A pilot study for a randomized clinical trial assessing chiropractic care, medical care and self-care education for acute and subacute neck pain patients.

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Objective: To conduct a pilot study in preparation for a full-scale randomized clinical trial, assessing conservative treatments for acute and subacute neck pain.

Study design: Prospective, randomized pilot study.

Setting: Primary contact chiropractic and medical clinics.

Patients: Ages 21-65 with current episode of neck pain less than 12 weeks in duration.

Outcome measures: Patient self-report questionnaires and cervical spine motion were assessed at baseline and three and 12 weeks postrandomization.

Interventions: Chiropractic spinal manipulation, prescription medications and self-care education.

Results: Recruitment took place over a one-month period. Twenty-eight patients were randomized to treatment, and one patient (medical care group) refused treatment assignment and was lost to further follow-up. Twenty-three patients were either "very satisfied" or "completely satisfied" with the care they received in the study. More than half the patients reported 75% or 100% improvement (n=17). No between-group comparisons were planned or performed, due to the small sample size.

Conclusion: Recruitment of patients appears feasible for a full-scale, randomized clinical trial evaluating chiropractic spinal manipulation, medical care and self-care education for acute and subacute neck pain. Patient and provider compliance with study protocols were excellent, and the pilot study allowed us to further develop and optimize our data collection processes. Although pilot studies such as these require substantial time, money and effort, they provide valuable information for future research efforts.
Randomized clinical trial of conservative treatment for patients with whiplash-associated disorders: considerations for the design and dynamic treatment protocol.

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**Background:** Whiplash presents a considerable problem to health care. Available evidence from systematic reviews indicates beneficial effects of active interventions for patients with whiplash injury. To evaluate whether a general practitioner or a physiotherapist should provide these active interventions, we have designed a randomized clinical trial.

**Objective:** The purpose of this article is to present the design of the trial and to provide transparency into the dynamic treatment protocol used.

**Patients:** Patients with whiplash-associated disorders, grades I and II, who still have symptoms and disabilities four weeks after the accident.

**Interventions:** A dynamic treatment protocol consisting of four different subprotocols. The primary aim is to increase their activities and to improve their quality of life. Content and intensity of treatment are described.

**Outcome measures:** The primary outcome measures are pain and disability. The short-term effects are measured at 12 weeks; long-term effects at one year after the trauma.

**Conclusion:** To date, generally, the effect of one intervention, compared to another intervention, has been examined. In our opinion, this cannot be considered usual care for physiotherapy or general practice. Therefore, a dynamic treatment protocol has been developed to structure the black box of usual physiotherapy and general practice treatment. The results of this trial will be available in two years.

**Key indexing terms:** Conservative treatment; design; general practice care; physiotherapy; randomized clinical trial; whiplash.
Chiropractic treatment of temporomandibular disorders using the Activator Adjusting Instrument - a prospective case series.

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Objective: To determine if there was basis for the treatment of temporoman-dibular disease (TMD) using the chiropractic protocol developed by Activator Methods, Inc.

Setting: Private, solo practice of an Activator advanced proficiency rated chiropractor with 15 years’ experience.

Design: Prospective case series.

Participants: Nine adult volunteers with articular TMD recruited from the practice of the treating clinician.

Main outcome measures: Change from baseline to follow-up of visual analog scale (VAS) for temporomandibular joint (TMJ) pain and maximum active mouth opening without pain.

Interventions: Full spine and TMJ adjusting in accordance with the advanced protocol of Activator Methods. Participants were typically seen three times per week for two weeks and according to individual progress thereafter for six more weeks.

Results: Eight participants completed outcome assessments. The median VAS decrease was 45 mm (range of 21-71); all experienced improvement. The median increase of mouth-opening was 9 mm (range of 1-15); all showing improvement.

Conclusion: The results of this prospective case series indicated that the TMD symptoms of these participants improved following a course of treatment using the Activator protocol. Consequently, further investigation of this type of chiropractic treatment for patients with the articular type of TMJ is warranted.

Key indexing terms: Temporomandibular disorder; temporomandibular joint; chiropractic.
Onset and recovery of hyperalgesia and hyperexcitability of sensory neurons following intervertebral foramen volume reduction and restoration.

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Objective: To investigate the relationships between L4 and L5 intervertebral foramen (IVF) stenosis (IVFS), as well as the restoration, onset and recovery of behavioral hyperalgesia and alterations in the primary sensory neurons’ excitability.

Methods: IVFS was produced by surgically implanting stainless steel rods unilaterally into the intervertebral foramen at L4 and L5. The insertion of a stainless steel rod in the IVF caused IVF volume reduction, which mimics IVFS. The rods were kept in 16 rats for up to 14 weeks, and for 2-4 weeks in another 32 rats. Rod withdrawal was expected to restore the IVF volume. The rods were withdrawn in 20 rats on the seventh day; and in another 20 rats on the 14th day, postoperatively. Two additional groups of control rats received no surgery or sham operation. Behavioral hyperalgesia was evidenced by the significantly decreased threshold and shortened latency of foot withdrawal to mechanical and thermal stimulation of the plantar surface. Electrophysiological intracellular recordings were obtained in vitro from L4 and/or L5 dorsal root ganglia (DRG).

Results: The IVFS rats exhibited rapid-onset (image - Copyright á Stock Photo / Register Mark 1day), long-lasting (10-11 weeks), mechanical and thermal hyperalgesia. DRG neurons in each category, large-, medium- and small-sized, from IVFS rats, were more excitable than those from control evaluated by the significantly decreased threshold and action potential threshold, and increased number of discharges evoked by depolarizing current and incidence of spontaneous activity. IVF volume restoration significantly reduced behavioral hyperalgesia and the increased excitability of DRG neurons. In contrast, sham surgery produced no behavioral or electrophysiological changes in the ganglion neurons.

Conclusion: The present study demonstrates that hyperalgesia and hyperexcitability of the primary sensory neurons can be induced following the IVF volume reduction produced by insertion of a stainless steel rod, and mostly relieved by rod withdrawal. The recovery of excitability of DRG cells to normal levels is associated with the abatement of hyperalgesia. These results support the hypothesis that increased excitability of DRG is associated with the generation and maintenance of hyperalgesia, and suggest that relief of the IVF stenosis, which could compress all of the normal constituents within the IVF (i.e., DRG, nerve root, blood and lymph vessels, and adipose), and may help to alleviate chronic pain in humans.
Reliability of measuring iliac crest level in the standing and sitting position, using a new measurement device.

*Sara Piva; Richard Erhard, DC; John Childs; Gregory Hicks; Hamza Al-Abdulmohsin*

**Background:** To date, the reliability studies of iliac crest (IC) level used nominal scales and presented conflicting results. To perform the IC level measurement, we propose the use of a measurement device composed of an inclinometer mounted on a crest level tester that measures the IC level in degrees.

**Objectives:** To determine the interrater reliability of measuring the IC level in the standing and sitting position, using an experimental device, and to assess the precision of the measurements taken with the experimental device.

**Method:** Forty individuals (mean age 40 ± 12) referred to physical therapy for treatment of low back pain (LBP) Sixteen males participated in the study; six examiners performed the measurements; and three of the six examiners performed the measurements in each individual. Each examiner independently performed the measurement of IC level in standing and in sitting using the measurement device.

**Results:** Intraclass correlation coefficients, (formula [1, 1]) for measurement of the IC level in standing and sitting were 0.80 (95% CI = 0.7 to 0.9) and 0.73 (95% CI = 0.6 to 0.8), respectively. Standard errors of measurement for IC level in standing and sitting were 0.91 and 0.86 degrees, respectively.

**Conclusion:** The use of a measurement device resulted in good reliability of IC level measurement in degrees in standing and moderate reliability of IC level in sitting position. This finding is relevant to plan future studies that will investigate if changes in IC level may be associated with outcomes of pain and function in patients with low back or pelvic dysfunctions.

**Key Indexing Terms:** Reliability; measurement; iliac crest symmetry; standard error of measurement.
The effects of bite line deviation on lateral cervical radiographs when upper cervical joint dysfunction exists: a pilot study.

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Purpose: To demonstrate the impact of inconsistent bite-line positioning during pre- and postlateral cervical radiographic examinations, and to suggest certain additional imaging studies if the bite line cannot be consistently maintained.

Methods: Radiographic measurements of relative flexion and extension in the atlantal-occipital (AO) and atlantal-axial (AA) joints were taken from neutral lateral cervical and cervical flexion and extension radiographs of 20 subjects.

Results: The average relative AO flexion was -0.9¼ and 12.0¼ of extension, while the average relative AA flexion and extension values were 8.5¼ and 2.8¼, respectively. In addition, 12 out of the 20 subjects (60%) exhibited paradoxical motion at the AO joint during cervical flexion. Of these 12 subjects, 10 also displayed excessive relative AO extension (beyond 7.5¼).

Conclusions: If a bite-line deviation exists in pre- and postlateral cervical radiographic examinations, dynamic cervical flexion and extension radiographs should be taken to calculate the maximum tolerances in the upper cervical spinal joints. If these tolerances are exceeded, the measurement of the cervical lordosis from the back of the second cervical vertebra and seventh cervical vertebra may be altered, thus incorporating the possibility of a 20.3% measurement error on the postlateral cervical radiograph.

Key indexing terms: Radiography; cervical spine; joint motion.

Vertebrobasilar ischemia and spinal manipulation.

Thomas Jensen, DC, DABCI

Objective: To examine cerebral arterial blood flow on two patients exhibiting signs of vertebrobasilar arterial ischemia (VBI), before and after spinal manipulative therapy.
**Clinical features:** Two patients had repetitive/resting tremor: one from a spastic torticollis with the onset immediately after self-manipulation by the patient six months earlier; and one with a generalized resting tremor, hip clonus, dizziness and pre-syncopy. The diagnosis of vertebrobasilar ischemia (VBI) was established by continuous-wave Doppler ultrasound and physical examination.

**Intervention and outcome:** Nonrotary cervical manipulation and diversified technique to the thoracic spine were performed. In the first patient, the spastic tremor improved by 80%. The repeat Doppler performed 13 months later showed an improvement in the arterial flow in the right external carotid artery peak flow from 0.7khz to 1.75khz. In the second patient, the resting tremor diminished in four days, with the right common carotid artery peak systolic flow improving from 1.0khz to 1.9khz, and the left vertebral artery flow improving from 0.175khz to 0.5khz. The symptoms of VBI and objective Doppler findings improved following spinal manipulation. Both cases had impaired vertebral arterial flow.

**Conclusion:** Spinal manipulation may have a normalizing affect to the sympathetic nervous system, allowing for a change in vasospastic cerebral vascular arteries.

**Key indexing terms:** Chiropractic manipulation; vertebrobasilar ischemia; continuous-wave Doppler ultrasound.

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**Chiropractic management of Ehlers-Danlos syndrome: a report of 2 cases.**

*Christopher Colloca, DC; Bradley Polkinghorn, DC*

**Objective:** To discuss two patients with Ehlers-Danlos syndrome seeking chiropractic evaluation and management of their disabling musculoskeletal pain and associated disorders.

**Clinical features:** Two disabled patients diagnosed with Ehlers-Danlos syndrome had spinal pain, including neck and back pain, headache, and extremity pain. Commonalities among these two cases included abnormal spinal curvatures (kyphosis and scoliosis), joint hypermobility and tissue fragility. One patient had postsurgical thoracolumbar spinal fusion (T11-Sacrum) for scoliosis and osteoporosis. The other patient had moderate anterior head translation.
**Intervention and outcome:** Both patients were treated with mechanical-force, manually assisted spinal adjustments delivered to various spinal segments and extremities utilizing an Activator II adjusting instrument and Activator Methods chiropractic technique. Patients were also given postural advice, stabilization exercises, and postural corrective exercises as indicated in Chiropractic BioPhysics Technique protocols. Both patients were able to reduce pain and anti-inflammatory medication usage, in association with chiropractic care. Significant improvement in self-reported pain and disability as measured by visual analog score, Oswestry Low-Back Disability Index and Neck Pain Disability Index was reported, and objective improvements in physical examination and spinal alignment were also observed following chiropractic care. Despite these improvements, work-disability status remained unchanged in both patients.

**Conclusion:** Chiropractic care may be of benefit to some patients with connective tissue disorders, including Ehlers-Danlos syndrome. Low-force chiropractic adjusting techniques may be preferred techniques of choice in patients with tissue fragility, offering clinicians a viable alternative to traditional chiropractic care in attempting to minimize risks and/or side-effects associated with spinal manipulation. Psychosocial issues, including patient desire to return to work, were important factors in work-disability status and perceived outcome.

**Key indexing terms:** Chiropractic; disability; Ehlers-Danlos syndrome; pain; rheumatology; scoliosis; spine.

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