SUMMARY OF TWO STUDIES - EYERMAN

Journal of Neuroimaging

Eyerman, Edward MD.

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Subjects Condition

- Herniated Discs
- Degenerated Discs
- Torn Annulus

Prior to Treatment

- Pain in back and down the leg
- Numbness in legs
- Weakness

Post Treatment

- Over 90% reduction of nucleus herniation in 71% of patients
- Torn annulus repair is seen in all
- Virtually all subjects have sufficient relief of pain to return to work.
- 71% had significant pain relief and complete relief of weakness
- 90%+ had numbness in the leg disappear
- 86% had "good" to "excellent" relief of sciatic and back pain
- 28% had rapid relief in as few as 3 treatments
- 85% improved clinically
- Only 6% recurrence rate at 1 year

71%
Patients with Significant Reductions in Disc Herniations

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Dr. Ramah J. Wagner, B.S., D.C., F.I.A.M.A., D.C.R.C.
(352) 589-5443
www.WagnerChiro.com

RESEARCH SHOWS SPINAL DECOMPRESSION

REDUCES DISC HERNIATION SIZE UP TO 90%

MRI Evidence of Nonsurgical, Spinal Decompression Shows Rehydration and Repair of the Herniated Lumbar Disc

71%
Patients with Significant Reductions in Disc Herniations

C. Norman Shealy, MD, PhD.
Graduate of Duke Medical School, taught at Harvard Medical School
Vera Borgmeyer, RN, MA.

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EUSTIS

C. Norman Shealy, MD, PhD.
Graduate Duke University, taught at Harvard and Vera Borgmeyer, RN, MA.
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ABSTRACT

Simple pelvic traction gives inconsistent relief to herniated lumbar disc sufferers. A new decompression table system applying fifteen 60-second tractions of just over one-half body weight in twenty 1/2 hour sessions was reported to give good or excellent relief of sciatic and back pain in 86% of 14 patients with herniated discs and 75% of 8 with facet joint arthrosis. (Shealy, C.N., Borgmeyer, V., Am J Pain Management 1997; 7:63-65). Herniated and degenerated discs can be shown at discography-discomanornetry to have elevated intradiscal pressures made even worse by sitting and standing, thus preventing proper disc nutrition. Therefore, decompressing the over pressurized disc should allow for healing and repair of disc prolapse, herniation and annulus tears. Serial MRI imaging of 20 patients treated with the decompression table shows in our study up to 90% reduction of subligamentous nucleus herniation in 10 of 14. Some re-hydration occurs detected by T2 and proton density signal increase. Torn annulus repair is seen in all. Transligamentous ruptures show lesser repair. Facet arthrosis can be shown to improve chiefly by pain relief. Follow up studies for permanency or relapses are in progress.

STUDY

INTRODUCTION! Standard pelvic traction has been unsatisfactory in relieving sufferers with herniated lumbar discs and radiculopathy achieving, at best, about 25% effectiveness with little in the way of imaging change in the status of the disc. A new mechanical distraction system, the Decompression Reduction and Stabilization System (DRS), was described by Dr. Norman Shealy[1] to give 50% improved outcome over conventional treatment with standard pelvic traction. Seventy-five percent of subjects improved clinically, and in one case, an L5/S1 disc herniation on midsagittal MRI was shown to have a 50% reduction in size of the herniation after 20 distraction treatments. During distraction a 7mm separation of the L5 from the S1 vertebral body was demonstrated.[2]

The present study was undertaken to determine whether clinical betterment can be correlated directly to improvement in MRI image and whether MRI findings shed any light on the mechanism of improvement.

That an abnormal pressure is present in an abnormal disc can be appreciated often at discogram and discography-discomanetry, sometimes elevated and sometimes reduced. In discs with relatively intact annular envelopes, the pressure can be found to be elevated at rest over normal values, especially in the sitting position. Yet, in discs with radial tears or fissures, there can be a demonstrated leakage of the discs and therefore, at the initial of contrast infusion on discography, opening pressures are actually lower than normal. They become even lower at the end of infusion because of leakage of contrast, which can be demonstrated by x-ray or CT.[3] One postulate is that in the well-contained abnormal disc an abnormally elevated pressure results in faulty diffusion of nutrients from surrounding vessels in bone and the epidural space into the nucleus with inadequate patching or repair of the fissured annulus. In the discs with low initial pressure from torn annulus, leakage would impair retention of nutrients.[4] Thus restoring the integrity of the annulus is likely an important mechanism of healing the disc and helping to restore the integrity of gel pressure and chemistry. Adequate distraction treatment to promote lowering of intradiscal pressure for disc repair has been emphasized by Nachemson and his group for over 3 years.[5,6]

Neurosurgeons Ramos and Martin[7] at percutaneous discectomy applied lumbar distraction and showed that it is possible to lower elevated intradiscal pressure in herniated L4/5 discs into the negative range of -100 to -150mm mmHg using as little as 90 lbs of pelvic traction. In theory, such negative pressures would encourage fluid entry to re-hydrate the nucleus and perhaps repair the injured annulus. Onel and "colleagues" demonstrated by CT significant retraction of lumbar disc herniation in 21 of 30 patients using a continuous lumbar distraction for 40 minutes at 60-80% body weight. They hypothesized that a significant negative pressure applied to the disc space had improved blood flow from adjacent bony end plates and epidural vessels to provide healing fluids and nutrients to the disc.
The present study was done to determine whether serial MRI imaging can shed any light on the mechanism of improvement in lumbar disc herniation treated with an adequate course of mechanical distraction delivered in as optimal manner as possible.

METHODS AND PATIENTS

Twenty patients with lumbar radiculopathy documented on clinical examination and electromyography were treated on the DRS decompression table system, a mechanical, split-table distraction device. Subjects were placed supine, knees flexed over a cushion with chest harnessed to the head of the table. The lumbar spine was then distracted at one-half body weight plus 10 to 20 lbs by a pelvic harness belted to a tower that could be raised or lowered to give a focused angle optimal to the disc space being treated.

Twenty lumbar decompression treatments were given over a four to five week period to 13 patients, and a double course of 40 treatments in 10 weeks were given to 2 additional patients with very large disc herniations. These did show continual slow improvement. In each session 20-60 seconds, full weight distractions were alternated with 30 seconds of relaxation to 50 pounds. Distraction angle on the pelvic harness was adjusted from 10 degree for L5/S1 to 15-20 degree for L4/L5 herniations and above. Distraction angle adjustments towards adjacent posterior vertebral margins were done to promote optimal recession of disc protrusion by pulling these margins apart. Subjects were twelve males and eights females, ages 26 to 74. Radiculopathy, confirmed by EMG, was from disc herniation in 14 patients and from minor disc protrusion plus foraminal stenosis, facet arthropathy and lateral spinal stenosis in six. Significant herniations treated were 4-10 mm in size, and all were subligamentous. Six herniations were at L5/S1, six at L4/L5, and one each at L3/L4 and L2/L3. An MRI on either high or midfield units were performed within four weeks before and after treatment. Clinical status was assessed before, during and after treatment using standards analog pain scale measurements of lumbar mobility and full neurologic exam results.

MRI OUTCOMES

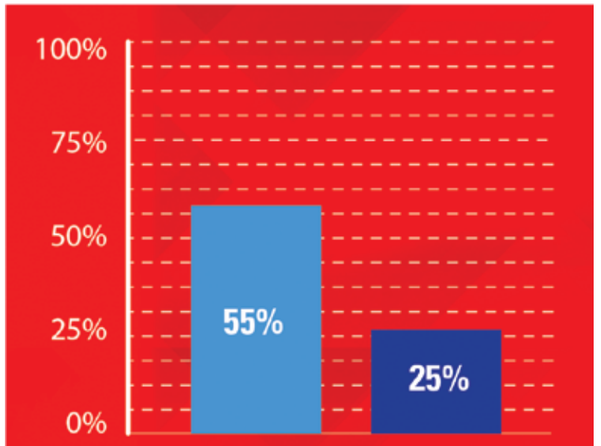
Disc herniations reduced significantly in 10 of 14 subjects. Large reductions of 50-100% were observed in six herniations, and 25-50% herniations in four. Reduction in two smaller herniations resulting in marked clinical improvement occurred in disc protrusions placed in the lateral recess in what could be called the "critical zone" for the nerve root.

On large disc herniations, three showed global reduction of 90-100% after treatment. For example, Figure I shows a relatively acute disc herniation of under 4 week at the L2/3 level in a 67-year-old man, which resolved completely after 20 DRS treatments in four weeks. Sealing of the torn posterior annulus is observed in the follow-up MRI. Figures 2 and 3 show before and after MRI axial views with complete retraction of disc prolapsed at L5/S1 after distraction. These subjects, a 40-year-old physical education teacher and a 39-year-old female service supervisor, had complete relief of disabling posterior calf pain and of toe flexor weakness. Figure 4 pictures a 60% retraction of a prolapsed disc on the left which had been completely covering the S1 nerve root, the arrow indicating the free space between the retracted disc prolapsed and the now visible S1 nerve root.

This individual, a 28-year-old male chemist having to do heavy maintenance work lifting up to 150 pounds, was returned to full work duty within two weeks after completing treatment as were the subjects in Figures 2 and 3. Figure 5 shows a remarkable example of an over 90% reduction of disc herniation in a 40-year-old female dog groomer who had been unable to bend at the waist in any direction for three months because of a large L4/L5 disc protrusion with L5 radiculopathy and had failed conventional treatment. Her treatment was extended to 40 sessions over 10 weeks. Repeat proton density and a T2 MRI confirmed in this patient and also in three additional cases in this series) not only a remarkable retraction of the herniated disc but an increase of proton and T2 weighted signals indicating at least some re-hydration of the dehydrated nucleus, Also seen are a sealing of the torn annulus at a very unusual "empty pouch sign" between the now restored annulus and the still bowed out posterior longitudinal ligament.
Such a vacated space after disc retraction was seen in two additional cases in this series (not shown). One also noted in Figure 5 complete clearing of the "high intensity spot" on the underside of the posterior annulus which was said to represent a healing area in a radial tear (4).

CLINICAL OUTCOMES

Irrespective of MRI status, all but three patients had significant pain relief and complete relief of weakness when present and of immobility. Numbness in the leg disappeared in all but one patient who had far lateral disc herniation and in two with foraminal stenosis without much herniation. In those patients with disc herniation, 10 out of 14 had 90% improvement in pain and disability, two had roughly 50% relief and one had only 20% relief. In those patients with foraminal syndrome but without much frank herniation of disc, four had 75-100% improvement in pain, one had 50% relief and one with severe spinal stenosis had little relief and was sent for surgery. Thus, the degree of clinical improvement roughly followed the MRI changes.



Over 71% of patients experienced at least a 25% decrease in size. Over 40% experienced a decrease of 55% or greater.

DISCUSSIONS

In this study there appeared to be a general correlation between improvement and retraction of the lumbar disc as shown by the MRI. This can certainly be argued strongly for those patients who achieved improvement with near 100% retraction of the herniation. Yet those showing improvement with lesser degree of MRI change might have to be explained in other ways. We could find a freeing up of the nerve root from lateral or foraminal herniations in what could be called "the critical zone" as seen in Figure 4. Clinical improvement in those patients with primarily foraminal stenosis or disc space narrowing without much herniation could be explained by joint mobilization in the freeing up of an impacted nerve root or improvement of nerve root circulation by the distraction treatment. Since abnormal disc specimens obtained at surgery lack chrondroitin sulfate six hydrated content demonstrated by Hutton the finding of increased proton signal of at least some degree in four of our subjects studied might well be another mechanism of improvement.

The leakage of sulfates and carboxylates through fissures or tear in the annulus is likely not only a cause of signal loss in disc degeneration but could be a cause of nerve root irritation as shown in recent discography studies. We noted very rapid relief of pain occurring in four subjects in this study in as few as the first three sessions. This was very likely occurring before any MRI changes could possibly be seen, although we did not look that early for an MRI change. It is known that prolapsed discs have pain-sensitive nerve in growth beyond the normally enervated outer third of the annulus into the inner portion and also into the nucleus. Immediate local and radicular pain is produced on discogram in contrast injection as well. Therefore, possibly the very early pain relief may be accomplished in segmental distraction by lowering intradiscal pressure enough to cause retreat or to lessen sensitivity of the nerve fibers. A suction effect of the negative pressure applied to the vertebral end plates and intervertebral space can also be thought of as improving the nutrition and leading to the healing of the disc. Disc nutrition comes primarily from the cartilaginous end plate, partly from epidural vessels, and partly through vertebral end plates.[2] Modiceta showed that the earliest vertebral end plate change associated with early disc degeneration is a hyperemia. In fact, the type one hyperemic vertebral end plate changes has been shown through high resolution SPECT imaging to occur even before MRI changes in the bone can be appreciated.[1] Thus, nutrient delivery to heal an ailing disc is likely a crucial factor in both clinical and anatomic improvement. One summary, therefore, the primary mechanism to explain the beneficial efforts of focused high weight distraction treatment on the herniated disc as described in this report is likely to be a lowering of the pressure in the intervertebral disc space to accelerate and promote nutrient diffusion essential to disc repair. The suggestion of Onel[3] that the beneficial suction effect on the disc space is created by the negative pressure of distraction may well be correct. The follow up of the 17 patients who showed clinical improvement in the present series at one year revealed only one to have a recurrence. It could be argued that reversing leakage through fissures and tears in the annulus allows the most direct repair of the herniated lumbar disc by promoting fibroblast repair of the inner and outer annulus layers and improved retention of nutrition. This study remains to be confirmed by larger, more extended controlled trials with MRI confirmation. In twenty patients presented here, however, 85% improved clinically, and the improvement could be correlated fairly well with MRI changes. It would appear, therefore, that there is a role for the application of high-weight, focused lumbar distraction treatment as obtained with the DRS. This type of treatment should be considered as a promising alternative to surgery or long term disability for lumbar disc sufferers.

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SUMMARY OF STUDY

Symptoms Prior to Treatment
- Radiating pain into the buttocks and legs
- Burning sensation down both legs into the feet and the right inguinal region.

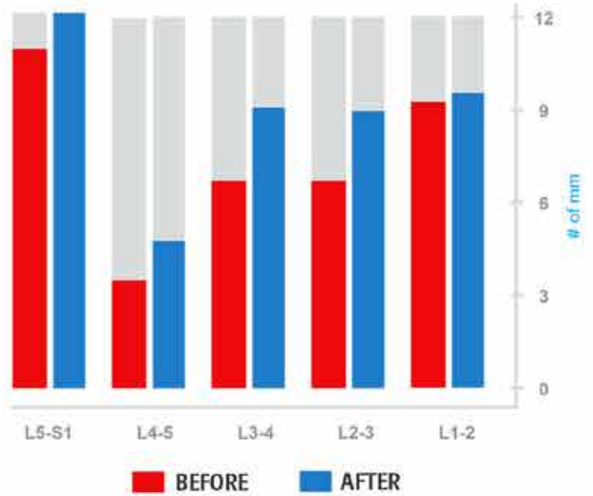
Activities Making Symptoms Worse
- Walking and standing for more than 15 minutes
- Disrupted sleep
- Difficulty moving from a sitting to a standing position

MRI showed
- Disc protrusions at all lumber levels
- Degenerative changes throughout lumbar spine
- Decreased Disc Space

7 Week Protocol
- 22 Treatments

Post Treatment
- Pain went from a 10 on a scale of 1-10 down to a 1
- No longer felt the burning sensation in the buttocks or legs
- Decrease in the frequency of burning in the right inguinal region
- Improvement in muscular strength

MRI revealed
- Decreased herniation size
- Increased disc height at multiple lumbar levels



A report by Joseph V. Pergolizzi Jr., Adjunct Assistant Professor, Department of Medicine, Johns Hopkins University School of Medicine, Baltimore; Frank Florio, Director of Clinical Research, Axiom Worldwide, Tampa; William R. Martin, Medical Director, Upper Valley Interventional Radiology, McAllen; and Charlotte Richmond, Director of Clinical Research, NEMA Research, Inc., Miami Beach.

Individual results may vary. These statements have not been evaluated by the FDA. All spinal decompression devices currently registered with the FDA have received their 510 K clearance by claiming their device is substantially similar to predicate traction devices.

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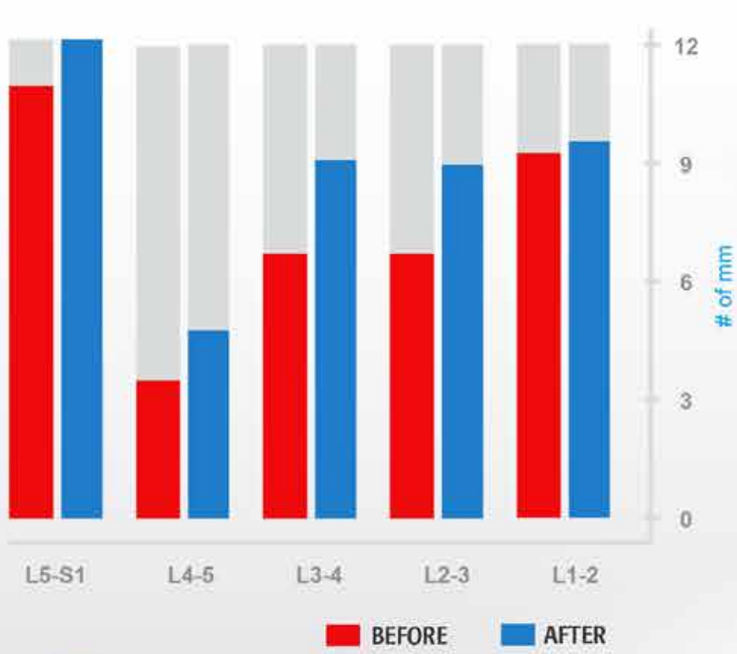
Research Shows Spinal Decompression can lead to an INCREASE IN DISC HEIGHT AND UP TO 90% REDUCTION IN PAIN

A Johns Hopkins Doctor Study



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A report by Joseph V. Pergolizzi, Jr., Frank Florio, William R. Martin and Charlotte Richmond

Chronic low-back pain (LBP) is a widespread and debilitating syndrome. Approximately 25% of adults in the US report having experienced LBP in the past three months. LBP is the second most common reason for a visit to a physician, the fifth most common cause of admission to a hospital, the third most common indication for surgery, among the top 10 reasons for visits to internists and the most common and most expensive reason for work disability.[3] While there are three broad treatment options for treating LBP - surgical, Non-surgical and pharmacological there is little consensus on which approach is appropriate or preferable for various scenarios. Current evidence-based guidelines recommend conservative treatment for at least two months, and often for much longer, before a surgical option is considered.[4,5] Surgery is associated with risks, and the outcome in many patients with discogenic back pain is unpredictable. Conservative treatments vary widely and are individualized to the patient. These include exercise, yoga, cognitive behavioral therapy, analgesics, superficial heat therapy, patient education/school, muscle relaxants, systemic corticosteroids, opioids, spinal manipulation, acupuncture, acupressure and transcutaneous electrical nerve stimulation. More recently, a variety of mechanized and motorized spinal decompression systems have been developed to address the pitfalls of the aforementioned therapies. The first of these was the Vertebral Axial Decompression (VAX-D) system (Vat-Tech, Inc.). Several other devices have since been developed, including the ACCUSPINA & DRX9000. Non-surgical Spinal Decompression system was designed to provide maximum patient benefits with the use of a non-invasive approach that may help minimize healthcare resources and offer a potentially optimal therapeutic approach to the treatment of LBP.

Non-surgical Spinal Decompression aims to relieve pain by enlarging intradiscal spaces, reducing herniation and decreasing intradiscal pressure during treatment. A retrospective chart audit of 94 patients provided preliminary data that chronic LBP may improve with Non-surgical Spinal Decompression. A prospective trial with 18 patients found that pain improved significantly after Non-surgical Spinal Decompression, with patients requiring fewer analgesics and experiencing better function. Information continues to emerge on non-invasive spinal decompression. Christian C. Apfel, and colleagues at the University of California at San Francisco, conducted a retrospective review of lumbar computed tomography (CT) scans of 16 patients with chronic musculoskeletal, mechanical or discogenic LBP who underwent a six week course of non-invasive spinal decompression treatment using Non-surgical Spinal Decompression. Dr. Apfel's investigation showed a significant reduction in chronic LBP after non invasive spinal decompression correlated with an increase in disc height. The case report presented here explores the use of the DRX9000 Non-surgical spinal decompression protocol for the management of chronic LBP.

PRESENTATION OF CASE

A 69 year-old man, Patient A, presented at an outpatient facility in October 2007. He complained of having experienced LBP during the past year. Patient A said the pain had progressively worsened over the past two months. Patient A also reported radiating pain into the buttocks and legs, as well as a burning sensation down both legs into the feet and the right inguinal region. Patient A was 68 inches tall and weighed 192 pounds. His medical history revealed cervical spine surgery, diabetes, hypertension and lumbar surgery 13 years previously. Activities that exacerbated Patient A's condition included walking and standing for more than 15 minutes. The pain disrupted his sleep and he had difficulty moving from a sitting to a standing position. Magnetic Resonance Imaging (MRI) of the lumbar spine performed on 4 October 2007 showed disc protrusions at all lumbar levels with degenerative changes throughout; the size of Patient A's herniated disc and height of his disc space at first visit are shown in Table 1. Patient A under went 22 treatments of Non-surgical Spinal Decompression over a seven week period. The initial parameters began at a maximum decompressive force of 80 pounds, with a minimum force of 40 pounds; the final treatment parameters were a maximum of 125 pounds and a minimum of 62 pounds. The decompressive force was raised in increments of five pounds at the discretion of the physician. The angle of treatment force which allows the physician to make adjustments to treat the affected lumbar region, ranged from 10 to 200. Adjunctive treatment included electric stimulation, as well as instruction on therapeutic exercise and nutritional support upon discharge. At initial treatment, Patient A reported pain at '10' on a scale of 0 to 10; at the end of the treatment protocol he reported pain at "1". Post-treatment, Patient A stated that he no longer felt the burning sensation in the buttocks or legs and noticed a decrease in the frequency of burning in the right inguinal region. At final evaluation the examiner also noted an improvement in Patient A's muscular strength and sensation to pinprick. MRI of the lumbar spine performed on 28 January 2008, four months after the initial visit - revealed decreased herniation size and increased disc height at multiple lumbar levels (see Table 1 for Patient A's pre and post treatment MRI measurements, and Figure 1 for pre and post treatment MRIs of Patient A's lumbar spine).

	Size of Herniated Disc (mm)		Height of Disc Space (mm)	
	Pre-Tx MRI	Post-Tx MRI	Pre-Tx MRI	Post-Tx MRI
Date	4 Oct 2007	28 Jan 2008	4 Oct 2007	28 Jan 2008
L5-S1	2.5 (left) 5.1 (centre) 2.5 (right)	2.0 (left) 2.2 (centre) 1.6 (right)	10.2	11.9
L4-5	4.5 (left) 5.1 (centre) 4.8 (right)	3.3 (left) 4.1 (centre) 3.5 (right)	3.3	5.1
L3-4	5.0 (left) 5.9 (centre) 5.2 (right)	3.2 (left) 4.1 (centre) 5.0 (right)	6.4	8.4
L2-3	4.7 (left) 4.6 (centre) 4.8 (right)	2.5 (left) 5.1 (centre) 2.5 (right)	6.1	8.1
L1-2	2.9 (left) 4.0 (centre) 2.7 (right)	- - -	8.6	8.9

Table 1: Pre- and Post-treatment Magnetic Resonance Imaging Measurements for Patient A

DISCUSSION

Non-surgical Spinal Decompression has become more prominent in clinical practice for the treatment of LBP. These systems were developed to provide a non-invasive intervention for the treatment of LBP of discogenic origin, with the goal of expanding the intervertebral space and reducing disc protrusion. As described by research, true Non-surgical Spinal Decompression System applies spinal distraction forces by using a sensitive computerized feedback mechanism to provide relief of LBP and symptoms associated with herniated discs, bulging or protruding intervertebral discs, degenerative disc disease, posterior facet syndrome and sciatica. Non-surgical Spinal Decompression uses a split-table design to reduce friction between the patient and the device. The patient lies supine; a chest and shoulder support system controls the upper body and a knee rest is used to eliminate pelvic rotation. The apparatus has built-in air bladders, disc-angle-pull adjusters and harnesses and can increase the decompression force more slowly in the latter part of the therapy. Non-surgical Spinal Decompression uses a motor pulley to deliver mechanized segmental distraction, which can be delivered in a static or an oscillatory fashion for a pre-selected duration. The location of lumbar spinal disease determines the best pull-angle settings. "A recent review of clinical trials evaluating spinal decompression systems concluded that currently available data are too limited to determine whether spinal decompression provides greater benefit over other Non-surgical treatments." Since that review, two new studies have demonstrated the safety and efficacy of Non-surgical Spinal Decompression. The first study was retrospective and analyzed the treatment of 94 patients.[6] At presentation, patients reported a mean pain rating of 6.05 on a scale of 0 to 10; this decreased significantly to 0.89 at the end of treatment. Analgesic use and physical function were also improved at the end of treatment. No adverse events were noted. The authors acknowledged that the clinical outcomes noted in the study necessitate further investigation. The second study was a prospective, multi center, non-randomized phase II pilot study to evaluate the effectiveness and safety of Non-surgical Spinal Decompression. Eighteen evaluable study participants underwent a protocol Non-surgical Spinal Decompression treatments over the course of six weeks, with five sessions per week in the first two weeks tapering to two sessions per week in the last two weeks. Two patients were removed from the study after the start of treatment because they did not meet the study inclusion criteria. Adjunctive treatment included ice, stretching exercises and analgesics as required. Pain, analgesic use, functionality, patient satisfaction and safety were evaluated throughout the study. Average daily LBP scores decreased from 6.4 to 3.1 after two weeks of treatment and continued to decrease to 0.8 at completion. This represents a >50% reduction in pain after two weeks of Non-surgical Spinal Decompression. Sixteen patients (88.9%) reported better function as measured by activities of daily living. On a satisfaction scale of 0 to 10, patients gave the Non-surgical Spinal Decompression an average score of 8.1. Adjunctive pain medication use was decreased with treatment and no significant adverse events or safety issues were reported. Diagnostic imaging is currently being utilized to evaluate physical changes within the intervertebral disc after treatment with the DRX9000. The use of imaging findings may be beneficial for explaining the clinical improvement in pain and function often observed. Preliminary Data from a retrospective review of 16 patients with chronic musculoskeletal, mechanical or discogenic LBP who underwent a six week course of noninvasive spinal decompression care using Non-surgical Spinal Decompression which appeared to reveal a decrease in chronic LBP correlated with an increase in disc height.[8] A recently published case study of a 33 year-old male with persistent LBP also demonstrated the positive hydrating effect that the Non-surgical Spinal Decompression has on the intervertebral disc. MRI measurements showed an increase in intradiscal signal on T2-weighted images at L2-3, L3-4, L4-5 and L5-S1.[9].

CONCLUSIONS

Evidence-based data that show the promising effects of Non-surgical Spinal Decompression on the safe and effective treatment of LBP continue to accumulate. This case report further builds on previous findings that have demonstrated improvements in disc morphology after treatment with Non-surgical Spinal Decompression. Patient A experienced pain relief, protrusion reduction and disc space enlargement with treatment. To further test the effect of Non-surgical Spinal Decompression on clinical and radiographic measures in patients with chronic LBP, additional prospective clinical studies are needed.

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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 reduction of pain at four years.

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Robert H. Odell Jr., MD. Ph.D., Boudreau D. DO.
EXCERPTS/ SUMMARY

Individual results may vary. These statements have not been evaluated by the FDA. All spinal decompression devices currently registered with the FDA have received their 510 K clearance by claiming their device is substantially similar to predicate traction devices.

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Dr. Ramah J. Wagner, B.S., D.C., F.I.A.M.A., D.C.R.C.
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Anesthesiology News Study Shows Spinal Decompression's "EXCELLENT" LONG TERM EFFECTIVENESS EVEN 4 YEARS LATER!

DR. ODELL, M.D., P.H.D.

STUDY:

SPINAL DECOMPRESSION REDUCES CHRONIC BACK PAIN: A FOUR YEAR OUTCOME

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STUDY

SPINAL DECOMPRESSION REDUCES CHRONIC BACK PAIN: A FOUR YEAR OUTCOME

Dr. Ramah J. Wagner, B.S., D.C., F.I.A.M.A., D.C.R.C.
(352) 589-5443
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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., an orthopedic surgeon in private practice in Mesquite, Texas, told Anesthesiology News.

VAX-D, manufactured by VAX-D Medical Technologies, Palm Harbor, FL., 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 4 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 PILOT STUDY CONDUCTED BY:
MAYO CLINIC

SUPERVISED BY:
JOHN LESLIE, M.D.
AFILIATE MAYO CLINIC

Subjects Conditions
- Herniated Discs • Bulging Discs
- Degenerative Discs • Failed Back Surgery
- Facet Syndrome

Prior to Treatment
- Average Pain Score 6.4 out of 10
- Pain Greater Than 6 Months

6 Week Treatment Protocol
- 20 Treatments

Post Treatment
- Average Pain Decreased to 0.8 out of 10
- Decreased Pain • Improved Function
- Required Fewed Analgesics After Treatment
- No Safety Issues or Adverse Effects

Presented at:
American Academy of Pain Management
AAPM 18th Annual Clinical Meeting
Sept. 27-30, 2007 I Las Vegas, NY

New York State Society of Anesthesiologists
61st Post Graduate Assembly in Anesthesiology
Dec. 7-11, 2007 I New York, NY

American Conference in Pain Medicine
April 4-5, 2008 I New York, NY

Study Team:
John Leslie, MD; Charlotte Richmond, PhD[2]; Alex Macario, MD; Christian Apfel, MD[4]; Frank Florio, De, Darren Clair, MD[6], Martin Auster, MD[7]; Joseph Perfolizzi, MD[2]*
[1]Mayo Clinic Arizona, [2]NENIA Research, [3]Stanford University, [4]University of California at San Francisco, [5]Vibrance Medical, [6]Johns Hopkins University

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Dr. Ramah J. Wagner, B.S., D.C., F.I.A.M.A., D.C.R.C.
(352) 589-5443
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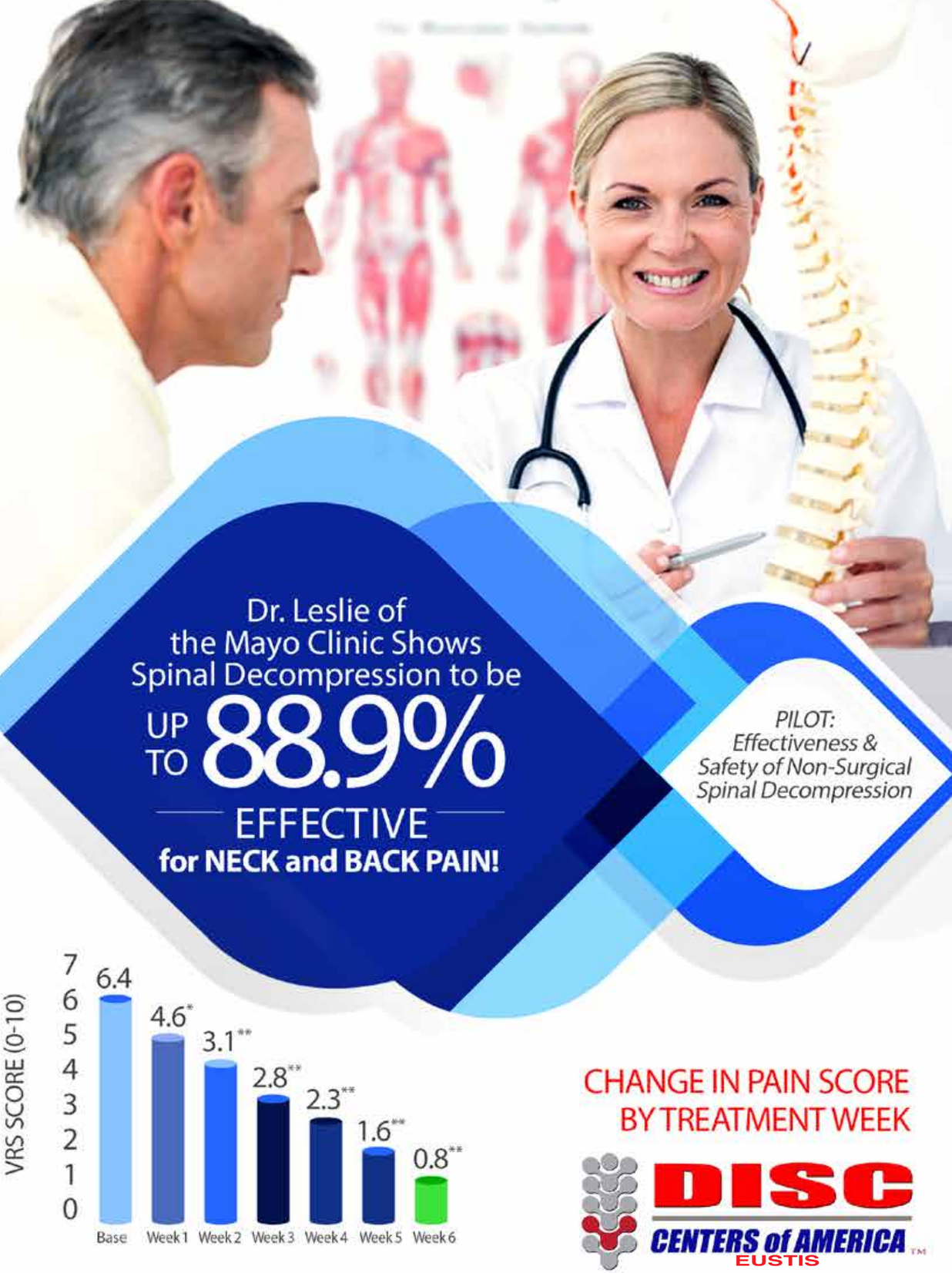

Dr. Leslie of the Mayo Clinic Shows Spinal Decompression to be UP TO 88.9% EFFECTIVE for NECK and BACK PAIN!

PILOT: Effectiveness & Safety of Non-Surgical Spinal Decompression

CHANGE IN PAIN SCORE BY TREATMENT WEEK

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PILOT:
EFFECTIVENESS AND SAFETY OF NON-SURGICAL SPINAL DECOMPRESSION

ABSTRACT

OBJECTIVE:
Prospective, multicenter, phase II, non-randomized, clinical study to evaluate the effectiveness and safety of Non-surgical Spinal Decompression for active treatment of chronic Lower Back Pain (LBP) utilizing a standardized clinical research multimodal protocol.

METHODS:
20 patients with chronic LBP based on a diagnosis of musculoskeletal or mechanical LBP, herniated discs, bulging or protruding discs, degenerative disc, pain from failed back surgery more than 6 months previously, posterior facet syndrome or sciatica underwent a series of 20 Non-surgical Spinal Decompression treatments (28 mins each) for 6 weeks with 5 sessions the first week tapering to 1 session per week. Treatment multimodal protocol included ice after Non-surgical Spinal Decompression sessions, lumbar stretching exercises and adjunct analgesics as required. Assessments of pain, analgesic use, functionality, satisfaction, activities of daily living and safety were collected through examinations, questionnaires and patient diaries.

RESULTS:
Eight evaluable subjects (33.3% female, 83.3% white, mean age 46.6, 77.8% employed) had mean pain score of 6.4 on a 0 to 10 scale (0=no pain; 10=worst pain) prior to first Non-surgical Spinal Decompression. That decreased to 0.8 after the last Non-surgical Spinal Decompression. 88.9% of patients (16 out of 18) reported an improvement in back pain and better function as measured by activities of daily living. On a 0 to 10 scale (0=Not satisfied; 10=Very satisfied) patients rated the Non-surgical Spinal Decompression an 8.1. No patient required any invasive therapies (e.g., epidural injections, surgery).

CONCLUSION:
Overall, patients' pain improved after Non-surgical Spinal Decompression, requiring fewer analgesics and improved function. There were no safety issues identified with the multimodal treatment routine, non-treatment or control.

BACKGROUND

- Paucity of literature on benefits of Non-surgical Spinal Decompression over other Non-surgical treatments
- Previous studies are poorly designed
- Results are descriptive in nature
- Efficacy versus placebo or spontaneous recovery difficult to determine
- Over 1,200 Doctors utilize Non-surgical Spinal Decompression today

MATERIAL AND METHODS

METHODS:
- Prospective, multi-center, phase II, non-randomized clinical trial
- 3 free-standing clinics (2 MDs and 1 DC)
- Diagnosis: Low back pain > 12 weeks
- Outcome measures assessed:
  - Daily Pain Diary • Verbal Rating Scale (VRS)
  - Oswestry Pain Questionnaire
  - Adverse Events • Satisfaction Survey

TREATMENT PROTOCOL:
- Non-surgical Spinal Decompression sessions
  - 28-minute sessions for 6 weeks
  - Total of 20 treatments
- 5 sessions week 1 & 2
- 3 sessions week 3 & 4
- 2 sessions week 5 & 6
- Additional Therapy
  - Ice therapy post Non-surgical Spinal Decompression - (Individual results may vary)
  - Back exercises after week 2

RESULTS

DEMOGRAPHICS

Total Number of Subjects = 18

Male	66.7%	Mean Age	46.6 yrs
LBP Sympton Duration mean	526 weeks	Mean Height	175 cm
Employed	77.8%	Mean Weight	102 kg
Retired	16.6%	White	83.3%
Other	5.6%	Hispanic	16.7%

SUMMARY OF LOW BACK PAIN

Diagnosis		Location	
Bulging/Protruding Disc	15	L1 - L2	1
Degenerative Disc	8	L2 - L3	3
Herniated Disc	6	L3 - L4	4
Posterior Facet Syndrome	2	L4 - L5	14
Failed Back Surgery	1	L5 - S1	12

FAILED THERAPY PRIOR TO DRX9000™

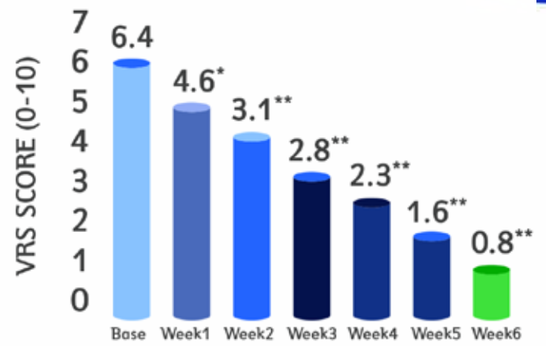
Procedure	#	Procedure	#
Chiropractic	16	Tens	5
Muscle Stimulation	10	Acupuncture	3
Ice Therapy	9	Lumbar Support	3
Massage Therapy	9	Epidural Injections	3
Exercise	6	Facet Injections	1
Heat	5	Ultrasound	1
Physical Therapy	5	Other Decompression Therapy	1

ADVERSE EVENTS

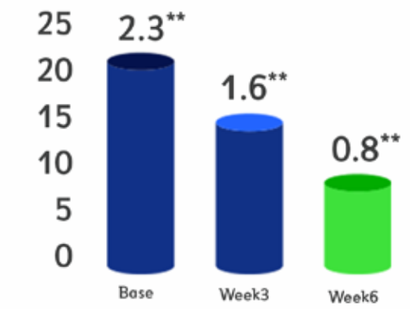
Adverse Event	Related to Device	Adverse Event	Related to Device
Neck Pain	Possibly	Shoulder Pain	No
Head Cold (2)	No	LBP/Flu-like symptoms	No
Sinus Headache (2)	No	Vertigo	No
Sinus Infection	No	Adrenal Insufficiency	No

RESULTS

CHANGE IN PAIN SCORE BY TREATMENT WEEK



CHANGE IN OSWESTRY SCORES



SATISFACTION SURVEY

Satisfaction by Week		Would you recommend DRX9000™ to anyone else?	
Week 3	Week 6	YES	NO
7.6	8.1	88.9	11.1

CONCLUSION

- A 6 week course of 20 Non-surgical Spinal Decompression significantly reduced the severity of chronic LBP in 89% (16 of 18) of treated patients from 6.4 to 3.1 after 2 weeks and to only 0.8 (scale 0-10) after completion of treatment
- Oswestry Disability scores improved from 23.7 to only 5.5 at end of therapy
- Adjunctive pain medication consumption was decreased by Non-surgical Spinal Decompression
- No significant adverse events or safety issues resulted from Non-surgical Spinal Decompression
- The Non-surgical Spinal Decompression shows great promise in treating chronic LBP arising from multiple causes
- Comparative outcome trials utilizing a set of standardized and validated multiple outcome variables, as was utilized in this study, are being planned to document the value of Non-surgical Spinal Decompression in routine treatment of chronic LBP

SUMMARY OF STUDY

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Subjects' Conditions

- Herniated Discs
- Degenerated Disc

Prior to Treatment

- Average Pain Score 5.99 out of 10
- Pain lasting greater than 12 weeks

Treatment Protocol

- 23 Non Surgical Spinal Decompression sessions Over 8 Weeks
- Lumbar stretching exercises and Ice or muscle stimulation

Post Treatment

- Pain decreased from initial average 5.99 to .87 out of 10
- NSAID and Opioid use went from 65% of patients to <5%
- Patients reported a mean 90% improvement in back pain
- Better function as measured by activities of daily living
- Patients rated Non-surgical Spinal Decompression an 8.98 out of 10 in Satisfaction
- No patient required more invasive therapies (i.e. surgery)
- 100% would recommend Non-surgical Spinal Decompression to someone else

Average Satisfaction with Non-Surgical Spinal Decompression on a scale of 0-10

Individual results may vary. These statements have not been evaluated by the FDA. All spinal decompression devices currently registered with the FDA have recieved their 510K clearance by claiming their device is substantially similar to predicate tranction devices.

DISCLAIMER: THIS PAMPHLET DOES NOT PROVIDE MEDICAL ADVICE

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Dr. Ramah J. Wagner, B.S., D.C., F.I.A.M.A., D.C.R.C.
(352) 589-5443
www.WagnerChiro.com

PRESENTED IN JOURNAL OF MEDICINE 2008
Medical Doctors From Stanford and Johns Hopkins University Show Patient Rate Spinal Decompression

8.98 OUT OF 10 IN SATISFACTION

AND 100% WOULD RECOMMEND SPINAL DECOMPRESSION

LEVEL OF PAIN

Alex Macario, *MD, MBA, Standford University;*
Sunil J. Panchal, *MD, COPE Foundation, Florida Pain Management;*
Charlotte Richmond, *PhD, Nema Research & Education Foundation;*
Joseph V. Pergolizzi, Jr., *Johns Hopkins University & Nema Research*

Non-Surgical Spinal Decompression Via Motorized Distraction for Chronic Discogenic Low Back Pain

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Non-Surgical Spinal Decompression Via Motorized Distraction for Chronic Discogenic Low Back Pain

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OBJECTIVES

Conduct retrospective chart audit to assess outcomes of a random sample of outpatients treated with motorized spinal decompression via the Non-surgical Spinal Decompression for chronic low back pain lasting more than 12 weeks.

METHODS

- **Data from charts of 100 adults cared for in 2004-2006 at four clinics, one hospital-based and three free-standing, were abstracted using a standardized data collection form.**
- **Protected health information was accessed in accordance with the HIPAA privacy rule. Workman's compensation patients were excluded.**
- **Non-surgical Spinal Decompression sessions (28-30 mins each) were for 8 weeks (mean) with 4-5 sessions the first week tapering to one session/wk (mean treatments = 23).**
- **Treatment protocol included instruction on lumbar stretching exercises and ice or muscle stimulation after Non-surgical Spinal Decompression sessions.**
- **Pain, analgesic use and activities of daily living were assessed pre- and post-treatment.**
- **Subjects (62% female, 94% male, mean age 55, 53% employed) had mean pain score 5.99 on a 0 to 10 scale (0= no pain 10=worst pain) at time of initial presentation that decreased to 0.87 after last treatment. NSAID (410/c of patients) and opioid (24% of the patients) use decreased (<5%) after treatment.**
- **Patients reported a mean 90% improvement in back pain and better function as measured by activities of daily living. On a 0 to 10 scale (0=Not satisfied and 10=Very satisfied), patients rated the Non-surgical Spinal Decompression an 8.98.**
- **No patient required more invasive therapies (i.e. surgery)**

- Mean satisfaction with Non-surgical Spinal Decompression (0-10 scale) 8.98 0=not satisfied 10=Very satisfied

Average Satisfaction with Non-surgical Spinal Decompressionon a scale of 0-10

- **Improvements in LBP provided by Non-surgical Spinal Decompression = 90%**
- **Recommend Non-surgical Spinal Decompression to someone else = 100%**
- **Chronic LBP improves after treatment**

Level of Pain

Analgesic Use	Pre-DRX9000	Post-DRX9000
No Meds	40%	20%
NSAIDs	43%	0%
Opiods	23%	0%
Muscle Relax	12%	1%
Steroids	4%	1%
Unknown	0%	59%

CONCLUSIONS

- **Achieve better function after treatment**
- **No patients contacted required surgery**
- **Practice variability exists in how clinics add adjunct therapies to Non-surgical Spinal Decompression**
- **Difficult to assess placebo or spontaneous recovery versus Non-surgical Spinal Decompression without control group**
- **Randomized clinical trials are needed to measure efficacy of motorized spinal decompression**
- **Prospective trials with long-term assessment needed**

reported pain prior to treatment, patients with depression significantly improved after treatment. This leads me to believe that IDD Therapy not only decreases pain, but also lifts depression associated with pain. Overall, the success rate was 88.2% for this sample, which fell between the ranges of success found in our initial estimates of 79-92% success.

Future Studies-Anger and Stress

In light of supporting a more holistic approach to pain, we have begun to look at back pain in broader terms than the physical pain our patients experience. We have also started to examine the severity of impairments as a consequence of the pain, and how this affects patients' daily lives. We began to assess and examine the influence of other factors, such as stress and anger levels, on the outcome of IDD Therapy. So far, 65 patients have participated in this most recent study, called the Anger and Stress Study. The results are preliminary, as most patients have not completed the follow-up portion of this study. Our preliminary findings include:

- Number of Daily Activities Affected by: Pain: Patients who report high numbers of daily activities affected by pain score significantly higher on the anger assessment, significantly higher on the depression scale, and report significantly higher pain.
- Stress Effects: Patients who score high on the Social Readjustment Scale score significantly higher on the anger assessment.
- Anger Effects: Patients who score high on the anger assessment score significantly higher on the depression scale.
- Depression Score Effects: Patients who score high on the depression scale report significantly higher pain prior to treatment.

Conclusions

A number of implications can be made from the analyses above. However, since these are preliminary in nature, we will not elaborate on the potential meaning from each analysis. Instead, we hope to convey information by moving the conception and treatment of back pain in a new direction, one that uses safer, non-invasive treatments such as IDD Therapy for the initial treatment of low back pain, recognizing the complexity of our patients and treatment through a more holistic approach.

Table 2: Success Rates According to Diagnosis Prior to Treatment of IDD Therapy

Diagnosis type	Reported success rate (%)	Sample size (n)
Lumbar back pain	79	330
Surgical lumbar candidates	92	129
Cervical pain	84.7	33
Post-laminectomies	79	52

Figure 1: MRI Examples

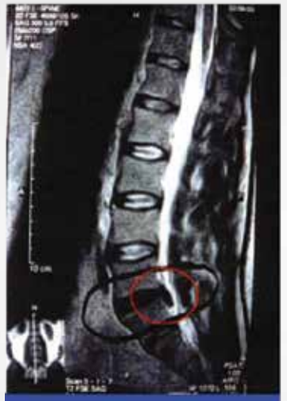

Figure 1a: Pre-treatment MRI (02/02/05)

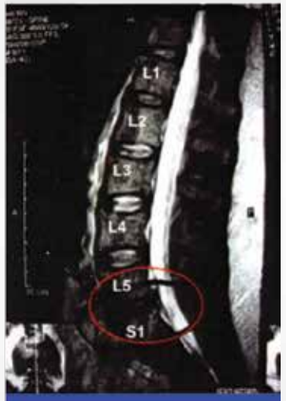

Figure 1b: Post-treatment MRI (03/14/05)

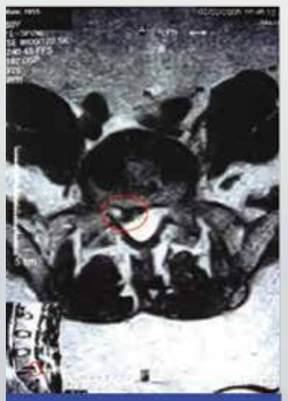

Figure 1c: Pre-treatment MRI (02/02/05)

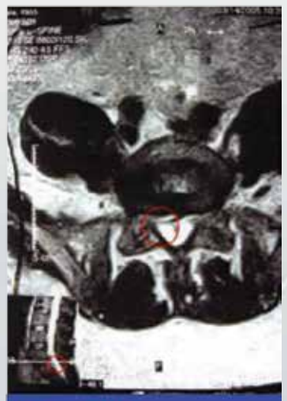

Figure 1d: Post-treatment MRI (03/14/05)

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INTERVERTEBRAL DIFFERENTIAL DYNAMICS THERAPY

A New Direction for the Initial Treatment of Low Back Pain

a report by Dennis McClure, MD. and Bethany Farris, MD.

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Dr. Ramah J. Wagner, B.S., D.C., F.I.A.M.A., D.C.R.C.
Dr. Eric Kaplan, D.C., F.I.A.M.A.

(Originally published in US Musculoskeletal Review 2006)

INTERVERTEBRAL DIFFERENTIAL DYNAMICS THERAPY

A New Direction for the Initial Treatment of Low Back Pain

a report by Dennis McClure, MD. and Bethany Farris, MD.
Private Practice, Dayton, Ohio

(Originally published in US Musculoskeletal Review 2006)

Dennis McClure has been in private practice in Dayton, Ohio since 1995. He was certified by the American Board of Neurological Surgery in 1988 and served in the US Air Force from 1984. He is a lifetime member of the American Association of Neurological Surgeons. Dr. McClure obtained his MD from Indiana University in 1978 and completed neurosurgery training at University Wisconsin Hospitals Madison in 1984.

Patients with back pain usually present a neurosurgeon or spine specialist with an abnormal magnetic resonance image (MRI), while their referring physician tells them they have a degenerated disc causing their pain. Throughout my years of practice, it has become apparent to me that patients with back pain want to know why they are having pain, the cause of their back pain and how to effectively treat their back pain in order to avoid surgery. In addition to improving pain, another goal in treatment is to improve flexibility, as well as quality of life, in the safest and most effective manner prior to recommending more invasive procedures for treating the patient's pain due to degenerative disc disease. It is a misconception by the public that surgery 'fixes' a person's back pain. If this were true, we would never see patients with failed back syndrome.

There has been no established uniform or conservative management to effectively treat low back pain.

In November of 2003, I introduced Intervertebral Differential Dynamics (IDD) Therapy to my neurosurgical practice. IDD Therapy is a noninvasive spinal rehabilitation treatment developed by Norman Shealy, MD, PhD, and is delivered by the Accu-SPINA spinal care device. IDD Therapy provides computer directed physio-therapeutic treatment to the lumbar and cervical intervertebral discs and face joints, with a course of treatment consisting of 20 sessions of 25 to 30 minutes, spread over a six-week period. IDD Therapy protocols allow for the controlled distraction of targeted vertebrae to mobilize the joint and to create a negative pressure inside the intervertebral disc. This negative pressure leads to the diffusion of fluid and nutrients into the disc to stimulate its metabolism and promote hydration and healing. The negative pressure can also lead to the retraction of a herniated nucleus pulposus. IDD Therapy treatment further delivers a passive exercise element to release spasmodic behavior and to reeducate supporting soft tissues. Since introducing IDD Therapy to the practice, I have treated over 1,700 patients. Initial studies of IDD Therapy indicated success rates of 86% and 76% one year post-treatment. Our results of treatment are similar to the initial reports of IDD therapy; in fact, in some cases we believe they are higher. We present our results of over 415 patients who have been analyzed so far in looking at success rates that contribute to variables affecting the outcome of IDD Therapy.

Questions and Direction

After treating patients for two years, it seemed apparent that most of them reported significant recovery of back pain after completing IDD Therapy. This raised several important questions: What are the reasons patients do not improve with IDD Therapy? What factors about these patients led to a good prognosis with treatment? What factors led patients to experience different severities of pain prior to and after treatment. Understanding the answers to these questions was crucial for us to quantify and improve the quality of treatment we could give to our patients. We therefore employed a research analyst to answer these questions and analyze the data extracted from the patients' files, which included medical history, assessment measures (taken and recorded upon initial evaluation), diagnoses, treatment parameters and follow-up measures.

Preliminary Analyses and Results

This preliminary analysis was conducted by analyzing the success from self-reports given by the patient on follow-up. Success with IDD Therapy was rated by patients after treatment (2-4 weeks and 12 months) (see Table 1).

In the preliminary analysis, we defined success as an improvement rating of 2 or 3. A patient must report a 50% or greater decrease in pain in order to be considered a success in this analysis. Data from the past 415 patients completing treatment was analyzed between two months and two years after completion of the course of IDD Therapy treatment, at an average time of one year post treatment. Any patient failing to give an improvement rating was excluded. Success rates were examined according to diagnosis assigned prior to treatment (see Table 2).

Of particular interest are lumbar surgical candidates, those patients who had been advised to undergo surgery and who came to the practice for a second opinion or patients who I might have previously operated on. This group showed a success rate of 92%. This is quite an exciting find, considering the next alternative for these patients would have been surgery. Although the sample size for cervical and post-laminectomy patients was limited, the success rates are promising for these groups as well.

Having determined initial success rates of treatment led us to inquire about variables influencing the outcome of treatment. In particular, what makes patients have these exciting success rates and more importantly, what variables affect the outcome of treatment for patients who did not benefit from IDD (Intervertebral Differential Dynamics) Therapy? We contacted the lumbar surgical candidates for additional follow-up information at 12 months. Out of 129 patients, 84 were contacted. The data for these patients was analyzed and the results are follows:

- Effects of Gender: females reported significantly higher pain after treatment.
- Effects of Age: (90% confidence interval) there was a significant increase in pain after treatment as age increased.
- Effects of Time: patients who reported initial success (rating of 2 or 3) directly after treatment continued to have a significant reduction in pain at the time of the follow-up (anywhere from two months to two years after completing treatment).
- Effects on Activity Level: patients who reported success (reduction in pain) after treatment also reported improvement in other aspects of their life, including a significant increase in capacity to live a more active lifestyle.
- Factors that had no effect on outcome measures included body mass index, number of diagnoses number of serious illnesses, number of prior treatments and angle of distraction.
- Flexibility measuring forward bending and straight leg-raising improved by 60% post-treatment. These results were encouraging and led us to examine other aspects related to pain prior to and after treatment. More specifically, psychological processes

Depression and Attitude Study and Results

To more accurately assess improvement and factors affecting it, a study was designed to assess patients prior to and post-treatment. Participants gave consent and took a battery of surveys prior to treatment, including a pain assessment, a self-rated depression inventory and an attitude assessment. After patients completed treatment, they took the pain assessment again and results were analyzed. Analyses are based on a sample size of 50 patients.

The first important finding was that patients who reported higher pain prior to treatment showed significantly higher rates of depression, which gave us important insight into psychological aspects of a patient's health affecting their perception of pain. Second, patients with negative attitudes (skeptic or cynic) reported slightly higher pain prior to treatment, although not enough to be statistically significant in a one-way analysis of variance (ANOVA). These findings suggest that conceptual treatment of pain should take a more holistic approach.

This study also replicated the effect of age from the previous analysis. Patients in this sample showed that, as age increases, pain after treatment also significantly increased. Number of prescription medications also had a significant effect on the outcome of treatment. Patients taking more medication report significantly higher pain after treatment. Patients on more prescription medications are in overall poorer health prior to treatment. If this holds true, it would also reinforce the idea of treating back pain using a more holistic approach. This would allow us to address and treat additional areas of patients' health such as psychological, physical and spiritual areas, resulting in better improvement in pain from IDD Therapy, and overall quality of life.

It is also worth noting that, while different factors may significantly affect the outcome of IDD Therapy, the sample had a significant decrease in pain according to a matched pairs test. In addition, although depression significantly affected

Table 1: Patient Rated Success of IDD Therapy

Improvement rating	Interpretation	Pain adjustment
0	No improvement	0-24% decrease
1	Minimal improvement	25-49% decrease
2	Moderate improvement	50-79% decrease
3	Excellent improvement	80-100% decrease