ORIGINAL ARTICLE

Outcomes After a Prone Lumbar Traction Protocol for Patients With Activity-Limiting Low Back Pain: A Prospective Case Series Study

Paul F. Beattie, PhD, PT, OCS, Roger M. Nelson, PhD, PT, Lori A. Michener, PhD, PT, ATC, SCS, Joseph Cammarata, DC, Jonathan Donley, DPT

ABSTRACT. Beattie PF, Nelson RM, Michener LA, Cammarata J, Donley J. Outcomes after a prone lumbar traction protocol for patients with activity-limiting low back pain: a prospective, case series study. Arch Phys Med Rehabil 2008; 89:269-74.

Objective: To determine outcomes after administration of a prone lumbar traction protocol.

Design: Prospective, longitudinal, case series.

Setting: Suburban, chiropractic practice.

Participants: A total of 296 subjects with low back pain (LBP) and evidence of a degenerative and/or herniated intervertebral disk at 1 or more levels of the lumbar spine. We excluded patients involved in litigation and those receiving workers' compensation.

Intervention: An 8-week course of prone lumbar traction, using the vertebral axial decompression (VAX-D) system, consisting of five 30-minute sessions a week for 4 weeks, followed by one 30-minute session a week for 4 additional weeks.

Main Outcome Measures: The numeric pain rating scale and the Roland-Morris Disability Questionnaire (RMDQ) were completed at preintervention, discharge (within 2 weeks of the last visit), and at 30 days and 180 days after discharge. Intention-to-treat strategies were used to account for those subjects lost to follow-up.

Results: A total of 250 (84.4%) subjects completed the treatment protocol. On the 30-day follow-up, 247 (83.4%) subjects were available; on the 180-day follow-up, data were available for 241 (81.4%) subjects. We noted significant improvements for all postintervention outcome scores when compared with preintervention scores ($P<.01$).

Conclusions: Traction applied in the prone position using the VAX-D for 8 weeks was associated with improvements in pain intensity and RMDQ scores at discharge, and at 30 and 180 days after discharge in a sample of patients with activity-limiting LBP. Causal relationships between these outcomes and the intervention should not be made until further study is performed using randomized comparison groups.

Key Words: Back pain; Decompression; Intervertebral disk; Lumbar region; Rehabilitation; Traction; Treatment outcomes.

LUMBAR TRACTION IS AMONG the oldest known treatments for low back pain (LBP).[1] Described by Hippocrates, lumbar traction in various forms has been used for centuries, and continues to be used in today's clinical environment.[1-7] Recent clinical studies,[4,8] systematic reviews of literature,[5,7,9-11] and evidence-based guidelines[12,13] have concluded that the preponderance of evidence fails to support lumbar traction as an effective treatment for patients with LBP. There is concern, however, that the enormous array of potential treatment parameters,[3,6] and the lack of methodologic rigor of previous research,[5,7] have made the literature regarding lumbar traction inconclusive.

Recently, a newly developed lumbar traction system, vertebral axial decompression (VAX-D), has been gaining popularity.[14-19] During the traction applied with the VAX-D, the patient is prone, with no thoracic harness, on a table specifically designed to eliminate frictional resistance. The VAX-D system provides distraction forces and rest periods through a pelvic harness while the patient stabilizes himself/herself by holding a hand grip.[14] It is the manufacturer's claim that this technology reduces a patient's reflex spinal muscle contraction and allows distraction of the vertebrae, causing a subsequent symptom reduction.[14,15] The 30-minute treatment cycle applied with the VAX-D is typically administered on an outpatient basis 5 to 6 times a week for a period of approximately 4 weeks, then once a week for 4 weeks, for a total of approximately 8 weeks of treatment.

The current, limited body of evidence addressing VAX-D suggests that prone traction applied with VAX-D may decrease intradiscal pressure during load application[16] and that this intervention may be associated with improvements in reports of pain intensity.[17-19] These studies suggest promising findings; however, long-term outcomes after VAX-D intervention have not been reported, nor has the relationship between VAX-D intervention and measures of disability. Our goal was to expand on the current body of evidence by measuring outcomes after the application of prone lumbar traction applied with VAX-D in a prospective, longitudinal study using validated outcome measures of pain and disability on a large sample of patients. Favorable outcomes would provide data that would assist in the formation of hypotheses that could be tested with subsequent randomized clinical trials. The purpose of the present study, therefore, was to determine short- and long-term outcomes after administration of prone traction using the VAX-D protocol to a sample of patients with activity-limiting LBP that had been refractory to at least 2 bouts of previous, nonoperative interventions.

From the Program in Physical Therapy, Department of Exercise Science, Arnold School of Public Health, University of South Carolina, Columbia, SC (Beattie); Expert Clinical Benchmarks LLC, King of Prussia, PA (Nelson) and Department of Physical Therapy, Lebanon Valley College, Annville, PA (Nelson); Department of Physical Therapy, Virginia Commonwealth University—Medical College of Virginia Campus, Richmond, VA (Michener); Non-Surgical Solutions LLC, Narberth, PA (Cammarata); and Department of Internal Medicine, Richland-Palmetto Health, Columbia, SC (Donley).

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Reprint requests to Paul Beattie, PhD, PT, OCS, Program in Physical Therapy, Dept of Exercise Science, Arnold School of Public Health, University of South Carolina, Columbia, SC 29208, e-mail: *pbeattie@gwm.sc.edu.*

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METHODS

Participants

Subject inclusion criteria are summarized in appendix 1. Subjects were eligible for this study if they were aged 18 to 60 years, and had specified medical insurance coverage. Subjects must have reported activity-limiting LBP, with or without the presence of associated lower-extremity pain that had an average intensity greater than 4/10 on an 11-point numeric pain rating scale (NPRS)[20,21] during the month prior to admission. In addition, all subjects had to have a score of greater than 6/24 on the 24-point Roland-Morris Disability Questionnaire (RMDQ),[22] and have imaging evidence of a degenerative and/or herniated intervertebral disk at a segmental level consistent with current symptoms. All subjects must have reported a lack of favorable outcomes after at least 2 previous, nonoperative interventions (eg, joint manipulation, transcutaneous electric nerve stimulation, or oral medication) for their current symptoms (see appendix 1).

We excluded subjects who were currently involved in a workers' compensation claim, were involved in legal action regarding their back pain, or were on, or applying for, permanent disability related to their low back problem. Additional exclusion criteria included previous treatment with supine or prone applied lumbar traction, activity-limiting pain in areas other than low back and legs, a history of lumbar surgery, current pregnancy, or the use of prescription anticoagulants, corticosteroids, or opiate-based pain medication. Subjects were also excluded if there were radiographic or physical examination evidence of conditions that would represent precautions or contraindications for prone traction applied with VAX-D. These are listed in appendix 2.

We recruited subjects by local newspaper and radio advertisements, and by referral from local health care practitioners. Patient screening and intervention was performed at 2 health care facilities in the greater Philadelphia area between October 2002 and January 2005. All subjects signed a consent form approved by MedRisk's Human Subject Review Board.

Outcome Measures

Pain intensity. Highest, average, and lowest pain intensity on a typical day were assessed by using an 11-point NPRS.[20,21] Anchor points were defined as 0 (none) and 10 (worst imaginable). Previous research has shown measures obtained by this technique to be reliable and sensitive to meaningful change when repeated measures exceed ± 2.0.[23,24]

Roland-Morris Disability Questionnaire. Back-pain–related activity limitation was assessed by using the 24-point RMDQ.[22] We determined the RMDQ score based on the frequency of items that were checked by the patient; the scores ranged from 0 (no back pain–related activity limitation) to 24 (severe back pain−related activity limitation). Measures obtained from the RMDQ have been shown to have reliability and content validity, and reflect meaningful clinical change when repeated measures exceed $\pm 4/24$.[22,25-27]

Procedure

Subject screening and intake measures. Prior to admission to the study, potential subjects watched a videotape developed by the manufacturer that described the VAX-D traction. Next, subjects underwent a screening procedure performed to verify the entry and exclusion criteria. If no recent magnetic resonance imaging or computed tomography examination was available, it was obtained prior to admission in the study and was evaluated by a radiologist. Subjects who met the entry and exclusion criteria, and provided written informed consent, were enrolled in the study. At this time, the subjects completed an intake form that contained demographic information and the outcome measures. Each subject was scheduled for daily (5d/wk) prone traction of 30 minutes each for 4 weeks, then once a week for 4 weeks. The entire protocol consisted of 24 visits over 8 weeks.

Administration of the prone traction. The treating clinician attached a pelvic harness and positioned the patient prone on the VAX-D table.[a] The clinician attached an anchor strap to the table and used it to pull the pelvic harness until tension on the digital readout was between 4.5 to 5.4kg, per the VAX-D protocol. The hand grips were adjusted to accommodate the subject. The pulling force on the pelvic harness applied traction as the patient stabilized himself/herself via the handgrips. The relaxation and distraction times were set at 60 seconds each, with the cycle counter set at 15 cycles. The working pressure was then adjusted to the desired level. The working pressure was typically between 8.9 and 9.8kg/cm^2, and was based on patient comfort. After the 30-minute treatment, the subject was instructed to roll onto his/her side and sit on the side of the table for approximately 1 minute prior to leaving the facility.

Follow-up measures. We obtained outcome measures at the time of the last treatment visit (discharge), which was 8 weeks after the start of intervention. Additional measures were obtained at 30 days postdischarge, and at 180 days postdischarge. The treating clinicians were blinded to these measures. The original protocol called for all patients to provide follow-up measures in person at 30 and 180 days after discharge. However, because of poor compliance with this process, the protocol was modified to allow patient follow-up measures to be completed by telephone when subjects failed to appear for follow-up visits. Despite this effort, 18.6% of subjects did not provide follow-up data at 180 days. We monitored protocol and documentation compliance by having an independent blinded clinician perform audits of the 2 facilities performing the study. This process was carried out in the first 6 months of the project. Within that 6-month period, the auditor reported that the protocol for patient data collection and intervention was carried out appropriately by the providers. After the 6-month period, the auditor would appear at clinics, unannounced, each month to perform a complete audit of cases.

Data Analysis

We mailed the study's intake and follow-up data sheets to a research assistant who coded and entered all data. To account for those subjects lost to follow-up, the preintervention scores were used as follow-up measures, thus conservatively assuming no change from preintervention status (intention-to-treat [ITT] strategy).[28,29] Demographic data and outcome measures were summarized. A single-factor, general linear model, repeated-measures analysis of variance was used to determine differences in each of the outcome measures over time. Mean differences from preintervention scores and 95% confidence intervals (CIs) were computed for each of the outcome measures for discharge, 30 days postdischarge, and 180 days postdischarge. Because of the repeated-measures design, a Bonferroni correction was made to the CIs to reduce the likelihood of type I statistical error. Effect size differences were quantified by using the d-index described by Ottenbacher and Barrett[30] where:

$$\text{Effect size } (d) = 2(t)\sqrt{(df_{\text{error}})}$$

A small effect size is d less than .50; medium effect size is d

Table 1: Subject Characteristics at the Time of Study Entry (N=296)

Characteristic	n	%
Duration of symptoms (mo)		
Less than 2	25	8.5
Between 2−6	29	9.8
Greater than 6	234	79.0
Missing	8	2.7
Marital status		
Single	87	29.4
Married	200	67.6
Unknown	9	3.0
Job status		
Working, without restriction	178	60.1
Working, with restriction due to LBP	62	20.1
Not working because of LBP	10	3.4
Other	46	16.4
Smoking status		
Currently smoke	69	23.3
Previous smoker but quit	108	36.5
Never smoked	113	38.2
Missing	6	2.0
Exercise frequency		
Every day	23	7.8
Most days	68	23.0
Occasionally	97	32.8
Rarely or never	102	34.4
Missing	6	2.0
Vigorous exercise frequency		
Every day	11	3.7
Most days	44	14.9
Occasionally	83	28.0
Rarely or never	152	51.4
Missing	6	2.0
Body mass index		
Underweight	1	0.3
Normal	58	19.6
Overweight	146	49.3
Obese	86	29.1
Missing	5	1.7

ranging between .50 and .79; and large effect size is *d* greater than .80. All analyses were performed with SPSS.[b]

RESULTS

Subject Characteristics

A total of 303 subjects enrolled in the study between October 2002 and January 2005. Six subjects were not included in this analysis because of incomplete initial data. One additional subject was not included because of failure to meet an inclusion criterion (RMDQ admission score, <6/24). From the sample of 296 subjects used for this analysis, 203 were men, 85 were women, and 8 did not indicate sex. Subjects' mean age ± standard deviation (SD) was 44.2±9.2 years. The majority of subjects (n=234 [79%]) reported that their presenting symptoms of LBP were present for greater than 6 months. Of the remaining subjects, 25 (8.5%) reported symptoms of less than 2 months, and 29 (9.8%) had symptoms of between 2 and 6 months in duration. Subject characteristics are summarized in table 1.

The majority of the 296 subjects (n=250 [84.5%]) received 16 to 24 treatment visits of prone traction. Because of difficulties with transportation and bad weather, not all subjects received the full 24 visits. Of the subjects who completed the protocol, 247 (83.4%) provided follow-up data at 30 days postdischarge and 241 (81.4%) provided follow-up data at 180 days postdischarge. There were no adverse events reported during the course of the study.

Numeric pain rating scale. The mean preintervention measures of lowest, average, and highest pain intensity on a typical day are depicted in table 2. When ITT strategies were used, significant improvements were noted for all follow-up measures of pain intensity compared with the preintervention measures ($P<.01$) (see table 2). Highest pain intensity was significantly lower at 180 days follow-up than at discharge ($P<.01$). There were no significant differences between the other follow-up measurement points for pain intensity. The mean decreases in pain intensity from the preintervention scores ranged from −1.6 (lowest pain at discharge) to −2.8 (highest pain at 180 days follow-up) on the 0 to 10 NPRS. Effect size reductions in pain intensity were high, ranging from 1.6 (lowest pain at 30 days follow-up) to 2.0 (highest pain at 180 days follow-up, and average pain at 30 days follow-up) (see table 2). The

Table 2: Overall Mean, Mean Difference From Preintervention, and Effect Size Differences of Outcome Measures at Follow-Up Compared With Preintervention Scores (N=296)

Measure	Preintervention	Discharge	30-Day Follow-Up	180-Day Follow-Up
Lowest pain intensity*	3.9±1.9	2.3±2.1	2.2±2.2	2.1±2.2
Difference from preintervention		−1.6 (−1.4 to −1.8)	−1.7 (−1.4 to −1.9)	−1.8 (−1.6 to −2.1)
Effect size		1.7	1.6	1.7
Average pain intensity*	5.8±1.7	3.7±2.3	3.5±2.4	3.4±2.7
Difference from preintervention		−2.1 (−1.8 to −2.3)	−2.3 (−2.0 to −2.6)	−2.4 (−2.1 to −2.7)
Effect size		1.9	2.0	1.8
Highest pain intensity*	7.3±1.7	5.0±2.7	4.7±2.8	4.5±3.0
Difference from preintervention		−2.3 (−2.0 to −2.6)	−2.6 (−2.3 to −2.9)	−2.8 (−2.5 to −3.1)
Effect size		1.7	1.8	2.0
RMDQ†	12.6±4.8	7.0±6.0	6.0±6.0	5.9±6.4
Difference from preintervention		−5.6 (−4.9 to −6.2)	−6.6 (−5.9 to −7.2)	−6.7 (−6.0 to −7.4)
Effect size		2.0	2.3	2.2

NOTE. Values are mean ± SD, mean (95% CI), and effect size. To account for subjects lost to follow-up, a subject's preintervention scores were used for missing post-treatment data. For all measures, the mean scores obtained at follow-up were significantly different when compared with preintervention mean scores ($P<.01$).
*Scale range: 0 (none) to 10 (worst imaginable).
†Scale range: 0 (no disability) to 24 (severe disability).

lower boundary of 95% CI was greater than the proposed minimal detectable change score of 2.0[23,24] for all follow-up measures of highest pain intensity, and for 30 days and 180 days follow-up measures of average pain intensity when compared with preintervention scores.

Roland-Morris Disability Questionnaire. The mean preintervention measure ± SD of the RMDQ was 12.6±4.8 (range, 0 [normal] to 24 [worst possible score]). Significant improvements were noted for all follow-up measures compared with the preintervention score ($P<.01$). The mean RMDQ score at 180 days follow-up was significantly improved compared with discharge ($P<.01$). Mean change in the RMDQ scores compared with preintervention were −5.6 at discharge, −6.6 at 30 days postdischarge, and −6.7 at 180 days postdischarge. In all cases, the lower boundary of the 95% CI indicated a reduction of 4.0 or more points, suggesting the likelihood of clinically detectable change (see table 2).[26,27] The effect sizes ranged from 2.0 to 2.3 for the 3 follow-up measures compared with preintervention scores (see table 2).

DISCUSSION

This prospective, longitudinal case series provides preliminary information describing outcomes after prone traction with VAX-D. Patients reported significantly improved pain and RMDQ scores after 16 to 24 visits of prone traction at discharge, and at 30 days and 180 days postdischarge. However, there was large variation in the magnitude and meaningfulness of the degree of change in these measures. We noted large effect size differences for highest and average pain intensity, and for the RMDQ scores at all follow-up measures (see table 2). The lower boundary of the 95% CI was greater than the minimal detectable change score for highest pain intensity[23,24] and the RMDQ score[26,27] at each follow-up measure and for average pain intensity at 180 days postdischarge, indicating the likelihood that these measures reflected clinically detectable improvement. The effect size differences for lowest pain intensity were also large; however, the lower boundary of the 95% CI was less than the minimal detectable change at each follow-up measure. Therefore, there is uncertainty regarding the meaningfulness of the degrees of improvement that occurred with the lowest pain intensity.

Prone traction applied with the VAX-D has the advantage of being noninvasive with a relatively low risk of injury to the patient. Although Deen et al[31] described an occurrence of acute intervertebral disk protrusion associated with this form of traction, we were unable to locate other reports of adverse events. One limitation of the VAX-D, however, is that it is more expensive to administer than most conventional traction protocols. The manufacturer justifies this cost as based, in part, on the presence of the VAX-D's automated "logic-control mechanism" that is purported to provide a unique type of traction pull not available in less expensive, conventional traction devices.[14,15]

Arguments can be made that if outcomes after prone traction using the VAX-D are superior to those after conventional traction or other equivalent interventions, investing in and reimbursing for traction provided by the VAX-D system may be cost-effective. Further study is necessary to substantiate this. It is important to note that the traction applied via VAX-D also differs from most conventional lumbar traction in a variety of ways; the subject is positioned prone on a low-friction surface as opposed to supine on a high-friction surface; a pelvic harness is used as opposed to a thoracic harness; and the protocol indicates a high frequency of treatments over a 2-month period. Thus, it is unknown to what degree subject positioning, surface, type of stabilizing harness, and treatment dosage, rather than the unique traction pull of the VAX-D, contribute to the outcomes after intervention. We were unable to locate any studies that provided direct comparison of outcomes of traction via VAX-D compared with less expensive forms of conventional lumbar traction.

Our preliminary results suggest a generally favorable association between the prone traction applied with the VAX-D and the outcome measures used in this study; however, because we lacked a randomized control group, we cannot imply a causal relationship between the traction applied with VAX-D and outcome. For example, although we chose a sample that potentially had an unfavorable prognosis for recovery, ie, a history of previous failed treatment,[32] we cannot determine the degree to which the natural history of a subject's condition influenced outcome. We also cannot determine the degree to which changes in outcome measures were related to biologic effects resulting from the VAX-D versus a placebo effect.[33] All subjects had preintervention imaging evidence of lumbar intervertebral disk degeneration and/or herniation; however, the degree to which these findings were associated with symptoms,[34-36] or were influenced by the treatment, is not known. Further study is needed using randomized control groups and intervertebral disk imaging before and after intervention.

Study Limitations

Several limitations must be addressed in this study. It is also important to note that our findings can be generalized only to a sample of patients with activity-limiting LBP. We did not classify subjects based on the presence or absence of spinal nerve compression. None of our subjects were on permanent disability due to back pain, were receiving workers' compensation, or were involved in litigation. Subjects were included in this intervention trial only if they lacked favorable outcomes after at least 2 previous nonoperative treatments for their LBP. Our sample was primarily composed of middle-aged adults who were currently working and reported moderate to high preintervention pain intensity (range, 3.9–7.3) and moderate pain-related activity limitation (mean RMDQ score, 12.6). Most subjects had symptoms of greater than 6 months in duration, were nonsmokers, tended to be overweight or obese, and did not exercise regularly. It is not known if prone traction applied with the VAX-D would be associated with similar findings in patients who have different characteristics from our sample.

CONCLUSIONS

Prone traction delivered with VAX-D for 16 to 24 visits was associated with significant improvements in pain intensity and RMDQ scores in both short- and long-term follow-up, in patients with activity-limited LBP who had previously failed 2 nonoperative interventions for their current symptoms. Causal relationships between the outcomes and the intervention cannot be made. Further study is needed using randomized comparison groups.

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APPENDIX 1: STUDY INCLUSION CRITERIA

Variable	Criterion
Age (y)	18–60
Symptom type and distribution	Pain must be present in low back and may also be present in any of the following areas: 1 or both buttocks, 1 or both thighs, 1 or both legs. Pain must be the primary complaint, although dysesthesias (pins and needles, numbness) or lower-extremity weakness may also be present.
Symptom severity	Average pain of equal to or greater than 4/10 over the last month. The RMDQ score must be at least 6/24.
Diagnosis and medical examination findings for current condition	Must have undergone a medical examination by a primary care physician, rheumatologist, orthopedist, neurosurgeon, or neurologist that has ruled out nonmusculoskeletal causes for the current symptoms. Must have undergone spinal imaging (magnetic resonance imaging, computer tomography scan, diskography or myelography) that confirms the presence of a degenerative and/or herniated lumbar intervertebral disk at a segmental level consistent with the current symptoms.
History of "failed" prior treatment	All subjects must have had persistence of symptoms after a reasonable course of at least 2 prior, nonoperative treatment approaches. These treatments must have been discontinued due to worsening of symptoms or failure of symptoms to substantially improve.*

Abbreviation: RMDQ, Roland-Morris Disability Questionnaire.
*Examples include: exercise, massage, joint manipulation, acupuncture, injection therapy (either epidural, facet, or soft tissue), transcutaneous electric nerve stimulation or other form of electrotherapy, a course of pain-relieving oral medications (steroidal, nonsteroidal, opiate), biofeedback, or a lumbar orthosis.

APPENDIX 2: STUDY EXCLUSION CRITERIA

- Currently involved in a worker's compensation claim or personal injury litigation
- Currently on, or applying for, permanent disability related to LBP
- Previous treatment using lumbar traction or VAX-D
- Activity-limiting pain arising from any site other than listed in specific entry criteria
- A history of a surgical procedure to the lumbar spine
- Known or suspected current pregnancy or recently postpartum
- Currently taking prescribed anticoagulants (this does not include low doses of aspirin), corticosteroids, and/or opiate-based analgesics
- Vertebral osteoporosis, spondylolisthesis or retrolisthesis of greater than 50%, or vertebral fracture with current bony instability or measurable deformity
- Severe lumbar stenosis (anteroposterior diameter of the thecal sac of less than 5mm at any level, from mid-sagittal lumbar magnetic resonance imaging)
- Inflammatory, infectious, or neoplastic disease involving the spine
- Spinal or lower-extremity nerve impairment not resulting from spinal nerve compression in the lumbosacral spine.
- Abdominal aortic aneurysm, chronic ileus, inflammatory bowel disease, unstable angina, congestive heart failure, orthopnea, or severe hypertension
- Any surgical procedures to the abdomen, thorax, upper extremities, head, or neck in the 6 months prior to enrollment in the study
- Any condition involving the cervical-thoracic spine or upper extremity that would be adversely affected by VAX-D. This is defined as an inability to assume and maintain the prone position while "pulling" with both upper extremities, for example, severe kyphosis, adhesive capsulitis of the shoulder, and weakness of handgrip
- Open wounds or skin rash on the back

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Suppliers

a. VAX-D Medical Technology LLC, 310 Mears Blvd, Oldsmar, FL 34677.
b. Version 12.0; SPSS Inc, 233 S Wacker Dr, 11th Fl, Chicago, IL 60606.