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Effects of vertebral axial decompression on intradiscal pressure

GUSTAVO RAMOS, M.D., AND WILLIAM MARTIN, M.D.
Departments of Neurosurgery and Radiology, Rio Grande Regional Hospital, McAllen, and Division of Neurosurgery, Health Sciences Center University of Texas, San Antonio, Texas

The object of this study was to examine the effect of vertebral axial decompression on pressure in the nucleus pulposus of lumbar discs. Intradiscal pressure measurement was performed by connecting a cannula inserted into the patient's L4-5 disc space to a pressure transducer. The patient was placed in a prone position on a VAX-D therapeutic table and the tensionometer on the table was attached via a pelvic harness. Changes in intradiscal pressure were recorded at resting state and while controlled tension was applied by the equipment to the pelvic harness. Intradiscal pressure demonstrated an inverse relationship to the tension applied. Tension in the upper range was observed to decompress the nucleus pulposus significantly, to below -100 mm Hg.

SURGICAL procedures utilizing conventional and percutaneous approaches have established the merits of decompression of intravertebral disc spaces in the management of low-back pain syndrome associated with lumbar disc herniation.4,12,13,15 Surgery will continue to play an important role in the treatment of patients with low-back pain and sciatica associated with herniated discs and degenerative disc problems. However, for patients who are not candidates for surgery, there is a need to establish a conservative approach that offers an effective means of returning the patient to a functional level of activity.

Considerable controversy exists in regard to the various techniques currently employed. Aside from basic bed rest, there are few noninterventional modalities that have been adopted as standards of therapy. Manipulative techniques for mechanical low-back pain associated with posterior facet syndrome or muscle strain have not been found as useful in the management of herniated or degenerated lumbar discs. Similarly, other modalities including ultrasound treatments, various electrical stimulation techniques, short-wave therapy, acupuncture, steroid injections, and the administration of anti-inflammatory agents and muscle relaxants all have a following among some practitioners but fall short of addressing the underlying problems associated with intervertebral disc lesions. All of these treatment methods fail by comparison to surgery, in our opinion, because they have the common problem of not relieving the pain from neurocompression or from the stimuli associated with a prolapsed nucleus pulposus. The only noninterventional method that has been shown to hold any promise of relieving pressure on vital structures of the lumbar region is that of distraction of the lumbar vertebrae by mechanical forces applied along the axis of the spinal column.2,3,5,14

There has been some investigation into the effects of distracting segments of the spinal column excised from cadavers,11,14 as well as radiological studies that provided evidence that the application of certain forms of tension can distract vertebral bodies.3,5 On the other hand, there are equally pertinent studies that failed to demonstrate any positive effects from other methods of applying spinal tractions.1,10 Nachemson and Elfstrom6-9 have studied the effects of movement and posture on intradiscal pressure. Their measurements show pressure changes caused by positioning and posture range between 25 and 275 mm Hg, suggesting that some positions and postures may be inadvisable for patients suffering from lumbar disc lesions. Anderson, et al.,1 and others have shown that certain traction techniques can actually cause an increase in intradiscal pressure, which would be undesirable in the treatment of low-back pain associated with herniated discs and a neurocompression etiology.

A new form of therapy, termed "vertebral axial decompression," has recently been introduced in the physical therapy department of the Rio Grande Regional Hospital. This treatment modality has shown considerable promise in relieving low-back pain associated with herniated discs or degenerative disc disease of the lumbar vertebrae in patients who are not considered candidates for surgery. The purpose of this research project was to investigate the influence of this new treatment modality on intradiscal pressure in the lumbar spine of patients receiving this form of therapy.

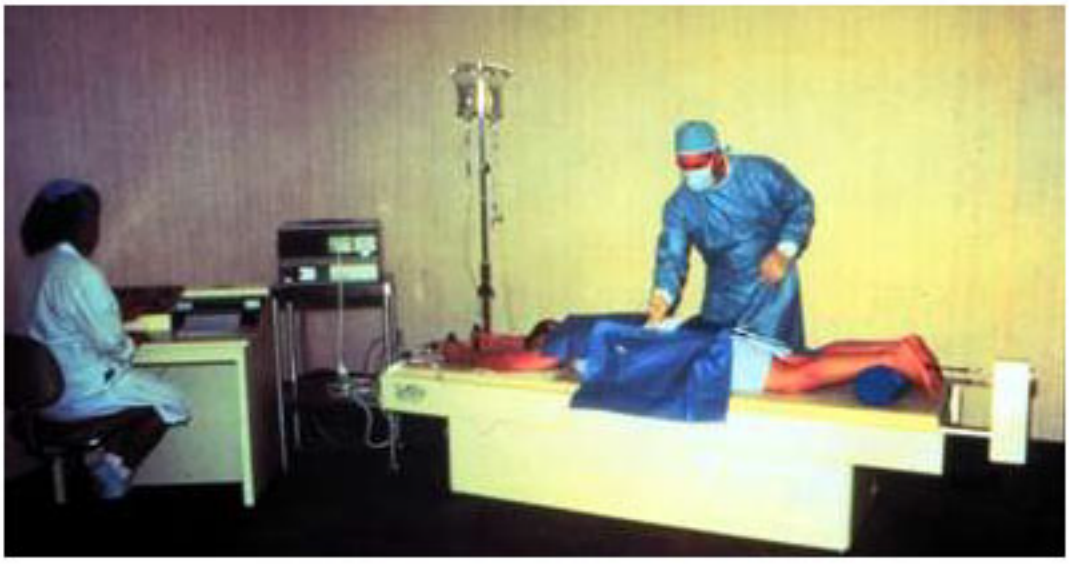

Fig. 1. Photograph illustrating the equipment and the position of the patient as the system is activated. The caudal end of the table extends, applying tension to the pelvic belt. Upper body movement is restrained by having the patient grasp the hand grips. A graph of the tension applied is plotted by a chart recorder on the control console and the intradiscal pressure readings are entered on the same graph at the apex of each distraction curve.

Clinical Material and Methods

Five cases were selected from among individuals who were referred for a neurosurgical consultation and had previously sustained a work-related injury that resulted in herniation of a lumbar disc at one or more levels. The diagnosis in each case was confirmed by magnetic resonance imaging. The patients chosen were scheduled for percutaneous discectomy. Introduction of the cannula for the purpose of performing percutaneous discectomy offered an opportunity to measure pressure changes in the disc prior to the operative procedure.

The patient was prepared and a cannula was inserted under local anesthesia into the nucleus pulposus of the L4-5 intervertebral disc using anteroposterior and lateral fluoroscopy to position the end. With the cannula in place, the patient was moved to a VAX-D table. The VAX-D equipment is routinely utilized in our nonsurgical treatment program for patients suffering from low-back pain. The equipment consists of a split table design with a tensionometer mounted on the caudal, moveable section. The patient lies in a prone position and grasps hand grips to restrain movement of the upper body, which is supported on the fixed section of the table (Fig. 1).

The cannula was then connected to a pressure monitor using a disposable pressure transducer. The lines were filled with normal saline. The pelvic harness designed for this therapy was fastened around the pelvic girdle and connected to the tensionometer via straps attached to the harness. When the system was activated the caudal section supporting the lower body extended slowly, applying a distraction force via the pelvic harness connected to the tensionometer. The level of tension was preset by the operator on the control console and observed and plotted on a chart recorder. The movement of the table was stopped and held when the desired tension was reached. An average course of therapy consisted of 30-minute sessions on the table once a day for 10 to 15 days. During each session the patient undergoes alternating cycles of distraction and relaxation, the timing and periodicity having been programed by the therapist.

In this study various distraction tensions, ranging from 50 to 100 lbs, were used for vertebral axial decompression therapy. The distraction tensions applied were monitored on a digital readout and recorded on a continuous graph tracing by a chart printer incorporated in the control console. The resulting changes in intradiscal pressure in the L4-5 nucleus pulposus were observed on a digital readout on the pressure monitor, and the readings were entered onto the chart recording at the point when the apex of distraction tension was achieved. The pressure readings were then applied to the negative-range calibrated curves prepared for each transducer to derive accurate intradiscal pressure readings.

TABLE 1

Effect of lumbar traction on intradiscal pressure*

Case No.Sex, AgeIndex Monitored#1#2#3#4#5#6#7#83M, 23traction tension, lbs intradiscal pressure, mm Hg0 7547 -2555 -3958 -4369 -664F, 41traction tension, lbs intradiscal pressure, mm Hg0 6020 3040 -7655 -11060 -12663 -11765 -16070 -1065M, 34traction tension, lbs intradiscal pressure, mm Hg0 6250 -10690 -13894 -13498 -157*See Fig. 2 for graphs of data points.

Measurements in the first two patients could not be translated accurately and are omitted (see text).

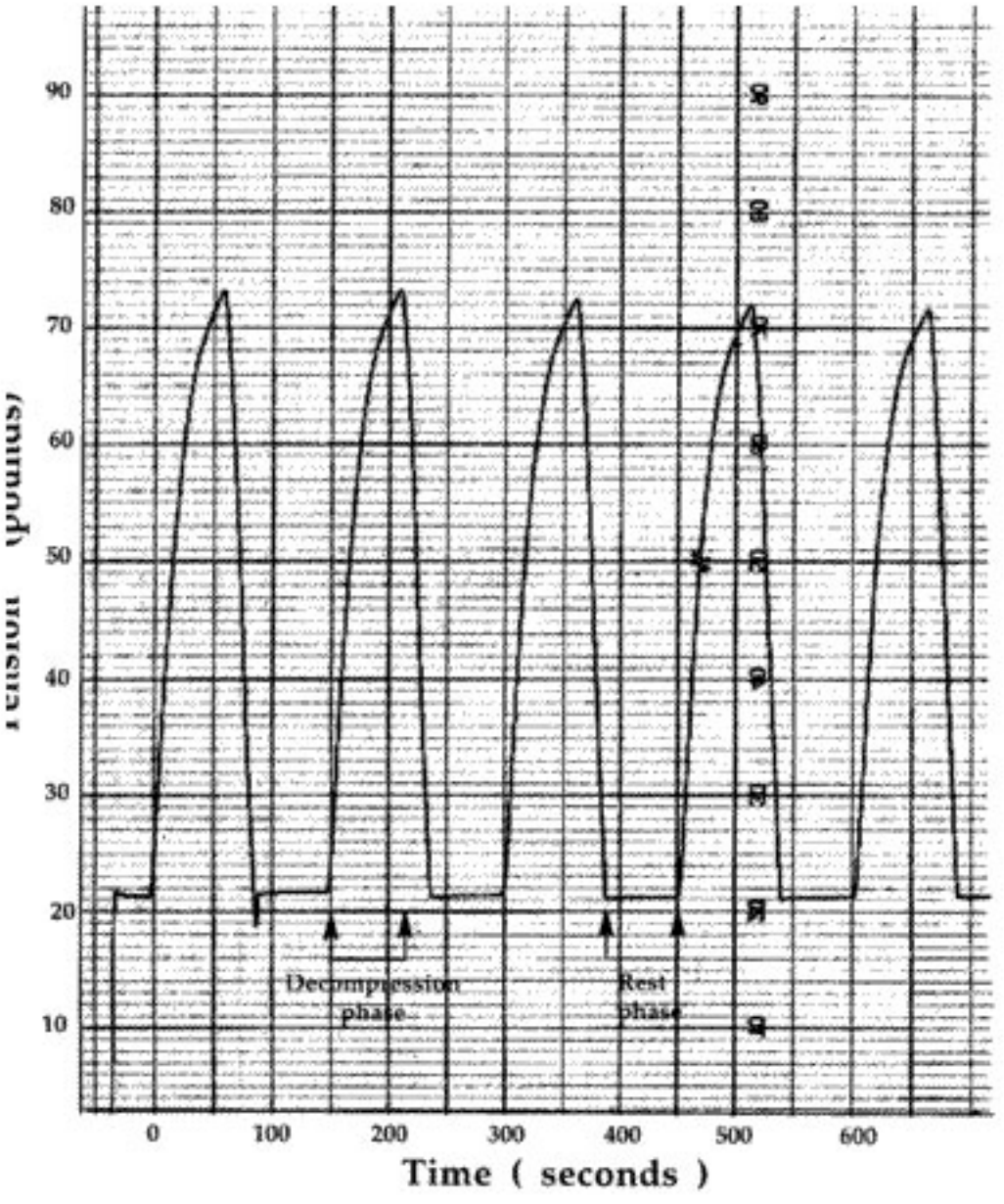

Fig. 2 Graphs showing the intradiscal pressures recorded in the L4-5 nucleus pulposus of three patients (Case 3, *upper*; Case 4, *center*; and Case 5, *lower*) with a herniated disc at this level. Pressure is plotted against distraction tension consistent with the range of tension recommended as the therapeutic protocol for the equipment used in this study.

The biological transducers employed in this study are primarily designed to measure pressure changes in the positive range. Following each procedure the presssure monitor and the disposable pressure transducer used for each patient were individually calibrated and a correction curve was plotted showing the transducer readings versus actual pressures, to correct for the nonlinearity of the instrumentation in the range of negative pressures achieved. A pneumatic calibration analyzer with an accuracy of 2% was used for this purpose.

Results

Intradiscal pressure measurements showed that distraction tension routinely applied by the VAX-D equipment reduced the intradiscal pressure significantly to negative levels in the range of -100 to -160 mm Hg. The relationship between distraction tensions and intradiscal pressure changes for three patients is presented in Table 1. The extent of decompression (measured in mm Hg) shows an inverse relationship to the tension applied and may be expressed by a polynomial equation.

Discussion

Intradiscal pressure changes were monitored in five patients. When the first two patients were tested, it was not recognized that biological transducers produce nonlinear measurements in the negative ranges at the levels achieved in this study. Since the disposable units had been discarded it was not possible to translate the findings accurately: however the intradiscal pressures were observed to be significantly lowered. Also the findings were consistent with the later three patients, for whom the transducers were retained and individually calibrated, permitting accurate interpretation of the results.

An interesting observation was that changes in intradiscal pressure appeared to be minimal until a threshold distraction tension was reached. When the threshold was exceeded the intradiscal pressure was observed to decrease dramatically to levels in excess of 300 mm Hg below the positive pressure observed prior to the application of pelvic tension. As indicated in the curves plotted for intradiscal pressures versus distraction tension, it appeared that the decrease in pressure tends to level off as the applied distraction tensions approached 100 Ibs. The concept of a threshold distraction tension and the levels observed in these trials are consistent with radiographic studies of vertebral body separation reported in other publications.2

The results indicate that it is possible to lower pressure in the nucleus pulposus of herniated lumbar discs to levels significantly below 0 mm Hg when distraction tension is applied according to the protocol described for vertebral axial decompression therapy. These findings may offer a plausible explanation for the mechanism of action for this therapeutic modality. Future research is warranted to study the decompression phenomenon achieved with this technology and its relationship to clinical outcome in patients with anatomical dysfunction of the lumbar spine. We are preparing a follow-up study on the clinical efficacy of this treatment modality.

Acknowledgments

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Disclosure

The authors have no financial interest in either the equipment or the methodology advanced in this study.

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VAX-D has been subjected to clinical trials at major hospitals in the United States and Canada, and has proven to be an effective treatment for lowback pain. VAX-D is applicable as a primary, active treatment modality for the management of most patients with disabling low-back pain and neurological deficits associated with herniated discs, degenerative disc problems and posterior facet syndrome.

The therapy combines a number of patented principles, which are administered via an automated and closely monitored system incorporated in the design of the VAX-D Therapeutic Table and Control console. This equipment is a Class II medical device registered originally in 1989 under the 510K No. K894435. The FDA registration has recently been updated as K951622 in response to a submission of the published article on intervertebral decompression. Please note under the section entitled "Intended use" in the updated FDA Summary of Safety and Effectiveness, reference is made to VAX-D achieving relief of low back and radicular pain through decompression of intervertebral discs.

Clinical research establishing the efficacy and safety were conducted at major hospitals in the U.S. and Canada. In these studies the patients were primarily Worker's Compensation cases who were referred to the Neurosurgical service of the respective hospitals following several months on conservative care without achieving significant progress.

The initial clinical trials, the 'Low Back Distress Study' was done at University Hospital, London. This was a study with subjective indices of pain and disability recorded daily along with analgesic use, Neurological dysfunction was assessed on a weekly basis. All the patients had a CT scan to confirm their diagnosis before starting treatment. The trials were conducted under the supervision of the Neurosurgical department.

Additional trials were carried out at the Departments of Neurosurgery and Radiology, Rio Grande Regional Hospital, McAllen, Texas. The patients were primarily Worker's Compensation cases who were referred to the Neurosurgical service following several months on conservative care, without achieving significant progress. In addition to replicating the basic results observed at University Hospital, significant research into the mechanism of action was also carried out.

These studies were conducted as a collaborative effort by the departments of Neurosurgery and Diagnostic imaging. The diagnosis, confirmed by MRI on all patients, was a herniated lumbar disc at one or more levels, often associated with additional complications such as degenerative changes and / or facet problems.

Clinical discomanometry research, in which intradiscal pressure changes were recorded during VAX-D Therapy, established that decompression (that is, unloading due to distraction and positioning of the patient on the VAX-D Table) of the intravertebral disc of the lumbar spine can be achieved with this equipment. The extent measured in mm. Hg. follows an inverse relationship to the tension applied to the pelvic belt during therapy. Resting positive pressure readings were observed to decrease to levels in the range of minus 150mm. Hg. in patients on VAX-D Therapy. An article on these clinical studies was published by Dr. G. Ramos, and Dr. W. Martin in the journal of Neurosurgery in September 1994.

To rule out artifact the investigators employed standard biological transducers and pressure monitoring equipment. Their paper also notes that they took the added precaution of individually calibrating the equipment employed in each case to make sure the negative pressure readings were accurate.

Furthermore it is important to note that the investigators were able to reproduce their results when distraction tensions were applied according to the VAX-D protocol.

The publication of this study was a first in the reported literature of this phenomenon and we feel has made an important contribution to the scientific knowledge regarding the clinical application of this technology. Equally important is the fact that the decreases recorded in the intradiscal pressures were well beyond physiological variations and therefore represented findings that could only have been attributed to the conditions of the clinical trial, that is treatment on the VAX-D table.

In addition to the definitive measurements, the study included a group of patients, referred for a neurosurgical consultation, who were treated with VAX-D Therapy. The incidence of patients that experienced a positive outcome, with relief of pain and distressing symptoms, following a course of 15 daily (half hour) sessions, was in the range of 65 to 70%. The data also notes that of the patients that achieved remission of symptoms, 90% suffered from a herniated lumbar disc. Diagnostic imaging confirmed that 89 % of the successfully treated hernias were classified as subligamentous, whereas 11% had extruded segments that had perforated the annular ligament.

Analysis of the clinical data showed that 70% of the successfully treated cases presented with sciatic pain. Similar results are reported from over 90 independant VAX-D Clinics throughout the United States, Canada and Puerto Rico.

A follow up of patients for up to 12 months at the trial centers, has not uncovered any unexpected level of relapse. However some have returned voluntarily for 'reduced frequency' sessions on the Table from time to time. Patients that require further therapy generally appear to be those with complicating factors such as degenerative disc changes, or stenosis.

VAX-D OUTCOME STUDY

Following two seperate FDA approvals (one for the device and one for the safety and efficacy of the treatment/decompression), 22 medical centers were asked to collect data on all patients who received VAX-D therapy for low back pain. The purpose of the study was to assess the efficacy of Vertebral Axial Decompression Therapy in the treatment of low back pain resulting from documented lumbar disc disease.

The patients ranged in age from 25 to 60 years at the treatment onset and they were followed from one to two years. All patients had failed proir attempts at treatment which included physical therapy, acupuncture, chiropractic care, epidural injections, and in some cases, surgical intervention. All patients had documented chronic back pain and pathology was found on MRI or radigraphic images. Use of a "double blind" type study was not practical as patients very early in the study would guess whether they were part of the "sham" group receiving only regular traction or part of the VAX-D therapy group. An earlier study in Canada designed to be "double blind" soon found that patients refused regular traction as they discerned or discovered that they "were not getting the better treatment".

The study was divided into five diagnostic groups which were comprised of patients with extruded herniated discs; multiple herniated discs without extrusion, with or without degenerative disc disease; single herniated disc, regardless of degenerative disease; degenerative disc disease. without herniation; and facet syndrome.

Each patient chose a subjective pain index ranging from 0 to 5 (5 being severe pain) and a disability index of 0 to 3 (3 being bedfast). Each was also assessed for objective signs of decreased mobility on a 0 to 3 scale (3 being completely immobile). They were assigned by diagnosis into one of the above five groups.

All patients received VAX-D Therapy of at least 10 sessions plus additional treatments if the patient continued to improve. Patient history, schedule, including frequency and intensity of therapy, was recorded along with patient symptoms and satisfaction with treatment. Measurements were made at the beginning, mid-point, and end of treatment.

If treatment success is defined as a reduction in pain to 0 or 1 on a 0 to 5 scale, the treatment was successful in 75% of the patients. The success rate varied from 67% for the patients with extruded herniated discs, to 77% for patients with degenerative disc disease or single herniated discs. It was 71% for people with multiple herniated discs and 70% for facet syndrome.

On a pain scale of 0 (none) to 5 (severe), the people with extruded herniated discs had an average pain of 4.19 at the beginning of treatment and an average of 1.33 after treatment, a reduction of 68%. The cases of multiple herniated discs went from 4.15 to 1.17, a reduction of 72%. The patients with a single herniation had a reduction from 4.14 to 1.08, or 74%. The degenerative disc cases went from 3.94 to 1.03, a 74% reduction. Those with facet syndrome went from 4.10 to 0.97, a 76% reduction in pain.

In summary, the data on mobility and ADL appear to correspond to pain results and it appears that approximately 20 treatments with VAX-D Therapy has been proven to be effective in about three-fourths of all patients who have any combination of these types of disc disease.