

## 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 then 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 thixotrophic 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.