THE UNIVERSITY OF CALGARY

Ultrasonic Indentation: A technique for the non-invasive quantification of spinal force-displacement properties.

by

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A DISSERTATION

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Abstract

Force-displacement (FD) properties of lumbar vertebrae have been shown to be altered in pathological processes such as degenerative disc disease *in vitro*. Unfortunately, few non-invasive procedures exist that are capable of quantifying the FD properties of a specific vertebra in a clinical setting. Consequently, the clinical relevance of the relation between spinal disorders and FD properties is not understood at present. Therefore, the purpose of this dissertation is to report the development of a non-invasive procedure capable of quantifying the FD properties of specific lumbar vertebrae *in vivo*.

First, a design process was established to optimize the envisioned procedure's performance. The result, Ultrasonic Indentation (UI), is a novel technique that uses an electromechanical actuator to apply an external indentation load to the spine. The indenter itself is an ultrasonic transducer that permits 1] pre-indentation positioning to specific anatomical targets and 2] quantification of vertebral displacement in the plane of indentation. These displacements are determined by subtracting the change in tissue thickness between ultrasonic images collected at tissue contact and maximal load from the displacement of the actuator over the same period.

The bench-top reliability of UI was shown to range between 0.99 and 1.00 (Intra-class Correlation Coefficient). Error in UI-generated measures was observed to be minimal in linear regions of FD plots and maximal in non-linear regions. The validity of UI in quantifying vertebral displacement was assessed from a variety of cadaveric preparations instrumented to provide criterion displacement measures. Error magnitudes ranged from 6.74% to 13.46%. Sources of additional error were quantified and included process-based variables (image resolution, frame deflection, off-axis loading, indentation site location/re-location and FD modeling) and subject-based variables (intra-abdominal pressure, subject movement and muscular activity in response to indentation).

Finally, an *in vivo* porcine model was used to evaluate the ability of UI to distinguish between control and experimental animals that received a surgical intervention resulting in lumbar degenerative disc disease. Compared to other modalities used to detect arthritic change, UI demonstrated equal or superior ability in distinguishing between control and degenerative animals three months post-surgery (sensitivity = 75.0%, specificity = 83.3%).

Preface

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Dedication

To my love, Janet, and my life, Jonathan and Michael,
without whom this work could not have be started nor finished.

Fanks you dairy much!

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List of Symbols and Abbreviations

ρ	density
E	elastic modulus
f	frequency
−ve	negative
+ve	positive
λ	wavelength

A/D	analog to digital
CDN	Canadian
CRIT	criterion displacement
BMI	body mass index
cm	centimeters
ESD	emergency shutdown system
ESR	erythrocyte sedimentation rate
FD	force-displacement
EMG	electromyography
ERR	displacement error
GCV	generalized cross-validation
Hz	Hertz
ICC	intraclass correlation coefficient
I/O	input / output
IVD	intervertebral disc
kHz	kiloHertz
kPa	kiloPascal
LBP	low back pain
max-load	maximal indentation load
MHz	megaHertz
mm	millimeters
Mpixel	megapixel
ms	milliseconds
MSE	mean square error
MSK	musculoskeletal system

MTS .... Materials Testing System
MTSraw .... raw MTS data
N .... Newtons
OBS .... observed displacement
OC .... on centre
PreFacet^{-2} .... 2^{nd} indentation trial before facetectomy
PreFacet^{-1} .... 1^{st} indentation trial before facetectomy
PostFacet^{+1} .... 1^{st} indentation trial after facetectomy
pre-load .... pre-indentation load
r .... Pearson's correlation coefficient
RF .... radio frequency
RMS .... root mean square
RMSE .... root mean square error
s .... seconds
SD .... standard deviation
SE .... standard error
Sobel .... Sobel edge detection
STI .... soft tissue indenter
SubPixel .... sub-pixel edge detection
SubWhite .... modified sub-pixel edge detection
UI .... ultrasonic indentation
UIcorr .... corrected indentation data
UIraw .... raw indentation data
U/S .... ultrasound
VisImg .... human visualization edge detection
VisInt .... pixel intensity edge detection

Chapter 1

Introduction

Dissertation Rationale and Clinical Significance

Dissertation Objective and Hypothesis

Dissertation Overview

DISSERTATION RATIONALE AND CLINICAL SIGNIFICANCE

Low back pain (LBP) has vexed humanity since time immemorial[1]. At present, LBP is a significant source of morbidity and expense. At any given time, 28% of Canadians are affected by LBP creating direct and indirect costs of $4 billion CDN/year[2]. Reduction of the prevalence and expense associated with LBP has been arduous for several reasons including the inability of health care professionals to obtain an accurate diagnosis in 90% of cases[3]. Given these conditions, numerous attempts have been made to identify prevalent causes of spinal pain.

Of all possible LBP etiologies, those most often studied relate to the paramount function of the lumbar spine: movement. Movement of the lumbar spine involves a remarkable complex of 15 joints, and greater than 100 identifiable muscles and ligaments[4]. While other spinal regions have many more of these structures, none other must bear greater load magnitudes for longer periods of time. Given this level of function and complexity, spine investigators have long sought to determine the clinical significance between lumbar movements, pathology and pain.

The earliest evidence of a relation between spinal mechanics and pathology was obtained from *in vitro* experimentation. Nachemson[5], and other since[6-8], described the kinematic aberrations of spinal segments having degenerative processes. These experiments applied pre-defined loads in conditions remote from those found *in vivo* (i.e. with isolated specimens devoid of most soft tissues). As a result, the observations derived from these experiments were limited in that 1] they could not confirm that these aberrant motions were present *in vivo* and 2] they could not determine whether these same motions were clinically relevant.

As a result of the limitations of *in vitro* testing, a variety of *in vivo* procedures have been developed to ascertain the relevance of spinal kinematics with respect to spinal pain and pathology. Kaigle et al.[9] directly affixed instrumentation to lumbar vertebrae in control and LBP subjects who were confirmed to have spinal pathology. These authors concluded that on voluntary forward bending, vertebral motions were significantly altered in the LBP population. Similar findings have been observed from studies based on radiological techniques. These studies typically assess forward bending motions in subjects with different spinal pathologies[10-14]. In addition to these techniques, non-invasive procedures have been used in similar investigations with similar results[15-18]. As a result, a significant body of evidence has been accumulated that supports the existence of a relation between lumbar mechanics, pathology and pain.

These studies have not been considered definitive, however, as there are almost an equal number of contradictory investigations obtained by exactly the same techniques[12,19-21]. In support of this contradictory viewpoint, other investigations have demonstrated a lack of correlation between the presence of lumbar pathology found on static diagnostic imaging (i.e. herniation of intervertebral discs and degenerative disc disease) and the presence of pain[18,22-24]. As a result, a lack of consensus regarding aberrant spinal mechanics and their clinical significance exists presently.

The contradictory nature of the above literature may be due largely to the limitations of current *in vivo* testing procedures. While a broad spectrum of techniques exists, each has prerequisites that severely affect its ability to quantify spinal kinematics in a clinically relevant manner. First, a majority of these techniques are invasive and/or potentially harmful. These include procedures that break the skin or use ionizing radiation. Second, in the vast majority of these procedures, invasive or otherwise, change in vertebral position is brought on by active motions that affect the entire lumbar spine (e.g. forward flexion of the trunk while standing). In these activities, there is potential for considerable variability in how the neuromusculoskeletal system achieves the end result — there is no controlled application of load to the vertebra of interest. The presence of controlled loading has been suggested to be of importance in spinal experimentation[25] — a speculation supported indirectly by the successful use of this strategy in the testing of other joint systems, particularly the knee[26-29]. Additionally, these same movements have been shown to result in muscular activity which may act to influence vertebral mechanics — pathomechanical or otherwise[11,30,31]. Therefore, while *in vitro* studies have demonstrated the presence of aberrant mechanics in pathological vertebra loaded in a specific manner, corresponding *in vivo* techniques do not exist, thereby making comparison of these results difficult at best.

Epidemiological studies, which describe a lack of correlation between the radiological presence of degenerative changes and pain, exemplify this issue. Without direct loading, the segment may not be challenged sufficiently to generate pain — a circumstance not unlike "judging a book by its cover". For example, Boden et al.[32] have shown that 35% of subjects in their study population with herniated intervertebral discs had no history of pain. However, when spines with herniated discs are stimulated externally by vibration, the production of pain increases the sensitivity of detecting a symptomatic disc to 86%[33,34].

Given these limitations, there are in existence non-invasive techniques that are capable of applying specific loads to specific areas of the spine. These techniques are based on external indentation loading where a specific load is applied to the surface of the back without penetration[35-37]. These traditional indentation techniques quantify bulk tissue properties only — they cannot quantify spinal mechanics directly. At present, only one *in vivo* study has been performed which has quantified spinal mechanics during indentation loading by deadweight[38]. Unfortunately, this study employed radiography to quantify spinal motion, a potentially hazardous imaging modality.

To study the clinical relevance of spinal motion with respect to pathology and pain, the argument has been made that an optimal technique would non-invasively apply pre-defined loads to specific spinal segments and quantify the resultant motions directly. Such a technique could be used safely to study large populations. At the present time, there is no procedure that encompasses all of these features.

DISSERTATION OBJECTIVE AND HYPOTHESIS

The overall objective of this dissertation project was to develop a non-invasive procedure capable of reliable and accurate assessment of the force-displacement properties of a single vertebra during indentation loading. It was hypothesized that by controlling, reducing, eliminating or monitoring sources of error found in traditional indentation techniques, ultrasonic imaging could be added successfully to external indentation to quantify FD properties of the spine.

DISSERTATION OVERVIEW

This dissertation is comprised of a background literature review, six chapters of original research, an overall discussion, overall conclusions and overall bibliography. For convenience, each chapter includes its own list of references. The order of the papers presented here represents the order of the development of the dissertation project. Papers 1,2,4,5 and 6 are either published, in press or have been submitted to a peer-reviewed journal.

Paper 1 - *Validation Of Displacement Measurements Obtained From Ultrasonic Images During Indentation Testing.* This paper describes the accuracy of ultrasonically derived measures of displacement obtained during indentation testing of an ultrasonic phantom.

Paper 2 - *Ultrasonic Quantification Of Osseous Displacements Resulting From Skin Surface Indentation Loading Of Bovine Para-Spinal Tissue.* This paper describes the error of an ultrasound-based technique that quantified uni-planar sub-cutaneous displacement of a static osseous object that resulted from an externally applied load.

Paper 3 - *A Case Study Outlining The Design Process Used To Realize A Non-Invasive Device For Quantifying Spinal Force-Displacement Properties.* This case study outlines the design process used to create the indentation device employed in all subsequent investigations.

Paper 4 - *Ultrasonic Indentation (UI): A Procedure For The Non-Invasive Quantification Of Force-Displacement Properties Of The Lumbar Spine.* This study quantifies the bench-top reliability and accuracy of the equipment fabricated in Paper 3. In addition, validation of the measures provided by this equipment was performed using a dynamic cadaveric porcine preparation.

Paper 5 - *Sources Of Variation In Spinal Indentation Testing: Indentation Site Relocation, Intra-Abdominal Pressure, Subject Movement, Muscular Response, And Stiffness Estimation.* This study quantifies previously unidentified or incompletely characterized variables with respect to spinal indentation.

Paper 6 - *Determination Of Vertebral Displacement By Ultrasonic Indentation In An In-Vivo Porcine Model Of Degenerative Disc Disease.* This paper provides a preliminary evaluation of the ability of ultrasonic indentation to distinguish between control and experimental groups of animals that received a surgical intervention resulting in lumbar degenerative disc disease.

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Chapter 2

Review of Background Literature

REVIEW OF BACKGROUND LITERATURE

The intent of this chapter is to provide a review of the basic knowledge and concepts pertaining to this dissertation project. To familiarize the reader with the anatomical area related to this project, a brief discussion of lumbar spine anatomy is provided (*Anatomy Of The Lumbar Spine*). Many of the measurements created in the dissertation project rely on quantification of ultrasonic images, thus, a review of the physics of ultrasonic imaging are presented (*Basis Of B-Mode Ultrasonic Imaging*). Finally, to provide a framework for the discussion of a novel procedure presented in this dissertation, a review of techniques that quantify lumbar kinematics is given (*Quantification Of Lumbar Spine Kinematics*).

ANATOMY OF THE LUMBAR SPINE

Osseous Structures: The lumbar spine of the human is normally comprised of five individually distinct vertebrae, which as a series, are articulated superiorly to the terminal thoracic vertebra and inferiorly to the sacrum (Figure 2.1). The lumbar vertebrae can be apportioned into two major osseous units: the vertebral body and the posterior elements. Bodies of the lumbar vertebrae are cylindrical in shape surrounded at the waist by a shell of cortical bone and at each end by cartilagenous endplates. The functions of the bodies include structural contributions to the natural curvatures of the spine, creation of inter-vertebral forminae and the distribution of load. The posterior elements of each of the lumbar vertebrae are a series of bony prominences that, as a whole, are connected to the vertebral body by two struts of bone (pedicles) which extend from the superior, anteriolateral aspect. The posterior elements of the lumbar vertebrae can be sub-divided into mechanical and articular processes. Mechanical processes provide points of attachment for ligamentous and muscular structures and therefore, determine the directions of forces endured or transmitted by these tissues. Mechanical processes are termed the spinous, transverse, mammilary and accessory. The articular processes exist as superior and inferior pairs with the superior pair receiving the inferior pair of the adjacent cephalad vertebra. The boundaries of the vertebral body, posterior elements and pedicles form the protective spinal canal where the central nervous tissues descend. Spinal nerves exit laterally from the spinal canal to the body through symmetrical pairs of intervertebral forminae formed by the boundaries of the pedicles, bodies and posterior elements.

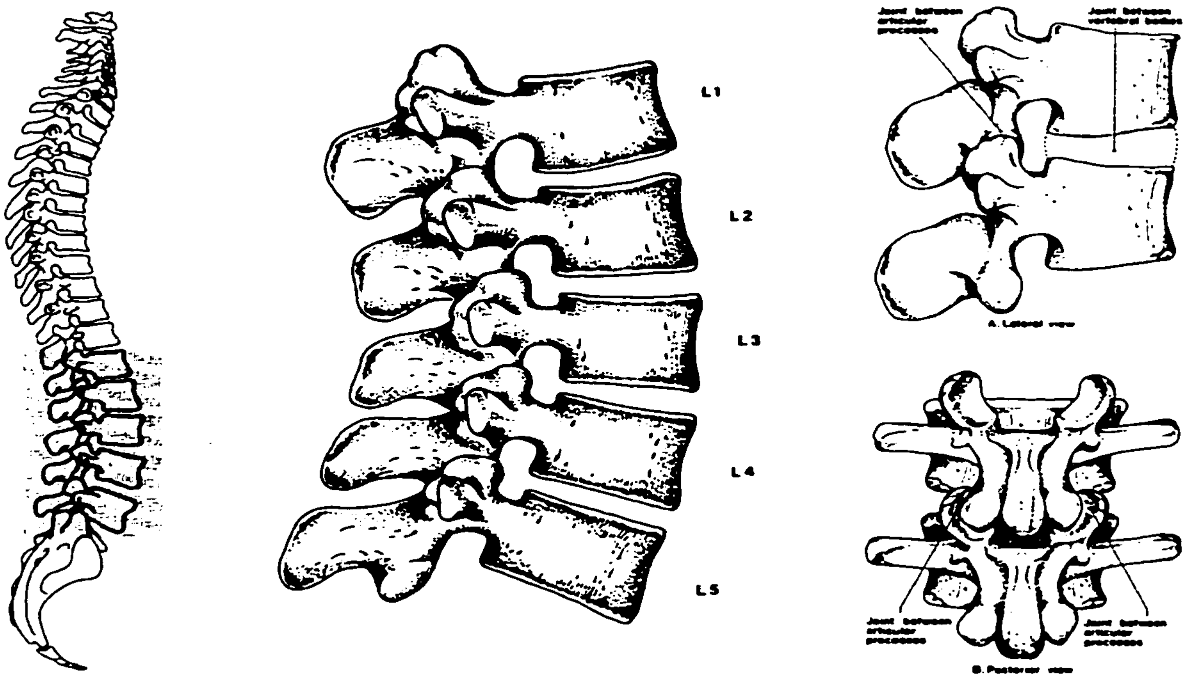

Figure 2.1: *Osseous relations of lumbar vertebrae*[1].

Lumbar Articulations: Between each pair of vertebrae there are three articulations or joints comprised of the intervertebral disc (IVD) — which unites adjacent vertebral bodies — and a pair of facet, or zygapophysial joints which couple each vertebra's posterior elements. The IVD is the largest avascular structure in the human body. It consists of the annulus fibrosus, a series of fibrous concentric rings of alternating lamellae that contain the central nucleus pulposus, which is a gelatinous matrix of proteoglycans, collagen and water. Nutrients and other materials enter and leave the IVD via endplate diffusion. The primary function of the IVD is ligamentous; it distributes load and provides stability for all six degrees of freedom available to the spine. Under normal weight bearing conditions, a 70 kPa pressure is contained by the IVD which contributes substantially to its mechanical properties[2]. The zygapophyseal joints are typical diarthroidial joints with opposing cartilagenous surfaces lubricated by synovial fluid and surrounded by a fibrous joint capsule. Like all synovial joints, zygapophyseal joints permit movement through passive or active loads but restrict extremes of specific movements by bony geometry — in this case, posteroanterior translation and rotation about the sagittal axis. These joints have been estimated to bear up to 40% of axial loads with the remainder distributed to the body-IVD-body complexes[3].

Passive Restraints: While the bony geometry of the spine contributes to interconnection of vertebrae, it is the ligamentous system which is chiefly responsible for spinal integrity. Given the multiple degrees of freedom of the lumbar spine and the nature of the loads it may experience, the ligamentous structures of the spine are numerous and substantial. Excluding the IVD from discussion, the ligaments of the spine can be categorized by their anatomical location. Classically, spinal ligaments are classified by those which interconnect vertebral bodies (anterior longitudinal, posterior longitudinal), those which interconnect posterior elements (ligamentum flavum, interspinous, supraspinous) and those which connect vertebrae to extra-vertebral structures (iliolumbar ligament)[1]. Increasingly, ligaments are being seen as more than passive in their function in that the receptor populations they house act as load and displacement "transducers" for coordination of spinal function through the central nervous system[4]. From *in vitro* studies, the ranges of intervertebral motion are described in Table 2.1.

Rotation Type	Degrees	Translation Type	mm
Flexion	5.5	Anterior	1.3
Extension	2.9	Posterior	0.7
Lateral Flexion	5.6	Lateral	1.0
Rotation	1.1		

Table 2.1: *Representative ranges of inter-segmental motion in the male cadaveric lumbar spine*[5].

Active Tissues: By definition, active tissues are muscular tissues which normally respond to neurological inputs by altering their length and/or their tension resulting in the application of a load to the structures to which they are attached. Although the musculature of the spine is primarily responsible for spinal movement, its role in spinal stabilization is becoming increasingly evident, as without it, the lumbar spine would buckle under an axial load of 80N[6]. The muscles attached directly to the spine are traditionally divided into anterior and posterior groups by a divisor formed within the frontal plane at the level of the transverse processes. The primary function of anterior musculature is to flex the spine, although when upright, gravity plays a significant role in allowing this movement. Extension of the spine is the chief function of the posterior muscles. Posterior and anterior muscles act in concert to create many other motions including rotation, lateral flexion and the combinations of these movements (coupled motions). Global motions of the lumbar spine are listed in Table 2.2.

Active Motion	Degrees
Flexion	58
Extension	26
Lateral Flexion	33
Rotation	24

Table 2.2: *Ranges of lumbar motion in asymptomatic human subjects (males, 30-39 years of age) during active motions*[7].

THE BASIS OF B-MODE ULTRASONIC IMAGING

Introduction: The assessment of the physical properties of biological matter is of interest to biomechanists. Increasingly, researchers are embracing experimental methods that attempt to assess biomechanical behaviors of tissues *in vivo*. These approaches permit testing of a tissue's functions and properties in a physiologically relevant setting. Arguably, advances in the field of imaging and the ability to quantify information gathered from diagnostic images have created important advancements in the non-invasive assessment of many different bio-materials. Ultrasound (U/S) is particularly suited to *in vivo* use in human subjects as it has no recognizable adverse effects and can produce real-time images that are obtained from relatively inexpensive equipment[8].

The production of an ultrasonic image is the result of three separate processes: generation of the ultrasonic beam, detection of the returning echo and processing of the signal for display[8]. Diagnostic ultrasonography uses acoustical waves in the frequency range of 1 to 20 MHz[9].

Wave Generation: Ultrasonic waves, or signals, are typically generated using the "piezoelectric effect" where natural or synthetic crystals undergo expansion and contraction when a cyclical voltage is applied to them. This expansion/contraction generates an ultrasonic wave that can propagate through human tissue from a transducer which contacts the skin[10,11]. A single ultrasound pulse is approximately 1 microsecond in duration[8].

Figure 2.2: *Examples of a B-mode, two dimensional ultrasonic image.*

This wave can be described with respect to its amplitude (power), wavelength (peak to peak distance), and frequency (cycles/sec, or Hz). From the relation displayed in Equation 2.1, the propagation velocity of the wave can be described by its frequency, f, and its wavelength, λ. As can be seen in the following equation, the pulse frequency is inversely related to the depth of the tissue that can be imaged.

Equation 2.1 velocity = distance/time = λ (meters/event) * f (event/sec)

In human tissue, ultrasonic waves are presumed to travel at 1540 m/s — the average wave velocity in all soft tissues. An ultrasonic wave will continue to propagate away from the originating transducer until it is fully attenuated. The velocity at which a wave will pass through a substrate can be shown to be related to the substrate's density (ρ) and its impedance or elastic modulus, E. Materials which are less dense and more stiff tend to increase wave propagation velocity compared to materials that are more dense and/or less stiff[9,12].

Equation 2.2 $velocity^2 = E/\rho$

If the propagating ultrasonic wave encounters a change in tissue density, wave reflection occurs according to Snell's laws[9]. The intensity of the reflected wave is dependent on two factors: 1] the change in density occurring at the density interface and 2] the angle at which the wave strikes the interface. The amount of wave reflection caused by the density interface is related to the "echogenicity" of the interface. Therefore, a "hyper-echoic" interface produces large amounts of wave reflection. Large density gradients causing considerable wave reflection are found between soft tissue and bone (very dense), as well as between soft tissue and gas (less dense).

Signals which are reflected back toward the transducer can be quantified by having the piezoelectric crystal "listen" during the intervals when signals are not being generated. This is known as the reverse piezoelectric effect — the production of a voltage from reflected ultrasonic waves striking the piezoelectric crystal found in the transducer. The "listening" time is typically of 0.25 ms duration or less[8]. If the velocity of the wave is assumed to be 1540 m/s and the time between signal generation and reception can be measured, then the distance the signal has traveled can be calculated. As a result, the dimension of the echogenic object and its position with respect to the transducer can be found with ultrasonic techniques.

Ultrasonic data can be displayed one-dimensionally by plotting the distance from the origin to the point where a density gradient occurs (depth), and assigning a brightness value to that point based on the modulated echo amplitude (single scan line). To create a two-dimensional image which represents underlying anatomy, various techniques are used to move the transducer over an area of tissue to produce several scan lines, which are plotted beside each other to result in a B-mode ultrasonic image (Figure 2.2). Real-time scanning, or rapid B-scanning techniques, provides continuous data acquisition at a rate sufficient to give the impression that motion of structures is continuous[9].

The ability of B-mode ultrasound to characterize an object's dimension is a function of its axial and lateral resolution. Axial resolution is determined by a number of parameters including the frequency of the transducer and the focal length of the beam. The lateral resolution is chiefly a function of the bandwidth of the transducer and the lateral "distance" between the array of elements that make up the transducer. Beyond these resolution limits, echogenic objects can be discriminated as well as movements of that object. Accuracy of ultrasonic estimates of echogenic object motion is negatively affected by out-of-plane motions as well as by objects that may change shape or deform over the course of movement[13].

In the spine, several investigators have used B-mode images to detect vertebral motion. Ledsome et al.[14] observed diurnal changes in spinal column length by quantifying the distance between adjacent transverse processes ultrasonically. Ultrasonic imaging has also been used to quantify dynamic vertebral motion. Ruston[15] followed the movements of cervical vertebrae over a variety of ranges of motion and noted changes in these motions over the course of time. In each of these cases, the ultrasonic transducer remained stationary.

QUANTIFICATION OF LUMBAR SPINE KINEMATICS

Movement is a normal function of the spine. Like any other biological system, excessive or insufficient quantities of that function may be undesirable. Indeed, early clinical observations noted that gross alterations of spinal integrity could be manifest as pain and/or loss of function[16]. Ever since, abnormal vertebral movements have been thought to reflect deranged spinal mechanics resulting in the investigation of this relation[17].

Spinal Kinematics: The quantification of spinal motions, or spinal kinematics, is the quantification of vertebral body movement without concern to the forces involved[18]. Assuming vertebral bodies are themselves rigid (in that they do not undergo significant deformation within a given range of loading compared to other structures in the system of interest), motion of vertebral bodies can be described in terms of translation, rotation, or combinations of the two in a pre-defined orthogonal coordinate system[19] (Figure 2.3). While it is possible that a vertebra may move in any direction along and about these coordinates, there are certain movements that are physiological in nature and frequently occurring. As an alternative to describing these motions in terms of a coordinate system, specific phrases are often used to refer to these motions. These phrases describe what are known as motion patterns[20] and include flexion (+ve rotation about y-axis), extension (–ve rotation about y-axis), lateral bending (+ve or – ve rotation about the x-axis) and rotation (+ve or – ve about the z-axis) (Figure 2.3). In reality, these motions do not occur as pure motions, but in combination with secondary motions of lesser magnitude known as coupled motions[21,22].

In Vitro Quantification of Spinal Kinematics: In vitro protocols permit substantial control over the environment from which spinal kinematics are quantified. In such a setting, investigators have several advantages including: 1] the ability to remove specific tissues in specific sequences, 2] use of a wide range of kinematic instrumentation, 3] numerous tissues to quantify and 4] the choice of using load- or displacement-controlled protocols. As a result, *in vitro* testing has provided a substantial body of information regarding segmental kinematics including the effects of viscoelasticity[17,23-25] and the effects of temperature and humidity[24]. In other applied studies, *in vitro* approaches have been used to assess spinal kinematics in the testing of surgical instrumentation[26-30] and in the presence of pathological processes such as disc degeneration[5,31-34]. In these studies, spinal kinematics of diseased segments were found to be significantly altered from those of normal controls. Unfortunately, results obtained *in vitro* do not allow direct comparison to physiologic conditions due to tissue loss and lack of tissue function. For these reasons, magnitudes of movement obtained *in vitro* are often greater than those obtained from *in vivo* settings. By their nature, *in vitro* settings are additionally unable to associate their results with clinical phenomena such as pain and/or function.

In Vivo Quantification of Spinal Kinematics: In vivo protocols allow testing of human subjects in physiological settings in addition to being able to ascertain subjective information such as pain and function. These advantages have led to the development of a variety of *in* *vivo* techniques, some of which are capable of assessing aspects of spinal motion by directly contacting the surface of the skin. These instruments include skin-mounted transducers[7,35-37], markers[38-40], linkages[41], rulers[42,43] and indentation devices[44-46]. Findings from studies utilizing these techniques have provided support for a hypothesized relation between spinal function and spinal pain; however, these techniques do not quantify directly mechanical properties of specific spinal segments[47]. These techniques usually assess gross kinematics of spinal *regions* resulting from voluntary movement — there is no control of the input load or displacement to the system. In addition, these approaches are subject to significant error in assessing the kinematics of underlying osseous structures[48], especially vertebrae[49].

To assess more directly vertebral kinematics and reduce error caused by skin-based measures, several investigators have placed sensors directly into vertebra in ambulatory human subjects[50-52]. While these approaches provide compelling clinical data regarding intervertebral mechanics, they are highly invasive. Like non-invasive methods, they are dependent on voluntary motion.

Due to their availability and economy, conventional imaging techniques based on plain film radiography are the most common form of spinal kinematic assessment *in vivo*. These techniques result in static two-dimensional images taken over the course of voluntary subject movement, most often at the end-points of motion. The resulting two-dimensional representations of anatomical features lend themselves to many different analyses of specific intervertebral kinematics such as centres of rotation[53,54], coupled motions[55,56] and neutral zone magnitude[57]. In a number of studies using these techniques, a relation has been observed between vertebral motion, the presence of spinal disorders and the presence of pain[58-62]. However, the utility of these measures has been questioned due to: 1] their reliance on voluntary subject movement, 2] low resolution, 3] their significant potential for error, 4] the variability of these measures in normal populations and 5] their potentially harmful effects[51,55,60,63-73].

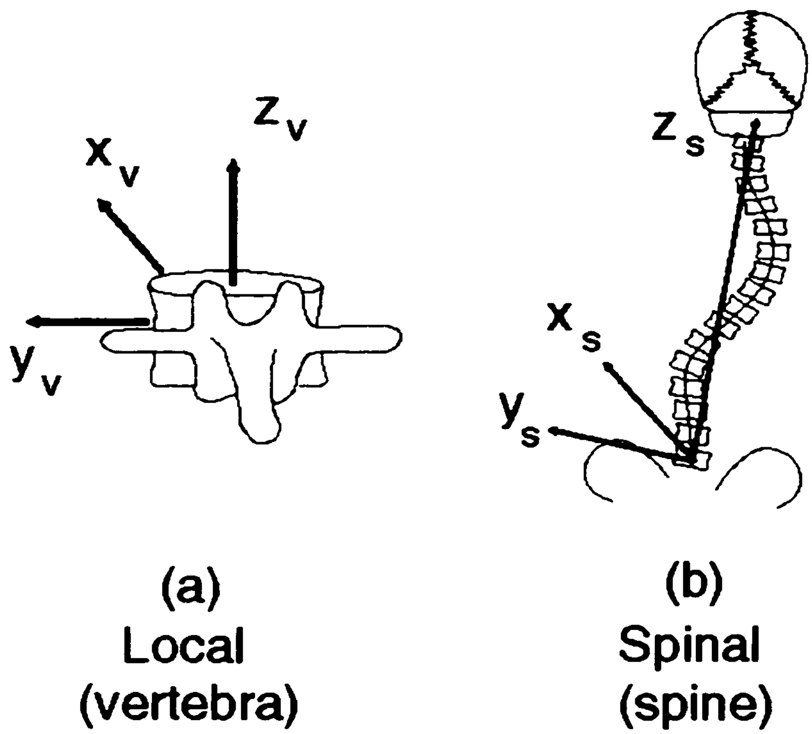

Figure 2.3: *Three-dimensional coordinate system used to describe spinal motions as viewed from the posterior aspect*[19].

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Chapter 3

Validation of displacement measurements obtained from ultrasonic images during indentation testing

Introduction:

The characterization of biomechanical properties of soft tissues is thought to be meaningful in the study of the human musculoskeletal system. A common method of assessing these properties is by indentation testing, a procedure where the tissue of interest is depressed by a blunt probe and the resulting deformation of the external surface recorded. From this type of testing, properties such as the instantaneous tissue stiffness can be determined by obtaining the first derivative of the applied force plotted against the tissue displacement.

As a tissue may be made up of many components, measurements obtained from traditional indentation processes are a summation of each component's contribution to the overall measurement. To determine the separate contribution of any one component, it is often necessary to use an invasive protocol, an undesirable approach in the analysis of whole tissues or *in-vivo* preparations. If it were possible to visualize sub-surface anatomy during the indentation process, biomechanical investigation of internal tissue properties such as strain and stiffness may be feasible.

It is hypothesized that by employing ultrasonic techniques over the course of indentation testing, measures of displacement may be obtained from internal structures. This hypothesis is based on the knowledge that ultrasonic waves propagate with specific velocities. Given the time in which a sound wave takes to contact a structure, estimates of distance can be made (distance = propagation speed * transit time)[1]. Therefore, the purpose of this experiment was to determine the accuracy of ultrasonically derived measures of displacement obtained during indentation testing when compared to a criterion measurement.

Background:

The assessment of tissue properties by ultrasonic means has been well established in the literature. Most commonly, ultrasonic imaging has been used to determine tissue dimensions[2-6]. While the accuracy of these results was judged to be acceptable, the results may not be indicative of the accuracy of ultrasonic measurements of displacement taken when a transducer is constantly moving as would be the case during indentation testing.

In addition to quantifying tissue dimension, stiffness is another biomechanical feature which has been characterized ultrasonically by several different techniques. Sonoelastography is one such technique based on the principle that by exciting an object with a known vibration, structures of different stiffness within the object will respond with different motions based on their shape, homogeneity and density[7]. These motions are discernible with Doppler ultrasonography and can be processed and displayed as a map of the relative stiffness of the imaged area. These vibrational methods have been used to detect masses within tissues[8], to determine muscle stiffness during static loading conditions[9] and to assess tissue properties in residual limbs[10]. Elastography is a similar technique where baseline ultrasonic signals are compared to those developed during the application of a high velocity, small amplitude compression to the tissue of interest[11]. The result of this analysis is an "elastogram" which displays stiffness characteristics of the imaged field. Ultrasonic techniques have also been used to study the elastic properties of bone at the infrastructure level[12,13].

While previous methods of assessment have generated ultrasonically-based measures of dimension, stiffness or elasticity, these measures are static in nature: they have not been obtained during indentation and therefore do not provide biomechanical information regarding tissue behavior under various loading conditions. Numerous instruments have been developed to assess tissue stiffness by indentation [14-25], but only recently have any attempts been made to visualize internal tissue deformations during indentation.

Cavanagh has proposed that deformation of the foot during gait may be studied by utilizing an in-ground ultrasound transducer but this concept has not yet been reported (Cavanagh, personal communication). Zheng and Mak[26] have described an indentation probe that contains an in-series ultrasound transducer and load cell. Their results, obtained from the indentation of porcine tissue placed on a rigid, immobile surface, were compared to those obtained from a materials testing machine and found to agree "very well". Being hand-held, the ability of this instrument to indent tissue at a specific rate in a reliable and accurate manner may be limited, as may be the ability to assess tissue displacements relative to the displacement of the indenter itself.

Materials:

Validation Apparatus: The validation apparatus used in this experiment was fabricated by the authors and consisted of a 7.8 cm (diameter) by 12.5 cm (height) plastic cylinder mounted rigidly to an inanimate surface (Figure 3.1). A thin, metallic coin (2.6 cm diameter) acted as the target surface and was placed at the bottom of the cylinder and then covered by a circular standoff pad (9.0 cm diameter by 2.0 cm height, Parker Laboratories, U.S.A.). Due to its position in the cylinder, this pad was termed the distal standoff pad. The cylinder was then filled with ultrasonic coupling gel (Parker Laboratories, U.S.A.) to approximately 75% of the total height of the cylinder. A second standoff pad was then placed on the surface of the gel, coated with coupling gel and termed the proximal standoff pad.

Indenter: Force was applied to the proximal standoff pad by a device known as a tissue stiffness meter[17]. This device (Figure 3.1) consists of a rigid, blunt indenter that is advanced by an electronic stepping motor (Hurst Motors, U.S.A.) by discrete increments at a specific rate. When a preset force threshold is reached, the stepping motor is instantaneously reversed and the indenter removed. The applied force and the number of steps performed during the procedure are obtained by a load cell (Entran, U.S.A.) placed in series with the indenter and by sampling the electronic output of the stepping motor respectively. The cumulative number of motor steps was simultaneously displayed on an L.E.D. readout.

Ultrasonic Transducer: Using a custom fabricated vice grip, an ultrasonic transducer was placed in-series with the indenter making the active face of the transducer the indentation surface. The transducer utilized was a 5 MHz sector probe with a square contact footprint of 1 cm^2 (model # 46-267246G1, General Electric Medical Systems, Canada).

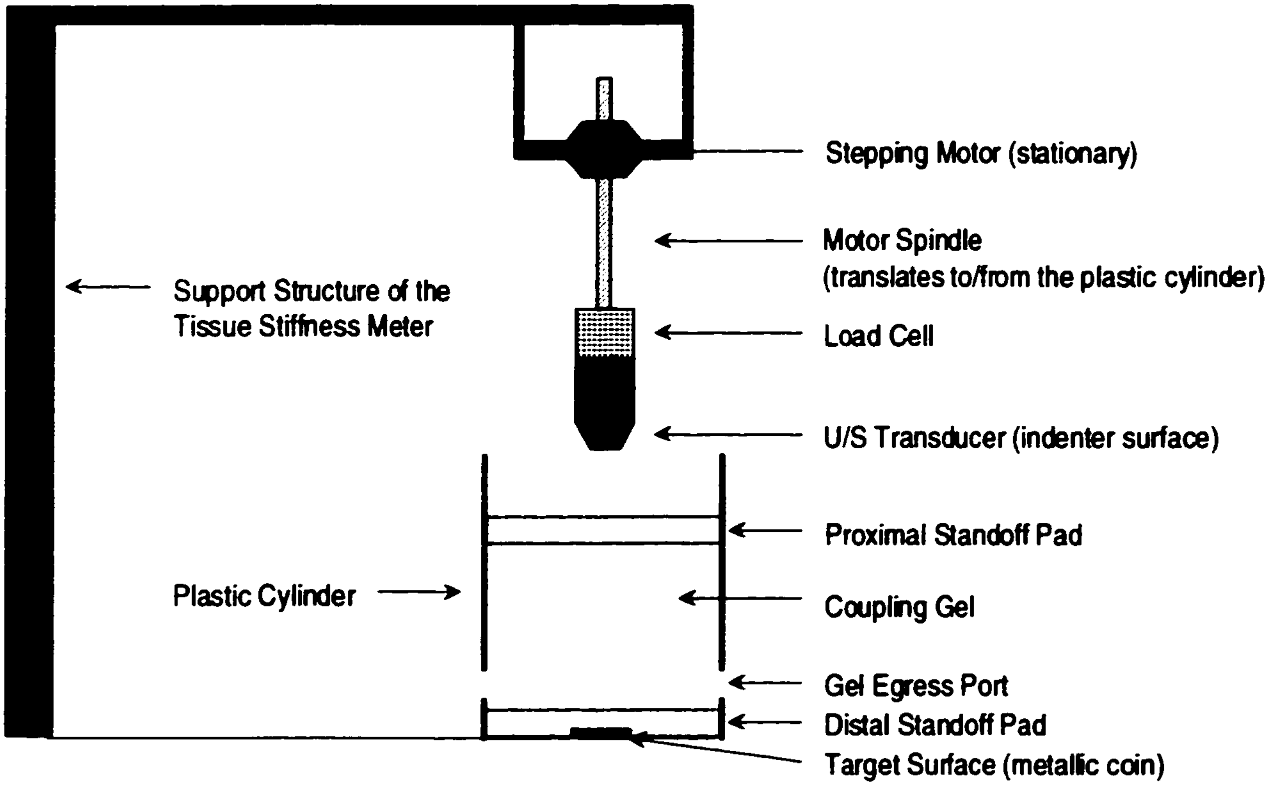

Figure 3.1: *Schematic of validation apparatus (not to scale).*

Video storage/processing: Images obtained by the ultrasonic transducer were processed and displayed in real time (B-mode) with a RT3600 ultrasound unit (General Electric Medical Systems, Canada). A video camera was used to obtain an additional video image of the L.E.D. readout of cumulative motor steps. The two video signals (ultrasound image and L.E.D. display) were superimposed by a MX-1 digital video mixer (Videonics, U.S.A) and sent to a VHS video recorder. Single frame images from the videotape were captured for analysis of target surface location by a Media 100 real-time JPEG video capture card (Figure 3.2) at a rate of 100 MHz (Data Translations, U.S.A.).

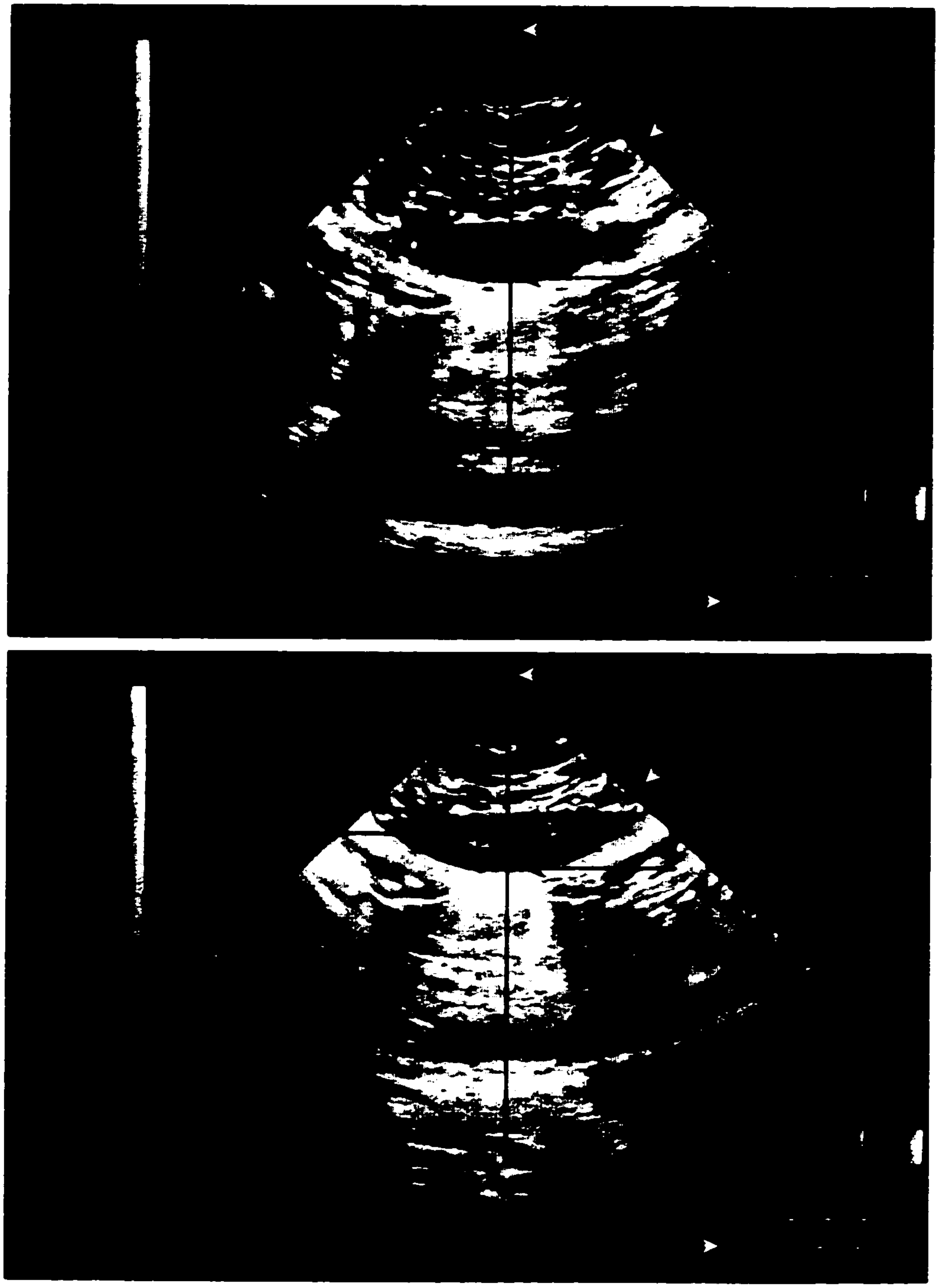

Figure 3.2: *An example of a captured 8 bit image.*

Methods:

Data Collection: At the time of data collection, the ultrasonic transducer was advanced by the tissue stiffness meter at a rate of 2.12 mm/s beginning several millimeters above the proximal standoff pad. The output of the load cell and the stepping motor were recorded at 1000 Hz/channel and stored directly to disk using an analog to digital signal acquisition board (Dataq, U.S.A.). The display of the RT3600 was set to a magnification factor of 1.0 (zero magnification) and the maximal transmitting focal depth of the transducer set to 100 mm. Before indentation, the validation apparatus was allowed to settle for approximately ten minutes. During indentation, gel was allowed to egress freely from the cylinder via eight outlet ports (12 mm diameter each) drilled through the cylinder above the level of the distal standoff pad. To retain the gel within the cylinder prior to testing, a tight fitting sleeve was placed over the cylinder and removed when necessary. The threshold for the indenter reversal was 60 Newtons.

Image Processing: After the completion of indentation, 24 still images were captured from videotape which contained the superimposed ultrasound and L.E.D. readout images and then converted to 8 bit gray scale images. All images were then displayed at a 640 X 480 pixel resolution on a personal computer using Matlab Software (Figure 3.2) (Mathworks, U.S.A.). Still images were captured at approximately 50 step intervals, starting at the point of discernible contact between the transducer and the proximal standoff pad (300 steps). A vertical line from the origin of the ultrasound signal to the distal border of the image was superimposed on each captured image with Matlab software (Figure 3.2). The column of pixels that contained this line was identified and termed the vertical pixel corridor. Images were successively captured from videotape at approximately 50 step intervals until step 1500, where the maximum travel of the indenter was reached.

Target Surface Detection: Five separate surface detection methods were employed to locate the target surface (metallic coin) within each captured image. These methods were: human visualization of the ultrasonic image (VisImg), human visualization of a plot of pixel intensity (VisInt), a Sobel edge detection algorithm (Mathworks, U.S.A.), a sub-pixel edge detection algorithm (sub-pixel)[27] and a modification of the sub-pixel algorithm (sub-white). A description of each of these methods follows. Of the five methods used to locate the target surface, 3 surface detection routines were employed which identified the surface at discrete pixel boundaries (VisImg, VisInt, and Sobel) and two methods were used which were capable of locating surfaces within pixel boundaries (sub-pixel and sub-white).

The VisImg method employed a human observer to locate the presumed target surface from a still image and then digitally mark the presumed location of the target surface of the vertical pixel corridor using a computer cursor. The resulting pixel location from this marking procedure was then truncated to create an integer which represented the proximal boundary of the selected pixel. The location of this pixel with respect to the upper border of the image was then determined (units = pixels). The VisInt method detected the target surface by having a human observer locate the presumed target surface by visualizing a plot of pixel intensity values from the vertical pixel corridor. Using a computer cursor, the observer indirectly identified the target surface by selecting the pixel at which the intensity was thought to increase significantly. The location of the identified pixel was then truncated and the distance from the upper image boundary was calculated. The Sobel method applied an automated edge detection algorithm to the vertical pixel corridor of the captured image. The algorithm identified the pixel within the vertical pixel corridor that presumably contained the target surface by determining where the first derivative of the image intensity values of the chosen pixels was maximal or minimal (Mathworks, U.S.A.). The pixel located by this process was defined by its proximal boundary and the number of pixels from this boundary to the upper image border determined.

The sub-pixel method applied the algorithm of Tabatabai and Mitchell[27] to the intensity values of the vertical pixel corridor. This algorithm was capable of estimating the presumed location of the target surface within pixel boundaries. The sub-white algorithm, a variation of the sub-pixel algorithm, was employed as it was thought that alterations in pixel intensity distal to the target surface may negatively influence the algorithm's output. As a result, the sub-white routine was created to provide a constant pixel intensity subsequent to the presumed target edge. In this method, the presumed target surface was marked by sight and all pixels following the third pixel distal to this location were assigned the same intensity value as the marked pixel. The resulting column of pixels was then processed by the sub-pixel algorithm. For the sub-pixel and sub-white methods, the distance in pixels from the upper border of the image to the presumed target surface along the vertical pixel corridor was determined.

Distance Calculations: To convert displacements from pixels to millimeters, the distance scale observed in the ultrasound image of the RT3600 was utilized. For the specific transducer used in this experiment, at the quoted scale-interval and focal depth value, each scale-interval corresponded to 10.0 mm (Nick Waterton, personal communication). To determine the number of pixels per scale division, the entire length of the scale was determined, divided by the number of scale intervals present, and the number of pixels per scale division determined triginometrically. Additionally, a correction was employed to account for the propagation velocity of a coupling gel environment (1490 m/s, Parker Labs, U.S.A) compared to the propagation velocity assumed by the RT3600 (1540 m/s). Using these relationships and corrections, it was determined that there were 0.3617 mm/pixel along the vertical pixel corridor.

Validation:

Twenty-four still images were captured from videotape. Selection of each of the 24 ultrasonic images occurred by isolating sections of videotape that displayed the superimposed L.E.D. readout which corresponded to stepping motor intervals of 50 steps (Figure 3.2). The criterion displacement for each of these images was determined by multiplying the number of cumulative steps seen on the L.E.D. readout within the captured image by the stepping motor's rating of 0.0254 mm/step. This criterion measure and the measures derived from each target location method were then subtracted from the values calculated in the previous image. This calculation provided the change in distance, or distance interval between successive images.

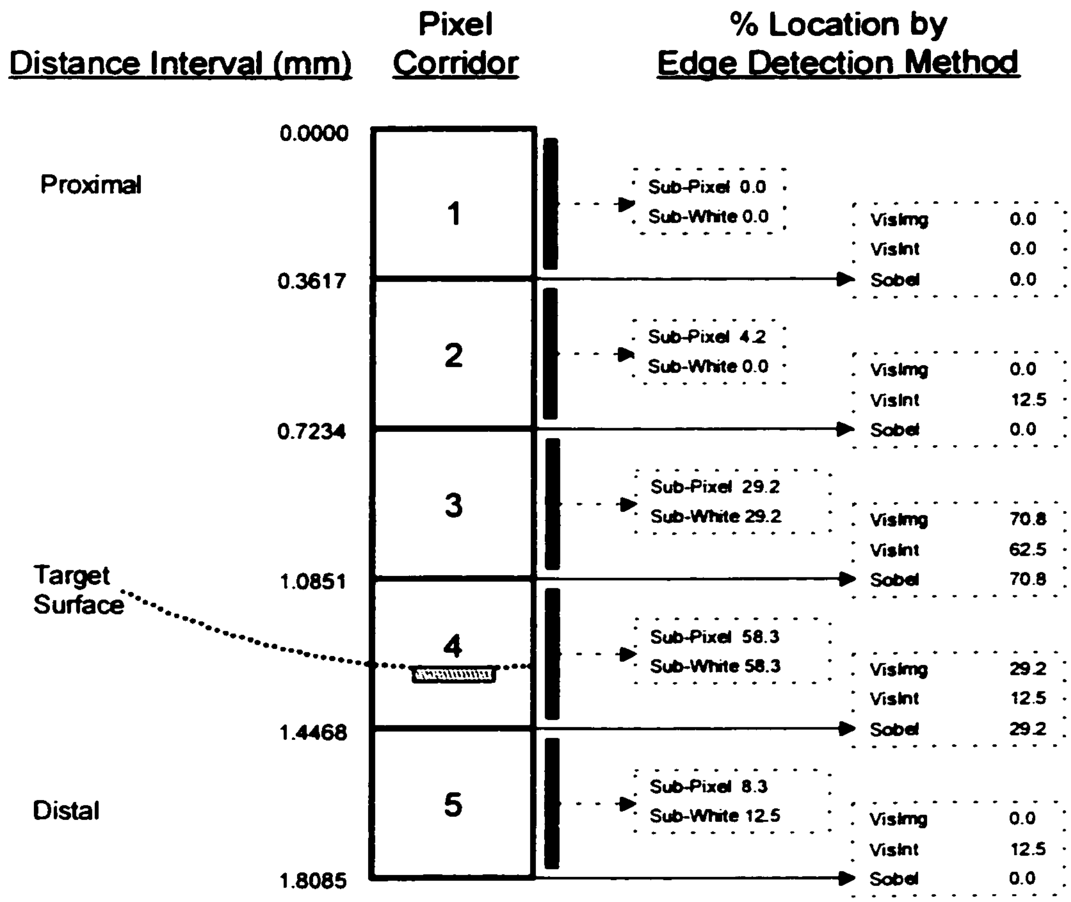

Figure 3.3: *Frequency distribution of distance intervals obtained by ultrasonic methods stratified by surface detection method. For each image, the location of the target surface was expected to change by 1.2730 mm, or 3.51 pixels.*

Results:

For images 2 through 24, the mean criterion distance interval was 1.2730 mm. As each pixel was found to have a proximal to distal dimension of 0.3617 mm, the location of the target surface was presumed to change location on each image by 3.51 pixels. As a result, the target surface was expected to fall within the proximal-distal boundaries of a single pixel.

The percent errors of the distance intervals determined by ultrasonic methods for each surface detection method are displayed in Table 3.1. The error of the ultrasonic displacement measures from all captured images ranged from 0.58% to 56.65% with the mean percent error for each surface detection method ranging from 14.37% (VisImg and Sobel) to 22.05% (VisInt). Figure 3.3 displays the distribution of distance intervals by surface detection method. For surface detection methods which located target surfaces at discrete pixel boundaries (VisImg, VisInt, Sobel), distance intervals were stratified by the multiple of the mm/pixel distance (0.3617 mm) they represented. Sub-pixel and sub-white distance intervals were stratified by which pixel boundaries they fell between.

Comparison of the percentage error for each distance interval between surface detection methods was performed by Student's t-test assuming an unequal variance between groups. Significant differences between VisInt and all other methods were observed at a 95% confidence level while all other comparisons demonstrated non-significance.

	Edge Detection Method				
	VisImg	**VisInt**	**Sobel**	**Sub-Pixel**	**Sub-White**
Mean % Error	14.70	22.05	14.37	14.68	14.53
St. Deviation	1.23	12.56	1.32	12.15	9.67
Min. % Error	11.69	12.82	11.69	0.58	2.74
Max. % Error	16.25	45.31	16.25	56.65	32.84

Table 3.1: *Percentage error data stratified by target surface localization method.*

Discussion:

Compared to other modalities such as plain film radiography, computed tomography and magnetic resonance imaging, measurements obtained by ultrasonic methods are low in cost, readily available in most centers, and typically produce images without delays related to scanning time or image processing. For these reasons, ultrasonic imaging is suited to visualizing certain tissue features during indentation testing.

In this experiment, an image-based approach was used to determine ultrasonically the displacement during an automated indentation procedure. It must be mentioned that although an image-based approach was used in this experiment, it is not necessary to use images to assess distance via ultrasound. The output from specific ultrasonic transducers can be plotted as the returning or transmitted signal intensity versus time of flight[1]. Peaks in such a plot correspond to echoic interfaces; the height of the peak being related to the intensity of the received signal. By knowing the propagation velocity of the transmission environment, the position of a peak along the x-axis corresponds to the distance of that interface from the signal source. As a result, distance measures can be directly obtained from ultrasonic methods without image creation or analysis, a method employed by Zheng and Mak[26]. One advantage of this approach is that complicated equipment and techniques used to display and assess visual images are eliminated. Conversely, if many echoic interfaces exist, it can be extremely difficult to determine which peaks correspond to which echoic interface, especially as interface distances and orientations may change during indentation applications. By using an image-based method, distances can be computed based on anatomical landmarks, an intuitive process compared to peak identification. While an image-based approach to displacement measurement may be advantageous, it must be noted that such a system is dependent on the ability to identify accurately landmarks on a still image[28,29]. This ability can be influenced by several factors, one of which is the quality of imaging technology used. For this experiment, video equipment of broadcast quality or greater was utilized. Additionally, automated methods of indentation may be advantageous compared to hand-held methods when assessing tissue mechanics as the rate of displacement can be controlled and used to create relative measures of tissue displacement.

As the target surface was expected to change location on each successive image by 3.51 pixels, it was expected that target surface location methods which were capable of within-pixel localization would be superior to those capable of identifying surfaces at discrete pixel boundaries. Excluding the VisInt method, there were no statistically significant differences between methods of target surface localization. While comparisons between these methods were statistically insignificant, the methods which were capable of generating within-pixel estimates of surface target location displayed far greater variation in the resultant distance intervals than methods limited to locating surfaces at pixel boundaries (VisImg, Sobel). Only fifty-eight percent of the distance intervals generated by the sub-pixel and sub-white methods fell between the pixel boundaries surrounding the mean criterion distance interval in comparison to the VisImg and Sobel methods which located the surface target at either the proximal or distal pixel boundary more than 99% of the time (Figure 3.3). For this reason, the VisImg and Sobel methods of surface location were considered to be superior to the other surface location methods tested.

To improve on the accuracy of displacement measures generated by ultrasonic means in this experiment, several strategies may be employed. Most obviously, the accuracy, and therefore, the percentage error of the resultant measurement depends on the magnitude of the criterion distance interval. If all factors remain constant, the error in distance measurement would be smaller in percentage if a 100 step interval were used versus a 50 or 25 step interval. Therefore, in practical circumstances, the error of the measurement will depend largely on the total displacement expected under the indentation conditions tested. Additionally, if technical factors relating to the production of the original ultrasonic image are adjusted (scale and transducer focal depth), the distance per pixel within the image can be decreased and therefore so may error. It should also be pointed out that ultrasonic equipment which is more recent than that used in this experiment may provide improved image resolution which may decrease measurement error. Finally, the accuracy of this procedure would presumably increase if a surface detection algorithm was employed that was superior to those used in this experiment.

Summary:

In the conditions of this experiment, the mean error of ultrasonically derived measures of deformation observed during indentation testing ranged from 14.37% (Sobel) to 22.05% (VisInt) when compared to displacements derived from a criterion measure. Technically, improvements in the accuracy of ultrasonically derived measures of displacement can be made, but are ultimately dependent on the magnitude of the distances measured. Use of this protocol for human tissue assessment, *in-vivo* or otherwise, may be appropriate if the displacements of interest are greater than the error of the procedure.

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Chapter 4

Ultrasonic quantification of osseous displacements resulting from skin surface indentation loading of bovine para-spinal tissue

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Introduction:

During normal physiological conditions, the osseous structures of the spine can be displaced when acted on by internal or external loads. Osseous displacements that are considered to be excessive, insufficient, or atypical, have been implicated as manifestations of various spinal pathologies, spinal pain or inversely, their etiologies. While implied, the relation between the spine and aberrant osseous displacement is vague - a reflection of numerous factors including ill-defined mechanisms of pain and pathology[1-5] as well as limitations of the techniques used to investigate such displacements[6]. Given these circumstances, it is understandable that the assessment and treatment of the spine in relation to osseous displacement is varied and generally controversial[7-12].

Of the direct techniques used to quantify osseous displacements, those based on two-dimensional radiographic imaging are most common due to clinical availability and low cost. These radiographic techniques typically quantify the change in position of an osseous structure from two successive static images collected at the endpoints of a dynamic movement. While common, these techniques have significant limitations including the use of ionizing radiation - a potentially dangerous physical agent. To address these limitations, investigators have inserted bone pins directly into lumbar vertebrae and quantified continuously, osseous displacements during dynamic motions using mechanical linkages or remote sensing systems[13,14]. While the improvements gained by such techniques are obvious, their invasive nature may be limiting. Should a technique be developed that is capable of quantifying displacements of spinal structures in a non-invasive manner, the clinical relevance of these displacements with respect to spinal pathology may be more easily investigated and understood.

Ultrasonic scanning is potentially such a technique as it is a non-invasive, non-ionizing modality that is capable of continuously assessing the change in location of echogenic sub-cutaneous structures. In principle, the location of a subcutaneous object can be determined by measuring the time required for an ultrasonic wave, traveling through a tissue at an specific speed, to reach a reflective interface then return to the wave source (transducer). The distance to the reflective, or echogenic, interface can be estimated from the following relation: distance = speed * time. Using a variety of techniques, positional change of an object can be assessed by comparative analysis of ultrasonic signals[15].

Using the above principle, several studies have been performed to assess the displacement and/or deformation of echogenic structures resulting from external tissue loading[16-18]. While the various ultrasonic techniques used in these studies may be of potential value to musculoskeletal researchers and clinicians alike, to the author's knowledge, the validity of such techniques has remained unknown. In the previously described studies, none of the techniques employed were validated against a criterion measure that directly quantified the true displacement and/or deformation of the object in question.

Therefore, the purpose of this study was to describe and to validate a non-invasive technique that utilizes ultrasonic imaging to quantify the one dimensional displacement of an osseous structure within a two-dimensional image plane during indentation loading of bovine para-spinal tissue preparations *in vitro*.

Methods:

Materials: Indentation was performed by a device developed at the University of Calgary (Soft Tissue Indenter, or STI (Figure 4.1)). The STI consists of an electromechanical actuator mounted within a rigid support frame that linearly translates a metal thrust tube (Industrial Devices Corporation, Novato, CA, USA). Actuator direction, speed and acceleration were controlled by commands sent at 1kHz to a motor driver (Industrial Devices Corporation) through LabView software (National Instruments, Austin, TX, USA). A cylinder-type load cell (Load Cell Central, Towanda, PA, USA) was mounted serially on the thrust tube which was then mounted serially to one of two ultrasonic transducers: a 5MHz sector transducer or a 7MHz linear array transducer (Acuson, Mountain View, CA, USA). A linear position transducer was mechanically linked to the actuator to quantify its displacement (Data Instruments, Acton, MA, USA).

Tissue specimens in this experiment were bovine "bone-in-chuck" short ribs (XL Meats, Calgary, AB, Canada) measuring approximately 20 x 20 x 10 cm. Externally to internally, the samples consisted of para-spinal muscle, the posterior (convex) surface of the costal bone and the pleural (concave) surface of the costal bone.

Each specimen was placed on a testing stage within the STI support frame and the apex of the convex surface of the costal bone positioned immediately below the ultrasound transducer (Figure 4.1). The ends of each bone were ground flat to decrease rotation of the rib about its long axis during indentation. A digital dial gauge (Fowler Gauges, Newton. MA, USA) was placed on a rigid surface beneath the testing stage, in alignment with the ultrasonic transducer and its stylus placed through an access hole in the stage to make contact with the pleural (concave) surface of the costal bone. Output from the dial gauge was read directly and used as a criterion measure of osseous displacement along the principal load axis.

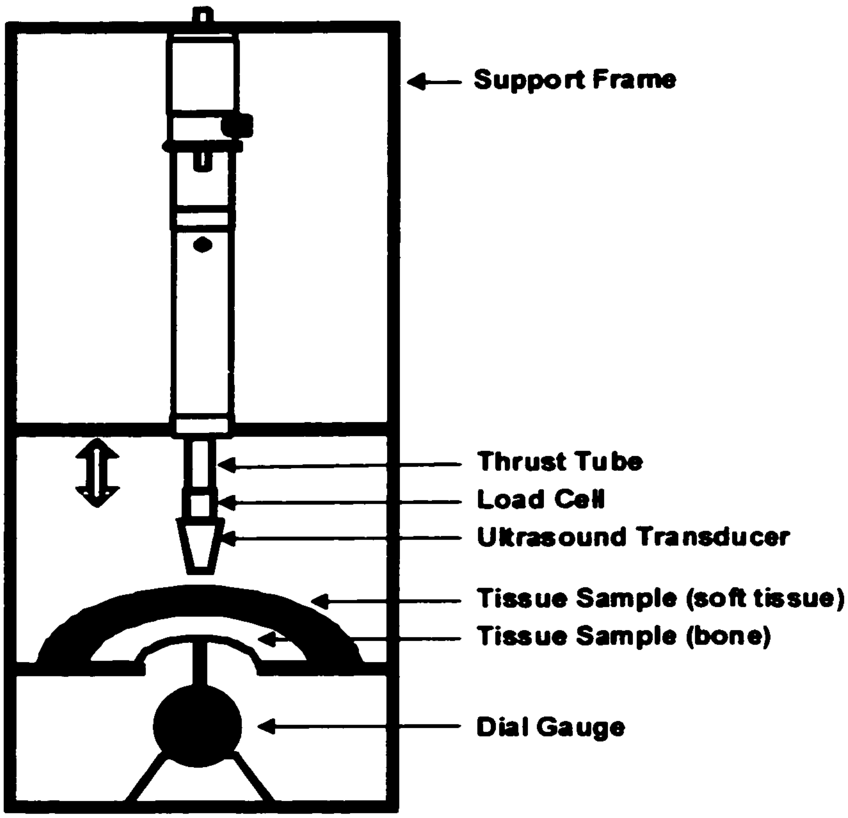

Figure 4.1: *Schematic representation (not to scale) of the Soft Tissue Indenter (STI) and a tissue specimen.*

Indentation: Each specimen (n = 6) was indented ten times at one minute intervals at a rate of 2.5 mm/s (60 trials total). Three specimens were indented in this manner using a 5MHz sector transducer and three with a 7MHz linear array transducer. Ultrasonic coupling gel (Parker Laboratories, Orange, NJ, U.S.A.) was spread on the contact surface of each specimen prior to indentation. Force and displacement data were continuously collected by a computer controlled data acquisition system at 1kHz (National Instruments, Austin, TX, USA). Advancement of the thrust tube into the tissue was halted when the indentation load corresponded to a value of 3N thus ensuring direct contact of the transducer with the tissue. At tissue contact, a single ultrasonic image containing the posterior surface of the costal bone in the field of view was recorded (Figure 4.2). Indentation then proceeded to a maximal load of 50N at which time actuator advancement was halted and a second ultrasonic image was collected (Figure 4.2). In preliminary testing, this load magnitude was observed to create osseous displacement without loss of osseous integrity.

Both initial-contact and terminal (maximal-load) images obtained from the sector transducer were displayed at the minimally allowable imaging depth of 60 mm resulting in a vertical resolution on each image of 0.1899 mm/pixel. Linear array transducer images were displayed at the minimally allowable imaging depth of 30 mm resulting in a vertical resolution on each image of 0.0938 mm/pixel. Focal depths were optimized for individual samples.

Calculation of Osseous Displacement (positional change): Determination of sub-cutaneous osseous displacement in the plane of the principal load (vertical) was achieved by subtracting the change in tissue thickness observed to occur between ultrasonic images collected at tissue contact and maximal load, from the displacement of the actuator over the same period (OBS). Specifically, the magnitude of soft tissue compression was determined by obtaining the distance in pixels of a computer generated vertical line drawn from a fiducial point on the horizontal axis of the image to the presumed convex surface of the costal bone as determined by visual localization (Figure 4.2). This technique has performed comparably to edge detection algorithms in similar experimental conditions[19]. The resulting number of pixels in this line was converted to millimeters based on the vertical resolution of a single pixel. The magnitude of tissue deformation in the plane of the principal load was calculated by subtracting the transducer/bone distance of the tissue contact image from the transducer/bone distance of the maximal load image.

Figure 4.2: *Ultrasonic images from the linear array transducer (7MHz) taken at tissue contact (left image) and maximal load (right image). Solid white lines represent the vertical line drawn by image processing software from a fiducial point on the horizontal scale to the presumed convex surface of the costal bone. Arrowheads are present for illustration purposes only.*

To assess overall measurement error, the change in output of the dial gauge between times of tissue contact and maximal load was used as a criterion measure of osseous displacement along the principal load axis (CRIT). The overall measurement error was calculated as the absolute difference between the observed and criterion osseous displacement values and expressed as a percent of the criterion value (ERR).

One-way analyses of variance were performed ($\alpha = .05$) on error data for specimens indented by different transducer types. Based on the results of this analysis, a second, one-way analysis of variance was performed on data pooled by transducer type ($\alpha = .05$).

Results:

Mean and standard deviations for the observed osseous displacement (OBS), the criterion displacement (CRIT), the measurement error (ERR) and the percentage error attributable to the vertical dimension of a single pixel (Pixel Error) are displayed in Table 4.1. Values of OBS ranged from 0.58mm to 1.82 mm over all measurements of all specimens. One-way analysis of variance of ERR values for either the sector or linear array transducers showed no significant difference between specimens ($p = 0.67$ sector, $p = 0.51$ linear array), therefore, ERR values were pooled by transducer type. The mean pooled ERR for the sector transducer was 12.73% (SD, 7.49, $R = 0.86$, RMSE = 0.15 mm) over a mean CRIT of 1.02 mm and 6.74% (SD, 3.98, $R = 0.95$, RMSE = 0.11 mm) over a mean CRIT of 1.43 mm for the linear array transducer. One-way analysis of variance (ANOVA) found the ERR data to be significantly different between transducer types ($p = 0.0003$).

Transducer	n	OBS(mm)	CRIT(mm)	ERR(%)	Pixel Error (%)
Sector	1	1.1604(SD, 0.0501)	1.04(SD, 0.03)	12.91(SD, 2.52)	18.19
	2	1.2646(SD, 0.0486)	1.33(SD, 0.02)	11.10(SD, 2.27)	14.33
	3	0.6645(SD, 0.0459)	0.68(SD, 0.02)	14.17(SD, 2.46)	27.76
		1.0298(SD, 0.3042)*	1.02(SD, 0.28)*	12.73(SD, 7.49)*	20.09
Linear Array	4	1.5033(SD, 0.0161)	1.39(SD, 0.01)	7.96(SD, 1.21)	6.73
	5	1.8134(SD, 0.0245)	1.73(SD, 0.03)	6.03(SD, 1.41)	5.41
	6	1.1937(SD, 0.0278)	1.16(SD, 0.02)	6.24(SD, 1.18)	8.09
		1.5035(SD, 0.2670)*	1.43(SD, 0.25)*	6.74(SD, 3.98)*	6.74

Table 4.1: *Descriptive statistics for observed costal bone displacement (OBS), criterion bone displacement (CRIT,) and measurement error (ERR) grouped by transducer type/specimen. Pixel error is equal to the resolution of the vertical pixel dimension expressed as a percentage of the mean CRIT for each specimen. An asterisk (*) indicates pooled data for that sample.*

Discussion:

The results of this study indicate that the described technique has an error of less than 7% over a mean displacement of 1.43mm (SD, 3.98, r = 0.95, RMSE = 0.11 mm). At the present time, the clinical significance of this magnitude and direction of displacement is not fully known. However, in a study which assessed spinal kinematics through a bone-pin linkage attached to the lumbar vertebrae of human subjects diagnosed as having clinically instability, shear translations between vertebrae in symptomatics vs. controls during flexion-extension movements were found to differ by 1.5 mm on average[6]. A similar device[13] has been shown to have a root mean square error (RMSE) totaling 0.57 mm for shear displacements. Other techniques using ionizing radiography have reported changes in segmental translation of 1.6 to 5.0 mm[20] between normal vs. degenerative vertebral segments. The RMSE of a similar technique has been reported to be less than 2.0 mm[21]. Given the magnitude of displacements and error in these invasive techniques, we speculate that the non-invasive technique described in this study may be potentially useful in the clinical assessment of conditions such as instability and osteoarthritis of the spine. It must be noted that at the present time, this technique is limited to assessing displacements normal to the applied load which occur at the endpoints of the resultant motion. Currently, work is being performed to test similar ultrasonic-based techniques that quantify complex osseous displacements throughout a displacement range.

The authors are presently unaware of any prior study that has validated an ultrasonic technique against internal tissue displacements during indentation. Although Zheng and Mak[16] mounted a hand-held device to a materials testing machine, the displacement of the affected tissue was not measured directly as was the case in this study. Additionally, the methods employed in this study provided control over the indentation rate and angle, variables not controlled for in hand-held devices but considered to be significant with respect to outcomes obtained from indentation loading[22,23].

While there are advantages in using ultrasonic scanning to assess sub-cutaneous displacements of osseous structures, there are limitations to the technique which may be of potential significance. Firstly, compression of soft tissues caused by indentation may alter the speed of wave propagation within the tissue and therefore alter the resulting image. Given the observation that ERR was almost completely related to the vertical pixel resolution of the B-mode image, we speculate that any change in propagation properties due to tissue compression was negligible. Secondly, estimations of positional change found by A and B-mode ultrasonic techniques can be negatively affected by large, non-axial and out-of-plane displacements[15,24-26]. As our criterion displacement was found to be less than 2 mm and the preparation of the sample and direction of the applied load combined to result in what was observed to be predominately axial displacement, these potential sources of error were assumed to be minimal. Thirdly, given equality in variables shared between scanning modes (i.e. transducer frequency), one dimensional RF scanning (A-mode) in the axial plane is more precise in estimating position changes of an echogenic structure than two dimensional image-based scanning (B-mode). This precision loss in B-mode is the result of demodulation of the RF signal, conversion to a brightness value and the display of those values at discrete locations within an image (pixel) array[24]. Although A-mode scanning has superior precision with respect to the estimation of positional change, the resultant plots may be difficult for operators to correlate with actual anatomical structures, especially when multiple echogenic structures are present. We speculate that the interpretation of the anatomical representation presented by B-mode images is likely more intuitive to health care professionals as it provides a quick and familiar means of comprehending what is being scanned at any moment in time. Added to these advantages, B-mode equipment is likely to be accessible in most major centres. Lastly, while more sophisticated techniques exist with respect to the ultrasonic identification and tracking of tissue landmarks[19,27-29], this study demonstrates that localization techniques based on simple visual assessment do not necessarily result in relatively large error magnitudes (defined as greater than 10%).

Conclusion:

The results of this study indicate that when using the technique in question, sub-cutaneous uni-planar displacements of bone arising normal to indentation loading can be quantified non-invasively with accuracy comparable to similar invasive techniques over a comparable displacement range. The magnitude of the measurement error in this technique was observed to be most strongly influenced by the capability of the ultrasound equipment. The magnitude of this error may be clinically acceptable taking into consideration the advantages offered by B-mode scanning including: equipment and personnel availability, potential ease of landmark identification and its non-invasive nature. The technique described in this paper may be beneficial in assessing the clinical relevance of vertebral displacements in relation to conditions such as hypermobility and osteoarthritis where traditionally invasive methodologies have been employed.

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Chapter 5

A case study outlining the design process used to realize a non-invasive device for quantifying spinal force-displacement properties

INTRODUCTION:

Design is an integral element of engineering which attempts to understand completely a problem, then systematically find its optimal solution[1]. Resources and time assumed to be saved by omission of a formal design process are often consumed by substantial product revision, modification or amendment. While the importance of a design process is evident, examples of its formulation and execution are infrequent in health related literature. Therefore, the primary purpose of presenting this case study is to document the creation and deployment of a design process for the realization of an instrument intended for investigation of spinal mechanics.

BACKGROUND:

Alterations in the force-displacement (FD) properties of musculoskeletal tissues have been associated with dysfunction, injury and pathology. Traditionally, the determination of a tissue's FD properties has occurred through palpation — a psycho-motor skill where a clinician applies manual force to the tissue of interest while simultaneously interpreting the resulting tissue displacement. Palpation remains the most prevalent mode of FD assessment as it is inexpensive, easy to administer, and draws on everyday human experience within a tactile world. Without devaluing the importance of human contact in health care, the subjective nature of palpation may hinder the advance of understanding of the true relation between tissue FD properties and tissue abnormalities[2-4]. Rapid development of modern technology has facilitated the evolution of instrumentation capable of objectively quantifying information from traditionally subjective assessment modes. At present, instrumented quantification of FD properties has been developed for several joints of the musculoskeletal system including the ankle[5,6], shoulder[7,8] and most commonly, the knee[9-11]. While the majority of these devices are restricted to research roles, instrumented assessment of the knee has evolved furthest toward becoming a clinical standard. As a result, a significant body of clinically relevant knowledge regarding knee FD properties has been generated[12]. Comparatively, development and application of similar procedures for assessment of spinal FD properties has been lacking for several reasons including the size and accessibility of spinal anatomy and the limitations of current non-invasive techniques in assessing specific spinal mechanics[13-15]. As a result, the clinical significance of spinal FD properties has been difficult to ascertain.

DESIGN OVERVIEW:

Many pre-defined algorithms, hierarchies, or procedures exist which attempt to simplify and optimize the creation and implementation of a design process[16-23]. These methodologies formalize the perceived sequence of steps or stages within design, thereby directing attention and reducing oversight[16,24]. While these methodologies are useful, no single pre-defined process exists that will suit all design projects: each design process must be adapted to the unique and specific environment of the project. Central to this adaptation is the designer whose role it is to apply his or her own creativity and experience in balancing resources and requirements ultimately to develop a satisfactory design solution. In this capacity, the designer must also satisfy the needs of a number of clients and do so within specific time and resource constraints. Thus, the realization process is facilitated by establishing a design methodology which is overseen by a designer who can manipulate the process for an optimal outcome.

The design process established for this project is an amalgam of many different sub-processes. For the purposes of this project, sub-processes were selected for their ability to be used by a small design team (including non-engineers) given that only a single unit would be manufactured. The overall schematic representing the design process for the spinal indentation device is displayed in Figure 5.1.

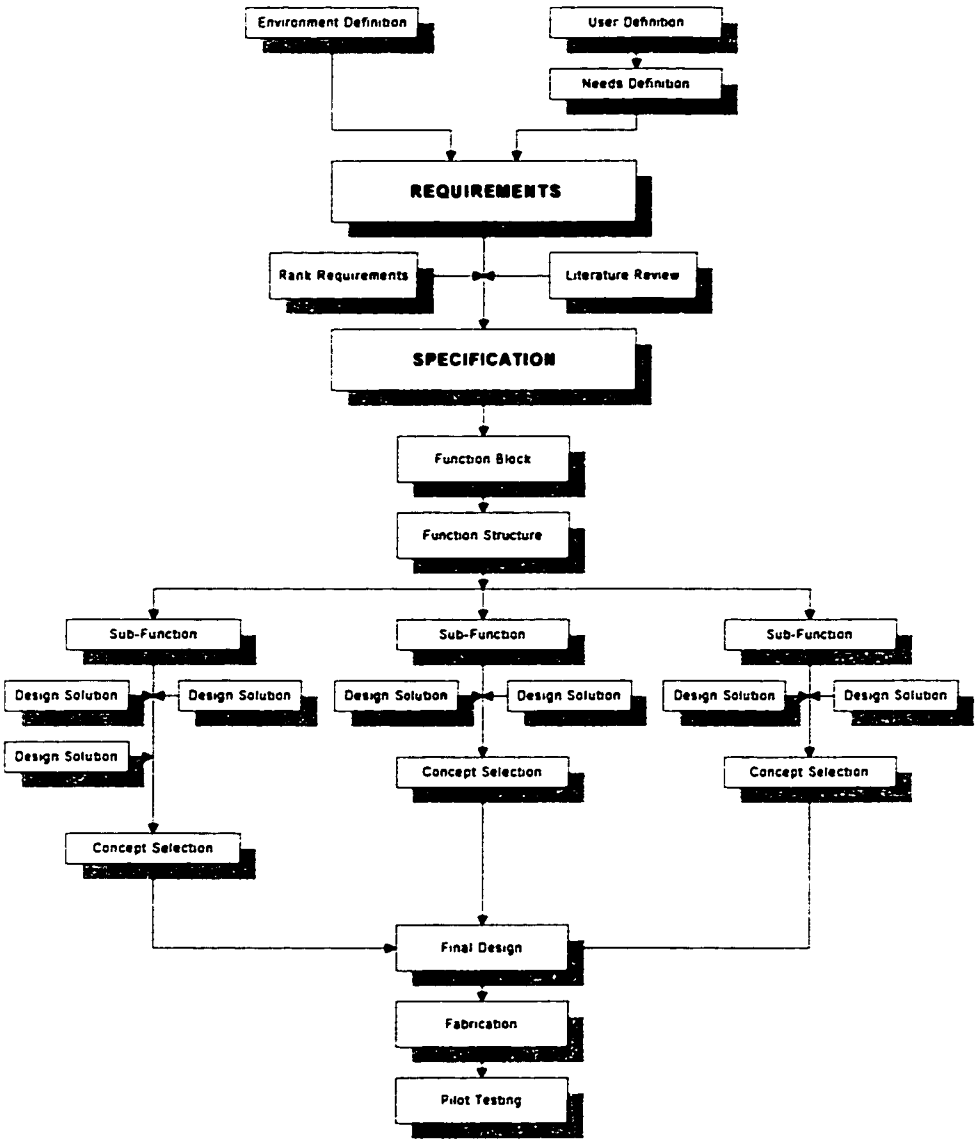


Figure 5.1: *Overall design outline.*

DESIGN PROCESS:

Definition of Environments, Users and User Needs: The design process used in this case study was initiated by first establishing two parallel processes with reference to creation of a device to quantify spinal FD properties: environment definition and user definition[20,25]. Environments of the device may include physical environments such as the site of testing or more abstract environments such as periods of subject preparation or instrument calibration. Definition of the user group may include individuals or groups of individuals who are considered to be the people that will utilize or influence the end design. These definitions may be performed in an expedient manner through the use of a single rater; however, reliance on a single person may result in oversights that are not easily corrected in later design stages[17]. To reduce this subjectivity, groups of persons with varying skills and experiences relating to the final product can be polled, surveyed or interviewed[16,20,26]. While subjectivity in this process can be reduced even further by the use of survey questions with known reliability and validity, this level of detail may not be required if consensus can be reached between the panel members considered to be "expert"[27-29]. Following environment and user definition, all users were surveyed to determine their needs with respect to a device capable of assessing FD properties of the spine. Needs are informal statements that describe the physical, procedural or performance properties of the issue under consideration. The general needs for this project/system/device are presented in Table 5.1.

Design Requirements and Requirement Ranking: Despite a large and varied range of available design methodologies, one concept is universal to most: the creation of a set of specific design requirements. Design requirements are needs of users that have been rephrased to describe a condition or situation that is required in the final design outcome. Compared to needs, requirements are formal, concise descriptions which include a statement of quantity or quality[20,30].

Environments	Users	User Needs
Calibration	[redacted]	data reliability
Subject preparation		data accuracy
Subject dismissal		for use in clinical environments
Operation		immediate data availability
Anatomical		
Operation	[redacted]	transportable
Data analysis		single person set-up
		single person operation
		ergonomically viable
		subject management unobtrusive
	[redacted]	comfort
		safety
	[redacted]	design and testing documentation
		quality assurance of end-product
		realization of clinical utilization

Table 5.1: *Listing of instrument environments, users and user needs.*

Following compilation of design requirements, an integral part of most design systems is valuation of those requirements by one or several characteristics important to the design process. These characteristics may include cost, importance and/or feasibility[31]. By use of a defined system of requirement valuation, variability and bias in the assignment of value may be decreased[31]. These techniques include use-value analysis and binary assessment. Use-value analysis or UVA, is a derivative of cost-benefit types of analysis[19] which establishes a graphical representation that singularly describes design requirements, their relationships, as well as their relative levels of importance. The UVA technique is a reliable, cost-effective and easily understood process[19], however, it may add a level of complexity to a design which is not required. Binary techniques function by comparing all of the design requirements against each other, two at a time with respect to a specific characteristic. In each comparison, the more important of the two requirements is assigned a value of *one* and the remaining requirement a value of *zero*[17]. The results of these comparisons are tabulated, totaled, and the results converted to a percentage that represents the overall importance of each design requirement. For designs with a small number of requirements, the binary technique is a fast and easy method of ranking requirements[19]. In addition, the binary process is easily used by persons who are unfamiliar with valuation processes. For these reasons, a modified binary type system was used in this design case to rank each requirement on its importance and feasibility. With respect to importance, all requirements were categorized as demands or wishes. Demands were considered to be requirements that must be met under all circumstances without which the final design would not be acceptable. Wishes were considered as requirements that should be taken into consideration whenever possible, but their fulfillment was not seen as critical for acceptance of the overall solution. Each wish was then sub-ranked as having low, medium and high importance. The resultant requirements were then additionally ranked to a second characteristic: feasibility. Feasibility was pre-defined by six criteria and weighted by a binary process. It should be noted that feasibility does not pertain to the design requirement, but to the ability to implement that requirement[32,33]. Each design requirement was then scored against these feasibility criteria, and the resulting scores for each requirement ranked as normalized percentages (Table 5.2).

Requirements		Criteria a	b	c	d	e	f	Score	%1	%2	Rank	Ranked Requirements
Device	Translation DOF		1	1		1	1	0.600	2.480	65	100	Good U/S Integrate
	Rotation DOF		1	1		1	1	0.600	2.480	65	100	Good Containment
	Good U/S Integrate						1	0.930	3.845	100	100	Accur Positioning
	Quick Positioning			1	1		1	0.590	2.439	63	92	Rel Positioning
	Accur Positioning						1	0.930	3.845	100	92	On Time
	Rel Positioning			1			1	0.860	3.555	92	92	Good Skin Access
	High Frame Rigidity		1	1		1	1	0.600	2.480	65	92	Easy In/Egress
	Good Skin Access			1			1	0.860	3.555	92	78	Visualize Indenting
	Const Displ Rate		1	1	1	1	1	0.330	1.364	35	78	Short Warm-up
	High Max Force		1	1	1	1	1	0.330	1.364	35	78	Oper/Sub Commun
	High Max Displ		1	1	1	1	1	0.330	1.364	35	78	Large # Seq Trials
	Fast Indent Revers			1	1	1	1	0.460	1.902	49	78	Infreq Maint
	High Displ Accur			1	1	1	1	0.460	1.902	49	78	Infreq Calib
	High Displ Rel			1	1	1	1	0.460	1.902	49	78	Good Subject Comf
	High Force Rel		1	1		1	1	0.600	2.480	65	78	Good Oper Comf
	High Force Accur		1	1		1	1	0.600	2.480	65	65	Translation DOF
	Low Noise			1	1	1	1	0.460	1.902	49	65	Safe Power Loss
	Low Vibration			1	1	1	1	0.460	1.902	49	65	Rotation DOF
	Good Containment						1	0.930	3.845	100	65	Quick Set Up
	Good Subject Comf			1		1	1	0.730	3.018	78	65	Optimal Size
	Easy In/Egress			1			1	0.860	3.555	92	65	Low Weight
	Fast Processing	1	1	1	1	1	1	0.000	0.000	0	65	High Frame Rigidity
	High Collect Rate	1	1	1	1	1	1	0.000	0.000	0	65	High Force Rel
	Real time display	1	1	1	1	1	1	0.000	0.000	0	65	High Force Accur
	All Var On-Screen				1	1	1	0.530	2.191	57	65	EasyTranport
Environment	Low Weight		1	1		1	1	0.600	2.480	65	63	Quick Positioning
	Optimal Size		1	1		1	1	0.600	2.480	65	57	All Var On-Screen
	EasyTranport		1	1		1	1	0.600	2.480	65	49	Visually Good
	Quick Set Up		1	1		1	1	0.600	2.480	65	49	Low Vibration
	Accessible Power	1	1	1	1	1	1	0.000	0.000	0	49	Low Noise
	Visualize Indenting			1		1	1	0.730	3.018	78	49	Low Cost
	Good Oper Comf			1		1	1	0.730	3.018	78	49	High Displ Rel
	Oper/Sub Commun			1		1	1	0.730	3.018	78	49	High Displ Accur
	Short Warm-up			1		1	1	0.730	3.018	78	49	Fast Indent Revers
	Large # Seq Trials		1	1			1	0.730	3.018	78	49	Bad Param Exclude
	Infreq Calib			1		1	1	0.730	3.018	78	35	Subject Terminable
	Infreq Maint			1		1	1	0.730	3.018	78	35	High Max Force
	Subject Terminable		1	1	1	1	1	0.330	1.364	35	35	High Max Displ
	Safe Power Loss		1	1		1	1	0.600	2.480	65	35	Const Displ Rate
	Bad Param Exclude			1	1	1	1	0.460	1.902	49	0	Real time display
	Low Cost		1	1	1		1	0.460	1.902	49	0	High Collect Rate
	On Time			1			1	0.860	3.555	92	0	Fast Processing
	Visually Good			1	1	1	1	0.460	1.902	49	0	Accessible Power

Table 5.2: *Feasibility ranking of design requirements.*

The resulting importance and feasibility rankings were then plotted against each other. By ranking the project's requirements on two scales, importance and feasibility, thresholds of acceptance can be created that when applied against each other, categorize the requirements into four groups: important/feasible, not important/feasible, important/not feasible and not important/not feasible. From this analysis, six important/feasible requirements were identified: 1] safety mechanisms for operator and subject, 2] ability to assess non-invasively internal spinal mechanics during indentation, 3] re-locate indenter to internal anatomy, 4] control of subject movement during indentation, 5] constant indentation rate and angle, and 6] adequate equipment rigidity and support.

REVIEW OF PRIOR INSTRUMENTS:

Once the principal design requirements were established and ranked, literature review and analysis was employed to identify the strengths and weaknesses of the current design requirements. This process helped identify important design items that have been overlooked in the current project[20,34]. While this process can be very worthwhile, caution must be exercised as knowledge of previous designs can bias the current design process. As a result, this process was performed after the formulation and ranking of design requirements.

To identify and assess procedures and equipment related to the design of a spinal indentation device, a review of the literature was conducted to identify all papers, reports and descriptions of instruments designed for the collection of force-displacement data from musculoskeletal tissues by the process of indentation. Specifically, literature searches were conducted of the Medline (Medical Abstracts), Compendex Plus (Engineering Abstracts) and

Manual Alternative and Natural Therapy Index System (MANTIS) databases. All databases were searched through all available years with the following search terms used separately or in combination: stiffness, compliance, tissue stiffness, tissue compliance, indentation and ultrasonography. The searches resulted in the identification of 13 non-invasive instruments or procedures designed to collect force-displacement data from indentation of the musculoskeletal system. These instruments were rated as to their ability to satisfy the top six design requirements identified in this study. The percentage of these 13 instruments/procedures that could satisfy these requirements was as follows: provision of constant indentation rate and angle (69%), adequate equipment rigidity and support (62%), control of subject movement during indentation (8%), ability to re-locate indenter to internal anatomy (0%) and ability to assess internal spinal mechanics non-invasively during indentation (0%).

CONVERSION OF REQUIREMENTS TO SPECIFICATIONS:

Following design requirement identification, ranking and comparison to prior instruments/procedures, design specifications were created. Specifications are requirements that have been quantified. A specification provides a defined goal for all subsequent stages of the design process including conceptualization, fabrication and evaluation.

RELATIONSHIPS BETWEEN REQUIREMENTS:

Following the creation of the design specification, it was necessary to summarize the specifications of the design as well as the relations between them to facilitate user interactions throughout the remainder of design process (Figure 5.2). This was achieved by creation of a general schematic called a Function Block [35]. The objective of creating the Function Block was to establish and graphically represent, the 'flow' of the design process and to identify areas of design subdivision for ease of project management. As a result, the Function Block was further divided into Sub-Blocks (or sub-functions), each with a lesser complexity than the Function Block. Sub-Blocks were identified in this project as 1] tissue indentation (Figure 5.3), 2] subject positioning, 3] subject movement restraint, 4] emergency systems, and 5] signal management. Each of these Sub-Blocks was addressed singularly and in context with other Sub-Blocks for potential design solutions. In this way, temporal and spatial interactions between Sub-Blocks could be assessed. The relation between Sub-Blocks could be envisioned as the Function-Structure (Figure 5.4).

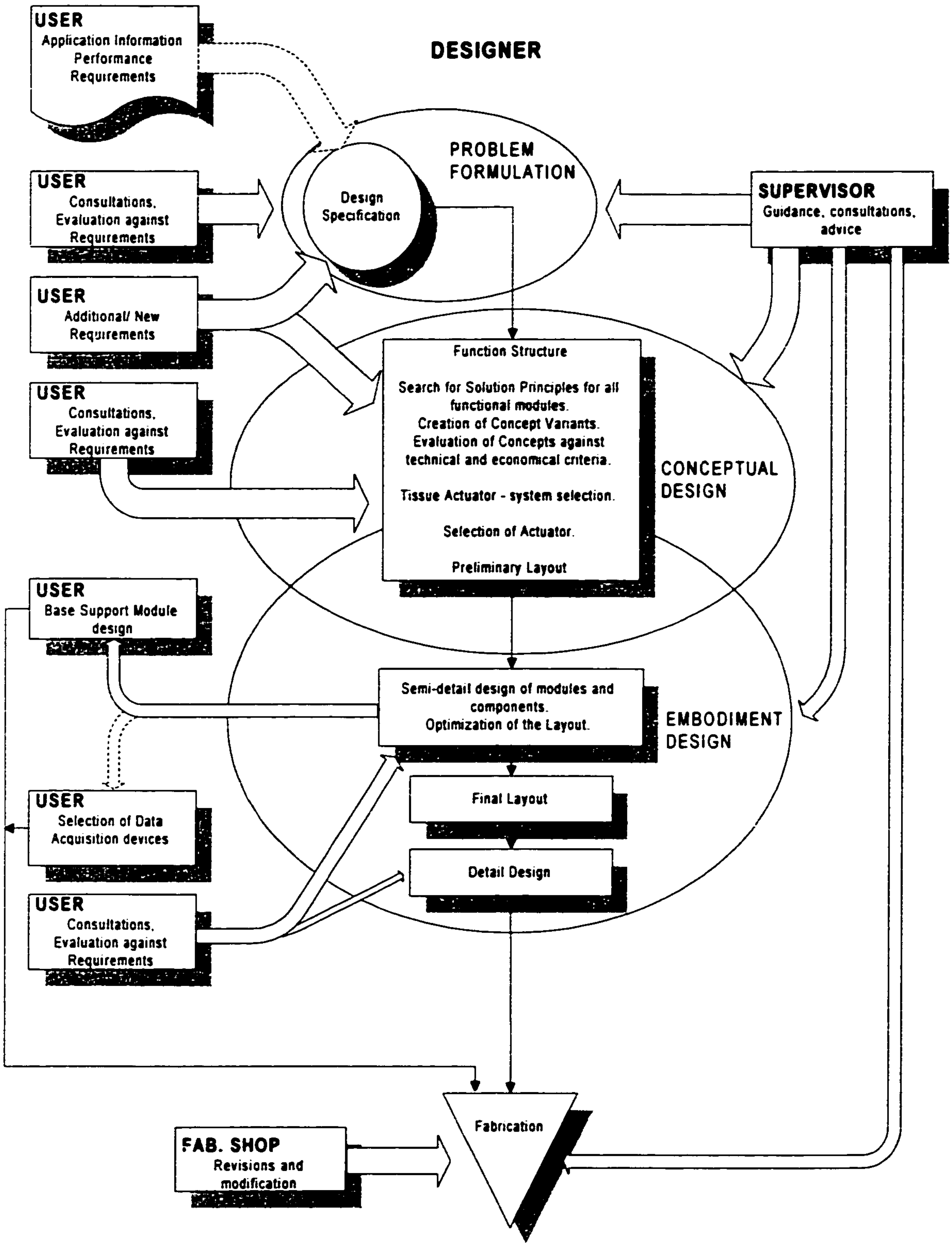


Figure 5.2: *Design Interactions*[35].

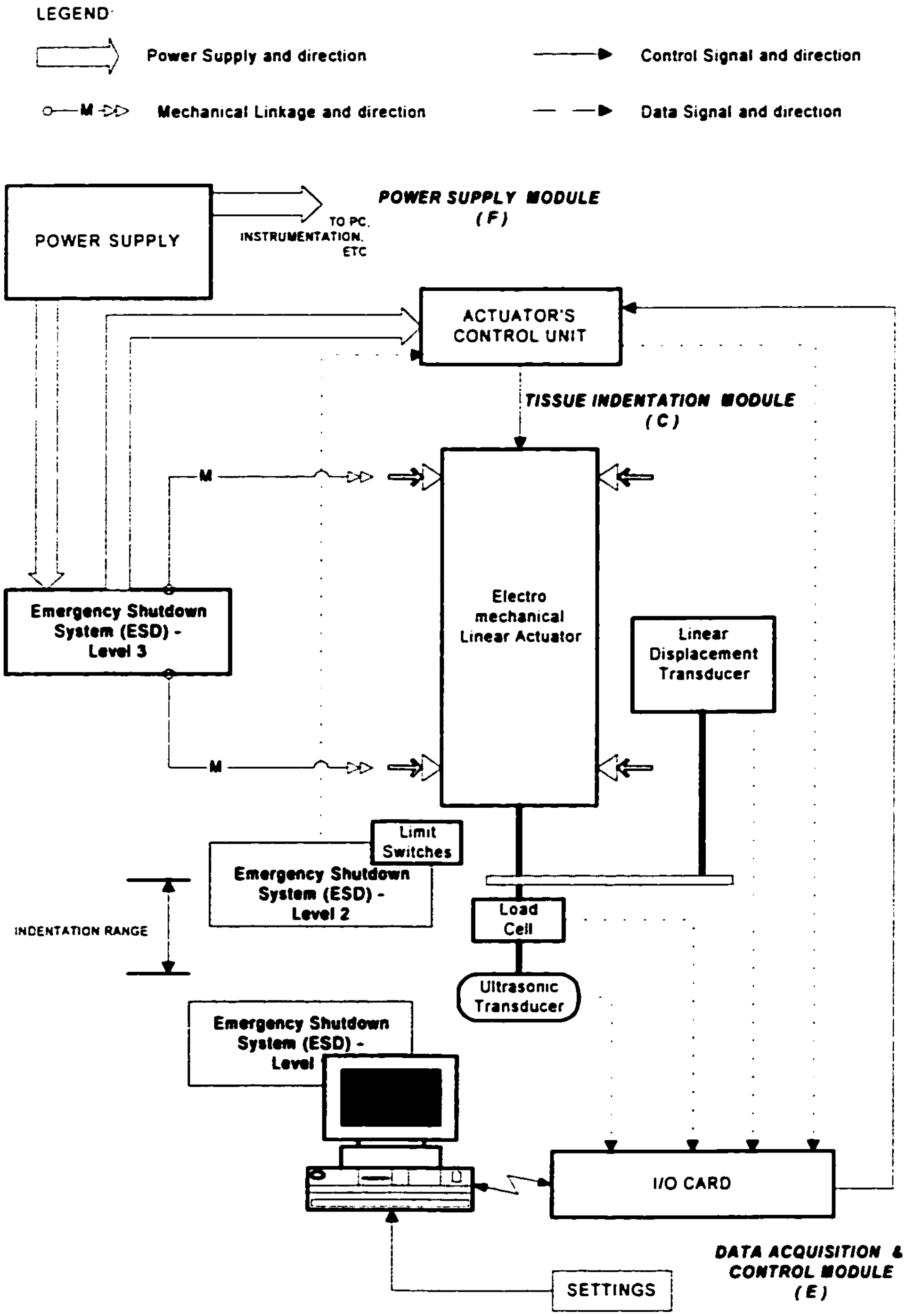


Figure 5.3: *Tissue Indentation Sub-Block*[35].

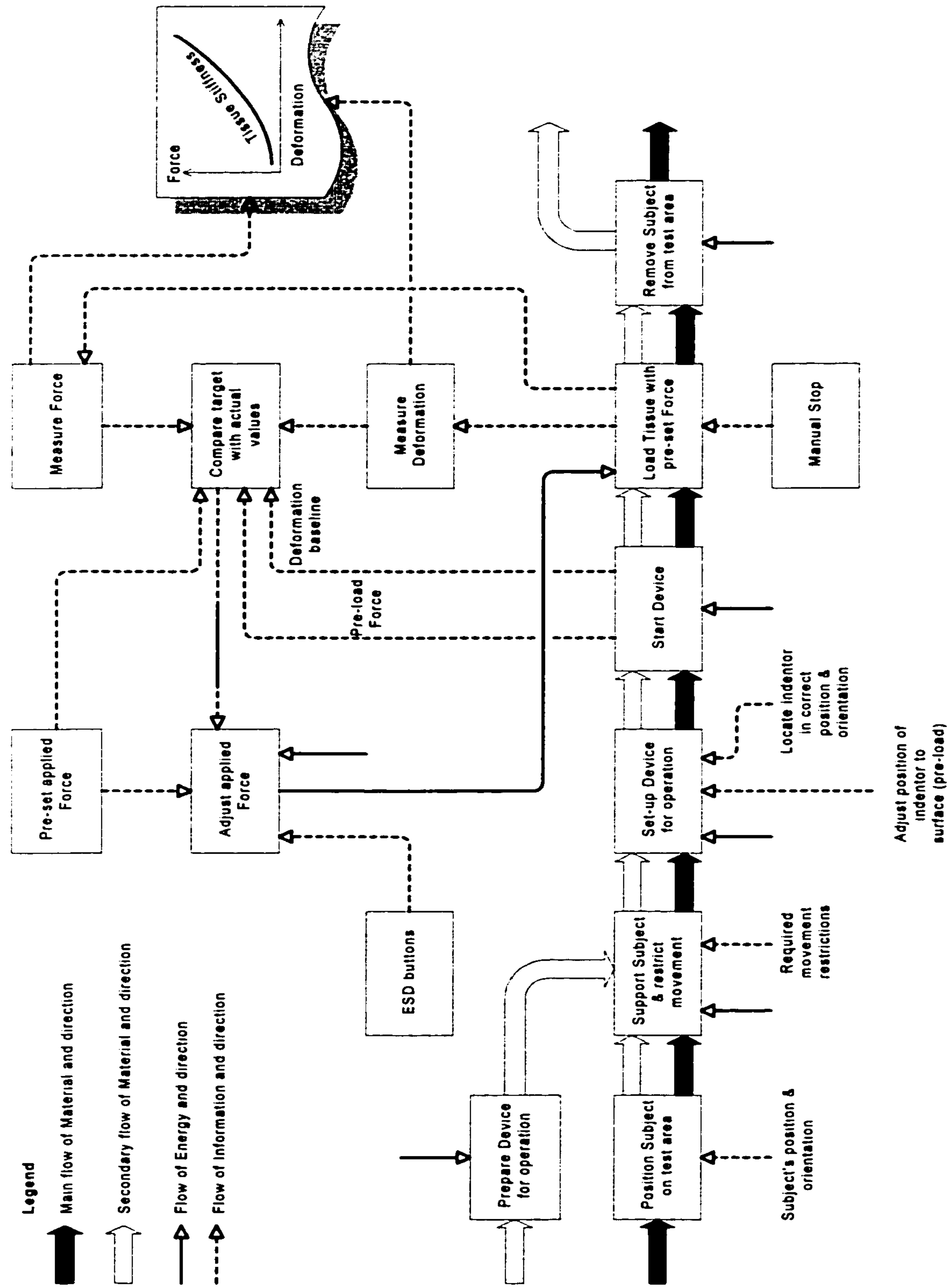


Figure 5.4: *Function Structure*[35].

Sub-Block	Concept
[redacted]	Subject platform of caster wheels
	Pre-manufactured hospital bed on caster wheels
	Subject platform on horizontal rail system
	Subject platform on bearing surface
	Subject platform on pneumatic guides
	Instrument on caster wheels
	Instrument on horizontal rail system
	Instrument on pneumatic guides
[redacted]	Strap restraints of prone subject
	Peripheral compression of subject - actuators
	Peripheral compression of subject - spring cams
[redacted]	Electromechanical
	Pneumatic
	Hydraulic
[redacted]	Mechanical removal of instrument from subject
	Electronic cessation of instrument function
[redacted]	Separate data acquisition and control signal generation
	Concurrent data acquisition and control signal generation

Table 5.3: *Sub-Blocks and a selection of their proposed design solutions.*

SUB-BLOCK DESIGN SOLUTIONS:

Based on iterative review of the design specifications with respect to the Function Structure, various concepts were formulated by the designer and users for the design solution of each Sub-Block (Table 5.3). The final selection of any particular concept as a design solution was based on the ability of that concept to meet the design specifications of that Sub-Block and their compatibility with preferential concepts of other Sub-Blocks. Each concept was then additionally reviewed in terms of its financial impact. Final concepts for each Sub-Block were chosen in this manner. After selection of each Sub-Block concept, preliminary layout sketches and final detail drawings of parts and components were created before the acquisition or fabrication of the relevant materials. However, prior identification of the temporal relations between Sub-Blocks identified that should construction of the Tissue Indentation and Signal Management Sub-Blocks occur before all other Sub-Blocks, pilot evaluations could be performed that would allow for more accurate selection of design solutions for other Sub-Blocks. Therefore, determination of Sub-Block solutions was an iterative process that employed pilot data. This preferential deployment of Sub-Block fabrication additionally permitted expedient evaluation of the final design as many systems were in place and tested prior to fabrication of the entire device.

FINAL PRODUCT - SOFT TISSUE INDENTER:

The design process outlined in this case study resulted in the fabrication of a device called the Soft Tissue Indenter (STI). The STI (Figure 5.5) is an electromechanical actuator (Industrial Devices Corporation, Petaluma, CA, U.S.A) suspended in an aluminum frame. The frame itself is mounted on lockable wheels that provide gross positioning movements which allows the entire device to be positioned over a prone, stationary, subject. Once locked into position, a series of horizontal slides allow the actuator to be positioned with respect to the subject with greater precision. Other mechanisms within the frame permit vertical angulation as well as translation of the actuator in the vertical plane. A guide system attached in-parallel to the actuator housing provides side-load support when the actuator is extended from its housing as well as a linear displacement transducer to quantify the position of the actuator with respect to the actuator housing (Data Instrument, Acton, MA, U.S.A.). A load cell (Load Cell Central, Monroeton PA, U.S.A.) and ultrasonic transducer (Acuson, Mountainview, CA, U.S.A.) are attached in-series to the terminal end of the actuator. The load cell transducer is used to quantify applied load while the ultrasonic transducer is used to position the actuator to sub-cutaneous anatomical targets prior to indentation and to visualize these same targets during indentation. Load and displacement transducers are powered and amplified independently while the ultrasonic transducer is part of a commercial diagnostic ultrasound system(Acuson, Mountainview, CA, U.S.A.). Digital signals generated from an analog to digital board (A/D) (National Instruments, Austin, TX, U.S.A) by customized software (Figure 5.6), are sent to a hardware controller (Industrial Devices Corporation, Petaluma, CA, U.S.A) which governs actuation and actuation rate of the load cell and ultrasonic transducers. Voltage signals corresponding to load and displacement are simultaneously collected by the same A/D hardware. Electronic control of the endpoint of actuation may be performed by setting load or displacement voltage thresholds. Safety mechanisms include electronic cessation of indentation upon operator request, limit switches within the actuator, and a mechanical system operated by the subject to release a sprung rail system instantaneously which translates the actuator vertically away from the subject. Two pairs of horizontal, manually operated linear actuators mounted on each side of the STI framework are used to restrain subject movements by compressing the shoulders and hips of the subjects.

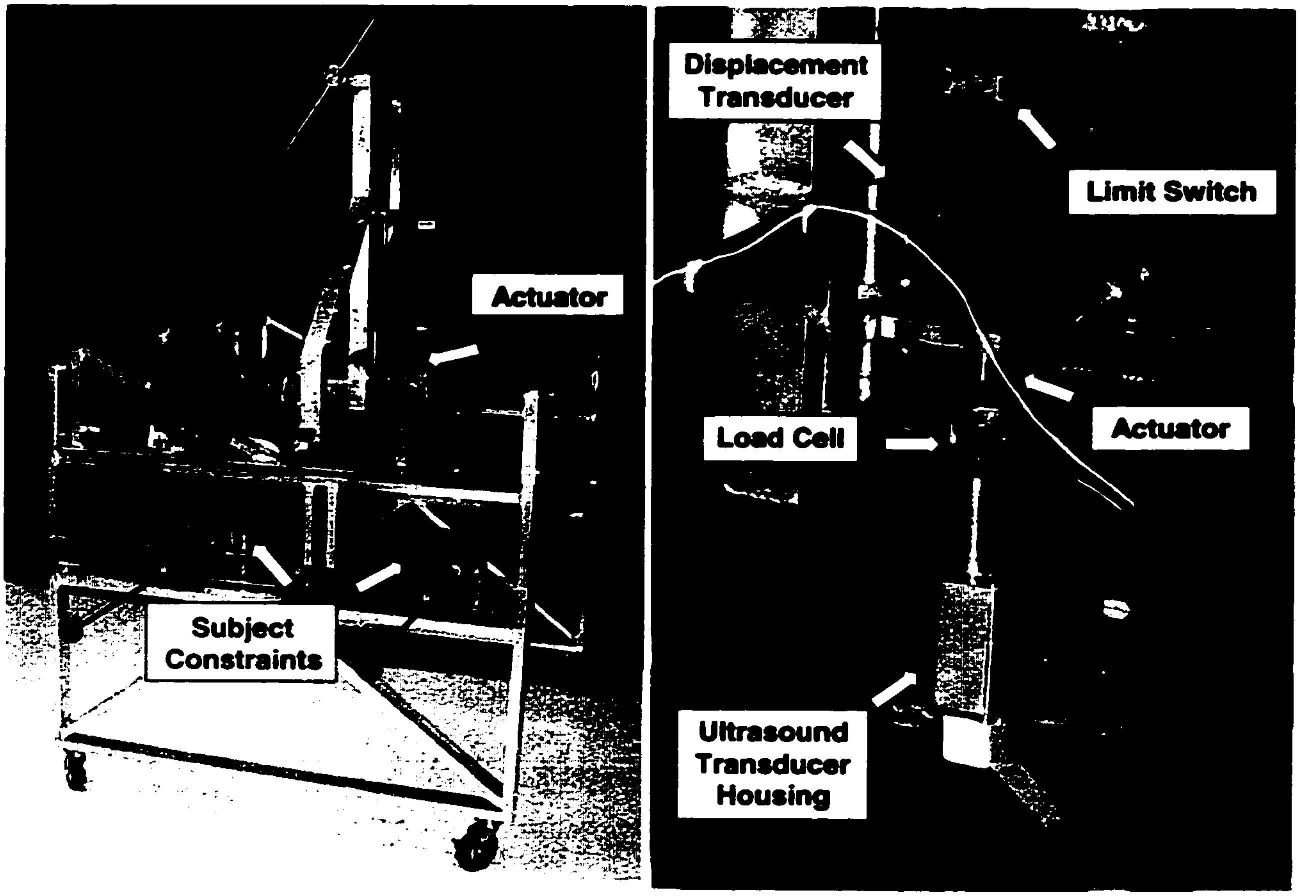
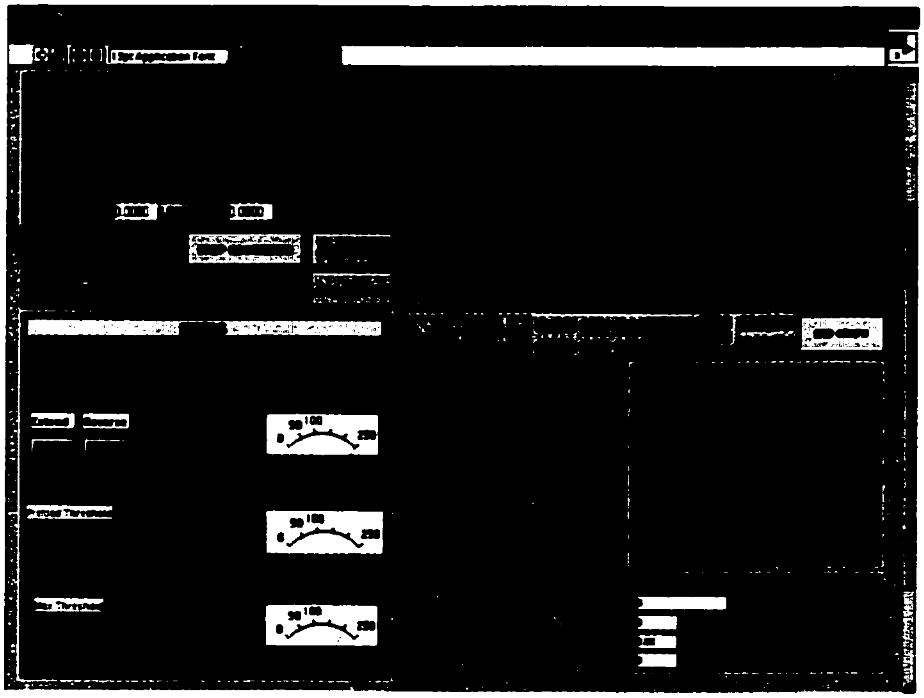


Figure 5.5: *Soft Tissue Indenter (STI).*



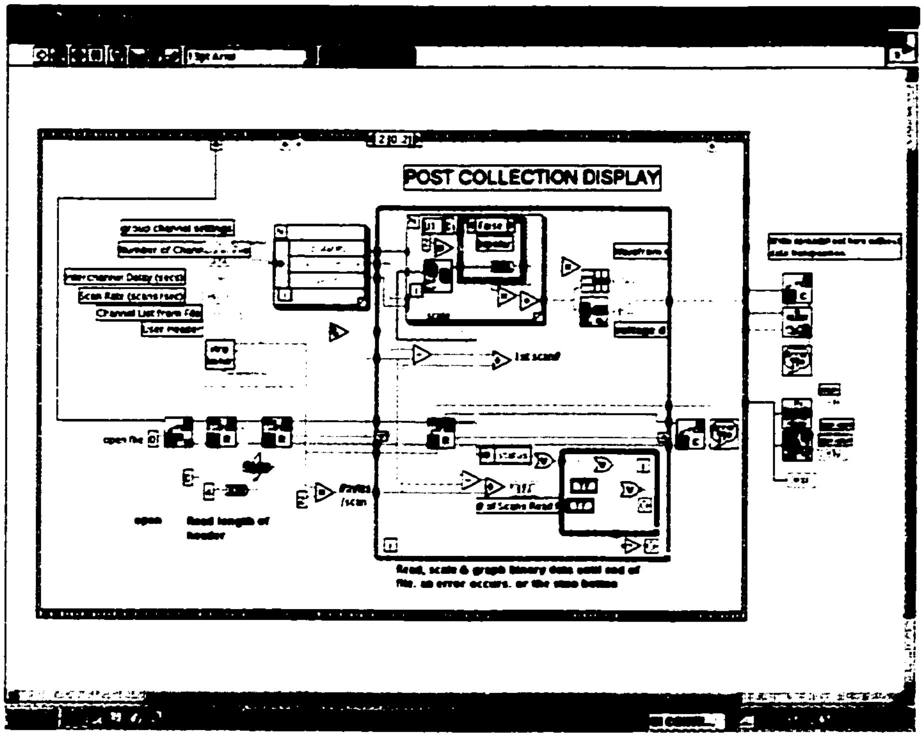


Figure 5.6: *Program interface and example coding for actuator control/data acquisition program.*

DESIGN EVALUATION:

The purpose of the evaluation process was to determine the relative value of the design with respect to the objectives and fulfillment of the requirements. This evaluation was performed through: 1] review of the final embodiment based on evaluation criteria, 2] an evaluation of the stiffness of the framework in order to verify its rigidity, and 3] evaluation of the final costs and schedules. Additionally, bench-top evaluation of STI performance was conducted. This evaluation consisted of quantification of frame deflection, off-axis loads and signal noise. These results are described in detail in the following chapters.

Review of the final embodiment was accomplished by setting evaluation objectives based on the performance requirements and the design specification. These objectives included geometry, ergonomics, performance, operation, safety, production, and maintenance[19]. These objectives were further categorized to reflect individual items of the design specification and then weighted by the designer to reflect their performance[35]. Weighting given to the evaluation objectives was highest for safety items and lowest for production items. After weighting, each category was assigned a value by the designer from "Unsatisfactory" (0) to "Very Good" (4) and the final score of the item calculated. A final rating of 3.60 points was deemed as "minimally acceptable" for any of the rated requirements. The overall rating of the STI was calculated to be 3.88 and was therefore considered to satisfy the evaluation criteria.

One of the six important/feasible requirements of the design was that there be adequate equipment rigidity and support. To assess the fulfillment of this requirement, stiffness calculations were performed to determine the maximal value of deflection of the indentation framework under the load of the actuator and frame itself. Based on these calculations[35], the maximum vertical deflection of the indentation framework was 0.15 mm. The magnitude was deemed acceptable as the resolution of the vertical displacement transducer onboard the STI was 0.12 mm (Chapter 7). Therefore, it was established, theoretically, that the framework of the STI should provide stable and adequate support for the actuator during indentation procedures.

In total, the costs of the STI were approximately $21,500 CDN. This figure was broken down into materials ($6,500) and labour ($15,000). As a total budget was not established for this project, budgetary analysis was inappropriate. Finally, the timeline of the project was extended on several occasions to reach a total length of two years (100% increase). This increase was the result of accommodating the schedule of the designer and users (who were unpaid) and the availability of a fabrication shop that could de-prioritize STI construction based on the importance of other incoming work-orders.

CONCLUSION:

In general, the design process used in this case study for product realization was seen as beneficial in that the STI has performed up to or beyond its design specification. Since its fabrication, the STI has performed an estimated 1000 indentation cycles over 12 months. Very few revisions have been necessary to achieve this level of performance. To date, repair or maintenance of the system has been almost nil. In addition, the STI has been dismantled and re-assembled on two occasions for shipment overseas. With respect to costs, no accurate analysis could be performed given the fluid nature of the initial budget. The timeline of the project was lengthened on several occasions resulting in a doubling of the originally scheduled time-to-completion. However, given the performance of final product, the magnitude of timeline extension was considered acceptable.

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Chapter 6

Ultrasonic Indentation (UI): A procedure for the non-invasive quantification of force-displacement properties of the lumbar spine

INTRODUCTION:

Historically, force-displacement (FD) properties of musculoskeletal (MSK) tissues have been observed to deviate from normal in response to, or as a cause of, injury and pathology. Accordingly, many health care disciplines employ FD assessment techniques in the diagnosis, treatment and ongoing evaluation of a wide spectrum of MSK disease and dysfunction. As traditional forms of these assessment techniques are subjective in nature (e.g. palpation), objective FD quantification techniques have become increasingly prevalent.

To date, such objective techniques have been utilized to quantify FD properties of soft tissue (muscle)[1,2] and joints including the shoulder[3,4], ankle[5,6] and knee. Of these areas of interest, quantification of the anterior displacement of the tibia with respect to the femur is the most prevalent and well developed form of MSK FD assessment as disruption of the tissues responsible for the constraint of this motion[7-9] have been shown to be related to knee disorders of high prevalence and morbidity[10]. Arguably, the KT-1000 (MedMetric, U.S.A.) is the best-known and well-tested of these devices in terms of its accuracy[11,12], reliability[11,13] and potential sources of variation including: quantity of soft tissues around the knee[14], direction of applied force and instrument position[12], body weight[15] and knee angle[15,16]. The accumulation of these data has allowed investigators to explore confidently the relations between knee stability and pathology, which in turn, has led to a sophisticated body of literature regarding the clinical significance of these conditions. These studies encompass such clinically relevant topics as the variation of anterior knee stability in normal and injured populations[13-15,17-19], false positive and false negative rates[20], risk of injury[19], relation of knee stability to pain and function[18,21], assessment of treatment[22-28], and prognostication[18,24].

Unfortunately, the development and application of non-invasive quantification techniques in the knee have been unmatched in other MSK tissues. With respect to the spine, several reasons have been proposed for such a deficiency[29]. The location of the joints of interest in relation to the surface of the body, their number and their size make spinal articulations exceedingly difficult to isolate. As a result, *in vitro* techniques have been employed to remove these soft tissues thus permitting a more detailed inspection of spinal mechanics. While *in vitro* approaches have provided valuable information regarding the relation between spinal motion and degeneration[30-32], surgical procedures[33,34] and injury conditions[30,35,36], *in vitro* techniques have obvious limitations that include the inability to relate measurements to clinical phenomenon such as pain or function. *In vivo* approaches resolve many limitations of *in vitro* testing, but may themselves be invasive[37-39], costly[40], lack reliability and/or accuracy [41,42], or be incapable of assessing spinal mechanics directly[43-45]. As a result, few techniques exist currently which can generate data pertaining to the clinical relevance of spinal FD properties from a single vertebra in large human populations.

As a result, a design process was established to develop a procedure capable of assessing spinal FD properties *in vivo*. Specifically, this process was optimized to improve on FD assessment instruments developed previously and to satisfy specific performance requirements established by literature review and expert panel consensus[46]. Three of these performance requirements were designated as "critical" and dictated that the procedure be:

1] non-invasive, 2] clinically accurate and 3] capable of distinguishing vertebral displacement from bulk tissue properties. As a result of this process, a FD quantification procedure was proposed which would utilize real-time ultrasonic imaging to quantify spinal FD properties during load-controlled indentation. Therefore, the purpose of this paper was to investigate the accuracy and reliability of spinal FD measures generated by the resultant procedure (Ultrasonic Tissue Indention or UI).

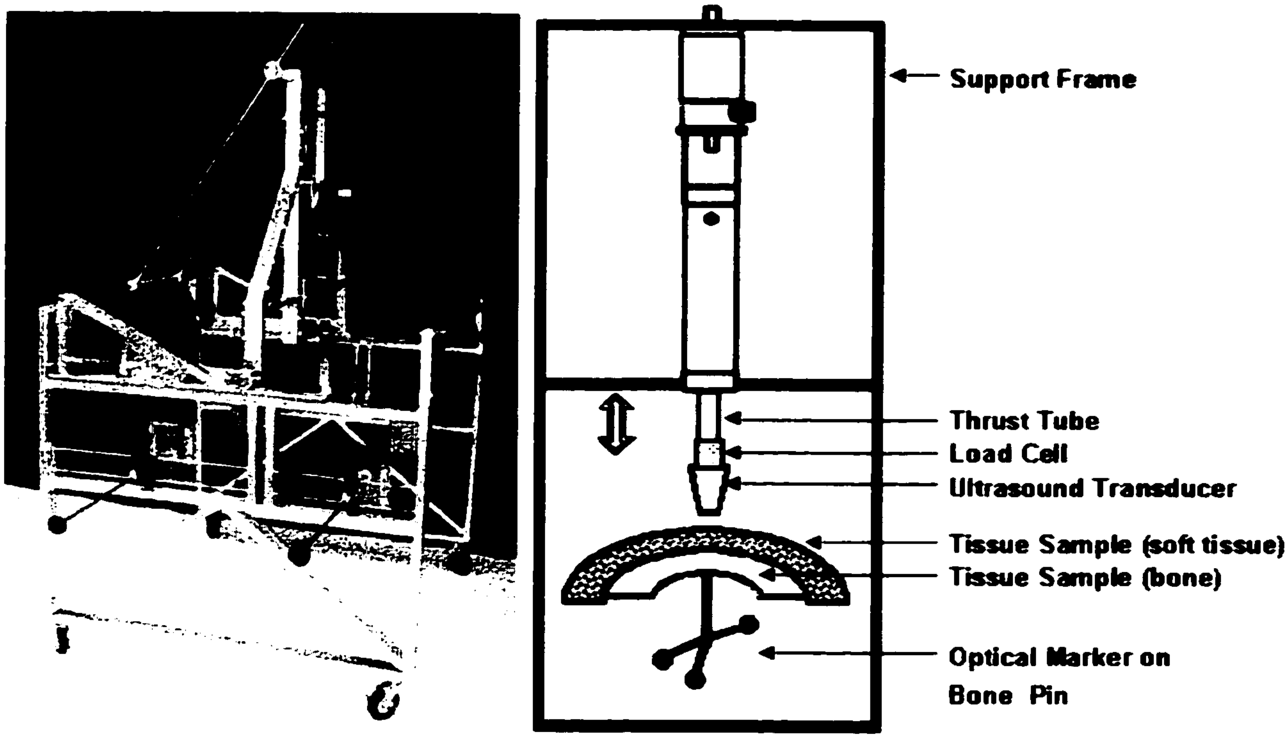

Figure 6.1: *Photographic and schematic representation of Ultrasonic Indentation equipment.*

MATERIAL and METHODS:

UI Equipment

Equipment used for UI was designed and fabricated at the University of Calgary (Figure 6.1) and consisted of an electromechanical linear actuator (Industrial Devices Corporation, Petaluma, CA, U.S.A) mounted on a custom aluminum framework. Attached to the terminal end of the actuator was a load cell transducer used to quantify the load applied to the tissue of interest (Load Cell Central, Monroeton PA, U.S.A.) and an ultrasonic transducer capable of imaging sub-surface echogenic anatomy (Acuson, Mountainview, CA, U.S.A.). A linear displacement transducer attached in-parallel to the actuator quantified the actuator's displacement (Data Instrument, Acton, MA, U.S.A.). Customized software (National Instruments, Austin, TX, U.S.A) was used to collect voltage signals from the load cell and displacement transducer via computer-based hardware (National Instruments, Austin, TX, U.S.A). This same system controlled concurrent translation of the actuator via a motor control unit (Industrial Devices Corporation, Petaluma, CA, U.S.A) that governed the rate, distance and end-points of actuator translation. The UI frame allowed independent horizontal translation and vertical angulation of the indenter with respect to the mobile base of the structure. Electronic and mechanical safety mechanisms allowed for premature cessation and reversal of actuation at the request of the operator and/or patient.

Calibration

Calibration of the load and displacement sensors was conducted while each of these transducers was installed in its intended location on the UI equipment. Each sensor was calibrated to a magnitude corresponding to the loads and displacements that were foreseen as applicable to future human trials[47]. Specifically, the load cell was calibrated by vertical loads applied to the indentation interface (8 sample points to a maximum 200 N). The displacement transducer was calibrated by extending the actuator in random intervals against a digital dial gauge placed vertically beneath the indentation interface of the actuator (11 sample points over 21.58 mm). The baseline noise of the load and displacement transducers was determined by calculating the standard deviation of a 5 second signal collected at a 1 kHz sampling rate during unloaded and stationary conditions. The minimal detectable voltage increment of the data collection system was found empirically, by determining the minimal voltage change between all data points of the baseline signal data and theoretically, by use of the following formula:

Equation 6.1: minimal detectable voltage increment $= \dfrac{voltage\ range}{2^{(bits)} * gain}$

During the load cell calibration process, a previously calibrated linear displacement transducer was placed vertically against the indentation interface to quantify vertical deflection of the actuator during indentation testing. The resulting frame deflections were plotted against the applied load and approximated by a 5th order polynomial function.

Signal processing

Data acquisition was accomplished with analog-to-digital computer hardware (A/D) that was additionally used to send simultaneous digital control signals to the motor control unit. As the A/D hardware was capable of concurrent input and output, a single operating frequency of 1 kHz was selected so that appropriately fast motor control signals could be provided. Based on spectral analysis of the load and displacement signals, data collected at 1 kHz were determined to be over-sampled. As a result, load and displacement signals were re-sampled (decimated) to 2x the Nyquist Frequency: the frequency found to contain 99.5% of load signal's frequency content. Finally, to remove electromagnetic noise in the re-sampled signals, the smoothing protocol of Giakkas et al was employed[48] (Figure 6.2). This smoothing routine determined the optimal cut-off frequency for low-pass smoothing based on a frequency analysis algorithm.

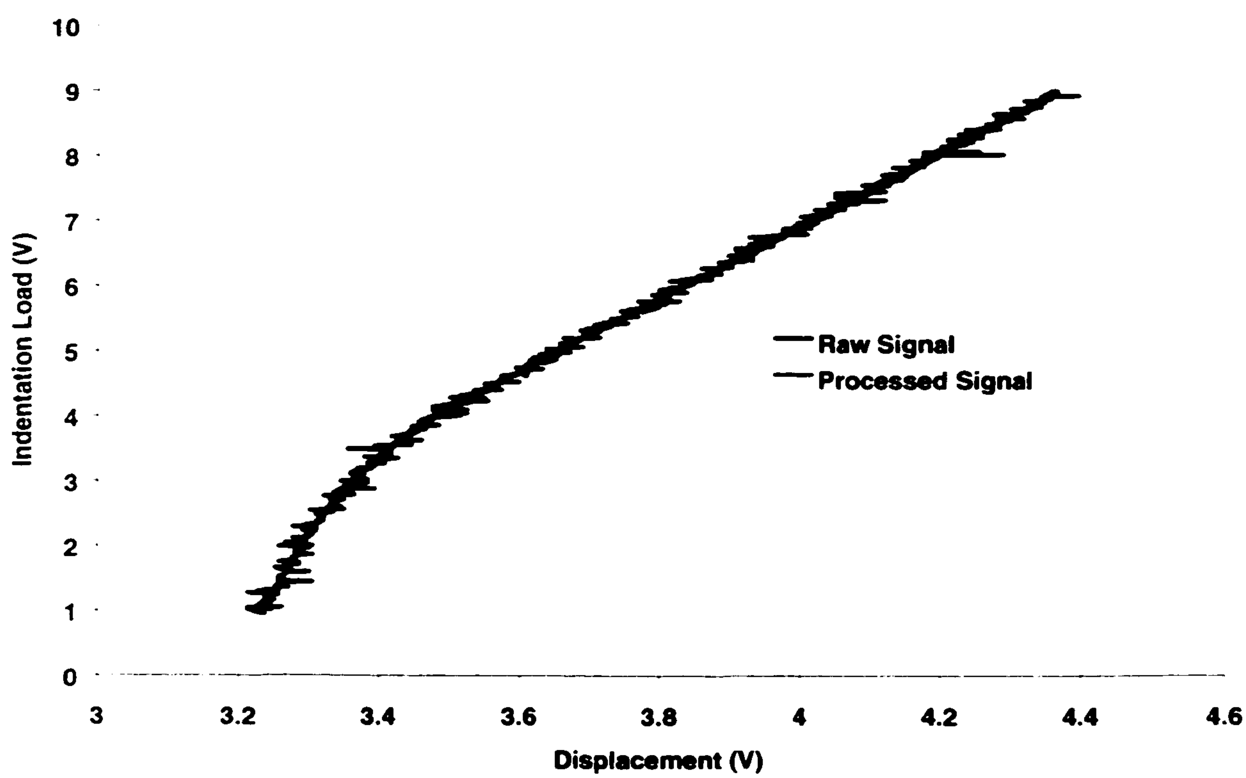

Figure 6.2: *Force-displacement data (raw and processed) obtained from a single indentation trial of a sprung platform.*

UI accuracy

To assess the accuracy of measurements obtained by UI, several experiments were conducted. First, a rigid frame was constructed that suspended a rectangular, flat, rigid platform by four springs of equal spring constant. The centre of the platform was located and designated as the indentation target. UI equipment was programmed to engage the indentation target five times at a rate of 2.5 mm/s. Indentation was initiated and proceeded to a load of approximately 20 N (pre-load) at which time loading was paused for 20 s. Indention then proceeded to a load of 200 N (max-load). The mean load between the five indentation trials was then calculated at 1 mm intervals (UIraw). The resulting loads were then substituted into the previously obtained polynomial function representing vertical frame deflection and the resulting displacements subtracted from the original data points to correct for frame deflection (UIcorr).

For use as a criterion, a second set of indentation data were collected from the spring platform using a MTS Test Star II (MTS, Edin Prairie, MN, U.S.A.). Signals were collected from the MTS at 1 mm/s at 100 Hz using a 20 N pre-load and a 200 N max-load. A hardware filter for noise reduction was employed at 50 Hz. Signals obtained from the MTS were not re-sampled nor additionally smoothed. The MTS system was assumed to be rigid in that there would be no appreciable vertical deflection of the system at the maximally applied load. The mean load between five indentation trials was calculated at 1 mm intervals (MTSraw). The absolute difference in load between the MTSraw and the UIcorr data was then determined and described as the percentage error with respect to the MTSraw data. To assess the accuracy of the resultant stiffness measures, the derivative of a 5th order polynomial approximation of each data set was found. The difference in stiffness magnitudes between the

MTSraw and the UIcorr data was determined at 1 mm intervals and described as a percentage of the MTS stiffness magnitude.

To assess the impact of off-axis loads on the UI and MTS equipment, a 10 cm diameter disc was constructed as an indentation interface (Figure 6.6). Holes were drilled and tapped at the centre of the disc at 90 degree intervals on a 3.8 cm and 7.6 cm diameter OC. These holes provided locations where a capscrew could be placed to create a variety of off-centre loads relative to the load cell. Five indentation trials performed by UI and MTS equipment were conducted at each capscrew location using the previously described indentation parameters. For each indentation, the indentation target was realigned to the capscrew position. Each resultant FD curve was then fitted by a 5th order polynomial and the resultant displacement found at approximately half the applied load (90N). These displacements were averaged for each capscrew position and then normalized to the centre location for comparison.

To determine the accuracy of vertebral displacement measures obtained by UI, a freshly eviscerated lumbar porcine spine was suspended horizontally between two supports attached by bone screws to each terminal vertebra (Figure 6.1). A 7 MHz linear array ultrasonic transducer mounted to the terminus of the indenter was used to confirm the position the indenter along the long axis of the L4 transverse process prior to indentation (Acuson, Mountainview, CA, U.S.A.). UI was performed 13 times at a rate of 2.5 mm/s to the paravertebral tissues posterior to the left transverse process of L4. This same transducer was used to collect static ultrasonic images at applied indentation loads of 1 N (pre-indentation) and 70 N (peak-indentation). Using previously defined methodology[49], vertebral displacement in the plane of indentation was calculated by determining the change in transducer-to-bone tissue thickness in ultrasonic images from pre-to-peak indentation (as determined from edge detection analysis) and subtracting this value from the change in indenter displacement over the same period (Figure 6.3). Pre-load and max-load ultrasonic images were collected as 0.3 Mpixel images (640 x 480 pixels) at an imaging depth of 60 mm. The focal depth was set to the depth of the transverse process. As a criterion measure, a reflective marker system (Traxtal Technologies, U.S.A.) was screwed into the ventral aspect of the transverse process and optically tracked (Northern Digital, Canada) at 10 Hz. The overall measurement error was calculated as the absolute difference between the estimated vertical displacement and the optically tracked vertical displacement and expressed as a percent of the criterion value.

UI reliability

Force-displacement data collected from five spring platform indentations were used to determine the reliability of the load measurements by 1] determining the standard deviation of the load values between all five trials at regular 1 mm intervals along the x-axis and 2] determining the Intraclass Correlation Coefficient (ICC) from these data. The reliability of the related displacement measurements was assessed similarly.

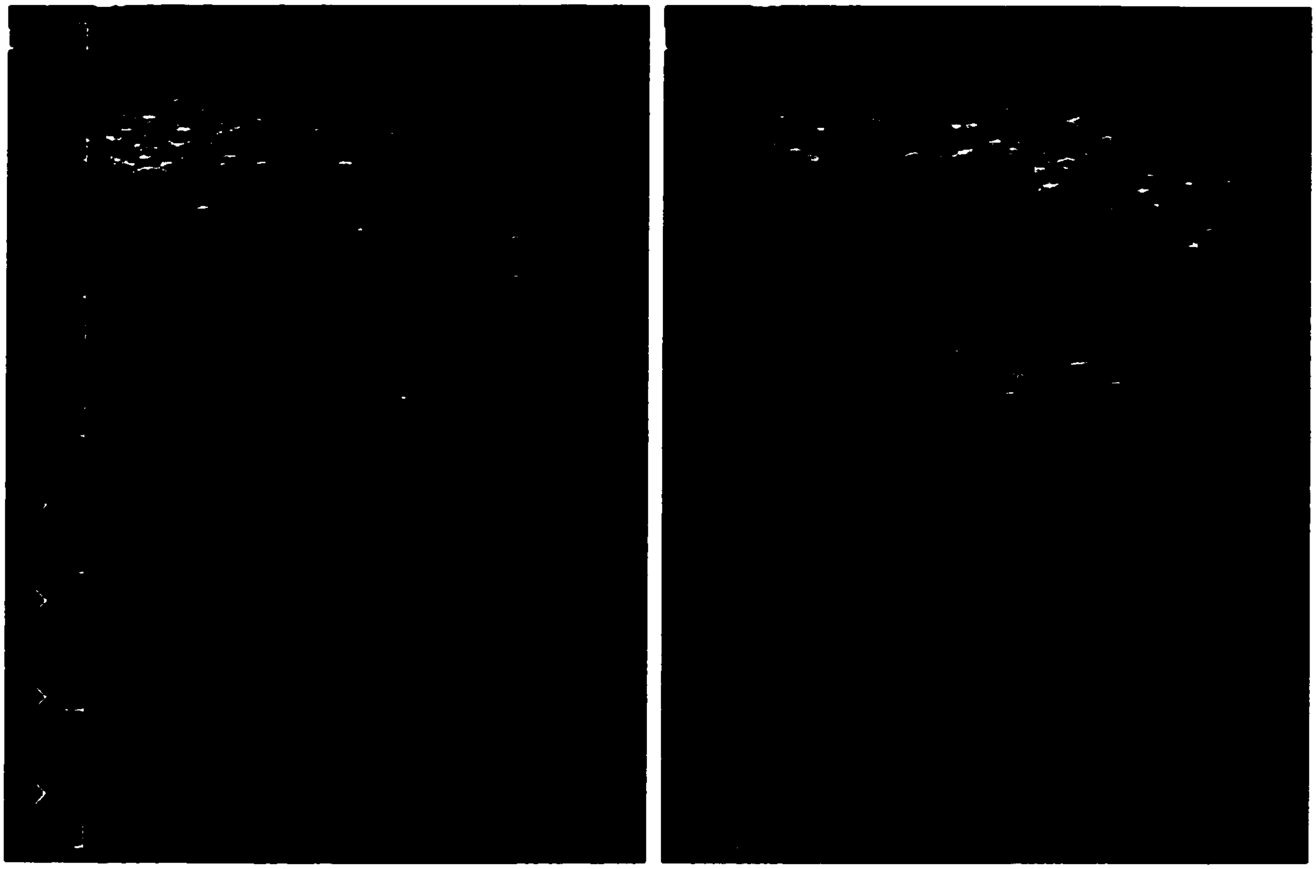

Figure 6.3: *Ultrasonic images of a porcine fourth lumbar transverse process collected at pre-load (L) and max-load (R).*

RESULTS:

Calibration

Load cell and linear potentiometer calibration resulted in linear correlation coefficients of 0.99 and 1.00 respectively (Figure 6.4). The empirical and theoretical minimal detectable voltage intervals for each of the UI and MTS procedures were equal. Table 6.1 displays the minimal detectable voltage intervals converted to the appropriate units as well as the unit conversions of the baseline noise.

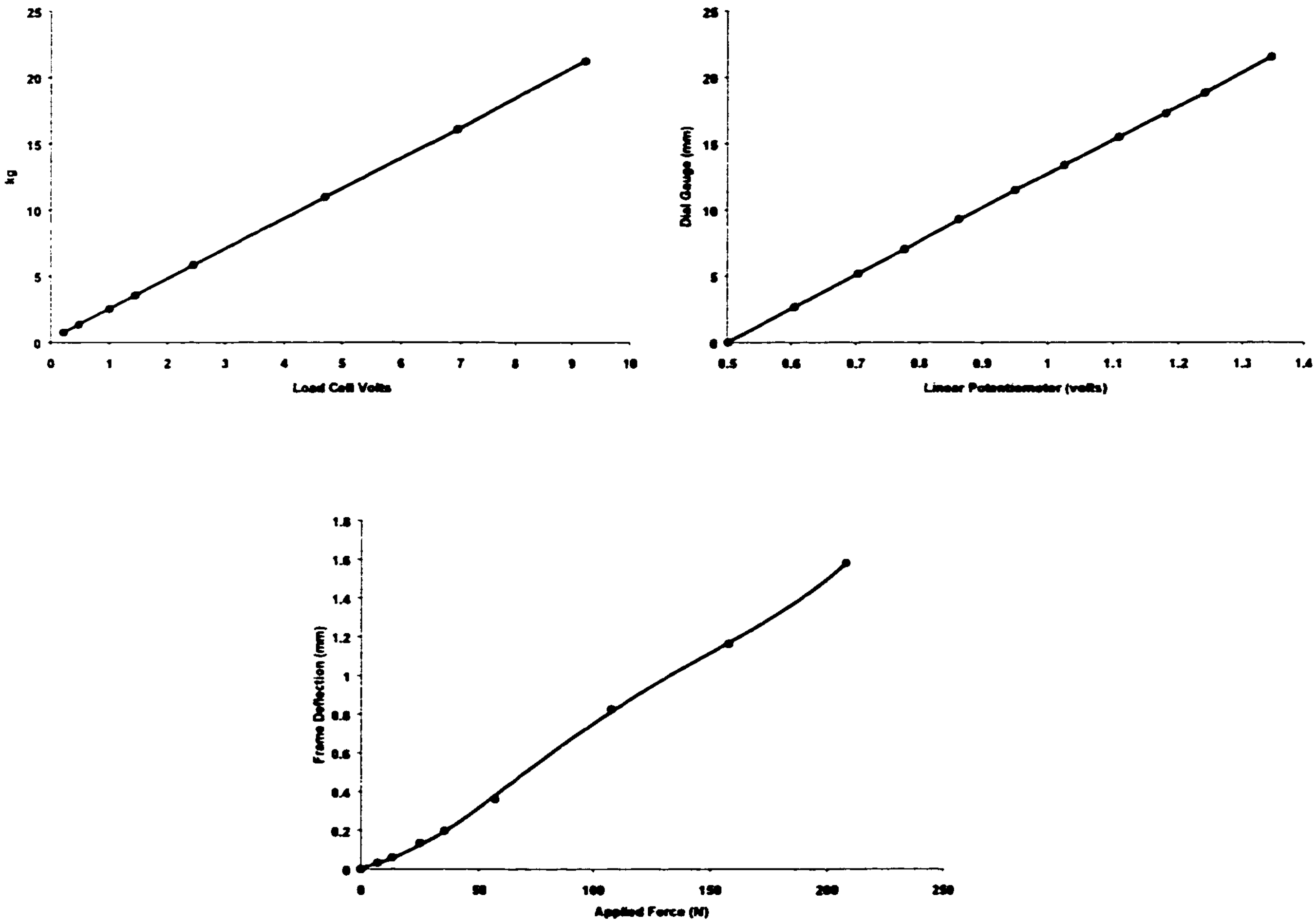

Figure 6.4: *Load cell, linear potentiometer and frame deflection calibration curves.*

	Theoretical Minimal Detectable Voltage Increment (V)	Actual Minimal Detectable Voltage Increment (V)	Actual Minimal Detectable Voltage Increment (Units)	Baseline Noise (standard deviation of signal at rest)
[redacted]	0.0049	0.0049	0.1222 mm	0.1222 mm
[redacted]	0.0049	0.0049	0.0568 N	0.0267 N
[redacted]	0.0003	0.0003	0.0034 mm	0.0098 mm
[redacted]	0.0003	0.0003	0.0172 N	0.0130 N

Table 6.1: *Minimal detectable voltages and baseline noise ratings of UI components.*

	Mean Error % (all points)	Mean Error % (toe region)	Mean Error % (linear region)
[redacted]	1.21%	2.79%	0.45%
[redacted]	1.75%	3.96%	1.24%
[redacted]	6.21%	13.62%	0.81%

Table 6.2: *Accuracy data for UI.*

	Mean StDev of Displ (mm)	Mean StDev of Load (N)	ICC Displacement	ICC Load
[redacted]	0.04	0.30	1.00	0.99
[redacted]	0.01	0.07	1.00	1.00

Table 6.3: *Reliability data for UI.*

UI accuracy

Figure 6.5 displays FD data collected from cyclical indentation of a spring platform. The mean load error between the MTSraw and UIcorr data was 1.21% while the mean displacement error was 1.75%. With respect to stiffness, the mean error between the MTSraw and UIcorr data was 6.21%. Table 6.2 describes error data for different regions of the FD data plots.

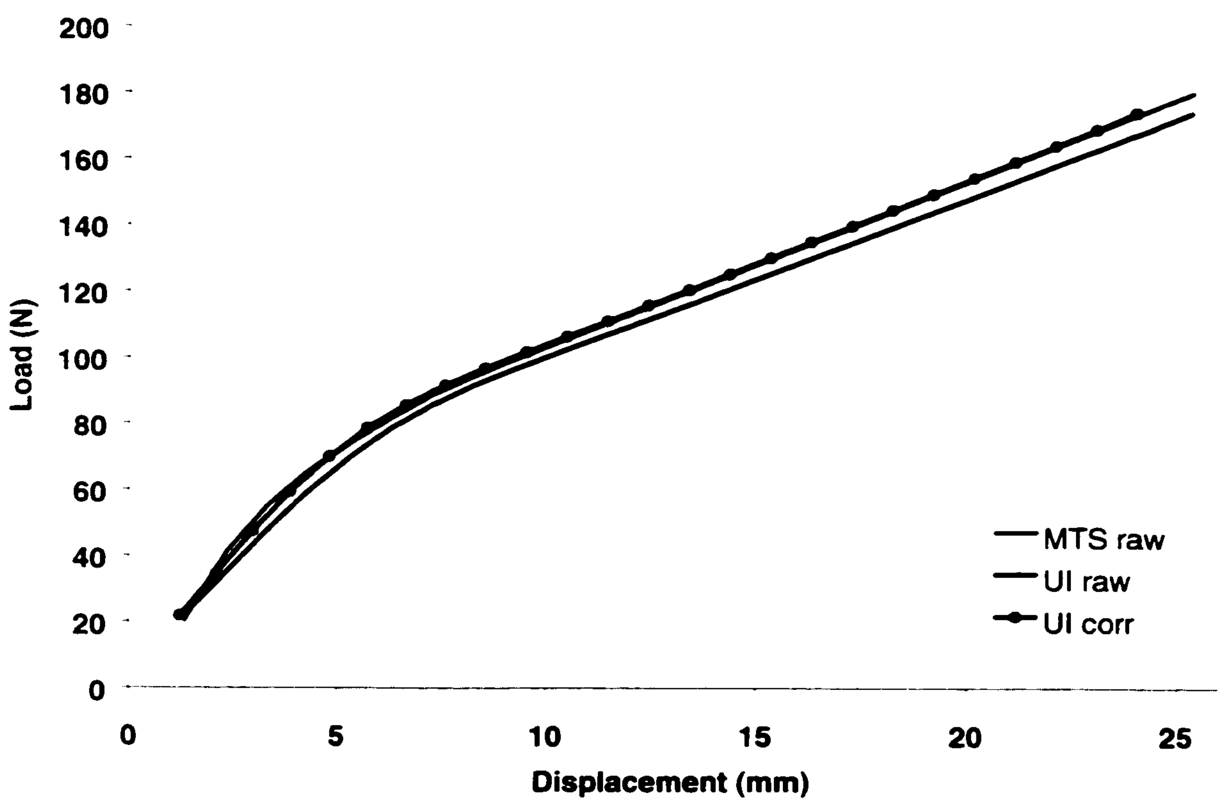

Figure 6.5: *Mean force-displacement plots of data collected from cyclical indentation of a spring platform. Plots represent data collected by a Material Testing System (MTSraw), Ultrasonic Indentation Equipment (UIraw) and UI data corrected for frame deflection (UIcorr).*

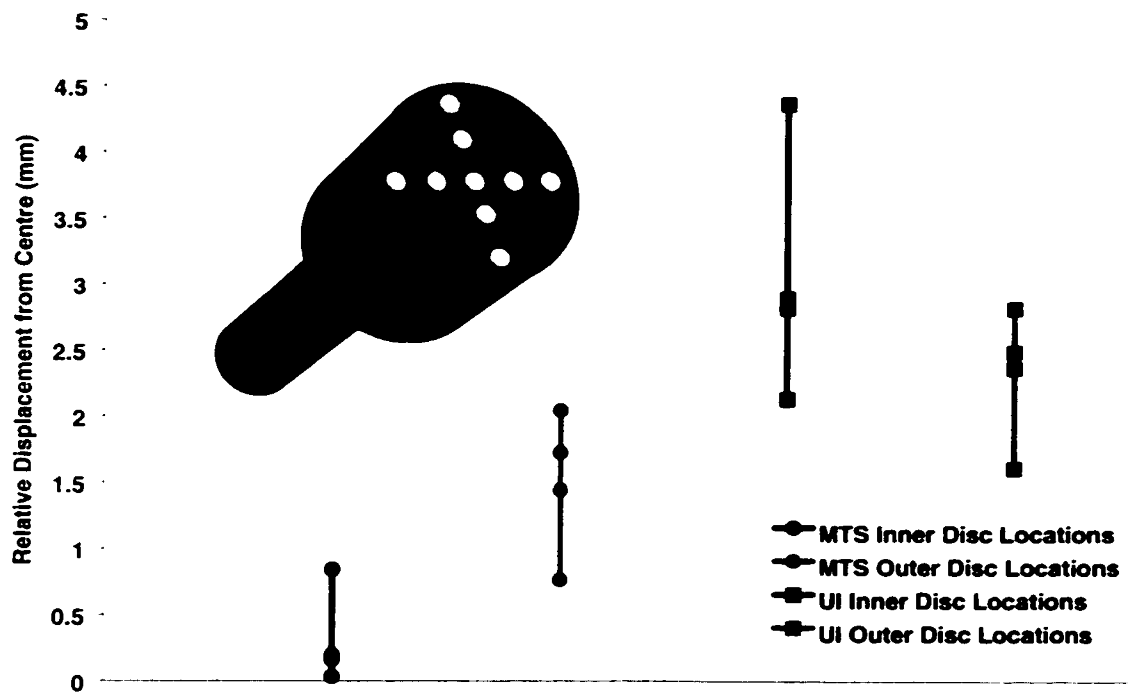

Figure 6.6: *The nine position capscrew disc used to create off-axis loads and the resulting relative displacements of a sprung platform obtained from 90 N indentation loads for each capscrew position. Displacements are normalized to the centre location.*

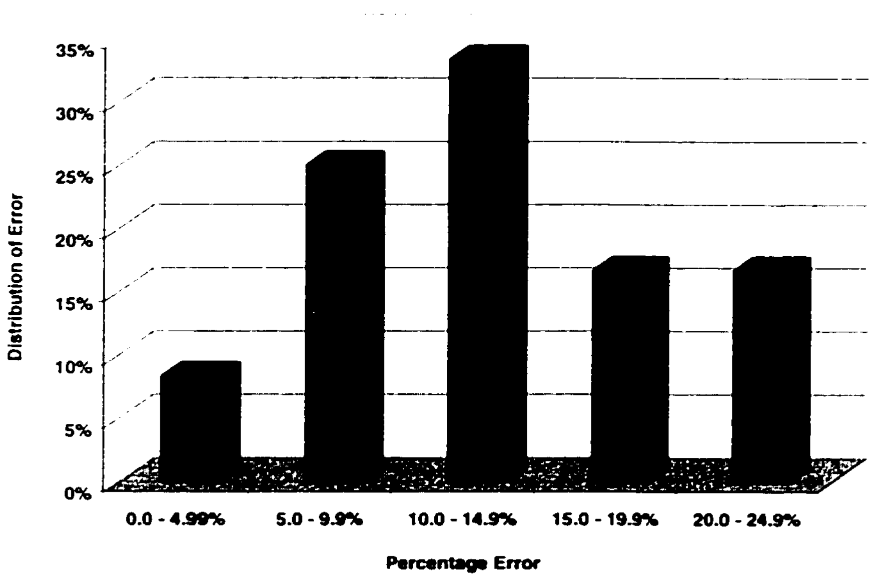

Figure 6.7: *Frequency distribution of error from porcine (cadaveric) indentation.*

A plot of the frame deflection vs. applied indentation load was found to be non-linear (Figure 6.4). Polynomial modeling of this curve (r = 0.99) predicted a maximal frame deflection of 1.58 mm at a 200 N load.

Displacement of the spring platform resulting from the application of 90 N off-axis loads was non-significant between the MTS and UI procedures. As a trend, differences between the systems decreased when the capscrew was positioned anywhere on the outer (7.6 cm) diameter of the loading disc (Figure 6.6).

UI derived values of vertical vertebral displacement from the cadaveric porcine preparation ranged from 1.81 to 2.36 mm. The mean error of ultrasonically derived estimates of vertebral displacement was 13.46% (SD = 0.11 mm, r = 0.84, RMS = 0.31 mm) over a mean criterion displacement (vertical) of 2.17 mm (SD = 0.18). The frequency distribution of this error is displayed in Figure 6.7. Non-vertical vertebral motion resulting from indentation included concurrent medial (1.11 mm, 51%) and superior (0.36 mm, 17%) translations. Rotations about all axes were less than 1°.

UI reliability

Five force-displacement trials were obtained from spring platform indentation by UI and MTS (Figure 6.8). The standard deviation between UI plots was 0.04 mm (ICC = 1.00) and 0.30 N (ICC = .99) on average. The standard deviation between MTS plots was 0.01 mm (ICC = 1.00) and 0.07 N (ICC = 1.00) on average.

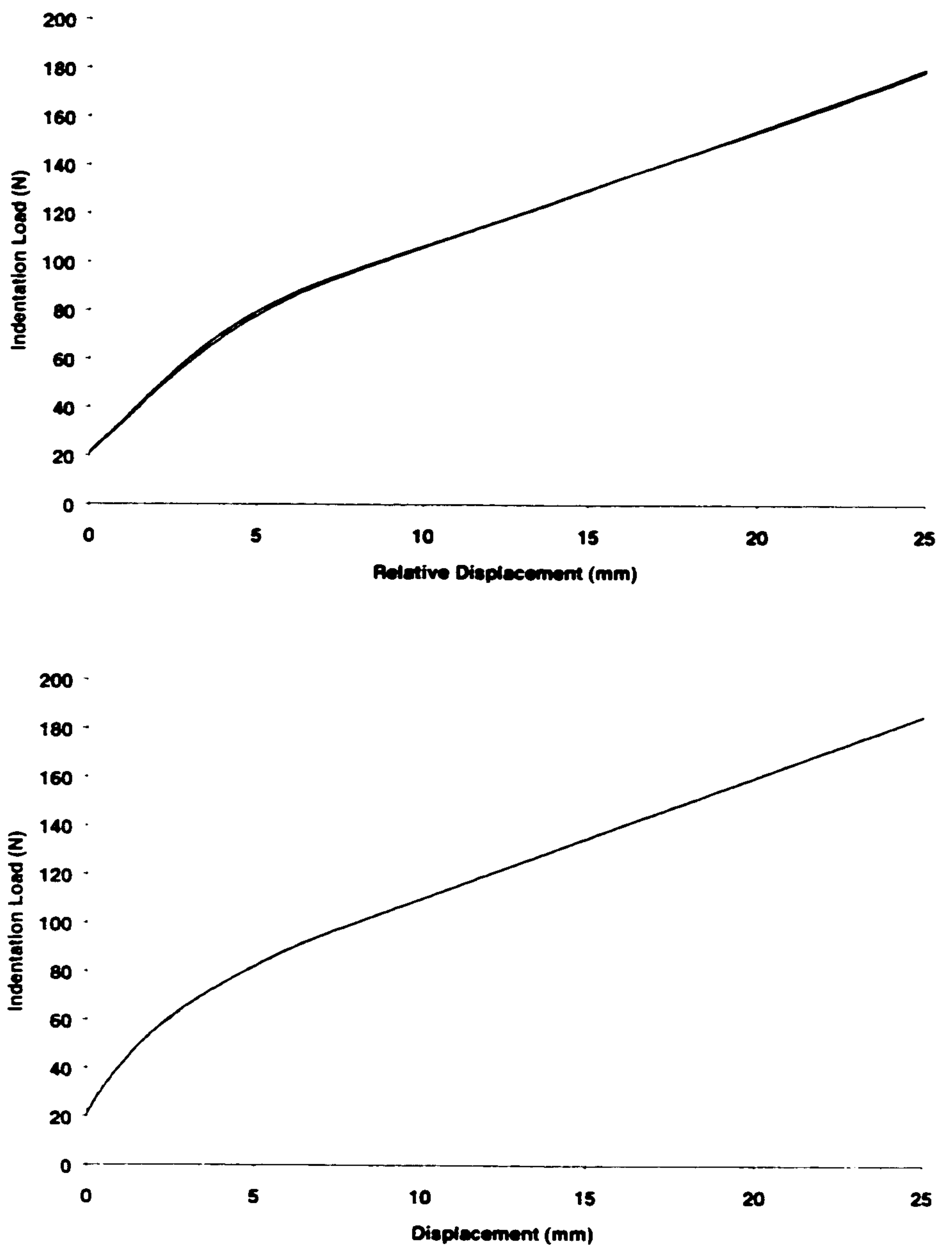

Figure 6.8: *Force-displacement curves obtained from indentation of the spring platform by UI equipment (top, 5 trials displayed) and MTS equipment (bottom, 5 trials displayed).*

DISCUSSION:

This study quantified the accuracy and reliability of spinal FD measures obtained by a novel, non-invasive procedure (ultrasonic indentation, UI) that is capable of real-time ultrasonic imaging during load-controlled external indentation. Accuracy and reliability of UI were quantified from a number of bench-top and *in vivo* settings designed to simulate operational conditions.

The use of ultrasonic imaging during indentation is a unique feature of UI that enables it to distinguish, non-invasively, the contributions of soft and osseous tissues with respect to overall spinal FD properties. Displacements quantified by UI are the result of pre-defined loads applied at a specific rate and angle to a specific anatomical target identified by ultrasonic imaging prior to indentation. These features are thought to be important in FD assessment[50-52] and have not been previously combined[3,53-70]. The general inability of non-invasive techniques to quantify FD properties of a specific vertebra from a pre-defined load may be a contributing factor to the inability of investigators to agree on the significance of the relation between spinal motion, pain and pathology. Given the cost, prevalence and morbidity associated with spinal disorders[71], the availability of investigative techniques, which possess these features, may be significant.

UI Accuracy

From the results of this study, the accuracy of UI is comparable or superior to other devices with respect to linear regions of FD curves[1,60,61]. It is difficult to compare the performance of UI in assessing non-linear FD curve regions, as the accuracy of related devices in this capacity is largely unknown. Possible explanations for the reduced accuracy of UI in non-linear FD regions include: 1] an insufficient number of data collection points obtained in the non-linear FD region, 2] the assumption of MTS rigidity was incorrect and 3] the presence of error in non-linear modeling techniques. Ultimately, the overall impact of this error is dependent on the magnitude of non-linearity in the curve region of interest.

With respect to off-axis loads and their impact on accuracy, the trends observed in this study suggest that point loads that occur outside of the load cell diameter are most undesirable in UI or criterion procedures — in spite of the stabilization systems present. To decrease the effect of this error on an indentation system's output, protocols should be adopted to reduce changes in loading profiles between indentations.

It must be stated that the accuracy of the measurements obtained in this study is a function of the A/D hardware used to collect voltage signals relating to displacement and load. Whereas the resolution of these signals cannot exceed the theoretical minimal detectable voltage increment (Table 6.1), this resolution cannot be assumed to be the functional resolution of the system. Should the baseline noise of the signal exceed the A/D resolution, the baseline noise must be considered to be the resolution of that signal.

The *in vivo* accuracy of UI with respect to quantifying anterioposterior displacements (0.31mm RMS, 0.11mm SD) was comparable to those found from invasive measures such as radiography and bone pin linkages (RMS range = 0.14 - 2.0 mm, SD range = 0.25 - 0.80 mm)[39,72-76]. Previously, Kawchuk et al[49] have quantified the *in vivo* error of UI as less than

13% at a 60 mm imaging depth in a bovine preparation. This preparation was limited in that it was unable, anatomically, to represent the potential motions that a spinal segment may undergo during indentation loading. To approximate *in vivo* conditions for improved UI validation testing, a cadaveric porcine spine was employed in this investigation as this preparation has been shown to have mechanical similarities to human posterior elements[77]. The 13.46% error described in this study for estimating anterioposterior displacements at a 60 mm imaging depth are very similar to the percentage error obtained from the previous study employing a bovine preparation. The similarity of these results suggests that the magnitudes of rotations and non-vertical translations (out-of-plane motions) are minimal in this study and do not contribute to error[78,79].

In the present study, ultrasonic imaging was restricted to a depth of 60 mm due to the paraspinal tissue thickness of mature porcine specimens. As imaging resolution increases with reduced imaging depths, animals with tissue thickness of less than 60 mm would have reduced UI error — a result observed in prior validation testing[49]. Immature animals, which may have a tissue thickness of 30 mm or less, could not be used in this study as the cross-sectional shape of the trunk is more cylindrical than in adults. This shape permits the indenter to migrate from the initial indentation site and is especially apparent when ultrasonic coupling agents are used. These observations illustrate potential limitations of UI which include the 1] shape of the indentation surface with respect to the indentation site and 2] the depth of the osseous target. Current investigations are underway to increase the accuracy of UI in assessing vertebral displacements in human subjects.

Given that few *in vivo* techniques exist currently that can quantify segmental spinal mechanics under applied loads, the accuracy necessary for UI to quantify clinically significant anterioposterior motions of the spine is unclear. Speculation in this matter is best made with data from Kaigle et al[38] who directly quantified anterioposterior displacements in symptomatic human subjects using a spatial linkage system attached by bone pins to the lumbar vertebrae. In that study, anterioposterior translations between vertebrae in symptomatics vs. controls were found to differ by 1.5 mm on average. This magnitude of change is well outside the magnitude of UI error. Given these data, UI would be capable of detecting such changes between these two groups.

UI Reliability

The reliability of UI was found to be almost equal to that of the criterion system (MTS) and comparable or superior to other published devices[56,60,61]. The small difference in reliability between the MTS and UI procedures may be the result of lower baseline noise in the MTS equipment which has hydraulic actuation, not electromechanical, and the application of smoothing algorithms used in UI data analysis to reduce electromagnetic noise.

CONCLUSION:

Ultrasonic indentation is a unique procedure that is capable of assessing, non-invasively, FD properties of spinal tissues including vertebral displacement in the indentation plane. The data collected from this study demonstrate that the bench-top accuracy and reliability of UI are comparable, if not superior to, related procedures while the *in vivo* performance of UI would permit it to identify clinically relevant alterations in spinal mechanics as found by others. These results suggest that UI may be a useful tool toward quantifying spinal FD properties *in vivo*.

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Chapter 7

Sources of variation in spinal indentation testing: indentation site relocation, intra-abdominal pressure, subject movement, muscular response, and stiffness estimation

INTRODUCTION:

Indentation is a non-invasive procedure used to assess the force-displacement (FD) properties of spinal tissues. These properties are thought by many to have clinical significance — a hypothesis supported in part by the understanding these properties have brought to the diagnosis and treatment of other musculoskeletal tissues[1-9]. At the present time, the clinical significance of FD properties arising from spinal indentation remains questionable as there are considerably more studies outlining its variability than its relevance. These sources of variability include time-dependency of spinal tissues, body mass, and respiratory status. Unfortunately, this body of literature is by no means complete. Upon review, a number of uncharacterized sources of error exist which may have a negative impact on the performance of FD measures in clinical applications.

Therefore, the purpose of this study was to identify and quantify where possible, previously unidentified or incompletely characterized sources of variation with respect to spinal indentation and if appropriate, attempt to reduce or eliminate those sources. The variables investigated included subject-based variables (paraspinal muscle activity in response to indentation, changes in intra-abdominal pressure, subject movement between indentations) and process-based variables (indentation site relocation, stiffness estimation from FD data).

METHODS:

This investigation was made up of four distinct experiments:

1. Twelve asymptomatic subjects were indented with concurrent electromyography during conditions of rest, held inspiration, increased intra-abdominal pressure and lumbar extension.
2. Changes in the recumbent position of twelve subjects were measured while performing a series of movements in restrained and unrestrained conditions.
3. Ten clinicians attempted to locate, and relocate, a subcutaneous anatomical landmark through visualization/palpation and ultrasonic imaging.
4. The performance of three methods of FD curve modeling was compared with respect to stiffness estimation of FD data.

Subjects

All subjects participating in this study were asymptomatic with respect to spinal pain and were free of any conditions that may place them at risk. Each subject provided written consent having read a description of the study that was approved by the Office of Medical Bioethics of the University of Calgary. Sample sizes used in each of the following protocols were calculated in advance of testing.

Experiment #1: Muscular response to indentation / Changes in intra-abdominal pressure

Each subject in this experiment (n = 12) was placed in a prone position on a clinical treatment table while their lumbar spine was exposed and prepared for surface electrode electromyography (EMG) using an established protocol[10]. A single pair of bipolar, silver/silver chloride, adhesive electrodes were placed 5 cm apart on the longitudinal axis of the right paravertebral muscle spanning the third lumbar segment. Pre-amplification of EMG signals occurred approximately 10 cm from the electrodes (2500x). While prone, each subject underwent indentation at the site located immediately between the paravertebral electrodes. Indentation was provided by a flat, rigid, 3 x 3 cm surface mounted serially to an electromechanical actuator fitted with load and displacement transducers (Figure 7.1). This equipment has been described previously[11]. During indentation, applied load, actuator displacement and EMG signals were collected at a 1kHz sampling rate by analog-to-digital hardware that was additionally used to control actuator movement through a separate hardware unit.

Prior to indentation, subjects were instructed to exhale and then hold their breath until the indention event was complete. Indentation was initiated approximately 5 cm above the surface of the back and proceeded vertically downward at a rate of 2.5 mm/s until a load of 1 N was attained at which time indentation position was held for 5 s. Loading was then allowed to proceed at the same rate to a maximal load of 30 N in the first trial and 50 N on five subsequent trials. At maximal load, indentation was paused for 5 seconds before indentation reversal. These six trials were labeled as resting indentations. Electronic and mechanical safety mechanisms permitted the subject and/or operator to initiate immediate removal of indentation at any time.

Following these six indentations, each subject was indented on three additional occasions while performing the following three activities: 1] held full inhalation, 2] maximal voluntary increase in abdominal pressure (Valsalva maneuver) and 3] voluntary contraction of the extensors of lumbar spine (chest raised off the treatment table). These activities were labeled as activity indentations. All subjects were allowed to practice these activities prior to indentation. The total number of indentation trials per subject was nine (six resting, three activity) resulting in 108 indentations.

In all indentation trials, stiffness was determined by modeling the FD data with a fifth order polynomial, differentiating the resulting equation and determining the stiffness at the point of displacement corresponding to ~75% of the applied load (35N). All load and displacement signals were re-sampled and filtered based on the frequency content of each signal[12] while electromyographic signals were rectified then low-pass filtered (Butterworth, fourth-order, bi-directional, low-pass at 60Hz) and the root mean square (RMS) calculated (Figure 7.2). For each subject, differences in EMG activity and stiffness between pre-indentation, pre-load and max-load measures were assessed non-parametrically using the Kruskal-Wallis test at a significance level of 0.05. Activities during indentation of any one subject were considered to be significantly different from the resting condition if the max-load EMG or max-load stiffness values were two standard deviations less than, or greater than, the respective mean of the max-load data from the same subject's six resting trials.

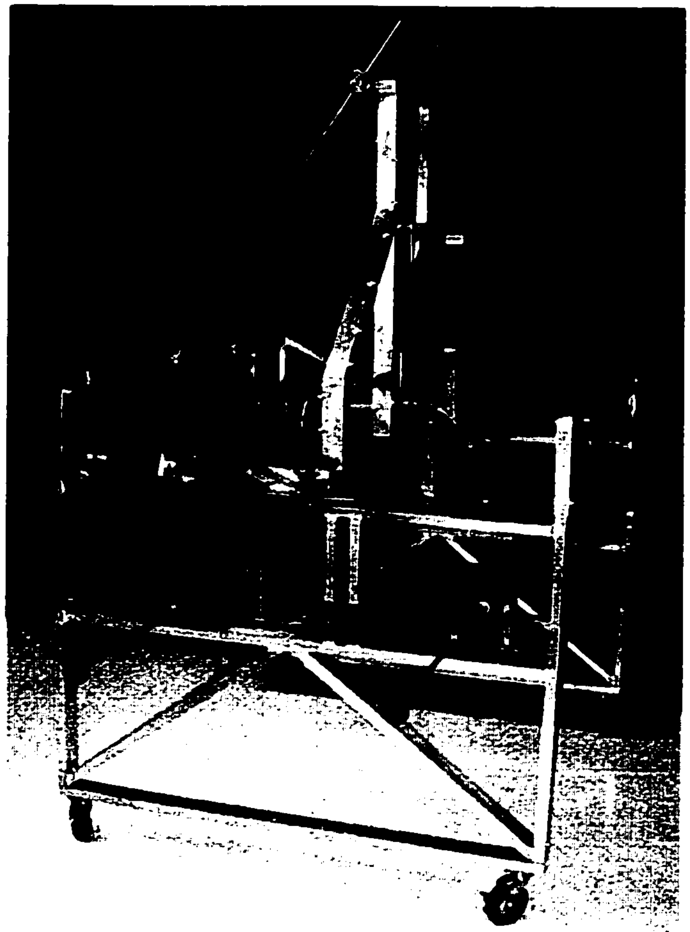

Figure 7.1: *Photograph of ultrasonic indentation equipment with subject restraint system.*

Experiment #2: Subject Movement

Subjects in this study (n = 12) were each asked to lay prone on a clinical treatment table and perform a series of pre-defined movements designed to mimic behaviors observed to occur in previous pilot studies. These movements were bilateral 1] head rotation, 2] lateral flexion of the spine and 3] lateral displacement of the hips. Each movement type took place over a period of time not greater than 30 s. During all movements, a stationary optical camera system (Northern Digital, Canada) tracked the position of a reflective marker (10 Hz) mounted with double-sided adhesive tape to the midline of the lumbar spine (Traxtal Technologies, U.S.A.). These movements were recorded a second time after the subject was restrained. Restraint was provided by a system of four extendable horizontal rods (2 per side) mounted on the indentation equipment (Figure 7.1). Each rod was capable of vertical and horizontal movement to allow positioning against the sides of the prone subject. In this protocol, each subject was restrained bilaterally at the greater trochanters and axillae. For each of the three movement types, the change in position of the marker and the maximal excursion of the marker were determined in the cranio-caudal and medial-lateral planes. Significance of these changes was determined non-parametrically by the Wilcoxon Signed Rank Test at a level of 0.05.

Experiment #3: Indentation site location and re-location

An eviscerated porcine lumbar spine with intact posterior tissues was mounted horizontally by its terminal vertebrae between two vertical plates attached to a rigid platform. After mounting, the indentation equipment was placed over the platform. For this experiment, indentation equipment included an ultrasonic transducer mounted serially to the actuator to visualize sub-cutaneous echogenic anatomy before and during indentation[12]. The restraint system described in the previous experiment was employed to secure the external framework of the indentation equipment against the platform supporting the specimen. Although restrained in this manner, the design of the indentation equipment permitted the indenter to be positioned in the horizontal plane above the specimen.

Following specimen preparation, the indenter/ultrasonic transducer was positioned 5 cm above the specimen. Ten clinicians were then asked to use visualization and/or palpation to position the indenter directly above the mid-length position of the transverse process of the fourth left lumbar vertebrae. Each clinician was allowed to mark the surface of the specimen with an adhesive sticker then re-position the indenter four additional times. Acoustic coupling gel was then placed on the specimen, the sticker removed and the indenter lowered until the ultrasonic transducer contacted the specimen at 1 N. Each clinician was then asked to use the resulting real-time ultrasonic images to position the indenter 5 additional times to the same anatomical landmark. After each positioning attempt, the indenter was returned to neutral position. Following the testing of all clinicians, the specimen was dissected and the mid-substance of the L4 transverse process located by visualization (anatomical target). In all positioning attempts, the location of the indenter was determined via optical tracking (10 Hz) of a reflective marker mounted on the indenter itself.

Experiment #4: Stiffness estimation

A reference curve was plotted from a single human indentation trial obtained from experiment #1 (50N max-load, 81 FD data pairs). The stiffness of the reference curve was found by differentiating one of three techniques employed to approximate the reference curve: 1] generalized cross validation (GCV), 2] polynomial modeling and 3] linear modeling. Generalized cross validation was performed using third and fifth order splines and the mean squared error values (MSE) with respect to original data calculated for each. Polynomial functions (third to ninth order inclusive) were employed and the MSE calculated for each function. For linear modeling, lines of best fit were created by a least squares method that ranged in length from 3 point to 81 point intervals (odd increments only). Each interval was moved between the boundaries of the reference curve beginning at point 1/81 and ending at point 81/81. For any one interval at any point on the reference curve, the slope (stiffness) was determined, assigned to the midpoint of the interval and the MSE calculated. All MSE values generated from any one interval were then averaged. For the comparison of stiffness estimates between techniques, the approximation with the least MSE was chosen.

RESULTS:

Subjects

The mean age of the twelve subjects who underwent indentation was 29 years (SD 4.33) with a mean weight of 71.3 kg (SD 15.8) and height of 173.6 cm (SD 7.21). The mean body mass index (BMI) for this cohort was 23.5 kg/m^2 (SD 3.77).

Experiment #1: Muscular response to indentation and intra-abdominal pressure

For all resting trials, changes in the EMG activity between pre-indentation, pre-load or max-load were insignificant for nine of twelve subjects (Table 7.1). Of the three subjects demonstrating significant changes, one reported a mild discomfort near the end of the indentation process. Additionally, three of the nine subjects demonstrated singularly high EMG activity in the first of six resting trials between pre-indentation and pre-load. For all indentation trials with concurrent activity (held inspiration, Valsalva maneuver or lumbar extension), Table 7.1 summarizes the number of subjects who demonstrated significant increases in EMG and/or stiffness.

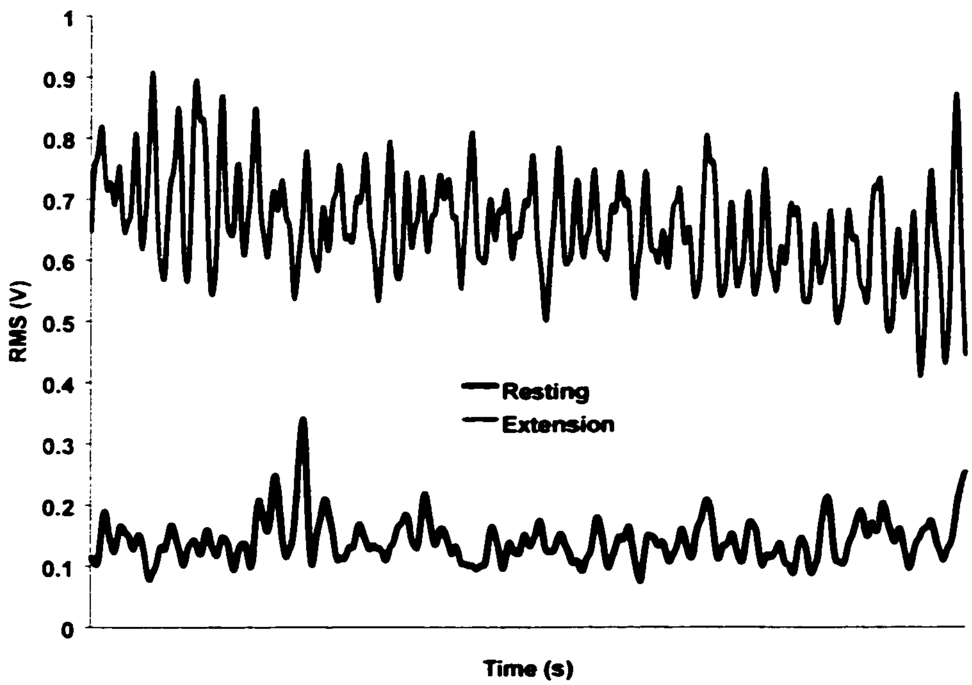

Figure 7.2: *Representative EMG data (fully rectified) from a single subject in resting and extension conditions.*

	No Change Stiffness No Change EMG	Increase Stiffness Increase EMG	Increase Stiffness No Change EMG	No Change Stiffness Increase EMG
[redacted]	9	1	2	0
[redacted]	3	3	5	1
[redacted]	1	11	0	0

Table 7.1: *Numbers of subjects grouped by paraspinal muscle activity and indentation stiffness stratified by concurrent indentation activity.*

Experiment #2: Subject Movement

In all motions other than head rotation (i.e. lateral spine flexion, lateral hip displacement), there was a significant difference in marker excursion and/or marker start/finish position between the unrestrained and restrained conditions for the cranio-caudal and medial-lateral planes. ($p = 0.01$). On average, the change in the start/finish position of the marker system was 7.13 (SE 1.15) mm when unrestrained and 3.65 (SE 0.79) mm when restrained. The average maximal excursion of the marker system was 54.66 (SE 13.73) mm unrestrained and 22.02 (SE 2.26) mm restrained.

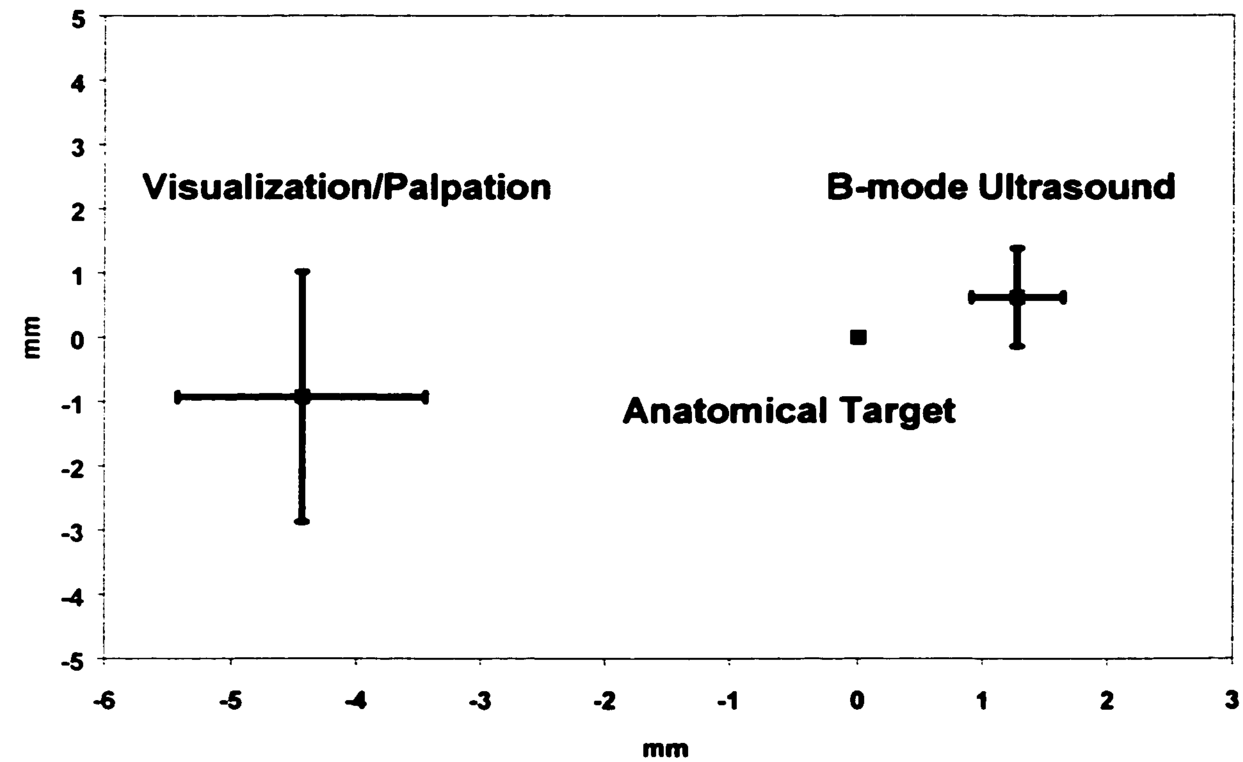

Figure 7.3: *Resultant mean indenter position with standard error bars of two methods (visualization/palpation, ultrasonic visualization) used by 10 clinicians to localize a sub-cutaneous anatomical landmark.*

Experiment #3: Indentation site location and re-location

Inter-clinician variability for each localization technique is displayed in Figure 7.3 where the average of five localization attempts per clinician is displayed. The horizontal coordinate corresponds to the cranial-caudal axis and the vertical to the medial-lateral axis. Localization by visualization/palpation was on average 4.53 mm from the anatomical target (SE x = 0.99, y = 1.95) while ultrasonic localization averaged 1.42 mm from the anatomical target (SE x = 0.37, y = 0.76). The standard error for localization of the anatomical target was 0.03 mm (x) and 0.02 mm (y). The standard error for intra-clinician localization was 0.33 mm for visualization/palpation and 0.55 mm for ultrasonic localization.

Experiment #4: Stiffness estimation

For all three GCV approximations of the reference curve, the MSE values were considered to be equal (<0.0000 N), therefore, to select the result with the least MSE, the 5th order GCV splinic approximation was chosen as Vint and Hinrichs have suggested that quintic splines offer more accurate derivatives[13]. The minimal MSE of all polynomial approximations was found to occur in the 5th order equation (0.02 N). For linear modeling, an interval length of 3 points resulted in the minimal MSE (0.0001 N). The MSE of interval length 13 was found to be most similar to the MSE of the fifth order polynomial. This 13 point interval generated 69 stiffness measures from data point 7 through 75. The stiffness estimated from each method is shown in Figure 7.4 in addition to the range of stiffness values generated by each linear increment for each displacement point.

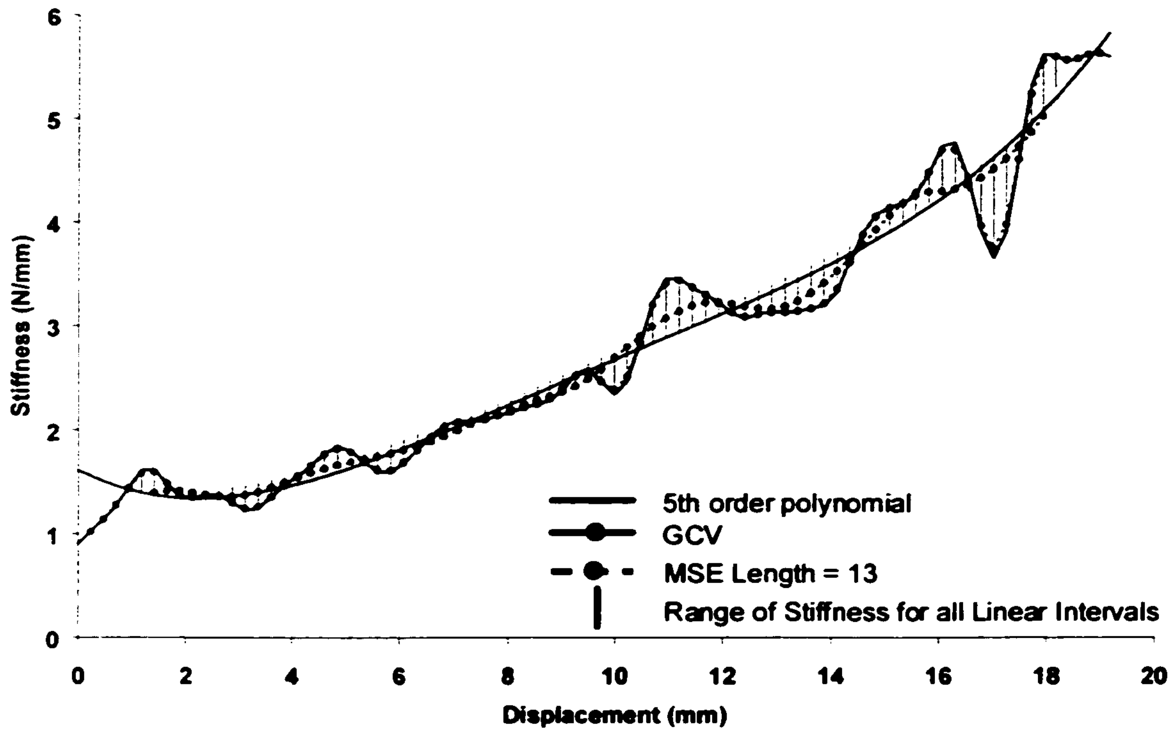

Figure 7.4: *Stiffness estimates resulting from four different curve modeling techniques. Also displayed are the possible stiffness values generated by linear approximations ranging from increments of 3 to 81 data points.*

DISCUSSION:

Variability in any form of measurement is unavoidable, however, whether that variability influences a measurement is ultimately dependent on the magnitude of the error with respect to the needs of the investigator. Should that variation be significant, three courses of action can be entertained: elimination, reduction, or monitoring. While elimination is most desirable, there are some variables that can be neither eliminated nor reduced — only quantified so as to determine their impact (i.e. weather). In any case, these three courses of action cannot be acted upon unless the source of variation has been identified and characterized.

With respect to spinal indentation, many authors have identified numerous sources of variation that can be categorized as subject-based and process-based variables. Subject-based variables include muscle contraction during indentation[14-16], subject respiration[17-19], time-dependency of spinal tissues [20-24] and gross location of indentation[22,25-27]. Process-based variables include indentation angle[22,26], equipment design[28] and the method of subject support during indentation[29]. While these studies have added considerable knowledge to the field of spinal indentation, many of these variables have not been characterized completely nor have all sources of error been identified. As investigators have found differences in indentation stiffness of less than 1 N/mm between non-pain subjects and less than 1.5 N/mm in symptomatics[30], variability in spinal indentation is poorly accommodated. Therefore, attention to identification and control of sources of variability is of importance if measures derived from spinal indentation are to be considered clinically relevant.

Muscular response to indentation

For the majority of subjects in this protocol, no detectable increase in paravertebral muscle activity was observed throughout the indentation process. This observation suggests that in these subjects, indentation itself does not generate alterations in muscle activity. This observation is an important one as other investigators have suggested that the process of indentation may create contraction of paraspinal muscles[31]. There were, however, a number of exceptions observed in this experiment that deserve discussion.

Three subjects were observed to have singularly high levels of muscular activity between pre-indentation and pre-load of their first of six indentation trials. In these cases, the probability that such a response was reflexive in nature is low as these responses were extinguished after only one trial of slowly applied load. More likely, the immediate loss of this response suggests a non-reflexive mechanism. As subjects were unable to tell when indentation contact would occur, EMG activity prior to indentation may be the result of "indentation anxiety" and/or bracing against an unknown load applied in an unknown manner. Should the patient find the experience acceptable, this behaviour may not exist in subsequent trials. This speculation suggests that there is a potential training effect of indentation and that factors other than viscoelasticity may alter FD properties over the course of time. As a result, the authors recommend exclusion of initial indentation trials from data analysis.

In addition to this transient response, three other subjects demonstrated significant alterations in EMG activity throughout the course of all 6 resting indentations. This observation is consistent with those of Lee et al. who have observed changes in baseline EMG activity between indentation trials of subjects performing extension contractions[15]. These observations contrast the pilot results of Herzog et al. (n = 2) who suggested that slow applications of force in the thoracic spine do not elicit muscle activation[32]. While the design of the present study cannot provide an explanation for these observations, several possibilities exist including: 1] the lack of an indentation training effect, 2] an attenuated training effect, or 3] a reflex activity resulting from tissue stretching or pain. Therefore, the authors of this study conclude that spinal indentation performed at 2.5 mm/s is capable of eliciting muscle activation in some subjects. As a result, interpretation of indentation data must be made cautiously as the process itself may confound the FD data it is attempting to collect.

Lumbar Extension, Respiration and Intra-abdominal pressure

To ensure that the equipment used in this experiment was capable of quantifying increases in spinal stiffness resulting from various perturbations, indentation with concurrent lumbar extension was performed as stiffness is known to increase under these conditions[14-16]. While the equipment successfully detected stiffness increases in 11/12 subjects during lumbar extension, it is possible that muscle activity and spinal stiffness of sufficiently low magnitudes were not detected.

As respiration is known to effect the movement of the human torso[33-36], it can be hypothesized that respiration may influence spinal stiffness. Indeed, many have noted its effect[17-19]. However, results from this experiment suggest that although this effect exists, it was a factor in less than half of subjects tested — a finding similar to those of other investigators[17,18]. Given the results of this study, it is most probable that held respiration could be achieved through a variety of subject-specific strategies that may or may not result paraspinal muscle activity and/or spinal stiffness.

While the stiffness measures obtained from the majority of subjects were not affected by held inspiration, eight of twelve subjects displayed increased spinal stiffness from a Valsalva Maneuver. This observation is consistent with the observations of McGill et al.[37] and

Cholewicki et al.[38] who demonstrated that increases in intra-abdominal pressure stiffen the spine. However, this increase in stiffness is primarily due to contraction of muscles other than the lumbar erector spinae[39]. This observation provides a potential explanation for the lack of EMG activity observed to occur during Valsalva Maneuvers in the presence of increased spinal stiffness. Although the argument can be made that the Valsalva maneuver performed in this study was voluntary and therefore would be of little concern during typical indentation protocols, it is possible that increases in abdominal pressure may occur involuntarily in response to pain, as a strategy for the requisite breath holding employed in indentation studies or from indentation anxiety — a condition observed in this study. Given the number of subjects whose stiffness increased during Valsalva maneuvers, changes in intra-abdominal pressure may create a significant potential to alter indentation results. As a result, the authors recommend that investigators develop indentation protocols which make subjects equally aware that alterations in intra-abdominal pressure during indentation are to be avoided as much as alterations in respiration.

Subject Movement

As movement artifacts are a common source of variability in human measurement[40-42], it is likely that these artifacts affect indentation data as well. Should the site of indentation change between trials via subject movement, quantification of FD properties from a new anatomic site may result in an incorrect observation. To study this question, a restraint system was designed to reduce subject movement, but at the same time, not affect the natural response of the spine to indentation. Therefore, belts or détentes used directly on the spine or pelvis were avoided as it has been shown that lumbo-pelvic movements during indentation are substantial[43]. Assuming that the marker system placed on the lumbar spine correctly represented gross trunk mobility, the results of this study demonstrate that the system of restraint employed in this experiment significantly reduced the magnitude of two common movements observed to occur during indentation testing. While restraint did not decrease these variables to zero, the restraint system reduced the change in subject position, reduced subject movement, reduced the indenter/subject "force loop" and presumably increased the awareness of the subject that movement during indentation was undesirable.

Indentation site location and re-location

Warner et al.[24] have observed that hysteresis patterns of spinal biomechanical data changed shape when subjects returned for recumbent testing after standing briefly. While this observation may have been the result of changes in tissue properties caused by alterations in posture and movement, there is no way to ensure that such a difference was not produced by testing two different anatomical areas on two different occasions. Similarly, should therapeutic interventions be given between trials of spinal indentation, the presence, or lack of, pre/post differences in spinal FD properties may in part result from inaccurate relocation of the indentation site. Results from this study which demonstrate relatively large error when non-ultrasonic methods were used for indentation site localization support such a statement. Although related studies have been performed which demonstrate the accuracy of injection site determination[44,45] the authors are not aware of prior studies which have determined the accuracy of visualization/palpation or indentation positioning against an anatomical landmark located by a criterion system other than palpation. It should be noted that the accuracy of each localization technique (visualization/palpation and ultrasonic imaging) was in part determined by the accuracy in which the anatomical target was identified (visually).

Should comparison of FD properties be confounded by errors from indentation location and re-location, the use of techniques such as ultrasonic localization would be advantageous in decreasing variability of this type. Improvements in the performance of ultrasonically determined indentation site localization and re-localization observed in this study may be possible if clinicians would have been allowed to utilize visualization/palpation concurrently with ultrasonic methods and/or were provided with training in ultrasonic image interpretation. Based on the finding of this study, the authors suggest that ultrasonic-relocation of indentation sites is necessary to ensure that indentation testing occurs with respect to the same sub-surface targets on multiple-occasions.

Stiffness estimation

In the assessment of FD properties, overall displacement may not be the primary outcome of interest. Rather, determination of tissue stiffness, or the slope of the FD curve, may be more appropriate based on the analysis that is required. Unfortunately, FD data from biological systems, including the spine, are typically curvi-linear, making assessment of stiffness difficult[46]. The most accurate method of stiffness determination of curvilinear data is to determine the slope of tangent lines fit to small sections of the curve — a result confirmed by this study. While this technique is very sensitive to small changes in stiffness, it is very sensitive to noise and over-sampled data. To combat this behaviour, larger linear intervals are often used to determine a single stiffness value for a greater range of data points. The use of larger intervals has three positive effects: 1] smoothing, as one stiffness value now represents a larger area of the curve, 2] ease of interpretation, as fewer points are generated and 3] a reduction in calculation time. However, use of large linear intervals may be a source of variation when these techniques are used to model non-linear FD data [47,48]. From the results of this study, use of increasing interval sizes increases the MSE of the linear approximation substantially. Additionally, this error may be increased as the size of the linear increment used in stiffness analysis is typically determined by arbitrary means.

In practice, the choice of which method of modeling FD behaviour is employed is partly dependent on the accuracy, smoothing and other needs required by the investigation. With respect to smoothing, methods such as GCV provide a minimal effect[49]. Polynomials can have a much greater smoothing effect, although they are prone to error in estimating the stiffness of the terminal ends of FD plots[50]. Polynomials may be additionally advantageous as they can approximate non-linear trends as well as determine stiffness along any point on the curve while maintaining a low MSE. In contrast, the use of linear methods potentially add significant error to stiffness data when the FD data is non-linear and the linear interval is large. As a result, the authors suggest that use of linear methods in estimating stiffness from FD data be used only when linear approximations of low MSE can be used and/or other alternatives are not appropriate.

CONCLUSION:

This series of experiments has described a number of previously uncharacterized sources of variation with respect to spinal indentation including: site location and relocation, intra-abdominal pressure, subject movement, muscular response, and stiffness estimation of FD data. These variables have been unaccounted for in previous indentation studies and as such, may be responsible for differences in FD properties between pre-intervention and post-intervention indentation trials. Based on the results of this study, the authors recommend that investigators who utilize spinal indentation adopt protocols or utilize technology that will decrease and/or eliminate these sources of variability.

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Chapter 8

Determination of vertebral displacement by ultrasonic indentation in an *in vivo* porcine model of degenerative disc disease

INTRODUCTION:

The spine is a multi-joint structure that must simultaneously provide the paradoxical functions of rigidity and flexibility. Spinal rigidity is necessary for the protection of neural elements, integrity of spinal structures and the provision of a stable base for human movement, while flexibility is required to permit such movement[1-3]. Each of these two functions is achieved through a number of active and passive mechanisms that are coordinated by the neurological system[4,5]. Imbalances between spinal rigidity and flexibility may be manifest as excessive or insufficient vertebral movements which have been hypothesized to be related to spinal pathology and/or spinal pain[6].

Accordingly, numerous investigators have attempted to define the clinical relevance between spinal kinematics, pathology and pain. *In vitro* approaches have described aberrant spinal kinematics in the presence of pathological processes such as disc degeneration[7-9]. Observations from these studies are limited in their physiological relevance due to tissue loss, lack of tissue function and an inability to assess clinical phenomenon such as pain. *In vivo* techniques resolve many of these limitations and are therefore better suited to assess the clinical relevance of spinal motion. However, *in vivo* techniques are not without concern. Many *in vivo* techniques are invasive and/or have the potential for harm. These techniques include osseous fixation[10,11] and ionizing radiation[12-15] which preclude their use in large populations. For this reason, *in vivo* techniques that are non-invasive are preferred, yet most are not capable of direct quantification of spinal mechanics and/or controlled loading conditions thought to be advantageous in spinal testing [16,17,18-20].

To address this issue, a non-invasive technique has been developed that directly quantifies displacement of a specific vertebra in response to a pre-defined, externally applied load. More specifically, this technique, known as ultrasonic indentation (UI), incorporates non-invasive imaging (ultrasound) with concurrent external indentation of spinal tissues to quantify the sub-cutaneous displacement of an osseous target in the plane of indentation. The accuracy, reliability, validity and potential sources of variation of this technique have been described previously[21-24]. Given these data, the ability of UI to differentiate between normal and abnormal spinal mechanics can be tested. Therefore, the purpose of this study was to determine the capability of UI to delineate normal from abnormal porcine spine mechanics created by specific surgical interventions. These interventions included a previously developed technique to produce conditions of lumbar disc degeneration[25] and multi-level facetectomies.

METHODS:

Endplate Injury Surgery. A total of sixteen domestic pigs were used in this study (Swedish Landrace). Eight of these sixteen animals were selected at 3 months of age to undergo a surgical procedure known to cause lumbar disc degeneration through direct endplate injury[25]. Specifically, each animal was sedated by intra-muscular injection of ketamine (30 mg/kg body weight; Parke-Davis, Pontypool, Gwent, UK), intubated, ventilated, and then placed in a prone position. Prior to surgery, anesthesia was given intravenously with α-chloralose (100 mg/kg body weight; Sigma, St. Louis, MO) and the vital signs of each animal monitored continuously. To create endplate injury, a left retroperitoneal approach was used to expose the L3-L4 disc. The cranial endplate of the L4 vertebral body was then perforated by inserting a 3.5 mm drill into the anterior mid-body of L4 then drilling toward the centre of the endplate at a 45° angle until nuclear material was contacted (Figure 8.1).

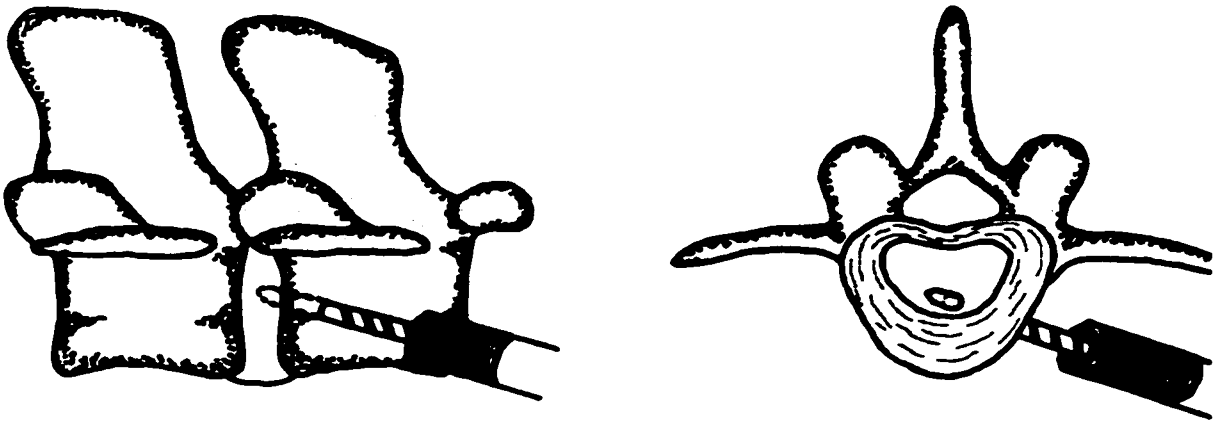

Figure 8.1: *Schematic diagram illustrating the technique used to create a surgical injury in the cephalad endplate of L4 which resulted in L3/L4 disc degeneration in three months time.*

Post-injury Testing. Three months later, all eight animals having undergone endplate surgery were collected for further testing in addition to eight age-matched control animals. Each of the sixteen animals were sedated, anesthetized and monitored in the manner described previously with the exception of intubation through tracheotomy.

Intradiscal Pressure. An 1.8 mm pressure needle (Gaeltec, Isle of Skye, Scotland) was inserted into the L3/L4 disc of each animal using a left-sided retroperitoneal approach. Following insertion, the cannula of the pressure needle was withdrawn, the needle anchored to the superficial fibers of the annulus fibrosus and the incision closed. Changes in intradiscal pressure during ultrasonic indentation were calculated between pre-load and max-load conditions and then normalized to the cross-sectional area of the instrumented disc.

Ultrasonic Indentation. Ultrasonic indentation equipment was then positioned over each prone animal[22]. This equipment consisted of a load cell transducer (Load Cell Central, Monroeton PA, U.S.A.) and a 7 MHz linear array ultrasonic transducer (Acuson, Mountainview, CA, U.S.A.) mounted in-series to the terminal end of an electromechanical linear actuator (Industrial Devices Corporation, Petaluma, CA, U.S.A). These two transducers were used during indentation to estimate applied load and to image sub-surface echogenic anatomy respectively. A linear displacement transducer attached in-parallel quantified the actuator's displacement. The actuator/transducer complex was suspended in an aluminum frame that allowed the complex to be translated horizontally and angulated vertically, while the frame itself could be restrained against the surgical table by a series of four détentes. Electronic and mechanical safety mechanisms permitted premature cessation and reversal of actuation at the request of the operator.

Prior to indentation, the long axis of the ultrasonic transducer was oriented to the long axis of the transverse process of the fourth lumbar vertebra by ultrasonic imaging. This method of indentation site localization has been shown to be superior to methods based on visualization and/or palpation[21]. Indentation was then initiated approximately 5 cm above the surface of each animal's back and proceeded vertically downward at a rate of 2.5 mm/s until a load of 1 N was attained (pre-load) at which time loading was paused for 3 s and an ultrasonic image collected. Loading was then allowed to proceed at the same rate to a maximal load of 70 N (max-load). At max-load, indentation was paused for another 3 seconds before indentation reversal and a second ultrasonic image was collected. During indentation, the respiratory effort of each animal was maintained in a static state for a period of approximately 10 s through removal of the main ventilation hose from the ventilator. A minimum of four trials were collected in this manner at 120 s intervals.

Facetectomy. Following ultrasonic indentation, four small longitudinal incisions were made para-sagittal and posterior to the zygapophyseal joints of L3/L4 and L4/L5 and each joint removed individually with a rongeur. Following facetectomy, the previously indented transverse process was relocated by ultrasound and the actuator re-positioned to this point to collect a minimum of four post-facetectomy indentations. After all indentations, each animal was sacrificed and their spine removed for further examination.

Chemical and Histological Analysis. Following removal of the spine, the L3/L4 and L4/L5 intervertebral discs of each animal were sectioned and photographed. Discs directly affected by endplate injury and discs from an adjacent level were then tested for their water content, proteoglycan content, collagen content, collagen organization, and cellularity using established methods[26,27].

Data Acquisition and Analysis. Voltage signals related to indentation load, actuator displacement and intradiscal pressure were acquired by a single analog-to-digital board (National Instruments, Austin, TX, U.S.A). Customized software (National Instruments, Austin, TX, U.S.A) permitted data collection and concurrent generation of actuator control signals. So that appropriately rapid control signals could be sent to the actuator, a sampling/control rate of 1kHz was selected. As a result of this sampling rate, load and displacement signals were determined to be over-sampled[22] and were subsequently re-sampled (decimated) to 2x the Nyquist frequency (frequency at 99.5% of the load signal's frequency content). Load and displacement signals were then filtered based on their frequency content[28]. Bulk tissue stiffness over the course of indentation was determined by fitting a 5th order polynomial to the resultant displacement-force data then solving for displacement at 50% of the applied load. The resulting displacement was then substituted into the first derivative of the force-displacement data (modeled by a 5th order polynomial) and the bulk tissue stiffness estimated.

Pre-load and max-load ultrasonic images were obtained as 0.3 Mpixel images (640 x 480 pixels) at an imaging depth of 60 mm (Figure 8.2). The focal depth was set on a per-subject basis to best coincide with the depth of the transverse process. Resultant vertebral displacement was calculated by determining the change in transducer-to-bone tissue thickness in ultrasonic images from pre-to-max load then subtracting this value from the change in indenter displacement over the same period[24]. Transducer-to-bone tissue thickness was determined by a visually based, edge-detection algorithm[23]. All images were analyzed at 3x magnification. Each measure of displacement and tissue stiffness was then normalized to the animal's body weight and soft tissue thickness as determined from the pre-load image.

Within-animal comparisons of vertebral displacement, intradiscal pressure, and bulk tissue stiffness were made non-parametrically (Wilcoxon Signed Rank Test) for all animals. These within-animal comparisons were made for the final two indentation trials before facetectomy (PreFacet^{-2} and PreFacet^{-1}) and the trials before and after facetectomy (PreFacet^{-1} and PostFacet^{+1}). Between-group (control, degenerative) comparisons of vertebral displacement, intradiscal pressure, and bulk tissue stiffness were made non-parametrically (Mann-Whitney Test) for the PreFacet^{-1} and PostFacet^{+1} conditions. Receiver Operating Characteristic (ROC) curves were created to determine the sensitivity and specificity of all procedures in differentiating control from degenerative animals in PreFacet^{-1} and PostFacet^{+1} conditions.

RESULTS:

Data obtained from indentation of all animals (vertebral displacement (normalized), tissue stiffness (un-normalized), tissue stiffness (normalized) and intradiscal pressure (normalized)) are displayed in Table 8.1. The results of within animal and between group (control and degenerative) significance testing (p values) for the above variables are presented in Table 8.2. The sensitivity and specificity of these same variables are presented in Table 8.3.

Animals. All animals were approximately seven months in age at the time of final testing. There were no significant differences between the control and the degenerative animals with respect to weight or thickness of paraspinal tissues as determined ultrasonically. The mean weight and tissue thickness of the animals were 76 (SD 5) kg and 45.7 (SD 3.4) mm respectively. Data from two control animals were eliminated from final analysis, as the investigators were unable to maintain a static respiratory effort in these animals during indentation.

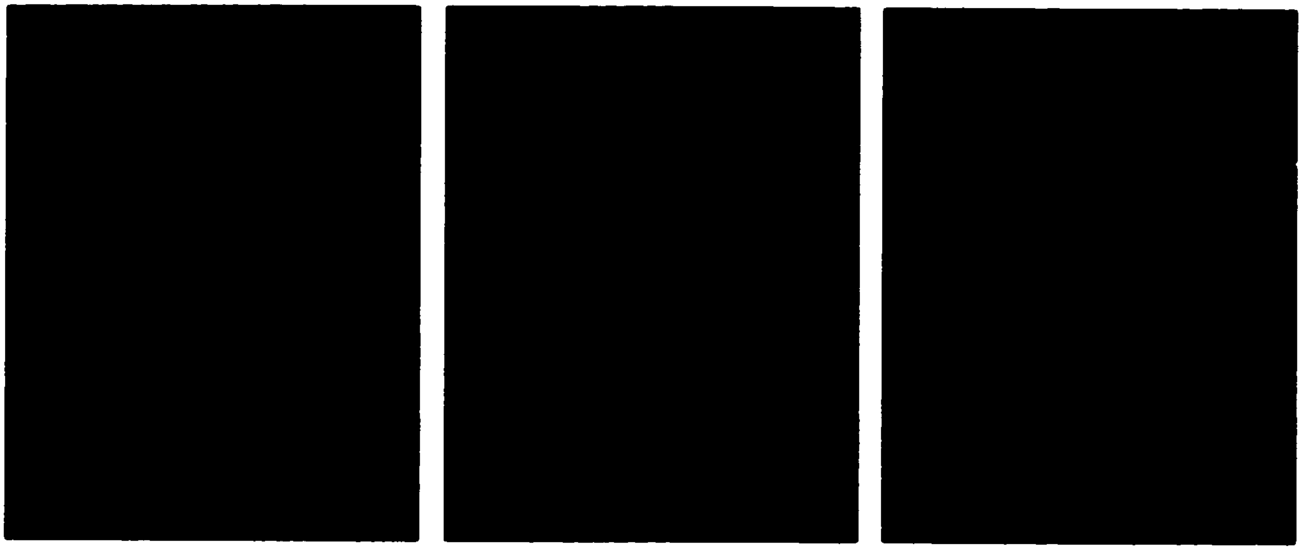

Figure 8.2: *Three ultrasonic images obtained during indentation of a single animal at a 60 mm imaging depth using a 7 MHz linear array transducer (Acuson, Mountainview, U.S.A.). From left to right, pre-load image (pre-facetectomy), max-load image (pre-facetectomy) and max-load image (post-facetectomy).*

Vertebral Displacement. Within-animal changes in vertebral displacement were found to be significantly higher following facetectomy but were insignificant in PreFacet^{-2} vs. PreFacet^{-1} comparisons. Between control and degenerative groups, differences in vertebral displacements were significant at the 0.09 level prior to facetectomy with a sensitivity and specificity of 75.0% and 83.3% respectively. Following facetectomy, vertebral displacements in the PostFacet^{+1} data were significantly different between control and degenerative animals (p= 0.03) with a sensitivity of 87.5% and a specificity of 83.3%.

Tissue Stiffness. Figure 8.3 demonstrates force-displacement curves (PreFacet$^{-4,}$ PreFacet^{-2}, PreFacet^{-1} and PostFacet^{+1} trials) obtained by indentation of a single representative animal. Force-displacement (FD) curves were significantly altered within each animal following facetectomy, but not in PreFacet^{-2} vs. PreFacet^{-1} comparisons. Differences in un-normalized tissue stiffness between control and degenerative groups were non-significant while normalized measures of tissue stiffness were significantly different between animal groups before and after facetectomy

Intradiscal Pressure. Intradiscal pressure was recorded from eight of the sixteen animals due to difficulties instrumenting the degenerative disc (5 control, 3 degenerative). The change in intradiscal pressure during indentation (pre-load to max-load) was found to be significantly higher within each animal following facetectomy. Similar changes were not observed to occur in the PreFacet $^{-2}$ vs. PreFacet $^{-1}$ comparison. The change in intradiscal pressure was found to be significant between groups (control and degenerative) prior to and following facetectomy.

All animals	PreFacet $^{-1}$	PostFacet $^{+1}$
Vertebral Displacement* (mm)	17.38 (0.66)	18.48 (0.71)
Tissue Stiffness (N/mm)	3.73 (0.09)	3.43 (0.09)
Tissue Stiffness* (N/mm)	3.72 (0.11)	3.42 (0.11)
Between-groups (PreFacet $^{-1}$)	**Control Animals**	**Degenerative Animals**
Vertebral Displacement* (mm)	18.69 (0.84)	16.39 (0.85)
Tissue Stiffness (N/mm)	3.65 (0.13)	3.79 (0.13)
Tissue Stiffness* (N/mm)	3.43 (0.11)	3.94 (0.14)
Between-groups (PostFacet $^{+1}$)	**Control Animals**	**Degenerative Animals**
Vertebral Displacement* (mm)	20.20 (0.99)	17.18 (0.75)
Tissue Stiffness (N/mm)	3.32 (0.16)	3.51 (0.09)
Tissue Stiffness* (N/mm)	3.12 (0.13)	3.65 (0.10)

Table 8.1: *Mean vertebral displacement and mean tissue stiffness values (with standard error) obtained from indentation loading of the fourth lumbar vertebra (* = normalized).*

Within-animal change (Wilcoxon)	PreFacet $^{-2}$ vs. PreFacet $^{-1}$	PreFacet $^{-1}$ vs. PostFacet $^{+1}$
Vertebral Displacement*	0.86	< 0.00
Tissue Stiffness	0.44	< 0.00
Tissue Stiffness*	0.42	< 0.00
Intradiscal Pressure*	0.27	< 0.00

Between-groups (Mann-Whitney)	PreFacet $^{-1}$	PostFacet $^{+1}$
Vertebral Displacement*	0.09	0.03
Tissue Stiffness	0.52	0.25
Tissue Stiffness*	0.03	0.03
Intradiscal Pressure*	0.05	0.03

Table 8.2: *Results of non-parametric tests of significance (p values) for within-animal and between-group comparisons (control vs. degenerative) for three variables: vertebral displacement obtained from ultrasonic indentation, bulk tissue stiffness obtained from non-imaging indentation and intradiscal pressure obtained from direct instrumentation (* = normalized).*

Variable	Pre-facetectomy Sensitivity (%) / Specificity (%)	Post-facetectomy Sensitivity (%) / Specificity (%)
Vertebral Displacement*	75.0(35.0-96.1) / 83.3(36.1-97.2)	87.5(47.4-97.9) / 83.3(36.1-97.2)
Tissue Stiffness	62.5(24.7-91.0) / 66.7(22.7-94.7)	100.0(100.0-100.0) / 50.0(12.4- 87.6)
Tissue Stiffness*	75.0(35.0-96.1) / 100.0(100.0-100.0)	87.5(47.4- 97.9) / 83.3(36.1- 97.2)
Intradiscal Pressure*	100.0(100.0-100.0) / 80.0(28.8-96.7)	100.0(100.0-100.0) / 100.0(100.0-100.0)

Table 8.3: *Sensitivity and specificity (with 95% confidence intervals) of different variables in distinguishing between animal groups (control and degenerative) before and after facetectomy (*normalized).*

Chemical and Histological Analysis.

Figure 8.4 displays an injured L3/L4 disc and the adjacent uninjured L4/L5 disc from a single degenerative animal. All discs having undergone endplate injury were observed to have reduced disc height, reduced hydration, alteration of the nucleus morphology, but a lack of osseous adaptation such as the presence of osteophytes. These morphological observations are consistent with early degenerative disc disease in humans. In the injured disc, there was a significant decrease in water content in the peripheral annulus and central nucleus areas, but no change in the collagen content of either area. The injured disc additionally demonstrated reduced proteoglycan content and cellularity in the nucleus area; these same parameters were not significantly affected in the outer annular region.

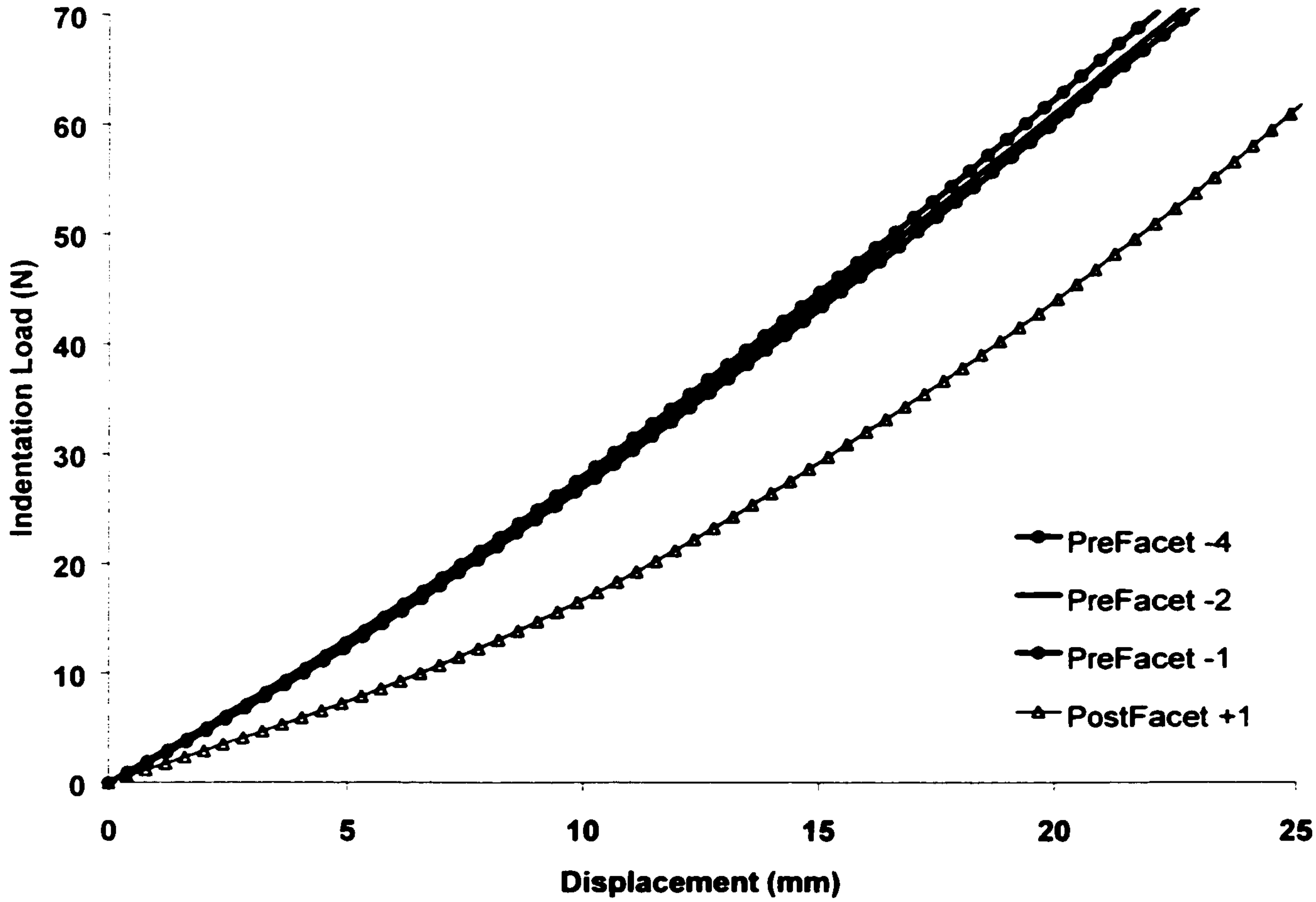

Figure 8.3: *Force-displacement curves obtained from indentation of a single animal at the fourth lumbar vertebra demonstrating data from three indentation trials prior to facetectomy and a single indentation immediately post-facetectomy.*

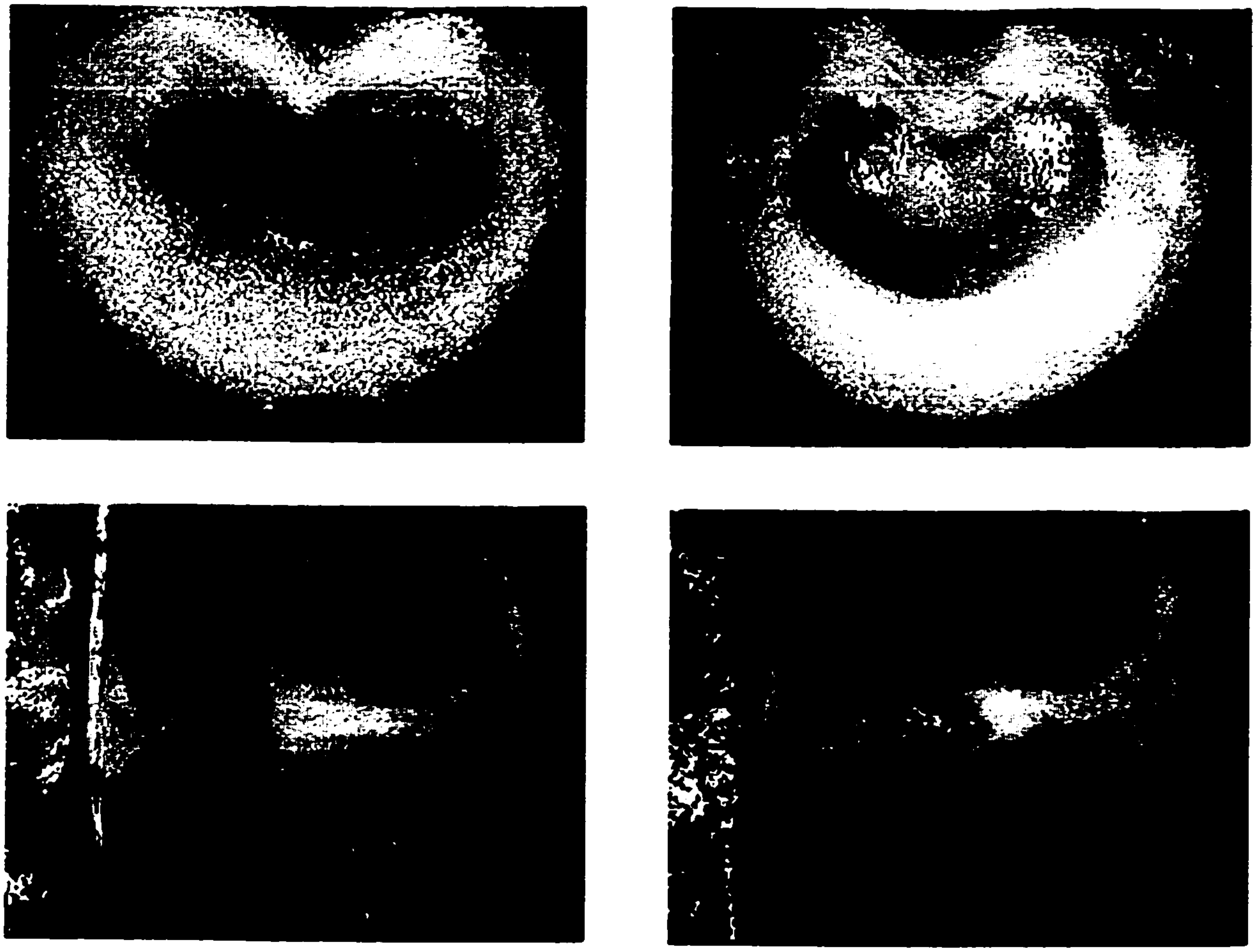

Figure 8.4: *Comparative photographs of cross and sagittal sections of a lumbar disc affected by endplate injury (L3/L4) and an adjacent disc from the same animal (L2/L3).*

DISCUSSION:

Posterior to anterior vertebral displacement was quantified in this study by a novel technique (ultrasonic indentation, UI) that utilized external indentation loading and concurrent ultrasonic imaging to distinguish between control and degenerative animals. Significance testing of UI-generated measures of vertebral displacement and tissue stiffness (normalized) between control and degenerative animals (pre-facetectomy) resulted in p values of 0.09 and 0.03 respectively.

In vitro investigations have established that degenerative vertebrae possess significantly different kinematics from normal controls when tested in a pre-defined manner[7-9]. The clinical relevance of these results has not been supported unanimously by *in vivo* investigations as the relation between lumbar kinematics, pathology and pain has been questioned[29-32]. As a result, the clinical relevance of spinal kinematics is undecided at best. This lack of clarity may be explained in some part by the current nature of *in vivo* testing. The most common forms of *in vivo* testing are limited presently in their application due to their invasive nature (i.e. techniques based on osseous fixation, ionizing radiography) and/or their reliance on voluntary actions to quantify spinal motion (i.e. standing forward flexion of the trunk). While these motions may mimic functional tasks, they do not specifically apply load to a target vertebra as is possible with *in vitro* testing. As a result, the mechanics of the vertebra of interest may not be challenged sufficiently, or may be restricted by coexistent muscular activity[13,33,34]. Spinal indentation is one of the few techniques to load a specific vertebra *in vivo* without requiring a voluntary motion of the spine to do so, however, without concurrent imaging, techniques based on indentation are incapable of quantifying kinematics of specific vertebra — a common limitation to most non-invasive assessment techniques. Ultrasonic indentation (UI) represents a novel combination of features that permits non-invasive quantification of the displacement of a specific vertebra under controlled loading conditions.

An endplate injury model of disc degeneration was chosen as the primary perturbation in this experiment as it offers several unique advantages. Endplate surgery is a controlled intervention that results in a defined mechanical change at a specific motion segment *in vivo*. This approach provides uniformity in the experimental group in comparison to the use of a symptomatic, heterogeneous human population. While a human population was not used, Holm et al. have shown that the degenerative changes created by this procedure are chemically and histologically similar to those changes found in human disc degeneration[25]. These parameters include a decline in the water content, proteoglycan content, cellularity, as well as the demonstrated morphological changes. The endplate injury model is additionally capable of reproducible and defined biomechanical alterations which affect intradiscal pressure and disc stiffness. This model also creates degenerative changes in a relatively short period of time in a manner that has a common physiological correlate (endplate disruption) versus models of degeneration which are based on disruptions of the anterior disc [35-37].

In this study, estimates of vertebral displacement obtained from UI were found to increase significantly within all animals following facetectomy. Stratification of animals into control and degenerative groups revealed similar within animal changes. These UI results were paralleled by those obtained from more established measures of biomechanical function (tissue stiffness and intradiscal pressure). Such observations were expected given that the structure of porcine facet joints act to restrict posterior to anterior displacement — the plane of indentation. This result is in agreement with the findings of other investigators who have observed that disruption or removal of posterior elements was manifest as a decrease in segmental stiffness and/or increased displacement[38-41].

While the above findings support a conclusion that UI was able to identify substantial mechanical alterations resulting from facetectomy, facetectomy is an extreme intervention that is presumably infrequent in persons with low back pain. To assess the ability of UI-generated measures to detect more subtle mechanical change, measures of vertebral displacement were compared to measures of tissue stiffness and intradiscal pressure between animal groups prior to facetectomy.

Prior to facetectomy, vertebral displacements obtained from UI were significantly different between control and degenerative animals at the 0.09 level. In comparison, differences in intradiscal pressure between these animal groups were significant at the 0.05 level — a measure known to distinguish between these groups[42]. Estimates of tissue stiffness obtained from traditional indentation methods (without imaging), were unable to distinguish between these groups. Only when stiffness measures were normalized by 1] animal weight and 2] paravertebral thickness was there a significant distinction between animal groups. These two factors, which were not strongly related ($r = -0.367$), were selected for normalization based on the rationale that increases in these dimensions decrease the indentation load experienced by the vertebral tissues (i.e. two identical vertebral segments undergoing indentation loads will undergo unequal displacements if surrounded by different amounts of similar soft tissue). Indirect evidence for the application of this normalization strategy is provided by Latimer et al. who observed that subjects who lay prone on surfaces of differing stiffness (plinths) had significantly different values of stiffness resulting from indentation of the posterior spine[43]. If the abdomen can be considered to be a "plinth", then abdomens of different stiffness may alter the FD properties of the spine during indentation loading. Such normalization procedures have not been employed previously in spinal indentation protocols.

Although UI measures of pre-facetectomy vertebral displacement were not significant at the traditional 0.05 level, comparison of the sensitivity and specificity of UI to other modalities used to detect arthritic change in the spine[44-46] suggests that UI has equal or superior performance. Interestingly, while traditional (non-imaging) indentation measures of tissue stiffness did not approach acceptable levels of sensitivity and sensitivity, the normalization of tissue stiffness measures by ultrasonically derived factors (tissue thickness) improved the measure's performance considerably. Therefore, UI is capable of generating two measures having clinically relevant levels of sensitivity and specificity: vertebral displacement and tissue stiffness (normalized). We speculate that UI would be increasingly capable of identifying biomechanical differences between control animals and those whose degeneration processes were allowed to progress beyond three months.

Ultrasonic indentation is a novel procedure for non-invasive investigation of spinal disorders. From the results of this study, the authors surmise that UI has potential as a technique capable of providing relevant data pertaining to disorders which affect the mechanics of the spine. In its present format, the use of ultrasonic imaging concurrent to indentation permits qualification of vertebral displacements in the plane of indentation. allows for normalization of data and provides a method of indentation site positioning and re-positioning with respect to subcutaneous, echogenic anatomical landmarks. Each of these features is limited by the constraints inherent to B-mode ultrasonic imaging[24]. Future studies must be performed with larger sample sizes and differing time intervals of degeneration to define further the relation of UI-generated measures with respect to degenerative disc disease.

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Chapter 9

Discussion and Conclusions

Summary

Discussion

Conclusions

SUMMARY

The experiments performed in this dissertation project were formulated to assess the ability of a novel procedure (Ultrasonic Indentation or UI) to quantify displacement of a specific vertebra. UI is a unique procedure that non-invasively quantifies vertebral displacement from the application of a pre-defined load without the need for subject movement to generate that load. The first two studies in the dissertation project established that B-mode ultrasonic images could be used to quantify the change in position of an ultrasonic transducer with respect to a phantom preparation and a static bovine preparation. The third installment of this dissertation described the design process used to develop the equipment necessary to conduct UI *in vivo*. The fourth and fifth studies characterized the reliability, accuracy and sources of error of UI as well as its validity in a dynamic cadaveric spine preparation. The performance of UI was considered acceptable when compared to data describing the range of anterior to posterior vertebral displacements in a population of low back pain patients[1]. In the last of the six studies presented here, eight adolescent pigs underwent a surgical procedure to generate lumbar disc degeneration. After three months recovery, these and eight age-matched control animals were assessed by UI. The results of this study demonstrated UI to have equal or superior sensitivity and/or specificity in distinguishing control and degenerative animals when compared to other methods used to detect arthritis in the spine (i.e. physical examination and radiography). From the results these studies, the goals of the dissertation project were met.

DISCUSSION

Given the cost and morbidity of spinal conditions[2], numerous attempts have been made to identify spinal tissues that generate pain. These tissues include intervertebral discs, facet joints, ligaments, bones, and joint capsules[3]. It has been estimated that 98% of low back pain (LBP) is caused by injury to these tissues[4] resulting in "mechanical" back pain. While these tissues may be commonly injured, their relation to LBP is not understood completely. For example, Boden et al.[5] observed that 35% of subjects ranging from 20 to 39 years of age had herniated intervertebral discs without any history of LBP. Unfortunately, this study and others like it have resulted in the perception that tissue derangement is not correlated to LBP — a potentially incorrect conclusion given the present lack of non-invasive techniques capable of assessing the *function* of these deranged tissues *in vivo*[6-10]. Therefore, while 98% of LBP results from "mechanical" causes, there are very few techniques that define lumbar mechanics *in vivo* — a fact reflected by the inability of clinicians to diagnosis 90% of all LBP[11]. These observations underscore the need for development of an *in vivo* procedure that is non-invasive and capable of quantifying the mechanics of an individual vertebra.

UI assumptions and limitations

While the procedure developed in this dissertation satisfies the above requirements, UI has a number of limitations and assumptions which merit discussion. As in all ultrasonic applications, increasing the depth of the resulting ultrasonic image results in a decrease in the resolution of the image[12]. As a result, the accuracy of ultrasonic techniques, including UI, decreases as the depth of the target of interest increases. Therefore, the accuracy of UI will not be equal between subjects imaged at different depths. Depending on the accuracy needs of the investigation, a certain percentage of the population may not be able to be assessed by this technique should their transverse processes be at too great a depth. While other modes of ultrasound partially solve this issue by offering improved time delay estimation[12], the output of these devices is non-graphical which exclude them from use in pre-indentation target identification[13].

The calculation used in UI to determine vertebral displacement assumes that out-of-plane motions and rotations are minimal[14]. Out-of-plane motions are known to generate error in estimates of displacement obtained from two-dimensional images. This assumption appears to be reasonable given that the out-of-plane translation of the preparation used to assess *in vivo* UI accuracy was less than 17% of the primary motion (vertical displacement) and concurrent rotations were less than 1°. These magnitudes are considered by others to be insignificant with respect to motions of uniform surfaces[9,15]. This same calculation additionally assumes that the target vertebra does not deform under the indentation load — another reasonable assumption given the loads used in this study are less than one percent of the load required to cause vertebral endplate fractures in normal porcine specimens[16].

Given these assumptions, UI is limited to quantifying displacement of a single vertebra in the plane of indentation due to the relative motion of the transducer during indentation. While other techniques have used stationary transducers to observe voluntary motions in multiple planes[17-19], the resulting anatomical movements are difficult to interpret due to lack of a controlled input load and/or difficulty in maintaining a consistent transducer/tissue interface — problems addressed and solved by UI.

Given this, the single direction displacements quantified by UI are a function of subject/device orientation. In its present use, the displacements characterized by UI are sagittal plane translations. While there is presently a lack of agreement in the literature regarding the clinical significance of any vertebral motion[20], sagittal plane motions are most often associated with aberrant motion and/or pain, are largest in magnitude and are most likely to have clinical significance[21]. At the present time, it is not known whether UI measures could be performed at other indentation sites, at other indentation angles or what the significance of the resulting motions would be.

Other limitations and sources of UI error exist that are not ultrasonic in nature. In this dissertation, rates of loading and indentation angles were kept constant to aid in data comparison. Lee et al.[22,23] have shown that during spinal tissue indentation, increases in loading rate and indentation angle affect spinal FD properties by decreasing tissue displacement and increasing tissue stiffness. In the last of the dissertation experiments, alterations of these parameters may have accentuated differences between control and degenerative animals. At present, the systematic effect of these parameters on vertebral displacements is unknown.

Finally, assuming a viable ultrasonic image is collected during UI, localization of the osseous target within that image is based on edge detection algorithms that rely to some extent on human input[13]. At present, the inter-rater reliability of these edge-detection techniques is unknown.

UI utility

Given these results and limitations, the magnitude of UI error can only be judged as acceptable when that error is less than the change in the generated measure. As a result, the utility of UI is dependent on the magnitude of the phenomena it is attempting to quantify. Determination of this magnitude is problematic, for as pointed out in this dissertation, deficiencies in present-day techniques inhibit accurate quantification of spinal motions *in vivo*. Arguably, the best data collected to date with respect to *in vivo* spinal motions is that of Kaigle et al.[1] who used invasive, but direct techniques to assess sagittal plane translations during forward bending in asymptomatic and LBP patients. Their findings indicate that a difference of 1.5 mm exists between these groups — almost an order of magnitude larger than the error of UI. While the sample size of this study was small, (n = 7 LBP, 6 Controls), its results indicate that lumbar motion in relation to LBP need not be minuscule.

Should other forms of pathology of LBP be related to sagittal plane translations, UI in its present form would be able to discriminate movements of ~0.2 mm or greater. This magnitude of error would permit UI the ability to identify normal coupling translations — the smallest magnitude of normal translation thought to occur in the spine[24,25]. In the future, advances in ultrasonic technology will likely improve the ability of UI to detect smaller magnitude translations.

In the final study of this dissertation, normalization was employed to equalize measurements obtained from indentation loading of a fairly homogeneous population of animals (vertebral displacement and tissue stiffness). While this strategy could be considered successful, it assumes that time dependent changes in spinal tissues were equal between subjects for each indentation cycle. Therefore, between-animal comparison could be made at any indentation cycle, but were done so at equilibrium (trial four). Although *in vitro* protocols may apply over 100 load cycles to an isolated tissue before equilibrium is reached[26], data from Latimer et al.[27] and Dickey et al.[28] suggest that the posterior tissues of the spine reach equilibrium after 3-5 trials *in vivo* — observations supported by the results of this dissertation. Should a more heterogeneous population be used (i.e. adult humans), additional pre-conditioning trials may be required to ensure all subjects reach equilibrium before indentation results are analyzed.

It is speculated that the ability of UI to detect differences between control and pathological populations (e.g. degenerative disc disease) may be improved under a number of circumstances including: increased severity of pathology and use of pain localization. Assuming the degenerative process is related directly to the mechanics of the vertebra of interest, advanced degenerative process would likely result in increased sensitivity and specificity of UI. In addition, numerous studies have demonstrated that the diagnostic performance of procedures used in the spine can be increased when pain localization is used[29-32]. Therefore, the sensitivity and specificity of UI may increase in clinical scenarios where instruments could be employed to assess pain levels during the indentation procedure. This speculation is supported by Latimer et al.[33] who have shown bulk tissue properties of the spine change in relation to LBP.

At present, the sensitivity and specificity of UI compares well to other modalities used to detect arthritic change. In a meta-analysis of eight studies that assessed the sensitivity and specificity of physical examination procedures in detecting ankylosing spondylitis[34], no single physical exam procedure attained a sensitivity higher than 52%. Specificity averaged 75%. Comparatively, a laboratory test (erythrocyte sedimentation rate, ESR) was found to have a sensitivity and specificity of 68%. In another study, a diagnostic imaging technique (magnetic resonance imaging, MRI) was able to distinguish between symptomatic subjects with herniated IVDs and asymptomatic controls based on the presence of degeneration with a sensitivity of 96% and a specificity of 15%[35]. Using more prevalent and less expensive imaging techniques such as plain film radiography, the diagnostic accuracy of detecting degenerative changes decreases to 68% at the lumbosacral junction[36]. Other than the sensitivity of MRI, the performance of these techniques is less than that of UI-generated measures of vertebral displacement and tissue stiffness (normalized), however, the degenerative vertebrae identified in these studies were significantly advanced in their pathogenesis (Grade III - V out of V). In comparison, the low magnitude morphological changes observed to occur in degenerative animals at three months in this dissertation are not typically visible on plain film analysis. Therefore, should comparison of diagnostic performance be made between UI and other imaging modalities for equally low pathological grades, the performance of UI is speculated to be significantly higher than other methods of diagnostic imaging. Therefore, it is speculated that the present sensitivity and specificity of UI would improve should it be used to assess degenerative conditions which were more advanced.

Further discussion regarding the experiments of this dissertation can be found in the preceding chapters.

CONCLUSIONS

The studies presented in this dissertation indicate that ultrasonic imaging can be utilized with concurrent external indentation of the spine to generate non-invasive measures of vertebral displacement within the plane of indentation. The resulting procedure is called Ultrasonic Indentation (UI). Bench-top investigations of the equipment fabricated to perform UI indicate that the output of UI is reliable, accurate and of a magnitude equal to or superior to related procedures. The error of vertebral displacement measures generated by UI was quantified from cadaveric testing of a lumbar spine preparation and found to be well within the resolution required for detection of aberrant spinal mechanics identified by invasive methods. Finally, a study was conducted to evaluate the ability of UI to distinguish between control and experimental groups of animals that received a surgical intervention resulting in lumbar degenerative disc disease. Compared to other modalities used to detect arthritic change in the spine (i.e. physical examination and radiography), UI demonstrated equal or superior sensitivity and specificity. From the results these studies, the goals of the dissertation project were met.

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AWARDS

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