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Advances in Biotechnology Improve Clinical Outcomes for Spinal Decompression

by

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INTRODUCTION

Recent advances in biotechnology, focusing on spinal decompression, have evolved into effective non-surgical treatment for herniated and degenerative spinal disc disease – major causes of spinal pain. Injured discs can be treated by non-surgically decompressing the affected spinal segment, which significantly reduces intradiscal pressures, thereby permitting healing and recovery (1). The purpose of this study was to investigate the clinical outcomes of spinal decompression therapy for patients suffering from low back pain caused by herniated and degenerative disc disease.

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, spinal discs deform as a result of pressure changes within the disc. As a result of disc deformation, nuclear migration and elongation of annular fibers occurs. The intervertebral disc is a mechanical structure, which acts in a purely mechanical manner, consists of sheets of fibers forming a fibrocartilagenous structure, creating a strong supporting outer wall and an inner mucopolysaccharide gel nucleus. The outer wall and gel act hydrodynamically because of intrinsic pressure, to create a fluid enveloped within a semi rigid container (2).

Over the years, Nachemson (3) has conducted extensive research on the intradiscal pressure changes that accompany common daily activities. Change in intradiscal pressure are 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 (4). Based on this research, an abundance of ergonomic devices and exercise programs have been designed for prevention and treatment of lower back injury.

Subjects

Over 500 potential patients were screened for the following inclusion criteria: (1) pain due to herniated and bulging lumbar discs that is more than four weeks old, (2) recurrent pain from a failed back surgery that is more than six months old, (3) persistent pain from degenerated discs not responding to four weeks of conservative therapy, (4) patients available for four weeks of treatment protocol, and (5) 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 (37) 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 had been continuously undergoing various therapies without resolution. Seventy-three (73) patients had previously experienced one to three epidural injections, prior to this episode of back pain. Twenty-two (22) of those patients had epidurals for their current condition. Use of pain medication to avoid surgery was common, as expected.

For the purpose of this study, a revised Oswestry questionnaire was utilized in attempts to quantify information related to measurement of functional status. Ten categories of questions, about everyday activities, were asked prior to the first session. Thirty days following the last treatment, the patient underwent a final consultation wherein the investigator re-examined the symptom status and documented answers according to a point value system. The investigator had no prior knowledge of the patient's prior responses. The

numerical point value was assigned only to compare before and after levels of perceived disability and was not intended to determine degrees of disability.

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 as 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 measured 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 the presence of gross sensory deficit in the lower extremities. Patient findings were consistently recorded during each stage of treatment.

Procedure

The patient protocol (Appendix A) provided for twenty (20) treatments of spinal decompression over a six-week course of therapy. Each session consisted of a forty-five minute treatment on the DRX9000 equipment, which creates decompression in the disc space. The treatment was followed by fifteen minutes of ice and interferential frequency therapy in attempts to consolidate the lumbar paravertebral muscles. Patients reported some increased soreness directly from treatment, which was immediately relieved with the use of these modalities. The patient regimen included two weeks of daily spinal decompression 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 the patient's body weight on the first day of treatment, half the patient's body weight on the second day of treatment, and finally 10 lbs above half the patient's body weight thru the duration of their sessions. The angle of treatment was set according to manufacturer's protocol.

During the initial two weeks of treatment, the patients were instructed to wear lumbar support belts, limit activities, and were 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 was permitted. Patients who had improved by 50% were instructed on various lumbar stretching exercises to be performed in conjunction with treatment.

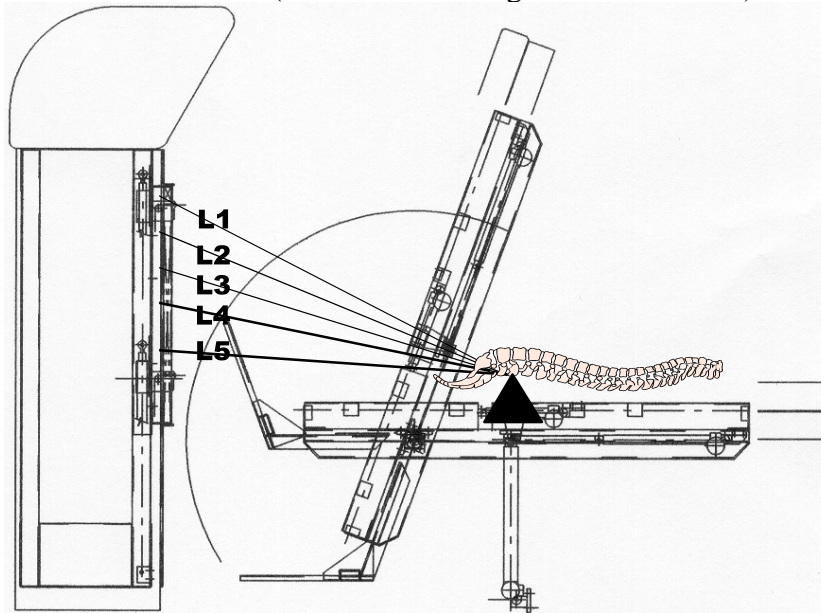
A typical session would begin with the patient being fitted with a customized lower and upper harness to fit their specific body frame. The patient would step onto a platform located at the base of the DRX9000, which simultaneously calculated body weight and determined proper treatment pressure. The patient was then lowered into the supine position, where the investigator would align the split of table with the 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 the patient's upper body. A knee pillow was placed to maintain slight flexion of the knees. Using the previously calculated treatment pressures, spinal decompression was then applied. After treatment, the patient received interferential frequency (80-120Hz) therapy and cold packs to consolidate paravertebral muscles.

Biotechnology

The equipment used in this study was the DRX9000, which represents significant innovations in the biotechnology and is FDA approval for use in the performance of patient spinal decompression. The DRX9000 was designed to lower intradiscal pressures in a controlled manner for a sustained period of time.

Parameters of treatment are determined according to patient the weight, extent and nature of disc herniation, disability of the patient, age, and pain intensity. After proper placement of the patient on the treatment table in the supine position, the physician assures that the split of the table is placed at the top of the patient's iliac crest so as to achieve separation of the lumbar joint. By using a specially designed chest harness and shoulder support system, the upper body is then fixed to the treatment table. Utilizing a pneumatic air pump, positioned below the lordotic curve of the lumbar spine, a fulcrum to the angle of distraction is then created.

(schematic drawing of the DRX9000)



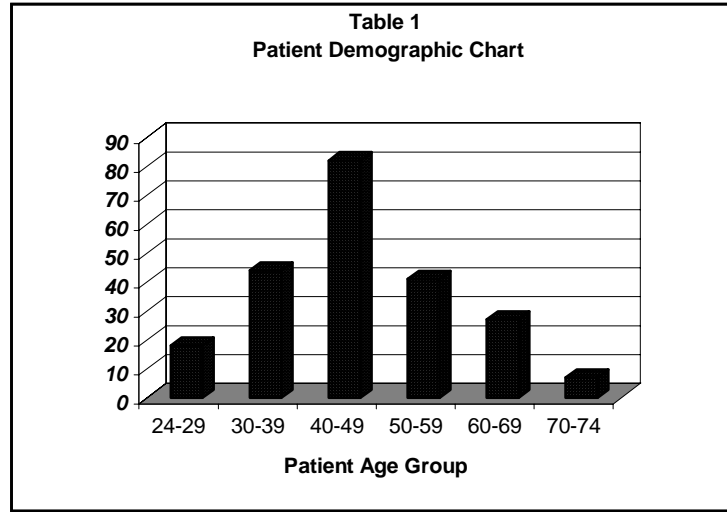
After identifying a specific lumbar disc correlated with MRI findings, specific angulation is provided automatically by the DRX9000 so that the physician can maximize the decompression effect on individual lumbar motor units, levels L1-L5. Precisely controlled distractive forces are then applied minimizing any traumatic effect on injured paraspinal ligaments and muscles, allowing intradiscal pressure to decrease significantly. The DRX9000 utilizes advanced Servomotor technology to apply these forces precisely on a logarithmic curve, thereby avoiding proprioceptor responses which may create muscle spasm.

Through use of the DRX9000's software programming, the treating physician has the ability to make specific adjustments in various degrees of applied distraction pressure. The resultant applied negative pressure allows diffusion of fluids and nutrients into the disc space that otherwise are blocked by increased intradiscal pressure.

DATA ANALYSIS

Data was collected from 219 patients treated during this clinical study. Study demographics consisted of 79 female and 140 male patients. The patients treated ranged from 24 to 74 years of age. Fourteen (14) patients dropped out of treatment, due to various causes ranging from scheduling conflicts to discomfort. Their results were not included in the computation of data. Only patients who were diagnosed by MRI with herniated disc and degenerative disc and received at least ten (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.



The data was divided in six groups:

1. The first group contained 67 cases which included all patients with a single lateral herniation.
2. The second group contained 22 cases which included all patients with a single central herniation.
3. The third group contained 24 cases which included all patients with a single herniation with disc degeneration.
4. The fourth group contained 17 cases which included all patients with multiple herniations (two or more) with disc degeneration.
5. The fifth group contained 57 cases which included all patients with multiple herniations (two or more) without disc degeneration.
6. The sixth group contained 32 cases which included 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 this study was to explore whether there was a positive clinical outcome for the treatment of herniated and degenerative disc disease using improved biotechnological 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 pre-treatment 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). In fact, one study by Mangion (7) concluded that any benefit derived from continuous traction devices was due to enforced immobilization rather than actual traction. In another study, Weber (8) compared patients treated with traction to a control group that had simulated traction and demonstrated no significant differences. Research confirms that traditional traction does not produce spinal 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.

SUMMARY

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 biotechnological advances of the DRX9000, spinal decompression was found to relieve symptoms and restore mechanical function to 86% of patients previously thought to be surgical candidates. Our results indicate that in treating 219 patients with MRI documented disc herniation and degenerative disc diseases, treatment was successful as defined by (1) pain reduction, (2) reduction in use of pain medications, (3) normalization of range of motion, and (4) recovery of sensory or motor loss. Biotechnological advances of spinal decompression indeed reveal promising results for the future of effective management of patients with disc herniation and degenerative disc diseases.

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