Immediate Effects of Region-Specific and Non–Region-Specific Spinal Manipulative Therapy in Patients With Chronic Low Back Pain: A Randomized Controlled Trial


Background. Manual therapists typically advocate the need for a detailed clinical examination to decide which vertebral level should be manipulated in patients with low back pain. However, it is unclear whether spinal manipulation needs to be specific to a vertebral level.

Objective. The purpose of this study was to analyze the immediate effects of a single, region-specific spinal manipulation defined during the clinical examination versus a single non–region-specific spinal manipulation (applied on an upper thoracic vertebra) in patients with chronic nonspecific low back pain for the outcome measures of pain intensity and pressure pain threshold at the time of the assessment.

Design. This was a 2-arm, prospectively registered, randomized controlled trial with a blinded assessor.

Setting. The study was conducted in an outpatient physical therapy clinic in Brazil.

Patients. The study participants were 148 patients with chronic nonspecific low back pain (with pain duration of at least 12 weeks).

Randomization. The randomization schedule was generated by an independent statistician and was concealed by using consecutively numbered, sealed, opaque envelopes.

Interventions. A single high-velocity manipulation was administered to the upper thoracic region of the participants allocated to the non–region-specific manipulation group and to the painful lumbar levels of the participants allocated to the region-specific manipulation group.

Measurements. Pain intensity was measured by a 0 to 10 numeric pain rating scale. Pressure pain threshold was measured using a pressure algometer.

Limitations. It was not possible to blind the therapist and participants.

Results. A total of 148 patients participated in the study (74 in each group). There was no loss to follow-up. Both groups improved in terms of immediate decrease of pain intensity; however, no between-group differences were observed. The between-group difference for pain intensity and pressure pain threshold were 0.50 points (95% confidence interval = −0.10 to 1.10) and −1.78 points (95% confidence interval = −6.40 to 2.82), respectively. No adverse reactions were observed.

Conclusion. The immediate changes in pain intensity and pressure pain threshold after a single high-velocity manipulation do not differ by region-specific versus non–region-specific manipulation techniques in patients with chronic low back pain.
Low back pain is a significant health condition worldwide due to its impact on work disability, absenteeism, and costs. A systematic review on the global prevalence of low back pain identified that the 1-month prevalence was estimated to be 23.2% (standard error of the measurement = 2.9%) and is higher in women and in patients aged between 40 and 80 years. This high prevalence is associated with high treatment costs.

The most recent systematic review on the prognosis of this condition indicates that, although patients with acute low back pain (with a pain duration of at least 6 weeks) recover rapidly, only a third of patients with chronic low back pain (with a pain duration of at least 12 weeks) recover within 12 months after the onset of symptoms.

In an attempt to reduce the great impact associated with chronic low back pain, a large number of treatments have been recommended by the European guidelines for the management of chronic nonspecific low back pain. These guidelines endorse the use of spinal manipulative therapy (SMT) in patients with chronic low back pain given that SMT is potentially effective and cost-effective when used alone or in combination with other techniques compared with general practitioner care, exercises, or general physical therapy. These conclusions are very similar to the low back pain guidelines recently published by Delitto et al.

Although SMT is considered a potentially effective intervention for patients with low back pain, different theories and mechanisms of action for SMT are still under discussion. Many manual therapists, osteopaths, and chiropractors are still heavily orientated by a biomechanical mechanism where mechanical forces applied to specific vertebral regions may alter segmental biomechanics by releasing trapped meniscoid lesions, releasing adhesions, or reducing distortions of the annulus fibrosus. This biomechanical mechanism of action would allow the vertebral segments to move in a greater range of motion and would reduce the mechanical stress on paraspinal muscles, thus reducing pain and discomfort. However, the mechanisms underlying the effects of SMT seem much more complex than a simple biomechanical-oriented model and are more likely to be better explained by a combination of biomechanical and nonbiomechanical effects.

A large bulk of evidence on nonbiomechanical effects of SMT in people who are healthy and those with symptoms of low back pain has been published over the last decade. It is now known that spinal manipulation increases pain threshold and pain tolerance, evokes paraspinal muscle reflexes, alters motoneuron excitability and thermal pain sensitivity, and reduces temporal summation in both individuals who are healthy and those without symptoms of low back pain. A recent systematic review investigating changes in pain sensitivity following spinal manipulation identified significant changes in pain sensitivity in both local and remote anatomic sites. These findings suggest that SMT can be beneficial beyond the effects on the local site of the manipulation in terms of pain sensitivity. However, most of the individual studies from this review were performed in participants who were healthy or recruited a small sample of patients with low back pain (N = 36). Therefore, larger studies with patients with low back are needed to elucidate the effects of region-specific or non-region-specific effects of SMT in this patient population.

Therefore, the objectives of this study were: (1) to analyze the immediate effects of a single manipulation at a defined, region-specific vertebral level of the lower back during a clinical examination versus a non-region-specific vertebral level (high thoracic vertebrae) in patients with chronic nonspecific low back pain in terms of pain intensity and (2) to compare the effects of these 2 interventions on PPT.

**Method**

**Study Type**

A 2-arm, randomized controlled trial with a blinded assessor was conducted.

**Inclusion and Exclusion Criteria**

We considered eligible for the study patients who were seeking physical therapy treatment for chronic non-specific low back pain (ie, lasting more than 12 weeks) and those recruited from the community with
symptoms of chronic low back pain who were aged from 18 to 80 years of both sexes and with a minimum pain intensity score of 3 on an 11-point numeric pain rating scale (ranging from 0 to 10 points)\textsuperscript{20,21} at the time of the assessment. The exclusion criteria were: contraindications to the treatment (eg, spinal canal stenosis, spinal fracture, acute rheumatic diseases, hemorrhagic diseases, active tuberculosis, recent deep vein thrombosis), pregnancy, nerve root compromise, and previous spinal surgery.

Source of Patients

The study was conducted at the Physical Therapy Department of the city of Santo Antônio de Aracanguá, Brazil, between September 2011 and January 2012.

Procedure

All participants were informed about the study objectives and procedures and, if they agreed to participate, signed an informed consent form. Following that, they were assessed by a therapist who was blinded to the allocation to treatment groups. The therapist also collected demographic data and assessed pain intensity (measured by the numeric pain rating scale),\textsuperscript{20,21} pressure pain threshold (measured with a pressure algometer) at lumbar levels L3 and L5 bilaterally and at the middle of the tibialis anterior muscle bilaterally, and disability associated with low back pain (measured by the Roland-Morris Disability Questionnaire).\textsuperscript{23,24} Due to the nature of the interventions, it was not possible to blind the therapist and the study participants.

Random Allocation, Physical Assessments, and Interventions

After the initial assessment, the participants were taken to the treatment room and the therapist conducted the anamnesis and the clinical examination (details below). Based on the clinical examination, the therapist determined the vertebral level in the lumbar area to be manipulated. Next, the therapist opened the randomization envelope informing whether the vertebral level should be manipulated “according to the physical examination” or “at the level of the upper thoracic vertebrae.” A researcher not involved in the data collection generated the randomization codes with a 1:1 allocation ratio using Excel for Windows software (Microsoft Corporation, Redmond, Washington). The randomization codes were placed in consecutively numbered, sealed, opaque envelopes, thus ensuring the concealed allocation of participants to groups.\textsuperscript{25}

Assessment and Physical Examination

The therapist who took part in the study had 4½ years of clinical experience in treating patients with low back pain and was specialized in manual therapy, working mainly with SMT techniques at the health center of the city where the study was conducted. During the physical examination, the therapist asked each participant to identify the painful vertebral level, which was confirmed upon inspection and palpation. The therapist then asked the participant to perform all of the trunk movements (flexion, extension, side bending, and rotation) to observe the presence of pain and restricted movement, as well as antalgic posture, followed by palpation of bone and muscle tissues. The diagnostic palpation test in the transverse plane, also known as the Mitchell test, was used to verify vertebral positioning and mobility.\textsuperscript{22}

Interventions

If the participant had been allocated to the non–region-specific manipulation group, he or she received a single, “global” high-velocity manipulation (not defined by the clinical examination) at the upper thoracic region between T1 and T5 levels in the dorsal decubitus position (Fig. 1A). If allocated to the region-specific manipulation group, the participant was manipulated between L2 and L5 according to the therapist’s clinical examination (Fig. 1B). Then, the participant was reassessed for the outcome measures of pain intensity and PPT by a therapist who was masked with regard to the treatment allocation. The participant also was interviewed regarding any possible adverse effects of the treatment. These possible adverse effects were assessed by 2 open-ended questions: (1) “Did your symptoms get worse after this treatment?” and (2) “Are you feeling any different symptoms after this treatment?”
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Blinding

The assessor was blinded to the treatment allocation and performed an assessment before and after the intervention. To test the blinding, the assessor, after the assessment of the clinical outcomes, wrote on the patient’s chart which type of manipulation he thought the patient had received. These codes were later compared with the randomization codes.

Measurement Instruments and Outcomes

To assess the participants, a chart was used containing the following: start date of treatment and inclusion and exclusion criteria. The participants provided demographic data such as age, body mass, marital status, educational level, and contact details. They also provided data related to disability associated with low back pain, pain intensity, and PPT. The description of each measurement instrument is given below.

Numeric pain rating scale. An 11-point numeric pain rating scale\(^{20,21}\) was used to assess pain intensity (primary outcome measure), with 0 representing “no pain” and 10 representing the “worst possible pain” at the time of the assessment. Pain intensity was measured before and after treatment.

Pressure algometer. The algometer is a device that measures pressure or applied force on any part of the body. The PPT (secondary outcome) was measured by the blinded assessor with a pressure algometer (Kratos model DDK, Kratos Ltd, São Paulo, Brazil) before and after the treatment. The assessor asked the participant to lie down on the table and marked 2 points bilaterally: the first point was located 5 cm laterally from the L3 spinous process, and the second point was located 5 cm laterally from the L5 spinous process.\(^{26}\) A point also was marked bilaterally on the middle third of the tibialis anterior muscle.\(^{27}\)

During PPT measurement, the assessor positioned the algometer’s circular probe (1 cm\(^2\) in area) perpendicularly to the skin and pressed at a rate of approximately 5 N/s. The participants were asked to say “stop” when the sensation of pressure or discomfort became a clear sensation of pain. Three measurements (in newtons) were collected for each area at 30-second intervals. The mean of 3 measurements was used for the data analysis. If the participant did not report pain to a force equivalent to 100 N, the test was interrupted, and this value was considered the PPT.\(^{27}\) For each participant, the assessor performed 2 demonstrations of the procedure on the extensor muscles of the dominant forearm to ensure that the participant understood the test. If the participant had any questions, a third demonstration was performed. For the pain threshold data analysis, the mean values for the lumbar region and the tibialis anterior muscle were used.

The assessor of the present study performed a preliminary intra-examiner reliability study for the PPT measurement of the points described above. Ten participants with chronic low back pain were recruited and assessed on 2 occasions with a 48-hour interval. Reliability was considered excellent, with intraclass correlation coefficients (type 3,3) of \(r = .95\) (95% confidence interval [CI] = .82 to .99) and \(r = .92\) (95% CI = .69 to .98) for the tibialis anterior and lumbar muscles, respectively.

Roland-Morris Disability Questionnaire. The Roland-Morris Disability Questionnaire has been translated and cross-culturally adapted to the Brazilian population,\(^{23}\) and it measures disability levels associated with low back pain. The questionnaire contains 24 items related to daily activities that patients may have difficulty performing due to low back pain. The more items checked, the greater the disability.\(^{28}\) This questionnaire was applied only in the pretreatment assessment to describe the participants’ level of disability at baseline.

Data Analysis

The sample size was calculated \textit{a priori} to detect a difference of 1.0 point for pain intensity as measured with the numeric pain rating scale (with an estimated standard deviation of 1.84 points). A statistical power of 80%, alpha of .05, and sample loss to follow-up of 15% were considered; therefore, 74 patients were needed per group (148 total).

Data normality was tested through visual inspection of histograms, and all of the outcomes had normal distribution. Participant description was performed through descriptive statistical tests. Assessor blinding was tested with the chi-square test. Within-group differences and their respective 95% CI values were calculated using paired-samples \(t\) tests. The between-group differences and their respective 95% CI values were calculated through mixed linear models using the interaction terms of time versus group. These interaction terms are equivalent to the between-group differences (ie, the effect of the intervention). Pearson correlation coefficients (\(r\)) were calculated using the entire sample to investigate whether changes in pain intensity were correlated with changes in PPT. We used the SPSS version 18 software (SPSS Inc, Chicago, Illinois) for the analyses, which were performed on an intention-to-treat basis.

Results

Participant recruitment and inclusion were conducted between Sep-
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tember 2011 and January 2012. Participant characteristics at baseline are described in Table 1. The participants were mainly female with a mean age of 46 years and with long-term symptoms of low back pain (mean duration of symptoms of more than 100 months) and moderate levels of pain intensity and disability. The demographic characteristics and the outcomes were similar at baseline. A total of 150 patients were considered for inclusion, and only 2 were excluded due to low levels of pain intensity (lower than 3 points on the numeric pain rating scale). All participants were followed up. A detailed flow diagram of the process of recruitment, exclusion, assessment, and intervention is presented in Figure 2.

Both groups improved in terms of pain intensity; the within-group difference was 1.91 points (95% CI = 1.51 to 2.30) in the region-specific manipulation group and 1.41 points (95% CI = 0.95 to 1.87) in the non-region-specific group. However no between-group statistically significant differences were detected (Tab. 2). The between-group difference for pain intensity was 0.50 points (95% CI = 0.10 to 1.10; \( P = .10 \)).

No changes in PPT were observed in the region-specific manipulation group at lumbar levels (within-group difference = −1.86 N, 95% CI = −5.34 to 0.12) or at tibialis anterior muscle level (within-group difference = −2.23 N, 95% CI = −4.77 to 0.30). The non-region-specific manipulation group increased PPT locally (ie, at lumbar levels) (within-group difference = −3.65 N, 95% CI = −6.73 to −0.57) but not remotely (ie, tibialis anterior muscle level) (within-group difference = −1.04 N, 95% CI = −3.90 to 1.82). Similar to pain intensity, there were no statistically significant between-group differences for PPT at lumbar levels (between-group difference = −1.78 N, 95% CI = −6.40 to 2.82, \( P = .44 \)) or at tibialis anterior muscle level (between-group difference = 1.19 N, 95% CI = −2.60 to 4.98, \( P = .53 \)). No adverse effects were observed in any of the participants.

Assessor blinding was confirmed as the assessor only guessed the correct location of manipulation in 48.1% of the cases (\( P = .92 \)). We observed a positive and moderate correlation between changes in PPT at lumbar levels and changes in PPT at tibialis anterior muscle level (\( r = .56, P < .01 \)). We also observed a negative and small correlation between changes in pain and changes in PPT at lumbar levels (\( r = −.25, P = .003 \)) and at tibialis anterior muscle level (\( r = −.32, P < .01 \)).

### Table 1. Demographic Characteristics of the Participants at Baseline

<table>
<thead>
<tr>
<th>Variable</th>
<th>Non–Region-Specific Manipulation Group</th>
<th>Region-Specific Manipulation Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y)</td>
<td>45.95 (12.30)</td>
<td>46.32 (10.22)</td>
</tr>
<tr>
<td>Height (m)</td>
<td>1.64 (0.10)</td>
<td>1.63 (0.68)</td>
</tr>
<tr>
<td>Body mass (kg)</td>
<td>74.84 (13.93)</td>
<td>75.45 (16.42)</td>
</tr>
<tr>
<td>Duration of symptoms (mo)</td>
<td>103.82 (112.07)</td>
<td>112.47 (125.55)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>50 (67.6)</td>
<td>59 (79.7)</td>
</tr>
<tr>
<td>Male</td>
<td>24 (32.4)</td>
<td>15 (20.3)</td>
</tr>
<tr>
<td>Marital status</td>
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<tr>
<td>Single</td>
<td>10 (13.5)</td>
<td>6 (8.1)</td>
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<tr>
<td>Married</td>
<td>54 (73)</td>
<td>56 (75.7)</td>
</tr>
<tr>
<td>Divorced</td>
<td>4 (5.4)</td>
<td>9 (12.2)</td>
</tr>
<tr>
<td>Widowed</td>
<td>6 (8.1)</td>
<td>3 (4.1)</td>
</tr>
<tr>
<td>Education status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elementary degree (incomplete)</td>
<td>1 (1.4)</td>
<td>2 (2.7)</td>
</tr>
<tr>
<td>Elementary degree (complete)</td>
<td>32 (43.2)</td>
<td>36 (48.6)</td>
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<tr>
<td>High school</td>
<td>22 (29.7)</td>
<td>23 (31.1)</td>
</tr>
<tr>
<td>Graduate</td>
<td>18 (24.3)</td>
<td>12 (16.2)</td>
</tr>
<tr>
<td>Postgraduate</td>
<td>1 (1.4)</td>
<td>1 (1.4)</td>
</tr>
<tr>
<td>Smoking status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>12 (16.2)</td>
<td>10 (13.5)</td>
</tr>
<tr>
<td>No</td>
<td>62 (83.8)</td>
<td>64 (86.5)</td>
</tr>
<tr>
<td>Disability (RMDQ, 0–24)</td>
<td>9.36 (5.68)</td>
<td>11.26 (5.69)</td>
</tr>
<tr>
<td>Outcome measures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain intensity (NPRS, 0–10)</td>
<td>5.95 (2.20)</td>
<td>6.07 (2.12)</td>
</tr>
<tr>
<td>Pressure pain threshold (N)</td>
<td>48.90 (23.99)</td>
<td>49.63 (19.46)</td>
</tr>
<tr>
<td>Lumbar spine levels</td>
<td>60.21 (22.36)</td>
<td>61.11 (19.55)</td>
</tr>
</tbody>
</table>

* Categorical variables are expressed as number (%); continuous variables are expressed as mean (SD). RMDQ = Roland-Morris Disability Questionnaire, NPRS = numeric pain rating scale.
Discussion
This study aimed to test the immediate effects of a single, high-velocity manipulation performed at a region-specific vertebral level defined during the clinical examination versus at a non–region-specific vertebral level (upper thoracic vertebrae) in patients with chronic nonspecific low back pain for the outcome measures of pain intensity and PPT. No between-group differences were observed for both pain intensity and PPT outcomes.

There is high-quality methodological evidence to support the use of SMT in the treatment of patients with chronic low back pain. This intervention also is recommended by clinical practice guidelines for the treatment of low back pain and other musculoskeletal disorders. In our study, both groups had a reduction of nearly 30% from baseline in pain intensity after treatment. The results of the present study question the need for the detailed assessment advocated in the manual therapy field, when the goal is immediate pain relief, given that non–region-specific manipulation was just as effective as region-specific manipulation. Therefore, our results refute that a biomechanical approach would explain the reductions in pain intensity that were experienced by the study participants. Nevertheless, studies with longer follow-up times and with a placebo or nontreatment group are needed determine the clinical relevance of these findings.

SMT and Pain Intensity
The observed reductions in pain intensity observed in this study are more likely to be explained by spinal, supraspinal, or even nonspecific mechanisms that can mediate pain, as suggested by a theoretical model developed by Bialosky et al. This
model suggests that a mechanical force from a spinal manipulation initiate a cascade of neurophysiological responses from both the peripheral and central nervous systems that might explain improvements in clinical outcomes, such as pain intensity. Nonspecific effects, such as expectation and psychosocial factors, also might explain the pain reduction observed in both groups.\textsuperscript{10,12} New studies are needed to better investigate these factors.

Finally, the reductions in pain observed in both groups also may be due to the placebo effect or to regression to the mean. The only way to control for these confounding factors would be to include a placebo manipulation group, which is a controversial topic in the literature,\textsuperscript{31} given that the leading low back pain researchers have not been able to establish the ideal placebo for vertebral manipulation. However, we could have controlled for regression to the mean by including a non-treatment control group, which can be considered one of the limitations of our study.

### SMT and PPT

We also did not identify a between-group difference in PPT. Participants allocated the region-specific group did not increase their PPT. Participants allocated to the non-region-specific group increased PPT locally (ie, at lumbar levels) but not remotely (ie, at tibialis anterior muscle level). Our findings are very similar to those of a recent meta-analysis that investigated changes in pain sensitivity following spinal manipulation.\textsuperscript{31} The included studies showed an increase in PTT only for patients with neck pain after spinal manipulation or mobilization.\textsuperscript{32-34} However, the only study that included assessment of PPT in patients with chronic mechanical low back pain did not showed PPT changes after spinal manipulation or mobilization.\textsuperscript{35} In

![Table 2](image-url)
conclusion, the summary effect estimate demonstrated a small favorable, but nonsignificant, effect of spinal manipulation or mobilization on increasing PPT in participants who were symptomatic. This review also concluded that the effect of spinal manipulation on PPT was largest when measured at a remote anatomical region, which was not observed in our study. Our study can add important information about the effects of SMT on PPT in patients with chronic low back pain, as more than a half of the studies included in the systematic review recruited only people who were healthy. A surprising finding observed in the present study was a statistical significant difference for hypoalgesia in the non–region-specific group at lumbar levels. However, the difference observed was small (ie, lower than 4 N) and may have been due to chance or measurement error. It has been suggested that a difference in PPT of at least 9.9 N would be necessary to represent a clinically relevant change.\textsuperscript{56}

**Strengths and Limitations of the Study**

All possible care was taken to ensure that the present study had a low risk of bias by including adequate randomization procedures, concealed allocation, blinding of the assessor, similarity at baseline, sample size calculation, and intention-to-treat analysis in the methods. Blinding of the assessor was confirmed by the fact that the assessor was not able to guess which patients were allocated to the region-specific and non–region-specific manipulation groups. In contrast, it was not possible to blind the therapist or the patients due to the nature of the interventions, which does not eliminate the risk of bias. Blinding of therapists and patients is not feasible in trials with active treatment interventions, such as exercise or manipulation, or ethical (given requirements of information sheet information). Therefore, lack of blinding of the therapist or patients could be interpreted as a limitation of the study. Other limitations of this study include recruiting a mixed population of patients who were seeking physical therapy for their low back pain and patients from the community, the lack of a placebo or nontreatment group, and a selection of patients with long-standing pain. These factors may have limited the response of these interventions.

**Suggestions for Future Studies**

The results of this study are restricted to the immediate effects of manipulation (less than 24 hours); however, it is not known whether these effects are maintained over a longer period of time. Therefore, these results would have to be validated for long-term treatment. The effects and mechanisms of action of these techniques could be analyzed in a sample of patients who were more likely to respond to SMT as determined by a clinical prediction rule.\textsuperscript{57} Studies investigating nonspecific effects also are needed. Finally, it is important to note that the results of this study are generalizable only to patients with chronic and acute low back pain. Similarly, our results are only generalizable for the immediate effects of a single, high-velocity manipulation. As neuroplastic changes take time to develop and the responses to spinal manipulation are different between patients with chronic and acute low back pain, it is likely that studies recruiting patients with acute low back pain and with longer follow-up periods will provide different results.

**Conclusion**

This study showed that immediate changes in pain intensity and PPT after a single high-velocity manipulation do not differ by region-specific versus non–region-specific manipulation techniques in patients with chronic low back pain.

All authors provided concept/idea/research design. Mr de Oliveira, Professor Liebano, Dr Luciola Costa, and Dr Leonardo Costa provided writing and data analysis. Mr de Oliveira and Ms Risatto provided data collection and study participants. Mr de Oliveira, Ms Risatto, and Dr Leonardo Costa provided project management. Dr Leonardo Costa provided institutional liaisons. Mr de Oliveira, Professor Liebano, Ms Risatto, and Dr Leonardo Costa provided facilities/equipment and consultation (including review of manuscript before submission).

Ethics approval for this study was obtained from the Research Ethics Committee of the Universidade Cidade de São Paulo. This trial was registered prior to the beginning of data collection with the Brazilian Registry of Clinical Trials (RBR-7CB99yc).


**References**


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PHYS THER. Published online February 21, 2013
Originally published online February 21, 2013

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