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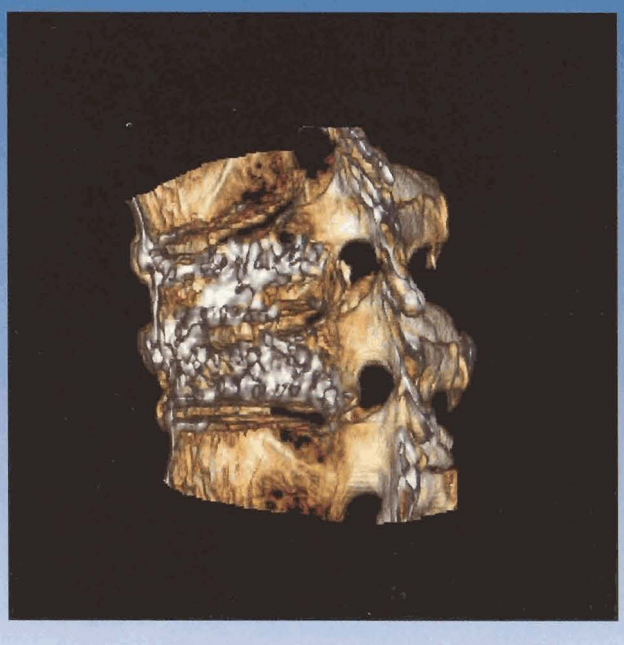

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ORIGINAL ARTICLE

Systematic Literature Review of Spinal Decompression Via Motorized Traction for Chronic Discogenic Low Back Pain

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■ **Abstract**

Objective: The objective of this study was to systematically review the literature to assess the efficacy of nonsurgical spinal decompression achieved with motorized traction for chronic discogenic lumbosacral back pain.

Design: Computer-aided systematic literature search of MEDLINE and the Cochrane collaboration for prospective clinical trials on adults with low back pain in the English literature from 1975 to October 2005. Methodologic quality for each study was assessed. Studies were included if the intervention group received motorized spinal decompression and the comparison group received sham or another type of nonsurgical treatment.

Results: Data from 10 studies were fully analyzed. Seven studies were randomized controlled trials using various apparatus types. Because of this low number, we also analyzed three nonrandomized case series studies of spinal decompression systems. As the overall quality of studies was low and the patient groups heterogeneous, a meta-analysis was not appropriate and a qualitative review was undertaken. Sample sizes averaged 121 patients (range 27–292), with six of the seven randomized studies reporting no difference with motorized spinal decompression and one study reporting reduced pain but not disability. The three unrandomized studies (no control group) of motorized spinal decompression found a 77% to 86% reduction in pain.

Conclusions: These data suggest that the efficacy of spinal decompression achieved with motorized traction for chronic discogenic low back pain remains unproved. This may be, in part, due to heterogeneous patient groups and the difficulties involved in properly blinding patients to the mechanical pulling mechanism. Scientifically more rigorous studies with better randomization, control groups, and standardized outcome measures are needed to overcome the limitations of past studies. ■

Key Words: low back pain, outcome, spinal decompression, mechanized or motorized traction, discogenic pain

INTRODUCTION

Chronic low back pain (defined as lasting longer than 12 weeks) is an expensive benign condition in industrialized countries.[1] The main mechanical causes are either injury to lumbosacral muscles and ligaments, or discogenic disorders related to trauma or degenerative disc disease. Treatments vary widely, and should be individualized to the patient.

If noninvasive modalities are preferred, then oral analgesics,[2] muscle relaxants, physical therapy, exercises,[3,4] acupuncture,[5] manipulation,[6,7] or back school[8] are options. More invasive therapies include epidural

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injections,[9] percutaneous intradiscal radiofrequency thermocoagulation,[10] and surgical spinal decompression via removal of disc fragments and/or fusion when there is evidence of spinal column instability.

Another treatment alternative is traction. Data supporting the use of traction to widen the intervertebral space or reduce disc protrusion exist in the literature.[11,12] Traction also may improve motor evoked potentials in lumbosacral radiculopathy and reduce intradiscal pressure.[13,14] Using the straight-leg raise test as the endpoint, static traction with 30% or 60% of body weight (but not 10% of body weight) improved leg mobility in patients with low back pain and radicular symptoms.[15]

The spinal decompression force can be delivered manually by the therapist, via gravity (the weight of the patient) through a suspension device,[16] or by the patient while lying on a specially designed table, the pelvis secured, pulling the bars at the head of the table.[17] These types of traction can be difficult to standardize because of the patient's or therapist's fatigue or intolerance to the force or position.[18,19] Additionally, difficulties in the development of standards for traction application strategies may be influenced by the different ways in which patients are diagnosed, grouped, and managed. Perhaps for this reason, efficacy for traction was not found in previous systematic reviews regarding the treatments for chronic low back pain and/or neck pain.[20–23]

For traditional traction, the pull force (delivered manually or with gravity) is linear and may elicit the body's proprioreceptive response that triggers paravertebral muscle contraction, which could reduce the distractive effect. In contrast, a motor pulley can be designed to deliver mechanized segmental distraction that can be delivered in a static or oscillatory fashion for a preselected timeframe. This approach could be applied, for example, 2–3 times per week, 30 min per session, and with weights ranging from 30 to 85 kg.[17] The DRX9000 (Axiom Worldwide, Tampa, FL, USA) and the vertebral axial decompression (VAX-D) (VAX-D Medical Techologies, Oldsmar, FL, USA) are mechanical apparatus types that offer this type of nonsurgical spinal decompression. The DRX 9000 system, for example, has built-in air bladders, disc angle pull adjustments, harnesses, and the ability to increase the distraction force more slowly in the latter part of the decompression.

Unlike previous systematic reviews, which looked at a variety of different traction methods, we focused on mechanized apparatus types. The objective of this study was to systematically review the literature to assess the efficacy of nonsurgical spinal decompression achieved with motorized traction for chronic discogenic low back pain.

METHODS

Systematic reviews apply strategies that limit bias to the assembly, appraisal, and synthesis of relevant studies on a specific topic.[24,25] We followed published guidelines[26,27] to identify prospective clinical trials in the international, peer-reviewed, published literature regarding adults with lumbosacral back pain lasting more than 12 weeks.

We used electronic searches of the National Library of Medicine's MEDLINE database, the Cochrane Central Register of Controlled Trials, and the Cochrane Database of Systematic Reviews for articles from 1975 to October 2005. Studies prior to 1975 were excluded, as healthcare standards and practice from more than 30 years ago may not be applicable in today's practice environment. In addition, non-English articles were excluded.[28,29]

"Low back pain, mechanized or motorized traction, non-surgical spinal decompression, discogenic pain, clinical trial, DRX 9000, and VAX-D" were entered separately as medical subject headings and as text words. No minimum sample sizes were invoked for inclusion of studies, while only studies on adults (ages >18 years) were included. The last literature search was completed on November 15, 2005.

Studies were included if the intervention group received motorized traction as the main treatment and the comparison group received sham or another type of nonsurgical treatment. Thirty articles were initially screened, but 15 were disqualified for a variety of reasons, including studies of other types of traction ($n = 8$), non-English articles ($n = 2$), studies on patients with back pain due to infection or neoplasm ($n = 2$), and reports available only as a published abstract or case reports ($n = 3$). We excluded trials that investigated patients using force generated by pulling with the arms[30,31] (not via a mechanized apparatus), without a sham control group,[32] or cervical motorized traction.[33]

Two reviewers independently conducted data extraction from the 10 fully analyzed studies. Each investigator read each article and completed a data sheet. Differences between the two reviewers were resolved by reexamination of the original article until consensus was attained about the study's data. A third investigator was available, but not necessary to help achieve consensus.

The following study characteristics were recorded: the first author's name, the year of publication, the country in which the study was conducted, the method

of patient enrollment (prospective, retrospective, and whether patients were randomized), and the number of patients. Primary endpoints were categorized depending on how they were described in each study analyzed.

Methodologic quality for each study was assessed using the Jadad scale based on randomization procedures, blinding of the patients and the investigator, and the description of withdrawals.[34] We determined whether or not each study reported a statistically significant result in favor of motorized traction.

RESULTS

Data from 10 studies were fully analyzed. Seven studies were randomized controlled trials of motorized traction using various apparatus types, including split tabletop, plain tabletop, and friction-free couch with weights. Only three of the seven randomized controlled studies provided a description of the randomization procedure. None of the studies had blinded outcome assessments.

Because the overall quality of studies was low and the patient groups were heterogeneous (eg, symptom duration and diagnoses), a meta-analysis was not appropriate and a qualitative review was undertaken.

The seven randomized controlled studies had a total of 408 patients receiving placebo and 438 patients receiving motorized spinal decompression (Table 1). Sample sizes averaged 121 patients (range 27–292) per study. Follow-up averaged 28 weeks (range 6–64 weeks). Six of the seven randomized studies reported no difference with motorized spinal decompression, and one study reported reduced pain but not disability.

Because of the low number of randomized studies, we additionally analyzed three nonrandomized case series studies of motorized spinal decompression, with no control group (Table 2). The three studies each reported reduction in pain, ranging from 77% to 86%.

DISCUSSION

Our literature review suggests that the efficacy of spinal decompression achieved with motorized traction for chronic discogenic low back pain remains unclear. This may be due, in part, to heterogeneous patient groups and the difficulties involved in properly blinding patients to the mechanical pulling mechanism.

Often times the anatomic cause of persistent low back pain remains unknown. This is because structural imaging and symptoms are poorly correlated, and because the patient's baseline psychosocial variables may affect the development of chronic low back pain.[35] Previous reviews of treatments for low back pain found low overall methodological quality.[36] Despite pleas by those authors for more rigorous studies, few exist today. The length of symptoms, location (back or back/leg), results of imaging studies, and specific diagnoses (eg, nonspecific low back pain, sciatica) are often not reported.

Unlike previous literature reviews on chronic low back pain that evaluated a variety of treatments, we were specifically interested in assessing the effect of mechanized traction via different apparatus types. We identified seven randomized controlled studies of motorized traction with placebo groups that received either transcutaneous electric nerve stimulation,[37] infrared heat,[38] manipulation,[39] interferential therapy,[40] hot pack with ultrasound,[41] or sham (two studies[42,43]). Although motorized traction has the advantage that the weight applied can be standardized, six of the seven randomized controlled studies reported no difference in clinical outcomes. One study reported that even though there were no differences in disability scale scores, 68% of patients in the active treatment group had a 50% or more visual analog pain scale score reduction vs. 0% for control group at 24-week follow-up.

Three unrandomized studies of motorized spinal decompression reported a 77% to 86% reduction in pain.[44–46] We chose to include nonrandomized case series of spinal decompression systems because of the low number of randomized clinical trials available for analysis. However, the cases series did not have control groups, making it difficult to know how much of the benefit was placebo or associated with spontaneous recovery and how much was due to the intervention. A separate retrospective study also showed benefit with motorized spinal decompression, but 9/33 patients were lost to 1-year follow-up.[47] Taking the results of all studies together suggests that the efficacy of motorized nonsurgical spinal decompression for discogenic lumbosacral back pain remains unclear.

Spinal loading may negatively impact the normal hydrostatic milieu of the disc with progression to degeneration and herniation. 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.[48,49] Despite this basic science, this article documents the continuing problems with the methodologic quality of clinical research related to the noninvasive treatment of discogenic low back pain.

One could ponder why more randomized controlled studies are not being performed. Part of the explanation

Table 1. Characteristics of Prospective Randomized Clinical Trials

First Author (Year & Country)	Primary Endpoint	Blinding	Method of Randomization	Withdrawals Described	Back Pain Duration	Back Pain Diagnosis	Inclusion Criteria	Patient Demographics	Placebo Type	Motorized Intervention Apparatus	Treatment Protocol	Sample Size Placebo/ Intervention	Result (Time to Follow-up)
Mathews (1975[42] U.K.)	What % pain had changed assuming the level on entry to trial was 100%	Patient	Not stated	No	2–46 weeks with mean 13 weeks	Sciatica with or without low back pain	20–60 years of age; no previous traction: not hospital worker	Mean age: 44 years; 33% female;	Sham couch with 9 kg	Couch with pelvic harness	Fifteen 30-minute treatments over 3 weeks: between 36 and 61 kg	14/13	No difference (6 weeks)
Werners (1999[40] Germany)	Oswestry Disability Index and 100-mm VAS pain	None	Computer generated	Yes: 7 in the control group and 3 in the TESI group	<5 years to >10 years	Severe enough to warrant orthopedist visit: patients with sciatica included	No previous spine surgery; no spinal disorder on X ray; 20–60 years of age	Mean age: 39 years; 46% female; 45% on sick leave	Interferential therapy	TESI	Six 10-minute treatments over 14–21 days: between 10 and 20 kg	74/73	No difference (12 weeks)
Beurskens (1997[43] Netherlands)	Global recovery as perceived by patient on 7-point scale ranging from recovered to vastly worsened*	Patient	Computer generated	Yes: 1 in sham group left country for work	>6 weeks†	Nonspecific low back pain‡; mean severity 74 on 100-mm VAS	>18 years of age; patients never had traction before	Mean age: 40 years; 44% female	Sham with maximum traction force of 20% of patient weight: with tight brace around iliac crest	Eltrac	12 times in 5 weeks for 20 min/session; traction force = 35%–50% of patient weight	74/77	Both traction and sham groups improved but no difference (12 and 24 weeks)
Coxhead (1981[39] U.K.)	VAS pain and global recovery (are you better or worse after 4 wks of treatment? Yes/no)	None	Not stated	Yes	Mean of 14 weeks	Sciatica with radiations at least to buttock	No spine surgery in previous 3 months; no spinal disorder on X ray; 20–60 years of age	Mean age: 42 years; 44% female	None, manipulation exercises, or corset	Motor-driven Tru-Trac	Daily for first week and less often in following 3 weeks; intermittent split top alone or with manipulation, or exercises, or corset	143/149	No difference (16 and 64 weeks)
Mathews (1987[38] U.K.)	Global recovery	None	Not stated	No	<13 weeks	Back pain plus nerve root pain	No spinal disorder on X ray; 18–60 years of age	Median age: 40 years; 44% female	Infrared heat for 15 min 3 times a week, advice, or corset	Friction-free couch, & advice, corset	Maximum of 15–30 minute treatments over 3 weeks: >45 kg each weekday	60/83	Traction relieved pain during treatment but no difference (2 and 52 weeks)
Sherry (2001[37] Australia)	VAS pain and 4-point disability scale of activities most affected by pain	None	Sequential	Yes: 1 in control group did not wish to participate anymore; 3 in active treatment group	>12 weeks	Low back pain with mean severity 57 on 100-mm VAS	Confirmed disc protrusion by CT or MRI; chronic low back pain (VAS > 2) and associated leg pain; 18–65 years of age	Mean age: 42 years; 48% female	Transcutaneous electric nerve stimulation	Vertebral axial decompression	Twenty 30-minute treatments over 8 weeks: 5 times/week first 4 weeks then once a week: 23 to 43 kg	22/22	68% in active group had 50% or more VAS pain score reduction vs. 0% for control group (24 weeks): No difference in disability scale
Borman (2003[41] Turkey)	Global recovery on 4-point scale	None	Not stated	Yes	>6 months	Persistent nonspecific; mean severity 56 on 100-mm VAS	No previous surgery; no spinal disorder; <65 years of age;	Mean age: 40 years; 66% female	Back school & physical therapy with hot pack, ultrasound, & exercise	Eltrac (along with back school & physical therapy)	5 times a week for 10 treatments in 2 weeks, each lasting 20-min sessions with maximum of 50% body weight	21/21	No difference (12 weeks)

*A condition-specific disability scale (Roland Morris) was also collected.
†Patients did not have imaging evidence of disc damage. Pain duration was greater than 6 weeks instead of our inclusion criteria of 12 weeks, but was included in our study to increase the number of analyzable studies.
‡Nonspecific was defined as no evidence of underlying diseases or anatomic abnormalities.
CT, computerized tomography; MRI, magnetic resonance imaging; VAS, visual analog scale.

Table 2. Characteristics of Nonrandomized Case Series of Motorized Spinal Decompression Systems

First Author (Year & Country)	Primary Endpoint	Blinding	Method of Randomization	Withdrawals Described	Back Pain Duration	Back Pain Diagnosis	Inclusion Criteria	Patient Demographics	Treatment Protocol	Sample Size	Result (Time to Follow-up)
Gionis (2003[44] U.S.A.)	Pain intensity score on the Oswestry scale	NA	NA	Yes: 10 due to transportation issues, family emergencies, schedule conflicts	2–46 weeks of MRI confirmed herniated disc or DDD	Sciatica with or without low back pain	Pain due to herniated & bulging lumbar discs; >18 years of age; no previous back surgery	Mean age: 45 years; 36% female	Twenty 45-minute treatments over 6 weeks: one-half the patients' body weight plus 10 or more lb	229	86% patients had pain reduced to 0 or 1 on Oswestry pain scale (12 weeks)
Gose (1998[45] U.S.A.)	0–5 pain scale	NA	NA	No	Mean of 40 months	Single herniation: 382; degenerative discs: 147, multiple herniation: 195	Herniated disc, degenerated disc, facet syndrome confirmed by imaging study	Not stated	VAX-D	778	72% of patients had pain reduced to 0–1
Naguszewski (2001[46] U.S.A.)	Pain and evoked potentials	NA	NA	No	8 weeks to 38 months	Mechanical low back pain severity 58 on 100-mm VAS	Low back pain with referred leg pain in L5 or S1 distribution with CT or MRI confirmed disc bulging or herniation	Mean age: 42 years; 43% female	VAX-D Mean of 17 treatments (range of 10–35 per patient)	7	77% mean pain reduction to 13 on 100-mm VAS; 17 of 28 nerve roots improved, 8 unchanged, and 3 deteriorated (2–7 weeks)

NA, not applicable; CT, computerized tomography; DDD, degenerative disc disease; MRI, magnetic resonance imaging; VAS, visual analog scale; VAX-D, vertebral axial decompression.

may be related to the heterogeneous patient types seen in clinics, as well as the difficulties involved in properly blinding patients to the mechanical pulling mechanism. In the U.S.A., another possibility for the lack of randomized controlled studies is that unlike new drugs that are required to have two separate double-blinded randomized controlled studies for regulatory approval from the Food and Drug Administration (FDA), new devices intended for human use are not held to the same rigorous standard and often receive 510(k) approval. A 510(k) is a premarketing submission made by a manufacturer to the FDA to demonstrate that a device is substantially equivalent to a similar device currently and legally (marketed prior to 1976) available in the market. Because this regulatory process for devices, including spinal decompression systems, does not require randomized controlled studies to demonstrate safety and efficacy, device manufacturers historically have not undertaken such studies.

In the seven prospective randomized trials we examined, pain or global recovery measures were the most common primary endpoints. However, these endpoints varied widely, including recognized measures such as the Oswestry scale and the 100-mm visual analog pain scale. A study published in 1975 used "What % pain has changed assuming the level on entry to trial was 100%" as the primary endpoint. Other more recent studies used global recovery endpoints as perceived by patient on a 7-point scale ranging from "recovered" to "vastly worsened" or "Are you better or worse after 4 wks of treatment? Yes/no." Ideally, the outcome measure is sufficiently reliable, valid, and sensitive and specific for measuring small but clinically relevant changes. However, quantitative measures such as range of movement, straight-leg raising, and muscle strength may be more reproducible and reliable but are notorious for not reflecting patient perceptions of pain and quality of life.

Clinical and radiographic inclusion criteria need to be standardized to compare studies. For example, the studies that met our inclusion criteria for analysis reported several diagnoses for inclusion, including sciatica with or without low back pain, nonspecific low back pain, sciatica with radiations at least to buttock, or back pain plus nerve root pain. These heterogeneous populations complicate pooling data from multiple studies to overcome the sample size limitations of any one particular study.

Blinding of the patients is difficult. Only two of the seven prospective randomized studies that we assessed blinded the patients by using sham traction with reduced weights. At least 26% of the patient's body weight is required to overcome friction.[50] However, sham traction with low weights may provide some relief in addition to the placebo effect. Blinding the assessor after therapy may be the simplest portion of the protocol to achieve practically, but is often not conducted.

The lengths of the treatment protocols varied widely, ranging from a low of 2 weeks to as long as 8 weeks, and the follow-up averaged 7 months (range 6–64 weeks). Treatment weights in the studies ranged from 10–20 to 36–61 kg or were reported as a percentage of the patient's weight. Future studies with even longer-term follow-up are merited to evaluate the optimal method, frequency, and details of motorized spinal decompression application taking into account the known basic and clinical science.

Potential limitations of this study include those with any systematic review, in that any unpublished data were not retrieved for analysis. Also, we may not have found all the relevant articles, as our search was limited to the English language.

CONCLUSIONS

Discogenic pain is a major problem in lumbar degenerative disc disease. For evidence-based practice to work, practitioners need the many articles available in the literature on a particular topic analyzed and synthesized. Also, to be useful, clinical trials must study treatments that the practitioner uses during his or her daily practice. Whereas the studies included in this review often looked at the efficacy of nonsurgical spinal decompression in isolation, the practitioner caring for patients with chronic low back pain would typically offer various combinations of treatments. The evidence for the efficacy of motorized spinal decompression for discogenic lumbosacral back pain remains inconclusive. Scientifically more rigorous studies with better randomization, more complete control groups, uniform selection criteria, evidence-based diagnostic measures, and standardized outcome measures are needed to identify the best responders to this conservative intervention.

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