TECHNOLOGY REVIEW

Motorized Lumbar Traction Devices: What's the Evidence?

Mark Tyburski, MD
Permanente Medical Group, Inc
Department of Physical Medicine and Rehabilitation, Spine Clinic
Roseville, CA

Venu Akuthota, MD
The Spine Center at the University of Colorado Hospital
Aurora, CO

This review investigates the evidence supporting utilization of this "new" device as well as other technologically similar devices described for the treatment of low back pain. It is provided to help spine care providers come to a decision on motorized traction devices such as DRX9000 and VAX-D.

Recently, there has been an aggressive marketing campaign for a device (DRX9000) that purports using "space age technology" to provide "surgical decompression without surgery." The DRX9000 is one of a number of spinal "distraction or decompression" devices currently in use in the medical community.

The Food and Drug Administration (FDA) subjects these devices to their class II controls. As with other devices in this category such as power wheelchairs, infusion pumps and surgical drapes, class II controls may include special labeling or postmarket surveillance requirements.

The DRX9000 is distributed by Axiom Technologies Worldwide. Advertisements from Axiom and clinics that purchase and promote this device make claims such as: "The DRX9000™ is clinically proven to have an 86% success rate with patients suffering from lower back pain."[1] This marketing blitz has led to numerous inquiries from patients to their spine physicians. The cost of this intervention ranges into several thousands of dollars and is not covered by most insurance carriers. Spine physicians serve a major role in advising often desperate low back pain patients on the cost/benefit ratio of new interventions.

This review investigates the evidence supporting utilization of this "new" device as well as other technologically similar devices described for the treatment of low back pain. It is provided to help spine care providers come to a decision on motorized traction devices such as DRX9000 and VAX-D.

Marketing a New Breed of Traction

The DRX9000 is marketed as spinal decompression therapy, as opposed to spinal traction therapy, because it provides alternating cycles of distraction and relaxation instead of a constant traction force. The theory behind this system is that, through the cyclic process of distraction and relaxation, there is pressure relief of spinal structures that may be pain generators (eg, intervertebral disc). Devices in this decompression therapy category include VAX-D, DRX2000, DRX3000, DRX5000, DRX9000, Tru Trac 401, Lordex Power Traction Equipment and SpineRx LDM. Our contention, like the one formulated by the FDA, is that these decompression devices are akin to distraction or motorized traction devices.

Its marketers have touted the DRX9000 as the only device cleared by the FDA to provide "True Non-Surgical Spinal Decompression."[1] However, this attempt to differentiate this device from others is purely semantic as a review of their 510 (k) filing reveals that the only difference was the addition of the tag line "True Non-Surgical Spinal Decompression" to the name and application. The class II FDA approval of the DRX9000 and its derivatives appears to be based on the predicate device, ie, VAX-D, as all these devices are based on the same principles of operation. The majority of the peer-reviewed literature evaluating spinal decompression is based on the study of the VAX-D device. The results can generally be applied to any of the devices in the decompression therapy category.

Proposed Mechanisms of Action. The description of the DRX9000 from Axiom Worldwide's Web site makes curious claims regarding the mechanisms of pain relief. The product description states:

> *The DRX9000™ is a nonsurgical, noninvasive procedure that was developed for the treatment of lower back pain caused by disc herniations, degenerative disc disease, sciatica and posterior facet syndrome. The process has been proven to relieve pain by enlarging intradiscal space, reducing herniation, strengthening outer ligaments to help move herniated areas back into place, and reversing high intradiscal pressures through application of negative pressure.*[1]

What is the Evidence?

The claim that this decompression or traction process reduces intradiscal pressure is controversial. Ramos and Martin[2] performed a case series measuring the intradiscal pressure of L4-5 intervertebral disc of five patients prior to and during traction on the VAX-D table. They only published data on three of the five patients. They found an inverse relationship between traction force and intradiscal pressure. However, Andersson et al[3] found that intradiscal pressure remains near baseline measurements with passive traction and actually increases with active traction. Some may argue that these negative findings were likely a result of muscular contraction during the manually applied traction and that this effect may be mitigated by the cyclic distraction/relaxation nature of decompression therapy tables.

In addition, the statement, "reversing high intradiscal pressures through application of negative pressure," insinuates that high intradiscal pressure is observed in patients with low back pain. However, the opposite has been noted. Sato et al[4] and Panjabi[5] have shown that intradiscal pressure is actually lower in degenerative discs than in normal discs. Theoretically, decompression/distraction may reduce intradiscal pressure in those with a so-called high pressure disc, as measured on discography with manometry, rather than in a degenerative disc. A 2001 study appears to support the contention that VAX D treatment temporarily decompresses the nerve roots in that dermatomal somatosensory evoked potentials appeared to improve after intervention.[6]

A 2006 Cochrane review of 24 randomized controlled trials on various forms of lumbar traction concluded that there was strong evidence that traction as a single treatment is no more effective than placebo, sham, no treatments or other treatments for patients with low back pain who may or may not have sciatica.

A recent systematic review focusing on spinal decompression via motorized traction for chronic discogenic low back pain was published in the September 2006 issue of *Pain Practice*.[7] The article was funded in part by Axiom Worldwide, the developer of the DRX9000. It is the first to focus specifically on motorized traction devices and analyzed the data from seven randomized controlled trails of low quality and three case series studies of low quality. Six of the seven randomized studies reported no difference with motorized "spinal decompression," with the other study reporting reduced pain but not reduced disability. The three case series studies (without control groups) reported 77%-86% reduction in pain. The article concluded that "data suggest that the efficacy of spinal decompression achieved with motorized traction for chronic discogenic low back pain remains unproved."[7]

The Workers' Compensation Board (WCB) of British Columbia, Canada, evaluated the use of vertebral axial decompression for low back pain in 2005.[8] The WCB Evidence Based Practice Group conducted "a systematic review on the effectiveness of VAX-D in treating low back pain associated with lumbar disc herniation, degenerative disc disease, posterior facet syndrome, sciatica or radiculopathy."[8] They concluded there is no evidence that the VAX-D system is effective in treating chronic low back pain caused by the aforementioned conditions.

A 2006 Cochrane review of 24 randomized controlled trials on various forms of lumbar traction concluded that there was strong evidence that traction as a single treatment is no more effective than placebo, sham, no treatments or other treatments for patients with low back pain who may or may not have sciatica.[9] However, lumbar traction continues to be utilized by physical therapists, and chiropractic and medical physicians based on empiric, anecdotal evidence. As with most treatments for spinal disorders, there may be a subset of individuals who benefit from lumbar traction. Fritz and George[10] described a clinical prediction rule to determine if lumbar traction is appropriate for some cases of lumbar radiculopathy.

The efficacy of DRX9000 therapy has not been studied in randomized trials. Claims made by Axiom Worldwide and practitioners marketing the DRX9000 device are based on a single uncontrolled study of 219 patients published in *Orthopedic Technology Review* (*OTR*).[11] *OTR* is not a peer-reviewed journal, but a newsletter targeted at orthopedic practitioners and health care administrators, self-touted as a "showcase for new products and a source of industry news to help improve the economics of the orthopedic practice."

In the *OTR* study, subjects completed a recommended protocol that included 20 treatments of "spinal decompression" over six weeks. The treatment sessions included 45 minutes on the equipment

followed by 15 minutes of ice and interferential current therapy "to consolidate the lumbar paravertebral muscles."[11] In addition, appendix A of the study described the treatment protocol as providing a daily predecompression myofascial release session using vacuum/interferential current treatment for 30 minutes with heat application. During the initial two weeks of the study period, patients were instructed to wear lumbar support belts, limit activities, were placed on light duty at work and were prescribed an anti-inflammatory medication. After two weeks, "medication was decreased" and moderate activity was permitted.

The authors reported successful treatment in 86% of the 219 patients. Success was defined as a reduction in pain to 0 or 1 on the Oswestry Pain Scale (presumably referring to the Pain Intensity question on the Oswestry Disability Index). They also reported complete resolution of pain, normalized lumbar range of motion and recovery of any sensory or motor loss. However, there is no documentation or quantification of the reported pretreatment sensory or motor loss in the article. The report mentions that 31 patients reported significant pain and disability despite some improvement in their overall pain and disability score. They did not qualify how they measured disability and there was no mention of the complete Oswestry Disability Index as being utilized in the study. From this report, the authors conclude that "with the biotechnological advances of spinal decompression, symptoms were restored by subjective report in 86% of patients previously thought to be surgical candidates and mechanical function was restored in 92% using objective data."[11]

At best, the Gionis study may be considered Level IV evidence[12] because of its methodology as an uncontrolled case series study. They study has obvious short-comings including lack of a control group, incomplete presentation of data and the confounding use of concomitant therapies including activity restriction, lumbar support belts, anti-inflammatory medications, ice packs and interferential therapy before and after each treatment session.

These devices' efficacy in the management of low back or radicular pain remains unsupported in the peer reviewed literature... This lack of proven clinical efficacy should be seriously considered before referring or seconding a recommendation that a patient pay out-of-pocket for these therapies.

Incidentally, the use of interferential therapy with motorized decompression type traction is a common practice in Germany. To evaluate the effectiveness of these treatments in isolation, Werners et al[13] conducted a randomized controlled trial comparing motorized decompression type traction therapy plus massage with interferential therapy. They found no significant difference in outcomes between the two groups.

Risks

Motorized controlled traction devices are not completely risk free. The VAX-D Web site (www.vaxd.net) states that not one single patient has sustained an injury since the first VAX-D treatment in 1987. However, Deen et al[14] reported on sudden progression of a lumbar disc protrusion during VAX-D treatment. During a patient's fifth treatment, his radicular pain abruptly increased to 10/10 on the visual analog scale (VAS) and VAX-D therapy was discontinued. Repeat magnetic resonance imaging revealed an extrusion with a caudally migrated fragment. The patient underwent microdiscectomy and the VAS score reduced to 0/10 at six weeks.

Insurance Coverage and Billing Issues

Private health insurance companies such as Aetna, Blue Cross of California and the Regency Group consider the VAX-D and other "spinal decompression" interventions as experimental treatment and do not provide reimbursement for this service. The out-of-pocket cost runs approximately $200 per session, with the recommended protocol being 20 sessions for a total cost of approximately $4000.

Axiom Worldwide partners with a company named Peer Review Network to provide insurance billing guidance to practitioners who own the DRX9000 device. In addition, Peer Review Network publishes a document entitled "PRN Newsletter" which attempts to promote the insurance coverage of the DRX9000 through CPT code "97799," an "Unlisted Physical Medicine/Rehabilitation Procedure," for 26 RVUs at a reimbursement of $284 per session. Peer Review Network's Web site[15] describes their medical technology assessment service which they offer to medical device manufacturers in an attempt to help establish successful reimbursement with insurance companies.

Conclusion

Myriad decompression-type powered traction devices are on the market, including the DRX9000 and VAX-D. These devices' efficacy in the management of low back or radicular pain remains unsupported in the peer reviewed literature. There may be a role for traction in some cases of low back pain; however, there is no current data to support these devices as being more effective than manual traction. This lack of proven clinical efficacy should be seriously considered before referring or seconding a recommendation that a patient pay out-of-pocket for these therapies.

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FDA Device/Drug Status

DRX9000: approved. VAX-D: approved.

Author Disclosures

- M Tyburski: nothing to disclose.
- V Akuthota: f-3, Physiatric Association of Spine. Sports and Occupational Rehabilitation (PASSOR).

Disclosure Key

Direct or indirect remuneration: a. royalties. b. stock ownership (options, warrants). c. consulting fees. d. loans from the sponsor. e. speaking arrangements. *Position held in a company:* f. board of directors. g. scientific advisory board. h. other office in a company. *Support received from sponsors:* i. endowments. j. research support for investigator salary. k. research support for staff and materials. l. discretionary funds. m. support of clinical staff or training. n. trips/travel. o. other sponsorship. *Degree of Support:* 1. less than $250 per year. 2. $250 up to $10,000 total support (from all sources combined) per year, or less than or equal to 5% company ownership if value of ownership is less than or equal to $10,000. 3. more than $10,000 total support (from all sources combined) per year, or more than 5% company ownership.