stiffness characteristics. Two control surfaces were used. The first control surface (CS1), was a secure, rigid laboratory bench top. The second control surface (CS2), was a rigid metal plate fixed to the plunger of a 60 cm^3 syringe. The syringe's barrel was fitted with a spring to provide resistance, then oriented in a vertical position. All foam surfaces and CS1 were the same surfaces as those used in previous research when studying the reliability and accuracy of the TCM (Chapter 3).

Methods: The individual electronic components that make up the TSM (Chapter 4) were individually tested. The stepping motor and the displacement transducer were calibrated with gauge blocks of known widths, while the strain gauge was calibrated using blocks of known masses. Each of these testing procedures was repeated ten times for each block and each mass. The accuracy of the displacement and force measurements was assessed using linear regression/calibration curves. The reliability of these measurements was assessed using a root mean square (RMS) analysis (Basmajian and DeLuca, 1985a). The TSM was tested for reliability and accuracy using the five surfaces described above. Ten trials were performed on each test surface using a constant stepping motor speed (4.23 mm/s) for all trials (Chapter 4). The sampling frequency used in data collection was 2000 Hz/channel for the foam surfaces and 5040 Hz/channel for the control surface. The reliability between trials was assessed by calculating an intraclass correlation coefficient (ICC 3,1) (Shrout and Fleiss, 1979) for each surface tested, while the accuracy of the TSM procedure was determined by assessing the relative deformations obtained from CS1 and CS2.

Results

Components: With regard to each electronic component, the smallest r^2 value generated from the calibration curve of any component, was found to be 0.99. Therefore, the relationship between the measured value and the expected value was deemed to be linear within the tested range for each component. The reliability of each electronic component was assessed by calculating the root mean square for each of the ten surface test repetitions and expressing this number as a percentage of the mean test measurement. The RMS values were smaller than, or equal to, 0.025% of the mean in all cases.

TSM: Figure 6 displays the deformation-force curves of ten trials collected from each foam test surface using the TSM. The median ICC when using the TSM for all three foam test surfaces was 0.99. Prior testing of the TCM had shown the median ICC to be 0.005.

Figure 7 displays the relative deformations registered on each test surface using the TCM and TSM. For the TSM, the maximum deformation measured on CS1 was 0.34 ± 0.14 mm at 44.0 N of input force, while the maximum relative deformation for the second control surface, CS2, was 0.008 ± 0.013 mm. Using the TCM, the maximum deformation collected from the first control surface, CS1, was 1.28 ± 0.57 mm at 49.10 N of input force.

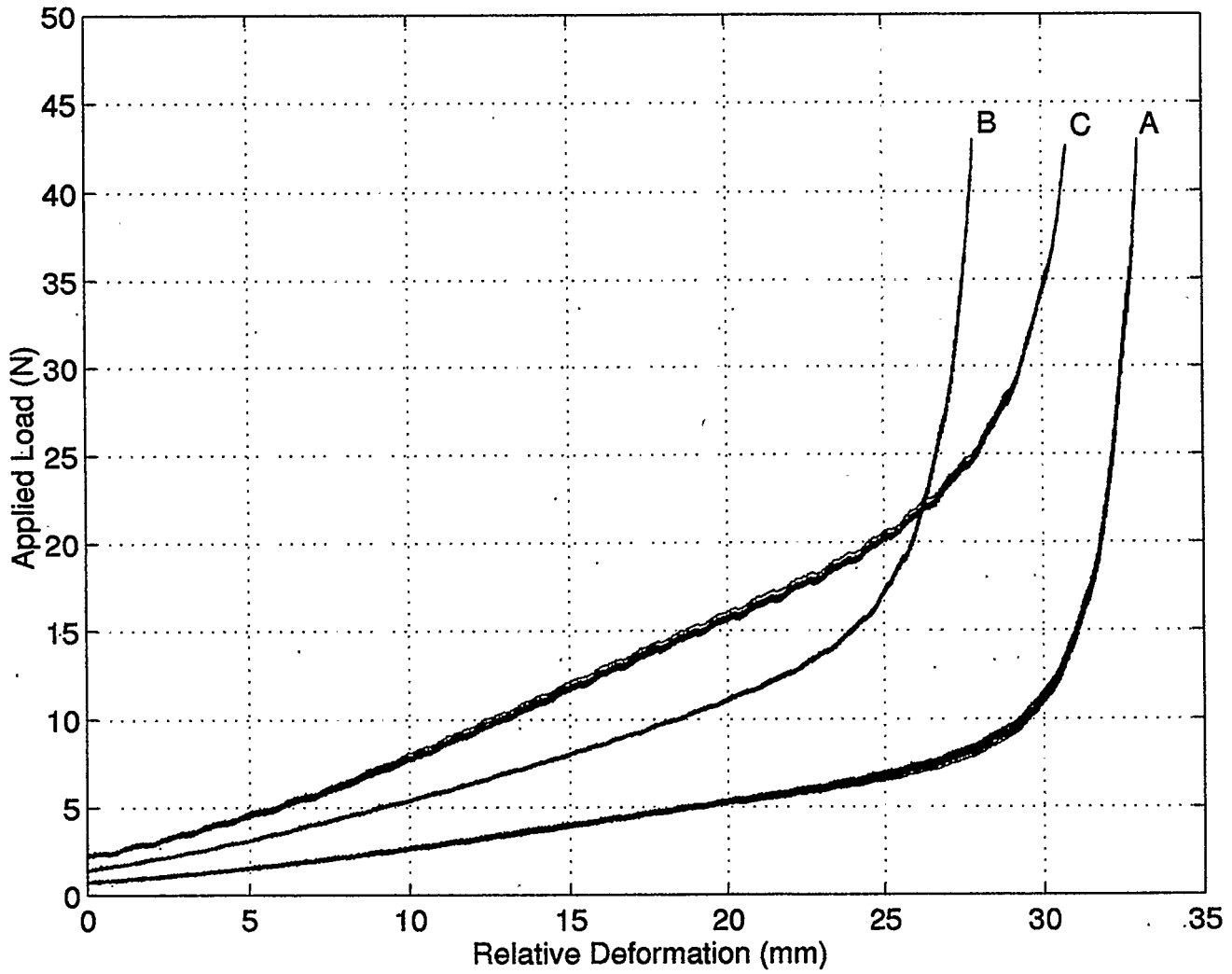
Discussion

In terms of inter-examiner reliability, the TCM demonstrated not only a significant improvement in reliability compared to the TCM, but the value obtained (ICC = 0.99) makes the TSM acceptable for clinical and research applications.

When assessed for accuracy, the TSM displayed a mean relative displacement of 0.34 millimeters compared to the mean of 1.28 mm for the TCM. While this difference is significant, in contrast to the improvement in the reliability findings, the difference in accuracy may not be clinically significant. The largest change in tissue displacement associated with a clinical intervention has been 2.0 mm (Vernon and Gitelman, 1990, Mongini et al., 1993, Sakai et al., 1995, Albright and Fischer, 1990, Granges and Littlejohn, 1993, Hogeweg et al., 1995, Lawson and Sanders (1992a, 1992b) , Nansel et al., 1993), therefore, 0.34 mm represents a 17% error of a 2.0 mm change in displacement. For the purpose of stiffness measurements in clinical and research settings, a mean displacement error of 0.34 mm was considered unacceptable.

It was determined that the relative deformation recorded by the TSM from CS1 was primarily an artifact due to the rigidity of the test surface and the inability of the stepping motor spindle to

Figure 6. Force - deformation curves for three foam surfaces where stiffness increases from foam A to foam C (ten repetitions/surface). At input forces of greater than 20 N, the stiffness relationship between the foams changes due to differences between absolute foam heights (Foam A = 32.99 mm, Foam B = 27.86 mm, Foam C = 30.76 mm).

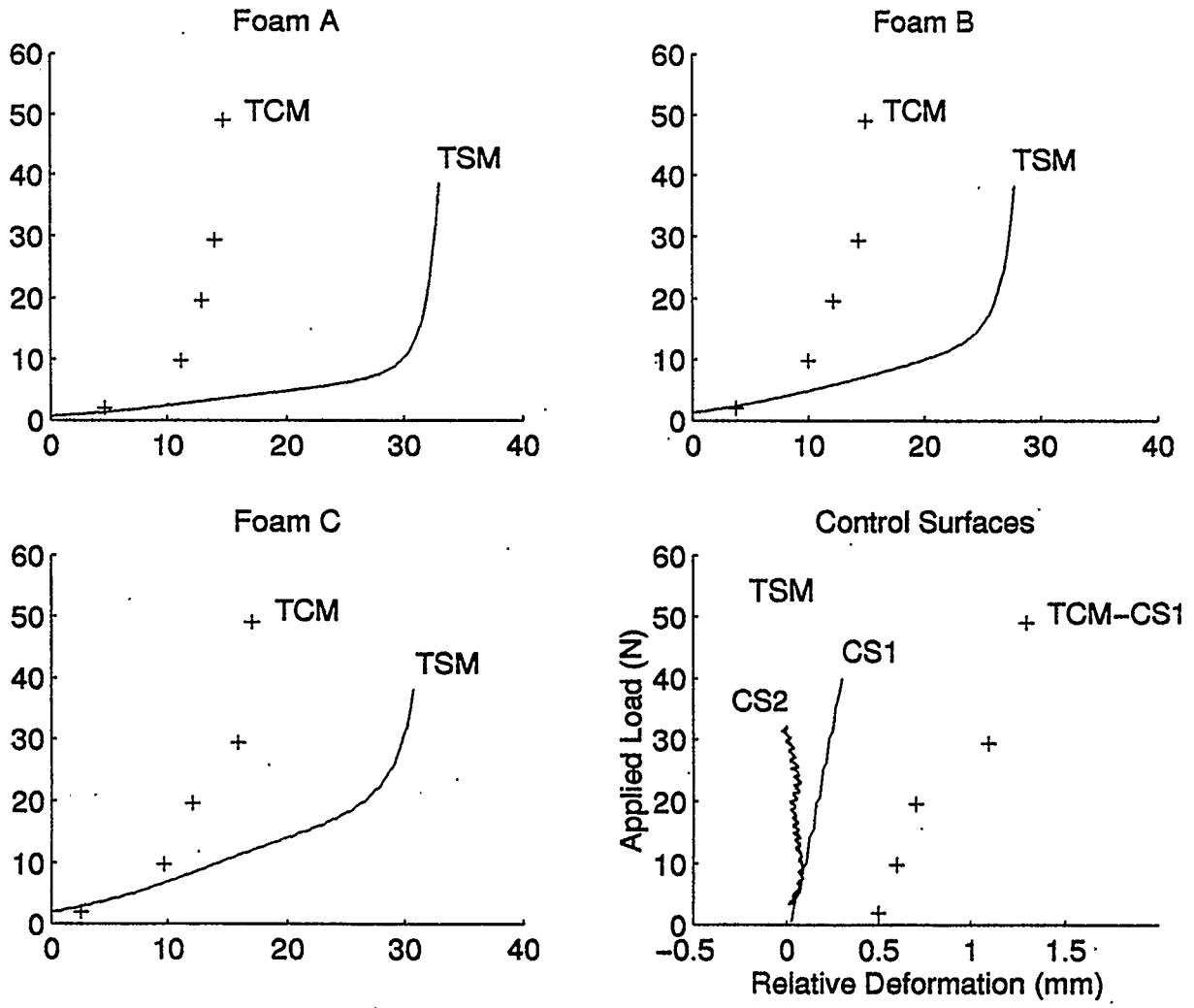


withdraw quickly after spindle/surface contact. It was observed that when a high force threshold was reached at high motor speeds, the spindle locks in the stepping motor housing while the stepping motor continues to turn, thus falsely increasing the displacement measured by the signal collection system. In order to better judge the accuracy of the TSM, a new control surface (CS2) was created. This surface was made by taking a rigid metal plate and mounting it to a spring-loaded base. Therefore, if the spindle and the LVDT were both in contact with the metal plate, the relative displacements between the stepping motor and the LVDT should be zero, although absolute displacements of the rigid surface were possible due to spring compression. Using CS2, the mean relative displacement was found to be 0.008 ± 0.0132 mm, which corresponded to approximately 1/3 of the displacement produced by one full rotation of the stepping motor or 0.4 % of a 2.0 mm displacement measurement. This magnitude of error was deemed acceptable.

Reliability and accuracy were improved in the TSM measurements compared to the TCM measurements because many of the problems associated with the TCM (Chapter 3) were solved in the TSM design. As the TSM collects and displays data directly, errors of analog gauge interpretation are eliminated. The rubber tip at the end of the TCM, which was shown to create problems with the accuracy of tissue stiffness measurements, was eliminated in the TSM. Also, inconsistencies in instrument application from one trial to the next are reduced because the recording sensors of the TSM are fixed within a rigid frame. Errors arising from the inconsistent application of the TCM were one of the major problems identified when using the TCM.

Surface deformation results produced by the TSM were larger than those reported by the TCM at almost all input forces on any test foam (Figure 7). This finding is consistent with the premise that the TSM successfully solved the problems arising from instrument design within the TCM, particularly the phenomenon of "submarining" which tends to under-estimate true surface deformation. Unlike the TCM, the exact moment of tissue-instrument contact can be identified with the TSM, thus allowing for the calculation of absolute displacement from a standardized point. It should be noted that the increased displacement recorded by the TSM compared to the TCM, is not a result of differences in probe surface area and the associated differences in pressures applied, as the TSM target contact area is approximately three times larger than the TCM target contact area, therefore providing less pressure than the TCM for the same force.

Figure 7. Comparison of the mean force-deformation profiles created by the TCM and the TSM for each foam and control surface.



Another advantage of the TSM over the TCM is that the TSM produces a continuous force/displacement output which when plotted, creates a graphical portrayal of a test surface (Figure 6-7). The resultant curve allows an immediate visual comparison between test scenarios. From this graphical output, other surface characteristics can be determined such as tissue compliance and the energy absorbed by a surface. With the TCM, continuous force/displacement measurements cannot be made, although they may be approximated by making hundreds of stiffness measurements at different loads, a time consuming endeavor. Even if several trials were recorded with the TCM to roughly estimate the output of the TSM, it is presumed that repeated trials may alter the stiffness of the tissue, and therefore, bias repeat measurements (Oomens et al., 1987, Viidik 1968, Zeigert and Lewis, 1978).

Figure 6 displays ten force-deformation curves for foam test surfaces A, B, and C, where the stiffness of each surface increases from foam A to foam C. In this figure, increasing slopes are observed for test surfaces with increasing stiffness values to approximately 20 N. With stiffness values of 20 N or greater, the stiffness relationship between the test foams is altered, and presumed to be the result of unequal heights between the foam surfaces (Foam A = 32.99 mm, Foam B = 27.86 mm, Foam C = 30.76 mm).

A limitation of the present study was that it did not use a multi-examiner design, as was used in the previous TCM testing of accuracy and reliability. Because of the automation involved, we have assumed that TSM is virtually examiner independent in terms of data collection. The TSM procedure may be examiner dependent with regard to the setup of the device and subject preparation, points which were not addressed in this study.

Conclusion:

When compared to the results for the TCM, the reliability and accuracy of the TSM are acceptable for future use in clinical and research settings. Many problems that existed with the TCM were overcome in the design of the TSM, particularly problems relating to specific instrument components and instrument application. Improvements made in tissue stiffness measurement were typically manifest as higher estimates of displacement for any given input force. Using the TSM, it may be possible to determine if various features of tissue stiffness have clinical importance.

Chapter 6

Within Subject Changes in the Tissue Stiffness of the Human Lumbar Spine between Resting and Contraction Conditions

Introduction

Stiffness assessment has traditionally been used in many health care disciplines as a way of evaluating the status and/or the function of various tissues in the human musculoskeletal system. Specifically, tissue stiffness has been used in attempts to distinguish between various states of muscle tone, quantify treatment efficacy, and characterize specific diseases. While it is not unreasonable to assume that tissue stiffness may have some importance in musculoskeletal assessment, it has recently been demonstrated that the most common methods of assessing tissue stiffness are unreliable and inaccurate (Maher and Adams, 1994, Kawchuk, Chapter 3). Methods used to assess tissue stiffness include manual assessment by palpation and assessment by instrumentation. As the majority of reports in the literature today have used one of these methods to quantify tissue stiffness, the current body of knowledge regarding tissue stiffness is suspect. Recently, a device called the tissue stiffness meter (TSM) has been described as an accurate and reliable method of assessing tissue stiffness (Chapter 5). With this device, it may now be possible to perform experiments regarding tissue stiffness, and to possibly draw conclusions which are unaffected by instrument performance.

While it is tempting to immediately use the TSM in clinical research, many basic questions regarding tissue stiffness currently remain unanswered. One of these questions concerns the range of potential stiffness in the human musculoskeletal system. The human body, with all of its different structures, presumably has a range of tissue stiffness. This range may be wide, especially

when tissues, such as muscle, are considered which can dramatically change their stiffness in short periods of time due to voluntary, involuntary or pathological conditions. The range of possible stiffness in the human body is not known. Studying this range is of great importance, for if it is found to be narrow, it may not be possible to discriminate between changing stiffness conditions.

Purpose

The primary purpose of this experiment was to use the TSM to quantify tissues stiffness in the human lumbar spine during changing stiffness conditions.

Subjects, Materials, and Methodology

Subjects: Subjects were comprised of volunteers who were recruited from the author's clinical population and from the Faculty of Kinesiology at the University of Calgary. The minimum sample size for this study was found to be eighteen subjects (Appendix A). After providing informed consent to participate in the study, each subject was asked to fill out a questionnaire which had pre-defined criteria to identify subjects at risk (Appendix B).

Materials: Stiffness samples were collected from subjects using the TSM at the spinous process of the third lumbar vertebrae. The specifics of stiffness assessment using the TSM have been outlined in detail in Chapter 4. A maximum force of approximately 50 N was applied at a speed of 4.23 mm/s. At this speed, it took approximately 8 s to obtain a stiffness sample. The contact rod of the LVDT was set at the L2 spinous process. Concurrently, a single channel EMG signal was collected using surface electrodes placed on the left para-vertebral muscles at the level of the third lumbar vertebrae. EMG signals were preamplified near the site of signal acquisition (500 preamplifier x 10 amplifier = 5000 gain). The raw EMG signal was split into an unprocessed signal that was recorded and a raw signal that was processed with a hardware linear envelope filter (400 ms), then redisplayed on an oscilloscope for subject training purposes. All raw voltage signals from the TSM and EMG systems were collected at 3360 Hz using a CODAS analog to digital collection system.

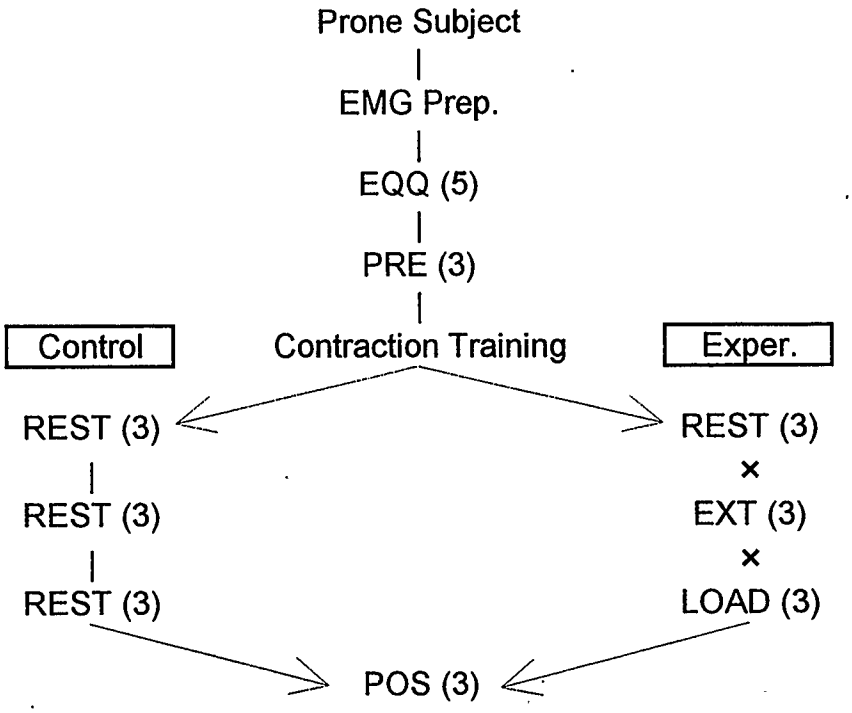
Methodology: Subjects who met the study's inclusion/exclusion criteria (Appendix B) were randomly assigned to either the experimental or the control group (Figure 8), with approximately 15% of the subjects assigned to the control group. Prior to data collection, subjects were asked to lay prone for a period of approximately ten minutes while the site of stiffness assessment was

identified and the back was prepared for EMG measurements by one individual in accordance with procedures described in Basmajian and DeLuca (1985b). The site of electrode placement was lateral to the collection site on the left para-vertebral musculature at the level of L3. After preparation, the subject was asked to lay prone on a flat treatment table and placed under the TSM. All subjects were trained in obtaining a functional residual lung volume (air left in the lungs following passive exhalation), and then maintaining this condition for approximately ten seconds. This training process was done to standardize lung volumes between subjects and to decrease subject variability between trials (Lee et al., 1993a). In all trials, subjects were restrained by straps around the legs and pelvis to decrease movement during contractions.

If a subject was assigned to the experimental group, stiffness samples were collected in the following manner (Figure 8). With the subject at rest, five samples were collected to pre-condition the sample site. These trials were termed EQQ_{1-5} . Following EQQ samples, three additional stiffness measures under the same conditions were recorded and considered to be baseline measures of stiffness (PRE_{1-3}). After these samples were collected, the subject was trained in producing a constant, voluntary, sub-maximal, isometric contraction of the lumbar spine extensor muscles by using visual feedback from an oscilloscope readout of muscle activity. The amount of extension for each subject was limited by placing a horizontal bar approximately 5 cm from the apex of the subject's thoracic spine. The subject was then informed to use as little effort as possible, to keep the oscilloscope readout constant, and to extend their back until it touched the horizontal bar. After this training session, three separate trials were collected for each of three test conditions selected in random order: rest, extension contraction, and extension contraction against a 19 kg load placed on the lower thoracic spine ($REST_{1-3}$, EXT_{1-3} and $LOAD_{1-3}$). Following these trials, three samples of stiffness were collected at rest (POS_{1-3}). Between sets of trials (EQQ, PRE, REST, EXT and LOAD), three minute rest intervals were observed. In total, 20 samples of stiffness were collected per subject in the experimental group.

If the subject was assigned to the control group, 20 trials were recorded under resting conditions spaced in time to approximate the length of data collection observed in the experimental group. As in the experimental group, the control subjects were trained in how to obtain a voluntary isometric contraction of the lumbar spine in extension.

Figure 8. Experimental design flowchart.



Evaluation: Resultant force/displacement data were converted to appropriate units using calibration information obtained in earlier experiments. These data were plotted and approximated using a quintic spline. The first derivative of the force/displacement curve (stiffness), was calculated from the spline approximation. The smoothing coefficient used in the spline approximation was determined by finding the baseline RMS of the strain gauge signal (noise component) and adding a 10% increase. Four variables of interest were identified: the root mean square of the EMG signal (EMG), the maximum deformation at peak force (D_{max}), the maximum stiffness at peak force (S_{max}), and the stiffness occurring at 1/3 of the maximum deformation ($S_{1/3}$). For each subject, a mean was calculated for each trial and for each of the four variables. These mean values were stratified by control or experimental designation. Within subject, paired analysis of variance comparisons (alpha = 0.05) were then made on the resultant change between the PRE group and all remaining groups, as well as a comparison of EXT-LOAD groups. Means and standard errors were obtained for the percentage change in each of the above comparisons for experimental and control data.

Results

A total of 19 experimental subjects and three control subjects were studied (n = 22). The mean subject age, mass, height, and body mass index (BMI) (Burton and Forster, 1985) are shown in Table 1. Figure 9 displays the raw force-deformation curves plotted from a single subject of the experimental group. Plots of the means for all trial groups are presented in Figure 10. Quintic spline approximations of these mean plots can be seen in Figure 11, while Figure 12a displays the stiffness-deformation curves derived from the plots in Figure 11. Figures 12a, 12b, and 12c describe stiffness-deformation data for three subjects who respectively represent low, medium, and high percent change in values of S_{max} for PRE-EXT and PRE-LOAD comparisons (Figure 15). From the paired analysis of variance, p-values were obtained between specific trial group comparisons for subjects in the experimental and the control groups (Table 2). The mean percentage change between trial groups was compiled for experimental and control subjects and is displayed in Figures 13-16 (error bars represent the standard error).

Table 1. Subject characteristics: n = 22

Mean Age (yr)	% Female (10/22)	Mean Mass (kg)	Mean Height (cm)	Mean BMI (kg/m^2)
32.3 ± 6.4	45	71.8 ± 15.0	174.1 ± 8.5	23.4 ± 3.2

Table 2. Levels of significance from paired analysis of variance for trial groups stratified by experimental and control subjects.

Parameter	Group	pre-eqq	pre-rest	pre-ext	pre-load	ext-load	pre-pos
EMG	Exper.	0.60	0.94	< 0.01	< 0.01	0.53	0.32
	Control	0.29	0.13	0.11	0.08	0.52	0.05
D_{max}	Exper.	0.43	0.42	< 0.01	< 0.01	0.57	0.33
	Control	0.99	0.83	0.57	0.63	0.11	0.53
S_{max}	Exper.	0.77	0.93	< 0.01	< 0.01	0.71	0.42
	Control	0.98	0.45	0.72	0.97	0.73	0.68
$S_{1/3}$	Exper.	0.98	0.29	< 0.01	< 0.01	0.94	0.53
	Control	0.36	0.87	0.96	0.77	0.84	0.73

Figure 9. Raw force-deformation curves for subject #6. EQQ = subject at rest (pre-conditioning trials), PRE = subject at rest (baseline trials), REST = rest trials occurring in random order with EXT & LOAD groups, EXT = subject performed a lumbar extension, LOAD = subject performed a lumbar extension with a 19 kg load on the thoracic spine, POS = subject at rest following all previous trials.

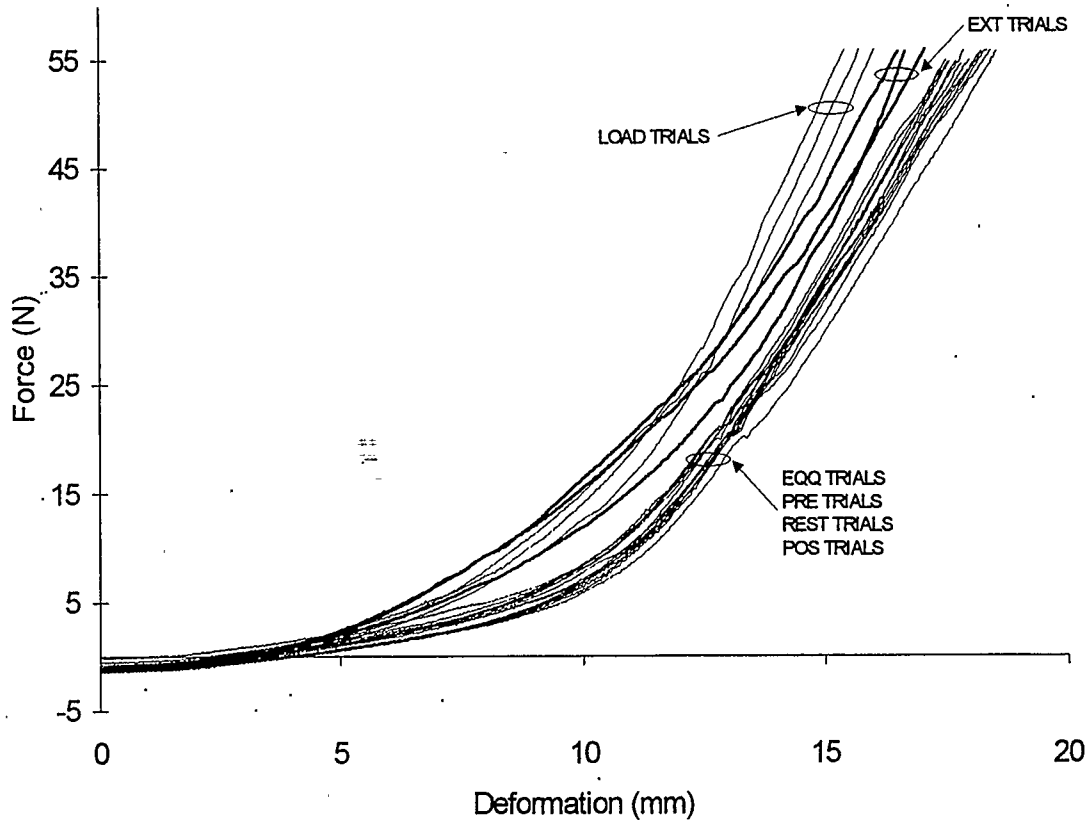


Figure 10. Mean force-deformation curves for subject #6. EQQ = subject at rest (pre-conditioning trials), PRE = subject at rest (baseline trials), REST = rest trials occurring in random order with EXT & LOAD groups, EXT = subject performed a lumbar extension, LOAD = subject performed a lumbar extension with a 19 kg load on the thoracic spine, POS = subject at rest following all previous trials.

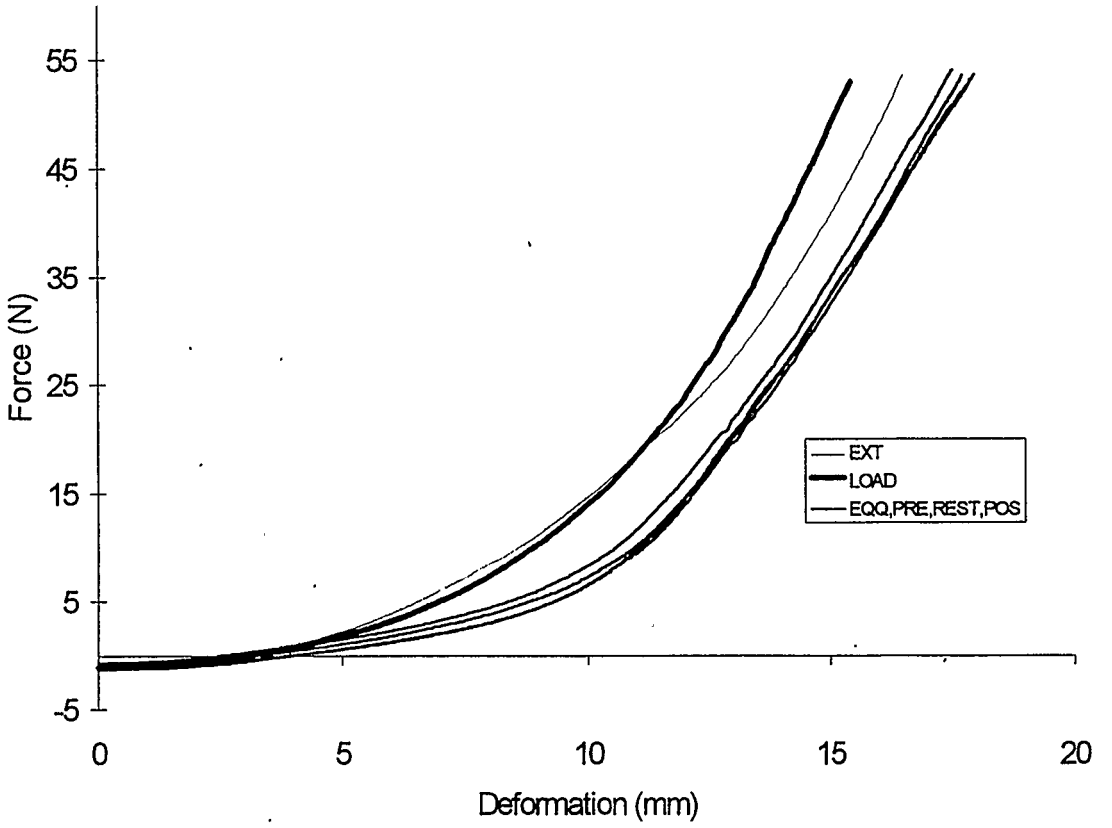


Figure 11. Quintic spline approximations of mean force-deformation curves for subject #6. EQQ = subject at rest (pre-conditioning trials), PRE = subject at rest (baseline trials), REST = rest trials occurring in random order with EXT & LOAD groups, EXT = subject performed a lumbar extension, LOAD = subject performed a lumbar extension with a 19 kg load on the thoracic spine, POS = subject at rest following all previous trials.

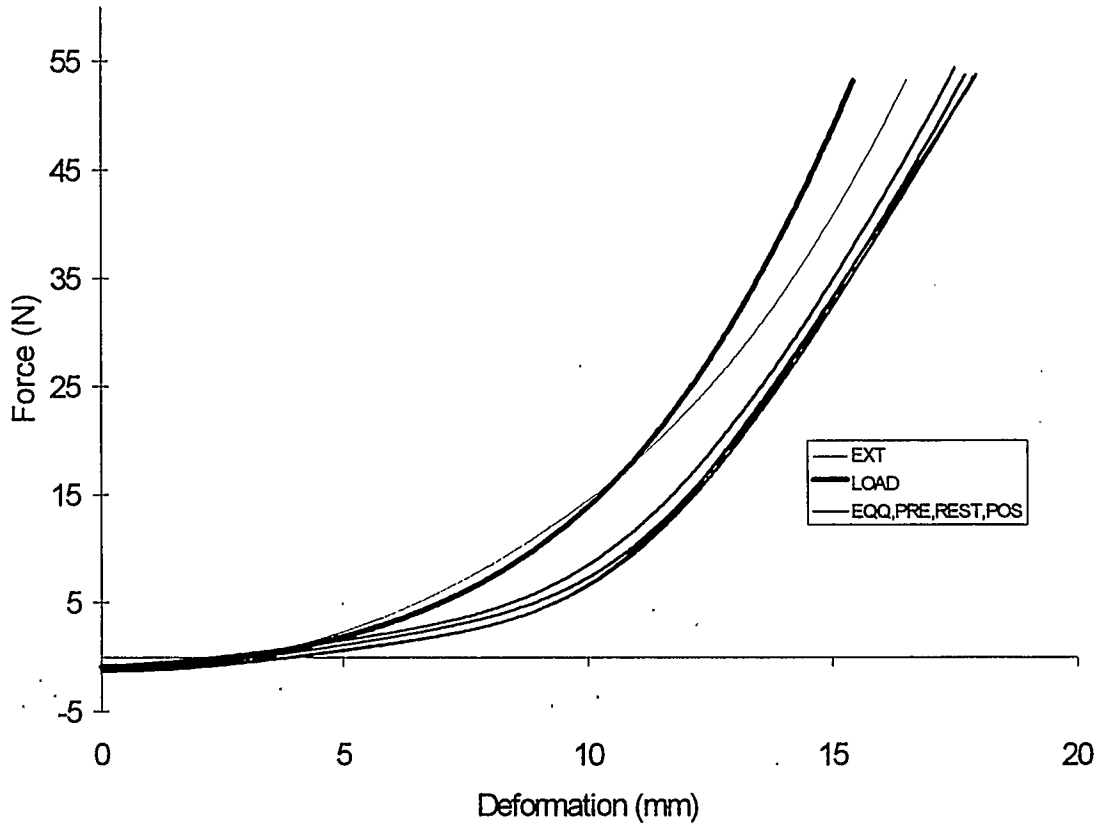


Figure 12a. Mean stiffness-deformation curves derived from quintic spline approximations for subject #6. The S_{max} value of subject #6 represents a below average percentage change with respect to pre-ext and pre-load comparisons (Figure 15) EQQ = subject at rest (pre-conditioning trials), PRE = subject at rest (baseline trials), REST = rest trials occurring in random order with EXT & LOAD groups, EXT = subject performed a lumbar extension, LOAD = subject performed a lumbar extension with a 19 kg load on the thoracic spine, POS = subject at rest following all previous trials.

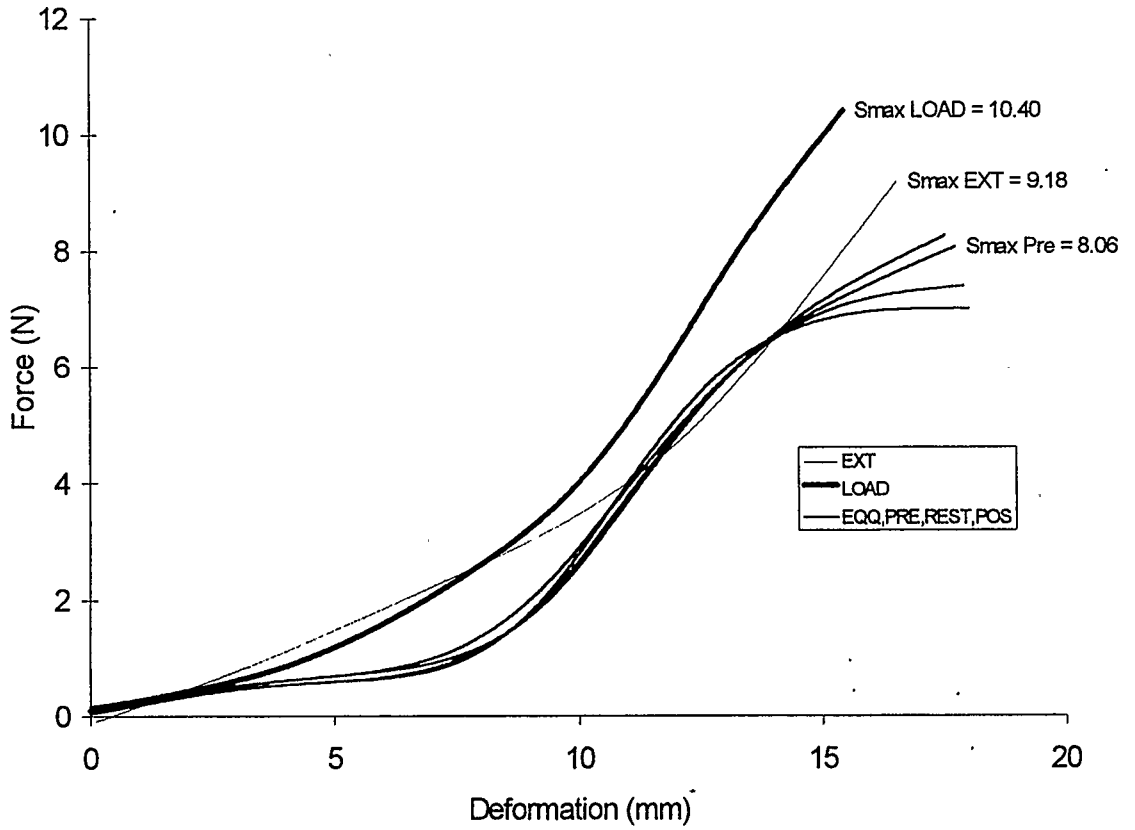


Figure 12b. Mean stiffness-deformation curves derived from quintic spline approximations for subject #18. The S_{max} value of subject #16 represents an average percentage change with respect to pre-ext and pre-load comparisons (Figure 15) EQQ = subject at rest (pre-conditioning trials), PRE = subject at rest (baseline trials), REST = rest trials occurring in random order with EXT & LOAD groups, EXT = subject performed a lumbar extension, LOAD = subject performed a lumbar extension with a 19 kg load on the thoracic spine, POS = subject at rest following all previous trials.

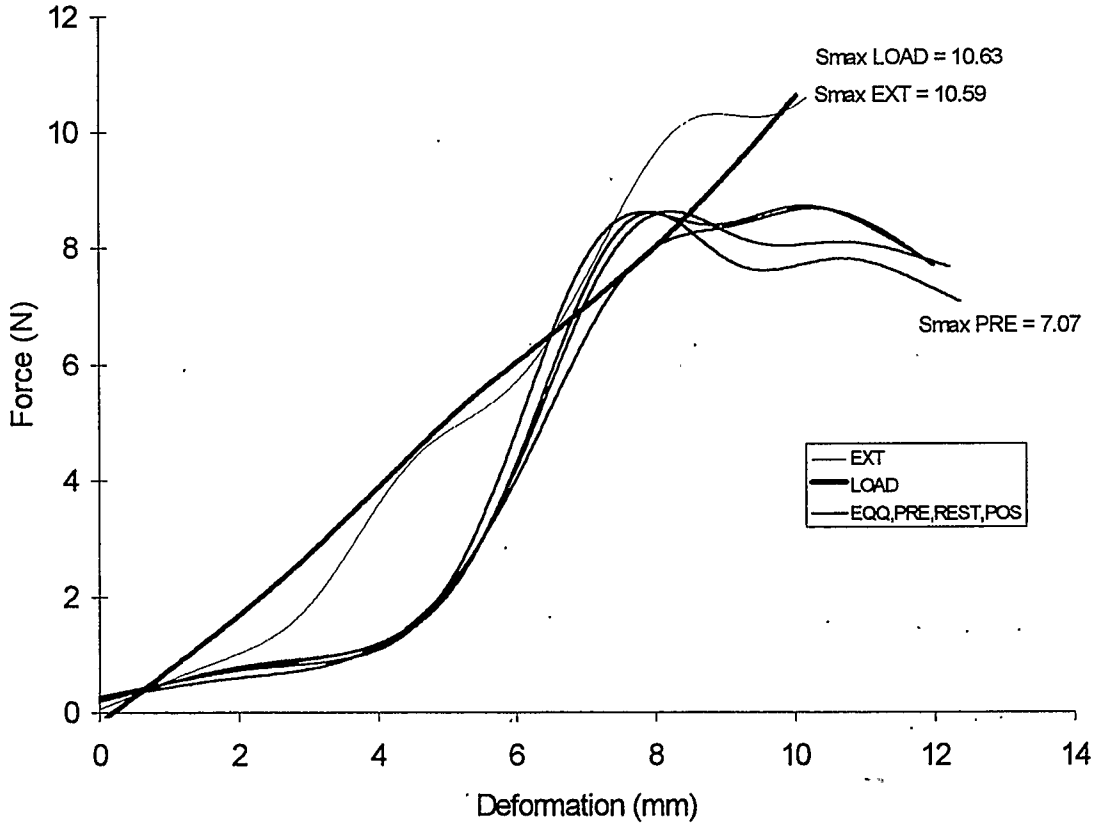


Figure 12c. Mean stiffness-deformation curves derived from quintic spline approximations for subject #20. The S_{max} value of subject #18 represents an above average percentage change with respect to pre-ext and pre-load comparisons (Figure 15). EQQ = subject at rest (pre-conditioning trials), PRE = subject at rest (baseline trials), REST = rest trials occurring in random order with EXT & LOAD groups, EXT = subject performed a lumbar extension, LOAD = subject performed a lumbar extension with a 19 kg load on the thoracic spine, POS = subject at rest following all previous trials.

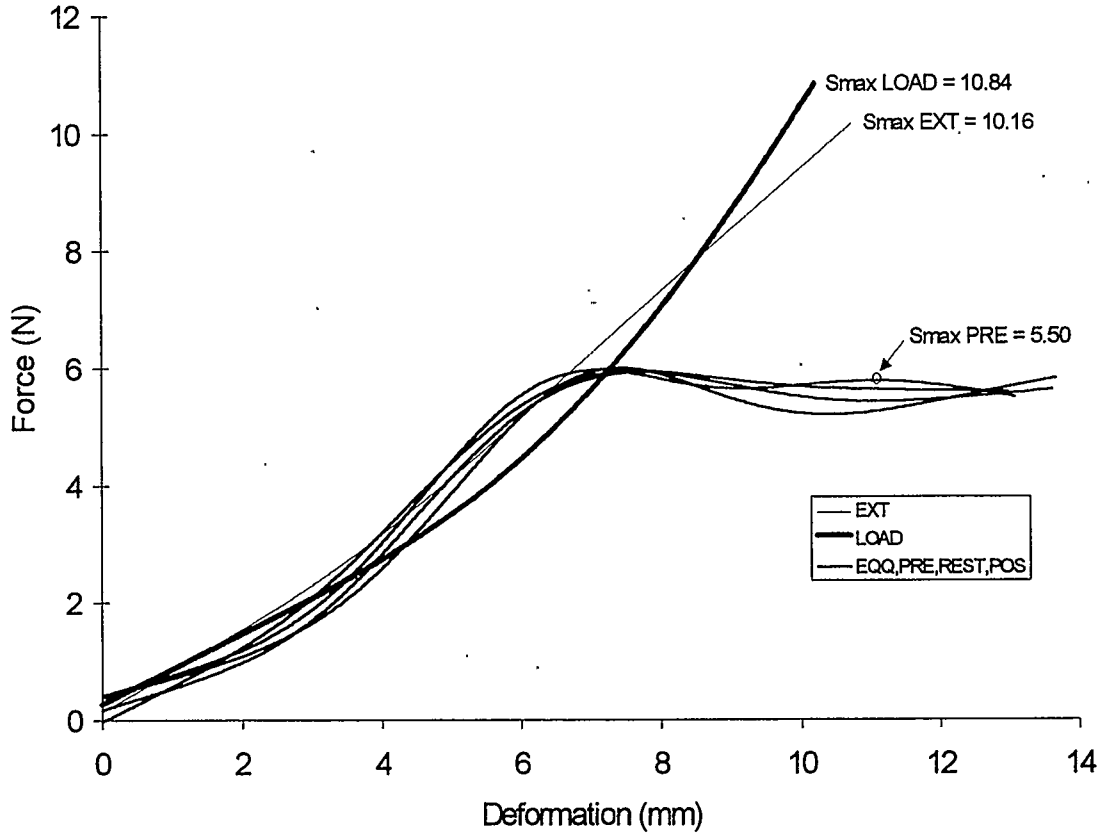


Figure 13. Mean percentage change of EMG output (RMS) where percentage change = ((Smax of group of interest/Smax PRE) * 100) - 100. Experimental group, n = 19. Control group, n= 3

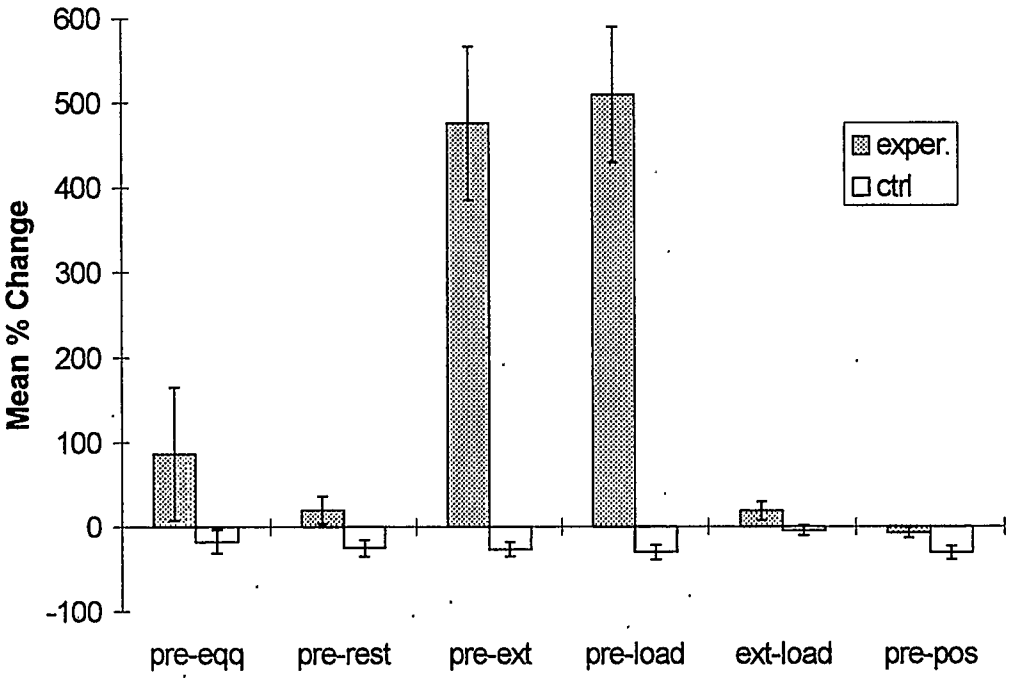


Figure 14. Mean percentage change in the maximum deformation where percentage change = ((Smax of group of interest/Smax PRE) * 100) - 100. Experimental group, n = 19. Control group, n= 3

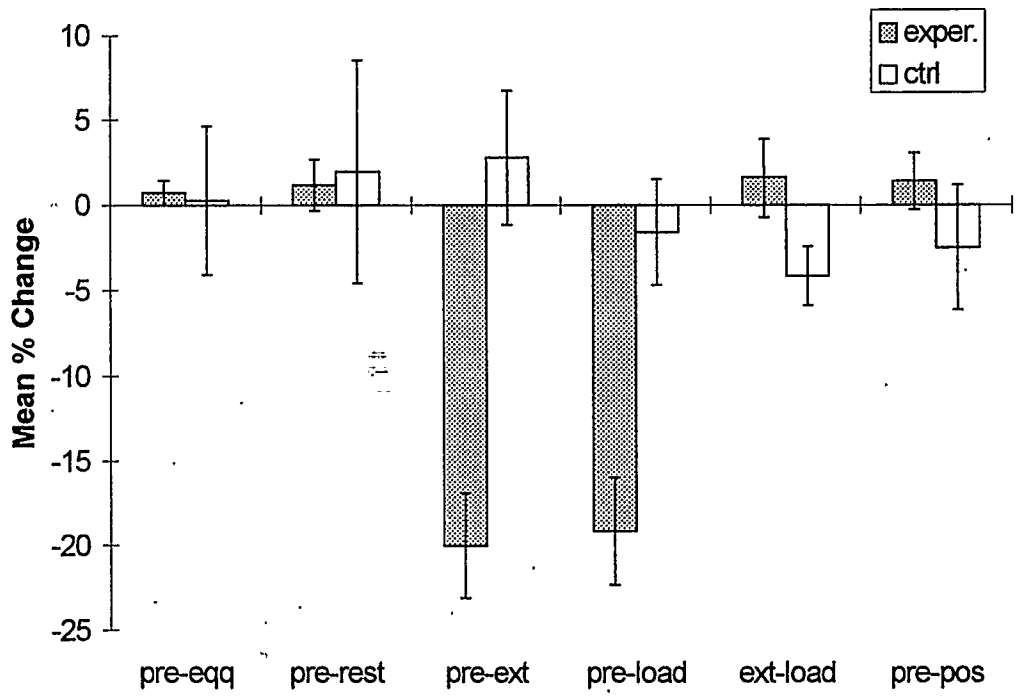


Figure 15. Mean percentage change in the maximum stiffness where percentage change = ((Smax of group of interest/Smax PRE) * 100) - 100. Experimental group, n = 19. Control group, n= 3

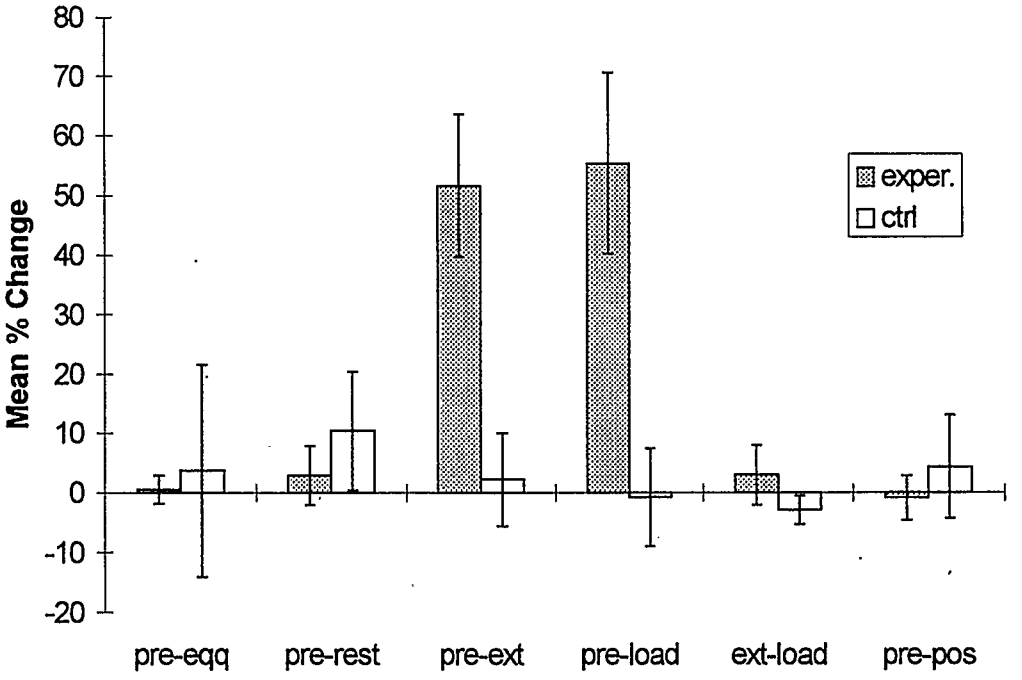
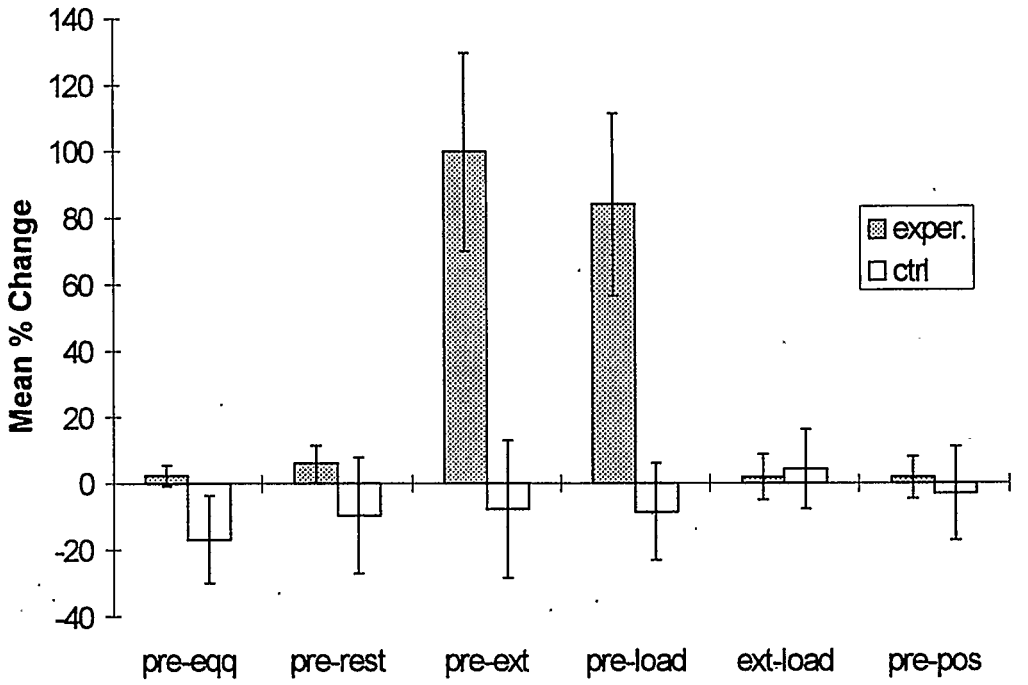


Figure 16. Mean percentage change in $S_{1/3}$ where percentage change = ((Smax of group of interest/Smax PRE) * 100) - 100. Experimental group, n = 19. Control group, n= 3



Discussion

While studies outlining the specific stiffness characteristics of the target site used in this study have not been encountered, it is surmised that the tissue superficial to the L3 spinous process behaves like most other soft tissues: visco-elastically (Viidik, 1968). Pilot data collected for this study indicated that three trials of 50 N applied at 4.23 mm/s, are sufficient to pre-condition the tissue overlying the target site (L3). Therefore, prior to the recording of the baseline trials (PRE), five stiffness samples were collected in an attempt to pre-condition the target tissue.

From Figure 13, it can be seen that in the experimental subjects, the EXT and LOAD data differed significantly from the PRE data ($p < 0.01$) with respect to EMG output, while the remaining comparisons were not significant. These findings suggest that with respect to EMG, muscle activity in the two groups differed significantly from the baseline EMG measurements. Assuming that muscles in a state of contraction are stiffer than those at rest, these data suggest that the stiffness of the para-vertebral muscles increases. It was assumed that activation of the para-vertebral muscles in the L3 region would increase the functional stiffness of the vertebral motion segment in the same region.

With respect to the design of this study, it was assumed that EXT and LOAD groups would have different mean muscle activity levels, and therefore, different mean stiffnesses. It was noted that the EXT and LOAD trial groups did not differ significantly with respect to EMG output. Several explanations for this observation are possible. Firstly, subjects may be able to employ different contraction strategies, presumably involuntarily, that would enable them to maintain the same approximate stiffness in the spine, independent of loading conditions. It is known that in an extension contraction of the lumbar spine, muscle groups are used in alternating ways to reduce fatigue (van Dieen et al., 1993), but it is not known if specific patterns are employed as loading conditions change. If this were the case, an EMG signal recorded at one location may not be representative of the overall contraction phenomenon. Secondly, fatigue of the para-vertebral muscles over several contractions may have affected the EMG data. Given that several calculations in the literature show that an 8 second maximal voluntary contraction is one half the time estimated for fatigue onset (Manenica, 1986, van Dieen and Vrielink, 1994), and that randomness between REST, EXT and LOAD trial groups occurred, it seems unlikely that muscle fatigue was a major factor causing equivalency between EXT and LOAD comparisons. It should be noted that the

LOAD condition utilized one load for all subjects (19 kg), therefore, by not using subject-relative load increases, the amount of force needed to contract against the load may have been substantially different among individuals causing a wide range of percentage change. Lastly, the reproducibility of the subjects to perform EXT and LOAD trials was not quantified. It should also be recognized that despite the EMG signals being considered "flat" when observed at the highest gain available in PRE trials, significant changes were observed in the EMG output of the control subjects. These changes were found to be negative (decreased muscle activity) and were presumably due to 1] subjects becoming more relaxed as time passed, 2] the TSM having a treatment effect that decreased EMG output or 3] a combination of both.

While it has been demonstrated in this experiment that changes in muscle activity as measured by EMG exist between contraction and resting conditions, it can not be assumed that any resulting change in stiffness would be large enough in magnitude to be detected by the TSM. In order to determine if the differences in EMG output can be detected by the TSM, three different parameters were studied: D_{max} , S_{max} , and $S_{1/3}$.

Significant changes were seen (Table 2) between the PRE-EXT and PRE-LOAD groups for all test parameters (D_{max} , S_{max} , and $S_{1/3}$). Specifically, there is a decrease in the amount of the maximum deformation (D_{max}) in the EXT and LOAD groups when compared against the PRE group (Figure 14). This finding is presumably associated with increased stiffness of the target site resulting in a decreased deformation for a given force. This speculation was supported by observing that the maximum stiffness (S_{max}) significantly increased in the PRE-EXT and PRE-LOAD comparisons.

It can not be concluded that because the maximal stiffness increased between rest and contraction conditions, that the stiffness of the tissue was increased throughout the test range. One method of addressing this question is to qualitatively observe plotted data (Figure 12). It can be seen that in applied forces greater than approximately three Newtons, the REST and LOAD groups are higher in stiffness throughout each of their plots when compared to the PRE plot (Figure 12). While the qualitative method described above is useful, quantitative methods can be employed to compare single stiffness values that occur at some point prior to maximal deformation ($S_{1/3}$). As with D_{max} and S_{max}, significant changes were noted in the $S_{1/3}$ comparisons of PRE-EXT and PRE-LOAD.

While significant changes were detected for all test parameters in PRE-EXT and PRE-LOAD comparisons, insignificant changes were noted in EXT-LOAD comparisons for S_{max} , D_{max} , and $S_{1/3}$. This finding may be anticipated, given comparisons of EXT-LOAD were non-significant for EMG. While there may be EMG-specific explanations as to why these changes were not observed, these explanations may not clarify why comparisons using TSM generated variables were non-significant. One explanation why these changes were not observed, may be that the experimental protocol did not limit the movement of the subjects sufficiently when they were asked to perform EXT and LOAD trials. Although unknown at this time, different vertebral alignments attained in different degrees of extension, may distribute stiffness differently in the spine.

Few studies have provided reliable, accurate stiffness data where pre-conditioning protocols were employed. Therefore, the magnitude of the change in stiffness from rest to contraction was not known prior to this study, nor was the variability of these changes. If the variability was found to be relatively large, then the change between stiffness states would be difficult to detect in spite of the magnitude of the changes. It appears that the changes in D_{max} , S_{max} , and $S_{1/3}$ were large enough and that the variability was small enough to observe significant changes in all three of these parameters.

Limitations of the study: In study designs where multiple comparisons between variables are made (D_{max} , S_{max} , and $S_{1/3}$), there is arguably no primary statistical analysis, therefore, the resultant p value of each comparison is typically multiplied by the total number of comparisons made. Because the comparisons in this study are essentially descriptive in nature, the multiplication of p values by total number of comparisons made is not appropriate.

An original aim of this study was to quantify the relative deformation between L2 and L3. Because of difficulties with skin traction, the LVDT probe could not function properly, resulting in large artifacts in the relative deformation data. As a result, the absolute, not the relative spindle deformation, was quantified. Therefore, errors caused by breathing or other movements of the trunk during stiffness sampling could not be eliminated and were part of the raw deformation data.

Finally, it can be presumed that inconsistencies in how subjects were prepared, trained, and handled during data collection could potentially affect the results, but it is believed that the methodology used in this experiment minimized this possibility.

Conclusion

The TSM is capable of distinguishing between various tissue variables for conditions of rest versus conditions of lumbar spine extensor musculature contraction. This finding implies that the magnitude of the observed changes were larger than the variations in the measurements.

Chapter 7

Discussion

TSM development

This thesis was inspired by two observations: first, that the vast majority of tissue stiffness assessment instruments have not been tested for reliability or accuracy, and second, that one of these untested devices, the TCM, had been used in a large number of scientific reports. Based on these observations, the reliability and accuracy of the TCM was tested and found to be poor. Not only has the field of tissue stiffness measurement been afflicted by a lack of reliability and accuracy reporting, other limitations regarding tissue stiffness assessment devices have be identified. Specifically, some devices are highly invasive and not useful in clinical circumstances. Other devices are limited to assessing stiffness in one specific anatomical area or are limited to assessing tissues of restricted dimensions. With these problems and limitations in mind, the TSM was developed to create an accurate and reliable tissue stiffness measurement system for that can potentially be used to assess any external anatomical landmark, and to do so in a non-invasive manner.

The TSM was designed to overcome the limitations found in the design and application of the TCM (Chapter 5). Some of the altered design features include: a rigid spindle indentor, the use of an independent reference system regarding tissue deformation and automated stiffness sample collection. The implementation of these features in the creation of the TSM may be considered as a primary reason why the TSM has significantly higher reliability and accuracy in comparison to the TCM.

The primary improvements seen in the TSM's accuracy are believed to be the result of eliminating the phenomenon of "submarining". The chief manifestation of this improvement is an increase in the measured deformation for a given input force (Figure 7). While it is possible that the phenomenon of "submarining" may be a systematic process which could be corrected for, many other factors contributing to poor TCM accuracy make this possibility doubtful. As a result, it may be expected that in clinical applications, the TSM would show larger absolute measurements of tissue deformation, and possibly, demonstrate larger changes in tissue deformation than the current literature maximum of 2.0 mm.

Regarding the TSM, its improvement in reliability over the TCM is thought to be the result of the TSM's automated data collection and automated force application. These processes greatly improve reliability by removing human errors. As a result, a change in sequential stiffness samples may be assumed to be an undistorted reflection of the tissue's properties. Practically, this improvement has already been used in pilot work to identify tissue pre-conditioning trends in the superficial tissues of the lumbar spinous processes. The possibility of defining pre-conditioning properties of various tissues may have applications in many clinical areas such as massage, algometry, and surgery. These types of data may also be important in the determination of protocols regarding stiffness measurement collection and interpretation.

TSM: Contraction Study

In this thesis, significant within subject changes in tissue stiffness were found between resting and contraction conditions. This finding supports previously published reports (Krouskop et al., 1987, Owen, 1988). On further inspection, these investigators detected tissue stiffness increases at sample sites directly superficial to the muscle of interest, a protocol which most directly assesses the effect of muscle contraction on external stiffness measures. In contrast, the protocol used in this thesis measured stiffness from a site distant to direct muscular activity, namely at the spinous process of L3. At the L3 spinous process, there is little, (if any), hypodermal tissue. Accordingly, the stiffness measured at L3 is the result of a distant effect, making the direction and magnitude of the potential change in stiffness less obvious than in the work of Krouskop et al. (1987) and Owen (1988). Therefore, while the results of this research corroborate the findings of Owen (1988) and Krouskop et al. (1987), the results also demonstrate that the TSM is capable of detecting changes in tissue

stiffness at sites distant to the origin of stiffness causation. This conclusion is supportive of statements made by Torres-Moreno et al. (1992), that sample site location and underlying tissue activity greatly effect the magnitude of the resultant stiffness.

In the future, the TSM may be used to study issues regarding tissue stiffness which are more clinically oriented. Unlike the contraction study presented here, clinical studies would presumably be directed at studying the effects of treatment, the majority of which attempt to decrease the stiffness of injured or pathological tissues. It can not be presupposed, however, that a decrease in stiffness is detectable. Although as yet unquantified, it may be assumed for the area of the L3 spinous process, that upper and lower boundaries of stiffness exist with an associated baseline value occurring somewhere between these boundaries. If the baseline stiffness of a tissue was in close proximity to the lower stiffness boundary, it may be a very difficult task to detect a decrease in stiffness from baseline conditions, especially if the variabilities of the baseline and the lower boundary overlap. In this case, even very accurate and reliable instruments will not be able to detect possible stiffness alterations (Lee et al, 1993b). It is recommended that future clinical studies use designs which incorporate symptomatic subjects; these subjects will likely have an elevated baseline stiffness which may decrease substantially with treatment.

It must be noted that the TSM, particularly this prototype, has limitations of its own. The length of the spindle and the LVDT rod are finite, which is problematic when assessing tissues where the expected deformation is beyond the equipment's range. It was observed that irregularities in the test surface, or non-congruence between the test surface and spindle indentor, caused translation of the spindle inside its housing, resulting in stepping motor malfunction. This problem could be solved by using an advanced bearing system which may reduce friction during translations of the spindle. It was observed that when the LVDT is in close approximation to the point of spindle/tissue contact, the skin underneath the LVDT rod will be displaced laterally, causing erratic LVDT movement, particularly if large tissue deformations are expected at the site of applied load (Lee and Liversidge, 1994). Solutions to this problem include placing the LVDT at a site more distant to the spindle/tissue interface or using alternate methods of detecting tissue movements, such as video recording. Lastly, because subjects must hold their breath at the functional residual capacity (FRC) in stiffness measures taken in the chest and trunk, the ability of a subject to maintain a FRC will limit the sample collection time, preventing the use of low rates of force application.

Chapter 8

Conclusion

Purposes of this thesis were to determine the reliability and accuracy of the TCM, to design and build a device which would improve the accuracy and reliability of stiffness assessment, and to use that device in a practical application. Each purpose was achieved.

More specifically, it was demonstrated that the most common device used in clinical tissue stiffness assessment, the TCM, was lacking reliability and accuracy. A new device, the TSM, was designed, constructed, and found to be reliable and accurate. When used to determine differences in tissue stiffness in the lumbar spine between resting and contraction states, the TSM was able to distinguish between these conditions. While the TSM may be considered to be an improvement over the status quo with respect to accuracy, reliability and the capacity to collect stiffness data at multiple anatomical landmarks, the TSM in its present form is a research tool. The TCM has been widely used in research and clinical settings because it is easily applied, unlike the TSM. While the TSM provides high quality information regarding stiffness which can lead to clinically relevant studies, the TSM may not have as much impact in health care unless it can be designed to be more practical.

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Appendix A

The formula used to calculate minimal sample size was as follows:

$$N = \frac{(Z\alpha/2 + Z\beta)^2 * \sigma_D^2}{\delta^2} \quad (1)$$

where $Z\alpha/2 = 1.96$
where $Z\beta = 0.842$
where $\sigma_D^2 = 2*(1-p)\,\sigma^2$

where p = (bms-wms) / (bms+(m-1)wms)) = .94
where bms = between sum of squares of the pilot rest condition / (n-1) = 3.66
where wms = within sum of squares of the pilot rest condition / n(m-1) = 0.0825
and n = subjects in pilot = 22
and m = measurements / subject = 3

where σ^2 = the variation in the means of the measurements for all subjects **
**(to increase N, the largest single observed variance was used) = 4.60
**(the actual σ^2 is 1.16, which results in an N of 5 subjects)

where δ^2 = expected absolute difference = 0.5 N / mm

$$N = \frac{(1.96 + 0.842)^2 * (2 * (1 - 0.94) * 4.60)}{(0.5)^2} \quad (2)$$

N = 17.32 = 18 subjects

Appendix B

Subject Consent Form

Principal Investigator: Dr. Greg Kawchuk
Co-Investigator: Dr. Walter Herzog

This consent form, a copy of which has been given to you, is only part of the process of informed consent. It should give you the basic idea of the goals of the study and what your involvement in the study will be. If at any time you would like more information about the items in this form or information not included here, please do not hesitate to ask. Please take your time and read this form carefully.

PURPOSE

The purpose of this experiment is to compare the amount of tissue compliance, or "give", in the lumbar spine during rest and then during muscular contraction.

EXPLANATION OF YOUR INVOLVEMENT

You will be asked to attend a training session and possibly a data collection session. In the training session, you will be asked to fill out a questionnaire about you medical history. The investigators will then immediately review your questionnaire. If an aspect of your medical history is of concern, you be asked not to participate in the study. If allowed to continue, you will have your height, and weight measured. You will then be assigned to one of two groups.

If you are selected for group one, you will be asked to lay face down on a comfortable therapy table, with your back exposed for 10 minutes. If you are not experiencing any discomfort, a measurement of tissue compliance will be taken. This involves you taking a breath in, then gently blowing it out and holding your breath for 20 seconds. In the time that you are holding your breath, a device known as a tissue compliance meter will be gently lowered onto your back. This device will slowly push on your back and take measurements of how stiff your back is. The device will then be removed from your back, and after a total of 20 seconds, you will be instructed to breath normally again. Twelve of these measurements will be taken over the course of about a half an hour.

If you are selected for group two, a harness will be attached to your middle back which is like a mountain climbers harness. You will then be asked to lay face down on a comfortable therapy table and the harness will be connected to the table and two straps will be gently tightened around your back. This is done to prevent movement in your back, but at any time, you may ask to have the straps removed. You will then be asked to take a breath in, gently breath out and hold your breath for 20 seconds. In the time that you are

holding your breath, you will be asked to contract your back muscles. An electronic readout in front of you will show you how powerful your contraction is. You will be asked to practice this contraction with different amounts of strength that you will see on the electronic display. If at any time the contraction process is painful to you, you may ask to have the study stopped. You will then be asked to rest for 10 minutes. After this time, if you are not experiencing any discomfort, you will be have twelve measurements of tissue compliance taken from your back in the way described above. Six of these measurements will be taken while you are at rest, and six while you are asked to contract your back over the course of about a half an hour.

POTENTIAL RISKS AND DISCOMFORTS

The risks involved are minimal. Some people experience discomfort in their backs when they lay on their stomach for long periods of time or when they perform the types of muscle contractions described here. By taking your medical history before you start the experiment and testing you in the training sessions, we believe that we can identify persons who will have difficulty with the tasks of this study.

BENEFITS

This study will assist the investigators in the understanding of how to measure back stiffness in humans. In the future, it is hoped that this method of assessing back stiffness can be used to determine how effective various methods of treating back pain are.

CONFIDENTIALITY

All information obtained in this study will be kept confidential. Some or all of the information gathered may be used for publication in a scientific journal, but your name will not appear in any published report.

FREEDOM OF CONSENT

Your agreement to perform in this study, as outlined in this form, is voluntary and you are free to withdraw from the study whenever you choose. Your continued participation should be as informed as your initial consent, so you should feel free to ask for clarification of any new information throughout your participation. If you have further questions about this study, please contact Dr. Greg Kawchuk at 278-2077. If you have any concerns as to the conduct of this study, you may contact the Joint Faculties Research Ethics Committee by calling the vice-president (research) office and ask for Karen McDermid (220-3381).

I have read this form and I understand the procedures required of me. I consent to participate in this study.

_____

Subject Date

_____

Investigator Date

_____

Witness Date

Inclusion / Exclusion Criteria

The subject shall be **included** in the study if the following conditions are met:

1. The subject has given his/her written consent to participate and is of legal age to do so.
2. The subject has completed a medical history questionnaire.
3. The subject is ambulatory and exhibits no outward sign of illness nor describes any symptom of illness that would exclude his/her from this study as described in the exclusion criteria.

The subject shall be **excluded** from participation in this study if any of the following are true:

1. The subject does not provide written consent.
2. The subject does not complete the medical history questionnaire.
3. The subject indicates in the questionnaire that he/she have one of the following:
    - A history of pulmonary disease which prevents he/she from holding his/her breath for 20 seconds and experiencing illness.
    - A history of previous spinal surgery, or the presence of specific spinal congenital anomalies.
    - A neuromuscular disease as outlined in the questionnaire.
    - A current injury of the spine and/or associated anatomy.
    - Pain in the spine with or without radicular symptoms or referred pain.
4. The subject has had any form of treatment directed at their lumbar spine (medication, manipulation, massage, therapeutic modalities including exercise) in the last 6 weeks

Subject Medical History Survey

1. What is your age? _____

2. Do you have any problem with your health that would be aggravated by holding your breath out for 20 seconds (please circle)? Y N

3. Do you have any problem with your health that would be aggravated by bending backwards for 20 seconds (please circle)? Y N

4. Do you have any problem with your health that would be aggravated by laying on your stomach for 30 minutes (please circle)? Y N

5. Do you currently have any back or neck pain? Y N

6. Have you had any treatment to your low back in the last 6 weeks (medication, massage, chiropractic, physical therapy etc.) ? Y N

7. Have you had any surgery to your spine? Y N

8. Do you have any of the following (please circle):

asthma
arthritis
herniated or slipped disk
spondylolithesis
spina bifida
multiple sclerosis
muscular dystrophy
fused vertebrae
sciatica
contagious skin conditions

THE UNIVERSITY OF
CALGARY
Human Performance Laboratory
Faculty of Kinesiology

To: G. Kawchuk and W. Herzog

From : M. R. Hawes, Chair Faculty Ethics Panel

Date: May 4, 1995

Re: Submission for Ethics approval

"The characterization of functional tissue compliance in the human lumbar spine"

All ethical concerns with respect to this study have been cleared and the project is approved. Please note that the approval is for the procedures as stated, any proposed changes to the approved procedures should be brought to the attention of the Ethics chairperson before they are incorporated into the study.

Michael R. Hawes
Chair, Departmental Ethics Panel

Appendix C

An explanation of splines and their use in this thesis.

Single polynomial functions are often used to approximate simple x-y functions. Generally, as the function to be modeled becomes more complex, a higher order polynomial is required to approximate the function's x-y characteristics. When the data to be modeled has a relatively significant noise component, a spline is often employed to approximate the signal component of the data.

A spline divides the function in question into sub-sections and uses separate polynomials of degree *n* to approximate each section. The type of spline used in this thesis was a *smoothing spline* which uses separate polynomials between each data point. The final approximation is a continuous function made of several individual polynomials stitched together. A smoothing factor is used to determine how closely the spline should approximate the original data or display an underlying trend.

The spline itself is composed of polynomial functions and can be differentiated because the high order derivatives of points of intersection are forced to be the same (smoothness conditions). The spline can also be integrated, providing that the initial conditions are known.

In this thesis, a quintic spline was used to approximate force-deformation curves. A quintic spline was chosen because a variable of interest was taken from the terminal portion of the first derivative of the original data (i.e. the stiffness - deformation curve; S_{max}). The smoothing value used for each approximation was determined by calculating the percentage of noise within the strain gauge signal (root mean square analysis) and adding an additional ten percent.

The program used to generate the splines was the "Woltring Routine" (Woltring, 1986), a public domain program customized by Dr. Ton van den Bogert of the University of Calgary.