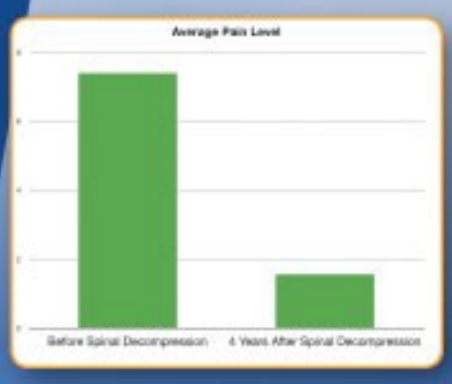
Research Proves Spinal Decompression's

"Excellent" Long Term Effectiveness

Even 4 Years Later!



STUDY: SPINAL DECOMPRESSION REDUCES CHRONIC BACK PAIN: A FOUR YEAR OUTCOME

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

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 (Vertebral Axial Decompression). '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).

Four Year Follow Up Study

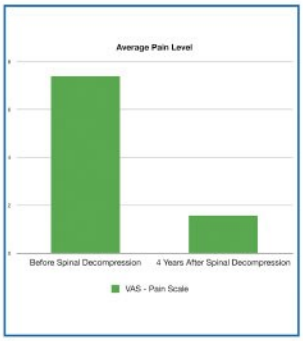
"Of the 23 patients who responded, 52% had a pain level of zero. 91% were able to resume their normal daily activities, and 87% were either working or were retired without having back pain as the cause for retirement," emphasized Dr. Odell. "There were no complications with this treatment."

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."



SUMMARY OF STUDY

Subjects' Conditions

- Herniated Discs
- Degenerated Discs

Prior to Treatment

- Average pain level 7.41 out of 10

Directly After Treatment

- Average pain level 3.41 out of 10

4 Years Later

- 52% had a pain level of zero
- 91% were able to resume their normal daily activities
- 87% were working or retired without having back pain as the cause of retirement.

SUMMARY: 71% showed more than 50% reduction in pain immediately after treatment and 86% showed a 50% or better showed a pain reduction at 4 years.

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