Treatment of the Cervical Spine with the Spineliner®
Results of a pilot study

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Study design.
Double-blind, randomized, placebo-controlled trial

Objective.
To determine the efficacy of the Oscillating Percussion Technique used by the Spineliner to treat chronic neck pain.

Summary of Background Data.
Segmental dysfunction with restricted motion is considered to be an indication for manual therapy. Alternatively the Oscillating Percussion Technique analyses vertebral segmental mobility by transmission of percussive impulses. In the therapy mode it achieves resonance between the percussive sensor head and the restricted joint.

Methods.
Fifty-one chronic neck pain patients (mean age: 54,3 years, f:m = 33:18) were randomly assigned to two groups. The study group received segmental treatment of the cervical spine according to the results of the Spineliner-examination. The control group received sham-treatment determined by sham computer-generated examination findings. Treatment was performed on a single occasion by an orthopedic physician trained in manual medicine. Clinical examinations were performed by a blinded physician, trained in manual medicine, before and immediately after treatment and after one week. The main outcomes included the SF 36 Health Survey, the NDI Neck Disability Score, a 1-0-1 numeric rating scale for neck pain and the range of cervical motion with a Goniometer

Results.
As compared with the sham-treatment subjects, the patients who received treatment with the Spineliner showed statistically significant improvements in neck pain and range of motion immediately after the treatment. After one week a slight but not significant improvement of range of motion was found.

Conclusion.
Treatment with the Spineliner, using the Oscillating Percussion Technique is effective in order to improve ROM and to reduce pain as short term effects.
Further studies with a larger number of treatment sessions will have to prove long term effects.

Key words: clinical trial, spinal manipulation, chronic neck pain, Oscillating Percussion Technique, segmental dysfunction

Pain and restricted range of motion is a major complaint of patients with chronic cervical disorders. 70% of individuals are affected by neck pain at some time in their lives.[1] Approximately 10% to 20% of the population report neck problems.[2,3] In the Finnish national study 9.5% of the male and 13.5% of the female population is affected by chronic neck disorders (prevalence per year).[4]
There exist various treatment options, including conventional pharmacological and invasive pain therapy, physiotherapy, complementary approaches and manual treatment.[5,6] Among drug and invasive pain injection therapy treatment options, manual medicine has been found to be beneficial for persistent neck pain, especially in combination with exercise.[7,8,9] Some of its benefits shown include improvement in pain as measured by validated instruments in sub-acute and chronic pain compared with muscle relaxants or usual medical care.[10,11,12,13] The use of manipulative techniques, especially of HVLA (high velocity low amplitude) manipulations can be potentially harmful[14], worsening preexisting cervical disc herniation[15] or causing vertebral artery dissections.[16]
With the goal to make manual examination methods more accurate and reliable and to minimize the occurrence of adverse effects new technical instruments have been introduced.
The Spineliner was designed to facilitate a systematic and objective approach for diagnosing and treating musculoskeletal pain. Its Technology is based on the Resonance Method Theory, the physical phenomenon of energy conversion: from kinetic to potential to kinetic. Resonance Method Theory is furthermore based on the scientific principle that vibration damping, as a physical science phenomenon, is measurable and quantitative.
In the analytical mode, a mild percussive impulse is transmitted through a piezoelectric sensor and into a vertebral segment. Vertebral segment mobility and resonance are calculated from each wave form generated by the tester head. The electronically sensed information compiled during the testing process is stored and analyzed by specialized software on a computer monitor.
In the therapy mode the Spineliner intends to achieve resonance between the percussive sensorhead and the specific joint. The instrument utilizes a low impact, high velocity, periodic

driving force to impart an induced harmonic motion to spinal segments of the body with the objective of achieving the resonance of a vertebral unit.[17,18,19] When the computer registers 10 consecutive “taps” that are measured equally it registers that the vertebrae is less rigid and automatically stops the percussion. By reassessment the pre-treatment and post-treatment conditions can be compared to document the successful effect of treatment.

Methods

Design.

After obtaining the approval from the local Ethics Committee at the KAV (Union of Vienna Hospitals) and written informed consent, 51 otherwise healthy adult patients with chronic neck pain were enrolled in the randomized, prospective double-blinded study. The Study was conducted at the outpatient ward of the Orthopedic Hospital Vienna-Speising.

Patients.

Patients who had a primary problem of neck pain with and without radiation into the head or the upper extremities that had persisted for more than twelve weeks were eligible for this study.

During the study no intake of NSAIDs or muscle relaxant drugs was allowed. Any physical therapy had to be paused four weeks before the participation in the study and during it.

Exclusion criteria were acute neck pain, cervical disc herniation with radiculopathy, previous cervical spine surgery, rheumatoid arthritis, history of malignoma, recent trauma of the cervical spine, severe osteoporosis and acute infections.

Patients were recruited from the waiting list for admission to the Department of Orthopedic Pain Management. Initial screening was accomplished by telephone and eligible persons attended a baseline evaluation appointment.

Randomization.

Eligible patients were randomized to the treatment- (TR) or the sham-group (SH) on the basis of a computer-generated list using a 1:1 allocation ratio.

Interventions.

The participating patients were examined by a doctor, experienced in manual medicine at baseline before and immediately after Spineliner-treatment and at follow up after one week.

Spineliner treatment group. During a segmental examination of the cervical spine with the Spineliner segmental restrictions were diagnosed. One to two restricted segments were treated by series of impulses generated by the sensorhead of the Spineliner. After reassessment with the Spineliner one restricted segment was treated in the same way.

Sham treatment group. As the participants never before have been treated by the Spineliner-method, they had no imagination how examination or treatment would be performed. So a probe that was not connected to the Spineliner was used for examination and treatment. The impulses that generate sounds and curves and bars on the computer display were directed on the examiner's forearm. None of the participants had any doubt of not having received real treatment.

Outcome Measures.

Pain, the primary outcome measure, was rated by patients on a Numeric Rating Scale from 0 (no symptoms) to 100 (highest severity of pain)[22,23] at baseline, after treatment and at follow up after one week. Patient self-report questionnaires were administered at baseline. Disability was measured by the Neck Disability Index[20] and functional health status by the Short Form (SF-36).[21]

Neck performance. Cervical range of motion was recorded at baseline, after treatment and at follow-up after one week by observers blinded to patient group allocation. Active rotation, flexion-extension and sidebending were measured by a three plane gauge goniometer (CROM Goniometer, Performance Attainment Associates, St. Paul, MN).

Statistical Analysis. Analyses were performed with SPSS for Windows, Version 10.0 (SPSS, Chicago, IL). Baseline values were compared using unpaired Student's t-tests. P-values <0.05 were considered as statistically significant. The random allocation of patients resulted in two groups comparable in all baseline variables.

Results.

Fifty two patients were included, at the initial examination one person had to be excluded because of severe pain, so fifty one patients were enrolled in the study. Five patients did not show at the follow-up appointment through noncompliance. Accordingly 51 patients (33 women and 18 men) were analyzed.

No significant difference was found between the groups concerning the baseline parameters listed in Table 1.

	TR (n = 26)	SH (n= 25)	P-Value
Age in years, mean (SD)	53,75	57,87	p<0.01
Sex: female/male	17:9	16:9	
Socioeconomic status			
Retired	9	8	
working full time	14	13	

housewives	2	1	
Unemployed or on sick leave	1	3	
Family status			
Single	6	4	
Partnership	12	11	
With family	6	9	
Without details	2	1	
Profession			
Employee	9	9	
Retired	9	8	
Self-employed	5	2	
Unemployed	0	3	
Housewife	0	2	
Sick leave	1	0	
Without details	2	1	
Education			
Primary school	12	11	
College	9	8	
University	2	5	
Without details	3	1	

Table 1, Baseline Parameters

Patient-Rated Outcomes.

At baseline patients rated their pain on the Numeric Rating Scale with 4.136 in group TR and 3.391 in group SH. After one Spineliner treatment pain was reduced in group TR to 1.477 versus 3.304 in group SH, showing statistical significance ($p < 0.01$). At follow up after one week the pain rating was almost equal (2.727/2.696).

Neck Performance Outcomes.

At baseline range of motion in the three planes was measured in degrees for flexion-extension 96.14 in group TR versus 105.22 in group SH, for sidebending 69.77 versus 70.65, for rotation 130.68 versus 125.0 and for total range of motion 293.59 versus 300.87. After one Spineliner treatment motion in each plane increased. The measured values for flexion-extension were 96.14 versus 105.22 ($p < 0.1$), for sidebending 80.23 versus 67.83 (< 0.01), for rotation 141.14 versus 125.43 ($p < 0.04$) and for total range of motion 334.09 versus 298.26 (< 0.03). So there was found a significant increase in sidebending and rotation as well as in total range of motion. At follow up after one week the following values were found: flexion-extension 110.0 in group TR versus 107.3 in group SH, for sidebending 71.14 versus 70.65, for rotation 135.68 versus 125.0 and for total range of motion 316.82 versus 303.0. These results still indicate a trend to improved motion in group TR but lacking of significance.

Side effects.

No notable increases in neck or headache pain were reported. Two patients described a mild headache between treatment and the 1 week follow-up.

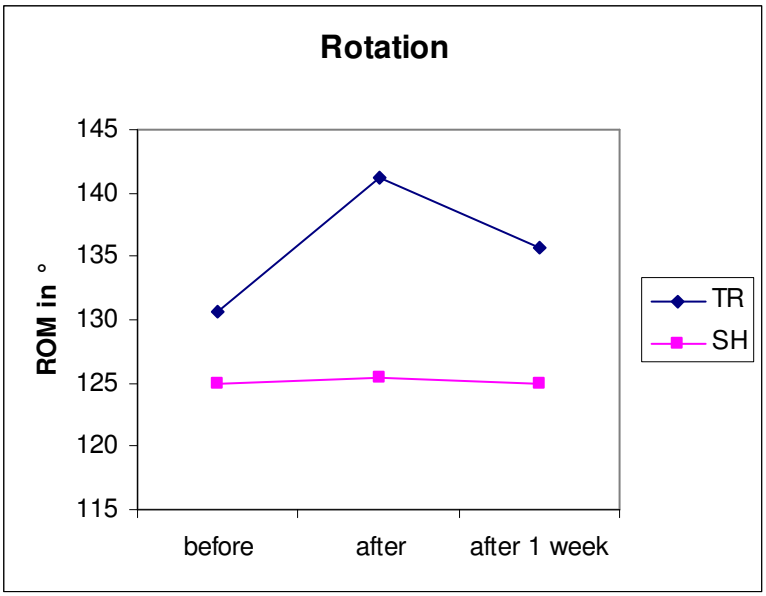

Figure 1. Rotation p<0,01

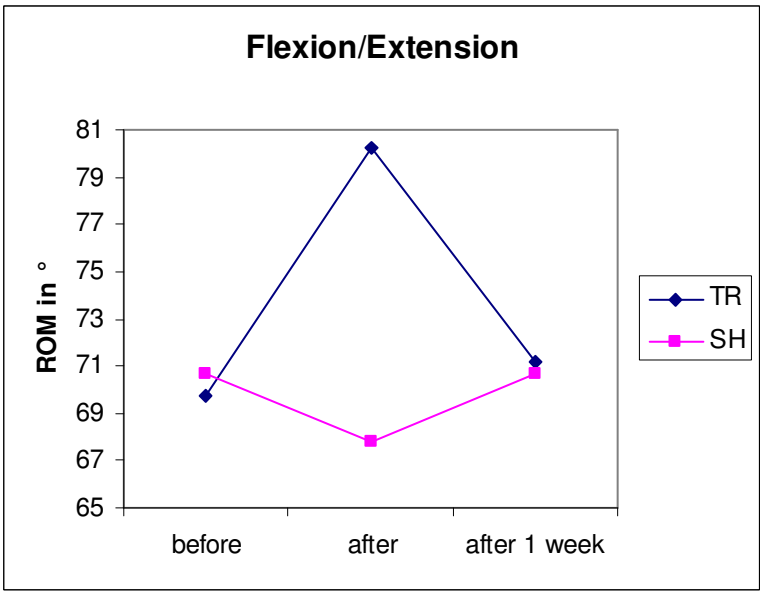

Figure 2. Flexion/Extension p<0,01

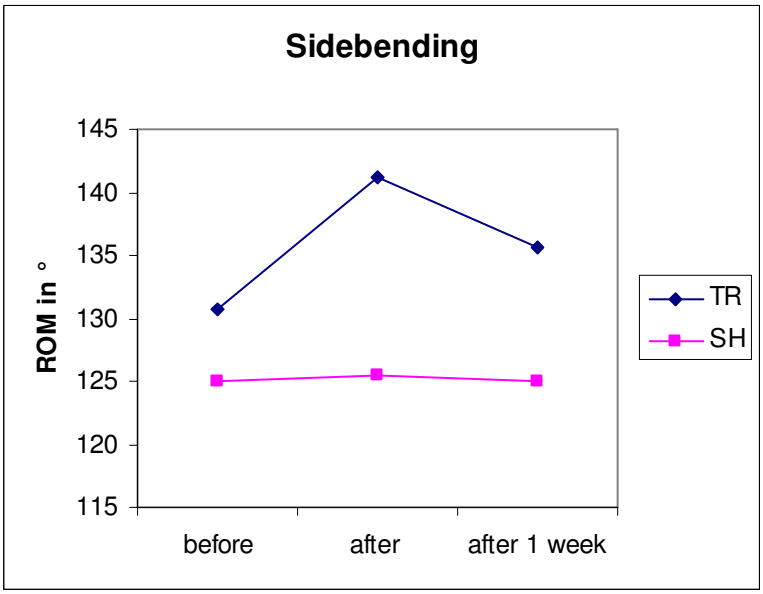

Figure 3. Sidebending p<0,01

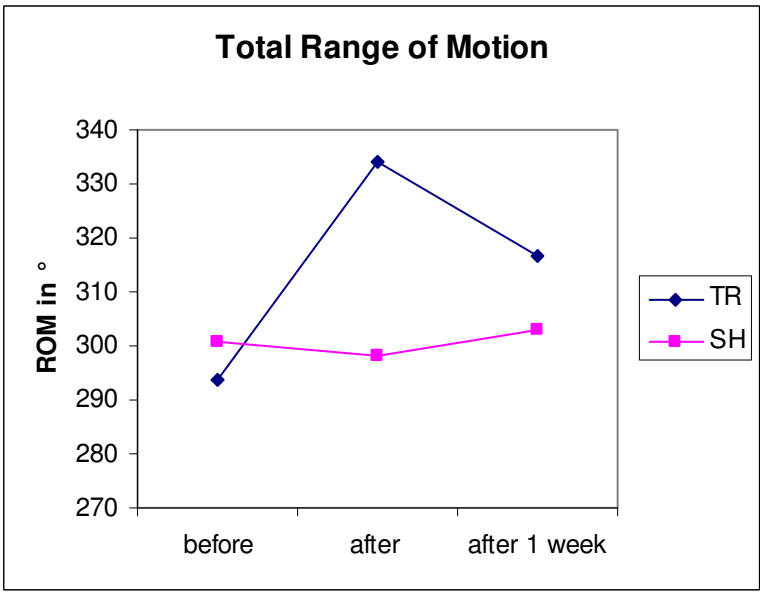

Figure 4. Total Range of Motion p<0,01

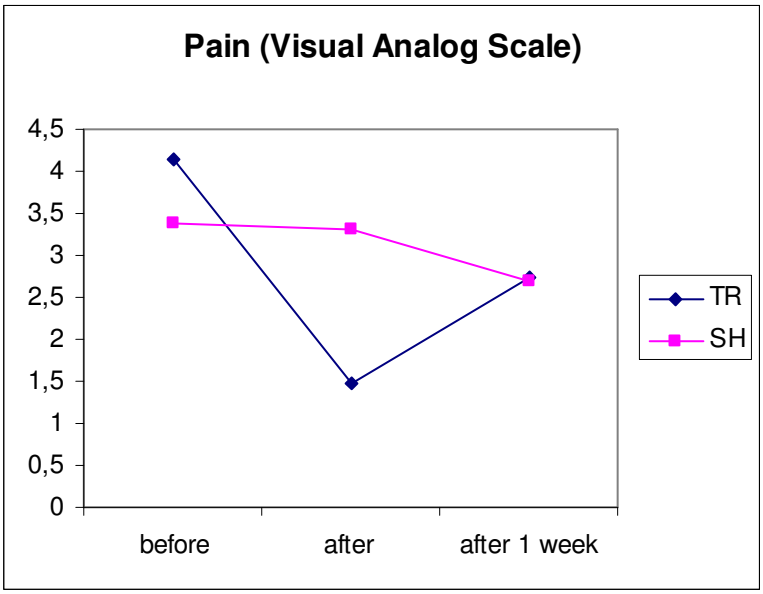

Figure 5. Pain (VAS) p<0,01

Discussion.

In this clinical trial, investigating the oscillating percussion technique of the Spineliner on patients with chronic neck pain an effect could be measured. As compared with the sham-treatment subjects, the patients who received treatment with the Spineliner showed statistically significant reduction of neck pain. Rotation and sidebending as coupled motion and total range of motion increased immediately after treatment with statistical significance. After one week still a tendency towards improved range of motion was found. The method seems to be safe without notable side effects.

Treatment of chronic pain of the musculoskeletal system turns out to be a challenge for health care specialists. Numerous therapies and ways of treatment are commonly recommended for neck pain, yet controversy persists over their effectiveness. For chronic mechanical neck disorders at short-term follow-up, intramuscular injection of lidocaine was superior to placebo or dry needling, but similar to ultrasound. In chronic neck pain with radicular findings, epidural methylprednisolone and lidocaine reduced neck pain and improved function at one-year follow-up compared to the intramuscular route. There was moderate evidence that Botox A intramuscular injections for chronic neck pain were no better than saline.[24] Single sessions of manipulation or multiple sessions (3 to 11 weeks) of manipulation or mobilisation, or manipulation and mobilisation showed a nonsignificant benefit in pain relief when assessed against placebo, control groups or other treatments for chronic mechanical neck disorders with or without headache. Multimodal care has short-term and long-term maintained benefits for chronic mechanical neck disorders with or without headache. The common elements in this care strategy were mobilisation and/or manipulation plus exercise. The evidence did not favour manipulation and/or mobilisation done alone or in

combination with various other physical medicine agents; when compared to one another, neither was superior. People with neck pain as well as people with neck pain plus related headache that lasted at least one month, who received multimodal care that included exercises plus mobilisation [movement imposed onto joints and muscles] or manipulation [adjustments] reported greater pain reduction, improved ability to perform everyday activities and an increase in their perceived effects of treatment than those who received no treatment. A review of 33 trials did not favour manipulation or mobilisation done alone or in combination with various other physical medicine agents. It was unclear if manipulation and mobilisation performed in combination were beneficial, but when compared to one another, neither was superior.[8] For chronic neck pain, the use of strengthening exercise, whether in combination with spinal manipulation or in the form of a high-technology MedX program, appears to be more beneficial to patients with chronic neck pain than the use of spinal manipulation alone .[7] The effectiveness of electrotherapy as a physiotherapy option has remained unclear. The current evidence on Galvanic current (direct or pulsed), iontophoresis, TENS and permanent magnets is either lacking, limited, or conflicting.[25]

Physicians trained in manual medicine assess joint motion before the application of joint mobilization techniques. Spinal motion analysis i.e. motion palpation is a concept used by all practitioners of spinal manipulative therapy for assessing the relative mobility of spinal segments. Devices have been designed or adapted from mechanical testing equipment for the purpose of obtaining more objectivity in the measurement of joint stiffness and for measuring the effects of applied force and oscillation frequency on human spinal segments.[26, 27] Panjabi has devised a model to clarify and explain the complexities of the mechanics of coupled motions of the human spine.[28] DiFabo has reviewed and commented on the efficacy of joint mobilization techniques.[29] Laboratory models have been constructed and experimental studies have been designed to test inter-practitioner accuracy and precision in estimating the amount of force applied and the amount of joint mobility achieved during spinal joint mobilization techniques.[30, 31] The conclusion of one study was that inter-therapist variability was high and there was a universal bias toward underestimating the magnitude of the applied force and overestimating the motion of spinal segments during mobilization therapy.[30] Even so, joint mobilization technique is considered to be an effective therapy for patients with spinal segment dysfunction. Use of the Spineliner System in the application of joint mobilization techniques will improve the inter-therapist reliability and precision.

Limitations of this study are the small sample of test persons and the short follow-up period.

Conclusion.

Treatment with the Spineliner, using the Oscillating Percussion Technique is effective in order to improve range of motion and to reduce pain as short term effects.

Further studies with a larger number of treatment sessions will have to prove long term effects.

References

1. Cote P, Cassidy JD, Carroll L. The Saskatchewan health and back pain survey: The prevalence of neck pain and related disability in Saskatchewan adults. *Spine* 1998;23:1689–98.

2. Helewa A, Goldsmith CH, Lee P, et al. The prevalence of neck pain in a university community. *Phys Ther* 1994;74:S26.

3. Holmstrom EB, Lindell J, Moritz U. Low back and neck/shoulder pain in construction workers: Occupational workload and psychosocial risk factors: Part 2. Relationship to neck and shoulder pain. *Spine* 1992;17:672–7.

4. Makela M, Heliovaara M, Sievers K, Impivaara O, Knekt P, Aromaa A. Prevalence, determinants and consequences of chronic neck pain in Finland. *Am J Epidemiol* 1991;134:1356-67.

5. Zenz M, Jurna I. *Lehrbuch der Schmerztherapie* [Textbook of Pain]. 2nd Ed. Stuttgart: Wissenschaftliche Verlagsgesellschaft, 2001.

6. Tilscher H, Eder M. *Lehrbuch der Reflextherapie* [Textbook of Reflextherapy], 2nd Ed. Hippokrates Verlag, Stuttgart, 1989.

7. Bronfort G, Evan R, Nelson B, et al. A randomized clinical trial of exercise and spinal manipulation for patients with chronic neck pain. *Spine* 2001;26:788–99.

8. Gross AR, Hoving JL, Haines TA, Goldsmith CH, Kay T, Aker P, Bronfort G, Cervical overview group. Manipulation and mobilisation for mechanical neck disorders. *The Cochrane Database of Systematic Reviews 2002*, Issue 3. Art. No.: CD004249.pub2. DOI: 10.1002/14651858.CD004249.pub2.

9. Jull G, Trott P, Potter H, Zito G et al. A Randomized Controlled Trial of Exercise and Manipulative Therapy for Cervicogenic Headache. *Spine* 2002; 27:1835–1843.

10. Koes B. A randomized clinical trial of manual therapy and physiotherapy for persistent back and neck complaints. Subgroup analysis and relationship
between outcomes measure. *J Manipulative Physiol Ther* 1993;16:211–19.

11. Koes BW, Bouter LM, van Mameren H, et al. Randomized clinical trial of manipulative therapy and physiotherapy for persistent back and neck complaints:
results of one year follow up. *Br Med J* 1992:601–5.

12. Koes BW, Bouter LM, van Mameren H, et al. The effectiveness of manual therapy, physiotherapy, and treatment by the general practitioner for nonspecific
back and neck complaints. *Spine* 1992;17:28–35.

13. Cassidy JD, Lopes AA, Yong-Hing K. The immediate effect of manipulation versus mobilization on pain and range of motion in the cervical spine: a randomized controlled trial. *J Manipulative Physiol Ther* 1992;15:570–75.

14. Assendelft WJJ, Bouter LM, Knipschild PG. Complications of spinal manipulation: A comprehensive review of the literature. *J Fam Pract* 1996;42:475-480.

15. Malone DG, Baldwin NG, Tomecek FJ, Boxell CM et al. Complications of cervical spine manipulation therapy: 5-Year retrospective study in a single-group practice. *Neurosurg Focus* 13(6), 2002.

16. Haldeman S, Kohlbeck FJ, Mc Gregor M. Unpredictability of cerebrovascular ischemia associated with cervical spine manipulation therapy: A review of 64 cases after cervical spine manipulation therapy. *Spine* 2002;27:49-55.

17. Wood TG, Colloca CJ, Matthews R. A pilot randomized clinical trial on the relative effect of instrumental (MFMA) versus manual (HVLA) manipulation in the treatment of cervical spine dysfunction. *J Manipulative Physiol Ther*. 2001 May;24(4):260-71.

18. Fuhr AW, Smith DB. Accuracy of piezoelectric accelerometers measuring displacement of a spinal adjusting instrument. *J Manipulative Physiol Ther*. 1986 Mar;9(1):15-21.

19. Polkinghorn BS. Treatment of cervical disc protrusions via instrumental chiropractic adjustment. *J Manipulative Physiol Ther*. 1998 Feb;21(2):114-21.

20. Vernon H, Mior S. The Neck Disability Index: A study of reliability and validity. *J Manipulative Physiol Ther* 1991;14:409–15.

21. Brazier JE, Harper R, Jones NM, et al. Validating the SF-36 health survey questionnaire: New outcome measure for primary care. *BMJ* 1992;305:
160–4.

22. Jensen MP, Karoly P, Braver S. The measurement of clinical pain intensity: A comparison of six methods. *Pain* 1986;27:117–26.

23. Jensen MP, Turner JA, Romano JM, et al. Comparative reliability and validity of chronic pain intensity measures. *Pain* 1999;83:157–62.

24. Peloso P, Gross A, Haines T, Trinh K, Goldsmith CH, Aker P, Cervical Overview Group. Medicinal and Injection therapies for mechanical neck disorders. *The Cochrane Database of Systematic Reviews 2005,* Issue 2. Art. No.: CD000319.pub3. DOI: 10.1002/14651858.CD000319.pub3.

25. Kroeling P, Gross A, Goldsmith CH, Houghton PE, Cervical Overview Group. Electrotherapy for neck disorders. *The Cochrane Database of Systematic Reviews 2005*, Issue 2. Art. No.: CD004251.pub3. DOI: 10.1002/14651858.CD004251.pub3.

26. Latimer J, et al. Evaluation of a New Device for Measuring Responses to Posteroanterior Forces in a Patient Population, Part 1: Reliability Testing. *Physical Therapy* 1996; Vol. 76:2.

27. Lee M, Moseley A, Refshauge K. Effect of Feedback on Learning a Vertebral Joint Mobilization Skill. *Physical Therapy* 1990;Vol. 70:2.

28. Panjabi MM. Experimental Determination of Spinal Motion Segment Behavior. *Orthopedic Clinics of North America* 1977;Vol. 8 No. 1.

29. DiFabio RP. Efficacy of Manual Therapy. *Physical Therapy* 1992;Vol. 72:12.

30. Simmonds MJ, Kumar S, Lechelt E. Use of a Spinal Model to Quantify the Forces and Motion That Occur During Therapists' Tests of Spinal Motion. *Physical Therapy* 1995;Vol. 75:3.

31. Gonnella C, Paris SV, Kutner M. Reliability in Evaluating Passive Intervertebral Motion. *Physical Therapy* 1982;Vol. 62:4.