VAX-D TREATMENT vs TRACTION

1. Unlike most traction devices that treat the patient in the supine position, the patient is only treated in the prone position on the VAX-D Table, and there are several reasons for this. The primary one is that most disc protrusions and herniations that result in nerve compression are posterior in nature. Traction forces that distract this intervertebral spaces in the supine position may aggravate the condition, whereas distraction in a prone position is believed to be biomechanically more appropriate for the retraction of a posterior herniation. In the Summary of Safety and Effectiveness from the US Food and Drug Administration it states that "the VAX-D® Therapeutic Table is designed to relieve pressure on structures that may be causing low back pain. It relieves the pain associated with herniated discs, degenerative disc disease, posterior facet syndrome and radicular pain. It achieves these effects through decompression of intervertebral discs, that is, unloading, due to distraction and positioning".

In addition, most patients are unable to relax and comfortably hold on to handgrips in the supine position when forces of up to 100 pounds are being applied for 30 minutes, so the patient positioning is critical with this type of treatment.

2. With conventional lumbar mechanical traction the patient's upper body is secured with a thoracic corset (i.e., a chest harness). At the distraction tensions utilized in VAX-D, conventional thoracic corset used to restrain the upper body are uncomfortable, they tend to restrict respiration and can compromise venous return to the heart. Under arm restraints under strong traction can place the brachial nerve plexus in jeopardy. Axillary pressure has long been recognized as a cause of brachial palsy as in such cases as people who carry their body weight on the axillae when using the older type of crutches.

VAX-D utilizes handgrips which the patient grasps with arms extended above the head (like hanging from a bar) to stabilize the upper body during lumbar distraction thus eliminating the use of a thoracic corset. Consequently, there is no risk of circulatory or respiratory compromise.

The distraction strength applied is limited by the ability of the patient to maintain a firm hold of the hand grips throughout a treatment session. The distraction strength is generally increased to the 'hand hold' tolerance level of the individual patient during a treatment session. Another important safety advantage of VAX-D is the fact that the patient can release their grip at any time terminating the distraction forces immediately. This quick release feature is not possible with axillary/chest harness restraints.

- 3. The pelvis is secured with a patented harness that adjusts snugly and is designed to apply forces primarily to the lateral pelvic area thus minimizing anterior-posterior pressures.
- 4. Distraction mechanism:

The treatment combines a number of internationally patented principles, which are administered via an automated system incorporated in the design of the Therapeutic Table and Control console. Unlike conventional lumbar traction devices, the VAX-D Table utilizes pneumatic cylinders (coupled with hydraulic damping) as a drive mechanism 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 df 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 higher the tension increases, the slower the distraction rate becomes). 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.

In addition, unlike conventional traction devices that apply forces in a cyclic fashion, the VAX-D Table maintains a baseline static tension of 20-24 pounds to the patient's pelvis throughout the treatment session (even during the rest periods) and the distraction cycles then move from the 20-24 pound range up to 100 pounds. The above parameters are absolutely critical to the success of the treatment.

The 'actual' tensions transmitted to the lumbar spine are accurately (and directly) measured by a tensionometer attached to the patients pelvic belt. The distraction tensions are monitored on a digital gauge as well as recorded on a pan-writer chart recorder printout.

5. Treatment time for conventional traction varies from 15 to 30 minutes and the frequency varies depending upon the patient's diagnosis and response to treatment. With VAX-D, the treatment time is set at 30-45 minutes daily. Patients can be treated longer in each daily session if their arms will tolerate the forces. The treatment cycles should be continued until the patient is 'pain-free' on the Table and 'pain-free' upon rising from the Table. Patients must then lie and/or sit to rest for about a half an hour after the actual treatment has been completed to prevent reactive paravertebral muscle spasm. Treatments do not vary in frequency, but must be given consecutively (daily) for approximately 18-26 sessions.

Many standard traction devices often provide 'step wise' traction for patients. The VAX-D Table does not utilize gradual stop wise traction. VAX-D distraction is applied in a logarithmic t1me/force curve.

Anderson et al. (1) placed pressure transducers in the L3 disc in four healthy volunteers during autotraction and manual traction. They found that intradiscal pressure went up in direct proportion to the force of pull during autotraction. Mean intradiscal pressure in the supine position was 110 kPa arid standing was 270 kPa. During autotraction, intradiscal pressure went up to 504 kPa and during manual traction intradiscal pressure averaged 280 kPa. It was hypothesized that contraction of trunk muscles was responsible for increased intradiscal pressure during these two forms of traction. Anderson at al. concluded that at no time was negative intradiscal pressure observed, and therefore the disc could not be sucked back in, as previously proposed by Cyriax. They went on to suggest that in order to produce a relative reduction in disc pressure (le. below that obtained in the supine position but not actually negative), traction must be administered in such a way as to allow trunk muscle relaxation. In fact, increasing intradiscal pressures is considered contraindicated in patients with herniated discs. There have been no published studios demonstrating that traction is capable of lowering intradiscal pressures.

Cyriax (2) has hypothesized that distractive forces can produce negative intradiscal pressures, which if strong enough can actually suck the herniated disk back in. Clinical discomanometry research carried out at the Departments of Neurosurgery and Radiology, Rio Grande Regional Hospital, McAllen, Texas, in which intradiscal pressure changes were recorded during VAX-D, established that "Tension in the upper range was observed to decompress the nucleus pulposus significantly, to below -100 mm Hg". The extent measured in mm. Hg. follows an inverse relationship to the tension applied to the pelvic harness during treatment in patients on VAX-D. An article on these clinical studies was published by Dr. G Ramos, and Dr. W. Martin (J. Neurosurgery 81:350-353,1994). This is one of the fundamental difference between VAX-D and conventional traction.

6. Follow up treatment. With conventional lumbar traction, a follow up treatment of exercise, work hardening, posture and training is recommended. With VAX-D, patients are advised not to commence any work hardening exercise program for at least 4 weeks post treatment. We do not wish to increase the patients intradiscal pressures during the post treatment period.

According to the '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 (3,4,5,6,7,8,9). It is clear that gravity inversion has important ocular and cardiovascular side effects. These data clearly support the consensus view of the Quebec Task Force 011 Spinal Disorders which concluded that there was no scientific evidence to support the use of spinal traction despite its widespread application in practice (10). "

In a recent study Dr. Earl Gosa (Professor of Bioengineering, University of Illinois at Chicago) and Drs. William and Robert Naguszowskl (Neurologists with the Coosa Neurosurgical Clinic in Georgia) (11), reported on data from over 780 patients, demonstrating an overall success rate of 71 percent for VAX-D treatment.

<u>Relative Value Studies, Inc. (RVSI)</u>, the most widely utilized system for private payer relative value information, authors, edits and contracts for the publishing of the Relative Values for Physicians. RVSI supplies information, products and services to health care providers, federal and state agencies, insurance companies, associations, health care attorneys and consultants. RVSI was responsible for conducting the Relative Value Survey for the VAX-D Medical Treatment. The Relative Value for Vertebral Axial Decompression as established by the Relative Value Survey is 28.

Effective January 1, 1999 an Interim Code for Vertebral Axial Decompression was issued. The actual code and descriptor is as follows:

97532. Dynamic Vertebral Axial Decompression Progressive; through variable timed tension distraction - relaxation cycles with continuous monitoring, recording and interpretation, per session.

This code is a medical procedure code that is considered as "incident to" services provided by a physician (M.D/D.O.). The interim code is published in the 1999 Relative Values for Physicians (RVP)