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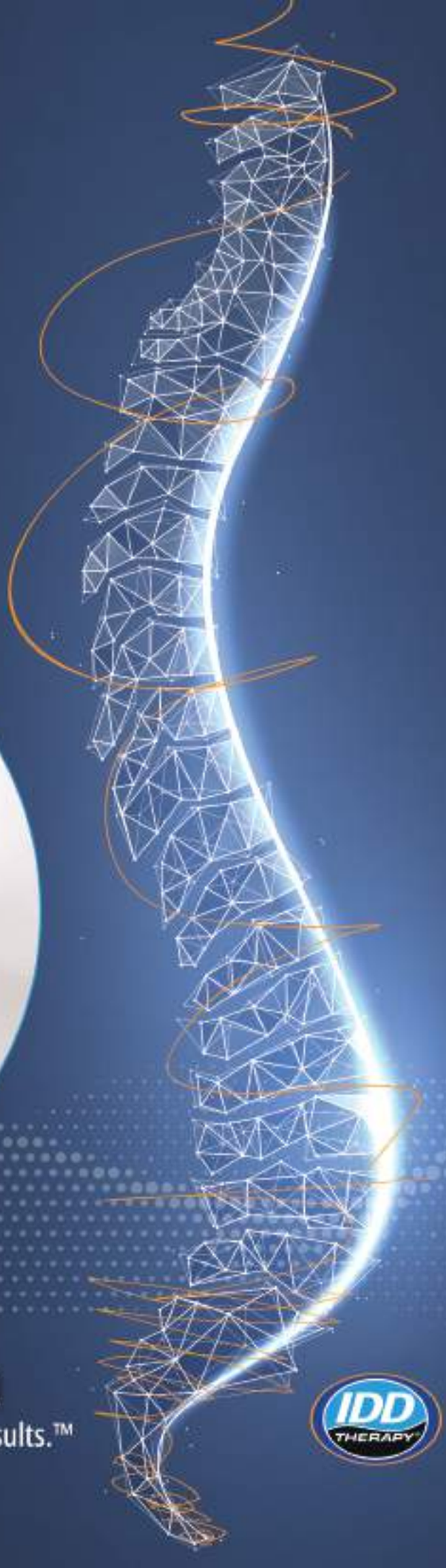

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CLINICAL LITERATURE

Table of Contents

North American Medical

COMPENDIUM TABLE OF *Contents*

ARTICLE / STUDY TITLE	AUTHOR / AFFILIATED MEDICAL ENTITY	YEAR PUBLISHED	PAGE #
American Journal of Physical Medicine & Rehabilitation: A Randomized Controlled Trial	Schaufele, MD *Author Affiliation:* *Harvard Medical School*	2006	99
U.S. Musculoskeletal Review: A New Direction for Initial Treatment in Low Back Pain	McClure, MD *Author Affiliation:* *Indiana Univ. School of Medicine*	2006	104
Albert Einstein College of Medicine: Current Therapeutic Options for Chronic Low Back Pain	Shah, MD/ Schaufele MD *Author Affiliation:* *NY Medical / Harvard Medical School*	2005	110
Understanding Intervertebral Differential Dynamics (IDD Therapy®)	North American Medical Corp.	-	122
Southern Medical Association: Oral Presentation - A Clinical Trial Comparing Key Diseases of Low Back Pain	Shealy, MD,PhD *Author Affiliation:* *Duke University/Harvard Fellow*	2005	126
White Paper: IDD Therapy for Treatment of Painful Lumbar Degenerative Disorder	Schaufele, MD *Author Affiliation:* *Harvard Medical School*	2005	130
American Journal Pain Management: Long Term Effect Analysis of IDD Therapy in Low Back Pain	Shealy, MD,PhD *Author Affiliation:* *Duke University/Harvard Fellow*	2005	134
Case Study Report: Total Resolution of Disc Herniation After Failed Surgery	Shalaby, MD *Author Affiliation:* *M.B.R. University of Medicine*	2005	139
Practical Pain Management Technology Review: Intervertebral Differential Dynamics Therapy	Shealy, MD,PhD *Author Affiliation:* *Duke University/Harvard Fellow*	2005	147

ESTEEMED
Luminaries

North American Medical

Foreword

By H. Leon Brooks, MD., F.A.C.C.S.

As a practicing orthopedic spine surgeon in Beverly Hills for over 45 years, I've performed countless spine surgeries. Yet, for some people, surgery may be an unnecessary risk, and thus I believe that effective non-surgical treatment options must be encouraged. That is why, in 2004, I made the decision to invest in an Accu-Spina® device for my practice, and I have found IDD Therapy® to be an excellent treatment tool.

I have always been a man of science; I have devoted my life to medicine and have a deep love of innovation. Naturally, when asked to serve as a founding chair of the Scientific Advisory Board for North American Medical in 2005, I accepted.

Staying active in healthcare doing consultations and determining appropriate care coverage for insured patients, I am often more than willing to sign off on IDD Therapy® with the Accu-Spina® because of my personal experience using it.

I am pleased to help present this compilation of clinical evidence and literature on IDD Therapy® treatment. I believe it will be a helpful resource for clinicians.

As coverage determinations must also rely on the existing literature, I know firsthand how important it is that we continue to conduct research, improving our understanding of this aspect of non-surgical spinal care. This is why I have committed to assist North American Medical with newer studies on IDD Therapy® treatment outcomes.

I have no financial stake in North American Medical; my interest in IDD Therapy® is borne of an appreciation of this unique treatment and the integrity of the people behind the mission.

Sincerely yours,

Dr. Harry L. Brooks
Orthopedic Surgery Specialist, Beverly Hills, CA

Dear Fellow Physicians:

I have dedicated my life and neurosurgical career to the research and advancement of medical treatments that I believe truly benefit the human condition, in doing so; I have performed extensive research and published over 250 medical papers in journals all over the world. While I am honored to have been referred to as "the foremost expert" on non-invasive spinal treatment and decompression, with this notoriety comes the difficult task of clarifying claimed associations with people or companies who create an impression of association with me, yet with whom I have no dealings whatsoever.

As the decompression market has proliferated in recent years, so have the companies building all sorts of back treatment devices. I believe many of these misrepresent their product by utilizing my studies to support their efficacy. Not only do I take moral issue with this practice, but I believe it is important to make clear that this is not good science.

Currently, any manufacturer can claim their product is built to accomplish an outcome, but until they actually test their own device to prove that outcome, they cannot honestly make that claim! And they cannot claim to have equipment which is providing effects similar to mine. I've even seen traction devices and ordinary decompression which don't have an oscillation sinusoidal waveform patent like the Accu-Spina - yet they are referencing my studies as performed on completely different designs, biomechanics, and technology. I believe this to be grossly misrepresentative.

Medical research today is a costly and arduous endeavor that takes true commitment. The Accu-SPINA® system is the ONLY model that built upon and continues to improve upon my work. I have no financial interest in NAM itself but consult with only them because I believe in their integrity and how they are advancing this science.

Sincerely,

C. Norman Shealy, MD, PhD

CLINICAL LITERATURE

Articles & Studies

North American Medical

Reduction in Chronic Low Back Pain Using Intervertebral Differential Dynamics Therapy (IDDT) and Routine Physiotherapy: A Retrospective Pre-Post Study.

Journal of Musculoskeletal Disorders and Treatment vol. 7:2 Open Access

Patients with prior failed conservative care achieved significant relief with cost modified regimen of IDD Therapy treatment on the Accu-SPINA System.

AUTHOR

Ekediegwu EC, Chukka C, Nwosul, Uchenwoke C, et al., Faculty of Health Sciences and Technology, Dept. of Medical Rehabilitation, Nnamdi Azikiwe University

METHOD

Retrospective Pre-Post Physiotherapist conducted.

CONDITIONS

Discogenic pathology (bulging, protruded or degenerative discs) facet, mild cord compression.

CONCLUSION

- **141 Patients (most failed previous conservative care)**
- **Patients treated averaged only 10 session regimen**
- **136 patients experiences statistically significant reduction in pain levels (.964%)**

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ORIGINAL ARTICLE

Reduction in Chronic Low Back Pain Using Intervertebral Differential Dynamics Therapy (IDDT) and Routine Physiotherapy: A Retrospective Pre-Post Study

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Abstract

Background: The plethora of treatments for Low Back Pain (LBP) has increased in recent times. Opioids, spinal injection, bed rest, skin traction and surgery have remained the common forms of treatment. However, there is less emphasis on pharmacological and surgical treatments in national clinical practice guidelines. Non-surgical Spinal Decompression (NSD) is a modern, though investigational non-surgical treatment technique for LBP. The aim of this report was to analyse the outcome of LBP using NSD technique delivered by an Intervertebral Differential Dynamics Therapy (IDDT) device amidst other conservative treatments.

Method: We conducted a retrospective pre-post study of 141 one hundred adult patients who visited a private physiotherapy clinic over a three and quarter-year period. Patients were treated for an average number of 10 sessions over a 2-month period using NSD therapy (IDDT), in addition to routine physiotherapy management for LBP intensity assessed using numerical pain rating scale. To analyse the obtained data, descriptive statistics and paired t-test were used, significance level was set at $\alpha = 0.05$.

Results: One hundred and forty-one patients (81 males, 60 females) were analysed. The mean age and weight of the patients were 54.73 ± 13.82 years and 192.39 ± 36.10 lbs (87.27 ± 16.37 kg) respectively. The mean starting and ending pain intensity scores were 5.03 ± 1.86 and 4.13 ± 1.82 respectively on an 11-point Numerical Pain Rating Scale (NPRS). There was a statistically significant decrease in pain intensity ($t = 12.301$, $p < 0.001$).

Conclusion: Statistically significant improvement in LBP could be achieved using NSD and other traditional conservative management. Long-term follow up post NSD is needful.

Keywords

Non-surgical spinal decompression, Intervertebral differential dynamics therapy, Low back pain, Nigeria

Introduction

Back-related disabilities as well as population burden have been on the increase despite numerous treatments and health-care resources [1,2]. This will ine-

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vitably increase, especially the number of older adults with chronic incapacity associated with inability to work which as a result, impacts on health-care costs and the workforce of a nation [3,4]. Chronic LBP (continuous pain lasting for duration of equal to or greater than 3 months) occurs in 2% to 8% of individuals with LBP [5]. In Nigeria, there is a conflicting report on the prevalence of LBP; male predominance (0.45:0.36), female preponderance (1:1.5) and equal prevalence (1:1) [6-12].

Increasing prevalence of LBP in Africa has been associated with some major risk factors such as bad posture, prolonged sitting or standing, occupational hazard, poor knowledge of back care ergonomic, poor sitting, poor transferring and lifting techniques, obesity, pregnancy, long distance driving, duty stress, psychological stress, and heavy physical work [6-8,12-19]. Other trauma-related risk factors include fall from a height and Road Traffic Accident (RTA) [12,19]. Amongst these factors, poor lifting technique is the most common risk factor to LBP [8].

However, breakthroughs in health outcomes of musculoskeletal conditions such as LBP which has been achieved in most Western countries are yet to be observed in Africa owing to an increased focus on other health-related issues such as malaria, poliomyelitis, communicable diseases, malnutrition and HIV/AIDS [20]. Results of previous studies revealed that supervised and individualised exercise therapy is the most effective means of preventing LBP, reducing its recurrence and resultant disability; however, opioids and bed rest are still the common forms of treatment in Africa [21-23]. Anecdotally, other forms of treatment for LBP include Tai Chi, spinal manipulation, acupuncture, massage and yoga according to current national clinical practice guideline in developed countries [24-26]. In recent times, a Non-surgical Spinal Decompression (NSD) modality has been developed for management of LBP.

Non-surgical spinal decompression is the most recent incarnation of traction therapy which entails spinal stretching on a traction table or similar motorized device (such as the modern Intervertebral Differential Dynamics Therapy (IDDT) machine (Figure 1) with the goal of relieving neck or back pain [23,27]. It works with the mechanism of creating a negative intra-disc pressure to promote retraction or re-positioning of the bulging or herniated disc material and create a lower pressure in the disc for the influx of healing nutrients into the disc using intermittent motorized traction [23,27]. Indications for NSD using IDDT machine include degenerative disc disease, facet joint syndrome, disc bulge or herniation [28]. It significantly reduces disc herniation size with resultant improvements in straight leg raise, disability and pain [29-31]. However, there is dearth of studies in Africa that investigated management of LBP involving non-surgical spinal decompression [2], seeing that cultural and ethnic influences on LBP have been established [32-34].

Following the limitations of hands-on treatment techniques and the pitfalls of traditional traction, Intervertebral Differential Dynamics (IDD) was developed in the late 1990's for isolated 5 to 7 millimetres of vertebral distraction surrounding an injured cervical or lumbar disc

Figure 1: IDD therapy machine by Accu-Spina (Steadfast Corporation Limited, Essex, United Kingdom).

as well as nerve [27]. It provides static, intermittent, and cycling forces on structures which causes neck or low back pain. IDD therapy comprises of different treatment sessions specifically designed for each patient lasting for 25 to 30 minutes. The negative intra-disc pressure provided by vertebral distraction helps to promote diffusion of oxygen, water and nutrients into the vertebral disc area, resulting to improved disc health by re-hydrating the degenerated disc. Retraction of a herniated nucleus pulposus (the soft gelatinous central portion of the intervertebral disc which resists compression) occurs with repeated pressure differential. The IDD therapy, therefore, decreases pressure on the discs, spinal nerves and vertebral joints through intermittent mobilizations while promoting retraction of herniated discs, disc healing, re-education of soft tissues, re-alignment of spinal structures and rehabilitation of damaged discs, which invariably reduces LBP. European Conformity (CE) as well as Food and Drug Administration (FDA)-cleared Class II fastest-growing medical devices, licenced to deliver IDD Therapy spinal decompression include the Accu-Spina and SDS (Safety Data Sheet) Spina. Clinicians can correctly and properly evaluate and adjust every single treatment on the IDD because every aspect of the therapy is recorded and adjustable [27].

This study therefore, was aimed at evaluating pain scores before and after using IDDT machine to achieve NSD amidst other conservative treatment (Low Level Laser Therapy (LLLT) and ultrasound therapy, spinal mobilisation, core strengthening and flexibility exercises and/or heat therapy) for adult patients with chronic mechanical LBP with or without radiculopathy. This study, therefore is pertinent in that chronic mechanical LBP is becoming prevalent in Africa and focus of management has only been on pain reduction using opioid pain medications which most often have drastic side effects. Non-surgical Spinal Decompression (NSD) delivered with IDDT machine may be cost-effective and a treatment of choice compared to spinal injection or surgery for most patients with low back pain [35]. Pain could be influenced by cultural and ethnical factors, therefore evaluating the outcome of LBP using routine physiotherapy management and IDDT amongst the Igbo tribe of Nigeria is deemed necessary.

Method

Design & sample

We performed a retrospective pre-post study of a three and quarter year period (November, 2015 through March, 2019) on 141 consecutive adult patients with chronic LBP ± radiculopathy who visited Astella physiotherapy clinics (which is located in Enugu; one of the states in South-Eastern Nigeria dominated by the Igbo tribe) and had routine physiotherapy (ultrasound and Low Level LASER therapy, spinal mobilisation, core strengthening and flexibility exercises, heat therapy) as well as NSD (Accu-Spina® with IDD Therapy® by North American Medical Corporation) of an average of 10 sessions over a 5 week-period. Data were collected from the Astella physiotherapy clinic records and IDD machine treatment records by the authors (EE, IN).

Eligibility

All adult patients who visited the clinic at some point within the three and quarter year period and presented with the following conditions were eligible: Bulging, protruded or degenerative discs with or without radiculopathy, spinal stenosis, sciatica, posterior facet joint dysfunction, chronic low back pain without improvement from prior conservative management. The above diagnoses were made by expert musculoskeletal physiotherapists (licensed physiotherapists with at least 5 years of clinical experience) following a broad and robust clinical evaluation based on the clinical assessment protocol established by the American College of Physicians and American Pain Society [36] and confirmed with Magnetic Resonance Imaging (MRI) reports where necessary. Patients who presented with muscular strain, spondylolysis, symptoms of cauda equina syndrome, diagnosed inflammatory disorder of the spine, spinal instability, spinal infection, previous lumbar surgery with hardware, spondylolisthesis greater than grade II, severe canal stenosis, presence of pacemaker, severe osteoporosis, evidence of lumbar compression fracture, spinal metastasis diagnosed upper motor neurone disorder and scoliosis were excluded. However, smokers and those with co-morbidities such as hypertension, diabetes, high cholesterol level were not excluded, though each patient was properly educated and treatment sessions spaced where necessary.

Ethical consideration

The study was conducted in accordance with Helsinki Declaration as revised in 2013 [37]. Every personally identifiable protected health information was excluded from this study in order to ensure the privacy and confidentiality of patient health information.

Treatment protocol/procedure

All the patients involved in this study had Non-surgical spinal decompression; however, it was preceded by the following: Low Level Laser Therapy (LLLT) and ultrasound therapy on the lumbar spine, spinal mobilisation (if not contraindicated), core strengthening and flexibility exercises and/or heat therapy. Initial treatment on the IDD started with a distraction force of half-body weight which was gradually increased from 5 to 20 pounds as the treatment progress. The most symptomatic spinal segment(s) were targeted first in relation to setting the angle of distraction.

Decompression was followed by cold therapy to reduce myogenic tension around the lumbar spinal area. Where indicated, Low Level Laser Therapy (LLLT) by

Chattanooga group, Germany was applied for 5 to 10 minutes to the affected levels of the lumbar spine at the pre-programmed treatment settings {5 × 100 mW (2.5 Hz, 3.8 joules/cm^2)} if indicated. Low-level Laser Therapy is the minimum power density radiation (minimum red and infrared frequencies) irradiated on cells or tissues for reduction of pain and inflammation as well as activation of tissue regeneration [38,39]. Home exercise programs to increase core strength and flexibility were prescribed. These varied but were not limited to clamshell, pelvic tilt or shift, bridge, prone knee extension, bird dog, dead bug, prone leg raise, cat/camel, lumbar extension and rotation exercises with or without elastic band depending on patient's tolerance and capability. Some of these exercises target the local stabilizing muscles (transversus abdominis, lumbar multifidus, internal oblique muscle, and quadratus lumborum), providing accurate motor control and are therefore, primarily responsible in stabilizing the spine [40-43].

Other exercises involved the internal and external oblique muscles, erector spinae, quadratus lumborum, rectus abdominis, gluteal and hip muscle groups (also known as the global stabilizing muscles) which enable spinal control and are secondarily responsible for spinal stability. Strong core muscles help to protect the spine, maintain spinal stability and lower stress which impacts the lumbar vertebrae and intervertebral discs; therefore, the core muscles are also called "the natural brace" in individuals [41,43-46]. It is important to note that core muscle strengthening has been described as the cornerstone of conservatism in low back care [47]. More so, flexibility exercises were abdominals, quadratus lumborum, erector spinae, calf, piriformis, hamstrings, gluteal and hip flexors stretch as well as neural slides and myofascial release on the thoracolumbar fascia, quadratus lumborum, gluteal, piriformis and hamstring muscles and along sciatic nerve distribution on the affected leg(s) if indicated.

Patients were instructed to do 1 or 2 sets of 5 to 10 repetitions of each exercise once to twice daily as can be tolerated. The 11-point Numerical Pain Rating Scale (NPRS) was used to rate patients' pain prior and after intervention, with 10 as the "worst pain imaginable" and 0 as "no pain". On each patient's visit, starting and ending pain scores were recorded. The starting pain score at the beginning of the treatment plan and the ending pain score at the conclusion of the treatment regimen were recorded on each visit. In the event that the patient failed to complete with the treatment, the ending pain at the date of the last visit was used.

Outcome/outcome measures

Pain intensity: This was assessed using the Numerical Pain Rating Scale (NPRS). NPRS is a well-established self-reported measure for assessing pain intensity. It is a very simple-to-use 11-point pain rating scale with 0 at the left, corresponding to "no pain", and 10 at the right side which means "worst possible pain" or "maximum pain". The scale provides valid and reliable pain scores [48]. In addition, NPRS has wide usability (can be used amongst individuals with low level of literacy) as well as applicability in several pain-related conditions [48-51].

Data analysis: Obtained data were cleaned and analysed with Statistical Package for Social Sciences (SPSS) version 15 by one of the authors (EE). Descriptive statistics of mean and standard deviation, frequency and percentage were used to summarize the demographic and clinical variables of the participants. Paired t-test was used to compare their mean pain intensities before and after treatment. Level of significance was set at $\alpha = 0.05$.

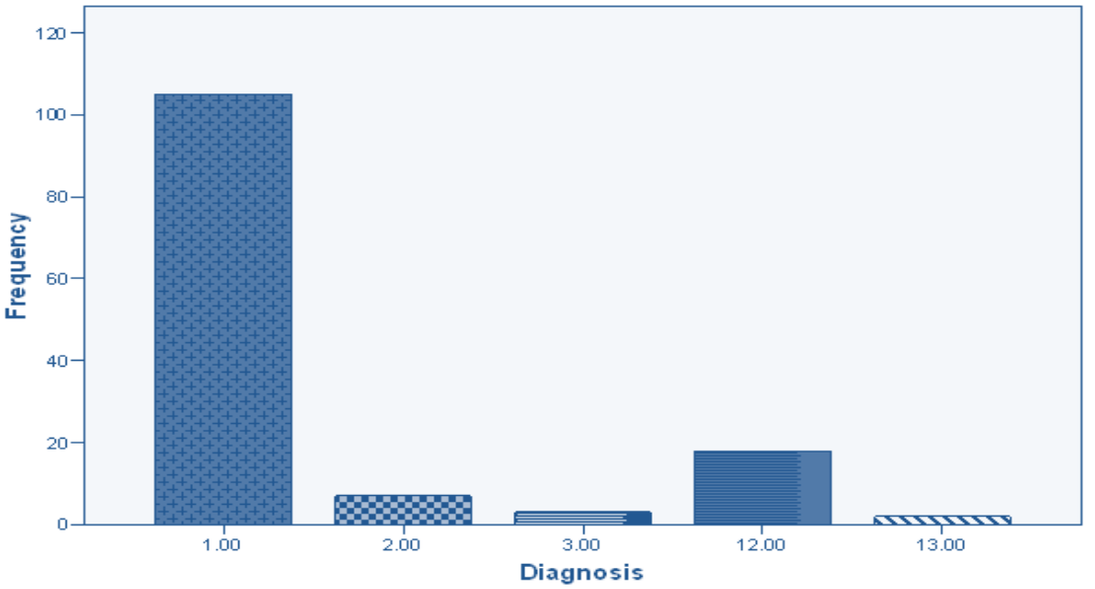
Results

One hundred and forty-one patients (81 males, 60 females) with LBP who visited the clinic during the study period were analysed in this study. Most of the patients have had unsuccessful previous conservative management before reporting to the clinic. All patients had significant improvement except for 3 patients who reported an increased ending mean score and 2 patients who reported no change in average pain intensity score (pre-treatment and post treatment). A thorough clinical assessment was carried out on each patient. Magnetic Resonance Imaging (MRI) reports as well as broad and robust clinical assessments were used to confirm diagnosis. Diagnoses were made not just on MRI report but also, on broad and robust clinical assessments. One hundred and eleven cases were either suspected or confirmed discogenic pathology (such as disc bulge, disc herniation and degenerative disc disease); seven cases were facet syndrome while eighteen cases were combination of these two (discogenic pathology and facet syndrome). Furthermore, three cases had MRI-confirmed mild cord compression whereas only two cases were a combination of mild cord compression and disc dysfunction employing the classification of LBP by Jenkins [52] (Figure 1).

Table 1: Mean difference in pain intensity.

Pain Intensity	Mean	Standard deviation	Paired-samples T test		
			df	*t*	*p*
Starting pain intensity	5.025	1.857	134	12.301	< 0.001*
Ending pain intensity	4.130	1.816			

df: Degrees of freedom for each estimate of variance; *t:* Size of the difference relative to the variation; *p*: Significance level.



Key: Diagnosis-

1: Discogenic pathology (disc bulge or herniation and/or degenerative disc disease{spondylosis});

2: Facet syndrome;

3: Cord compression;

12: Combination of discogenic pathology and facet syndrome;

13: Discogenic pathology with cord compression.

Figure 2: Diagnosis of the patients (majority confirmed with Magnetic Resonance Imaging {MRI}).

All the subjects were prescribed with core strengthening and flexibility exercises while hot pack and LLLT were applied pre-IDD treatment. Cold pack was applied after each IDD session to reduce or prevent muscular soreness even though this was not common among the patients. There were no serious adverse effects before, during and after treatment. The mean age of the patients was 54.73 ± 13.82 years ranging from 20 to 87 years with average weight of 192.39 ± 36.10 lbs (87.27 ± 16.37 kg). Number of therapy sessions ranged from 5 to 52 sessions. The average starting pain intensity score was 5.03 ± 1.86 whereas the mean ending pain intensity score was 4.13 ± 1.82 on an 11-point NPRS (Table 1 and Figure 2).

Discussion

This study examined, among other conservative treatments (Low Level Laser Therapy (LLLT) and ultrasound therapy, spinal mobilisation, core strengthening and flexibility exercises and/or heat therapy) in Nigeria, the outcome of LBP with or without radiculopathy for NSD delivered with IDDT machine. In this retrospective study, the patients were overwhelmingly male in their middle age. The findings of previous studies performed in Nigeria showed male predominance in line with this outcome, although there was no statistically significant gender gap [7,53]. These findings, however, contrast with the results of a previous systematic review, resulting in female preponderance or equivalent prevalence [9-12].

Majority of patients involved in this study were diagnosed with discogenic pathology. Consequently, this provides an example of the class of LBP prevalent in this population (i.e. LBP with or without radiculopathy, which is a more extreme form of mechanical LBP). This is not consistent with the finding of a previous study in Nigeria that reported spondylosis as the most common form of LBP [12]. In addition to this, a few of the patients in this study were clinically diagnosed with facet syndrome, which is also known as a basic mechanical type of LBP. Nevertheless, there may be some psychosocial overlay in patients studied in this research, but this cannot be determined as it is outside the scope of this research.

Exercises that target the core muscles (natural brace of human beings) have been reported to offer spinal protection, maintain spinal stability and decrease stress on the discs as well as the lumbar vertebrae [45,46]. Therefore, the resultant pain reduction in this study could also be attributed to the incorporation of these exercises in the treatment protocol.

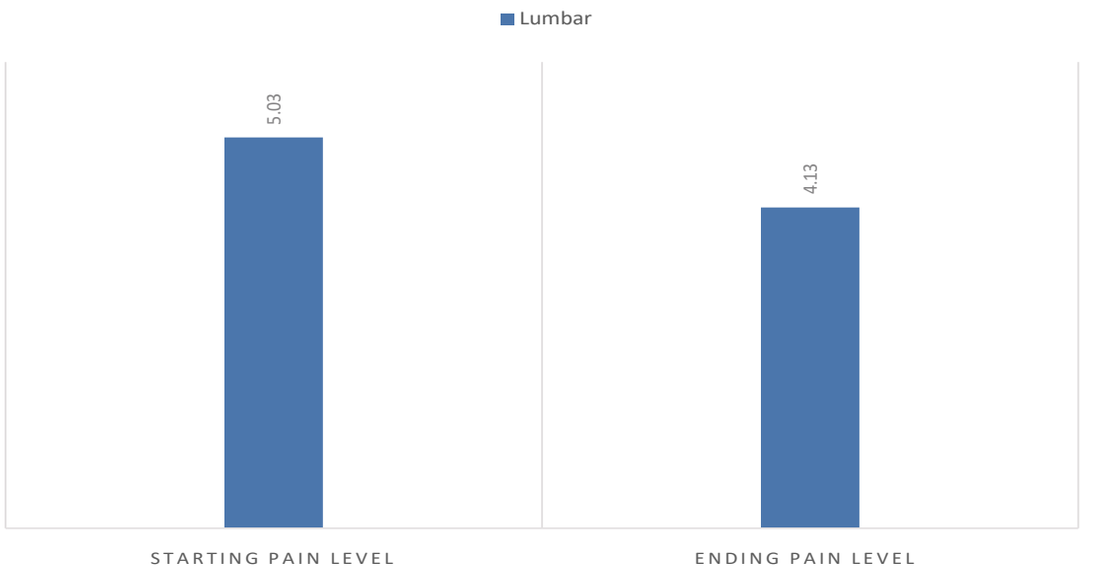


Figure 3: Low back (lumbar) pain prior and post intervention (including Non-surgical Spinal Decompression using IDDT device).

Despite its recommendation for cervical radiculopathy in the European 2017 National Clinical Guidelines, NSD is currently tagged as investigational due to insufficient evidence of its efficacy for various stages of LBP. Lack of comparative studies with established conservative treatments (standard medical care, exercise therapy and spinal manipulation) as well as cost have been the subject of controversy on NSD [54].

Nevertheless, the effectiveness of IDDT in the management of chronic LBP has been shown by findings from previous studies [28,35,55,56]. In a retrospective chart audit, it was confirmed that NSD uses DRX9000 and a treatment regimen (lumbar stretching, myofascial release, muscle relaxation and hot/cold application) to treat chronic LBP [57].

A preliminary study showed decompression relieved pain in patients with ruptured lumbar intervertebral disc pathology (86%) as well as those with facet arthrosis (75%) using the prototype of the Accu-Spina system [29]. However, these figures were based on very low sample sizes of 14 and 8 participants, respectively. Conversely, in a single-blind, randomized controlled study, two groups of low back pain patients treated with normal graded activity found that NSD was unsuccessful, with one of the groups receiving IDD Therapy® and the other group receiving sham therapy with a negligible amount of distractive force [55]. In the midst of this controversy, this present research shows a slightly lower mean patients ending pain severity score that were statistically significant despite these patients having reported no improvement with previous interventions (such as medication, routine physiotherapy, surgery). This is in line with previous findings in support of the efficacy of IDD therapy in conjunction with other conventional conservative treatment studies [28,35,55-57]. Although there was no control group used in this research, the authors would argue that it is difficult for a physical intervention to offer a persuasive placebo treatment. In addition, in a way, when the participants' pre and post intervention pain scores were compared, the patients served as their own "controls".

Our research was limited by certain factors. There was no definite set of routine physiotherapy for low back pain used in this study and as such, could have interfered with the results gotten. More so, exercise compliance was not assessed in this study as this could be a confounding factor. A major limitation was the absence of data on the use and the number of analgesic and anti-inflammatory drugs by the patients, since these drugs may have interfered with the quality and intensity of LBP. Due to the fact that only individuals with chronic (continuous pain lasting for duration of equal to or greater than 3 months) LBP were included in this research, the generalizability of these findings to a broader population with LBP may be limited. Therefore, a follow-up study with a control group is highly recommended. The recommended 20 intermittent sessions as recommended by the protocol, with a full 13 minutes of joint mobilization was strictly based on the manufacturer's experience. It remains uncertain if this is the optimal traction therapy protocol in the Accu-Spina system.

Conclusion

Mechanical LBP is more prevalent in middle-aged Nigerian men than in females. Combined with other pain

relief physiotherapy modalities and exercises, non-surgical spinal decompression tends to provide pain relief in patients with LBP. There is a need to further study non-surgical spinal decompression for neck pain and long-term follow-up on low back pain with a control group.

Acknowledgement

The authors wish to thank the participants of this report.

Conflicts of Interest

There are no conflicts of interest.

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Non-surgical Treatment of Cervical and Lumbar Diseases in Guangxi- Non-surgical Spinal Decompression System (IDD): A Case Study Report

Hospital department assessment of first case utilizing non-surgical spinal decompression with IDD Therapy on the Accu-SPINA System.

AUTHOR

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METHOD

MRI confirmation and examination.

CONDITIONS

Lumbar disc herniation.

CONCLUSION

Case study highlights biomechanical improvements demonstrated after just one session of non-surgical spinal decompression with IDD Therapy treatment.

The best non-surgical treatment for cervical and lumbar pain in the world

Department of Rehabilitation Medicine,
Second Affiliated Hospital of Guangxi Medical University, 2021.4.8

The first non-surgical treatment of cervical and lumbar diseases in Guangxi - non-surgical spinal decompression system (IDD)

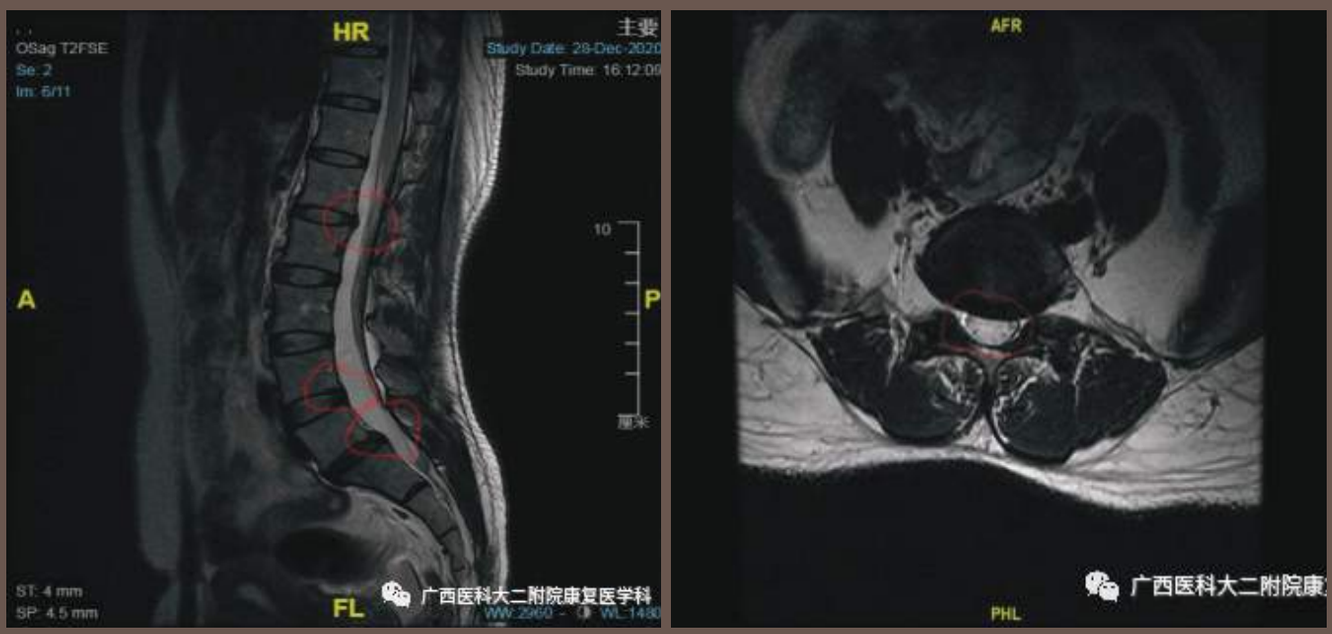
The rehabilitation medicine department of our hospital introduced the first non-surgical treatment of cervical and lumbar spondylosis - "non-surgical spinal decompression system". The system is recognized as the best non-surgical treatment system for cervical, lumbar and back pain in the world. It is a safe, painless, non-invasive and efficient non-surgical physical therapy method, which provides a new non-surgical treatment technology for patients with lumbar and cervical spondylosis. Clinical studies have shown that the success rate of this system in the treatment of patients with spine related pain is as high as 92% (cervical spine) - 93% (lumbar spine).

IDD (Intervertebral Differential Dynamics) therapy is a non-invasive treatment. It focuses on repairing the injured spine by computer differential static processing, precise angle and force for soft traction, and can reduce the pressure in the intervertebral disc to - 150 to - 200 mmHg. It is a technical solution for a long-term unsolved problem in the medical field, to make the intervertebral disc in a continuous high negative pressure state.

Case analysis

Ms. L 37 years old, female, walked into the rehabilitation department on February 22, 2021 due to low back pain for seven years. She was initially diagnosed as lumbar disc herniation. Her specialty: limited range of motion of lumbar spine, obvious tenderness of lumbar spine, positive bilateral straight leg raising test and positive strengthening test. Auxiliary examination: lumbar MRI plain scan: L1 / 2 disc herniation, L4 / 5, L5 / S1 disc herniation.

SUPPLEMENTARY EXAMINATION



DURING THE FIRST TREATMENT

BEFORE TREATMENT

AFTER TREATMENT

BEFORE TREATMENT

AFTER TREATMENT

IDD THERAPY IS A BREAKTHROUGH IN BIOTECHNOLOGY

Comparison items	IDD Therapy	Traditional traction
Mode of force	Dynamic mode of continuous control	Continuous or intermittent linear mode
Sensor pressure reduction feedback system	Helps to eliminate muscle resistance	Non
Paravertebral muscle contractile resistance	Almost non	Often
Action point of force	Accurate location of the lesion disc	Acting on the entire spine
Disc pressure drop	Continuous negative pressure, up to -200 mmhg	It is difficult to reach negative pressure in general
Increase of the height of the intervertebral space	Significantly increased	Not obvious
Treatment results	To make the protrusion back to the nutrition of the disc	Relieve the patient's condition by forcing the patient to brake only
Patient comfort	Extremely high	Low
Clinical research	More global studies confirm	Less systematic research reports

INDICATION

- Herniation of cervical and lumbar disc
- Degenerative lesions of the disc
- Prevention and treatment of discogenic pain
- Small joint syndrome
- Interventional treatment of disc and rehabilitation treatment after discectomy
- sciatica
- Kyphosis
- Rehabilitation after vertebral body operation
- Vertebral artery cervical spondylosis
- Spinal stenosis

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A Case Series of Non-Surgical Spinal Decompression as an Adjunct to Routine Physiotherapy Management of Patients with Chronic Mechanical Low Back Pain

Journal of Spine 8:1 Open Access

High population regions in Africa can help back pain sufferers with even reduced dosing regimen using IDD Therapy on the Accu-SPINA System.

AUTHOR

Ekediegwu EC, Chukka C, Nwosul, Uchenwoke C, et al., Faculty of Health Sciences and Technology, Dept. of Medical Rehabilitation, Nnamdi Azikiwe University

METHOD

Prospective, Practice- based.

CONDITIONS

Chronic low back pain, HNP, DDD, Spinal stenosis, Sciatica, Facet disfunction.

CONCLUSION

- **All but five participants in this study achieved significant improvement**
- **125 patients analyzed showed clinically significant post IDD Therapy pain intensity levels upon completion of only half the recommended protocol (average 10 sessions.)**

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Case Study Open Access

A Case Series of Non-Surgical Spinal Decompression as an Adjunct to Routine Physiotherapy Management of Patients with Chronic Mechanical Low Back Pain

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Abstract

Background: Treatments for low back pain (LBP) vary widely. In Africa, the most common forms of therapy include rest and pain medications. However, a novel conservative therapy for LBP is the non-surgical spinal decompression (NSD) (with Intervertebral Differential Dynamics (IDD)) even though considered investigational, improves LBP. This study was aimed to investigate the outcome of chronic LBP with or without radiculopathy using NSD amidst other conservative treatment.

Method: Patients were treated with an average number of 10 sessions within 2 months of NSD therapy, in addition to spinal mobilisation, cervical and lumbo-pelvic muscles re-education programme, soft-tissue therapy, low-level laser therapy, hot or cold application and home exercise programme if indicated. Pre- and post-intervention scores of pain intensity of each treatment session on a Numerical Pain Rating Scale (NPRS) were compared using a paired t-test to determine statistical significance.

Results and Main findings: One hundred and twenty-five patients (73 males, 52 females) were analysed. The mean age and weight of the patients were 54.70 ± 14.07 years and 192.10 ± 35.91 lbs (87.14 ± 16.29 kg) respectively. The mean starting pain intensity score was 4.98 ± 1.86 whereas the mean ending pain intensity score was 4.11 ± 1.84 on a 10-point NPRS. The mean ending pain intensity score was less and also, statistically significant (p=0.000).

Conclusion: Statistically significant improvement in LBP could be achieved using NSD and other traditional conservative management. Long-term follow up post NSD is needful.

Keywords: Intervertebral differential dynamics; Low back pain; Nigeriay

Introduction

The prevalence of low back pain (LBP), one of the causes of disability, is increasing and is of great concern in Africa [1,2]. This growing prevalence will inevitably increase, especially the number of older adults with chronic incapacity associated with inability to work which as a result, impacts on healthcare costs and the workforce of a nation [3,4]. In Nigeria, there is a conflicting report on the prevalence of LBP; male predominance (0.45:0.36), female preponderance (1:1.5) and equal prevalence (1:1) [5-10].

Increasing prevalence of LBP in Africa has been associated with some major risk factors such as bad posture, prolonged sitting or standing, occupational hazard, poor knowledge of back care ergonomic, poor sitting, poor transferring and lifting techniques, obesity, pregnancy, long distance driving, duty stress, psychological stress, and heavy physical work [5-7,11-18]. Other trauma-related predisposing factors include fall from a height and Road Traffic Accident (RTA) [18]. Amongst these factors, poor lifting technique is the most common predisposing factor to LBP [7].

However, breakthroughs in health outcomes of musculoskeletal conditions such as LBP which has been achieved in most Western countries are yet to be observed in Africa owing to an increased focus on other health-related issues such as malaria, poliomyelitis, communicable diseases, malnutrition, HIV/AIDS and the likes [19].

There has been increasing evidence that exercises are the most effective means of reducing LBP recurrence and resultant disability, however, analgesics and rest are still the common forms of treatment in Africa [2,20,21]. Anecdotally, other forms of therapy options for LBP include manual therapy and electrotherapy. In recent times, non-surgical spinal decompression (NSD) modality has been developed for management of LBP.

NSD entails spinal stretching on a traction table or similar motorized device with the goal of relieving neck or back pain. It is a type of therapy applied to the spine in order to create a negative intra-discal pressure to promote retraction or re-positioning of the bulging or herniated disc material and create a lower pressure in the disc for the influx of healing nutrients into the disc [22]. Indications for non-surgical spinal decompression include degenerative disc disease, facet joint syndrome, disc bulge or herniation [23]. It significantly reduces disc herniation size with resultant improvements in straight leg raise, disability and pain [24-26]. Non-surgical spinal decompression (NSD) has been found to be more effective than any other conservative treatment for LBP [24,26]. Nevertheless, LBP management involving non-surgical spinal decompression is very scarce in Africa [2].

This study therefore, was an initial step aimed at investigating

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the outcome of low back pain using NSD amidst other conservative treatment for patients with chronic low back pain with or without radiculopathy. This study is pertinent in that low back pain is becoming prevalent in Africa and focus of management has only been on pain reduction using opioid pain medications which most often have drastic side effects. Non-surgical spinal decompression (NSD) may be cost-effective and a treatment of choice compared to spinal injection or surgery for most patients with low back pain.

Methodology

This practice-based case series comprised of 130 participants who had conservative management including non-surgical spinal decompression (Accu-Spina® with IDD Therapy® by North American Medical Corporation) of an average of 10 sessions over a 5 week-period. The data was collected over a two and half-year period at a private physiotherapy clinic (Astella physiotherapy clinics). In accordance with the manufacturer's protocols, recommendations for treatment were for 20 visits over 6 to 8 weeks, however, very few patients could afford this due to financial constraint. Time frame for patient selection was November, 2015 through May, 2018 (30 months). Initial treatment on the Intervetrebral differential Dynamics (IDD) started with a distraction force of half-body weight with gradual increase from 5 to 20 pounds as the treatment progress. The most symptomatic spinal segment(s) were targeted first in relation to setting the angle of distraction.

Patients were eligible for inclusion if they met the following criteria: bulging, protruded or degenerative discs with or without radiculopathy, spinal stenosis, sciatica, posterior facet joint dysfunction, chronic low back pain without improvement from prior conservative management. Exclusion criteria included spondylolysis, symptoms of cauda equina syndrome, diagnosed inflammatory disorder of the spine, diagnosed upper motor neurone disorder, spinal infection, previous lumbar surgery with hardware, scoliosis, severe canal stenosis, presence of pacemaker, severe osteoporosis, and evidence of lumbar compression fracture, spinal instability, spinal metastasis and spondylolisthesis greater than grade II.

No personally identifiable protected health information was included in this study in order to ensure the privacy and confidentiality of patient health information.

Treatment protocol

Non-surgical spinal decompression was preceded by one or all of these: Low Level Laser Therapy (LLLT), spinal mobilisation (if not contraindicated), core strengthening and flexibility exercises and/or hot therapy. Decompression was followed by cold therapy to reduce myogenic tension around the lumbar spinal area. Low Level Laser Therapy (LLLT) by Chattanooga group, Germany was applied for a minute to each of the affected levels of the spine and associated myofascial trigger points at 5 × 100 mW (2.5 Hz, 3.8 joules/cm^2) if indicated. Home exercises to improve core strength and flexibility were prescribed. Home exercises varied but included clamshell, pelvic tilt or shift, bridge, prone extension, bird dog, dead bug, prone leg raise, cat/camel, lumbar rotation with or without elastic band depending on patient's tolerance and capability. Flexibility exercises were calf, piriformis, hamstrings, gluteal and hip flexors stretch as well as neural slides and myofascial release on the iliolumbar fascia, gluteal and hamstring muscles as well as sciatic nerve distribution on the affected leg(s) if indicated.

Patients were instructed to do 1 or 2 sets of 5 to 10 repetitions of each exercise once to twice daily as can be tolerated. The 10-point Numerical Pain Rating Scale (NPRS) was used to rate patients' pain prior and after treatment, with 10 being the worst pain imaginable. On each visit, pre- and post- intervention pain intensity scores were recorded. The starting pain score at the beginning of the treatment plan was compared with the ending pain score at the conclusion of the treatment regimen. In the event that the patient failed to complete with the treatment, the ending pain at the date of the last visit was used. The mean pre- and post-intervention pain intensity scores were compared using the paired t-test. In addition, gender difference of the diagnosis was analysed using the Chi-square. A statistically significant difference was considered to be present if the two-tailed p-value was less than or equal to an alpha level of 0.05 (Figure 1).

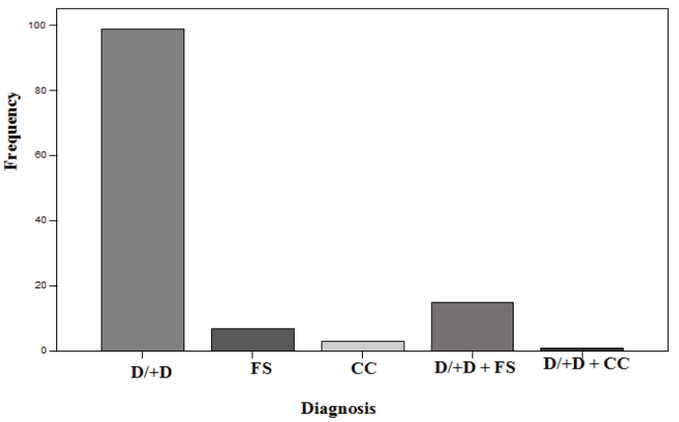

Figure 1: Diagnosis of the patients (majority confirmed with lumbar Magnetic Resonance Imaging (MRI).
D/+D: Discogenic pathology and/or Disc bulge/herniation with or without radiculopathy;
FS: Facet syndrome;
CC: Cord compression;
D/+D + FS: Combination of facet syndrome, Discogenic pathology and Disc bulge/herniation with or without radiculopathy;
D/+D + CC: Cord compression associated with disc herniation with radiculopathy.

Results

One hundred and twenty-five patients (73 males, 52 females) with LBP were analysed in this study (Table 1). All except 3 patients with increased mean score of ending pain intensity and 2 patients with no change in average pain intensity score (pre-treatment and post treatment) had significant improvement. A thorough clinical assessment was carried out on each patient. Magnetic Resonance Imaging (MRI) reports as well as broad and robust clinical assessments were used to confirm diagnosis. Diagnoses were made not just on MRI report but also, on broad and robust clinical assessments even though few patients were unable to afford MRI scans. Ninety-nine cases were either suspected or confirmed lumbar discogenic pathology (degenerative disc disease) and/or disc bulge/herniation with or without radiculopathy; seven cases were facet syndrome while fifteen cases were combination of all these aforementioned. Furthermore, three cases had MRI-confirmed mild cord compression whereas only a case was a combination of mild cord compression and lumbar disc herniation with radiculopathy (Figure 2).

All the subjects were prescribed with core strengthening and flexibility exercises while hot pack and LLLT were applied pre-IDD treatment. Cold pack was applied post each IDD session to reduce or prevent soreness even though muscular soreness was not common among the patients. There were no serious adverse effects before, during and after treatment. The mean age of the patients was 54.70 ± 14.07 years with average weight of 192.10 ± 35.91 lbs (87.14 ± 16.29 kg).

The mean number of sessions was 10.86 ± 7.07 ranging from 5 to 52 sessions. Even though the recommended number of sessions for optimum result on non-surgical spinal decompression is 20, only few patients could afford 20 sessions due to financial constraint as aforementioned. The average pre-intervention pain intensity score was 4.98 ± 1.86 whereas the mean post-intervention pain intensity score was 4.11 ± 1.84 on a 10-point NPRS. A statistically significant difference between mean pre- and post-intervention pain intensity ($p<0.05$) was observed this study. However, there was no statistically significant gender difference amongst the patients ($p>0.05$) (Table 2).

Discussion

The present study appears as the first to examine the outcome of LBP using IDD therapy and other traditional conservative management in Africa. The patients observed in this present case series were predominantly males in their middle-age even though there was no statistically significant gender difference. Results of earlier studies conducted in Nigeria and overseas revealed conflicting prevalence [6-11,27]. This has been attributed to occupational factors, female hormonal imbalance, pregnancy, psychological factors and menstruation [6,9]. However, the report of no significant gender difference in LBP is therefore, open to speculations, as to the knowledge of the authors, no explanation has been postulated.

Noteworthy is the report of majority of the patients being diagnosed with discogenic pathology and/or disc bulge/herniation with or without radiculopathy. This therefore gives a clue to the class of LBP common in this population that is, LBP with or without radiculopathy which is a more serious form of mechanical LBP [28]. Moreover, the result of a previous study has revealed that spondylosis as the commonest diagnosis in Nigeria [11]. In addition to this, facet syndrome which is also known as a simple mechanical form of LBP formed the clinical diagnosis of a few number of the patients in this study. Nonetheless, this does not mean that the patients observed in this present study do not have any psychosocial overlay as this is beyond the scope of this study.

Non-surgical Spinal Decompression (NSD) is currently tagged investigational owing to insufficient evidence on its effectiveness for different stages of back pain despite its recommendation for cervical radiculopathy in European 2017 National clinical guidelines. Lack of comparative studies with established conservative treatments (standard medical care, exercise therapy and spinal manipulation) as well as cost has been the target of controversy on NSD [29].

Nevertheless, results from previous studies have revealed the efficacy of IDD therapy in the management of chronic LBP [23,30-32]. In a retrospective chart audit, it was reported that NSD improves chronic low back pain using DRX9000 and a treatment protocol (lumbar stretching, myofascial release, muscle stimulation and hot/

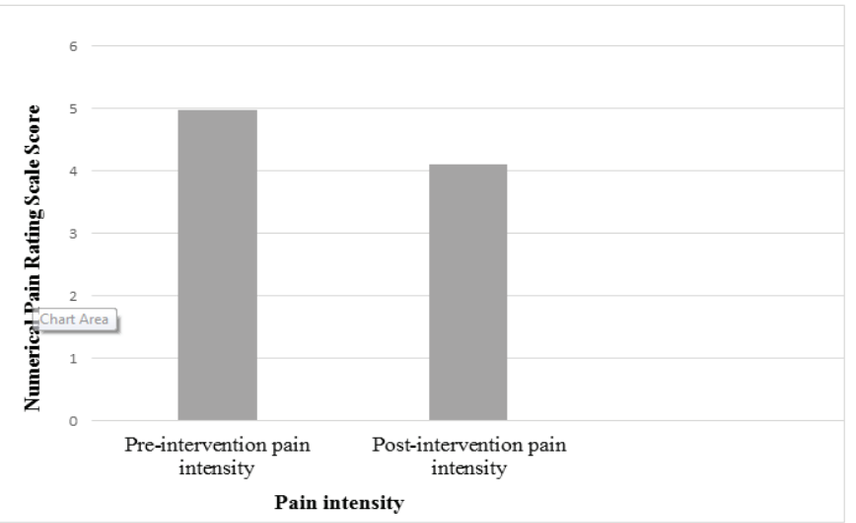

Figure 2: Low back pain prior and post non-surgical spinal decompression.

Variables	Diagnosis				Chi-Square test				
		D/+D	FS	CC	D/+D + FS	D/+D + CC	X^2	df	p-value
Gender	Male	59	3	3	7	1	5.880	4	0.208
	Female	40	4	0	8	0			

Table 1: Gender distribution of the diagnosis.

S. No	Pain intensity	Mean	Standard deviation	Paired-samples T test		
				Df	*t*	p-value
1.	Pre-intervention pain intensity	4.9834	1.85672	124	11.51	0.000*
2.	Post-intervention pain intensity	4.1138	1.84060			

Table 2: Mean difference in pain intensity.

cold application) [33]. Conversely, in a single-blinded randomized controlled trial concluded on the ineffectiveness of NSD in two groups of patients with back pain treated with standard graded activity, with one group receiving IDD Therapy® and the other a sham therapy using a negligible amount of distractive force [30]. Amidst this controversy, this present study reveals a significantly less mean ending pain intensity score of the patients in accordance with previous findings of the studies in support of the effectiveness of IDD therapy together with other traditional conservative management [23,31-33]. Improvement of associated paraesthesia, numbness, trunk control and posture were also reported by patients in this study.

Conclusion

Among Nigerians, mechanical LBP is more common in men than women. Non-surgical spinal decompression combined with other physiotherapy modalities appear to offer pain relief, decrease paraesthesia and numbness as well as improve poor trunk control and postural abnormality due to LBP. Further investigation of non-surgical spinal decompression on neck pain and long-term follow up is needful.

Limitations

There are however, several limitations to these conclusions. The generalizability of these results to a larger population with LBP may be limited due to the fact that only individuals with chronic (continuous pain lasting for a period of equal to or greater than 3 months) back pain were included in this study.

Acknowledgement

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Conflicts of Interest

There are no conflicts of interest.

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Traction, Decompression, and IDD Therapy®: A Historical Perspective

Manual spinal traction, mechanical traction, decompression, and IDD Therapy® treatment all share one common principle; they all perform a physical pull. So does that make them the same?

Understanding the differences rather than focusing on the common traits can provide a deeper understanding of the physiological differences.

NON-SURGICAL SPINAL DECOMPRESSION

Spinal decompression is a surgical procedure performed on vertebral structures to relieve pressure in the spine that may be causing severe pain. It may involve shaving or removing bone or cutting into the disc to remove a piece of the herniation that is pressing on a nerve root. Non-surgical spinal decompression aims at the same result, utilizing movement and positioning to effect change rather than surgical intervention.

Spinal decompression was born of an understanding that "just pulling" at a human spine does not necessarily result in a therapeutic outcome. That in fact, the body has certain thresholds which must be understood in order to effect the desired outcome, particularly one that can create a retraction of bulging disc material if the inverse relationship between intradiscal pressures and distraction of the involved structures is understood.

Applying variable pulling of the spine in an effort to relieve painful spinal pressure that builds up as a result of dysfunctional biomechanics or injury. The primary goal of spinal decompression is to decompress the painful, herniated disc.

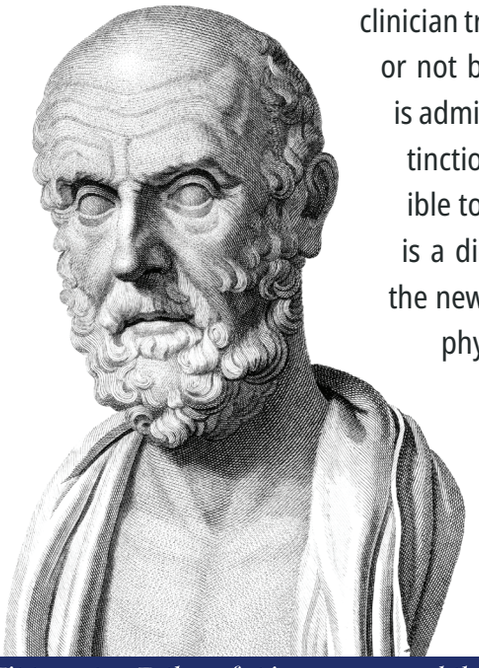
The first device to make the claim of performing non-surgical spinal decompression was developed, and FDA cleared in 1996 by Dr. Allan Dyer, an MD from Canada. This early generation machine was a pneumatic drive, splittable design. Patients were treated in a prone position while grasping handles at the top of the bed in order to resist the straight line pull of the lower table hydraulics. The goal was to apply a pulling force great enough to relieve pressure off the disc but still allow the patient the ability to let go of the handles if the force felt too great.

Armed with the Nachemson[1] study from 1981 documenting in vivo measurements of intra-discal pressures whereupon the hydrostatic properties of the nucleus pulposus of the normal lumbar intervertebral disc were proven, Dr. Dyer set out to test his decompression table.

In what may have been the single-most-important discovery made using Dyer's device, a pivotal paper published in 1994 was the first to demonstrate that negative pressures could be created inside the human disc by applying variable pressures of increasing force to the spine. Using live subjects, volunteers submitted to have a cannula with a pressure gauge inserted through their back into the spinal disc. Readings were recorded while the patient was undergoing treatment on the hydraulic table with a tensiometer.

The resulting measurements proved that variable, repetitive application of forces to the spine could result in a reduction of relative pressure inside a herniated disc. This in-vivo experiment showed the lowering of intra-discal pressures to the point of creating a negative pressure reading of as much as 160mmg- what has come to be known as a "decompression event."

This 1994 paper, known as the Ramos Study *(found in the "Additional Studies" section of this Compendium)*, established the basis for utilizing decompression treatment to relieve spinal pain. The Ramos Study also went on to birth an entire category of non-surgical spinal treatment devices indicated to relieve back pain applying the principles demonstrated by Ramos and Martin.



Hippocrates, Father of spine surgery and the inventor of the Jacobs ladder for spinal pain.

As more outcome studies with Dyers' early hydraulic devices went on to document respectable success rates in the 70% range, spinal decompression success rates quickly began outperforming disc surgery success rates. But it wasn't until 14 years after the famous 1994 Ramos paper that Dr. Dyer developed and applied for a patent on his logarithmic curve algorithm (September 2008).

TRACTION HISTORY

A review of the "Annotated Bibliography on the History of Traction (Appendix A) summarizes the conclusion regarding conventional traction, that is, that clinical outcomes are highly variable. Many studies purport that use of conventional traction can actually increase pressure inside the disc. GB Andersson[2] concluded that when traction is applied so that the back muscles contract, then disc pressures will increase.

This and other continuing research on the spine began to show that the therapeutic benefit was frequently dependent not on whether the clinician treated a spine by pulling force or not but by HOW the pulling force is administered to the spine. The distinction is one that is not largely visible to the naked eye. But certainly, is a distinction that can be seen in the newer medical literature: human physiology responds differently from one method to another form of physical medicine.

Therefore, a great deal of confusion is promulgated by the persistent use/misuse of the term "traction" as a generic catch-all categorization in much of the clinical literature. Even leading research institutions will sometimes insist on utilizing the traction term for all device treatment types in this broader category, though akin to categorizing a smartphone as a telephone.

Though the basic principles appear similar to medieval devices employed to pull the body, technological advancements have changed and expanded the performance capabilities of some devices. The methods and science behind different technologies to apply a pulling force can be as different as the modern-day automobile is to its predecessor of times past.

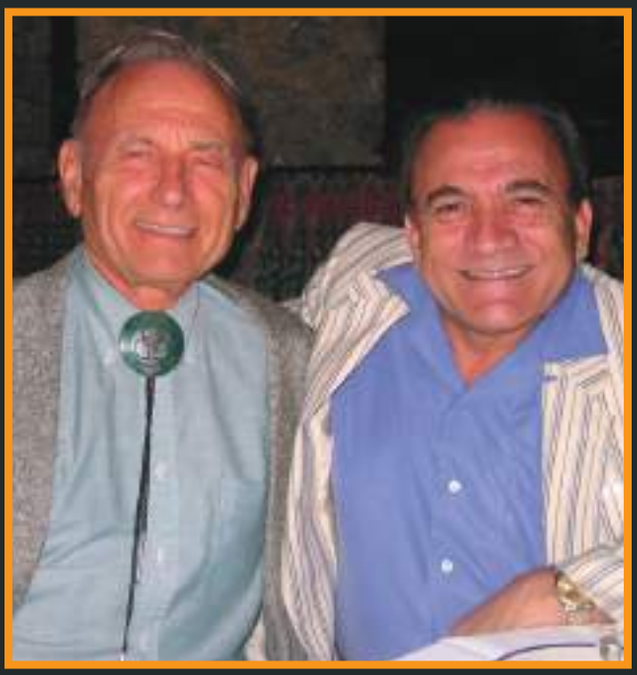
ORIGINATORS OF MODERN-DAY ADVANCED DECOMPRESSION- IDD THERAPY®

Meanwhile, also in the late '90s, the publication of a non-surgical decompression event caught the interest of neurosurgeon and researcher Dr. C. Norman Shealy. Dedicated to bettering of the human condition through minimal or non-invasive medical approaches, Dr. Shealy noted the limitations of the pneumatic device used in the Ramos study. In collaboration with Carlos Becerra, Dr. Shealy set out to identify improvements to the treatment concept set forth by Dyer. Together, Becerra and Shealy patented the first non-surgical spinal decompression device with a high tower angle design for specific disc level targeting. They also eliminated active patient demands by utilizing body harnesses instead of handgrips during treatment, creating a completely passive treatment. And they changed the treatment methodology from prone to supine.

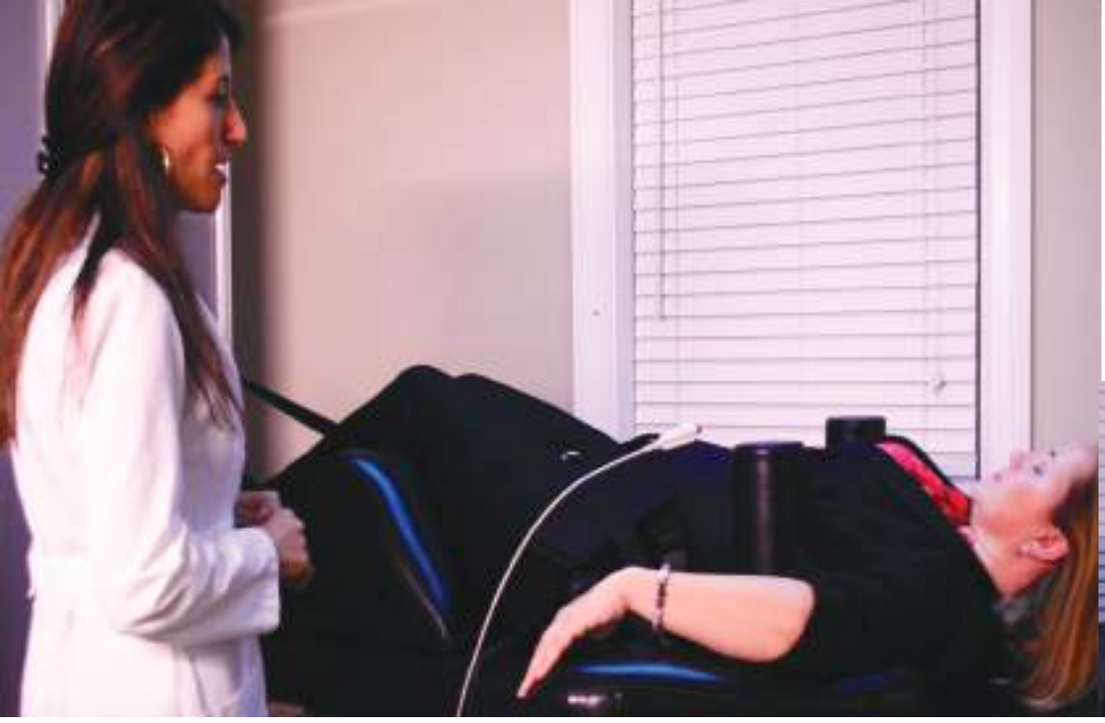
This Decompression, Reduction, and Stabilization system (branded DRS for short) was introduced, and FDA cleared in 1998. Shealy's protocols further improved patient biomechanics with air bladders and knee bolsters to eliminate the lordotic curve. Utilizing the principles set forth in Ramos' paper combined with his own research defining clinically successful device improvements, this early Shealy-Becerra device set off an era of imitators because of its efficacy. Known as the DRS, this Accu-Spina predicate utilized programmed chip logic for creating pre-determined pulling cycles, thus replacing the inaccuracies of treatment with a pneumatic pulling versus handgrip device. As such, this newer approach to decompression went on to document the first 86% success rates in treating back pain with non-surgical decompression therapy.

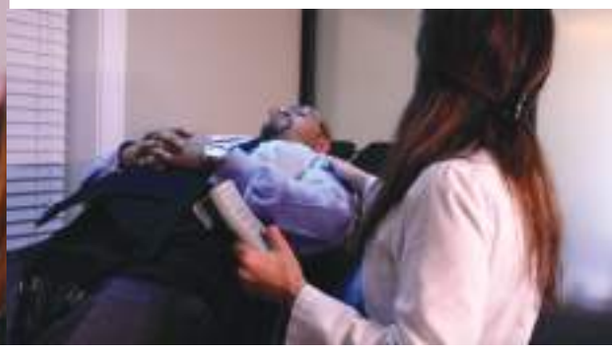
In 2000, Becerra formed North American Medical Corporation employing a research and engineering think-tank ideology. The DRS/Spina System was evolved into the first fully software-driven spinal treatment physiotherapeutic and decompression device capable of exacting, quantifiable, and reproducible treatment detail. The reproducible nature of this advanced treatment approach quickly proved a key component of improved patient outcomes.

C. Norman Shealy, MD., Ph.D., collaborated once again with the Becerra family as chair of the Scientific Advisory Board in 2004. Working with seven active orthopedic surgeons, physiatrists, and pain management physicians, all utilizing and contributing to the science of what was now known as Intervertebral Differential Dynamics protocol, the Accu-Spina system evolved.



Dr. C. Norman Shealy (left) and Carlos Becerra (right).





SETTING INDUSTRY STANDARDS

As the first system ever developed with high-level computing capability and closed-loop treatment feedback monitoring, the Accu-Spina® System with IDD Therapy® treatment protocols was honed to meet the demands of the most scientific-minded physicians on the advisory board. These physicians met monthly to exchange data and discuss in-clinic patient observations with their own IDD Therapy® patient groups. Ideas were exchanged not only on the mechanical effects of ideal unloading but also on how different Accu-Spina® algorithms appeared to elicit different physiological responses in patients who had been previously treated on different equipment. Knowing how the cells and organs of the body take signals from the environment, many experts pointed to the importance of creating the right signaling and dynamic pattern for each patient session.

This understanding- that specific force patterns and specific mathematical variations of dynamic energy applied to the spine would elicit dramatically different physiological outcomes- went hand in hand with the development of the FIRST DECOMPRESSION DEVICE ALGORITHM*.

In 2004, Becerra-North American Medical applied for its Oscillatory Signaling Sinusoidal algorithm, submitted for U.S. Patent in 2004 and awarded in 2011. Concurrent and subsequent clinical papers show patient success rates for pain relief and reduction of disability climbed significantly with the advent of the patented "Decompression Modalities Using the "Oscillatory Signaling and Smooth Transition" algorithm on the Accu-Spina® System.

**The logarithmic curve algorithm invented by Dyer is sometimes mistakenly credited as having been used in the 1998 Ramos study; however, a careful review of the legal record shows it was not possible as Dyer developed and applied for the logarithmic curve patent September 30, 2008. That was nearly a ten-year time span after Ramos' study identified negative intra-discal pressures utilizing the 1998 hydraulic Vax-D table design described in the paper. In fact, Dyer-VaxD filed their patent for inventing the logarithmic curve four years after North American Medical developed and filed a patent on the first specific treatment algorithm for a spinal decompression algorithm (see oscillation algorithm patent December 2004)- well ahead of Dyer's logarithmic patent.*

HOW DOES THE ACCU-SPINA® WORK?

Using our cutting-edge Accu-Spina®, Intervertebral Differential Dynamics (IDD) Therapy® works by administering mathematically precise treatment forces to mobilize and elongate targeted segments of the spine. The process of administering decompressive forces provides gradual, effective distraction of the vertebral structures that may be causing a patient's pain. As pressure drops within the compressed structures, the disc and nerve roots are freed up. Rehydration begins to occur, bringing a rush of oxygen-rich blood to the primary treatment site, triggering as well as supporting the natural healing process.

What truly sets the Accu-Spina® apart from its competitors is our patented sinusoidal oscillation method. As the vertebrae and discs are gently moved, the AccuSpina's® state-of-the-art technology simultaneously provides an additional and unique pumping effect at the peak of each sinusoidal wave to help each disc take in more fluids, oxygen, and nutrients. These precursors to cell respiration can act as signals for surrounding tissues to begin their own regeneration. When applied to the intervertebral structures of the spine, this dynamic process promotes a higher level of self-healing and rehabilitation to damaged discs and surrounding muscle tissues to more effectively relieve pain.

Pre and post MRIs have confirmed a reduction in the size of herniations and visibly increased disc height and hydration. Pre and post-biomechanics evaluation show dramatic improvements in range of motion, pain-free mobility, and even correction of foot drop.

Our patented sinusoidal oscillation method provides patients with an experience unlike any other, gives them a better treatment than others, and more effectively leads them to a place of long-term pain relief.

WHY SHOULD MY PRACTICE CHOOSE THE ACCU-SPINA® OVER OTHER OPTIONS?

There are many treatment options available, but not all are created equal.

The Accu-Spina® is the only therapeutic device certified to provide IDD Therapy® treatment- which has been proven to have as high as 92% success rates. IDD Therapy® treatment on the AccuSpina® is able to treat specific segments of the spine with technology that is able to ensure that each patient receives an individualized and more effective treatment plan. The Accu-Spina® is the only device that performs the patented sinusoidal oscillation method to treat both lumbar and cervical diagnoses. No fancy bells and blinkers to distract from the true science, just real results, with real people.

For over twenty years, the Accu-Spina® system by North American Medical has maintained a reputation for superior quality with durability, scientifically rooted origins, and uncompromising integrity. Accu-Spina® is also one of the most established and independently studied spinal therapeutic devices in use at major teaching hospitals and universities throughout the world. Through its long-lasting relationships with luminary healthcare professionals, North American Medical Corporation maintains a progressive focus committed to continued advancements to benefit its family of IDD Therapy® treatment providers.

(1) Nachemson AL.Disc pressure measurements. Spine. 1981 Jan-Feb;6(1):93:7. Doi: 10.1097/00007632-198101000-00020

(2) Scand J Rehabil Med Suppl. 1983:88-91 PMID: 6585945

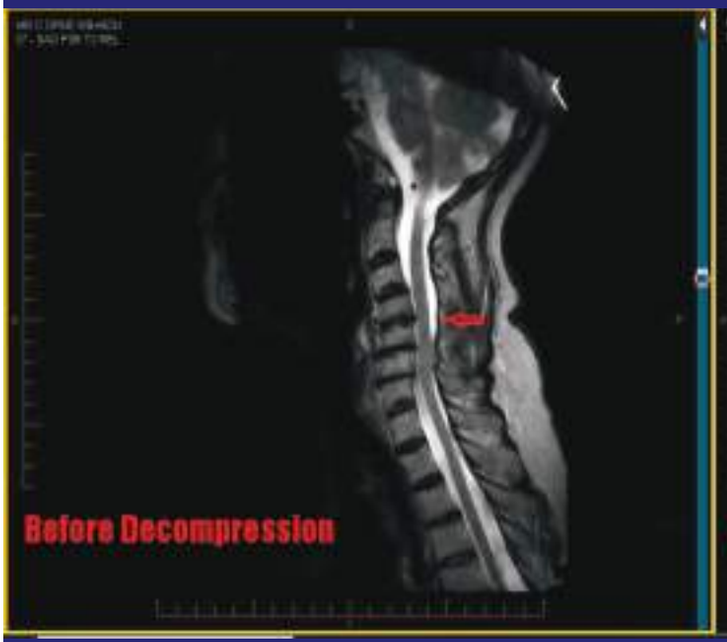
Non-Surgical Spinal Decompression MRI Evidence Case Studies

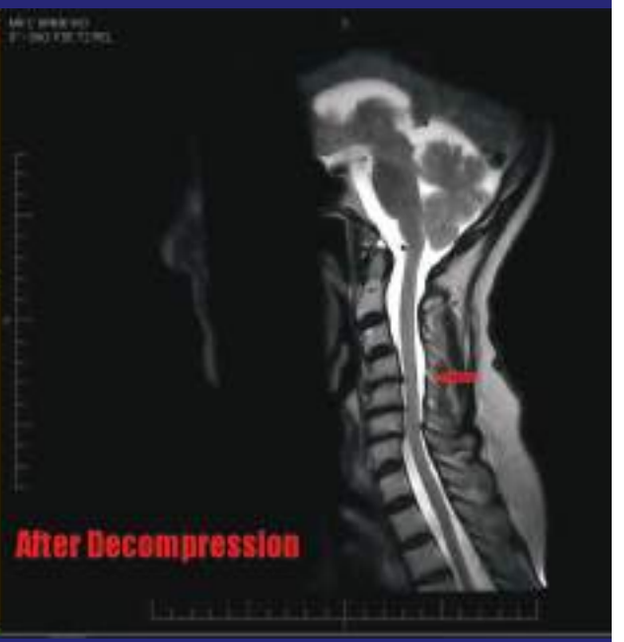
By Dr. Luke Henry

With Assistance from Dr. Eric Kaplan

2019 National Decompression Certificate Program,
Parker University, Dallas, Texas

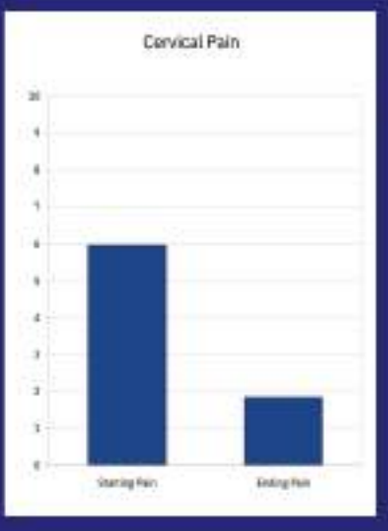
64 year old female
Chronic Neck Pain





MRI demonstrating decreased canal stenosis. Post MRI ~2 weeks post-treatment.

Average Pain Reduction Cervical



- 95% of cervical cases showed improvement
- Average pain reduction of 76%

Henry L (2015) Nonsurgical spinal decompression of lumbar disc herniation: a case report and proposed multimodal chiropractic treatment approach. The Internet Journal of Chiropractic 4: 1.

45 year old male
Neck Injury

Restaurant owner referred by Brazilian Jiu-Jitsu instructor after being injured with an arm bar. PPW neck pain radiating to left upper extremity pain, paresthesia and weakness. Difficulty sitting and working at a computer.

PC: chiropractic – no improvement + Distraction and Jackson's compression tests.

Objective left upper extremity weakness and unable to do a pushup.

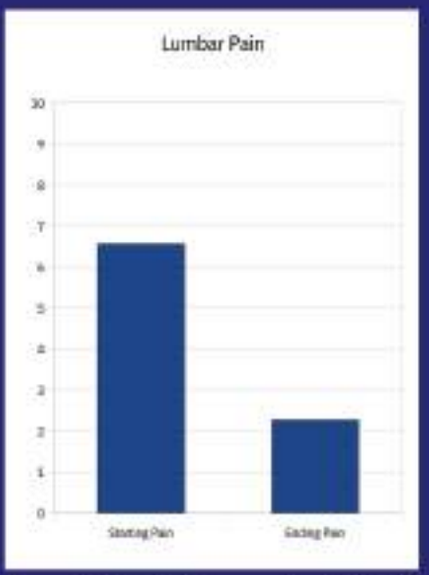
T2 sagittal. Post MRI approximately 6 weeks post-treatment. Reduced stenosis compared to study 14 weeks prior.

Henry L (2015) Nonsurgical spinal decompression of lumbar disc herniation: a case report and proposed multimodal chiropractic treatment approach. The Internet Journal of Chiropractic 4: 1.

52 year old female
Chronic Low Back Pain

Post MRI approximately 4 weeks post-treatment. L5-S1 disc bulge reduced compared to study 6 months prior.

Average Pain Reduction Lumbar



- 96% of lumbar cases showed improvement
- Average pain reduction of 74%

Henry L (2017) Non-surgical Spinal Decompression an Effective Physiotherapy Modality for Neck and Back Pain. J Nov Physiother Phys Rehabil 4(3): 062-065. DOI: 10.17352/2455-5487.000049

Role of IDD Therapy in the Back and Neck Pain

HSOA Journal of Medicine, Study & Research 1:002
Review Article

Previously failed chiropractic care, conventional physical therapy or epidural/ facet injection interventions, observational study.

AUTHOR

Gourishankar Patnaik, Dept. of Orthopedics, and Spine Surgery
Narayan Medical College, Oman

CONCLUSION

Biomechanics and treatment protocol of this non-surgical treatment show statistically significant improvements in both cervical and lumbar pain.

Patnaik G, J Med Stud Res 2018, 1: 002
DOI: 10.24966/MSR-5657/100002

HSOA Journal of Medicine: Study & Research

Review Article

Role of IDD Therapy in the Back and Neck Pain

Gourishankar Patnaik*

Department of Orthopedics and Spine Surgery, American Spine center, Muscat, Sultanate of Oman, Oman

Abstract

Intervertebral Differential Dynamics (IDD) Therapy treatment is a non-surgical spinal decompression programme for low back pain, neck pain and some related conditions. It was developed in the late 1990's to address the failings of traditional traction and the natural limitations of what can be achieved with the hands alone. IDD Therapy can isolate each lumbar vertebra (L1, L2, L3, L4 or L5) and distract the vertebrae surrounding an injured disc 5 to 7 millimeters. The 25 to 30 minute treatment provides static, intermittent, and cycling forces on structures that may be causing low back pain. Negative pressure promotes the diffusion of water, oxygen, and nutrients into the vertebral disc area, thereby re-hydrating the degenerated disc. Repeated pressure differential promotes retraction of a herniated nucleus pulposus (the elastic core of the intervertebral disc). The IDD Therapy treatment can reduce pressure on the vertebral joints, promote retraction of herniated discs, and promote self-healing and rehabilitation of damaged discs, thereby relieving low back pain.

This article highlights the biomechanics, indications and treatment protocol of this important non-surgical treatment regimen of back and neck pain.

Keywords: IDD; Intermittent distraction; Intervertebral disc; Spine

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Citation: Patnaik G (2018) Role of IDD Therapy in the Back and Neck Pain. J Med Stud Res 1: 002.

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Introduction

Back pain affects nearly everyone at some point during their life. Whilst most back pain resolves itself or with a short course of treatment, for some people back pain can become an unwelcome companion. Neck pain affects thousands of people every year and yet treatment options for neck pain are somewhat limited in comparison to back pain. Traction therapy has been utilized in the treatment of low back pain for decades. The most recent incarnation of traction therapy is non-surgical spinal decompression therapy which can cost over $100,000. This form of therapy has been heavily marketed to manual therapy professions and subsequently to the consumer. The purpose of this paper is to initiate a debate pertaining to the relationship between marketing claims and the scientific literature on non-surgical spinal decompression. Traction as a therapeutic intervention in the treatment of low back pain has existed for many years. Its use has progressed from simple static traction to intermittent motorized traction. A recent systematic review found only seven randomized controlled trials for intermittent motorized traction and six reported no difference in outcomes between the traction groups and the control groups. The most recent incarnation of traction has been a form of intermittent motorized traction commonly referred to as spinal decompression therapy. Developers and manufacturers of the equipment along with clinicians often consider it to be a unique form of traction.

Intervertebral Disc Decompression (IDD) is a modern non-surgical technology providing decompression therapy to the spine. It comprises of a series of treatment sessions that are specifically designed for each patient. The Accu SPINA and SDS SPINA are CE and FDA cleared Class II medical devices, licenced to deliver IDD Therapy spinal decompression (Figure 1).

Figure 1: IDD machine by AcuSpina.

Manual therapists use a variety of techniques to treat neck pain but when these standard treatments fail to produce adequate results, the treatment options are very limited. IDD Therapy is the non-surgical spinal decompression treatment for people suffering with chronic back pain and neck pain. Treatment works by gently distracting and mobilizing targeted spinal segments using a series of carefully

controlled pulling forces which we call distraction forces. The goal of treatment is to address the causes of pain.

Every aspect of the treatment is recorded and this enables clinicians to accurately monitor progress and adjust treatment appropriately, as (part of a commitment to evidence-based medicine. The distraction helps to improve mobility in the painful area and this is important for healing. It also helps relieve pressure on structures such as the intervertebral disc, spinal nerves and the joints of the vertebrae themselves, which can be causing pain.

A key benefit of IDD Therapy is the ability to adjust and focus distraction forces to a targeted level of the spine. This is achieved using precisely measured angles, which are adjusted deepening on the level of the spine being treated.

Features

- Computerized & personalized program based on the patient's pathology
- Mobilize and manipulate specific spinal segments to induce negative intradiscal pressure
- Designed to provide static, intermittent and cyclic oscillation forces
- Forces applied to a specific disc in variable direction, frequency and amplitude

How does IDD work?

An intervertebral disc (or intervertebral fibrocartilage) lies between adjacent vertebrae in the vertebral column. Each disc forms a fibro cartilaginous joint (a symphysis), to allow slight movement of the vertebrae, and acts as a ligament to hold the vertebrae together. Intervertebral discs rely on movement and pressure differentials for hydration and nutritional pathways (Figure 2). Compression is the number one enemy of the intervertebral disc and that is why "decompression" has always been appealing and why releasing pain to allow movement in the vertebral joints is a key objective of any spinal treatment. Traction in one form or another has been around for centuries but the technology and knowledge of the spine has only taken off in the last 20 years to enable the treatment to evolve.

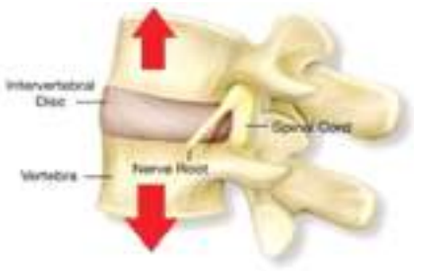

Figure 2: Disc with nerve roots.

Opening targeted spinal segments to create negative pressure is what separates IDD Therapy spinal decompression from traditional traction. IDD Therapy is not a cure-all, but it is a highly-effective treatment tool which when used as part of a complete program of care, offers clinicians the opportunity to tackle back pain, neck pain and in particular disc-related conditions in a manner previously not possible [1].

This technology is designed to provide non-surgical treatment utilizing differential dynamics. This relieves pressure on the spinal nerves involved, especially those associated with herniated discs, degenerative disc disease, posterior facet syndrome, and alleviates sciatica. With intermittent distraction, technique of IDD the spinal decompression has a maximum high tension and a low tension and the low force does not go to zero thereby maintaining the tension throughout the treatment (Figure 3).

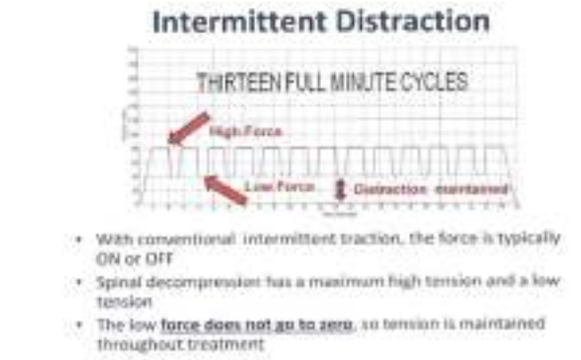

Figure 3: Chart showing Intermittent Distraction.

The treatment protocol achieves these effects through decompression of intervertebral discs, unloading through distraction and positioning. Each treatment session is designed according to the level of problem. During the session, the patient is closely monitored and after 10 treatments, the patient is reviewed for progress, which can be in terms of pain, motor activity, sensation, function and ROM.

Parameters

Patient specific information is entered into the computer and the computer analyzes the data and creates a specific protocol.

- Progression Time
- Decompression Weight
- Regression Time
- High Hold
- High Tension
- Low Hold
- Oscillation Parameters
- Transition Time
- Frequency
- Target Level L4, L5, S1
- Amplitude
- Angulation

Angulation System

The IDD system can isolate each vertebra (L1, L2, L3, L4, L5 etc.,) depends on the angulation in the set up.

Treatment Protocol

25 session, 20 sessions over 10 weeks and 5-maintenance session over 5 months. This will insure long-term success. Patient starts to feel better after the 5th-7th session. IDD is a highly integrated software program allowed to keep real time tracking of the force applied to the specific segment of the spine that is injured The IDD program gives real time patient response, to the specific program applied during therapy session to ensure suitability of the forces applied.

The first graph illustrates the patient is lagging on the IDD Graph (Figure 4). The graphs below then detail specifically how we can cater to each patient depending on their specific need (Figure 5). Whether they need low, medium, or high level oscillation. We also have low and high amplitude.

Figure 4: Graph illustrating the patient is lagging on the IDD Graph.

Figure 5: The graphs below then detail specifically how we can cater to each patient depending on their specific need. Whether they need low, medium, or high level oscillation.

Once set, the patient relaxes and is ready for treatment. As with all treatments, patient safety is paramount and IDD treatment has many safety features for complete peace of mind. Treatment on the SPINA machine lasts for approximately 25 minutes, during which time there are 13 minutes when the joint is fully distracted. Unique to IDD Therapy is a patented oscillation capability, which gently mobilizes the joint at the point of maximum joint distraction [2]. As well as comfort, the oscillation enables patients to adapt to higher pulling forces whilst remaining completely relaxed for the duration of treatment. (Some patients actually go to sleep during treatment). Different oscillation waveforms gives the clinicians idea about the effectiveness of the pulling forces (Figure 6).

IDD Therapy is a tool used as part of a complete programme of care. As treatments progress and pain is relieved, patients are shown simple exercises to help condition the body and are advised on lifestyle changes to help get the most from the treatment and achieve lasting pain relief. The number of treatments a patient requires will vary depending on the nature of your condition. Some patients can experience relief within a few treatments, whilst other patients require a course of treatments to give the body time to adapt to changes, heal and strengthen.

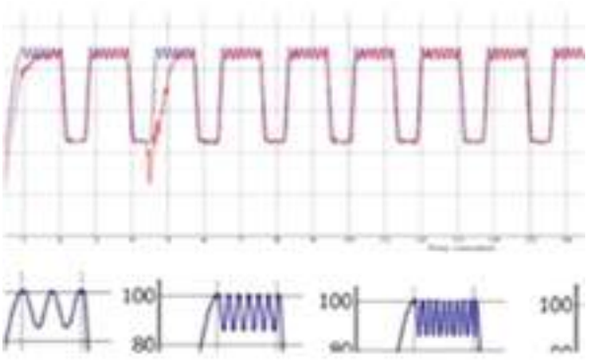

Figure 6: Different Oscillation Waveforms.

IDD Therapy spinal decompression vs traction

IDD Therapy Spinal Decompression is able to distract and mobilize specific segments of the spine and thus decompress a targeted intervertebral disc. Traditional traction has been outmoded for a number of years and one of the shortcomings of traction was the inability to focus and control forces at specific spinal levels at the origin of the problem.

The four goals of IDD Therapy spinal decompression are to:

- Release pressure on nerves
- Improve Disc Health
- Re-educate soft tissues
- Re-align spinal structures

IDD Therapy treatment is applied by distracting and mobilizing targeted spinal segments at precisely measured angles, using high distraction forces which incorporate joint mobilization in a longitudinal plane [3]. Controlled forces are high enough to comfortably stretch the paraspinal tissues, open and create pressure differentials in disc space and are applied for sufficient time to have a therapeutic effect.

Ergonomic pelvic and thoracic harnesses secure the patient to the bed and a computer controlled cyclic distraction force is applied. Treatment is delivered by CE& FDA cleared Class II SPINA devices. All aspects of treatment and outcomes are recorded as part of a commitment to evidence-based medicine. Spinal decompression therapy resolves problems with the disc and removes the pressure applied to the disc by supplying nutrients and oxygen to the disc. This creates a state of non-gravitation or negative pressure within the spinal canal and reduces pressure inside the intervertebral disc by softly increasing a specific part of the disc through the decompression of a precise part of the lesion. Lee et al., reported that a group that received spinal decompression therapy and manual therapy showed a larger degree of pain reduction and a higher increase in the range of motion (ROM) of

the hip joint than a group that received spinal decompression therapy and general physical therapy [4].

Decompression of a targeted spinal segment

In order to decompress a targeted level, engineers applied the principles of vector forces from physics to the spine. They observed that by focusing a controlled distraction force at a specific angle, they could open targeted spinal segments by between 5mm -7mm [1]. As the angle, which a pulling force makes with the horizontal increases, the component of force in the horizontal direction (Fx) decreases and the vertical component of force (Fy) increases (Figure 7). This causes the relative direction of the pulling force to change and therefore the focus point of application of the pulling force to move progressively along the x-axis.

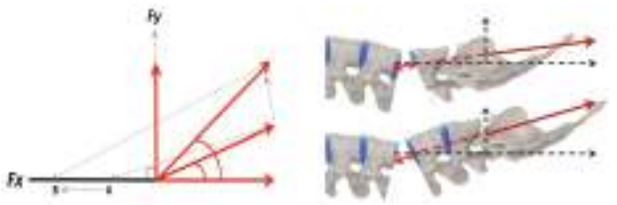

Figure 7: Measured changes in the angle of applied pulling force enable clinicians to focus and direct distraction forces accurately to injured spinal segments.

Measured changes in the angle of applied pulling force enable clinicians to focus and direct distraction forces accurately to injured spinal segments. A difference of just 5 degrees can have a bearing on the patient experience. Traditional traction was applied without thought to measuring angles to treat targeted segments. Without this knowledge, practitioners were in effect treating blindly [5].

Sinusoidal distraction force: This patented waveform replaces linear pulling forces allowing greater comfort and application of higher distraction forces of up to half body weight plus 5-10kgs (Figure 8). Patient comfort was a shortcoming for some traction machines and the risk of applying adequate force to distract the spine was that the patient could go into spasm, causing an actual increase in intradiscal pressure and pain [2].

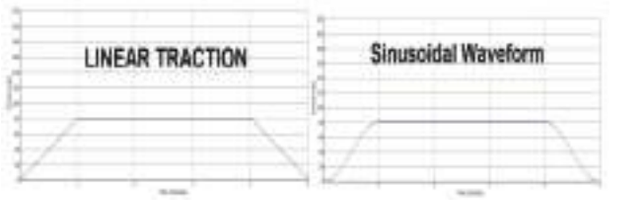

Figure 8: Linear Traction vs Sinusoidal waveform.

Longer treatment duration: Twenty-five minute treatment during which time joints are distracted for 13 times to a high tension, whilst soft tissues are worked and remain under constant tension. With traditional traction, not only was it uncomfortable for patients to tolerate higher distraction forces for adequate time (necessary to open the disc space), traction was applied for shorter periods to accommodate other treatment techniques within a standard 30-minute treatment slot.

Thus whilst some patients might feel some comfort during traction, traction was applied for insufficient time to have an adequate therapeutic effect. A case of fitting the treatment to the needs of the clinic timetable rather than to the therapeutic objectives of treatment, which require a longer treatment time. After completion of 25 minute of treatment on the IDD machine the distraction and oscillation graph is studied (Figure 9).

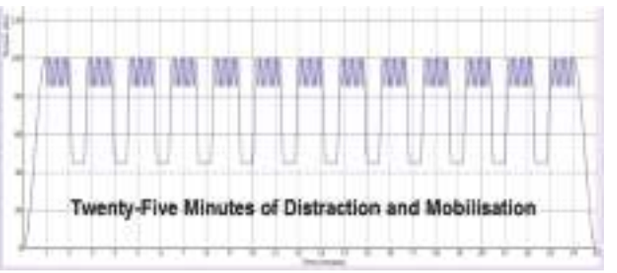

Figure 9: Graph showing 25 minutes of distraction and oscillation.

Joint Mobilization

The sinusoidal waveform allows for the application of oscillatory forces to mobilize the joint in a longitudinal, rather than anterior-posterior plane at the point when the joint is distracted. When mobilizing any other joint in the body, clinicians open the joint and then apply mobilization to so not to rub the joint surfaces and to create a synovial pumping mechanism. The challenge with the spine is to not only distract the vertebrae longitudinally to decompress the disc, but also to apply adequate force, hold it and then mobilize at the point of maximum distraction (Figure 10)

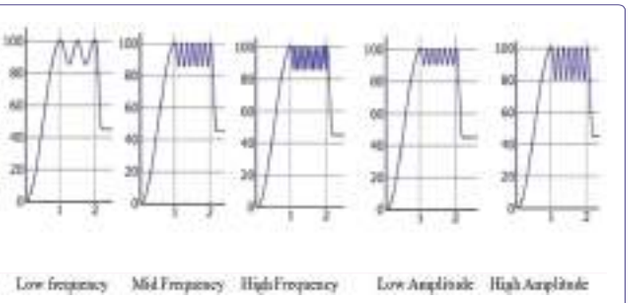

Figure 10: Patterns of graph after IDD treatment.

McClure et al., show that 92% of 129 patients considered surgical candidates had a greater than 50% reduction in pain with IDD Therapy [6].

Schimmel et al., show IDD Therapy to be no different from sham treatment whilst Shealy et al., show pain relief at the end of treatment and continuous pain reduction one year after completion of treatment [7,8].

Scanning

MR Scanning is much more widely available now. IDD Therapy providers use an MRI scan to rule out contraindications and to assist in both the diagnosis and setting of the treatment plan. Whilst a disc prolapse may be asymptomatic, many are not (Figure 11).

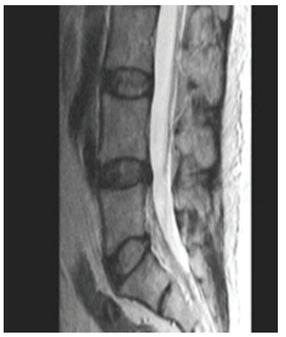

Figure 11: MRI scan of LS Spine.

Traditional traction was applied in most cases with a try it and see approach without the benefit of a scan. IDD Therapy providers know that a patient with a severely degenerated disc will take longer to notice changes than a patient with a large disc prolapsed. With traction, not only did the clinician have an inadequate tool to treat targeted segments, they didn't have the benefit of seeing the underlying pathology. Thus if a patient did not respond to treatment after a few sessions, that may not have implied that the treatment was ineffective, rather than the treatment plan had not taken account of the condition and likely response time! Negative pressure promotes the diffusion of water, oxygen, and nutrients into the vertebral disc area, thereby re-hydrating the degenerated disc. Repeated pressure differential promotes retraction of a herniated nucleus pulposus (the elastic core of the intervertebral disc) [9].

Conclusion

In order to decompress (take pressure off) a joint, it is necessary to distract it in the opposite direction to the compressive force. Where a joint has become stiff and immobile, gentle mobilization at the point of distraction helps to improve mobility in the joint and allow the natural mechanisms, which keep joints healthy to operate freely. Following salient features of IDD therapy enable patient for an optimal relief.

- Improved harnessing secures the pelvis
- Measured angle of distraction
- Computer controlled sinusoidal waveform
- Cyclical distraction, higher distraction forces
- Ergonomic harnesses
- Patient completely relaxed for 25 minutes, plus
- Benefit of a scan to determine the treatment plan enable the patient to get optimal benefit from back and neck pain

IDD Therapy Spinal Decompression applies new technology to physical laws to enable clinicians to distract and mobilize targeted spinal segments as part of a complete programme of care, including manual therapy and exercise rehabilitation. Hence rather than a brand new revolution, IDD Therapy treatment is a true paradigm shift in non-invasive spinal care. We hope that in these pages you will get a good understanding of how IDD Therapy can help your patients. There is very limited evidence in the scientific literature to support the effectiveness of non-surgical spinal decompression therapy. This intervention has never been compared to exercise, spinal manipulation, standard medical care or other less expensive conservative treatment options which have an ample body of research demonstrating efficacy. Considering the cost-benefit relationship, many better researched and less expensive treatment options are available to the clinician. This study examined the clinical effects of conducting spinal decompression therapy and general traction therapy, which are non-surgical treatment methods, for patients with intervertebral disc herniation. In conclusion, physical therapists may be required to select an appropriate treatment method considering the condition of a patient, cost, and time. Follow up studies should be conducted on the long-term effects of these therapies, increasing the treatment period and the number of treatments.

In the future, we see the IDD Therapy spinal treatment programme as a key cost-effective resource to tackle both back pain itself and the ever-increasing costs of chronic back pain to society and health care.

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Non-surgical Spinal Decompression an Effective Physiotherapy Modality for Neck and Back Pain

Journal of Novel Physiotherapy And Physical Rehabilitation 4 (3):062-065

Observational study with inclusion of patients who previously failed chiropractic, physical therapy or epidural/ facet injection interventions.

AUTHOR

Lucian Henry, D.C., Sherman College of Chiropractic

METHOD

209 patients
Observational

CONDITIONS

HNP, DDD, sciatica, chronic neck/back including person who failed previous chiropractic care, physical therapy or steroid injections.

CONCLUSION

- Efficacy of non surgical spinal decompression utilizing the IDD Therapy® treatment system demonstrated statistically significant improvements in both cervical and lumbar pain, associated paresthesia and weakness.

96% of lumbar cases showed improvement.

95% or cervical cases showed improvement.

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Keywords: Intervertebral differential dynamics therapy; Low-level laser therapy; Non-surgical spinal decompression; Spinal manipulation; Lumbar disc herniation; Cervical disc herniation; Radiculopathy

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Research Article

Non-surgical Spinal Decompression an Effective Physiotherapy Modality for Neck and Back Pain

Abstract

Background: Non-surgical spinal decompression is a novel physiotherapy that improves on conventional traction by adding computer technology and it is commonly used along with other physiotherapy modalities. Indications include bulging or herniated discs, degenerative disc disease, facet syndrome, sciatica, neck pain and lower back pain.

The purpose of this practice-based observational study was to investigate the effectiveness of decompression for patients with radiculopathy or chronic spinal pain that failed to improve with conventional treatments. Patients were treated with 6 to 8 weeks of non-surgical spinal decompression therapy, including low-level laser therapy, superficial cold, home exercise and spinal manipulation if indicated. Starting and ending pain levels on a numerical pain scale were compared using a paired t-test to determine statistical significance.

Main findings: A sample of 41 cervical spine cases and 168 lumbar spine cases was analyzed. Ending pain scores for cervical spine cases (mean = 1.8, standard deviation = 1.8) were significantly less compared to the starting pain scores (mean = 6.0, standard deviation = 2.3), with a mean pain reduction of 4.2 ($p < 0.0001$). The average number of treatments was 13. Ending pain scores for lumbar spine cases (mean = 2.3, standard deviation = 2.6) were significantly less compared to the starting pain scores (mean = 6.6, standard deviation = 2.4), with a mean pain reduction of 4.3 ($p < 0.0001$) after an average of 15 visits.

Conclusion: Non-surgical spinal decompression brought statistically significant improvements in cervical and lumbar pain. Associated paresthesia and weakness also frequently improved. Further investigation of non-surgical spinal decompression, including long-term follow up and comparison to surgical decompression is encouraged.

Abbreviations

NSD: Non-surgical spinal decompression; LLLT: Low-level laser therapy; RCT: Randomized Controlled Trial

Introduction

Non-surgical spinal decompression (NSD) is a novel physiotherapy that is an improvement on older traction modalities by adding computer technology. Computerized distraction with alternate high and low tensions, an actuator, fixed tower and variable angle repetitively unloads the spinal discs and facets at a specific segmental level without eliciting muscular contraction. NSD has been shown to lower intradiscal pressure [1]. An increase in disc height following decompression has also been noted with improvement in discogenic pain [2]. Indications include bulging or herniated discs, degenerative disc disease, facet syndrome, sciatica, neck pain and lower back pain. NSD is commonly used along with other physiotherapy modalities. Shealy recommended decompression in conjunction with heat, ice, TENS, and myofascial release [3]. NSD has been taught in chiropractic postgraduate education department at Parker University since 2012, used with other modalities for discogenic neck or back pain [4]. Henry described NSD in case report and proposed multimodal treatment approach for lumbar disc herniation in conjunction with spinal manipulation, therapeutic exercise and low-level laser therapy (LLLT) [5].

Choi et al. compared NSD with traction for chronic pain associated with lumbar disc herniation, finding both effective, with statistically significant improvements in pain (measured

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by visual analog scale), disability (measured by Oswestry) and straight leg raise (measured by goniometer) [6].

Kang et al. compared NSD and exercise with conventional traction and exercise in a randomized controlled trial, finding NSD more effective, with a significant reduction in disc herniation compared to control [7].

Demirel and colleagues used NSD with electrotherapy, deep friction massage and stabilization exercise to treat lumbar disc herniation in a double-blinded randomized controlled trial. Compared to a control group receiving the other modalities without NSD, there was a greater reduction in herniation size with no other significant difference between the groups. The authors suggested NSD as an adjunct to other therapies for lumbar disc herniations [8].

The purpose of the present practice-based observational study was to investigate the effectiveness of decompression for patients with radiculopathy or chronic spinal pain. This study differs from previous studies in that NSD and low-level laser therapy were used on a subset of patients that failed to improve with conventional treatments (i.e. medication, chiropractic, physical therapy, and injections).

It is important to investigate NSD as a non-drug and non-surgical physiotherapy approach because 1) chronic neck and back pain are leading causes of disability, 2) there is an opioid pain medication epidemic in the United States, 3) many patients wish to avoid the risks of surgery or are not good candidates for surgical intervention, and 4) NSD may offer cost savings compared to surgery.

Materials and Methods

Non-surgical spinal decompression was used to treat patients over a 5-year period at a private chiropractic practice. Patients were treated using FDA cleared medical devices (Disc Force™ and / or Accu-Spina® with IDD Therapy® by North American Medical Corporation and ML830 laser®). There was no "off-label" device use. Treatment recommendations were for 20 visits over 6 to 8 weeks in accordance with the manufacturer's protocols. Time frame for patient selection was February 2012 through May, 2017. Inclusion criteria for patients was as follows: bulging, herniated or degenerative discs with radiculopathy, sciatica, and chronic neck or back pain that had failed to improve with previous care. Some patients had been previously treated by the author using chiropractic manipulation, hot or cold packs, electrical stimulation, traction, and therapeutic exercise. Previous care from other providers typically included non-surgical methods (medication, chiropractic, physical therapy, and epidural steroid injections or facet injections). Two percent of patients had prior spine surgery without hardware. Exclusion criteria was as follows: prior spine surgery with hardware, acute fracture, instability, metastasis, infection, spondylolisthesis greater than grade 2, severe osteoporosis, and symptoms of cauda equina syndrome. The 209 participants were 103 males and 106 females, with an average age of 55 years. Patients' written consent was obtained using 1) Authorization for Exam, X-rays, Treatment and Release of Information and 2) Acknowledgment of Receipt of Notice of Privacy Practices, in accordance with HIPAA Privacy Policy and Procedure. The Notice of Privacy Practices stated, "Research/Teaching/Training: We may use your information for the purpose of research, teaching, and training". No personally identifiable protected health information was included in this study.

Decompression was followed by superficial cold and low-level laser therapy (LLLT). LLLT at 830 nm and 90 mW was applied to the involved levels of the spine and associated myofascial trigger points. Most patients also received chiropractic manipulation (unless there was no palpable spinal joint fixation or asymmetry or if the patient preferred no manual treatments). Home exercises to improve flexibility and strength were recommended. For cervical spine cases the exercises consisted of neck stretches, neck isometrics, and axial retraction (chin tuck). For lumbar spine cases, exercises included knee to chest, pelvic tilt, bridge, crunch, prone extension, prone leg raise, side leg raise, quadruped leg raise, and cat / camel. Patients were instructed to do 5 repetitions on each exercise once per day as tolerated.

Patients rated their pain on a standard 10-point numerical pain scale (NPS), with 10 being the worst pain imaginable. Starting and ending pain levels were recorded each visit. The starting pain at the beginning of the treatment plan was compared with the ending pain at the conclusion of the treatment regimen. In the event that the patient discontinued treatment prematurely, the ending pain at the date of the last visit was used. Starting NPS scores were compared to ending NPS scores using the paired t-test (Apache OpenOffice™ Calc). A statistically significant difference was considered to be present if the two-tailed p-value was less than or equal to an alpha level of 0.05.

Results

Forty-one cervical spine cases and 168 lumbar spine cases were analyzed. A majority (95% of cervical cases and 96% of lumbar cases) had improvement. Two cervical cases and three lumbar cases had no change in pain. Zero cervical cases and four lumbar cases had a higher ending pain. Temporary soreness was common following lumbar decompression, which was generally relieved by the subsequent application of cold and LLLT. There were no serious adverse effects.

Average ending pain for cervical spine cases was 1.8, standard deviation (SD) = 1.8, which was significantly less (statistically speaking) compared to the average starting pain score of 6.0 (SD = 2.3), with a mean pain score reduction of 4.2 ($p < 0.0001$; Table 1)[Figure 1]. The average number of treatments was 13.

Average ending pain for lumbar spine cases was 2.3, SD = 2.6, which was significantly less (statistically speaking) compared to the average starting pain level of 6.6, SD = 2.4, with a mean pain reduction of 4.3 ($p < 0.0001$; Table 2)[Figure 2] after an average of 15 visits.

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Table 1: Cervical Spine Statistics. A sample of 41 cervical cases treated with non-surgical spinal decompression had an average pain reduction of 4.2 points on a 10-point numerical pain scale following a mean of 13 visits. The pre-post pain reduction was statistically significant (p<0.0001).

Variable	Obs	Mean	Std Dev
Starting Pain	41	6.0	2.3
Ending Pain	41	1.8	1.8

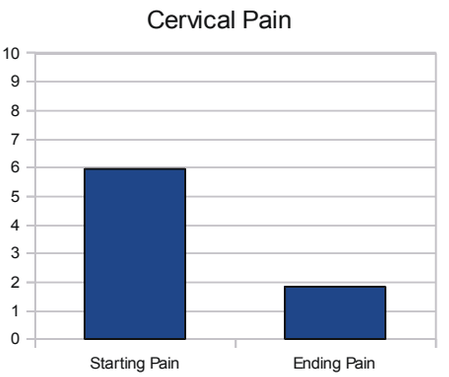

Figure 1: Cervical Pain Before and After Non-surgical Spinal Decompression.

Table 2: Lumbar Spine Statistics. A sample of 168 lumbar cases treated with non-surgical spinal decompression (mean 15 visits) had statistically significant improvement (p<0.0001), with an average pain reduction of 4.3 points on a 10-point numerical pain scale.

Variable	Obs	Mean	Std Dev
Starting Pain	168	6.6	2.4
Ending Pain	168	2.3	2.6

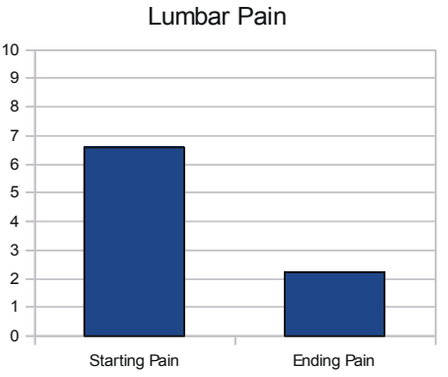

Figure 2: Lumbar Pain Before and After Non-surgical Spinal Decompression.

Discussion

NSD is presently considered investigational (and therefore not covered) under Medicare and most health insurances due to insufficient evidence. This coverage determination is in spite of the fact that NSD devices are FDA cleared. The 2017 American College of Physicians Guidelines found that evidence was insufficient to determine the effectiveness of traction for acute, subacute and chronic low back pain [9]. Conversely, the 2017 National clinical guidelines in the European Spine Journal recommended traction for cervical radiculopathy [10]. Criticism of NSD focused on cost and lack of comparison studies with established conservative treatments, such as manipulation, exercise and standard medical care [11].

In a single-blinded randomized controlled trial Schimmel et al compared two groups of back pain sufferers, both of which were treated with standard graded activity, with one group receiving IDD Therapy® and the other a sham using a negligible amount of distractive force. The authors concluded that NSD was of no additional benefit after finding no significant difference between the two groups [12]. Werners et al performed a RCT that compared interferential to mechanical traction and massage. Both groups experienced progressive back pain relief and improvement in Oswestry scores but there was no significant difference between the groups [13]. Fritz and colleagues suggested that there may be a subset of back pain sufferers who are likely to benefit from traction [14].

In the present study, NSD along with LLLT was associated with pain score improvements that were statistically significant despite these patients having failed with prior interventions. Associated paresthesia also improved and in many cases there was concomitant objective improvement in upper or lower extremity motor upon physical examination. While there was no control group per se, the author would argue that it is difficult to provide a convincing sham treatment for a physical intervention. Moreover, in a sense, the patients acted as their own "controls" when their pre and post intervention scores were compared.

Conclusion

Patients in this observational study experienced relief from their neck and back pain following non-surgical spinal decompression used with other modalities. Further investigation of non-surgical spinal decompression, including before and after MRI (which was not possible in the present study due to cost), long-term follow up, and comparison to surgical decompression is encouraged.

Acknowledgment

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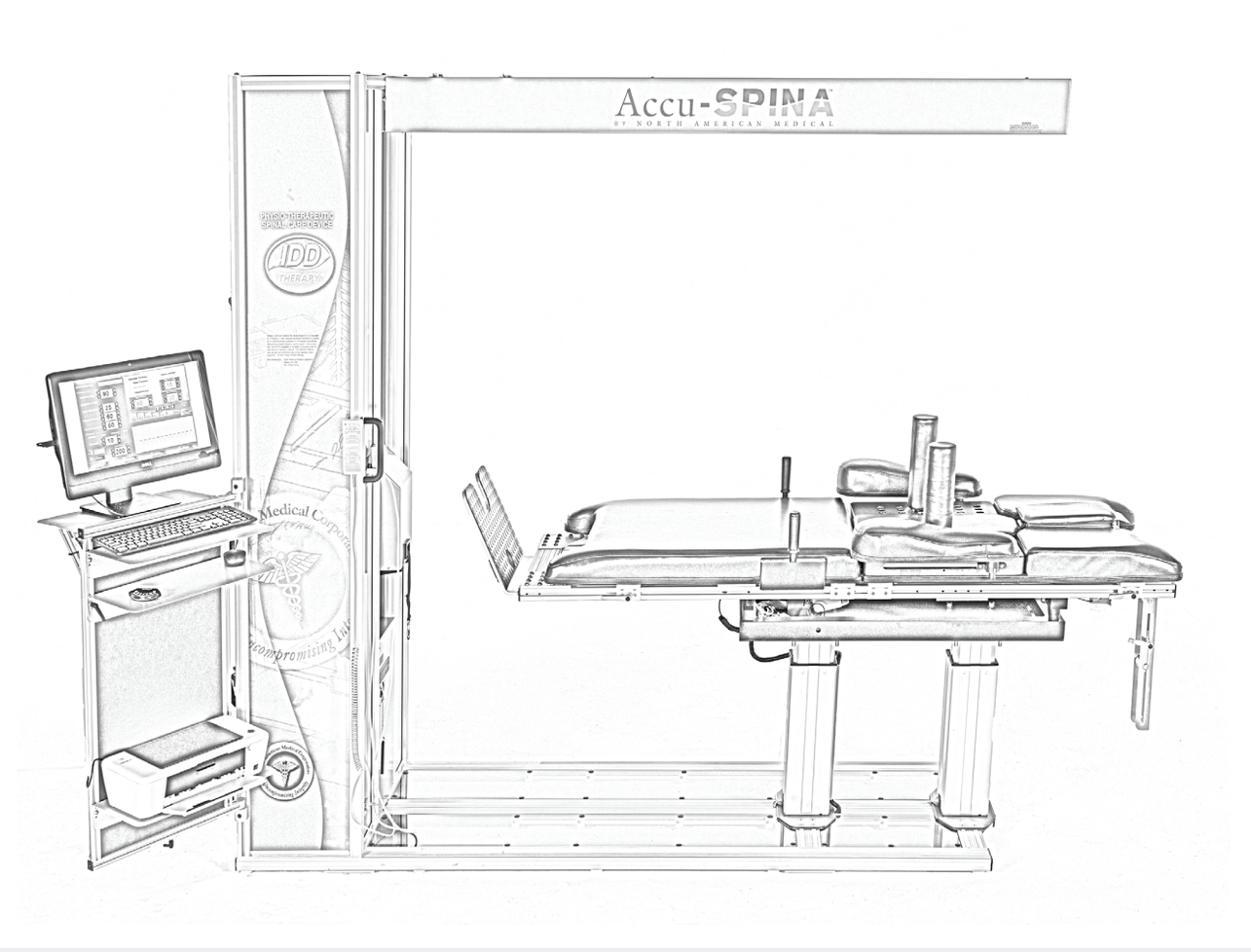

Citation: Henry L (2017) Non-surgical Spinal Decompression an Effective Physiotherapy Modality for Neck and Back Pain. J Nov Physiother Phys Rehabil 4(3): 062-065. DOI: http://doi.org/10.17352/2455-5487.000049

Effect of Spinal Decompression on the Lumbar Muscle Activity and Disk Height in Patients with Herniated Intervertebral Disk

Journal of Physical Therapy Science (11):3125-3130

31 total participants received trunk stabilization exercise program with decompression therapy or with traction therapy; disc height measures taken before and after the intervention using MRI.

AUTHOR

Jeong-Il Kang, et al
Corresponding author, Hyun Choi, Dept of Physical Therapy, Mokpo Mirae Hospital, Republic of Korea

METHOD

Randomized, comparative with control group receiving traditional traction versus decompression.

CONDITIONS

Herniated lumbar disc

CONCLUSION

Decompression therapy was demonstrated to be more effective clinically than conventional traction for disc disease based on disc height and disc herniation index.

Journal of Physical Therapy Science

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Effect of spinal decompression on the lumbar muscle activity and disk height in patients with herniated intervertebral disk

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Abstract

[Purpose] This study was conducted to clarify the difference in therapeutic effects between traction and decompression therapies, and their clinical therapeutic significance. [Subjects and Methods] The subjects were 31 patients aged 35 to 50 years who had unilateral or bilateral lumbar and radicular leg pain. An intervention program was implemented in 31 patients with lumbar herniated intervertebral disks. For the experimental group, 15 subjects were randomly selected to receive decompression therapy and trunk stabilization exercise. For the control group, 16 subjects were randomly selected to receive traction therapy and trunk stabilization exercise. [Results] Activities of the rectus abdominis, transverse abdominis, and external oblique muscles increased significantly in both groups. However, the activity of the erector spine muscle decreased, which was the only significant change in muscle activity among those of the other muscles in both groups. The disk herniation index in the experimental group decreased significantly in comparison with that in the control group, and the difference in the change in disk herniation index between the groups was significant. [Conclusion] Decompression therapy was demonstrated to be more effective clinically than conventional traction therapy as an intervention method for disk disease.

Keywords: Decompression therapy, Herniated intervertebral disk, MRI

INTRODUCTION

Human beings walk upright and maintain their postures with a narrow base of support and with the center of gravity of the upper trunk. Even if muscle tension slightly loosens, low back pain occurs because of stress from the mechanical posture of the muscle involved[1)]. This causative factor of low back pain can lead to problems in sense and timing of muscle contraction awareness, sense of heaviness, acting force, and acting load force[2)]. Of the cases of low back pain syndrome, 80% are related to the lumbar disk; and herniation of disk material is known as a secondary inflammatory response to stimulation of the dorsal root ganglion and nerve root is known as the cause of low back

An Evaluative Study of Patient-Based Outcomes Due to IntraDiscNutrosis® Treatment

Retrospective Outcomes analysis of patient treatment outcomes performed on the FDA cleared Accu-Spina device.

AUTHOR

Dr. Joseph Mannella D.C, Logan University, Founder of The Disc Institute
P. Thomlinson, PhD, University of Southern Mississippi

METHOD

External third party chart review.

CONDITIONS

Lumbar and cervical pain.

CONCLUSION

- Third party attestation clinically significant improvement in up to 98% of patients treated.
- 93% reported significant increases in activities of daily living (bathing, dressing, grooming, working and leisure) resulting from treatment

An Evaluative Study of Patient-Based Outcomes Due to IntraDiscNutrosis Treatment

FDA Device / Drug Status used for this research: Accu-SPINA ® System

Randomized, independent medical study conducted by research scientist
Paul Thomlinson, Ph.D. and Dr. Joe Mannella of The Disc Institute.

INTRODUCTION

The treatment under evaluation in this study is called IntraDiscNutrosis®, a non-surgical therapeutic intervention for patients with bulging, herniated, degenerative discs and other disco genic disorders. These conditions result in substantial back and/or neck pain, radiculopathies and extremity pain and/or numbness, along with associated disabilities and functional limitations. What distinguishes this treatment from other forms of treatment (e.g., physical therapy, surgery, chiropractic, epidural injections, pain management, exercise, stretching, yoga, Pilates, weight loss, etc.) is that (a) it noninvasively and specifically treats the disc directly, and the associated pain indirectly; (b) it treats the problem of why the disc is dying, instead of treating the conditions or symptoms that manifest from a dying disc; (c) it recreates the missing physiology of the disc, so that the established and innate physiological mechanisms are restored and bring back the natural self-repair process to the disc; and (d) it promotes and honors the natural healing process of the disc while all other forms of treatment ignore this in favor of only altering pain perception, Unlike many forms of treatment for these conditions, IntraDiscNutrosis® is not simply a palliative approach to care and has no iatrogenic risks.

BACKGROUND ON PATHOPHYSIOLOGY OF DISC DEGENERATION

Intervertebral disc (IVD) degeneration and associated lesions are strongly associated with back and extremity pain, affect a large proportion of the population and are a burden for the affected patients and because of high health-care and societal costs (Khan et al., 2017; Wenig, Schmidt, Kohlmann, & Schweikert, 2009). These disorders represent a complex problem with multiple contributing factors, and despite a significant increase in spinal research and number of studies, the pathologic pathway is not fully understood. Although genetic predisposition appears significant (Adams & Dolan, 2012), degenerative pathways are also influenced by factors such as mechanical loading (Fahy, Alini, & Stoddart, 2018; Neidlinger-Wilke et al., 2012) and changes and alterations to the physiochemical environment(Urban & Winlove, 2007) of the disc cells. Of the environmental factors thought to influence degenerative changes in the disc, decreased nutrition is widely thought to be a key contributor (Neidlinger-Wilke & Wilke, 2010).

Normal healthy discs are avascular and nutrient supply and removal of wastes occurs via diffusion through the blood vessels at the cartilaginous end plate. Disc cells require glucose and produce lactic acid at a high rate (Bibby, Jones, Ripley, & Urban, 2005; Maroudas, Stockwell, Nachemson, & Urban, 1975). It is thought that a reduction in supply of required nutrients and water or the failure to remove lactic acid is a major reason for disc degeneration. Disc cells are very sensitive to changes and alterations of nutritional components and accumulation of metabolites.

In vitro experiments have demonstrated that disc cells need to maintain critical concentrations of glucose, a suitable pH and oxygen supply to stay. Disc cells are very sensitive to changes and alterations of nutritional components and accumulation of metabolites. In vitro experiments have demonstrated that disc cells need to maintain critical concentrations of glucose, a suitable pH and oxygen supply to stay viable and metabolically active (Grunhagen, Wilde, Soukane, Shirazi-Adl, & Urban, 2006; Urban, Smith, & Fairbank, 2004) It has been demonstrated in the literature

that disc cells die if glucose levels fall below around 0.5mM. Also, disc cells are very sensitive to fall in pH arising from accumulation of lactic acid. This accumulation of lactic acid inhibits the production of proteoglycans and increases the activation of matrix-degrading enzymes. All of the above mentioned physiology contributes to degenerative changes to the IVD (Raj, 2008). Some well-designed in vivo studies have examined the effects of controlled dynamic distraction and the effects of mechanical loading on diffusion of solutes in the recent literature. These observations may be related to the IntraDiscNutrosis methodology since this treatment is designed to replicate the normal pump mechanism of the targeted IVD. In the Kroeber study, they were able to induce disc degeneration by axial dynamic loading, presumably due to a complex path mechanism initiated through a change in cell shape, or an adverse biochemical environment produced by water loss. They demonstrated a slowing and declining diffusion of substances through the IVD and a demonstrated a slowing and declining diffusion of substances through the IVD and a deprivation of oxygen that compromised cell viability. As cell density decreased, consequently, synthesis of matrix macromolecules is adversely affected. The accumulated breakdown of matrix materials in turn impairs diffusion. A vicious circle is created, with progressive deterioration in oxygen, nutrient, and waste transport, leading to further cell death and depletion of the matrix (Rinkler et al., 2010).

In the same study the unloaded IVDs demonstrated through histological studies a physiologic organization of the nucleus, annulus and cartilage endplate after distraction. The authors stated that the discs showed signs of tissue regeneration. With increaser duration of distraction, the changes became more pronounced with the disappearance clefts or fissures in the annulus fibrosis and less herniation of disc materials or osteophyte formation (Rinkler et al., 2010). The developers of IntraDiscNutrosis®, the treatment under review in this evaluative Study, believe that similar physiological and biochemical mechanisms may be involved in vivo with proper application of approach. This is logical in that one major clinical goal of IntraDiscNutrosis" is the specific targeting of the biomechanical pump mechanism movement restoration of the IVD. The researchers involved in the present study plan to expand research in this area and are clearly encouraged with the clinical results and outcomes detailed later in this report.

BACKGROUND ON THE HEALTH ECONOMICS OF DISC DEGENERATION

A growing number of hospitals and health systems around the country are rethinking how they provide spine care; given the mounting research evidence that too many Americans are undergoing unnecessary spinal procedures and experiencing poor outcomes. The steep jump in spine surgeries in the late 1990s and 2010s has prompted many health insurers to tighten coverage policies for particular indications and procedures, particularly spinal fusion for degenerative disc disease in the lower back. With recent studies (e.g., in The Journal of Bone and Joint Surgery) suggesting that the total cost of low back pain to the United States totaled $33 to $66 billion ($39 and $78 billion when expressed in 2014 dollars)(McCarthy, Hostin, O'Brien, Saigal, & Ames, 2013), it is clearly advisable on multiple levels for there to be an honest re-evaluation on policies and standards of care in this particular segment of care. About 87% of spinal procedures in 2013 were fusion-based, according to the research firm Global Data. There were more than 465,000 fusion operations in the U.S. in 2011, compared with 252,400 in 2001, according to the Agency for Healthcare Research and Quality. The estimated cost of spinal fusion procedures was more than $12.8 billion in 2011, according to AHRQ. Hospital costs alone for this procedure average $27,568. Total costs can hit well over six figures for major spinal fusion procedures.

CONCLUDING REMARKS

These sobering realities make it all the more crucial that effective treatments be developed and implemented in collaboration with hospitals, health systems and health insurers—that innovators develop statistical models in which further research and analysis can be carried out to demonstrate the potential mitigation of high cost, high risk spinal procedures in favor of lower cost, lower risk non-surgical procedures within a fee-for-service and/or other payment model.

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5. *[...]*

Notarized statment by Dr. Paul Thomlinson...

Statement on Outcomes Evaluation for THE DISC INSTITUTE®

September 16, 2015

Background: A study has been completed by an external third-party Ph.D. researcher specializing in health care evaluation. This study included sophisticated random selection of a large and statistically valid sample of patients who consented to and completed IntraDiscNutrosis® treatment at THE DISC INSTITUTE®. Results were based on analyses of de-identified data from that representative sample. Measures of treatment success included percentage of improvement in overall functioning, and increases in activities of daily living. The latter, known as ADL, refers to patients' capacity for self-care (e.g., bathing, dressing, grooming, working, homemaking, and leisure)—this measure is used as a very practical indication of ability/disability in many disorders, including back & neck problems.

Results: An analysis of typical patients receiving care at the Institute revealed that 98% reported clinically significant improvement. Among all those patients who showed clinically significant change, the most common range of improvement was between 75% to 90%. Also, among this group, 93% reported significant increases in ADLs resulting from treatment. These statements are accurate, based on a statistical analysis of data collected during the course of standard IntraDiscNutrosis® treatment.

[redacted], Ph.D.

STATE OF MISSOURI

COUNTY OF GREENE

On this 16th day of September in the year 2015, before me, the undersigned notary public, personally appeared Paul Thomlinson, known to me to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged that he/she/they executed the same for the purposes therein contained.

In witness whereof, I hereunto set my hand and official seal.

Notary Public

Print Name: Timothy Feiel

TIMOTHY FEIEL
Notary Public - Notary Seal
State of Missouri
Greene County
My Commission Expires 03-15-2019
Commission # 15773329

My commission expires: 3-15-2019

Burrell

Conservative Treatment Approaches In Low Back Pain

IDD Therapy Observational Study

Prospective Outcome: Patients with prior failed physiotherapy, failed chiropractic care, failed injection or failed nerve ablation trialed on IDD Therapy treatment instead.

AUTHOR

Lead author Dan Smith BSc Phys MCSP, University of Liverpool (Hons)

METHOD

MRI confirmation; sample size 17. All subjects had to have failed prior treatments.

CONDITIONS

HNP/ bulging disc, Degenerative Disc Disease, sciatica, Foraminal Stenosis.

CONCLUSION

- Of patients who completed treatment, 85.71% achieved clinically significant improvement receiving only IDD Therapy treatment intervention after all after having failed conservations interventions
- IDD Therapy appears to be clinically effective to lower pain and decrease disability for low back pain sufferers who do not respond to other non-surgical treatment approaches

Conservative Treatment Approaches in Low Back Pain

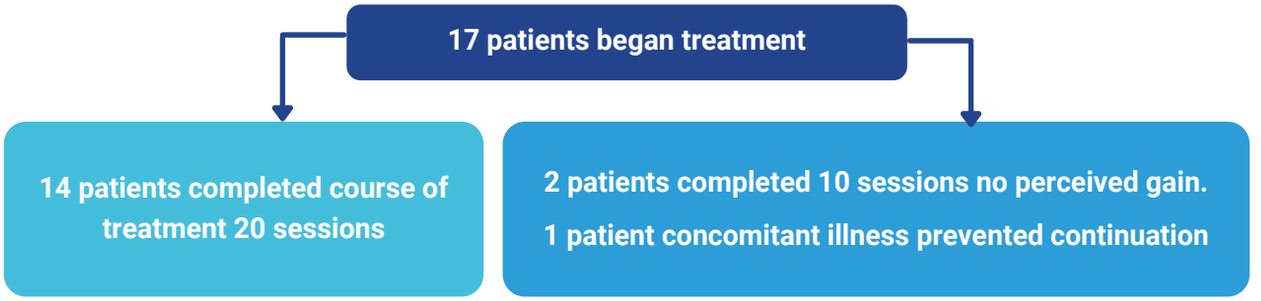
IDD observational study, outcomes for pain and disability index measures

By Dan Smith, BSc (Hons) Phys MCSP, Member of the Chartered Society of Physiotherapy

INTRODUCTION

A prospective outcome study was conducted on patients with chronic low back pain due to degenerative disc disease, herniated nucleus pulposus and facet arthropathy. Between March 2003 and January of 2004, ten physicians in private practices across the United States, with a high volume of patients with spinal disorders, participated in this study. Specialties included Inter Medicine/ Rheumatology, Neurology, Orthopaedic, and Pain Management. Prior to entering the study, the patients were evaluated by the physician and diagnosed with a painful lumbar degenerative condition based on history and physical and appropriate imaging studies. Prior to each treatment, the patients completed an Oswestry Disability Index (ODI) questioninaire1. The ODI scores range from 0-50. A change of more than 4 points is considered clinically meaningful 4. Each patient was treated for 25 min with decompression

INTENTION TO TREAT FLOW DIAGRAM



Inclusion criteria

- Prior failed treatment from osteopathy, physiotherapy, chiropractor for low back pain due to disc or facet dysfunction
- Prior failed facet joint injections or failed nerve ablation for low back pain due to disc or facet dysfunction
- MRI scan to indicate, either herniated or prolapsed disc bulge, degenerative disc disease, sciatica, foraminal stenosis with or without radicular pain.

Exclusion criteria

- Osteoporosis (T score -2.5 to -2.8 or greater)
- Unresolved compression fractures on the spine
- Spondylolithesis
- Spondyloysis
- Open growth plates
- Severe canal stenosis
- Surgical hard ware in spine
- Severe scoliosis
- Abdominal aortic aneurysm
- Vertebral fusions
- Pacemaker
- Pregnancy
- Genetically unstable or defects of the spine

DEMOGRAPHIC PROFILE OF SUBJECTS

Sex	**12 male**	**5 female**
Age range	**34-71 years male**	**40-68 years female**

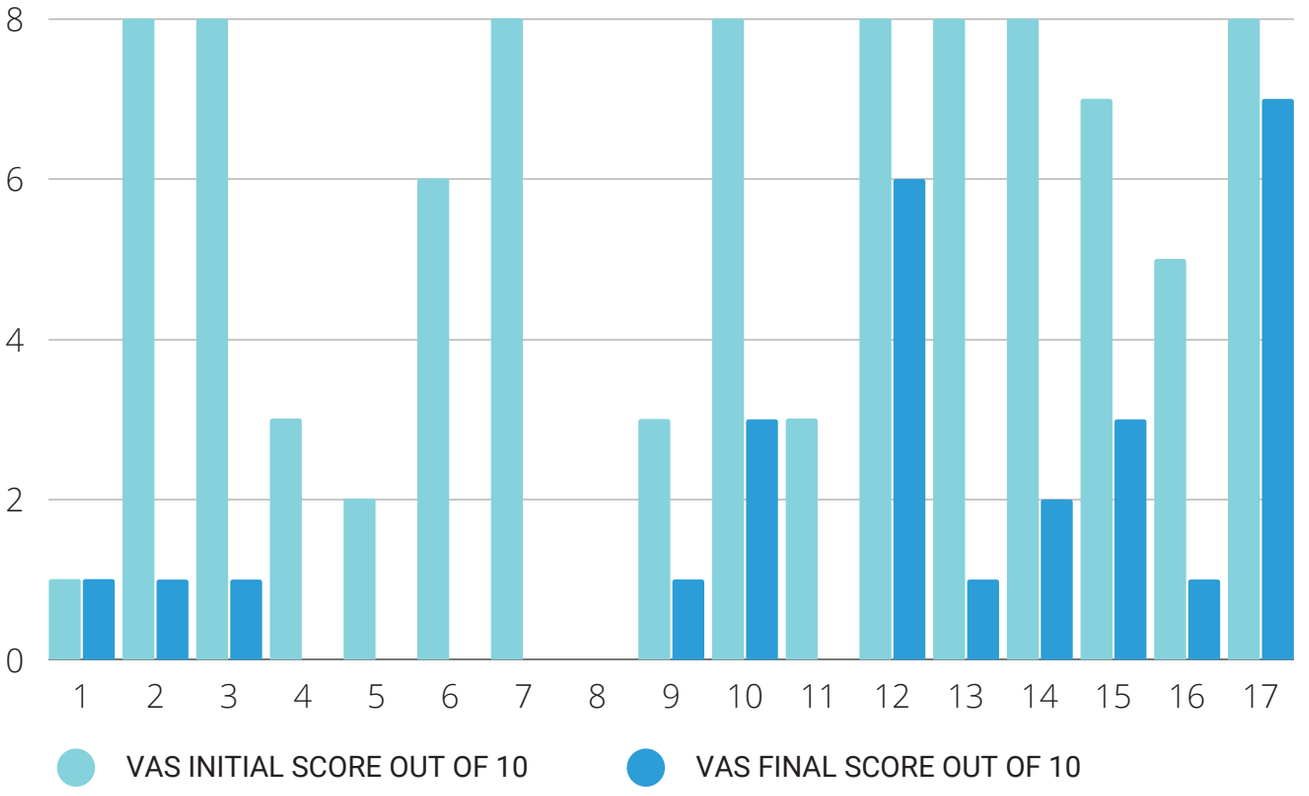
RESULTS

Patient number	Oswestry DI score before treatment	Oswestry DI score post treatment	Change (10% change is clinically significant)	VAS before treatment	VAS after treatment
1	8	16	+8	1	1
2	32	22	-10	8	1
3	66	32	-34	8	1
4	44	12	-32	3	0
5	44	28	-16	2	0
6	18	4	-14	6	0
7	64	40	-24	8	0
8	12	26	+14	0	0
9	16	16	-10	3	1
10	60	34	-26	8	3
11	6	2	-4	3	0
12	68	68	0	8	6
13	20	10	-10	8	1
14	26	8	-18	8	2
15	30	13	-17	7	3
16	26	14	-12	5	1
17	35	34	-1	8	7

DATA ANALYSIS

- Pain score
- Median score before treatment was 6/10 with lower quartile 3/10 and upper quartile 8/10
- Median pain score post treatment was 1/10 with lower quartile 0/10 and upper quartile 2/10
- Standard deviation was ±2.85 before treatment and ±2.09 after treatment
- Student t-test (96% CI) p=0.0000054 (statistically significant)

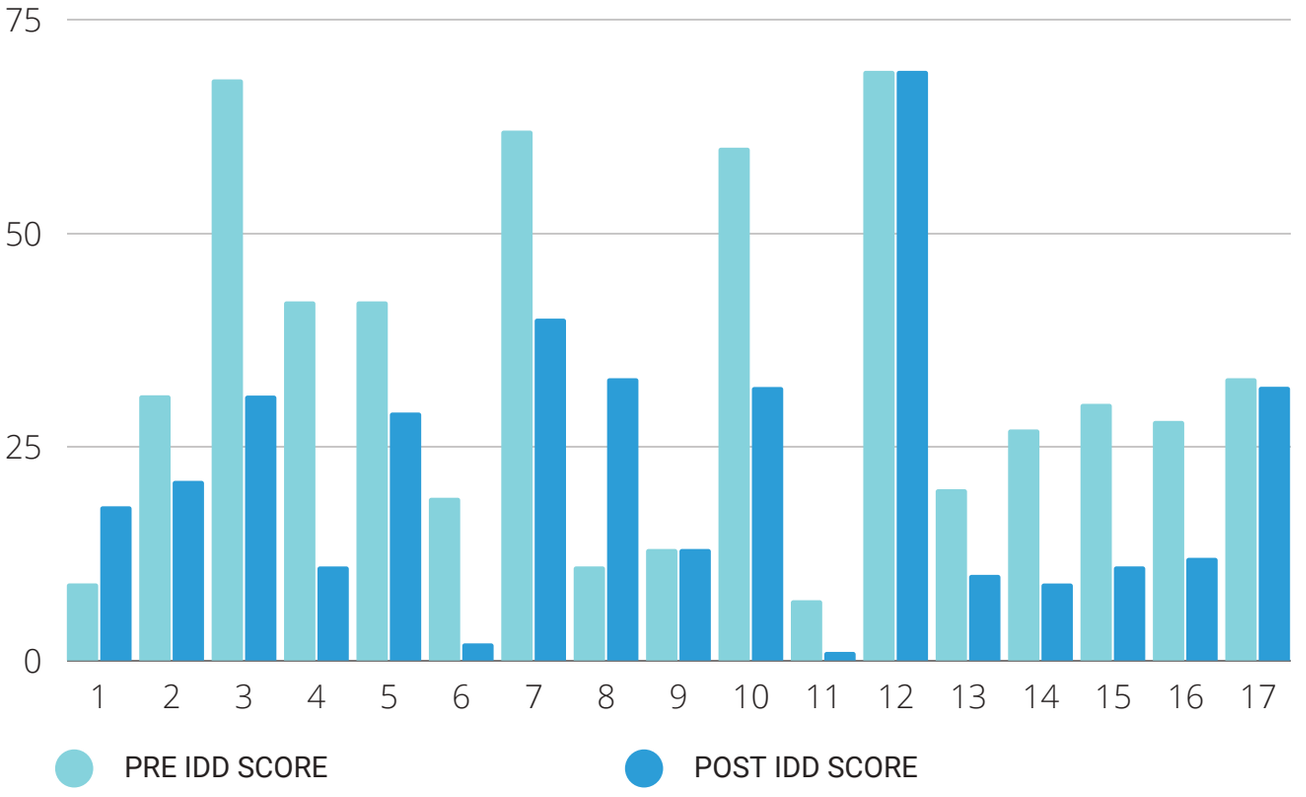
GRAPH TO SHOW INDIVIDUAL PRE AND POST TREATMENT PAIN SCORES



OSWESTRY DISABILITY INDEX SCORES

Number patients with a greater than 10% change	**12**
Percentage of patients with a clinically significant change	**70.59**
Patients who completed treatment with clinically significant change	**85.71**

GRAPH TO SHOW INDIVIDUAL PRE AND POST OSWESTRY DI SCORES



CONCLUSION

IDD Therapy appears to be a clinically effective treatment to lower pain and decrease disability due to low back pain for those patients who failed physiotherapy, osteopathy or chiropractor treatments and steroid and epidural injections.

Evolving Conservative Spinal Treatment Modalities

Spinal Surgery News

Clinical practice review of IDD Therapy treatment case study on 26 year old ex-professional wrestler.

AUTHOR

John Wood, P.T., Member of the Chartered Society of Physiotherapy
Faculty Sheffield Hallam University

METHOD

Case study, with 20 session protocol breakdown.

CONDITIONS

Severe disc bulge, DDD, Lumbar pain, severe debilitation in waking and ADL's.

CONCLUSION

- Complete resolution of pain from session 12 on.
- Re-organization of muscle tone and connective tissue by using IDD Therapy led to improved spinal mobility.

Issue 34 | Autumn 2014

Spinal Surgery News

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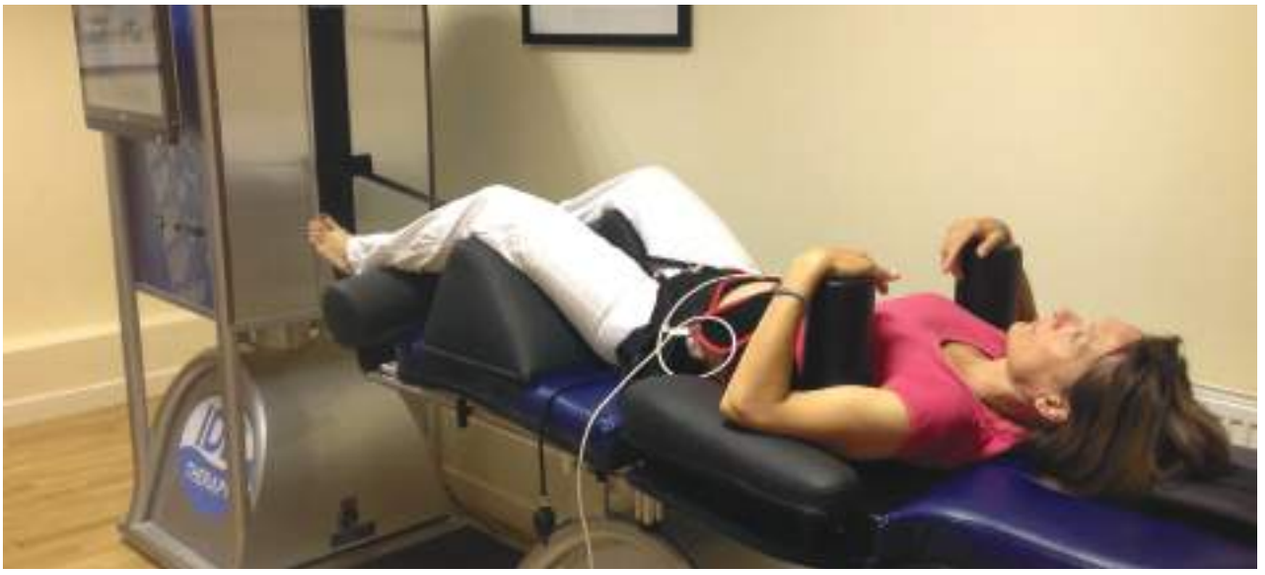
IDD Therapy: Evolving conservative spinal treatment modalities

John Wood, MCSP looks at the physiological effects of IDD Therapy spinal decompression on connective tissues



As part of conservative care, IDD Therapy® spinal decompression is emerging as an invaluable tool for physiotherapists treating chronic herniated disc conditions and related symptoms such as radicular pain and radiculopathy.

Developed to address the failings of traditional traction, IDD Therapy combines mechanical decompression with exercise to form a programme of spinal rehabilitation which significantly improves pain and function in lumbar and cervical patients.

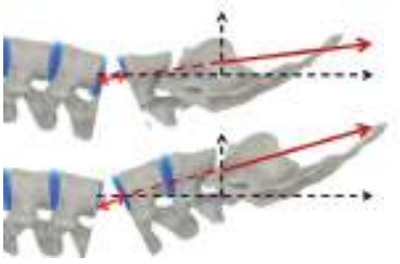
Applying computer-controlled pulling forces at precisely measured angles, clinicians are able to distract and mobilise and thus decompress targeted spinal segments with greater precision and adequate force than previously possible with traction.

With referrals from GPs, pain consultants and surgeons, UK clinicians report 70–90% success rates in selected patients – many of whom have exhausted manual and invasive procedures. This article examines some of the physiological mechanisms which may contribute to the clinical outcomes in IDD Therapy patients.

Background

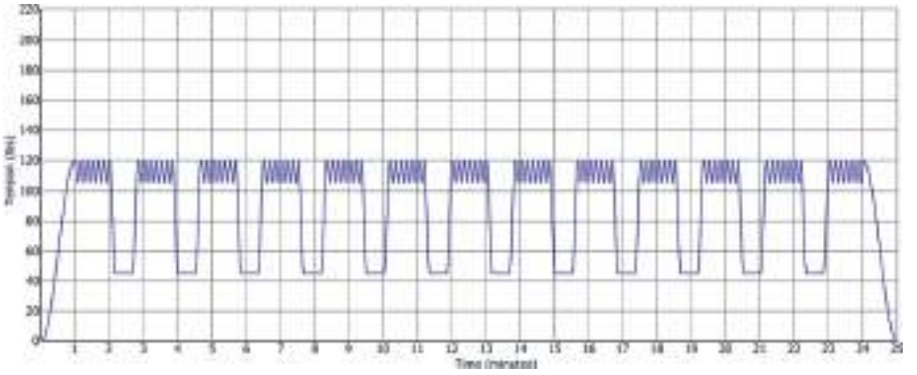
The origins of IDD Therapy date back to the late 1990s. An early study by Ramos measuring the effects of vertebral axial decompression recorded a significant reduction in intradiscal pressure – to between -100 and -160mm Hg.[1]

From these promising findings, US neurosurgeon Norman Shealy applied the principles of vector forces to treated isolated spinal segments. By altering the angle of application of controlled distraction forces, Shealy was able to demonstrate the opening of targeted spinal segments, by 5mm–7mm in lumbar patients.



In 1997, Shealy and Borgmeyer's randomised controlled trial comparing traditional traction with decompression techniques in patients with lumbosacral pain – many with sciatic radiation – showed a good to excellent improvement in 86% of cases.[2] A follow-up study revealed continued pain reduction in IDD

Longitudinal Joint Mobilisation



Therapy patients one year after treatment.[3]

With modifications along the way, the team finally produced an FDA-cleared class II decompression machine which addressed the failings of traction quite systematically. Applying the new technology to manual therapy principles, the IDD Therapy machines now incorporate an oscillation feature, capable of mobilising the joint at the point of maximum distraction in a longitudinal plain – which, given the strength of the spine, is difficult to do with the hands alone.

Moreover, a gently-progressing pulling force (sinusoidal waveform) makes the treatment more comfortable at higher tensions: a gentle stretch applied to the Golgi Tendon Organ causes it to fire and inhibit tension in the muscle, allowing the sarcomere to remain relaxed and lengthened throughout the slow and consistent stretch without going into spasm. Thus patients can enjoy the necessary higher pulling forces for longer, whilst remaining completely relaxed.

And so, a set of protocols for the advanced form of spinal decompression known as Intervertebral Differential Dynamics (IDD) Therapy was developed. In 2005, neurosurgeon Dennis McClure studied 415 IDD patients over a two-year period: 79% of lumbar patients showed a 50% or more decrease in pain and results showed a 92% success in 129 lumbar-surgery candidates.[4]

The IDD Therapy programme

IDD Therapy is a structured programme of regular treatments spread over a number of weeks, allowing time for the body to adapt to treatment whilst progressively improving spine function.

Sessions begin by 'warming up' the affected area with infrared heat, allowing for a deeper and more comfortable distraction. Secured to the SPINA machine by ergonomic pelvic and thoracic harnesses, patients lie supine on the treatment bed with knees flexed to straighten the lordotic curve.

Once the angles and forces are determined, the computer-controlled cyclic distraction begins. During the cycle the lumbar spine and soft tissues are exposed to forces equal to and above half the patient's body weight.

Importantly, the soft tissues are under constant cyclic tension for 25 minutes and there are 13 minutes when the joint is fully distracted – which clinicians cannot achieve manually.

Pulling forces are gradually increased over the course of treatments as the body becomes conditioned to the treatment. All aspects of treatment are recorded by the SPINA machine using the in-built Oswestry Disability Index and Visual Analogue Scale.

Treatment effects

Such distraction and mobilisation exerts a powerful effect on the body with patients reporting progressively decreased pain levels, greater mobility and improved sleep patterns.

Decompressing an injured disc can lead to symptomatic relief relatively quickly if pressure differentials cause a bulging nucleus pulposus to retract, taking pressure off an impinged nerve.

Decompression is also pertinent given the sometimes indistinct origins of radicular pain: the flow of nutrients and oxygen assist in the dilution of any inflammatory toxins while pressure is lifted from neural structures.[5]

Improved mobility of joints prone to spasm can improve nutrition delivery and release pressure on facets. The effects on connective tissues are especially interesting as we consider improved mobility in chronic disc patients.

Effects on connective tissues

Immediately after treatment, patients tend to feel 'stretched' and somewhat delicate for a period of minutes. In my experience, this post-decompression state is central to how and why IDD Therapy works.

Essentially, it involves a complex reorganisation of muscle tone and the connective tissue tone/elasticity. When connective tissue is stretched, this stimulates an active contraction of the fibroblasts, which are cell-residing within the tissues.

Rather counter-intuitively, the contracted cells become sheet-like (rather than bulging) causing expansion of the tissues: the surrounding tissues are firm when the muscle is working minimally but when muscle activity increases and the muscle expands to increase its blood supply, the tissues expand to accommodate its increased size.

That is one half of the theory: the other is that the stretch will affect the stretch receptors within the tendons.

Post-treatment when the stretch is removed, the muscle tone drops: the muscles respond as if their agonist has relaxed.

Decreased tone leads to instability and unguarded movements which produce a strain/stretch on the tendon, causing the muscle tone to convert to more normal levels.

Immediately following treatment, patients should not be exposed to sudden movement: the IDD Therapy machines incorporate a bed tilt so patients disembark with ease and retain posture. Rest time is vital to reset the system and cold therapy assists in preventing any temporary soreness.

The two components are integral to the success of IDD Therapy since the injured area is splinted by muscle spasm – like an arm immobilised in plaster: the elbow is stiff and the muscles wasted and of low tone. In the spine we see the muscles outside of the spasm becoming wasted (observed as increased fat content on MRI) and the damaged segment becoming stiff due to contracture of the soft tissues.

IDD Therapy mobilises the segment, stretching the connective tissues; the increased segmental mobility then stimulates the wasted muscles to become active again by stimulation of the stretch/strain reflex. It is at this stage that we progressively introduce exercise to strengthen these muscles which are being used again.

During the programme, we observe that patients tolerate higher distraction forces. As patients progress, they often feel that distraction forces have decreased, suggesting that there has been some adaptation of the soft tissues.

Case Study

26 year old male, industrial engineer and ex–professional wrestler presented with Degenerative Disc Disease with disc bulging to left L5 intervertebral foramen. Lumbar pain and radiation into both legs causing severe debilitation with regard to walking, sleeping and ADLs.

- **Onset of symptoms:** 2004 during professional wrestling at a high level and extensive weight training. Gradually worsening 2012; worsened significantly autumn 2013.
- **Previous treatments:** Physiotherapy, chiropractic, massage.
- **Medication:** Cocodamol.
- **Results:** After 20 sessions of IDD Therapy and a phased rehabilitative exercise programme, patient experienced significant improvement in symptoms, including complete resolution of radicular symptoms (both legs) and significant reduction in back pain. After six months, patient remains asymptomatic.

Treatment summary

It may be noted that the patient continued to have treatment even after the pain had completely resolved from session 12 onwards. The reason for this is that the pain is actually quite a poor guide to the health of the disc and surrounding tissues. It can be seen that we continued to increase the treatment parameters throughout the 20-session protocol, with the aim to maximise the beneficial effects on the disc. In such a way

No	Date	Angle°	High Force	½ body weight +/-	Oscil'n	VAS	Observations
1	06/01/14	10	90 lbs	-20lbs	5lbs	5	Considerable pain, with symptoms into both legs. Soreness after therapy for 1–2 hours.
2	08/01/14	10	90lbs	-20lbs	5ibs	5	
3	10/01/14	10	95lbs	-15lbs	5lbs	1	
4	13/01/14	10	95lbs	-15lbs	5lbs	2	
5	20/01/14	10	85lbs	-25lbs	5lbs	1	Very sore after last treatment, no pain with lowered tension during treatment session.
6	22/01/14	10	85lbs	-25lbs	5lbs	3	Treatment becoming much more tolerable.
7	24/01/14	10	85lbs	-25lbs	5lbs	2	
8	27/01/14	10	95lbs	-15lbs	5lbs	1	
9	29/01/14	10	100lbs	-10lbs	5lbs	1	Feeling much better post-treatment.
10	03/02/14	10	95lbs	-15lbs	5lbs	1	Very sore after treatment then felt great. Able to go swimming.
11	05/02/14	10	100lbs	-10lbs	5lbs	0	Back much better, still some pain at end of range forward flexion.
12	07/02/14	10	100lbs	-10lbs	5lbs	0	
13	10/02/14	10	105lbs	-5lbs	5lbs	0	Progressed exercise programme into stage 4, incorporating twisting movements.
14	12/02/14	10	110lbs	0lbs	10lbs	0	
15	14/02/14	10	120lbs	+10lbs	10lbs	0	
16	17/02/14	10	125lbs	+15lbs	10lbs	0	
17	19/02/14	10	130lbs	+20lbs	10lbs	0	Coping well – able to progress intensity and duration of each exercise.
18	21/02/14	10	130lbs	+20lbs	10lbs	0	
19	24/02/14	10	130lbs	+20lbs	10lbs	0	
20	28/02/14	10	135lbs	+25lbs	10lbs	0	Patient asymptomatic and back to high-functioning level of activity.

we build resilience within the tissues, which can help prevent recurrence of symptoms, therefore maximising the long-term benefit of IDD Therapy.

Conclusion

Observing the clinical outcomes of my patients, the available research and the experience of other clinicians, IDD Therapy provides an assured non-invasive approach to relieving pain and returning function to those patients who have not responded to manual therapy and who wish to exhaust non-invasive options.

From a physiotherapy viewpoint, the complex reorganisation of muscle tone and connective tissue brought about by IDD Therapy leading to improved spinal mobility, appears to be a key driver in the clinical outcomes of this evolving treatment modality. ⬟

John Wood is the Clinical Director of Sheffield Physiotherapy. With over 20 years' experience as a physiotherapist, he is a recognised tutor for the AACP and has taught on postgraduate courses in manipulative therapy at Sheffield Hallam University.

John specialises in chronic spinal problems. He uses IDD Therapy spinal decompression to treat his chronic disc patients.

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Clinical Feature: IDD Therapy

Osteopathy Today British Osteopathic Assoc. Vol. 18.3

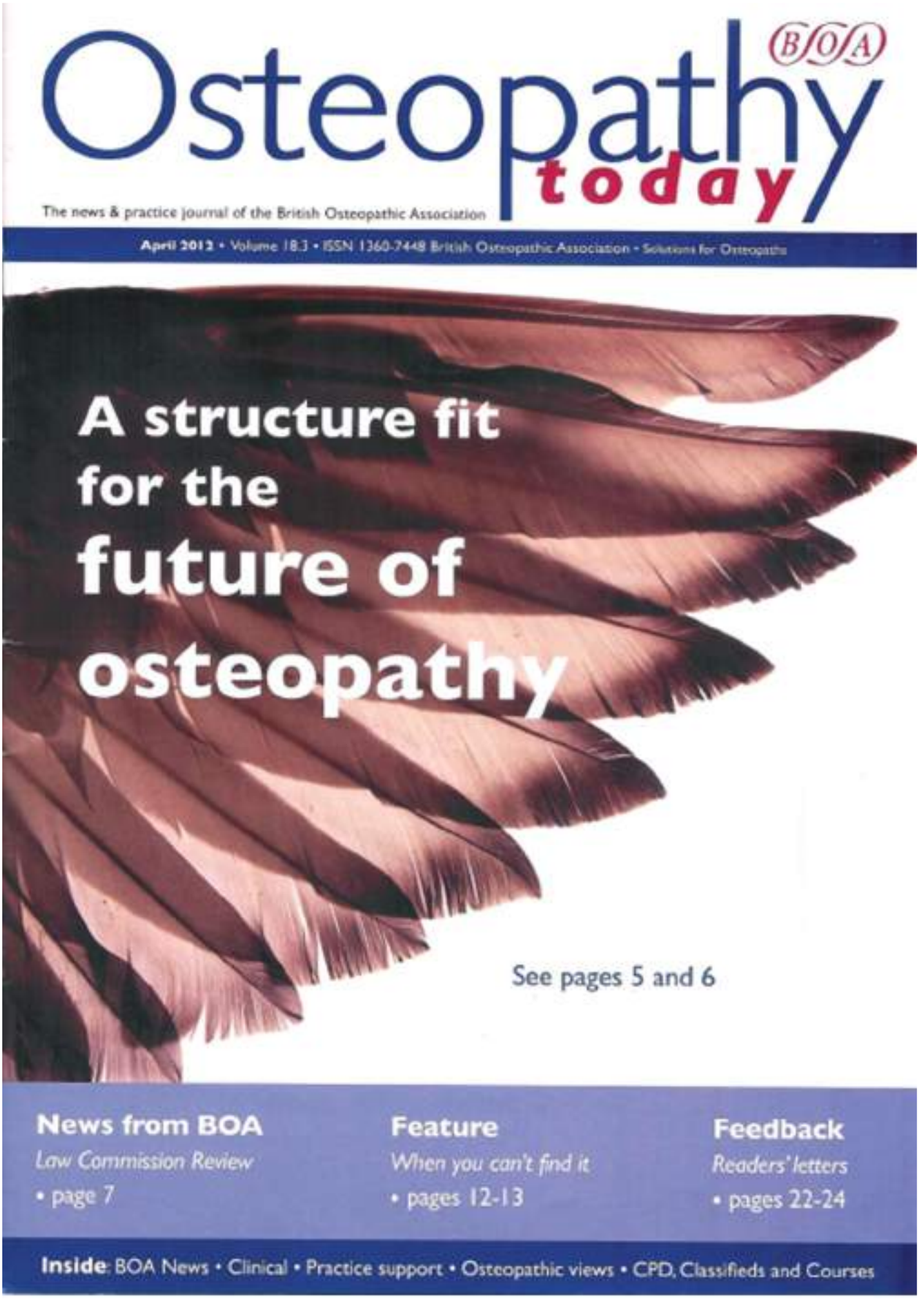
Osteopathic doctors review a new category of back pain treatment in the United Kingdom.

AUTHOR

Sally Lansdale, DO (BSO), Simeon Asher BSc(Ost) BPhil in CHS, University of Exeter James Sneddon ND, DO, GOsC and David Brogan Chartered Physiotherapist, Queens College Glasgow

CONCLUSION

- **Moderate to dramatic improvement seen amongst majority of patients**
- **A very important tool in the cases where surgery is the usual next step**
- **85% successful improvement in symptoms where improvement means reduced pain scores, decrease in pain medication usage, improved functional testing, increased walking distance, and ability to return to work.**
- **Safe treatment option for prolapsed (bulging) discs**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• page 7
Feature
When you can't find it
• pages 12-13
Feedback
Readers' letters
• pages 22-24
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IDD Therapy®

Sally Lansdale, DO (BDO);
Aimeon Asher BSc(Ost),
James Sneddon ND, DO,
GOsC, David Brogan

IDD or Intervertebral Differential Dynamics Therapy was first drawn to my attention by the late osteopath, Simon Lichtenstein and his wife, Sally Lansdale, who is also an osteopath, when | bumped into them at a BOA conference in 2009.

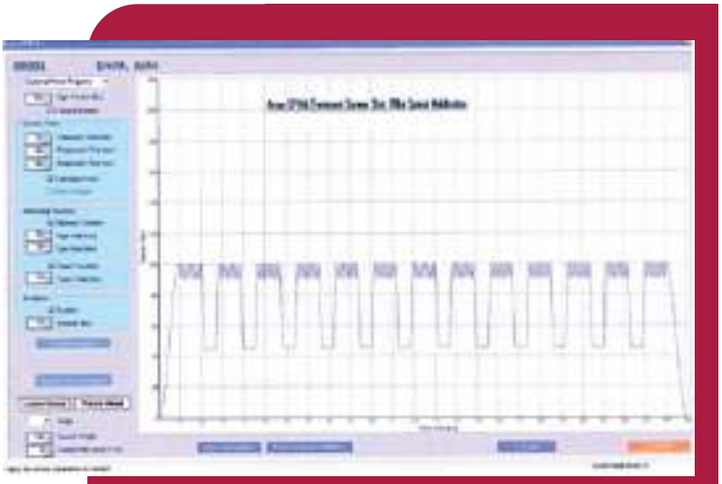
Interested in the potential of the technology and looking for a solution to Sally's own unresolved back problems, they had just decided to invest in an IDD machine for their practice in Leominster, Herefordshire.

Knowing them to be respected, "hands on" osteopaths with over 30 years' experience - (they both qualified from the BSO in the early 80s) | was curious about their decision to invest a not inconsiderable sum in something that sounded rather like a rhythmic traction device and thought it might be helpful to other osteopaths to find out more.

SO WHAT IS IDD THERAPY®?

It belongs to a relatively new category of treatment for back problems known as "nonsurgical spinal decompression' which, in very general terms, is a treatment delivered by a motorized machine, controlled by a computer, that applies a variable distraction/traction force to the spine

There are a number of different design of spinal decompression systems and IDD Therapy® is one type of patented design - delivered by machines that operate to The North American Medical System Design from The North American Medical Corporation. The current IDD® machines in use in the UK are the Accu-SPINA® or the slightly cheaper SDS Spina® which deliver identical treatment although each model has slightly different features. This article looks solely at IDD®.



HISTORY

The IDD Therapy® model was first developed in the mid-nineties by a group of American doctors and engineers led by neurosurgeon Norman Shealy, MD, PhD, based on treatment principles gleaned from chiropractic, neurosurgery, orthopedics, osteopathy, physiatry.

It is now offered in a number of clinics internationally and is currently making inroads in the UK where there are six clinics, mainly osteopathic, offering treatment.

WHAT CONDITIONS IS IT USED FOR?

The manufacturers advise that IDD may be used in the treatment of herniated or bulging discs, degenerative disc disease, posterior facet syndrome, sciatica and acute or chronic back pain. Patients tend to be those that haven't responded to conservative manual treatments and may be considering invasive procedures like surgery.

HOW DOES IT WORK?

The patient lies supine on the treatment table with knees flexed to flatten the lordotic curve. The patient is connected to the table by a thoracic harness and an ergonomic pelvic harness connects the patient to a motorized decompression belt. The IDD Therapy treatment protocols include angles at which the distraction force is to be applied in order to focus the pulling force at targeted spinal levels. By progressively increasing the angle of distraction, the point of application of the pulling force moves along the spine to the desired level. Once set, a series of cyclic distraction and oscillatory forces are applied for 25 minutes to open the disc space and mobilise the joint in a longitudinal plain.

WHAT IS THE DIFFERENCE BETWEEN SPINAL DECOMPRESSION AND TRACTION?

According to Stephen Small, Director of Steadfast Clinics, which supplies IDD machines and trains clinicians in the UK and Europe, a common reaction when people first hear of spinal decompression is to say it's traction but he says there are many differences:

"The origins of IDD spinal decompression lie partly in addressing the failings of traditional traction and understanding the objectives of spinal (disc) treatments in the context of the limitations of what can be achieved with the hands alone. Unlike traction where linear pulling forces were applied in an unprecise general manner, with IDD spinal decompression, the pulling forces are applied at precisely measured angles which has been shown to open the disc space by between 5mm-7mm at specific spinal segments. (5)

The next aspect is the manner and duration in which the force is applied. With traditional traction, different pulling forces were used in a non-systematic manner and a danger was that spasm would cause an actual increase in intradiscal pressure. With spinal decompression, the pulling forces are applied using a natural sinusoidal waveform.This means that it is possible to apply higher pulling forces (up to half body weight plus [0-1 5Ibs) and maintain comfort.

The pulling forces are applied in a series of cycles with a high tension and low tension.At the point of maximum distraction, IDD spinal decompression has a patent-pending oscillation component which is applied in a 'longitudinal' direction along the spine, rather than anteriorposterior. As with other joint distractionmobilisation techniques, the same is applied to the spine. Importantly rather than a ten minute treatment, patients have 25 minutes during which time the soft tissues are under constant cyclic tension and there are !3 minutes when the joint is fully distracted. Whilst this is possible to some extent manually, to achieve such a distraction and longitudinal mobilisation with controlled force at precise angles for this amount of time is simply not possible manually, These are the principles which resonate with osteopaths."

TREATMENT PROTOCOLS?

Treatment can be intensive - the original IDD protocols are based on a course of 20 treatments over a period of 4 to 6 weeks but in some cases desired outcomes can be achieved for less. Heat and ice are used pre and post treatment and patient education and exercise are key components. Each treatment lasts for between 45 minutes and one hour and costs approximately £60 to £70 per session. An MRI scan is required beforehand to help determine or confirm the level to be treated and to rule out any contraindications such as fractures, spondylolysthesis, severe canal stenosis, cauda equina, osteoporosis, metastasis etc as well as some severe annual strains.

PRACTITIONER VIEWS?

Simeon Asher BSc(Qst) BSO 1992, BPhil in CHS. University of Exeter (1995). Won the CAM award for outstanding practice in 2007.

He started using the Accu-SPINA® in 2009 and bought a second machine in 2011 and has treated about 65 patients with IDD®. He finds it particularly effective for disc bulges and prolapses especially in the cervical spine.

"I was first told about IDD by a 62 year old female patient who is a children's psychologist of great repute. She presented to me with three bulging discs at C4/5/6 in her neck, radiations into her arms, severe back pain and weakness in the hands. She also had chronic low back pain due to disk problems at L3/4/5. In the 20 years since it started she had tried everything; chiropractic, specialist physiotherapy, medication and pain clinics but nothing had cured her. By the time | saw her she was unable to sit for any length of time at a computer and she had reduced strength and power in her hands; even after five minutes sitting at a computer she was forced to lie down flat. She needed to make lengthy patient reports in the computer and she even took to building a special set-up so she could lie on her back in front of her laptop.

"Osteopathy seemed to help a little but she was desperate and in her desperation she read on the Internet about IDD therapy" that was only available in the USA. Feeling there was very little to lose she flew all the way to the USA and began a course with a chiropractor. The results were spectacular, her pain was 90% better and she started to live again. She sent all her friends and family to IDD® and she came back to see me demanding that | buy a machine!
"I distinctly remember the feel of her muscles before the IDD® - they were tight and knotty all the way from the top of her back to her neck. Her Splenius and Erector Spinae groups felt as if they were constantly switched on and struggling to maintain her postural loss of lordosis.
"When she returned | felt her muscles again; the change was dramatic, they no longer felt tight and knotted they were soft, healthy and yielding. Best of all she was pain-free, able to sit at the computer again and back to an almost normal life after being in pain for 20 years! In my 19 years as an osteopath | had never felt anything like it! So bought a machine and have been working with IDD since 2009 and in the last two years have treated 65 patients. ! would say more than 75% of all cases have shown moderate to dramatic improvement.

On the negative side, patients can sometimes be in more pain after the first 3-4 sessions. Some patients do not respond to IDD. It can be expensive if patients are self paying. The machines cost a lot of money which as osteopaths we are not used to BUT talking to my dentist friends it is not even as much as a good dental chair! Overall, my sense is that, combined with good osteopathic and rehab treatments the results of IDD have been better than good. It is good to be able to offer disc patients a genuine alternative and the technology fits nicely into an osteopathic - body self-healing model. | am still very impressed and excited by the technology."

Sally Lansdale. DO (BSO). Osteopath of 27 years. She has been a clinical tutor at the BSO and lectured in diagnosis and technique. She also has an interest in cranial work. She currently practices in Leominster. The Accu-SPINA"® was installed in Sally's practice in January 2010 and she has treated approximately 40 patients.

"We MRI scan every patient who has [DD Therapy" - patients mainly have degenerative disc disease, bulging, herniated or prolapsed discs... They tend to be those very difficult patients who get better for a while but then get worse again and have really severe episodes.
"We had four like that when we first got the machine and we had fantastic results with three of them.
One was a 62 year old ex-army officer who hadn't slept for three months with back pain and intractable pain in his calf muscle from a prolapsed disc. He wasn't getting much better with osteopathic treatment but had positive results within two treatments with IDD and is now back cycling and very fit again. It has been very good for us - to be able to help those very difficult patients who otherwise you would have had to turn away has been brilliant."

James Sneddon ND.DO is a second generation osteopath. His father was a naturopath and osteopath who established The Glasgow School of Natural Therapeutics where James qualified in naturopathy and osteopathy in 1972. He has worked from The Buckingham Clinic in Glasgow since then and joined the GOsC in 2002.

James was the first osteopath to use IDD Therapy" in Britain. He has worked with it for about four years mainly treating cases of prolapsed disc or degenerative disc disease both in the cervical and lumbar spine. James works within his multi-disciplinary clinic and assesses patients prior to them undergoing IDD Therapy.

"I of course consider the usual osteopathic issues such as facet joint implication and pelvic imbalances etc. and if appropriate will carry out osteopathic treatment before and/or during a course of IDD Therapy. The IDD itself is carried out by a qualified physiotherapist and it's not the easier cases of prolapsed disc that we find it so helpful, it is the cases that have not responded to a range of treatments and where surgery is the usual next step.

"I would hate not to have it as a weapon in my armory, It's a very important tool to me. | don't want to be sounding over the top about it but we have bought a second machine - | guess you don't buy a second one if you don't think the first one is doing its job! Patients enjoy it, generally they don't find it painful. It's an easing effect.... a lovely gentle pumping action and because its computer-driven it's a very gentle, even pull. I've only ever had one patient that found it painful. The downside is that in severe cases, it is at least a 6 to 8 week programme so it's not immediate in its actions. We follow up with a course of core stability using specialist Medx medical gym equipment to target the core."

David Brogan is a Chartered Physiotherapist who studied at Queens College in Glasgow (1984.) He works at The Buckingham Clinic in Glasgow and now specializes in IDD Therapy. He works with IDD approximately 35 hours a week and he and his colleague Peter Krzeminski, also a Chartered Physiotherapist, have seen about 650 cases over the last 2 years.

David says patients tend to be those difficult ones who have either a confirmed prolapsed disc through an MRI or a highly suspected case based on clinical signs and most have had treatment with other modalities.

"We haven't tabulated the data but | would say that we have between a 70 and 80% success rate and by success | mean improvements in their pain score, decrease in pain killer usage and improvement in certain functional tests like a patient's ability to put on their socks, walking distance and ability to return to work. Overall between 70 and 80 per cent of patients will have about an 85% improvement in their symptoms. "

"I would say, certainly for those patients who have a confirmed prolapsed disc, IDD Therapy" is a very positive and proactive treatment option that can be added into the equation. | think | would certainly miss it now if | didn't have it. "It's not so much a single treatment .... more of a programme or an approach of which IDD® is a big part and it's really taught us how to manage the prolapsed disc much better. For example, when we embark on the treatment we have a nice clear plan with the patient - we spend a lot of time ensuring they fully understand what a disc prolapse is as there are a lot of misconceptions, and we try and give them their confidence back. It's an intensive programme - we see them every day for the first 10 days so we get to know the patients really well and we address one of their fears right from the start which is that they are actually afraid to move.We focus very much on setting out the end point which is that it's not just about getting pain under control but actually about restoring function and getting the patient back to doing what they want to do. I try to get them away from the concept of "I've got a bad back....I've got this for life..... this is me!". We monitor each patient and adapt as we go along mixing in a core stability exercise program along the way.

"My overall view is that it is a very useful treatment for a clinic that sees a lot of discs disease; a very good safe treatment option for these difficult prolapsed discs that most clinics must be finding difficult to treat."

COST?

The cost of an IDD® machine is in the region of £40,000 upwards and a clinic averaging 7 treatments a day has, according to Steadfast, the potential to generate over £100,000 a year in revenue. There are various lease arrangements and finance schemes available. For further information contact: Stephen Small at Steadfast Clinics Ltd Tel: +44 (0)1279 602030. www.steadfastclinics.co.uk

This article is for information only. It does not imply endorsement for IDD Therapy® by the BOA or the author. All the practitioners quoted declare no interest in the company which produce/distribute IDD machines apart from he fact that they own or work with the machines except in the case of Sally Lansdale, who is a UK and Europe trainer for Steadfast Clinics Ltd.

Intervertebral Differenzial Dynamics (IDD) Therapie im Vergleich zur trainings orientierten Pysiotherapie- Ergebnisse einer randomisierten

Physicalische Medizin Rehabilitations-medizin, Kurortmedizin Phys Med Rehab Kuror 21: 34-40

Prospective, randomized, controlled trial.

AUTHOR

Michael Schaufele, M.D. Physical Medicine and Rehabilitation from Harvard Medical School, Director Spine Center Munich, Program Director Emory Spine Center. Newsome, Michael PT, Medical College Of Georgia, Emory Spine Center.

CONCLUSION

- Efficacy of IDD Therapy treatment was clinically significant and offers similar clinical improvement compared to exercise-based physical therapy in patients with symptomatic lumbar degenerative disc disease.
- Patients experienced further improvement at 1 year follow up after treatment
- Note: this study criteria called for restricted IDD treatment regimens by (a) eliminating any concurrent core stabilization, an important component of IDD Therapy protocols and (b) by including data from patients who completed as little as 30% of the IDD protocol regimen. While these factors may have compromised optimal outcomes of IDD Therapy treatment. The study demonstrated, partial "dosing" of IDD Therapy treatment proved as effective as exercise based physical therapy.

Intervertebral Differential Dynamics (IDD) Therapy vs. Exercise Based Physical Therapy – Results from a Randomized Controlled Trial

Intervertebral Differenzial Dynamics (IDD) Therapie im Vergleich zur trainingsorientierten Physiotherapie – Ergebnisse einer randomisierten Studie

Authors M. K. Schaufele[1], M. Newsome[2]

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Key words
- low back pain
- exercise therapy
- conservative therapy

Schlüsselwörter
- Rückenschmerzen
- Physiotherapie
- konservative Behandlung

Abstract

Study Design: Prospective, randomized controlled trial.

Objective: To compare the effectiveness of Intervertebral Disc Dynamics (IDD) therapy with an exercise-based physical therapy program in patients with chronic low back pain caused by degenerative disc disease.

Background: IDD therapy is commonly used in clinical practice, but has not been studied extensively in a controlled trials.

Methods: 48 patients with chronic low back pain > 3 months secondary to mild to moderate degenerative disc disease were included. Patients were randomized in a 2:1 ratio to IDD therapy or a physical therapy program based on lumbar stabilization exercises (PT). Patients in both groups had to complete a minimum of 6 treatments over a 6-week period.

Results: In the IDD group, the mean Visual Analog Scale (VAS) score improved from 43.1 to 27.4 (95% CI 2.3-29.1, average 36.4% decrease, $p < 0.05$) after completion of treatment to 22.1 after 1 year (95 % CI 7.8-34.1, av. 48.6 % decrease, $p < 0.01$). In the PT group the mean VAS score improved from 58.5 to 36.9 (95 % CI 0-43.3, av. 37.0% decrease, $p = 0.05$) after completion of treatment to 26.0 (95% CI 13.1–51.9, av. 55.6% decrease, $p < 0.01$) after 1 year. There were no significant differences in mean pain scores between groups at any follow-up interval. The mean Oswestry Disability Index (ODI) improved significantly in both groups only at the 1 year follow-up. There were no significant differences in mean ODI scores between the groups at any follow-up interval.

Conclusions: Patients in both groups experienced a mild to moderate improvement in pain symptoms after completion of treatment, with further improvement at 1 year. There was significant improvement in back-related function only at 1 year. IDD therapy offers similar clinical

Zusammenfassung

Studien Design: Prospective, randomisierte klinische Studie.

Ziel: Die Effektivität der Intervertebral Differenzial Dynamics (IDD) Therapie wurde mit einer trainingsorientierten Krankengymnastik an Patienten mit chronischen, bandscheibenbedingten Rückenschmerzen verglichen.

Hintergrund: Die IDD Therapie ist eine weit verbreitete physikalisch-medizinische Behandlungsmethode, die bisher nur in wenigen klinischen Studien kritisch untersucht wurde.

Methoden: 48 Patienten mit chronischen, mehr als 3 Monaten bestehenden spezifischen Rückenschmerzen, bedingt durch leichte bis mittelschwere degenerativen Bandscheibenveränderungen, wurden in die Studie aufgenommen. Die Patienten wurden in einem 2:1 Verhältnis IDD Therapie zu stabilisierender Krankengymnastik randomisiert. Die Patienten in beiden Gruppen mussten an mindestens 6 Behandlungen über einen Zeitraum von 6 Wochen teilnehmen.

Ergebnisse: In der IDD Gruppe verbesserte sich der durchschnittliche Schmerzscore (VAS) von 43,1 auf 27,4 nach Behandlungsabschluss (95% Vertrauensintervall 2,3–29,1, durchschnittliche Verbesserung 36,4%, $p < 0,05$) und auf 22,1 nach einem Jahr (95% Vertrauensintervall 7,8–34,1, durchschnittliche Verbesserung 48,6%, $p < 0,01$). In der KG Gruppe verbesserte sich der durchschnittliche Schmerzscore von 58,5 auf 36,9 nach Behandlungsabschluss (95% Vertrauensintervall 0–43,3, durchschnittliche Verbesserung 37,0%, $p = 0,05$) und auf 26,0 nach einem Jahr (95% Vertrauensintervall 13,1–51,9, durchschnittliche Verbesserung 55,6%, $p < 0,01$). Zu keinem Zeitpunkt gab es signifikanten Unterschiede in den Schmerzscores zwischen den Gruppen. In der IDD Gruppe verbessert sich der durchschnittliche Oswestry Score (ODI) von 26,8% auf 20,4% nach Behandlungsabschluss (95% Vertrauensintervall −1,0–13,8, durchschnittliche Verbesse-

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improvement compared to exercise-based physical therapy in patients with symptomatic lumbar degenerative disc disease.

rung 24,1%, n.s.) und auf 13,8% nach einem Jahr (95% Vertrauensintervall 4,8–21,2, durchschnittliche Verbesserung 48,5%, $p<0,05$). In der KG Gruppe verbesserte sich der durchschnittliche ODI von 33,0% auf 29,1% nach Behandlungsabschluss (95% Vertrauensintervall −15,1–22,8, durchschnittliche Verbesserung 11,7%, n.s.) und auf 17,6% nach einem Jahr (95% Vertrauensintervall −1,9–32,7, durchschnittliche Verbesserung 46,8%, $p<0,05$). Zu keinem Zeitpunkt gab es signifikanten Unterschiede in den ODI scores zwischen den Gruppen.

Zusammenfassung: In beiden Gruppen wurden signifikante Verbesserungen in den Schmerzscores nach Therapieabschluss festgestellt, die sich ein Jahr nach Therapieabschluss noch weiter verbesserten. Die funktionellen Scores verbesserten sich nur nach einem Jahr, aber nicht unmittelbar nach dem Therapieabschluss. Es gab keine signifikanten Unterschiede in den Ergebnissen im Gruppenvergleich. Diese Studie zeigte keine Unterschiede in den Behandlungsergebnissen zwischen IDD Therapie und stabilisierender Krankengymnastik.

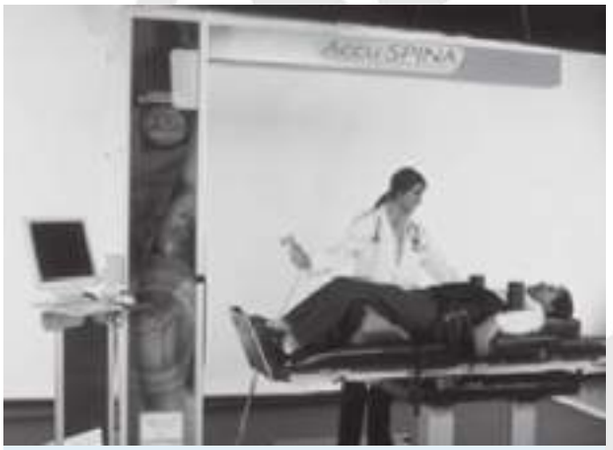

Fig. 1 IDD equipment.

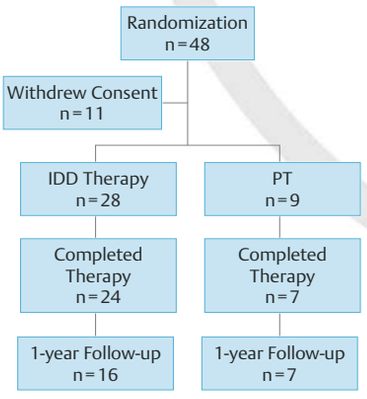

Fig. 2 Randomization table.

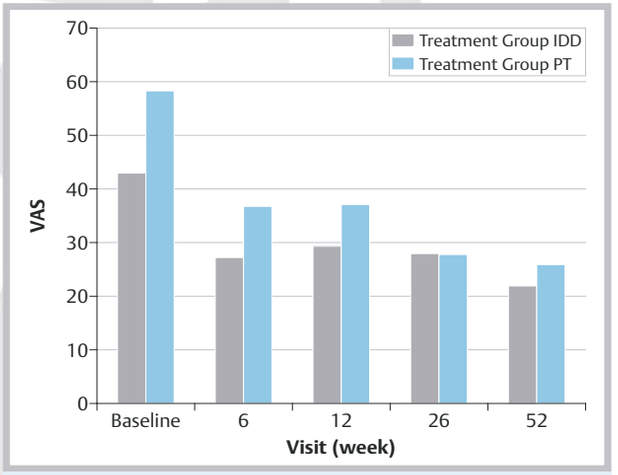

Fig. 3 VAS scores for IDD and PT groups.

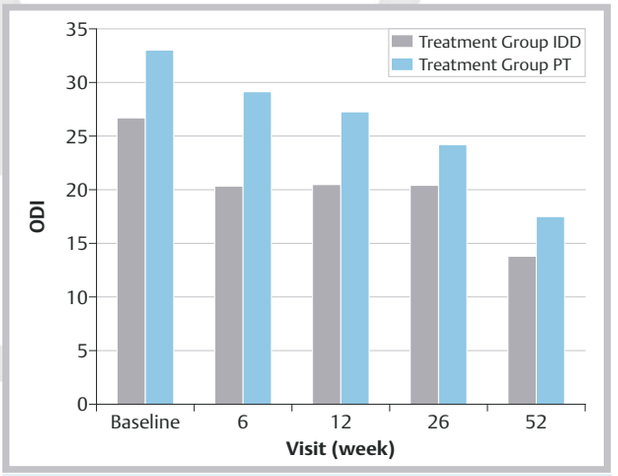

Fig. 4 Oswestry scores for IDD and PT groups.

Visit (week)	Treatment Group						P-Value, Wilcoxon Signed Rank Test for Differences (2-Sided)
	IDD			PT			
	N	Mean (VAS)	Standard Deviation	N	Mean (VAS)	Standard Deviation	
baseline	28	43.1	22.4	9	58.5	17.9	0.09
6	24	27.4	22.7	7	36.9	22	0.21
12	16	29.4	22.5	6	37	26.1	0.53
26	15	28.1	21.4	6	27.8	12	0.46
52	16	22.1	14.2	7	26	16.7	0.34

Table 1 Comparision of Visual Analogue Scale (VAS) scores between IDD and PT groups by Visit Date.

Visit (week)	Treatment Group						P-Value, Wilcoxon Signed Rank Test for Differences (2-Sided)
	IDD			PT			
	N	Mean (ODI)	Standard Deviation	N	Mean (ODI)	Standard Deviation	
baseline	28	26.8	13.9	9	33	17.9	0.38
6	24	20.4	11.2	7	29.1	18	0.18
12	16	20.6	10.4	6	27.2	14.8	0.25
26	15	20.4	12.7	6	24.2	13.2	0.48
52	16	13.8	9.5	7	17.6	13.6	0.36

Table 2 Comparision of Oswestry Disability Index (ODI) scores between IDD and PT groups by Visit Date.

Visit (week)	Wilcoxon Statistic, Standardized (VAS)	P-value, Wilcoxon Test (2-sided)	Wilcoxon Statistic, Standardized (ODI)	P-value, Wilcoxon Test (2-sided)
0–6	1.25	0.21	1.33	0.18
0–12	0.63	0.53	1.14	0.25
0–26	0.74	0.46	0.7	0.48
0–52	0.94	0.34	0.91	0.36

Table 3 Wilcoxon analysis comparing the in-group improvements between the 2 groups for both VAS and ODI scores (n.s. at all time points).

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Stress in lumbar intervertebral discs during distraction: a cadaveric study

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Mayo clinic research study utilizing non-proprietary means to distract a disc, and document effects of distraction therapy on the disc.

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METHOD

Measured vertical and horizontal stress during disc distraction.

CONDITIONS

Degenerated discs

CONCLUSION

- **Distraction therapy appears to predictably reduce nucleus pulposus pressure.**


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Technical Reviews

Stress in lumbar intervertebral discs during distraction: a cadaveric study

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Abstract

BACKGROUND CONTEXT: The intervertebral disc is a common source of low back pain (LBP). Prospective studies suggest that treatments that intermittently distract the disc might be beneficial for chronic LBP. Although the potential exists for distraction therapies to affect the disc biomechanically, their effect on intradiscal stress is debated.

PURPOSE: To determine if distraction alone, distraction combined with flexion, or distraction combined with extension can reduce nucleus pulposus pressure and posterior annulus compressive stress in cadaveric lumbar discs compared with simulated standing or lying.

STUDY DESIGN: Laboratory study using single cadaveric motion segments.

OUTCOME MEASURES: Strain gauge measures of nucleus pulposus pressure and compressive stress in the anterior and posterior annulus fibrosus.

METHODS: Intradiscal stress profilometry was performed on 15 motion segments during 5 simulated conditions: standing, lying, and 3 distracted conditions. Disc degeneration was graded by inspection from 1 (normal) to 4 (severe degeneration).

RESULTS: All distraction conditions markedly reduced nucleus pressure compared with either simulated standing or lying. There was no difference between distraction with flexion and distraction with extension in regard to posterior annulus compressive stress. Discs with little or no degeneration appeared to distribute compressive stress differently than those with moderate or severe degeneration.

CONCLUSIONS: Distraction appears to predictably reduce nucleus pulposus pressure. The effect of distraction therapy on the distribution of compressive stress may be dependent in part on the health of the disc.

Keywords: Lumbar spine; Spinal manipulation; Intervertebral disk; Biomechanics; Stress profilometry

Introduction

Low back pain (LBP) is a ubiquitous problem in developed countries. The cost of LBP to the United States economy is estimated to be more than 100 billion dollars annually [1,2]. The relationship between disc degeneration and back pain is incompletely understood. Disc degeneration is a progressive process that results in biomechanical compromise of the motion segment. Nucleus pulposus pressure decreases in proportion to the degree of degeneration in persons with chronic LBP [3]. The tensile modulus and Poisson's ratio of the annulus fibrosus are likewise reduced [4]. As a result, annulus fibrosus fibers fail at lower loads leading to further degeneration [5] and abnormal spinal motion [6–8]. Although the course of disc degeneration cannot be predictably altered, many investigators are seeking ways to enhance disc physiology and retard or reverse degeneration.

Many treatments using traction (axial distraction) have been devised in an attempt to relieve LBP by affecting the disc and nerve roots. A meta-analysis of the traction literature concluded that, as a group, there was no evidence that traction therapies were beneficial for LBP [9].

FDA device/drug status: not applicable.

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Nonetheless, some randomized trials have suggested that chronic LBP might be relieved by traction methods [10–13] and these treatments continue to be used in practice. The most commonly used methods are intermittent axial traction (which includes various proprietary devices issued under various trade names) and distraction manipulation. Distraction manipulation combines axial distraction with intermittent off-axis moments, usually flexion or extension. It is different than typical spinal manipulative therapy which uses a high velocity impulse during treatment. It is commonly used by chiropractors [14] as well as physical therapists and osteopathic and medical physicians.

Several mechanisms have been proposed to explain how distraction therapies might affect the disc. These include reducing nucleus pulposus pressure, changing the position of the nucleus relative to the posterior annulus, reducing posterior annulus stress, and changing the disc-nerve interface [15–17]. Although both axial distraction and distraction manipulation may temporarily reduce nucleus pulposus pressure [18,19], their effect on the distribution of stress in the disc is unknown.

The objective of this study was to determine the effect of distraction therapies (axial distraction, distraction with flexion, and distraction with extension) on vertical (compressive) and horizontal stress in anterior annulus, posterior annulus, and nucleus pulposus regions of the disc. We used the technique of intradiscal stress profilometry to estimate the stress in human cadaver motion segments under five conditions [20,21]. We hypothesized that all three forms of distraction would significantly reduce nucleus pulposus stress compared with axial loads simulating standing or sitting. We also hypothesized that distraction with flexion would reduce posterior disc stress more than axial distraction or distraction with extension. Finally, we sought to determine if degenerative discs were affected by distraction differently than relatively healthy ones.

Materials and methods

Specimens

Ten fresh, frozen (−20°C) cadaveric lumbar spines (L1–S1) with mean age of 66.4 years (SD 13.8 years, range 40 to 82) were chosen for testing. These spines were screened for HIV/AIDS, Hepatitis B and C, tuberculosis, and Creutzfeldt-Jakob disease. Prospective specimens were imaged with anterior-posterior and lateral radiographs; those with severe osteoporosis, posttraumatic deformity, bone pathology, or significant anatomical anomaly were excluded. Spines with diffuse (multilevel), severe degenerative changes that might make stress profilometry testing difficult were also excluded.

Cadavers were thawed overnight in a refrigerator and L1 through S3 was removed en bloc. The iliotransverse ligaments were sacrificed in this process. Nonligamentous soft tissues were then removed leaving intact the lumbar vertebral bodies and all ligamentous structures including anterior longitudinal ligament, posterior longitudinal ligament, interspinous ligaments, intertransverse ligaments, and facet joint capsules. Each specimen was divided into either two or three separate vertebra-disc-vertebra units, yielding 25 motion segments. K-wires were placed in the vertebral bodies and facet joints and each motion segment was potted in circular acrylic fixtures using polymethylmethacrylate. A custom jig kept the superior and inferior fixtures parallel to each other and to the plane of the disc. Specimens were kept moist with saline-soaked toweling during preparation and testing.

Preliminary testing

The degree of distraction force and flexion-extension moments necessary to simulate these treatments in isolated motion segments was unknown. Studies have reported the amount of vertebral displacement occurring during traction [22–24] and distraction manipulation [16] in vivo or in cadavers. Therefore, we conducted preliminary tests with four randomly chosen lumbar motion segments to estimate the forces needed to produce similar displacements. Distraction of 90 N produced an average increase in posterior disc height of 1.8 mm. Adding a pure moment of 5 Nm to the distracted motion segments produced an average angular displacement of 4.3° in flexion and 4.5° in extension. These displacements were similar to those previously reported to occur during distraction. An axial load of 500 N was used to simulate the load on the lumbar spine during quiet standing and 300 N to simulate lying (nonweightbearing) [25].

The transducer (Model OrthoAR; Medical Measurements, Inc., Hackensack, NJ, USA) was previously shown to accurately measure positive hydrostatic pressure up to 2 MPa [26] but the linearity of measurements in the negative range had not been reported. Because negative values might be encountered during distraction, negative pressure values (from a custom calibration chamber) were plotted against the transducer output. The response was linear to −30 kPa (−225 mmHg) with R^2=0.9996. This range includes the negative pressures reported to occur during distraction therapies [18,19].

Intradiscal stress profilometry technique

The technique of intradiscal stress profilometry was performed as described by McNally and Adams [20]. Measurements were obtained with a high-pressure strain gauge transducer mounted on a blunt 1.3 mm×15 cm needle. By pulling the transducer through the disc at a constant rate, a ''stress profile'' is produced. Stress in the normal nucleus pulposus is isotropic (equal in all directions) but stress in the annulus is typically anisotropic. Therefore, the transducer was oriented to measure both the vertical and horizontal stress values in each specimen. The

transducer output from the annulus (oriented to detect vertical or compressive stress) has been shown to be proportional to the compressive stress perpendicular to the transducer-sensing surface [21].

Biomechanical testing set-up

The potted motion segments were attached to a custom testing device that could apply pure bending moments and axial compression or distraction simultaneously (Fig. 1). The lower vertebra was centered on a 6 degrees of freedom load cell (JR3; Woodland, CA, USA) and maintained in a neutral (0 moment) position with respect to the global coordinate system. Compression and distraction loads were applied to the upper vertebra using pneumatic actuators. Pure moments in flexion or extension were applied with a pulley apparatus fixed to the upper acrylic fixture with force supplied by pneumatic actuators. Angular displacement of the upper and lower fixtures (relative to the transverse or X axis) was measured with miniature tilt sensors with a resolution of 0.03° over their 20° range (Model CXTLA02; Crossbow Technology Inc., San Jose, CA, USA). The transducer was extracted by a stepper motor/pulley system that pulled a cable attached to the needle hub at 2 mm/second. LabVIEW software (National Instruments Inc., Austin, TX, USA) was used for data acquisition and to control transducer extraction. Data was collected at 30 Hz. The transducer was calibrated using a custom pressure chamber and a known amount of positive and negative pressure before tests.

Biomechanical testing

The 21 remaining motion segments were tested in the same manner. A preload of 300-N compression was applied for 30 minutes to expel excess fluid [20]. A 1.3 mm spinal needle with stylet (ground to a point) was then introduced into the anterior disc and advanced in the mid-sagittal plane through the posterior annulus under fluoroscopic guidance (Fig. 2). This created a track for the transducer midway between the vertebral end plates. The guide needle was removed and the blunt transducer needle with transducer inserted and oriented to measure the vertical component of stress. The first condition was then applied to the motion segment. The cable from the needle hub to a stepper motor/pulley was properly aligned and the transducer was withdrawn at 2 mm/second. The needle was then reinserted to measure the horizontal component of stress and again extracted. Each of five test conditions were applied in a constant order: 1) axial compression 300 N (simulation of nonweightbearing or lying) [25], 2) axial compression 500 N (simulation of relaxed standing) [25], 3) axial distraction 90 N (simulation of axial distraction in neutral or traction), 4) axial distraction 90 N and extension 5 Nm (simulation of extension-distraction), and 5) axial distraction 90 N and flexion 5 Nm (simulation of flexion-distraction). There was at least 1 minute between conditions to allow for viscoelastic recovery.

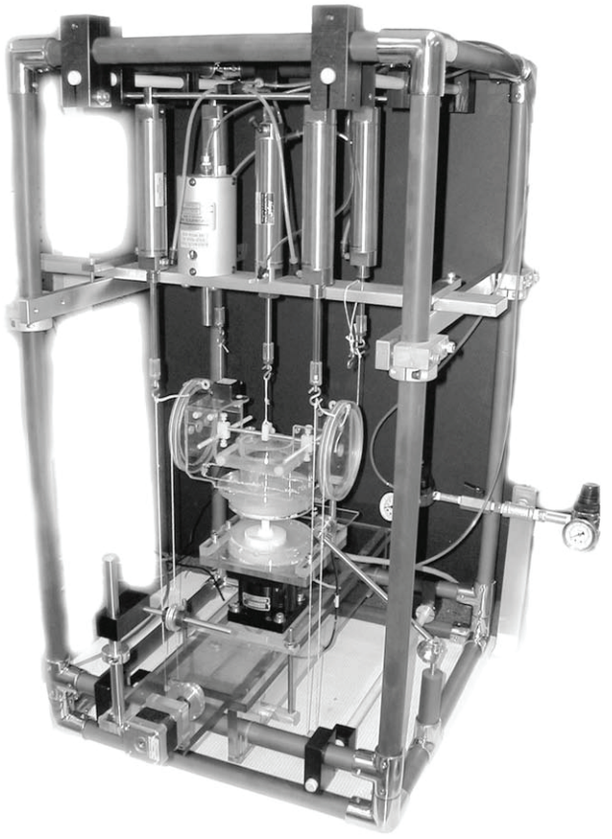

Fig. 1. Spine testing apparatus.

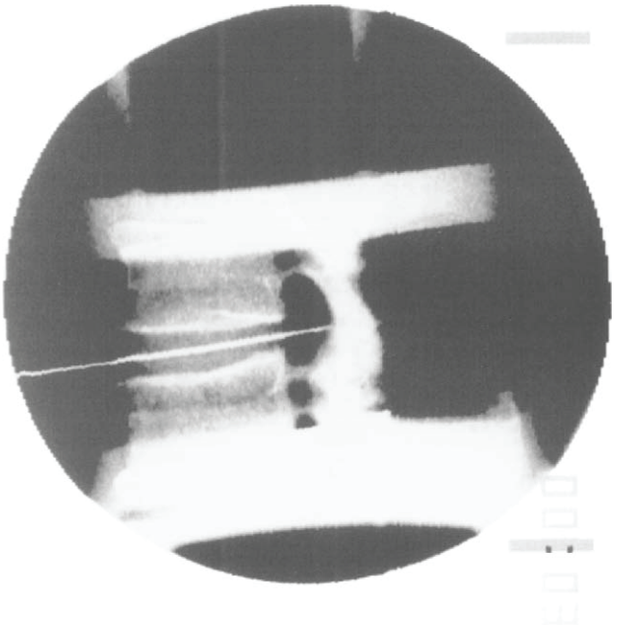

Fig. 2. Path of guide needle and transducer in the intervertebral disc.

Grading of disc degeneration

After testing, each disc was sectioned in sagittal and coronal planes and graded by two observers (an orthopedic spine surgeon and a rehabilitation physician) as normal (grade 1), mild, moderate, or severe (grades 2, 3, or 4, respectively) according to the scale of Adams et al. [5]. In the case of a disagreement between observers, a third observer (an orthopedic spine surgeon) determined the final grade. All graders were blinded to results of individual motion segment tests.

Data reduction and analysis

The relative stress values in the posterior, middle, and anterior disc regions were examined by partitioning the data into thirds. Because these regions could best be identified on profiles collected during compressive loading, each 500-N stress profile was reviewed to ensure that the middle third of the data was consistent with the hydrostatic region, which represented the functional nucleus pulposus [20]. The anterior and posterior thirds of the data (excluding the outermost data points with a precipitous drop in stress) were taken to represent the anterior and posterior disc regions (annulus fibrosus). Vertical and horizontal data were analyzed separately for each test condition in each motion segment. Peak vertical stress values were calculated for the anterior and posterior regions by averaging the single highest point value with the point values before and after it (an average of 3 point values).

The effect of the five conditions on regional vertical and horizontal stress values was examined using repeated measures ANOVA. When global F-tests were significant ($p<.05$), pairwise comparisons (contrasts) of nucleus stress (pressure) were made between the axial compression (500 N and 300 N) and each of the three distracted conditions. Because of the limited number of motion segments, the degenerative grades were collapsed into low degeneration (grades 1 and 2) and high degeneration (grades 3 and 4) groups. The effect of test condition and degeneration were evaluated using two-way ANOVA with repeated measures; generalized estimating equations were used to account for the correlation of the data within motion segments. After this, analysis using one-way ANOVA for repeated measures was performed by degenerative group. Finally, the distribution of vertical stress among the anterior, nucleus, and posterior disc regions was qualitatively examined in each of the five conditions. Analyses were carried out with SAS (SAS Institute Inc., Cary, NC). An α level of .05 (two-tailed) was used for all tests.

Results

Three motion segments from a single spine (L1–2, L3–4, and L5–S1) were excluded as a result of unexpected pathology found upon grading. Two more L5–S1 motion segments could not be tested because of difficulty in obtaining stable potting, so the one remaining L5–S1 segment was excluded. Data from the remaining 15 motion segments (9 lumbar spines) were analyzed. Distribution of disc levels was L1–2 (2), L2–3 (5), L3–4 (3), and L4–5 (5). The effect of disc level was not formally examined because of the small sample size and the risk of type II error; nonetheless, ANOVA indicated no large differences between disc levels suggesting that pooling of the levels was appropriate.

Distribution of degenerative grades was grade 1 (3), grade 2 (5), grade 3 (4), and grade 4 (3). This resulted in 8 in the low degeneration group and 7 in the high degeneration group. Only one cadaver was female. Fig. 3 shows a representative set of vertical stress profiles for five conditions recorded from a single disc with mild (grade 2) degeneration. These profiles are representative of the raw data collected.

Regional vertical and horizontal stress values

Table 1 shows the regional vertical and horizontal stress values for the five conditions for all specimens combined, low degeneration discs (n=8), and high degeneration discs (n=7). The regional (mean) vertical stress values for all specimens combined during each of the five conditions are shown graphically in Fig. 4. The vertical and horizontal stress values in each disc region are compared in Table 2. Vertical and horizontal values were statistically different (paired *t* tests) only in the anterior disc region and only for some conditions. Vertical and horizontal peak values in the posterior and anterior disc regions are also included in Table 2 but no statistical comparison was made as the peak values within a region did not always coincide with the same point value position.

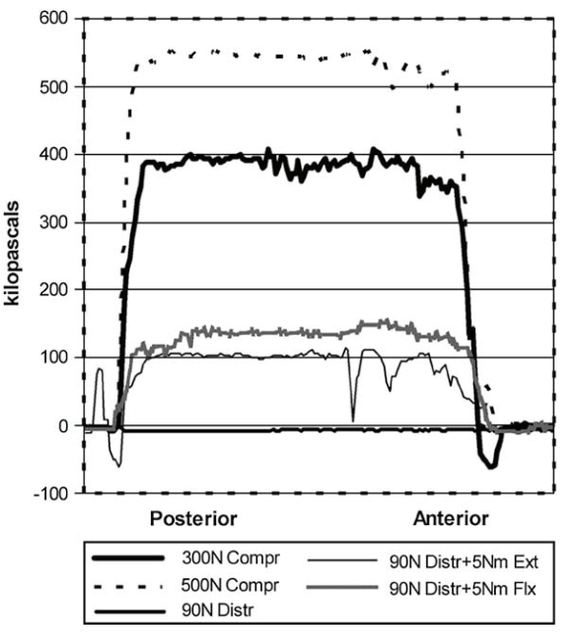

Fig. 3. Vertical stress profiles in a grade 2 (mildly degenerated) L3–4 motion segment (five conditions).

Table 1
Mean (SD) vertical and horizontal stress values (kPa) in three disc regions for five test conditions

Region	300 N compression	500 N compression	90 N distraction	90 N distraction, 5 Nm extension	90 N distraction, 5 Nm, flexion
Anterior h					
All	231.4 (139.9)	305.0 (188.8)	−0.7 (9.1)	61.9 (59.0)	104.6 (44.9)
Low	302.4 (134.3)	383.2 (202.3)	2.1 (10.7)	94.2 (53.0)	111.8 (49.2)
High	150.3 (101.0)	215.6 (134.1)	−3.8 (6.1)	25.0 (43.1)	96.3 (41.6)
Anterior v					
All	269.9 (141.0)	331.3 (185.6)	3.1 (11.8)	76.4 (56.5)	124.6 (46.2)
Low	345.7 (121.5)	411.5 (190.0)	5.5 (8.9)	107.8 (48.5)	135.6 (56.5)
High	183.2 (112.8)	239.7 (141.0)	0.4 (14.8)	40.6 (43.6)	112.0 (30.3)
Nucleus h					
All	337.9 (160.4)	447.6 (228.8)	0.9 (17.2)	89.7 (74.1)	120.7 (73.5)
Low	434.1 (115.4)	563.5 (222.8)	7.3 (15.9)	132.9 (66.1)	146.6 (72.8)
High	227.9 (134.2)	315.2 (160.8)	−6.4 (16.7)	40.3 (48.8)	91.1 (67.2)
Nucleus v					
All	341.7 (158.1)	439.9 (228.6)	2.9 (10.3)	92.5 (68.1)	119.3 (76.6)
Low	430.4 (123.1)	552.9 (223.5)	6.5 (9.1)	130.2 (64.2)	149.2 (76.3)
High	240.3 (134.7)	310.8 (164.9)	−1.3 (10.7)	49.4 (44.1)	85.1 (65.9)
Posterior h					
All	287.6 (125.0)	391.9 (207.5)	−0.7 (14.7)	84.7 (59.9)	91.1 (78.2)
Low	355.3 (97.3)	478.1 (211.9)	2.0 (18.0)	120.0 (51.6)	123.3 (70.2)
High	210.1 (110.9)	293.5 (163.9)	−3.9 (10.3)	44.4 (41.2)	54.3 (74.5)
Posterior v					
All	275.5 (144.9)	369.0 (210.3)	1.3 (8.9)	82.1 (62.5)	87.3 (75.7)
Low	345.4 (120.2)	449.8 (217.6)	2.3 (11.7)	112.6 (66.2)	113.8 (77.6)
High	195.6 (134.7)	276.8 (171.2)	0.2 (4.8)	47.3 (36.9)	57.1 (66.1)

h, horizontal; v, vertical; All, all specimens combined (n=15); Low, low degeneration (grades 1 and 2, n=8); High, high degeneration (grades 3 and 4, n=7); Posterior, posterior annulus; Nucleus, nucleus pulposus; Anterior, anterior annulus.

Effect of distraction on disc stress measures

Vertical and horizontal stress values in the nucleus pulposus were nearly the same (Table 1), suggesting that the measures from the nucleus were consistent with nucleus pressure. Nucleus pressure, posterior vertical stress, and anterior vertical stress were all significantly decreased in the three distracted conditions as compared with either 300 N or 500 N compression (pairwise post hoc contrasts, $p<.001$ for each comparison). This was also true when both low-and high-degeneration groups were analyzed separately with one exception. Comparison of anterior vertical stress in high degeneration discs between 300-N compression and flexion-distraction was not significant ($p=.76$). Axial distraction (without flexion or extension) yielded the lowest mean nucleus pressure. Compared with 300-N compression (simulated lying), nucleus pressure decreased 99% with axial distraction, 73% with extension-distraction, and 65% with flexion-distraction. Statistical analysis of the differences between disc regions was not carried out.

Effect of flexion-distraction and extension-distraction on stress distribution

The mean vertical stress values in each disc region of low degeneration discs (grades 1 and 2) during flexion-distraction and extension-distraction are shown in Fig. 5. The highest mean value for both conditions was in the nucleus. There was little difference between the two conditions in any disc region. The same data for high degeneration discs (grades 3 and 4) are shown in Fig. 6. A formal statistical comparison was not made because of the small numbers in each group. Inspection of Fig. 6 suggests no statistical difference in vertical (compressive) stress between distraction

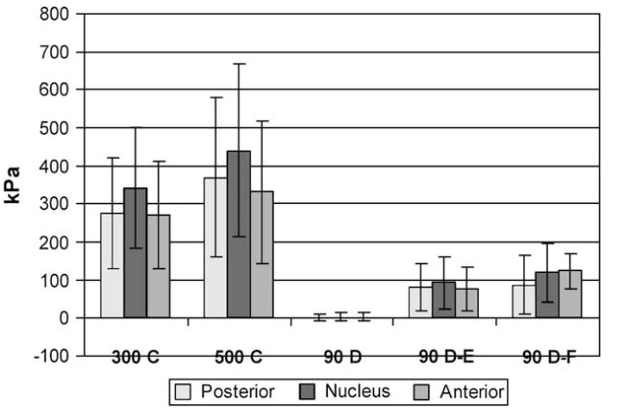

Fig. 4. Mean (SD) regional vertical (compressive) stress during five load conditions (all specimens, n=15), (C = compression, D = distraction, E = extension, F = flexion). Differences between compression (either 300 N or 500 N) and each distraction condition were statistically significant in all disc regions (repeated measures ANOVA with post hoc contrast tests, $p<.001$ for all comparisons).

Table 2
Comparison of mean (SD) and peak vertical and horizontal stress (kPa) values in five conditions (n=15)

Region	300 N compression	500 N compression	90 N distraction	90 N distraction, 5 Nm extension	90 N distraction, 5 Nm flexion
Anterior v	269.9 (141.0)	331.3 (185.6)	3.1 (11.8)	76.4 (56.5)	124.6 (46.3)
Anterior h	231.4 (139.8)	305.0 (188.8)	−0.7 (9.1)	61.9 (58.0)	104.6 (44.9)
p Value*	0.008	0.139	0.226	0.004	0.009
Nucleus v	341.7 (158.1)	439.9 (228.6)	2.9 (10.3)	92.5 (68.1)	119.3 (76.6)
Nucleus h	337.9 (160.4)	447.6 (228.8)	0.9 (17.23)	89.7 (74.1)	120.7 (73.6)
p Value*	0.574	0.244	0.435	0.334	0.737
Posterior v	275.5 (144.9)	369.0 (210.3)	1.3 (8.9)	82.1 (62.5)	87.3 (75.7)
Posterior h	287.6 (125.0)	391.9 (207.5)	−0.7 (14.7)	84.7 (59.9)	91.1 (78.2)
p Value*	0.435	0.177	0.597	0.625	0.589
Peak posterior v	380.7 (161.6)	505.0 (220.3)	42.8 (67.9)	130.9 (59.4)	123.9 (77.5)
Peak posterior h	388.4 (158.2)	505.1 (236.7)	21.7 (24.1)	121.1 (72.5)	146.2 (101.9)
Peak anterior v	367.5 (138.5)	476.7 (207.7)	31.1 (22.9)	117.2 (66.5)	198.8 (92.3)
Peak anterior h	336.9 (153.9)	441.2 (223.1)	11.9 (11.1)	95.3 (70.9)	159.6 (54.1)

h, horizontal; v, vertical.
*Paired *t* test between v and h values.

with flexion and distraction with extension. Yet, vertical stress appeared to be distributed differently in these conditions when the trend from anterior to posterior was considered. During extension-distraction of high degeneration discs, vertical stress was greater in the posterior and nucleus regions and least in the anterior region. A very different pattern was seen during flexion-distraction. The vertical stress appears to decrease from anterior to posterior suggesting a gradient.

Discussion

In this experiment, all three distraction conditions temporarily reduced nucleus pressure compared with simulated standing and lying. The largest effect was observed during axial distraction without flexion or extension which reduced pressure to near zero. Degenerated discs responded differently than relatively normal discs; they had greater temporary net reductions in nucleus pressure. Although not examined quantitatively, the distribution of stress among disc regions in normal or minimally degenerated discs (grade 1 or 2) was similar in flexion-distraction and extension-distraction. This could be a result of the nucleus being pressurized and efficiently distributing the stress. In discs with higher amounts of degeneration (grades 3 and 4), the nucleus had much less pressure when extension or flexion was introduced indicating that stress distribution may have been dependent on the moment applied to the segment. Flexion-distraction resulted in compressive stress being temporarily qualitatively lower in the posterior region compared with the nucleus and anterior regions. Conversely, extension-distraction of degenerated discs yielded similar vertical stress in all three regions.

Nucleus pulposus pressure has been used to calculate axial loads on the spine [25,27]. This is appropriate because the normal nucleus acts as a fluid with the stress being hydrostatic or isotropic (equal in all directions). As such, it is a scalar quantity that can be measured with strain gauge technology. Quantifying stress in the annulus is more problematic. Annular stress is not isotropic but anisotropic with different vertical and horizontal components [5]. Pressure and stress have the same SI unit of measure (Pascal). Although strain gauge transducers have been used to estimate stress in the annulus, it is debatable exactly what the measurements represent. Rao et al. interpreted the output from strain gauges placed in the annulus (to detect vertical stress) to be ‘‘intradiscal pressure in the axial direction’’ [28] despite the fact that pressure is nondirectional. McMillan et al. attempted to determine the validity of strain gauge transducer measures in the annulus and found the output of their transducer to be linearly proportional to the vertical force applied to the disc. They reasoned that the output was also proportional to the compressive stress perpendicular to

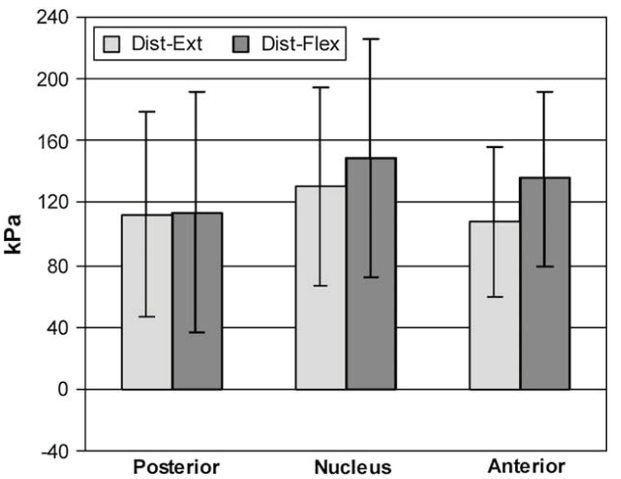

Fig. 5. Mean (SD) regional vertical stress in low degeneration discs (grade 1 and 2) during extension-distraction and flexion-distraction (n=8).

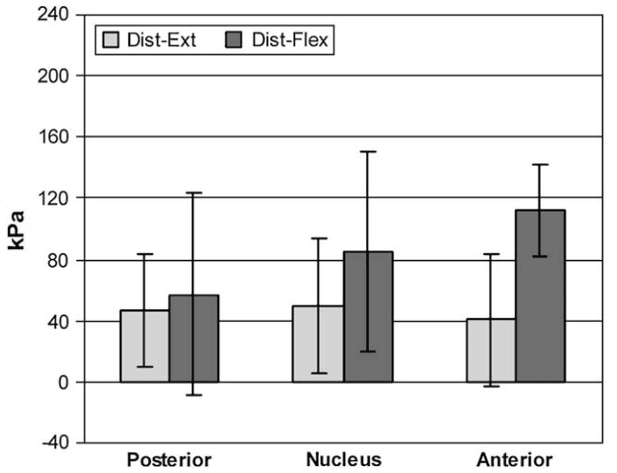

Fig. 6. Mean (SD) regional vertical stress in high degeneration discs (grade 3 and 4) during extension-distraction and flexion-distraction (n=7).

the transducer membrane [21]. Interestingly, they found that the same calibration coefficient was applicable to liquids, nucleus pulposus, and all but the outer 2 to 4 mm of the annulus fibrosus. Although we recorded both horizontal and vertical stress components in this experiment, we were primarily interested in the ability of distraction to ''unload'' the disc, that is, reduce the vertical or compressive stress. Therefore, we have referred to the vertical measures as vertical stress. Vertical stress measures in the nucleus were essentially the same as the horizontal measures, and therefore were interpreted as nucleus pressure.

The normal lumbar nucleus is displaced anteriorly by extension and posteriorly by flexion when lying [29,30] but changes in nucleus pressure and position in degenerated discs are not as predictable [29,31,32] and degenerated discs have been noted to bulge posteriorly with extension [30,33]. Our findings are consistent with reports that degenerated discs may respond differently from healthy discs to flexion and extension [30,31,33] and extend that observation to include flexion and extension combined with distraction. The qualitative differences we observed in stress distribution between relatively healthy and degenerated discs might be because of the degenerated discs being unable to generate or maintain nucleus pressure. They may also be explained in part by anatomy. When the motion segment is extended, the facet joints contact each other and the center of rotation moves posteriorly toward the facets, causing the anterior disc space to widen. This effectively shields the posterior disc from further compression [32]. Conversely, flexion-distraction of degenerated discs may result in anterior compression and an anterior shift of the center of rotation. This appears to produce a stress distribution with the least compressive force in the posterior annulus. These observations suggest that the normal response of lumbar discs to flexion and extension is dependent to some extent on the health of the disc.

The primary mechanical theory underlying the use of distraction therapies for disc herniation is that they reduce nucleus pressure and pull peripheral nucleus tissue toward the center of the disc [34–36]. Distraction has been shown to produce temporary negative pressure in the nucleus of living patients [18]. Nucleus pressure in the present experiment became negative during axial distraction in 4 of 8 low degeneration discs but in only 1 of 7 high degeneration discs. Gudavalli et al. [19], recorded negative pressures during flexion-distraction in a whole cadaver model but we did not observe that in this study. This may have been a result of violation of the annular ''seal'' with the transducer, but that is unlikely considering the instruments used by Gudavalli et al. were similar to the ones we used. Other possible explanations include dissimilar forces used during flexion-distraction or the difference between whole cadaver and single motion segment models. Gudavalli et al. used intermittently applied, short-duration forces and continuous measurement. We measured pressures 1 to 2 minutes after the force was applied which might also explain this difference.

This study has several weaknesses that should be considered. First, a cadaver model may not accurately represent the response of the disc to loading in vivo. At this time there is no safe and acceptable method of obtaining similar in vivo measurements in humans. The age of tissue donors was generally older than persons presenting with discogenic back pain. The effects of freezing and thawing lumbar spine tissues is not thought to significantly affect the physical properties of human spine specimens [37]. Yet, dehydration and prolonged exposure to room temperatures are known to affect their material properties. The specimens in this experiment were kept moist [38] and the exposure to room temperature minimized. Our results were not likely affected by soft-tissue changes because of exposure. Second, the method we used to simulate treatments is most consistent with intermittent traction and lasting 1 to 2 minutes. It may not reflect the exact time course of stress change during shorter treatments such as distraction manipulation. Third, although the output of the transducer we used has been shown to be proportional to the applied compressive stress (perpendicular to the sensing element), it may not provide a highly accurate measure of compressive stress. Nonetheless, it provides a reasonable measure of stress change within specimens [21]. Fourth, we excluded all L5–S1 motion segments from our data. The L5–S1 segment has different ligamentous anatomy and slightly different kinematics than the other lumbar segments. Further, it can be difficult to secure and test. We did encounter difficulties with potting and as a result elected to exclude the single L5–S1 motion segment with usable data from analysis. Fifth, the results must be considered carefully in light of the small sample size and risk of error. Yet, the study was designed as a repeated measures study to maximize the power.

Our findings provide insight into the mechanical effects of distraction therapies but they do not establish a mechanism by which distraction might benefit those with back

pain or sciatica because of disc injury. It is possible that the motion or change in stress results in mechanobiological events that lead to pain relief or promote disc health [39,40]. Studies using both animal and in vitro models have demonstrated that mechanical stress may play a role in the regulation of both degradative and anabolic processes in discs [41–43]. Kroeber et al. [42] using a rabbit model found that degenerated discs (created by compression) treated with distraction had restoration of disc height and histological evidence of regeneration. Although the method of producing degeneration in that model can be questioned, the results provide preliminary evidence that distraction might potentially have a beneficial affect on disc physiology. Distraction might also reduce local stress peaks in the annulus fibrosus which are thought to produce LBP [44]. Further studies are needed to establish a clear clinical benefit of distraction therapies. Additionally, studies are needed to examine the relationship between stress distribution and clinical markers of disc biology such as the degree of nucleus hydration [45].

Acknowledgments

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Trunk Muscle Response to Various Protocols of Lumbar Traction

Journal of Manual Therapy 2008 PP1-5

An experimental research study to explore the effects of trunk muscle activity with spinal decompression forces, and identify any relationships between trunk flexibility with variable degrees of angle, variable frequency of sinusoidal oscillation waveforms utilizing the Accu-Spina and also compare a sham traction, in an effort to obtain greater insights on the effects of compressive/decompressive forces .

AUTHOR

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Department of Orthopaedics and Rehabilitation
Department of Biomedical Engineering

METHOD

- **19 healthy subjects underwent EMG monitoring to record electrical activity in primary trunk muscle groups while being treated with various sessions of variable waveforms performed on the device specific algorithms.**
- **The protocol for this study was approved by Yale University's Human Investigation Committee.**

CONCLUSION

- **The various force algorithms produced by the Accu-Spina device showed significantly less electrical activity in thoracic and lumbar erector muscles. Significant loss in trunk flexibility noted by the investigators as likely due to an increase in disc hydration; increase of disc height.**
- **Results point toward fluid exchange in the disc as one of the key biomechanical effects**

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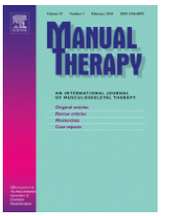
Manual Therapy

Manual Therapy xxx (2008) doi:10.1016/j.math.2008.08.005



Trunk muscle response to various protocols of lumbar traction

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ABSTRACT

The purpose of this study was to compare trunk muscle activity, spinal decompression force, and trunk flexibility resulting from various protocols of spinal traction. Four experiments explored the effects of (1) sinusoidal, triangular, square, and continuous distraction-force waveforms, (2) 0, 10, 20, and 30 degrees of pull angle, (3) superimposed low, medium and high frequency force oscillations, and (4) sham traction.

Nineteen healthy subjects volunteered for this study. Surface EMG was recorded during traction and later used in a biomechanical model to estimate spine decompression force. Trunk flexibility was measured before and after each treatment.

Thoracic and lumbar erector spinae muscles were significantly less active during sham than real traction ($p = 0.01$ and $p = 0.04$, respectively).

The estimated L4–L5 spine compression force was 25 N. Trunk flexibility decreased after each experimental session ($p = 0.01$), and there were no differences between sessions. Our results suggest that the trunk muscle activity is minimal and point toward fluid exchange in the disc as one of the key biomechanical effects of spinal traction.

INTRODUCTION

With low back pain (LBP) remaining one of the most prevalent and costly health problems in Western Society (Andersson, 1999), the search continues for an effective treatment. Because spinal surgery is expensive and not always effective, the management of LBP begins usually with a conservative approach.

One such conservative approach is mechanical spinal traction. This type of treatment relies on the application of a continuous or intermittent distraction-force between the pelvis and ribcage. Over 30% of physical therapists surveyed in Ontario, Canada, used spinal traction as the preferred treatment for subacute LBP and acute LBP with sciatica (Li and Bombardier, 2001), which represents the trends in North America. Similarly, lumbar traction is frequently used in the UK despite numerous recommendations suggesting it is ineffective (Harte et al., 2003). These recommendations, based on comprehensive reviews of randomized clinical trials, state that lumbar traction cannot be recommended as a single therapy for LBP with or without sciatica (Harte et al., 2003; Airaksinen et al., 2006; van Tulder et al., 2006a,b; Clarke et al., 2007). However, these reviews also state that the literature does not allow for a firm negative conclusion to be made due to the small number of high quality studies published. Most of the studies had too few subjects, mixed patient population, and other methodological flaws. The exact mechanism through which traction might be effective is not known. It has been suggested that spinal elongation, by increasing intervertebral space, inhibits nociceptive nerve activity, improves mobility, reduces muscle spasm, relieves nerve root compression, and lessens adhesions around the facet joints. None of these mechanisms have been supported sufficiently by empirical data (van der Heijden et al., 1995; Clarke et al., 2007). However, all of these possible mechanisms depend on adequate distractionforce being transmitted directly to lumbar segments. During traction, muscle tension and friction between the body and the support surface should be taken into account in the form of counterforces (van der Heijden et al., 1995). While the counteractive friction force can be eliminated with

various technological solutions, such as a split and sliding table, the effects of trunk muscle response to lumbar traction are unknown (van der Heijden et al., 1995; Krause et al., 2000; Clarke et al., 2007). Two previous studies looked only at EMG of sacrospinalis muscles (Hood et al., 1981; Letchuman and Deusinger, 1993). Thus, relaxation of spinal muscles appears to be the most important prerequisite for spinal traction to be mechanically effective. The most recent developments in spinal traction involve new technologies that allow for varying angles of pull, varying load duty cycles; waveforms; their frequency; and concurrent application of superimposed oscillations (Shealy et al., 2005). Such a treatment, named Intervertebral Differential Dynamic (IDD) therapy, claims to be more effective in treating patients with LBP than a standard traction technique (Shealy et al., 2005). However, further refinement of IDD therapy requires quantification of trunk muscle activity and the resultant spinal loads under various waveforms, angles of pull, and oscillations. Currently, no studies comparing trunk muscle response to these protocols exist. Therefore, the purpose of this study was to compare trunk muscle activity, spinal decompression force, and trunk flexibility resulting from various protocols available with the Accu-Spina device (North American Medical Corporation, Marietta, GA) used for IDD therapy. The premarket approval for this device was granted by the FDA in 2005 (510(k) #K033231).

METHODS

2.1. Study design

The entire study consisted of four separate experiments, each exploring changes in trunk muscle activity, spinal decompression force, and trunk flexibility during various treatment options available with the Accu-SPINA device (Fig. 1). Each experiment lasted between 24 and 28 min, per manufacturer's recommendations, and contained all experimental conditions presented in random order:

(1) The effects of various distraction-force waveforms (sinusoidal, triangular, square, and continuous). The angle of pull was kept at 10.

(2) The effects of various angle of pull (at 0, 10, 20, and 30) using sinusoidal distraction-force waveform.
(3) The effect of force oscillations (low, medium and high frequency) superimposed on the square distraction-force waveform. The angle of pull was kept at 1
(4) The effects of sham traction consisting of lying supine without any distraction-force. It should be noted that it was not possible to investigate all of the independent variables in one experiment because we did not want to expose the subjects to traction longer than the recommended 30-min limit.

The difference in sit-and-reach tests performed before and after each experiment served as an indicator of possible changes in the fluid content of intervertebral discs. Because in addition to hip and hamstring, this test also measures low back flexibility; and because the range of motion of the back (i.e. modified Schro¨ber test) reflects diurnal changes in disc hydration, (Wing et al., 1992), we included the sit-and-reach test as one of the outcome measures.

Trunk muscle activity was monitored with surface EMG, which was later used in an EMG-assisted spine model to estimate net forces acting on the osteoligamentous spine during traction.

Fifteen subjects were tested in each experiment. However, most of the subjects volunteered for more than one experiment and were thus tested multiple times on separate days. In total, 13 males and 6 females, each without a history of LBP, were recruited for all experiments. On average (standard deviation) they were 26.4(6.2) years old, 1.76(0.10) m tall, and weighed 74.3(13.3) kg. All subjects read and signed an informed consent form prior to testing. The protocol for this study was approved by Yale University's Human Investigation Committee.

2.2. Procedures

Prior to traction treatment, all subject performed three trials in a sit-and-reach flexibility test according to a standard protocol (Allen, 1988). This protocol involved sitting on the floor with straight legs braced against a box. With palms facing down, the subject reaches forward along the measuring line on the box as far as possible. The maximum reach was held for 3 s and all three trials were averaged to obtain a flexibility score. The flexibility test was repeated at the end of each traction experiment. After appropriate skin preparation, Ag–AgCl, bipolar, disposable surface EMG electrodes were placed over the following muscles on the right side of the body: rectus abdominis (RA, 3 cm lateral to the umbilicus), external oblique (EO, medial to the mid auxiliary line at the level of the umbilicus), internal oblique (IO, approximately midway between the anterior superior iliac spine and symphysis pubis, above the inguinal ligament), latissimus dorsi (LD, lateral to T9 over the muscle belly), thoracic erector spinae (TE, 5 cm lateral to T9 spinous process), and lumbar erector spinae (LE, 3 cm lateral to L4 spinous process) (Cholewicki and McGill, 1996). Each pair of electrodes was spaced 3 cm center-to-center along the muscle belly. A reference electrode was placed over the 10th rib on the right side. After verifying the quality of EMG signals on an oscilloscope, subjects performed maximum isometric exertions in trunk flexion, extension, and lateral bending on an examination table against the resistance provided manually by one of the investigators.

These tasks were designed to elicit maximum voluntary activation (MVA) levels from trunk muscles, for the purpose of EMG normalization (McGill, 1991). For the abdominal muscles, an exertion in a sit-up position was modified from McGill (1991) in that the subjects produced a sequence of maximal efforts in trunk flexion as well as trunk flexion with superimposed left and right torso twists.

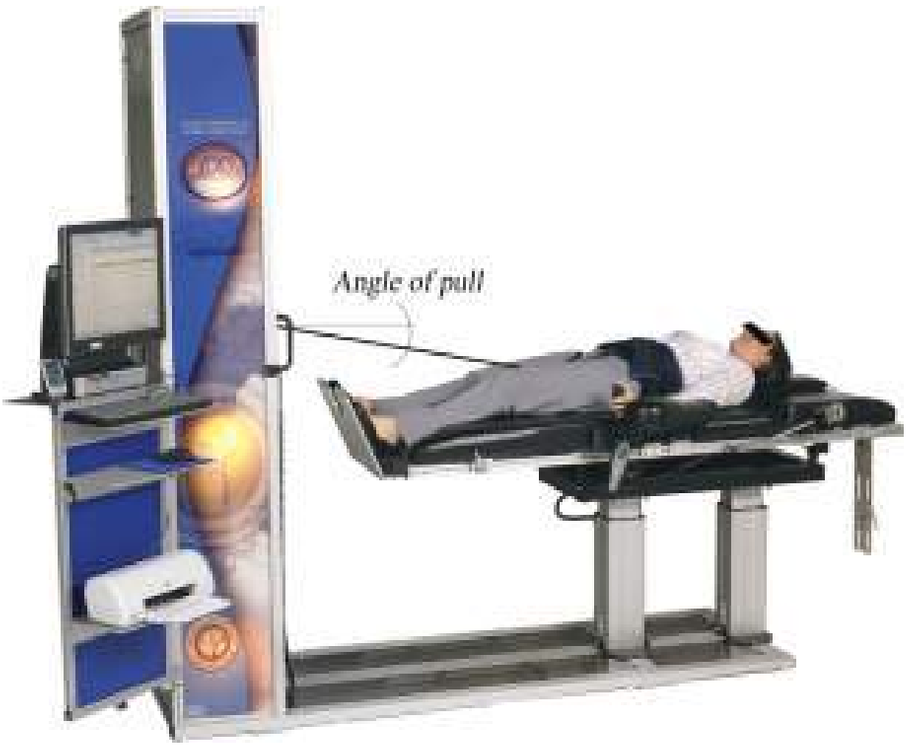

Figure 1:
The Accu-SPINA device used in this study (North American Medical Corporation, Marietta, GA). The table was split, such that the lower body of a subject moved with the bottom part of the table on linear bearings during traction.

Next, subjects donned chest and pelvic harnesses and lay supine on the Accu-SPINA table (Fig. 1). The chest harness was affixed to the immovable part of the table, while the pelvic harness was attached to the motorized traction assembly. This assembly moved up or down for adjusting the angle of pull, which was verified with an inclinometer. At this point, 3 s of EMG data were recorded while subjects lay fully relaxed to obtain a baseline EMG value. The exact shapes of all force waveforms applied are presented in Fig. 2.

According to the manufacturer's recommendations, the peak force was set at half body weight plus 44.5 N (10 lb), while the low force was set at half of the peak value. Each traction experiment began with a 60 s ramp-up to the peak force followed by two cycles of a given force waveform application. The bottom part of the split table was then released to slide freely on linear bearings.

This release reduced the friction between the person and the table and allowed the distraction-force to be transmitted to the trunk. The release also marked the beginning of the treatment, which consisted of three cycles of each experimental condition applied consecutively. The EMG data and the distraction-force were recorded with the same data acquisition board on the third cycle of each condition using 1 kHz analog-to-digital conversion (A/D). A 60 s ramp-down concluded each condition. In the sham experiment, EMG data were collected every 5 min. Prior to the A/D conversion, the EMG signals were band-pass limited between 20 and 450 Hz and differentially amplified (input impedance = 100 GU, CMRR > 140 dB).

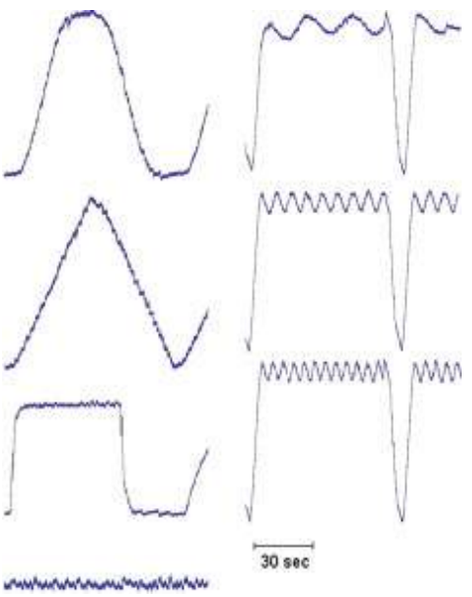

Figure 2:
Various waveforms of distraction-forces applied via Accu-SPINA device (left panel). Low, medium and high frequency oscillations are presented in the right panel

2.3. Data analysis

Mean absolute values of EMG signals were computed between heart beats (QRS waves) in epochs corresponding to the peaks and troughs of the force waveforms. The data were examined for normality using the Anderson–Darling test and corrected with the Box–Cox transformation prior to the statistical analyses, if they were not normally distributed. Repeated measures ANOVAs and Tukey's post hoc tests ($p \quad 0.05$) were used to evaluate differences in muscle activities. First, the comparison was made between EMG corresponding to peaks and troughs of the distraction-force. Next, EMG data corresponding to peak force were compared between all experimental conditions in the first three experiments (various waveforms, angle of pull, and oscillations). Finally, we compared the sham and real traction using the EMG collected during the last time point for the sham and the last experimental condition from experiment 1 (various waveforms). Because the data for this comparison came from different testing sessions, we normalized the EMG using the baseline EMG value obtained from the relaxed lying condition. Because these data were not normally distributed, even after the transformation, a non-parametric Kruskal–Wallis test was used. A nested repeated measures (subjects nested within each experiment) ANOVA was used to compare sit-and-reach flexibility before and after each experiment. Before and after condition served as a within-subjects factor and four experiments constituted a between-subjects factor. All analyses were performed using the Minitab statistical software (Minitab Inc., State College, PA). All data were presented as % MVA. The net decompression force transmitted to the osteoligamentous spine was computed as the difference between the sum of all trunk muscle forces and the distraction-force applied to the trunk by the Accu-SPINA device. Muscle forces were estimated based on the level of their EMG activation using the biomechanical model of a lumbar spine system. A detailed description of this model has been previously published (Cholewicki and McGill, 1996). It consists of a rigid pelvis and sacrum, five lumbar vertebrae separated by a lumped parameter disc and ligament equivalent, rigid ribcage and 90 muscle fascicles. Each muscle consists of an active contractile part, a passive parallel elastic element and a passive nonlinear tendon. Forces in all 90 muscle fascicles were calculated with the help of EMG and the cross-bridge bond distribution moment approach (Cholewicki and McGill, 1995). As in the original work, assumptions were made regarding the neural activation of deep muscles not accessible via surface EMG. Psoas and quadratus lumborum were driven with the EMG signals of their synergists (IO and LE, respectively). Left/right muscle activation symmetry was also assumed.

3. Results

There were no differences between EMG activity corresponding to the peaks and troughs of the distraction-force in any of the six muscles tested ($p > 0.50$, DF = 1, $F < 0.5$). Therefore, only peak force EMG was used for subsequent analyses.

Within the three traction experiments, no effects of angle of pull ($p > 0.06$, DF = 3, $F < 2.6$) or superimposed oscillations ($p > 0.36$, DF = 2, $F < 1.1$) were found in any of the six trunk muscles. With respect to waveform, however, a significantly lower EMG activity was present in the TE muscle during constant compared to a sinusoidal distraction-force waveform (ANOVA: $p = 0.02$, DF = 3, $F = 3.6$; Tukey's post hoc: $p = 0.02$, $T = 3.0$) (Fig. 3).

A comparison between sham and real traction was made using EMG collected at the end of the sham traction and the EMG obtained from the last waveform tested in experiment 1, which gave similar duration of treatment in both cases. Both TE and LE were significantly less active during sham than during real traction ($p = 0.01$, DF = 3, $H = 6.2$ and $p = 0.04$, DF = 3, $H = 4.1$, respectively) (Table 1).

To compute spine decompression force, the counter force (spine compression force) stemming from the activity of all trunk muscles was estimated with a biomechanical model. Because overall muscle activity was very low with little differences between various experimental conditions, two representative cases were considered: sham and sinusoidal traction.

The input to the model consisted of the across-subjects average EMG data expressed as % MVA (Table 1). The L4–L5 spine compression force was 218 N for sham and 434 N for the sinusoidal waveform traction. Considering that on average 409 N of peak distraction-force was applied, the spine was decompressed to 25 N during the sinusoidal waveform traction.

Trunk flexibility decreased after all of the four experimental sessions (main effect: $p = 0.01$, DF = 1, $F = 7.2$). There was no significant interaction between the sessions and flexibility ($p = 0.90$, DF = 3, $F = 0.2$), suggesting that flexibility decreased similarly after each session. On average, subjects lost 6 (SD = 2) mm in their reach during a traction or sham session.

4. Discussion

The main finding of this study was that the overall trunk muscle activity is very low during traction and varies very little between different protocols of applying distraction-force in healthy subjects. For example, the average overall activity during sinusoidal waveform traction was 0.65% MVA. As expected, this value is lower than 1.7% MVA reported during upright standing (Cholewicki et al., 1997), because the demands on spine stability are lower when lying as compared to standing postures. These results agree with the only two previous studies that looked at EMG activity of sacrospinalis muscle. Hood et al. (1981) found no difference in EMG in healthy subjects between lying supine on a table and applying traction.

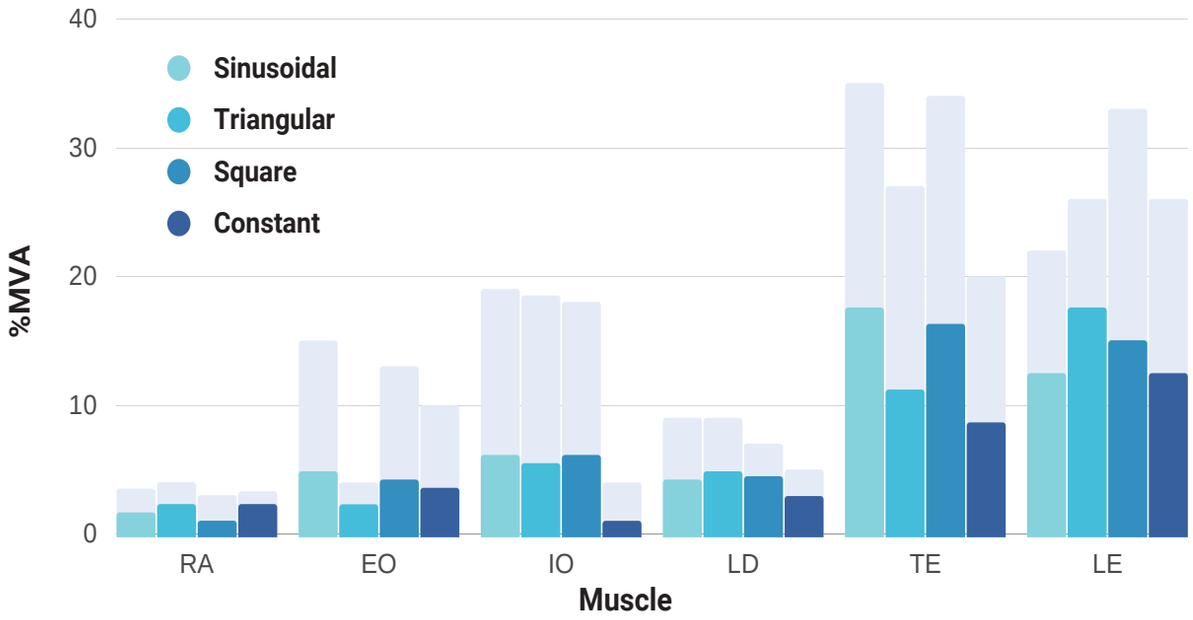

Figure 3: Comparison of trunk muscle activities (mean (SD)) during traction using various force wave forms. An asterisk indicates significant difference ($p < 0.05$).

Letchuman and Deusinger (1993) recorded approximately 4% MVA of EMG activity in patients with LBP during traction, but there is always a doubt whether these patients were able to produce true maximum voluntary contractions.

Both of these studies recorded higher EMG during the initial traction cycle.

After approximately 4–6 min, this activity returned to baseline (Hood et al., 1981; Letchuman and Deusinger, 1993).

Because we pre-conditioned the subjects before data collection with a 60 s ramp-up and two cycles (4 min total), we did not find any differences in EMG activity between cycles during the subsequent treatment part.

Both studies found less sacrospinalis activity during continuous traction than during intermittent traction, although these differences were not statistically significant (Hood et al., 1981; Letchuman and Deusinger, 1993).

These results are again consistent with our finding of significantly lower TE activity during continuous traction compared to the traction with a sinusoidal waveform.

No other differences between waveforms, angle of pull, or superimposed oscillations existed in our study.

Any possible cumulative effects of EMG responses were circumvented by randomizing the order of conditions tested within each experiment.

It is quite likely that patients with LBP would demonstrate different muscle response to traction and this should be the focus of a future study. Patients with LBP demonstrate trunk muscle recruitment patterns that enhance spine stiffness, including greater antagonist co-activation (van Diee¨n et al., 2003). Therefore, it is also possible that in the face of reduced demands for spine stability during traction, patients would relax their muscle co-activation to some extent. Because prolonged muscle co-activation levels exceeding 5% MVA could lead to muscle fatigue and pain, such relaxation would have a positive result and could be one of the mechanisms by which traction might relieve back pain symptoms. This mechanism was proposed earlier for lumbosacral orthoses (Cholewicki, 2004; Cholewicki et al., 2007).

The estimated spine compression force was only 434 N during sinusoidal waveform traction. This compressive force was comprised of a passive elastic muscle force component and a very low active component, which some may call muscle tonus (Walsh, 1992). Combined with the peak distraction-force of 409 N, the spine was almost completely decompressed during traction. Ramos and Martin (1994) measured negative 100 mmHg pressure in a few patients' discs during the application of approximately a 100 lb (445 N) distraction-force. Taking 1500 mm2 as a disc's crosssectional area, this distraction-force would produce 55 mmHg in our experiment ((434 N–445 N)/0.0015 m2 /133 Pa mmHg 1). Therefore, both the documented muscle activity and the estimated spine decompression forces appear reasonable in our study.

	RA	EO	IO	LD	TE*	LE*
Sham	**0.14 (0.32)**	**0.07 (0.12)**	**0.73 (2.41)**	**0.01 (0.03)**	**0.08 (0.31)**	**0.13 (0.39)**
Traction	**0.18 (0.20)**	**0.29 (0.90)**	**0.17 (0.30)**	**0.27 (0.22)**	**1.06 (1.65)**	**0.84 (1.06)**

*, Significant difference between two conditions ($p < 0.05$).

Table 1: Average trunk muscle activity (% MVA, mean (SD)) during sham and traction

Despite the relatively short duration (approximately 0.5 h) of each experimental session, a significant loss in trunk flexibility occurred. This was likely due to an increase in disc hydration (Adams et al., 1990; Wing et al., 1992). Such changes increase disc height and decrease flexibility of the lumbar spine (Adams et al., 1990; Wing et al., 1992). These phenomena are well documented as diurnal changes during sleep and are considered an important mechanism for nutrient transport to the intervertebral discs (Grunhagen et al., 2006). Although there was no difference in flexibility between real and sham traction, the intermittent force application might be more advantageous for maximizing fluid exchange and nutritional transport. This could be another biomechanical effect of spinal traction. If differences in fluid flow exist between various distraction-force waveforms used in the Accu-SPINA device, it is possible that they could be detected with MRI modalities. The short treatment duration and rapid effects of fluid flow in our study should not be surprising, because the greatest increase in hydration of the unloaded disc takes place within the first hour of load removal (Costi et al., 2002).

In summary, our results suggest that overall trunk muscle response to traction does not pose a great problem for mechanically decompressing the intervertebral disc. The significant changes in trunk flexibility point toward fluid exchange as one of the key biomechanical effects of spinal traction, but this study did not address the overall effectiveness of traction as a treatment for LBP.

Acknowledgments

This study was supported by a research grant from the North American Medical Corporation (Marietta, GA), the manufacturer of Accu-Spina device.

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A Non-invasive Approach In the Treatment of Low Back Pain

American Association of Neurological Surgeons AANS Chicago Annual Meeting

An educational session directed towards pain neurological surgeons, residents, nurse clinicians and physician assistants to provide clinical and administrative framework to develop and build a successful neurosurgical pain practice.

AUTHOR

Dennis McClure, MD., University of Wisconsin, Indiana University School of Medicine

METHOD

Preliminary retrospective analysis of 465 patients treated with IDD Therapy from 2003 to 2006.

CONDITIONS

Lumbar and cervical surgery candidates for (PLI fusion, micro-disectomy, or decompressive laminectomy.)

CONCLUSION

- **92%** success rate for patients considered surgical candidates
- Including patients who were not yet surgical candidates, overall success rate was **88%**
- Patients who reported success in treatment also reported significant improvement in lifestyle
- Patients with depression significantly improved in pain

American Association of Neurological Surgeons

AANS
Annual Meeting

Intervertebral Differential Dynamics Therapy: a Non-invasive Approach In The Treatment Of Low Back Pain

Author Block: Dennis E. McClure,MD, Dennis E. McClureMD INC, Dayton, OH; Anna C. McClure,BS, Dennis E. McClureMD INC, Dayton, OH;

APRIL 26 - MAY 1

ABSTRACT INTRODUCTION

Back pain is a perception caused by tissue injury producing an emotional response. IDD therapy can assist the Neurosurgeon in the initial treatment of low back pain due to degenerative disc disease, as well as patients with failed back syndrome. Patients who experience pain often have accompanying depression IDD therapy can significantly improve back pain in patients who have depression due to degenerative disc disease. We have treated over 1500 patients to date.

METHODS

This is a preliminary retrospective analysis of 465 patients treated with IDD therapy from November 2003 to April 2006. Success with IDD therapy was rated by patients post treatment with an average of 1 year follow up. IDD success rate was assessed by a 50% or greater decrease in back pain. A Zung self rated depression score was administered to a sample of 50 patients.

RESULTS

There was an overall 88% success rate with a 92% success rate in patients who were considered surgical candidates. Patients with depression significantly improved in pain p < .0001 _ Patients who reported success in treatment also reported a significant improvement in lifestyle p < .0001. Patients reporting initial success in treatment continued to have a significant reduction in pain 2 months to 2 years follow up p < _0001.

CONCLUSIONS

As these analyses are preliminary in nature. I hope to convey information moving the perception and treatment of low back pain to a non-invasive approach utilizing IDD Therapy and recognizing the complexity of our patients.

AUTHOR DISCLOSURE INFORMATION: D.E. MCCLURE, NONE; A_C. MCCLURE, NONE,

Subject Category (Complete): Pain
Presentation Preference (Complete): Oral or Poster Presentation
Keyword (Complete): Intervertebral Differential Dynamics Therapy ; Low Back Pain ; Depression ; Degenerative Disc Disease

Additional Info (Complete): *Study Design: Retrospective Chart Review *Previously Presented or Published?: yes
Explanation of previous presentation: : Workshop presentation at Britspine 2006, Cardiff Wales, and publication in European Musculoskeletal Review 2006; Submitted to another meeting?: no; Sponsor Name: : Dennis E. McClure MD

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MEDICAL STUDY AND STATISTICAL RESULTS

Intervertebral Differential Dynamics- A New Direction for Initial Treatment of Low Back Pain

European Musculoskeletal Review

This self-funded independent research study was performed on over 500 patient population. All participants were surgical candidates Who opted for treatment with IDD Therapy in lieu of surgery. No ancillary modalities or concomitant interventions were performed on the treatment group other than IDD Therapy treatment.

AUTHOR

Dennis McClure, MD, Indiana University School of Medicine, University of Wisconsin
Bethany Farris, MD

METHOD

Analysis of Pre & Post treatment pain rating by diagnosis; 12 months post IDD Therapy® treatment duration outcome.

CONDITIONS

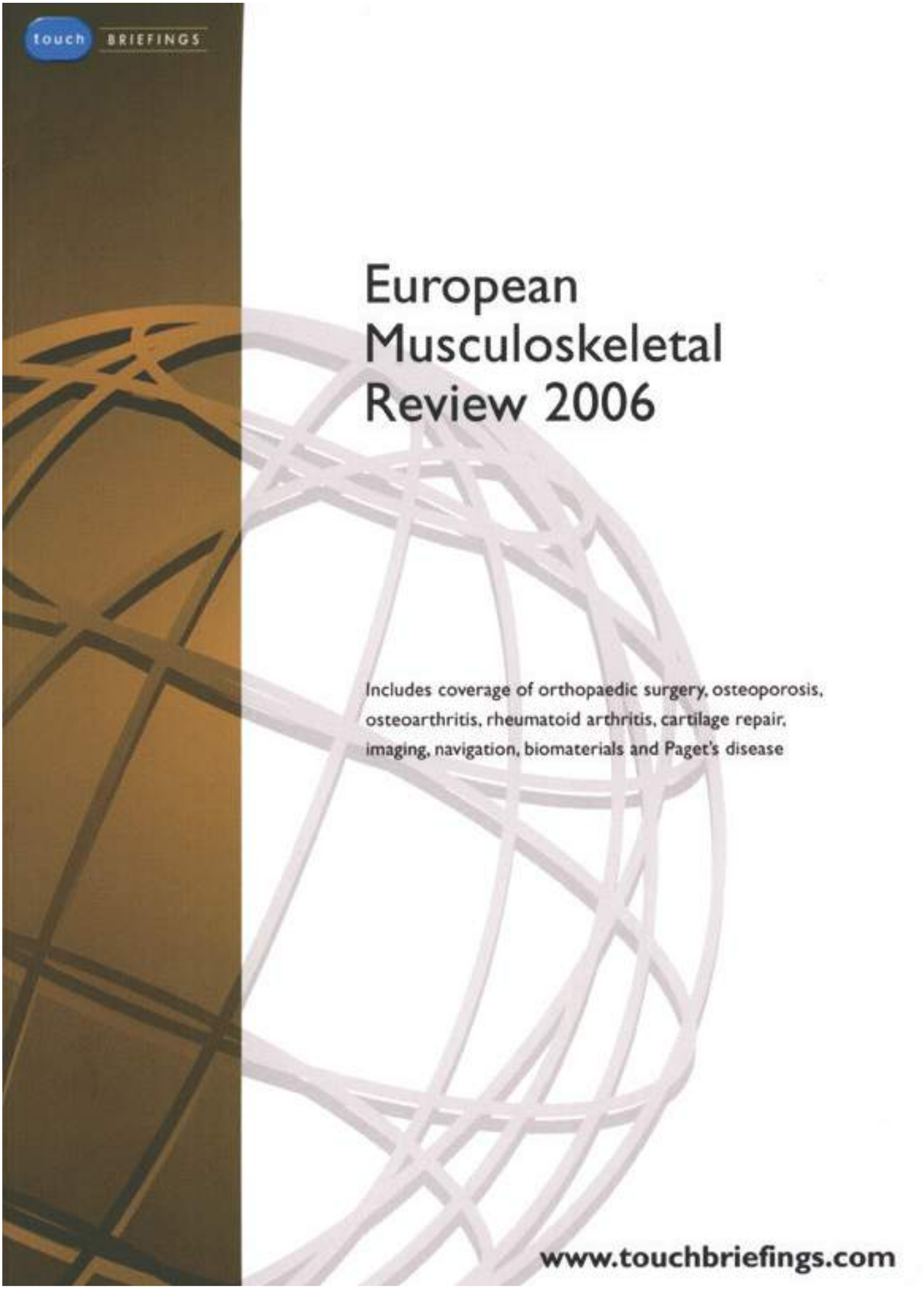
Lumbar and cervical surgery candidates specificity: PLI fusion, micro-disectomy, or decompressive laminectomy.

CONCLUSION

92% **success rate in patients who were sent for surgical intervention.**

IDD Therapy not only decreases pain, but also appears to lift depression associated with pain.

Patients who reported initial success in treatment upon completion continued to experience improvement in their pain after 12 months follow-up from completing IDD Therapy treatment.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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**

Patients with back pain usually present a neurosurgeon or spine specialist with an abnormal magnetic resonance imaging (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.

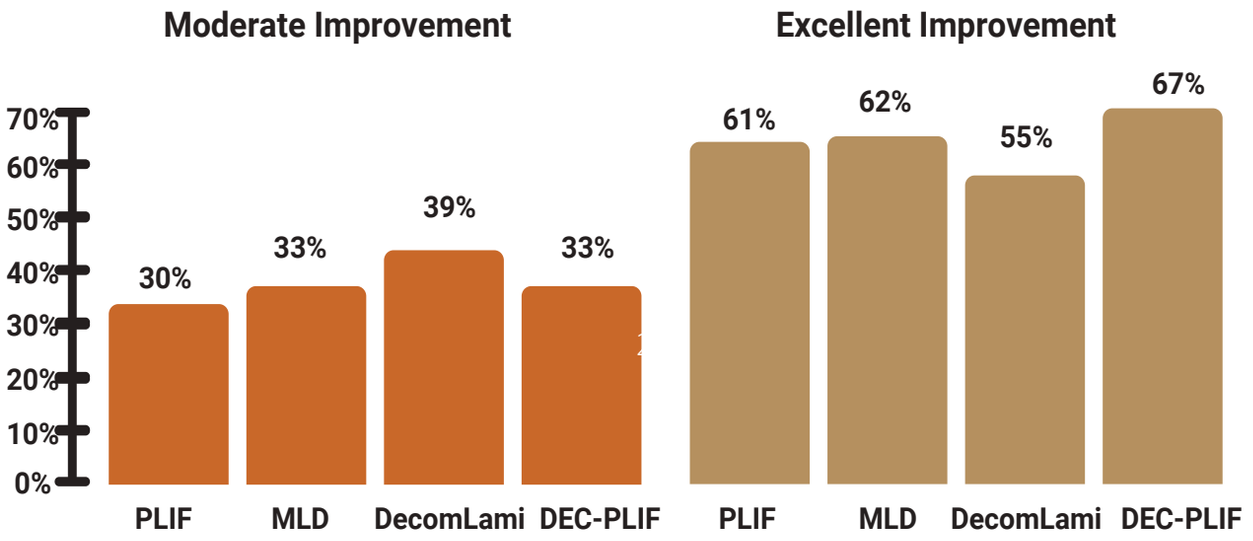
There has been no established uniform or conservative management to effectively treat low back pain.

In November 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 facet 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 mobilise 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 behaviour and to re-educate supporting soft tissues. Since introducing IDD Therapy to the practice I have treated over 1,200 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 analysed so far in looking at success rates that contribute to variables affecting the outcome of IDD Therapy.

European Musculoskeletal Review 2006

Improvement by Surgical Recommendation



PRELIMINARY ANALYSES AND RESULTS

This preliminary analysis was conducted by analysing 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% decrease or greater in pain in order to be considered a success in this analysis. Data from the past 415 patients completing treatment was analysed 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, that is, 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 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 analysed and the results are as follows:

- Effects of Gender — females reported significantly higher pain after treatment, ($p<.0058$)
- Effects of Age (90% confidence interval) — there was a significant increase in pain after treatment as age increased, ($p<.0955$).

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- 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) (p<.0001).

- 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, (p<.0001).

- 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. Diagnosis type Lumbar back pain Surgical lumbar candidates Cervical pain Post-laminectomies Reported success rate (%) Sample size (n) 79 330 rates were examined according to diagnosis assigned prior to treatment (see Table 2).

- 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 and attitudes, and how they may affect **IDD Therapy**.

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 analysed. 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, (p<.0071), 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 (p<.0110). Number of prescription medications also had a significant effect on the outcome of treatment. Patients taking more medication report significantly higher pain after treatment (p<.0143). 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 aspects of patients' health such as psychological, physical and spiritual areas, resulting in better improvement in pain from IDD Therapy, and overall quality of life.

European Musculoskeletal Review 2006

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, (p<.0001). In addition, although depression significantly affected reported pain prior to treatment, patients with depression significantly improved after treatment (p<.0001).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 (p<.0002), significantly higher on the depression scale (p<.0001), and report significantly higher pain (p<.0007).
- **Stress Effects** — Patients who score high on the Social Readjustment Scale score significantly higher on the anger assessment (p<.0001).
- **Anger Effects** — Patients who score high on the anger assessment score significantly higher on the depression scale (p<.0002).
- **Depression Score Effects** — Patients who score high on the depression scale report significantly higher pain prior to treatment (p<.0037).

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, recognising the complexity of our patients and treatment through a more holistic approach.

Dennis McClure, MD, 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.

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DATE OF PATENT:

Jan.10, 2006

INVENTOR:

Carlos Becerra

Atlanta, GA (US); et. al

United States Patent

BECERRA. ET AL.

CERVICAL DISTRACTION DEVICE

ASSIGNEE **North American Medical Corporation,** Atlanta, GA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. l 54(b) by O days.

APPL. NO. **10/889,422**

FILED **Jul. 12, 2004**

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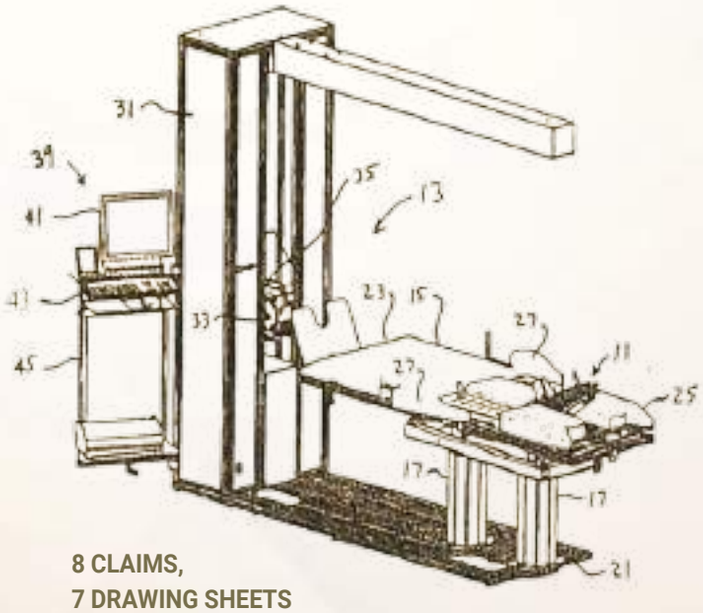
Provisional application No. 60/486,049, filed on Jul. 10, 2003.



8 CLAIMS,
7 DRAWING SHEETS

ABSTRACT

A cervical traction device includes a base, a cervical force application member, and a motor operably attached to the cervical force application member. The motor preferably drives the cervical application member through a direct drive system in order to provide a force to a person's cervical vertebra. The cervical traction device may also include a linear actuator for elevating the person's head to direct the force applied to the cervical vertebra. When integrated on a vertebral distraction machine, the cervical traction device includes its own motor for applying force to the cervical vertebra.

US006984217B2

Disc Distraction Shows Evidence of Regenerative Potential in Degenerated Intervertebral Discs As Evaluated By Protein Expression, MRI and Messengeer Ribonucleic Acid Expression Analysis

SPINE Journal 31(15): 1658-65

In vivo discs underwent compression for 28 days to induce moderate disc degeneration followed by 28 days of unloading/distraction. Comparison was also performed with compressed discs without distraction and quantitative outcome measures were examined.

AUTHOR

Guehring T, Omlor GW, Lorenz H, et al, Dept of Orthopaedic Surgery, University of Heidelberg, Germany

METHOD

Quantitative, non-proprietary decompression research experiment.

CONDITIONS

Moderate disc degeneration.

CONCLUSION

Distraction of discs results in disc rehydration and can stimulate extracellular matrix gene expression as well as increase the numbers of protein-expressing cells and up-regulation of collagen.

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Official Journal of the North American Spine Society

Kroeber, Markus MD; Unglaub, Frank MD; Guehring, Thorsten MD; Nerlich, Andreas MD; Hadi, Tamer BA; Lotz, Jeffrey PhD; Carstens, Claus MD

Disc distraction shows evidence of regenerative potential in degenerated intervertebral discs as evaluated by protein expression, magnetic resonance imaging, and messenger ribonucleic acid expression analysis

Spine: *15 January 2005 - Volume 30 - Issue 2 - pp 181-187 doi: 10.1097/01.brs.0000150487.17562.b1 Basic Science*

ABSTRACT

Objectives

Effects of temporary dynamic distraction on intervertebral discs were studied on the lumbar spine rabbit model to characterize the changes associated with disc distraction and to evaluate feasibility of temporary disc distraction to previously compressed discs in order to stimulate disc regeneration.

Methods

New Zealand white rabbits (n = 32) were used for this study. The rabbits were randomly assigned to one of five groups. In 12 animals, the discs were first loaded for 28 days using a custom-made external loading device to stimulate disc degeneration. After 28 days loading time, the discs in six animals were distracted for 7 days and in six animals for 28 days using the same external device, however, modified as dynamic distraction device. In six animals, the discs were distracted for 28 days without previous loading; and in six animals, the discs were loaded for 28 days and afterwards the loading device removed for 28 days for recovery without distraction. Six animals were sham operated. The external device was situated; however, the discs remained undistracted and they also served as controls.

Summary of Background Data

Studies have shown that accelerated degeneration of the intervertebral disc results from altered mechanical loading conditions. The development of methods for the prevention of disc degeneration and the restoration of disc tissue that has already degenerated are needed.

Results

After 28 days of loading, the discs demonstrated a significant decrease in disc space. Histologically, disorganization of the architecture of the anulus occurred. The number of dead cells increased significantly in the anulus and cartilage endplate. These changes were reversible after 28 days of distraction. The disc thickness increased significantly as compared with the specimens from the 28 days loading group without distraction. Histologically, the discs showed signs of tissue regeneration after 28 days of distraction. The number of dead cells decreased significantly in comparison with the loaded discs without distraction. The flexibility of compressed discs was higher than of compressed/distracted discs.

Conclusions

The results of this study suggest that disc regeneration can be induced by axial dynamic distraction in the rabbit intervertebral disc. The decompressed rabbit intervertebral discs showed signs of tissue recovery on a biologic, cellular, and a biomechanical level after 28 days of distraction

Intervertebral Differential Dynamics (IDD) Therapy vs. Exercise Based Physical Therapy- Initial From a Randomized Controlled Trial

American Journal of Physical Medicine & Rehabilitation Vol 85 (3) pp283-284

Evaluating efficacy of IDD Therapy treatment group for disc degeneration compared to the insurance based standard of care, conventional physical therapy exercise group.

AUTHOR

Michael Schaufele, M.D. Physical Medicine and Rehabilitation from Harvard Medical School, Director Spine Center Munich, Program Director Emory Spine Center.
Newsome, Michael PT, Medical College Of Georgia, Emory Spine Center.

METHOD

Randomized, Controlled Trial 2:1 ratio, minimum of six treatments in each group.

CONDITIONS

Degenerative Disc Disease

CONCLUSION

Efficacy proved clinically significant outperforming all other DDD treatment options.

Data shows that incomplete dosing of IDD Therapy treatment proves as effective at treating DDD as the standard of care (exercise based physical therapy).

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Poster Board S32

Intervertebral Differential Dynamics (IDD) Therapy vs. Exercise Based Physical Therapy - Initial Results from a Randomized Controlled Trial

2006 Association of Academic Physiatrists Annual Meeting Scientific Presentations

Schaufele, Michael K. MD; Newsome, Michael PT

EMORY CLINIC
Orthopaedics, Sports & Spine

BACKGROUND

Disc degeneration is probably the most common structural cause of chronic low back pain. Multiple nonsurgical treatment options exist, but few of them have undergone vigorous scientific evaluation. Recently, several advanced therapeutic modalities based on the principle of traction have been developed for this indication. These treatments are widely available, but are controversial because of the limited scientific evidence to support their claimed benefits.

METHODS

Patients with chronic low back pain secondary to mild to moderate disc disease were randomized in a 2:1 ratio to IDD (Intervertebral Differential Dynamics) therapy or a standardized program of physical therapy consisting of an exercise based, function oriented physical therapy program (PT). The patients had to complete a minimum of 6 treatments over a 6 wk period in each group. All treatments were performed by the same group of physical therapists. The primary objective of this study was to compare the changes in functional and pain scores (Oswestry, VAS) in bath groups and to assess the safety of IDD therapy.

RESULTS

13 patients in the IDD group and 5 patients in the PT group were available for an interim analysis after completion of 6 wk of treatment. In the IDD group, the mean Oswestry Scores decreased from 27.9-21.8 (-6.1. $P < 0.05$) and the mean VAS scores from 52.3-25.3 (-27, $P < 0.05$ In the PT group, the mean Oswestry scores decreased from 25.2-24.8 (-0.4. n.s.) and the mean VAS scores from 45.3-24.3 (-21, n.s.). No significant side effects or adverse events were noted in either group.

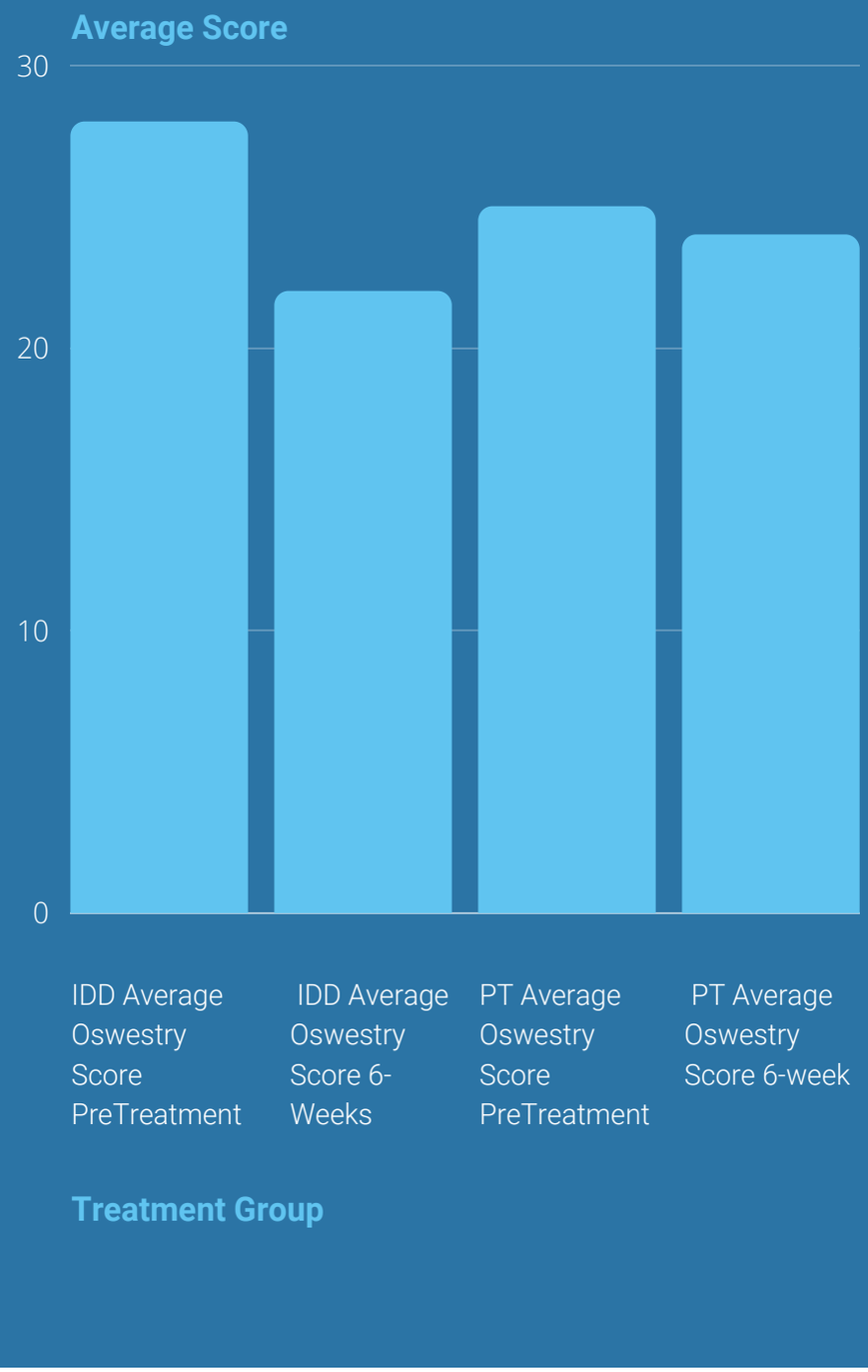
CONCLUSIONS

Patients in both groups experienced a moderate decrease in pain. Patients in the IDD group had a moderate reduction in low back pain related disability. Increased sample size and long-term data collection are necessary to corroborate these results.

American Journal of Physical Medicine & Rehabilitation

Results

Oswestry Scores IDD v PT @ Baseline and 6 weeks



American Journal of Physical Medicine & Rehabilitation

Results

Degenerative Disc Disease
Comparative Treatment Options

	Healing TX/ Time Req'd	Pt Disability Score After
Fusion surgery	24 months	> 11
IDET surgery	6 months	> 10
Physical Therapy (Exercise based)	8 weeks	10
IDD Therapy (Accu-SPINA)	**6 weeks**	**6.5**

Intervertebral Differential Dynamics- A New Direction for Initial Treatment of Low Back Pain

U.S. Musculoskeletal Review
Orthopedic Surgery
Spine PP19-22

Independent research performed on 544 patients referred for surgical intervention and treated with IDD Therapy protocols on the Accu-Spina® system instead.

AUTHOR

Dennis McClure, Indiana University School of Medicine, University of Wisconsin Hospitals -Madison
Bethany Farris, MD, University of Washington

METHOD

Pre & Post treatment analysis with 12 months post completion follow up.

CONDITIONS

Lumbar and cervical surgery candidates (PLI fusion, microdisectomy, or decompressive laminectomy)

CONCLUSION

Overall, 92% of cervical and lumbar patients who underwent IDD Therapy intervention instead of recommended surgery experiences successful outcomes.

Cervical surgery patients who completed a full course of IDD Therapy treatment instead of surgery showed an 85.5% success rate.

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**

Dennis McClure, MD, 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 imaging (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 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 facet 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 mobilise 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 behaviour and to re-educate supporting soft tissues. Since introducing IDD Therapy to the practice I have treated over 1,200 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 analysed 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 severity 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 analyses 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 analysing 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% decrease or greater in pain in order to be considered a success in this analysis. Data from the past 415 patients completing treatment was analysed 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).

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**

U.S. Musculoskeletal Review 2006

Table 2: Success Rates According to Diagnosis Prior to Treatment

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**

Of particular interest are lumbar surgical candidates, that is, 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 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 analysed and the results are as follows:

- Effects of Gender — females reported significantly higher pain after treatment, (p<.0058)
- Effects of Age (90% confidence interval) — there was a significant increase in pain after treatment as age increased, (p<.0955).
- 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) (p<.0001).
- 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, (p<.0001).
- 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. Diagnosis type Lumbar back pain Surgical lumbar candidates Cervical pain Post-laminectomies Reported success rate (%) Sample size (n) 79 330 rates were examined according to diagnosis assigned prior to treatment (see Table 2).
- 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 and attitudes, and how they may affect **IDD Therapy**.

U.S. Musculoskeletal Review 2006

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 analysed. 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, ($p<.0071$), 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 ($p<.0110$). Number of prescription medications also had a significant effect on the outcome of treatment. Patients taking more medication report significantly higher pain after treatment ($p<.0143$). 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 aspects 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, ($p<.0001$). In addition, although depression significantly affected reported pain prior to treatment, patients with depression significantly improved after treatment ($p<.0001$).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 ($p<.0002$), significantly higher on the depression scale ($p<.0001$), and report significantly higher pain ($p<.0007$).
- **Stress Effects** — Patients who score high on the Social Readjustment Scale score significantly higher on the anger assessment ($p<.0001$).
- **Anger Effects** — Patients who score high on the anger assessment score significantly higher on the depression scale ($p<.0002$).
- **Depression Score Effects** — Patients who score high on the depression scale report significantly higher pain prior to treatment ($p<.0037$).

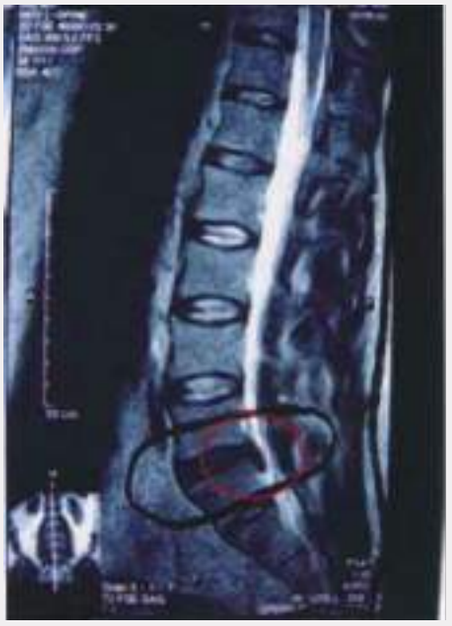


Figure 1a: Pre-treatment MR1 (02/02/05)

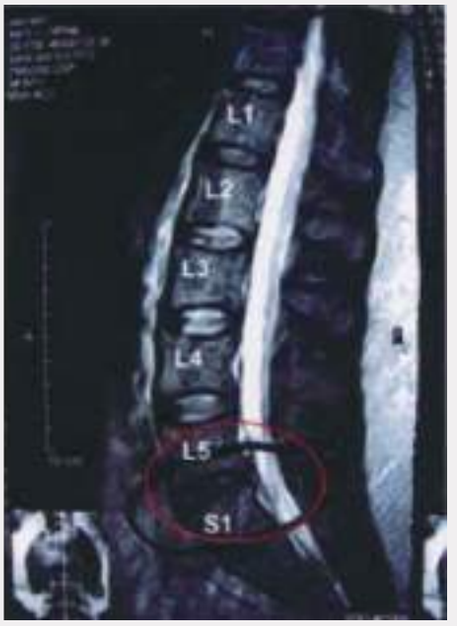


Figure 1b: Post-treatment MRI (03/14/05)

FIGURE 1: MRI EXAMPLE

A 50-year-old male with herniated disc at L5-S1. Severe law back pain radiating down into the right leg with straight leg raise of 10° (on the right). Received IDD Therapy in February 2005 and by March 2005 the patient had straight leg raises of 90 degrees and no pain.

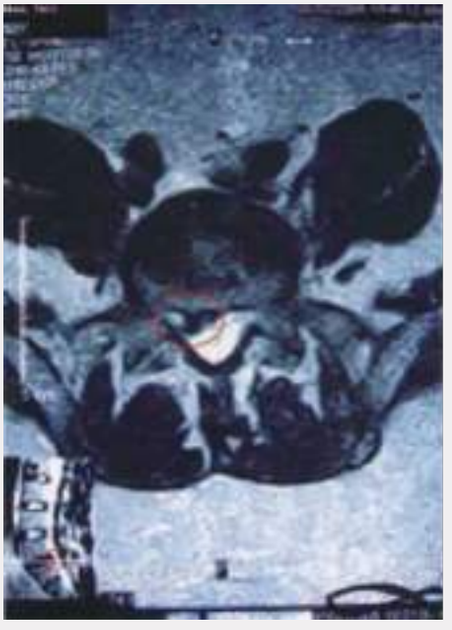


Figure 1c: Pre-treatment MRI (02/02/05)

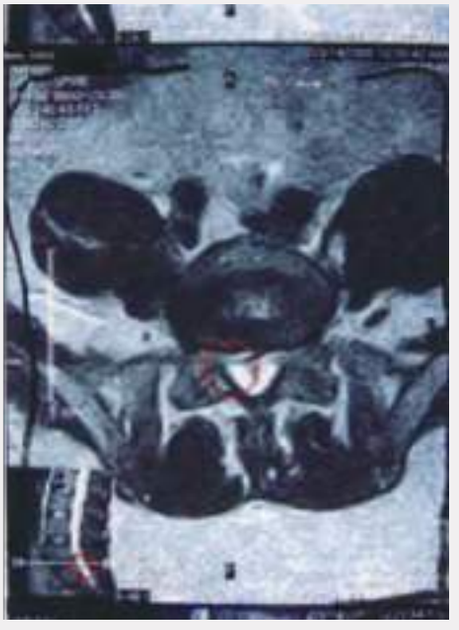


Figure 1d: Post-treatment MRI (03/14/05)

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, recognising the complexity of our patients and treatment through a more holistic approach.

U.S. Musculoskeletal Review 2006

Current Therapeutic Options for Chronic Low Back Pain: A Focus on Non-Surgical Approaches

Educational Medical Review
Albert Einstein College of Medicine

An education text drawing from research studies and clinical results. Compares a broad range of medical approaches to treating low back pain; breaks down differences in applied physical modalities including traditional traction, VaxD decompression and exercise based physical therapy versus computerized spinal mobilization with IDD Therapy treatment.

AUTHOR

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Michael K. Shaufele, M.D. Faculty, Physical Medicine and Rehabilitation Residency Harvard Medical School, Program Director Emory Spine Center

METHOD

Course director, faculty systematic review providing instructional insight on approaches to management of low back pain.

CONCLUSION

- **Traditional traction: many studies reported negative findings; others inconclusive.**
- **Spinal decompression (VaxD logarithmic): success rate of 71% reported.**
- **Fusion surgery: 70% success rate with 18% early complication rate.**
- **Computer monitored spinal mobilization (Intervertebral Differential Dynamics Therapy): 86% of ruptured disc patients achieved "good to excellent" results where "excellent" was defined as 90% or more improvement, no complication rate.**

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Albert Einstein College of Medicine

Continuing Medical Education (CME)

Current Therapeutic Options for Chronic Low Back Pain: A Focus on Nonsurgical Approaches

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Albert Einstein College of Medicine

The Significant Impact of Low Back Pain

Source: Advanstar Healthcare Communications Mediwire Network

EPIDEMIOLOGY

In recognition of the extreme burden and impact that musculoskeletal disorders have on society, the United Nations and the World Health Organization (WHO) have designated 2000 to 2010 as the Bone and Joint Decade. Musculoskeletal disorders—of which low back pain (LBP) is the most prevalent condition—are the most common cause of severe longterm pain and physical disabilityInternational studies indicate that the percentage of people that experience LBP during their lifetime ranges from 58% to 84%, (1) while point prevalence figures estimate that LBP affects an average of 30% of the population at any given time. (4) Currently, there are approximately 10 million Americans disabled by LBP(5).

The potential risk factors that increase the likelihood of developing LBP vary from smoking and obesity to jobs that require heavy lifting and job dissatisfaction.° Sixty percent to 70% of back pain patients recover within 6 weeks, and by week 12, 80% to 90% of patients with back pain have recovered. (4) However, people with low educational levels, tendencies for depressive moods and distress, obesity, and job dissatisfaction have a higher risk of having LBP develop into a chronic, disabling condition. LBP that persists for more than 3 months is considered "chronic", (2) and frequent episodes of LBP are described as "recurrent". Forty percent of patients with LBP have recurrences within 6 months. (2) The highest incidence of LBP is within the working population, persons aged 25 to 64 years. (3) Twenty percent to 44% of the working-population patients with LBP have further episodes within a year; overall, up to 85% of LBP sufferers have lifetime recurrences. (3), (4)

ECONOMICS

Back pain results in 19 million physician visits yearly, (5) making LBP second only to upper respiratory complaints in symptomatic reasons for seeing a doctor. (8) Correspondingly, the economic impact of LBP on society has been staggering. In the United States $14 billion is spent annually on the cost of care for LBP. (5) Beyond direct medical care expenditures, indirect costs for a patient with LBP include time away from work costs, disability payments, and diminished productivity. (8) Inclusion of both direct and indirect expenses for back pain in the United States yields an annual expenditure of between $20 billion and $50 billion. Approximately 2% of the American workforce is compensated for back injuries every year, (1) and it is estimated that 250 million workdays are lost annually in the United States due to LBP. (5)

A randomized, controlled trial of 681 patients published in 2005 considered the cost-effectiveness of 4 different treatment groups: simple medical care (MC), medical care with physical therapy (MC+PT), straight chiropractic care (CC), and chiropractic care combined with physical modalities (CC+PT). (9) When adjusted for covariates, average LBP outpatient costs were calculated to be $369 for MC, $560 for CC, $579 for CC+PT, and $760 for MC+PT. Patient satisfaction was rated higher for the patients given chiropractic care rather than medical treatment, (9) possibly due to the patient's perception of a more personal approach. (1) However, there were no differences in clinical outcomes between treatment groups, suggesting that a higher utilization of chiropractic care does not seem to be the most cost-effective solution to LBP. These findings corroborated the results of 2 out of 3 previous studies that found medical care to be less expensive than alternative therapies. (11) (12) A recent study in the United Kingdom (UK)—the UK back pain exercise and manipulation trial—reported the highest efficacy for treating LBP with a combined regimen of exercise and manual therapy; even each therapy separately was still moderately more efficacious than standard medical care. (13) There were only moderate additional costs incurred for the physical therapies— in contrast to the study in the United States (US). This difference may be due to the study groups; the UK study specifically defined the physical therapy treatments, while the US study included a heterogeneous collection of interventions in the physical therapy group. (10)

Furthermore, the expensive spinal-fusion operation has become a popular treatment option for LBP that has failed nonsurgical therapies. The surgery, which incurs an average hospital bill of more than $34,000 (excluding professional fees), has risen in number performed by 77% between 1996 and 2001. (14) The rates of fusion surgery have risen, in part, because of the added indication of discogenic pain, or LBP without sciatica, in patients with degenerative discs. Since back pain and disc degeneration are a natural part of the aging process, the number of potential candidates for fusion surgery is enormous. However, the high costs associated with the operation, combined with the high rates of re-operation, high incidence of operation complications, and limited support from randomized controlled clinical trials indicating efficacy for degenerative disc disease, suggests that further evidence needs to be collected to support the use of spinal-fusion surgeries for LBP. (14)

QUALITY OF LIFE

Typically, patients affected by chronic LBP have a background of pain with additional intermittent, debilitating flare-ups of pain. In fact, certain epidemiologic studies indicate that LBP would best be described as fluctuating over time with frequent recurrences or exacerbations, rather than simply as "acute" or "chronic". (7) Psychologically, this can have an impact on the activities that an LBP-afflicted individual will engage in. LBP patients can become limited by a fear of recurrence, leading to a reduction in their strenuous and leisure activities. (3) The condition can also restrict mobility and long distance vehicle travel, as well as disrupt sleep. (3) Although many people that suffer from LBP do not seek medical

care (61% never sought medical treatment for their LBP in one telephone survey) because of the brief nature of the condition, more than half of those that do seek medical care visit a primary care physician. (8) Since the majority of LBP sufferers are seen by primary care physicians, these physicians play a key role in determining where a patient is referred.

ETIOLOGY AND PATHOLOGY OF CHRONIC LBP

LBP has been defined as pain localized to the lumbosacral and paraspinal regions (5) and includes both somatic and radicular etiologies. Somatic pain originates from processes including the spine and surrounding muscles, ligaments, periosteum, facet joints, blood vessels, and intervertebral discs, (5) while radicular pain stems from neural structures. This monograph focuses on LBP that has a somatic origin.

The primary cause of low back pain is considered to be the natural aging of the discs of the spine. (15) This process results in degeneration of the discs, beginning with subtle biochemical alterations, progressing to microstructural changes, and finally leading to gross structural alterations. (15) The term "disc degeneration" covers a broad range of clinical, radiologic, and pathologic processes that can lead to the deterioration of the facets, ligaments, and muscles of the spine. At the cellular level, degeneration of the disc is caused by reduced production of extracellular matrix. (15) Degeneration is also promoted by reduced blood flow from the end plate, and the resulting lowered nutrient supply to disc cells. (15) These processes lead to macroscopic changes, which include a less distinct boundary between the nucleus and annulus, concentric fissuring and radial tears, and the loss of disc height and turgor. (15) These disc changes can have the secondary effect of increasing the load on the facets, resulting in cartilage degradation there. (15) Furthermore, a narrowing disc space within the lumbar vertebra has been strongly associated with LBP, more than other types of radiographic evidence.

Overall, the prevalence of disc degeneration and facet joint arthritis increases with age. The degeneration of the discs of the spine can become evident as early as the mid twenties and is nearly universal by age 50 years. However, typically the physical changes associated with disc degeneration are asymptomatic in most individuals. (6)

In a healthy individual, generating the sensation of pain begins with the stimulation of specialized primary afferent nociceptors in peripheral tissues. These neurons in turn create electrochemical impulses—or action potentials—that are transmitted to the dorsal horn of the spinal cord. At the dorsal horn, a complex cascade of events involving excitatory neurotransmitters (such as glutamate) and neuropeptides (such as substance P) cause the rapid depolarization of secondary afferent neurons. Subsequent action potentials are generated along the spinothalamic tract, up to the brain, where the signals are processed and interpreted as the perception of pain.

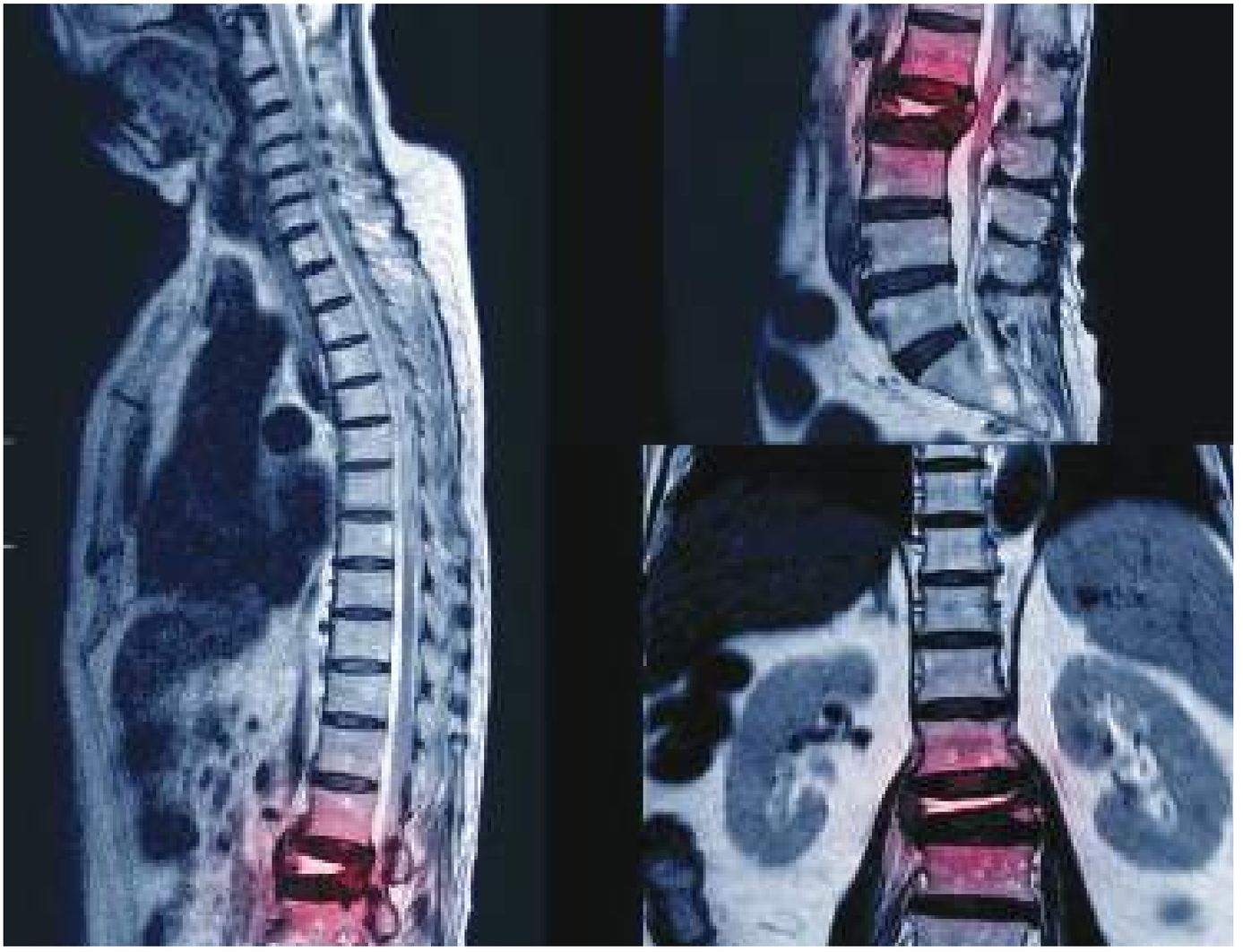
SYMPTOMS AND DIAGNOSIS

Despite advances in diagnostic and interventional techniques, it is often difficult to identify the origin of LBP. While some LBP has a specific suspected pathologic cause, the majority of cases are classified as "nonspecific back pain", (3) or labeled as musculoskeletal strain or degenerative disc disease. (8) Since the etiopathogenesis and mechanisms of the majority of chronic back pain are unknown, the therapies are often empirically based (6) and are directed at symptomatic relief.

However, it is important to efficiently identify rare, serious causes of LBP, such as neoplasia, infection, inflammation, rheumatoid arthritis, and fractures. (5), (7) Epidemiologic research in the US indicates that of all back pain patients being seen by primary care physicians, 4% have a compression fracture; 3% have spondylolisthesis; 0.7% have a tumor or metastasis; 0.3% exhibit ankylosing spondylitis; and 0.01% have an

infection. Identification of these specific causes of LBP can often be accomplished through a focused physical examination and a thorough patient history. The 1994 Clinical Practice Guideline entitled "Acute Low Back Pain Problems in Adults", detailed the symptoms that are critical to efficiently identify and that will assist in diagnosing a rare cause of LBP. These signs and symptoms include: weight loss, fever, chills, fatigue, night sweats, increased pain while supine, and recent infections, immunosuppression, trauma, or cancer. (17) Severe tenderness, bilateral neurologic deficits, saddle anesthesia, and hyperalgesia during physical examination also support the presence of a rare, underlying disorder that must be immediately identified. (17)

Patients presenting with LBP can be diagnosed through several modalities, beginning with taking a history, followed by clinical interviews and examinations, health questionnaires, pain inventories, and measurements of psychologic and behavioral dysfunction. (5) There are several measurement tools to assess the extent of LBP and to track the outcome of an intervention, including the Medical Outcomes Study 36-item short-form survey (SF-36 ®), the 12-item short-form survey (SF-12 ®) Oswestry questionnaire, Roland-Morris questionnaire, and EuroQol EQ-5D. (18-21) Following an initial evaluation, selective diagnostic testing can be used to further isolate an etiology; this testing commonly can include spinal x-rays, magnetic resonance imaging, computed tomography with or without myelography, discography, electromyography, and nerve conduction studies.(5) Infections and tumors can be screened for using laboratory techniques, (5) such as erythrocyte sedimentation rates, complete blood counts, or urinalysis. (8)



Approaches to Management of Low Back Pain

PHYSICAL MEDICINE INTERVENTIONS

A large variety of modalities is commonly used for the treatment of chronic LBP, including bed rest, activity modification, exercise therapy, and several physical interventions—heat, ice, electrical stimulation, ultrasound, TENS, and traction-based therapies. Overall, many of these treatments do not have rigorously conducted clinical trial evidence supporting their use, 29 but the available data supporting several of these physical medicine interventions are briefly discussed in the following section,

Exercise Therapies

Exercise therapy is considered a widely accepted method for the reduction of chronic LBP. 42 This type of therapy is intended to help recondition, increase the range of motion, and improve muscle strength and length. 5 However, the term "exercise therapy" encompasses a heterogeneous collection of exercises that lack definition of intensity, duration, and frequency. 42 There is no consensus on the most effective approach, nor is there a clear mechanism explaining why exercise is of benefit to LBP sufferers, to provide guidance towards defining an approach. 42 A meta-analysis of 43 randomized, controlled trials of chronic LBP patients indicated that exercise therapy can effectively reduce pain and functional limitations in the lower back, although the low quality of some of the studies limits conclusive interpretations. 43 In particular, studies reported that individually designed strengthening or stabilizing programs were effective in a healthcare setting. 43

Transcutaneous Electrical Nerve Stimulation

More than 30 years ago TENS was developed as an alternative to pharmacologic treatments for chronic pain." Despite its widespread use, there is no clinical evidence to support its efficacy for the relief of chronic LBP. A review of 5 clinical trials suggests that the technique is not effective for the treatment of chronic LBP. 5 ' 45 The clinical trials showed no significant difference between the TENS group and the placebo group.'" 45

Acupuncture Therapy

Acupuncture therapy involves the application of needles placed at specific locations on the skin 46 It has been proposed that acupuncture may provide pain relief by the gate control theory of pain (where the sensory input of needling inhibits the sensation of other inputs, ie, LBP) and by inducing the production of endorphins, serotonin, and acetylcholine within the central nervous system. 46 Data from 33 randomized, controlled trials were considered to assess the effectiveness of acupuncture at relieving LBP. 47 Measurements of pain relief, functional status, overall improvement, time to return to work, and analgesic consumption were included as outcomes. The authors conclude that acupuncture effectively relieves chronic LBP better than no treatment or sham treatment, but no more than other active therapies. 47

Massage Therapy

Massage therapy is directed at reducing muscle spasms and tension, and improving circulation. 28 The soft tissues are manipulated by hand or a mechanical device, and vary in types from Shiatsu, Swedish, and friction, to trigger point and neuromuscular. Studies indicate that massage is more effective at reducing chronic nonspecific LBP than sham treatment, but comparisons with conventional therapies have been inconclusive:48

Spinal Manipulation Therapy

Spinal manipulation therapy is a common treatment for LBP that involves a high-velocity thrust to a joint beyond its restricted range of movement. 48 The rationale for this type of rehabilitation involves reducing bulging discs, correcting the internal displacement of disc fragments, and freeing adhesions around a prolapsed disc or facet joint.48 Furthermore, other goals include relaxing entrapped synovial folds or plica, relaxing hypertonic muscles, and unbuckling motion segments that have undergone displacement. 48 Spinal manipulation has been shown to be more effective than the control comparison and just as effective as conventional therapies—such as analgesics, physical therapy, and exercise—at providing pain relief of the lower back. 48' 49

Traditional Traction Therapy

The primary rationale for traction therapy is to increase intervertebral space and the relaxation of spinal muscles. Harnesses are fitted on the lower rib cage and iliac crest for lumbar traction therapy. Force can be administered by the therapist (as in manual traction), by a motorized pulley (for motorized traction), or less commonly, by gravity (for inverted suspension), or by a pulley and weights (in bed-rest traction.) 5° It has been proposed that a traction force of at least 26% of the body weight is required to overcome friction and to begin to induce spinal elongation. 51 Forces below this value are often used as a placebo in controlled studies, 5° while traction therapies that exceed 50% of the body weight can have adverse effects. 50

A systematic review of the literature for studies conducted before February 1995 on traction therapy for the relief of back pain indicated that most studies were not rigorously conducted enough to demonstrate efficacy, and that many studies lacked power, due to small sample sizes. 50 The authors suggested that it was not possible to make a conclusive determination about the efficaciousness of traction. Further, properly designed trials were recommended to assess the effectiveness of traction therapy for LBP.

A more recent review of randomized, controlled trials on the efficacy of traction therapy identified and analyzed 13 LBP studies. Nine of these studies reported negative findings while 3 reported positive findings, and a pilot study was inconclusive. 52

The one recognized high-quality study52 was a randomized, controlled trial conducted by Beurskens and colleagues, which considered the efficacy of motorized, continuous high-dose traction for the reduction of nonspecific, chronic back pain. One hundred fifty-one patients were divided between the treatment group and a low-dose traction (control) group. The trial was not able to demonstrate a benefit in high-dose traction, when compared with the sham group. 53,

Approaches to Management of Low Back Pain

Spinal DecompressionTherapy

Vertebral axial decompression (VAX-D®) therapy has evolved from the basic rationales and methods originally used in traction therapy. This therapy uses spinal distraction to reduce intradiscal pressure by inducing disc and nerve root decompression. Ultimately this can lead to back pain relief.

During VAX-D® therapy, patients lie prone on a split table, with the upper body over the stationary portion of the table. 55, 56 Patients are required to actively participate by grasping pegs at the table's edge. Distraction tensions are applied through a pelvic harness attached to a tensionometer and by separation of the movable part of the table. 55,56 It has been shown in clinical studies to create negative intradiscal pressures, promoting the relief of chronic LBP for patients with associated leg pain. 57 Two randomized, controlled clinical studies have reported the efficacy of VAX-D® for the relief of LBP. Seven hundred seventy-eight patients undergoing VAX-D® treatment and diagnosed with herniated disc, degenerative disc, or facet syndrome were studied in data collected from 22 medical centers for one study. 58 VAX-D® therapy was successful for 71% of the patients, where success was defined as a reduction in pain to 0 or 1 on a 5-point scale. 58 Although VAX-D has widely been promoted as an effective and safe treatment for degenerated and herniated lumbar intervertebral discs, there has been a report of a single case of exacerbated radicular pain and further enlargement of disc protrusion following VAX-D therapy. This required urgent surgical intervention to lessen the potential for sudden deterioration. 59

SPINAL MOBILIZATION THERAPY (COMPUTER MONITORED)

Intervertebral Differential Dynamics Therapy (IDD Therapy ®) was developed in the late 1990s to reproducibly mobilize and distract isolated lumbar segments. A computer-directed patient harness system delivers manipulative forces to the patient lying supine. The device induces a negative pressure state that has a mobilizing effect on the disc. The pull angle can be adjusted to accommodate lumbar lordosis and allow for the greatest patient comfort while targeting the affected intervertebral segment. Furthermore, specifically applied waveform adjustments at varying angles promote intermittent force release, reducing the incidence of posttreatment flare-up and allowing for higher maximum treatment force (where target treatment force is 50% of the body weight + 10 lbs). Also, standardized IDD Therapy includes the application of heat and ice, pretreatment and posttreatment, as well as instruction in lumbar stabilization exercises. Overall, a negative hydrostatic pressure within the affected disc is reported to induce physiologic changes that ultimately relieve LBP. 60 The original clinical data on IDD Therapy ® indicated that 86% of ruptured intervertebral disc patients achieved "good" to "excellent" results with 1130 Therapy ® (where "good" is 50% to 89% improvement and "excellent" is 90% to 100% improvement).89 The active control group—which received classic traction therapy—had 55% of the patients achieve "good" results and no patients report a rating of excellent". 89

More recently, a review of results from 10 clinics confirmed the initial IDD Therapy findings, 61 as did a retrospective study of 33 patients. 62 Although 54% of the patients in the cohort had previous failed therapy for LBP, the mean improvement following IDD Therapy was 5.23 points on the Neuropathic Pain Scale. The authors recommend further clinical trials to confirm these findings. 62

Surgery

Screening a patient's history is an important step in the selection process to determine appropriate patients for surgical treatments of LBP. Patients with untreated mood disorders, opioid dependency, and/or legal claims such as workers compensation LBP should not be treated surgically for LBP. Patients with radiculopathy that exhibit progressive motor deficits and/or cauda equina syndrome should be treated with surgery to avoid long-term neurological deficits. 63 However, the majority of surgeries are performed because of lack of improvement with nonsurgical measures. Even successful surgeries have a 15% relapse rate within 4 years. 83 Some authors believe that as many as 50% of spinal surgeries are considered unnecessary and fail to provide long-term pain relief. 1 Despite this, the rate of surgical intervention for back pain in the US is at least 40% higher than in other countries. 4

For appropriately selected patients, lumbar fusion surgery can result in pain relief. A randomized, controlled, multicenter study of 294 patients with radiologic evidence of disc degeneration compared lumbar fusion therapy with physical therapy." Fritzell and colleagues reported that the surgical group had a 33% reduction in back pain, compared to 7% in the non-surgical group (P=0.0002). Pain improved the most during the initial 6 months following surgery then gradually deteriorated. Also, the disability of the surgical group was reduced by 25% compared to 6% in the nonsurgical patients (P=0.015), measured by Oswestry Disability Index. The net back-to-work rate was 36% in the surgically-treated patients, compared to 13% in the nonsurgical group (P=0.0002). The surgical group had an early complication rate of 17%." In contrast, a single-blind, randomized trial compared the effectiveness of lumbar fusion with cognitive intervention and exercises for patients with chronic LBP, and found similar effectiveness between the therapies. 65 Oswestry Disability Index scores were significantly reduced following surgery from 42 to 26, compared to 42 to 30 with the non-surgical intervention group—a mean difference of 2.3 (P=0.33). I mprovements in back pain, analgesic use, emotional distress, life satisfaction, and return-to-work were similar between the 2 therapy groups. An independent observer rated the success rate following surgery at 70% and following cognitive intervention/exercises at 76%. The early complication rate in the surgical group was 18%. 85

Multidisciplinary Approach to the Management of Low Back Pain

A comprehensive approach to pain management involving both pharmacologic agents and physical therapy methods will likely prove to be the most effective way for controlling chronic LBP. The Multidisciplinary Pain Center (MPC) is an interdisciplinary approach to the diagnosis and management of chronic pain. This model can provide a comprehensive program that addresses clinical symptoms and associated distress, dysfunction, and disability. 66 The MPC model can successfully provide pain relief, while incurring smaller long-term expenditures. A meta-analysis of the efficacy of 65 multidisciplinary treatments for chronic LBP indicated that actively treated patients functioned 60% better than control subjects on the short term. 67 Furthermore, the patients undergoing a multidisciplinary approach remained 55% better than controls on the long term and were twice as likely to return to work. 67 Comprehensive pain clinics and spine centers can provide both pharmacologic approaches and physical therapy methods to manage chronic LBP. Physical medicine approaches as adjuncts to pharmacologic therapies will likely achieve the highest success in providing relief for chronic LBP. Surgical treatments for chronic LBP should be reserved for patients with identifiable pain generators, significant functional limitations, and a favorable psychosocial profile.

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Understanding Intervertebral Differential Dynamics (IDD Therapy®)

As a medical provider, finding effective treatment plans for patients in pain is your primary goal. Surgical intervention for back pain is an all too common prescription when a patient is in pain, and even the best medical doctors suggest surgery only after all non-surgical, first-line treatment options have been exhausted.

But for those patients with chronic back or neck pain, there is a state-of-the-art alternative unlike any other that many surgeons do not know about - ***the FDA cleared and fully patented Accu-Spina® with sinusoidal oscillation IDD Therapy® protocols.***

The Accu-Spina® System is a one-of-a-kind, software-driven platform that uses advanced technology to provide an effective treatment plan for those with chronic back or neck pain. The Accu-Spina® is also the only therapeutic device that offers Intervertebral Differential Dynamics (IDD) Therapy® combined with our patented Sinusoidal Oscillation Method for lumbar AND cervical modalities.

IDD Therapy® on the Accu-Spina® System is a form of advanced spinal decompression that allows the body to heal many back and neck problems without invasive surgery, injections, or addictive substances.

HOW DOES THE ACCU-SPINA® WORK?

Using our cutting-edge Accu-Spina® System, IDD Therapy® works by administering mathematically precise treatment forces to mobilize and elongate targeted segments of the spine. The process of applying decompressive forces to the spine provides a gradual, effective distraction to the vertebral structures that may be causing a patient's pain.

During an IDD Therapy® session, the Accu-Spina® applies mathematically calculated forces to create a precise rehabilitative spinal mobilization plan (unique to the patient in that session). This calculation triggers the body's natural healing mechanisms directly at a targeted spinal segment where the injured disc is located.

The Accu-Spina® System then gently moves the vertebrae and discs to relieve pressure within the compressed structures. At the peak of each sinusoidal wave, our state-of-the-art technology simultaneously provides an additional and unique micro-vibration at the peak of each sinusoidal wave. This vibration signals the cells in each disc to take in more fluids, oxygen, and nutrients and helps enhance tissue regeneration and improve nutrient diffusion - essential to disc repair. It is this patented Sinusoidal Oscillation Method that truly sets the Accu-Spina® apart from its competitors.

It is during this process that IDD Therapy®, in conjunction with our patented Sinusoidal Oscillation Method, that rehydration begins to occur, and a rush of oxygen-rich blood travels to the primary treatment site, triggering and supporting the body's natural healing process. This course of action also relieves the concern of any muscle spasms during a treatment session.

These precursors to cell respiration act as signals for the surrounding tissues to begin their own regeneration. This dynamic process, when applied to the intervertebral structures of the spine, promotes a higher level of self-healing and rehabilitation to damaged discs and surrounding muscle tissues to more effectively relieve pain.

Our patented Sinusoidal Oscillation Method provides patients with an experience unlike any other, gives them a better course of treatment than others, and more effectively leads them to a place of long-term pain relief.

WHAT PATIENTS CAN EXPECT

The Accu-Spina® system delivers IDD Therapy® treatment through a series of exacting, sensor responsive mechanisms that create precise dynamic forces. Precisely engineered and calibrated components at the heart of the Accu-Spina® system movement create a smooth, sinusoidal motion that is soothing to the body while it gently moves vertebral segments.

Results vary for each patient, but in most cases, patients report that they feel some relief within 4-6 sessions. Some patients even report an improvement after their first treatment.

In addition:

- Treatment sessions are so comfortable and relaxing that many patients fall asleep.
- Segment-specific therapy relieves pressure from the injured disc to free the affected nerve root nonsurgically.
- Less sensitivity and pain in nerve fibers as elongation begins in the surrounding muscle.
- And pressures inside the disc begin to drop.
- Restored performance of a younger, healthier spine without the risk and expense of surgery.

92% of IDD Therapy® patients enjoy relief from disc pain.

Randomized trials suggest degenerated discs and herniated discs respond positively to treatments that properly and safely manipulate the spine.

- Research studies funded by the National Institute of Health conducted at Mayo Clinic, as well as others performed by medical doctors associated with Emory, Harvard, and other leading health institutions, confirm a dramatic reduction in pain and disability can be achieved nonsurgically with IDD Therapy® treatment on the Accu-Spina® System.
- Pre and post MRIs have confirmed a reduction in the size of disc bulges and herniations.
- Pre and post-biomechanics evaluations show dramatic improvements in range of motion, pain-free mobility, and even correction of foot drop.
- MRI's confirmed a visible increase in disc height and fluid retention after a full treatment course.
- In one independent neurosurgical study conducted on over 500 patients referred to have surgery, 92% achieved relief with IDD Therapy® instead of surgery.
- The Accu-Spina® is the only spinal therapy and decompression system to win patent after patent for exceptional disc treatment capabilities.
- ONLY IDD Therapy® on the Accu-Spina® System utilizes the patented Sinusoidal Oscillation Method that is able to yield such impressive 92% success rates.
- Multiple studies have shown IDD Therapy® is not only highly effective but also long-lasting, with most patients studied reporting that they continue to experience improvements one full year after completing their treatment protocol.

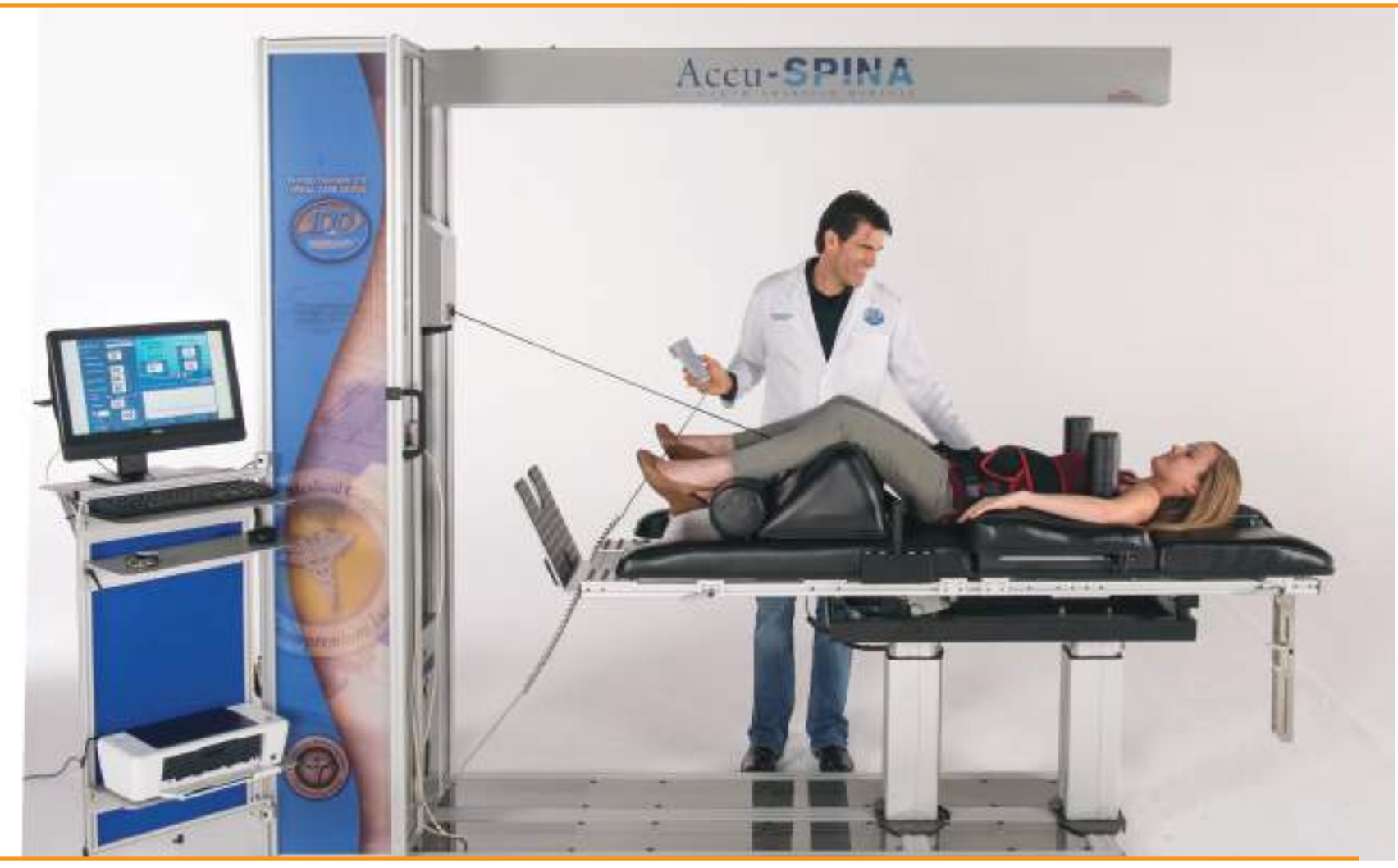
WHY SHOULD MY PRACTICE CHOOSE THE ACCU-SPINA® OVER OTHER OPTIONS?

There are many treatment options available, but not all are created equal.

For over twenty years, the Accu-Spina® System by North American Medical has maintained a reputation for superior quality with durability, scientifically rooted origins, and uncompromising integrity. The Accu-Spina® is also one of the most established and independently studied spinal therapeutic devices in use at major teaching hospitals and universities throughout the world.

The only therapeutic device certified to provide IDD Therapy® treatment which has been proven to have as high as 92% success rates, the Accu-Spina® is the only device that performs the patented Sinusoidal Oscillation Method to treat both lumbar and cervical diagnoses with technology that can ensure that each patient receives an individualized and more effective treatment plan. The Accu-Spina is also one of the most studied, safest spinal treatment systems for non-surgical disc pain relief.

With the Accu-Spina® System, there are no fancy bells and whistles to distract from the true science. Just real results from real people.



A Clinical Trial Comparing Key Diseases of Low Back Pain

Oral Presentation
Southern Medical Association
Annual Meeting

Significant pain relief for 94% of patients studied and treated with IDD Therapy treatment pointing to significant therapeutic benefits of the Accu-Spina® device.

AUTHOR

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Teaching Fellow at Harvard University School of Medicine.
Surb Guram MD. Columbia Medical School, et al

METHOD

Retrospective study of 52 patients aged 30-86, all previously referred to surgery.

CONDITIONS

Herniated nucleus pulposis (bulging disc), spinal canal stenosis, spondylosis, DDD and facet syndrome.

CONCLUSION

Intervertebral differential dynamics led to satisfactory pain relief and improved quality of life in up to 94% of patients studied.

Even patients who failed other conventional treatment approaches achieved improvement within this trial.

83% of patients who did not complete a full treatment regimen prescribed, still reported greater than 50% pain relief.

SMA
SOUTHERN MEDICAL ASSOCIATION

Oral Presentation

IDD Therapy in Back Pain Treatment: A Clinical Trial Comparing Key Diseases of Low Back Pain.

Norman Shealy, M.D., Ph.D., FACS,
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Annual Meeting
Southern Medical Association
November 12, 2005

Low back pain impacts more than 65 million Americans per year and ranks second only to headaches as the most frequent cause of pain. The most common site for back pain is the lower lumbar area because it bears the most weight and stress. Even thought back pain is rarely life threatening, the annual cost in terms of lost productivity, medical expenses and workers' compensation benefits runs into the tens of billions of dollars annually in the United States.

Although some form of spinal traction/distraction has been used for centuries, the results were erratic and inconsistent, so that most spinal specialists began to abandon this approach in the 1960s . Then, Burton and Nida introduced the concept of Gravity Lumbar Reduction Therapy. They literally strapped patients upright in a harness for eight hours a day for one to four weeks, with results best in patients with ruptured discs; but the complication of hypotension and eight hours of immobilization doomed this radical approach.

Later, a pneumatic traction/distraction device that reputedly "decompressed" the lumbar spine using a fixed table became popular. This device required the patient to actively hold themselves in the prone position by manually grasping two grips at the front of the table to counteract the traction being applied to the axis of the spine for thirty minutes. Smart et al evaluated this system at six months after the end of treatment.

Twenty seven percent (6/22) of patients reported positive responses which questions the long term efficacy of this device . Even more troubling was the observation that the prone position actually increased lumbar lordosis and that the active patient involvement makes relaxation of the paravertebral muscles difficult, clearly undesirable for optimal spinal dynamics.

In 1997, Borgmeyer and Shealy presented a significant new approach to the management of back pain. The preliminary results suggested that decompressive mobilization of the lumbar spine was beneficial in 86% of patients with ruptured intervertebral disc and 75% of those with facet arthrosis. This led to 29 patients to vertebral distraction of 7 to 15 minutes and good to excellent pain relief in 12%, 14 patients, with MRI confirmed ruptured discs. All had had surgery recommended. Only one subsequently required surgery. Of eight patients with degenerative disc disease or facet arthrosis, six achieved good to excellent pain relief.

Continuing evolution of the technology discussed above has led to further improvements in computerized physical therapy[4] of the lumbar spine. The newest devices such as AccuSPINA® deliver remarkably comfortable, smooth therapy which definitely delivers Intervertebral Differential Dynamic, IDD®, therapy. IDD Therapy® does not require active participation of the patient in order to achieve the desired effects.

Comfort during the treatment has improved as well as the ability to focus on specific spinal structures with optimum mobilization and clinical relief. Forces applied to vertebral levels are precise, graduated, and reproducible.

I have been able, as an independent consultant, to review results currently being reported from ten clinics in over 500 patients. Improvement rates of 65 to 88% confirm my earlier results. Of considerable importance is the fact that patients who receive the recommended 20 IDD treatments improve much more than those who receive less. For reasons that are not obvious, some patients do not complete the treatment protocol despite the fact that they are improving.

Annual Meeting, Southern Medical Association, November 12, 2005

More importantly, the study cited demonstrates average pain reduction of 76% one year after treatment which indicates this may be a curative treatment and differentiates IDD Therapy® from previous technology which reports palliative effects [6].

Current exploration of vibration, heat, interferential stimulation, distraction, oscillation and other adjunctive mobilization adjustments offer even greater potential for the future of Intervertebral Differential Dynamic Therapy. [6]

Presented here is a retrospective study of 52 patients treated at two clinics. Fifty-seven percent were female and 43% were male, ranging in age from 30 to 86.

This is the first study of its kind to focus a data compilation of specific diseases, specifically spinal canal stenosis, spondylosis, degenerative disc disease, facet syndrome, and herniated nucleus pulposus.

Only 25% of patients completed all 20 treatment sessions, but 94% of the patients achieved improvement in pain and 83% achieved 50% or greater pain relief. The overall pain relief is significant at the 0.001 level. Interestingly, patients with facet syndrome improved even more than those with degenerative disc disease. These statistics compare favorably with those achieved by surgical intervention, with far greater safety and considerably lower costs. [6]

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SUMMARY

During the past decade, the Accu-SPINA® has markedly increased successful outcomes of nonsurgical physical therapeutic mobilization for spinal pain, including ruptured discs, as well as locked and degenerative facet pain syndromes.

Specific individual spinal segment dynamic mobility has lead to satisfactory pain relief and improved quality of life in up to 94% of patients, many of whom have failed other "conventional" approaches.

This pain relief is significant at the 0.001 level. Intervertebral Differential Dynamic Therapy, IDD®, appears to be the current optimal recommendation for most lumbar pain syndromes and should be considered before surgical intervention, except in those patients who have nerve root symptoms requiring intervention.

While this is a very supportive retrospective study, which points to significant therapeutic benefits of the Accu-SPINA®, additional controlled prospective studies are being conducted to more effectively quantify these promising indicators.

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IDD THERAPY FOR TREATMENT OF PAINFUL

Lumbar Degenerative Disorders

White Paper Review

A multi-center, prospective outcome study conducted with ten private practice medical doctors in the fields of rheumatology, neurology, orthopaedic, internal medicine and pain management collaborating to evaluate the therapeutic effect of IDD Therapy decompression treatment on the Accu-Spina device.

AUTHOR

Michael Schaufele, M.D. Physical Medicine and Rehabilitation Residency Harvard Medical School, Director Spine Center Munich, Program Director Emory Spine Center

METHOD

409 patients enrolled. Average age 57 years. Physical examination and appropriate imaging.

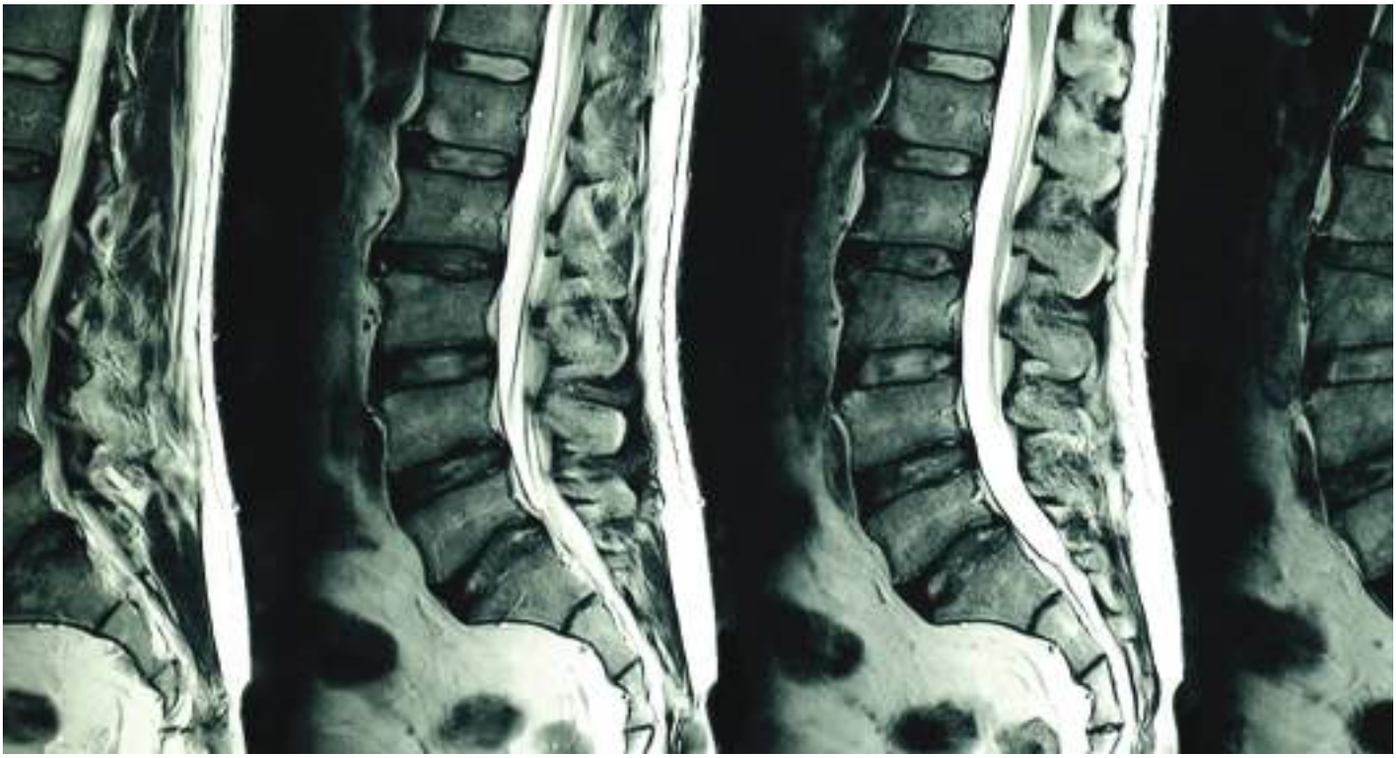
CONDITIONS

Painful lumbar degenerative conditions.

CONCLUSION

Significant functional improvement throughout full treatment course of 20 sessions

WHITE PAPER



IDD Therapy For Treatment Of Painful Lumbar Degenerative Disorders

Michael K. Schaufele, MD;

Physical Medicine and Rehabilitation Harvard Medical School, Director Spine Center Munich, Program Director Emory Spine Center

BACKGROUND:

Chronic low back pain is one of the most common complaints of patients requiring medical care. The cause of the chronic low back pain is often poorly understood. However, degenerative conditions of the spinal segment are probably the most common structural causes of chronic low back pain. The pain can be caused by degenerative changes of the disk itself, but degenerative changes in other structures of the spine, such as the facet joints, can contribute to the pain syndrome.

Multiple treatment options have been advocated over the years, including relative rest, activity modification, medication such as anti-inflammatories and muscle relaxants, exercise therapy, physical therapy, including modalities (hear, ice electrical stimulation, ultrasound, TENS units, tractions), chiropractic care, spinal injections and surgery.

The goal of this study is to evaluate the therapeutic effect of the new medical device, which is intended to give patients with chronic love back due to degenerative causes a non-surgical treatment alternative. IDD Therapy treatment uses controlled distraction of the affected lumbar spinal segments through a motorized cable/harness system to cause the decompression effect on the disk by creating a negative pressure within the disk. This negative pressure may increase the water content and the shock-absorbing qualities of the disk, which may result in decreased low back pain. Previous studies have demonstrated that forces in excess of 26% body weight have a distraction effect on the lumbar spine3. 60-80 pounds of weight result in an average vertebral distraction of 0.2 mm per lumbar spinal segment 2.

METHODS:

A prospective outcome study was conducted on patients with chronic low back pain due to degenerative disc disease, herniated nucleus pulposus and facet arthropathy. Between March 2003 and January of 2004, ten physicians in private practices across the United States, with a high volume of patients with spinal disorders, participated in this study. Specialties included Inter Medicine/ Rheumatology, Neurology, Orthopaedic, and Pain Management. Prior to entering the study, the patients were evaluated by the physician and diagnosed with a painful lumbar degenerative condition based on history and physical and appropriate imaging studies. Prior to each treatment, the patients completed an Oswestry Disability Index (ODI) questioninaire1. The ODI scores range from 0-50. A change of more than 4 points is considered clinically meaningful 4. Each patient was treated for 25 min with decompression force of approximately 50% of their total body weight in the device. A total of 20 treatments are recommended over s six week interval.

RESULTS

A total of 409 patients entered the study. The patients' average age was 57.0 years. 45 patients (63.4%) were female. The average patient's weight was 181.4 pounds. The average ODI improved from 32.3 (SD 11.3) to 13.8 (SD 9.6) in all patients. 72 (17.6%) patients completed a total of 20 treatments, 67 patients improved (93%, greater than 4points improvement on ODI). The mean ODI improved from 34.4 (SD 10.9) to 13.8 9SD 9.6) in these patients (see graph below).

No complications were observed. A temporary increase in pain immediately after the treatment session was common, but usually subsided quickly.

CONCLUSION

Patients with painful degenerative spinal disorders treated with IDD Therapy showed significant functional improvement in the prospective multi-center study. Controlled, randomized studies are necessary to corroborate these results and to determine the long-term, treatment effects of this non-invasive treatment device as well as the optimal number of treatment sessions. Biomechanical studies may be helpful to identify the cause of the observed treatment effect.

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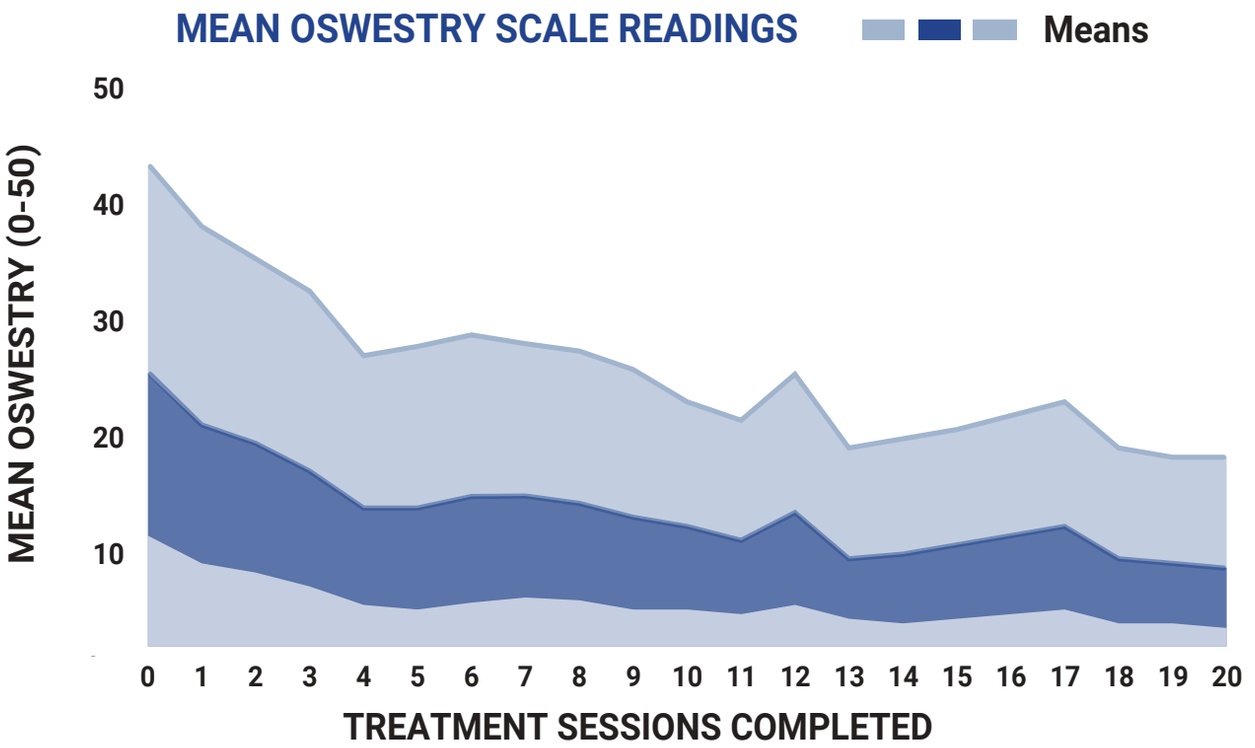

LONG-TERM EFFECT ANALYSIS OF IDD THERAPY IN LOW BACK PAIN:

A Retrospective Clinical Pilot Study

American Journal Pain Management Vol. 15 No.3

An analysis of the duration effect of intervertebral differential dynamics (IDD Therapy) documented in patients who had failed to achieve relief with other treatment approaches

AUTHORS

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Nirman Koladia, MD, Rutgers University
Merrill M. Wesemann, MD Indiana University School of Medicine

METHOD

Study in conventional physical therapy candidates with low back pain administered IDD Therapy instead.

CONDITIONS

Back pain pathologies ranging from L1-S1 including DDD, HNP & non-specific.

CONCLUSION

- Results revealed initial improvement of 4.46 on numeric pain scale from first to last treatment session
- Patients completing IDD Therapy® treatment continued to improve even one full year after finishing last session.

PILOT: Preliminary Findings

LONG-TERM EFFECT ANALYSIS OF IDD THERAPY IN LOW BACK PAIN: A RETROSPECTIVE CLINICAL PILOT STUDY

C. Norman Shealy,[1] MD, PhD, Nirman Koladia,[2] MD, and Merrill M. Wesemann,[3] MD

ABSTRACT

An analysis of the duration effect of intervertebral differential dynamics therapy (IDD Therapy®), to ascertain the benefits of rehabilitation treatment is presented. Patients from a private practice clinic were administered IDD Therapy®. The treatment was evaluated on 33 patients (17 females), using a numeric pain scale at the first session, last session, and at one year. The mean age of the patients and duration of treatment were 73.49 years (SD = 6.87) and 362.00 days (SD = 148.48), respectively. The mean pain level for the first session (FS), last session (LS), and at one year (1yr) were 6.88 (SD = 2.47), 2.42 (SD = 2.18) and 1.65 (SD = 2.47), respectively. Improvement in pain scores of 4.46 (FS - LS) were noted and corresponded with a previous study. Improvements of 5.23 (FS - 1Yr) and 0.77 (LS - 1 Yr) established that benefits continue after the treatment completion. This correlates to a reported 76% decrease in pain one year after the last therapy session. Of the patients enrolled, 54% (18/33) improved by 5.23 points on the scale (mean improvement) after previous unsatisfactory treatments for low back pain; these previous treatments included vertebral axial decompression (VAX-D), traction, and other modalities.

DESCRIPTORS

IDD, intervertebral differential dynamics, low back pain, traction, vertebral axial decompression

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Reprints: www.AJPMOnline.com

INTRODUCTION

Low back pain is one of the most common problems treated by orthopedic surgeons. Eighty percent of adults will experience significant low back pain sometime during their life. Second to the common cold, problems caused by the lower back are the most frequent cause of lost workdays in adults under the age of 45 (1).

1.Duke University School of Medicine, 2. Rutgers University, 3. Indiana University School of Medicine

INTERVERTEBRAL DIFFERENTIAL DYNAMICS THERAPY

Intervertebral differential dynamics (IDD) therapy is a physical modality, which is capable of isolating a lumbar vertebra (L1, L2, L3, L4, or L5) and mobilizing the vertebrae. The treatment can be utilized to alleviate the pain emanating from an injured disc by distracting and re-positioning of the surrounding vertebra. The distraction, on average, is between 5 and 7 millimeters. The 25 to 30-minute treatment utilizes variable therapeutic forces on structures that may be causing low back pain.

The protocol is termed IDD Therapy®. The treatment objectives of IDD Therapy® are comparable to a conventional physical therapy regimen, whereby the pathology may benefit from a rehabilitative approach. One of the primary differences with this approach is this technology enables the physical modality to be computer directed, and is, therefore, highly duplicable.

The treatment regimen is selected by the therapist according to the diagnosis presented. The treatment objective for facet syndrome is to mobilize the facet thereby relieving dysfunction. In cases where a disc is compressed, a treatment protocol may be utilized specifically targeted to the relief of intradiscal pressure. Protocols intended for this application emphasize a spinal pumping effect to promote retraction of a herniated nucleus pulposus (2).

In some cases, intradiscal pressure levels may be diminished from positive 25 millimeters of mercury to negative 150 millimeters of mercury.

This negative pressure promotes the diffusion of water, oxygen, and nutrients into the vertebral disc.

Degenerative disc pathologies may also be treated more effectively than with conventional physical therapy by utilizing a protocol targeted at disc rehydration and re-positioning of the vertebra at the affected disc level.

OBJECTIVES

The objectives of this study were (i) to produce a follow-up to the Shealy and Borgmeyer Study (3), (ii) to evaluate longterm benefits of IDD Therapy® treatment, and (iii) to determine any benefits of IDD Therapy® in comparison to other treatment options. In 1997, Shealy and Borgmeyer presented a significant new approach to the management of back pain (3). Their preliminary results suggested that decompressive mobilization of the lumbar spine was beneficial in 86% of patients with ruptured intervetebral disc and 75% of those with facet arthrosis (3). The present study served as a follow-up to the previous study.

IDD Therapy®, as previously explained, is a modality that utilizes a technology designed to conjoin the successful protocols originally set forth by Shealy, with an expanded physical therapy component to address the pathogenesis of low back pain conditions. We expected therefore, the treatment benefits should continue after the sessions are over, this study aimed to find out the level of such long term benefits obtained.

There is anecdotal observation amongst IDD Therapy® clinicians that IDD Therapy® treatment benefits many patients who have failed with other treatment modalities, including traction, vertebral axial decompression, conventional physical therapy, NSAIDs and corticosteroids. This study also aimed to serve as a pilot to evaluate this observation.

METHODOLOGY

Patient selection. The investigation presented was a pilot study to establish the maintenance of the therapeutic effect of IDD Therapy® at one-year follow-up. The authors expected that the private practice sample chosen would not be very different from a randomized sample. The ideal random sample for IDD Therapy® treatment would be patients suffering from low back pain.

The patients were selected from a private practice clinic from a group of patients who may otherwise have been referred for conventional physical therapy rehabilitation and who, instead, were prescribed a computer directed regimen with IDD Therapy® technology best suited to their specific pathologies. This sample should closely represent the ideal sample because IDD Treatment is prescribed to patient suffering from low back pain, with or without previous treatments. A bias would be potentially manifested if the patients presenting to this clinic were significantly different from the general population of such patients, which in the authors' opinion, is but a slight possibility considering the setup and location of the medical practice.

Inclusion/exclusion criteria. Patients with low back pain, with/without previous failed attempts with other treatments, were included in the study. The study included patients of all ages, gender, and ethnicity. Patients with severe osteoporosis, vertebral fractures, spondylolisthesis (grade 2 or higher), unstable post-surgical conditions, any kind of surgical hardware, vertebral fusion (within 6 months), and spinal instability were excluded. Patients who could not provide a legal consent were also excluded.

Protocol. The included patients were administered the appropriate IDD Therapy® treatment protocol; administered via the IDD Therapy® approved equipment. The parameters of the protocol involve treatment time, treatment intensity, and positioning angle (4). These parameters are set on the basis of pathology, vertebral level indicated, and patient characteristics (4). Twenty treatment sessions are recommended within a 4-6 week range, provided that early evaluation is showing a positive patient response. Patients with protocol deviations were dropped-out of the study (see also, Results).

Pain scale and endpoints. The pain scale selected for this study was the numeric pain scale (NPS) (5). Each patient was asked to delineate her/his pain intensity from 0-10 (0- no pain, 10-most unpleasant pain imaginable) on the administered NPS. The first NPS evaluation was administered before the first session of IDD Therapy® treatment.

After completion of the full regiment, the second NPS was administered and designated last session. After an average of one year subsequent to the last treatment, the patients were again administered the NPS for the third time.

RESULTS

The study was initiated with 35 patients. Two (2) patients were dropped from the study because they could not complete the treatment. Therefore, the total number of patients completing this treatment was 33. Nine (9) patients could not be contacted for the 1-year follow-up. This left 24 patients that could be assessed for the 1-year duration effect analysis.

Of the 24 patients (17 female and 18 males), the mean age was 73.49 years (SD = 6.87). The last treatment sessions were completed between November 8, 2002 and March 5, 2004. The date of the first session was 4-6 weeks before the last session for each patient. The date for 1-year duration effect analysis was May 18, 2004. The mean duration for the study group was 362.00 days, or approximately 1 year (SD = 148.48). The average number of sessions per patient was 19.24 (SD = 5.44).

The mean pain level (Figure 1) for the first session was 6.88 (0-10 NPS, SD = 2.47). The mean pain level for the last session and 1-year duration effect analysis were 2.42 (SD = 2.18) and 1.65 (SD = 2.47), respectively. Therefore, the mean improvement for the first session to last session was 4.46 ($p<0.01$), and the mean improvement from the first session to 1-year duration effect analysis was 5.23 ($p<0.01$), a 0.77 improvement over the last session. This correlates to a reported 76% decrease in pain one year after the last therapy session.

The vertebral levels were L1 through S1. Previous treatments involved acupuncture, back support, back surgery, chiropractic, epidural block, pain medication, conventional physical therapy, and trigger point therapy. Forty-five percent (16/35) of the patients had previous treatments before being enrolled into the present study.

CONCLUSIONS

The study results have revealed an improvement of 4.46 points (on the NPS) from the first session to last session. An overall improvement of 5.23 points occurred from the last treatment session to the 1-year duration effect analysis. Improvement from the last treatment session to the date of the 1- year duration effect analysis was 0.77 points. A direct conclusion that can be drawn from the data is that improvement in pain continues after the treatment sessions are completed.

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DISCUSSION

Possible explanations of the conclusions drawn from this study regarding prolonged therapeutic effect phenomenon include (i) an etiological solution to the pathology being achieved during the session which slowly leads to the decrease in pain, (ii) the patient adapting to pain over time, or (iii) the patient undergoing other treatments. Further trails should be designed to address these possible theories.

Forty-five percent (16/35) of patients in this study were administered their IDD Therapy® after previous treatments of low back pain. The average improvement of 5.23 points on the NPS suggested that IDD Therapy® benefits patients when other treatment options have failed.

The results of this study beg the questions - could IDD Therapy® computer directed physical therapy protocols lead to prevention of reoccurrence in patients that have been treated by IDD Therapy® protocol equipment, and could these treatment protocols prevent the pathologies of back pain, before the first occurrence.

This study involved only 35 patients; a large study should be devised to confirm further the results and address the explanations proposed. **Disclosure.** The authors have a proprietary interest in IDD Therapy®.

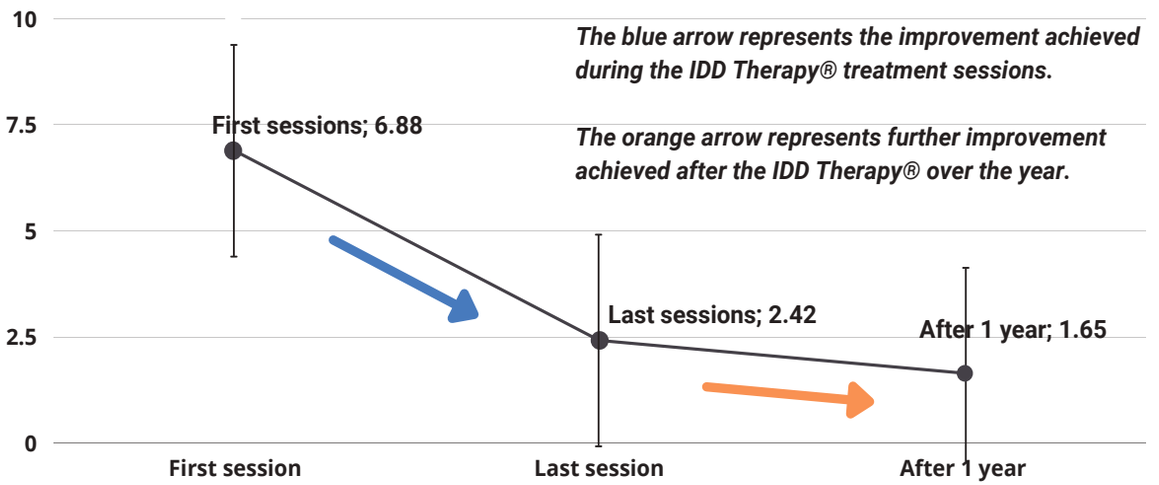


Figure 1. The chart shows mean NPS of 6.88 at the beginning of IDD Therapy® treatment after the completion of treatment the mean NPS is reduced to 2.42 (last session). After a duration of one year the patients continue to improve and the mean NPS is 1.65.

Total Resolution of Posterior Disc Herniation after Failed Spinal Surgery

Case Study Report
Dr. Robert Shalaby, M.D.

A Case History of Patient Suffering of Multiple Failed Back Surgeries Ultimately Resolved with an Extended Course of IDD Therapy® treatment.

AUTHOR

Dr. Shalaby graduated from Mohammed Bin Rashid University of Medicine and Health Sciences, Dubai United Arab Emirates, multi-disciplinary clinical training in orthopedic surgery, general surgery and pain/rehabilitation. Licensed to practice in the US, England, Egypt, and Canada.

METHOD

Pre - Post MRI

CONDITIONS

Multiple failed back surgeries (no hardware)

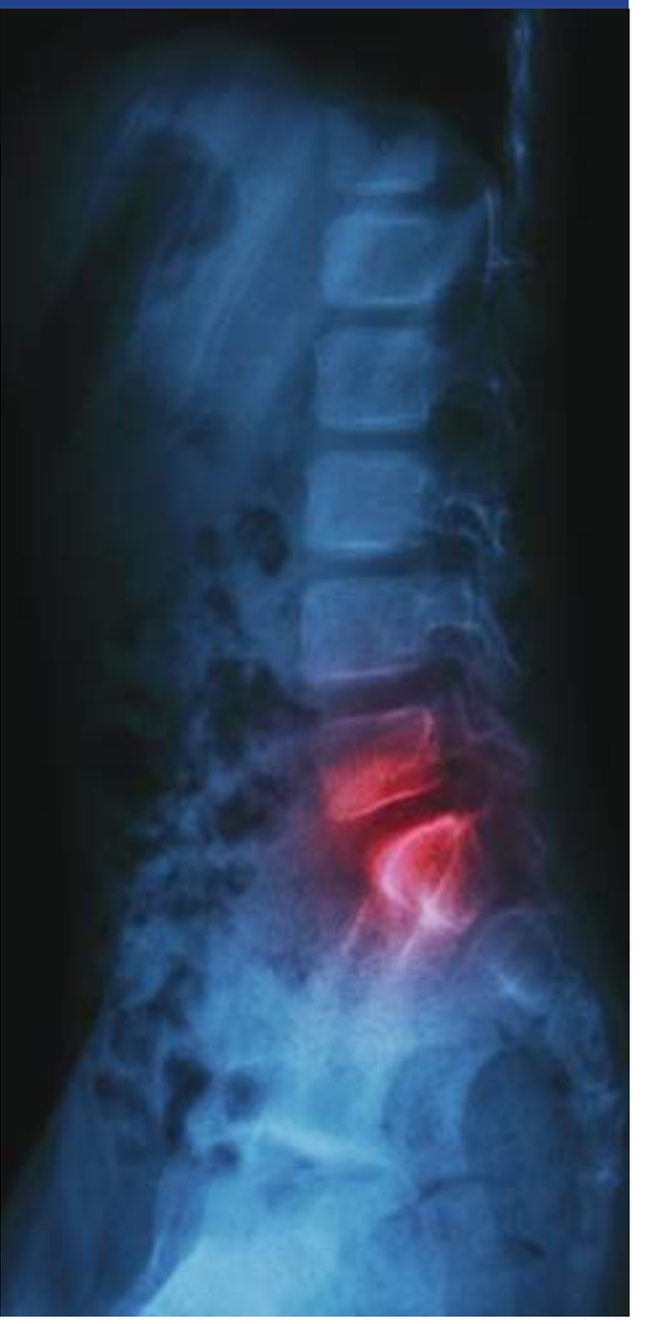
CONCLUSION

Extremely painful, severe cases that have failed to improve with surgical interventions may still achieve successful relief with a conservative, extended-dose regimen of IDD Therapy® treatment.

Case Report

Total resolution of posterior disc herniation after failed spinal surgery: A retrospective IDD Therapy® case study using MRI and other investigations

Abstract



INTRODUCTION

We studied the case of a 44-year old woman, who has 3 sons and a daughter, university level education, who is at present a housewife.
Four years ago she started suffering from severe low back pain radiating to both lower limbs but more to the left side. She was asked by her surgeon to perform an M.R.I. which showed a large L4, L5 posterior & posterolateral disc herniation, she had an open discectomy at that time.
After one year of the surgery she started to feel the pain again in the same area which gradually increased over the following two years, incapacitating her (bed bound). She was asked by her surgeon to perform a repeat discectomy with spinolaminectomy and release the adhesions.
Six months following the second procedure the pain started again & the M.R.I. showed recurrence of the L4, L5 Posterior & postero-lateral disc herniation. The M.R.I. reports were sent to a hospital in Germany, they recommended a fusion at L4-L5 as the last resort.
At this time she came to our clinic to ask whether there was any solution to her problem instead of the surgery. She was treated with our ISYS treatment protocol, central part of this protocol is IDD Therapy®. The results show great improvement (as follows).

METHODS

At the initial assessment she reported that she suffers from low back pain referring to both lower limbs which affected her daily living activities, she also said that the pain is intolerable in the mornings so that it prevents her from getting out of bed (it took three hours before the stiffness abated, and she can fully stand).

PHYSICAL EXAMINATION

- **Range Of Motion: there was limitation in the flexion range up to 3/4 of the normal range & the extension range is totally lost due to severe pain**
- **Palpation:**
  - Active trigger points at left quadrates lumborum, multifidus.
  - Iliotibial band & Pyriformis.
  - Difference in the level of both pubic bones with a superior left.
  - Some trigger points around right & left adductors origin.
  - Prominence of right sacral base.
- **Neural examinations:**
  - Dermatomes: Pain in the areas of L4, L5 dermatome of the left leg.
  - Myotomes: Normal.
  - Neural tension: Left SLR 10
    Right SLR 40
- **Muscle Function: There was muscle imbalance in the following areas:**
  - Gluteus maximus inhibition & Ilio psoas shortening.
  - Weakness of Gluteus medius with hyper activation of Ilio tibial band & adductors
  - Shortening of the left Piriformis

CONCLUSIONS OF THE EXAMINATION

- **Posterior & left posterolateral disc herniation.**
- **Adhesions of the left Sciatic nerve at its origin.**
- **Pubic shear & posterior sacral torsion.**
- **Many patterns of muscular imbalance**

TREATMENT SUGGESTIONS

- **Decrease disc herniation through decreasing the intervertebral pressure especially between L4&L5.**
- **Break down the adhesions around the left sciatic nerve.**
- **Regain the normal curve of the lumbar region & promote anterior torsion of the sacrum & extension of the lumbar region.**
- **Muscle re-education.**

This needed a treatment program consisting of 40 sessions.

THE TREATMENT PROTOCOL IN BRIEF

In the first session we started as follows:

- **Proprioception inhibition and neural exhaustion using PRO-Genesis Mainframe Electroceutical system followed by**
- **Neural block using an Electroceutical current on the sciatic nerve root for 30 minutes.**
- **Intervertebral Decompression (I.D.D) with initial tension of 50lbs. which is increased every two sessions by 5lbs. till we reach half of the body weight in 20 sessions, the patient experienced severe spasm during the first 10 sessions but this spasm decreased gradually as treatment progressed (Spina-System Accu-Spina® by North American Medical)**
- **Ice therapy to decrease pain & inflammation after the decompression for 10-15 min.**
- **Photon Nerve Stimulation using a 90 watt impulse photon emission device on the left & right nerve roots at the level of L4, L5 for 10 min, 100 joules on each point.**
- **After 10 sessions we started mobilization of the sciatic nerve to increase its extensibility & to break down the adhesions around its roots through passive S.L.R. & oscillatory dorsi flexion.**
- **We started also applying pressure on the active trigger points.**

After 20 sessions we assessed the pain again using the V.A.S, it had decreased up to 2 on the scale but at this time she fell down at home so the pain increased up to 3.5, the Oswestry was 1 at this time , she could do full trunk flexion, half of the range of trunk extension & S.L.R. of 70 degrees.

At the beginning of the following 20 sessions we took a break for 4 days after her falling down to give her chance to take some rest & then started again the same previous program for 5 sessions then the program was continued as follows:

- **Same as before using a tension of 92lbs. on the IDD Therapy®.**
- **Manipulation to symphysis pubis & sacroiliac joint for 5 times.**
- **Stretching of shortened muscles & re-education of the inhibited muscles (Piriformis, Q.L, T.F.L., adductors, Gluteus maximus, medius, and hamstrings).**

At the last ten sessions we increased the tension of the IDD Therapy® up to 100lbs. (half body weight+10) and she didn't experience any pain.

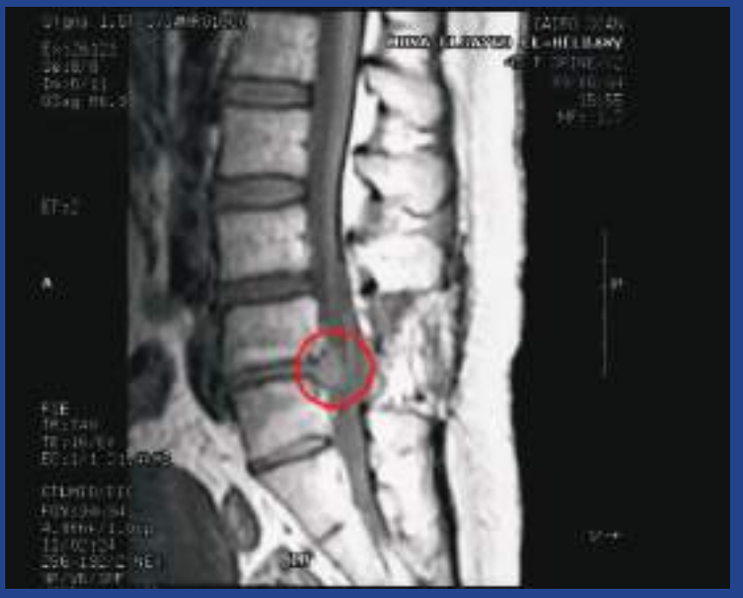
Results

PRE-TREATMENT (NON MRI)

The visual analog scale (V.A.S.) was 9.9 out of 10, The Oswestry functional scale was 9.4 out of 10. Testing for Range of Motion - there was limitation in the flexion range up to 3/4of the normal range & the extension range is totally lost due to severe pain.

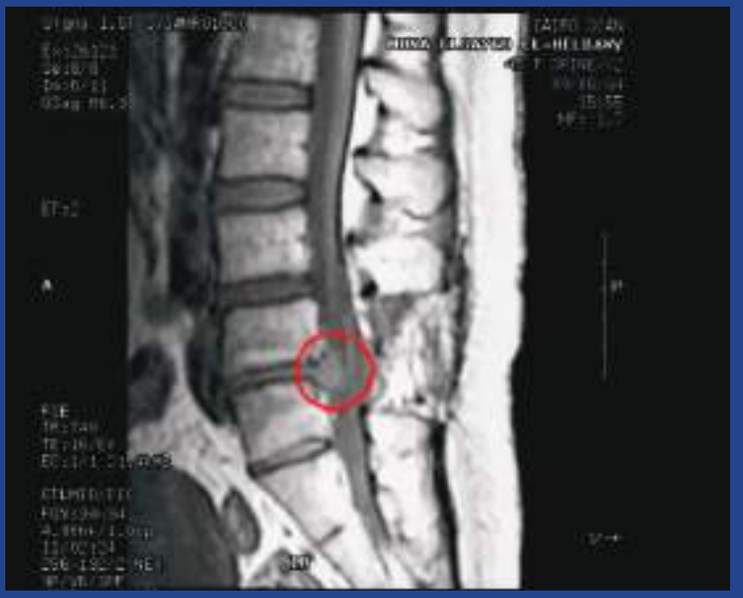
POST-TREATMENT (NON MRI)

Pain on the V.A.S was 0. The Oswestry functional scale was 0. Flexion was full, free of pain range of motion. Extension ¾ of the normal range of motion. S.L.R. was 90.



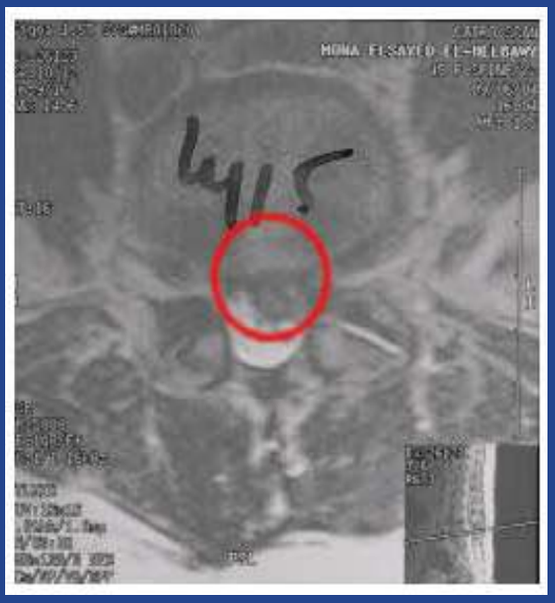
(MRI) LONGITUDINAL PRE-TREATMENT

The MRI to the left shows a bulging disc (circled in red) located between the 4th and 5th lumbar vertebrae. The lumbar vertebrae are white and rectangular shaped. The discs are located between the lumbar vertebrae and are gray with a distinct darker outline. Please note that the herniated disc has a disrupted border on the right side of this image.



(MRI) LONGITUDINAL POST-TREATMENT

In the MRI to the left the distinct border of the disc is intact. The MRI has no abnormal findings and the herniated nucleus pulpusus has resolved.



TRANSVERSE POST-TREATMENT

The MRI to the left has no abnormal findings and the spinal canal (circled in red) which appears as a white circular object is no longer obstructed.

TRANSVERSE PRE-TREATMENT

The MRI to the left shows a herniated nucleus pulposus between the 4th and 5th lumber vertebra. A normal spinal canal appears as a white circle on an MRI. This MRI clearly shows dark gray material obstructing part of the spinal canal (circled in red).

DISCUSSION AND CONCLUSIONS

Results clearly indicate that IDD Therapy® has benefited this failed surgery patient. Improvement on the VAS Scale is 10 which is highly significant [3], a 2 point improvement on VAS is considered significant improvement. Additional investigations including Oswestry and others also show significant improvement.

MRI: The report was done by the same center that did the pre-treatment films showing quote “Complete disappearance of the recurrent L4-L5 posterior and posterior lateral disc herniation and healing of the scarring around the Dura”. Original pre-and post MRI’s and have been attached (results) with these abstract show complete improvement (Figure 7, 8).

This study shows that extremely painful, severe cases that have failed to improve with surgical intervention may still achieve successful relief with a conservative, non-invasive high-dose regimen of IDD Therapy® treatment (provided there is no surgical hardware implanted). In this case study, we significantly increased the quantity of treatment sessions from the standard 20 treatment.

The integration of IDD Therapy® treatment protocol in a case such as this, allows us to infer it is possible that the gentle nature of the sinusoidal oscillation waveform created by the Accu-Spina® device offers unique treatment variations. When faced with a particularly challenging patient case, this clinician was able to achieve dramatic results with extended treatment sessions (rather than attempting application of extreme dynamic forces) which could yield superior results when tissues have been compromised by surgery.

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PRE-MRI

CAIRO RADIOLOGY CENTER
CAIRO SCAN

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كايرو سكان

DIAGNOSTIC RADIOLOGY & IMAGING (MRI - CT) UNIT

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Dr. A. SELIM	M.D.	Dr. M. MAHFOUZ	M.D.
Dr. H. KIKI	M.D.	Dr. H. ATTIA	M.D.
Dr. A. DARWICH	M.Sc.	Dr. A. TAHA	M.D.

INTERVENTIONAL & VASCULAR RADIOLOGY :

Dr. M. MOSTAFA M.D.

REPORT

Patient's name : MRS. M[redacted]
Date : 9.6.2004
Ref. Physician :

MRI EXAMINATION OF THE LUMBAR SPINE

TECHNIQUE OF EXAMINATION:-

Sagittal T1 and T2 WI (plate 1,2).
Axial T1 and T2 WI (plate 3,4).
Sagittal , axial post GD DTPA , T1 WI (plate 5,6).

MRI FINDINGS :-

Post operative status with spinolaminectomy at L4-5 level .
Straightened lumbar lordotic curvature .
L4-5 posterior and left posterolateral disc herniation is seen obliterating the anterior epidural fat compressing the left ventrolateral aspect of the thecal sac.
Reduced height and bright T2 signal of L4-5 and L3-4 discs with subchondral fatty marrow conversion of L4-5 opposing vertebral end plates.
No MRI evidence of significant scar tissue formation, or disc space infection.
No paraspinal abnormality detected.

OPINION:

Status post operative showing:
L4-5 posterior and left posterolateral disc herniation.

DR. HASSAN [redacted] M.D.

REV.
REF.A.M/04

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Maadi Branch : Maadi Corniche El Neel - Tel: 5269955 -44

المركز الرئيسى : ٣٥ شارع سليمان أباظة - المهندسين - الجيزة
ت : ٧٦١٦٧٧٠ - ٣٣٨٠٤٠٥/٦/٧/٨/٩ - فاكس : ٧٦٠٢٥٣٦
فرع برج الأطباء :٥٥ ش عبد المنعم رياض-المهندسين - الجيزة
ت : ٣٠٥٥٩٧٠/١/٢/٣/٤ - ٣٤٥٨٤٧٧ - فاكس : ٣٠٢٥٢٣٠
فرع العباسية :٩١ ش العباسية ت :٦٨٥٥٠٦٩- فاكس:١٠٠٠٦٨٦
فرع المعادى : كورنيش النيل أول طريق المعادى ت: ٤٤ - ٥٢٦٩٩٥٥

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Figure 7

Post IDD Therapy-MRI

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Dr. H. KIKI	M.D.	Dr. H. ATTIA	M.D.
Dr. A. DARWICH	M.Sc.	Dr. A. TAHA	M.D.

INTERVENTIONAL & VASCULAR RADIOLOGY :

Dr. M. MOSTAFA M.D.

REPORT

Patient's name : Mrs. M[redacted]
Date : 12.10.2004
Ref. Physician :

FOLLOW UP MRI OF THE LUMBAR SPINE

Technique of Examination:

- Sagittal T1, T2 WIs (Plates 1, 2).
- Axial T1, T2 WIs (Plates 3, 4).
- Post contrast series (Plates 5, 6).

MR Findings:

- Compared to the previous study dated 9/6/2004;
  - There is total resolution of the forenoted L4/5 central posterior disc herniation in today's study, with stationary appearance of degenerative marrow changes of its opposing end plates.
  - The spinolaminectomy at L4/5 level is the same with regression of the left epidural sacrring. No discitis, arachnoiditis or pseudo-meningocele formation.
  - Normal Sagittal diameter of the bony lumbar spinal canal.
  - Normal appearance of the conus medullaris and cauda equina.
  - No abnormal paraspinal soft tissues.
  - No newly developed lesions detected.

Opinion:

Follow up study of the lumbar spine, showing total disappearance of the recurrent L4/5 disc herniation that was seen in the study dated 9/6/2004.

[redacted] Selim

Rev.:
Ref.: R.A.Y./2004

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المركز الرئيسى : ٣٥ شارع سليمان أباظة - المهندسين - الجيزة
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فرع برج الأطباء : ٥٥ ش عبد المنعم رياض-المهندسين - الجيزة
ت : ٣٠٥٥٩٧٠/١/٢/٣/٤ - ٣٤٥٨٤٧٧ - فاكس : ٣٠٢٥٢٣٠

Figure 8

Intervertebral Differential Dynamics Therapy

Practical Pain Management Technology Review

Author review on technology evolution of IDD Therapy from its early predicate iteration; from computer directed primary waveforms to new addition of oscillating waveforms and increasing non-surgical spinal treatment outcomes

AUTHOR

C. Norman Shealy, M.D., Ph.D., F.A.C.S. Duke University School of Medicine. Teaching Fellow at Harvard University School of Medicine.

METHOD

Independent review of multi-center patient cohort of over 500 participants; with MRI confirmation of ruptured discs

CONDITIONS

Ruptured disc (with surgery recommended) DDD and Facet Arthrosis

CONCLUSION

- Improvement rates as high as 88%
- Pain reduction levels continued to lower one full year after treatment.
- Author's review postulates introduction of new force forms, oscillation during treatment many be linked to higher success rates.

Intervertebral Differential Dynamics Therapy

By C. Norman Shealy, MD, PhD

The author reviews the evolution of back pain technology and presents results of a study utilizing differential dynamics rehabilitation.

The annals of medicine offer countless examples of widely used diagnostic and treatment protocols that represented the standard of care for the time. Through clinical observation and data analysis, physicians are able to identify necessary refinements for improving outcomes. In essence, an evolution takes place yielding better refined, more effective standards of care.

Consider for example, the standard of care established over six decades ago for diagnosing ruptured intervertebral discs, namely Pantopaque® myelography. Although it provided excellent radiological contrast, twenty-five percent of patients developed adhesive arachnoiditis after a single myelogram — leading to progressive disability far worse than the ruptured disc. Fortunately, MRI replaced the more risky Pantopaque myelogram, giving rise to a more refined standard of care. The MRI, a more specific diagnostic approach, proved highly effective and much less traumatic to the patient.

Now consider one of the standards of care for low back pain. Although some form of spinal traction/distraction was used for centuries, the results were erratic and inconsistent, so that most spinal specialists began to abandon this approach in the 1960's.[1] Then Burton and Nida introduced the concept of gravity lumbar reduction therapy.[2] They literally strapped patients upright in a harness for eight hours a day, for one to four weeks, with results best in patients with ruptured discs. However, the complication of hypotension and eight hours of immobilization doomed this radical approach.

Back to the Drawing Board

In 1996, the author was asked by an emerging company to evaluate a pneumatic traction/distraction device that reputedly "decompressed" the lumbar spine. The author was shocked to see patients required to hold themselves in the prone position manually with their arms and hands overhead for 30 minutes of considerable distraction. Five, of six patients interviewed, reported significant shoulder discomfort. The author's attempt on this device resulted in a subluxation of the right shoulder, resulting in several weeks of shoulder pain. Even more troubling was the observation that the prone position actually increased lumbar lordosis — clearly undesirable for optimal spinal dynamics. It occurred to this author that it was definitely no great improvement over the old Hippocratic technique of strapping a patient upright on a door that was dropped out a window!

Optimal Mechanisms

The author evaluated the mechanisms considered optimal for lumbar decompression, reduction and stabilization. Working with several models, x-ray confirmation, and manual palpation, the following conclusions were reached for optimal mechanical distraction of the lumbar spine:

1. split table separation,
2. flexion of the knees,
3. flexion of the lumbar spine to raise the angle and distraction segmentally,
4. comfort and non-slippage of the pelvic restraining belt,
5. comfort and non-slippage of the chest restraint,
6. concomitant use of TENS, heat, ice and myofascial release,
7. a graduated limbering, strengthening and stabilization exercise program,
8. angle of distraction ranging from 10 to 30 degrees.

In the author's review and experience, as of a decade ago, no single device incorporated all these major factors that are important in achieving clinical results. Yet using these guidelines led to vertebral distraction of 7 to 15 millimeters and good to

Practical PAIN MANAGEMENT, April 2005
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excellent pain relief. Of 14 patients having MRI-confirmed ruptured discs with surgery recommended, only one subsequently required surgery. Of eight patients with degenerative disc disease or facet arthrosis, six achieved good to excellent pain relief.[3]

Device Evolution

Continuing evolution of the technology discussed above has led to further improvements now being incorporated in new generation devices utilizing computer-directed physical therapy of the lumbar spine, along with refinements of treatment protocols employing differential dynamic rehabilitation.

Treatment objectives include freeing a locked facet joint, correcting spinal misalignment which has rendered it dysfunctional, relieving pressure on a nerve root, or bulging disc, stimulating inhibition of annular fluids, restoration and rehabilitation of normal spinal function and the underlying musculature that is typically compromised.

Comfort during the treatment has improved as well as the ability to focus therapeutic force on specific vertebral levels with optimum mobilization, manipulation, and clinical relief. The ability to utilize multiple primary waveforms, as well as a secondary oscillatory waveform designed more specifically to apply a neuromuscular component, further illustrate the progression evolution of this rehabilitative therapy. Active tracking of applied forces, the ability to individualize treatment according to patient needs and the ability to quantify patient response to the treatment regimen pre- and post-therapy sessions further improves therapeutic results.

The device used in the following study was the Accu-SPINA™, manufactured by North American Medical, and utilizing the 'Intervertebral Differential Dynamic (IDD®) Therapy' protocol.

Study Results

The author was able, as an independent consultant, to review results currently being reported from ten clinics comprising a cohort of over 500 patients. Improvement rates of 65 to 88% confirm the author's earlier findings regarding differential dynamic rehabilitation. Most importantly, the latest study demonstrates not only an average 65% decrease in pain at completion of IDD therapy, but average pain reduction of 76% one year after treatment (see Figure 1, courtesy of North American Medical).

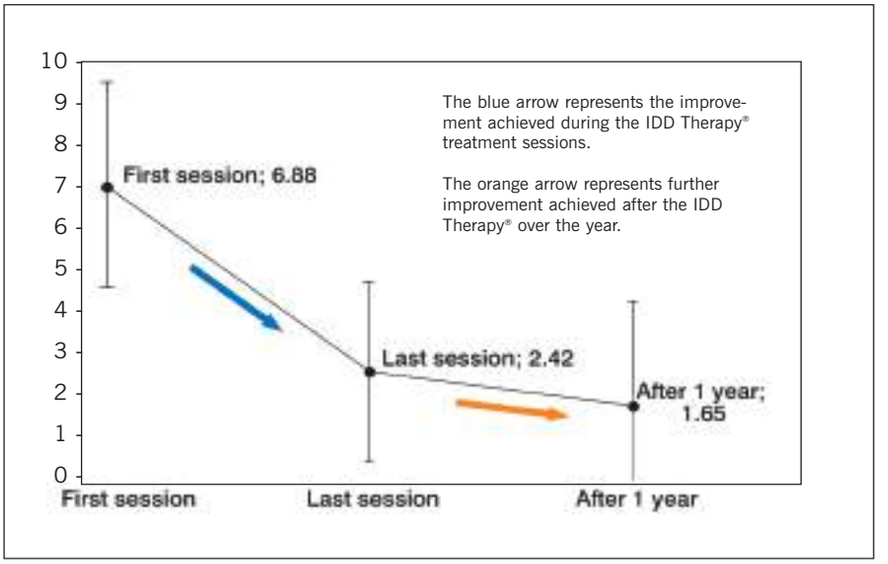

FIGURE 1. *The chart shows mean NPS of 6.88 at the beginning of IDD Therapy® treatment after the completion of treatment the mean NPS is reduced to 2.42 (last session). After a duration of one year the patients continue to improve and the mean NPS is 1.65.*

Current exploration of vibration, distraction, oscillation and other adjunctive mobilization adjustments offer even greater potential for the future of inter-vertebral differential dynamics rehabilitation.

Summary

During the past decade, computerized technology has markedly increased successful outcomes of non-surgical physical therapeutic mobilization for spinal pain, including ruptured discs, as well as locked and degenerative facet pain syndromes. Specific individual spinal segment dynamic mobility leads to satisfactory pain relief and improved quality of life in up to 88% of patients — many of whom have failed other "conventional" approaches. Based on author's review of recent study results, inter-vertebral differential dynamic rehabilitation appears to be the current optimal recommendation for most lumbar pain syndromes. ■

C. Norman Shealy, MD, PhD, is a neurosurgeon, trained at Massachusetts General Hospital, after medical school at Duke University. He has taught at Harvard, Western Reserve, University of Wisconsin, University of Minnesota, Forest Institute of Professional Psychology. He currently serves as President of Holos University Graduate Seminary, which offers doctoral programs in Spiritual Healing and Energy Medicine. Dr. Shealy introduced the concepts of Dorsal Column Stimulation and Transcutaneous Electrical Nerve Stimulation (TENS), both now used worldwide. In 1971, he founded the first comprehensive, holistic clinic for pain and stress management. The Shealy Institute became the most successful and most cost-effective pain clinic in the U.S., with 85% success in over 30,000 patients. The Shealy protocols for management of depression, migraine, fibromyalgia and back pain are increasingly being integrated into hospitals and individual practices. The Shealy Wellness Center focuses on these four major chronic problems. Dr. Shealy holds nine patents for innovative discoveries, has published over 300 articles including 22 books, the latest of which is Youthful Aging — Secret of the Fountain. *His free e-newsletter is available at www.norm shealy.net. Holos University information is at www.hugs-edu.org.*

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2. Burton C and Nida G. *Gravity lumbar reduction therapy program.* Sister Kenny Institute. Minneapolis. 1976.
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4. Wesemann M, Koladia N, and Shealy CN. *Long term effect-analysis of IDD Therapy® in low back pain: A retrospective clinical study.* (Submitted for publication.)

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PATENT NUMBER:

US 2006/0287619 Al

DATE OF PATENT:

Dec. 21, 2006

INVENTOR:

Carlos Becerra

Atlanta, GA (US); et. al

United States Patent

BECERRA. ET AL.

SYSTEM AND METHOD FOR PROVIDING DECOMPRESSION MODALITIES USING SMOOTH TRANSITION SIGNALING AND OSCILLATORY SIGNALING AT HIGH TENSION LEVELS FOR SPINAL TREATMENT

ASSIGNEE **North American Medical Corporation,** Atlanta, GA (US)

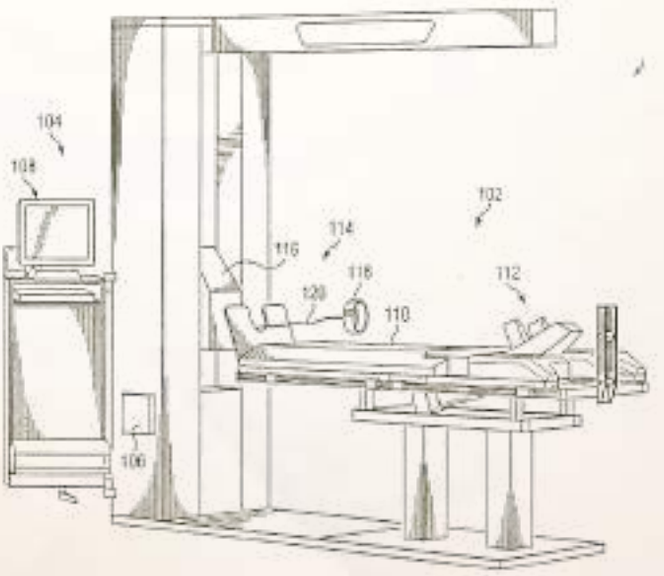
APPL. NO. **11/025,631**

FILED **Dec. 29, 2004**

Related U.S. Application Data

Provisional application No. 60/533,182, filed on Dec. 30, 2003.

Provisional application No. 60/604,989, filed on Aug. 27, 2004.



ABSTRACT

A modality system and method for performing modality treatments on patients. The modality system may compute a signal having a first tension level, a second tension level, and transition tension levels between the first and second tension levels. At least a portion of the transition tension levels may form a curve. The higher of the first and second tension levels may include an oscillation. The signal may be com municated to an electromechanical actuator to apply a modality treatment to a patient.

US 20060287619A1

North American Medical

THE SINUSOIDAL OSCILLATION METHOD

Relieving Patient Pain and Promoting Healing Through the Use of Dynamic Forces

For decades, scientists have argued whether or not sinusoid wave frequencies impact the world and our bodies. However, it is now accepted fact in medicine that every single organ and cell in the human body is constantly vibrating or oscillating. In fact, in a 2009 study, a team of scientists from MIT studying cell membrane dynamics showed that living red blood corpuscles are in a state of constant vibratory motion.[1]

At North American Medical Corporation, our team of scientists and top neurosurgeons developed a one-of-a-kind, software-driven platform that uses advanced technology to provide an effective treatment plan for those with chronic back or neck pain - ***the FDA cleared and fully patented Accu-Spina® with sinusoidal oscillation IDD Therapy® protocols.***

FULLY PATENTED
The only patented sinusoidal oscillation technology to encourage spinal regeneration.

COMPUTER PRECISION
Adjusts the spine through variable pressure and high-intensity micro-movements to ensure individualized treatment plans.

PREFERRED TREATMENT
Thousands of Accu-Spina's® sold worldwide with more than 10 million successful treatments performed.

INNOVATIVE TECHNOLOGY. BETTER RESULTS. HAPPIER PATIENTS.

(1) Proceedings of the National Academy of Sciences Dec. 2009. IDD Therapy® and Accu-Spina are registered marks. U.S. patent(s) apply*.

The Sinusoidal Oscillation Method, Accu-Spina®, and IDD Therapy®

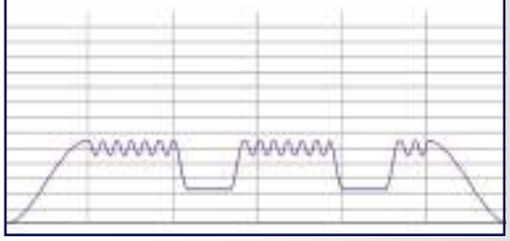
Research has shown that human cells respond better to variations in their micro-environment, and sinusoidal oscillatory signaling can aid in that adaptation.[2] The Accu-Spina® uses a specific sine wave *(sinusoid)* as part of its Intervertebral Differential Dynamic (IDD) Therapy® to gently direct treatment forces to the spine. At the peak of each wave, a combination of variable pressure, stretching, and high-intensity micro-movements begin "signaling" the spinal structures *(our patented Sinusoidal Oscillation Method)*.

While the primary decompression waveform provides exacting and calculated amounts of sinusoidal force to "distract" the vertebrae and relieve pressure on the disc and nerve roots, the oscillation signals at the peak high hold aim to enhance and support the bodies' natural cellular healing abilities.

With its unique treatment capabilities, IDD Therapy® on the Accu-Spina® helps each disc take in more fluids, oxygen, and nutrients at the cellular level, promoting a higher level of self-healing, rehabilitation of damaged discs, and regeneration in surrounding muscle tissues. This waveform provides patients with an experience unlike any other, gives them a better treatment, and more effectively leads them to a place of long-term pain relief.

Regeneration and healing happen in the cells; the sine waves created using the Accu-Spina's® Sinusoidal Oscillation Method work to target those cells to promote greater levels of self-healing and rehabilitation.

The Sinusoidal Oscillation Method by North American Medical Corporation



What truly sets the Accu-Spina® apart is a commitment to scientific principles. The Accu-Spina® is *the only therapeutic device* that also offers IDD Therapy® oscillation capability for lumbar AND cervical modalities. Treating with disc-specific technology, our precise variable dynamic waveforms are exclusive to the Accu-Spina® System. Studies led by top U.S. neurosurgeons have proven that even patients already scheduled for surgery can avoid it entirely and achieve lasting relief with IDD Therapy® treatment on the Accu-Spina® System. ***No other spinal rehabilitation device on the market can truly make these claims.***

MORE FOCUSED THERAPY
Sinusoidal Oscillation ensures each patient receives a unique and more effective treatment plan.

HIGHER SUCCESS RATES
Focused therapy allows for up to 92% in success rates using our Accu-Spina® technology.

CLINICALLY PROVEN
Cutting-edge technology with proven success rates for disc treatment and relief of back and neck pain.

(2) Cheong R, Levchenko A, Oscillatory signaling processes; the how, the why and the where; Curr Opin Genet Dev.2010 Dec;20(6); 665-669.

Distraction Techniques for Lumbar Pain

Practical Pain Management
Mar/April 2003
Pp 18-22

Pre & Post treatment MRI studies show clear reduction of bulge and hydration of formerly desiccated disc with IDD Therapy treatment utilizing predicate Accu-Spina device.

AUTHOR

A. Ottenstein, M.D., Thomas Jefferson University, Hahnemann University School of Medicine specializing in Neurology, Physical Medicine & Rehabilitation, and Pain Medicine

METHOD

Case study review assessing post MRI evidence, pre/post pain assessments and activities of daily living.

CONDITIONS

Bulging and desiccated discs.

CONCLUSIONS

- Marked improvement of disc herniation after IDD Therapy treatment despite completion of only half the prescribed treatment regimen
- Improved disk hydration and disk height documented in two out of three patient cases
- All cases reviewed showed marked improvement in pain and ability to return to normal activities

Distraction Techniques For Lumbar Pain

by A. Ottenstein, MD

Inter-vertebral decompression — utilizing distraction techniques — widens disk spaces, lowers intradiscal pressure and promotes disk recovery.

Practical Pain Management
Mar/Apr 2003

INTRODUCTION

At the dawn of the 21st century there are still a great many patients still suffering from common lumbar pain syndromes. Fortunately, unlike just a few decades ago, we now have many treatments to help these patients. These treatments run the gamut from doing "nothing" (eg. bed rest or passive modalities only) to doing "everything" (for example, open spinal surgery, discectomy, laminectomy, and/or interbody fusion).

Choosing an appropriate treatment for a particular patient, however, is a complex process. Unfortunately for all concerned, the exact diagnosis is rarely clear cut. Using only the anatomical information found on imaging studies such as MRI and CT, the physician typically has a very low probability of making the proper etiological diagnosis for lumbar pain.

The physician must also consider the patient's complaint, abnormalities on neurological examination, limitations in activities of daily living, functional limitations, objective studies such as magnetic resonance imaging, EMG and nerve conduction studies, and other special studies that may be needed.

Dr. Ottenstein graduated Hahnemann University School of Medicine specializing in Neurology, Physical Medicine & Rehabilitation, and Pain Medicine

On top of all this, the physician must factor in the patient's preferences. The patient's lifestyle, personal preferences, prejudices, and philosophy toward medical interventions are the key final factors in determining which treatment will ultimately be given. Evaluation of any large group of patients—all having the same symptoms, findings, test results, diagnoses, and the same objective degree of disability—will reveal a wide range of prejudice in regards to suitable treatments. Some patients do not wish to take any medications whatsoever, while other patients may wish to use medications exclusively and not consider any other therapy. Still other patients will wish to have whatever therapy is available—no matter how aggressive and risky the treatment may be—as soon as possible. These patients are not unreasonable, they simply desire to do whatever may be necessary to get them back to "normal" as quickly as possible.

Background

We now have the benefit of many years of research to demonstrate that old treatments that we once thought were beneficial (for example passive physical therapy modalities and lumbar traction) are no longer believed to be useful or beneficial to patients suffering from serious lumbar spinal or neurological injuries. It has also become more widely appreciated that traditional lumbar surgery—with or without discectomy, laminectomy or interbody fusion, with or without installation of surgical hardware—can help some severely injured and disabled patients. However, surgery is not a panacea for most spinal problems. We now understand that there are great limitations to what surgery can accomplish. For example, open surgery performed for relief of pain alone rarely has a successful outcome. Surgeries performed for reasons of progressive neurological deficit, on the other hand, are more often successful. Recent years have seen a decrease in the percentage of patients undergoing these types of surgery as a result of more stringent selection criteria. As a result, a much higher proportion of these surgically treated patients now enjoy good outcomes. Many of our patients that only a decade or two ago would have undergone open spinal surgery can now be helped by treatments that are far less invasive. These treatments include procedures performed through a small incision less than one inch long such as microscopic discectomy. There are also many "less invasive" procedures performed with only the insertion of a large needle or catheter into the spine or perispinal tissues. These treatments include using a laser, rotors, clips, suction devices, or application of heat energy or radiofrequency energy to remove or alter part of the annulus or of the nucleus pulposus. Injection of agents that dissolve or chemically alter the nucleus or other spinal tissues have been used in this country and abroad for over two decades. These treatments have been well described in this and other publications.

> ***"...interventional but noninvasive therap(ies)... actively intervene in the disease process and help to bring about improvement in the patient's symptoms, and the disease itself—but do so without penetrating the patient's body. "***

Over the past decade a new procedure category has arisen: that of interventional but noninvasive therapy. Fortunately for today's patients, therapies in this class actively intervene in the disease process and help to bring about improvement in the patient's symptoms, and the disease itself—but do so without penetrating the patient's body. The most useful of these— and the most widely used at present—are the lumbar distraction techniques.

Pioneering Lumbar Distraction

The first lumbar distraction technique to enjoy widespread use was the vertebral axial decompression technology (VAX-D®) developed in 1991 by Alan E. Dyer, PhD, MD, formerly a Deputy Minister of Health in Ontario, Canada.

Practical Pain Management 2003

This VAX-D® device was shown to actually improve lumbar disk injuries and neurological symptoms in some patients. Despite a significant incidence of side effects, the procedure gained rapidly in popularity throughout Canada and the United States over the past decade because it could do what no other procedure had done before. This procedure could actually decrease the disability due to a herniated disk and actually affect the herniated disk without the need to physically invade the body.

A study conducted by Ramos and Martin in 1995 directly measured the effects of vertebral axial decompression on intradiscal pressure utilizing the VAX-D® and recorded significant reduction in pressure —up to -100 mm Hg—with applied tension in the upper range.1

VAX-D® began its use in the United States in the early 1990s and was quite widespread by the late 1990s. However, many physicians became disenchanted with several of the drawbacks of the VAXD®. The device transmitted a general force to the lumbar spine and could not individually select a vertebral level. The device required a patient's cooperation, and was dependent upon relaxation of the lumbar paravertebral muscles to allow distraction to take place while, at the same time, the therapy required the patient to maintain contraction of the shoulder girdles and cervical paraspinal muscles. Physiologically, this is a very difficult task to accomplish.

Despite some complications, VAX-D® therapy has remained popular throughout the United States due to the continuing benefit to many people with disabling spinal injuries—without the risks and costs associated with almost any surgical procedure. There are still many VAX-D® units in clinical practice.

Lumbar Distraction with IDD Therapy®

In the late 1990's a team of neurosurgeons, orthopaedic surgeons and other physicians headed by C. Norman Sheely, MD, developed a device that had most of the advantages of the VAX-D® but without the primary complications seen in VAXD® therapy

This device called the DRS (distraction reduction stabilization) gained FDA clearance for use in the United States in January of 1998. The DRS device, currently marketed as the SPINA SystemTM by Adagen Medical International, Inc., Atlanta, GA, has since rapidly gained market share and has replaced the use of VAX-D® in many physicians' offices because of increased efficacy and decreased degree of complications. This next generation technology utilizes internal disk decompression protocols known as IDD Therapy®.

Prospective double blind studies performed in the mid 1990s, comparing conventional lumbar traction with the distraction decompression techniques of IDD Therapy® in a series of patients, revealed that the latter was much more beneficial to patients than lumbar traction. The patients studied had been suffering from various lumbar pain syndromes including lumbar radiculopathy, lumbar disk degeneration and herniation, and lumbar facet syndrome.2

We believe that the DRS device, utilizing IDD Therapy®, is inherently more effective at accomplishing the spinal distraction than is the older VAX-D® technology, although we are not aware of any specific comparative studies. However, early experience with this device has shown that it is superior to the VAX-D® treatment with decreased complications. In particular, usage of IDD Therapy® has so far demonstrated a noticeable improvement in both the theoretical and actual complication rate. This improved safety factor is one of the main reasons we usually suggest IDD Therapy® instead of VAX-D® if it's geographically available to the patient. The precise technical description of the DRS device is beyond the scope of this article. What the DRS device with IDD Therapy® does is create and focus a distraction force at a given level of the lumbar spine through adjustment of the applied forces.3 The patient undergoing this treatment does not need to do anything to cooperate with the treatment other than relax. Unlike the VAX-D®, no force or strength on the part of the patient is needed. As a result, relaxation of the patient's muscles-especially lumbar paravertebral muscles can be accomplished.

Practical Pain Management 2003

Edward L. Eyerman, MD, wrote that DRS mechanical decompression distraction provided not only symptomatic improvement in patients with lumbar pain syndromes described above—but also improvement in magnetic resonance imaging findings from pre-treatment to post-treatment.4 An actual before and after comparison of MRIs of one of the author's patients—presenting with a disk herniation at L3-4 —demonstrated marked improvement after IDD Therapy® (see Figure 1). Herniation of the disk was reduced, disk height was increased and the disk was rehydrated after only 11 sessions during a 7-week period.

Treatment Protocols

The goal of the distraction treatment is significant relief of pain with restoration or improvement of physical spinal and neurological injury. The treatment protocols include:

1. Mechanical distraction to widen the intervertebral disk space resulting in decreased intradiscal pressure on nerves and blood vessels in the spine. The reduced pressure encourages shrinkage or a retraction of the herniated or bulged portion of the nucleous pulposus. The reduced pressure also allows improved diffusion of oxygen, nutrients, and hydration to the injured annulus and speeds healing.

2. Nutrition (foods and supplements) to provide the necessary precursors to provide building blocks necessary for disk repair.

3. Precautions to avoid re-injury during the healing phase.

4. Mobilization, daily stretching, and exercises to strengthen the muscles and prevent recurrence. This phase is initiated after the disk has been stabilized and healing is well under way

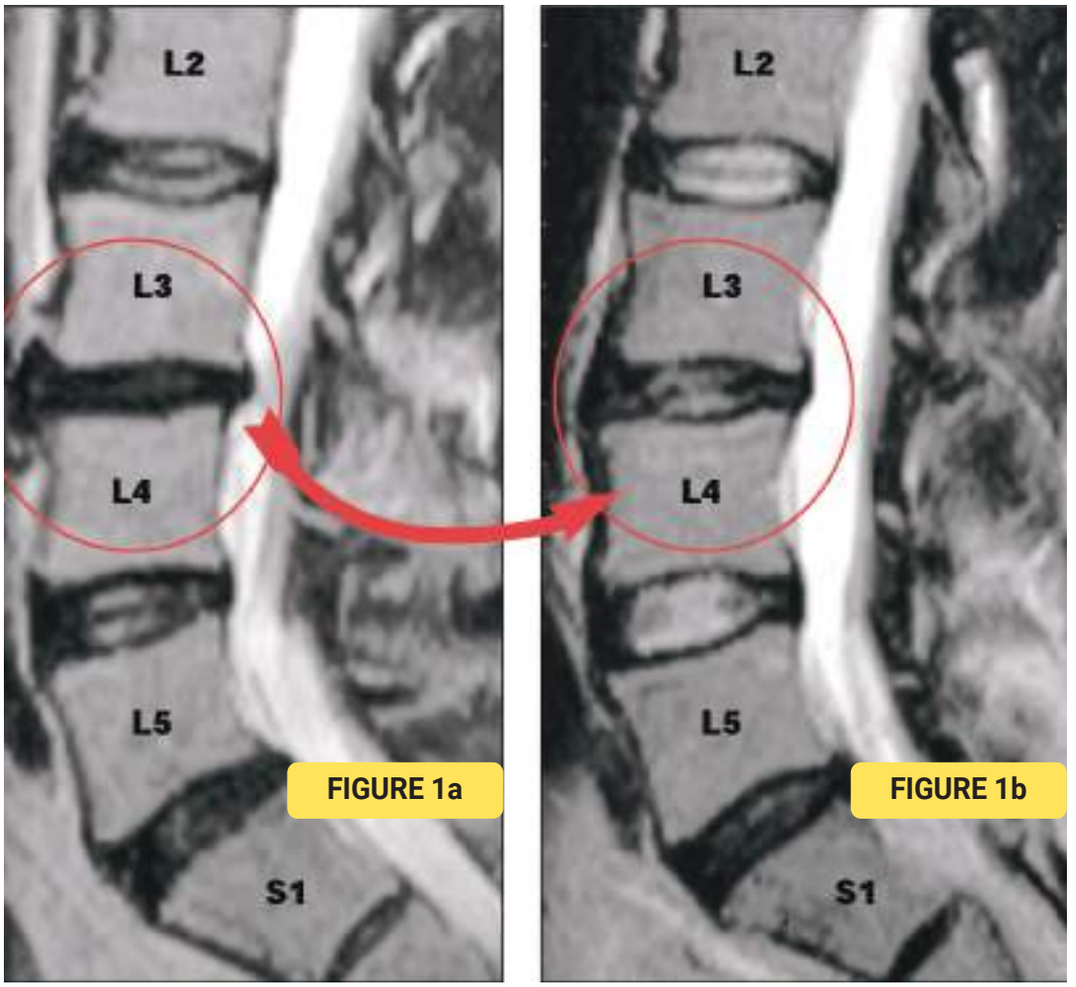


FIGURE 1A.
Pre-treatment MRI (2/2/2000) of a patient with disk desiccation at L3-4 with rupture of the annulus.

FIGURE 1B.
Post-treatment MRI (3/20/2000) of the same patient after 11 sessions of treatment.

Patients' Perspective

The treatment experiences on the part of patients have been overwhelming positive. The actual procedure is generally pain free, fast and safe. First the patient is custom-fitted to upper and lower spinal harnesses by a trained technologist. These harnesses and other applied devices help position the lumbar spine for comfort, as well as for proper alignment in the treatment process. Once fitted to the harnesses, the patient is slowly reclined to the treatment position. The therapist then applies distractive forces according to the patient's physical characteristics (ie. weight, body type) and directed to specific disk levels per the physician's specific orders. Through a series of treatments, each lasting twenty to thirty minutes, the patient's pain is quickly improved. Once patients begin to experience some pain relief and improved spinal function, they usually find the treatments comfortable, relaxing, and even enjoyable—many even look forward to their treatments

Case Study 1: Neo

Neo is a 32-year-old white male computer programmer. He had been working for six years at his job and never missed a day of work. One day he was working at home and injured his back. The pain was so severe he could not get off the floor and lay on the floor for three weeks. Despite multiple visits to various physicians including treatment with medications, narcotics and epidural injections, the pain did not resolve. He remained essentially housebound and unable to stand, walk or sit for any appreciable period of time. This patient was evaluated and found to have a herniated disk at L4-5, which appeared acute to sub-acute on MRI. His symptoms and clinical lumbar radiculopathy syndrome correlated with his examination and with his abnormal EMG and NCV studies. The patient underwent 20 DRS treatments using IDD Therapy®. Following the treatments, the patient noted marked improvement in his pain. He also noted improved activities of daily living and was able to return to work full-time with no restrictions. In follow-up, the patient was stable and remained improved.

Case Study 2: The Hospital Executive

The hospital executive is a 52-year-old president and CEO of a community hospital in Pennsylvania, about one hour from the author's offices. This individual noted onset of severe lumbar pain while lifting a heavy object. Evaluation at his hospital showed herniated disk posteriorly at L3-4. He underwent nine months of physical therapy with some slight improvement in his pain but no improvement in his disability. The patient was subsequently evaluated at our institution, and DRS with IDD Therapy® administered. Despite the 20 treatments that were advised, the patient felt well enough after 11 treatments that he did not wish further therapy. Upon discharge—after six weeks of IDD Therapy® consisting of only 11 of the 20 recommended treatments—he had much improved range of motion, decreased pain, and improved abilities to perform activities of daily living and activities at work. An MRI performed at the same time showed substantial improvement in disk height and disk hydration as well as some improvement in disk herniation at the L3-4 level. The patient subsequently returned back to work and resumed all hobbies including actively hunting, fishing and boating, and has been stable. He continues to have improved pain, ADLs, and can still engage in all his favorite vocations and avocations.

> ***" The concept of using a distractive force to increase disk height and decrease the amount of herniation has been conceptually attractive to physicians for most of the last century. "***

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Case Study 3: Great-grandma

An 89-year-old retired schoolteacher complained of severe low back pain with radiation to her legs. She was ultimately unable to follow her daily activities, which she had enjoyed for many years. Her symptoms progressed to the point where she was unable to do any of the things that gave her the most pleasure. She liked to play bridge, but was unable to sit at the card table. She liked to entertain guests but was no longer able to cook, serve her guests, nor load her dishwasher without pain and so she ceased cooking and entertaining. She also became unable to tend her small garden.

This patient was evaluated and then underwent 20 DRS treatments utilizing IDD Therapy®. Following treatment, she noted improved freedom from pain and no longer needed medications for pain. She noted improved ability to walk, bend and stoop. She also regained the ability to drive and regained the ability to walk while shopping, both in the grocery store and in the mall. A follow-up MRI study showed improvement in disk hydration and height. Follow up evaluation revealed that she had again been happily gardening, playing bridge, shopping, cooking, and entertaining friends at her home.

Discussion

The concept of using a distractive force to increase disk height and decrease the amount of herniation has been conceptually attractive to physicians for most of the last century. Unfortunately, attempts with various treatments and devices over the past 100 years have yielded no significant benefit to patients from lumbar traction. The current consensus of most physicians specializing in spine care and back pain organizations, and the conclusion of the U.S. Agency for Health Care Policy and Research (AHCPR) in a 1994 report on treatments for lumbar pain,5 was that lumbar traction was of no use in the treatment of the lumbar pain syndrome. We now know that lumbar traction does not benefit most patients—furthermore, we now understand why lumbar traction does not work.

Not only is lumbar traction ineffective in treating lumbar pain, but it can actually increase intradiscal pressure through a variety of mechanisms. These mechanisms include promoting a reflex co-contraction of lumbar paraspinal muscles. This contraction increases the axial load on the local disk segments and promotes increased intradiscal pressure. This increases the pressure on the annulus and may worsen an existing herniation, and/or raise the pressure enough to cause a new herniation.

Studies over the past decade have demonstrated that the new spinal distraction techniques discussed here, including VAX-D® and DRS with IDD Therapy,® are not traction. These new techniques work in an altogether different way than traction and, more importantly, they are effective—whereas lumbar traction is not. In recognition of this distinction, the United States government awarded a second level HCPCS code to VAX-D® effective January 1, 2000 to differentiate this effective treatment from the older, noneffective treatments—namely, lumbar traction. The prospective double blind study published by Dr. Shealy demonstrated the effectiveness of distraction techniques for disk injury, herniation, and degeneration as well as for lumbar facet syndrome.2

Conclusion

These distraction devices are gaining market share in physician's offices—and for good reason. DRS with IDD Therapy® and the older VAX-D® treatments are part of the continuum in available treatments —from simple physical therapy and exercise to interventional surgery. As the above case studies demonstrate, distraction treatments that provide internal disk decompression have proven to be of very real benefit to these different patients, despite the differences in ages and pathologies. We have not yet determined all of the different pathologies that are amenable to treatment by this technology. We recommend at this time that physicians using this technology restrict their treatments to the FDA approved indications. This technology is currenlty cleared by the FDA as being safe and effective forconditions and injuries producing

spinal pain—including disk herniations, disk bulges, disk damage, disk degeneration, and facet syndrome. There is interest in using these therapies for other conditions and investigations are currently underway. We do not use this technology for simple back pain at this time, nor do we use DRS with IDD Therapy® for spinal strains or sprains alone. The IDD Therapy® appears most beneficial to patients with disk or facet joint pain, with or without accompanying lumbar and/or sacral radicular irritation.

While we have come to appreciate that passive physical therapy is not considered to be of long term benefit in most patients with lumbar spine syndromes —active physical therapy, exercise and stretching, and aerobic and other exercises undergone with the patient's cooperation are quite beneficial indeed. We believe that after an acute injury is properly treated and healed, a commitment to the appropriate exercises and simple lifestyle changes can give our patients a good chance of life-long freedom from a recurrence of spinal symptoms and disability.

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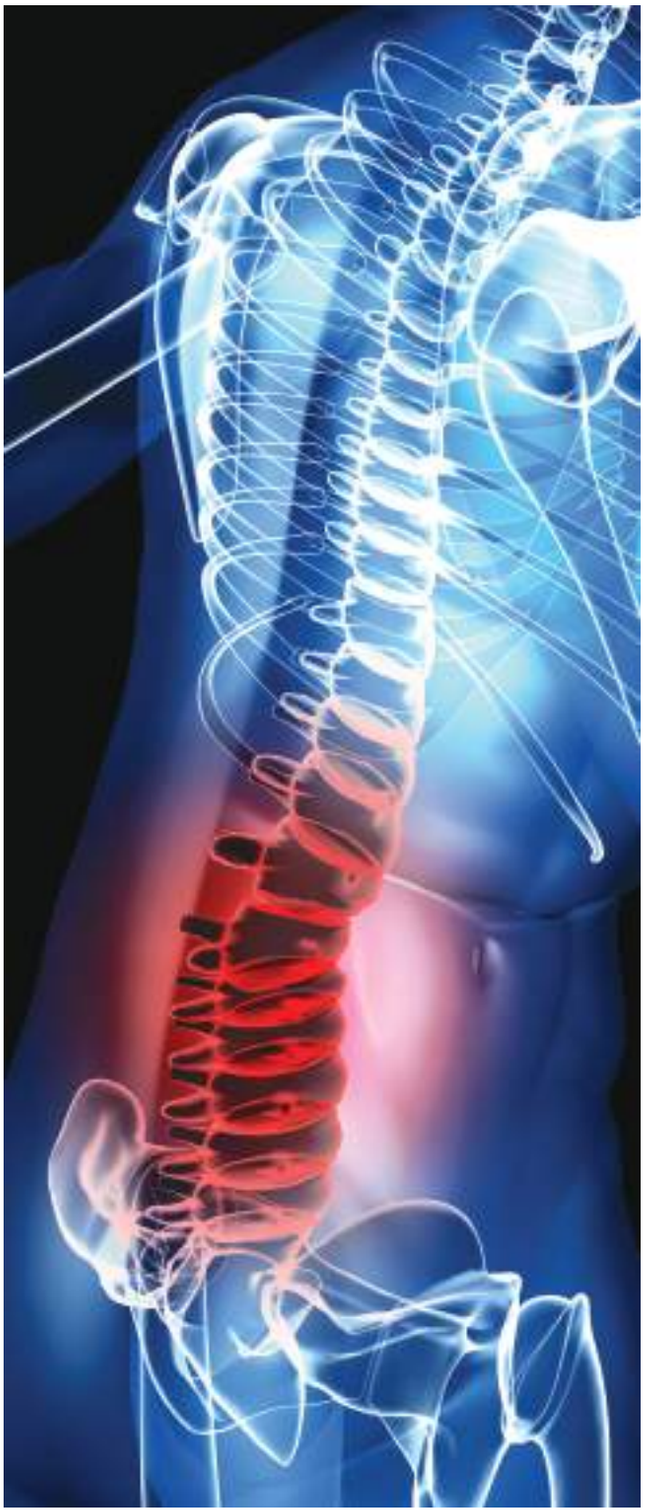

MRI Evidence of Nonsurgical Mechanical Reduction, Rehydration and Repair of the Herniated Lumbar Disc

21st Annual Meeting of the American Society of Neuroimaging Vol 8/No 2

Imaging study to determine whether clinical betterment can be correlated directly to improvement in MRI findings and whether MRI findings shed light on mechanism of improvement in patients successfully treated with decompression utilizing predicate Accu-Spina device

AUTHOR

Edward L. Eyerman, M.D.

Columbia University, National Institutes Of Health, and University of Virginia

METHOD

- Patients chosen with imaging confirmation of visible disc herniation/protrusion.
- Patients treated with full course treatment, then MRI performed again within four weeks after treatment.

CONDITIONS

- Herniated disc
- Stenosis
- Foraminal syndrome

CONCLUSION

- All but 3 patients had significant pain relief regardless of MRI status
- General correlation between improvement/retraction of disc was shown by MRI.
- Other observations indicating mechanisms of improvement freeing up of the nerve root, joint mobilization, likely lowering of pressure in ivd space to accelerate nutrient diffusion and disc repair.
- Disc herniations reduced significantly in 10 out of 14 subjects treated with 85% clinical improvement.
- An over 90% reduction of disc herniation was documented in this study.
- Rehydration of torn annulus repair was also evident with virtually all subjects.

Journal of Neuroimaging - Official Journal of the American Society of Neuroimaging
CT MRI Neurosonology | PET SPECT Brain Mapping

MRI Evidence of Nonsurgical, Mechanical Reduction, Rehvdration and Repair of the Herniated Lumbar Disc

21st Annual Meeting of the American Society of Neuroimaging 1998 Paper Presentation

Edward L . Eyerman, M.D. , St. Louis University School of Medicine

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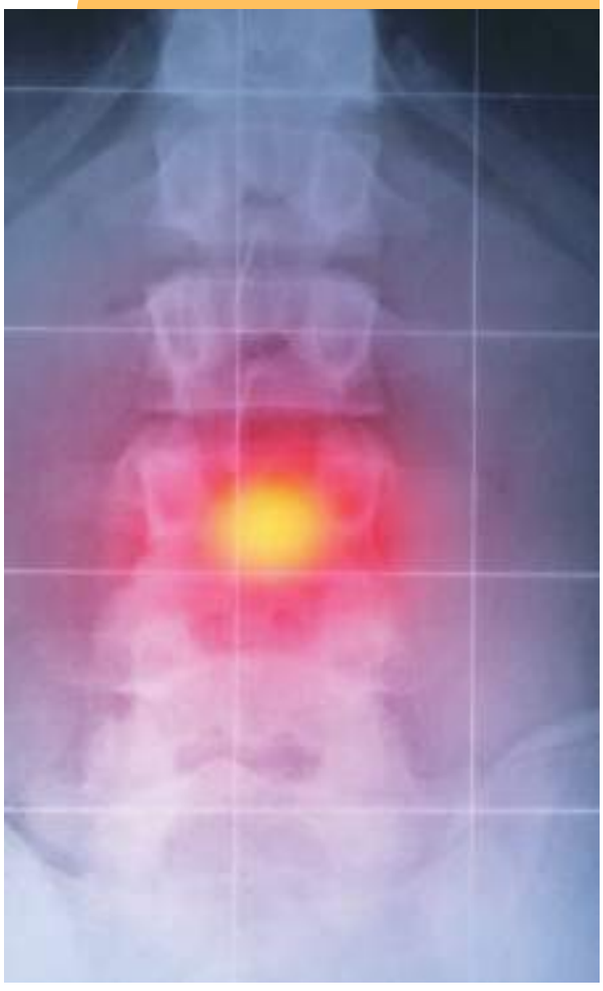
ABSTRACT

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 bod/ weight in twenty V-i hour sessions was reported to give good or excellent relief of sciatic and back pain in 86% of 14 patients with herniated discs and 73% of 8 with facet joint arthrosis. (Shealy, CM , Borgmeyer, V., Am J Pain Management 1997; 7:63-65). Herniated and degenerated lumbar discs can be shown at discography- discomanometry 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 stud/ over 90% reduction of subligamentous nucleus herniation in 10 of 14. Some rehydration 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. Virtually all subjects have sufficient relief of pain to return to work. Follow-up studies for permanency or relapse are in progress



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 mid-sagittal 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 SI 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 discomenometry, 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 demonstrated a leakage of contents of the disc and therefore at the initiation of contrast infusion on discography, opening pressures are actually lower than normal. They become even lower at he 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 30 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 pounds of pelvic traction. In theory, such negative pressures would encourage fluid entry to rehydrate the nucleus and perhaps repair the injured annulus. Onel and colleagues (8) 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 pounds 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 IS 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 L4/5 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 stenos is in six.

Significant herniations treated were 4-10 mm in size, and all were subligamentous. Six herniations were at L5/S1, six at L4/5, and one each at L3/4 and L2/3. 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 protrusiond placed in the lateral recess in what could be called the “critical zone” for the nerve root. On large dischernіations three showed global reduction of 90-10C% after treatment. For example, figure 1 shows a relatively acute disc herniation of under 4 weeks 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 SI nerve root, the arrow indicating the free space between the retracted disc prolapsed and the now visible Slnerve 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 able to bend at the waist in any direction for three months because of a large L4/5 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 an T2 weighted signals indicating at least some rehydration 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 our 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 had75-10C% 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.

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 chondroitin sulfate 6 hydrated content demonstrated by Hutton (9), 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 (10). 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 (11). 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 though 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 (12). Ivlodic et al (13) 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 (14). Thus nutrient deliveiy to heal an ailing disc is likely a crucial factor in both clinical and anatomic improvement.

In 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 (8) 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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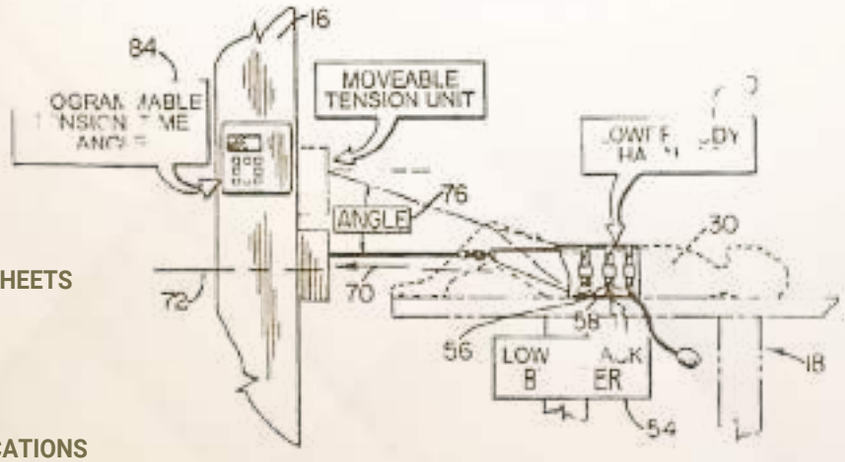
SHEALY ET AL.

APPARATUS FOR THERAPEUTIC TREATMENT OF LOW BACKPAIN

ASSIGNEE **Cluster Technology Corp.,** Tampa, Fla. **APPL. NO.** **09/052,665** **FILED** **Mar. 31, 1998**

ABSTRACT

A therapeutic traction table for the treatment of low back pain includes a bed pivotable from a vertical to a horizontal position for facilitating the placement of a person in a horizontal position on the bed. An upper body harness and underarm supports anchor the upper body of the person to ' the bed. A lower body harness is attached to the lower body pelvic portion of the person, and includes an inflatable air bladder for positioning within the posterior cavity of the lumbar spine formed between the lower back of the person and the bed for relaxing low back muscles during a pulling force on the spine. A traction unit includesastrap connected to the lower body harness for providing a pulling force between the upper body and the lower body. The traction unit is vertically movable from a position generally along an axis of the spine to a vertically displacedposition for pulling at a pre-selected and measurable angle to the axis of the spine and isolating the pulling force to a preselected portion of the spine during a programmable back treatment protocol.



35 CLAIMS,
13 DRAWING SHEETS

OTHER PUBLICATIONS

C. Norman Shealy, MD, PhD, and Vera Borgmeyer, RN, MA, Emerging Technologies: Preliminary Findings, Decompression, Reduction, and Stabilization of the Lumbar Spine: A Cost-Effective Treatment for Lumbosacral Pain, American Journal of Pain Management, vol. 7, No. 2, Apr. 1997.

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A Practical Guide for Clinicians Chapter 20: New Concepts in Back Pain Management

Pain Management
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Discussion of previous traction techniques evolving into segment specific decompression techniques utilizing the decompression reduction stabilization legacy device to the Accu-Spina® Spina System.

AUTHORS

Pierre L. Leroy, M.D., F.A.C.S. Rockefeller Foundation Fellowship in Neuroanatomy and Neurophysiology at New York University. Received the John Liebeskind award for Lifelong Commitment to Medical Education and Research in Pain Medicine.
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METHOD

50 patient clinical trial

CONDITIONS

Ruptured intervertebral discs and facet arthrosis

CONCLUSION

19 of 23 **Patients with ruptured discs were markedly improved.**

20 out of 27 **with facet arthrosis reported 50-100% pain reduction**

All patients with success pain reduction also showed improvement in flexibility and total physical activity.

PAIN MANAGEMENT

A Practical Guide for Clinicians

FIFTH EDITION

Executive Editor
Richard S. Weiner

Volume 1

Chater 20

20

New Concepts in Back Pain Management: Decompression, Reduction, and Stabilization

C. Norman Shealy, M.D., Ph.D., F.A.C.S. Pierre L. LeRoy, M.D., F.A.C.S.

ABSTRACT

A thorough evaluation of previous traction techniques reveals no consistent pattern in prior literature. We have evaluated a variety of devices and found that seven major factors are important in achieving optimal clinical results. These include: (1) split table design to minimize effects of gravity; (2) flexion of the knees for hip relaxation; (3) controlled flexion of the lumbar spine during treatment which alters the location of distraction segmentally; (4) comfort and nonslippage of the pelvic restraining belt, (5) comfort and nonslippage of the chest restraint; (6) concomitant use of TENS, heat, ice, and myofascial release; and (7) a graduated limbering, strengthening, and stabilization exercise program. Using this system, successful pain control was achieved in 86% of patients studied with ruptured intervertebral discs and 75% of those with facet arthrosis.

INTRODUCTION

New advances centering on the use of specific segmental distraction as an adjunct to managing low back pain with and without neuropathic sciatica are reported here. These should be of special interest to both primary care and multidisciplinary medical specialists when symptoms pérsist despite comprehensive management of acute back pain. The utility of physical modalities has been well established in many forms (Wall & Melzack, 1984); however, the use of traction techniques has been largely empirical. Relatively few studies have specifically discussed ergonomics and the biomechanics of spinal pathology as it relates to practical clinical outcomes employing powered or weight distraction forms of therapy.

Previous outcome studies have lacked the applied principles of quantifications and biomechanics that correlated clinical data with a specific diagnosis resulting from structural abnormalities such as discal herniation, lumbar facet arthropathy, foraminal stenosis, and motion segment abnormality syndromes or their comorbid combinations (Anderson, Schultz, & Nachemson, 1968; Lind, 1974; Bettmann, 1957; Binkley, Strafford, & Gill, 1995). Anatomically, the low back is relatively clinically inaccessible.

A reevaluation of mechanical therapy is needed since the various etiologies have overlapping features. Different symptom complexes associated with dysfunction due to complex ipsilateral, contralateral, and segmental neural networking, as well as combined somatic and autonomic neural interactions, may serve to confound the clinician.

A novel approach to mechanotherapy is presented to review these six considerations: (1) outcomes validation, (2) relative safety, (3) ease of use by the patient or healthcare professional, (4) introduction of new principles of treatment, (5) appropriate utilization, and (6) cost effectiveness resulting in shortened morbidity with optimal improvement.

TYPES OF LOW BACK PAIN

Classically, there are four broad categories of low back pain syndrome, each requiring different treatment pathways (O'Brien, 1984; Bogduk, 1987):

1. Acute muscular low back pain which is usually selflimiting
2. Acute low back pain involving sciatic radiation:
   a. With neurological dysfunction
   b. Without neurological dysfunction .
3. Chronic low back pain which has recurring symptoms modified by therapy .
4. Neoplastic low back pain syndrome which is recurring, but eventually becoming progressive, constant, and intractable

Each type of low back pain syndrome has common features which vary with the intensity of symptoms: (1) regional pain, (2) impairment and mechanical dysfunction exacerbated by activities of daily living, and (3) mood and behavioral changes. All need to be addressed for overall successful outcome.

PRINCIPLES OF BIOMECHANICS

Mechanical traction is the technique of applying a distracting force to produce either a realignment of a structural abnormality or to relieve abnormal pressure on nociceptive receptor systems (Colachis & Strohm, 1969; Cyriax, 1950; Gray & Hosking, 1963; Judovich, 1954; Nachemson, 1966). Frequently, both problems co-exist in differing combinations, which generates a number of clinical concerns. Should treatment be constant or intermittent?

What is the reasonable duration of treatment? Should gravity or a weight formula based on the patient's weight be utilized to determine the amount of force for the treatment? Can both mechanoreceptors and chemoreceptors that produce unwanted symptoms be integrated and harmonized? It has been previously described that the distracting force must be greater than the specific pathophysiology causing symptoms, and these mechanisms must be individualized for each patient (Judovich, 1995). Caution not to exacerbate symptoms should always be exercised. The old maxim "no pain, no gain" is both passe and disingenuous. The magnitude of the force correlates with the amount of distraction and must be closely monitored. At what force do we obtain better and more successful results, while reducing costs and morbidity? Katz et al. (1986) reported that 25% of the body weight as a traction force applied to 15 degrees positive elevation from the paral lel prone sins for a 14-day series was found to be effective. We differ j our findings, as will be reported below (Katz et al, | 086) When successful, the patient clinically reports Sin " tomatic improvement of well-being and objective Clinica} verification of (1) improved range of motion, (2) reduction of verifiable regional muscle spasm, (3) improvement in regional tenderness by evaluating health professionals, an d (4) improved neuropathic signs when compared to pre. treatment findings. How can there be more individualize 4 bioclinical integration? Pathophysiology of regional low back pain syndromes varies on a highly personal, individualized basis in such factors as etiology, causation, resulting activity dysfunc. tion, and psychopathological considerations. These factors must not be overlooked or underestimated in prescribing treatment.

HISTORY OF TRACTION

A review of the "Annotated Bibliography on the History of Traction" (Appendix A) summarizes 41 articles, from Neuwirth, Hilde, and Campbell in 1952 to Engel, Von Korff, and Katon in 1996. The reader is referred to Ap. pendix A fora review from medieval times to the present, A summary of this bibliography leads to the following conclusions:

1. Clinical outcomes are highly variable.
2. There are different types of traction techniques, such as intermittent or constant.
3. Variable angles of traction may be applied.
4. Differing weight sequences may be utilized.
5. Suspension devices are useful.
6. Time-scheduled sequences are described, but without specific guidelines and with many variables.

The present chapter is not intended to criticize the previous authors or data presented, but demonstrates that many variables being considered lack quantification. Neurological surgeons have gained extensive experience dealing with and managing problems of intracranial pressure using methods of quantification and have now applied those principles to the intradiscal pressure manometry for clinical correlation of low back pain syndrome.

The first application of quantification by relatively recent studies of quantitative intradiscal pressure changes has been reported by Ramos and Martin (1994). By cannulizing the nucleus pulposus of L4-5 and monitoring intradiscal pressure via a pressure transducer, three Patients were observed to have lowered pressures below 100 mm Hg as a result of traction technique.

Other methods employing visualization were advanced by Gray (Gray et al., 1968). Radiological assessment of the effect of body traction was reported by Gray et al, (1968). Using only the body's weight with a thoracic restraint and only a 12-degree incline, significant lengthening of the spine occurred within S minutes and even more significantly afier this modified gravity reduction traction for 25 minutes.

Combined studies by Anderson, Schultz, and Nachemson (1968) of intervertebral disc pressures during traction demonstrated by radiographic studies concluded that disc space increases in height and lumbar disc protrusion can be reduced during traction. Myelographic evidence of disc herniation was found to disappear after traction (Anderson, Schultz, & Nachemson, 1968).

Shealy and Borgmeyer (1997) introduced a new biomedical application device that can apply all these positive effects to individual disc levels. To clinically document improvement, clinical data combined with radiofluoroscopy was employed. This new approach delivers precise treatment to decompress the lumbar disc space and then stabilize once asymptomatic through a program of physical rehabilitation.

THE DRS SYSTEM

The major goal of the DRS System (Fig. 1) is decompression, reduction, and stabilization of the lumbar spine. In a series of 50 paticnts with chronic pain, 23 having ruptured intervertebral disc and 27 with facet joint pain, it was noted that conventional spinal traction was less effective and biomechanically insufficient for optimal therapeutic outcome. Extensive observations led to the conclusion that five major factors were important for lumbar traction efficacy:

1. Separation of the lumbar component of the joint
2. Flexion of the knees
3. Flexion of the lumbar spine by raising the angle of distraction
4. Comfort and nonslippage of the pelvic belt
5. Comfort and nonslippage of the chest restraint

X-rays confirmed that significant distraction of the lumbar vertebrae required a weight of at least 50% of the patient's body weight (see Figs. 2 to 7). Thus, we have set the parameters of distraction to build up to 50% of the patient's body weight plus 10 pounds.

The knees are flexed over a comfortable bolster that gives optimal relaxation. When the major focus of the patient's pain is at the LS-S] intervertebral disc, no elevation of the pelvis is necessary. At L4-5, optimal focus of the distraction is obtained by raising the angle of distraction 10 degrees. For L3-4 or 12-3, an elevation of 20 degrees is generally optimal.

There is cnough variation in the normal lumbar lordotic curvature that manual palpation of the tension on the lumbar spine, as well as the paticnt's assessment of the focus of distraction, can help in making minor adjustments to these angles. With the DRS System, the distraction angle is accurately determined via a laser pointer to give precise angulation. The table on which the patient lies is divided with a smooth hydraulic component to separate the lumbar division as traction/distraction is applied. The traction/distraction is achieved with a computerized device that allows gradual build-up over a 2-minute period to the desired distraction force. Automatically, the optimal distraction weight is maintained for | minute, and then the pressure is reduced to 50 pounds for 20 seconds before the process repeats itself. The entire treatment process requires 30 minutes.

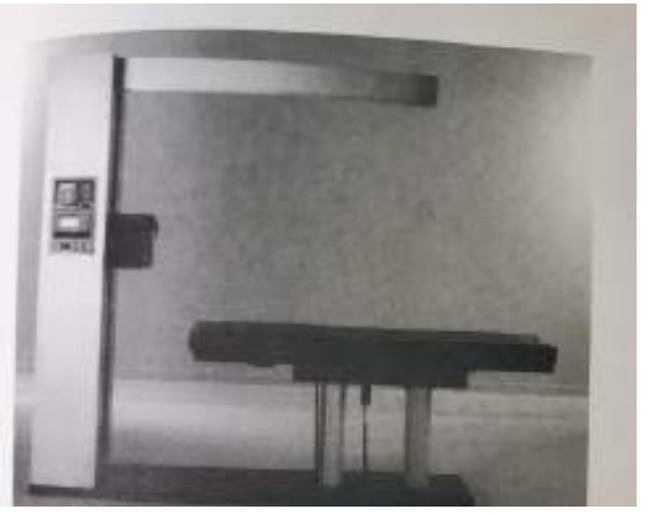

Fig. 1. The DRS™ decompression-reduction-stabilization device

CLINICAL RESULTS

In our study, 19 of 23 patients (86%) with ruptured intervertebral discs were markedly improved, and 75% of those with facet arthrosis (20 of 27) similarly reported a 50-100% reduction in pain. These results are based upon a pain analog scale with patient evaluation before and no later than 1-4 weeks after completion of therapy. All patients with pain reduction of 50-100% showed improvement in flexibility and total physical activity.

CONCLUSION

A thorough evaluation of the literature reveals NO clini. cal outcomes to correlate with different techniques, In our review and experience, no single device incorporates all seven major factors that are important In achieying clinical results.

These include: (1) split table separation; (2) flexion of the knees; (3) flexion of the lumbarspine to raise the angle and distraction segmentally; (4) comfort and nonslippage of the pelvic restraining belt; (5) comfort and nonslippage of the chest restraint; (6) concomitant use of TENS, heat, ice, and myofascial release; and (7) a graduated limbering, strengthening, and stabilization exercise program.

Using this system, successful pain control is achieved in 86% of patients with ruptured intervertebral discs and 75% of those with facet arthrosis. Because of space constraints, we did not discuss the psychological and psychiatric management of pelvic pain technique, and the reader is referred to other sources. It is worthwhile to consider also that by alternating the pathophysiology of the macro-mechanoreceptor—pain pathway, we may secondarily affect the chemoreceptors as well as reduce noxious stimuli of the richly enervated somato-autonomic lumbar spine, thereby reducing the chronicity of activity-related lumbar pain syndrome.

This benefit may also reduce need for medications. The new DRS System is a welcome addition to the problematic low back pain syndrome. The DRS System appears to be cost effective; it merits more widespread utilization and awaits additional ergonomic studies.

This approach can provide pain relief, and physicians are invited to take advantage of this gratifying treatment approach.

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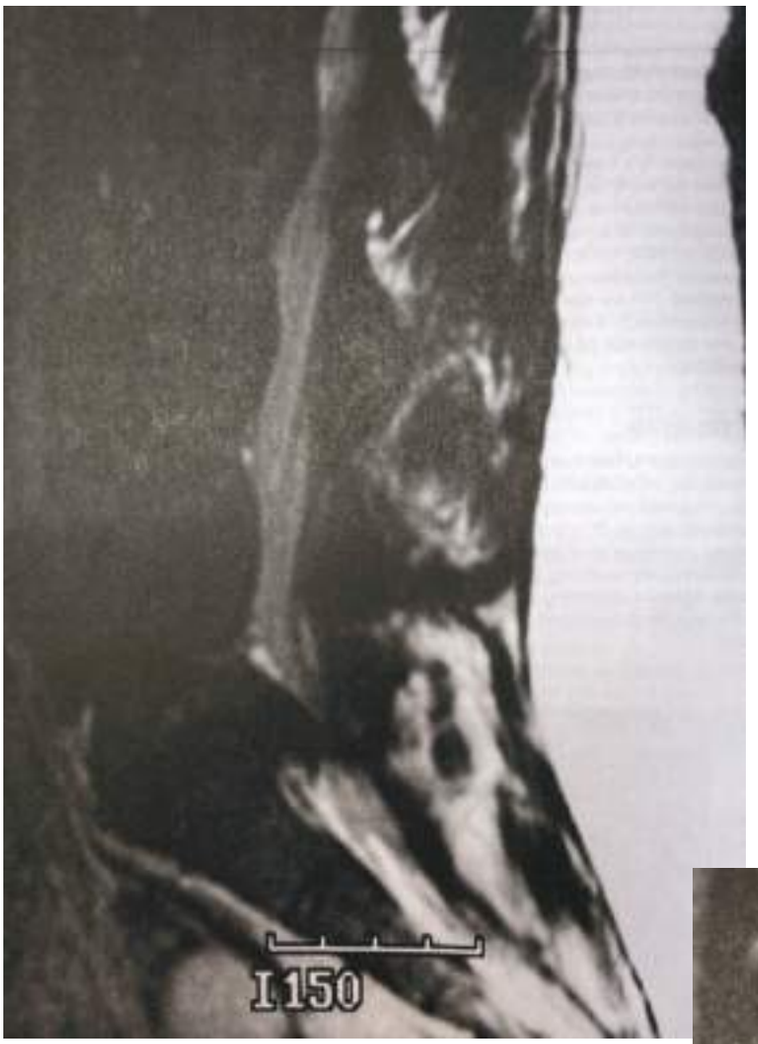

Fig. 2. MRI, patient A, showing large ruptured intervertebral disc and L5-S1, pretreatment.

Fig. 3. MRI, patient A, after 4 weeks of DRS. The ruptured intervertebral disc is approximately 50% reduced. Patient is free of pain and has marked improvement in mobility.

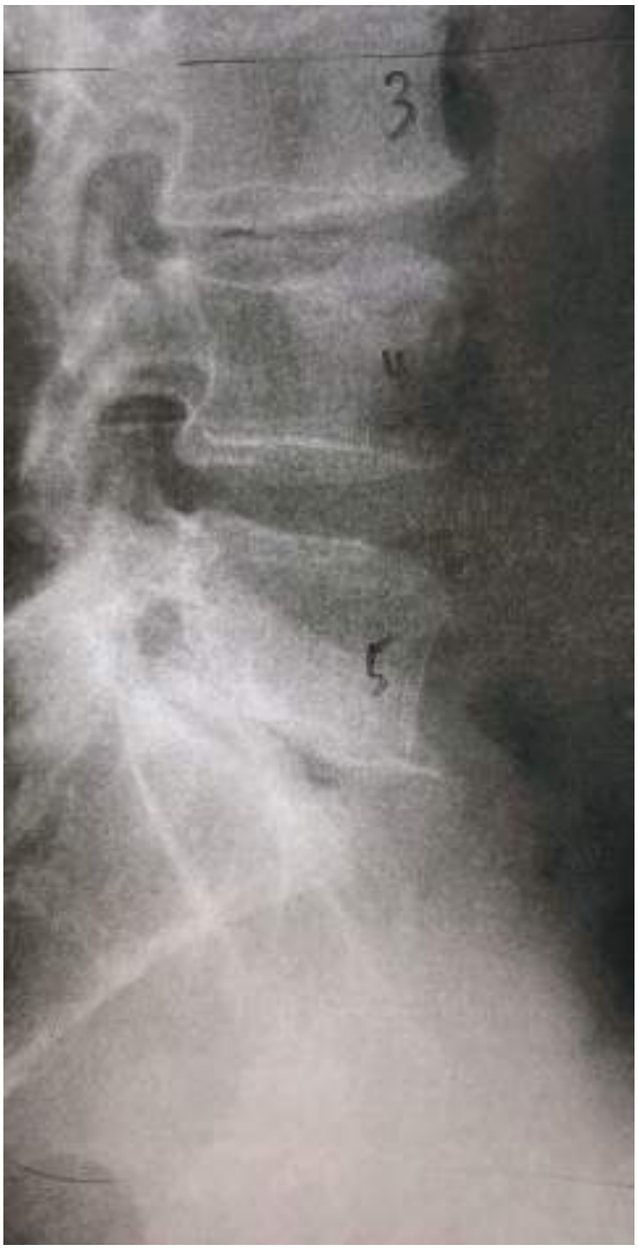

Fig. 4. Lateral Jumbar x-ray, patient B, neutral position.

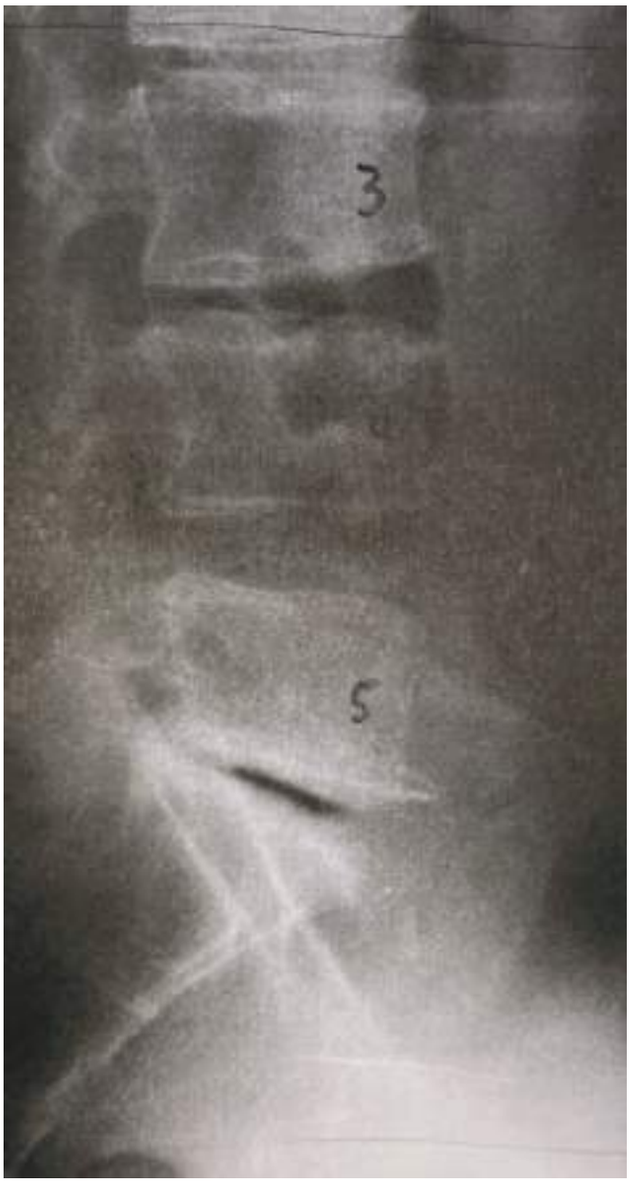

Fig. 5. Patient B, with traction-decompression, one-half body weight plus 10 pounds, knees bent.

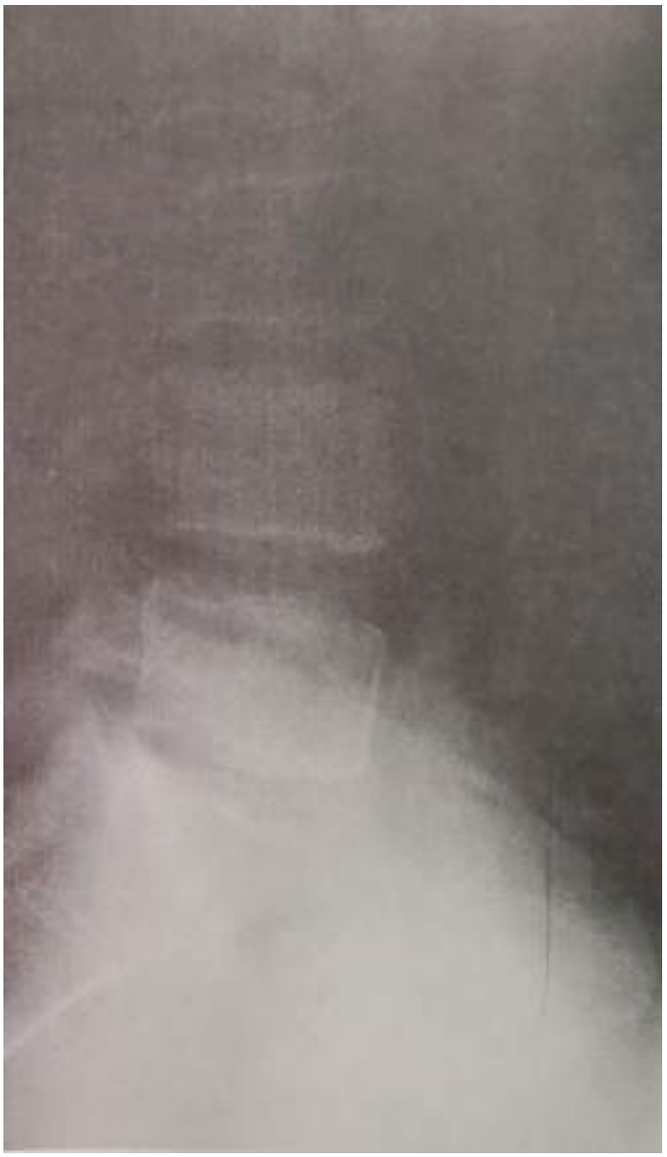

Fig. 6. Patient C, neutral position, no traction, decompression.

Fig. 7. Patient C, 30 degrees flexion, one-half body weight traction, decompression, resulting in increased widening of disc space, most prominent at L2-3 and L3-4.

EMERGING TECHNOLOGIES: PRELIMINARY FINDINGS

Decompression, Reduction and Stabilization of the Lumbar Spine: A Cost-Effective Treatment for Lumbosacral Pain

American Journal of Pain Management, vol 7, No.2, Apr. 1997

This paper established the pain relieving results of a device design to decompress spinal discs non-surgically (per the Ramos negative pressure study of 1994) utilizing a 30 degree tower and computer applied force specificity as compared to a traditional mechanical traction device.

AUTHORS

C. Norman Shealy, M.D., Ph.D., F.A.C.S. Duke University School of Medicine and Teaching Fellow at Harvard University School of Medicine.

Borgmeyer RN, MA

METHOD

Blinded, randomized, comparative between traditional mechanical traction and system designed for optimal non-surgical decompression of the spine (Shealy, Becerra et al)

CONDITIONS

- Ruptured discs
- Facet arthrosis

CONCLUSION

	Traction Vs. Decompression Results ↓	↓
Relieving Pain	55%	86%
Ruptured Disc with Excellent Results	0%	50%
Facet Arthrosis with Good Results	50%	75%


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Emerging Technologies: Preliminary Findings

DECOMPRESSION, REDUCTION, AND STABILIZATION OF THE LUMBAR SPINE: A COST-EFFECTIVE TREATMENT FOR LUMBOSACRAL PAIN

C. Norman Shealy, MD, PhD, and Vera Borgmeyer, RN, MA

This study was performed using the decompression reduction predicate to the Accu-SPINA System ® invented by Shealy/Becerra.

INTRODUCTION

Pain in the lumbosacral spine is the most commonofall pain complaints. It causes loss of work and is the single most commoncause of disability in persons under 45 years of age (1). Back pain is the most dollar-costly industrial problem (2). Pain clinics originated over 30 years ago, in large part, because of the numbers of chronic back pain patients. Interestingly, despite patients' reporting good results using "upside-down gravity boots," and commenting on how good stretching made them feel, traction as a primary treatment has been overlooked while very expensive and invasive treatments have dominated the management of low back pain.

Managed care is now recognizing the lack of sufficient benefit-cost ratio associated with these ineffective treatments to stop the continued need for pain-mitigating services. Wefelt that by improving the "'traction-like" method, pain relief would be a less costly.

Although pelvic traction has been used to treat patients with low back pain for hundreds of years, most neurosurgeons and orthopedists have not been enthusiastic aboutit secondary to concerns overinconsistent results and cumbersome equipment. Indeed, simple traction itself has not been highly effective, therefore, almost no pain clinics even include traction as part of their approach. A few authors, however, have reported varying techniques which widen disc spaces, decompress the discs, unload the vertebrae, reduce disc protrusion, reduce muscle spasm, separate vertebrae, and/or lengthen andstabilize the spine (3-12).

Over the past 25 years, we have treated thousands of chronic back pain patients who have not responded to conventional therapy. Our most successful approach has required treatment for 10-15 days, 8 hours a day, involving physicians, physical therapists, nurses, psychologists, transcutaneouselectrical nerve stimulator (TENS) specialists, and massage therapists ina multidisciplinary approach whichhasresulted in 70% of these patients improving 50-100%. Our program has been recognized as one of the most cost-effective pain programsin the US (13).

The average cost of the successful pain treatment has beencited as less than half the national average (13).

Our protocol combined traditional, labor-intensive
physical therapy techniques to produce mobilization of the spinal segments. This, combined with stabilization, helped promote healing. In addition we used biofeedback, TENS, and education to reinforce the healing processes. We wanted to produce a simpler and more cost-effective protocol that could be consistently reproduced. The biofeedback and education could be easily replicated. The problem was producing spinal mobilization to the degree that we could decompress a herniated nucleus and relieve pain. Stabilization would come after pain relief.

The DRS System was developed specifically to mobilize and distract isolated lumbar segments. Using a specific combination of lumbar positioning and varying the degree and intensity of force, we produced distraction and decompression. With fluoroscopy, we documented a 7-mm distraction at 30 degrees to L5 with several patients. In fact, we observed distraction at different spinal levels by altering the position and degree of force.

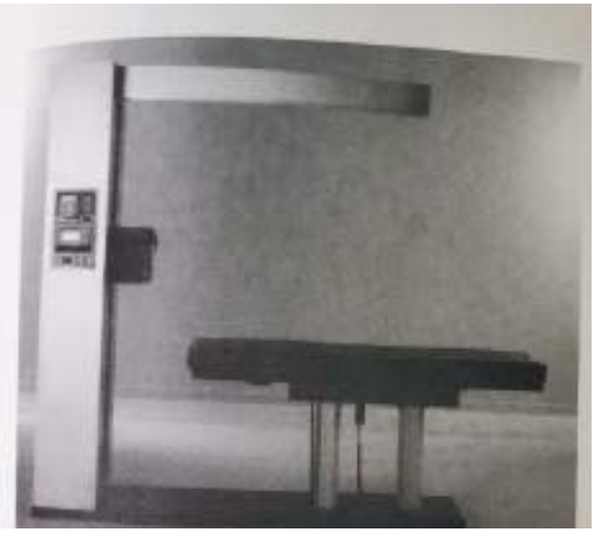
We set out to evaluate the DRS system with outpatient protocols compared to traditional therapy for both ruptured lumbar discs and chronic facet arthroses.

Subjects. Thirty-nine patients were enrolled in this study. There were 27 men and 12 women, ranging in age from 31 to 63. Twenty-three had ruptured discs diagnosed by MRI. Of these, all but four had significant sciatic radiation, with mild to moderate LS or SI hyperalgesic. All had symptoms of less than one year.

The facet arthrosis patients also underwent MRI evaluations to rule-out ruptured discs or other major pathologies. They had experienced back pain from one to 20 years. Six had mild to moderate sciatic pain with significant limitations of mobility.

METHODOLOGY

Patients were blinded to treatment and were randomly assigned to traction or decompression tables. Traction patients were treated on a standard mechanical traction table with application of traction weights averaging one-half body weight plus 10 pounds, with traction applied 60-seconds-on and 60-seconds-off, for 30 minutes daily for 20 treatments. Following the traction, Polar Powder® ice packs and electric stimulation were applied to the back for 30 minutes to relieve swelling and spasm, and patients were then instructed in use of a standard TENS use to be employed at home continuously when not sleeping. After two weeks, the patients received a total of three sessions with an exercise specialist for instruction in and supervision of a limbering/strengthening exercise program. They were re-evaluated at five to eight weeks after entering the program.



Decompression patients received treatment on the DRS System, designed to accomplish optimal decompression of the lumbar spine. Using the same 30 minute treatment interval, the patients were given the same force of one-half the body weight plus 10, but the degree of application was altered by up to 30 degrees. The effect was to produce a direct distraction at the spinal segment with minimal discomfort to the patient.

Eighty-six percent of ruptured intervertebral disc (RID) patients achieved “good” (50-89% improvement) to “excellent” (90-100% improvement) results with decompression. Sciatica and back pain were relieved. Only 55% of the RID patients achieved “good” improvement with traction, and none “excellent.”

Of the facet arthrosis patients, 75% obtained “good” to “excellent” results with decompression. Only 50% of these patients achieved “good”to “excellent” results with traction.

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Table I.

Patient assessment of pain relief secondary to decompression and to traction.

		RID	Facet arthrosis
DECOMPRESSION	excellent	7 (50%)	2 (25%)
	good	5 (36%)	4 (50%)
	poor	2 (14%)	2 (25%)
TRACTION	excellent	O	2 (25%)
	good	5 (55%)	2 (25%)
	poor	4 (45%)	4 (50%)

Excellent = 90 - 100% improved
Good =50-89% improved
Poor =< 50% improved

DISCUSSION

Since both traction and decompression patients received similar treatment (except for the differences in the traction table versus the decompression table) with similar weights, ice packs, and TENS, the results are quite enlightening. The decompression system is encouraging and supports the considerable evidence reported by other investigators stating that decompression, reduction, and stabilization of the lumbar spine relieves back pain. The computerized DRS System appears to produce consistent, reproducible, and measurable non-surgical decompression, demonstrated by radiology.

Of equal importance, the professional staff facilities required, as well as the time and cost, are all significantly reduced. Since the more complex treatment program of the last 25 years has already been shown to cost 60% less than the average pain clinic, the cost of this simpler and more integrated treatment program should be 80% less than that of most pain clinics—a most attractive solution to the most costly pain problem in the US. In addition, patients follow a 30-day protocol that produces pain relief yet allows them to continue daily activities and not lose workdays.

SUMMARY

We have compared the pain-relieving results of traditional mechanical traction (14 patients) with a more sophisticated device which decompresses the lumbar spine, unloading of the facets (25 patients).

The decompression system gave “good”to “excellent”relief in 86% of patients with RID and 75% of those with facet arthroses.

The traction yielded no “excellent”results in RID and only 50% “good”to “excellent” results in those with facet arthroses.

These results are preliminary in nature. The procedures described have not been subjected to the scrutiny of review nor scientific controls. These patients will be followed for the next six months, at which time outcome-based data can be reported. These preliminary findings are both enlightening and provocative.

The DRS system is now being evaluated as a primary intervention early in the onset of low back pain—especially in workers’ compensation injuries.

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ADDITIONAL STUDIES *& Information*

Effects of Vertebral Axial Decompression On Intradiscal Pressure.

Ramos G., MD, Martin W., MD,
Journal of Neurosurgery 81: 350-353, 1994

ABSTRACT

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 -100mmHg.

INTRODUCTION

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 neuro-compression 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 Elfstrom (6,9) 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 mmHg, 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.

MATERIALS 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 (Figure 1).

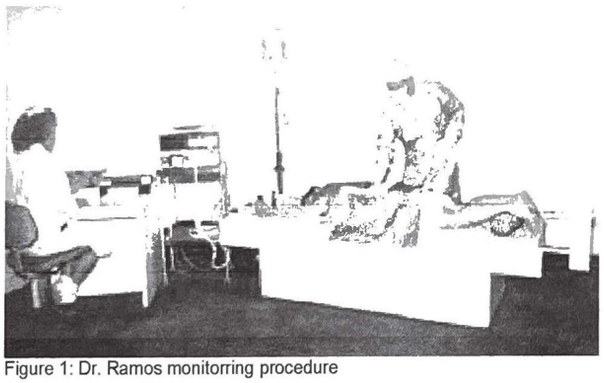


Figure 1: Dr. Ramos monitorring procedure

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 programmed 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.

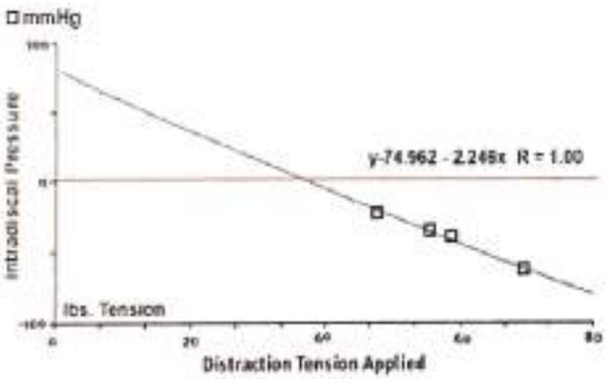
The biological transducers employed in this study are primarily designed to measure pressure changes in the positive range. Following each procedure the presssure monitor and the disposable pressure transducer used for each patient were individually calibrated and a correction curve was plotted showing 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.

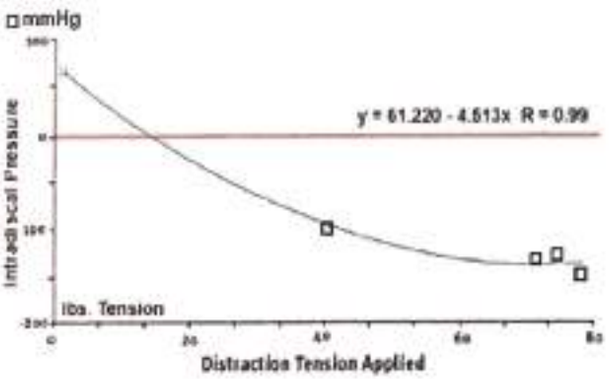
RESULTS

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 -100mmHg to -160mmHg. 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 (Figure 2).

Case Number	Sex Age	Index Monitor	Session Number							
			1	2	3	4	5	6	7	8
3	M 23	Traction tension (lbs) Intradiscal Pressure (mmHg)	0 75	47 -25	55 -39	58 -43	69 -66			
4	F 41	Traction tension (lbs) Intradiscal Pressure (mmHg)	0 60	20 30	40 -76	55 -110	60 -126	63 -117	65 -160	70 -106
5	M 34	Traction tension (lbs) Intradiscal Pressure (mmHg)	0 62	50 -106	90 -138	94 -134	98 -157			

Table 1. Effect of lumbar traction on intradiscal pressure. Measurements in the first two patients could not be translated accurately and are omitted (see text).





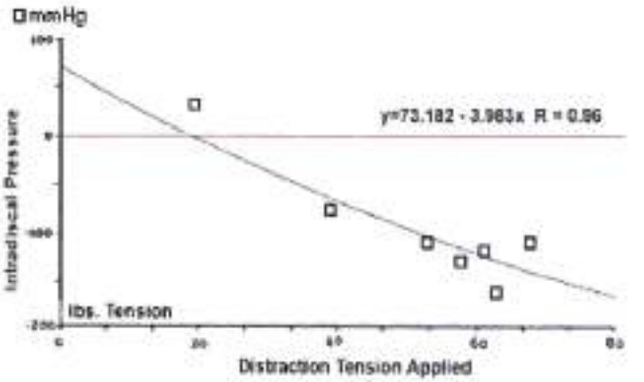


Figure 2: Graphs showing the intradiscal pressures recorded in the L4-5 nucleus pulposus of three patients (Case 3, upper left; Case 4, upper right; and Case 5, lower left) with a herniated disc at this level. Pressure is plotted against distraction tension consistent with the range of tension recommended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

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 200 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, (Figure 2.) it appeared that the decrease in pressure tends to level off as the applied distraction tensions approached 100 lbs. 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 0mmHg 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.

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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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