

**Vertebral Axial Decompression (Vax-D)
Technology Assessment
Washington State Department of Labor and Industries**

1. Background

How it came to our attention

The manufacturer contacted the department directly to request that special consideration and reimbursement be given to the Vax-D table.

Mechanics

Invented by Allen Dyer, MD, Vax-D is an air-powered version of a manual auto-traction table, split down the middle, which applies cycles of tension to the lumbar vertebral column. The table is designed to create lumbar vertebral body separation, which the company says unloads the spine through negative decompression of the nucleus pulposas.

A pelvic harness is attached to the lower body of the patient who lays prone on the Vax-D table. The patient grips handholds on the upper part of the table. The table separates in two, applying traction to the spine. An attached tensionometer delivers either automated or variably timed cycles of distraction and relaxation. The patient can stop the movement of the table by releasing the handgrips, which stops the tension immediately.

An average course of treatment in one study was considered 10-15 days of one 30 minutes session. The Vax-D manufacturer recommends 20 treatments at a rate of 5 times per week.

Purpose and Indications

The purpose of Vax-D is to provide traction without accompanying abdominal muscular contractions that other types of traction elicit. This is intended to lead to a condition where there is negative intradiscal pressure. Negative intradiscal pressure is speculated to help heal the annulus through the sucking back in of a herniation and a variety of other ways.

Other purposes served by the use of Vax-D's include:

- Displacement of the fluid to the internal portion of the nucleus thereby ameliorating pain and enhancing healing, creation of a diffusion gradient that enhances solute transfer,
- Reduction of inflammatory mediators responsible for inflammation and pain,
- Allowance for greater concentrations of anti-inflammatory medication to gather in the disc, and
- Sequestering the disc that may lead to quicker spontaneous resolution¹.

¹ Tilaro, F. *An overview of vertebral axial decompression*. 1998. Canadian Journal of Clinical Medicine. 5(1):1-7

Indications for use of Vax-D are limited to patients that have demonstrable presence of disc protrusion or nerve root entrapment. Information from the various studies and from the manufacturer suggests that contraindications include: Spondylolidthesis or spondylolysis, infection, neoplasm, osteoporosis, bilateral pars defect, fractures, surgical hardware in the spine, caudal equina syndrome, and lateral or central stenosis with severe secondary changes.

2. Regulatory Status

Vax-D was approved, as powered traction equipment, under 510(k) status in 1989 as being substantially equivalent to a pelvic traction belt called Vax-T, marketed by the same company. In 1996, Vax-D received clearance to market the Vax-D table, and named the modality “Vertebral Axial Decompression.” The 1996 FDA clearance allows the manufacturer to market the Vax-D in the following manner: “Vax-D achieves these effects through decompression of the intervertebral discs and facet joints, that is, unloading due to distraction and positioning².” Medicare does not cover VAX-D, by a 1996 HCFA decision.

3. Literature Review

There have been two peer-reviewed studies of Vax-D published in *Neurological Research* and *Journal of Neurosurgery*. Both studies were uncontrolled. Department consultants and medical practitioners in the field have noted problems with the design and methodology of these studies. In two studies done on auto-traction in 1985 and 1998, both by Gillstrom and Ericson, good clinical outcomes were noted, yet the herniated discs did not register any differences, so the actual mechanism by which the decompression of the spine is related to the outcomes is not clearly understood in the field.

Vax- D and Intradiscal pressure

Ramos. G., Martin, W. *Effects of vertebral decompression on intradiscal pressure*. 1994. Journal of Nuerosurgery. 81:350-353

The object of this study was to examine the effect of Vax-D on pressure in the nucleus pulposus of lumbar discs. Of the five cases, all had MRI-confirmed diagnosis of herniation of the disc. The study found that intradiscal pressure could be lowered to levels significantly below 0mm Hg, using the protocol of distraction/relaxation. The authors conclude that follow-up studies were warranted to look at clinical outcome achieved through the technology.

² Vertebral Axial Decompression manufacturers packet

In a letter to the editor of Journal of Neurosurgery, Dr. Alf Nachemson, whose work on intradiscal pressure is quoted in this study, stated that he believed the test results obtained were invalid on four accounts:

- The design did not incorporate a closed system to measure the pressure of the disc, which means that in degenerated discs, saline leaks out,
- Disregard of temperature and its effects,
- The authors did not calibrate the negative readings, and
- Lack of RCTs in scientific study should be of first importance.

Vax-D and Efficacy

Gose. E et al. *Vertebral axial decompression therapy for pain associated with herniated disc or degenerated disc or facet syndrome: An outcome study.* 1998. Neurological Research. 20:186-190

The second study is a non-comparative, descriptive outcome study of 778 cases from 22 medical centers. Patients were included who underwent a minimum of 10 sessions and had an MRI-confirmed diagnosis of a herniated or degenerative disc, or facet syndrome. The study measured patient's assessment of pain, mobility and ADLs. Treatment success was defined as a reduction in pain to 0 or 1 on a scale of 0-5.

Overall, 71 percent experienced a reduction in pain to 0 or 1. One percent had increased pain, 7 percent had no change and 70 percent improved by 3 units or more. Of the patients with mobility limitations, 77 percent experienced an increase in spine mobility of one or more grades. Of those patients unable to walk or capable of only limited walking, 78 percent had functional increases of one percent or more. Average satisfaction with the treatment was 2.4 on a scale from 0-3. The authors concluded that Vax-D should be considered a primary treatment modality for low back pain associated with lumbar disc herniation at single or multiple levels, degenerative disc disease, facet arthropathy and decreased spine mobility.

Vax-D: No evidence from controlled trials to support claims of efficacy. The Back Letter. 1998. Lippincott Williams & Wilkins. 13(9):97-105.

In the Back Letter, a publication for practitioners, the authors noted that the latter study had no control group, and suffered other methodological limitations. These included inadequate documentation of outcomes, no information on the form/methods of patient selection, little demographic information, no information on the way outcome data was collected, no long-term outcome data and no statistical analysis of their results. The authors conclude that the study, if viewed as one wing of a crossover study wherein patients try a variety of treatments and then crossed over to Vax-D, was flawed in not including information on other treatments.

Traction efficacy

Heijden. G, et al. *The efficacy of traction for back and neck pain*. 1995. Physical Therapy. 75(2): 18-28.

In a meta-analysis published in *Physical Therapy* magazine, the authors analyzed various research studies of traction devices. They concluded that the studies of efficacy of traction as a modality to decrease pain contain too many methodological flaws to determine that any specific traction devices had greater efficacy compared to other treatments. In the two studies noted earlier on auto-traction, which involved tables similar to Vax-D, clinical outcomes were noted but no change in discs occurred upon MRI imaging.

Classic studies on traction treatment have shown that active, or subject induced traction may only be effective at decreasing pressure and opening up disc space when the trunk muscle's of the patient are relaxed³.

Though Vax-D's manufacturer claims that their design does not evoke reflexive muscular contractions, and that negative pressure is induced, there is no evidence with randomly controlled, large scale studies, either on animals or humans that confirm that a lack of muscular contractions leads to negative pressure induction in the disc, or that this is conducive to healing.

4. Economic Issues

Vax-D has a high potential for use in workers compensation populations because its purpose is to treat degenerated and herniated discs without surgery. The Vax-D literature states that an average total cost for treatment course costs \$3,750.00, which includes initial, mid term and final evaluation. The Vax-D network online web-site states an average course of treatment generally runs from \$4,000 - \$5,000 dollars.

The cost per treatment is up to the provider but is suggested to be about \$175.00 and the recommended treatments per case is 10-20, depending on the diagnosis. According to the company web-site, "herniated discs generally respond within 15 to 25 sessions while patients with degenerated discs often achieve significant relief with 10 to 20 sessions. Patients with posterior facet syndromes usually achieve complete remission with fewer than 10 sessions."

When compared to less costly forms of traction, for an 11 month period, mechanical traction was billed to the Department 3660 times using CPT code 97012. An average single treatment cost the Department \$49.24 and average total costs per claim was \$90.62 with an average of 1.84 treatments per claim.

³ Andersson G., Schultz. A., Nachemson. A.L. *Intervertebral disc pressures during traction*. 1983. *Scandinavian Journal of Rehabilitative Medicine*. 9: 88-91

5. Other Health Insurer's Positions

Pacificare, QualMed and Blue Cross were contacted to determine if they covered this treatment modality. Though none of the respondents had heard of Vax-D, it would generally go to utilization review, and could possibly be covered if the primary doctor had referred the patient and it was medically justifiable and covered by the type of health plan.

Vax-D maintains an online bulletin board where many of the queries are about insurance coverage. The majority of these deal with rejected claims, including Blue Cross/Blue Shield, United Healthcare, and Cigna. The company recommends that the claimant be insistent with their policy holder, that they retain an attorney to collect from the insurance company or that the patient private pay through Vax-D's payment plan⁴.

6. Medical Profession's Opinion

The Department of Labor and Industries Physical Therapy consultant suggests that an MD oversee treatment, that specific contraindications are listed and made known to the provider, and would like to see data on any injuries incurred by this product. She also noted the lack of controlled studies and evidence to support the Vax-D claims and the lack of information about how many treatments creates clinical improvement upon MRI.

There was concern voiced from the Department's Associate Medical Director of Chiropractic that the studies did not incorporate an appropriate design (i.e. lack of comparative analysis, descriptive measurements used for conclusions, not enough information on patients).

Furthermore he was concerned that there have been no human or animal studies to determine that active traction of this type does not elicit muscle contractions, and that the findings in the various studies did not support Vax-D's claims that:

- ✓ Vax-D creates negative pressure
- ✓ Negative pressure is curative
- ✓ Other mechanisms of action occur and are curative

The Department recently received some information from ECRI on Vax-D, the purpose of which was to look at the state of the literature based on their search. The information included general comments noting the mechanics of the table, the decision by HCFA not to cover Vax-D, the uncontrolled nature of the case series and results from their search inquiries, see attached.

7. Governmental Policy

The Agency for Health Care Policy and Research's Clinical Practice Guidelines for Acute Low Back Pain in Adults does not recommend traction as an effective modality for treatment of acute low back pain, though the studies did not delineate what type of traction was analyzed.

⁴ *Vax-D Network Bulletin Board*. 7/20/98. Vax-D Network. www.vaxd.net/wwwboard/messages/549.html

8. Comparison with Established Technologies

Traction

There are two forms of traction, active and passive. Furthermore, active or mechanical traction can be applied intermittently and continuously. Vax-D is listed by the FDA as powered traction equipment. The table provides intermittent traction, designed to be effective by distracting the vertebrae, creating negative pressure in the disc, which then sucks back a protrusion. In several studies it has been shown that active traction increases, rather than decreases intradiscal pressure due to the muscular forces that the patient exerts to withstand the traction. The company recognizes this and states their design is drastically different from traction because it does not activate muscle contractions. Whether Vax-D reduces intradiscal pressure to the negative ranges is still in question because of the questions regarding the research design used in the study measuring pressure during treatment with Vax-D.

Although Vax-D claims to be the only device on the market which delivers the type of traction needed to unload the spine, there are two other FDA listed and approved devices that also are designed to unload the spine, Tru-Trac and the DRS system. The DRS system, most often compared to Vax-D has a similar design and used Vax-D as their listed predicate device for FDA approval⁵. DRS' FDA 510(k) statement describing the effects is identical to Vax-D.

Flexion/Distraktion

There have been no studies to date comparing Vax-D with flexion/distraktion methods employed by chiropractors and osteopaths. The Vax-D network states that “the difference with Vax-D seems to be the greater amount of intradiscal pressure and the straight axial positioning, rather than placing the disc in flexion which sometimes produces greater stress on the damaged disc ⁶.

In a longitudinal study that looked at 1,000 cases, distraction methods used by chiropractors have shown evidence of demonstrated usefulness in the care of low back problems. The results showed that less than 4 percent needed subsequent surgery, less than 9 percent reached chronicity, average numbers of days until maximum improvement was 29 and the average number of treatments was 9⁷.

Conclusion

Vax-D is an FDA approved and classified form of traction, which, as a treatment modality, has not been established as more or less beneficial than other forms of traction. There have been no controlled studies that compare Vax-D with other types of traction, surgery or any other treatment, nor have there been studies on length of treatment. In the descriptive, outcome study mentioned above, a majority of patients surveyed felt improvement in pain and mobility. Other types of auto-traction have also shown good clinical results, though the mechanism for why has yet to be ascertained

⁵ DRS 510k summary. *FDA releasable 501k details*. June, 1998. www.fda.gov/scripts/cdrh/cfdocs

⁶ Online Vax-D Bulletin Board. *Vax-D versus Chiropractic/Osteopathic Technique*. 10/31/98. www.vaxd.wwwboard/messages

⁷ Cox, J., et al. *Distraction Chiropractic Adjusting: Clinical Application and Outcomes of 1,000 cases*. Topics in Clinical Chiropractic. Sept. 1996. 3 (3): 45-59