

## **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 one month and at six months, using the Roland Morris Questionnaire methods. All subjects exhibited radiological evidence of herniated intervertebral disc at one or more levels, and had chronic activity-limiting pain that was refractory to previous non-operative procedures. Statistically significant improvements in pain and activity scores were recorded at short and long term follow-up for 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 distraction that is administered with the patient in the prone position. Although its utilization in clinical settings has been growing, we need more 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.**

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*The Official Publication of the Orthopaedic and Sports Physical Therapy Sections of the  
American Physical Therapy Association*

*The JOSPT is also an officially recognized journal of Sports Physiotherapy Canada (SPC), a division of the  
Canadian Physiotherapy Association, and of the International Federation of Sports Physiotherapy (IFSP).*

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A two and one-half year study on the treatment of chronic back pain has now been completed. The study demonstrated that VAX-D Treatment was 88% successful in the 450 patient study. The patients selected for the study had failed at least two previous non-surgical treatments.

All patients were examined for pain reduction and activity modifications at the end of treatment, at one month and at six months to ensure the long-term benefits of the treatment. The study on VAX-D was designed, written and analyzed by ***Expert Clinical Benchmarks***, headed up by Paul Beatty, Clinical Associate Professor, Department of Exercise Science at the University of South Carolina.

The study design was a prospective case series, the third most reliable outcome measuring tool. Patients for the study came from sources such as the Philadelphia Teamsters, Teachers Unions, Street and Municipal Workers in Pennsylvania.

A research overview of the first 118 patients was released in the January 2005 Issue of the *Journal of Orthopedic & Sports Physical Therapy, Volume 35, Number 1*. The complete study is being submitted for publication.