THE PRACTICE OF
MINIMALLY INVASIVE
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2005 EDITION
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Martin H Savitz, John C. Chiu, Wolfgang Rauschning, Anthony T. Yeung

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Introduction

Reduction of nuclear protrusion by spinal distraction was practiced even before the intervertebral disc was recognized. A 14th Century translation of Albusasia’s Surgery illustrates lumbar manipulation during spinal traction. Appolonius of Kitium describes a form of distraction 2000 years ago. Guidi (1544) illustrates a traction table in his Cirugia, and one of his tables can be found in the Wellcome Historical Museum of London. In their book on manipulation past and present, Cyriax and Schotz illustrate the employment of traction by Hippocrates (400 BC), Galen (131-202 AD), and the Spanish-Arabian physician Abu’ L Qasim (1013-1106).

Today, two methods of performing traction are practiced – the sustained manner preferred by Cyriax and various forms of intermittent traction. Intermittent traction can be done electronically, manually (therapist), or by the patient (autotraction). The effects of sustained traction have been investigated. An increase in body length of 10-30 mm was demonstrated in healthy males when a sustained force of 60kg was applied for 1 hour and was lost at 4mm/hr. In the excised spine the greatest separation was in those subjects with wide disc spaces and least where there is evidence of disc degeneration. Other investigators confirmed an increase in stature
over and above that known to occur when the load is taken off the spine by lying down. The findings suggest that most of the vertebral separation takes place within the first 30 minutes. During normal traction, the enlargement between two consecutive lumbar endplates is between 1.0 and 1.5 mm. Other studies have demonstrated a widening of the lumbar intervertebral space of between 3 to 8 mm measured radiographically due to gravitational traction.\textsuperscript{10,20} Anderson et al have shown an increase in intradiscal pressure with certain traction techniques.

The heavy lumbar paravertebral muscles exert resistance to distraction, and at least 30-35 kg of force is required to influence the lumbar spine.\textsuperscript{10} Others have shown that a force of at least 25\% of body weight is necessary to achieve lumbar distraction. With the split table, designed by Dr. Allan Dyer, he demonstrated that 25\% of the traction force is required for distraction to occur.

The effects of distraction include tightening of the posterior longitudinal ligament which exerts a centripetal force at the back of the joint. This maneuver may be of therapeutic value, particularly if the protrusion is located anterior and remains in close contact with the ligament. On the basis of biomechanical calculations significant intradiscal negative pressure may be achieved during sustained traction.\textsuperscript{5} One study has shown that a traction load of 30 kg causes intradiscal pressure to lower from 30 kp to 10 kp in the L3 intervertebral disc. Improvement in nutrition and deposition of reparative collagen and healing of annular tears and fissures has been suggested as a benefit of axial distraction.

Dr. Allan Dyer, former Deputy Minister of Health from Ontario, Canada a pioneer in the development of the external cardiac defibrillator, designed the VAX-D Therapeutic Table to apply distraction tension to the patient's spine without eliciting reflex paravertebral muscle contractions. A harness is attached to a tensionometer during separation of the movable pallet of the table. The distraction-relaxation cycles are automated or variable. Distraction tensions and rates are continuously monitored and measured by the tensionometer, and the output is shown on a digital gauge and captured on written printout.

**Procedure**

The VAX-D Table utilizes pneumatic cylinders coupled with hydraulic damping, as the drive/damping mechanism for the pretension and the program. The technology applies and maintains a baseline tension of 20 pounds (the pretension) to the patient's pelvis throughout the treatment (even during the rest periods) and the distraction cycles then move from the pretension level up to a pre-selected therapeutic tension. The above processes are absolutely critical to the success of the treatment. The pneumatic drive cylinders separate the lower table section from the upper section and apply tension to the patient's pelvis. The pneumatic/hydraulic drive mechanism provides for a precise control of the amount of tension and is able to apply the force in a logarithmic time/force curve. The pneumatic/hydraulic drive mechanism is applied in both the distraction and retraction movements of the VAX-D Table, and provides a smooth controlled operation with gradual return of the pallet to the starting position each time. To achieve optimum control of the applied distractive tensions, it was found essential to develop a harness that would attach directly to an electronic tensionometer that continuously monitors and provides feedback of the tensions being applied to the spinal column. The harness design also facilitates proper placement necessary to attain reproducible results.

Patients with discogenic low back pain with or without radiculopathy, who have failed conventional therapy, after 6-8 weeks are candidates for VAX-D therapy.\textsuperscript{21} Patients with
neurological deficits are also candidates since outcome studies have shown no difference with surgical or medical management.\textsuperscript{9} Patient with fusion or failed back surgery syndrome are also candidates.

Contraindications for VAX-D therapy include infection, neoplasm, osteoporosis, bilateral pars defect, unstable grade-2 spondylolysis, fractures, and the presence of surgical hardware in the spine. The patient should be evaluated by a therapist or physician prior to initiating therapy, and routine spine films are necessary to rule out any contraindications. A CT or MRI is not a prerequisite before therapy, but most patients have undergone neuro-imaging. A trained VAX-D technician administers the daily therapy for approximately 20 sessions. The occasional patient may require a short maintenance period where 2 to 3 treatments a week are given for 2 to 4 weeks following initial therapy. The average patient has required 20-25 sessions. Each session is 15 cycles, each cycle being one minute of distraction and one minute of relaxation.

Patients are instructed to wear loose clothing for each treatment. The patient is placed prone on the table such that the superior border of the pelvic harness is level with the split. The patient then grasps the adjustable handgrips, which are positioned to maintain the arms straight without bending the elbows. A small roll is placed under the patient's ankles; a chin or forehead roll is optional. Patients who have difficulty lying prone can use a pillow placed under the abdomen. Patients with shoulder pathology may employ a roll under the axilla. The patients are instructed to hold tightly to the handgrips, since motion artifact can be seen on the graph printout if the patients are pulling with their arms. This maneuver inhibits decompression. The patient is allowed to release their grip during the relaxation phase.

Figure 2. Note phases of pretension, tension ramping up, and desired tension stabilized on chart recording during treatment cycle of VAX-D.
A pretension level of 20 lbs. is set and maintained throughout the resting phase. Ramos \(^\text{15}\) demonstrated that 50 pounds of tension was the threshold tension necessary to develop negative intradiscal pressures. Women start with 50 lbs and work up to 70 lbs of tension. Men usually start at 60 lbs and work up to 80 lbs. Tension increments are in the order of 5 pounds every 3-4 days, although some patients tend to proceed more slowly. Tension should remain constant for each treatment (figs. 2, 3 and 3B).

If the centralization phenomenon, the movement of a pain pattern from a distal to a more proximal location, occurs in the early treatment stages, the patient is most likely respond to physical therapy and not require further VAX-D. Centralization may appear at a later stage of treatment or shortly after completion of a full VAX-D course. In patients with an intact annulus, no researcher has yet reported the results of CT discography prior to treatment, and following the onset of centralization. \(^3\) Pain during distraction that lessens with relaxation is probably due to stretching shortened tissue. If pain persists for more than 30 minutes after treatment the tension should be reduced for the next few sessions. The tension should be lowered or the treatment cycle stopped for pain that increases with each 2-minute cycle. Some patients require a 2-3 day hiatus from therapy if they have too much discomfort. The daily response to treatment, and any changes made, are recorded in the patients chart and reviewed by the physician and technician every few days.

Figure 3A. Decompression formula: $\text{Exp} (C^N \times \ln(BTi)) = BTn + (N \times \ln)$
Patients are encouraged to remain active but should not engage in strenuous activities while undergoing therapy. They should not be receiving any other treatment modalities while receiving VAX-D therapy. Patients may wear a back support after therapy, but it should be removed within 1-2 hours. Once the VAX-D course is completed, patients are encouraged to enter some form of rehabilitation program and learn proper biomechanics.

Discussion

Ramos and Martin \(^{15}\) studied intradiscal pressures during VAX-D treatment. Five cases with subligamentous disc herniation at L4-5, confirmed by MRI and scheduled for percutaneous discectomy, were chosen. Using lateral and antero-posterior fluoroscopy, a cannula was inserted into the nucleus pulposus of the L4-5 intervertebral disc. The pressure measurements were recorded by an Ohmeda pressure transducer connected to a Hewlett Packard pressure monitor via a saline bridge and a Camino fiberoptic intracranial transducer adapted for intradiscal measurements. Since the pressure transducers were designed to measure changes in the positive range, calibration was necessary. The pressure transducer and monitor for each patient were individually calibrated, and a correction curve was plotted showing the transducer readings versus actual pressures to correct for the nonlinearity of the instrumentation in the range of the negative pressures achieved. A pneumatic calibration analyzer was employed.

Distraction tensions ranging from 50 to 100 pounds were monitored on a digital readout and recorded on a continuous graph tracing by a chart printer incorporated in the control console. Intradiscal pressure changes were observed on the pressure monitor. Intradiscal pressures were significantly reduced to negative levels, ranging from 100 mm of Hg to a negative 160 mm of Hg. Changes in intradiscal pressure were minimal until a threshold distraction tension was reached. The relationship between percentage maximum tension and time was a logarithmic function. If one plots the percentage of maximum tension reached in 60 seconds vs. time, it takes 17-20 seconds to reach 50%, 25-28 seconds to reach 70%, and 42-45 seconds to attain 90%.
of the maximum. The retraction phase followed a linear time/tension relationship and returned to baseline in 25-30 seconds.

The first large-scale retrospective study\(^7\) involved over 700 patients with low back pain and with/without radicular symptoms. Over 70% achieved a positive outcome. Even though the study was not a randomized blinded trial, the majority of patients were suffering beyond the period where natural resolution would be expected. All had failed treatment with other modalities and demonstrated positive response during treatment and/or immediately thereafter.

Sherry et al\(^19\) conducted a prospective randomized controlled trial of VAX-D versus TENS. All patients had chronic symptoms (average duration of pain 7 years). TENS was regarded as a placebo. The data revealed an attributable success rate of 68.4% for VAX-D, significantly superior when compared to TENS (\(p<0.001\)).

A study by Ramos\(^15\) compared the effects of a sub-therapeutic treatment versus the protocol treatment. All patients had symptoms of sciatica and were referred to a neurosurgeon after failing conventional therapy. Imaging studies and the clinical examination were concordant. The protocol group demonstrated significantly superior results compared to the sub-therapeutic treatment group.

Two similar studies evaluating the effect of VAX-D on sensory dysfunction in cases of low back pain came to similar conclusions.\(^{14,22}\) Either Current Perception Threshold Neurometer or Dermatomal Somatosensory Evoked Potentials protocol was employed. Both studies demonstrated VAX-D capable of positively influencing sensory nerve dysfunction associated with compressive radiculopathy. Although compression is a frequent finding in sciatica compression does not explain all the observed symptomatology. Other factors include the force and rapidity of compression, the effect on arterial and circulation, and the release of pain, vascular, and neural modulators: nitrous oxide, phospholipase A2; the prostaglandins, and leukotrienes.\(^{3,6,16,17}\)

**Summary**

VAX-D should not be considered traction in the traditional sense but as decompression. VAX-D is the only non-invasive treatment that has been proven to decompress the disc; with other traction devices, there has only indirect proof. The patented therapeutic curve demonstrates that, when time is plotted against force, one observes a logarithmic function. Conventional traction devices have a linear time-force relationship. Non-steroidal anti-inflammatory drugs, steroids, and doxycycline have been given in conjunction with VAX-D therapy to study possible diffusion into the disc and any beneficial effects. Other concerns for the future include investigation of immunomodulators, transplanting fibroblast and chondrocytes, and minimally invasive surgical techniques in conjunction with VAX-D. The current focus may shift from treating back pain to repair and healing of a damaged disc.
References

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