

Efficacy of Cervical Endplay Assessment as an Indicator for Spinal Manipulation

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

Objectives. To evaluate the effect of manual endplay assessment on neck pain and stiffness outcomes in neck pain patients receiving spinal manipulation.

Summary of the Background Data. There have been no studies on the efficacy of palpation used as an indicator for manipulation in the management of back and neck pain.

Methods. Neck pain patients ($n = 104$) were randomly assigned to two groups. The study group received manipulation targeted to individual cervical vertebrae according to endplay restriction noted by the examining clinician. The control group received manipulation determined by sham, computer-generated examination findings; endplay examination was ignored and served as a placebo assessment. Treatment was rendered on a single occasion by a chiropractor. Outcomes were neck pain and stiffness assessed before and after manipulation and at least 5 hours following treatment.

Results. The study and control groups showed clinically important improvement in neck pain and stiffness. However, there were no clinically important or statistically significant differences between the study and control groups in terms of pain or stiffness outcomes. Findings were robust across patient, complaint, and treatment characteristics.

Conclusions. Endplay assessment in and of itself did not contribute to the same-day pain and stiffness relief observed in neck pain patients receiving spinal manipulation. The impact on a longer course of treatment remains to be investigated. The data suggest that pain modulation may not be limited to mechanisms associated with manipulation of putative motion restrictions. [Key words: chiropractic, joint manipulation, manipulation indicator, palpation, neck pain, randomized controlled trial, test efficacy] *Spine* 2003;28:1091–1096

Joint motion palpation, particularly passive endplay assessment, is recognized as an essential skill by manual medicine disciplines and is used extensively by chiroprac-

tors,¹ physical therapists,² osteopaths,³ and some medical doctors⁴ in clinical practice as an indicator for spinal manipulation and mobilization. However, little is known about the validity, or more importantly, the efficacy of these palpation procedures. The focus of this study was to evaluate the efficacy of endplay in terms of its impact on pain and stiffness in patients receiving spinal manipulation for neck pain.

The assessment of reliability has dominated motion palpation research. Eight reviews of the literature are consistent in their conclusions regarding agreement on active and passive segmental motion restriction. Interexaminer reliability of motion palpation is poor throughout the spine ($\kappa < 0.2$), whereas intraexaminer reliability is moderate (0.4–0.6).^{5,6,7,8,9,10,11,12} There is also only indirect evidence of motion palpation validity. Mechanical models have been used to demonstrate moderate sensitivity (0.48–0.54) for identifying segmental fixation¹³ and to demonstrate that therapists can discriminate the small gradation in spinal stiffness required to identify endplay restriction in clinical practice.^{14,15} Studies have shown that examiners can discern endplay improvement following manipulation¹⁶ and can accurately identify segmental dysfunction (verified by facet injection).¹⁷

There remain important questions regarding the usefulness of motion palpation as an indicator for spinal manipulation. Most investigators have focused on identifying specific segmental motion restriction. This is consistent with the practice tenet that the identification and treatment of dysfunction or lesions in specific motion segments are necessary for optimal patient care. However, the mechanism and clinical importance of this tenet have yet to be investigated. If treatment efficacy of spinal manipulation does not require exact segmental specificity, then the usefulness of manipulation indicators has not been evaluated in a clinically relevant manner.¹⁸

Furthermore, there is at present no gold standard for the evaluation of the validity of manual assessment procedures used to guide therapists in determining the need for manipulation or the precise vertebral location and direction of the dynamic thrust to be imparted. This is because the mechanical and physiologic mechanisms of manual therapy and its therapeutic effects have yet to be elucidated.

The ultimate criterion for determining the usefulness of any assessment procedure is its impact on patient outcomes (test utility or efficacy).¹⁹ Efficacy of a test is determined through randomized trials comparing outcomes in patients receiving the test to those not receiving

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Acknowledgement date: August 19, 2002. First revision date: October 17, 2002. Acceptance date: October 21, 2002.

The submitted manuscript does not contain information about medical devices or drugs. Federal funds were received in support of this work. No benefits in any form have been or will be received from a commercial party related directly or indirectly to the subject of this manuscript. Address correspondence to Mitchell Haas, DC, MA, Professor and Dean of Research, Western States Chiropractic College, 2900 NE 132nd Ave., Portland, OR 97230, USA; E-mail: mhaas@wschiro.edu

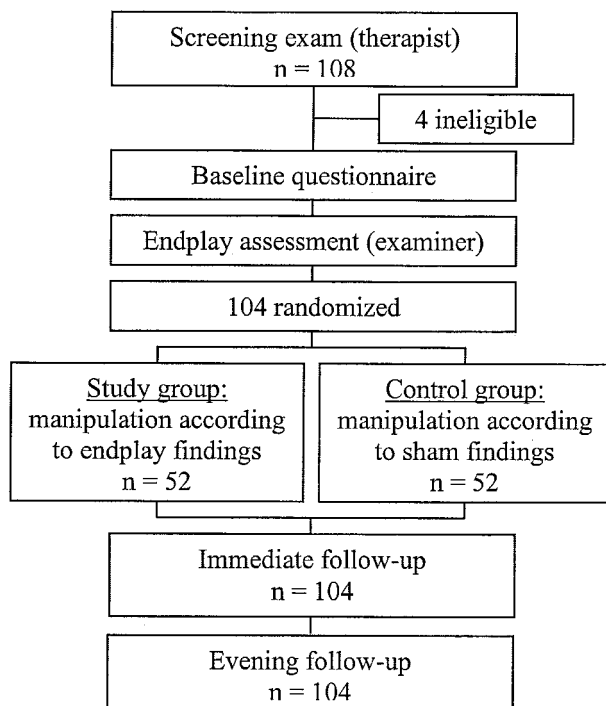


Figure 1. Study flowchart.

the test or receiving an alternative test. Test efficacy is contingent on a treatment effect of the indicated therapy.¹⁹ Although not a consensus opinion,^{20,21} two systematic reviews suggest the efficacy of spinal manipulation for the treatment of neck pain.^{22,23} Furthermore, a randomized trial demonstrated substantial immediate pain abatement following cervical manipulation.²⁴ To date, no published studies have evaluated the efficacy of any manipulation indicators or other manual test procedures. As a first step in the evaluation of test efficacy, the purpose of this study was to determine if the large immediate neck pain reduction following cervical manipulation was attributable to a widely used indicator, cervical endplay restriction. There was one primary research question: whether there was a clinically important effect of endplay assessment on neck pain compared with a placebo assessment procedure. The safety of manipulation based on a sham assessment control was also evaluated in anticipation of trials of routine practice requiring multiple visits to a therapist.

Methods

Participants and Setting. The efficacy of endplay assessment was evaluated in a prospective, double-blind, randomized, placebo-controlled trial (Figure 1). This study was conducted at the Western States Chiropractic College (WSCC) Outpatient Clinic in Portland, Oregon, and at a private practice in a Portland suburb.

Potential participants were recruited for the study by therapist referral or advertisement. Participants were included if they were at least 18 years old, reported a minimum pain level of 10 on a 100-mm visual analogue scale (VAS), and had received no cervical manipulation within the preceding 48 hours.

Contraindications to cervical manipulation included cancer, blood dyscrasias, severe osteopenia, severe trauma or fracture, disc herniation or cervical radiculopathy, and signs of vertebral insufficiency. All participants (n = 104) signed a study information and consent form. The study was approved by the institutional review boards of WSCC and Palmer College of Chiropractic.

Outcomes and Sample Size. The primary outcome of the study was neck pain evaluated immediately after cervical manipulation on the VAS.^{25,26} The sample size (n = 52/group) was selected *a priori* to detect a 10-point difference between groups in the primary outcome with 80% power for a two-sided test set at the 0.05 level of significance. Secondary outcomes included immediate posttreatment stiffness evaluated on a VAS as well as evening pain and stiffness reported by telephone using 11-point numerical rating scales.²⁷ These were converted to 0 to 100 point scales for the analysis. To help minimize biased reporting, participants were assured that study physicians would not see their questionnaires and that exaggerating relief to make the therapist look better would actually have a negative impact on study findings.

Assessment. The therapist conducted an initial screening examination to determine eligibility of the prospective participant. Once accepted, the participant filled out a baseline questionnaire, supplying information about demographics, VAS for current neck pain and stiffness, duration of symptoms, and the Neck Disability Index.²⁸

The two examiners who performed the cervical endplay assessment were WSCC faculty, chiropractors with 18 and 11 years of teaching and practice experience. Before the study, practice sessions were conducted to standardize all procedures. Each examiner performed an endplay assessment on half of the study participants in both the study and control groups. Restriction at the endpoint of passive range of motion was assessed manually in the supine position for the atlanto-occipital (C0–C1) and C1–C2 to C6–C7 motion segments in all three planes of motion, as described by Bergmann *et al.*¹ Endplay restriction, considered to be of sufficient magnitude to indicate spinal manipulation, was recorded on an examination form with respect to vertebral level and side. Participants and therapists performing manipulation were blinded to the findings of the endplay assessment performed by the examiner.

Randomization and Therapy Assignment. Group allocation was concealed from participants and all study personnel before randomization. Participants and physicians remained blinded to group allocation throughout the study. Participants were randomized to study or control group by the project manager using a computerized design adaptive randomization algorithm to balance baseline neck pain and stiffness across groups.^{29,30} Randomization was stratified by examiner. The study group received manipulation targeted to individual cervical vertebrae according to whether cervical endplay restriction was noted by the examining clinician. However, the control group received manipulation according to sham endplay findings, generated by a second computer algorithm used to match the number and site of manipulations for the control group to the patterns of manipulation received by the study group.²⁹ The actual endplay examination served as a placebo in the control group.

Treatment. The therapists were two chiropractors; one had 20 years of experience, and the other had 2 years. Each therapist treated one half of the study participants with supine high-velocity, low-amplitude manipulation of the cervical spine, as described by Bergmann *et al.*¹ The therapists received an instructive form from the project manager designating the vertebral level and side on which the manipulation was to be performed. As an additional safety precaution, individual manipulations were omitted if pain was provoked by light pressure administered during the set-up for the manipulation. Therapist blinding was maintained because the therapists were aware that they would often disagree with the examiners on the site of endplay restriction and hence could not distinguish real and sham endplay findings.

Statistical Analysis. The primary analysis was conducted using the intention-to-treat principle. Analysis of covariance (ANCOVA) was used in the primary analysis to compare immediate, postmanipulation neck pain (primary outcome) in the study and control groups, with baseline pain score as the covariate. ANCOVA was also performed on the secondary outcomes with the baseline score of the outcome variable as covariate: immediate postmanipulation neck stiffness, evening stiffness, and evening neck pain. Within-group changes (follow-up minus baseline) were evaluated using repeated measures *t* tests.

Secondary analysis was also carried out by extension of the ANCOVA model to determine the effect of examiner and therapist in a three-way ANCOVA. In addition, the independent effects of potential predictors of the four outcomes were explored using multiple regression models. The models included group, baseline outcome variable score, gender, neck pain duration, age, and number of restrictions in cervical endplay recorded by the examiner. To evaluate safety, logistic regression was used to compare the risk of exacerbation in neck pain and stiffness between the study and control groups after adjusting for baseline severity. Data were scanned into a Microsoft Fox Pro file (Bellevue, WA) and verified. Analysis was carried out using Stata (Version 5.0, College Station, TX) and SPSS for Windows (Version 11, Chicago, IL).

Results

Of the 108 people receiving a screening examination, four were excluded from the study because of cervical radiculopathy, dizziness on neck rotation, no pain and stiffness, and disinterest (Figure 1). There were no dropouts or missing data for the 104 randomized participants (52/group). Five in the study group were excluded from the primary analysis because they were inadvertently enrolled without meeting the neck pain inclusion criterion. Such postrandomization exclusion is appropriate in an intention-to-treat trial and yields unbiased results.³¹ An additional person from each group was omitted from the secondary analysis of neck stiffness because they did not have a minimum of 10 points on a 100-point stiffness VAS.

Participant and Treatment Characteristics

The demographic, complaint, and treatment characteristics of study participants were well balanced across groups (Table 1). On average, participants had moderate baseline pain, stiffness, and pain-related functional dis-

Table 1. Baseline Participant and Treatment Characteristics

	Study Group (n=47)		Control Group (n=52)	
	Mean/%	SD	Mean/%	SD
Sociodemographics				
Age	42.2	12.9	42.9	14.4
Sex: female	59%		67%	
Race: White, nonHispanic	92%		92%	
Complaint Characteristics				
Neck Pain	42.3	16.5	40.4	20.9
Neck stiffness*	44.5	17.7	43.9	20.4
Neck Disability Index†	28.4	12.2	27.5	11.6
Pain duration (>3 mo)	51%		63%	
Cervical exam & treatment				
Endplay restrictions‡	1.9	1.0	1.9	0.9
Cervical manipulations	1.9	1.0	1.9	1.0

* N=47, 51 (2 additional subjects with stiffness, <10 omitted from the analysis).

† Evaluated on a 0 to 100 scale.

‡ 74% had 1 or 2 restrictions; range = 0 to 5 restrictions and manipulations.

ability. More than half reported chronic neck pain. The median number of cervical endplay restrictions and manipulations was 2 in both groups (range, 0–5). The design adaptive algorithm successfully matched the number of manipulations in the control group to the study group in terms of the distribution of cervical vertebral level and side of application of the manipulations (Figure 2). The Figure shows that manipulations were concentrated between C1 and C3.

Endplay Efficacy

Study outcomes are presented in Table 2. There was no clinically important or statistically significant difference between groups in the primary outcome, immediate postmanipulation pain (adjusted mean difference, 0.9; SE, 3.5; *P* = 0.806). *Post hoc* power analysis revealed that the study had 80% power to detect a 9.8-point difference between groups with 95% confidence. The results for the secondary outcomes were consistent with those for the primary.

The secondary analysis further demonstrated uniform results across all potential confounding variables. There were no clinically important or statistically significant effects of examining physician, treating physician, or their interactions. There were also no effects of gender, age, duration of complaint, or number of endplay restrictions in the cervical spine. Baseline pain was a predictor of pain outcomes, and baseline stiffness was a predictor of stiffness outcomes (*r* = 0.50–0.53, *P* = 0.000). However, there was no interaction of baseline variables with group. This means that outcomes were consistent across study and control groups throughout the range of baseline pain and stiffness. Sensitivity analysis was conducted by repeating the analysis with all 104 participants included. There were no effects on study results of eliminating the ineligible participants that were inappropriately included in the study.

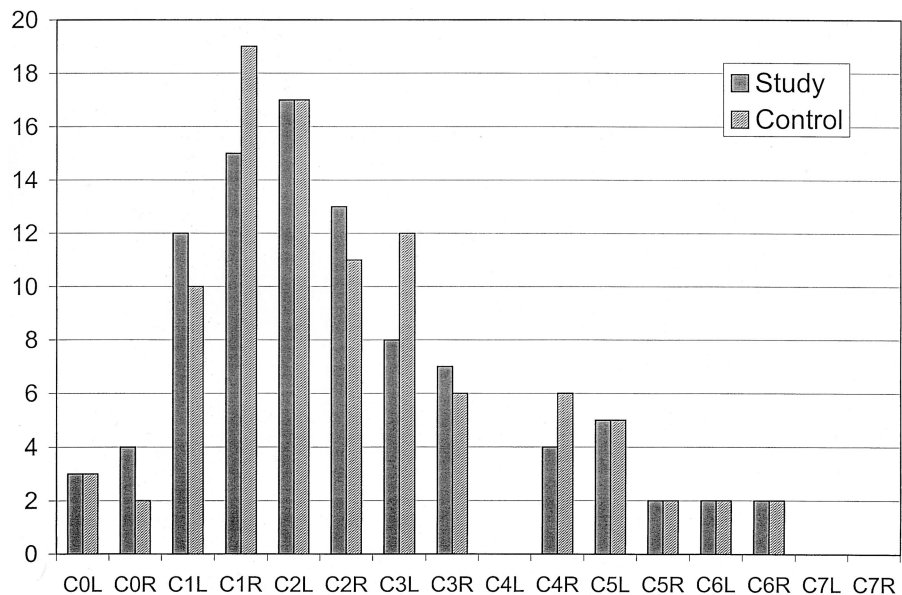


Figure 2. Distribution of manipulations. The contact points for the manipulations are designated by vertebral level and side of the neck. Manipulations performed and motion restrictions identified were identical in the study group.

In terms of safety, logistic regression showed the risk of immediate pain exacerbation for examination-based manipulation was no different from the risk associated with computer-generated indication for manipulation (odds ratio, 1.05; 95% CI, 0.36–3.04; $P = 0.932$). Results were similar for the secondary variables.

Within-group Improvement

As shown in Table 2, participants achieved immediate, clinically important pain improvement in both the study group (mean, -15.7 ; SD, 18.0; $P = 0.000$) and the control group (mean, -15.7 ; SD, 20.4; $P = 0.000$). Large, immediate improvement was found for stiffness as well. Average improvement was between 37 and 46% for the two variables. Important pain and stiffness improvement was sustained through the evening follow-up. However, evening change scores must be interpreted with caution because of potential systematic bias between the two

pain scales used. There was also the possibility of analgesic use before evening follow-up.

Overall, 81% of the participants had immediate pain improvement, 17% showed mild exacerbation, and 2% showed no change. In addition, 88% had immediate improvement in stiffness, 11% had increased stiffness, and 1% had no change. The maximum immediate improvement in pain was 72 points, while the maximum exacerbation was 21 points. The maximum immediate improvement in stiffness was 71 points, and the maximum exacerbation was 19 points.

Discussion

This was the first study to evaluate efficacy of an indicator for spinal manipulation selection. The principal finding was that a diagnostic indicator, endplay restriction, did not contribute to neck pain and stiffness outcomes

Table 2. Pain and Stiffness Outcomes (0 to 100 Point Scales)

Outcome	Study Group			Control Group			Adjusted Group Difference		
	Mean	SD	P	Mean	SD	P	Mean*	SE	P
Immediate follow-up									
Pain (n=47, 52)									
Score	26.6	20.2		24.7	19.5		0.9	3.5	.806
Change†	-15.7	18.0	.000	-15.7	20.4	.000			
Stiffness (n=46, 51)									
Score	26.0	20.2		24.4	19.4		1.3	3.4	.711
Change	-19.3	19.2	.000	-20.3	18.1	.000			
Evening follow-up									
Pain (n=47, 52)									
Score	31.9	20.3		28.7	19.6		2.2	3.5	.523
Change	-10.4	19.2	.001	-11.7	19.0	.000			
Stiffness (n=46, 51)									
Score	34.6	18.5		30.2	22.3		4.0	3.6	.266
Change	-10.8	19.0	.000	-14.5	19.1	.000			

* The adjusted between-group difference for study group—control group. A positive number favors the control group.

† Change is defined as follow-up (post) score—baseline score. A negative score indicates within-group improvement.

following cervical manipulation. In conjunction with this observation, participants experienced immediate, and in some cases quite dramatic, clinically important improvement. The findings were robust with respect to examining and treating physician, baseline pain and stiffness, complaint duration, age, and gender. It would appear that most patients achieve some immediate relief following manipulation (be it from specific or nonspecific effects of care) in spite of the manipulation indicator.

There are several possible explanations. First, endplay assessment may not be a valid indicator for manipulation that directly affects pain. This does not preclude endplay assessment as an efficacious indicator for manipulation to improve spinal function over time and hence affect pain indirectly in the long run. Second, immediate pain and stiffness relief may be attributable, to a large degree, to placebo or nonspecific effects associated with assessment and treatment.³² The affective and psychophysical components of pain are well described by Price.³³

There are also several intriguing biomechanical or neurophysiologic explanations. First, the mechanical effects of manipulation may lack spatial specificity.^{18,34,35,36} To optimize specificity, the therapists were instructed to perform manipulation gently and to localize mechanical impact on the spine. However, segmental motion at some distance from the target motion segment may have caused sufficient tonic and phasic input to mechanoreceptors and nociceptors to relieve pain.³³ Motion segments with actual endplay restriction may have been distracted inadvertently, or segments with different, unevaluated indications for manipulation may have received threshold stimulation. An alternative consideration is that specificity of the site and vector of manipulation is not as important as generally thought.^{18,34,36} Localized stimulation of the nervous system by manipulation of spinal segments, with or without putative lesions, may have nonlocal palliative effects.^{37,38}

Our study further suggests that manipulation in the control group does not increase the risk of same-day pain and stiffness exacerbation. Segmental provocative pain (in addition to general screening) is an adequate safety screen for individual manipulations determined by computer algorithm. Mild to moderate side effects can be expected in study and control groups, mostly local muscle soreness of short duration.³⁹

Several study limitations must be recognized. This study was but a first step in determining the efficacy of manipulation indicators. It cannot rule out efficacy of endplay assessment for longer-term therapy of pain and stiffness or efficacy for other patient outcomes. Endplay may also be clinically useful in conjunction with test batteries. Finally, an efficacy study design can suggest test validity, but it cannot rule it out because of competing explanations for the absence of efficacy. Tests can indeed be valid without being efficacious.¹⁹

In conclusion, the manipulation indicator, manual endplay assessment, does not contribute to same-day neck pain and stiffness relief associated with spinal ma-

nipulation. The data suggest that pain modulation may not be limited to mechanisms associated with manipulation of putative motion restrictions, and that the immediate palliative effects observed may not require the specificity of manipulation site and vector presumed by some chiropractors. The randomized, placebo-controlled trial design appears safe for test efficacy studies, including extended care of neck pain with spinal manipulation. Future studies of test efficacy should include an extended treatment regimen and follow-up as well as a sham treatment group. Research into the biomechanics and neuroscience of manipulation should include investigation into nonlocal mechanisms of pain relief.

■ Key Points

- Endplay assessment in and of itself does not contribute to the same-day pain and stiffness relief observed in neck pain patients receiving spinal manipulation.
- The data suggest that pain modulation may not be limited to mechanisms associated with manipulation of putative motion restrictions.
- A randomized, placebo-controlled study design appears safe for test efficacy studies, including more visits for care of neck pain with manipulation of the cervical spine.
- Future studies of test efficacy should include a longer-term treatment regimen and sham treatment group. Nonlocal mechanisms of joint stimulation and pain relief may be fertile fields for biomechanics and neuroscience investigation of manipulation.

Acknowledgments

This study could not have been completed without the efforts of Alisa Fairweather, MPH, Carol Lloyd, Michael Attwood, Bonnie Ganger, and David Corll, DC. The authors also wish to thank Richard Gillette, PhD, and David Peterson, DC, for their thoughtful editorial comments.

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Point of View

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In the accompanying article, Haas *et al* report an investigation into the potential mechanisms of the effect of spinal manipulation on improvement in the patient's symptoms. In this study, patients with neck pain were randomized to receive cervical spinal manipulation at levels identified by palpation as having restricted motion

versus manipulation at levels randomly generated by a computer. The results show that both groups had similar improvements in symptoms directly after receiving manipulation. Their data argue against the importance of cervical endplay restriction as a predictor variable to guide the use of spinal manipulation and support the hypothesis that spinal manipulation has a more generalized, nonspecific mechanism of action in relieving symptoms. What cannot be concluded from this study is whether the manipulation, *per se*, was associated with improvement in symptoms, since both groups received manipulation. Adding a sham treatment group would be a fascinating extension of this work.

The submitted manuscript does not contain information about medical devices or drugs.

No funds were received in support of this work. No benefits in any form have been or will be received from a commercial party related directly or indirectly to the subject of this manuscript.

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