Three-Dimensional Vertebral Motions Produced by Mechanical Force Spinal Manipulation

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Abstract

Objective: The aim of this study was to quantify and compare the 3-dimensional intersegmental motion responses produced by 3 commonly used chiropractic adjusting instruments.

Methods: Six adolescent Merino sheep were examined at the Institute for Medical and Veterinary Science, Adelaide, Australia. In all animals, triaxial accelerometers were attached to intraosseous pins rigidly fixed to the L1 and L2 spinous processes under fluoroscopic guidance. Three handheld mechanical force chiropractic adjusting instruments (Chiropractic Adjusting Tool [CAT], Activator Adjusting Instrument IV [Activator IV], and the Impulse Adjusting Instrument [Impulse]) were used to randomly apply posteroanterior (PA) spinal manipulative thrusts to the spinous process of T12. Three force settings (low, medium, and high) and a fourth setting (Activator IV only) were applied in a randomized repeated measures design. Acceleration responses in adjacent segments (L1 and L2) were recorded at 5 kHz. The multiaxial intersegmental (L1-L2) acceleration and displacement response at each force setting was computed and compared among the 3 devices using a repeated measures analysis of variance ($\alpha = .05$).

Results: For all devices, intersegmental motion responses were greatest for axial, followed by PA and medial-lateral (ML) measurement axes for the data examined. Displacements ranged from 0.11 mm (ML axis, Activator IV low setting) to 1.76 mm (PA axis, Impulse high setting). Compared with the mechanical (spring) adjusting instruments (CAT, Activator IV), the electromechanical Impulse produced the most linear increase in both force and intersegmental motion response and resulted in the greatest acceleration and displacement responses (high setting). Significantly larger magnitude intersegmental motion responses were observed for Activator IV vs CAT at the medium and high settings ($P < .05$). Significantly larger-magnitude PA intersegmental acceleration and displacement responses were consistently observed for Impulse compared with Activator IV and CAT for the high force setting ($P < .05$).

Conclusions: Larger-magnitude, 3D intersegmental displacement and acceleration responses were observed for spinal manipulative thrusts delivered with Impulse at most force settings and always at the high force setting. Our results indicate that the force-time characteristics of impulsive-type adjusting instruments significantly affects spinal motion and suggests that instruments can and should be tuned to provide optimal force delivery. (J Manipulative Physiol Ther 2006;29:425-436)

Key Indexing Terms: *Biomechanics; Chiropractic; Manipulation, Spinal; Spine; Mechanical Force*

Spinal manipulation is the most commonly performed therapeutic procedure provided by doctors of chiropractic.[1] Likewise, chiropractic techniques have evolved, providing clinicians with choices in the delivery of particular force-time profiles deemed appropriate for a particular patient or condition. Clinicians often rely upon mechanical advantages in performing spinal manipulation through patient positioning and mechanical assistance

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CASE REPORTS

Chiropractic Treatment of Coccygodynia via Instrumental Adjusting Procedures Using Activator Methods Chiropractic Technique

Bradley S. Polkinghorn, DC,[a] and Christopher J. Colloca, DC[b]

ABSTRACT

Objective: To discuss a case of coccygodynia that responded favorably to conservative chiropractic adjusting procedures with the Activator Methods Chiropractic Technique (AMCT) and the Activator II Adjusting Instrument (AAI II).

Clinical Features: A 29-year-old woman had unremitting coccygeal pain of 3 weeks' duration. The problem began after she had moved heavy boxes while at work. The pain was characterized by a continual dull ache in the coccygeal region, accompanied by intermittent sharp pain, particularly upon sitting or rising from a seated position. She had been taking self-prescribed over-the-counter analgesics (aspirin and ibuprofen) for 3 weeks without obtaining relief.

Intervention and Outcome: Treatment consisted of mechanical force, manually assisted, short-lever (MFMA) chiropractic adjusting procedures to the coccygeal area, primarily the sacrococcygeal ligament. The AAI II was used to deliver the adjustment according to diagnostic and treatment protocol specified for AMCT. The patient experienced a complete resolution of her pain after the first treatment.

Conclusion: Chiropractic coccygeal manipulation may be effectively delivered via instrumental adjustment in certain cases of coccygodynia. The use of an AAI II in administering the coccygeal adjustment has the benefit of being a gentle, noninvasive procedure, as well as being comfortably tolerated by the patient. This method of coccygeal adjustment may bear consideration in certain cases of coccygodynia. (J Manipulative Physiol Ther 1999;22:411-6)

Key Indexing Terms: Chiropractic Manipulation; Coccyx; Pain

INTRODUCTION

Coccygodynia (also called coccydynia), a distressing condition characterized by pain in and near the coccyx, was first described by Simpson in 1861.[1] Discomfort is usually felt when sitting or when rising from the seated position. This may indicate coccygeal luxation or hypermobility likely corresponding to movement of the coccyx back to its resting, neutral position.[2] The pain of coccygodynia may range from mild to severe; and urogenital, rectal, and sciatic-like complaints and general nervousness may be associated.[3] It is more common in women than men.[4] A fall or similar trauma (as well as the birth process) may result in a sprain of the sacrococcygeal ligaments, with the resulting onset of symptoms. In the majority of cases, however, there is no specific identifiable cause, and the results of imaging studies are typically normal.[5] In the absence of well-defined pathologic conditions such as recent fracture, neoplasm, avascular necrosis, perineural cysts, or infectious diseases, a mechanical basis for the pain is most likely.

Different types of mechanical lesions may be involved in the production of coccygodynia. Like most examiners, Schafer[4] believes that frank misalignment of the coccyx itself represents the usual mechanical lesion. Maigne et al[6] reported that common coccygeal pain originates from instability of the coccygeal disk in up to 70% of cases, and more recently Maigne and Tamalet[2] noted that it occurs in 48.4% of patients with a luxation or hypermobility of the coccyx. Cox has proposed that coccygodynia may, in fact, be another manifestation of lumbar degenerative disc disease,[7] because it has been shown by Lora and Long[8] that stimulation of the L3-4, L4-5, and L5-S1 facets characteristically produces sensation or reproduces referred pain in the coccyx. Little research has investigated the exact mechanisms involved in coccygodynia, with most research on the area focusing on utilization of the coccygeal discs as controls for the biomechanical study of intervertebral disks.[9-11]

The treatment of coccygodynia varies and includes nonsteroidal anti-inflammatory drugs, use of doughnut cushion while sitting, local injection with corticosteroids, local anesthetic, manual manipulation, and even coccygectomy (in up to 20% of all cases).[5,12-14] A 1991 study by Wray[12] found physical therapy (comprised of ultrasound and diathermy) to be ineffective in treating coccygodynia, with better results noted by using corticosteroid injections and manipulation. Injections, however, are a delicate matter and can require fluoroscopic guidance for maximum effectiveness.[5]

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Prize-Winning Papers From the World Federation of Chiropractic 7th Biennial Congress

First Prize

Biomechanical and Neurophysiological Responses to Spinal Manipulation in Patients With Lumbar Radiculopathy

Christopher J. Colloca, DC,[a] Tony S. Keller, PhD,[b] and Robert Gunzburg, MD, PhD[c]

Abstract

Objective: The purpose of this study was to quantify in vivo vertebral motions and neurophysiological responses during spinal manipulation.

Methods: Nine patients undergoing lumbar decompression surgery participated in this study. Spinal manipulative thrusts (SMTs) (~5 ms; 30 N [Sham], 88 N, 117 N, and 150 N [max]) were administered to lumbar spine facet joints (FJs) and spinous processes (SPs) adjacent to an intraosseous pin with an attached triaxial accelerometer and bipolar electrodes cradled around the S1 spinal nerve roots. Peak baseline amplitude compound action potential (CAP) response and peak-peak amplitude axial (AX), posterior-anterior (PA), and medial-lateral (ML) acceleration time and displacement time responses were computed for each SMT. Within-subject statistical analyses of the effects of contact point and force magnitude on vertebral displacements and CAP responses were performed.

Results: SMTs (≥ 88 N) resulted in significantly greater peak-to-peak ML, PA, and AX vertebral displacements compared with sham thrusts ($P < .002$). SMTs delivered to the FJs resulted in approximately 3-fold greater ML motions compared with SPs ($P < .001$). SMTs over the SPs resulted in significantly greater AX displacements compared with SMTs applied to the FJs ($P < .05$). Seventy-five percent of SMTs resulted in positive CAP responses with a mean latency of 12.0 ms. Collectively, the magnitude of the CAP responses was significantly greater for max setting SMTs compared with sham ($P < .01$).

Conclusions: Impulsive SMTs in human subjects were found to stimulate spinal nerve root responses that were temporally related to the onset of vertebral motion. Further work, including examination of the frequency and force duration dependency of SMT, is necessary to elucidate the clinical relevance of enhanced or absent CAP responses in patients. (J Manipulative Physiol Ther 2004;27:1-15)

Key Indexing Terms: *Chiropractic Manipulation; Vertebral Motion; Neurophysiology*

Introduction

Because spinal manipulation (SM) is a mechanical intervention, it is inherently logical to assume that its mechanisms of therapeutic benefit may lie in the mechanical properties of the applied force (mechanical mechanisms), the body's response to such force (mechanical or physiologic mechanisms), or a combination of these and other factors. Basic science research, including biomechanical and neurophysiological investigations of the body's response to SM, therefore, should assist researchers, educators, and clinicians to understand the mechanisms of

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This study was presented at the 7th Biennial Congress of the World Federation of Chiropractic, Orlando, Florida, May 1-4, 2003 and received the Scott Haldeman Award—1st Prize in the international research paper competition.

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ORIGINAL ARTICLE

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Anterior thoracic posture increases thoracolumbar disc loading

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Abstract In the absence of external forces, the largest contributor to intervertebral disc (IVD) loads and stresses is trunk muscular activity. The relationship between trunk posture, spine geometry, extensor muscle activity, and the loads and stresses acting on the IVD is not well understood. The objective of this study was to characterize changes in thoracolumbar disc loads and extensor muscle forces following anterior translation of the thoracic spine in the upright posture. Vertebral body geometries (C2 to S1) and the location of the femoral head and acetabulum centroids were obtained by digitizing lateral, full-spine radiographs of 13 men and five women volunteers without previous history of back pain. Two standing, lateral, full-spine radiographic views were obtained for each subject: a neutral-posture lateral radiograph and a radiograph during anterior translation of the thorax relative to the pelvis (while keeping T1 aligned over T12). Extensor muscle loads, and compression and shear stresses acting on the IVDs, were calculated for each posture using a previously validated biomechanical model. Comparing vertebral centroids for the neutral posture to the anterior posture, subjects were able to anterior translate +101.5 mm±33.0 mm (C7–hip axis), +81.5 mm±39.2 mm (C7–S1) (vertebral centroid of C7 compared with a vertical line through the vertebral centroid of S1), and +58.9 mm±19.1 mm (T12–S1). In the anterior translated posture, disc loads and stresses were significantly increased for all levels below T9. Increases in IVD compressive loads and shear loads, and the corresponding stresses, were most marked at the L5–S1 level and L3–L4 level, respectively. The extensor muscle loads required to maintain static equilibrium in the upright posture increased from 147.2 N (mean, neutral posture) to 667.1 N (mean, translated posture) at L5–S1. Compressive loads on the anterior and posterior L5–S1 disc nearly doubled in the anterior translated posture. Anterior translation of the thorax resulted in significantly increased loads and stresses acting on the thoracolumbar spine. This posture is common in lumbar spinal disorders and could contribute to lumbar disc pathologies, progression of L5–S1 spondylolisthesis deformities, and poor outcomes after lumbar spine surgery. In conclusion, anterior trunk translation in the standing subject increases extensor muscle activity and loads and stresses acting on the intervertebral disc in the lower thoracic and lumbar regions.

Keywords Posture · Sagittal alignment · Intervertebral disc · Biomechanics · Spinal load

Active Trunk Extensor Contributions to Dynamic Posteroanterior Lumbar Spinal Stiffness

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Abstract

Background: Assessments of posteroanterior (PA) spinal stiffness using mobilization apparatuses have demonstrated an increase in PA spine stiffness during voluntary contraction of the lumbar extensor muscles; yet, little work has been done to this degree in symptomatic subjects.

Objective: To use a previously validated dynamic mechanical impedance procedure to quantify changes in PA dynamic spinal stiffness at rest and during lumbar isotonic extension tasks in patients with low back pain (LBP).

Methods: Thirteen patients with LBP underwent a dynamic spinal stiffness assessment in the prone-resting position and again during lumbar extensor efforts. Stiffness assessments were obtained using a handheld impulsive mechanical device equipped with an impedance head (load cell and accelerometer). PA manipulative thrusts ($\approx$150 N, <5 milliseconds) were delivered to skin overlying the L3 left and right transverse processes (TPs) and to the L3 spinous process (SP) in a predefined order (left TP, SP, right TP) while patients were at rest and again during prone-lying lumbar isotonic extension tasks. Dynamic spinal stiffness characteristics were determined from force and acceleration measurements using the apparent mass (peak force/peak acceleration, kg). Apparent mass measurements for the resting and active lumbar isotonic task trials of each patient were compared using a 2-tailed, paired *t* test.

Results: A significant increase in the PA dynamic spinal stiffness was noted for thrusts over the SP (apparent mass [17.0%], $P = .0004$) during isotonic trunk extension tasks compared with prone resting, but no statistically significant changes in apparent mass were noted for the same measures over the TPs.

Conclusions: These findings add support to the significance of the trunk musculature and spinal posture in providing increased spinal stability. (J Manipulative Physiol Ther 2004;27:229-237)

Key Indexing Terms: *Apparent Mass; Biomechanics; Electromyography; Low Back Pain; Lumbar Spine; Chiropractic; Manipulation; Muscle Coactivation; Stiffness; Stability*

Introduction

Maintenance of posture and performance of purposeful trunk motion are the result of coordinated load sharing between passive and active paraspinal tissues that act to balance the external loads.[1] Indeed, the spinal musculature plays a major role in spine stability.[2,3] Voluntary contraction of the erector spinae muscles acts to stiffen the intervertebral joints.[4] Physiologic deformation of the viscoelastic structures of the spine have also been shown to elicit active and reflexive muscular contraction of the multifidus and longissimus muscles, which, in turn, act to stiffen and stabilize the spine during movements.[5]

Disturbances in the musculoskeletal system that result in excessive load sharing, abnormal motion, and higher strains in the highly innervated lumbar spinal soft tissues have been suggested as possible causes of some low back disorders and chronic low back pain.[6,7] Clinically, increased levels of muscle coactivation may constitute an objective indicator of the dysfunction in the passive stabilizing system of the lumbar spine.[4] Biomechanical assessments that provide noninvasive estimates of spinal stiffness together with other objective tests and outcome measures may help clinicians to discriminate and treat patients with spinal disorders.[8]

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This study was presented, in part, at the 2000 International Conference on Spinal Manipulation, Bloomington, Illinois, September 21-23, 2000.

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ORIGINAL ARTICLES

A Rigid Body Model of the Dynamic Posteroanterior Motion Response of the Human Lumbar Spine

Tony S. Keller, PhD,[a] and Christopher J. Colloca, DC,[b]

Abstract

Background: Clinicians apply posteroanterior (PA) forces to the spine for both mobility assessment and certain spinal mobilization and manipulation treatments. Commonly applied forces include low-frequency sinusoidal oscillations (<2 Hz) as used in mobilization, single haversine thrusts (<0.5 seconds) as imparted in high-velocity, low-amplitude (HVLA) manipulation, or very rapid impulsive thrusts (<5 ms) such as those delivered in mechanical-force, manually-assisted (MFMA) manipulation. Little is known about the mechanics of these procedures. Reliable methods are sought to obtain an adequate understanding of the force-induced displacement response of the lumbar spine to PA forces.

Objective: The objective of this study was to investigate the kinematic response of the lumbar spine to static and dynamic PA forces.

Design: A 2-dimensional modal analysis was performed to predict the dynamic motion response of the lumbar spine.

Methods: A 5-degree-of-freedom, lumped equivalent model was developed to predict the PA motion of the lumbar spine. Lumbar vertebrae were modeled as masses, massless-spring, and dampers, and the resulting equations of motion were solved by using a modal analysis approach. The sensitivity of the model to variations in the spring stiffness and damping coefficients was examined, and the model validity was determined by comparing the results to oscillatory and impulsive force measurements of vertebral motion associated with spine mobilization and 2 forms of spinal manipulation.

Results: Model predictions, based on a damping ratio of 0.15 (moderate damping) and PA spring stiffness coefficient ranging from 25 to 60 kN/m, showed good agreement with in vivo human studies. Quasi-static and low-frequency (<2.0 Hz) forces at L3 produced L3 segmental and L3-L4 intersegmental displacements up to 8.1 mm and 3.0 mm, respectively. PA oscillatory motions were over 2.5-fold greater for oscillatory forces applied at the natural frequency. Impulsive forces produced much lower segmental displacements in comparison to static and oscillatory forces. Differences in intersegmental displacements resulting from impulsive, static, and oscillatory forces were much less remarkable. The latter suggests that intersegmental motions produced by spinal manipulation may play a prominent role in eliciting therapeutic responses.

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This study was presented at the 12th Conference of the European Society of Biomechanics, Dublin, Ireland, August 27-30, 2000.

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Intervertebral Disc Degeneration Reduces Vertebral Motion Responses

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Robert Gunzburg, MD, PhD,§ and Deed E. Harrison, DC||

Study Design. A prospective *in vivo* experimental animal study.

Objective. To determine the effects of disc degeneration and variable pulse duration mechanical excitation on dorsoventral lumbar kinematic responses.

Summary of Background Data. *In vitro* and *in vivo* biomechanical studies have examined spine kinematics during posteroanterior loading mimicking spinal manipulation therapy (SMT), but few (if any) studies have quantified SMT loading-induced spinal motion responses in the degenerated intervertebral disc.

Methods. Fifteen sheep underwent a survival surgical procedure resulting in chronic disc degeneration of the L1–L2 disc. Ten age- and weight-matched animals served as controls. Uniform pulse dorsoventral mechanical forces (80 N) were applied to the L3 spinous processes using 10-, 100-, and 200-ms duration pulses mimicking SMT. L3 displacement and L2–L1 acceleration in the control group were compared with the degenerated disc group.

Results. Dorsoventral displacements increased significantly (fivefold, $P < 0.001$) with increasing mechanical excitation pulse duration (control and degenerated disc groups). Displacements and L2–L1 acceleration transfer were significantly reduced (~19% and ~50%, respectively) in the degenerated disc group compared with control (100- and 200-ms pulse duration protocols, $P < 0.01$).

Conclusion. Dorsoventral vertebral motions are dependent on mechanical excitation pulse duration and are significantly reduced in animals with degenerated discs.

Key words: biomechanics, degeneration, intervertebral disc, manipulation, mobilization. **Spine 2007;32: E544–E550**

The intervertebral disc (IVD) is a known pain generator among patients with low back pain, and the IVD is therefore a primary target of intervention for clinicians applying manual therapies.[1] Progressive degenerative changes of the IVD are associated with increased age, trauma, and abnormal postural loading.[2] Indeed, a large proportion of the population who receive manual therapies have some degree of disc disease.[1] To influence the peripheral pain generator, patients with discogenic disease commonly undergo spinal manipulative therapy (SMT) with the primary goal of normalizing loads and improving spinal mobility.[3]

A wide range of manual techniques have been developed providing clinicians with choices of force amplitude, speed, and vector among other variables of SMT delivery in patient care. Force-time characteristics, including the applied force magnitude, speed, and/or frequency, have therefore been attributed to the underlying mechanisms of SMT.[4] Both *in vitro*[5,6] and *in vivo*[7,8] biomechanical studies have examined segmental and intersegmental displacements and vibration responses during SMT, but few (if any) studies have quantified SMT-induced spinal kinematics in the degenerated IVD.

The purpose of this experimental study was to examine the *in vivo* motion behavior of the normal disc and degenerated disc ovine lumbar spine subjected to varying mechanical excitation force-time profiles. Disc degeneration was established using a validated animal model.[9] We hypothesized that vertebral kinematics would be reduced in animals with disc degeneration.

Materials and Methods

Twenty-five adolescent Merino sheep (mean, 47.2 kg; SD, 5.1 kg) were examined. Fifteen sheep (mean, 47.7, kg; SD, 4.9 kg) underwent a survival surgical procedure designed to experimentally model chronic disc degeneration.[9] The remaining 10 animals (mean, 46.5 kg; SD, 5.6 kg) served as controls. Control and degenerated disc animals underwent a comprehensive biomechanical assessment designed to characterize segmental/intersegmental displacement/acceleration responses to varying force-time mechanical excitation protocols mimicking SMT. The disc degeneration procedure and biomechanical assessment protocol were approved by the Animal Ethics Committees and Institutional Review Board of the Institute of Medical and Veterinary Science (Adelaide, South Australia).

Disc Degeneration Model. Under general anesthesia (1 g thiopentone; 2.5% halothane), the lumbar spine was approached *via* a direct lateral left-side retroperitoneal approach. In each animal, a controlled stab incision was made in the left posterolateral anulus fibrosus midway between the endplates of the L1–L2 disc.[9] Incisions were made with a number-15 scalpel blade directed transversely through the outer aspect of the posterior anulus towards the midline and inserted to the hilt

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Validation of the Force and Frequency Characteristics of the Activator Adjusting Instrument: Effectiveness as a Mechanical Impedance Measurement Tool

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ABSTRACT

Objective: To determine the dynamic force-time and force-frequency characteristics of the Activator Adjusting Instrument and to validate its effectiveness as a mechanical impedance measurement device; in addition, to refine or optimize the force-frequency characteristics of the Activator Adjusting Instrument to provide enhanced dynamic structural measurement reliability and accuracy.

Methods: An idealized test structure consisting of a rectangular steel beam with a static stiffness similar to that of the human thoracolumbar spine was used for validation of a method to determine the dynamic mechanical response of the spine. The Activator Adjusting Instrument equipped with a load cell and accelerometer was used to measure forces and accelerations during mechanical excitation of the steel beam. Driving point and transfer mechanical impedance and resonant frequency of the beam were determined by use of a frequency spectrum analysis for different force settings, stylus masses, and stylus tips. Results were compared with beam theory and transfer impedance measurements obtained by use of a commercial electronic PCB impact hammer.

Results: The Activator Adjusting Instrument imparted a very complex dynamic impact comprising an initial high force (116 to 140 N), short duration pulse (<0.1 ms) followed by several lower force (30 to 100 N), longer duration impulses (1 to 5 ms). The force profile was highly reproducible in terms of the peak impulse forces delivered to the beam structure (<8% variance). Spectrum analysis of the Activator Adjusting Instrument impulse indicated that the Activator Adjusting Instrument has a variable force spectrum and delivers its peak energy at a frequency of 20 Hz. Added masses and different durometer stylus tips had very little influence on the Activator Adjusting Instrument force spectrum. The resonant frequency of the beam was accurately predicted by both the Activator Adjusting Instrument and electronic PCB impact hammer, but variations in the magnitude of the driving point impedance at the resonant frequency were high (67%) compared with the transfer impedance measurements obtained with the electronic PCB impact hammer, which had a more uniform force spectrum and was more repeatable (<10% variation). The addition of a preload-control frame to the Activator Adjusting Instrument improved the characteristics of the force frequency spectrum and repeatability of the driving point impedance measurements.

Conclusion: These findings indicate that the Activator Adjusting Instrument combined with an integral load cell and accelerometer was able to obtain an accurate description of a steel beam with readily identifiable geometric and dynamic mechanical properties. These findings support the rationale for using the device to assess the dynamic mechanical behavior of the vertebral biomechanical effectiveness of various manipulative, surgical, and rehabilitative spinal procedures. (J Manipulative Physiol Ther 1999;22:75-86)

Key Indexing Terms: Spine; Biomechanics; Chiropractic Manipulation

INTRODUCTION

Knowledge of spine segment, or functional spinal unit (FSU), motion patterns (kinematics) and forces (kinetics) is of importance for understanding the response of the spine to externally applied forces such as spinal manipulative therapy (SMT). SMT is generally considered to be therapeutic, but little is understood regarding the mechanisms of its positive treatment effects. To understand the biomechanical consequences of SMT more fully researchers are currently focusing on quantifying the applied forces and the response of the spine to these forces.[1-11]

During SMT, posterior to anterior (PA) forces can range from 50 to 550 N, depending on the procedure used.[1-11] Preload forces during these procedures can be as low as 20 N or as high as 200 N. In general, higher peak forces (up to 550 N) are associated with SMT of the sacroiliac joint, whereas lower peak forces have been demonstrated in SMT of the cervical spine.

In principle, a dysfunctional or unstable FSU may exhibit increased displacement or decreased stiffness compared with adjacent segments.[12] Consequently, the displacement of the FSU and the resistance of spinal tissues to applied forces during SMT may be potentially very useful in spinal diagnosis and for establishing effective treatment protocols. Ideally, measurements of the mechanical response of the

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ORIGINAL ARTICLE

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A non-randomized clinical control trial of Harrison mirror image methods for correcting trunk list (lateral translations of the thoracic cage) in patients with chronic low back pain

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Abstract Spinal trunk list is a common occurrence in clinical practice, but few conservative methods of spinal rehabilitation have been reported. This study is a non-randomized clinical control trial of 63 consecutive retrospective subjects undergoing spinal rehabilitation and 23 prospective volunteer controls. All subjects presented with lateral thoracic-cage-translation posture (trunk list) and chronic low back pain. Initial and follow-up numerical pain rating scales (NRS) and AP lumbar radiographs were obtained after a mean of 11.5 weeks of care (average of 36 visits) for the treatment group and after a mean of 37.5 weeks for the control group. The radiographs were digitized and analyzed for a horizontal displacement of T12 from the second sacral tubercle, verticality of the lumbar spine at the sacral base, and any dextro/levo angle at mid-lumbar spine. Treatment subjects received the Harrison mirror image postural correction methods, which included an opposite trunk-list exercise and a new method of opposite trunk-list traction. Control subjects did not receive spinal rehabilitation therapy, but rather self-managed their back pain. For the treatment group, there were statistically significant improvements (approximately 50%) in all radiographic measurements and a decrease in pain intensity (NRS: 3.0 to 0.8). For the control group, no significant radiographic and NRS differences were found, except in trunk-list displacement of T12 to S1, worsened by 2.4 mm. Mirror image (opposite posture) postural corrective exercises and a new method of trunk-list traction resulted in 50% reduction in trunk list and were associated with nearly resolved pain intensity in this patient population. The findings warrant further study in the conservative treatment of chronic low back pain and spinal disorders.

Keywords Exercise · Posture · Rehabilitation · Spine · Traction · Trunk List

SPINAL MANIPULATION REDUCES PAIN AND HYPERALGESIA AFTER LUMBAR INTERVERTEBRAL FORAMEN INFLAMMATION IN THE RAT

To the Editor:

We write to address some critical concerns regarding the article by Song et al.[1] A methodological flaw in their study was the use of the Activator III Adjusting Instrument (AAI3), a device designed for use in human patients, for application of spinal manipulative therapy (SMT) to the rat spine. The AAI3 produces peak forces ranging from 115 to 212 N depending on the device setting.[2] Assuming that the lowest setting was used, it corresponds to an applied force equivalent to more than 58 times the reported mass (200-250 g) of the rats! Considering that the average human individual weighs 70 kg, generalizing the forces that Song et al imparted to the rat would be the equivalent of applying approximately 40 000 N in human beings, which is 88 times greater than the highest forces administered in clinical practice. In our opinion, this is unreasonable and a fatal flaw in the study design.

The AAI3 does not produce a "<.01 ms thrust" as claimed by the authors and instead produces a pulse duration of 2 to 5 milliseconds. Its peak force is dependent on the applied preload and device setting.[2] Despite their specificity claims (p 12), there was no indication of how the segmental contact point was identified to apply assisted SMT (ASMT). Furthermore, the neoprene tip of the AAI3's stylus clearly encompasses at least two spinous processes of the rat lumbar spine (Fig 1, p 8). Regardless, the use of a stylus designed for use in human-scale spinal tissues compromises any claim concerning adjusting specificity.

The authors did not indicate how they controlled the 20-N preload of the AAI3. Indeed, simply applying a 20-N preload to a 200-g rat would be equivalent to applying a 10 body-weight force to a human being, which is on the order of 2 to 3 times greater than forces applied during lumbar spine manipulation in human beings.[3,4] This is another significant if not fatal flaw in the design of the said study.

Song et al did not quantify the actual applied ASMT forces and resultant spinal motions and thus cannot confirm whether ASMTs were actually delivered. Other neuro-mechanical studies have validated the applied forces and spinal motions produced during MFMA (mechanical force, manually assisted) SMT that Song et al did not incorporate.[5]

Specific SMT force vectors as minimal as 20° have been found to influence in vivo neuromechanical responses in human subjects.[6,7] Song et al reportedly applied the ASMT at a 40° to 50° rostral angle. What is the facet orientation in rats? The authors' argument that vertebral motion is the probable mechanism for their observed results is not supported in any manner. Lastly, the authors did not include a sham procedure, further limiting the interpretation of their study's results.

Song et al present a novel inflammatory model with precise methodology that is not carried through to their mechanical interventions. Unfortunately, the design flaws associated with the SMT intervention used in their study make the interpretation of their results untenable for any future basic science or clinical application.

Sincerely,

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Conflict of interest statement: Dr. Colloca is the majority shareholder of Neuromechanical Innovations, LLC, the manufacturer of the Impulse Adjusting Instrument. Drs. Colloca and Keller currently hold pending patents specific to the Impulse Adjusting Instrument, whose assignee is Neuromechanical Innovations, LLC.

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Prediction of Osteoporotic Spinal Deformity

Tony S. Keller, PhD,* Deed E. Harrison, DC,† Christopher J. Colloca, DC,‡
Donald D. Harrison, DC, PhD,§ and Tadeusz J. Janik, PhD||

Study Design. A biomechanical model was developed from full-spine lateral radiographs to predict osteoporotic spinal deformity in elderly subjects.

Objective. To investigate the biomechanics of age-related spinal deformity and concomitant height loss associated with vertebral osteoporosis.

Summary of Background Data. Vertebral bone loss and disc degeneration associated with aging causes bone and disc structures to weaken and deform as a result of gravity and postural stresses.

Methods. An anatomically accurate sagittal-plane, upright-posture biomechanical model of the anterior spinal column (C2–S1) was created by digitizing lateral full-spine radiographs of 20 human subjects with a mean height of 176.8 cm and a mean body weight of 76.6 kg. Body weight loads were applied to the model, after which intervertebral disc and vertebral body forces and deformation were computed and the new spine geometry was calculated. The strength and stiffness of the vertebral bodies were reduced according to an osteopenic aging model and modulus reduction algorithm, respectively.

Results. The most osteopenic model (L3 F_{ult} = 750 N) produced gross deformities of the spine, including anterior wedge-like fracture deformities at T7 and T8. In this model, increases in thoracic kyphosis and decreases in vertebral body height resulted in a 25.2% decrease in spinal height (C2-S1), an 8.6% decrease in total body height, and a 15.1-cm anterior translation of the C2 spine segment centroid. The resulting deformity qualitatively resembled deformities observed in elderly individuals with osteoporotic compression fractures.

Conclusions. These predictions suggest that postural forces are responsible for initiation of osteoporotic spinal deformity in elderly subjects. Vertebral deformities are exacerbated by anterior translation of the upper spinal column, which increases compressive loads in the thoracolumbar region of the spine. [Key words: biomechanicalmodeling, deformity, fracture, kyphosis, osteoporosis, posture, spine] **Spine 2003;28:455–462**

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Presented in part at the 2002 International Society for the Study of the Lumbar Spine, May 14–18, Cleveland, Ohio, and received the Sofamor Danek Group Oral Poster Presentation Award.
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In the United States, 10 million individuals have a diagnosis of osteoporosis. Another 18 million have low bone mass, which places them at increased risk for osteoporosis and fracture. It is estimated that 500,000 white women in the United States experience vertebral deformities for the first time each year, and that more than 7 million white women 50 years of age and older may be affected at any given time.[29] The cost for treatment of osteoporotic fracture is estimated to reach $15 billion annually.[31] Vertebral compression and compression–flexion fractures, particularly anterior wedge fractures in the middle and lower thoracic region, produce spinal deformities characterized by increased thoracic kyphosis and associated with significant performance impairments in physical, functional, and psychosocial domains.[12,28]

The normal spine is characterized by a thoracic kyphosis of approximately 40° when measured between T2 and T10.[4,9,19] A single anterior wedge fracture can increase thoracic kyphosis by 10° or more, and thoracic curves exceeding 70° are common in elderly subjects with multilevel compression fractures (Figure 1). In a study of 98 elderly, postmenopausal women, Cortet *et al*[5] reported a mean thoracic kyphosis increase of 11° in osteoporotic women with radiographic evidence of fracture, as compared with women who had no radiographic evidence of fracture (mean kyphosis, 52°). Moreover, the severity of thoracic kyphosis has been shown to increase with decreasing bone mineral density (BMD)[9] and anterior translation of the thorax.[17] In advanced osteoporosis, compression fractures of the thoracic vertebrae, particularly T6 and T7, result in a loss of vertebral height, wedging of several thoracic vertebrae, and formation of a kyphotic deformity or "Dowager's Hump."[37] This deformity often is associated with severe pain and loss of mobility.[12,28]

Given the fragility of osteoporotic vertebrae,[13] trauma is not necessarily a factor in the production of fractures in the thoracic spine. As postulated by Schmorl and Junghanns,[37] "the cause is usually to be found in the stresses of everyday life."(pg. 65) Thus, in the presence of osteoporosis, postural stresses alone are sufficient to produce collapse at the anterior margins of the thoracic vertebral bodies and the resulting wedge deformity.

Keller and Nathan[23] developed an upright-posture, sagittal-plane model of the C2–S1 spine, which they used to estimate disc forces and stresses as well as the concomitant diurnal changes in disc height and stature associated with upright posture loading. Vertebral body (VB) and intervertebral disc (IVD) geometries were modeled as quadrilaterals. Static equilibrium forces and moments were computed about each IVD centroid for forces asso-

Neuromechanical Characterization of In Vivo Lumbar Spinal Manipulation. Part II. Neurophysiological Response

Christopher J. Colloca, DC,[a] Tony S. Keller, PhD,[b] and Robert Gunzburg, MD, PhD[c]

Abstract

Objective: To simultaneously quantify vertebral motions and neuromuscular and spinal nerve root responses to mechanical force, manually assisted, short-lever spinal manipulative thrusts.

Methods: Four patients underwent lumbar laminarthrectomy to decompress the central spinal canal and neuroforamina, as clinically indicated. Prior to decompression, finely threaded, 1.8-mm diameter intraosseous pins were rigidly fixed to the lumbar spinous process (L1 or L3) using fluoroscopic guidance, and a high-frequency, low-noise, 10-g, triaxial accelerometer was mounted to the pin. Following decompression, 4 needle electromyographic (nEMG) electrodes were inserted into the multifidus musculature adjacent to the pin mount bilaterally, and 2 bipolar platinum electrodes were cradled around the left and right S1 spinal nerve roots. With the spine exposed, spinal manipulative thrusts were delivered internally to the lumbosacral spinous processes and facet joints and externally by contacting the skin overlying the respective spinal landmarks using 2 force settings ($\approx$ 30 N, $<$ 5 milliseconds (ms); $\approx$ 150 N, $<$ 5 ms) and 2 force vectors (posteroanterior and superior; posteroanterior and inferior).

Results: Spinal manipulative thrusts resulted in positive electromyographic (EMG) and compound action potential (CAP) responses that were typically characterized by a single voltage potential change lasting several milliseconds in duration. However, multiple EMG and CAP discharges were observed in numerous cases. The temporal relationship between the initiation of the mechanical thrust and the neurophysiologic response to internal and external spinal manipulative therapy (SMT) thrusts ranged from 2.4 to 18.1 ms and 2.4 to 28.6 ms for EMG and CAP responses, respectively. Neurophysiologic responses varied substantially between patients.

Conclusions: Vertebral motions and resulting spinal nerve root and neuromuscular reflex responses appear to be temporally related to the applied force during SMT. These findings suggest that intersegmental motions produced by spinal manipulation may play a prominent role in eliciting physiologic responses. (J Manipulative Physiol Ther 2003; 26:579-91)

Key Indexing Terms: *Biomechanics; Electromyography; Low Back Pain; Chiropractic Manipulation; Neurophysiology; Sciatica*

Introduction

In the understanding of musculoskeletal pain and the treatment of spinal disorders, basic science research has revealed a variety of pain generators in spinal tissues. The presence of mechanosensitive and nociceptive afferent fibers in spinal tissues (disk, facet, ligaments, and muscles)[1-5] and the subsequent neurophysiologic research demonstrating the role of such afferent stimulation in pain production[6-8] and coordinated neuromuscular stabilization of the spine[9-14] provide a theoretical framework to investigate the mechanisms of chiropractic adjustments or spinal manipulative therapy (SMT). The mechanical and physiologic influence of SMT on the targeted spinal tissues has recently begun to be quantified experimentally. An important first step in validating chiropractic theories is to quantify the mechanical and neurophysiologic responses that occur during chiropractic adjustments.

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Neuromechanical Characterization of in vivo Lumbar Spinal Manipulation. Part I. Vertebral Motion

Tony S. Keller, PhD,[a] Christopher J. Colloca, DC,[b] and Robert Gunzburg, MD, PhD[c]

Abstract

Objective: To quantify in vivo spinal motions and coupling patterns occurring in human subjects in response to mechanical force, manually assisted, short-lever spinal manipulative thrusts (SMTs) applied to varying vertebral contact points and utilizing various excursion (force) settings.

Methods: Triaxial accelerometers were attached to intraosseous pins rigidly fixed to the L1, L3, or L4 lumbar spinous process of 4 patients (2 male, 2 female) undergoing lumbar decompressive surgery. Lumbar spine acceleration responses were recorded during the application of 14 externally applied posteroanterior (PA) impulsive SMTs (4 force settings and 3 contact points) in each of the 4 subjects. Displacement time responses in the PA, axial (AX), and medial-lateral (ML) axes were obtained, as were intervertebral (L3-4) motion responses in 1 subject. Statistical analysis of the effects of facet joint (FJ) contact point and force magnitude on peak-to-peak displacements was performed. Motion coupling between the 3 coordinate axes of the vertebrae was examined using a least squares linear regression.

Results: SMT forces ranged from 30 N (lowest setting) to 150 N (maximum setting). Peak-to-peak ML, PA, and AX vertebral displacements increased significantly with increasing applied force. For thrusts delivered over the FJs, pronounced coupling was observed between all axes (AX-ML, AX-PA, PA-ML) (linear regression, $R^2 = 0.35\text{-}0.52$, $P < .001$), whereas only the AX and PA axes showed a significant degree of coupling for thrusts delivered to the spinous processes (SPs) (linear regression, $R^2 = 0.82$, $P < .001$). The ML and PA motion responses were significantly ($P < .05$) greater than the AX response for all SMT force settings. PA vertebral displacements decreased significantly ($P < .05$) when the FJ contact point was caudal to the pin compared with FJ contact cranial to the pin. FJ contact at the level of the pin produced significantly greater ML vertebral displacements in comparison with contact above and below the pin. SMTs over the spinous processes produced significantly ($P < .05$) greater PA and AX displacements in comparison with ML displacements. The combined ML, PA, and AX peak-to-peak displacements for the 4 force settings and 2 contact points ranged from 0.15 to 0.66 mm, 0.15 to 0.81 mm, and 0.07 to 0.45 mm, respectively. Intervertebral motions were of similar amplitude as the vertebral motions.

Conclusions: In vivo kinematic measurements of the lumbar spine during the application of SMTs over the FJs and SPs corroborate previous spinous process measurements in human subjects. Our findings demonstrate that PA, ML, and AX spinal motions are coupled and dependent on applied force and contact point. (J Manipulative Physiol Ther 2003;26:567-78)

Key Indexing Terms: *Acceleration; Biomechanics; Chiropractic; Kinematics; Lumbar Spine; Manipulation*

Introduction

As spinal manipulation (SM) and chiropractic adjustment continue to be investigated for their clinical outcomes, basic science research into the mechanisms of the interventions lag behind and remain poorly understood. Because spinal manipulation is a mechanical intervention, it is inherently logical to assume that its mechanisms of therapeutic benefit may lie in the mechanical properties of the applied force (mechanical mech-

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Research

Increased multiaxial lumbar motion responses during multiple-impulse mechanical force manually assisted spinal manipulation

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Abstract

Background: Spinal manipulation has been found to create demonstrable segmental and intersegmental spinal motions thought to be biomechanically related to its mechanisms. In the case of impulsive-type instrument device comparisons, significant differences in the force-time characteristics and concomitant motion responses of spinal manipulative instruments have been reported, but studies investigating the response to multiple thrusts (multiple impulse trains) have not been conducted. The purpose of this study was to determine multi-axial segmental and intersegmental motion responses of ovine lumbar vertebrae to single impulse and multiple impulse spinal manipulative thrusts (SMTs).

Methods: Fifteen adolescent Merino sheep were examined. Tri-axial accelerometers were attached to intraosseous pins rigidly fixed to the L1 and L2 lumbar spinous processes under fluoroscopic guidance while the animals were anesthetized. A hand-held electromechanical chiropractic adjusting instrument (Impulse) was used to apply single and repeated force impulses (13 total over a 2.5 second time interval) at three different force settings (low, medium, and high) along the posteroanterior axis of the T12 spinous process. Axial (AX), posteroanterior (PA), and medial-lateral (ML) acceleration responses in adjacent segments (L1, L2) were recorded at a rate of 5000 samples per second. Peak-peak segmental accelerations (L1, L2) and intersegmental acceleration transfer (L1–L2) for each axis and each force setting were computed from the acceleration-time recordings. The initial acceleration response for a single thrust and the maximum acceleration response observed during the 12 multiple impulse trains were compared using a paired observations t-test (POTT, alpha = .05).

Results: Segmental and intersegmental acceleration responses mirrored the peak force magnitude produced by the Impulse Adjusting Instrument. Accelerations were greatest for AX and PA measurement axes. Compared to the initial impulse acceleration response, subsequent multiple

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Increased multiaxial lumbar motion responses during multiple-impulse mechanical force manually assisted spinal manipulation

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Abstract

Background: Spinal manipulation has been found to create demonstrable segmental and intersegmental spinal motions thought to be biomechanically related to its mechanisms. In the case of impulsive-type instrument device comparisons, significant differences in the force-time characteristics and concomitant motion responses of spinal manipulative instruments have been reported, but studies investigating the response to multiple thrusts (multiple impulse trains) have not been conducted. The purpose of this study was to determine multi-axial segmental and intersegmental motion responses of ovine lumbar vertebrae to single impulse and multiple impulse spinal manipulative thrusts (SMTs).

Methods: Fifteen adolescent Merino sheep were examined. Tri-axial accelerometers were attached to intraosseous pins rigidly fixed to the L1 and L2 lumbar spinous processes under fluoroscopic guidance while the animals were anesthetized. A hand-held electromechanical chiropractic adjusting instrument (Impulse) was used to apply single and repeated force impulses (13 total over a 2.5 second time interval) at three different force settings (low, medium, and high) along the posteroanterior axis of the T12 spinous process. Axial (AX), posteroanterior (PA), and medial-lateral (ML) acceleration responses in adjacent segments (L1, L2) were recorded at a rate of 5000 samples per second. Peak-peak segmental accelerations (L1, L2) and intersegmental acceleration transfer (L1–L2) for each axis and each force setting were computed from the acceleration-time recordings. The initial acceleration response for a single thrust and the maximum acceleration response observed during the 12 multiple impulse trains were compared using a paired observations t-test (POTT, alpha = .05).

Results: Segmental and intersegmental acceleration responses mirrored the peak force magnitude produced by the Impulse Adjusting Instrument. Accelerations were greatest for AX and PA measurement axes. Compared to the initial impulse acceleration response, subsequent multiple

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Dynamic dorsoventral stiffness assessment of the ovine lumbar spine

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Abstract

Posteroanterior spinal stiffness assessments are common in the evaluating patients with low back pain. The purpose of this study was to determine the effects of mechanical excitation frequency on dynamic lumbar spine stiffness. A computer-controlled voice coil actuator equipped with a load cell and LVDT was used to deliver an oscillatory dorsoventral (DV) mechanical force to the L3 spinous process of 15 adolescent Merino sheep. DV forces (48 N peak, ~10% body weight) were randomly applied at periodic excitation frequencies of 2.0, 6.0, 11.7 and a 0.5–19.7 Hz sweep. Force and displacement were recorded over a 13–22 s time interval. The in vivo DV stiffness of the ovine spine was frequency dependent and varied 3.7-fold over the 0.5–19.7 Hz mechanical excitation frequency range. Minimum and maximum DV stiffness (force/displacement) were 3.86 ± 0.38 and 14.1 ± 9.95 N/mm at 4.0 and 19.7 Hz, respectively. Stiffness values based on the swept-sine measurements were not significantly different from corresponding periodic oscillations (2.0 and 6.0 Hz). The mean coefficient of variation in the swept-sine DV dynamic stiffness assessment method was 15%, which was similar to the periodic oscillation method (10–16%). The results indicate that changes in mechanical excitation frequency and animal body mass modulate DV spinal stiffness.

Keywords: Lumbar spine; Dynamic stiffness; Biomechanics; Sheep; Frequency

1. Introduction

Segmental instability and pathology of the spine are believed to produce abnormal patterns of motion and forces, which may play a significant role in the etiology of low back pain (LBP) (Nachemson, 1985). The ability to quantify in vivo spine segment motion (displacement) and stiffness (force/displacement) in response to forces is widely considered to be of clinical significance in the diagnosis and treatment of spinal disorders. Knowledge of spine segment motion patterns, forces and stiffness is also of fundamental interest in understanding the postural, time-dependent and dynamic response of the spine, the role of spinal implants in mechanical load sharing, and the response of the extremities (appendicular skeleton) and spine (axial skeleton) to externally posteroanterior (PA) applied forces such as spinal manipulation. Biomechanics researchers and therapists have therefore been seeking in vivo methods to assess the mechanical behavior of axial skeleton.

For spine testing, periodic excitation or oscillations with known frequency and magnitude is the most commonly used mechanical testing approach. Periodic excitation delivers large amounts of energy at each frequency, with a precisely controlled force. A number of studies have used low-frequency oscillatory or 'mobilization' devices to evaluate PA lumbar spinal stiffness in symptomatic and asymptomatic subjects (Kawchuk et al., 2001; Latimer et al., 1996a, b, 1998; Shirley et al., 2002; Kawchuk and Elliott, 1998). These studies indicate that the PA mechanical response of the lumbar spine is dependent upon many factors, including the intensity, direction, duration and frequency of the applied force. Of these factors, the frequency-dependent

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ORIGINAL ARTICLE

Muscular contributions to dynamic dorsoventral lumbar spine stiffness

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Abstract Spinal musculature plays a major role in spine stability, but its importance to spinal stiffness is poorly understood. We studied the effects of graded trunk muscle stimulation on the in vivo dynamic dorsoventral (DV) lumbar spine stiffness of 15 adolescent Merino sheep. Constant voltage supramaximal electrical stimulation was administered to the L3–L4 interspinous space of the multifidus muscles using four stimulation frequencies (2.5, 5, 10, and 20 Hz). Dynamic stiffness was quantified at rest and during muscle stimulation using a computer-controlled testing apparatus that applied variable frequency (0.46–19.7 Hz) oscillatory DV forces (13-N preload to 48-N peak) to the L3 spinous process of the prone-lying sheep. Five mechanical excitation trials were randomly performed, including four muscle stimulation trials and an unstimulated or resting trial. The secant stiffness (k_y = DV force/L3 displacement, kN/m) and loss angle (phase angle, deg) were determined at 44 discrete mechanical excitation frequencies. Results indicated that the dynamic stiffness varied 3.7-fold over the range of mechanical excitation frequencies examined (minimum resting $k_y = 3.86 \pm 0.38$ N/mm at 4.0 Hz; maximum $k_y = 14.1 \pm 9.95$ N/mm at 19.7 Hz). Twenty hertz muscle stimulation resulted in a sustained supramaximal contraction that significantly ($P < 0.05$) increased k_y up to twofold compared to rest (mechanical excitation at 3.6 Hz). Compared to rest, k_y during the 20 Hz muscle stimulation was significantly increased for 34 of 44 mechanical excitation frequencies (mean increase = 55.1%, $P < 0.05$), but was most marked between 2.55 and 4.91 Hz (mean increase = 87.5%, $P < 0.05$). For lower frequency, sub-maximal muscle stimulation, there was a graded change in k_y, which was significantly increased for 32/44 mechanical excitation frequencies (mean increase = 40.4%, 10 Hz stimulus), 23/44 mechanical excitation frequencies (mean increase = 10.5%, 5 Hz stimulus), and 11/44 mechanical excitation frequencies (mean increase = 4.16%, 2.5 Hz stimulus) when compared to rest. These results indicate that the dynamic mechanical behavior of the ovine spine is modulated by muscle stimulation, and suggests that muscle contraction plays an important role in stabilizing the lumbar spine.

Keywords Biomechanics · Electromyography · Lumbar spine · Dynamic stiffness · Muscle stimulation

This study was presented, in part, at the 31st Annual Meeting of the International Society for the Study of the Lumbar Spine, New York, NY, May 11–14, 2005.

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Report

A review of the literature pertaining to the efficacy, safety, educational requirements, uses and usage of mechanical adjusting devices Part 2 of 2

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Over the past decade, mechanical adjusting devices (MADs) were a major source of debate within the Chiropractors' Association of Saskatchewan (CAS). Since Saskatchewan was the only jurisdiction in North America to prohibit the use of MADs, the CAS established a committee in 2001 to review the literature on MADs. The committee evaluated the literature on the efficacy, safety, and uses of moving stylus instruments within chiropractic practice, and the educational requirements for chiropractic practice. Following the rating criteria for the evaluation of evidence, as outlined in the Clinical Guidelines for Chiropractic Practice in Canada *(1994), the committee reviewed 55 articles – all of which pertained to the Activator. Of the 55 articles, 13 were eliminated from the final study. Of the 42 remaining articles, 6 were rated as class 1 evidence; 11 were rated as class 2 evidence and 25 were rated as class 3 evidence.*

In this article – the second in a series of two – we review the results of uses and usage, safety and educational requirements. Of the 30 articles designated under the category of usage, 3 were rated as Class 1 evidence; 9 studies were classified as Class 2 evidence

Au cours de la dernière décennie, les appareils à mise au point mécanique (MAD) ont été une source majeure de débat au sein de l'Association des chiropraticiens de Saskatchewan (CAS). Comme la Saskatchewan était la seule juridiction nord-américaine à interdire l'utilisation des appareils à mise au point mécanique, l'Association a mis sur pied, en 2001, un comité chargé de revoir la documentation de ces appareils. Ce comité a évalué la documentation selon l'efficacité, la sécurité et l'utilisation d'instruments palpeurs mobiles dans la chiropractie et les exigences académiques de la pratique chiropratique. Suivant les critères d'évaluation lors de l'appréciation des preuves, tel que décrits dans les Directives cliniques des pratiques chiropratiques du Canada (1994), le comité a révisé 55 articles, tous en relation avec le Activator. Sur les 55 articles, 13 ont été éliminés de l'étude finale. Sur les 42 articles restants, 6 ont été classés dans les éléments de preuve de classe 1; 11 dans les éléments de preuve de classe 2; et 25 dans les éléments de classe 3.

Dans cet article, le second d'une série de deux, nous examinons les résultats de l'évaluation des utilisations, de la sécurité et des exigences scolaires. Sur les 30

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Report

A review of the literature pertaining to the efficacy, safety, educational requirements, uses and usage of mechanical adjusting devices
Part 1 of 2

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In this article – the first in a series of two – the background and the methods utilized by the MAD committee's activities are described, as well as the results for the review of the literature on efficacy. Of the 21 articles related to efficacy, five were identified as Class 1

Au cours de la dernière décennie, les appareils à mise au point mécanique (MAD) ont été une source majeure de débat au sein de l'Association des chiropraticiens de Saskatchewan (CAS). Comme la Saskatchewan était la seule juridiction nord-américaine à interdire l'utilisation des appareils à mise au point mécanique, l'Association a mis sur pied, en 2001, un comité chargé de revoir la documentation de ces appareils. Ce comité a évalué la documentation selon l'efficacité, la sécurité et l'utilisation d'instruments palpeurs mobiles dans la chiropractie et les exigences académiques de la pratique chiropratique. Suivant les critères d'évaluation lors de l'appréciation des preuves, tel que décrits dans les Directives cliniques des pratiques chiropratiques du Canada (1994), le comité a révisé 55 articles, tous en relation avec le Activator. Sur les 55 articles, 13 ont été éliminés de l'étude finale. Sur les 42 articles restants, 6 ont été classés dans les éléments de preuve de classe 1; 11 dans les éléments de preuve de classe 2; et 25 dans les éléments de classe 3.

Dans cet article, premier d'une série de deux, le contexte et les méthodes utilisées lors des activités du comité sur les appareils à mise au point mécanique ont

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evidence; 4 were identified as Class 2 evidence; and 12 were identified as Class 3. Overall, the committee reached consensus that the MAD procedures using the Activator were as effective as manual (HVLA) procedures in producing clinical benefit and biological change. A minority report was also written, arguing that there was not enough evidence to support or refute the efficacy of MADs.
(JCCA 2004; 48(1):74–88)

KEY WORDS: Activator, mechanical adjusting device.

été décrits, de même que les résultats de la révision de la documentation sur l'efficacité. Sur les 21 articles liés à l'efficacité, cinq ont été classés dans les éléments de preuve de classe 1, 4 dans les éléments de preuve de classe 2 et 12 dans les éléments de preuve de classe 3. Pour l'ensemble, le comité en est arrivé à un consensus : les méthodes des appareils à mise au point mécanique utilisant le Activator étaient aussi efficaces que les méthodes manuelles (HVLA) pour produire des avantages cliniques et des changements biologiques. Un rapport minoritaire a aussi été rédigé, expliquant qu'il n'y avait pas assez de preuves pour appuyer ou réfuter l'efficacité des appareils à mise au point mécanique.
(JACC 2004; 48(1):74–88)

MOTS CLÉS : Activator, appareils à mise au point mécanique.

Introduction

The use of Mechanical Adjusting Devices (MAD) in Saskatchewan has been debated for the past decade. The use of MADs in Saskatchewan is currently not sanctioned by the CAS as part of chiropractic scope of practice and contrary to Regulatory Bylaw 19(1)C which states that : **"no member shall use a machine or mechanical device as a substitute method of adjustment by hand of any one or more of the several articulations of the human body."** This has led to several motions and votes to change the bylaw to allow its use within the scope of practice in Saskatchewan. Saskatchewan is the only jurisdiction in North America which prohibits the use of mechanical adjusting devices. The membership has repeatedly voted against its use within the province, which has led to this review of the literature.

On June 2, 2001 at the Annual General Meeting of the Chiropractors' Association of Saskatchewan (CAS), a motion was passed to strike a committee to review the literature on the Activator and other mechanical adjusting devices. The motion read as follows:

> THAT, a separate committee be created within the Modes of Care committee to review the literature pertaining to the use of the Activator and other similar instruments. This committee shall provide a report to the CAS membership at least one month prior to the Fall General Meeting of 2001. A reasonably held minority opinion will also be allowed for in this report. The committee shall be comprised of 3 members of the Board's choosing and 3 members acceptable to the 42 members' who called for the special meeting in April, 2001. At least two of the members are to be female. No member of the Board since 1990 shall sit on this committee, nor shall any member directly involved in the lawsuit from either side.

This exclusion clause was included in the above motion because a group of practitioners sued the CAS when the Activator became an issue. Some members of the Board were named individually as defendants and others were involved as witnesses. It was felt that anyone involved in the lawsuit should be excluded from the MAD committee.

In the establishment of the committee, it became clear that there would be a significant cost of conducting a review of the literature, and therefore, the CAS allocated a budget for the MAD committee. In addition, a chairperson, who was named separately from the committee members, was responsible for the administration of the commitee. The chairperson would not hold voting privileges and served as a facilitator.

During the November of 2001 fall general meeting of the CAS, debate arose whether the committee should proceed or not and the motion was amended to read the following:

> THAT, the Activator committee evaluate the literature with the intent that they will report back to the membership with a recommendation on the efficacy, safety, uses and educational requirements/standards of mechanical adjusting devices for consideration for use in Saskatchewan and this to be accomplished, if possible, by May 1, 2002.

The motion was intended to direct the committee to evaluate the scientific literature concerning mechanical adjusting devices and provide a time line for filing the report. The motion was passed and the chairperson was given the budget and charged to proceed with the committee.

The committee consisted of the following:
Dr. Shane Taylor, Chair

Dr. John Triano	Dr. Dale Mierau
Dr. Lesley Biggs	Dr. Christopher Colloca
Dr. Nicole Arnold	Dr. Bruce Symons

The committee held several conference calls to determine the process they would follow and set the guidelines which they felt would best suit the needs of the members of the CAS, as well the needs of the committee members who were spread throughout North America.

Methods

Due to the fact that the members of this committee live throughout North America, teleconference and e-mail were considered the easiest and least expensive way to carry out the mandate of the committee.

It was agreed by the committee members that a conflict of interest statement which was signed by each committee member, would become part of the final report. (See Appendix A) One member raised a potential conflict of interest which was discussed within the group. It was agreed that this member should remain part of the process due to his/her expertise in this area.

At the outset, the committee decided that there needed to be agreement on exactly what the questions should be asked. After reviewing the CAS motion, the committee decided that the following questions needed to be answered:

> **What is the evidence in the literature on efficacy, safety, and uses of moving stylus instruments within chiropractic practice?**
>
> **If evidence exists, what are the educational requirements for moving stylus instruments within chiropractic practice?**

The committee agreed that each member would submit keywords for a literature search by February 8, 2002. The literature search was performed at the Canadian Memorial Chiropractic College utilizing the following keywords and searching MEDLINE, MANTIS, and CINAHL and the INDEX TO CHIROPRACTIC LITERATURE:

Literature Search for Mechanical Adjusting Devices Committee
March 2002

Index to Chiropractic Literature and Mantis

Subject terms searched:
Activator method
Chiropractic/adverse effects
Chiropractic/instrumentation
Chiropractic/methods
Diagnosis/instrumentation
Pettibon method

Keywords searched:
Activator
Instrumentation
Instruments
Stylus
Mechanical adjusting device(s)

CINAHL

Headings searched:
Chiropractic
Chiropractic assessment
Chiropractic manipulation

Text words searched:
Chiropract*
Activator*
Spinal manipulation
Mechanical adjusting device*
Integrator
Stylus

MEDLINE

MeSH terms used:
Electromyography
Manipulation, Spinal
Chiropractic/instrumentation

Text words searched:
Same as for the other indexes

The MAD Committee, via the CAS, invited the membership of the CAS to submit information for the committee's consideration by February 28, 2002. All information was to be sent directly to the chairperson. The committee decided not to accept newspaper articles, magazine articles, conference proceedings and journal articles that were not peer-reviewed. Dr. Colloca had an initial reference list[a] which he submitted to the group to use as a cross reference for material gathered. All new material was added to Dr. Colloca's list.

In total there were 55 pieces of evidence that were accepted for review. The committee decided that the chairperson would separate the literature into six equal parts and distribute 1/6th to each members of the committee. Each member classified each piece of evidence according to an agreed data extraction template (See Appendix B). The assessment of the evidence followed a procedure rating which answered to one of three statements: 1) That the evidence supports safety, uses, efficacy and educational requirements. 2) That evidence does NOT support safety, uses, efficacy and education requirements. 3) That there is NO evidence to support safety, uses, efficacy and educational requirements. The quality of the evidence was determined according to the rating guidelines in the Glenerin proceedings found in *Clinical Guidelines for Chiropractic Practice* in Canada 1994. The guidelines were amended (as identified in bold) to reflect the mandate of the committee

> Class 1: Evidence provided by one or more well-designed controlled clinical trials; or well-designed experimental studies that address reliability, validity, positive predictive value, discriminability, sensitivity, **efficacy or safety**.
>
> Class 2: Evidence provided by one or more well-designed uncontrolled, observational clinical studies, such as case-control, cohort studies, etc; or clinically relevant basic science studies that address reliability, validity, positive predictive value, discriminability, sensitivity, specificity, **efficacy or safety**; and published in refereed journals.
>
> Class 3: Evidence provided by expert opinion, descriptive studies or case reports **on the topics of safety or efficacy.**

Once completed, each member submitted their review to the chairperson who copied and sent out all the information to each member who, in turn, reviewed all pieces of evidence and determined whether they agreed or disagreed with the classification.

The committee then held a conference call to discuss and resolve points of dispute. There were nineteen articles disputed. Some disputes were minor word changes and others changed the class of evidence. The final classification for all nineteen were unanimously agreed upon and changed accordingly. The chairperson then took all of the information and formed evidence tables under the headings of SAFETY, USES OR USAGE, EFFICACY and EDUCATIONAL REQUIREMENTS. Utilizing these evidence tables, the members of the committee were asked to write an essay on the four topics indicating whether they thought there was enough evidence, not enough evidence or no evidence to support safety, uses or usage, efficacy and educational requirements.

a Dr. Colloca's original reference list included conference proceedings which were eliminated from the list. In addition, two letters to the editor were included on the reference list which unfortunately were included as part of the package that was sent out to the members. Upon discussion, the committee agreed that these letters would be included in the reference list but were not included as part of the study.

The committee decided beforehand how the vote would be interpreted in order to determine if the committee had reached consensus. If there was a vote of 4:2, then the committee had reached consensus. The two members who disagreed would be invited to submit a minority report to attach to the final report. If there was a tie (a tie meaning either a 3:3 or 2:2:2 split), then the committee had not reached consensus. If there was a 3:2:1 vote split after discussions, then three would be considered majority and a consensus had been reached. The others who voted 2:1 would be invited to give a minority report to attach to the final report.

The chairperson distributed the essays to each member for their review prior to the final conference call, at which time the committee voted on the questions regarding the safety, efficacy and uses of MAD. Before the voting took place, each question was discussed, giving each member an opportunity to provide a rationale for their point of view. Following voting, the members gave final instructions and guidance to the chairperson, who compiled the final report which was then submitted to committee members for their comments on style but not content.

Although the committee was asked to review all mechanical adjusting devices, only research about the Activator instrument was found utilizing the inclusion criteria established by the committee. Since no other mechanical adjusting device material was found , Activator Methods was the only device that the committee reviewed.

"The Activator Adjusting Instrument (Activator Methods, Inc., Phoenix, Ariz.) is a low-force, moving stylus-type of mechanical instrument. The AAI is powered by the fixed potential energy of a spring that propels a 16-g hammer into a 30–g stylus. The spring is compressed manually by squeezing a sliding handle located on the shank of the instrument, and at a predetermined point is activated, propelling the hammer into the stylus. An 80-durometer rubber tip is attached to the end of the stylus and reduces the impulse force shock delivered to the spine slightly when the instrument is activated."[26] AMCT. St. Louis: Mosby, 1997, p 447.

Statistics

Following the conference call discussing the classification of articles, the following statistics were extrapolated.

1) 55 articles were accepted for review.
2) 13 of them did not relate at all to the questions to be answered and were therefore not included in the evidence tables.
3) The 42 remaining articles were rated as follows:
   a. 6 were rated as class 1 evidence
   b. 11 were rated as class 2 evidence
   c. 25 were rated as class 3 evidence
4) 30 of the articles were related to usage or uses.
5) 20 of the articles related to efficacy.
6) 16 of the articles related to safety.
7) 5 of the articles related to educational standards.

Evidence tables[b] were created for each subcategory of efficacy, safety, usage or uses and educational standards.

The remainder of this article provides a review of the literature on the efficacy of MAD. The issues of safety, use and usage, and educational requirements will be discussed separately in a subsequent article appearing the JCCA.

Results

Summary of the literature on efficacy

Of the 21 studies examining efficacy either implicitly or explicitly, 4 were RCT and 1 was a cohort (Class 1 Evidence), 2 were experimental (Class 2 Evidence), 1 was a clinical trial (Class 2 evidence), 11 were case studies, 1 was a case series and 1 was a review of the literature.

Class 1 Evidence

Of the RCT studies, Wood, Colloca, Mathews (2001) compared standard Diversified Technique to Mechanical Force Manually Assisted (MFMA) manipulation in the treatment of cervical spine dysfunction in a sample of 30 patients.[1] These authors found no statistical differences between the two groups; both groups showed significant improvement after the treatment phase and at a one month follow-up. Cervical range of motion (ROM) showed statistically significant changes for both groups during the treatment phase, but the differences between groups was not significant at the end of treatment or one month following.

b The evidence tables can be found on the JCCA website; the references for efficacy, safety, use and usage, and educational requirements will be presented separately in the article reviewing these issues.

Keller and Colloca (2000) demonstrated that maximal voluntary contraction of the lumbar paraspinal musculature was increased according to electromylography (EMG) measurements following Activator adjusting.[2] It is uncertain if the patients were randomized into treatment, sham and control groups. But because of the nature of treatment, it would have been obvious to the control group that they were in fact the control. This article is an interesting demonstration of the various factors mechanical adjusting devices and potentially manual adjusting can effect.

In a pilot study ($n = 14$) of patients with unilateral neck pain, Yurkiw and Mior (1996) found no statistically significant differences on left and right lateral flexion scores, and VAS scores differences for patients receiving MAD and SMT treatments.[3] Although the trend was toward clinical improvement for both treatments, it was not statistically significant. The clinical significance and clinical relevance of the results of both of these studies are limited by the small sample sizes of subjects participating in the research protocol making them both prone to Type II error. A lack of the ability to blind the experimenters could be a source of experimenter bias. Similarly, Gemmell and Jacobson (1995) found in sample of 30 patients no statistical differences between Meric and Activator adjustments to reduce acute low back pain.[4]

Yates et al., (1988) conducted a study ($n = 21$) of patients with elevated blood pressure who were randomly assigned to one of three conditions, active treatment (which received a chiropractic adjustment delivered by an Activator); a placebo group (which received a sham adjustment delivered by an Activator delivered in the off position); a control group (which received no treatment).[5] The study found statistically significant differences between the Active Treatment Condition Group, and the placebo group and control group. Lower blood pressure readings were documented for the active treatment group. The study also reported lowered states of anxiety for the active treatment group and control groups but an elevated anxiety score for the placebo group. This study was prone to the placebo effect; however it is unclear whether or not the lower blood pressures and lowered states of anxiety were statistically significant.

The number of patients/subjects included in the studies of the effect of the activator instrument on musculoskeletal conditions:

	N	number treated with activator
Low Back Pain		
8. Keller and Colloca	40	20
31. Gemmel and Jacobson	30	15
	70	35
Cervical spine pain		
6. Wood Colloca Mathews	30	15
28. Yurkiw and Mior	14	7
	44	22
Total	114	57

When the data from the four Class I clinical studies was pooled, the total number of subjects treated with the activator instrument was 57; 35 subjects experienced cervical spine pain and 22 experienced low back pain.

Class 2 Evidence

Basic science research comprises two of the three studies rated as Class II Evidence. Symons et al., (2000) demonstrated physiologic responses associated with Instrument delivered spinal adjustments.[6] In a sample of 9 patients and 83 observations reported, Symons et al reported that thrusts delivered by an Activator instrument to the entire spine elicited an 68% positive response rate overall. However, positive responses varied across the spine ranging from 94% for sacroiliac SMT thrusts to 50% for cervical thrusts. They concluded that a reflex response elicited by treatment with an Activator instrument is quantitatively and qualitatively different than the response elicited by a manual treatment and that the physiologic and clinical relevance of the reflex response they observed remains unknown.

Herzog, Kawchuk and Conway (1993) attempted to quantify the pre-load and peak forces associated with moving stylus instruments and spinal manipulative therapy (SMT).[8] They reported no significant correlation between preload and ΔF forces for treatments using the Activator instrument in contrast to the four of the five manual techniques. A statistically significant correlation between preload and ΔF was found for the manual techniques.

A moving stylus device has been found to be effectively used in a research setting "detuned" as a placebo in a study by Hawk et al. (1999).[7] In a comparison of flexion-distraction table technique with the AAI set on 0 used to perform a sham adjustment, they found that VAS and GWBS scores improved with both treatments; a somewhat greater improvement occurred in most cases with the active treatment. This study was also subject to the placebo effect. That same cohort study ($n = 18$) indicates that the role of placebos needs to be examined more thoroughly.

Class 3 Evidence

In a descriptive case series study of 10 patients suffering whiplash, Osterbauer et al., (1992) reported a statistically significant decrease in overall mean pain scores and increased range of motion after treatment.[18] In case series study of 10 patients with low back pain, Osterbauer et al. (1993) found a statistically significant difference in VAS scores and Oswestry Index scores after receiving a MFMA SMT.[17] The majority, but not all patients, reported a decline in back pain and increased function; these improvements remained stable at a one year follow-up.

Improved clinical outcomes were reported in case reports of patients with post-surgical neck syndrome[9], ccocygodynia[10], lumbar disc herniation[11], frozen shoulder[13], frozen shoulder with metastatic carcinoma[14], plantar fascitis[15], torn medial meniscus[16], two cases of Bell's palsy[19], otitis media[20], and sciatic neuropathy and lumbar disc herniation[21]. Of these studies, 5 provided opinion that MFMA SMT may provide an alternative when there are contraindications to using manual SMT.[10,11,13–15]

Conclusion

After reviewing the literature and after much debate the committee reached consensus (4 to 2) that, while all of these studies are flawed to varying degrees and the literature is generally weak, the evidence in the literature supports the statement that MAD procedures using Activator are as effective as manual HVLA in producing clinical benefit and biological change. More research, particularly a larger scale randomized controlled trial, would be helpful in determining efficacy to a further degree.

MAD Minority Report

Submitted by Dale Mierau DC, MSc, FCCSC and Lesley Biggs, PhD

October 4, 2002

Introduction

As the Report indicates "the committee reached consensus that while all of these studies are flawed to varying degrees and the literature is generally weak in strength, the evidence in the literature supports the statement that MAD procedures using Activator are as effective as manual HVLA in producing clinical benefit and biological change."

We agree with the conclusion that "the studies are flawed to varying degrees" and that "the literature is generally weak in strength." Where we disagree is over the statement that "the evidence in the literature supports the statement that MAD procedures using Activator are as effective as manual HVLA in producing clinical benefit and biological change." Based on our reading of the literature, we believe that the findings of studies classified as Class I do not indicate MFMA as more or less efficacious than other SMT techniques. In total, only 56 subjects over 4 studies were treated with the Activator instrument in studies classified as Class 1. Of those 56, 10 had subacute neck pain (7 in Yurkiw and Mior, 1996; 3 in Wood et al., 2001), 12 had chronic neck pain (Wood et al., 2001) 14 had acute low back pain (Gemmell and Jackson, 1995), and the duration of the LBP was unknown for 20 (Keller et al., 2000).

The tally of subjects treated with the Activator instrument across the 4 studies was:

Neck Pain	
Acute neck pain	0
Subacute neck pain	10
Chronic neck pain	12
Total	22
Low Back Pain (LBP)	
Acute LBP	14
Subacute LBP	0
Chronic LBP	0
Unknown LBP	20
Total	34
Total spine pain	56
Other	
Blood pressure and anxiety	21
TOTAL	77

The review of the literature did not reveal any studies of the efficacy of MAD for patients with acute neck pain, subacute LBP or chronic LBP.

For studies with outcome measures that can be directly related to patient centered outcomes such as pain and function (omitting the study that used sEMG as the only outcome measure), the review of the literature documented results for 24 patients with neck pain (10 patients with subacute neck pain, 14 patients with chronic neck pain) and 14 patients with acute LBP were treated with MAD.

Smaller studies are, on average, conducted with less methodological rigor than larger studies. Trials of lower quality tend to show larger treatment effects (Schultz 1995, Moher 1998)

In our view, there is not enough evidence in the literature at this time to draw a definitive conclusion that MAD are more or less efficacious. Moreover, the limitations of the studies outlined by the authors themselves (see below) should not be taken lightly, and deserve consideration. In each of the 4 clinical studies, the authors present their findings as preliminary (i.e. as pilot studies) and call for a full-scale randomized controlled trial in order to verify their findings.

In the following sections, we present a more detailed analysis in support of our argument. We examine the types and strengths of evidence and its relationship to randomization; the relationship between statistical sources of error, statistical and clinical significance, effect size and sample size; measurement error; outcome measures; and a summary of the investigators' comments on the relevance of their work to clinical practice. Where applicable, we have included definitions of technical terms.

A. Types and Strength of Evidence

Strength of evidence	Method of study
Strongest	Randomized controlled trial
	Controlled clinical trial
	Comparative clinical trial
	Cohort study
	Case control study
	Case series
Weakest	Case report

A **randomized controlled trial** is without any doubt the best way to address questions of therapeutic efficacy. A random numbers table or some other mathematical method of randomization is used. Two or more groups are chosen at random, one receives the treatment and one does not. The only study in the literature reviewed that could be considered a full-scale randomized controlled trial was by Yates et al (1988).

Controlled clinical trials study at least one treatment and one control treatment with concurrent enrolment and follow-up of the test and control treated groups. The treatments to be administered are selected by a pseudo-random process, (e.g. a coin toss, odd-even numbers, medical record number). The Keller and Colloca (2000) study would likely have fallen into this category had they described their method of randomization of subjects.

A **comparative clinical trial** differs from a randomized control trial and a controlled clinical trial because it does not include an untreated control group. It is designed to compare two treatments by randomly allocating subjects to treatment groups. It is useful tool to compare treatments for a condition but it has limited strength because of the lack of an untreated control group. The trials published by Yurkiw and Mior (1996), Gemmel and Jacobson and Wood et al (1995) fall into this category.

For the purposes of this review, randomized controlled trials, controlled clinical trials and comparative clinical trials were assigned to the category of Class 1 evidence.

The Importance of Randomization

There are two important reasons for the use of caution when interpreting the results of non-randomized studies.

1 Randomization is the only way to control for unknown or unmeasured confounders. Non-randomized studies tend to overestimate the effects of health care intervention or treatment (Sacks et al., 1982; Chalmers et al., 1983; Schulz et al., 1995).

2 The inclusion of studies other than controlled trials in a review can increase the risk that the result of the review is influenced by publication bias (Dickersin and Min, 1993) or selection bias (Kunz et al., 1998).

It is appropriate to conduct a review of non-randomized studies of the effects of an intervention if the effects of the condition are so uniform or dramatic that it is unnecessary or unethical to wait for an RCT. The only method to establish confidence that a treatment if efficacious, without a randomized controlled trial, is in the circumstance that the treated condition is followed by, or results in, death. (Sackett et al., 1985).

In the absence of evidence from randomized controlled trials, it is incorrect to simply default to the best available evidence, such as weak cohort studies or case series (Sackett et al, 1985)[c].

B. The relationship between statistical sources of error, statistical and clinical significance, effect size and sample size

Conclusions from a study should not be considered as evidence of efficacy unless there are clear statistical and clinical differences between groups. The lack of a statistical difference in outcome measures between two or more groups (treated with different interventions in a small, uncontrolled study) does not allow one to reach a conclusion that the effect(s) of the interventions are equivalent. What follows is an explanation and rationale for this statement.

Definitions

Clinical significance refers to the practical importance of a reported difference in clinical outcomes between treated and control patients. It is usually expressed in terms of the size of the treatment effect.

Statistical significance is used to identify whether or not the results and conclusions drawn by the authors are likely to be true (regardless of the clinical importance or significance).

The two potential sources for statistical error are summarized in Table I (appendix A) (Sackett el. al., 1985: 183):

- a false positive result (cell x) is called a type I error. A type I error is easy to spot because the reported P value (or α as it is called before the study begins i.e. $p < .05$) is greater than 0.05 or 1 chance in 20. The smaller the reported p value, the more confident one can be that MAD is better than MM.
- an erroneous false negative conclusion is called a type II error (cell y). The size of the risk to arrive at this erroneous conclusion is called B.

By convention, investigators usually accept a 5% risk of drawing a false-positive type I error (a error of 0.05) and accept a 20% risk of concluding that the outcomes of the compared treatments do not produce different clinical outcomes when they really do (a false negative type II error of 0.20). If B is 0.20 then the power of the study is 1-B (80%).

The probability of arriving at a true positive conclusion when one is correct in doing so is called the power of the study.

The accepted settings for statistical risk are:

- the false positive risk (α) at 0.05
- the false negative risk (B) at 0.20.

To the risks of statistical error are added:

- the expected rate of outcome events for patients assigned to treatment and/or control groups.
- the degree of difference in outcomes that are considered clinically significant between treated and non treated groups or between two or more treated groups.
- the number of subjects in each group.

If one can estimate, 4 of the 5 variables, one can calculate the 5th. Pilot studies are done to allow investigators to more accurately predict or estimate some of the error variables. A larger sample size can counteract underestimation of the other sources of error including α and B.

Relevance

Three of the 5 studies categorized as Class 1 did not re-

c An example of the misuse of poor evidence is illustrated by an example of 'historical comparison' (not to be confused with 'historical controls'). Clinicians sometimes judge the efficacy of a modern treatment by comparing an experience with a new treatment to a former experience with older methods. An example cited by Sackett et al. is the rise and fall of the 'gastric freeze'. Sackett et al. 1985; p. 176–77). After reporting their results, the inventors and purveyors of a procedure called the 'gastric freeze' were pleased that their surgical service was inundated with patients who all reportedly did well after the procedure. Years later, a randomized controlled trial demonstrated that patients who underwent the 'gastric freeze' had more complications and did no better (and sometimes worse) than patients who underwent a sham treatment (Ruffin et al., 1969). The documentation of this experience speaks volumes about the confidence in new methods by patients and surgeons and highlights the importance of being careful about substituting a new untested treatment for a tested conventional one without compelling evidence from well-designed randomized controlled studies.

port a statistically significant difference between the MAD and MM groups. If the difference between MAD and MM is not statistically significant, were the trials large enough to show a clinically important difference if it was really there? This decision can be easily made with tables that provide sample size guidelines based on predetermined statistical criteria. (Sackett 1985:186–87).

Yurkiw and Mior (1996) estimated that a sample size of 150 subjects was required in each treatment group to adequately study the relative effects of MAD and MM on subacute neck pain. Gemmel and Jacobsen (1995) estimated that 1200 subjects in each treatment group were required to study the relative effects on acute low back pain. These sample sizes are far larger than the number of subjects used in the Yurkiw and Mior (1996), and Gemmel and Jacobsen (1995) studies.

This review of the literature did not identify published sample size estimates for the future investigation of acute neck pain, chronic neck pain, subacute low back pain and chronic low back pain with the MAD device. Clinical investigation of the treatment of these conditions with MAD still requires more investigation to estimate sample size.

C. Measurement Error

Wood et al., 2001: 264)) and Yurkiw and Mior (1996: 161) alerted readers to the precision, or lack of it, in the cervical range of motion measurement device (CROM). The CROM scale is in 2 degree increments. One could safely assume at least a +/- 2 degrees (4 degree total margin of error), although the margin of error could be greater due to error inherent in examiner testing as described by Yurkiw and Mior (1996).

D. Outcome Measures

Outcomes reported in clinical trials of efficacy should measure changes that are important to patients. At the Mercy Center Conference, in his discussion of selecting outcome measures when evaluating clinical interventions, Paul Shekelle (1993) emphasized that every effort should be made to base decisions regarding efficacy on ‘scientific demonstrations of benefit to patients.’ Further, he argued that ‘benefit to patients’ means outcomes that matter to patients such as ‘relief of pain or ability to resume usual activities.’ ‘Benefit to patients’ does not mean improvement in the results of diagnostic tests such as EMG or x-rays (Shekelle, 1993). One investigation, included as Class I evidence of efficacy, studied a treated group, a sham treated group and a control group (Keller and Colloca, 2000). The outcome measure used in the study (sEMG), while it may be of interest to those who study spinal pain, has no application to the treatment, or the outcome of a treatment for spinal pain. The results of this study do not support the efficacy of the Activator instrument because the outcome measure has no relevance to patients.

E. Sources of Error in Uncontrolled Studies, including Comparative Clinical Trials

Definitions

Placebo effect refers to the psychological or psycho physiological effects of a placebo; i.e. a patient’s need or tendency to report a treatment effect. A patient’s perception of the effects of a treatment can have an effect on the subject (placebo effect) that may be as profound or measurable as the treatment itself (Turner et al., 1994).

Hawthorne Effect refers to the tendency for subjects who are being watched or studied to perform in an unusual manner. Usually subjects perform at a higher level, or a level that the subject perceives to be better, when being watched or studied. The intangible effect of participating in a study (Hawthorne effect) can affect the results of such participation.

Relevance

Four studies compared MAD (in one case MAD set to 0 to provide a placebo treatment) to another intervention for spinal pain. In all four studies, there was documented improvement for the entire subject sample without a significant difference between the groups. (Yurkiw and Mior, 1996; Gemmell and Jacobson, 1995; Wood et al., 2001; Hawk et al; 1999.)

The study with the placebo treatment was a two-period crossover study of a sham adjustment with an Activator instrument (set to 0) and a flexion distraction technique. Both interventions demonstrated the same phenomenon; that is, improvement in outcome measures in both treated groups without a significant difference in outcomes between the groups (Hawk et al., 1999). The authors attributed the improvement in outcome measures of both groups without a significant difference between the groups to the placebo effect.

Three comparative clinical studies documented a very slight, but statistically significant improvement in outcome measures for both interventions, but no difference in outcome measures for the interventions individually or compared to one another (Yurkiw and Mior, 1996; Gemmell and Jacobson, 1995; Wood et al., 2001). Yurkiw and Mior (1996) mentioned the possibility of a placebo effect to explain the improvement in outcomes for both groups. Keller and Colloca (2000) couldn't attribute the positive changes in MVC lumbar sEMG changes directly to the Activator treatment. Wood et al. (2001) concluded that it was necessary to include an untreated control to understand the true clinical effects of the manipulative procedures. Gemmell and Jacobson (1995) discussed the possibility that subjects, knowing that they were involved in a research project, may have been biased toward reporting an expected reduction of pain. The design and results of these studies does not allow one to reach a conclusion about the efficacy of the treatments.

F. Summary of the Investigators' Comments on the Relevance of their Work to Clinical Practice

The review performed by the MAD committee was conducted to assess the present state of the literature on the efficacy of the Activator instrument. All clinical studies to date are described as inadequate to support a conclusion of efficacy by the authors who conducted the studies. We agree with these conclusions for the reasons given above. All the authors state that studies with more subjects, and an untreated control group, are required to draw conclusions regarding the relative efficacy of MAD in a clinical setting. To illustrate this point we submit the following:

1. Keller and Colloca (2000) reported a statistical difference between MAD treatment, sham treatment and a control group using sEMG as the outcome measure. The study was not randomized, the investigators were not blinded and the nature of the LBP was not documented (i.e. acute, subacute or chronic). The clinical significance and relevance of this finding should be carefully assessed. The value of the outcome measure used (sEMG) with respect to 'benefit to patients' is not known. To quote the authors:
   - 'a larger group size comparison is necessary to substantiate this finding.'
   - 'the positive changes in MVC lumbar sEMG output cannot be directly attributed to the SMT treatment alone ...'

2. Wood et al. (2001) stated in their conclusion: ' ... these results would have supported the use of MFMA (MAD) and HVLA (MM) manipulation for cervical spine dysfunction only if a control group had been studied with the investigation.'

3. Yurkiw and Mior (1996) identified their results as not statistically significant and recommended modifications for future study including a larger sample size. Their sample size estimate was for at least 150 subjects in each group.

4. Gemmell and Jacobsen (1995) documented no difference in relative effectiveness between MAD and MM. They implicated a Type II error and recommend that 'judgment be suspended until the study can be repeated by other researchers.'

5. Yates et al. (1988) authored a study that was sound in design and recommendations for future study. It is a shame that the work was not carried forward.

G. Conclusion

Conclusions regarding the strength of published evidence for efficacy of a treatment can be subjected to the following 5 considerations (Hill, 1971):

1. How good is the quality of the reviewed trials?
   The committee agreed unanimously that the quality of the reviewed trials was weak.
2. How large and significant are the observed effects?
   The observed effects were not large. Rather, relative to the hypotheses, they were insignificant.
3. How consistent are the effects across trials?
   The lack of a significant difference between compared treatments was consistent across trials.
4. Is there a clear dose-response relationship?
   A dose-response relationship was not discussed in any of the reviewed trials.
5. Is there indirect evidence that supports the inference?

Indirect evidence (i.e. both interventions improved scores on outcome measures) was present and it was discussed, but the indirect evidence (improvement in outcome measures for both treatments (including a de-tuned Activator) was not specific to either intervention.

6. Have other plausible competing explanations of the observed effects (e.g. bias or co-intervention) been ruled out?

Plausible competing explanations for the observed effects are presented above.

We submit that the deliberations of this committee overestimated the validity and clinical relevance of the literature reviewed about the Activator instrument. We feel compelled to put forward the position, that a larger, robust randomized controlled trial is necessary to support the conclusion of a level of efficacy equivalent to that of manual manipulation/adjustment for the treatment of spinal pain/dysfunction.

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Appendix A

Disclosure of Potential Conflict of Interest

For the CAS MAD Committee

Having an interest or affiliation with a corporate organization which is involved in the manufacture of, training for or marketing of mechanical adjusting devices may not prevent a member from participating in the MAD Committee. This relationship or affiliation, however, must be disclosed in advance to MAD Committee and the CAS.

Although it is impossible to list every circumstance which could potentially result in a conflict of interest, the following will serve as a guide to the types of activities or conditions which should be reported:

- **To hold, directly, or indirectly, a position with a commercial company for which payment or financial reward is received.**
- **To render directive, managerial, or consultative services to a company.**
- **To accept substantial entertainment, favours, or rewards from a company.**
- **To have a significant stockholding or other material interests in which performance of the company effects financial gain.**
- **To receive payment for presentations made on behalf of a company, i.e., payment for service on speaker's bureaus, etc.**

Name of Committee: MAD committee membership and deliberations
Date of Activity: 2001–2002
Name of MAD Committee Member:

PLEASE COMPLETE AND SIGN ON THE SIGNATURE LINE BELOW

I certify that I do not have now, nor have ever had, any financial interest in the subject matter to be reviewed by the MAD Committee that was struck by the Chiropractors' Association of Saskatchewan; not do I have now nor have ever had any affiliation with, or involvement in, any organization or entity with a direct financial interest in the subject matter to be reviewed by the MAD Committee.

_____ I do not now, nor have I ever had a conflict of interest

_____ I do now, or have had in the past a financial interest, affiliation with, or involvement in any organization or entity with a direct financial interest in the subject matter to be reviewed by the MAD Committee, the details of which are disclosed below.

If you have now or have you ever had a financial interest in the subject matter to be reviewed by the MAD Committee that was struck by the Chiropractors' Association of Saskatchewan; or any affiliation with, or involvement in, any organization or entity with a direct financial interest in the subject matter to be reviewed by the MAD Committee including financial interest or affiliation with (1) the manufacturer of any products, devices or services to be discussed in your presentation at this activity; or (2) with any of the companies providing commercial support for this activity, please identify your involvement below.

Affiliation or Financial Interest	**Name of Company/Organization**
Grant or Research Support	______________________________
Employee or Paid Consultant	______________________________
Speaker's Bureau	______________________________
Stock/Investment Holder	______________________________
Other	______________________________

Signature of Committee Member: **Date:**

Appendix B

AUTHOR(S):
TITLE:

JOURNAL (YEAR/VOLUME/PAGES):

Answer all questions in cell E
Answer yes = Y no = N or does not apply = N/A

DOES THIS STUDY ADDRESS USE OR USAGE?

DOES THIS STUDY ADDRESS EFFICACY?

DOES THIS STUDY ADDRESS SAFETY?

DOES THIS STUDY ADDRESS EDUCATIONAL REQUIREMENTS?

NOTES:

SPECIFIC INFORMATION

STUDY CHARACTERISTICS:
VERIFICATION OF STUDY ELIGIBILITY:
Correct population, interventions, outcome and study design

POPULATION CHARACTERISTICS
1) target population (describe)
2) inclusion criteria
3) exclusion criteria
4) recruitment procedures used
5) characteristics of participants
6) number of participants
7) were interventions and control groups comparable?

METHODOLOGICAL QUALITY OF STUDY
1) DESIGN OF THE STUDY:
A) RCT
B) COHORT STUDY
C) CASE STUDY
D) CASE CONTROL
E) EXPERIMENTAL

INTERVENTIONS
1) TYPE OF INTERVENTION
2) OR DESCRIPTION OF TEST

OUTCOMES, OUTCOME MEASURES
1) WHAT WAS MEASURED AT BASELINE?
2) WHAT WAS MEASURED AFTER THE INTERVENTION?
3) WHO CARRIED OUT THE MEASUREMENT?
4) WHAT WAS THE MEASUREMENT TOOL?
5) WAS/WERE THE TOOL VALIDATED AND HOW?

ANALYSIS
1) STATISTICAL TECHNIQUE USED?
2) DOES TECHNIQUE ADJUST FOR CONFOUNDING?
3) UNIT OF ANALYSIS?
4) ATTRITION RATE?

RESULTS
1) QUANTITATIVE RESULTS?
2) EFFECT OF THE INTERVENTION ON THE OTHER MEDIATING VARIABLES?
3) QUALITATIVE RESULTS?
4) COST OF INTERVENTION?
5) COST EFFECTIVENESS?

CLASS OF EVIDENCE (1, 2, 3):

ARTICLES THAT FALL INTO CLASS 1 SHOULD BE FURTHER ASSESSED USING THE FOLLOWING:
Mark cell under your choice with an X.

WAS THE ASSIGNMENT TO THE TREATMENT REALLY RANDOM?
ADEQUATE PARTIAL INADEQUATE UNKNOWN

WAS THE TREATMENT ALLOCATION CONCEALED?
ADEQUATE INADEQUATE UNKNOWN

WERE THE GROUPS SIMILAR AT BASELINE REGARDING THE PROGNOSTIC FACTORS?
REPORTED UNKNOWN

WERE THE ELIGIBILITY CRITERIA SPECIFIED?
ADEQUATE PARTIAL INADEQUATE UNKNOWN

WERE OUTCOME ASSESSORS BLINDED TO THE TREATMENT ALLOCATION?
ADEQUATE INADEQUATE UNKNOWN

WAS THE CARE PROVIDER BLINDED?
ADEQUATE PARTIAL INADEQUATE UNKNOWN

WAS THE PATIENT BLINDED?
ADEQUATE PARTIAL INADEQUATE UNKNOWN

WERE THE POINT ESTIMATES AND MEASURE OF VARIABILITY PRESENTED FOR THE PRIMARY OUTCOME MEASURE
ADEQUATE PARTIAL INADEQUATE UNKNOWN

DID THE ANALYSIS INCLUDE AN INTENTION TO TREAT ANALYSIS?
ADEQUATE PARTIAL INADEQUATE UNKNOWN

DEALING WITH MISSING VALUES
ADEQUATE PARTIAL INADEQUATE UNKNOWN

LOSS TO FOLLOW UP
ADEQUATE PARTIAL INADEQUATE UNKNOWN

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Report

A review of the literature pertaining to the efficacy, safety, educational requirements, uses and usage of mechanical adjusting devices Part 1 of 2

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Over the past decade, mechanical adjusting devices (MADs) were a major source of debate within the Chiropractors' Association of Saskatchewan (CAS). Since Saskatchewan was the only jurisdiction in North America to prohibit the use of MADs, the CAS established a committee in 2001 to review the literature on MADs. The committee evaluated the literature on the efficacy, safety, and uses of moving stylus instruments within chiropractic practice, and the educational requirements for chiropractic practice. Following the rating criteria for the evaluation of evidence, as outlined in the Clinical Guidelines for Chiropractic Practice in Canada *(1994), the committee reviewed 55 articles – all of which pertained to the Activator. Of the 55 articles, 13 were eliminated from the final study. Of the 42 remaining articles, 6 were rated as class 1 evidence; 11 were rated as class 2 evidence and 25 were rated as class 3 evidence.*

In this article – the first in a series of two – the background and the methods utilized by the MAD committee's activities are described, as well as the results for the review of the literature on efficacy. Of the 21 articles related to efficacy, five were identified as Class 1

Au cours de la dernière décennie, les appareils à mise au point mécanique (MAD) ont été une source majeure de débat au sein de l'Association des chiropraticiens de Saskatchewan (CAS). Comme la Saskatchewan était la seule juridiction nord-américaine à interdire l'utilisation des appareils à mise au point mécanique, l'Association a mis sur pied, en 2001, un comité chargé de revoir la documentation de ces appareils. Ce comité a évalué la documentation selon l'efficacité, la sécurité et l'utilisation d'instruments palpeurs mobiles dans la chiropractie et les exigences académiques de la pratique chiropratique. Suivant les critères d'évaluation lors de l'appréciation des preuves, tel que décrits dans les Directives cliniques des pratiques chiropratiques du Canada (1994), le comité a révisé 55 articles, tous en relation avec le Activator. Sur les 55 articles, 13 ont été éliminés de l'étude finale. Sur les 42 articles restants, 6 ont été classés dans les éléments de preuve de classe 1; 11 dans les éléments de preuve de classe 2; et 25 dans les éléments de classe 3.

Dans cet article, premier d'une série de deux, le contexte et les méthodes utilisées lors des activités du comité sur les appareils à mise au point mécanique ont

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ELSEVIER

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THE SPINE JOURNAL

Influence of spine morphology on intervertebral disc loads and stresses in asymptomatic adults: implications for the ideal spine

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Abstract

BACKGROUND CONTEXT: Sagittal profiles of the spine have been hypothesized to influence spinal coupling and loads on spinal tissues.

PURPOSE: To assess the relationship between thoracolumbar spine sagittal morphology and intervertebral disc loads and stresses.

STUDY DESIGN: A cross-sectional study evaluating sagittal X-ray geometry and postural loading in asymptomatic men and women.

PATIENT SAMPLE: Sixty-seven young and asymptomatic subjects (chiropractic students) formed the study group.

OUTCOME MEASURES: Morphological data derived from radiographs (anatomic angles and sagittal balance parameters) and biomechanical parameters (intervertebral disc loads and stresses) derived from a postural loading model.

METHODS: An anatomically accurate, sagittal plane, upright posture, quadrilateral element model of the anterior spinal column (C2-S1) was created by digitizing lateral full-spine X-rays of 67 human subjects (51 males, 16 females). Morphological measurements of sagittal curvature and balance were compared with intervertebral disc loads and stresses obtained using a quadrilateral element postural loading model.

RESULTS: In this young (mean 26.7, SD 4.8 years), asymptomatic male and female population, the neutral posture spine was characterized by an average thoracic angle (T1-T12)=+43.7° (SD 11.4°), lumbar angle (T12-S1)=−63.2° (SD 10.0°), and pelvic angle=+49.4° (SD 9.9°). Sagittal curvatures exhibited relatively broad frequency distributions, with the pelvic angle showing the least variance and the thoracic angle showing the greatest variance. Sagittal balance parameters, C7-S1 and T1-T12, showed the best average vertical alignment (5.3 mm and −0.04 mm, respectively). Anterior and posterior disc postural loads were balanced at T8-T9 and showed the greatest difference at L5-S1. Disc compressive stresses were greatest in the mid-thoracic region of the spine, whereas shear stresses were highest at L5-S1. Significant linear correlations ($p<.001$) were found between a number of biomechanical and morphological parameters. Notably, thoracic shear stresses and compressive stresses were correlated to T1-T12 and T4-hip axis (HA) sagittal balance, respectively, but not to sagittal angles. Lumbar shear stresses and body weight (BW) normalized shear

FDA device/drug status: not applicable.

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This study was presented, in part, at the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine, Vancouver, British Columbia, Canada, May 13–17, 2003.

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INCREASING THE CERVICAL LORDOSIS WITH CHIROPRACTIC BIOPHYSICS SEATED COMBINED EXTENSION-COMPRESSION AND TRANSVERSE LOAD CERVICAL TRACTION WITH CERVICAL MANIPULATION: NONRANDOMIZED CLINICAL CONTROL TRIAL

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ABSTRACT

Background: Cervical lordosis has been shown to be an important outcome of care; however, few conservative methods of rehabilitating sagittal cervical alignment have been reported.

Objective: To study whether a seated, retracted, extended, and compressed position would cause tension in the anterior cervical ligament, anterior disk, and muscle structures, and thereby restore cervical lordosis or increase the curvature in patients with loss of the cervical lordosis.

Study Design: Nonrandomized, prospective, clinical control trial.

Methods: Thirty preselected patients, after diagnostic screening for tolerance to cervical extension with compression, were treated for the first 3 weeks of care using cervical manipulation and a new type of cervical extension-compression traction (vertical weight applied to the subject's forehead in the sitting position with a transverse load at the area of kyphosis). Pretreatment and posttreatment Visual Analogue Scale (VAS) pain ratings were compared along with pretreatment and posttreatment lateral cervical radiographs analyzed with the posterior tangent method for changes in alignment. Results are compared to a control group of 33 subjects receiving no treatment and matched for age, sex, weight, height, and pain.

Results: Control subjects reported no change in VAS pain ratings and had no statistical significant change in segmental or global cervical alignment on comparative lateral cervical radiographs (difference in all angle mean values $<$ 1.3°) repeated an average of 8.5 months later. For the traction group, VAS ratings were 4.1 pretreatment and 1.1 posttreatment. On comparative lateral cervical radiographs repeated after an average of 38 visits over 14.6 weeks, 10 angles and 2 distances showed statistically significant improvements, including anterior head weight bearing (mean improvement of 11 mm), Cobb angle at C2-C7 (mean improvement of $-13.6°$), and the angle of intersection of the posterior tangents at C2-C7 (mean improvement of 17.9°). Twenty-one (70%) of the treatment group subjects were followed for an additional 14 months; improvements in cervical lordosis and anterior weight bearing were maintained.

Conclusions: Chiropractic biophysics (CBP) technique's extension-compression 2-way cervical traction combined with spinal manipulation decreased chronic neck pain intensity and improved cervical lordosis in 38 visits over 14.6 weeks, as indicated by increases in segmental and global cervical alignment. Anterior head weight-bearing was reduced by 11 mm; Cobb angles averaged an increase of 13° to 14°; and the angle of intersection of posterior tangents on C2 and C7 averaged 17.9° of improvement. (J Manipulative Physiol Ther 2003;26:139-51)

Key Indexing Terms: *Cervical Vertebrae; Lordosis; Traction; Posture; X-Ray; Kyphosis; Rehabilitation*

INTRODUCTION

Neck pain is becoming increasingly prevalent in today's society.[1,2] In a recent 10-year follow-up of 200 asymptomatic subjects, Gore[1] reported an incidence of 15% for the development of neck pain. Neck pain has multiple causes including tumor, infection, trauma, spinal degeneration, and mechanical factors. Concerning mechanical factors, the configuration of the sagittal cervical curve has been shown to be an important clinical outcome

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Comparison of Mechanical Force of Manually Assisted Chiropractic Adjusting Instruments

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Abstract

Objective: To quantify the force-time and force-delivery characteristics of six commonly used handheld chiropractic adjusting devices.

Methods: Four spring-loaded instruments, the Activator Adjusting Instrument; Activator II Adjusting Instrument, Activator III Adjusting Instrument, and Activator IV Adjusting Instrument, and two electromechanical devices, the Harrison Handheld Adjusting Instrument and Neuromechanical Impulse Adjusting Instrument, were applied to a dynamic load cell. A total of 10 force-time histories were obtained at each of three force excursion settings (minimum to maximum) for each of the six adjusting instruments at preload of approximately 20 N.

Results: The minimum-to-maximum force excursion settings for the spring-loaded mechanical adjusting instruments produced similar minimum-to-maximum peak forces that were not appreciably different for most excursion settings. The electromechanical adjusting instruments produced short duration (~2-4 ms), with more linear minimum-to-maximum peak forces. The force-time profile of the electromechanical devices resulted in a more uniform and greater energy dynamic frequency response in comparison to the spring-loaded mechanical adjusting instruments.

Conclusions: The handheld, electromechanical instruments produced substantially larger peak forces and ranges of forces in comparison to the handheld, spring-loaded mechanical devices. The electromechanical instruments produced greater dynamic frequency area ratios than their mechanical counterparts. Knowledge of the force-time history and force-frequency response characteristics of spinal manipulative instruments may provide basic benchmarks and may assist in understanding mechanical responses in the clinical setting. (J Manipulative Physiol Ther 2005;28:414-422)

Key Indexing Terms: *Biomechanics; Chiropractic; Spine*

Spinal manipulation is the most commonly performed therapeutic procedure provided by doctors of chiropractic.[1] Chiropractic techniques have evolved to provide the clinician with choices in the delivery of particular force-time profiles deemed appropriate for a patient or condition. Clinicians rely on mechanical advantages in performing spinal manipulation through patient positioning, mechanical assistance from a table, or handheld instruments.[2] Specifically, manual articular manipulative and adjusting procedures have been classified into four categories to better describe the technique and mechanism of force production: specific contact thrust procedures using

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This research was presented, in part, at the 6th Biennial Congress of the World Federation of Chiropractic, Palais des Congrès, Paris, France, May 24-26, 2001.

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ORIGINAL ARTICLE

Effect of a novel interspinous implant on lumbar spinal range of motion

Robert Gunzburg · Marek Szpalski · Stuart A. Callary · Christopher J. Colloca · Victor Kosmopoulos · Deed Harrison · Robert J. Moore

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Abstract Interspinous devices have been introduced to provide a minimally invasive surgical alternative for patients with lumbar spinal stenosis or foraminal stenosis. Little is known however, of the effect of interspinous devices on intersegmental range of motion (ROM). The aim of this in vivo study was to investigate the effect of a novel minimally invasive interspinous implant, InSwing®, on sagittal plane ROM of the lumbar spine using an ovine model. Ten adolescent Merino lambs underwent a destabilization procedure at the L1–L2 level simulating a stenotic degenerative spondylolisthesis (as described in our earlier work; Spine 15:571–576, 1990). All animals were placed in a side-lying posture and lateral radiographs were taken in full flexion and extension of the trunk in a standardized manner. Radiographs were repeated following the insertion of an 8-mm InSwing® interspinous device at L1–L2, and again with the implant secured by means of a tension band tightened to 1 N/m around the L1 and L2 spinous processes. ROM was assessed in each of the three conditions and compared using Cobb's method. A paired *t*-test compared ROM for each of the experimental conditions ($P < 0.05$). After instrumentation with the InSwing® interspinous implant, the mean total sagittal ROM (from full extension to full flexion) was reduced by 16% from 6.3° to 5.3 ± 2.7°. The addition of the tension band resulted in a 43% reduction in total sagittal ROM to 3.6 ± 1.9° which approached significance. When looking at flexion only, the addition of the interspinous implant without the tension band did not significantly reduce lumbar flexion, however, a statistically significant 15% reduction in lumbar flexion was observed with the addition of the tension band ($P = 0.01$). To our knowledge, this is the first in vivo study radiographically showing the advantage of using an interspinous device to stabilize the

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Force-Time Profile Characterization of the McTimoney Toggle-Torque-Recoil Technique

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Abstract

Objectives: The purpose of this study was to characterize the force-time profile of the McTimoney toggle-torque-recoil (MTTR) technique.

Methods: Two licensed chiropractors trained in the McTimoney Method applied MTTR thrusts to a tabletop where a dynamic load cell had been mounted. Each clinician applied 10 thrusts (5 with each hand) to the load cell in a repeated measures design. Peak forces, time durations, and time to peak force were computed from each of the force-time histories. Descriptive statistics were performed to compare the forces, durations, and times to peak force of the MTTR thrusts. A Mann-Whitney U test compared variables between the 2 clinicians, whereas a Wilcoxon signed-rank test compared right- and left-handed thrusts within clinicians.

Results: Considering all MTTR thrusts, the average peak force was 87.22 N (SD = 24.18 N), the average overall thrust duration was 36.38 milliseconds (SD = 9.58 milliseconds), and the average time to peak force was 12.31 milliseconds (S.D. = 4.39 milliseconds). No significant differences in mean peak force, duration, or time to peak force were observed between clinicians. When comparing intraclinician right and left hand thrusts, differences in peak force and duration were observed individually ($P < .05$).

Conclusion: For the 2 chiropractors tested, MTTR thrusts were relatively lower in peak force and appreciably faster than other commonly used chiropractic techniques. Future work aims to investigate the relationships between the force-time profiles of MTTR thrusts and resultant physiologic and clinical responses. (J Manipulative Physiol Ther 2009;32:372-378)

Key Indexing Terms: *Biomechanics; Chiropractic; Manipulation, Spinal*

A variety of chiropractic techniques have been developed to provide doctors of chiropractic with choices of technique application for a particular patient or condition in the application of chiropractic adjustments. Specifically, manual articular manipulative and adjusting procedures have been classified into four categories to better describe the technique and mechanism of force production: Specific contact thrust procedures (ie, high-velocity, low-amplitude thrusts), nonspecific contact thrust procedures (ie, mobilization), manual-force, mechanically-assisted procedures (ie, drop tables or flexion-distraction tables), and mechanical-force, manually-assisted (MFMA) procedures (ie, stationary or handheld instruments).[1] Biomechanical investigations of individual differences in performance have begun to be studied for the purposes of education and assessing proficiency of particular technique strategies.[2-4] Common among all technique categories are the inherent goals of optimizing the potential for therapeutic benefits, while maximizing the comfort and safety of the patient and maximizing the efficiency of the thrust application.[5]

Developed by the late John McTimoney in the 1950s in the United Kingdom,[6] the McTimoney method is a light, whole-body approach to chiropractic care which is now estimated to be used by over a quarter of the chiropractors in the United Kingdom.[7] Based on the toggle-recoil technique developed by Palmer,[8] McTimoney adapted the classic hand position to better isolate the pisiform bone to ensure a more

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Electromyographic Reflex Responses to Mechanical Force, Manually Assisted Spinal Manipulative Therapy

Christopher J. Colloca, DC,* and Tony S. Keller, PhD†

Study Design. Surface electromyographic reflex responses associated with mechanical force, manually assisted (MFMA) spinal manipulative therapy were analyzed in this prospective clinical investigation of 20 consecutive patients with low back pain.

Objectives. To characterize and determine the magnitude of electromyographic reflex responses in human paraspinal muscles during high loading rate mechanical force, manually assisted spinal manipulative therapy of the thoracolumbar spine and sacroiliac joints.

Summary of Background Data. Spinal manipulative therapy has been investigated for its effectiveness in the treatment of patients with low back pain, but its physiologic mechanisms are not well understood. Noteworthy is the fact that spinal manipulative therapy has been demonstrated to produce consistent reflex responses in the back musculature; however, no study has examined the extent of reflex responses in patients with low back pain.

Methods. Twenty patients (10 male and 10 female, mean age 43.0 years) underwent standard physical examination on presentation to an outpatient chiropractic clinic. After repeated isometric trunk extension strength tests, short duration (<5 msec), localized posteroanterior manipulative thrusts were delivered to the sacroiliac joints, and L5, L4, L2, T12, and T8 spinous processes and transverse processes. Surface, linear-enveloped electromyographic (sEMG) recordings were obtained from electrodes located bilaterally over the L5 and L3 erector spinae musculature. Force–time and sEMG time histories were recorded simultaneously to quantify the association between spinal manipulative therapy mechanical and electromyographic response. A total of 1600 sEMG recordings were analyzed from 20 spinal manipulative therapy treatments, and comparisons were made between segmental level, segmental contact point (spinous *vs.* transverse processes), and magnitude of the reflex response (peak–peak [p-p] ratio and relative mean sEMG). Positive sEMG responses were defined as >2.5 p-p baseline sEMG output (>3.5% relative mean sEMG output). SEMG threshold was further assessed for correlation of patient self-reported pain and disability.

Results. Consistent, but relatively localized, reflex responses occurred in response to the localized, brief duration MFMA thrusts delivered to the thoracolumbar spine and SI joints. The time to peak tension (sEMG magnitude) ranged from 50 to 200 msec, and the reflex response times ranged from 2 to 4 msec, the latter consistent with intraspinal conduction times. Overall, the 20 treatments produced systematic and significantly different L5 and L3 sEMG responses, particularly for thrusts delivered to the lumbosacral spine. Thrusts applied over the transverse processes produced more positive sEMG responses (25.4%) in comparison with thrusts applied over the spinous processes (20.6%). Left side thrusts and right side thrusts over the transverse processes elicited positive contralateral L5 and L3 sEMG responses. When the data were examined across both treatment level and electrode site (L5 or L3, L or R), 95% of patients showed positive sEMG response to MFMA thrusts. Patients with frequent to constant low back pain symptoms tended to have a more marked sEMG response in comparison with patients with occasional to intermittent low back pain.

Conclusions. This is the first study demonstrating neuromuscular reflex responses associated with MFMA spinal manipulative therapy in patients with low back pain. Noteworthy was the finding that such mechanical stimulation of both the paraspinal musculature (transverse processes) and spinous processes produced consistent, generally localized sEMG responses. Identification of neuromuscular characteristics, together with a comprehensive assessment of patient clinical status, may provide for clarification of the significance of spinal manipulative therapy in eliciting putative conservative therapeutic benefits in patients with pain of musculoskeletal origin. [Key words: biomechanics, electromyography, low back pain, manipulation-chiropractic, reflex responses, spine-thoracic/lumbar] **Spine 2001;26:1117–1124**

Spinal manipulative therapy (SMT) is a commonly used conservative treatment shown effective in studies of low back pain (LBP) treatment.[1,19,31,32] Although beneficial effects of SMT have been observed, considerable controversy exists regarding the precise nature of its therapeutic effects. Anecdotal evidence suggests that neuromuscular reflex responses may have a role in positive benefits derived from SMT, but little work has been done to date investigating physiologic responses.[11]

Neurophysiologic research has identified mechanosensitive and nociceptive afferents in the lumbar intervertebral discs,[3,6,25,28] zygapophysial joints,[7,20,23,45] spinal ligaments,[5,14,15,44] and paraspinal musculature[2,46] in both animal and human studies. When stimulated, these afferents contribute to an active reflex system acting to stabilize the spine.[34] Because stimulation or modulation of the somatosensory system has been put forth as a possible mechanism to explain the effects of SMT,[8,13,27,43] neuromuscular reflexes are of interest to researchers and clinicians. Beneficial effects of SMT have been thought to be associated with mechanosensitive af-

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Comparison of Dynamic Posteroanterior Spinal Stiffness to Plain Film Radiographic Images of Lumbar Disk Height

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Abstract

Background: Assessments of spinal stiffness have become more popular in recent years as a noninvasive objective biomechanical means to evaluate the human spine. Studies investigating posteroanterior (PA) forces in spinal stiffness assessment have shown relationships to spinal level, body type, and lumbar extensor muscle activity. Such measures may be important determinants to discriminate between patients with low back pain (LBP) and asymptomatic subjects.

Objective: To determine the relationships between dynamic PA spinal stiffness and radiographic measures of lower lumbar disk height and disk degeneration.

Methods: L4 and L5 posterior disk height (PDH), vertebral body height (PVH), anterior disk height (ADH), and vertebral body height (AVH) were obtained from digitized plain film anteroposterior (AP) and lateral radiographs of 18 symptomatic LBP patients presenting to a chiropractic office (8 female patients and 10 male patients, aged 15-69 years, mean 44.3, SD 15.4 years). Disk degeneration (DD) and facet arthrosis (FA) were qualitatively assessed from the films by an independent examiner. Anterior disk height ratios (ADHR = ADH/AVH) and posterior disk height ratios (PDHR = PDH/PVH) were calculated from the disk height measurements and were compared to L4 and L5 posteroanterior spinal stiffness obtained using a previously validated mechanical impedance stiffness assessment procedure.

Results: One third of the subjects were found to have radiographic evidence of mild or moderate DD and approximately two thirds of the subjects showed signs of mild or moderate FA. The L4 and L5 anterior disk height and posterior disk height were approximately one half and one fifth of the respective vertebral body heights, and the PA stiffness was greater at L4 than at L5. Male subjects had a greater ADHR than female subjects, but female subjects had a greater L4 and L5 PA stiffness in comparison to male subjects; however, these differences were not statistically significant. Posteroanterior L5 vertebral stiffness was found to be significantly correlated to the L5 PDHR.

Conclusions: Computations of spinal input impedance are relatively simple to perform, can provide a noninvasive measure of the dynamic mechanical behavior of the spine, appear to have potential to discriminate pathologic changes to the spine, and warrant further study on a larger sample of normal subjects and patients. (J Manipulative Physiol Ther 2003;26:233-241)

Key Indexing Terms: *Biomechanics; Chiropractic; Degeneration; Intervertebral Disk; Mechanical Impedance; Radiography; Spine; Stiffness*

Introduction

Evaluation of patients with musculoskeletal disorders routinely includes the use of plain film radiography to assess the spine for alignment and/or pathology. Radiographic examination and static biomechanical evaluation of the radiographs are commonly used procedures in the chiropractic profession.[1] Although many chiropractors use radiographic examination as a general screening tool and for medicolegal protection,[1] excessive use of ionizing radiation and cost containment have led to new attitudes and practice patterns among clinicians.[2] This may be attributed to recent clinical guidelines that have called for a decrease in the utilization of plain film radiography in patients with low back pain (LBP).[3,4] In the ab-

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Validation of a Noninvasive Dynamic Spinal Stiffness Assessment Methodology in an Animal Model of Intervertebral Disc Degeneration

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Deed E. Harrison, DC,§ and Robert Gunzburg, MD, PhD¶

Study Design. An experimental *in vivo* ovine model of intervertebral disc degeneration was used to quantify the dynamic motion response of the lumbar spine.

Objective. The purpose of this study was to: (1) compare invasively measured lumbar vertebral bone acceleration responses to noninvasive displacement responses, and (2) determine the effects of a single level degenerative intervertebral disc lesion on these responses.

Summary of Background Data. Biomechanical techniques have been established to quantify vertebral motion responses, yet their invasiveness limits their use in a clinical setting.

Methods. Twenty-five Merino sheep were examined; 15 with surgically induced disc degeneration at L1–L2 and 10 controls. Triaxial accelerometers were rigidly fixed to the L1 and L2 spinous processes and dorsoventral (DV) mechanical excitation (20–80 N, 100 milliseconds) was applied to L3 using a spinal dynamometer. Peak force and displacement and peak-peak acceleration responses were computed for each trial and a least squares regression analysis assessed the correlation between L3 displacement and adjacent (L2) segment acceleration responses. An analysis of covariance (ANCOVA) was performed to test the homogeneity of slopes derived from the regression analysis and to assess the mean differences.

Results. A significant, positive, linear correlation was found between the DV displacement of L3 and the DV acceleration measured at L2 for both normal ($R^2 = 0.482$, $P < 0.001$) and degenerated disc groups ($R^2 = 0.831$, $P < 0.001$). The L3 DV displacement was significantly lower (ANCOVA, $P < 0.001$) for the degenerated group (mean: 10.39 mm) in comparison to the normal group (mean: 9.07 mm). Mean peak-peak L2–L1 DV acceleration transfer was also significantly reduced from 12.40 m/s^2 to 5.50 m/s^2 in the degenerated animal group (ANCOVA, $P < 0.001$).

Conclusion. The findings indicate that noninvasive displacement measurements of the prone-lying animal can be used to estimate the segmental and intersegmental motions in both normal and pathologic spines.

Key words: biomechanics, disc degeneration, lumbar spine, stiffness. **Spine 2009;34:1900–1905**

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Knowledge of spine segment, or functional spinal unit (FSU), motion patterns (kinematics), and forces (kinetics) is of importance in understanding the response of the spine to externally applied loads. Such biomechanical analyses of the spine play an important role in providing objective data to better understand the biomechanical variables involved in spinal disorders and musculoskeletal pain. In principle, a dysfunctional or unstable FSU may exhibit increased displacement or decreased stiffness, compared to adjacent segments.[1] Conversely, lower lumbar vertebrae[2,3] or segments with degenerated discs[4,5] display increased stiffness. Consequently, the displacement of the FSU and the resistance of spinal tissues to applied forces during assessments or manual treatments may be potentially very useful in spinal diagnosis and for establishing effective treatment protocols.

Physicians, clinicians, and therapists assess the motion of the human spine in an attempt to assess the functional status of underlying anatomy during physical examination of patients with musculoskeletal pain. Clinicians have used mobilization palpation procedures to manually apply posteroanterior (PA) forces over various spinal segments to assess the perceived tissue resistance and pain provocation. Clinicians further use the perceived results of these assessments to formulate clinical diagnoses, to identify spinal levels to target treatment, and to judge the supposed effectiveness of their interventions. Due to the qualitative nature of such assessments, however, many studies have demonstrated that such clinical judgments are unreliable or inaccurate.[6–11] For this reason, mechanical devices have been developed to more objectively quantify spine stiffness.[12–17] To this extent, a series of studies have appeared investigating the reliability of mechanical devices or instruments to assess spinal stiffness with favorable results.[14–20]

Ideally, measurements of the mechanical response of the spine should be accomplished using a procedure wherein motions and forces are measured *in vivo* and directly on the spinal structures, but such measurements generally necessitate an invasive procedure.[21,22] In 1994, Nathan and Keller[23] were the first to quantify the *in vivo* motion char-

The Biomechanical and Clinical Significance of the Lumbar Erector Spinae Flexion-Relaxation Phenomenon: A Review of Literature

Christopher J. Colloca, DC,[a] and Richard N. Hinrichs, PhD[b]

Abstract

Objectives: The aim of this study was to review the biomedical literature to ascertain the biomechanical and clinical significance of the lumbar erector spinae flexion-relaxation phenomenon (FRP).

Data Sources: *Index Medicus* via PubMed, the Noble Science Library's e-journal archives, and the Manual Alternative and Natural Therapy Index System databases were searched using the same search terms.

Discussion: The presence of the FRP during trunk flexion represents myoelectric silence consistent with increased load sharing of the posterior discoligamentous passive structures. Passive contributions from erector spinae stretching during the flexion posture and active contributions from other muscles (quadratus lumborum and deep erector spinae among others) further assist in load sharing in the trunk flexion posture. A number of studies have shown differences in the FRP between patients with chronic low back pain and healthy individuals, and the reliability of the assessment. Persistent activation of the lumbar erector spinae musculature among patients with back pain may represent the body's attempt to stabilize injured or diseased spinal structures via reflexogenic ligamentomuscular activation thereby protecting them from further injury and avoiding pain.

Conclusions: The myoelectric silencing of the erector spinae muscles in the trunk flexion posture is indicative of increased load sharing on passive structures, which tissues have been found to fail under excessive loading conditions and shown to be a source of low back pain. The studies that show differences in the presence of the FRP among patients and control subjects are encouraging for this type of clinical assessment and suggest that assessment of the FRP is a valuable objective clinical tool to aid in the diagnosis and treatment of patients with low back pain. (J Manipulative Physiol Ther 2005;28:623-631)

Key Indexing Terms: *Biomechanics; Electromyography; Low Back Pain; Lumbar Vertebrae; Flexion-Relaxation Phenomenon; Trunk Flexion*

Movements in the lumbar spine, including flexion and extension, are governed by a complex neuromuscular system involving both active (muscle) and passive (vertebral bones, intervertebral disks, ligaments, tendons, and fascia) components.[1] Common among spinal disorders are disruption to the neuromuscular balance and load sharing of the spinal tissues, ultimately resulting in pain and disability, and an enormous economic burden to society.[2] In the assessment of patients with lumbar complaints, measuring the electromyographic (EMG) activity of the trunk musculature is one objective means used by biomechanists and clinicians to assess the function of the lumbar spine. The clinical utility of the use of electromyography, however, is controversial in the diagnosis of patients with low back pain without lower extremity symptoms.[3]

There is evidence to suggest that EMG differences exist between patients with back pain and healthy subjects during dynamic flexion tasks performed at peak flexion.[4,5] To this extent, several studies have examined the apparent myoelectric silencing of the low back extensor musculature during a standing to full trunk flexion maneuver or the flexion-relaxation phenomenon (FRP). The electrical signal reduction or silence that occurs in healthy subjects during lumbar spine flexion has been hypothesized to represent

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Effects of disc degeneration on neurophysiological responses during dorsoventral mechanical excitation of the ovine lumbar spine ☆

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Abstract

Mechanisms of spinal manipulation and mobilization include the elicitation of neuromuscular responses, but it is not clear how these responses are affected or altered by disc degeneration. We studied the neurophysiological responses of the normal and degenerated ovine spine subjected to mechanical excitation (varying force amplitude and duration) consistent with spinal manipulative therapy (SMT). Needle electromyographic (EMG) multifidus muscle activation adjacent to the L3 and L4 spinous processes and compound action potentials (CAPs) of the L4 nerve roots were measured during the application of dorsoventral mechanical excitation forces designed to mimic SMT force–time profiles used routinely in clinical practice. The magnitude and percentage of positive EMG responses increased with increasing SMT force magnitude, but not SMT pulse duration, whereas CAP responses were greatest for shorter duration pulses. Disc degeneration was associated with a reduction (20–25%) in positive EMG responses, and a concomitant increase (4.5–10.2%) in CAP responses.

Keywords: Electromyography; Compound action potentials; Intervertebral disc degeneration; Spinal manipulation; Neurophysiology

1. Introduction

Neuroanatomical research has demonstrated the presence of mechanosensitive and nociceptive afferent fibers in spinal tissues (disc, facet, ligaments, and muscles) (Jiang et al., 1995; McLain, 1994; McLain and Pickar, 1998; Mendel et al., 1992; Roberts et al., 1995), and neurophysiological research has identified the role of such afferent stimulation in pain production (Cavanaugh, 1995; Cavanaugh et al., 1996, 1997) and coordinated neuromuscular stabilization of the spine (Indahl et al., 1995, 1997; Solomonow et al., 1998, 1999, 2000; Stubbs et al., 1998). Active muscular recruitment and reflexes also play a major role in both spinal load and stability (Gardner-Morse and Stokes, 1998; Granata and Marras, 1995), and abnormal load sharing, and repetitive cyclic loading are implicated as mechanical factors involved in the pathomechanisms of musculoskeletal disorders including low back pain (Solomonow, 2004).

Imaging studies have demonstrated a relationship between muscular degeneration and disc degeneration (Parkkola and Kormano, 1992; Parkkola et al., 1993), and muscular degeneration is purported to further compromise

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Spinal manipulation force and duration affect vertebral movement and neuromuscular responses ☆

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Abstract

Background. Previous study in human subjects has documented biomechanical and neurophysiological responses to impulsive spinal manipulative thrusts, but very little is known about the neuromechanical effects of varying thrust force–time profiles.

Methods. Ten adolescent Merino sheep were anesthetized and posteroanterior mechanical thrusts were applied to the L3 spinous process using a computer-controlled, mechanical testing apparatus. Three variable pulse durations (10, 100, 200 ms, force = 80 N) and three variable force amplitudes (20, 40, 60 N, pulse duration = 100 ms) were examined for their effect on lumbar motion response (L3 displacement, L1, L2 acceleration) and normalized multifidus electromyographic response (L3, L4) using a repeated measures analysis of variance.

Findings. Increasing L3 posteroanterior force amplitude resulted in a fourfold linear increase in L3 posteroanterior vertebral displacement ($p < 0.001$) and adjacent segment (L1, L2) posteroanterior acceleration response ($p < 0.001$). L3 displacement was linearly correlated ($p < 0.001$) to the acceleration response over the 20–80 N force range (100 ms). At constant force, 10 ms thrusts resulted in nearly fivefold lower L3 displacements and significantly increased segmental (L2) acceleration responses compared to the 100 ms (19%, $p = 0.005$) and 200 ms (16%, $p = 0.023$) thrusts. Normalized electromyographic responses increased linearly with increasing force amplitude at higher amplitudes and were appreciably affected by mechanical excitation pulse duration.

Interpretation. Changes in the biomechanical and neuromuscular response of the ovine lumbar spine were observed in response to changes in the force–time characteristics of the spinal manipulative thrusts and may be an underlying mechanism in related clinical outcomes.

Keywords: Biomechanics; Dynamic loading; Electromyography; Lumbar spine; Spinal manipulation

1. Introduction

In the treatment of patients with pain of musculoskeletal origin, chiropractic practitioners typically employ short duration, high velocity thrusts (manipulation) designed to restore pain-free movement of the musculoskeletal system and to decrease disability (Meeker and Haldeman, 2002). Of the numerous treatments

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Intervertebral Disc Degeneration Reduces Vertebral Motion Responses

Christopher J. Colloca, DC,* Tony S. Keller, PhD,† Robert J. Moore, PhD,‡
Robert Gunzburg, MD, PhD,§ and Deed E. Harrison, DC||

Study Design. A prospective *in vivo* experimental animal study.

Objective. To determine the effects of disc degeneration and variable pulse duration mechanical excitation on dorsoventral lumbar kinematic responses.

Summary of Background Data. *In vitro* and *in vivo* biomechanical studies have examined spine kinematics during posteroanterior loading mimicking spinal manipulation therapy (SMT), but few (if any) studies have quantified SMT loading-induced spinal motion responses in the degenerated intervertebral disc.

Methods. Fifteen sheep underwent a survival surgical procedure resulting in chronic disc degeneration of the L1–L2 disc. Ten age- and weight-matched animals served as controls. Uniform pulse dorsoventral mechanical forces (80 N) were applied to the L3 spinous processes using 10-, 100-, and 200-ms duration pulses mimicking SMT. L3 displacement and L2–L1 acceleration in the control group were compared with the degenerated disc group.

Results. Dorsoventral displacements increased significantly (fivefold, $P < 0.001$) with increasing mechanical excitation pulse duration (control and degenerated disc groups). Displacements and L2–L1 acceleration transfer were significantly reduced (~19% and ~50%, respectively) in the degenerated disc group compared with control (100- and 200-ms pulse duration protocols, $P < 0.01$).

Conclusion. Dorsoventral vertebral motions are dependent on mechanical excitation pulse duration and are significantly reduced in animals with degenerated discs.

Key words: biomechanics, degeneration, intervertebral disc, manipulation, mobilization. **Spine 2007;32: E544–E550**

The intervertebral disc (IVD) is a known pain generator among patients with low back pain, and the IVD is therefore a primary target of intervention for clinicians applying manual therapies.[1] Progressive degenerative changes of the IVD are associated with increased age, trauma, and abnormal postural loading.[2] Indeed, a large proportion of the population who receive manual therapies have some degree of disc disease.[1] To influence the peripheral pain generator, patients with discogenic disease commonly undergo spinal manipulative therapy (SMT) with the primary goal of normalizing loads and improving spinal mobility.[3]

A wide range of manual techniques have been developed providing clinicians with choices of force amplitude, speed, and vector among other variables of SMT delivery in patient care. Force-time characteristics, including the applied force magnitude, speed, and/or frequency, have therefore been attributed to the underlying mechanisms of SMT.[4] Both *in vitro*[5,6] and *in vivo*[7,8] biomechanical studies have examined segmental and intersegmental displacements and vibration responses during SMT, but few (if any) studies have quantified SMT-induced spinal kinematics in the degenerated IVD.

The purpose of this experimental study was to examine the *in vivo* motion behavior of the normal disc and degenerated disc ovine lumbar spine subjected to varying mechanical excitation force-time profiles. Disc degeneration was established using a validated animal model.[9] We hypothesized that vertebral kinematics would be reduced in animals with disc degeneration.

Materials and Methods

Twenty-five adolescent Merino sheep (mean, 47.2 kg; SD, 5.1 kg) were examined. Fifteen sheep (mean, 47.7, kg; SD, 4.9 kg) underwent a survival surgical procedure designed to experimentally model chronic disc degeneration.[9] The remaining 10 animals (mean, 46.5 kg; SD, 5.6 kg) served as controls. Control and degenerated disc animals underwent a comprehensive biomechanical assessment designed to characterize segmental/intersegmental displacement/acceleration responses to varying force-time mechanical excitation protocols mimicking SMT. The disc degeneration procedure and biomechanical assessment protocol were approved by the Animal Ethics Committees and Institutional Review Board of the Institute of Medical and Veterinary Science (Adelaide, South Australia).

Disc Degeneration Model. Under general anesthesia (1 g thiopentone; 2.5% halothane), the lumbar spine was approached *via* a direct lateral left-side retroperitoneal approach. In each animal, a controlled stab incision was made in the left posterolateral anulus fibrosus midway between the endplates of the L1–L2 disc.[9] Incisions were made with a number-15 scalpel blade directed transversely through the outer aspect of the posterior anulus towards the midline and inserted to the hilt

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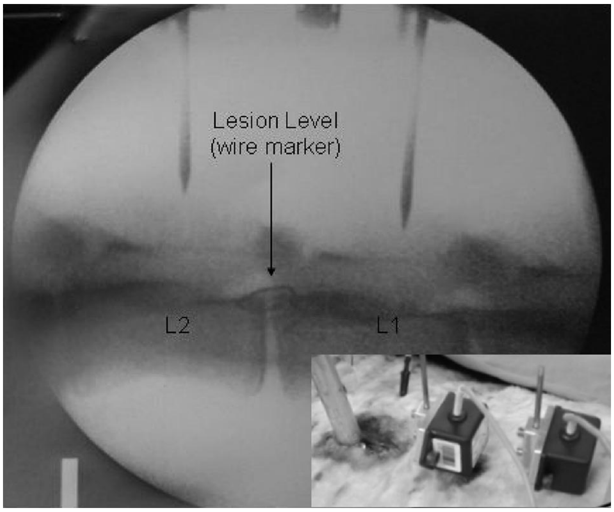

Figure 1. Fluoroscopic image of the L1–L2 ovine spine showing the accelerometer pins and location of lesion marked using a wire suture. The L1–L2 intervertebral disc was the site of the stab incision lesion. Inset shows actuator stylus over L3 and accelerometers attached to pins at L1 and L2.

of the scalpel handle (a depth of 5 mm). Fluoroscopic control was used to check the posterior limit of the blade. Care was taken to protect both the spinal cord and the exiting nerve root during the stab incision procedure. The injured disc level was marked by means of a wire placed around the associated transverse process. The wound was closed in layers, and the animals received an intramuscular antibiotic injection 2 mL/50 kg (consisting of procaine penicillin 250 mg/mL, streptomycin 250 mg/mL, and procaine HCl 20 mg/mL). Each animal recovered in an air-conditioned indoor facility on a 12-hour light/dark cycle for 3 days and was then transferred to an outdoor facility. Animals were kept on a paddock for 20 weeks, which allowed the posterior anular lesion-induced disc degeneration to mature.

Biomechanical Testing Procedures. Sheep were fasted for 24 hours before surgery, and anesthesia was induced with an intravenous injection of 1 g thiopentone. General anesthesia was maintained after endotracheal intubation by 2.5% halothane and monitored by pulse oximetry and end-tidal CO_2 measurement. Animals were ventilated and the respiration rate was linked to the tidal volume keeping the monitored CO_2 between 40 and 60 mm Hg. Biomechanical testing and kinematic measurement procedures have been described previously,[8,10–13] but a brief description follows.

Following general anesthesia, the animals were placed in a prone-lying position with the abdomen and thorax supported by a rigid wooden platform and foam padding, respectively, thereby positioning the lumbar spine parallel to the operating table and load frame; 10-g piezoelectric triaxial accelerometers (Crossbow Model CXL100HF3, Crossbow Technology, Inc., San Jose, CA) were attached to intraosseous pins that were rigidly fixed to the L1 and L2 lumbar spinous processes under fluoroscopic guidance (Figure 1). The accelerometers are high-frequency vibration measurement devices that feature low noise (300-μg rms), wide bandwidth (0.3–10,000 Hz) and low nonlinearity (<1% of full scale) and are precision calibrated by the manufacturer. The x-, y-, and z-axes of the accelerometer were oriented with respect to the medial-lateral, dorsoventral, and cranial-caudal or axial axes of the vertebrae. Only dorsoventral acceleration (z-axis motion) responses are reported in this study.

With the animals in a standardized prone-lying position, the bony preeminence of the L3 spinous process was exposed using electrocautery. Using a custom, computer-controlled mechanical testing apparatus, dorsoventral forces were applied directly to the L3 spinous process using a 12.7-mm-diameter actuator stylus equipped with a slotted tip that cradled the exposed spinous process bone surface. To simulate impulsive and manual SMT force-time profiles, 3 mechanical excitation pulse durations (10, 100, and 200 ms) were examined. In each case, an 80 N peak force with a 10 N preload was applied, and 5 trials were performed for each mechanical excitation protocol. The order in which the mechanical testing protocols were performed was randomly determined.

The dorsoventral L3 force, actuator displacement, L1, and L2 vertebral accelerations were recorded at a sampling frequency of 5000 Hz using a 16-channel, 16-bit MP150 data acquisition system.

Pathologic Examination of Intervertebral Discs. Following the experimental protocol, the sheep were killed by intravenous injection of 6.5-g pentobarbitone sodium and their lumbar spines were removed *en bloc* by transecting the thoracolumbar junction and the midsacrum. Individual motion segments were isolated by cutting midway through the adjacent vertebral bodies with a bandsaw and fixed in 10% buffered formalin for a minimum of 72 hours before being decalcified in a solution containing 9.5% nitric acid and 10% edetic acid (EDTA). The specimens were cut into 6 parasagittal slices of equal thickness. Slices showing the anulus lesion and a contralateral slice were processed into paraffin wax for histomorphometric examination. Tissue sections were cut at a nominal thickness of 5 μm, stained with hematoxylin and eosin, and independently examined without knowledge of each animal's identity. Intervertebral discs from all subjects were graded on a 1 to 4 scale of degeneration (1 = normal; 2 = mildly degenerated; 3 = moderately degenerated; 4 = severely degenerated) with respect to the overall condition of the disc (grade), as well as morphologic characteristics of the anulus fibrosus, nucleus pulposus, vertebral endplates, and subchondral bone.[14]

Data Reduction and Analysis. The actuator displacement (mm) and vertebral intersegmental (L2–L1) dorsoventral acceleration transfer were computed for each mechanical excitation trial. Effects of mechanical excitation pulse duration on the dorsoventral motion response (L3 displacement or L2–L1 acceleration transfer) were assessed using a repeated measures analysis of variance (ANOVA) ($P < 0.05$, significant difference). Statistical comparisons were performed between normal and degenerated animals and across mechanical test protocols within the normal and degenerated animal groups.

Results

Histologic Analysis

The macroscopic and microscopic features of the discs in this study closely resemble those described in a previous ovine study of rim lesions.[9] Among the animals subjected to the chronic lesion, macroscopically there was unequivocal evidence of the anular incision in the incised disc with extension of the lesion to involve the central

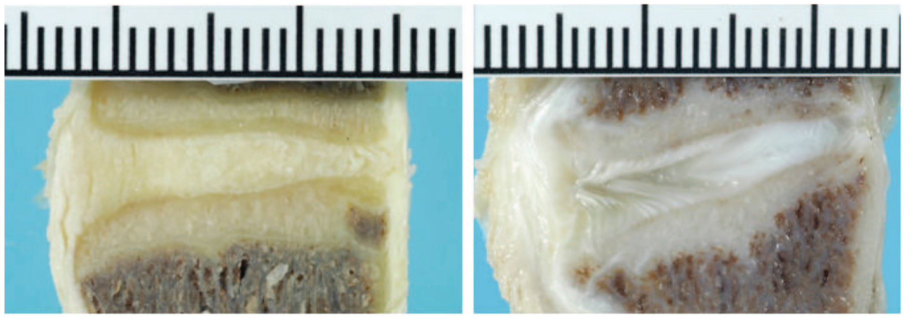

Figure 2. Low power mid sagittal photomicrographs of ovine L1–L2 lumbar intervertebral discs. A normal disc serving as a control in the current study is shown on the left, illustrating the normal arrangement of the anulus fibrosus and the central nucleus pulposus. The injured disc (right) is shown 20 weeks following anular incision and is characterized by extensive disruption of the anterior anulus, anterior migration of the nucleus pulposus, and medial contraction of the posterior anulus fibers. Markedly thickened repair tissue is present in the vicinity of the initial anular incision. Small transverse fissures and irregular thickening of the calcified zone are also observed at the vertebral body endplate in the injured disc.

nucleus pulposus in all cases (Figure 2). The lesion resulted in substantial loss of height due to breakdown of disc matrix. Microscopically, all discs showed advanced repair of the most peripheral anular fibers or in some case, more organized collagenous scar tissue. In most cases, there was radial and circumferential extension of the initial anular lesion with secondary displacement of the nucleus towards the anterior aspect, resulting in prominent inversion of the posterior anular fibers from their usual concave orientation. In most cases, the nucleus showed substantial migration with early clefting of the matrix in some cases.

The degenerated model discs were consistently at a stage of moderate to advanced degeneration compared with the normal discs (Table 1). In all normal subjects, the anulus fibrosus was graded as 1, whereas the degenerated group scored 3.30 (SD, 0.48). The nucleus pulposus averaged 1.40 (SD, 0.52) for the normal group compared with the degenerated group score of 2.60 (SD, 0.52). Vertebral body endplate and subchondral bone differences were less remarkable among the normal and degenerated groups. All normal group L1–L2 discs were graded as 1, whereas the mean score of the degenerated group was 3.10 (SD, 0.57). With the exception of 2 degenerated disc animals who were graded as 2, all of the incised discs were generally graded either as 3 (moderately) or 4 (severely) degenerated.

Mechanical Excitation Response

Typical force-time, displacement-time, and L2–L1 intersegmental acceleration responses produced by the uniform pulse duration mechanical excitation are illustrated in Figure 3. The uniform force pulse resulted in a haversine-like dorsoventral displacement response at the point of contact (L3). Dorsoventral displacement tended to lag behind the force by a few milliseconds. Intersegmental (L2–L1) dorsoventral vertebral accelerations showed

Table 1. Grading of Histologic Changes in the L1–L2 Lumbar Discs of the 10 Normal and 15 Degenerated Model Specimens Examined

AF		NP		EP		SCB		Grade	
Normal	Lesion	Normal	Lesion	Normal	Lesion	Normal	Lesion	Normal	Lesion
1	3	1	2	1	1	1	1	1	3
1	3	1	2	1	1	1	1	1	3
1	3	2	3	1	1	1	1	1	3
1	3	1	2	1	1	1	1	1	3
1	4	1	3	1	2	1	1	1	4
1	4	1	3	1	1	1	1	1	4
1	3	2	3	2	1	1	1	1	2
1	3	2	2	1	1	1	1	1	3
1	3	2	3	1	1	1	1	1	3
1	4	1	3	1	2	1	2	1	3
	4		2		3		2		3
	3		2		1		1		3
	3		2		1		1		3
	4		3		1		1		4
	2		3		1		1		2
Mean	3.30	1.40	2.60	1.10	1.20	1.00	1.10	1.00	3.10
SD	0.48	0.52	0.52	0.32	0.42	0.00	0.32	0.00	0.57

AF indicates annulus fibrosus; NP, nucleus pulposus; EP, vertebral endplate; SCB, subchondral bone.

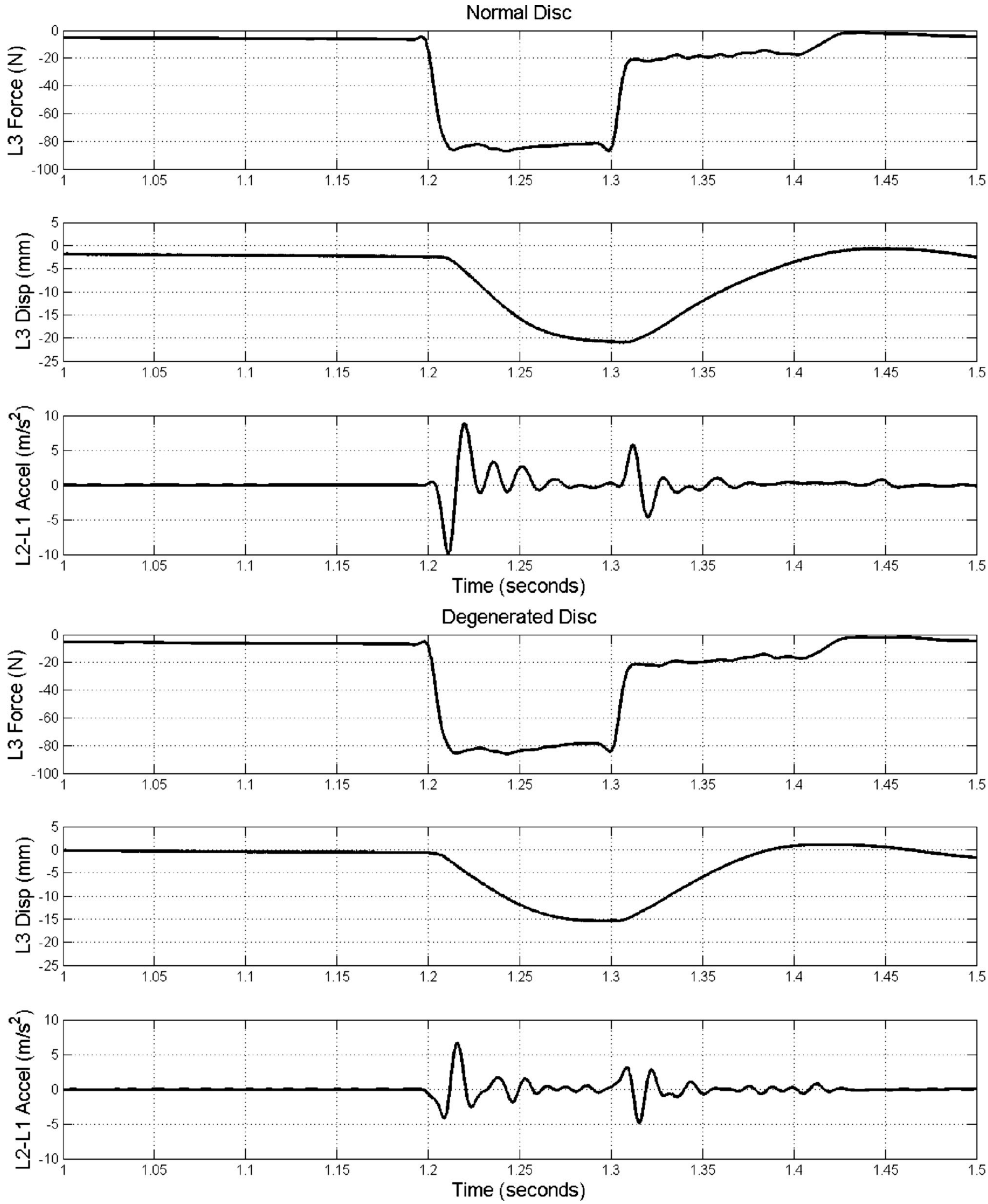

Figure 3. Typical actuator force, actuator displacement, and intersegmental (L2–L1) acceleration response obtained during the application of a uniform pulse mechanical excitation (100–ms pulse duration). The load was ramped from 0 N to a preload of approximately 10 N before the application of the 80 N variable pulse duration mechanical stimulation. Top, normal disc. Bottom, degenerated disc.

large amplitude motions during both the onset and removal of the uniform force pulse.

The 10-ms (80 N) mechanical excitation protocol produced the lowest L3 dorsoventral displacement response (normal = 3.69 mm; degenerated = 3.51 mm), whereas the 100-ms (80 N) mechanical excitation protocol produced the greatest L3 dorsoventral displacement response (normal = 17.84 mm; degenerated =

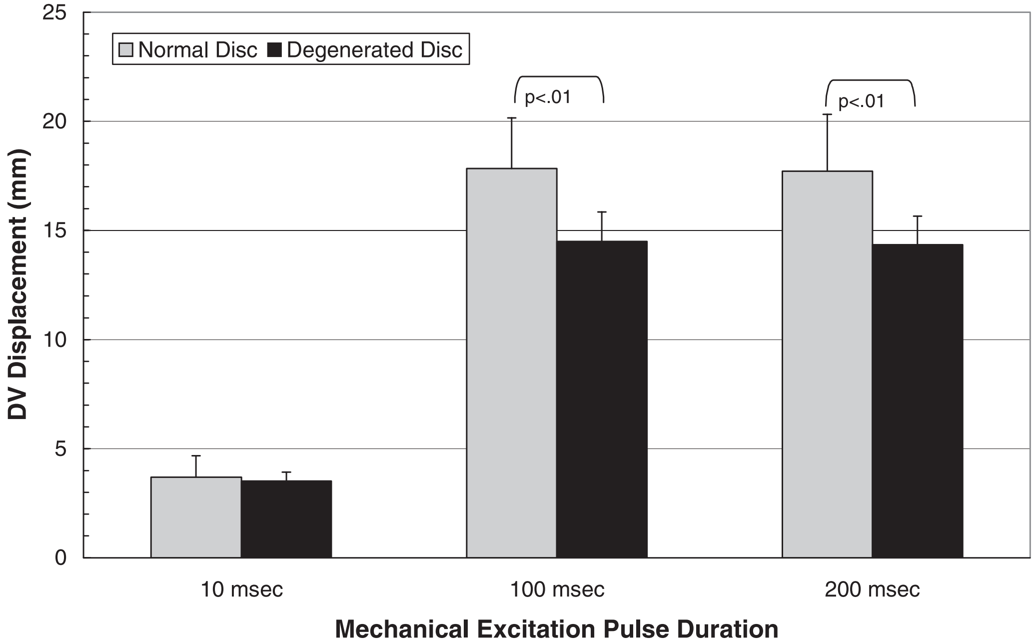

Figure 4. L3 dorsoventral displacement response for the 3 variable pulse duration mechanical excitation protocols. Bars indicated mean (SD) for the normal disc group (gray) and degenerated disc group (black). *P* values for significant across group (normal *vs.* degenerated) differences are indicated.

14.49 mm) (Figure 4). Both the 100- and 200-ms mechanical excitation protocols resulted in significantly greater (approximately fivefold, repeated-measures ANOVA, $P < 0.001$) L3 dorsoventral displacements in comparison to the 10-ms SMT protocol (both control animal and degenerated disc animal groups). Compared with the normal disc group, animals in the degenerated disc group showed significantly reduced (approximately 19%) L3 dorsoventral displacement responses for the 100- and 200-ms mechanical excitation protocols (repeated-measures ANOVA, $P < 0.01$).

Intersegmental acceleration responses were opposite of that observed for the displacement responses; namely, the intersegmental acceleration response was greatest for the shortest duration mechanical excitation pulse protocol (Figure 5). Compared with the normal disc group, animals in the degenerated disc group showed a significantly reduced (approximately 50%) L2–L1 acceleration

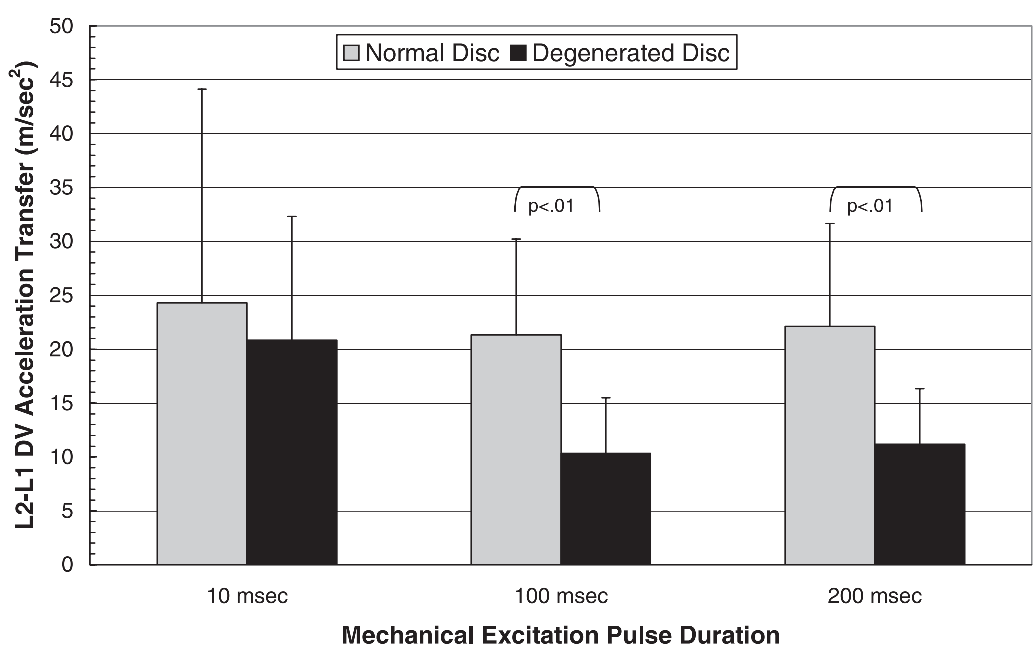

Figure 5. Lumbar intersegmental (L2–L1) acceleration response for the 3 variable pulse duration mechanical excitation protocols. Bars indicated mean (SD) for the normal disc group (gray) and degenerated disc group (black). *P* values for significant across group (normal *vs.* degenerated) differences are indicated.

response for the 100 and 200-ms mechanical excitation protocols (repeated-measured ANOVA, $P < 0.01$).

Discussion

In the current study, an established animal model of disc degeneration[9] was used that produces a clinically relevant healing response that is well established after 12 weeks.[15] Analogous to disc degeneration in humans,[16] the healing response of the ovine disc was associated with anular disruption, nuclear migration, and granulation tissue formation in the outer anular region of the ovine disc. Previous investigations have demonstrated biomechanical and biochemical similarities between sheep and human intervertebral discs.[17] Thus, the ovine animal model is deemed to be a valid model to investigate biomechanical responses to dorsoventral mechanical excitation.

Mechanical excitation pulse durations selected for the current study were chosen to closely resemble SMT thrusts delivered in clinical practice. Specifically, the 10-ms thrusts mimic the speeds of mechanical force manually assisted adjusting instruments,[18] whereas the 100- and 200-ms pulse durations more closely resemble speeds of high velocity low amplitude SMTs.[19,20] In addition, the loads imparted to the ovine spine were 25% of the animal body weight, which is consistent with loads commonly delivered among those practicing SMT.[19,20] We found shorter pulse duration (10 ms) mechanical excitation produced larger adjacent segment vertebral motions in comparison to longer pulse duration mechanical excitation (100 or 200 ms). Similar findings of adjacent vertebral motion in response to mechanical force manually assisted SMTs have also been reported in human subjects *in vivo*.[7,8,11] Impulsive forces (pulse durations <25 ms) are known to produce an abrupt change in velocity, which causes the spine to vibrate freely.[4] This is especially true in viscoelastic structures such as the spine. Given the putative effects of impulsive-type chiropractic adjustment procedures,[21–24] the enhanced vibration response observed during very short duration forces may represent one mechanism for impulsive-type SMTs.

Animals with degenerated discs showed significantly decreased dorsoventral displacement and L2–L1 intersegmental accelerations, which supports our hypothesis that vertebral kinematics would be reduced in animals with disc degeneration. However, statistically significant disc degeneration-related changes in segmental and intersegmental kinematics were not observed for the shorter duration (10 ms) mechanical excitation pulse protocol, which in this study seems to reflect the fact that impulsive loading produces a more variable kinematic response. In addition, Increasing pulse duration from 100 to 200 ms did not appreciably change the amount of dorsoventral displacement at the segmental contact point (L3) or adjacent segment motion at L1–L2. This suggests that spinal manipulation treatment strategies that use shorter duration SMTs (100 ms) are biomechanically more efficient since appreciably less energy is delivered to the spine. Further work examining the dynamic mechanical response of the normal and degenerated spine will assist in the understanding both the etiology of spinal disorders and putative effects of spinal manipulative therapy among different patient populations.

This is the first study demonstrating differences in vertebral kinematics for specimens with degenerated discs, an important finding for clinicians. Clinicians practicing SMT cognitively and kinesthetically gauge the amount of force they deem appropriate for a particular patient or condition based on biomechanical (*i.e.*, anatomic) and clinical (*i.e.*, pain tolerance) variables alike. Knowledge that degenerated functional spinal units will undergo substantially less dorsoventral motion for a given dorsoventral force, as demonstrated in the current study, provides clinicians with important biomechanical information that can be considered in practice.

Measurement of vertebral movement using intraosseous pins equipped with accelerometers[7,8,11] and other invasive motion measurement devices[25,26] has been previously shown to be a precise measure of spine segmental and intersegmental motion, but invasive procedures currently have limited clinical utility. Noteworthy, however, was our finding that decreases in dorsoventral displacement associated with the degenerated disc model mirrored the reduced acceleration transfer across the disc lesion. This corroborates the findings of others who have demonstrated increased stiffness among dehydrated or degenerated discs *in situ*.[16] The ability to noninvasively detect biomechanical changes in degenerated discs *in vivo* using an indenter over the spinous processes may have implications for the development of quantitative biomechanical spinal assessment strategies.

Conclusion

Dorsoventral vertebral kinematics are dependent on mechanical excitation pulse duration and are significantly reduced in animals with degenerated discs. Further work is needed to identify “optimal” force-time profiles for spinal manipulative therapies and assessment strategies. Characterization of changes in the kinematic characteristics of the spine using spinal manipulative-like thrusts may assist in assessment of clinical outcomes.

Key Points

- We found that the kinematic responses of the ovine lumbar spine were sensitive to the duration of the applied mechanical excitation force.
- Compared with the normal disc group, animals in the degenerated disc group showed significantly ($P < 0.01$) reduced (~19%) L3 dorsoventral displacements for the 100- and 200-ms duration mechanical excitation protocols.

- Compared with the normal disc group, animals in the degenerated disc group showed significantly ($P < 0.01$) reduced (~50%) L2–L1 acceleration transfer during 100- and 200-ms mechanical excitation protocols.
- Characterization of spine kinematics during dorsoventral mechanical excitation mimicking spinal manipulative-like thrusts may assist in assessment of clinical treatment and outcomes for back disorders.

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