the journal of
medicine®
personalized | authoritative | peer reviewed

Personal Preview Issue

SEPTEMBER 2008
PERSONAL PREVIEW ISSUE

POSTMASTER Send address changes to Sequence Medical, East 59th Street, Suite 3800, New York, NY 10022. Printed in the USA.

DISPLAY AND CLASSIFIED ADVERTISING: Contact Charles Benaiah, Sequence Medical, LLC, 418 East 59th Street, Suite 3800, New York, NY 10022; Email charles@SequenceMed.com; Phone 212-755-4296.

The Journal of Medicine publishes new medical research findings, review articles, and editorial opinion on a wide range of topics and delivers specific information to match the individual clinical needs of each of our physician readers. Published materials emphasize the latest advances for diagnosing and treating conditions in internal medicine and medical specialties. The Journal of Medicine is an independent publication under the editorial control of Sequence Medical, LLC, and its editorial board. We enforce scientific rigor through a process of review that evaluates information presented for fair balance, objectivity, independence, and relevance to educational need. The opinions expressed in this publication are those of the contributors and are not attributable to the publisher, editor, editorial board, or advertisers of the Journal of Medicine. The authors, editors, publisher, their servants, assigns, or agents shall not be in any way liable for the currency of information or for any errors, omissions, or inaccuracies in the publication. Clinical judgment must guide each physician in weighing the benefits of treatment against the risk of toxicity. Information in this publication should not be relied upon in the care of patients. The publisher cannot be held responsible for any injury or damage to persons or property from any use of methods, products, instructions, or ideas contained in this publication.

Please direct all information requests, manuscript submissions, and advertising or business collaboration interests to Charles Benaiah at 212-755-4296 or charles@SequenceMed.com.

SequenceMedical

the journal of
medicine®

personalized | authoritative | peer reviewed

table of contents

This special Preview Issue of *the Journal of Medicine* was not subject to standard peer review.

Prospective Evaluation of the Efficacy of Spinal Decompression via the DRX9000 for Chronic Low Back Pain

John B. Leslie, MD, MBA;[1] Joseph V. Pergolizzi, MD;[2] Alex Macario, MD, MBA;[3] Christian C. Apfel, MD, PhD;[4] Darren Clair, MD;[5] Charlotte Richmond, PhD;[6] Frank Florio, DC;[7] Martin Auster, MD, MBA[8]

From the [1]Department of Anesthesiology, Mayo Clinic, Scottsdale, Arizona; the [2]Department of Medicine, Johns Hopkins University School of Medicine, Baltimore, Maryland; the [3]Departments of Anesthesia and Health Research and Policy, Stanford University, Palo Alto, California; [4]Clinical Research Consultants LLC, San Francisco, California; [5]Vibrance Medical Group, Beverly Hills, California; [6]NEMA Research, Inc., Naples, Florida; [7]Axiom Worldwide, Inc., Tampa, Florida; and the [8]Department of Radiology, Johns Hopkins University School of Medicine, Baltimore, Maryland

Address correspondence to: John B. Leslie, MD, MBA, Department of Anesthesiology
Mayo Clinic
13400 East Shea Boulevard
Scottsdale, AZ 85259
Email: leslie.john@mayo.edu

Abstract

Twenty patients presenting with low back pain averaging approximately 5 years in duration were prospectively enrolled in a 6-week course of 20 motorized spinal decompression treatments via the DRX9000™ (Axiom Worldwide, Tampa, Fla). Two patients withdrew for protocol violations. For the remaining 18 patients, the baseline median verbal pain intensity score on an 11-point scale (0 = no pain; 10 = worst possible pain) decreased from 7 (25th to 75th percentile = 5–7) to 0 (25th to 75th percentile = 0–1) at study conclusion at Week 6 ($P < .0001$). No device-related adverse events occurred. Overall, 16 of 18 patients reported clinically significant pain improvement after noninvasive spinal decompression.

Key Words: Chronic back pain, spinal decompression, verbal pain score

Disclosure: The study on which this article is based, "Pilot Study to Evaluate the Effectiveness and Safety of Axiom Worldwide DRX9000™ Spinal Decompression System," (ClinicalTrials.gov NCT00414596) was supported by an unrestricted grant from Axiom Worldwide (Tampa, Fla) to NEMA Research, Inc., a clinical research organization in Brooklyn, New York. The DRX9000 Spinal Decompression System was placed in the respective clinics on loan from Axiom Worldwide for exclusive use in study patients. Research support was provided to each center to cover study expenses associated with patient care and data collection.

Introduction

Chronic low back pain is an expensive benign condition in industrialized countries.[1] It is one of the most frequent reasons for visits to primary care physicians,[2] for time taken off from work due to sickness or short-term disability, and for hospital admission and surgery.[3,4] One-third to two-thirds of adults will suffer from low back pain at some time.[5,6] The prevalence of low back pain increases with age, and women are affected more often than men, with a peak in the sixth decade that results in substantial medical costs.[7,8] Low back pain is the most common and most expensive reason for work disability among US men and a frequent cause of early retirement.[9]

Mechanical causes of low back pain may be either injury to lumbosacral muscles and ligaments, facet or sacroiliac joint arthropathy, or discogenic disease due to degenerative changes. Discogenic pain most commonly affects the lower back, buttocks, and hips.[10] The American College of Physicians and the American Pain Society recommend avoiding routine imaging and other diagnostic tests in patients with nonspecific low back pain. Patients with chronic low back pain who do not improve with self-care should consider noninvasive treatments including acetaminophen or nonsteroidal anti-inflammatory drugs (NSAIDs), intensive interdisciplinary rehabilitation, exercise therapy, acupuncture, massage therapy, spinal manipulation, yoga, cognitive-behavioral therapy, or progressive relaxation.[11] Valid, peer-reviewed, prospective, randomized, clinical trials in appropriate patients with adequate outcome assessments still are needed for many treatment options for chronic low back pain.[12–14]

Although data exist that traction widens the intervertebral space,[15] reduces disc protrusion[16] and intradiscal pressure,[17] and improves motor-evoked potentials[18] and leg mobility,[19] systematic reviews have concluded that traction probably is not effective in improving low back pain compared to placebo, sham, or other treatments.[20,21] Traction can be delivered manually by the therapist via the weight of the patient through a suspension device or by the patient pulling the bars at the head of the table while lying on a specifically designed table. These types of traction can be dif-

ficult to standardize, and the patient may not tolerate the pull force, which may trigger paravertebral muscle contraction and affect efficacy.

Several different spinal decompression therapy systems have been developed to overcome these drawbacks. These systems include the DRX9000™ (Axiom Worldwide, Tampa, Fla), the VAX-D (Vat-Tech, Inc., Palm Harbor, Fla), SpineMED® (CERT Health Sciences, LLC, Baltimore, Md), and the Accu-SPINA® System (North American Medical Corporation, Aventura, Fla). The designs of these systems are different, including how patients are positioned for treatment. No comparative studies have been performed, and manufacturers recommend a varying number of sessions along with a variety of adjunctive therapies. A systematic review of what published clinical data exist suggests that data are too limited to determine whether spinal decompression provides incremental benefit to individuals over other nonsurgical treatments.[22] The goal of this prospective, single cohort study was to assess the efficacy of a spinal decompression system (the DRX9000) for patients with chronic low back pain using a standardized protocol.

Methods

The primary outcome was the verbal rating scale pain intensity score on an 11-point scale (0 = no pain; 10 = worst possible pain).

Hypothesis. Our hypothesis was that patients with chronic low back pain who undergo spinal decompression with a standardized 6-week regimen consisting of 20 treatments with the spinal decompression system (5 sessions per week for 2 weeks, followed by 3 sessions per week for 2 weeks and then by 2 sessions per week for the final 2 weeks) would experience > 50% reduction in their verbal score of pain intensity.

Power analysis for sample size. Mean pain scores at time of enrollment were assumed to equal 6 (standard deviation [SD] 3) with potential reduction in pain of 50%. To obtain 80% power at an α· level of 0.05, sample size was estimated as 20 patients.

Secondary objectives were to assess 1) safety and adverse events of the spinal decompression system when it was used in the office by staff members, 2) effects of the treatment protocol on patient function as measured by the Oswestry Disability Index, and 3) overall patient satisfaction. Oswestry Disability Index scores range from 0 (no limitations or disability) to 50 (maximum severe disability).

The study enrolled patients at 3 outpatient clinics in Tampa, Fla; Beverly Hills, Calif; and Naples, Fla. The spinal decompression systems were installed after approval of the respective institutional review boards. No clinical site investigator or any staff members had previous experience with the system. Instruction was provided for the office staff and site investigators regarding study protocol, data collection, and adverse event monitoring and reporting.

Patients were eligible for inclusion if they were at least 18 years of age, could provide written informed consent, agreed to 6 weeks of treatment sessions, and presented with chronic, nonoperative low back pain lasting at least 12 weeks. Patient symptoms were evaluated by medical history review, physical examination, and magnetic resonance imaging (MRI) within the previous 6 months to support a diagnosis of musculoskeletal or mechanical pathology, herniated discs, bulging or protruding intervertebral discs, degenerative disc disease, unsuccessful back surgery more than 6 months earlier, posterior facet syndrome, or sciatica. No included patients were candidates for surgery on the basis of their history, examination, and radiologic studies.

Table 1
Spinal Decompression Treatment Protocol

Treatment Sessions
28-minute active treatment sessions for 20 sessions over 6 weeks
5 sessions per week in Weeks 1 and 2
3 sessions per week in Weeks 3 and 4
2 sessions per week in Weeks 5 and 6
Additional therapy after spinal decompression sessions
Cold therapy to lumbar paraspinal area for 15 minutes
Back exercise after Week 2 with improved verbal pain score

Exclusion criteria were back fusion or placement of stabilization instrumentation or artificial discs; pregnancy; neurologic motor deficits; spinal cord compression or fracture; metastatic cancer; tumor; hematoma; infection; spinal stenosis with neurologic deficits or nerve root entrapment; bowel, bladder, or sexual dysfunction; litigation for a health-related claim (in process or pending for workers' compensation or personal injury); hemiplegia or paraplegia; alcohol or drug abuse; abdominal aortic aneurysm; or a history of severe cardiovascular or metabolic disease. Limitations of the spinal decompression system also led to the exclusion of patients with extremes of height (< 147 cm or > 203 cm) and body weight (> 136 kg).

Treatment Protocol

The spinal decompression system apparatus has built-in air bladders, disc angle pull adjustments, and harnesses and can increase the distraction force more slowly in the latter part of the decompression. A split table design is used to reduce friction on the lumbar muscles. Each spinal decompression session began with the patient being fitted with an adjustable lower body and upper body harness to fit the individual (Figure 1). The patient then stepped onto a platform at the base of the spinal decompression unit and was lowered into the supine position. The harness was tightened and attached to the upper and lower ends of the table, with a pillow under the patient's knees to prevent extension of the lumbar spine. The patient was handed a safety control button to press that would immediately release all tension if necessary.

The protocol included 20 sessions of spinal decompression over a 6-week period (Table 1). Distraction force and angle were determined by the patient's weight and the location of disc pain. Initial distraction force was adjusted to patient tolerance, starting at 4.54 kg less than half their body weight. If a patient described the decompression pull as "strong or painful," this distraction force was decreased by 10%–25%. In subsequent treatment sessions, the distraction force was increased as toler-

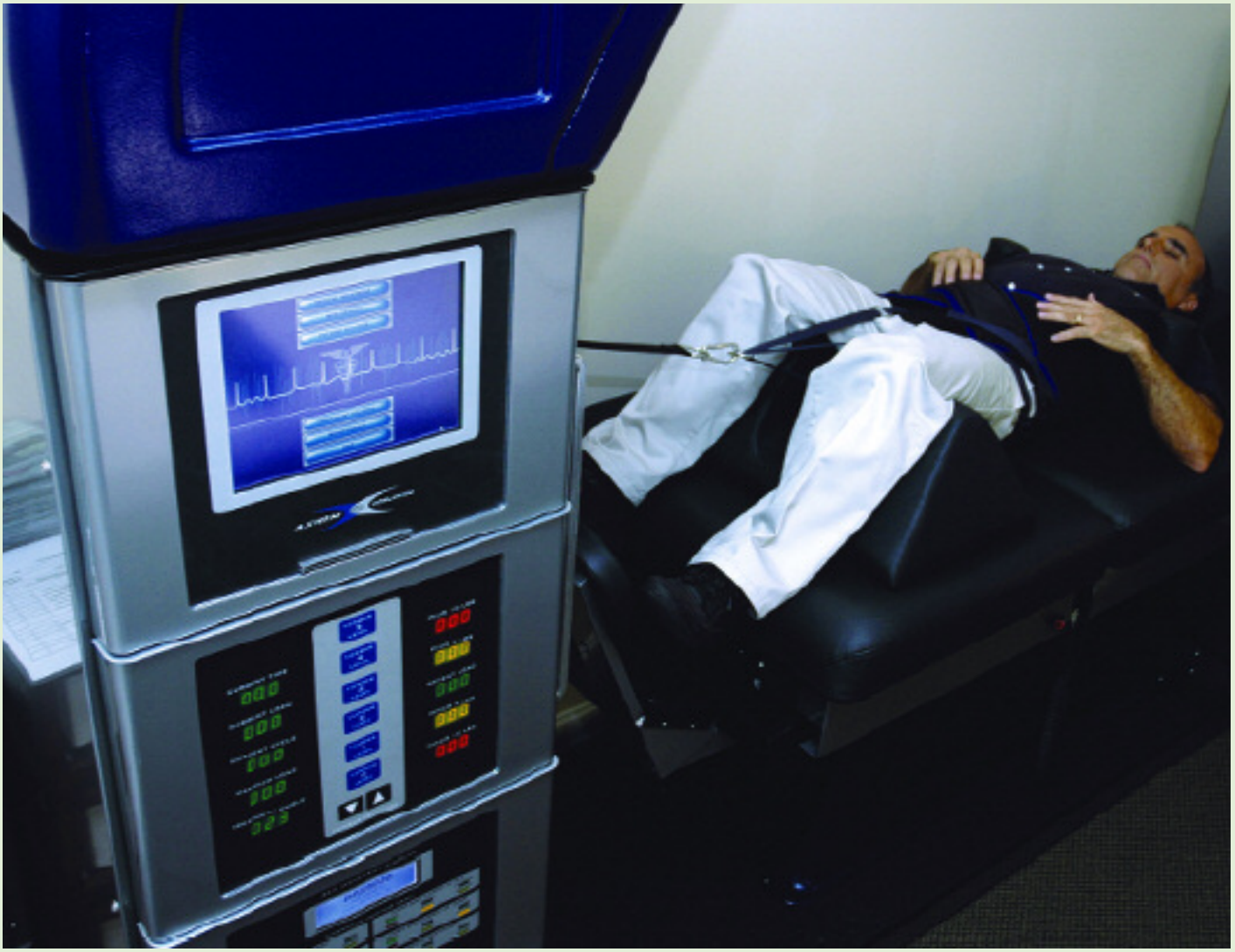

Figure 1. **A volunteer illustrates how the spinal decompression harness is attached for a treatment session.**

ed to final levels of 4.54 kg–9.07 kg more than half their body weight.

Patients were instructed to continue to use analgesics prescribed by their physicians before enrollment. Increased pain could be treated with additional NSAIDs or cyclooxygenase-2 inhibitors. The patient's physician was responsible for adjusting any adjunct medications to ensure the comfort of patients throughout the study.

At the end of the study, patients were asked, "How satisfied were you with the spinal decompression treatment (0–10 scale; 0 = not satisfied, 10 = very satisfied)?"

Data Collection and Statistics

Patient data, including treatment parameters, pain, and Oswestry Disability Index scores, and any adverse events (with the investigator's assessment of relevance to study treatment) were collected at each treatment session and with a daily diary. The primary pain endpoint was assessed by a mixed effect model with time (visit) and as fixed effects and subject as random effect. Due to the small pilot sample size, only summary statistics (n, mean, SD, median, range) was produced at each time point to test the hypothesis of pain score reduction. Since pain data are nonparametric, the median and interquartile range is presented.

Results

A total of 27 patients were screened for inclusion in the study. Three patients declined to participate and 4 did not meet one of the inclusion/exclusion criteria. Twenty patients were thus enrolled, the first on 1/5/07 and the last on 3/16/07 such that data collection ended on 4/27/07. Two of these 20 patients dropped out. One patient withdrew during the second week of treatment when his pain was discovered to be pelvic rather than discogenic in origin. A second patient was excluded after the third week when she revealed involvement in an unrelated personal injury claim (this is a per protocol exclusion

Table 2
Characteristics of 18 Patients with Low Back Pain who Underwent Spinal Decompression Treatment

Variable	Value
Male sex, %	66.7
Age, y*	46.6 (15)
Height, cm*	175 (11)
Weight, kg*	102 (44)
Race, %	
White	15 (83.3%)
Hispanic	3 (16.7%)
Symptom duration, wk*	266 (209)
Employment status, %	
Employed	14 (77.8%)
Retired	3 (16.6%)
Other	1 (5.6%)

*Values are expressed as mean (standard deviation).

criterion). Thus, data for 18 patients with a mean low back pain duration of 266 weeks (SD 209, range 20–520, median 286) were analyzed (Table 2).

The 18 patients had tried numerous therapies, including chiropractic (16 patients); muscle stimulation (10 patients); cold therapy and massage therapy (9 patients each); exercise therapy (6 patients); heat therapy, physical therapy, and transcutaneous electrical nerve stimulation (5 patients each); and acupuncture, lumbar support brace, epidural injection, and miscellaneous treatments (3 patients each). Table 3 summarizes their low back pain diagnoses.

The median verbal numerical pain intensity score decreased from baseline 7 (range 4–10, interquartile range [25th to 75th percentile], 5–7) to median of 0 (range 0–7, interquartile range [25th to 75th percentile], 0–1) at Week 6 ($P < .0001$) (Figure 2).

At the conclusion of the 6 weeks, 16 of the 18 patients reported improvement in low back pain > 50% from baseline. No patient required an opioid analgesic during or after the treatment sessions.

The median baseline Oswestry Disability Index score of 26 (interquartile range [25th to 75th percentile], 19.50–29.50, range 7–34) declined to 14 (interquartile range [25th to 75th percentile] 8.50–18.50, range 0–26) ($P < .0001$) by Week 3 of treatment to a final median at Week 6 of 3 (interquartile range [25th to 75th percentile] 1–6.50, range 0–26) ($P < .0001$) (Figure 3).

The reported adverse events included one episode of neck pain, possibly related to the decompression session. The other adverse events were deemed by the patients' physicians to be unrelated to the treatments: head colds and sinus headaches in 2 patients each and sinus infection, shoulder pain, influenza, vertigo, and adrenal insufficiency in 1 patient each.

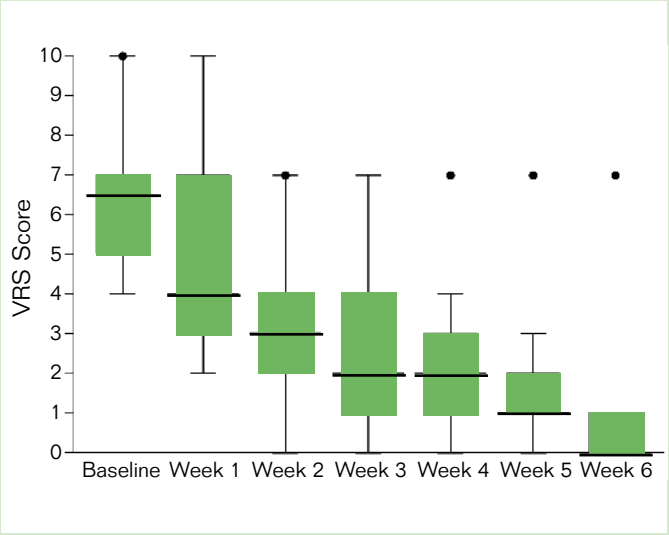

Figure 2. Box plot of weekly verbal rating scale pain scores of 18 patients with low back pain being treated with spinal decompression. Median interquartile range (25th to 75th percentile), minimum and maximum values, and outliers (indicated by dots) of the verbal pain score of patients completing the 20 treatment sessions with the spinal decompression system.

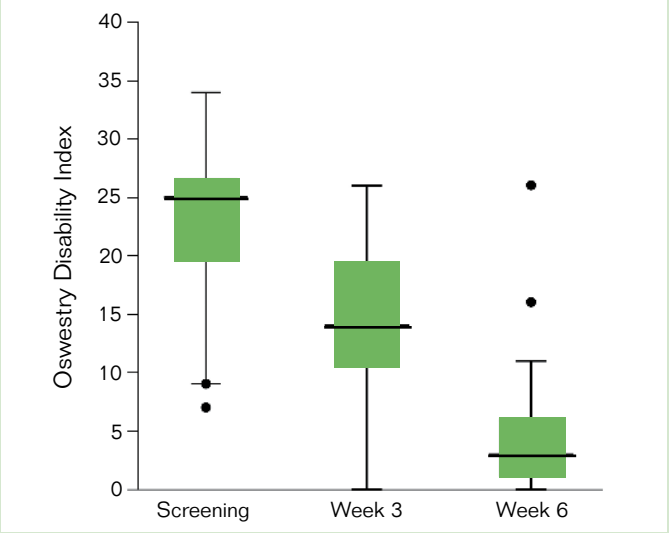

Figure 3. Mean Oswestry Disability Index scores, with median, interquartile range (25th to 75th percentile), minimum and maximum values, and outliers (indicated by dots) for 18 patients.

On a 0–10 scale, with 10 being the highest favorable rating, patients (data available for 14 of 18 patients) gave the spinal decompression treatments a mean rating of 7.61 (SD 1.9, range 4–10, 25th to 75th percentile 5–9) at the mid point of Week 3 and 8.1 (SD 3, range 0–10,

Table 3
Summary of Low Back Pain Diagnoses in 18 Patients

Variable	No. of Patients*
Diagnosis*	
Bulging or protruding disc	15
Degenerative disc	8
Herniated disc	6
Posterior facet syndrome	2
Failed back surgery	1
Location of Symptoms or Documented Pathology	
L1–L2	1
L2–L3	3
L3–L4	4
L4–L5	14
L5–S1	12

*Totals exceed 18 because some patients had multiple diagnoses and multiple levels of pathology.

25th to 75th percentile 7–10) after the final week (Week 6).

Sixteen of the 18 patients said that they would recommend this treatment protocol to others. The 2 patients who did not favor the treatment made the following statements: 1) "Did not work for me. Need more info on the type of back problems it works for and those it does not." 2) "No improvement from spinal decompression treatment."

Discussion

This is the first prospective evaluation of the efficacy of spinal decompression via the DRX9000 for the treatment of low back pain. Subjects were mostly Caucasian men in their 40s with discogenic lumbar back pain of several years in duration, with 78% being employed and 17% retired. The cohort had a median verbal numerical pain score of 7 on a 0–10 scale at time of initial presentation, which is consistent with pain scores obtained from patients with chronic low back pain in published studies.[23] Overall, 16 of 18 patients had clinically significant improvement as measured by a decline in chronic low back pain and improvement in the Oswestry Disability Index.

Investigators have reported that a minimum of 20 mm (out of 100 mm) difference on a self-reported visual analog scale is required to indicate a clinically important difference in chronic low back pain.[24] One could argue that the large benefit observed in this study might only be a temporary reversal in a chronic disease that has variable periods of low or high pain intensity. In fact, the natural history of low back pain has been hypothesized to be a reason for the proliferation of "unproved" treatments that may seem to be effective.[25] However, the long standing duration (often several years at the time of presentation) of pain in these patients as well as the large reduction in pain levels, along with the patients' qualitative positive comments, such as their satisfaction scores, support the argument that there is efficacy at the conclusion of 6 weeks with the spinal decompression system.

Discogenic pain is a major problem in lumbar degenerative disc disease and may be due to progressive annular breakdown and tearing, which stimulates pain fibers in the outer one-third of the annulus.[26] Experimental data exist to support the concept that spinal decompression reduces intradiscal pressure. This in turn may facilitate oxygen and nutrient uptake and improve disc metabolism and restoration.[27,28] However, oftentimes the anatomic cause of persistent low back pain remains unknown. Structural imaging and symptoms are poorly correlated.[29,30] Also, patients' baseline psychosocial variables may affect the development of chronic low back pain.[31] Job satisfaction, for example, remains a strong predictive factor for the identification of patients with acute low back pain who will develop chronic low back pain.[32] Certainly, a multidisciplinary approach can help patients with chronic discogenic low back pain by providing cognitive-behavioral therapy, patient education, NSAIDs, and physical therapy.

The results from our prospective clinical study are consistent with a retrospective medical record and outcomes analysis of 94 adults in 4 clinics (1 hospital-based and 3 free-standing) and suggested its clinical efficacy for in-office management.[33] The treatment protocol in that study included instruction on lumbar stretching exercises, myofascial release, or heat prior to spinal decompression treatment and the use of cold or muscle stimulation or both after the sessions. All clinical diagnoses were supported by MRI findings. In that study, the median pain duration before treatment was 260 weeks. Mean verbal rating pain scores equaled 6.05 at presentation and decreased significantly to 0.89 at the end of an 8-week treatment ($P < .0001$). Analgesic use also appeared to decrease, and activities of daily living improved. Follow-up (mean, 31 weeks) on 29 of the 94 patients reported mean pain improvement of 83%, mean verbal rating pain scores of 1.7, and satisfaction of 8.55 out of 10 (median, 9). No adverse events were identified in those patient records.

Such positive clinical outcomes warrant further investigation in a more rigorous prospective clinical study with an expanded patient population representing specific categories or lesions that result in chronic low back pain. In addition, the protocol of twenty 28-minute treatments should be explored to determine whether a dose-response curve exists. Less frequent treatment sessions would be easier to schedule, would be more appropriate for patients still working full time and trying to remain active, and could save the expense of additional sessions. A multivariate crossover trial design, for example, could help determine tension, angle of decompression, and frequency of treatment to minimize the number of treatments needed to achieve maximal efficacy and safety. As recommended by the manufacturer of the spinal decompression device, cold therapy was used as an adjunct treatment in this study. Other manufacturers have suggested different adjunct treatments in combination with decompression sessions, but no comparative trials are available.

The spinal decompression system used in the study was approved in May 2006 by the Division of General, Restorative, and Neurological

Devices in the US Department of Health and Human Services K060735. Its indications for use, per its 510(k) premarket notification of the manufacturer's intent to market the device, are as follows: "The DRX9000 True Non-Surgical Spinal Decompression System™ provides a primary treatment modality for the management of pain and disability for patients suffering with incapacitating low back pain and sciatica. It is designed to apply spinal decompressive forces to compressive and degenerative injuries of the spine. It has been found to provide relief of pain and symptoms associated with herniated discs, bulging or protruding intervertebral discs, degenerative disc disease, posterior facet syndrome, and sciatica."

Other spinal decompression systems available commercially are designed differently, such as position of patient (supine or prone), angle of pull (and whether it is adjustable), type of motor, use of feedback from tension sensors during distraction to attempt to minimize reflex muscle contraction, and measurement of delivered forces. These factors may lead to differing responses to therapy, so studies of one apparatus type should not be readily applied across all machines.

A systematic review by The Cochrane Library on the use of traction for low back pain with or without symptoms of sciatica documents little proof of efficacy.[34] Only 5 trials were considered of high quality. The types of traction reviewed included mechanical traction, manual traction (unspecified or segmental traction), autotraction, underwater traction, bed-rest traction, continuous traction, and intermittent traction. Data on this system of spinal decompression had not been published yet and thus were not available for inclusion in these analyses.

A limitation of our study was the end-point being the conclusion of the 6 weeks of treatment and not longer-term follow-up at one year, for example. Although it is encouraging to report that a 6-week course of in-office care will relieve chronic low back pain, we are unable to define recurrence rates from this study. Further studies will determine when repeat treatments may be needed and what might be a reasonable maintenance program after the 6-week treatment course. Another potential issue is that costs to the patient for the spinal decompression treatments were covered by the clinical research grant. Patients typically pay out-of-pocket for spinal decompression treatment although some payors do provide reimbursement. The free treatments provided as part of the clinical trial might have influenced patient interest in continuing and might even have influenced the efficacy they reported.

Conclusion

Of the patients completing the full 6-week course of spinal decompression, 16 of 18 reported improvement in pain. Patients also reported having better daily activity function as measured by the Oswestry Disability Index. No safety issues were identified. Future randomized, prospective, double-blind, long-term outcome trials will need to refine the treatment protocol and to allow a comparison of outcomes with other treatment options. ■

References

1. Maetzel A, Li L. The economic burden of low back pain: a review of studies published between 1996 and 2001. *Best Pract Res Clin Rheumatol.* 2002;16(1):23–30.
2. Deyo RA, Mirza SK, Martin BI. Back pain prevalence and visit rates: estimates from U.S. national surveys, 2002. *Spine.* 2006;31(23):2724–2727.
3. Krishnaney AA, Park J, Benzel EC. Surgical management of neck and low back pain. *Neurol Clin.* 2007;25(2):507–522.
4. Andersson GB. Epidemiological features of chronic low-back pain. *Lancet.* 1999;354(9178):581–585.
5. Cassidy JD, Cote P, Carroll LJ, Kristman V. Incidence and course of low back pain episodes in the general population. *Spine.* 2005;30(24):2817–2823.
6. Manek NJ, MacGregor AJ. Epidemiology of back disorders: prevalence, risk factors, and prognosis. *Curr Opin Rheumatol.* 2005;17(2):134–140.
7. Jones GT, Macfarlane GJ. Epidemiology of low back pain in children and adolescents. *Arch Dis Child.* 2005;90(3):312–316.
8. Luo X, Pietrobon R, Sun SX, Liu GG, Hey L. Estimates and patterns of direct health care expenditures among individuals with back pain in the United States. *Spine.* 2004;29(1):79–86.
9. McCamey K, Evans P. Low back pain. *Prim Care.* 2007;34(1):71–82.
10. Peng B, Hao J, Hou S, et al. Possible pathogenesis of painful intervertebral disc degeneration. *Spine.* 2006;31(5):560–566.
11. Chou R, Qaseem A, Snow V, et al; for the Clinical Efficacy Assessment Subcommittee of the American College of Physicians; American College of Physicians; American Pain Society Low Back Pain Guidelines Panel. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society. *Ann Intern Med.* 2007;147(7):478–491.
12. Liddle SD, Gracey JH, Baxter GD. Advice for the management of low back pain: a systematic review of randomised controlled trials. *Man Ther.* 2007;12(4):310–327.
13. Chou R, Huffman LH; American Pain Society; American College of Physicians. Nonpharmacologic therapies for acute and chronic low back pain: a review of the evidence for an American Pain Society/American College of Physicians clinical practice guideline. *Ann Intern Med.* 2007;147(7):492–504.
14. Chou R, Huffman LH; American Pain Society; American College of Physicians. Medications for acute and chronic low back pain: a review of the evidence for an American Pain Society/American College of Physicians clinical practice guideline. *Ann Intern Med.* 2007;147(7):505–514.
15. Gupta RC, Ramarao SV. Epidurography in reduction of lumbar disc prolapse by traction. *Arch Phys Med Rehabil.* 1978;59(7):322–327.
16. Onel D, Tuzlaci M, Sari H, Demir K. Computed tomographic investigation of the effect of traction on lumbar disc herniations. *Spine.* 1989;14(1):82–90.
17. Ramos G, Martin W. Effects of vertebral axial decompression on intradiscal pressure. *J Neurosurg.* 1994;81(3):350–353.
18. Guechev G, Guechev A. Fast dynamics of voluntary muscle strength and motor evoked potentials after traction therapy in patient with lumbosacral root lesion. *Electromyogr Clin Neurophysiol.* 1996;36(4):195–197.
19. Meszaros TF, Olson R, Kulig K, Creighton D, Czarnecki E. Effect of 10%, 30%, and 60% body weight traction on the straight leg raise test of symptomatic patients with low back pain. *J Orthop Sports Phys Ther.* 2000;30(10):595–601.
20. Harte AA, Baxter GD, Gracey JH. The efficacy of traction for back pain: a systematic review of randomized controlled trials. *Arch Phys Med Rehabil.* 2003;84(10):1542–1553.
21. Clarke J, van Tulder M, Blomberg S, de Vet H, van der Heijden G, Bronfort G.

Traction for low back pain with or without sciatica: an updated systematic review within the framework of the Cochrane collaboration. *Spine*. 2006;31(14):1591–1599.

22. Macario A, Pergolizzi JV. Systematic literature review of spinal decompression via motorized traction for chronic discogenic low back pain. *Pain Pract*. 2006;6(3):171–178.
23. Hurwitz EL, Morgenstern H, Kominski GF, Yu F, Chiang LM. A randomized trial of chiropractic and medical care for patients with low back pain: eighteen-month follow-up outcomes from the UCLA low back pain study. *Spine*. 2006;31(6):611–621.
24. Hagg O, Fritzell P, Nordwall A; Swedish Lumbar Spine Study Group. The clinical importance of changes in outcome scores after treatment for chronic low back pain. *Eur Spine J*. 2003;12(1):12–20.
25. Deyo RA, Weinstein JN. Low back pain. *N Engl J Med*. 2001;344(5):363–370.
26. Anderson MW. Lumbar discography: an update. *Semin Roentgenol*. 2004;39(1):52–67.
27. Matsui Y, Maeda M, Nakagami W, Iwata H. The involvement of matrix metalloproteinases and inflammation in lumbar disc herniation. *Spine*. 1998;23(8):863–868.
28. Fujita K, Nakagawa T, Hirabayashi K, Nagai Y. Neutral proteinases in human intervertebral disc. Role in degeneration and probable origin. *Spine*. 1993;18(13):1766–1773.
29. Jensen MC, Brant-Zawadzki MN, Obuchowski N, Modic MT, Malkasian D, Ross JS. Magnetic resonance imaging of the lumbar spine in people without back pain. *N Engl J Med*. 1994;331(2):69–73.
30. Boden SD, Davis DO, Dina TS, Patronas NJ, Wiesel SW. Abnormal magnetic-resonance scans of the lumbar spine in asymptomatic subjects. A prospective investigation. *J Bone Joint Surg Am*. 1990;72(3):403–408.
31. Carragee EJ, Alamin TF, Miller JL, Carragee JM. Discographic, MRI and psychosocial determinants of low back pain disability and remission: a prospective study in subjects with benign persistent back pain. *Spine J*. 2005;5(1):24–35.
32. Borenstein DG. Epidemiology, etiology, diagnostic evaluation, and treatment of low back pain. *Curr Opin Rheumatol*. 1999;11(2):151–157.
33. Macario A, Richmond C, Auster M, Pergolizzi JV. Treatment of 94 outpatients with chronic discogenic low back pain with the DRX9000: a retrospective chart review. *Pain Pract*. 2008;8(1):11–17.
34. Clarke JA, van Tulder MW, Blomberg SE, de Vet HC, van der Heijden GJ, Bronfort G. Traction for low-back pain with or without sciatica. *Cochrane Database Syst Rev*. 2005;(4):CD003010.