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Clinical Research

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The Management Of
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CLINICAL RESEARCH SUMMARIES
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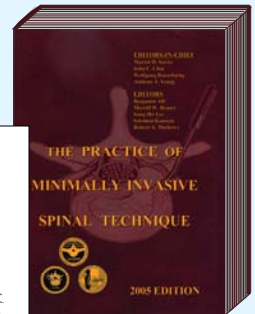
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“VAX-D should not be considered traction in the traditional sense but as decompression. VAX-D is the only non-invasive treatment that has been proven to decompress the disc.”



**Real Studies
Real Science
Real Results**

OUTCOMES AFTER A PRONE LUMBAR TRACTION PROTOCOL FOR PATIENTS WITH ACTIVITY-LIMITING LOW BACK PAIN: A PROSPECTIVE CASE SERIES STUDY

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Archives of Physical Medicine And Rehabilitation,
Volume 89, February 2008

ABSTRACT: This study is a prospective, longitudinal, case series. The study objective was to determine outcomes after administration of VAX-D. A total of 296 subjects with low back pain (LBP) and evidence of a degenerative and/or herniated intervertebral disk at 1 or more levels of the lumbar spine. The study was supported by a grant from Independence Blue Cross.

The results demonstrated significant improvements for all post intervention outcome scores when compared with pre-intervention scores ($P < .01$). The VAX-D protocol was associated with improvements in pain intensity and RMDQ scores at discharge, and at 30 and 180 days after discharge in a sample of patients with activity limiting LBP.



SUMMARY: Clinical studies, systematic reviews of literature, and evidence-based guidelines have concluded that the preponderance of evidence fails to support standard lumbar traction as an effective treatment for patients with LBP.

Recently, a newly developed lumbar traction system, vertebral axial decompression (VAX-D), has been gaining popularity. With VAX-D, the patient is prone, with no thoracic harness, on a table specifically designed to eliminate frictional resistance. The VAX-D system provides distraction forces and rest periods through a pelvic harness while the patient stabilizes himself/herself by holding a hand grip.

The purpose of the present study was to determine short- and long-term outcomes after administration of prone traction using the VAX-D protocol. In this study all subjects had pre-intervention imaging evidence of lumbar intervertebral disk degeneration and/or herniation; and they were included in this study only if they failed at least two (2) previous non-operative treatments for their LBP. The majority of subjects reported that their presenting symptoms of LBP were present for greater than 6 months.

In this prospective, longitudinal case series patients reported significantly improved pain and disability scores after 16 to 24 visits of prone traction at discharge, and at 30 days and 180 days post-discharge.

It is important to note that VAX-D differs from most conventional lumbar traction in a variety of ways; the subject is positioned prone on a low-friction surface as opposed to supine on a high-friction surface; a pelvic harness is used as opposed to a thoracic harness; and the protocol indicates a high frequency of treatments over a 2-month period.

VAX-D for 16 to 24 visits was associated with significant improvements in pain intensity and RMDQ scores in both short- and long-term follow-up, in patients with activity-limited LBP who had previously failed 2 non-operative interventions for their current symptoms

EFFICACY OF VERTEBRAL AXIAL DECOMPRESSION ON CHRONIC LOW BACK PAIN: STUDY OF DOSAGE REGIMEN

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Journal of Neurological Research, Volume 26, April 2004

Abstract Vertebral Axial Decompression (VAX-D) is capable of reducing intradiscal pressure to the negative range. The purpose of this study was to compare the effects of two dosage regimens of VAX-D treatments on the level of low back pain in patients who were referred to a neurosurgical practice after failing standard medical therapy. In this study one group of patients received an average course of treatment consisting of 18 daily sessions and another group received half that number of daily treatment sessions. The treatment parameters for all patients differed only in the number of sessions. Seventy-six percent of the higher dosage group achieved remission of low back pain compared to forty-three percent of the lower dosage group. Chi-square analysis revealed that the differences in response in the two dosage groups were statistically significant at a $P < .0001$.



Summary Low back pain continues to frustrate the medical profession, patients, employers and the insurance industry. Although many patients have an indolent course with spontaneous resolution, a significant number of patients continue to experience symptoms. Ninety percent of patients with acute low back pain improve within 6 to 12 weeks, this formed the basis for the AHCPR guidelines. However, many spinal physicians believe these guidelines to be inadequate. In a study of back pain in the primary care setting, Von Korff and Saunders found that 50% to 75% improve in one month, 33% report intermittent or persistent pain at one year, and 20% of patients had substantial limitations at one year.

The VAX-D has a direct effect on the disc through reduction of intradiscal pressure, thereby achieving medical decompression. Ramos and Martin performed intradiscal pressure measurements during treatment with VAX-D and pressures as low as minus 150 mm Hg. were recorded. Intradiscal pressures have been measured with conventional traction devices, both active and passive. A significant reduction in pressure was never observed, in fact active traction doubled intradiscal pressures.

The VAX-D applies distraction tensions to the patient's lumbar spine without eliciting reflex paravertebral muscle contractions, this differentiates this procedure from conventional traction. The purpose of this study was to evaluate the response to VAX-D therapy in patients with chronic low back pain with or without leg pain who were referred to a neurosurgical clinic after failing standard medical therapy. Patients who were considered appropriate candidates for surgery underwent surgery.

The average duration of symptoms was 10 months. Most patients were between 30 and 50 years of age, the youngest was 15 years and the oldest 76 years. The average age was 39.5 years. Fifty-five (55) women and eighty-seven (87) men took part in this study. Eighty-eight patients were Worker's Compensation cases. The level of pain on a scale of 10, with 0 as no pain and 10 as the worst possible pain, was recorded on each patient prior to the onset and on completion of the prescribed course of

treatment. Each patient also recorded their Activities of Daily Living (ADL) on a scale of 0 to 5 with 0 being no impediment to 5 being confined to bed-rest.

One hundred and forty-two patients that were consecutively treated with VAX-D therapy were included in this study. Table 1. shows the distribution of the diagnosis of the cases treated in this series. There were ninety-one (64%) patients in the 10 Sessions Group and fifty-one (36%) patients in the 20 Sessions Group. Intradiscal pressures above end-plate capillary pressures may impede oxygen and nutrient diffusion to the avascular disc. Oxygen has a steep concentration gradient across the disc, with peripheral concentrations 20 - 30 times greater than the center of the nucleus. Disc metabolism is principally anaerobic, thus limiting repair and healing. Ohshima and Urban have shown that in common with other cartilage, a decrease in pH reduces proteoglycan and protein synthesis.

The VAX-D represents a medical procedure specifically designed to treat the disc. Both mechanical and biochemical mechanisms may explain its mechanism of action. The disc exhibits thixotropic properties, it becomes more adhesive with compression and less adhesive with reduced intradiscal pressure. This property allows VAX-D to facilitate retraction of a protruding nuclear matrix to the center of the disc, relieving irritation and compression on pain sensitive structures. Augmenting the diffusion gradient by reducing the intradiscal pressure with VAX-D is believed to facilitate the transfer of oxygen and nutrients into the disc enhancing metabolism hence healing and repair.

A degraded nucleus can no longer accept compressive loads due to spinal loading. This function is now transferred to the annulus, and annular failure results. By presumably lowering levels of lactic acid in the center of the nucleus with VAX-D, the enzyme (matrix metalloproteinases) cascade responsible for disc degradation which is partially pH dependent, may be inhibited.

In this study two groups of patients with chronic low back pain were subject to a different dosage regimen with the VAX-D. All patients failed previous conservative therapy (medications, chiropractic care, and physical therapy) before treatment with the VAX-D.

VAX-D achieved a high success rate, 76% remission, and success appears to exhibit a dose-response relationship (number of sessions administered) indicative of a biochemical mechanism of action. We conclude the VAX-D is a very useful medical procedure for patients with low back complaints of discogenic origin. VAX-D should be utilized in all patients who are poor surgical candidates and before surgery is undertaken except in the emergent conditions.

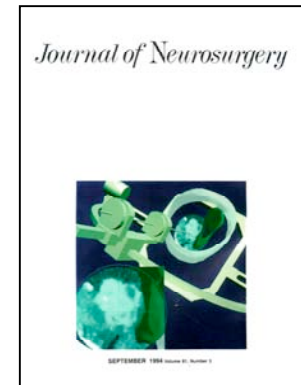


EFFECTS OF VERTEBRAL AXIAL DECOMPRESSION (VAX-D) ON INTRADISCAL PRESSURE:

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Journal of Neurosurgery 81:350-353 1994

Abstract The object of this study was to examine the effect of vertebral axial decompression on pressure in the nucleus pulposus of lumbar discs. Intradiscal pressure measurement was performed by connecting a cannula inserted into the patient's L4-5 disc space to a pressure transducer. The patient was placed in a prone position on a VAX-D therapeutic table and the tensionometer on the table was attached via a pelvic harness. Changes in intradiscal pressure were recorded at resting state and while controlled tension was applied by the equipment to the pelvic harness. Intradiscal pressure demonstrated an inverse relationship to the tension applied. Tension in the upper range was observed to decompress the nucleus pulposus significantly, to below -100 mm Hg.



Summary For patients who are not candidates for surgery, there is a need to establish a conservative approach that offers an effective means of returning the patient to a functional level of activity. Anderson, et al. and others have shown that certain traction techniques can actually cause an increase in intradiscal pressure, which would be undesirable in the treatment of low-back pain associated with herniated discs and a neurocompression etiology.

A new form of therapy, termed "vertebral axial decompression," has recently been introduced in the physical therapy department of the HCA Rio Grande Regional Hospital. The VAX-D equipment is routinely utilized in our non-surgical treatment program for patients suffering from low-back pain.



Fig. 1. Photograph illustrating the equipment and the position of the patient as the system is activated. The caudal end of the Table extends, applying tension to the pelvic belt. Upper body movement is restrained by having the patient grasp the handgrips. A graph of the tension applied is plotted by a chart recorder on the control console and the intradiscal pressure readings are entered on the same graph at the apex of each distraction curve.

In this study various distraction tensions, ranging from 50 to 100 lbs, were used for vertebral axial decompression therapy. The distraction tensions applied were monitored on a digital readout and recorded on a continuous graph tracing by a chart printer incorporated in the control console. The resulting changes in intradiscal pressure in the L4-5 nucleus pulposus were observed on a digital readout on the pressure monitor, and the readings were entered onto the chart recording at the point when the apex of distraction tension was achieved. The pressure readings were then applied to the negative-range calibrated curves prepared for each transducer to derive accurate intradiscal pressure readings.

RESULTS: The intradiscal pressure measurements showed that distraction tension routinely applied by the VAX-D equipment reduced the intradiscal pressure significantly, to negative levels in the range of -100 to -160 mm Hg. The relationship between distraction tensions and intradiscal pressure changes for three patients is presented in Table 1. The extent of decompression (measured in mm Hg) shows an inverse relationship to the tension applied and may be expressed by a polynomial equation (Fig. 2).

Discussion An interesting observation was that changes in intradiscal pressure appeared to be minimal until a threshold distraction tension was reached. When the threshold was exceeded the intradiscal pressure was observed to decrease dramatically, to levels in excess of 200 mm Hg below the positive pressure observed prior to the application of pelvic tension.

As indicated in the curves plotted for intradiscal pressures versus distraction tension (Fig. 2), it appeared that the decrease in pressure tends to level off as the applied distraction tensions approached 100 lbs. The concept of a threshold distraction tension and the levels observed in these trials are consistent with radiographic studies of vertebral body separation reported in other publications.

The results indicate that it is possible to lower pressure in the nucleus pulposus of herniated lumbar discs to levels significantly below 0 mm Hg when distraction tension is applied according to the protocol described for vertebral axial decompression therapy. These findings may offer a plausible explanation for the mechanism of action for this therapeutic modality.

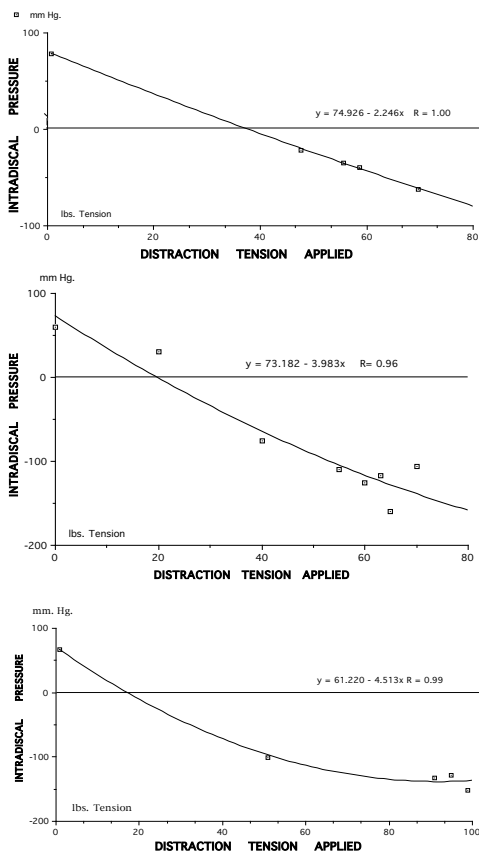


FIG. 2. Graphs showing the intradiscal pressures recorded in the L4-5 nucleus pulposus of three patients (Case 3, upper; Case 4, center, and Case 5, lower) with a herniated disc at this level. Pressure is plotted against distraction tension consistent with the range of tension recommended as the therapeutic protocol for the equipment used in this study.



PROSPECTIVE RANDOMIZED CONTROLLED STUDY OF VAX-D AND TENS FOR THE TREATMENT OF CHRONIC LOW BACK PAIN

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Journal of Neurological Research Volume 23, Number 7, October 2001

Abstract: Low back pain is one of the most significant medical and socioeconomic problems in modern society. The purpose of this randomized controlled trial is to address the question of efficacy and appropriateness of VAX-D (Vertebral Axial Decompression) Therapy, a new technology that has been shown in clinical research to create negative intradiscal pressures, and has been shown to be effective in treating patients presenting with chronic low back pain (>3 months duration) with associated leg pain. Successful outcome was defined as a 50% reduction in pain utilising a 10cm Visual Analogue Pain Scale and an improvement in the level of functioning as measured by patient-nominated disability ratings. Patients were randomly assigned to VAX-D or to TENS which was used as a control treatment or placebo. The TENS treatment demonstrated a success rate of 0% while VAX-D demonstrated a success rate of 68.4% ($P<0.001$). A statistically significant reduction in pain and improvement in functional outcome was obtained in patients with chronic low back pain treated with VAX-D.



Summary: Chronic low back pain is increasing faster than any other disability, and 5-7% of the population will report their back problems as being a chronic illness. Fifty percent of work loss caused by back pain is accounted for by duration of disability for longer than 4 weeks. Today's primary care practitioners have a comprehensive responsibility in the management of their patient's low back conditions, and they must be aware that recurrences after the presenting episode are likely.

If the disc is a major source of low back pain then applying specific target therapy for the treatment of disc pathology should improve patient outcomes. VAX-D is a primary, non-surgical treatment for the management of patients with disabling low-back pain and neurological symptoms associated with herniated and degenerative disc disease. Research has shown that the VAX-D table is a decompression device that is capable of reducing intradiscal pressures to negative levels.

Successful reduction of intradiscal pressures with VAX-D represents a technological advance that should provide a means of addressing compressive disc pathology. Creating negative intradiscal pressure is likely to affect both the biomechanical and biochemical causes of discogenic pain. Patients suffering from discogenic pain and/or associated sciatic pain are seeking conservative treatment without the risks associated with injections and surgical procedures.

VAX-D incorporates advanced technology that permits the application of distractive tensions without eliciting reflex muscle guarding. Conventional traction devices have not demonstrated this ability or the ability to reduce intradiscal pressures to negative levels. Studies published in the medical literature report

that intradiscal pressure either remains unchanged or increases during traction. It has also been demonstrated that paraspinal muscles are not able to fully relax during conventional traction.

The beneficial effects of VAX-D decompression in the relief of peripheral nerve dysfunction has been previously reported in the literature, and a multi-center outcome study reported that VAX-D treatment was successful in 71% of the 778 cases studied.

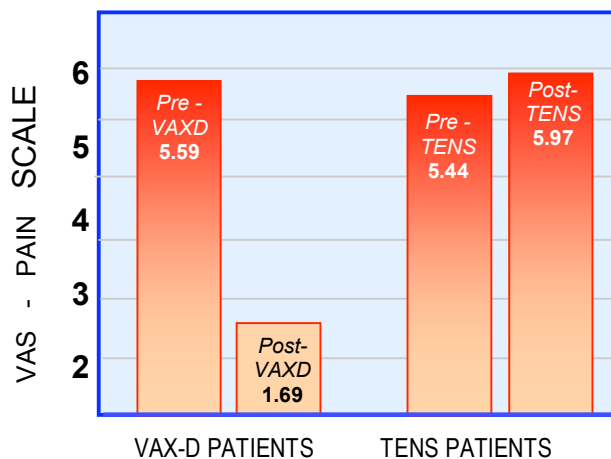
In association with Quintiles, the world's largest health care consultancy organization for data analysis in clinical trials, a protocol was developed and then approved by the Human Research Ethics Committee at the University of Wollongong, New South Wales, Australia. The instruments for determination of these outcomes were supplied by the National Musculoskeletal Initiative of Australia. The study itself was to be conducted in the medical clinics of the VAX-D Spinal Institute and so to prevent bias in the data collection Quintiles were engaged to collect and analyse the data. TENS was selected as an appropriate placebo treatment as a means of establishing a plausible but ineffective control for an unblinded treatment.

Forty-four patients with chronic low back pain greater than 3 months in duration, with associated leg pain, and a confirmed disc protrusion or herniation on CT Scan or MRI were selected and randomised into the two treatment methods, either VAX-D or TENS. The patients were randomised in sequential order and treatments were determined by a predefined central randomisation list. The average duration of pain in the patient population was 7.3 years.

Successful reduction of intradiscal pressures with VAX-D therapy represents a technological advance in lumbar spinal treatment and is likely to affect both the biomechanical and biochemical causes of discogenic pain.

The results from this study demonstrate that VAX-D is an effective treatment for the management of patients with chronic low back pain and is significantly superior when compared to TENS therapy. Analysis of the data demonstrated an attributable success rate of 68.4% for VAX-D. These findings are consistent with earlier studies by Gose E, Naguszewski W, Naguszewski R. At six-month follow-up, of the 13 successful cases, 2 have been lost to follow-up, 1 case suffered a significant other injury and of the remaining 10, seven have shown sustained success (ie. they still meet the criteria for successful outcome).

The results of this prospective study demonstrated that VAX-D can achieve a statistically significant improvement in pain and functional outcome in managing patients suffering from disc related chronic low back pain.



Treatment Efficacy - Randomized Control Trial



VERTEBRAL AXIAL DECOMPRESSION THERAPY FOR PAIN ASSOCIATED WITH HERNIATED OR DEGENERATED DISCS OR FACET SYNDROME: AND OUTCOME STUDY

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Journal of Neurological Research, Volume 20, April 1998

Abstract The outcomes of vertebral axial decompression (VAX-D) therapy for patients with low back pain from various causes are reported. Data was collected from twenty-two medical centers for patients who received VAX-D therapy for low back pain. Only patients who had a diagnosis of herniated disc, degenerative disc, or facet syndrome, which were confirmed by diagnostic imaging, were included in this study; a total of 778 cases. The average time between the initial onset of symptoms and the beginning of this therapy was 40 months, and it was four months or more in 83% of the cases.



The treatment was successful in 71% of the 778 cases, when success was defined as a reduction in pain to 0 or 1, on a 0 to 5 scale. Improvements in mobility and activities of daily living correlated strongly with pain reduction. The statistical significance of this study is indicated by the low 'P' value of $P < 0.00005$.

Summary Intuitively, lumbar traction should be successful in alleviating many of the conditions which cause low back pain and associated radiculopathy. Unfortunately, studies of clinical efficacy have yielded equivocal results. The avoidance of paravertebral muscle contraction, stimulated by homeostatic proprioceptor and axon reflex mechanisms allows the distraction of the vertebral bodies necessary to achieve decompression of the intervertebral disc. The therapy is administered via an automated logic control mechanism which systematically applies distractive tensions and rest periods in a cyclic fashion. The typical therapy session consists of 15 cycles of tension and relaxation.

VAX-D treatment has been shown to decompress the nucleus pulposus to pressures below - 100 mmHg. This creates a tremendous potential diffusion gradient across the disc space, which is otherwise an avascular structure. Glucose and oxygen enter the disc at the end plate region while sulphate ions needed for the production of new glycosaminoglycans enter from the annulus fibrosis. Thus therapy may augment nutrient flow into the disc, facilitating structural restoration of the disc and promoting disc rehydration, since proteoglycans bind water. These effects may be cumulative with repetitive therapy sessions.



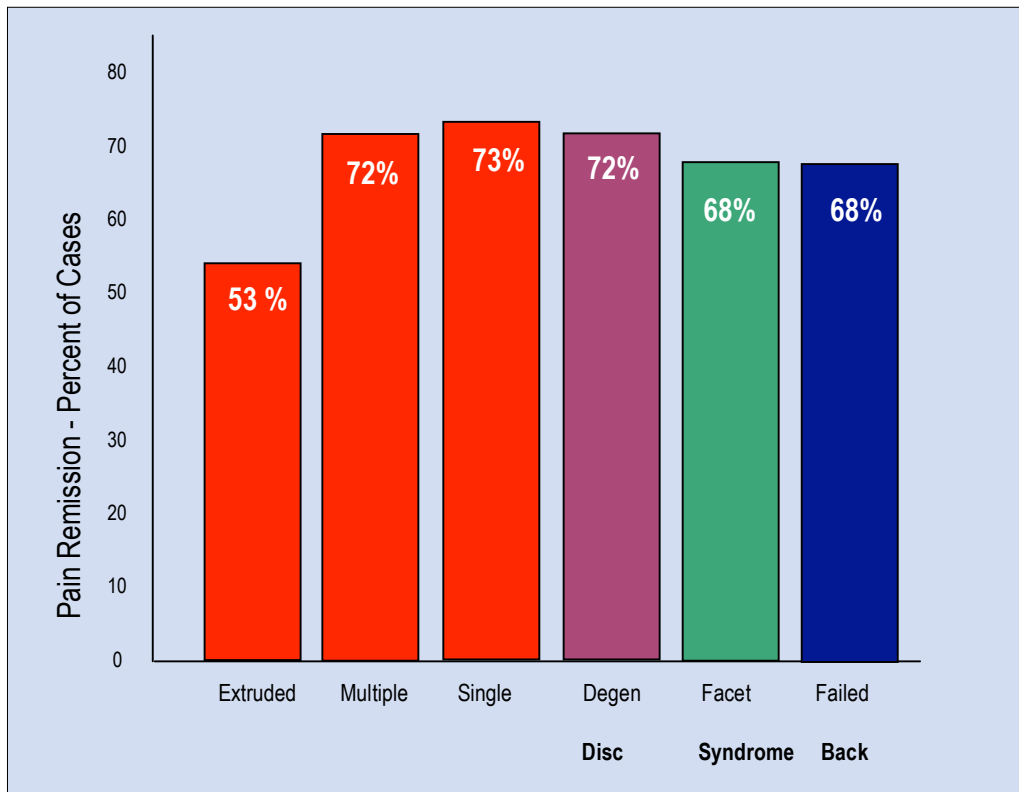
Data was collected from twenty-two medical centers in the USA for patients who received VAX-D therapy for low back pain. The average number of treatments was 17 for facet syndrome, 19 for degenerative disc disease, and 20 for other diagnoses. The data contained the patients' assessment of their own pain, mobility, and ability to walk and sit. The pain scale ran from no pain (0) to severe pain (3).

If treatment success is defined as a reduction in pain to 0 or 1 on a 0 to 5 scale, the treatment was successful in 71% of the 778 cases. The success rate varied from 53% for the patients with extruded herniated discs, to 73% for patients with a single herniated disc. It was 72% for people with multiple herniated discs and 68% for facet syndrome.

We consider VAX-D therapy to be 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. We believe that post-surgical patients with persistent pain or 'Failed Back Syndrome' should not be considered candidates for further surgery until a reasonable trial of vertebral axial decompression has been tried.

Low back mobility increased subsequent to therapy and correlated well with pain reduction. Both of these factors are important in areas such as Workers Compensation and personal injury. We submit that patients can usually be brought to a higher level of MMI by this therapy because of the anticipated improvements in mobility

In summary, the pain, activity, and mobility scores were all greatly improved after therapy. VAX-D by its unique design may more precisely address the physiology of persistent low back pain than other conventional therapies. We consider it to be a front line treatment for degenerative spondylosis, facet syndrome, disc disease and non-surgical lumbar radiculopathy.



DERMATOMAL SOMATOSENSORY EVOKED POTENTIAL DEMONSTRATION OF NERVE ROOT DECOMPRESSION AFTER VAX-D THERAPY

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Journal of Neurological Research Volume 23, Number 7, October 2001

Abstract: Reductions in low back pain and referred leg pain associated with a diagnosis of herniated disc, degenerative disc disease or facet syndrome have previously been reported after treatment with a VAX-D table, which intermittently distracts the spine. The object of this study was to use dermatomal somatosensory evoked potentials (DSSEPs) to demonstrate lumbar root decompression following VAX-D therapy.

Traditionally, the term “decompression” as applied to the spine has referred to nerve root decompression. This study, however, has demonstrated that most of the patients suffering from chronic low back pain and radiculopathy had multiple nerve root abnormalities based on abnormal DSSEPs, many of which would not be predicted radiographically.



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.

With VAX-D therapy, the concept of “decompression” can now be broadened to include the lumbar spine motion segment itself, with decompression not only of the nerve roots, but also the disc, facet joints and potentially, the paraspinal musculature as it is stretched and muscular spasm resolves. VAX-D therapy however addresses both primary and secondary causes of low back and referred leg pain. We thus submit that VAX-D therapy should be considered first, before the patient undergoes a surgical procedure which permanently alters the anatomy and function of the affected lumbar spine segment.

Summary: DSSEP’s are an established and effective physiologic tool for assessing single nerve root function pre- and post- operatively, and are useful as well for monitoring potential acute nerve root injury during surgical procedures.

All patients were studied bilaterally by DSSEP’s at L5 and S1 before and after VAX-D therapy. Overall, 28 nerve roots were studied before and after VAX-D Therapy. All patients had at least 50% improvement in radicular symptoms and low back pain and three of them experienced complete resolution of all symptoms. The average pain reduction was 77%.

“Surgery is often focused primarily on nerve root decompression to relieve radicular pain and any improvement in back pain follows as a secondary benefit. This secondary benefit occurs despite the fact that discectomy and laminectomy involve further disc and spine disruption. The literature is clear that not all patients benefit by surgical nerve root decompression and also that surgical patients on average fare no better long term than patients who are managed conservatively.

In this study, we found that multiple nerve roots appear to be decompressed in most of the patients. The DSSEP's reviewed provide physiologic evidence that this possibility not only exists but is likely. Our study suggests that VAX-D exerts its benefit at more than one level ipsilateral and contralateral to the direction of disc herniation.

We suggest that VAX-D therapy effectively manages mechanical low back pain with or without referred leg pain through spine segment mobilization. Spine segment motion integrity is a crucial concept and probably best explains the correlation previously found between reduced pain and improved gross spine mobility subsequent to VAX-D Therapy.

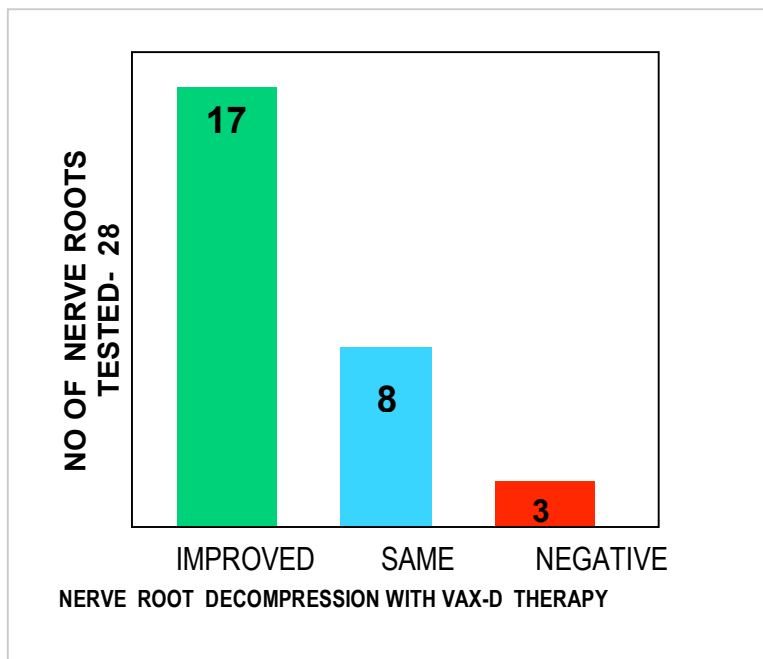
Traditionally, the term 'decompression' as applied to the spine has referred to nerve root decompression. Surgery for decompression has been directed at the radiographic sites of nerve root entrapment including the removal of herniated disc material or osteophytes. This study, however, has demonstrated that most of the patients suffering from chronic low back pain and radiculopathy had multiple nerve root abnormalities based on abnormal DSSEP's' many of which would not be predicted radiographically.

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.

With VAX-D therapy, the concept of 'decompression' can now be broadened to include the lumbar spine motion segment itself, with decompression not only of the nerve roots, but also the disc.

Surgery, by being directed at root decompression at the site of the herniation alone, may not be effective if secondary causes of pain have become predominant.

VAX-D therapy addresses both primary and secondary causes of low back and referred leg pain. We thus submit that VAX-D therapy should be considered first, before the patient undergoes a surgical procedure which permanently alters the anatomy and function of the affected lumbar spine segment. ”



VAX-D REDUCES CHRONIC BACK PAIN : A FOUR YEAR OUTCOME STUDY

Robert H. Odell Jr., MD. Ph.D., Boudreau D. DO.
Anesthesiology News – Volume 29, Number 3, March 2003

Abstract: Excellent four-year results have been reported in a small series of patients with chronic discogenic low back pain treated with a spinal decompression device, VAX-D. 'Of the 23 patients who responded, 52% had a pain level of zero, 91% were able to resume their normal daily activities, and 87% were either working or were retired without having back pain as the cause for retirement.'

Summary: Among 23 patients, 71% showed more than 50% reduction in pain immediately after treatment, and 86% showed a 50% or better pain reduction at four years. "After four years, 52% of respondents reported a pain level of zero. Thus, pain relief not only lasted but improved," reported Robert H. Odell Jr., MD. Ph.D.



The cost per year of improved quality of life is substantially less than for standard interventional pain and surgical techniques, Dr. Odell stressed in a poster presentation at the 2002 annual fall meeting of the American Society of Regional Anesthesia and Pain Medicine. Numerous low back pain treatments are available, and most have questionable outcomes, or unfavorable long-term results, Dr. Odell, an anesthesiologist in private practice in Las Vegas, and lead author Daniel A. Boudreau D.O., and orthopedic surgeon in private practice in Mesquite, Texas, told Anesthesiology News.

VAX-D, manufactured by VAX-D Medical Technologies, Palm Harbor, Fla., is a table that applies distractive forces to the lumbar spine via computer technology. The technology is designed to avoid stimulation of the proprioceptor sensors that elicit muscle guarding. The device was approved by the Food and Drug Administration in 1989 for treatment of herniated and degenerative disk disease and radicular pain. Thus far, only short-term results have been reported.

The retrospective survey included 34 patients treated between January and April 1995; of these, 23 patients responded. All had undergone several types of treatment before receiving VAX-D. Originally patients underwent 15 treatments, but some received up to 32 treatments. Those who received more treatments tended to have better pain relief. Subsequent studies have shown that patients with single-level discogenic disease require 20 treatments, but patients with multilevel discogenic disease may require 30 or more. Over Dr. Boudreau's six years of experience with VAX-D, the average number of treatments he administers to a patient is 27.

Patients were diagnosed by physical examination and lumbar magnetic resonance imaging as having a herniated, degenerated or bulging disk. Progress was measured with Visual Analogue Scale (VAS) pain scores. A 50% reduction in score was considered a successful result. At four years, patients were sent a questionnaire survey by mail (and surveyed by telephone if the questionnaire was not returned).

“Of the 23 patients who responded, 52% had a pain level of zero. 91% were able to resume their normal daily activities, and 87% were either working or were retired without having back pain as the cause for retirement,” emphasized Dr. Odell. “There were no complications with this treatment.”

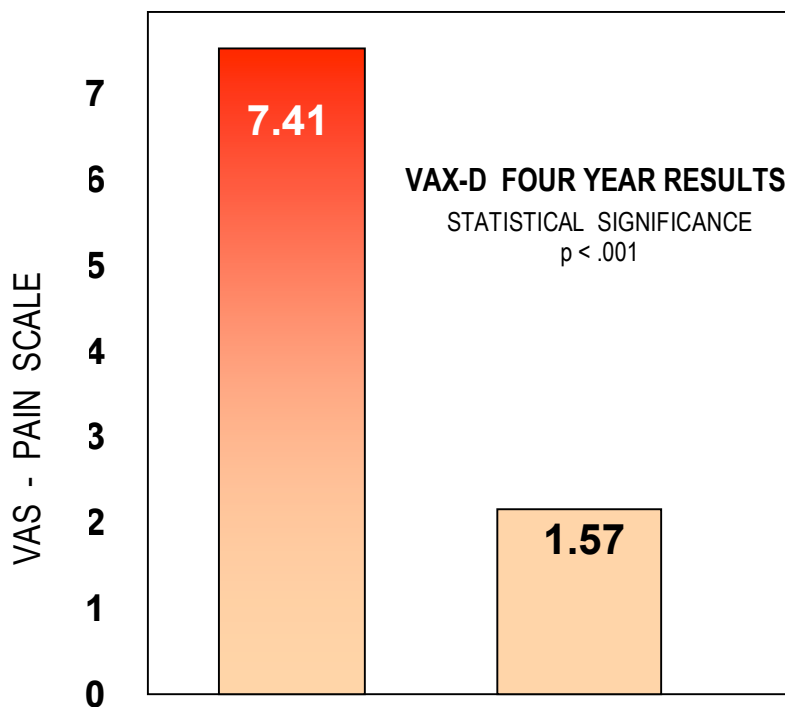
The average pain level was 7.41 before VAX-D treatment and 3.41 immediately afterward. None of the respondents underwent surgery for their back condition after receiving VAX-D treatment. The researchers believe that the pain reduction probably resulted from the effects of negative intradiscal pressure, which allowed nutrients, oxygen and water to be brought into the disk.

The researchers’ claim that VAX-D reduces cost, was based on calculations assuming that the average number of sessions was 27 and the cost per session was \$250. With those figures, VAX-D costs \$383 per year of improved quality of life. This cost is lower than that shown in one study for most traditional interventional therapies for low back pain (Pain Physician 2001, 4:24-98).

To contrast these results, the investigators also referred to a study of 575 patients with lumbar disk herniation. When surveyed four to 17 years after their surgery, 70% of respondents said they still had back pain (Spine 1988, 13:1418-1422).

Dr. Boudreau said that, to date, he has treated nearly 2,000 patients with VAX-D and has follow-up data on 1,500 patients. He acknowledged that the study sample size was small and that the study was not randomized and controlled.

In comments to Anesthesiology News, David P. Seamans, MD, of the Mayo Clinic Scottsdale, in Arizona, said that “there are millions of people suffering from low back pain, and many are not adequately treated. We don’t have all the answers in allopathic medicine, so there is always a need for new therapies.”



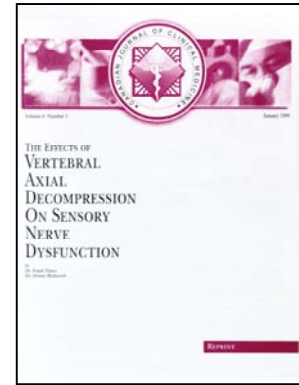
THE EFFECTS OF VERTEBRAL AXIAL DECOMPRESSION ON SENSORY NERVE DYSFUNCTION

Frank Tilaro, M.D. , Dennis Miskovich, M.D.

Canadian Journal of Clinical Medicine, Volume 6, Number 1 January 1999

Abstract Effective non-surgical decompression of the nerve root has not been available to this date. The vertebral axial decompression (VAX-D) therapeutic table has demonstrated an ability to significantly reduce intradiscal pressure to a negative 150mm Hg., allowing for disc decompression. The purpose of this study was to determine if VAX-D therapy could externally decompress the nerve root.

Patients with radiculopathy and abnormal sensory function determined by the Current Perception Threshold (CPT) Neurometer who had received VAX-D therapy were retrospectively studied. CPT readings on 22 peripheral nerves were taken before and after VAX-D therapy. Only patients with initial abnormal CPT readings, symptoms of sciatica, positive SLR, and positive imaging studies were reported on. The results after therapy were as follows: 14/22 nerves (64%) returned to normal function, 6/22 (27%) improved, 1/22 (4.5%) had no improvement and 1/22 (4.5%) showed deterioration. The average neurometer grade before therapy was 6.36 and after therapy 2.09 (a score of zero indicates normal function). Overall improvement was 67% ($p < 0.05$).



Summary Patients with nerve root compression secondary to a herniated disc are frequently treated surgically although there is evidence they may be managed conservatively. Non surgical decompression could have significant advantages over the surgical methods currently in use. These may be reduced cost, early back to work, lower morbidity, a reduction in post operative complications and elimination of the failed back syndrome.

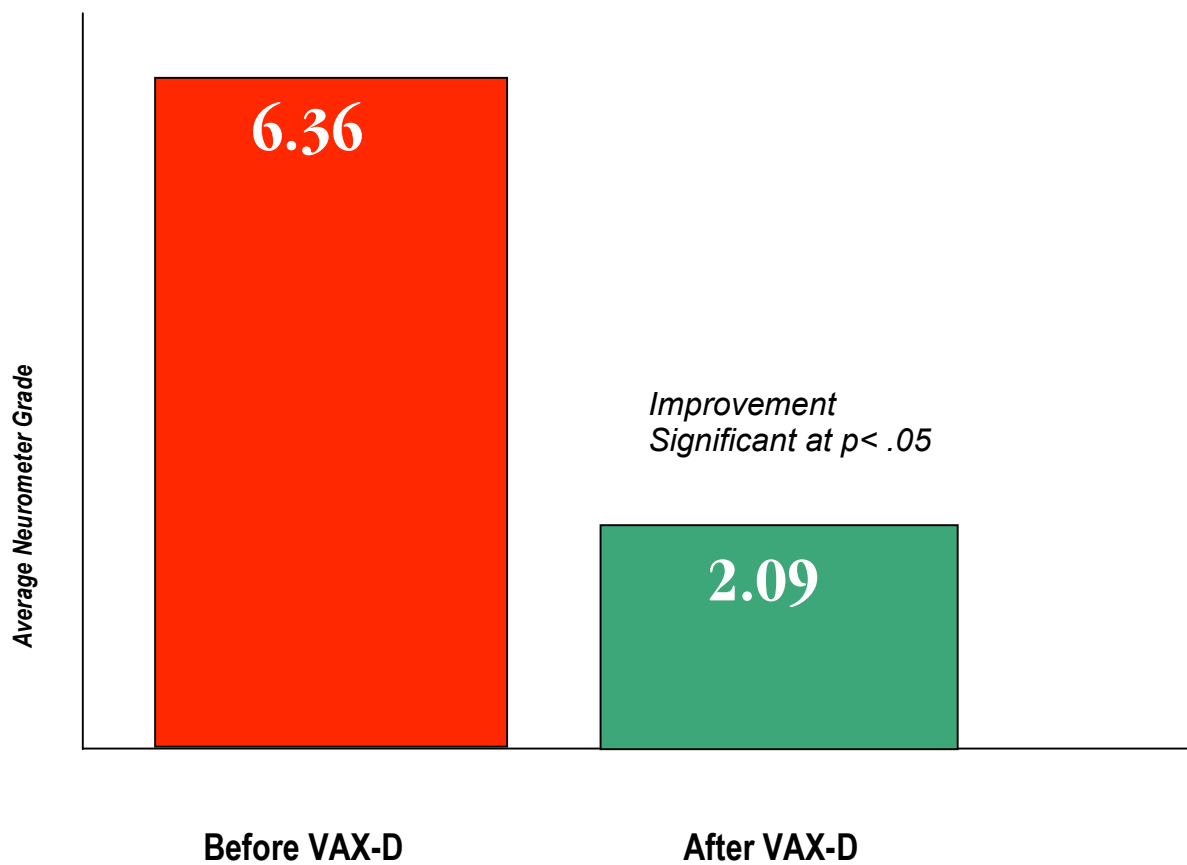
The vertebral axial decompression (VAX-D) therapeutic table has demonstrated its effectiveness in treating low back pain with and without radiculopathy. The table asserts its effects through decompression of the intervertebral disc and has reduced intradiscal pressures to a negative 150 mm Hg. It's assumed that reduction of intradiscal pressures to such significant levels should produce nerve root decompression but this has not been specifically investigated. The purpose of this study was to determine if VAX-D therapy effectively decompresses nerve roots.

All patients had Current Perception Threshold (CPF) neurometer testing before instituting VAX-D therapy and immediately after completion of a course of therapy. Only patients with abnormal CPT grades who had sciatica, positive SLR, and imaging studies that correlated with the observed clinical syndrome were reported on. A total of 17 patients qualified, 22 nerves were studied since some patients had multilevel involvement. The nerves measured were the peroneal and sural nerves from the LA-5 and L5-S I nerve roots respectively. Sensory nerve dysfunction was measured by the CPT neurometer.

The data from this study demonstrated that the VAX-D therapeutic table is capable of affecting spinal sensory nerve dysfunction in abnormal nerves secondary to a compressive radiculopathy.

Fourteen of twenty-two peripheral nerves (64%) showing abnormal dysfunction secondary to a compressive radiculopathy returned to normal function after a therapeutic course of VAX-D therapy. The data from this study implies that VAX-D therapy is capable of influencing sensory nerve dysfunction associated with a compressive radiculopathy.

Motor dysfunction returns before sensory dysfunction in compressive radiculopathies so it is rather striking that we observed total remission in 64% of the cases with sensory dysfunction. It is possible that reduction of intradiscal pressure by VAX-D significantly alters the biomechanics and biochemistry of the disc and nerve root.



64% Achieved Complete Remission
Current Perception Threshold Evaluation of Sensory Deficit

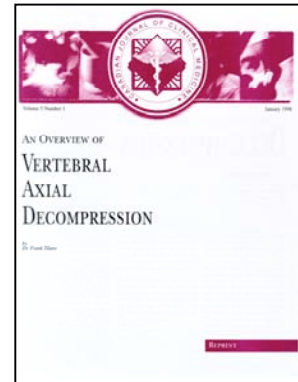


AN OVERVIEW OF VERTEBRAL AXIAL DECOMPRESSION

Frank Tilaro M.D.

Canadian Journal of Clinical Medicine Vol 5, No 1, January 1996

Abstract VAX-D Therapy addresses the biomechanical aspects of discogenic disease and should be utilized in patients with low back pain, with or without radiculopathy who have failed conventional therapy [physiotherapy and chiropractic], and should be utilized prior to addressing surgery. By addressing the altered biomechanics responsible for disc disease, the VAX-D Therapeutic Table not only alleviates pain but has been shown to exert a beneficial effect on a major determinant in the equation responsible for discogenic disease, that is, elevated intradiscal pressure.”

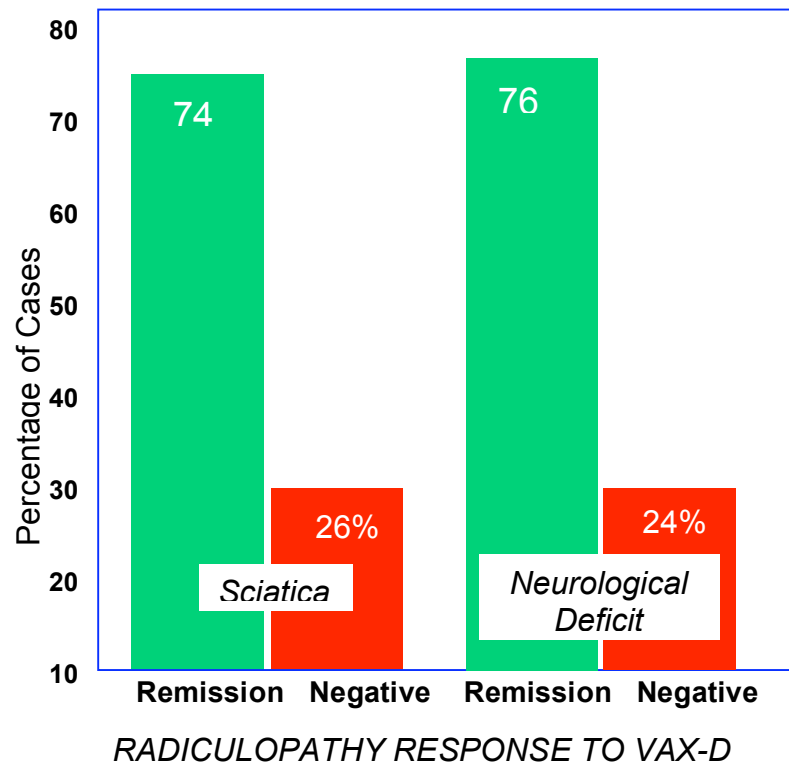


“The chronic back pain patients and surgical patients are very costly to society. Since many of these patients are responsive to “VAX-D therapy, this unique non-obtrusive means of managing the common forms of debilitating low back pain associated with discogenic disease could represent a considerable savings.”

Summary VAX-D is indicated for patients with low back pain that has been unresponsive to conventional therapy for 6-8 weeks. Patients with radiculopathies are also candidates. The presence of a neurological deficit does not affect patient eligibility since studies have revealed the outcome in patients with neurological deficits was not affected by surgical or medical management. The presence of a rapidly progressive neurological deficit is an indication for surgery. Patients presenting with a fusion and the post surgical failed back syndrome may also be candidates.

No serious side effects have been reported with VAX-D therapy. A limiting factor affecting the patient's tolerance to therapy is stress to the shoulder girdle and rotator cuff. This may be mitigated by placing a roll under the axilla of the affected side. Should a patient have discomfort from any cause, they may release the handgrips at any time. This adds an important safety factor to the treatment.

Clinical Studies The Acute Low Back Distress Study was conducted by the John P.



Robarts Research Institute, London Ontario. The efficacy of VAX-D therapy was established with this study. The parameters measured were severity and duration of pain and disability, including analgesic requirements, and the presence and degree of neurological involvement. One hundred and ten patients were entered into the study.

The treatment was considered a success if the baseline aggregate score for pain and disability was reduced by 50% after 10 treatments of VAX-D therapy. Sixty-six percent of the patients achieved success according to the study protocol. Prior to therapy the aggregate score for pain and disability was 5.1 and after 10 treatment sessions in the successful group it was 1.2.

The Clinical Outcome Assessment Study was conducted at McAllen HCA Hospital by Dr. G Ramos. Fifty-two patients completed VAX-D therapy as the primary modality. Thirty-eight patients (73%) achieved a positive outcome with remission of their low back pain symptoms and a return to functional levels of activity. Ninety percent of the recovered group were suffering from disc herniations, the majority (89%) being subligamentous while 11% had extruded herniations. Neurological deficits did not compromise the response to therapy.

Review of the patients clinical findings for those who achieved remission showed that 33% exhibited neurological deficits and 73% had sciatic pain prior to therapy with VAX-D.

Dr. E. Gose, Dr. W Naguszewski, and Dr. R Naguszewski have completed an outcome study of VAX-D therapy from over twenty medical centers that included over 700 patients. Patients with back pain, with or without leg pain were included in the study as well as the failed surgical back patient. All patients had a diagnosis of a herniated disc, degenerative disc or facet syndrome. The treatment was successful in 71% of the 778 cases studied. Improvements in mobility and Activities of Daily Living [ADL's] correlated strongly with pain reduction.

VAX-D therapy addresses the biomechanical aspects of discogenic disease and achieves its objective through decompression. It should be utilized in patients with low back pain, with or without radiculopathy who have failed conventional therapy (physiotherapy and chiropractic), and should be utilized prior to addressing surgery.

By addressing the altered biomechanics responsible for disc disease, the VAX-D therapeutic table not only alleviates pain but has been shown to exert a beneficial effect on a major determinant in the equation responsible for discogenic disease, that is elevated intradiscal pressure.

Further analysis of future and unpublished research should be considered to further validate the therapeutic benefit of VAX-D therapy, however, these clinical studies have shown it to be effective in back pain syndromes with or without radiculopathy including herniated discs and internal disc disruption.

The chronic back pain patients and surgical patients are very costly to society. Since many of these patients are responsive to VAX-D therapy, this unique non-obtrusive means of managing the common forms of debilitating low back pain associated with discogenic disease could represent a considerable savings.



AN INDUSTRY BASED, RETROSPECTIVE, COST ANALYSIS OF VERTEBRAL AXIAL DECOMPRESSION VS. SURGERY FOR LUMBAR DISC DISEASE: 10 CASE STUDIES

David C. Duncan, MD, Don Keenan, SPHR, Ph.D.
Sinclair Oil Corporation Study, Tulsa Oklahoma

Introduction *This study was undertaken to explore creative suggestions in controlling benefits costs while maintaining an overall competitive health care package; reducing pain, suffering, and absenteeism in the company workforce; and reducing the associated costs of medical insurance and employee absences to the company. The “costs” data for this paper was derived from a five (5) year study involving 10 employee case files from a small petrochemical refinery and the experience gained in the diverse worlds of medicine and business.*



The agreement offers refinery employees, Vertebral Axial Decompression (VAD) utilizing the VAX-D, as a self-selected alternative to back surgery. This agreement was not planned as a research tool, but as an open-ended, non-blinded, outcome based trial.

Cost Outcomes	Surgery	VAX-D
Time off work	17.6 weeks average The four patients that returned to work averaged 9 weeks TTD. The one now on PTD was on TTD for 52 weeks prior to adjudication.	36.75 hours
Average wage	\$22.50/hr.	\$22.50/hr.
Total Wages Paid while off work	\$15,840 each	\$826 each
Average overtime wage	\$33.75/hr	N/A
Total Overtime	\$23,760 each	None+
PTD/PPD	PTD \$672,000 for one PPD is pending on one and averages \$54,142	None
Procedures cost	\$263,434 Average = \$52,687/person	\$5,685 - \$6826 Average = \$6,227/person
Total Cash-Cost to the employer	<u>\$237,515 each</u>	<u>\$6,227 each**</u>

Discussion “VAX-D has demonstrated to us that it is medically safe and effective. The almost immediate absence from pain, the lack of invasive procedure, and the direct medical cost, as compared to surgery, is very cost effective to the employer. When factoring in additional non-medical direct costs such as paid sick time, replacement employee pay, and disability payment the cost effectiveness is orders of magnitude greater than surgery. The employees treated with VAX-D have less complaints of pain and generally are happier with the results. Thus far, I give VAX-D great marks in that it has proven to be a win-win situation for both the company and the employee” is the current assessment by the participating refinery’s Human Resource Administrator.

Efficacy of surgery We demonstrated a 60% “failure” rate of the initial surgery over a 5-year period. Many would argue that this rate of failure may be excessive, although recent reviews of back procedures (laminectomy discectomy with fusion) suggests that this may actually underestimate the failure rate. [1] However, in the following calculations, we have assumed surgery to be the gold standard, and 100% successful.

Efficacy of VAX-D A 100% “success” rate in this small group over-estimates the published efficacy of 70%. Calculations will be made assuming the published 70% success rate.

We recognize that these assumptions over-estimate surgical success and under-estimate VAD success as VAX-D “failures” generally are improved sufficiently to avoid surgery. [2]

Duration of efficacy for surgery is difficult to assess. Several different surgical procedures were undertaken, however, such is also the case in practice. Choice and frequency of surgical procedure seems to be more closely related to the number of available surgeons than any other criteria. [1]

Duration of efficacy for VAX-D has recently been demonstrated to be nearly 100% at 4 years. Those patients (70%) who achieved initial success did not regress over a 4-year period. [2]

The average, per patient, “cash-cost to industry” for the surgery treated injury was \$263,434. The average, per patient, “cash-cost to industry” for the VAX-D treated injury was \$6,227.

100 patients treated with VAX-D would cost industry \$622,700 dollars, using these assumptions, thirty would not have satisfactory results. (Although it is our experience that most of those VAX-D “failures” would have had sufficient improvement to no longer elect surgery, for these calculations, we assume all of the VAX-D failures would subsequently undergo surgery.)

The cost to industry for surgery on these 30 patients is \$7,125,450. “Cash-cost to industry” to treat 100 patients using VAX-D as a preferred treatment followed by surgery in VAX-D failures would be \$7,748,161. Actual cost could be substantially less with additional savings of \$237,515 for each of the 30 VAD failures that were sufficiently improved to avoid surgery.

To treat the same patients with only surgery would have a “cash-cost to industry” of \$23,751,500. The inclusion of VAX-D as a necessary step for qualifying patients who fail conservative treatment, would save industry a minimum of \$23,000,000 in direct costs for every 100 patients treated.



PROSPECTIVE RANDOMIZED STUDY OF VAX-D THERAPY FOR ACUTE LOW BACK DISTRESS

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L. Meissner MD, FRCP(C),
H. J. M. Barnett MD, FRCP,
C.R. Stiller MD, FRCP

The John P. Robarts Institute, University Hospital, London Ontario
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Abstract This study is a randomized control trial designed to assess the efficacy of VAX-D Therapy to significantly abbreviate the disability period in patients with acute incapacitating low back pain. Patients included in the study were those with acute distress with pain and/or spasm, unable to functionally bear weight or partake in the activities of daily living [ADL's]. One hundred and ten [110] patients were randomly assigned to either VAX-D or standard medical therapy groups.

Patients were initially assigned to VAX-D Therapy or a sham-treatment (VAX-D Therapy without application of distraction tensions). However, this approach was discontinued due to the failure of patient compliance in the sham group.

Sixty-eight percent [68%] of the fifty-five patients treated with VAX-D therapy achieve success according to the study parameters.



Summary Low back pain is the second commonest cause of disability in North America. In uncontrolled studies the VAX-D Table has been shown to alleviate both acute facet and disc disease related back pain. The potential value of this apparently benign procedure should have a great impact on the epidemiology of chronic lumbar pain. A variety of devices have been designed and utilized to apply tractive forces in novel ways, such as tilt tables, gravity inversion devices, bed traction with weights, electronic motor winches etc. in order to relieve the compressive forces sustained by the spine and the resultant pain and disability. The successful application of lumbar distractive forces has been limited by the technological design of mechanical devices and by patient tolerance.

This study was a two parallel group design, double-blind randomized controlled clinical trial. Patients who meet the eligibility criteria will be randomized to receive either a sham treatment or the VAX-D treatment. Patients will not know which of the two treatments they receive.

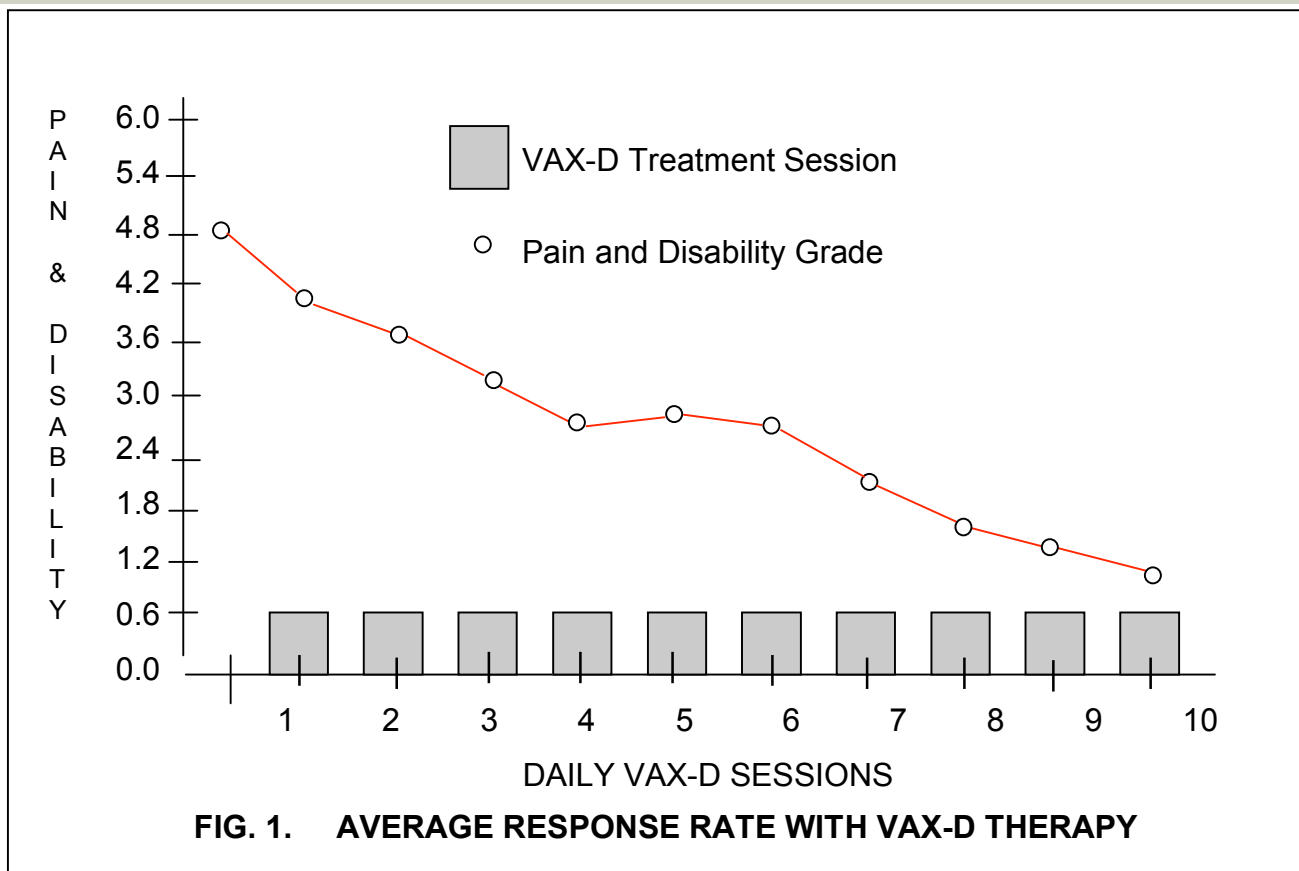
The primary parameters of efficacy are severity and duration of both pain and disability, including analgesic requirements. A secondary parameter of efficacy is presence and degree of neurological involvement. Radiologic changes, as measured by non-contrast CT scan of the lumbosacral spine, were studied. Although the nurse/physician assistant who gives the treatment will know whether it is a sham control or actual, this will not be disclosed to either the patient or Neurological Coordinator, who will assess the outcome of therapy. All patients will receive best standard therapy.

One hundred and ten [110] patients in total were randomly assigned to either VAX-D Therapy or standard medical therapy groups. Patients were initially assigned to VAX-D Therapy or a sham-treatment (VAX-D Therapy without application of distraction tensions). The treatment will be considered a success if the baseline aggregate score for pain and disability is reduced to 50% by therapy. It was reported that after

several weeks of attempting to conduct a sham treatment control that patient compliance suffered to such an extent that continuation was deemed impractical.

According to the requirements for clinical trials, all patients were advised before volunteering that some could be assigned to a control group. It was not possible to convince the sham-control patients that they were receiving a treatment and those assigned refused to continue to suffer the stress of travelling to the hospital each day unless assured they would be reassigned.

Fifty-Five (55) patients that were randomized to VAX-D Therapy had a reduction in their *Pain and Disability Grade* from an average level of 5.3 at the outset of the study to a level of 0.9 after ten (10) VAX-D Treatment sessions (See Graph Figure 1.) Sixty-three percent (63%) of the patients treated with VAX-D Therapy achieved success, obtaining a fifty (50%) reduction in their pain and disability score.



In this study one hundred and ten [110] patients were randomly assigned to either VAX-D or standard medical therapy groups. Patients were initially assigned to VAX-D Therapy or a sham-treatment (VAX-D Therapy without application of distraction tensions- as a control). However, this approach was discontinued due to the failure of patient compliance in the sham group.

Sixty-three percent [63%] of the fifty-five (55) patients that were treated with VAX-D therapy achieved success according to the study parameters. VAX-D Therapy provides a primary treatment modality for the management of pain and disability for patients presenting in acute distress from low back pain.



SHORT AND LONG-TERM OUTCOMES FOLLOWING TREATMENT WITH THE VAX-D FOR PATIENTS WITH CHRONIC, ACTIVITY-LIMITING LOW BACK PAIN

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Journal of Orthopaedic & Sports Physical Therapy, Volume 35, Number 1, January 2005

ABSTRACT: One hundred and eighteen patients treated with the VAX-D Therapy protocol were examined for pain reduction and activity modifications at end of treatment (discharge date), at thirty (30) days and at one hundred and eighty days (180), using the Roland Morris Questionnaire methods. All subjects exhibited radiological evidence of herniated intervertebral disc at one or more levels, and had significant pain that was refractory to at least two previous non-operative procedures. Statistically significant improvements in pain and activity scores were recorded at short and long term follow-up. This study provides evidence that the VAX-D protocol is associated with improvements in pain and activity-limitation in a sample of patients with unfavorable prognosis for recovery from chronic activity-limiting low back pain.



INTRODUCTION: This study was done to determine outcomes following treatment with the VAX-D protocol from a sample of patients with chronic low back pain that had been refractory to at least two (2) previous non-operative procedures

NUMBER OF SUBJECTS: One hundred and eighteen subjects with chronic, activity-limiting low back pain enrolled in the study. All subjects had radiological or spinal imaging findings of a herniated intervertebral disc at one (1) or more levels of the lumbar spine.

MATERIALS AND METHODS: Reports of pain (numeric rating scale 0-10) and activity-limitation (Roland Morris Questionnaire 0-24) were used as primary outcome measures. Subjects received an eight (8) week course of VAX-D treatment consisting of five thirty-minute sessions per week for four (4) weeks, followed by one thirty-minute session per week for four additional weeks. Follow-up measures were obtained at discharge and at thirty (30) and one hundred and eighty (180) days following discharge.

RESULTS: Ninety-six (96) subjects completed the entire treatment protocol. Complete follow-up data were available for sixty-seven (67) subjects. An intention-to-treat analysis was used to account for those subjects lost to follow-up. Significant improvements were noted for both dependent variables at discharge, and thirty (30) and one hundred and eighty (180) post-discharge. The pre-intervention group mean for average pain intensity (N=118) was 6.03/10. At one hundred and eighty (180) days following intervention the mean score improved by -1.51 [95% Confidence Interval = (1.05-1.98)], $P = .00$, effect size 0.88). The pre-intervention group mean for the Roland Morris Questionnaire (N=118) was 13.18. At one hundred and eighty (180) day follow-up the mean score improved by -5.41 [95% Confidence interval = (3.83- 6.23)], $P=.00$, effect size 1.07].

CONCLUSIONS: Following a conservative intention to treat analysis, statistically significant improvements were noted in average pain and the Roland Morris scores at short and long-term follow-up, although for the Roland Morris questionnaire the minimal detectable change score was within the 95% confidence interval for mean improvement at one hundred and eighty (180) days.

CLINICAL RELEVANCE: The VAX-D is a low risk, non-invasive form of pelvic traction that is administered with the patient in the prone position. Although its utilization in clinical settings has been growing, there is a lack of evidence that describes outcomes following this intervention.

This study provides preliminary evidence that the VAX-D protocol is associated with improvements in pain and activity-limitation in a sample of patients with unfavorable prognosis for recovery from chronic activity-limiting low back pain. Further study is needed using randomized comparison groups.



WELCOME RELIEF FOR LOW BACK PAIN

J. Stewart M.D.

CBS HealthWatch by Medscape

Beth Israel Deaconess Medical Center. Reviewed for medical accuracy by physicians at Beth Israel Deaconess Medical Center (BIDMC) Harvard Medical School

Introduction "It's a miracle. I feel like a whole new person," raves 61-year old Kathleen Ross about what some believe to be a remarkably effective form of therapy for low back pain called vertebral axial decompression, or VAX-D. "I was in such pain from a chronic slipped vertebra that I couldn't bear to sit. Then lying down was the only way to relieve the pain. I was afraid I'd be this way for the rest of my life."

For years people like Kathleen, who suffer from chronic and acute low back pain, have relied on conventional therapies that included bed rest, manipulation, pain medication, and, in the most severe cases, surgery. Now an increasing number of patients are being referred by their physicians and surgeons to VAX-D therapy. VAX-D is a noninvasive treatment that is said to work by alternately stretching and relaxing the lower spine, gently "distracting" the lumbar vertebrae and decompressing the intervertebral discs. In most cases, patients find they can now move more and get long-lasting relief from the crippling pain that comes with a variety of lower back problems.

Vertebral axial decompression (VAX-D) is a noninvasive treatment that is said to work by alternately stretching and relaxing the lower spine, gently "distracting" the lumbar vertebrae and decompressing the intervertebral discs. Low back pain is common in western culture, yet according to the North America Spine Society, the relationship between structural defect and pain is not always understood. Mechanical back pain can come from inflammation caused by injury or irritation, a bulging or herniated disc, or simply the degeneration of discs that comes with aging.

Compressive pain occurs when the spinal nerve roots are pinched or the blood supply to the nerve roots is cut off. In both cases pain can be aggravated by activities that increase "axial loading" such as sitting, standing, or lifting. Sometimes too much pressure from overexertion is the problem. Sometimes too little pressure from inactivity is to blame.

VAX-D is said to relieve the pressure between discs and decompress the nucleus within the disc in a controlled manner, which could cause healing to occur in a number of ways. The treatment is increasingly being recommended as front-line therapy in cases of herniated disc, degenerative disc, slipped vertebra, sciatica, posterior facet problems, and spinal nerve disorders, as well as for post-surgical patients who continue to suffer from "failed back syndrome."

Vertebral axial decompression (VAX-D) is a noninvasive treatment that is said to work by alternately stretching and relaxing the lower spine, gently "distracting" the lumbar vertebrae and decompressing the intervertebral discs.

The VAX-D Table The VAX-D Therapeutic Table was invented by Dr. Allan Dyer, the former Deputy Minister of Health of Ontario, Canada, and was approved by the FDA for use in the United States in 1994. At present, over 180



clinics offer VAX-D therapy throughout the US, and in Canada, Puerto Rico, Mexico and Australia. The equipment consists of a mechanically controlled two-part table and a logic control system operated by a technician who constantly monitors and records the therapy cycles. Dr. J. Robert Wootton, a Florida-based physician and one of the earliest practitioners of VAX-D therapy in the United States, explains the procedure. "The patient lies face down on the extendable table, the upper body resting over the stationary portion, holding on to adjustable handgrips that can be released at any time for safety. The patient wears a specially fitted pelvic harness, which is attached to a 'tensionometer' at the foot of the table.

"As the table separates hydraulically, the harness gently pulls the lumbar spine downward, decompressing the vertebrae and the intervertebral discs. A typical half-hour session consists of fifteen (15) alternating cycles of distraction and relaxation, lasting 1 minute each. In most cases, the desired results are achieved within 20-30 daily sessions." The amount of "pull" varies for each patient, depending on the degree of distraction necessary to treat the condition. In the beginning, and during relaxation cycles, the tensionometer maintains 20 pounds of pressure. Then it increases to between 65 and 85 pounds during decompression. A paper graph connected to the machine prints out a continuous record of the intradiscal pressure. Interestingly, many professional athletes use the VAX-D table, set at 55 pounds of pressure, as a pre-exercise warm-up, according to Dr. Wootton. "The nerves in the lower back supply the legs, so if you take the pressure off the nerves to the legs, you have more power."

Lowering Intradiscal Pressure As tension is continuously applied to the harness, the pressure within the discs reaches a threshold at which it changes from a positive to a negative level, indicating decompression, or a vacuum. The precise control provided by the VAX-D table enables the therapist to determine the exact pull required to achieve optimal decompression. Many patients report instant reduction of pain during the session, as well as afterward. Dr. Wootton further explains the multiple effects of high-level decompression within the discs. "The powerful negative pressure from the vacuum draws back the herniated disc into its proper orientation, draws nutrient-rich spinal fluid into the disc, and stimulates repair cells, effectively mending the disc." Wootton adds, "VAX-D is the most promising non-surgical medical treatment for lumbar pain to be developed in many years."

Not everyone, however, is a candidate for VAX-D therapy. Contraindications include infection, degenerative arthritis, tumors, osteoporosis, fractures, or any condition that compromises the integrity of the spinal column. Prospective patients should be evaluated by a therapist or physician prior to therapy, and routine spinal X-rays should be taken. A CT scan or MRI may also be necessary to rule out any contraindications. To date, no serious side effects have been reported with VAX-D Therapy.

Long-Term Effects According to clinical results gathered over the last 4 years, the vast majority of patients experience some degree of recovery with VAX-D therapy, and of those the majority remain in remission. (Some experts caution, however, that no well-designed trials have demonstrated the efficacy of this treatment.) Some patients choose to return for maintenance visits or to enhance the protective benefits of this treatment.

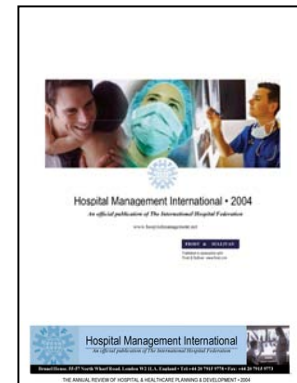
Although the safety and efficacy of VAX-D are said to be high, and the cost is relatively low (approximately 1/12 the cost of surgery), many insurance companies have yet to cover the procedure. This is changing, as VAX-D becomes more widely known.



ORTHOPAEDICS: NEW ANSWERS FOR AN AGE OLD PROBLEM: EVIDENCE-BASED EMERGING TECHNOLOGY IS HERALDING A NEW FUTURE FOR SUFFERERS OF LOW BACK PAIN

Hospital Management International:
The Annual Review of Hospital & Healthcare Planning & Development
The Official Publication of the International Hospital Federation, London UK

Acute low back pain (LBP) is one of the most common and significant musculoskeletal problems in the world. It is the cause of considerable suffering and disability, and the economic costs to patients, industry and governments are staggering. Back disorders now account for almost 30% of all occupational injuries. Recent studies reveal that the average cost of a workers compensation claim for LBP (in the US) is now close to \$10,000 which is more than twice the average cost for all other compensable claims combined.



Even though this ailment usually has a benign course, it is responsible for direct health care expenditures in the United States of more than \$25 billion annually, and as much as \$100 billion per year when indirect costs are included. Despite these overwhelming statistics, the magnitude of the problem continues to skyrocket. Chronic low back pain is increasing faster than any other disability.

Experience in the last decade has shown that traditional management based on rest and passive care has been unsuccessful, actually promoting disability. A new treatment and model of care has now provided an answer for this age old problem. Intuitively, lumbar decompression should be successful in alleviating many of the conditions that cause low back pain and associated radiculopathy. Technology has finally provided the answer and discs and nerves can now be effectively decompressed non-surgically.

Emerging Technology

VAX-D or Vertebral Axial Decompression is an emerging technology that addresses the biomechanical aspects of disc disease and is now being widely used in the United States for chronic low back pain sufferers. Clinical studies done by the Departments of Neurosurgery and Radiology, Rio Grande Regional Hospital, McAllen, and Division of Neurosurgery, Health Sciences Center, University of Texas, San Antonio, Texas have documented VAX-D's ability to actually lower the intradiscal pressure to negative levels. Prior to the introduction of VAX-D the successful application of lumbar distractive forces has been limited by the technological design of ineffective traction devices.

An outcome study on 778 patients and prospective Randomized Controlled Trial (RCT) done at the University of Sydney in Australia both reported approximately 70% success rates and improvements in functional outcomes with chronic disc cases. A recent RCT (2004) conducted by Dr. G. Ramos, Neurosurgeon at HCA Rio Grande Regional Hospital in Texas has also published success rates of 70%.

In addition, several research studies have now been published examining the mechanism of action of VAX-D. Studies in Canada and the US have reported that lumbar nerve root decompression is achieved with VAX-D Therapy. VAX-D has a growing body of research publications which include several randomized

control trials (RCT) conducted in the US, and RCT in Australia and many other studies examining the mechanism of action.

Public demand for VAX-D is driving the expansion of VAX-D centers in the United States, Australia, Mexico, Canada, Puerto Rico and Europe. The insurance industry views VAX-D as a standard of care that should be exercised prior to surgery.

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Putting People Back to Work

Workman's Compensation boards in the United States are rapidly reducing their costs by adopting policies referring injured workers with LBP for VAX-D treatment. Workers complete the target therapy in the initial phase of disease and return to work. Patients undergo 20-25 daily decompression treatments along with the concomitant use of agents such as Methylprednisolone, NSAID's and Doxycycline. They can then manage the disease thereafter if they are re-injured.

VAX-D therapy's continuing high success rates in private clinics, hospitals and respected schools such as Baylor College of Medicine is now making it the gold standard of conservative care.



Vertebral Axial Decompression

Frank Tilaro MD, Internal Medicine, Utah

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Introduction:

Dr. Allan Dyer, former Deputy Minister of Health from Ontario, Canada, and a pioneer in the development of the external cardiac defibrillator, designed the vertebral axial decompression (VAX-D) therapeutic table to apply distraction tension to the patient's lumbar spine without eliciting reflex paravertebral muscle contractions. A patented harness is attached to a tensionometer during separation of the movable part of the table. The distraction-relaxation cycles are automated or variably timed. Distraction tensions and rates are continuously monitored and measured by the tensionometer, and the output is shown on a digital gauge and captured on a pen-write printout.

Procedure

The technology applies and maintains a baseline tension of 20–24lb (the pre-tension) to the patient's pelvis throughout the treatment session (even during the rest periods), and the distraction cycles then move from pre-tension range up to a pre-selected therapeutic tension. The above parameters are absolutely critical to the success of the treatment.

The drive mechanism allows precise control of the amount of tension and is able to apply tensions in a logarithmic time/force curve. The logarithmic curve 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 patient to the starting position each time.

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, which continuously monitors and provides feedback of the tensions being applied to the spinal column.

Patients with discogenic low-back pain – with or without radiculopathy – who have failed conventional therapy become candidates for VAX-D therapy after six to eight weeks. Patients with neurological deficits are also candidates since outcome studies have shown no difference with surgical or medical management. Patients 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 spondylolisthesis, fractures and the presence of surgical hardware in the spine. The average patient requires 20–25 sessions. Each session is 15 cycles, each cycle being one minute in distraction and one minute in relaxation.

A pre-tension level of 20lb is set and maintained throughout the resting phase. Ramos demonstrated that 50lb of tension was the threshold tension necessary to develop negative intradiscal pressures. Women start with 50lb and work up to 70lb. Men usually start at 60lb and work up to 80lb. Tension increments are in the order of 5lb every three to four days, although some patients need to proceed more slowly.

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 one to two hours. Once the VAX-D course is completed, patients are encouraged to enter some form of rehabilitation program and learn proper biomechanics.

Discussion

The first large-scale retrospective study involved over 700 patients with low-back pain – with and 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 a positive response during treatment and/or immediately thereafter.

Sherry et al. conducted a prospective, randomized controlled trial of VAX-D versus TENS. All patients had chronic symptoms (with the average duration of pain being 7.3 years). TENS was regarded as a placebo. The data revealed an attributable success rate of 68.4% for VAX-D, significantly superior compared with TENS ($p < 0.001$).

Summary

VAX-D should not be considered as traction in the traditional sense, but as decompression: it is the only non-invasive treatment that has been proved to decompress only the disc.

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 concepts for the future include investigation of immunomodulators, transplanting live 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 the damaged disc.



VAX-D Medical Technologies

A Special Message For Physicians

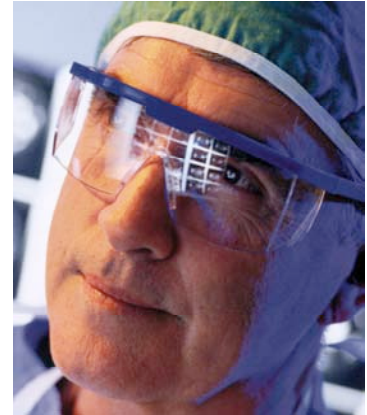
VAX-D Medical Technologies is a professionally directed company providing advances in medical technology for physicians. The American branch was established in 1995, and is located in Tampa Florida. The company has developed, patented, and manufactures the VAX-D Genesis System and Genesis G2 for the treatment of chronic back and neck pain.

VAX-D is the national leader in the conservative care for spinal disc problems. VAX-D systems are being utilized by physicians in the Orthopedic Medicine, Neurosurgery, Pain Management and Occupational Medicine, and Chiropractic care fields. Back pain and neck pain are two of the most common and significant musculoskeletal problems in the world.

VAX-D is currently being prescribed and provided across the United States and in many countries internationally.

VAX-D treatment is a safe, cost effective, non-surgical treatment that offers new hope for the millions of people who suffer from back and neck pain everyday.

Since our first VAX-D system was introduced in 1989, our focus has been to provide quality equipment and service for our customers. As we commemorate 18 years in the low back pain field, we celebrate a proud history and commitment to the patients for whom we care, and for those whose lives we have forever changed.



vax-d
Helping People Get Back To Life



We Invite You To
Learn About
Our Science

vaxi-D