

# **Efficacy of vertebral axial decompression on chronic low back pain : Study of dosage regimen**

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## ***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  $P < .0001$ . [Neurol Res 2004; 26: 320–324]*

*Keywords: Low-back pain; VAX-D; lumbar spine; discogenic; radiculopathy; nucleus pulposus; intradiscal; radiculopathy*

## **Introduction**

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 (1). 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 (2).

Determining the pain generating tissue has not been an exact science. The diagnosis is considered confirmed when imaging techniques reveal a herniated disc, nerve root compression, and objective signs in the appropriate dermatome. Discography and selective nerve root blocks can provide the diagnosis in patients without sciatica (Quebec 1 and Quebec 2 pain patterns) but are invasive, painful, frequently not covered by insurance companies and not readily available.

Understanding the clinical anatomy of the spine is a prerequisite to understanding pain generation. The disc is generally accepted as a pain generator, the outer third of the annulus is innervated by the sinu-vertebral nerve (3,4,5,6,7,8,9). Kuslich, employing progressive local anesthetic to explore the lumbar spine concluded the outer annulus is the tissue of origin in most cases of low back pain (10). The posterior longitudinal ligament is a highly innervated structure and is intimately connected with the posterior central portion of the annulus and Kuslich found it was frequently tender and produced central low back pain. Although Kuslich was unable to differentiate its specific role, in general, when the posterior annulus was tender the posterior longitudinal ligament was also sensitive. Nachemson believes the intervertebral disc is the likely structure responsible for pain and provides indirect proof (11). Compelling evidence points to the intervertebral disc as the significant pain generator (12).

Conservative medical care revolves around modalities, exercises, stretching, manipulative techniques, anti-inflammatory and other medications. The modalities have no intrinsic value and most exercise and stretching programs are generally empiric and may not benefit many patients. This is not to say that exercise in itself is not beneficial. Experimental data with dogs demonstrated that moderate exercise over long periods of time reduced lactate concentration in the outer portion of the annulus and the central nucleus pulposus (13). This may explain why general exercise and fit people have a lower incidence of low back pain (14).

Physical therapy has not been demonstrated to be useful for treating low back pain of discogenic origin (15). Anti-inflammatory drugs are useful in acute muscle strains but are ineffective in sciatica and chronic low back pain. Manipulation may break adhesions or displace an annular fragment from the joint but is ineffective in disc protrusions. Manipulation has not been proven to be of benefit in relieving low back pain of discogenic origin. (16). Pain from the SI joint can be ameliorated by manipulation and some chronic ligamentous sprains are amenable to prolotherapy (17,18). Myofascial conditions may be treated by trigger point release. Specific medical therapy for the disc is wanting.

Patients who fail therapy at the primary care level (general practitioners, internists, physical therapists, and chiropractors) are routinely referred to the neurosurgeon or orthopedic surgeon, especially if abnormalities are noticed on CT scan or MRI. The majority are not ideal surgical candidates and both the doctor and patient find themselves at an impasse. A rush to surgery in the poorly selected patient can result in the failed back syndrome which Kramer calls the “worse possible scenario the spine surgeon faces” (19). Unfortunately this iatrogenic disease is increasing at alarming rates in North America (20). Failed disc excision can result in a litany of procedures including fusion, hardware insertion, removal of hardware, and subsequent analysis of levels above and below the previous surgery.

Recently a medical procedure called the VAX-D (Vertebral Axial Decompression) has shown promise in patients with chronic low back pain. A retrospective study performed on 778 patients with low back pain with or without radiculopathy was published. Significant reduction in pain and significant increase in activity was found in over 70% (21). All patients had failed standard medical therapy and the average duration of symptoms for the group was over 3 years (43 months). A prospective randomized control trial conducted on patients suffering from chronic low back and leg pain reported that 68% of the group on VAX-D achieved remission. Statistical analysis established that the success rate with VAX-D was significantly higher than the control group. (22). A long term study that followed the progress of cases four years after VAX-D found that more than 50% had remained in remission without further treatments and 91% had been able to resume their normal daily activities. (23). Published data has also demonstrated the effectiveness of VAX-D in reversing sensory nerve dysfunction in patients with compressive radiculopathy (24,25)

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 (26). 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 (27). Biomechanical studies have implicated elevated intradiscal pressures in the equation for annular failure. (28,29,30,31,32).

The VAX-D applies distraction tensions to the patients lumbar spine without eliciting reflex paravertebral muscle contractions, this differentiates this procedure from conventional traction (33). A computer programmed logic computer, which accepts feedback during distraction, features in the unique performance. The resultant time-energy curve for the VAX-D is logarithmic and has been described mathematically in the patent on the procedure.

The procedure is very safe and patient friendly. The patient lies prone, the upper body is over the stationary portion of the table, and the body is restrained by the patient holding on to adjustable hand grips, which can be released at any time for safety. The table is a split table design, whereby distraction tensions are applied to the

patient through a pelvic harness attached to a tensionometer and by separation of the movable part of the table. The distraction-relaxation cycles are automated or variably timed. Continuous feed-back from the tensionometer throughout each distraction and relaxation cycle is captured on a chart printout, providing the operator with a time-energy curve that allows constant monitoring of the patient. Fatigue, decompression, and excessive muscle contraction can be observed from the chart printout. This allows the operator to adjust the therapy. The protocol has been formally amended since initiating this study. Patients receive on average 20 daily sessions, employing tensions from 55 to 85 pounds. Each session is 15 cycles characterized by 1 minute in distraction and 1 minute in relaxation. Once the patient is asymptomatic or the clinical symptoms have reached a plateau the tension is reduced by 10 to 15 pounds for the remaining course of therapy.

Indications for the VAX-D are patients with low back pain (Quebec 1,2, or 3) due to disc disease who have not responded appropriately to standard medical therapy. In the Gose study the best response were observed in patients with subligamentous hernias (21). Contraindications to therapy are cauda equina syndrome, tumor, infection, severe osteoporosis, fracture, bilateral pars defect, spondylolisthesis Grade 2, and the presence of surgical hardware. Patients with symptomatic osseous lateral stenosis are poor candidates and patients with osseous central canal stenosis are not expected to respond.

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.

## **Materials and Methods**

The patient population for the trial consisted of cases that were referred for neurosurgical evaluation after exhausting standard medical management by family practitioners, internists, orthopedist, physical therapist and chiropractors in the Rio Grande Valley, Texas. Over 150 new patients are seen annually with a diagnosis of herniated lumbar disc(s). Patients were selected for VAX-D therapy if they had low back with or without sciatica, non-progressive neurological deficits and no contraindications to VAX-D therapy. Some patients considered surgical candidates declined surgery and opted for VAX-D therapy. Patients with stable neurologic deficits underwent treatment with the VAX-D. All patients had imaging studies (MRI or CT scan) prior to VAX-D therapy to confirm the diagnosis of a discogenic disorder that was consistent with the clinical findings.

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.

Patients receiving VAX-D therapy were required to stop all other forms of therapy during their treatment period and for 4 weeks after terminating therapy. This included any modalities, back exercises, or stretching programs. Medications were allowed on a prn basis

All patients received 15 distraction and relaxation cycles per day on a daily basis administered five days per week. A complete session takes 30 to 45 minutes. Therapy was initiated at 55 to 65 pounds and increased to 70-90 pounds as tolerated. In a previous publication (26) by the author, 40 -50 pounds was the required threshold necessary to achieve negative intradiscal pressure. The treatment procedure administered to all patients was the same except for the number of sessions employed as the prescribed course of therapy. The prescribed course of therapy employed for a period of time was limited to 10 daily sessions ( 10 Sessions Group). Subsequently the prescribed course of therapy was increased to 20 daily sessions ( 20 Sessions Group) . Patients that achieved remission prior to completing the prescribed number of treatment sessions were included in the results for the assigned group but were not required to complete the prescribed course of therapy. The average course of therapy in the 10 Sessions Group was 9 daily sessions whereas the 20 Sessions Group received on average 18 daily sessions.

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 bedrest.

## Results

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 .

Remission was defined as no pain or 90% relief of pain, the ability to carry out ADL'S without limitation and back to work without limitations. Partial remission was defined as persistence of some pain but ability to carry out most ADL's and return to work with some restriction of duties, depending on the occupation. Negative response was defined as no change in level of pain and/or ADL.

Table 2. illustrates patient response according to the dosage regimen. Figure 1. illustrates the frequency distribution in a bar chart format. Results from the two dosage groups clearly indicate that patients receiving more than ten treatments had a better response with 76% in the 20 Sessions Group achieving remission whereas it was 43% in the 10 Sessions group. If one excludes the patients with stenosis the remission rate of the 10 Sessions Group is still significantly different than the 20 Sessions group (48% and 76% respectively). Partial response was similar in both groups but the 10 Sessions Group had a failure rate of 33% while the 20 Sessions Group had a failure rate of only 4 %.

The frequency distribution of responses observed with the two groups of cases was compared using a Chi-Square statistical analysis.

The difference in the frequency response, as show in Table 2, between the 10 Sessions group and the 20 Sessions group was statistically significant at  $p < 0.0001$ .

Table 3 shows the responses classed conservatively into two categories Remission and Not-Remission. For this purpose " Not-Remission " includes all cases classed as both Partial Responses and Negative Responses. The difference between the two dosage groups was found to be highly significant with a  $p < 0.0002$ .

Analysis of the Remission rate and Not-Remission rate was then subjected to null hypothesis as shown in Tables 4 and 5. "Null hypothesis" employs a stringent criteria based on the concept that if the procedure has no effect the frequency distribution would be equal between categories of response. Statistical analysis was performed to compare the observed frequency distribution and a normal binomial distribution.

Table 4 shows the responses classed as Remission and Not-Remission, for the 20 Sessions group compared to a null hypothesis distribution. Chi- Square analysis of this data concludes that the Remission rate in the 20 Sessions group was statistically significant with a  $p < 0.01$ .

Table 5. shows the responses classed as Remission and Not-Remission, for the 10 Sessions group compared to a null hypothesis distribution. Chi- Square analysis of this data was not statistically significant with a  $p > 0.3$  .

## Discussion

The likely source of pain is the disc, yet traditional care does not direct therapy to the disc. Fortunately the spontaneous remission rate for acute low back is high (37). Unfortunately morbidity and disability waiting for spontaneous remission is also high.

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 (35). 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 (38).

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 (4). 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 (3, 39). 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 (38,39,40,41).

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. Two significant observations can be made; 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.

## **Conclusions**

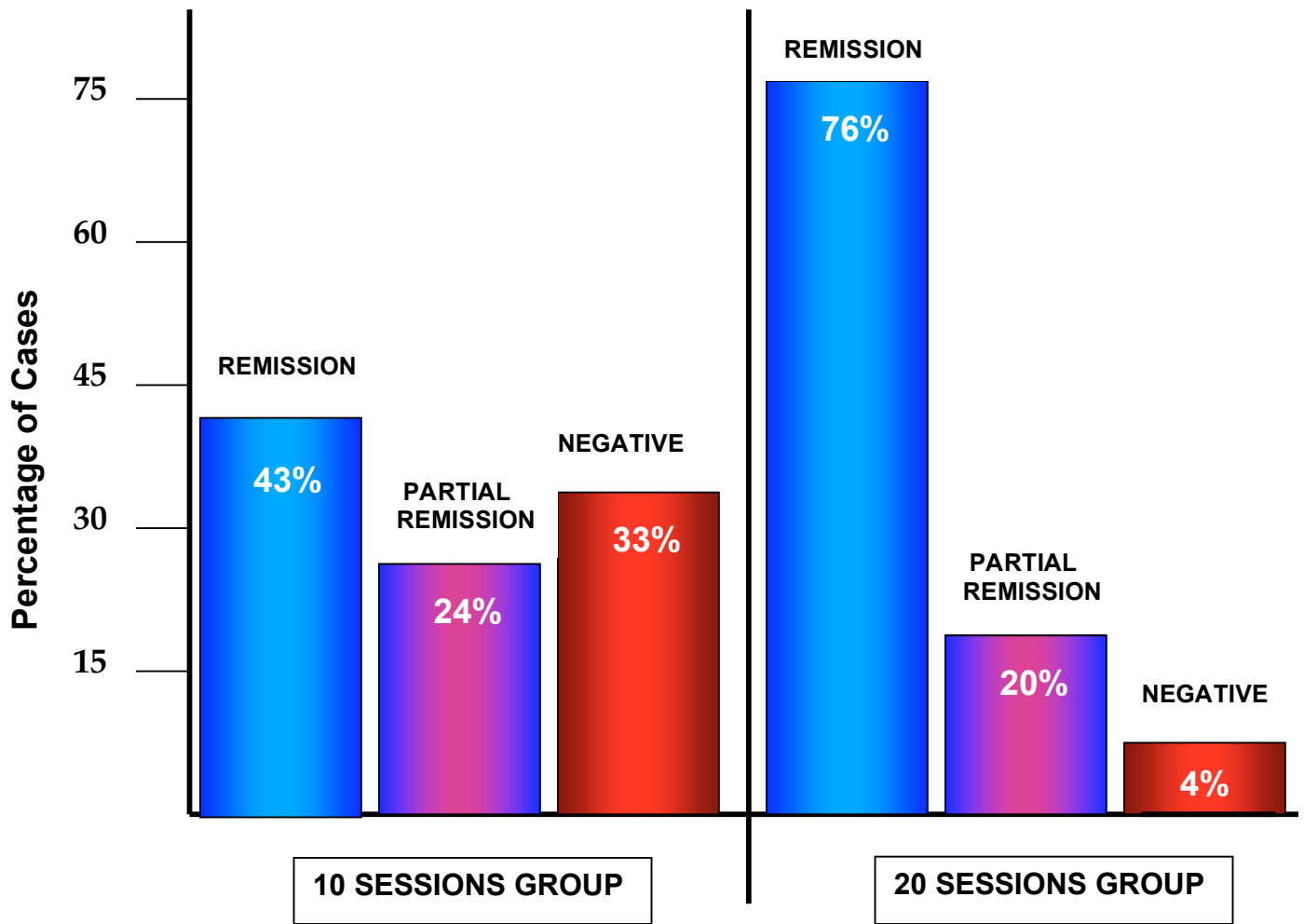
We conclude the VAX-D is a very useful medical procedure for patients with low back complaints of discogenic origin. Patients with Quebec 1, 2, or 3 designation are candidates for VAX-D provided contraindications are ruled out. The majority of patients in this study fit the Quebec 2 and/or 3 criteria. VAX-D should be utilized in all patients who are poor surgical candidates and before surgery is undertaken except in the emergent conditions.

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## ***Disclosure***

*The author has no financial interest or affiliation in the corporation that manufactures the equipment employed in this study.*



**Figure 1**

Illustrates the percentage of cases that achieved remission and partial remission with course of VAX-D therapy. 91 patients received on average 9 daily sessions (10 Sessions group). 51 patients received on average 18 daily sessions (20 Sessions group). Patients that failed to respond were classed as a negative response. Statistical analysis revealed:

Remission	20 Sessions vs 10 Sessions	p <.01
20 Sessions group	Remission vs Negative	p <.01
10 Sessions group	Remission vs Negative	p >.05

**TABLE 1. CASE DISTRIBUTION BY DIAGNOSIS**

No. Cases	Diagnosis - Confirmed by diagnostic imaging
111	Subligamentous herniation
41	Multi-level herniations
16	Extruded herniation
50	Degenerated disc disease
54	Neurological deficit
13	Stenosis
4	Spondylolisthesis
3	Failed back surgery
2	Fibrosis from previous surgery

**TABLE 2. FREQUENCY DISTRIBUTION OF RESPONSE**

Response	GROUP				
	20 SESSIONS		10 SESSIONS		
	Cases	%	Cases	%	
Remission	39	76.5	39	42.9	
Partial Remission	10	19.6	22	24.1	
Negative	2	3.9	30	32.9	
Total cases	51		91		142

Chi-Square = 19.14                      p < .0001                      @    df 2

The 20 Sessions group shows a statistically significant:

1.        Higher remission rate
2.        Lower failure rate ( negative response)

**TABLE 3.      FREQUENCY DISTRIBUTION OF RESPONSE**

Response	GROUP				
	20 SESSION		10 SESSIONS		
	Cases %	Cases %			
Remission	39	76.5	39	42.9	
Not-Remission*	12	23.5	52	57.1	
Total cases	51		91		142

\*Not-Remission = ( Partial Remission + Negative response )

Chi-Square = 19.14                      p < .0002                      @    df 1

The 20 Sessions group achieved a :

Statistically significant:

1.        Higher remission rate
2.        Lower failure rate

**TABLE 4.              20 SESSIONS GROUP • NULL HYPOTHESIS**

Response	20 SESSIONS GROUP		NBD*
Remission	39	25.5	
Not-Remission*	12	25.5	
Total cases	51	51	

\*Not-remission = (Partial remission + Negative responses)

Chi-Square = 7.6                      p < 0.01                      @    df 1

**Remission rate statistically significant**

Null hypothesis -

If procedure has no effect the frequency of  
Remission vs Not-Remission would be the same  
NBD ( Normal Binomial Distribution)

**TABLE 5.                      10 SESSIONS GROUP • NULL HYPOTHESIS**

Response	10 SESSIONS NBD GROUP	
Remission	39	45.5
Not-Remission*	52	45.5
Total cases	91	91

\*Not-Remission = ( Partial Remission + Negative response)  
Chi-Square = 0.93                      p > 0.3                      @    df 1

Remission rate not statistically significant from Not-Remission rate

Null hypothesis -

If procedure has no effect the frequency of  
Remission vs Not-remission would be the same  
NBD ( Normal Binomial Distribution)

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