



## Federation of Chiropractic Licensing Boards

High-velocity, low amplitude spinal adjusting / manipulation performance:  
Minimum criteria for safety and adequate competence.

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Spinal adjusting / manipulation methods represent a host of individual procedures that constitute a significant part of the therapeutic options used by Doctors of Chiropractic. Historically, Chiropractic has been and continues to be the discipline providing the majority of these services to benefit patients who need them (1). Clinical experience and scientific understanding of spinal manipulation methods have increased dramatically. The interdisciplinary interactions between Doctors of Chiropractic and other health care providers for referral, co-management and consultation has risen along with a more broad acceptance of appropriate use of spinal manipulation by health care policy makers. Patients with more widely ranging co-morbid and primary pathology are seeking and are being sent to Doctors of Chiropractic for their care.

The Federation of Chiropractic Licensing Boards recognizes the sustained positive relationship between licensure examination and practice performance and the professional responsibility to protect the public (2). In conjunction with Chiropractic professionalism, it is an incumbent responsibility to ensure that the care provided by its members meets minimum standards of training and competence for safe and effective administration of these procedures. Such consideration must account for professional responsibility, case complexity and diagnoses, relative risks, training and skill.

#### I. Characteristics of Professionalism

Chiropractic is one of society's consulting and scholarly professions. As a result, its members enjoy far more autonomy than those in other occupations. Primarily because its clientele are laypersons, legal controls are imposed by each jurisdiction in which a professional may practice. The process of licensure / registration, social structure grants professionals the right to organize their work and to determine who will be qualified to perform it(3,4). A principle feature of chiropractic that makes it a profession is the presence of prolonged training in a core of abstract knowledge that includes specialized or unique elements and skill sets that are generic to the discipline. One of the principle interventions within chiropractic is the application of high velocity, low amplitude manipulative methods as treatment for patients who have been determined by the treating practitioner to have the appropriate conditions through a differential diagnostic evaluation.

Professionals are service oriented and are bound to their patients, forming a unique and trusting relationship with each individual(4). Under these circumstances, the professional holds a moral and ethical responsibility to provide only therapeutically necessary care that is safe and effective.

- a. Unique body of knowledge – There are three foundations of knowledge for use of these procedures.
    - i. Procedural Administration: Manual methods of treatment involve the use of controlled loads applied to the spine for the purpose of resolving functional disorders classically described including the terms “subluxation” , “subluxation complex” or “nonallopathic lesion”. Loading characteristics (forces and moments) include preload amplitude, speed of application, peak load amplitude, load duration, direction and depth of displacements. Adjusting / manipulation procedures and the loads delivered to the targeted structures are controlled by two types of strategies (5, 6,7). They include 1) procedural selection where load characteristics are varied by the doctor to match patient needs and case complexity as well as 2) the adaptation of procedures to patient characteristics to achieve successful clinical outcome.
    - ii. Phenomenologic response: The pathophysiologic and pathomechanical bases of response to treatment may depend on procedure type(8,9,10,11,12). The effects can be either local, remote to the site of procedure administration or both depending on the extent of the underlying subluxation and related co-morbid conditions. Procedure load characteristics appear to have differing levels of benefit based on condition duration, severity and complexity. Therapeutic effects are known for range of joint motion, local and remote pain response, proprioceptive and reflex modulation.
    - iii. Diagnostic / Analytic: Signs and symptoms that are associated with spine related disorders which may be amenable to adjustment/manipulation procedures can also arise from non-spinal sources and pathology that may contraindicate or require modification of procedures to be administered. These may include potentially life-threatening disorders, for example cancers, heart disease, vascular anomalies and aneurysm among others. A differential diagnosis is a necessary basis for the administration of these procedures.
- II. Evidence of risk
- a. Utilization data on spinal manipulation
    - i. It is generally understood that any method of effective intervention to assist patients, can have unintended adverse reactions that may be unpredictable or occur when used incorrectly or under inappropriate conditions. Spinal adjusting / manipulation enjoys a very low risk, especially when performed by adequately trained providers. Chiropractors provide approximately 94% of the manipulation services delivered in the United States(1). The case series and case review literature(13,14,15,16), on the other hand, reflects that between 46% and 80% (average 62%) of

complications associated with manipulation have occurred at the hands of chiropractors. The evidence suggests that 6% of the procedures performed by other disciplines may be responsible for a disproportionate 20% to 34% of the complications.

b. Effectiveness data

Training for spinal manipulation ranges from formalized curricula embedded in full first professional degree (DC, DO, MD) programs to weekend seminars and individual demonstrations. The resulting varied levels of skill can influence the clinical outcome of treatment. Curtis et al (17) attempted to train general practitioners in a limited number of manipulation procedures as an adjunct to medical management for low back pain patients. The authors were explicit in their effort not to create “experts”. Patients treated by these providers received no greater benefit than medical treatment alone. Yet, multiple studies and meta analyses have concluded that there is benefit to using these procedures ( for example, 18,19,20,21,22,23).

III. Credentialing and certification in health care procedures.

- a. Purpose – A profession provides services using knowledge-based competence(3,24) unable to be effectively evaluated by the public that it serves. Autonomy is granted and periodically reviewed by society on the proviso of self-regulation favoring careful recruitment, training, formal organization, ethical standards and boards of colleagues who enforce these codes. The purpose of credentialing / certification, in short, is to protect the public from incompetent and unethical conduct by its members. Self-regulation is the test of professional autonomy (4).
- b. Methods – The process of self-regulation takes many forms from peer pressure to social mandate exercised through organization of formal licensing authority. Typically defined as licensing boards, these organizations describe the legal, moral and intellectual bounds of practice and the ability to perform services(24).

IV. Characteristics of skilled performance and competence

- a. Diagnostic criteria – Diagnosis and assessment of spine related disorders involving subluxation; either as a primary, secondary or co-morbid condition; requires the ability to accurately assess neuromusculoskeletal findings and to differentiate them from other conditions (e.g. cardiovascular, neurological, gynecologic, gastrointestinal or endocrine). Systemic or metabolic disorders with local contraindications to use of these procedures must also be discerned. The result of differential diagnosis must be the implementation of appropriate treatment as necessary or where warranted, the appropriate urgent/emergent or consultative referral.
- b. Safety and competency

High-velocity, low amplitude procedures are bimanual tasks requiring high levels of sensory/motor coordination (25,26,27).

- i. The evidence demonstrates that safe and effective care requires adequate skill in diagnosis leading to appropriate procedure-patient matching followed by adequate skill in procedural administration.
  - ii. Skill in procedural administration can be stratified into the following definitions(27,28,29):
    1. Safe – The ability to identify appropriate candidates and ability to administer procedures without increased risk of adverse reaction.
    2. Functionally adequate – Safe performance with ability to obtain successful clinical outcome for typical, uncomplicated cases.
    3. Masterful – Safe performance with ability to obtain successful clinical outcome using typical procedures in more complicated cases.
    4. Innovative – Safe performance with ability to adapt procedures to achieve successful clinical outcomes in highly complex cases where typical methods may not be effective.
- c. Heuristic criteria
- i. Based on the study of practitioners considered by their peers to be experts, the implementation of skillful high-velocity, low amplitude procedures meet the following descriptive characteristics (28,29,30,31) as rated by patients:
    1. Comfort – handling of the tissues perceived by the patient as being comfortable.
    2. Confidence- a composed and poised handling of the patient in preparation for administering the procedure.
    3. Fast – Rapid administration of the treatment loads.
    4. Force – Peak loads perceived as sufficiently strong.
    5. Precision – Loads are applied as a single peak amplitude event.
- d. Biomechanical qualities
- i. Biomechanical descriptions that relate to the heuristic descriptors of fast, force and precision of skillful performance are available(32,33).
  - ii. Expert performance, mean quantitative descriptors may be different for each spinal region and for each procedure type.
  - iii. For the most common lumbar spine procedure (lateral decubitus, mammillary push), for example, the mean load values acting through the torso for a patient of average stature are:
    1. Fast – 3800 N/sec; 998 Nm/Sec
    2. Force – Force ~ 500 N; Moment ~120 Nm
    3. Precision – a single peak thrust event
- e. Evidence of training criteria

- i. The ability to perform differential diagnosis for the purpose of
  - 1. Identifying the presence of a subluxation lesion amenable to adjusting / manipulation using high-velocity, low amplitude procedures.
  - 2. Identifying co-morbid conditions that may require modification of procedures for safe and effective use.
  - 3. Ruling out non-musculoskeletal disorders masquerading with clinical presentation emulating that of a manipulable lesion.
  - 4. Ruling out serious disease or disorder requiring urgent/emergent care or special studies.
  - 5. Monitoring response to treatment administered for signs of adverse reaction and their appropriate management.
- ii. Heavy emphasis on hands-on, practical training in laboratory settings for learning specific procedures (27,33,34) followed by supervised clinical practice for a minimum of 9 months.
- iii. A cumulative minimum of 150\* class (10 credit) hours of training across multiple procedures for each spinal region with ability to provide adequate speed, force and precision of procedure delivery.
- iv. Ability to provide, at minimum, safe and functionally adequate performance with sufficient use of control to meet the majority of patient needs.

V. Summary of Criteria for safe and adequate performance minimum criteria. Evidence suggests that condensed learning programs and learning without adequate prerequisite training involving skilled procedures is inappropriate and perhaps dangerous. A recommended minimum criteria for the performance of high-velocity, low amplitude procedures is the demonstrated ability to perform differential diagnosis in the context of section IVa above, with a skill level considered safe and functionally adequate based on a minimum of 150 class (10 credit) hours training that incorporates heavy emphasis for hands-on, practical training in laboratory and clinical settings with supervised clinical practice for at least 9 months.

\* Based on a total of 5867 hours training in manual treatment methods including 2922 hours of training in diversified HVLA procedures across 15 colleges per catalogue and curriculum audit for the index years of 1998 – 2000.

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## **Appendix of Definitions and Concepts**

**Manipulation/adjustment:** Application of controlled forces and moments to a joint over a short interval lasting less than 150 ms and within the boundaries of anatomical integrity of the joint complex to restore function and relieve local or remote symptoms associated with abnormal joint behavior or subluxation.

**Manipulable Lesion:** The lesion is essentially a mechanical event or behavior of the joint components that has detrimental influence on local and/or remote health and symptoms. These lesions are considered amenable to the application of loads (forces and moments) to the body, termed adjustment or spinal manipulation, with the intent of restoring normal behavior and reducing health effects.

**Subluxation/Subluxation Complex:** A form of manipulable lesion, the subluxation is a complex of functional and/or structural and/or pathological articular changes that compromise neural integrity and may influence organ system function and general health.

### **Manipulation vs. mobilization vs. massage:**

Manual treatments can be differentiated through analysis of their biomechanical characteristics. The mechanical effects similarly are determined by the properties of the tissues on which the procedures are administered (Figure 1).

- 1) Massage generally uses the application of pressures and stretches in slower movements on the surface of the skin. Load applications are through contacts that may be distributed over wide areas or concentrated. Its effects are primarily on muscle and fascia and may include mechanical, reflexive and psychological components (1). Its mechanism of action is the mobilization and transfer of fluids and the normalization of motion within the fascial planes and stimulation of touch, pressure and stretch receptors of the peripheral nervous system.
- 2) Mobilization targets regional joint motion (Figure 2) and the related soft tissues. Load application may be concentrated locally or may be remote, using leverage to exercise joint function. Its mechanism of action focuses on the viscoelastic and stiffness characteristics at lower speeds. Tissue compartment fluid transfer (e.g. reduction of edema and hydration of cartilage (2) and normalization of joint motion are the desired effects. Stimulation of skin and joint receptors occurs and mechanical, reflexive and psychological effects can be expected.
- 3) Manipulation with high-velocity, low-amplitude methods target the normalization of joint function (3-6) and related local or remote symptoms. The mechanisms of action focus on the relative stiffness properties of the constitutive joint tissues using high speed and impulsive loading of the tissues. Desired biomechanical effects are the redistribution of local joint stresses and maximizing normal motion. Like other manual methods, stimulation of skin and joint receptors occurs. In view of the relatively short duration of contact, the mechanical and reflexive mechanisms are thought to be more dominant than psychological effects although psychological responses can be expected.

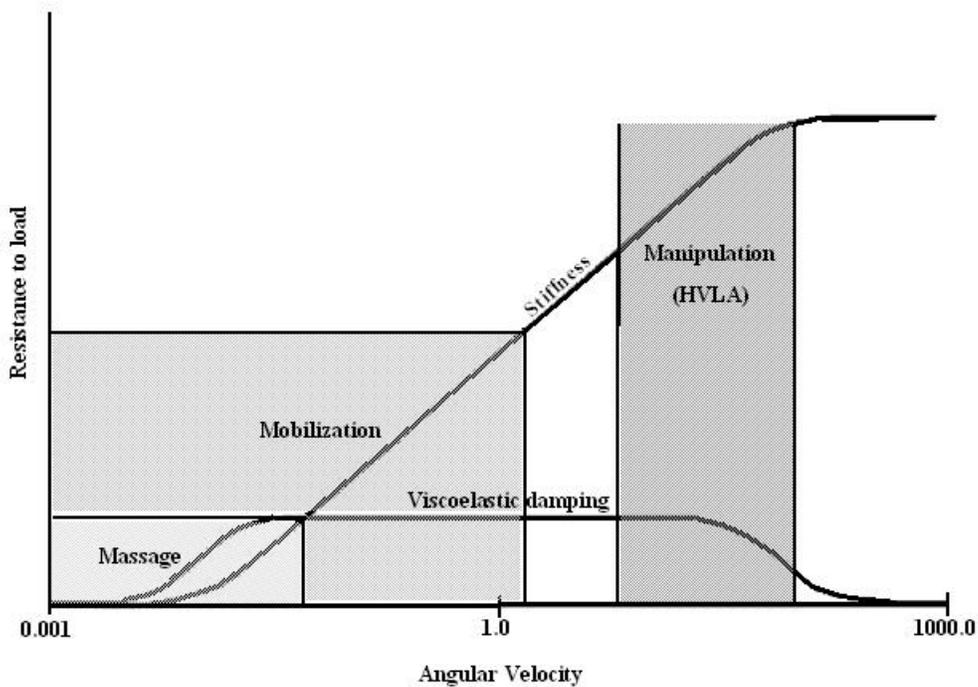


Figure 1: Relationship and influence of massage, mobilization and HVLA manipulation on targeted tissue properties as a function of procedure speed.

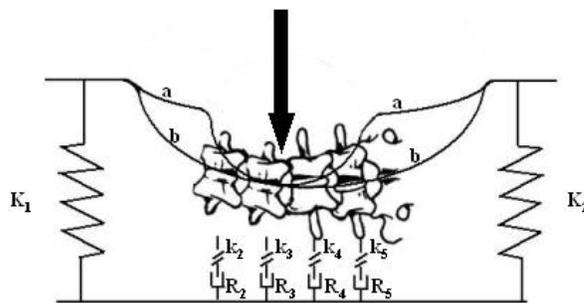


Figure 2: a-a Schematized relative local displacement behavior of joint components responding to HVLA maneuvers. b-b Relative regional displacement behavior from slower speed maneuvers.

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Spine Arthroplasty Society Statement of Accountability on skill.



A Not-for-Profit Educational Society

### Spinal Arthroplasty Society Educational Objectives

The Board of Directors of the Spinal Arthroplasty Society (SAS) has decided to take a unique step in establishing educational and training goals for spine surgeons interested in new Arthroplasty technologies. The ultimate goals of this effort are to improve clinical outcomes and reduce technical complications in patients undergoing surgical treatment utilizing these new technologies by providing a strong educational core of knowledge for surgeons:

Traditionally, rigorous patient selection criteria have been required for inclusion in FDA trials. Additionally investigators are specifically selected by the companies who design the studies, based on their reputations and experience. However, when devices are approved for marketing to surgeons in the community, there has been no formal standardization for training these physicians in their use.

Training historically has run the gamut from a product introduction by a company representative sitting across the surgeon's desk, to a brief course with a lecture in the morning followed by crowded hands-on training using Sawbones models, to a comprehensive training program incorporating surgeon education for diagnostic work-up, patient selection criteria, management of complications, and ample time in a cadaver lab developing familiarity with the instrumentation and surgical exposure.

Ideally, comprehensive formal training should be followed by proctorship at the training surgeon's hospital for his first case(s) by a teaching surgeon with a high level of expertise. This would serve to "close the loop" of the surgical proctoring process. Obviously, this level of training is expensive and time consuming, but it offers significant long-term advantages for patients, surgeons, industry and hospitals. For patients, technical complications may be reduced and outcomes improved. For surgeons, their patients' clinical results may be more gratifying and litigation avoided. It is important for industry so that their devices can produce the best results possible. A product may be unjustly criticized for high complications and poor outcomes if surgeons have poor technical skills or employ too broad patient selection criteria. Hospitals also have a vested interest in the training of surgeons. The hospital's mission, like that of the surgeon, is to ensure the maximum benefit to the patient.

While the technology of spinal surgery is steadily advancing, clinical safety and outcomes cannot be expected to improve unless appropriate patient selection and optimal surgical technique are taught. SAS is prepared to take a pro-active role in addressing surgeon education. A program of organized processes for training surgeons on new devices would incorporate didactic lectures, hands-on training and proctorships. The role of the society will be to develop guidelines for content of educational programs, identify training centers with adequate facilities and staffing for consistent quality training, and organize access to specialists who have experience with the specific devices to provide proctorships.

Due to liability issues, certification can verify that the surgeon has completed training, but not that (s)he has adequate skills. A document will be issued only to verify course attendance and subsequent proctorship. The fact that the training is provided through a society and performed in an organized, standardized format across the country (and hopefully the world), should enhance the overall quality of care for our patients.

All parties concerned recognize the importance of having surgeons properly trained when introducing new technologies. With the rapid developments in spinal implants, SAS has an unprecedented and unique opportunity to play an important role in improving patient care, optimizing the application of new technologies, and furthering the development of new implants by increasing the safety of new product introduction with adoption of these standardized training programs.

Handwritten signature of Rudolf Bertagnoli in blue ink.

Rudolf Bertagnoli, M.D.  
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Spine Arthroplasty Society

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