CLINICAL OUTCOMES FOR SPINAL DECOMPRESSION:

INTRODUCTION

The most prevalent cause of low back pain and disc disruption is an alteration of normal kinetic function. As a person utilizes various ranges of motion, the discs deform as a result of pressure changes within the disc space. This disc deformation causes nuclear migration and elongation of annular fibers. The intervertebral disc is a mechanical structure, devoid of vascular and nerve supply, which acts in a purely mechanical manner. Sheets of fibers form a fibrocartilagenous structure, creating a strong supporting outer wall and a mucopolysaccharide gel inner nucleus of the disc. Together they act hydrodynamically because of intrinsic pressure, creating a fluid enveloped within a semi rigid container (1).

Over the years, Nachemson (2) has conducted extensive research on the intradiscal pressure changes that accompany daily activities. This change in pressure is vital to maintaining homeostasis, both in and around the spinal disc. Discogenic injury is usually complicated by physical displacement, tissue edema, and muscle spasm, which combine to raise intradiscal pressures and restrict fluid migration (3). Based on this research, an abundance of ergonomic devices and exercise programs have been designed for prevention and treatment of lower back injury.

New advances in technology, focused on spinal decompression, have evolved into effective non-surgical treatment for herniated and degenerative disc disease. Injured discs can be treated by non-surgically decompressing the affected spinal segment, which significantly reduces intradiscal pressures for healing and recovery (4). The purpose of this study was to investigate the clinical outcomes of spinal decompression therapy for patients suffering from herniated and degenerative disc disease.

METHODS

SUBJECTS

Over 500 potential patients were screened for the following inclusion criteria: pain due to herniated and bulging lumbar discs that is more than four weeks old, recurrent pain from a failed back surgery that is more than six months old, persistent pain from degenerated discs not responding to four weeks of therapy, patients available for four weeks of treatment protocol, and patients at least eighteen years of age. The symptomatology of selected patients included both low back pain and radiating neuritis into the lower extremities. MRI documentation obtained six months or less from the initiating event was required. Only patients diagnosed with herniated and degenerative discs with at least a four-week onset were eligible.

Thirty-seven patients claimed their current injury was their first experience with low back and leg pain. Excluded were patients with prior surgical procedures, those with only disc degeneration documented by MRI, and patients exhibiting no radiation of pain. All patients selected have been continuously undergoing various therapies without resolution. Seventy-three patients had previously tried one to three epidural injections, prior to this episode. Twenty-two of those patients had epidurals for their current condition. Most patients reported use of pain medication to avoid surgery.

For the purpose of this study, a revised Oswestry questionnaire was incorporated to quantify information related to a measurement of functional status. Ten categories of questions, about everyday activities, were asked prior to the first session. Thirty days following the last treatment, a patient consultation allowed the investigator to re-examine symptom status and document answers according to a point value system, of which the investigator had no prior knowledge. The numerical point value was assigned only to compare before and after levels of perceived disability and not intended to give a disability level.

To standardize result analysis, MRI documentation was used to confirm diagnosis and specific disc level of injury. Objective categorization was used to regulate the findings of physical examination. Each category was determined either grossly present or not present. The same investigator would determine if reflexes were sluggish, normal, or absent. Straight leg raise that caused radiating pain into the lower back and leg was categorized as positive, but if pain remained isolated in the lower back it was considered negative. The investigator determined if an abnormal gait and kyphosis were present due to discopathy. Lumbar range of motion was checked with a goniometer. Limitations ranging from normal to over 15 degrees in flexion and over 10 degrees in rotation and extension were positive findings. The investigator used pin prick and soft touch to determine gross sensory comparison of both lower extremities, measuring sensory deficit. Patient findings were consistently recorded during each stage of treatment.

PROCEDURES

The patient protocol provided for twenty treatments over a six-week course of therapy. Each session consisted of a forty-five minute treatment on the DRX9000, which creates decompression in the disc space. The treatment was followed by fifteen minutes of the modalities of ice and interferential frequency therapy to consolidate the lumbar paravertebral muscles. Patients reported some increased soreness directly from treatment, which was immediately relieved with the use of these modalities. Patient regimen included two weeks of daily treatment, followed by three sessions per week for two weeks, concluding with two sessions per week for the remaining two weeks of therapy. The formula for determining the proper amount of pressure applied was 10 lbs less than half patient's body weight on the first day of treatment, half patient's body weight on the second day of treatment, and finally 10 lbs above half patient's body weight thru the duration of their sessions. The angle of treatment was set by manufacturer's protocol.

During the initial two weeks of treatment, the patients were instructed to wear lumbar support belts, limit activities, and placed on light duty at work. In addition, they were prescribed Naprosyn 375 mg, to be taken one hour before therapy and at bedtime during the first two weeks of treatment. After the second week of treatment, medication was decreased and moderate activity permitted. Patients who had improved by 50% were instructed on different lumbar stretching exercises to be performed in conjunction with treatment.

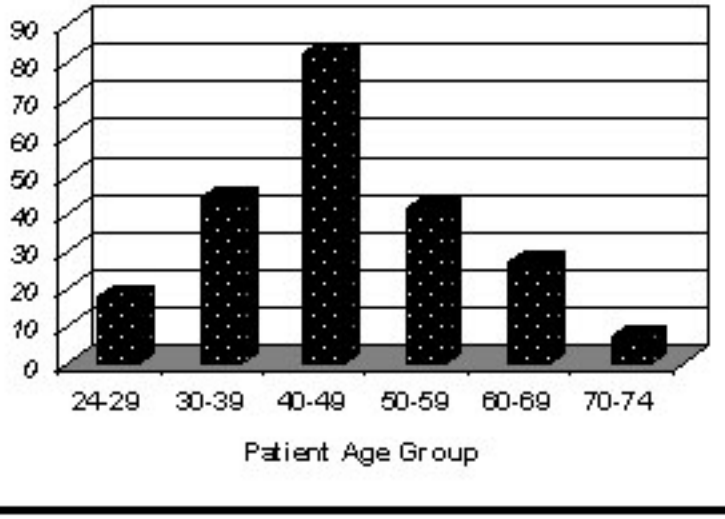
A typical session would begin with the patient being fitted with a customized lower and upper harness to fit their specific body frame. The patient would step onto a platform located at the base of the DRX9000, which simultaneously calculated body weight and determined proper treatment pressure. The patient was then lowered into the supine position, where the investigator would align the split of table with top of patient's iliac crest. A pneumatic air pump was used to automatically increase lordosis of the lumbar spine for patient comfort. The patient's chest harness was attached and tightened to the table. An automatic shoulder support system tightened and affixed patient's upper body. A knee pillow was placed to maintain slight flexion of the knees. Using the previously calculated treatment pressure, the patient undergoes spinal decompression. After treatment, the patient received interferential frequency (80-120Hz) therapy and cold packs to consolidate paravertebral muscles.

DATA ANALYSIS

Data was collected from 219 patients treated during this clinical study. Study demographics consisted of 79 female patients and 140 male patients. The patients treated ranged from 24 to 74 years of age. Fourteen patients dropped out of treatment, due to various causes ranging from scheduling conflicts to discomfort. Their results were not included during computation of data. Only patients, who were diagnosed by MRI with herniated disc and degenerative disc, receiving at least 10 treatment sessions, were included in this study.

The data collected contained detailed diagnostic studies and each patient's individual assessment of their pain and mobility. According to the Oswestry Pain Scale, patients reported their symptoms ranging from no pain [0] to severe pain [5]. All relevant patient data was recorded daily prior to treatment.

Table 1
Patient Demographic Chart



The data was divided in six groups:

1) The first group contained 67 cases, including all patients with a single lateral herniation.
2) The second group contained 22 cases, including all patients with a single central herniation.
3) The third group contained 24 cases, including all patients with a single herniation with disc degeneration.
4. The fourth group contained 17 cases, including all patients with multiple herniations (two or more) with disc degeneration.
10) The fifth group contained 57 cases, including all patients with multiple herniations (two or more) without disc degeneration.
11) The sixth group contained 32 cases, including all patients with a single lateral herniation with disc degeneration.

RESULTS

Treatment was successful in 86% of the 219 patients included in this study. Treatment success was defined by a reduction in pain to [0] or [1] on the pain scale. The perception of pain was none [0] to occasional [1] without any further need for medication or treatment in 188 patients. These patients reported complete resolution of pain, lumbar range of motion was normalized, and there was recovery of any sensory or motor loss. The remaining 34 patients reported significant pain and disability, despite some improvement in their overall pain and disability score.

In this study, only patients diagnosed with herniated and degenerative discs with at least a four-week onset were eligible. Each patient's diagnosis was confirmed by MRI findings. All selected patients reported [3] to [5] on the pain scale with radiating neuritis into the lower extremities. By the second week of treatment, 77% of patients had a greater than 50% resolution of low back pain. Subsequent orthopedic examinations demonstrated that an increase in spinal range of motion directly correlated with an improvement in straight leg raises and reflex response. Table 2 shows a summary of the findings obtained during this study by category and total results. At the thirty-day follow up, only five patients were found to have relapsed from the initial treatment program.

Table 2
Decompression Therapy
Study Group Categorized by MRI Findings

Diagnosis MRI Findings	No. of Cases	Female Patients	Male Patients	Positive Result (0-1)	No Result (2-5)	% of Success
Single Herniation Lateral	**67**	26	41	63	4	94
Single Herniation Central	**22**	11	11	20	2	90
Single Herniation w/ Degeneration	**24**	5	19	24	0	100
Multiple Herniations w/ Degeneration	**17**	2	15	13	4	77
Multiple Herniations w/o Degeneration	**57**	21	36	39	18	68
Single Herniation Lateral w/ Degeneration	**32**	14	18	29	3	91
Average over 219 cases:	**219**	79	140	188	31	86

DISCUSSION

The aim of the present study was to explore whether there was a positive clinical outcome for the treatment of herniated and degenerative disc disease using non-surgical spinal decompression. The findings demonstrate that 86% of patients reported complete resolution of pain, lumbar range of motion was normalized, and there was recovery of any sensory or motor loss. Spinal decompression therapy has been described in both the *Journal of Neurosurgery* (5) and the textbook *Pain Management: A Practical Guide for Clinicians* (6). Spinal decompression is distinguishable from conventional spinal traction. After reviewing the literature, one of the most significant differentiations between these two modalities, was that traditional traction has proven to be less effective and biomechanically inadequate to produce optimal therapeutic results (5,6,7,8). A study by Pal B, Mangion P, Hossain MA, et al (7), concluded any benefit derived from continuous traction devices is due to the enforced immobilization rather than actual traction. In another study, Weber (8) compared patients treated with traction to a control group that had simulated traction. The study showed no significant differences. Research confirms that traditional traction does not produce decompression.

Instead, decompression, that is, unloading due to distraction and positioning of the intervertebral discs and facet joints of the lumbar spine, has been proven an effective treatment for herniated and degenerative disc disease, by producing and sustaining negative intradiscal pressure in the disc space. Matthews (9) used epidurography to study patients thought to have lumbar disc protrusion. With applied forces of 120lb x 20 minutes, Matthews was able to demonstrate that the contrast material was drawn into the disc spaces by osmotic changes. Goldfish (10) speculates that the degenerated disc may benefit by lowering intradiscal pressure, affecting the nutritional state of the nucleus pulposus. Ramos and Martin (5) showed by precisely directed distraction forces, intradiscal pressure could dramatically drop into a negative range. A study by Onel (11) reported the positive effects of distraction on the disc with contour changes by CT scan. High intradiscal pressures associated with both herniated and degenerated discs interfere with the restoration of homeostasis and repair of injured tissue.

In conclusion, non-surgical spinal decompression provides a method for physicians to properly apply and direct the decompressive force necessary to effectively treat discogenic disease. Utilizing the DRX9000, spinal decompression was found to relieve symptoms and restore mechanical function to 86% of patients previously thought to be surgical candidates

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Appendix A: Back Pain Protocol

I. Inclusion criteria
- A Pain due to herniated and bulging lumbar discs that is more than four weeks old
- B Recurrent pain from a failed back surgery that is more than six months old
- C Persistent pain from degenerated discs not responding to four weeks of therapy
- D Patients available for four weeks of treatment protocol
- E Patient at least 18 years of age

II. Exclusion criteria
- A Pregnancy
- B Prior lumbar fusion
- C Metastatic cancer
- D Severe osteoporosis
- E Spondylolisthesis
- F Compression fracture of lumbar spine below L-1.
- G Pars defect
- H Pathologic Aortic aneurysm
- I Pelvic or abdominal cancer
- J Disc space infections
- K Severe peripheral neuropathy
- L Hemiplegia, paraplegia, or cognitive dysfunction

III. Negative influences
- A Smoking
- B Obesity
- C Medications: particularly chronic use of narcotics and steroids
- D Previous surgery which has a build up of scar tissue
- E Inadequate rest during first two weeks of therapy

IV. Evaluation
- A History
  - 1 Comprehensive exam
  - 2 Spinal/specific questions
  - 3 Onset of pain
  - 4 Decrease or increase of pain
  - 5 Location of pain
  - 6 Intensity
  - 7 Physical limitations
  - 8 Type, quality, and condition
  - 9 Sensory symptoms
  - 10 Bowel, bladder, or sexual dysfunction
  - 11 Spinal injuries
  - 12 Spinal surgery

B Physical Exam
1 General Exam
a Vital signs
b HEENT
c Neck
d Chest
e Abdomen
f Rectal
g Skin (lesions, redness)
h Extremities
i Neurological exam (sensory and motor)
2 Orthopedic Exam
a Lumbar Range of motion
b Straight leg raising
c Hip abduction
d Reflexes
e Sensory dermatomes
f Gait and posture abnormalities
g Muscle testing
C Diagnostic testing
1 Plain x-rays of the lumbar spine, including obliques and laterals within the past 6 months.
2 MRI if there is evidence of nerve root impairment
3 Baseline CBC and differential, chemistry panel 20, ESR with 200-mm column, urine analysis, TSH
4 EMG/NCV testing for neuritis

V. Treatment protocol

A Patients will receive a daily pre-decompression myofascial release using vacuum/interferential current treatment for 30 minutes with heat application for twenty sessions
B Set the angle for treatment according to MRI findings to target certain level lumbar disc
C Set the initial weight 10 lbs less than half body weight
D Patients will be positioned on the DRX9000 for 30-45 minutes. Regimen to include two weeks of daily treatment, followed by three sessions a week for two weeks, concluding with two sessions a week until therapy is completed (individual protocol may vary with patient progress). Weight is raised in increments of 5-10lbs per session first three sessions as tolerated in order to target one half the body weight plus 10-20 lbs
E After each treatment the patient to receive interferential therapy and cold packs to consolidate paravertebral muscles

F Re-exam after each five session to monitor patient progress. Increase or decrease pressure according to patient diagnosis, progress, and response to therapy. Multiple levels of herniations can change the angle of treatment. Target primary herniation first and then change angle to the next smallest herniation

G After ten treatments, patients who have improved by 50% are instructed on different lumbar stretching exercises to be performed in conjunction with treatment

H For those patients who have not improved by 50% after ten treatments, consider:

1. Facet nerve block injections
2. Trigger point injections
3. Refer for surgery

I After treatment protocol or significant improvement of patient's symptoms, patient will be put on a strengthening and rehabilitation program for about 4-6 weeks to help strengthen the paravertebral musculature. In addition, an after care program can include the use of tens, cold packs, exercise, relaxation training, walking techniques, and posture

J Patient to return one month after treatment for evaluation and follow-up