

AXIAL DECOMPRESSION DEVICES (VAX D)

VAX-D 3/2003

Dr S: What do you think of Vax-D Vertebral Axial Decompression? I have my own opinion which I openly share with my patients and insurance companies, but I would like to hear your thoughts. Thanks in advance

TH: Look at the FDA evaluation and approval of VAX-D- you will find it amusing. Particular note the information about advertising as a cure for herniated/degenerative discs. If someone in your community is advertising VAX-D as a treatment for herniated/degenerative discs and not just a traction device, they may have some legal issues to deal with. I would call and alert them to their potential problem as a matter of courtesy. I will check, but I think that is posted on the net.

M: I screened patients while in residency for Vax-D. I feel traction is a great treatment for radicular pain especially in the neck. In patients the Vax-D worked in, it was great. Unfortunately, when they discontinued the treatment the disc will over weeks return to its original form and the radiculopathy will return. I had to quit this job after 6 months because of my opinion. It is also very expensive. The company actually uses a percutaneous decompression code. On average, a patient has 20 treatments at an average cost of 250 dollars a treatment. This was in 1997. He is still advertising it today.

TH: This is FDA approved as a traction device- nothing more. I think your clinical experience with traction reflects that of many practitioners. VAX-D is very expensive and is one of the latest and greatest scams in medicine. I commend you for your honesty- if that practice involved promoting ineffective devices for financial gain, you are much better off without them. The "best" article, which was not randomized or blinded, showed an 80% efficacy in patients with lumbar herniated discs at one year. Gee, does that not just reflect the natural history of disc herniations? So, you can give me 4-6 grand and get better in a year, or you can do nothing and get better in a year. What a country.

TH: Here is an interesting page on VAX-D
Stephen Barrett, M.D

The VAX-D Therapeutic Table is a motorized device used to stretch the lower back. (VAX-D is an acronym for vertebral axial decompression.) The device is a two-part table in which the upper part is fixed to the table frame and the lower part slides back and forth to provide intermittent traction. [Click here for picture.] The patient is anchored to the lower part by a pelvic harness. United States patents have been issued for the table [1], the harness [2], and the table's operation [3]. VAX-D therapy is usually provided in an outpatient setting for the purpose of relieving back pain. Its providers -- chiropractors, medical and osteopathic physicians, and physical therapists -- commonly recommend 20 sessions of 30-45 minutes, with a total cost of several thousand dollars. During the treatment, the patient lies face-down with the upper part of the body on the stationary portion of the table, with arms overhead, grasping handles attached to the this part of the table. A pneumatic cylinder drives the two parts of the table apart and together to provide gradual stretching alternating with relaxation. (A typical cycle includes a minute of each.) [4] The patient can limit the amount of traction by releasing the handles if too much discomfort occurs.

The structures of the back include the spinal bones (vertebrae), their joints, the discs between the vertebrae, and the muscles and ligaments that hold these structures together. The intervertebral discs, which serve as cushions between the vertebrae, are composed of cartilage with a

gelatinous-like center called the nucleus pulposus. Discs can become damaged so that they bulge or tear. If a tear is large enough, the gelatinous material can leak out, a condition referred to as a herniated or "ruptured" disc, which can press against a spinal nerve and cause pain and loss of nerve function. Ordinary traction in which a steady stretching force is applied to the pelvis using weights and pulleys has not been proven effective against back pain [5,6]. VAX-D's intermittent traction can be effective for pain associated with bulging discs. However, manual manipulation, which costs far less, is equally effective. No type of traction has proven effective for herniated discs [7], which often require surgery. Although the VAX-D Therapeutic Table has FDA approval as a traction device, it is illegal to claim that it can correct a herniated disc.

Regulatory History

The Federal Food, Drug, and Cosmetic Act requires that all medical devices be safe and effective for their intended purposes and that manufacturers bear the burden of proof. The Act divides devices into three classes based on the principle that the greater the potential hazard, the more rigorous the regulatory requirements and the higher the class. Class I devices, such as bandages, tongue depressors, and others whose failure is unlikely to cause serious harm, usually do not require permission to market. However, to market a new Class II or Class III device, a manufacturer usually must go through an approval process. Devices that are "substantially equivalent" to others already approved require much less substantiation than would be required for those that are entirely new. Section 510(k) of the act requires manufacturers -- 90 days before starting distribution in interstate commerce -- to inform the FDA how they believe the device should be classified and what steps they have taken to comply with the rules for substantiation. The notice that is filed is commonly referred to as a "510K notification" or simply a "510K."

The VAX-D table and procedures were developed by Allan E Dyer, Ph.D, M.D., [8].who had served as Deputy Minister of Health in Ontario, Canada, from September 11, 1985, to October 5, 1987. Correspondence obtained from the FDA files suggests that Dyer obtained FDA approval for one purpose but later attempted to market it for another. On August 3, 1989, the VAX-T Pelvic Traction Belt secured 510K clearance to enter the United States marketplace after its manufacturer (VAT-TECH, Inc., of Ontario, Canada) notified the FDA that it was "substantially equivalent" to a pelvic traction device that had been marketed in interstate commerce for many years [8]. In 1991, Dyer amended this 510K to change the name to VAX-D [9].

In 1994, FDA district offices in Newark and Orlando began receiving calls from consumers asking whether the device was FDA-approved and whether claims made for it were valid [10]. As a result, early in 1995, Dyer was asked to clarify how the VAX-D was similar to the VAX-T and whether it has the same intended uses [11]. Dyer responded that "the VAX-D is the same device as previously identified as VAX-T in function and design," but he also claimed that the device could decompress the intervertebral discs as measured by a lowering of intradiscal pressures [12]. However, in May 1995, an FDA official concluded that the VAX-D was significantly different and that the "decompression" claim was a "new intended use" that required premarket approval and a new 510K application [13].

During the next few months, Dyer and a consultant attempted to explain that use of the word "decompression in VAT-TECH's literature was "an attempt to explain the mechanism of action" [14] and that other wording to which the FDA had objected were simply "meant to clarify or modernize terminology consistent with current medical practice." [15] In December 1995, the FDA notified Dyer that the new 510K application was deficient and that various claims would have to be either substantiated or stopped [16]. The key points were:

Although the device can reduce weightbearing forces on the spine, the term "decompression" could be misleading, since this is generally used to refer to surgical decompression of the spinal cord, which VAX-D does not do.

The device may be claimed to reduce pain but may not be claimed to relieve "neurological deficits" or any type of damage to the nerves that control movement.

Claims that herniated discs are corrected should not be made without substantiating evidence.

Claims that VAX-D therapy is "unique" must be stopped because the company has not proven that the device differs from other lumbar traction devices.

The claim that "almost all patients suffering from the common causes of low back pain and sciatica" must be stopped.

Claims for maintenance therapy should be discontinued [16].

VAT-TECH's responses described no information that the FDA considered sufficient to substantiate the claims that the FDA questioned. After some discussion, Dyer agreed to comply with all of the FDA's demands [17], initiated a recall of all previously distributed manuals [18], and warned its providers not to state that research had demonstrated that VAX-D caused "decompression." [19] VAT-TECH also notified its providers that its headquarters had been relocated (from Canada) to Palm Harbor, Florida [19]. The 510K application was approved on July 2, 1996. The company is now doing business as Vax-D Medical Technologies USA. The VAX-D table costs about \$125,000 [20].

Scientific Status

Proponents claim that VAX-D treatment can relieve low back pain by decompressing discs, improving the flow of nutrients into the disc, rehydrate dried-out discs, and thereby help restore the disc structure. Some of these claims are based on a 1994 study by Gustavo Ramos, M.D., and William Martin, M.D., who concluded that VAX-D can lower pressure inside the intervertebral discs [21]. The study involved five patients with protruding lumbar discs, but only the data for three patients were reported. The pressure within these discs was measured by inserting tiny tubes (cannulas) connected to a measuring device. The researchers reported that various levels of traction with the VAX-D device caused the intradiscal pressure to become lower. However, Alf Nachemson, M.D., Ph.D., the Swedish orthopedist who pioneered studies of intradiscal pressure severely criticized the experimental setup [22]. In the early 1980s, Nachemson and two colleagues found that during active traction, intradiscal pressure actually rises when the back muscles contract to resist the traction [23]. Equally important, it has not been demonstrated that intermittent lowering of intradiscal pressure can restore the structure or function of the disk. For these reasons, the FDA ordered VAT-TECH not to make any such claim [16]. Furthermore, even if VAX-D therapy can lower intradiscal pressure and reduce disk bulging while the patient is on the table, it has not been proven that such changes persist after the patient resumes standing.

Proponents also claim that a large study published in 1998 found that VAX-D was 71% effective in reducing pain in patients with herniated discs, degenerated discs, facet syndrome, and sciatica. This claim is based on data on 778 patients who had had at least 10 VAX-D treatments at one of 22 "medical centers." [24] However, the study was so poorly designed that no conclusions about effectiveness can be drawn from the published report:

The report does not specify how the patients were selected, how their diagnoses were made, what treatments each one had previously undergone, and whether they represented all of the patients who had undergone at least 10 treatments at these facilities. Nor does it indicate how many patients began treatment, how many dropped out before the tenth treatment, and why those who dropped out did so. Even assuming that the patients included in the report improved, the "percent improved" should be based on the number who began the treatment, not the number who completed it.

The assessments were made only by the patients. No objective assessments were made by the treating physicians or third parties. Although the report states that the amount of medication the patients used was recorded, these data were not included in the report. Before-and-after MRI studies capable of documenting whether the treatment reduced disc herniation were not reported and presumably were not done.

There is no control group, so that it is not possible to determine whether patients improved as a result of the treatment or would have recovered without it. Nor do the data enable comparison between VAX-D treatment and other forms of treatment.

The report does not state how the outcome data were collected, who collected them, and when they were collected. Nor is there follow-up information indicating whether any reported improvement was temporary or permanent.

Questionable Marketing

Vax-D Medical Technologies USA's Web site contains no violative claims. However, the company's medical director, Frank Tilaro, M.D., has made forbidden claims in journal articles published in 1998 and 1999 and in a presentation to insurance industry personnel in 1999. In the 1998 article, referring to the Ramos-Martin study, he stated:

"The significance of the study cannot be overemphasized. The reduction of intradiscal pressure to negative levels has far reaching therapeutic implications."

"Intradiscal pressure that is greater than capillary pressure in the vertebral body impedes oxygen diffusion to the disc which in turn impedes healing. Reducing intradiscal pressure with VAX-D creates a diffusion gradient into the disc that allows nourishment to proceed."

"By significantly reducing intradiscal pressure, VAX-D promotes retraction of the herniation into the disc." [4]

The article also stated that "Many patients who receive VAX-D therapy have had chronic back pain and failed numerous modalities including traction. Their positive response . . . confirms VAX-D's assertion that it is not conventional traction." [4] Dr. Tilaro's 1999 article reported on a study of the charts of 17 patients who had undergone VAX-D therapy at an unspecified outpatient clinic [25]. Certain sensory nerve function measurements had been made before and immediately after treatment. Although most patients had improved scores, the study has too many flaws to be considered clinically meaningful. There was no control group, which means that it is not possible to be certain whether the results were due to the treatment or to other factors (such as the passage of time). In addition: the patients were not randomly chosen; their clinical status was not reported; the people who measured and recorded the data were not blinded; and there were no follow-up scores.

An insurance investigator who attended Tilaro's 1999 presentation has told me that: (a) its purpose was to convince the attendees that VAX-D is different from traction and should be reimbursed at a higher rate using a different reimbursement code; (b) Tilaro claimed that special FDA approval distinguished VAX-D from traction; and (c) Tilaro distributed handouts [A] **containing claims prohibited by the FDA [26,27]. In addition, when the investigator requested further information through the company's Web site, he received a document containing violative claims [28].**

During the 510K clearance procedure, the FDA warned VAT-TECH that it would be inappropriate to use testimonials for marketing purposes. Although none appear on the company's Web site, other sites display them.

The VAX-D Network sponsored by Allied Health Management, Ltd, of Bridgeton, Missouri, offers information about the procedure, a practitioner directory; testimonials; and a message board where visitors can post comments and questions. The site states that more than 140 VAX-D units are operating throughout the United States, Puerto Rico, Canada and Australia and that more than 1,000 patients are treated each month. Several pages contain claims that the FDA told VAX-D's manufacturer not to make. The home page claims -- apparently based on the 1998 report -- that "low back pain sufferers with herniated discs, degenerated discs, facet syndrome and sciatica now have better than a 70% chance of resuming a normal life without the risks and complications associated with surgery." An interior page states:

The MRI picture which follows shows a severe herniated and extruded lumbar disc. A radiologist and surgeon, being unfamiliar with and having had no previous experience with VAX-D, both stated that surgery was the only solution available. However the patient, not wanting to undergo surgery, elected to be treated with VAX-D. After VAX-D, the MRI demonstrated significant improvement, the patient was pain free and returned to normal activities [29].

The testimonial page contains many brief messages in which patients describe how their

pain was relieved. The descriptions do not have enough detail to analyze what happened to these people.

Universal Pain Technology Canada (UPTC), Inc., of Prince George, British Columbia, is marketing the Decompression, Reduction, Stabilization System (DRS System), which it describes as a "redesign" of the VAX-D Table that received FDA-approval in 1998 as a mechanical traction device. The claims made for the DRS on UPTC's Web site and in its marketing materials are identical to those made for the VAX-D.

UPTC's president, Tim Emsky, also administers the Community Back Centers Web site, which offers articles, a directory, and many anecdotes in which patients describe how their pain was relieved with VAX-D therapy. Its "Question about VAX-D" page claims that the treatment was effective for patients with herniated discs suggests that it is an alternative to surgery. Most of these anecdotes contain insufficient detail to understand what happened, and some describe problems that could not possibly have been fixed by VAX-D treatment. A Chirobase consultant who reviewed the reports believes that the patients who found relief as a result of VAX-D traction could have experienced similar relief through less-expensive treatment by hand and, in some cases, with less risk of injury.

It is also clear that individual practitioners are making violative claims. In Allentown, Pennsylvania, for example, the Vax-D procedure has been heavily advertised on the radio and in the newspaper as an alternative to surgery [30]. No well-designed study has demonstrated that VAX-D therapy can substitute for appropriately recommended surgery.

Insurance Considerations

Each year, the American Medical Association issues a list of descriptive terms and numerical codes for reporting medical services and procedures performed by physicians. The resultant database -- called Current Procedural Terminology -- is then incorporated into manuals published by the AMA, insurance companies, and commercial publishers. These codes are referred to as "CPT codes." Some VAX-D providers have attempted to get paid by using CPT Code 64722, which is for surgical decompression of one or more nerves. Other providers have used CPT Code 97799, which is for "unlisted physical medicine/rehabilitation service or procedure." The correct code is 97012, which stands for mechanical traction.

One of the handouts at Dr. Tilaro's seminar for insurance personnel stated that in 1999, Relative Value Studies, Inc., had designated a temporary code of 97532. to represent "Dynamic Vertebral Axial Decompression Progressive; through variable timed tension distraction-relaxation cycles with continuous monitoring, recording and interpretation, per session." [25]. However, this code does not appear in either the 1999 or 2000 CPT manual.

Whether a service is covered depends on the contract between the insurance company and the insured person. Procedures considered unproven or experimental are not usually covered. Medicare and some insurance companies don't cover VAX-D. Aetna U.S. Healthcare considers it unproven and does not cover it through its managed-care and commercial plans [31]. Some companies cover it as a form of mechanical traction, for which they pay far less than the typical \$175 per session charged by VAX-D providers. I don't know whether any companies pay the full charge or -- if they do -- whether they understand what they are paying for.

The Bottom Line

VAX-D is an expensive high-tech form of mechanical traction that can provide relief in some cases of back pain but is widely promoted with unsubstantiated claims that it can correct degenerated and herniated discs without surgery. When the FDA cleared VAX-D table as a traction device, it set limits on what the manufacturer could claim. Individual

providers, provider associations, and the manufacturer itself have exceeded these limits. VAX-D therapy may provide relief for properly selected patients. However, there are good reasons to believe that manual treatment can usually accomplish the same thing more quickly, safely, and less expensively.

**Additional Information on Chirobase
Misleading Advertisement for Vax-D
Insurance Seminar Handout #1
Insurance Seminar Handout #2
Vax-D Flyer**

510K Correspondence (1995-1996)

Acknowledgement

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Chirobase Home Page

TH: Thanks for the informative article. Recently, I had the opportunity to review some of this literature and comment on the use of Vax-D. I thought it was "snake oil", but now I am sure of it. My conclusion after reading the multiple articles I had access to (which were provided by a Vax-D owner) was that "if you have a back, you are a candidate for Vax-D"