

# **Vertebral Axial Decompression For Low Back Pain**

**By**

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<b><u>TABLE OF CONTENTS</u></b>	<b>Page</b>
Background.....	1
Methods.....	1
Results.....	2
1. Level 1 evidence: systematic review and randomized controlled trial.....	2
2. Other published primary research on VAX-D.....	4
3. Workers' compensation boards and other insurance company policies on VAX-D.....	4
Summary/Conclusion.....	5
References.....	6
Appendix 1.....	8

# Vertebral Axial Decompression for Low Back Pain

## Background.

Vertebral Axial Decompression is one type of mechanical lumbar traction that has been promoted as a treatment method for patients with back pain associated with lumbar disc herniation, degenerative disc disease, posterior facet syndrome, sciatica or radiculopathy<sup>(1)</sup>. It consists of a specialized table and computer designed to apply distractive tension along the axis of the spine.

The Evidence Based Practice Group received a request to up-date a previous review done on this subject in 1999 by Dr. C. Dunn.

The purpose of this current review by the EBPG is to conduct a systematic review on the effectiveness of VAX-D in treating low back pain associated with lumbar disc herniation, degenerative disc disease, posterior facet syndrome, sciatica or radiculopathy. Level of evidence is graded according to information provided in Appendix I.

## Methods.

Systematic searches on various commercial medical literature databases (up to Week 1 February 2005), including Cochrane Database of Systematic Review, ACP Journal Club, Database of Abstracts of Reviews of Effectiveness (DARE), Cochrane Central Trial Registry, BIOSIS, CINAHL, EMBASE and Ovid MEDLINE, were done by employing keywords: VAX-D or vertebral axial decompression or vertebral axial decompression table. There were no inclusion or exclusion criteria in these searches.

There were 38 articles retrieved by employing these keywords. However, after examining the abstracts, only 6<sup>(2-7)</sup> articles were related to vertebral axial decompression. Of these 6 articles, 4<sup>(4-7)</sup> were published after 1999. Of these four articles published after 1999, one<sup>(4)</sup> was published in the Official Gazette of the United States Patent and Trademark Office Patents regarding the operation of a vertebral axial decompression table. As such, this article will not be included in the current review.

Searches were done on the International Network of Agencies for Health Technology Assessment and its member countries websites including Canada (CCOHTA), the US (Veteran Administration), UK, Australia (Medical Services Advisory Committee), New Zealand, Sweden, the Netherlands and Denmark. The searches were done by employing the same keywords as above.

The websites of other workers' compensation boards in Canada and the US, including Alberta, Ontario, Washington State and Colorado, and private/health insurances, including AETNA, Medicare-Medicaid, Blue Cross of California and the Regence Group were also searched by employing the same keywords.

## Results.

### 1. **Level 1 evidence: systematic review and randomized controlled trial.**

- **Medical Services Advisory Committee (MSAC): Vertebral axial decompression therapy for chronic low back pain<sup>(8)</sup>.**

The Australian Medical Services Advisory Committee (MSAC) conducted a systematic review on the effectiveness of VAX-D as compared to other treatments for chronic low back pain patients resistant to conservative treatments. A literature search was undertaken on various commercial databases (up to December 2000), including Medline, EMBASE, HealthSTAR, the Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effectiveness (DARE) and the Clinical Evidence Site of the British Medical Journal. Searches were also undertaken on other non-commercial databases including the International Society of Technological Assessment in Health Care (ISTAHC), the International Network of Agencies for Health Technology Assessment (INAHTA) and the National Library of Medicine. The search terms included 'VAX-D', 'vertebral axial decompression' and 'low back pain'

The MSAC reviewed 7 manuscripts (3 published articles and 1 unpublished randomized controlled trial (RCT) from Australia) submitted by the representative of the VAX-D manufacturer in support of their application for the reimbursement under the Australian Medicare program.

To provide evidence on the effectiveness of comparator treatments (to VAX-D) for chronic low back pain, the MSAC also conducted searches to collect level I and or level II (Appendix I) evidence on the effectiveness of the available treatment modalities for chronic, specific and non specific low back pain. Specifically, these comparative treatments included discectomy or microdiscectomy for radiculopathy caused by herniated intervertebral disc unresponsive to conservative therapy, laminotomy or laminectomy with or without fusion for radiculopathy caused by degenerative intervertebral disc unresponsive to conservative therapy and ongoing conservative treatment for chronic non-specific low back pain unresponsive to conservative therapy.

At that time, there were 4 articles (2 published and 1 unpublished case series, 1 unpublished (RCT)) available on the effectiveness of VAX-D. These four articles were then critically appraised and considered to be of poor quality by the Australian reviewers. Based on available evidence, the MSAC concluded that there was insufficient evidence pertaining to the effectiveness of VAX-D in treating chronic low back pain. Further, the MSAC concluded that for patients with radiculopathy associated with a herniated intervertebral disc, there was some evidence that surgical discectomy was more effective than VAX-D therapy in relieving pain in the short (up to 6 months) and medium term (up to 1 year). None of the available studies reported the incidence of adverse events or patient drop out rates due to adverse events.

Based on the available evidence MSAC suggested that Medicare should not reimburse VAX-D procedure for treating chronic low back pain.

It should be noted that this systematic review conducted by the MSAC is appraised by the EBPG as comprehensive, transparent and methodologically of high quality.

- The only published randomized controlled trial on the effectiveness of VAX-D was conducted by **Sherry et al<sup>(6)</sup>** in 2001. It should be noted that the MSAC<sup>(6)</sup> appraised the study by Sherry et al<sup>(6)</sup> which was only partially available from the manufacturer as an unpublished paper. The study is described below.

Through advertisements in local papers, 44 patients with chronic low back pain (LBP), associated leg pain and a confirmed disc protrusion or herniation on CT scan or MRI were selected and randomized into 2 treatment methods, VAX-D or Transcutaneous Electrical Nerve Stimulators (TENS). The patients were randomized in sequential order and treatments were determined by a pre-defined central randomization list. It should be noted that there was no information on the total number of eligible patients and the fact that randomization in 'sequential order' is a form of quasy-randomization.

The inclusion criteria included age 18-65 years, a minimum Visual Analog Scale (VAS) score of 2 (on a 10 point scale), residence within 45 minutes of the clinic location and capable of thoroughly understanding the information given and following of protocol. The exclusion criteria included spinal stenosis, unstable spine, spinal surgical implants, shoulder problems which prevent compliance with VAX-D therapy, spinal pain due to tumor, infection or inflammatory disease, pregnancy and previous VAX-D therapy.

Patients randomized to VAX-D were treated according to the manufacturer's protocol. Patients received VAX-D therapy 5 times per week for 4 weeks and then once per week for 4 weeks for 30 minutes each times, according to the protocol. All VAX-D treatments were administered by VAX-D certified technicians at 4 VAX-D clinics in the Sydney, NSW area. Patients randomized to TENS therapy received treatment at one of the four VAX-D clinics. These patients received TENS for 30 minutes daily for 20 days then once a week for 4 weeks. It should be noted that this group of patients (TENS treatment) may not have been adequately treated to reduce pain since TENS was only administered in the clinic for 30 minutes a day instead of on a continuous 'as needed' basis. Neither group received any physical therapy modalities, steroid injections or other treatments during the trial. Both group of patients were allowed to take non-narcotic analgesics and anti inflammatory drugs if necessary. The impact of this adjunct treatment was neither controlled nor reported in the manuscript.

Treatment success was defined as a 50% decrease in pain as measured on a 10 point visual analogue scale and an improvement in 'disability' as rated by patients. Disability measurement tools were supplied by the National Musculoskeletal Initiative of Australia. Any level of improvement in disability was acceptable. These two measurement tools are subjective in nature. This study was not blinded in any way. The authors adopted a so called 'efficacy-evaluable population' used for statistical analysis of efficacy. By the definition provided by the authors, this procedure alone breaks the randomization process which is necessary in a rigorous RCT.

Of the 44 patients enrolled, half were 'randomized' to VAX-D and half to TENS. Two patients (one from each group) withdrew from the trial. Two patients from the VAX-D group both had a baseline VAS score of < 2 and were excluded from the analysis. There was no information reported on adverse events from both procedures.

It should be noted that there was no prior hypothesis stated and tested, and no sample size calculation presented. The subsequent statistical analysis may not be adequate to investigate the effect of confounders, the analysis was not done according to the 'intent to treat' principle and at least one of the principle investigators declared a financial interest in VAX-D.

The authors concluded that VAX-D statistically reduced pain and improved functional outcome among patients with chronic low back pain as compared to those treated by TENS. However, it should be noted that this is the only published 'randomized' controlled trial on VAX-D and is a small, poorly designed, executed and poorly reported study.

## **2. Other published primary research on VAX-D.**

- **Naguszewski et al<sup>(5)</sup>** conducted a dermatomal somatosensory evoked potential study to demonstrate lumbar root decompression following VAX-D therapy. Seven consecutive patients diagnosed with LBP and unilateral or bilateral L<sub>5</sub> or S<sub>1</sub> radiculopathy were recruited for this study.

The EBPG did not undertake a critical appraisal of this article as it was not designed to provide evidence on the effectiveness of VAX-D in treating chronic LBP patients.

- **Deen et al<sup>(7)</sup>** have reported, perhaps the only published, data on adverse events occurring in a patient treated with VAX-D. The patient was a 46 year old man with a 3 month history of right leg pain and paresthesia radiating into the sole of the foot consistent with the diagnosis of S<sub>1</sub> radiculopathy. The MRI revealed a large L<sub>5</sub> - S<sub>1</sub> disc protrusion on the right. The patient was treated with daily treatment sessions of VAX-D therapy, supplemented with moist heat and ultrasonic therapy. No other treatment was used. Three hours after the 3<sup>rd</sup> treatment, the patient's radicular pain worsened and his VAS pain score increase to 5 (baseline score was 3). During the 5<sup>th</sup> session, while undergoing treatment, the patient's radicular pain abruptly worsened and his VAS pain score escalated to 10. VAX-D therapy was then discontinued and the patient began taking oral narcotics and had to quit his job because of severe pain. Repeated MRI performed two weeks after the final VAX-D treatment showed progression of the disc protrusion with a large free disc fragment in the spinal canal that had migrated caudally to the level of S<sub>1</sub> pedicle. Six weeks after emergency microdiscectomy, the patient's VAS pain score was 0 and he had no motor deficit.

## **3. Workers' compensation boards and other insurance company policies on VAX-D.**

- The EBPG was not able to find any information on the status of reimbursement for VAX-D treatment on the Alberta and Ontario Workers' Compensation Board websites.

- The Washington State Department of Labor and Industries<sup>(9)</sup> stated that the department will reimburse VAX-D traction when traction is a proper and necessary treatment and is administered by a licensed physical therapist or physiatrist using VAX-D only to the same extent that the Department would pay for traction therapy using other approved traction devices. Further, the department stated that the department will not pay an additional cost when VAX-D is used due to insufficient evidence that VAX-D was more effective than other similar forms of traction on the market.
- The State of Colorado, Department of Labor and Employment<sup>(10)</sup> stated that there was no evidence regarding the effectiveness of VAX-D to treat chronic LBP.
- The US Medicare and Medicaid<sup>(11)</sup> program considers VAX-D as experimental treatment. As such the program does not provide coverage for VAX-D.
- Private health insurance, such as Aetna<sup>(12)</sup>, Blue Cross of California<sup>(13)</sup> and the Regency Group<sup>(14)</sup>, consider VAX-D as experimental treatment. The companies do not provide reimbursement for VAX-D.

### **Summary/Conclusion.**

- VAX-D system is a specialized table and computer designed to apply distractive tension along the axis of the spine. The VAX-D system is promoted to alleviate pain and neurological deficits associated with nerve root compression. The system is also promoted as being 'completely risk free'
- To date there is no evidence that the VAX-D system is effective in treating chronic LBP associated with herniated disc, degenerative disc, posterior facet syndrome, sciatica or radiculopathy
- A survey on various workers' compensation board and health insurance company websites revealed that none of these entities reimburse or provide a special reimbursement for VAX-D treatment.

## References.

1. ..VAX-D treatment. Downloaded from VAX-D in June 9, 2004 from <http://www.vax-d.com/Pages/VAXDTreatment/Introduction.html>.
2. Ramos G. and Martin W. Effects of vertebral axial decompression on intradiscal pressure. *Journal of Neurosurgery*. 1994 Sep; 81(3):350-3.
3. Gose Earl E, Naguszewski William K, Naguszewski Robert K. Vertebral axial decompression therapy for pain associated with herniated or degenerated discs or facet syndrome: An outcome study. *Neurological Research*. 1998 Apr; 20(3):186-190.
4. Dyer Allan E. Operation of a vertebral axial decompression table. *Official Gazette of the United States Patent & Trademark Office Patents*. Mar; 1232(3):21, 2000.
5. Naguszewski William K, Naguszewski Robert K, Gose Earl E. Dermatomal somatosensory evoked potential demonstration of nerve root decompression after VAX-D therapy. *Neurological Research*. 2001 Oct; 23(7):706-714.
6. Sherry E, Kitchener P, Smart R. A prospective randomized controlled study of VAX-D and TENS for the treatment of chronic low back pain. *Neurological Research*. 2001 Oct; 23(7):780-4.
7. Deen HG Jr, Rizzo TD, Fenton DS. Sudden progression of lumbar disk protrusion during vertebral axial decompression traction therapy. *Mayo Clinic Proceedings*. 2003 Dec; 78(12):1554-6.
8. MSAC (2001). Vertebral axial decompression therapy for chronic low back pain. Assessment report. Medical Services Advisory Committee. Department of Health and Aged Care. Canberra ACT. Australia. Downloaded from <http://www.msac.gov.au/pdfs/reports/msac1012.pdf>. In June 9, 2004.
9. State of Washington. Department of Labor and Industries (Sept 2000). Provider Bulletin. PB 00-09. pp. 2-3. Health Services Analysis Section. Olympia. WA. USA.
10. State of Colorado. Department of Labor and Employment. Medical Treatment Guidelines, Rule XVII: Rule XVII, Exhibit A. Low Back Pain. Medical Treatment Guidelines. December 1, 2001. Downloaded from [http://www.coworkforce.com/DWC/Rule\\_XVII\\_Exhibit\\_A.asp#E.13.Vocational\\_Rehabilitation](http://www.coworkforce.com/DWC/Rule_XVII_Exhibit_A.asp#E.13.Vocational_Rehabilitation). In June 9, 2004.
11. ..Center for Medicare and Medicaid Services. Department of Health and Human Services. Health Care Financing Administration. Medical Coverage Issues Manual. Transmittal 161. Date 8 November 2002. Downloaded from [http://www.cms.hhs.gov/manuals/pm\\_trans/R161CIM.pdf](http://www.cms.hhs.gov/manuals/pm_trans/R161CIM.pdf). In June 9, 2004.

12. .. Aetna (May 2004). Clinical Policy Bulletins. Number: 0180. Subject: Vertebral Axial Decompression Therapy. Downloaded from <http://www.aetna.com/cpb/data/CPBA0180.html>. In June 9, 2004.
13. ..Blue Cross of California (March 2004). Medical Policy 2.07.05. Vertebral Axial Decompression. Downloaded from [http://medpolicy.bluecrossca.com/policies/medicine/vertebral\\_axial\\_decompress.html](http://medpolicy.bluecrossca.com/policies/medicine/vertebral_axial_decompress.html). In June 9, 2004.
14. ..The Regency Group. Medical Policy. Policy No. 45. Effective date June 01, 2004. Medicine Section - Vertebral Axial Decompression. Downloaded from <http://www.regence.com/trgmedpol/medicine/med45.html>. In June 9, 2004.

## Appendix I.

### Level of evidence <sup>(adapted from 1,2,3,4)</sup>.

1	Evidence from at least 1 properly randomized controlled trial (RCT) or systematic reviews of RCTs.
2	Evidence from well-designed controlled trials without randomization or systematic reviews of observational studies.
3	Evidence from well-designed cohort or case-control analytic studies, preferably from more than 1 centre or research group.
4	Evidence from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments could also be included here.
5	Opinions of respected authorities, based on clinical experience, descriptive studies or reports of expert committees.

### Reference.

1. Canadian Task Force on the Periodic Health Examination: The periodic health examination. CMAJ. 1979;121:1193-1254.
2. Houston TP, Elster AB, Davis RM et al. The US Preventive Services Task Force Guide to Clinical Preventive Services, Second Edition. AMA Council on Scientific Affairs. American Journal of Preventive Medicine. May 1998;14(4):374-376.
3. Scottish Intercollegiate Guidelines Network (2001). SIGN 50: a guideline developers' handbook. SIGN. Edinburgh.
4. Canadian Task Force on Preventive Health Care. New grades for recommendations from the Canadian Task Force on Preventive Health Care. CMAJ. Aug 5, 2003;169(3):207-208