Decompression Therapy for the Treatment of Lumbosacral Pain

Technology Assessment Program

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EXECUTIVE SUMMARY

The Centers for Medicare and Medicaid Services (CMS) requested that AHRQ commission an evidence report to assist in updating the CMS policy regarding decompression therapy for chronic low back pain. Accordingly, on January 17, 2006, AHRQ issued a Statement of Work (SOW) contracting ECRI to prepare an evidence report titled, "Decompression Therapy for the Treatment of Lumbosacral Pain."
The SOW specified that ECRI undertake the following tasks:

1. Systematically search, review, and analyze the relevant scientific evidence appropriate for each question. Search Medline and other suitable databases containing primary literature relevant to the questions to be addressed. Identify other sources of relevant literature, such as gray literature, clinical trials currently in progress, and clinical practice guidelines.
2. Retrieve and review full articles on eligible studies, assessing quality and extracting key data from each eligible study.
3. Prepare evidence tables and a summary of important findings.

Key Questions

In commissioning this report, AHRQ, in consultation with CMS and ECRI, developed four key questions. These four key questions are presented below:

Key Question 1: What are the patient inclusion and exclusion criteria used in studies of decompression therapy?

***Key Question 2*:** What are the efficacy or effectiveness outcomes measured in studies of decompression therapy? Are the efficacy/effectiveness outcome measured in studies of decompression therapy comparable to those used in studies of other non-surgical modalities for chronic low back pain due to a herniated disc or degenerative disc disease?

***Key Question 3*:** Is decompression therapy an effective treatment for chronic low back pain due to herniated disc or degenerative disc disease?

a. Do patients with chronic low back pain (due to herniated disc or degenerative disc disease) who are treated with decompression therapy have more, less, or the same level of pain relief than patients who are treated with other therapies?

b. Do patients treated with decompression therapy for chronic low back pain due to a herniated disc or degenerative disc disease utilize more, less, or the same number of adjunctive therapies (e.g., medications, bracing) than patients treated with other therapies?

c. Do patients treated with decompression therapy for chronic low back pain due to a herniated disc or degenerative disc disease return to work more quickly than patients treated with other therapies?

d. If the therapy is effective, what is the duration of relief achieved?

e. If the therapy is effective, what are the patient characteristics/indications of those for whom it appears to work? Is the therapy effective for the Medicare population (over 65 years of age)?

f. If it works, which, if any, particular decompression protocol provides the most pain relief?

***Key Question 4*:** What complications, harms, and adverse events associated with decompression therapy have been reported?

a. Would the characteristics of the Medicare population (osteoporosis, etc.) increase the likelihood of adverse events compared to the trial populations?

Data Sources

We searched 17 external and internal databases, including PubMed and Embase, for clinical trials on the use of decompression therapy to treat lower back pain. We also examined the bibliographies/reference lists from peer-reviewed and gray literature. (Gray literature includes reports and studies produced by local government agencies,

private organizations, educational facilities, and corporations that do not appear in the peer-reviewed journal literature.) Although we examined gray literature sources to identify relevant information such as reference listings and product information to address Question 1, we only utilize published, peer-reviewed literature in this report to address Questions 2, 3, and 4.

Evidence Bases

Our searches identified ten potentially relevant articles. Of these, we retrieved seven full publications of studies.(1-7) Three additional articles were identified during the process of external review.(8-10) We read each article in full to determine whether it met a set of question-specific *a priori* inclusion criteria. All ten of the retrieved articles met the inclusion criteria for at least one key question. Some of the included articles addressed more than one of our four key questions. The evidence base for Key Question 1 consisted of eight articles,(1,3,5-10) the evidence base for Key Question 2 consisted of nine articles,(1,3-10) and the evidence base for Key Question 3 consisted of three articles.(1,3,6) All ten articles were examined for Key Question 4.

Main Findings

Key Question 1: What are the patient inclusion and exclusion criteria used in studies of decompression therapy?

Eight articles addressed Key Question 1.(1,3,5-10) The only patient inclusion criterion consistently listed across of these studies was that enrolled patients must have suffered from chronic low back pain related to radiographically confirmed disc degeneration or herniation. Some studies included patients with facet joint arthritis or facet syndrome. Common exclusion criteria described in the three studies reporting them were tumor, infection, spinal instability, and surgical implants. Other reported inclusion/exclusion criteria were unique to individual studies.

Of particular relevance to the Medicare population is the fact that one included study specifically excluded patients with "severe osteoporosis,"(1) and the presence of osteoporosis is considered a contraindication. Two studies indicated that patients over the age of 65 were included.(1,10)

***Key Question 2*:** What are the efficacy or effectiveness outcomes measured in studies of decompression therapy? Are the efficacy/effectiveness outcome measured in studies of decompression therapy comparable to those used in studies of other non-surgical modalities for chronic low back pain due to a herniated disc or degenerative disc disease?

Eight included studies that enrolled a total of 1,032 patients and the health technology assessment(4) addressed Key Question 2.(1,3,5-10) The most frequently reported health outcomes evaluated by these studies of decompression therapy were change in pain score or percent improvement in pain (six studies) and functional outcome (three studies). These outcomes are also commonly assessed in studies of other non-surgical modalities for chronic low back pain due to herniated disc or degenerative disc disease. Other vertebral decompression studies reported possible surrogate outcomes such as intradiscal pressure(8), current perception threshold (CPT),(7) and dermatomal somatosensory evoked potentials (DSSEPs)(9) as indicators of nerve root decompression.

A number of outcomes which were evaluated in studies of other non-surgical modalities for chronic low back pain were not evaluated by studies of decompression therapy. These include: absenteeism, return to work, overall health, analgesic consumption, disability rates, and quality of life.

***Key Question 3*:** Is decompression therapy an effective treatment for chronic low back pain due to herniated disc or degenerative disc disease?

a. Do patients with chronic low back pain (due to herniated disc or degenerative disc disease) who are treated with decompression therapy have more, less, or the same level of pain relief than patients who are treated with other therapies?

b. Do patients treated with decompression therapy for chronic low back pain due to a herniated disc or degenerative disc disease utilize more, less, or the same number of adjunctive therapies (e.g., medications, bracing) than patients treated with other therapies?

c. Do patients treated with decompression therapy for chronic low back pain due to a herniated disc or degenerative disc disease return to work more quickly than patients treated with other therapies?

d. If the therapy is effective, what is the duration of relief achieved?

e. If the therapy is effective, what are the patient characteristics/indications of those for whom it appears to work? Is the therapy effective for the Medicare population (over 65 years of age)?

f. If it works, which, if any, particular decompression protocol provides the most pain relief?

Three studies that enrolled a total of 225 patients met inclusion criteria and addressed Key Question 3.(1,3,6) Two of the studies evaluated the VAX-D system(1,3); the remaining study evaluated the Decompression Reduction Stabilization (DRS®) system.(6) One included study was a randomized controlled trial,(6) one was an unblinded controlled trial with an inadequately described method of randomization,(3) and the third study was a non-randomized controlled trial that evaluated the effect of different “doses” of VAX-D) therapy.(1)

An evaluation of the quality of the three included studies found two of the studies to be of low quality.(3,6) The remaining study(1) was found to be highly susceptible to bias (e.g., did not ensure baseline comparability of the groups) and was not considered further in addressing Key Question 3.

One of the remaining two studies compared VAX-D therapy to transcutaneous electrical nerve stimulators (TENS) therapy and the other compared DRS® to traction therapy. Although both studies reported evidence in favor of decompression therapy (significant reductions in pain scores or patient reports of improvement in symptoms), the low quality and low quantity of evidence precludes us from drawing an evidence-based conclusion concerning the efficacy of decompression therapy for treating chronic low back pain at this time. One study described six-month follow up for a subset of patients(3), otherwise, none of the sub-questions could be answered. Neither study included any patients over the age of 65 years.

***Key Question 4*:** What complications, harms, and adverse events associated with decompression therapy have been reported?

a. Would the characteristics of the Medicare population (osteoporosis, etc.) increase the likelihood of adverse events compared to the trial populations?

All ten studies were evaluated for reports of adverse events associated with VAX-D or decompression therapy. The quality and generalizability of the information was not formally evaluated because we included case reports and case series in this evidence base. Uncontrolled studies cannot be used to determine causality or to estimate frequencies of adverse events; they can only be used to generate a list of adverse events possibly attributable to the device.

Adverse events were reported to occur in association with decompression therapy (one case report of an enlargement of an existing disc protrusion and several reports of treatment-related pain). However, inconsistencies in the reporting of adverse events limits one's confidence in the true extent of treatment related adverse events.
For example, according to a Medical Services Advisory Committee (MSAC) report presented to the Australian government, which included unpublished studies provided

by the manufacturer,(4) approximately 10% of individuals who undergo VAX-D therapy are unable to tolerate the procedure. None of the clinical trials included in the present report, including the large case series of Gose et al.(5) (which enrolled 778 patients), reported that any patients were unable to tolerate treatment. Of note, however, this case series was limited to patients who had received at least 10 treatments. Currently there is no evidence to establish whether the common characteristics of the Medicare population (such as the presence of undiagnosed osteoporosis) would increase the likelihood of adverse events when compared to the trial populations. It should be noted that the literature produced by providers of decompression therapy lists osteoporosis as a contraindication for this therapy.

Conclusions

Patient inclusion criteria for studies of decompression therapy were chronic low back pain, with or without radicular symptoms, due to degenerative or herniated disc disease or due to facet arthritis. Product literature and the exclusion criteria in the examined studies suggest that this therapy should be avoided in patients with osteoporosis, tumor, infection, spinal instability, and surgical implants. The health outcome measures reported in studies of decompression therapy are also reported in literature on other non-surgical treatments for low back pain. However, a number of additional outcomes (absenteeism, return to work, overall health, analgesic consumption, low back pain-related disability rates, and quality of life) have been reported for other non-surgical treatments.

Currently available evidence is too limited in quality and quantity to allow for the formulation of evidence-based conclusions regarding the efficacy of decompression therapy as a therapy for chronic back pain when compared with other non-surgical treatment options. Of the studies examined for assessment of efficacy, neither included patients over 65 years of age. Adverse event reporting for decompression therapy is infrequent. There was one case report of an enlargement of an existing disc protrusion, and other studies reported worsening of pain in some patients.

SCOPE OF REPORT

The Centers for Medicare and Medicaid Services (CMS) requested that AHRQ commission an evidence report to assist in updating the CMS policy regarding decompression therapy for chronic low back pain. Accordingly, on January 17, 2006, AHRQ issued a Statement of Work (SOW) contracting ECRI to prepare an evidence-based report on this topic. In commissioning this report, AHRQ, in consultation with CMS and ECRI, developed four key questions. These key questions are as follows:

1. What are the patient inclusion and exclusion criteria used in studies of decompression therapy?
2. What are the efficacy or effectiveness outcomes measured in studies of decompression therapy? Are the efficacy/effectiveness outcome measured in studies of decompression therapy comparable to those used in studies of other non-surgical modalities for chronic low back pain due to a herniated disc or degenerative disc disease?
3. Is decompression therapy an effective treatment for chronic low back pain due to herniated disc or degenerative disc disease?
    a. Do patients with chronic low back pain (due to herniated disc or degenerative disc disease) who are treated with decompression therapy have more, less, or the same level of pain relief than patients who are treated with other therapies?
    b. Do patients treated with decompression therapy for chronic low back pain due to a herniated disc or degenerative disc disease utilize more, less, or the same number of adjunctive therapies (e.g., medications, bracing) than patients treated with other therapies?
    c. Do patients treated with decompression therapy for chronic low back pain due to a herniated disc or degenerative disc disease return to work more quickly than patients treated with other therapies?
    d. If the therapy is effective, what is the duration of relief achieved?

e. If the therapy is effective, what are the patient characteristics/indications of those for whom it appears to work? Is the therapy effective for the Medicare population (over 65 years of age)?

f. If it works, which, if any, particular decompression protocol provides the most pain relief?

4. What complications, harms, and adverse events associated with decompression therapy have been reported?

   a. Would the characteristics of the Medicare population (osteoporosis, etc.) increase the likelihood of adverse events compared to the trial populations?

Procedures defined by the U.S. Food and Drug Administration (FDA) as "traction therapy" which are not part of the ITH 510k ('equipment, powered traction') product code, are beyond the scope of this report.

BACKGROUND

In this section, we provide background information on lumbosacral pain (low back pain) and decompression therapy. The purpose of this section is to provide context for the research syntheses presented later in this report. The information presented in this section may be based upon opinion and we have not critically assessed its accuracy. This section is therefore not, in the strictest sense of the term, evidence-based. Consequently, no statement in this *Background* section should be interpreted as an endorsement or a criticism by ECRI.

Lumbosacral Pain (Low back pain)

Low back pain is defined as pain, muscle tension, and/or stiffness localized below the costal margin and above the inferior gluteal folds, with or without leg pain.(11) It can be 'specific' (related to an organic disease such as osteoporosis or infection) or 'non-specific' (having no identifiable causes). Nociceptive, neuropathic, or psychological processes (or any combination of these processes) may cause low back pain. Nociceptive pain results from stretching of connective tissues or inflammation of innervated structures. Such pain is usually described as aching, dull, or throbbing.(12) Neuropathic pain is typically described as burning, shooting, or electrical in nature.(12) Both types of pain can result from any of a number of mechanical processes involving the spine and surrounding muscles, ligaments, joints, nerves, periosteum, blood vessels, and intervertebral discs.

Excessive mechanical loading and associated tissue damage have long been regarded as the main causes of low back pain, but recent research reveals that these environmental effects make only a modest contribution to vertebral pathology.(13) Herniated discs (compression of a spinal nerve by protrusion of the nucleus pulposus through the annulus fibrosus into the extradural space) can directly cause neuropathic pain (e.g., sciatica) and also cause mechanical injury leading to nociceptive pain due to compression or stretching of nerve roots.(12) Disc degeneration has been documented in asymptomatic groups age 11-16 years, with 20% of people in their teens

demonstrating mild disc degeneration. By age 50, some 10% of discs show degenerative pathology, and by age 70, 60% of vertebral discs are severely degenerated. Disc degeneration alone is associated with sciatica, disc herniation and prolapse, alteration of disc height and concomitant adverse effects on other special structures of the spine such as muscles and ligaments, and, potentially, spinal stenosis.

Extent of Problem

Low back pain is a major cause of disability and contributes substantially to economic and public health care burdens worldwide. In the United States, total health care expenditures to treat low back pain are estimated at $14 to $26 billion per year.(12,14) It has been estimated that low back pain will affect approximately 80% of the population at some point during the life span.(15) The prevalence of low back pain increases with age, peaking in the sixth decade. Women are affected more often than men.(15) In the United States, the 12-month prevalence of low back pain lasting ≥1 month has been reported to be 17.8% (males and females).(14)

Risk Factors

A wide variety of risk factors, including gender, age, education level, smoking, occupation, high birth weight (males only), depression, and social support/work relations are thought to be associated with the occurrence and the severity of low back pain.(16) Obesity, health-care provider attitudes, unemployment, depression, fear-avoidance behavior, and unavailability of light duty work are associated with the development of chronic low back pain.(16,17) The single best predictor of future low back pain is a previous history of low back pain.(15)

There are a wide variety of anatomic, biomechanical, biochemical, and genetic risk factors associated with the development of common non-specific acute and chronic low back pain. Biomechanical risk factors associated with the development of disc degeneration include repetitive trauma, vibration, or injury. Biomechanical risk factors related to disc degeneration include radiographic disc space narrowing of lumbar vertebra, facet joint arthritis, anterior and posterior synovial cysts, lumbosacral transitional vertebra, Schmorl nodes, annular disruption, composition of herniated disc

material, calcification of ligamentum flavum, and radiographic spondylolysis/spinal instability.

In a classic monozygotic twin study investigation of the potential for genetic influences on disc degeneration, the EURODISC research group in Finland demonstrated a dominant genetic component in lumbar disc degeneration with heritability estimates up to 74%. Inherited polymorphisms in the genes COL9A2 and COL9A3 (which encode proteins that are associated with Type IX collagen) have been found to increase the risk of developing low back pain, as have polymorphisms in the gene encoding for interleukin-1 (which may contribute to disc degeneration through the induction of proteoglycan-destroying enzymes).(16)

Chronic disabling low back pain may occur more frequently in patients who have a high level of “fear avoidance” (an exaggerated fear of pain leading to avoidance of beneficial activities), psychological distress, or job dissatisfaction.(17,18)

Diagnosis

Diagnosis of non-specific low back pain is complicated by the fact that a majority of imaging studies of individuals with low back pain reveal non-specific findings and no serious pathology. The probability that a particular case of low back pain has a specific identifiable cause is less than 1%.(16) Images of patients without low back pain commonly show the same pathological changes seen in individuals with low back pain, such as herniated disc, lumbar disc degeneration, signal changes in vertebral endplates, and annular fissures.(17) Medical evaluation of individuals presenting with low back pain primarily consists of a process of elimination—serious pathologies that may cause low back pain such as infection, tumors, and fractures need to be ruled out.(12) Laboratory tests such as erythrocyte sedimentation rate can establish the presence of infection or malignancy as a possible cause of the pain. Radiographic evaluation may be used for individuals with a medical history of cancer or corticosteroid use, or for those with a potential diagnosis of ankylosing spondylitis. Bone scintigraphy (bone scanning) is a potential diagnostic tool when clinical findings are suspicious for osteomyelitis, bony neoplasm or occult fracture.

Over 90% of patients recover spontaneously from episodes of low back pain within three months of onset.(12) Patients who remain active generally recover more quickly than patients who rest.(19) Physicians often prescribe pain relief medications and muscle relaxants to relieve symptoms during the healing period.(20)

Aims of Treatment

For patients with chronic low back pain (defined as pain persisting over three months), the complete eradication of pain is rarely achieved. The goals of treatment for the chronic pain patient are moderation of pain, increased functional capacity, and decreased healthcare utilization.(12) Treatment usually requires an inter-disciplinary program of physical therapy, adjunctive therapies, psychosocial interventions, and pain medication.(12) Two adjunctive therapies (TENS and lumbar traction) used as comparators in studies of vertebral axial decompression and decompression therapy are discussed below. High-dose supervised exercise therapy has been reported to be beneficial for relief of chronic low back pain in a recent meta-analysis, as has acupuncture.(21,22) The Institute for Clinical Systems Improvement Health Care Guideline (Sept 2006) has provided a useful algorithm for the assessment and management of adult low back pain.(23)

Decompression Therapy

Several different decompression therapy systems are available, including VAX-D, DRS, NuChoice Medical Healthstar Elite Decompression Therapy, Accu-Spina, AxiomWorldWide DRX9000, Antalgic-Trak, and Cert Health Services SpineMED. Each system utilizes a different treatment protocol.

Some decompression therapy system manufacturers recommend accompanying therapies such as pain medications, TENS treatment, exercise programs, relaxation programs, cold and/or heat applied to the back muscles, and/or physical therapy. The VAX-D system does not incorporate additional therapies in its treatment protocol, and in fact, the protocol advises against participation in exercise or physical therapy.

As VAX-D serves as the predicate device for the 510(k) FDA approved devices listed at the beginning of this section, an explanation of this technology appears below to provide more information on the basic principles of decompression of the spine.

Vertebral Axial Decompression (VAX-D)

Vertebral axial decompression therapy is the proprietary acronym for the VAX-D system, which utilizes a specialized table and computer system to apply directed distractive tension to the vertebral column via a computerized logarithmic ramp-up and release protocol designed to bypass the body's protective proprioceptor response. Proponents of the procedure contend that vertebral axial decompression therapy works by decreasing intra-discal pressure. This is believed to allow disc repositioning and triggers herniation shrinkage. Possible consequences of these physical changes may be the relief of nerve root compression, pain relief, and correcting of neurological deficits.

Vertebral axial decompression therapy is customized to the individual's physical specifications (weight and height) and pathologies indicated through diagnostic testing such as MRI, CT scanning, provocative discography, bone scintigraphy, needle electromyography and nerve conduction studies.(17,24) Treatment is carried out by a vertebral axial decompression technician under medical supervision.

The VAX-D system employs a prone position, which requires the patient to lie on the treatment table face down. Other technologies coded as ITH powered traction equipment by the FDA use either a supine position or a sitting posture. In the prone posture system for VAX-D, the patient stands and is fitted with a pelvic harness. The patient then lies prone on the distraction table with the lower portion of the belt placed at the level of the table separation point.

According to the manufacturer, adjustable handgrips are positioned so that the patient's elbows are straight, and the pelvic harness is repositioned, tightened, and attached to a movable pretension housing. Treatment begins with the application of approximately 50 lbs. of tension as the threshold necessary to develop negative intradiscal pressure. Tension is then applied in a logarithmic curve (in a reverse of the Weber-Fechner law to

avoid proprioceptor response), with the application of force slowing down logarithmically as the tension increases. The tension is subsequently reduced to a secondary ‘baseline’ tension according to a reverse logarithmic time frame. The rest phase is the third phase of treatment whereby tension is maintained by a separate movable device/component. This cycle is repeated a programmed number of times to effect a therapy session.(25)

Indications

Individuals with chronic low back pain that is resistant to conservative treatment.(3)

Contraindications

Use of decompression therapy is contraindicated for patients with infection, neoplasm, osteoporosis, bilateral pars defect or unstable Grade 2 spondylolisthesis, fractures, surgical hardware in the spine, cauda equina syndrome, or who are in the latter stages of pregnancy. Decompression therapy is not meant to be used for the treatment of soft tissue injuries, sprains, strains, or progressive inflammatory conditions.(3)

Care Setting

Decompression therapy is performed on an outpatient basis at a variety of locations, including chiropractic offices and low back pain treatment facilities.

Competing/Complementary Technologies

Few therapies are available for the treatment of patients with chronic low back pain that is unresponsive to conservative therapy. Available treatment options include surgery or continued conservative management. (Table 1).(4,26)

Table 1. Available Treatment Options for Chronic Low Back Pain Unresponsive to Conservative Therapy

Treatment Option	Available Treatment Options Defined
Physical therapy and exercise	Application of heat, ice, ultrasound, transcutaneous electrical stimulation (TENS), exercise, and muscle release techniques
Prescription medications	NSAIDs, muscle relaxants, antidepressants, narcotics (opioids), anesthetic injections, cortisone injections, self-administered pain medications delivered via a catheter/programmed pump system to the spine.
Laminectomy and laminotomy	Surgical removal of part of the vertebra
Fusion	Joining of vertebrae to eliminate painful movement
Intradiscal electrothermal therapy (IDET)	The use of a heated needle, applied to the disc wall, to thicken and seal the disc and reduce disc bulge and related nerve irritation.

TENS Therapy

TENS is a form of electroanalgesia used to relieve low back pain, myofascial and arthritic pain, neurogenic pain, visceral pain, and postsurgical pain. The electrical stimulation produced by the TENS device is thought to reduce pain through nociceptive inhibition at the presynaptic level in the dorsal horn of the spinal cord. Patients adjust the frequency and the intensity of electrical stimulation until they find the best settings for individual pain control.

Lumbar Traction Therapy

Lumbar traction involves stretching the spine by any of a number of mechanisms. Stretching may relieve pressure in the intervertebral discs, enabling disc protrusions to recede and vertebrae to realign. Stretching may also relax spinal muscles. Although traction is often used to treat back pain, its efficacy has not been documented in controlled trials.

Clinical Practice Guidelines

Our searches did not identify any clinical practice guidelines that specifically addressed the role of VAX-D or decompression therapy in the management of individuals with lumbosacral pain.

Previous Systematic Reviews of Decompression Therapy

The Australian Medical Services Advisory Committee (MSAC) published a technology assessment on VAX-D therapy for low back pain in 2001.(4) The authors of this technology assessment concluded that there was no evidence to support the contention that VAX-D therapy reduces the need for surgical decompression of the spine in any patient group, including patients with non-specific low back pain. The authors noted that it does appear that VAX-D therapy may provide some short-term symptomatic relief from nerve root compression; however, there was no evidence that VAX-D therapy provided long-term relief or resolved nerve root compression.

Ongoing Clinical Trials

ClinicalTrials.gov, which provides regularly updated information about federally and privately supported clinical research in human volunteers, listed one ongoing clinical trial examining the efficacy of decompression therapy in the treatment of low back pain. The official title of the study is Comparison of Internal Disc Decompression (IDD®) vs. a Standardized Non-Surgical Treatment Program for Chronic Low Back Pain Secondary to Mild to Moderate Degenerative Disc Disease. The study, which uses the Accu-Spina device, was scheduled for completion in December 2006.

Regulatory Issues

Manufacturers and U.S. Food and Drug Administration (FDA) Status

VAX-D (vertebral axial decompression) was designated an FDA-mandated Class II medical device in 1996 under the product code ITH, meaning it is classified as "equipment, powered traction". This classification means that each new device requires FDA 510k clearance before it can be marketed in the U.S. Nine ITH product coded decompression devices have been approved or cleared for marketing by the FDA since the approval of the first device, the VAX-D Therapeutic Table, which was manufactured by Vat-Tech, Inc. of Palm Harbor, FL. The nine spinal decompression devices (VAX-D and spinal decompression) that have obtained FDA 510k clearance are listed in Table 2.

Table 2. Decompression Devices

Device Name	Manufacturer	FDA 510k Clearance Date
Accu-Spina System	North American Medical Corporation 1649 Sands P1 SE, Suite A Marietta GA 30067	8/25/00
Spinemed S200b/S200c	Cert Health Sciences 7036 Golden Ring Road Baltimore, MD 21237	4/27/05
Bass Antalgic-Trak	Spinetronics LLC 9737 NW 65 Pl. Parkland, FL 33076	3/21/05
Healthstar Elite	NuChoice Medical 3162 Thoroughbred Loop W Lakeland, FL 33811	12/22/04
SpineRx-LDM	SpineRx Technology 6100 Brittmoore Road Bldg. S Houston, TX 77041	10/31/03
Lordex Power Traction	Lordex Inc. 15915 Katy Freeway Suite 645 Houston, TX 77094	7/17/03
DRX9000	Axiom WorldWide, Inc. 9423 Corporate Lake Drive Tampa, FL 33634	1/23/03
DRS System	Professional Distribution Systems, Inc. 1160 S Rogers Bldg A Boca Raton, FL 33487	6/24/98
VAX-D Therapeutic Table	VAX-D Medical Technologies LLC 310 Mears Blvd. Oldsmar, FL 34677	7/02/96

Training and Credentialing of Personnel to Use Decompression Therapy Machinery

VAX-D Medical Technologies LLC of Oldsmar, FL, offers a training and credentialing program for physicians and staff involved in the use of VAX-D (vertebral axial decompression therapy systems) (see: http://www.vax-d.com/Pages/EquipmentPurchase/VAXDEquipment.html). North American Medical Corporation (the manufacturer of the AccuSpina system, which utilizes IDD® or Intervertebral Differential Dynamics Therapy system) refers on its Web site (http://www.iddtherapy.com/ENGLISH/find_certified.html) to 'certified IDD® facilities' and 'certified clinicians;' however, the certification process is not explained on the Web site. The Web site does note that "usually a certified factory-trained Physical Therapist" provides a six- to eight-hour training session. Training and credentialing information for other decompression systems listed in this report was not available on company Web sites.

CMS Coverage Policy

Medicare Coverage Issues Manual transmittal 161, effective date 1 April 2003(27) states the following: "Vertebral axial decompression is performed for symptomatic relief of pain associated with lumbar disc problems. The treatment combines pelvic and/or cervical traction connected to a special table that permits the traction application. There is insufficient scientific data to support the benefits of this technique. Therefore, VAX-D is not covered by Medicare."

Third Party Payer Coverage

We searched the following Web sites for reimbursement information:

- Aetna US Healthcare
  (http://www.aetna.com/cpb/data/CPBA0180.html)
- Blue Cross/Blue Shield of Massachusetts
  (http://bcbsma.com)

- Blue Cross of California
  (http://medpolicy.bluecrossca.com/policies/SURG/spinal_therapy.html)
- Blue Cross/Blue Shield of Montana
  (http://www.bcbsmt.com/providers/Assets-Providers/Downloads-Providers/Source-Provider_Publications/pub_prov_capnews4q01.pdf)
- CareFirst of Maryland
  (http://www.carefirst.com)
- CMS Coverage Issues Manuals
  (http://cms.hhs.gov/manuals/06_cim/ci00.asp)
- Cigna
  (http://www.cigna.com/health/provider/medical/procedural/coverage_positions/medical/mm_0002_coveragepositioncriteria_vax_d.pdf)
- Health Care Plan of Nevada (subsidiary of Sierra Health Services, Inc.)
  (http://www.healthplanofnevada.com/documents/provider%20files/New%20Medical%20Technology/New%20Medical%20Technology%20-%20Denied%2006092003.pdf)
- Humana
  (http://apps.humana.com/tad/tad_new/returnContent.asp?mime=application/pdf&id=4846&issue=741)
- Medica
  (http://provider.medica.com/router/default.pdf?doc=/C1/CoveragePolicies/Document%20Library/VaxD_CP.pdf)
- OhioBWC
  (www.ohio**bwc**.com/downloads/blankpdf/BRM3.pdf)
- Regence Blue Shield
  (http://www.regence.com/trgmedpol/medicine/med45.html)
- Wellmark Blue Cross/Blue Shield
  (http://www.wellmark.com)

We also used the Google and Vivisimo Internet search engines to locate reimbursement information, using search terms: (reimburs* OR coverage OR “medical policy” OR “Medicaid”).

Aetna, BlueCross/BlueShield of Massachusetts, BlueCross/BlueShield of Montana, Blue Cross of California, CIGNA Healthcare, Health Care Plan of Nevada, Humana, Medica and Regence did not cover vertebral axial decompression (VAX-D) therapy.(28-32) CareFirst of Maryland, First Health Services Corporation, Alaska,(25), South Dakota Department of Labor(25), Arizona State Fund (Workers Compensation Insurance)(25), OhioBWC, and Wellmark Blue Cross/Blue Shield(33) cover VAX-D therapy.(34)

METHODS

Key Questions Addressed

We address four Key Questions in this report. These questions are presented below:

1. What are the patient inclusion and exclusion criteria used in studies of decompression therapy?
2. What are the efficacy or effectiveness outcomes measured in studies of decompression therapy? Are the efficacy/effectiveness outcomes measured in studies of decompression therapy comparable to those used in studies of other non-surgical modalities for chronic low back pain due to a herniated disc or degenerative disc disease?
3. Is decompression therapy a safe and effective treatment of chronic low back pain due to herniated disc or degenerative disc disease?
    a) Do patients with chronic low back pain (due to a herniated disc or degenerative disc disease) who are treated with decompression therapy have more, less, or the same level of pain relief than patients who are treated with other therapies?
    b) Do patients treated with decompression therapy for chronic low back pain due to a herniated disc or degenerative disc disease utilize more, less, or the same number of adjunct/chronic therapies, (e.g., medications, bracing) than patients treated with other therapies?
    c) Do patients treated with decompression therapy for chronic low back pain due to a herniated disc or degenerative disc disease return to work more quickly than patients treated with other therapy?
    d) If the therapy is effective, what is the duration of relief achieved?
    e) If the therapy is effective, what are the patient characteristics/indications of those for whom it appears to work? Is the therapy effective for the Medicare population (over 65 years of age)?

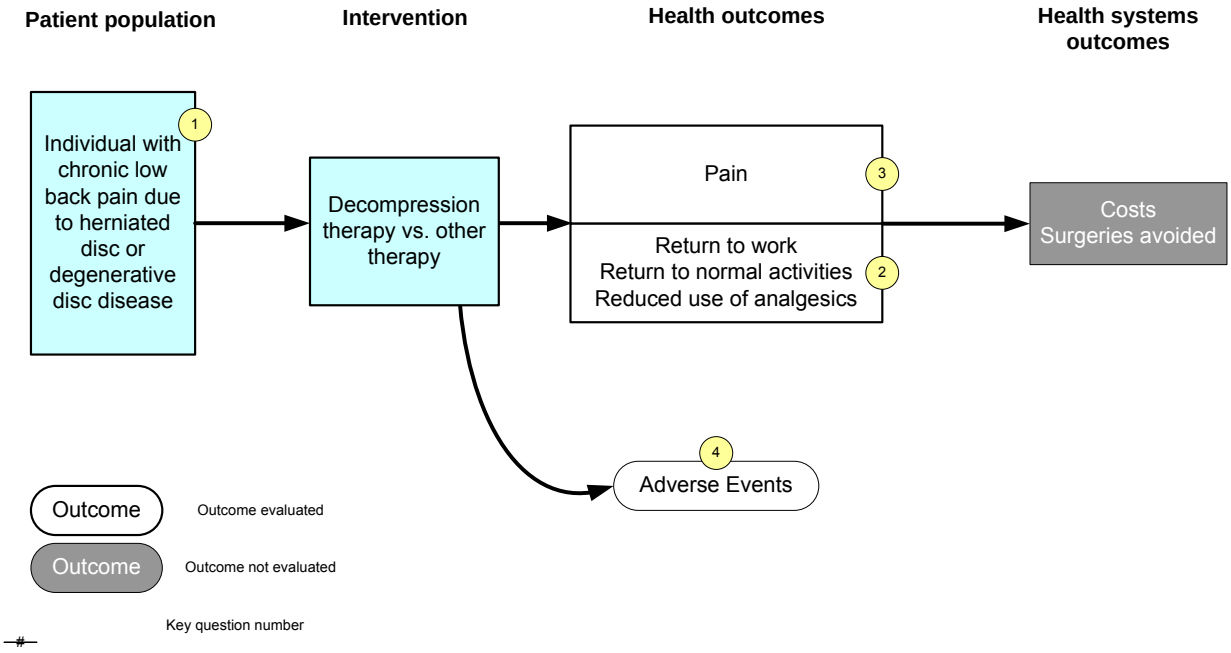
f) If it works, which, if any, particular decompression protocol provides the most pain relief?

4. What complications, harms, and adverse events associated with decompression therapy have been reported?

   a) Do conditions prevalent in the older Medicare population (such as osteoporosis, etc.) increase the risk of adverse events with decompression therapy?

The four Key questions are depicted in the Figure as numbers within a circle.

Figure 1. Analytical Framework



Study Inclusion/Exclusion Criteria

We selected the studies that we consider in this report using *a priori* inclusion criteria. As mentioned above, arriving at these criteria before beginning the analysis is one way of reducing bias. We developed different inclusion criteria for each question that this report addresses.

General Inclusion/Exclusion Criteria

The following inclusion/exclusion/criteria were general to all five Key Questions:

1. Studies must have been published in English. Moher et al. have demonstrated that exclusion of non-English language studies from meta-analyses has little impact on the conclusions drawn.(35) Juni et al found that non-English studies typically were of lower methodological quality and that excluding them had little effect on effect size estimates in the majority of meta-analyses they examined.(36) Although we recognize that there may be situations in which exclusion of non-English studies could lead to bias, we believe that it is insufficiently likely that we cannot justify the time and cost of translations to identify studies of acceptable quality for inclusion in our reviews.
2. Studies must have addressed one of the Key Questions.
3. Studies must have been published as full journal articles (no meeting abstracts). Meeting abstracts generally have insufficient description of methods to allow assessment of quality, and the reported results often contain discrepancies with results presented in later peer-reviewed publication of the same study.(37-40)
4. If the same study is reported in multiple publications, only the most recent publication will be included. This serves to avoid duplication of data.

Inclusion/Exclusion Criteria Specific to Key Question 1

The following inclusion/exclusion/criteria were specific to Key Question 1:

- *Any article that provides the inclusion/exclusion criteria for a unique study of the efficacy/effectiveness and safety of vertebral axial decompression therapy.*

  Study design has no impact on the validity of its inclusion/exclusion criteria. Consequently, we did not exclude any articles based on the design of the study that they described.

Inclusion/Exclusion Criteria Specific to Key Question 2

The following inclusion/exclusion/criteria were specific to Key Question 2:

- *Systematic reviews of other non-surgical treatments for chronic low back pain due to herniated disc or degenerative disc disease published after January 1st, 2004, will be used to describe outcomes typically reported by trials of non-surgical therapy for these conditions.*

Inclusion/Exclusion Criteria Specific to Key Question 3

The following inclusion/exclusion/criteria were specific to Key Question 3:

- *Article must describe a study that directly compared decompression therapy to other treatments or different decompressive therapy dosage regimes*.
  Although it is possible to compare different treatments when one group of studies reports the results obtained with one treatment, and another group of studies reports the results of another treatment, the results of such indirect comparisons should be viewed with caution. Several methodologists have shown that the difference in treatment effectiveness estimated using indirect methods is greater than the difference observed in trials that directly compare two treatments.(41,42)
- *Only outcomes within a study that had a score of 5.0 or greater on our quality scale were included.*
  Outcomes with scores of 4.9 or less are likely to be biased . We do not consider these reliable sources of information. Because each outcome in a study is given a quality score, some outcomes within a study may fall below 5.0 and be excluded, while other outcomes may score better than 5.0 and be included. It is possible for a

study to be “included” in the report because it met the other inclusion criteria, and yet have all of its data excluded from analysis due to quality reasons.

- *Only studies with at least 10 patients in each treatment were included.*
  The results of studies with very small patient groups are often not applicable to the general population.

Inclusion/Exclusion Criteria Specific to Key Question 4

The following inclusion/exclusion/criteria were specific to Key Question 4:

- *A study of any design that meets the general inclusion criteria for this report (including case series, case reports, and reports from ECRI’s Health Device Alerts database) were included.*
  Although uncontrolled studies cannot be used to determine causality or to estimate frequency of adverse events, they can be used to generate a list of adverse events possibly attributable to the device.

Literature Searches

One characteristic of a good technology assessment is a systematic and comprehensive search for information. Such searches distinguish systematic reviews from traditional literature reviews. Traditional reviews use a less rigorous approach to identifying and obtaining literature and allow a reviewer to include only articles that agree with a particular perspective, and to ignore articles that do not. Our approach precludes this potential reviewer bias because we obtained and included articles according to explicitly determined *a priori* criteria. This was particularly important for Key Question 3, the assessment of efficacy. We discuss articles that we included in the *Synthesis of Results* section.

Electronic Database Searches

We searched 17 external and internal databases, including PubMed and Embase, for clinical trials on the use of decompression therapy to treat lower back pain. We also examined the bibliographies/reference lists from peer-reviewed and gray literature.

(Gray literature includes reports and studies produced by local government agencies, private organizations, educational facilities, and corporations that do not appear in peer-reviewed journals.) We examined gray literature sources to identify relevant information such as reference listings and product information to address Question 1 and peer-reviewed and gray literature, as well as ECRI databases such as the Health Devices Alert Database to identify adverse events for Question 4. However, we only utilize published, peer-reviewed literature in this report to address Questions 2 and 3. All of the databases and the detailed search strategies used in this report are presented in Appendix A.

Identification of Evidence Bases

The selection process used to identify the articles that comprise the evidence base for the key questions addressed in this report is presented in Figure 2. Our searches identified ten articles that potentially addressed Key Questions 1 through 4. Of these ten articles, we retrieved seven. Three additional studies(8-10) were brought to our attention by reviewers, for a total of ten included studies (Table 3). These three additional studies did not meet criteria for Key Question 3 as they were not comparative studies and two had fewer than 10 patients, but we did review them for information relevant to the other Key Questions. Eight included articles addressed Key Question 1, nine included articles addressed Key Questions 2, three included articles addressed Key Question 3, and all ten articles were reviewed for adverse events, Key Question 4.

Figure 2. Summary of Article Selection Process

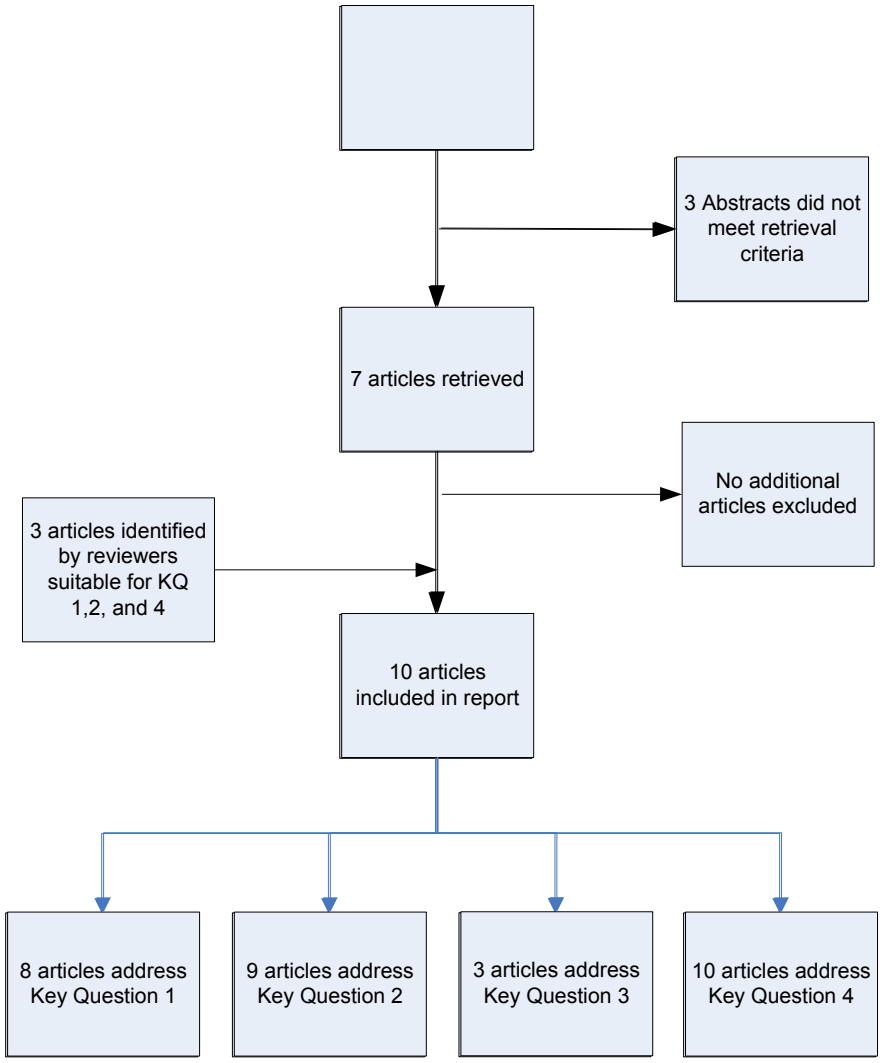


Table 3. Evidence Base

Reference	Year	Institution	Country	Key Question Addressed			
				1	2	3	4
Deen et al.(2)	2003	Mayo Clinic, Jacksonville, FL	USA				✓
Gose et al.(5)	1998	Coosa Medical Group, Rome, Georgia	USA	✓	✓		✓
MSAC(4)	2001	Medical Services Advisory Committee (Gov't)	Australia		✓		✓
Naguszewski et al.(9)	2001	Coosa Medical Group, GA University of Illinois, IL	USA		✓		✓
Ramos(1)	2004	University of Texas	USA		✓	✓*	✓
Ramos and Martin(8)	1994	Rio Grande Regional Hospital; University of Texas, TX	USA		✓		✓
Shealy et al.(10)	2005	Holos University and North American Medical Corporation	USA	✓	✓		✓
Shealy and Borgmeyer(6)	1997	Shealy Institute for Comprehensive Health Care and Clinical Research	USA	✓	✓	✓	✓
Sherry et al.(3)	2001	Sydney University; VAX-D Australasia Pty. Ltd	Australia	✓	✓	✓	✓
Tilaro and Miskovich(7)	1999	Advanced Spinal Institute, Ogden, UT	USA	✓	✓		✓
Number of articles included in Evidence Base				**8**	**9**	**3**	**10**

* Outcome data not considered when addressing Key Question 3 because of an unacceptably high potential for bias.

Evaluating the Strength of the Evidence

We used the ECRI strength-of-evidence system to evaluate the stability and strength of a body of literature (shown in Appendix B). This system considers numerous components of the evidence, including the internal validity of the trials, the size of the evidence base, consistency and robustness of trial results, and magnitude of the effect size. The system outputs two ratings. One is a stability rating (high, moderate, low, unstable) for a *quantitative* estimate addressing the question "How well does it work?" The other is a strength rating (strong, moderate, weak, inconclusive) for the evidence about the *qualitative* question "Does it work?" This distinction allows an evidence base to be considered weak in terms of the quantitative estimate of effect (e.g., if estimates vary widely among trials) but strong or moderate with respect to the qualitative conclusion (e.g., if all trials nevertheless demonstrate the same direction of effect). The system also employs *a priori* judgments, meta-analyses, and sensitivity analyses to provide sound bases for evidence ratings. Interpretations of the terms that define the strength of evidence (strong evidence, moderate evidence, weak evidence, and inconclusive evidence) and stability ratings (high stability, moderate stability, low stability or unstable) are presented in Table 4.(43)

The 10 decision points that comprise the ECRI strength-of-evidence system address five general aspects of the evidence (domains): quality, quantity, consistency, robustness, and magnitude of treatment effect. Quality refers to the degree of potential bias in the design or conduct of studies. Quantity refers to the number of studies and the number of patients enrolled in the studies. Consistency addresses the degree of agreement among the results of available studies. Robustness refers to the degree to which the findings are susceptible to being overturned by future studies. Magnitude of treatment effect concerns the quantitative amount of benefit (or harm) that patients experience after treatment. The ECRI strength-of-evidence system includes all five of these aspects when assessing the strength of the evidence (see Appendix B).

Table 4. Definitions of Strength and Stability of Evidence

Strength of Evidence Rating	Interpretation
Qualitative Conclusion (Direction of Effect)	
Strong Evidence	Evidence supporting the qualitative conclusion is convincing, making it highly unlikely that new evidence will lead to a change in this conclusion.
Moderate Evidence	Evidence supporting the qualitative conclusion is somewhat convincing. However, a small chance exists that new evidence will overturn or strengthen our conclusion. Regular monitoring of the relevant literature is recommended at this time.
Weak Evidence	Although some evidence supports the qualitative conclusion, this evidence is tentative and perishable. A reasonable chance exists that new evidence will overturn or strengthen our conclusions. Frequent monitoring of the relevant literature is recommended at this time.
Inconclusive	The available evidence that exists is not of sufficient strength to warrant drawing an evidence-based conclusion. Frequent monitoring of the relevant literature is recommended at this time.
Quantitative Conclusion (Magnitude of Effect)	
High Stability	The estimate of effect size in the conclusion is stable, making it highly unlikely that the magnitude of this estimate will substantially change as a result of the publication of new evidence.
Moderate Stability	The estimate of effect size in the conclusion is somewhat stable. However, a small chance exists that the magnitude of this estimate will substantially change as a result of the publication of new evidence. Regular monitoring of the relevant literature is recommended at this time.
Low Stability	The estimate of effect size in the conclusion is likely to be unstable. A reasonable chance exists that the magnitude of this estimate will substantially change as a result of the publication of new evidence. Frequent monitoring of the relevant literature is recommended at this time.
Unstable	Estimates of the effect size are too unstable to allow a quantitative conclusion to be drawn at this time. Frequent monitoring of the relevant literature is recommended.

We apply each kind of rating to the *body* of evidence that addresses each outcome, not to individual studies. We also rate on an outcome-by-outcome basis. Four primary factors determine our ratings for both strength and stability; the quality, quantity, robustness, and consistency of the evidence. Under certain circumstances, the size of the treatment's effect, and whether mega-trials are available also influence our ratings of the evidence underlying qualitative conclusions.

Statistical Methods

The current evidence base was too small to allow us to employ statistical methods such as meta-analysis.

Characteristics of Included Studies

Information on study characteristics is presented in Table 5. We present more complete details of these studies (study design details, information on enrolled patients, outcome data, and other relevant information) in the evidence tables that comprise Appendix D.

Table 5. Characteristics of Included Studies

Reference	Year	N	Study Design/Purpose	Interventions
Medical Services Advisory Committee (MSAC)(4)	2001	NA	**Design**: Technology assessment of vertebral axial decompression therapy for chronic low back pain which included a systematic review of published and unpublished studies for evidence of efficacy and adverse events **Purpose:** To provide evidence assessment for health care financing decisions for Commonwealth of Australia	**Treatment Intervention:** VAX-D device (2 published and 2 unpublished studies) **Comparators:** Indirect comparisons to discectomy, laminectomy and conservative therapy (NSAIDs or physical therapy)
Shealy and Borgmeyer(6)	1997	25	**Design:** Randomized Controlled Trial (RCT) **Purpose:** To evaluate the response to DRS + TENS therapy as compared to traction + TENS	**Treatment Intervention:** DRS System 30 minute treatment sessions; 60 seconds on, 60 seconds off; up to 30 degrees of distraction forces; 20 sessions total 30 minutes of ice and TENS applied after each session **Control Intervention:** Standard traction 30 minute treatment sessions; 60 seconds on, 60 seconds off; 20 sessions total; 30 minutes of ice and TENS applied after each session **Other intervention:** All patients were given a TENS unit for continuous home use, and were instructed and supervised in a limbering/strengthening exercise program
Sherry et al.(3)	2001	22	**Design**: RCT **Purpose**: To evaluate the response to VAX-D therapy when compared to TENS and medical management	**Treatment Intervention**: VAX-D device Prone position; 30 minute sessions; 15 cycles per session Five sessions per week for 4 weeks, then once per week for 4 weeks **Control Intervention**: TENS Prone position; 30 minute sessions; daily sessions for 20 days, then once a week for 4 weeks **Other Intervention**: No physical therapy, steroid injection, or other treatments allowed during the trial. Non-narcotic pain relievers and anti-inflammatory medications could be taken if necessary

Reference	Year	N	Study Design/Purpose	Interventions
Ramos(1)	2004	142	**Design**: Controlled trial **Purpose**: To evaluate the response to VAX-D therapy when compared to accelerated VAX-D therapy	**Treatment Intervention**: VAX-D device 30 minute sessions; 15 cycles per session Five sessions per week for a total of 20 sessions **Control Intervention**: VAX-D device 30 minute sessions; 15 cycles per session Five sessions per week for a total of 10 sessions **Other Interventions**: No exercises, stretching, or other physical therapy allowed. Pain relieving medication was allowed as necessary
Gose et al.(5)	1998	778	**Design:** Case series **Purpose:** To evaluate the response to VAX-D therapy in patients who underwent a minimum of 10 sessions	**Treatment: VAX-D therapy.** 30 minute sessions; 15 cycles per session
Shealy et al.(10)	2005	35	**Design:** Case Series **Purpose:** To evaluate long-term benefits of Intervertebral Differential Dynamics (IDD) Therapy®	**Treatment Intervention:** IDD Therapy® (utilizing the Accu-Spina device) **Other Intervention:** "an expanded physical therapy component," not otherwise described
Naguszewski et al.(9)	2001	7	**Design:** Case Series **Purpose:** To use dermatomal somatosensory evoked potentials (DSSEPs) to demonstrate lumbar root decompression following VAX-D therapy	**Treatment Intervention:** VAX-D device **Other Intervention:** None reported
Ramos and Martin(8)	1994	5	**Design:** Case Series **Purpose:** To examine the effect of vertebral axial decompression on pressure in the nucleus pulposus of lumbar discs	**Intervention:** Individuals with a cannula introduced into the nucleus pulposus of the L4-5 intervertebral disc underwent measurement of intradiscal pressure during 5 to 8 sessions of treatment with VAX-D at varying amounts of tension.

Reference	Year	N	Study Design/Purpose	Interventions
Tilaro and Miskovich(7)	1999	17	**Design:** Case Series based on retrospective chart review **Purpose:** To determine whether VAX-D therapy decompresses nerve roots based on Current Perception Threshold (CPT) neurometer testing	**Treatment Intervention:** VAX-D device (3-5 sessions per week for an average of 23 total treatments). **Other Intervention**: No physical therapy or exercise therapy other treatments allowed during the trial. Non-narcotic pain relievers and anti-inflammatory medications could be taken if necessary
Deen et al.(2)	2003	1	**Design**: Case Report	**Treatment Intervention:** VAX-D device **Other Intervention:** Microdiscectomy performed for disc protrusion and migration of disc fragment which was diagnosed following VAX-D treatment

We reviewed a technology assessment prepared for the Australian Medical Services Advisory Committee (MSAC) in support of health care financing decisions.(4) Three of the studies included in this report were controlled trials: a randomized controlled trial (RCT), a controlled trial with an inappropriate (sequential) method of randomization, and one non-randomized controlled trial.(1,3,6) One included study was a case series that reported on outcomes from 778 patients who received vertebral axial decompression therapy in one of 22 centers across the United States.(5) Another case series sought to examine long-term (12-month) outcomes in a group of patients who underwent IDD Therapy® in conjunction with “an expanded physical therapy component.”(10)
Three additional case series reported physiological outcomes. These included current perception threshold (CPT) as an indicator of nerve root decompression,(7) changes in intradiscal pressures during decompression therapy(8), and dermatomal somatosensory evoked potentials.(9) Finally, we included a case report describing an adverse event that occurred during vertebral axial decompression therapy.(2)

EVIDENCE SYNTHESIS

***Key Question #1*:** What are the patient inclusion and exclusion criteria used in studies of decompression therapy?

Eight studies described their inclusion and exclusion criteria.(1,3,5-10)

Quality of Evidence Base

Because this Key Question does not concern the causal relationship between decompression therapy and treatment outcome, an assessment of study quality is not relevant.

Findings

We present the inclusion and (for three studies) exclusion criteria reported in the eight studies that address this Key Question in Table 6. The only inclusion/exclusion criterion consistently listed across all of the studies was that enrolled patients must have suffered from chronic low back pain related to radiographically confirmed disc degeneration or herniation. Common exclusion criteria described in the two studies reporting them were tumor, infection spinal instability and surgical implants. Other reported inclusion/exclusion criteria were unique to individual studies. Of particular relevance to the Medicare population is the fact that the two studies which included patients over the age of 65 specifically excluded patients with “severe osteoporosis.”(1,10)

Table 6. Inclusion and Exclusion Criteria in studies of Vertebral Axial Decompression Therapy

Study	Inclusion criteria	Exclusion criteria
Gose et al. 1998(5)	• Patients must have undergone at least 10 sessions of VAX-D • Patients must have had a confirmed (through imaging studies) diagnosis of herniated disc, degenerative disc, or facet syndrome	No exclusion criteria were reported
Naguszewski et al. 2001(9)	• Patients with low back pain with referred pain in the L5 and/or S1 distribution; disc bulging or herniation on imaging study	No exclusion criteria were reported
Ramos 2004(1)	• Low back pain • Non-progressive neurological deficits • All patients were imaged with MRI or CT to confirm presence of discogenic disorder	• Cauda equina syndrome • Tumor • Infection • Severe osteoporosis • Fracture • Bilateral pars defect • Spondylolisthesis Grade 2 • Presence of surgical hardware
Ramos and Martin 1994(8)	• Patients with lumbar disc herniation confirmed by MRI and selected for Percutaneous discectomy	No exclusion criteria were reported
Shealy et al. 2004(10)	• Patients with low back pain, with/or without previous failed attempts with other treatments (acupuncture, surgery, medications, physical therapy, etc.)	• Severe osteoporosis • Vertebral fractures • Spondylolisthesis grade 2 or higher • Unstable surgical conditions or surgical hardware • Vertebral fusion within previous 6 months • Spinal instability
Shealy and Borgmeyer 1997(6)	• Ruptured lumbar disc and/or facet arthroses; all patients underwent MRI	No exclusion criteria were reported
Sherry et al. 2001(3)	• Chronic low back pain (>3 months duration) • Associated leg pain • Disc protrusion or herniation confirmed on CT scan or MRI • Age 18 to 65 years • Minimum VAS score of 2.0 • Live within 45 minutes of the clinic • Able to give informed consent	• Osseous stenosis • Unstable spine • Spinal surgical implants • Shoulder problems • Spinal pain due to tumor, infection, or inflammatory disease • Pregnancy • Previous VAX-D therapy
Tilaro and Miskovich 1999(7)	• Post-hoc: Patients must have had abnormal CPT (current perception threshold) grades with sciatica, positive SLR and imaging studies correlating with observed clinical syndrome.	No exclusion criteria were reported

Subsection Summary

The studies that addressed this question required that enrolled patients have radiographically confirmed disc degeneration or herniation or facet arthritis. Common exclusion criteria reported in the three studies reporting them were tumor, infection spinal instability and surgical implants.

Key Question #2: What are the efficacy or effectiveness outcomes measured in studies of decompression therapy? Are the efficacy/effectiveness outcomes measured in studies of decompression therapy comparable to those used in studies of other non-surgical modalities for chronic low back pain due to a herniated disc or degenerative disc disease?

Eight included studies(1,3,5-10) and the health technology assessment(4) presented efficacy or effectiveness outcomes. The efficacy or effectiveness outcomes assessed by the eight studies are listed in Table 13 of Appendix D. No additional outcome measures were identified in the previous health technology assessment.

Quality of Evidence Base

Because this Key Question does not concern the causal relationship between vertebral axial decompression or decompression therapy and treatment outcome, an assessment of study quality is not relevant.

Findings

The most frequently reported outcome measures evaluated by these studies of the efficacy or effectiveness of decompression therapy were pain relief (as pre-, post- or change in pain scores) or percentage improvement in pain score (six studies), functional outcomes (three studies) and physiological outcome measures (three studies). For the studies reporting physiological measures, only one also reported a patient-oriented outcome (percent improvement in pain).(9) The physiological measures were current perception threshold (for detecting sensory changes),(7) dermatomal somatosensory

evoked potentials (for detecting sensory changes)(9) and intradiscal pressure (to explore a possible mechanism for the clinical effects of VAX-D therapy).(8) The functional outcome measures included self-report of ADLs (0 – 5 scale),(1) a disability rating specific to the individual's most affected activities (0 – 4 scale),(3) and limitation of ambulation (0 – 3 scale).(5) The study which collected patient-reported ADL information did not report the results, but incorporated the data into an overall assessment (remission, partial remission or no response), which also incorporated pain relief and return to work.

Table 13 of Appendix D lists the outcomes in the decompression studies along with those commonly assessed in studies of other non-surgical modalities for chronic low back pain due to herniated disc or degenerative disc disease.(11,21,22,44-46) A number of outcomes have been evaluated and reported by studies of these other non-surgical modalities that have not been reported by studies of decompression therapy. These include absenteeism, return to work, overall health, analgesic consumption, low back pain-related disability rates, recovery time, gait analysis, and quality of life.

Subsection Summary

The outcomes in these studies of spinal decompression therapy also reported in studies of other non-surgical treatment options for low back pain are pain scores, pain relief and functional status. Data pertaining to a number of outcomes that are commonly reported by studies of other non-surgical treatment modalities (absenteeism, return to work, overall health, analgesic consumption, low back pain-related disability rates, recovery time, gait analysis, quality of life), are not yet available in the spinal decompression therapy literature.

Key Question #3: Is decompression therapy an effective treatment for chronic low back pain due to herniated disc or degenerative disc disease?

Three included studies that enrolled a total of 225 patients address Key Question 3.(1,3,6) Complete study design details of these three studies are presented in Table 14 and

Table 15 in Appendix D. Two of the studies evaluated the VAX-D system(1,3); the remaining study evaluated the DRS system.(6)

Quality of Evidence Base

The results of our assessment of the quality of the studies that comprise the evidence base for Key Question 3 are presented in Table 7. Details of the quality assessment are presented in Table 16 of Appendix D.

Table 7. Results of Assessment of Study Quality

Study	Year	ECRI Quality Score (Quality category)	Notes
Ramos(1)	2004	4.1 (Unacceptable)	VAX-D System Excluded from evidence base for Key Question 3 because of poor quality
Sherry et al.(3)	2001	6.6 (Low Quality)	VAX-D System
Shealy and Borgmeyer(6)	1997	6.6 (Low Quality)	DRS System

The study by Ramos(1) was an open (unblinded) comparative trial in which no attempt was made to ensure the patient groups were comparable at baseline. ECRI's evaluation of the study found it to be highly susceptible to bias. Consequently, we do not consider this study further for Key Question 3.

The study by Sherry et al.(3) was an open trial in which patients were randomized by sequential order, generally considered an inappropriate method of randomization. Our assessment of the quality of this study found it to be of low quality.

The study by Shealy and Borgmeyer(6) of the DRS® system was a blinded randomized trial. Despite this, our assessment of the quality of this study found it to be of low quality. A number of factors led to this categorization. First, the method of randomization was not described in the article describing the study. This precludes one from determining whether randomization was stochastic and whether concealment of allocation to treatment groups occurred. Second, although patients were blinded to their treatment assignments, the study did not report on the success of blinding or whether unblinded

investigators were involved in ascertaining patients' ratings of their response to treatment. Third, it appears that patients' ratings depended on their recollection of their symptoms prior to entering the study. Lastly, the authors of the study have significant financial interests in the company that manufactures the DRS® system; Dr. Shealy is the inventor of the DRS®system(47) and director of the Shealy Institute, a pain management facility which utilizes DRS® in its treatments, and Ms. Borgmeyer is a Research Coordinator at the same institute(6)

Characteristics of Enrolled Patients

Important characteristics of the patients enrolled in the two studies that comprise the evidence base for Key Question 3 are summarized in Table 8. We present further information on the characteristics of the patients enrolled in the two included studies in Table 12 in Appendix D.

In both included studies, enrolled patients suffered from chronic low back pain that was unresponsive to conservative treatment. As indicated below, patients in the Sherry et al. study had (on average) been symptomatic much longer than those in the Shealy and Borgmeyer study. Disc problems were confirmed by imaging studies in both studies. Patients with facet arthritis in the study by Shealy and Borgmeyer underwent MRI to rule out other pathology.(6) The enrolled patients are therefore representative of the type of patient likely to be treated by decompression therapy in the clinic. Neither study included patients over 65 years of age.

Table 8. Characteristics of Enrolled Patients (Key Question 3)

Study	Year	Mean duration of pain before entering trial	Mean age (years) and range	% older than 65	% female	Ethnicity
Sherry et al.(3)	2001	All: 7.3 years (0.25 to 30) VAX-D: 8.4 years (0.25 to 30) TENS: 6.2 years (0.5 to 2.8)	All: 42 (22-57) VAX-D: 41 (27-57) TENS: 43 (27-55)	0%	All: 47.7% VAX-D: 50.0% TENS: 45.5%	All: 90.9% white 9.1% Asian VAX-D: 90.9% white 9.1% Asian TENS: 90.9% white 9.1% Asian
Shealy and Borgmeyer(6)	1997	DRS system: All had symptoms of less than 1 year	Mean not reported range 31 to 63	0%	30.7%	Not reported

Findings

The findings of the two low quality studies that form the evidence base for Key Question 3 are presented in Table 17 and Table 18 of Appendix D. Both studies found that the two types of decompression therapy were effective in reducing pain.

Sherry et al. compared a typical VAX-D decompression protocol in 22 patients to treatment with TENS in 22 patients. The TENS protocol used has been criticized as being suboptimal, and not a typical TENS protocol in that patients received TENS therapy for thirty minutes once daily, five days a week, rather than continuously or as needed for pain. The protocol described for each type of therapy was to provide 24 treatments (five days a week for four weeks, then once a week for four weeks). However, the VAX-D treated patients received a mean of 24.1 treatments, with a range of 18 to 36, while the TENS group received a mean of 18.0, range 10 to 24 treatments. Whether the overall duration of treatment was longer in the VAX-D group is not noted.(4)

Post-treatment VAS scores in the study by Sherry et al(3) indicate that the “evaluable” patients treated with decompression therapy had greater pain relief than patients in the control group. The difference was both statistically and clinically significant. Of note, three of four randomized patients who were not considered “evaluable” were treated with VAX-D. Two of these patients were noted after treatment to have had baseline VAS scores <2.0, and another withdrew because treatment was no longer required. One patient in the TENS group did not wish to continue treatment. In addition to reporting changes in VAS scores, Sherry et al. also reported the percentage of patients achieving at least 50% pain relief. No patients in the control group achieved this level of pain relief, as compared to 68% of patients in the decompression group who did achieve this level of pain relief. This difference is both statistically and clinically significant.

Sherry et al. also asked the participants to rate their disability on four activities most affected by their low back pain. Mean disability scores pre- and post-treatment were reported without measures of variance or tests of statistical significance. On a scale of 1 – 4, with 1 indicating complete disability and 4 representing no limitation of activity,

the mean scores for the VAX-D group were 2.2 (pre-) and 2.9 (post-treatment); mean scores for the TENS group remained 2.2.(3)

Shealy and Borgmeyer(6) compared a typical DRS decompression protocol in addition to TENS to a standard traction therapy protocol in addition to TENS. They did not report changes in VAS scores, but did report the percentage of patients reporting “poor,” “good” or “excellent” improvement in symptoms. The article does not provide specific details on severity or nature of baseline symptoms or how patients’ assessments of improvement were ascertained. Patients treated with DRS decompression therapy were more likely to have excellent improvement in symptoms than patients treated with traction. However, when patients with excellent and good improvement after treatment were combined, the difference between treatment groups was not statistically significant.

Key Question 3 a: Do patients with chronic low back pain (due to herniated disc or degenerative disc disease) who are treated with decompression therapy have more, less, or the same level of pain relief than patients who are treated with other therapies?

Sherry et al. stated that after completion of VAX-D treatment, 13 of 19 (68.4%) of evaluable patients reported a successful treatment (defined as a 50% reduction in pain and any improvement in disability). Patients in the control group received TENS therapy, with none of 21 (0%) evaluable patients reporting a successful treatment. Shealy and Borgmeyer stated that 18 of 22 (81.8%) patients in the DRS therapy/TENS group reported an excellent/good treatment outcome (defined as ≥50% improvement). For patients in the traction/TENS control group this level of improvement was achieved in nine of 17 (52.9%). However, no evidence-based conclusion can be drawn from the limited, low quality evidence.

Key Question 3 b: Do patients treated with or decompression therapy for chronic low back pain due to herniated disc or degenerative disc disease utilize more, less, or the same number of adjunctive therapies (e.g., medications, bracing) than patients treated with other therapies?

The included studies did not provide data that would allow us to address this sub-question.

Key Question 3 c: Do patients treated with decompression therapy for chronic low back pain due to a herniated disc or degenerative disc disease return to work more quickly than patients treated with other therapies?

The included studies did not provide data that would allow us to address this sub-question. The study by Sherry et al. incorporated return to work into their definition of "remission," but did not report return to work separately.(3)

Key Question 3 d: What is the duration of pain relief achieved, if any?

Sherry et al. (low quality study) reported that of 13 patients who had been "successfully treated" (defined as >50% improvement in pain and any improvement in disability ratings), two were lost to follow up, 1 had "suffered a significant other injury," and of the 10 still available at 6 months, 7 still met criteria for a successful outcome.(3)

Key Question 3 e: If the therapy is effective, what are the patient characteristics/indications of those for whom it appears to work? Is the therapy effective for the Medicare population (over 65 years of age)?

As noted in Table 8, patients in the included studies were younger than the typical Medicare population. The limited quality and quantity of the evidence for efficacy of decompression therapy precludes the formulation of evidence-based conclusions regarding the efficacy of decompression therapy as a therapy for chronic low back pain for the Medicare population over the age of 65.

Key Question 3 f: If it works, which, if any, particular decompression protocol provides the most pain relief?

The two included studies did not compare different decompression protocols.

Subsection Summary

Because of a paucity of data from high quality studies, we do not draw evidence-based conclusions pertaining to the efficacy or effectiveness decompression therapy as a treatment option for the treatment of chronic low back pain due to herniated disc or degenerative disc disease at this time.

Key Question #4: What complications, harms, and adverse events associated with decompression therapy have been reported?

All ten publications were examined for adverse events associated with decompression therapy. One case report of an adverse event was identified, Deen et al.(2)

Quality

The quality and generalizability of the information were not formally evaluated because we included uncontrolled trials in the evidence base for this question. Uncontrolled studies cannot be used to determine causality or to estimate frequencies of adverse events; they can only be used to generate a list of adverse events possibly attributable to the device.

Findings

Adverse events reported in the included articles are presented in Table 9. The technology assessment performed for the Australian government included unpublished information on adverse events submitted by the manufacturer of the VAX-D system.

Table 9. Adverse Events and Harms Associated with Decompression Therapy

Study	Year	N =	Adverse events and harms reported
Deen et al.(2)	2003	1	Case report of a patient who developed sudden, severe exacerbation of pain during a VAX-D treatment session. Follow-up MRI found a marked enlargement of the disc protrusion, and urgent microdiscectomy was performed. The patient recovered fully and was pain-free with no motor deficit
Gose et al.(5)	1998	778	One percent of patients reported increased pain
MSAC(4)	2001	NR	• "Anecdotal evidence from the applicant states that 10 per cent of patients are not able to tolerate the positioning of the table or the distractive pressures and discontinue therapy." • Complications that have been reported: – Sharp burning, radiating pain during treatment – Stress to the shoulder muscles and rotator cuffs – Overstretching of the soft tissues of the back
Naguszewski et al.(9)	2001	7	No harms or adverse events mentioned in the 7 case descriptions.
Ramos(1)	2004	142	Presence or absence of harms or adverse events not reported.
Ramos and Martin(8)	1994	5	Presence or absence of harms or adverse events not reported.
Shealy et al.(10)	2005	35	Presence or absence of harms or adverse events not reported.
Shealy and Borgmeyer(6)	1997	25	Presence or absence of harms or adverse events not reported. (DRS system)
Sherry et al.(3)	2001	22	Presence or absence of harms or adverse events not reported.
Tilaro and Miskovich(7)	1999	17	Presence or absence of harms or adverse events not reported.

Adverse events have been reported to occur in association with vertebral axial decompression therapy (one case report of an enlargement of an existing disc protrusion and reports of treatment-related pain). According to the MSAC report presented to the Australian government in 2001,(4) information supplied by the manufacturer indicated that approximately 10% of individuals who undergo vertebral axial decompression therapy are unable to tolerate "the positioning of the table or the distractive pressures" and discontinue treatment. However, none of the published studies utilized in our report, including the large case series of Gose et al.(5) (which enrolled 778 patients) reported that any patients were unable to tolerate treatment, although one percent of the patients reported an increase in pain. Of note, this case series was limited to patients who had received at least 10 treatments, suggesting that those who did not tolerate the therapy were screened out.

Key Question 4 a: Would the characteristics of the Medicare population (osteoporosis, etc.) increase the likelihood of adverse events compared to the trial populations?

Findings

As noted in Table 12, patients in the included studies were younger than the typical Medicare population. Two studies included patients over the age of 65, but neither commented on the presence or absence of adverse effects.(1,10) Both studies excluded patients with "severe osteoporosis." Currently, there is no evidence to establish whether characteristics of the Medicare population (such as presence of undiagnosed osteoporosis) would increase the likelihood of adverse events when compared to the trial populations, although it should be noted that the literature produced by manufacturers and distributors of decompression therapies lists osteoporosis as a contraindication for this therapy.

Subsection Summary

Inconsistencies in the data and the limited amount of published data preclude evidence-based conclusions pertaining to the type and frequency of adverse events. However, there has been one case report of an enlargement of an existing disc protrusion and other reports of treatment-related pain in the published literature.

Conclusions

Patient inclusion criteria in studies of decompression therapy were chronic low back pain, with or without radicular symptoms, due to degenerative or herniated disc disease or facet arthritis. Product literature and the exclusion criteria in the examined studies suggest that therapy should be avoided in patients with osteoporosis, tumor, infection, spinal instability, and surgical implants. The health outcome measures reported in studies of decompression therapy (improvements in pain and radicular symptoms, improvements in function), are also reported in literature on other non-surgical treatments for low back pain. However, a number of additional outcomes (absenteeism,

return to work, overall health, analgesic consumption, low back pain-related disability rates, and quality of life) have been reported for other non-surgical treatments.

Currently available evidence is presently too limited in quality and quantity to allow for the formulation of evidence-based conclusions regarding the efficacy of decompression therapy as a therapy for chronic back pain when compared with other non-surgical treatment options. Of the studies examined for assessment of efficacy, neither included patients over 65 years of age. Adverse event reporting for decompression therapy is infrequent. There was one case report of an enlargement of an existing disc protrusion, and other studies reported worsening of pain in some patients.

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APPENDICES:

SUPPORTING DOCUMENTATION AND EVIDENCE TABLES

Appendix A: Literature Search Methods

Electronic Database Searches

The following databases have been searched for relevant information:

Database	Date limits	Platform/provider
CINAHL	1982 through January 2007	OVID
The Cochrane Central Register of Controlled Trials (CENTRAL)	Inception through 2006, Issue 4	http://www.thecochranelibrary.com
The Cochrane Database of Methodology Reviews (Methodology Reviews)	Inception through 2005, Issue 4	http://www.thecochranelibrary.com
The Cochrane Database of Systematic Reviews (Cochrane Reviews)	Inception through 2005, Issue 4	http://www.thecochranelibrary.com
CRISP	Searched January 2007	http://crisp.cit.nih.gov/crisp/crisp_query.generate_screen
Database of Abstracts of Reviews of Effects (DARE)	Inception through 2005, Issue 4	http://www.thecochranelibrary.com
ECRI Health Devices Alerts	1977 through January 2007	ECRI
ECRI Health Technology Forecast	Inception through January 2007	ECRI
ECRI Healthcare Standards	1975 through January 2007	ECRI
ECRI International Health Technology Assessment (IHTA)	Inception through January 2007	ECRI
ECRI Library Catalog	Inception through January 2007	ECRI
ECRI TARGET (Technology Assessment Resource Guide for Emerging Technologies)	Inception through January 2007	ECRI
Embase (Excerpta Medica)	1974 through January 2007	OVID
Health Technology Assessment Database (HTA)	Inception through 2005, Issue 4	http://www.thecochranelibrary.com
MEDLINE	1966 through January 2007	OVID
metaRegister of Controlled Trials (mRCT)	Searched January 2007	http://www.controlled-trials.com/mrct/
PubMed (PreMEDLINE, Publisher)	1966 through January 2007	http://www.pubmed.gov
U.K. National Health Service Economic Evaluation Database (NHS EED)	Inception through 2006, Issue 4	http://www.thecochranelibrary.com
U.S. Centers for Medicare & Medicaid (CMS) Web site	Searched January 2007	http://www.cms.gov
U.S. Food and Drug Administration (FDA) Web site	Searched January 2007	http://www.fda.gov
U.S. National Guideline Clearinghouse™ (NGC™)	Inception through January 2007	http://www.ngc.gov
U.S. National Library of Medicine (NLM) Catalog	Searched January 2007	http://gateway.nlm.nih.gov

Search Strategies

The search strategies employed combinations of freetext keywords as well as controlled vocabulary terms including (but not limited to) the following concepts. The strategy below is presented in OVID syntax; the search was simultaneously conducted across Embase, Medline, and PsycINFO. A parallel strategy was used to search the databases comprising the Cochrane Library.

Medical Subject Headings (MeSH), Emtree, PsycINFO and Keywords

Conventions:

OVID

$ = truncation character (wildcard)

exp = "explodes" controlled vocabulary term (e.g., expands search to all more specific related terms in the vocabulary's hierarchy).

.de. = limit controlled vocabulary heading

.fs. = floating subheading

.hw. = limit to heading word

.md. = type of methodology (PsycINFO)

.mp. = combined search fields (default if no fields are specified)

.pt. = publication Type

.ti. = limit to title

.tw. = limit to title and abstract fields

PubMed

[mh] = MeSH heading

[majr] = MeSH heading designated as major topic

[pt] = Publication Type

[sb] = Subset of PubMed database (PreMedline, Systematic, OldMedline)

[sh] = MeSH subheading (qualifiers used in conjunction with MeSH headings)

[tiab] = keyword in title or abstract

[tw] = Text word

Topic-specific Search Terms

Axial decompression:
Accuspina
Accu-spina
VAX-D
Vertebral axial decompression

Spinal:
Back
Intervertebr$
Lumbar
Spinal
Vertbra$

Traction:
Automat$
Computer$
Motor$
Powered
Traction
Traction therapy/

Adverse Events:
Ae.fs.
Co.fs.
Adverse
Complicat$
Error$
Hazard$
safety

CINAHL/Embase/Medline
English language, human

Set Number	Concept	Search statement
1	Axial decompression	VAX-D or (vertebral adj axial adj decompression).tw. or Accu-Spina
2	Traction	(exp traction therapy/ or traction$.tw.) and (automat$ or computer$ or powered or motor$)
3	Spinal	2 and (back or lumbar or vertebra$ or intervertebr$ or spinal)
4	Combine sets	1 or 3
5	Limit by publication type	4 not ((letter or editorial or news or comment or case reports or review or note or conference paper).de. or (letter or editorial or news or comment or case reports or review).pt.)
6	Eliminate overlap	Remove duplicates from 5
7	Limit by methodology	5 and ((Randomized controlled trials or random allocation or double-blind method or single-blind method or placebos or cross-over studies).de. or placebo$.mp. or random$.ti. or crossover$.mp. or cross over.mp. or ((singl$ or doubl$ or tripl$ or trebl$) and (blind$ or mask$ or sham$)).mp. or latin square.mp. or ISRTCN)
8	Adverse events	5 and (hazard$ or adverse$ or complication$ or safety or error$ or (co or ae).fs.)

Medline (PubMed) – 1/1/66 through 12/13/05
English language

Set Number	Concept	Search statement
1		(back OR disc* OR disk* OR spine OR spinal OR vertebra* OR intervertebral) AND (decompress* OR traction*) AND (automat* OR computerised OR computerized OR motorised OR motorized OR powered)
2		"VAX-D" OR "vertebral axial decompression"
		"internal disc decompression" OR "internal disk decompression" OR "kinetic decompression mobilisation" OR "kinetic decompression mobilization"
3	Limit by publication type	#2 NOT (letter[pt] OR editorial[pt] OR news[pt] OR comment[pt] OR case reports[pt])
4	Limit to human	#3 AND (humans[mh] OR premedline[sb] OR publisher[sb])
5	Limit by language	#4 AND English[la]
6	Limit by methodology	#5 AND (randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized controlled trials[mh] OR random allocation[mh] OR double-blind method[mh] OR single-blind method[mh] OR ISRCTN* OR clinical trial[pt] OR clinical trials[mh] OR research design[mh:noexp] OR comparative study[mh] OR evaluation studies[mh] OR follow-up studies[mh] OR prospective studies[mh] OR cross-over studies[mh] OR meta-analysis[mh] OR meta-analysis[pt] OR outcomes research[mh] OR multicenter study[pt] OR "clinical trial"[tw] OR "clinical trials"[tw] OR ((singl*[tw] OR doubl*[tw] OR trebl*[tw] OR tripl*[tw]) AND (mask*[tw] OR blind*[tw])) OR "latin square" OR placebos[mh] OR placebo* OR random* OR "control group" OR prospective* OR retrospective* OR volunteer* OR sham OR "meta-analysis"[tw] OR cohort)
7	Adverse events	#5 AND (co[sh] OR ae[sh] OR safety OR hazard* OR recall* OR complication* OR adverse* OR error*)

Hand Searches of Journal and Nonjournal Literature

Journals and supplements maintained in ECRI's collections were routinely reviewed. Nonjournal publications and conference proceedings from professional organizations, private agencies, and government agencies were also screened. Other mechanisms used to retrieve additional relevant information included review of bibliographies/reference lists from peer-reviewed and gray literature. (Gray literature consists of reports, studies, articles, and monographs produced by federal and local government agencies, private organizations, educational facilities, consulting firms, and corporations. These documents do not appear in the peer-reviewed journal literature.)

Appendix B: Excluded Studies

No retrieved studies were excluded.

Appendix C: Quality Assessment and Strength of Body of Evidence Rating (Key Question 3)

Study Quality Evaluation Scale

The 25-item quality assessment instrument used to assess the quality of the three studies that addressed Key Question 3 is presented below:

Comparability of Groups at Baseline

1. Were patients randomly assigned to the study's groups?
2. Did the study employ stochastic randomization?
3. Were any methods other than randomization used to make the patients in the study's groups comparable?
4. Were patients assigned to groups based on factors other than patient or physician preference?
5. Were the characteristics of patients in the different study groups comparable at the time they were assigned to groups?
6. Did patients in the different study groups have similar levels of performance on all of the outcome variables at the time they were assigned to groups?
7. Was the comparison of interest prospectively planned?
8. Did ≥85% of the patients complete the study?
9. Was there a ≤15% difference in completion rates in the study's groups?
10. Were all of the study's groups concurrently treated?
11. Was compliance with treatment ≥85% in both of the study's groups?
12. Was there concealment of allocation?

Blinding

13. Were subjects blinded to the treatment they received?
14. Did the authors perform any tests after completing the study to ensure that the integrity of the blinding of patients was maintained throughout the study?
15. Was the treating physician blinded to the groups to which the patients were assigned?
16. Were those who assessed the patient's outcomes blinded to the group to which the patients were assigned?

Measurement/Instrument

17. Was the outcome measure of interest objective and was it objectively measured?
18. Were the same laboratory tests, clinical findings, psychological instruments, etc., used to measure the outcomes in all of the study's groups?
19. Was the instrument used to measure the outcome standard?
20. Were the follow-up times in all of the study's relevant groups approximately equal?

Treatment

21. Was the same treatment given to all patients enrolled in the experimental group?
22. Was the same treatment given to all patients enrolled in the control group?
23. Were all of the study's groups treated at the same center?

Investigator Bias

24. Was the funding for this study derived from a source that does not have a financial interest in its results?
25. Were the author's conclusions, as stated in the abstract or the article's discussion section, supported by the data presented in the article's results section?

Strength of Body of Evidence Algorithm

In addressing Key Question 3, we used an algorithm developed by ECRI to determine the strength of the evidence supporting our conclusions. This algorithm formalizes the process of systematic review by breaking the process down into 12 discrete steps. At each step, rules that have been determined prior to the onset of the review, are applied that determine the next step in the systematic review process and ultimately the stability and strength-of-evidence ratings allocated to our findings. Because the application of the rules governing each step in the algorithm (henceforth called a decision point) guide the conduct of the systematic review process and how its findings are interpreted, much time and effort must be spent prior to the onset of data collection in ensuring that the rules and underlying assumptions for each decision point are reasonable. For the sake of transparency, all rules and assumptions made prior to the onset of this evidence report are included in the text that follows.

The algorithm is comprised of three distinct sections: a *General* section, a *Quantitative* section, and a *Qualitative* section. Only the *General* section is relevant to this report.

General Section of Algorithm

Decision Points 1 through 4 fall within the *General* section. The purpose of this section is to determine whether the available evidence for a given key question is sufficient (in terms of quality and power) to potentially allow evidence-based conclusions to be drawn (Decision Points 1 and 2). Assuming that the available evidence is deemed sufficient to allow evidence-based conclusions to be drawn, the next step of the general section (Decision Point 3) is to determine the overall quality of the available evidence. Regardless of the quality of the available evidence, it may be the case that the available data precludes one from performing a quantitative analysis. The purpose of the final decision point in the general section of the algorithm (Decision Point 4) is to provide a mechanism by which decision rules about the appropriateness of performing quantitative analyses can be formally determined.

Decision Point 1: Acceptable Quality?

Decision Point 1 provides a mechanism by which individual studies of very low quality are excluded from further consideration. Decision rules that define exactly what one considers to be a study of unacceptable quality are defined *a priori*. These decision rules depend on the mechanism that one is using to measure study quality. For example, if one is using a scale to measure study quality, one might determine that a quality score that falls below a certain threshold is unacceptable. Alternatively, if one is using a checklist, one might determine that certain study characteristics included among the checklist items must be met for the study to be considered acceptable (e.g., randomization, blinding, etc.).

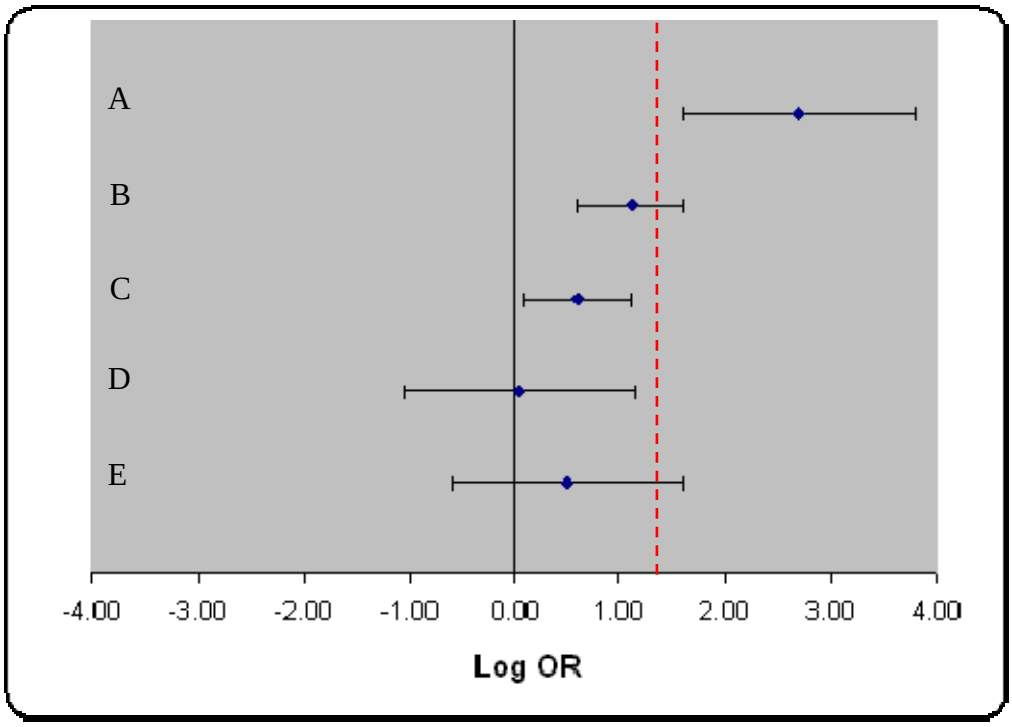
For this evidence report, we determined whether a study was of acceptable quality based on group comparability scores obtained using the quality checklist instrument presented above. In order for a study to be included in any of the evidence bases for this evidence report, the group comparability score must have been ≥5. In other words, ECRI required that all studies included in the evidence bases for each of the key

questions demonstrate that reasonable efforts were made to ensure that the included studies were protected from selection bias.

Decision Point 2: Potentially Conclusive?

Decision Point 2 provides a mechanism by which one can define the kinds of results that are required before one can have any hope at all of drawing an evidence-based conclusion. In essence, this decision point involves the evaluation of the statistical power of the overall evidence base and each of its constituent studies. Armitage and Berry(48) provide a mechanism by which one can create *a priori* decision rules that define what "potentially conclusive" findings are. Consider Figure 3. Four of the findings in this figure are conclusive (A to D). Only finding E is inconclusive.

Figure 3. Conclusive and Inconclusive Findings



Dashed Line = Threshold for a clinically significant difference

Finding A shows that the treatment is both statistically and clinically significantly more effective than placebo. Finding B shows that Treatment A is statistically significantly more effective than placebo but it is unclear whether this difference is clinically significant. Finding C shows that Treatment A is statistically significantly more effective than placebo but this difference is not clinically significant. Finding D shows that it is unclear whether there is a meaningful difference in efficacy between Treatment A and placebo, but regardless, this difference is not clinically significant. Finding E shows that it remains unclear whether Treatment A is more effective than placebo, but it is also unclear whether this difference is clinically important. This latter finding is thus inconclusive.

For this evidence report, we had decided that an evidence base would be considered potentially conclusive if the summary effect size estimate obtained from a meta-analysis met any of condition A to D in Figure 3. If a quantitative summary effect size estimate could not be obtained, then at least one included study in the relevant evidence base would have to meet one of conditions A to D.

Given the low quality of the evidence base, the limited data for each outcome, and the absence of reporting of measures of variance in the included studies, we did not calculate any within-study effect sizes for this report.

Decision Point 3: Quality of Evidence Base

Decision Point 3 provides a mechanism by which one can stratify the overall quality of the evidence base that one has established into one of three levels; high, moderate, or low[1] quality. From this point onward, high, moderate, and low quality evidence bases pass through different pathways of the algorithm. Thus, the quality of an evidence base acts as an important moderator of both the stability and strength-of-evidence ratings that are ultimately assigned to our quantitative and qualitative findings.

As is the case for Decision Point 1, the *a priori* decision rules for Decision Point 3 depend on the method by which one chooses to measure study quality. For example, one may decide that an evidence base with a median quality score measured using a predefined study quality scale that falls above a predefined threshold will be considered as high quality. Likewise, one may decide that an evidence base with a median quality score that falls below a different predefined threshold is low quality.

For this evidence report, our categorization of the quality of the evidence base for Key Question 3 was based on the median of the overall quality scores obtained using ECRI's checklist for controlled trials (Appendix C). The ranges of median scores that determined whether an evidence base was of high, moderate, or lowest acceptable quality used in this evidence report are presented in Table 10. The overall quality of the evidence relevant to Key Question 3 was judged to be low. (See Figure 5)

Table 10. Quality of Evidence Base

Question #	Instrument	Highest Quality	Moderate Quality	Lowest Quality
All outcomes for all questions	ECRI Controlled Trials Checklist	>8.4	>6.7 to ≤8.3	<5

[1] Low quality refers to an evidence base that is of "lowest acceptable" quality. Remember that studies with fatal flaws have been excluded at Decision Point 1 and are not included in the evidence base.

Decision Point 4: Reporting Allows Quantitative Analysis to be Performed?

When poor reporting does not allow one to calculate an accurate effect size estimate for all of the available studies that have addressed a key question, one must make a decision about whether to perform a meta-analysis of only a subset of the overall evidence base or whether to abandon a quantitative analysis of the available data altogether.

For this evidence report, it was decided that a quantitative analysis would be performed if an accurate effect size estimate was available from ≥50% of the available studies. In addition, it was decided that if an accurate effect size estimate could be obtained from ≥50% of the available studies, we would only attempt meta-analysis of the available data if this data came from at least three studies. Consequently, if an evidence base was comprised of fewer than three studies, we would not pool the data using meta-analysis. Instead, the assessment of such an evidence base would be aimed at drawing a qualitative conclusion.

Because the studies utilized for Key Question 3 of this Evidence Report were not of high quality, and because we did not have 3 or more studies addressing the same outcome, we did not consider any quantitative analyses appropriate. Had the quality and quantity of analyzable data been sufficient, we would have used the covariates listed in Table 11 in meta-regression analyses:

For details regarding the remainder of the ECRI protocol for assessing stability of quantitative estimates and robustness of qualitative estimates, please see the paper by Treadwell et al.(43)

Table 11. Covariates for Meta-Regression Analyses

Type of Covariate	Covariate	Continuous/ Categorical
Patient characteristics	Differential distribution of demographics	Categorical
	Differential distribution of comorbid conditions	Continuous
Intervention	Method of vertebral axial decompression (VAX-D)	Categorical
	Method of vertebral axial decompression (Other)	Categorical
	Number of sessions	Continuous
	Time of each session (minutes)	Continuous
Study design	Randomized	Categorical

Figure 4. General Section of ECRI Strength-of-Evidence Algorithm (Decision Points 1 through 3)

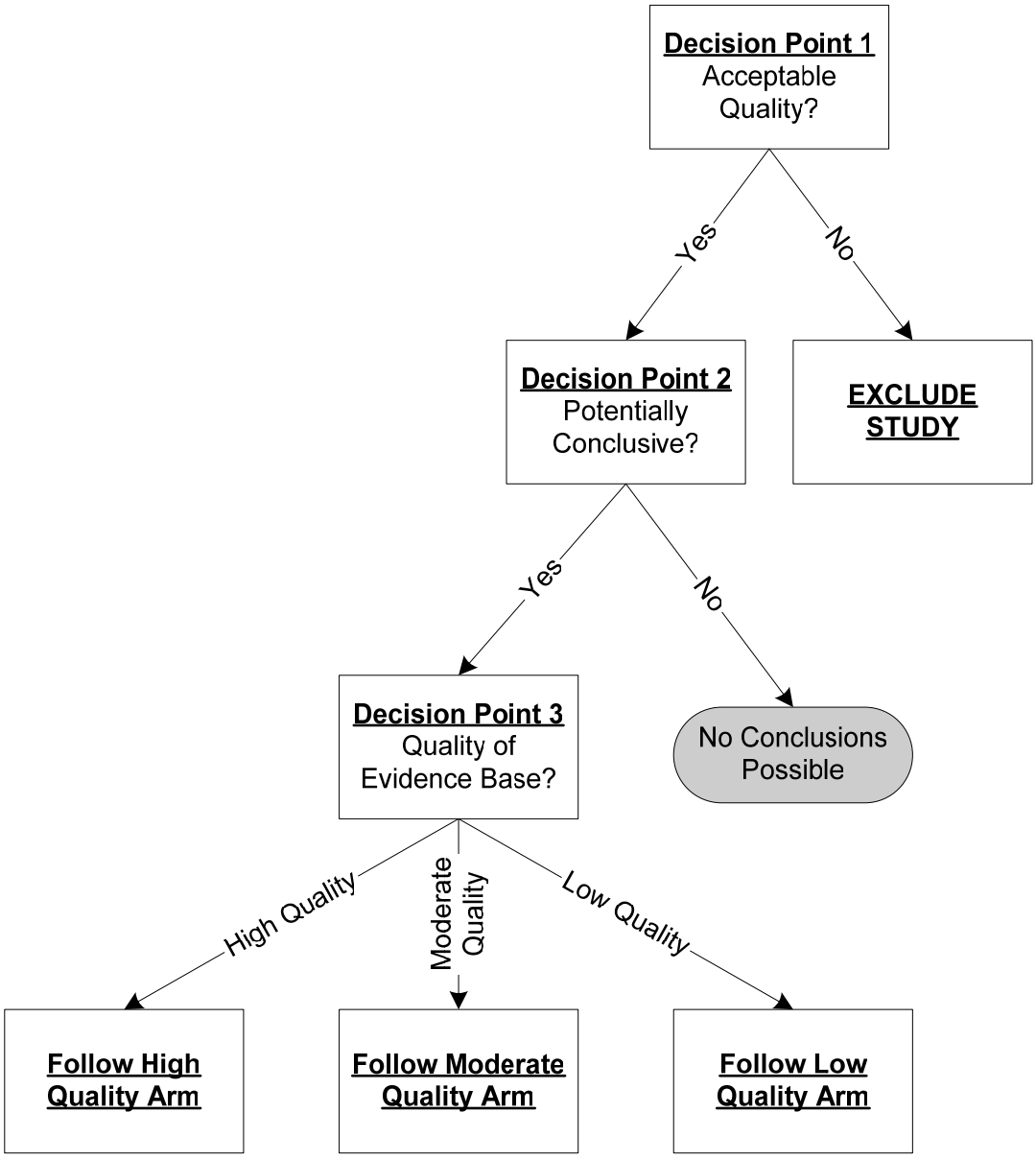
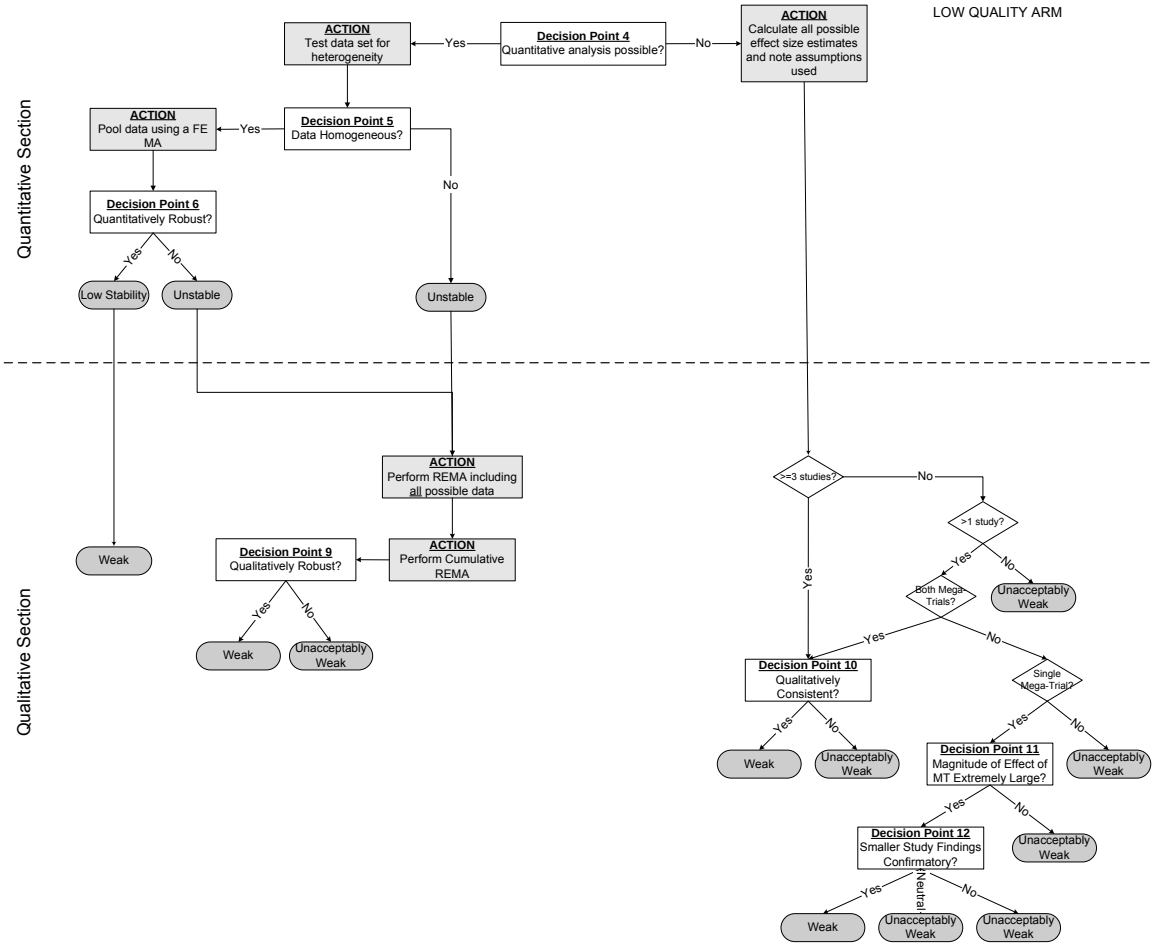


Figure 5 Low-Quality Section of ECRI Strength of Evidence



Appendix D: Evidence Tables

Table 12. Summary of Included Studies (by Study Design)

Author/Year	Study Design/Purpose	Intervention	Demographics	Results
Medical Services Advisory Committee (MSAC) 2001(4)	**Design:** Technology Assessment of vertebral axial decompression therapy for chronic low back pain which included a systematic review of published and unpublished studies for efficacy and adverse events **Purpose:** To provide evidence assessment for health care financing decisions for Commonwealth of Australia	**Treatment Intervention:** VAX-D device (2 published and 2 unpublished studies) **Comparators:** Indirect comparisons to discectomy, laminectomy and conservative therapy (NSAIDs or physical therapy)	Not described; **Conditions** considered separately: Radiculopathy or radicular pain caused by herniated intervertebral disc, unresponsive to conservative therapy Radiculopathy or radicular pain caused by degenerated intervertebral disc, unresponsive to conservative therapy Chronic non-specific low back pain, unresponsive to conservative therapy	Insufficient evidence pertaining to the effectiveness of vertebral axial decompression (VAX-D) therapy precluded MSAC from recommending that public funding should be supported at the time for the VAX-D procedure.

Author/Year	Study Design/Purpose	Intervention	Demographics	Results
Shealy and Borgmeyer 1997(6)	**Design:** Randomized controlled trial (RCT) **Purpose:** To evaluate the DRS system with outpatient protocols compared to traditional therapy **Quality Score:** 6.6	**Treatment Intervention:** DRS System 30 minute treatment sessions 60 seconds on, 60 seconds off Up to 30 degrees of distraction forces 20 sessions total 30 minutes of ice and TENS applied after each session **Control Intervention:** Standard traction 30 minute treatment sessions 60 seconds on, 60 seconds off 20 sessions total 30 minutes of ice and TENS applied after each session **Other intervention:** All patients were given a TENS unit for continuous home use, and were instructed and supervised in a limbering/strengthening exercise program	**Total Enrolled:** 39 in total 17 control group 22 treatment group **Mean age:** Mean not reported range 31 to 63 **Gender:** 30.7% Female **Ethnicity**: Not reported **Inclusion Criteria:** Ruptured lumbar discs and/or chronic facet arthroses (23 had ruptured discs diagnosed by MRI) **Exclusion Criteria:** Not reported **Average duration of pain before entering trial:** All had symptoms of less than one year	**Baseline VAS scores mean (range)** Treatment: NR Control: NR **Definition of successful treatment:** Patient-rated scale: Excellent 90-100% improvement in pain Good 50-89% improvement in pain Poor <50% improvement in pain **Treatment outcome:** 40.9% (9/22) Excellent 40.9% (9/22) Good 18.2% (4/22) Poor For patients with disc protrusion only: 50% (7/14) Excellent 36% (5/14) Good 14% (2/14) Poor **Control group outcome**: 11.7% (2/17) Excellent 41.2% (7/17) Good 47.1% (8/17) Poor For patients with disc protrusion only: 0% (0/9) Excellent 55% (5/9) Good 45% (4/9) Poor **6 months follow-up** Treatment: NR Control: NR

Author/Year	Study Design/Purpose	Intervention	Demographics	Results
Sherry et al. 2001(3)	**Design**: RCT **Purpose**: To address the question of efficacy and appropriateness of vertebral axial decompression therapy **Source of patients:** Volunteers responding to newspaper advertisements **Quality Score:** 6.6	**Treatment Intervention**: VAX-D machine, standard protocol Prone position 30 minute sessions 15 cycles per session Five times per week for 4 weeks, then once per week for 4 weeks **Control Intervention**: TENS Prone position 30 minute sessions Daily sessions for 20 days, then once a week for 4 weeks (not a normal TENS protocol, this is considered a sub-optimal treatment) **Other Intervention**: No physical therapy, steroid injection, or other treatments allowed during the trial. Non-narcotic pain relievers and anti-inflammatory medications could be taken if necessary	**Total Enrolled**: 44 22 per group **Mean age**: All: 42 (22-57) VAX-D: 41 (27-57) TENS: 43 (27-55) **Gender**: All: 47.7% VAX-D: 50.0% TENS: 45.5% **Ethnicity:** All: 90.9% white 9.1% Asian VAX-D: 90.9% white 9.1% Asian TENS: 90.9% white 9.1% Asian **Inclusion Criteria**: Chronic low back pain (>3 months duration) Associated leg pain Disc protrusion or herniation confirmed on CT scan or MRI Age 18 to 65 years Minimum VAS score of 2.0 Live within 45 minutes of the clinic Able to give informed consent **Exclusion Criteria**: Osseous stenosis Unstable spine Spinal surgical implants Shoulder problems Spinal pain due to tumor, infection, or inflammatory disease Pregnancy Previous VAX-D therapy **Average duration of pain before entering trial**: All: 7.3 years (0.25 to 30) VAX-D: 8.4 years (0.25 to 30) TENS: 6.2 years (0.5 to 2.8)	**Baseline VAS scores mean (range)** Treatment: 5.99 (2.1 to 8.7), n = 19 Control: 5.44 (2.7 to 8.5), n = 21 **Post-treatment VAS scores mean (range)** Treatment: 1.85 (0.0 to 5.6), n = 19 Control: 5.97 (1.8 to 8.5). n = 21 **Disability Rating (1 [most] to 4 [least disability] scale) mean (range):** **Baseline:** Treatment 2.2 (1.5 to 3) Control 2.2 (1.8 to 3.0) **Post-treatment:** Treatment 2.9 (2.0 – 4.0) Control 2.2 (1.5 to 3.0) **Definition of successful treatment**: 50% reduction in pain Treatment outcome: 68.4% (13/19) Control group outcome: 0% (0/21) **6-month follow-up** Treatment: Of 13 "successful" treatments, 2 were lost to followup, 1 had a "significant other injury," and of the remaining 10, 7 (70%) still met the successful treatment criteria Control: NR

Author/Year	Study Design/Purpose	Intervention	Demographics	Results
Ramos 2004(1)	**Design**: Controlled trial. **Purpose**: To evaluate the response to VAX-D therapy **Source of patients:** Cases referred to the center for neurosurgical evaluation after failure to respond to other treatments for low back pain **Quality Score:** 4.1	**Treatment Intervention**: VAX-D device 30 minute sessions 15 cycles per session Five sessions per week for a total of 20 sessions **Control Intervention**: VAX-D device 30 minute sessions 15 cycles per session Five sessions per week for a total of 10 sessions **Other Intervention**: No exercises, stretching, or other physical therapy allowed. Pain relieving medication was allowed as necessary	**Total Enrolled**: 142 91 in control group 51 in treatment group **Mean Age in years and range:** Mean 39.5 (15-76) Percentage over 65 y/a not reported. **Gender**: 38.7% female **Ethnicity**: N/R **Inclusion Criteria**: Low back pain, non-progressive neurological deficits, no contraindications to VAX-D. All patients were imaged with MRI or CT to confirm presence of discogenic disorder **Exclusion Criteria**: Cauda equina syndrome, tumor, infection, severe osteoporosis, fracture, bilateral pars defect, spondylolisthesis Grade 2, presence of surgical hardware **Average duration of pain before entering trial**: 10 months	**Baseline VAS scores mean (range)** Treatment: NR Control: NR **Definition of remission**: 90% reduction in pain, back to work without restriction Treatment group outcome: 76.5% (39/51) Control group outcome: 42.9% (39/91) **Partial Remission:** Some persistent pain; able to carry out most ADL's Treatment group outcome: 19.6% (10/51) Control group outcome: 24.1% (22/91)

Author/Year	Study Design/Purpose	Intervention	Demographics	Results
Gose et al. (1998)(5)	Case series	**Treatment Intervention**: VAX-D machine	**Total patients: 778** **Inclusion Criteria:** Patients must have undergone at least 10 sessions of VAX-D. Patients must have had a confirmed (through imaging studies) diagnosis of herniated disc, degenerative disc, or facet syndrome **Exclusion criteria:** Not reported **Group 1:** Extruded herniated disc(s) n = 34 **Group 2:** Multiple herniated discs without extrusion n = 195 **Group 3:** Single herniated disc, regardless of degenerative disease n = 382 **Group 4:** Degenerative disc disease n = 147 **Group 5:** Facet syndrome n = 19	**Baseline VAS scores (scale 0 – 5) means (no SD)** **Group 1:** 4.16 **Group 2:** 4.13 **Group 3:** 4.16 **Group 4:** 3.93 **Group 5:** 4.00 **Post-treatment VAS scores (scale 0 – 5) means (no SD)** **Group 1:** 1.82 **Group 2:** 1.18 **Group 3:** 1.09 **Group 4:** 1.17 **Group 5:** 1.13 **% VAS score Improvement** **Group 1:** 53% **Group 2:** 72% **Group 3:** 71% **Group 4:** 70% **Group 5:** 72% **Activity limitation (scale 0 – 3) means (no SD):** All patients pre: 1.24 All patients post: 0.27

Author/Year	Study Design/Purpose	Intervention	Demographics	Results
Shealy et al.(10)	**Design:** Case Series **Purpose:** To evaluate long-term benefits of Intervertebral Differential Dynamics (IDD) Therapy®	**Treatment:** Described as decompressive mobilization of the spine as in Shealy and Borgmeyer 1997(6) with an expanded physical therapy component; 25 – 30 minute sessions for decompression (for compressed discs) and/or mobilization (for facet syndrome) Utilized the Accu-Spina device	**Total enrolled:** 35 **Male:** 18 **Female:** 17 **Age:** mean 73.5 years, SD 6.9 **Prior treatments:** in 16 of 35 Acupuncture, back support, back surgery, chiropractic, epidural block, pain medication, conventional physical therapy, trigger point injections **Inclusion Criteria:** Low back pain with or without previous failed attempts with other treatments **Exclusion Criteria:** Severe osteoporosis, vertebral fractures, spondylolisthesis of grade 2 or higher, unstable post-surgical conditions, any kind of surgical hardware, spinal instability, inability to give legal consent	**Reported for** 24 patients at one year follow-up 2 patients unable to complete the treatment 9 patients could not be contacted at time of one-year follow up **Mean pain score** (0 – 10) on a numeric pain scale First session: 6.88 (SD: 2.47) (Unclear whether this represents score for all 35) Last session: 2.42 (SD: 2.18) One-year follow-up: 1.65 (SD: 2.47)

Author/Year	Study Design/Purpose	Intervention	Demographics	Results
Naguszewski et al. (2001)(9)	**Design:** Case Series **Purpose:** To use dermatomal somatosensory evoked potentials (DSSEPs) to demonstrate lumbar root decompression following VAX-D therapy	**Treatment:** VAX-D therapy. Each patient underwent DSSEPs of the L5 and S1 immediately before and within two weeks of VAX-D therapy.	**Total Enrolled: 7** **28 nerve roots** studied before and after VAX-D therapy **Gender:** **Male:** 57% (n = 4) **Female:** 43% (n = 3) **Age Range:** 23 to 56 years of age **Inclusion criteria:** Low back pain with referred pain in L5 and/or S1 distribution; disc bulging or herniation on imaging study **Exclusion criteria:** Not reported	**Average pain reduction:** 77% **Improvement in radicular symptoms by 50%:** 100% of patients **Improvement in radicular symptoms by 100%:** 43% of patients **Improvement in DSSEP in ipsilateral or contralateral leg after VAX-D therapy:** 100% of patients **Deterioration of DSSEP** in symptomatic leg in 2 (28.5%) patients despite clinically significant improvement in pain and radicular symptoms Seventeen nerve root responses improved, eight remained unchanged, and three deteriorated.
Ramos and Martin (1994)(8)	**Design:** Case Series **Purpose:** To examine the effect of vertebral axial decompression on pressure in the nucleus pulposus of lumbar discs **Source of patients:** Patients with work-related back injury referred for neurosurgical evaluation	Individuals with a cannula introduced into the nucleus pulposus of the L4-5 intervertebral disc underwent testing using a VAX-D machine. The purpose of this testing was to determine potential changes in intradiscal pressure associated VAX-D treatment. Digital readouts of intradiscal pressure were observed and recorded.	**Total enrolled:** 5 No information presented on the following: **Gender** **Mean Age** **Ethnicity** **Inclusion Criteria:** Patients with lumbar disc herniation confirmed by MRI and selected for percutaneous discectomy **Exclusion Criteria:** not reported	Tension associated with treatment was observed to decompress the nucleus pulposus to below -100 mm/Hg

Author/Year	Study Design/Purpose	Intervention	Demographics	Results
Tilaro and Miskovich (1999)(7)	**Case Series -** Retrospective chart review **Source of patients:** Patients attending an outpatient VAX-D clinic.	**Treatment Intervention**: VAX-D machine (3-5 sessions per week, for an average of 23 total treatments)	**N =** 17 **Number of involved nerves:** 22 **Gender:** 13 males, 4 females **Age:** Average age 40.8 years old **Average duration of symptoms:** 17.2 months **Inclusion criteria**: Selected cases with both abnormal CPT (current perception threshold) results and sciatica, positive SLR and imaging study correlation with observed clinical syndrome Three patients had multilevel involvement. **CPT(scores:** 5 - 11	**CPT scores: 14/22 nerves:** returned to normal function (64%) **6/22 nerves:** improved (27%) **1/22 nerves:** had no improvement (4.5%) **1/22 nerves:** was worse (4.5%) 91% demonstrated improved neurological function measured by CPT Neurometer post VAX-D therapy (average grade pre-therapy 6.36; post-therapy 2.09) **Overall improvement:** 67% **Complete recovery of neurological function:** 64%
Deen et al. 2003(2)	Case Report	Vertebral axial decompression	**Gender**: Male **Age**: 46 years of age **Pre-VAX-D Diagnosis**: Three month history of right S1 radiculopathy	Patient with a large lumbar disc protrusion experienced sudden severe exacerbation of radicular pain during a VAX-D therapy session. Follow-up MRI showed marked enlargement of the disc protrusion. Repeated lumbar MRI revealed notable progression of disc protrusion and large free disc fragment in the spinal canal which had migrated caudally to the level of the S1 pedicle.

[a] Calculated by ECRI.

CPT = Current Perception Threshold
95% CI = 95% Confidence Interval
NR = Not Reported
SD = Standard Deviation
VAS = Visual Analog Pain Scale

Table 13. Comparison of Outcomes Assessed by Studies of Decompression Therapy and Other Non Surgical LBP Treatments

Technology	Author	Year	Pain scores (VAS) or pain improvement	Functional status	Physiological variables	Short term duration of effects	Long term duration of effects	Absenteeism	Global improvement	Return to work	Overall health	Analgesic consumption	Recovery time	Work loss	Nerve conduction	Gait Analysis	Overall quality of life	Overall improvement	Return to full work	Low back disability
Studies of decompression therapy																				
DRS (Decompression Reduction System)	Shealy and Borgmeyer(6)	1997	✓																	
IDD (Intervertebral Differential Dynamics) Therapy®	Shealy et al.(10)	2005	✓																	
Vertebral axial decompression	Ramos(1)	2004	✓	✓																
Vertebral axial decompression	Sherry et al.(3)	2001	✓	✓																
Vertebral axial decompression	Gose et al.(5)	1998	✓	✓																
Vertebral axial decompression	Tilaro and Miskovich(7)	1999			✓															
Vertebral axial decompression	Ramos and Martin(8)	1994			✓															
Vertebral axial decompression	Naguszewski et al.(9)	2001	✓		✓															
Studies of other non-surgical LBP treatment options																				
SMT (systematic review)	Cochrane(44)	2005	✓	✓	✓	✓	✓	✓	✓			✓			✓	✓				
Traction (systematic review)	Cochrane(45)	2005	✓	✓					✓	✓										
CAM (systematic review)	Gagnier(11)	2005	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			✓	✓	✓			

Technology	Author	Year	Pain scores (VAS) or pain improvement	Functional status	Physiological variables	Short term duration of effects	Long term duration of effects	Absenteeism	Global improvement	Return to work	Overall health	Analgesic consumption	Recovery time	Work loss	Nerve conduction	Gait Analysis	Overall quality of life	Overall improvement	Return to full work	Low back disability
Acupuncture (meta-analysis)	Manheimer(22)	2005	✓	✓		✓	✓					✓						✓	✓	
Exercise Therapy (systematic review)	Hayden(21)	2005	✓	✓																
SMT (systematic review)	Bronfort(46)	2004	✓	✓		✓	✓		✓			✓	✓	✓						✓

CAM = Complimentary and Alternative Medicine
CG = Control Group
CPT = Current Perception Threshold
MOB = Spinal Mobilization
NR = Not Reported
SMT = Spinal Manipulation Therapy
TG = Treatment Group

Table 14. Study Design Details of Studies that Address Key Question 3 (Part I of II)

Study	Study purpose	Design	Treatment intervention	Control intervention	Other interventions
Ramos 2004(1)	To evaluate the response to VAX-D therapy	Controlled trial, control group treated first, then treatment group	**VAX-D machine** 30 minute sessions 15 cycles per session Five sessions per week for a total of 20 sessions	**VAX-D machine** 30 minute sessions 15 cycles per session Five sessions per week for a total of 10 sessions	No exercises, stretching, or other physical therapy allowed. Pain relieving medication was allowed as necessary.
Sherry et al. 2001(3)	To address the question of efficacy and appropriateness of vertebral axial decompression therapy	Prospective randomized controlled trial	**VAX-D machine, standard protocol** Prone position 30 minute sessions 15 cycles per session Five times per week for 4 weeks, then once per week for 4 weeks	**TENS** Prone position 30 minute sessions Daily sessions for 20 days, then once a week for 4 weeks (not a normal TENS protocol, this is considered a sub-optimal treatment)	No physical therapy, steroid injection, or other treatments allowed during the trial. Non-narcotic pain relievers and anti-inflammatory medications could be taken if necessary
Shealy and Borgmeyer 1997(6)	To evaluate the DRS system with outpatient protocols compared to traditional therapy	Prospective randomized controlled trial	**DRS System-n** 30 minute treatment sessions 60 seconds on, 60 seconds off Up to 30 degrees of distraction forces 20 sessions total 30 minutes of ice and TENS applied after each session	**Standard traction** 30 minute treatment sessions 60 seconds on, 60 seconds off 20 sessions total 30 minutes of ice and TENS applied after each session	All patients were given a TENS unit for continuous home use, and were instructed and supervised in a limbering/strengthening exercise program

Table 15. Study Design Details of Studies that Address Key Question 3 (Part II of II)

Study	Method of allocation to groups	Outcomes collected	Number of treatment centers	Patients blind to treatment?	Outcome evaluators blind to treatment?	Dropouts	Loss to follow up	ITT analysis?	Study funded by/conflicts of interest
Ramos 2004(1)	Patients enrolled first were allocated to the control group, patients enrolled later were allocated to the treatment group	Remission of pain (defined as at least 90% reduction in pain on 10 cm VAS), ability to carry out ADLs, return to work	1	No	No	NR	Average number of sessions was 9 in the control group, 18 in the treatment group	Yes	Author statement that he has no financial interest or affiliation with the company that manufactures the VAX-D equipment
Sherry et al. 2001(3)	Patients were randomized in sequential order (a pseudo-randomization method). Not reported if allocation was blinded.	Successful treatment (defined as a 50% reduction in pain on 10 cm VAS) Improvement in disability (patient-nominated 4-point disability rating). Outcomes collected before treatment initiated and after treatment was completed, and six months later	4	No	NR	2 patients withdrew, one from each group: TENS because "did not wish to continue", VAX-D because "no longer needed treatment". Two patients were randomized, but found to have VAS baseline score <2, so they were excluded (both were randomized to VAX-D)	VAX-D: mean 24.1 treatments per patient, range 18-36; TENS: mean 18.0 treatments per patient, range 10-24. Only reported data at 6-month follow up for "successful" cases.	No	Co- author is contracted to and holds shares in company that delivers VAX-D technology and services

Study	Method of allocation to groups	Outcomes collected	Number of treatment centers	Patients blind to treatment?	Outcome evaluators blind to treatment?	Dropouts	Loss to follow up	ITT analysis?	Study funded by/conflicts of interest
Shealy and Borgmeyer 1997(6)	Randomly assigned, method used not reported	Patient assessment of pain relief on a categorical scale	1	Yes	NR	Not reported	NR	NR	Author (Shealy) developed the DRS device (http://www.certhealthsciences.com/research3.html) ; Co-author (Borgmeyer) is a research coordinator at The Shealy Institute, which utilizes DRS technology in its therapeutic programs.(47)

ITT = Intent-to-Treat
NR = Not Reported

Table 16. Quality Assessment of Studies Addressing Key Question 3

Reference	Randomized?	Stochastic randomization?	Other methods used to attempt comparability between groups?	Patients assigned to groups based on factors other than patient or physician preference?	Baseline patient characteristics comparable?	Baseline performance levels comparable?	Comparison of interest prospectively planned?	Treatment group and control group concurrently treated?	Outcome measure objective?	Same outcome measures in both groups?	Standardized instrument used to assess outcomes?	All of the study's groups treated at the same center?	Subjects blinded?	Blinding of subjects tested?	Treating physicians blinded?	Assessors blinded?	Concealment of allocation?	Same treatment given to patients enrolled in experimental group?	Same treatment given to patients enrolled in control group?	Compliance ≥85% in both the study's groups?	Total attrition rate in the study ≤15%?	≤15% difference in attrition between groups?	Follow-up times in all of the study's groups approximately equal?	Study free from potential financial conflict of interest?	Authors conclusions supported by data presented?	Quality score =
Ramos(1)	N	N	N	N	NR	NR	NR	N	N	Y	N	Y	N	N	N	N	N	Y	Y	NR	NR	NR	Y	Y	Y	4.1
Shealy and Borgmeyer(6)	Y	NR	Y	Y	NR	NR	Y	Y	N	Y	N	Y	Y	NR	NR	N	NR	Y	Y	Y	Y	Y	Y	N	Y	6.6
Sherry et al.(3)	Y	N	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	N	N	N	N	NR	Y	Y	Y	Y	Y	Y	N	Y	6.6

N = No
Y = Yes
NR = Not Reported

Table 17. Studies that Address Key Question 3: Pain Outcomes: VAS Scores

Study	Baseline VAS scores mean (range)		Post-treatment* VAS scores mean (range)	
	Treatment	Control	Treatment	Control
Sherry et al. 2001(3)	5.99 (2.1 to 8.7) n = 19	5.44 (2.7 to 8.5) n = 21	1.85 (0.0 to 5.6) n = 19	5.97 (1.8 to 8.5) n = 21

VAS = Visual Analog Scale

Table 18. Studies that Address Key Question 3: Number of Patients Successfully Treated

Study	Definition of success	Post-treatment		6-month follow up	
		Treatment	Control	Treatment	Control
Sherry et al. 2001(3)	50% reduction in pain	68.4%* (13/19)	0% (0/21)	Of 13 "successful" treatments, 2 were lost to followup and 70% still met the successful treatment criteria	NR
Shealy and Borgmeyer 1997(6)	Patient-rated scale: Excellent 90-100% improvement in pain Good 50-89% improvement in pain Poor <50% improvement in pain	40.9% (9/22) Excellent 40.9% (9/22) Good 18.2% (4/22) Poor For patients with disc protrusion only: 50% (7/14) Excellent 36% (5/14) Good 14% (2/14) Poor For patients with facet arthrosis: 25% (2/8) Excellent 50% (4/8) Good 25% (2/8) Poor	11.7% (2/17) Excellent 41.2% (7/17) Good 47.1% (8/17) Poor For patients with disc protrusion only: 0% (0/9) Excellent 55% (5/9) Good 45% (4/9) Poor For patients with facet arthrosis: 25% (2/8) Excellent 25% (2/8) Good 50% (4/8) Poor	NR	NR

NR = Not Reported

* $p < 0.001$, Confidence Interval: 47.5% - 89.3% for difference in proportions