Low back pain is a common and costly condition in industrialized nations. Consequently, a variety of treatment modalities and providers are available. A widely recognized clinical practice guideline states that spinal manipulation, as potentially provided by various types of practitioners, can be helpful for patients with acute low back problems without radiculopathy when used within the first month of symptoms. The underlying principles of osteopathic manipulative treatment (OMT) suggest the potential utility of OMT in both acute and chronic low back pain. The author summarizes the methodologic characteristics and results of the three major clinical trials of OMT for low back pain conducted in the United States and discusses their implications for osteopathic medicine.

Low back pain is common in the United States and other industrialized nations. As much as 97% of low back pain is described as “mechanical,” meaning that the underlying cause is an anatomic or functional abnormality, rather than an inflammatory disease, malignant neoplasm, or manifestation of visceral disease.1 The common conditions in the differential diagnosis of mechanical low back pain are presented in the Figure.

The cost to society for treating patients with low back pain is enormous, both in terms of direct healthcare expenditures and indirectly through lost productivity. Medical care for nonspecific low back pain in the United States has been described as “overspecialized, overinvasive, and overexpensive.”2 Indeed, the cost of back pain in America could be in excess of $50 billion annually.3 This cost is largely driven by high healthcare utilization and substantial productivity losses that accompany chronic low back pain.4 Despite efforts by managed care organizations to control access to healthcare and to contain costs, low back problems continue to be leading causes of patient visits and costs.5

The Natural History of Low Back Pain

Most persons recover from an initial episode of low back pain relatively quickly and without complication.6,7 For example, about three fourths of persons with activity-related back pain return to work within 4 weeks.8 Nevertheless, about 40% of patients with low back pain have recurrences within 6 months, and up to 60% have recurrences within 1 year.9 Consequently, the natural history of low back pain has been likened to that of asthma, a chronic condition with intermittent, though generally not disabling, exacerbations.1

On a temporal axis, low back pain may be defined as acute (<3 months) or chronic (>3 months).9 The process that promotes progression from acute to chronic low back pain is not clearly understood but appears to transcend the traditional dichotomous view of pain as being either physical or psychological.7 Rather, the process appears to be multifactorial, potentially involving a complex interplay between anatomic structure, biomechanical function, environmental demands, and psychosocial responses.10 Some patients remain symptomatic even after surgery or other intensive therapy, and their chronic low back pain is a manifestation of the “failed low back syndrome.”

Low Back Pain Treatment Modalities and Providers

A variety of treatment modalities for low back pain has been introduced into clinical practice, including educational interventions, exercise, weight reduction, various classes of analgesics, nonsteroidal anti-inflammatory drugs (NSAIDs), muscle relaxants, antidepressants, physical therapy, behavioral therapy, spinal manipulation, other complementary and alternative modes of therapy, and surgery.11,12 Patients with low back pain in the United States are much more likely to have surgical treatment than patients in the United Kingdom.2

Low back pain, particularly that of nonspecific etiology, makes up a substantial part of primary care practice.13 Historically, it has been the second leading cause of office visits to primary care.14
Spinal Manipulation for Low Back Pain

A landmark evaluation of treatment modalities for low back pain was undertaken by the Agency for Health Care Policy and Research (AHCPR [now know as the Agency for Healthcare Research and Quality]) in its Clinical Practice Guideline on Acute Low Back Problems in Adults. The guideline recommended that spinal manipulation can be helpful for patients with acute low back problems without radiculopathy when used within the first month of symptoms. It further recommended that in such patients having symptoms lasting more than 1 month, a trial of manipulation is probably safe, but of unproved efficacy. The guideline also recommended discontinuation of manipulation and reevaluation for patients who did not show symptomatic improvement that increased functioning after 1 month of treatment. An updated review of this guideline found that only minor revisions were needed and that none of the important new evidence involved spinal manipulation.

A recent international comparison of clinical guidelines for the management of low back pain in primary care found that diagnostic and therapeutic recommendations were generally similar. This finding was not surprising, as several national recommendations were based on previously issued guidelines, such as that of the AHCPR.

More recently, investigators in collaboration with the Cochrane Back Review Group did a meta-analysis and concluded that spinal manipulation was neither more nor less efficacious than other standard treatment modalities for low back pain.

The Rationale for Osteopathic Manipulative Treatment of Patients With Low Back Pain

Chiropractors or physical therapists have done most of the studies of spinal manipulation; therefore, recommendations based on such research may not reflect manipulation as done by osteopathic physicians. It is important to learn more about the efficacy of osteopathic manipulative treatment (OMT) for low back pain because osteopathic physicians represent an exception to the prevailing view that spinal manipulation cannot be provided by primary care physicians and that substantial additional costs would be incurred by necessitating referral of patients with low back problems to chiropractors or other practitioners for spinal manipulation.

Osteopathic philosophy is based on four key principles:

1. The body is a unit;
2. Structure and function are reciprocally interrelated;
3. Rational therapy is based on an understanding of body unity, self-regulatory mechanisms, and the interrelationship of structure and function.

This philosophy suggests that OMT may be useful in treating patients with low back pain. Ideally, OMT should be used in the acute stage of low back pain, early in its natural history, to prevent progression. This ideal is consistent with guidelines regarding the use of spinal manipulation for acute low back pain. Nevertheless, the potential interactions between structure, function, environmental demands, and the patient's psychosocial response that may lead to chronicity suggest that an integrative osteopathic approach also may be useful at this stage in the natural history of low back pain.

Unlike treatment modalities offered by many allopathic physicians, including orthopedic surgeons and neurosurgeons, and spinal manipulation provided by chiropractors, OMT can be readily integrated with other primary healthcare services when patients visit osteopathic physicians. In fact, low back pain was the most common reason for visits to

Figure. Common conditions in the differential diagnosis of mechanical low back pain.
osteopathic physicians based on data from the National Ambulatory Medical Care Surveys of 1977 and 1978.14 Recently, the Osteopathic Survey of Health Care in America (OSTEOSURV), a national random telephone survey, confirmed that most patients (52% in the 1998 and 2000 administrations) visiting osteopathic physicians continue to seek treatment for musculoskeletal conditions.21,22

When considering back pain as a prototypical condition, osteopathic physicians make fewer referrals to other physicians and admit a lower percentage of patients to hospitals than allopathic physicians,14 while also treating patients for back pain episodes with substantially fewer visits than chiropractors.23 Although osteopathic family physicians are less likely to order radiographs or prescribe NSAIDs, aspirin, muscle relaxants, sedatives, and narcotic analgesics for low back pain than their allopathic counterparts, osteopathic physicians have a substantially higher proportion of patients returning for follow-up back care than do allopathic physicians.24 In a randomized controlled trial, OMT providers achieved low back pain outcomes comparable to those of usual allopathic medical treatment, but they prescribed fewer medications and less physical therapy.25

The ability of osteopathic primary care physicians in the United States to provide OMT to complement conventional medical treatment for patients with low back pain is in sharp contrast to the cost of using additional therapists to provide physical therapy, exercise interventions, or behavioral modification programs. The latter is a major factor that inhibits the translation of promising research on nonpharmacologic modes of therapy into clinical practice.26 Nevertheless, in the United Kingdom, where osteopaths must refer their patients to general practitioners for conventional medical treatment, OMT improved short-term physical and longer-term psychological outcomes in patients with neck or back pain, at little extra cost.27

Despite millions of OMT procedures administered each year in the United States, a review of the literature on major adverse events after manipulation found little evidence of risk.28 Among the 185 incidents attributed to manipulation during a span of six decades, most involved forceful, high-velocity techniques or manipulation done with the patient anesthetized. No injuries were attributed to muscle energy, indirect, or fascial techniques.

The Evidence Base on OMT for Low Back Pain in the United States
Evidence-based studies of OMT are becoming more common. The three major randomized controlled trials of low back pain that have been conducted in the United States,25,29,30 where osteopathic physicians can provide OMT to complement conventional medical treatment, are summarized in the Table. These trials span about 30 years. Interestingly, the trials have evolved to focus on the use of OMT in persons with low back pain of longer duration. The older subjects enrolled in the trial at the University of North Texas Health Science Center at Fort Worth—Texas College of Osteopathic Medicine (UNTHSC) reflect the study’s focus on chronic low back pain.

A few cautious generalizations may be made based on the findings summarized in the Table. First, OMT appears to decrease the use of other treatment modalities such as medications or physical therapy. Second, OMT benefits are more evident in comparisons with no-intervention controls than in comparisons with no-intervention control subjects: the control subjects are likely to deduce their group assignment and they will receive less attention than subjects receiving OMT.

OMT trials are those who receive “sham manipulation” along with their usual care and those who receive usual care without any other intervention. At least two important problems exist with using no-intervention control subjects: the control subjects are likely to deduce their group assignment and they will receive less attention than subjects receiving OMT.

Sham manipulation is intended to overcome these problems; however, in the process of providing this intervention, it is possible that some therapeutic benefit may occur, thereby reducing the observed efficacy of OMT. Indeed, a review of placebo effects found that in conditions involving pain, there is a small, but consistent, beneficial effect attributed to placebos.31 This placebo effect has been estimated to be the equivalent of one third of the effect of NSAIDs.32 The UNTHSC trial is unique in that it includes both sham manipulation and no-intervention control groups, thereby allowing a direct comparison of OMT efficacy relative to either control intervention.

Another important methodologic issue involves the OMT protocol itself. Should the same rigid OMT protocol be used to treat all subjects or should OMT be individualized to each subject? Should only one OMT technique be tested, or should the entire spectrum of OMT techniques be available for use? How often should OMT be provided, and by whom? These are just some of the questions that surface in OMT trials.

How generalizable should the results of an OMT trial be? Some trials may attempt to include only those subjects with low back pain most likely to respond to OMT. A study may be very selective, screening as many as 20 persons to identify a single trial subject.28 Others may be less selective, wishing to determine the benefits of OMT in a wider cross-section of patients with low back pain. The advantage of selective recruit-
ment is that OMT is more likely to be found efficacious; its deficiency is that favorable results cannot necessarily be extrapolated and assumed to apply to all or most patients with low back pain. Conversely, less-selective trial recruitment may decrease the likelihood of demonstrating OMT’s efficacy. However, if OMT’s efficacy is observed, it is then reasonable to conclude that OMT will be beneficial in many patients with low back pain.

Comment
It has been stated that the long-term survival of osteopathic medicine will depend on its ability to define itself as distinct from and yet still equivalent to allopathic medicine.33 Osteopathic manipulative treatment of low back pain represents an opportunity to establish this distinctiveness. Nevertheless, beyond the considerable methodologic challenges in demonstrating the efficacy of OMT, two cultural barriers may ultimately prove to be the most difficult to overcome.

First, is the belief in the conventional medical treatment–spinal manipulation dichotomy that views these two approaches to low back pain as mutually exclusive. This view is exemplified in the recommendations of the recent systematic review and meta-analysis in conjunction with the Cochrane Back Review Group.17 Second, is the belief that the entire spectrum of OMT simply can be distilled to a few elements that in practice

<table>
<thead>
<tr>
<th>Variable</th>
<th>Hoehler et al29</th>
<th>Andersson et al25</th>
<th>Licciardone et al30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location</td>
<td>California</td>
<td>Illinois</td>
<td>Texas</td>
</tr>
<tr>
<td>Setting</td>
<td>University clinic</td>
<td>Health maintenance organization</td>
<td>University clinic</td>
</tr>
<tr>
<td>Predominant Pain Chronicity</td>
<td>Acute Referred patients with low back pain, majority of less than 1-mo duration</td>
<td>Subacute Patients with low back pain of 3-wk to 6-mo duration</td>
<td>Chronic Recruited subjects with low back pain of at least 3-mo duration</td>
</tr>
<tr>
<td>No. of Participants</td>
<td>95 1880 (high)</td>
<td>155 1193 (high)</td>
<td>91 199 (low)</td>
</tr>
<tr>
<td>Control Group(s)</td>
<td>Sham manipulation</td>
<td>No intervention (usual care)</td>
<td>No intervention (usual care) Sham manipulation</td>
</tr>
<tr>
<td>OMT Protocol</td>
<td>High-velocity, low-amplitude thrust only OMT, 4.8±2.7 Control subjects, 3.9±2.5</td>
<td>Variety of techniques, individualized to patient 8 per protocol</td>
<td>Variety of techniques individualized to subject 7 per protocol</td>
</tr>
<tr>
<td>Participant Characteristics</td>
<td>OMT, 30.1±8.4 Control subjects, 32.1±9.8</td>
<td>OMT, 28.5±10.6 Control subjects, 37.0±11.0</td>
<td>OMT, 49±12 No-intervention control subjects, 49±12 Sham control subjects, 52±12</td>
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<tr>
<td>Gender</td>
<td>OMT, 59 Control subjects, 59</td>
<td>OMT, 41 Control subjects, 44</td>
<td>OMT, 31 No-intervention control subjects, 35 Sham control subjects, 43</td>
</tr>
</tbody>
</table>

* NS indicates not statistically significant results; S, statistically significant results favoring OMT.
† Significant across all time intervals.
‡ Significant only at 6 months (physical therapy was combined with other cotreatment modalities).
are interchangeable with spinal manipulation techniques administered by other providers such as chiropractors and physiotherapists. This view is exemplified by the United Kingdom Back pain Exercise And Manipulation (UK BEAM) trial.\textsuperscript{34}

The unique role of osteopathic physicians in the United States, as providers of both conventional medical treatment and OMT for low back pain, remains largely unrecognized. More intensive promotion of this professional role of osteopathic physicians and the performance of additional studies to demonstrate the efficacy and cost-effectiveness of OMT for low back pain are parallel paths that should be traversed.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Hoehler et al\textsuperscript{29}</th>
<th>Andersson et al\textsuperscript{25}</th>
<th>Licciardone et al\textsuperscript{30}</th>
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</thead>
<tbody>
<tr>
<td><strong>Outcomes</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Timing of outcome assessment(s)</td>
<td>First, 20–30 days Second, 41–51 days</td>
<td>12 wk</td>
<td>First, 1 mo Second, 3 mo Third, 6 mo</td>
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<tr>
<td>Visual Analog Scale for Pain</td>
<td>Not measured</td>
<td>NS*</td>
<td>Versus no-intervention control subjects, S Versus sham control subjects, NS</td>
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<tr>
<td>Subjective Pain Assessment</td>
<td>First, S Second, NS</td>
<td>Not measured</td>
<td>Not measured</td>
</tr>
<tr>
<td>Roland-Morris Disability Questionnaire</td>
<td>Not measured</td>
<td>NS</td>
<td>Versus no-intervention control subjects, NS Versus sham control subjects, NS</td>
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<tr>
<td>Oswestry Questionnaire</td>
<td>Not measured</td>
<td>NS</td>
<td>Not measured</td>
</tr>
<tr>
<td>Straight leg raising</td>
<td>First, S Second, NS</td>
<td>NS</td>
<td>Not measured</td>
</tr>
<tr>
<td>Flexion</td>
<td>Not measured</td>
<td>NS</td>
<td>Not measured</td>
</tr>
<tr>
<td>Extension</td>
<td>Not measured</td>
<td>NS</td>
<td>Not measured</td>
</tr>
<tr>
<td>Medication use</td>
<td>Not measured</td>
<td>S</td>
<td>Versus no-intervention control subjects, S Versus sham control subjects, NS</td>
</tr>
<tr>
<td>Physical therapy use</td>
<td>Not measured</td>
<td>S</td>
<td>Versus no-intervention control subjects, S† Versus sham control subjects, NS</td>
</tr>
<tr>
<td>Patient satisfaction</td>
<td>Not measured</td>
<td>NS</td>
<td>Versus no-intervention control subjects, S† Versus sham control subjects, NS</td>
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<tr>
<td>Lost work or school days</td>
<td>Not measured</td>
<td>Not measured</td>
<td>Versus no-intervention control subjects, NS Versus sham control subjects, NS</td>
</tr>
</tbody>
</table>

* NS indicates not statistically significant results; S, statistically significant results favoring OMT. † Significant across all time intervals. ‡ Significant only at 6 months (physical therapy was combined with other cotreatment modalities).
References


