Is VAX-D the same as Traction?
How is VAX-D different than other devices?

Many patients and physicians have asked if VAX-D Treatment is any different than 'traction'. In addition, the emergence and success of VAX-D Therapy has spawned a host of new medical devices (copycats) all claiming to be the same as VAX-D in their principles of operation and in their success rates. This has created a lot of confusion and questions about their similarities and effectiveness.

These devices claim to utilize newer 'state of the art technology' equivalent or superior to VAX–D Therapy. They claim to have equal or greater success rates than VAX-D (as high as 86%) with less complications, and at cheaper prices. Upon investigation, you will find that these statements are just not true. In fact, virtually all of the VAX-D imitators are using linear traction technology. This means an electric motor and winch and cable mounted in a column or attached to the end of a table on a bracket. These devices are actually using traction technology that emerged prior to 1986.

This is a very revealing excerpt from the Food and Drug Administration 510(k) clearance for DRX:

"The DRX System incorporates various principles and working characteristics of the predicate device the Tru-Trac 401 Traction Device (1986). A traction unit is mounted onto a separate vertical structure at the foot of the bed. The incorporation of the traction device and flat surface bed, whilst giving a new overall appearance to the apparatus has not impacted or changed the effectiveness of the device. The system is designed to provide static, intermittent and cycling distraction forces.

The Tru-Trac 401 has been in use in this country for more than ten years. The intent was to incorporate an existing and well tried device and produce an aesthetically pleasing medical device."

They also make all kinds of statements in their promotional campaigns that are not based upon scientific research. The following claim is an example:

"Research using the VAX-D machine shows a decrease in intradiscal pressure. Any traction protocol that uses the right amount of force and protocol will have the same positive results shown in the research. In other words, the decompression phenomenon is not unique to the VAX-D, but can be replicated on any traction machine."

This is like saying, because a 'Formula 1' car can do 200 mph, therefore all cars can do 200 mph. They all claim to achieve decompression of intervertebral discs, however there are no published clinical studies using pressure monitors to support their claims.

You will note that most of them quote VAX-D research in their promotional campaigns and websites. Many of their so-called 'clinical studies' are not published in *peer-reviewed medical journals.* Unfortunately, linear traction has not been shown to lower intradiscal pressures, and has had a dismal track record with chronic low back pain, and is even contra-indicated for patients with herniated discs!

VAX-D® is patented technology that is producing consistent results (70% success rate) in each of the 500+ systems in the field. Some of the current traction tables make the claims that VAX-D is actually simply a programmed intermittent traction mode. They claim that the same forces and cycling can be replicated with their traction tables by entering the appropriate ramping, static, rest and hold cycle programs. These claims are just not true.

History of Traction:

Traction has been in use for many years as an unsupervised physical therapy modality. A variety of devices have been utilized to apply traction forces in novel ways, such as electronic motors with winch and cable mounted on the table or in a separate column, bed traction with weights, split/ floating tables, tilt tables, gravity inversion devices etc.

Traction Table
-Electronic winch and cable
-Table Mount

According to the orthopedic text 'Adult Spine-Principles and Practice,' "at least seven randomized clinical trials of conventional traction have been published, with striking consistency in their results. None of those trials demonstrated any significant benefit for traction over the control treatment. The control treatments in these studies included sham traction, bed rest, heat and massage.

This data clearly supports the consensus view of the *Quebec Task Force on Spinal Disorders* which concluded that there was no scientific evidence to support the use of spinal traction in the either the diagnosis or treatment of low back pain and discogenic disease."

Many years ago a pioneer in the back pain field named Cyriax hypothesized that distraction ***should*** be able to produce negative intradiscal pressure, which, if strong enough, could suck a herniated disc back in. Another researcher Kuslich stated that "we may find a really effective treatment for low back pain and sciatica when we learn how to decompress a nerve atraumatically.

Anderson and Nachemson placed pressure transducers in four subjects in the lumbar spine during autotraction and manual traction procedures. They found that the intradiscal pressures went up dramatically in both cases. They concluded that at no time was negative intradiscal pressure observed, and therefore the disc could not be sucked back in as proposed by Cyriax.

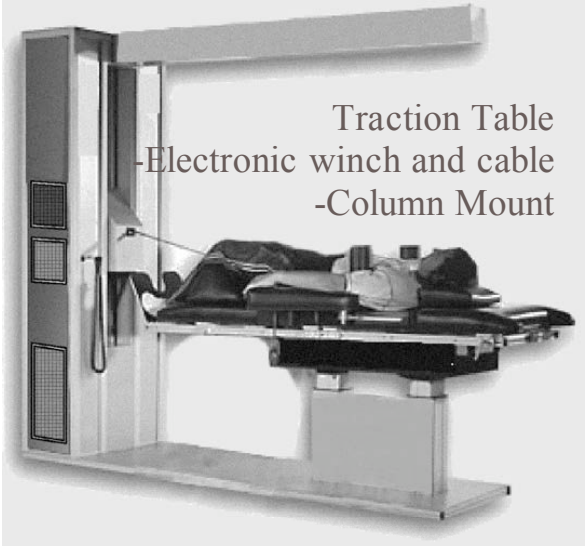
They suggested that in order to produce a relative reduction in disc pressure, traction must be administered in such a way as to allow trunk muscle relaxation. Traction can be expected to *increase* intradiscal pressure and could therefore aggravate a protruded, herniated or extruded disc.

Intuitively, lumbar decompression should be successful in alleviating many of the conditions which cause low back pain and associated radiculopathy. The successful application of lumbar distractive forces was limited by the design of mechanical devices.

VAX-D Therapy vs Traction Devices

Technological advances have now led to the development of equipment, the VAX-D Therapeutic Table and Console. The equipment allows controllable, effective axial distraction and decompressive tensions to be applied to the lumbar vertebral column. Distractive forces are applied and released in a progressive logarithmic fashion.

With conventional mechanical traction applied to the lumbar area, patients are treated in the supine (face up) position. With these devices the patient's upper body is secured and restrained with a chest harness (referred to as thoracic restraint). These tend to restrict respiration, and they may compromise venous return to the heart. More importantly, restraint of the upper body with chest harnesses rapidly causes trunk muscles and paravertebral muscles to guard against the pull, resist the tension, and then contract and resist. As demonstrated in the literature, this results in an increase in



intradiscal pressure. This is actually 'contraindicated' in the treatment of compressed discs and spinal structures.

Gravity lumbar traction utilizes the body's own weight as the source of traction force. Traction force is increased by increasing the angle of incline. There is a potential for brachial plexus nerve compression and damage in the axillae (under arm). The greatest limiting factor has been chest pain caused by chest compression. Several investigators have documented the adverse respiratory effects with chest compression. Trunk muscle contraction also tends to increase intradiscal pressure.

VAX-D patients are placed in a prone position and utilizes handgrips which the patient grasps with arms extended above the head (like hanging from a bar) to stabilize and restrain the upper body during lumbar distraction. Thoracic restraints are not used and there is no risk of chest compression and circulatory or respiratory compromise. Although holding on to handgrips may create some transient discomfort in the shoulders for a few patients, the stress on the shoulder girdle attests to the fact that the tension applied to the pelvis is, in fact, transmitted along the linear axis of the spinal column rather than via muscular recruitment that tends to be elicited when chest harnesses are employed.

The principles utilized in the treatment are patented (an operational patent or procedure patent). It is noteworthy that VAX-D as been recognized by the US government through the granting of US Patent No. 6,039,737 entitled 'The Operation of a Vertebral Axial Decompression Table.' This patent describes the complicated therapeutic equation and defines the logarithmic time/tension relationship. Traction devices are not capable of applying tension in a logarithmic time relationship.

Conventional traction devices apply traction forces by winding a cable around a pulley by an electric motor. The motor/device has several programmable modes to apply force in a *linear* fashion. Forces can be applied statically, stepwise (often called 'dynamic or progressive') in a cyclic fashion or in a combination of these. The forces are applied to a harness fitted to the patient, not to the movable sections. The VAX-D Table does not utilize gradual step-wise traction. The winch and cable mechanism common to these traction devices does not incorporate VAX-D patented technology, yet many refer to VAX-D published research to support their advertising claims.

The VAX-D Table utilizes pneumatic cylinders coupled with hydraulic damping, as the drive/damping mechanism for the pre-tension and for the therapeutic program. The technology applies and maintains a baseline tension of 20-24 pounds (the pre-tension) to the patient's pelvis throughout the treatment session (even during the rest periods) and the distraction cycles then move from the pre-tension range up to a pre-selected

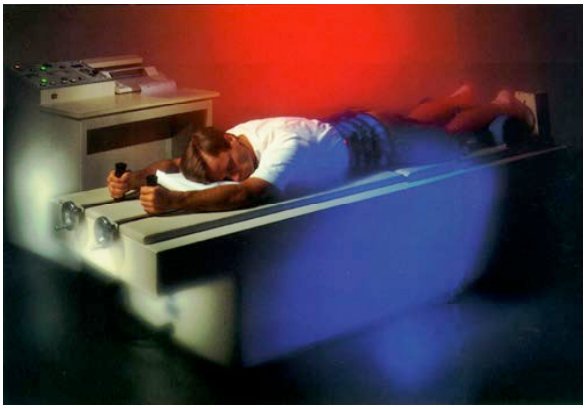
therapeutic tension. The above parameters are absolutely critical to the success of the treatment.

The pneumatic-hydraulic cylinders are used to separate the lower table section from the upper section and apply the tensions to the patient's pelvis. The pneumatic--hydraulic drive mechanism, as compared to the cable and pulley mechanism of most devices, provides for a precise control of the amount of tension and is able to apply tensions in a logarithmic time/force curve.

The pneumatic-hydraulic drive mechanism is applied in both the distraction and retraction movements of the Table providing for a smooth, controlled operation and a gradual return of the patient to the starting position each time.

The pelvis is secured with a patented harness that adjusts snugly and is designed to apply forces primarily to the lateral pelvic alae thus minimizing anterior-posterior pressures.

To achieve optimum control of the application of distractive tensions it was found essential to develop a harness that would attach directly to an electronic tensionometer that continuously monitors and provides feed-back of the tensions being applied to the spinal column. This harness is the subject of an individual patent. The harness design also facilitates proper placement necessary to attain reproducible results.



There is now a body of research that distinguishes and establishes VAX-D technology as the conservative treatment of choice for herniated and degenerative discs.

Decompression Therapy

There is also a lot of confusion and questions regarding a host of new medical devices on the market all claiming to utilize 'decompression therapy' for the treatment of low back pain.

A clinical study on nerve root decompression states the following:

"Traditionally, the term 'decompression' as applied to the spine has referred to nerve root decompression. Surgery for decompression has been directed at the radiographic sites

of nerve root entrapment including the removal of herniated disc material or osteophytes (relief of neurocompression). Surgery is often focused on nerve root decompression to relieve radicular pain and any improvement in back pain follows as a secondary benefit."

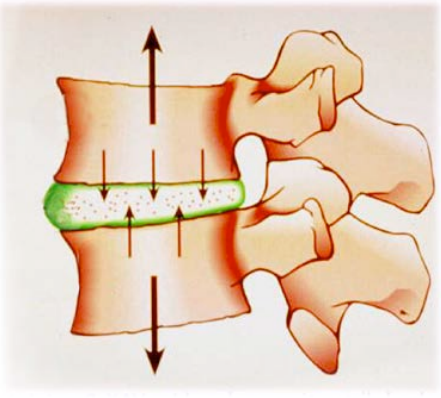
"Dermatomal Somatosensory Evoked Potentials (DSSEP's) are an established effective tool for assessing single nerve root function pre- and post-operatively. Successful treatment by VAX-D therapy resulted in clinical reduction in pain and improved DSSEP waveforms suggesting that nerve root decompression is occurring at multiple levels (Naguszewski W. Naguszewski R., Gose E.)."

The manufacturers of todays so-called 'decompression' devices' produce abundant amounts of marketing materials claiming success rates of 85% plus. They make claims of 'revolutionary breakthroughs' and of utilizing 'state of the art technology' and 'high tech pain reduction and healing systems'. All of this without published peer reviewed clinical research studies on intradiscal pressures or patient outcomes to support their claims. When considering any treatment, ask if the studies are valid. Who performed the study and what are their credentials? Was the study published in a peer reviewed (recognized) medical journal?

Decompression is defined as "a relief or reduction of pressure". The fact is, the only way to measure disc decompression (ie decreases in intradiscal pressure) is through the use of pressure sensing equipment, in a closed system, that has been introduced into the intervertebral disc, and measures pressure changes. Decompression of discs with VAX-D therapy has been measured by researchers at the Departments of Neurosurgery and Radiology, Rio Grande Regional Hospital, McAllen, and Division of Neurosurgery, Health Sciences Center, University of Texas, San Antonio, Texas.

Despite the claims by the copycat devices, pressure changes simply cannot be measured by radiography or fluoroscopy.

Have a close look at these revolutionary devices. Are they really offering different technology that the old Tru-Trac Traction device? Do they have an electric motor, winch and cable mounted on the table or in a column?



One thing is for sure, none of these systems incorporate the principles and working characteristics of the VAX-D Therapeutic Table as they state. The principles and working characteristics of VAX-D are in fact patented in the United States and Internationally.

Misleading Advertising: Is it legal or illegal?

According to the Federal Food, Drug & Cosmetic Act (FFDCA-Section 502) a product is considered '*Misbranded'* if its promotional material and labeling are false or misleading in any manner. Section 502(a) declares that a drug or device is misbranded if:

(a) its labeling proves false or misleading in any particular. This phrase "false or misleading" is not confined in meaning to untrue, forged, fraudulent, or deceptive. In fact, the word, statement, or illustration may be true in the strict sense of the word; however, the labeling can be deemed by the FDA to be in violation of the law if it proves deceptive to the customer. It is not a necessary condition that the labeling should be flatly and baldly false; the work "misleading" in the Act means that labeling is deceptive if it is such as to create or lead to a false impression in the mind of the reader. A "false impression" may result not only from a false deceptive statement, but may also be instilled in the mind of the purchaser by ambiguity or

(b) the product is promoted with unsubstantiated claims of therapeutic value;

(c) If there is any representation that created an impression of official approval because of the possession by the firm of an FDA registration number.

Summary

Today's healthcare market is replete with super-salesmen with a cloak of new promotional campaigns that utilize scientific references.

What sells is not the quality of the product, but the ability of the marketer to influence their audience. Even when they realize their treatment method is unproven, they attempt to minimize this by mentioning
that it has been proven to the satisfaction of the FDA or one of the recognized medical societies.

The best way to avoid being taken in is to do your homework when considering new treatments, and this includes ours. Ask for copies of all of the published research on the treatment including clinical and patient-relevant outcomes. Make sure they substantiate their claims of therapeutic value.

Unfortunately, in today's health care market separating the 'hope' from the 'hype' is no simple task.

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