CLINICAL STUDIES ON THE EFFECTIVENESS OF SPINAL DECOMPRESSION THERAPY

"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." "Of the facet arthrosis patients, 75% obtained 'good' to 'excellent' results with decompression."

C. Norman Shealy, MD, PhD, and Vera Borgmeyer, RN, MA.
Decompression, Reduction, and Stabilization of the Lumbar Spine: A Cost-Effective Treatment for Lumbosacral Pain. American Journal of Pain Management Vol. 7 No. 2 April 1997

"Serial MRI of 20 patients treated with the decompression table shows in our study up to 90% reduction of subligamentous nucleus herniation in 10 of 14. Some rehydration occurs detected by T2 and proton density signal increase. Torn annulus repair is seen in all."

Eyerman, Edward MD. Simple pelvic traction gives inconsistent relief to herniated lumbar disc sufferers. Journal of Neuroimaging. Paper presented to the American Society of Neuroimaging, Orlando, Florida 2-26-98.

"Results showed that 86% of the 219 patients who completed the therapy reported immediate resolution of symptoms, while 84% remained pain-free 90 days post-treatment. Physical examination findings showed improvement in 92% of the 219 patients, and remained intact in 89% of these patients 90 days after treatment."

Gionis, Thomas MD; Groteke, Eric DC. Surgical Alternatives: Spinal Decompression. Orthopedic Technology Review. 2003; 6 (5).

"All but two of the patients in the study improved at least 30% or more in the first three weeks." "Utilizing the outcome measures, this form of decompression reduces symptoms and improves activities of daily living."

Bruce Gundersen, DC, FACO; Michael Henrie, MS II, Josh Christensen, DC. A Clinical Trial on Non-Surgical Spinal Decompression Using Vertebral Axial Distraction Delivered by a Computerized Traction Device. The Academy of Chiropractic Orthopedists, Quarterly Journal of ACO, June 2004

CLINICAL STUDIES ON THE EFFECTIVENESS OF SPINAL DECOMPRESSION THERAPY

American Journal of Pain Management Vol. 7 No. 2 April 1997
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

C. Norman Shealy MD, PhD, is Director of The Shealy Institute for Comprehensive Health Care and Clinical Research and Professor Of Psychology at the Forest Institute of Professional Psychology. Vera Borgmeyer is Research Coordinator at the Shealy Institute for Comprehensive Health Care and Clinical Research. Address reprint requests to: Dr. C. Norman Shealy, The Shealy Institute for Comprehensive Health Care and Clinical Research, 1328 East Evergreen Street, Springfield, MO 65803.

Introduction

Pain in the lumbosacral spine is the most common of all pain complaints. It causes loss of work and is the single most common cause 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. We felt that by improving the "traction-like" method, pain relief would be achieved quickly and 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 about it secondary to concerns over inconsistent 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 and stabilize 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, transcutaneous electrical nerve stimulator (TENS) specialists, and massage therapists in a multidisciplinary approach which has resulted in 70% of these patients improving 50-100%. Our program has been recognized as one of the most cost-effective pain programs in the US (I 3). The average cost of the successful pain treatment has been cited 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 L5 or S1 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.

Table 1. Patient assessment of pain relief secondary to decompression and to traction.

Method	Rating	RID	Facet arthrosis
Decompression	excellent	7 (50%)	2 (25%)
	good	5 (36%)	4 (50%)
	poor	2 (14%)	2 (25%)
Traction	excellent	0	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.

References

1. Acute low back problems in adults: assessment and treatment. US Department of Health and Human Services; 1994 Dec; Rockville, MD.
2. Snook, Stover. The costs of back pain in industry. occupational back pain, State-of-art review. Spine 1987; 2(No. 1): 1-4.
3. Gray FJ, Hoskins MJ. Radiological assessment of effect of body weight traction on lumbar disk spaces. Medical Journal of Australia 1963;2:953-954.
4. Andersson GB, Gunnar BJ, Schultz, AB, Nachemson AL. Intervertebral disc pressures during traction. Scandinavian Journal of Rehabilitation Medicine 1968; (9 Supplement): 8891.
5. Neuwirth E, Hilde W, Campbell R. Tables for vertebral elongation in the treatment of sciatica. Archives of Physical Medicine 1952; 33 (Aug):455-460.
6. Colachis SC Jr, Strohm BR. Effects of intermittent traction on separation of lumbar vertebrae. Archives of Physical Medicine & Rehabilitation 1969; 50 (May):251-258.
7. Gray FJ, Hosking HJ. A radiological assessment of the effect of body weight traction on the lumbar disc spaces. The Medical Journal of Australia 1963; (Dec 7):953-955.
8. Gupta RC, Ramarao MS. Epidurography in reduction of lumbar disc prolapse by traction. Archives of Physical Medicine & Rehabilitation 1978; 59 (Jul):322-327.
9. Cyriax J. The treatment of lumbar disc lesions. British Medical Journal 1950; (Dec 23):1434-1438.
10. Lawson GA. Godfrey CM. A report on studies of spinal traction. Medical Services Journal of Canada, 1958; 14 (Dec):762-771
11. Cyriax JH. Discussions on the treatment of backache by traction. Proceedings of the Royal Society of Medicine 1955;48:805-814.
12. Mathews JA. Dynamic discography: a study of lumbar traction. Annals of Physical Medicine 1968; IX (No.7):265279.
13. Managed Care Organization Newsletter (American Academy of Pain Management). July 1996.

Simple Pelvic Traction Gives Inconsistent Relief to Herniated Lumbar Disc Sufferers.

EDWARD L. EYERMAN, MD
Journal of Neuroimaging June 1998

A new decompression table system applying fifteen 60 second tractions of just over one half body weight in twenty one-half hour sessions was reported to give good or excellent relief of sciatic and back pain in 86% of 14 patients with herniated discs and 75% of patients with facet joint arthrosis. (Shealy, C.N.,Borgmeyer, V., AMJ. Pain Management 1997,7:63-65).

Herniated and degenerated 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 of 20 patients treated with the decompression table shows in our study up to 90% reduction of subligamentous nucleus herniation in 10 of 14. Some 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. Follow up studies for permanency or relapses are in progress.

The DRS Mechanical Decompression Distraction System was described by Shealy and Borgmeyer (1) to give relief of lumbar herniated disc and facet joint arthrosis superior by 50% to conventional pelvic traction. Twenty DRS treatments produced on midsagittal MRI a 50% reduction in one case, and a 7mm distraction of 1.5 on SI was shown on lateral x-ray. (2) Clinical improvement in 75 to 85% of subjects was reported. Does clinical betterment correlate directly to improvement in MRI image and can MRI shed any light on the mechanism of improvement?

That the abnormal disc has an elevated pressure can be appreciated at discogram. It is postulated that this elevated pressure interferes both with diffusion of nutrients from surrounding vessels into the nucleus and with adequate patching or repair of the tom annulus. Nachemson's group has emphasized lowering intradiscal pressure for 30 years. (3) & (4) Neurosurgeons Rainon and Martin (5) at operation on a similar decompression table measured in an L45 herniated disc a lowering of intradiscal pressure from 30 to 50 mm above the normal 90 to 100 mmHg into the negative range of minus 100 to 150 mmHg during 90 to 95 LB traction. Will such negative pressures heal the annulus, rehydrate the nucleus?

The aim of the present study was to do before and after MRI to correlate clinical improvement with any MM evidence of disc repair in annulus, nucleus, facet joint or foramen as a result of DRS treatment. A course of 20 DRS Lumbar De-compression treatments were given in 4 to 5 weeks to 18 patients, and a double course of 40 in 10 weeks to 2 more. Pull of distraction was adjusted to one half-body weight plus IO lbs. Each session consisted of 20 repetitions in 30 minutes of full distraction for 60 seconds and 30 seconds of relaxation to 50 lbs. Distraction angle on pelvic harness was varied from 10% for L5-S I to 20 to 25% for L4-5 herniations and above.

Subjects comprised 12 males and 8 females from age 26 to 74. Radiculopathy in 14 patients was from herniated discs of varying sizes. (L5-S I level in 6, L4-5 in 6, and 1 each at L3-4 and L2-3). Radiculopathy without disc herniation was present in 6 patients from foraminal stenosis facet arthropathy and lateral spinal stenosis. EMGs confirmed radiculopathy in all. MRI's before and after were obtained on high and mid field units. Clinical status was assessed before, during, and after treatment with standard analog pain rating scale of 0- I0 and a neuro exam.

Range of motion for spinal mobility (initially impaired in all), myotomal weakness reflex and dermatomal sensory loss were tested.

A) MRI OUTCOMES

a) Disc Herniation: 10 of 14 improved significantly, some globally, some at least local at the site of the nerve root compression. Measured improvement in local or general disc herniation size varied in range of 0% in 2 patients, 20% in 4 patients, 30 to 50% in 4 patients and a remarkable 90 % in 2 patients who had the number of treatments at 40 sessions in 8 weeks.

b) Facet joint arthropathy and foraminal compression cases showed no demonstrable change save 2 cases with slight increase in height but not in hydration.

B) CLINICAL OUTCOMES

Irrespective of MRI status all but 3 patients had very significant pain relief, complete relief of weakness when present, and of immobility and of all numbness (save in 1 patient with herniation and 2 with foraminal stenosis without herniation). With disc herniation, 10 patients of 14 had 10 to 90% improvement in pain and disability. Two had 40 to 50%, one had only 20% with foraminal syndrome without herniation, 4 had 70 to 100 % improvement, one had 40 to 50 %, one with severe spinal stenosis had only 25% and was sent for surgery. Degree of clinical improvement roughly followed MRI changes but not totally with full correlation.

Improvement from DRS treatment clinical outcome of radiculopathy whether from disc herniation or foraminal syndromes is more impressive than most improvement shown consistently by MRI, at least with today's techniques and short time of follow-up. Relief of pain and disability by reduction of disc size is easy to argue in a small majority of this series. A few patients have dramatic anatomic improvement. The others with minimal or no significant MRI improvements are harder to explain. Also, many patients improved very early in treatment, probably before MRI change could be seen.

Nutrient diffusion increase and tom annulus healing resulting from lowering intradiscal pressures are likely causes of clinical improvement when MRI anatomy is not much altered by distraction. Leaking of important sulfates and carboxylates from the nucleus and posterior annulus have been shown in recent studies. (6) and (7) lowering of intradiscal pressure by DRS treatment likely can start to reverse these processes by allowing fibroblast repair of the annulus outer layers and some nutrition to the nucleus. Also penetration of nerves into inner annulus and nucleus of degenerated prolapsed discs has been recently demonstrated and could play a role in pain production. (8) Mechanical intradiscal pressure relief may help this feature as well as giving structural stability.

1. DRS distraction treatments afforded good or excellent relief of pain and disability whether from herniated disc or foraminal or lateral spinal stenosis.
2. MRI showed imperfect correlation with degree of clinical improvement but 10 to 90% reduction in disc herniation size could be seen at least at the critical point of nerve root impingement in 10 of 14 patients.
3. Two patients with extended courses of treatment showed 90% disc reduction and one of these had early rehydration of the degenerated disc at L4-5. An "empty pouch" sign on MRI at the site of previous herniation was seen in these 2 patients.
4. Foraminal and lateral spinal or facet arthrosis cases causing radiculopathy without herniation also improved but without MRI change.
5. Annulus healing or patching in the herniated disc can be shown by MRI and is postulated to be a primary factor in clinical and MRI improvement.

CLINICAL STUDIES ON THE EFFECTIVENESS OF SPINAL DECOMPRESSION THERAPY

Spinal Decompression

By Thomas A. Gionis, MD, JD, MBA, MHA, FICS, FRCS, and Eric Groteke, DC, CCIC

Orthopedic Technology Review, Vol. 5-6, Nov-Dec 2003.

The outcome of a clinical study evaluating the effect of nonsurgical intervention on symptoms of spine patients with herniated and degenerative disc disease is presented.

This clinical outcomes study was performed to evaluate the effect of spinal decompression on symptoms and physical findings of patients with herniated and degenerative disc disease. Results showed that 86% of the 219 patients who completed the therapy reported immediate resolution of symptoms, while 84% remained pain-free 90 days post-treatment. Physical examination findings showed improvement in 92% of the 219 patients, and remained intact in 89% of these patients 90 days after treatment. This study shows that disc disease-the most common cause of back pain, which costs the American health care system more than $50 billion annually-can be cost-effectively treated using spinal decompression. The cost for successful non-surgical therapy is less than a tenth of that for surgery. These results show that biotechnological advances of spinal decompression reveal promising results for the future of effective management of patients with disc herniation and degenerative disc diseases. Long-term outcome studies are needed to determine if non-surgical treatment prevents later surgery, or merely delays it.

INTRODUCTION: ADVANCES IN BIOTECHNOLOGY

With the recent advances in biotechnology, spinal decompression has evolved into a cost-effective nonsurgical treatment for herniated and degenerative spinal disc disease, one of the major causes of back pain. This nonsurgical treatment for herniated and degenerative spinal disc disease works on the affected spinal segment by significantly reducing intradiscal pressures.1 Chronic low back pain disability is the most expensive benign condition that is medically treated in industrial countries. It is also the number one cause of disability in persons under age 45. After 45, it is the third leading cause of disability.2 Disc disease costs the health care system more than $50 billion a year.

The intervertebral disc is made up of sheets of fibers that form a fibrocartilaginous structure, which encapsulates the inner mucopolysaccharide gel nucleus. The outer wall and gel act hydrodynamically. The intrinsic pressure of the fluid within the semirigid enclosed outer wall allows hydrodynamic activity, making the intervertebral disc a mechanical structure.3 As a person utilizes various normal ranges of motion, spinal discs deform as a result of pressure changes within the disc.4 The disc deforms, causing nuclear migration and elongation of annular fibers. Osteophytes develop along the junction of vertebral bodies and discs, causing a disease known as spondylosis. This disc narrows from the alteration of the nucleus pulposus, which changes from a gelatinous consistency to a more fibrous nature as the aging process continues. The disc space thins with sclerosis of the cartilaginous end plates and new bone formation around the periphery of the contiguous vertebral surfaces. The altered mechanics place stress on the posterior diarthrodial joints, causing them to lose their normal nuclear fulcrum for movement. With the loss of disc space, the plane of articulation of the facet surface is no longer congruous. This stress results in degenerative arthritis of the articular surfaces.

This is especially important in occupational repetitive injuries, which make up a majority of work-related injuries. When disc degeneration occurs, the layers of the annulus can separate in places and form circumferential tears. Several of these circumferential tears may unite and result in a radial tear where the material may herniate to produce disc herniation or prolapse. Even though a disc herniation may not occur, the annulus produces weakening, circumferential bulging, and loss of intervertebral disc height. As a result, discograms at this stage usually reveal reduced interdiscal pressure.

The early changes that have been identified in the nucleus pulposus and annulus fibrosis are probably biomechanical and relate to aging. Any additional trauma on these changes can speed up the process of degeneration. When there is a discogenic injury, physical displacement occurs, as well as tissue edema and muscle spasm, which increase the intradiscal pressures and restrict fluid migration.6 Additionally, compression injuries causing an endplate fracture can predispose the disc to degeneration in the future.

The alteration of normal kinetics is the most prevalent cause of lower back pain and disc disruption and thus it is vital to maintain homeostasis in and around the spinal disc; Yong-Hing and Kirkaldy-Willis7 have correlated this degeneration to clinical symptoms. The three clinical stages of spinal degeneration include:

1. Stage of Dysfunction. There is little pathology and symptoms are subtle or absent. The diagnosis of Lumbalgia and rotatory strain are commonly used.
2. Stage of Instability. Abnormal movement of the motion segment of instability exists and the patient complains of moderate symptoms with objective findings. Conservative care is used and sometimes surgery is indicated.
3. Stage of Stabilization. The third phase where there are severe degenerative changes of the disc and facets reduce motion with likely stenosis.

Spinal decompression has been shown to decompress the disc space, and in the clinical picture of low back pain is distinguishable from conventional spinal traction.8,9 According to the literature, traditional traction has proven to be less effective and biomechanically inadequate to produce optimal therapeutic results.8-11 In fact, one study by Mangion et al concluded that any benefit derived from continuous traction devices was due to enforced immobilization rather than actual traction.10 In another study, Weber compared patients treated with traction to a control group that had simulated traction and demonstrated no significant differences.11 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. In agreement with Nachemon's findings and Yong-Hing and Kirkaldy-Willis,1 spinal decompression treatment for low back pain intervenes in the natural history of spinal degeneration.7,12 Matthews13 used epidurography to study patients thought to have lumbar disc protrusion. With applied forces of 120 pounds x 20 minutes, he was able to demonstrate that the contrast material was drawn into the disc spaces by osmotic changes. Goldfish14 speculates that the degenerated disc may benefit by lowering intradiscal pressure, affecting the nutritional state of the nucleus pulposus. Ramos and Martin8 showed by precisely directed distraction forces, intradiscal pressure could dramatically drop into a negative range. A study by Onel et al15 reported the positive effects of distraction on the disc with contour changes by computed tomography imaging. High intradiscal pressures associated with

both herniated and degenerated discs interfere with the restoration of homeostasis and repair of injured tissue.

Biotechnological advances have fostered the design of Food and Drug Administration-approved ergonomic devices that decompress the intervertebral discs. The biomechanics of these decompression/reduction machines work by decompression at the specific disc level that is diagnosed from finding on a comprehensive physical examination and the appropriate diagnostic imaging studies. The angle of decompression to the affected level causes a negative pressure intradiscally that creates an osmotic pressure gradient for nutrients, water, and blood to flow into the degenerated and/or herniated disc thereby allowing the phases of healing to take place.

This clinical outcomes study, which was performed to evaluate the effect of spinal decompression on symptoms of patients with herniated and degenerative disc disease, showed that 86% of the 219 patients who completed therapy reported immediate resolution of symptoms, and 84% of those remained pain-free 90 days post-treatment. Physical examination findings revealed improvement in 92% of the 219 patients who completed the therapy.

Methods

The study group included 229 people, randomly chosen from 500 patients who had symptoms associated with herniated and degenerative disc disease that had been ongoing for at least 4 weeks. Inclusion criteria included pain due to herniated and bulging lumbar discs that is more than 4 weeks old, or persistent pain from degenerated discs not responding to 4 weeks of conservative therapy. All patients had to be available for 4 weeks of treatment protocol, be at least 18 years of age, and have an MRI within 6 months. Those patients who had previous back surgery were excluded. Of note, 73 of the patients had experienced one to three epidural injections prior to this episode of back pain and 22 of those patients had epidurals for their current condition. Measurements were taken before the treatments began and again at week two, four, six, and 90 days post treatment. At each testing point a questionnaire and physical examination were performed without prior documentation present in order to avoid bias. Testing included the Oswetry questionnaire, which was utilized to quantify information related to measurement of symptoms and functional status. Ten categories of questions about everyday activities were asked prior to the first session and again after treatment and 30 days following the last treatment.

Testing also consisted of a modified physical examination, including evaluation of reflexes (normal, sluggish, or absent), gait evaluation, the presence of kyphosis, and a straight leg raising test (radiating pain into the lower back and leg was categorized when raising the leg over 30 degrees or less is considered positive, but if pain remained isolated in the lower back, it was considered negative). Lumbar range of motion was measured with an ergonometer. Limitations ranging from normal to over 15 degrees in flexion and over 10 degrees in rotation and extension were positive findings. The investigator used pinprick and soft touch to determine the presence of gross sensory deficit in the lower extremities.

Of the 229 patients selected, only 10 patients did not complete the treatment protocol. Reasons for noncompletion included transportation issues, family emergencies, scheduling conflicts, lack of motivation, and transient discomfort. The patient protocol provided for 20 treatments of spinal decompression over a 6-week course of therapy. Each session consisted of a 45-minute treatment on the equipment followed by 15 minutes of ice and interferential frequency therapy to consolidate

the lumbar paravertebral muscles. The patient regimen included 2 weeks of daily spinal decompression treatment (5 days per week), followed by three sessions per week for 2 weeks, concluding with two sessions per week for the remaining 2 weeks of therapy.

On the first day of treatment, the applied pressure was measured as one half of the person's body weight minus 10 pounds, followed on the second day with one half of the person's body weight. The pressure placed for the remainder of the 18 sessions was equivalent to one half of the patient's body weight plus an additional 10 pounds. The angle of treatment was set according to manufacturer's protocol after identifying a specific lumbar disc correlated with MRI findings. A 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 equipment, 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 the 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. With use of the previously calculated treatment pressures, spinal decompression was then applied. After treatment, the patient received 15 minutes of interferential frequency (80 to 120 Hz) therapy and cold packs to consolidate paravertebral muscles.

During the initial 2 weeks of treatment, the patients were instructed to wear lumbar support belts and limit activities, and were placed on light duty at work. In addition, they were prescribed a nonsteroidal, to be taken 1 hour before therapy and at bedtime during the first 2 weeks of treatment. After the second week of treatment, medication was decreased and moderate activity was permitted.

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 (see Table 1). The average weight of the females was 146 pounds and the average weight of the men was 195 pounds. According to the Oswestry Pain Scale, patients reported their symptoms ranging from no pain (0) to severe pain (5).

Results

According to the self-rated Oswestry Pain Scale, 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 31 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 4-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 subjective findings obtained during this study by category and total results post treatment. After 90 days, only five patients (2%) were found to have relapsed from the initial treatment program.

Ninety-two percent of patients with abnormal physical findings improved post-treatment. Ninety days later only 3% of these patients had abnormal findings. Table 3 summarizes the percentage of patients that showed improvement in physician examination findings testing both motor and sensory system function after treatment. Gait improved in 96% of the individuals who started with an abnormal gait, while 96% of those with sluggish reflexes normalized. Sensory perception improved in 93% of the patients, motor limitation diminished in 86%, 89% had a normal straight leg raise test who initially tested abnormal, and 90% showed improvement in their spinal range of motion.

Summary

In conclusion, nonsurgical spinal decompression provides a method for physicians to properly apply and direct the decompressive force necessary to effectively treat discogenic disease. With the biotechnological advances of spinal decompression, symptoms were restored by subjective report in 86% of patients previously thought to be surgical candidates and mechanical function was restored in 92% using objective data. Ninety days after treatment only 2% reported pain and 3% relapsed, by physical examination exhibiting motor limitations and decreased spinal range of motion. Our results indicate that in treating 219 patients with MRI-documented disc herniation and degenerative disc diseases, treatment was successful as defined by: pain reduction; reduction in use of pain medications; normalization of range of motion, reflex, and gait; and 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. The cost for successful nonsurgical therapy is less than a tenth of that for surgery. Long-term outcome studies are needed to determine if nonsurgical treatment prevents later surgery or merely delays it.

Thomas A. Gionis, MD, JD, MBA, MHA, FICS, FRCS, is chairman of the American Board of Healthcare Law and Medicine, Chicago; a diplomate professor of surgery, American Academy of Neurological and Orthopaedic Surgeons; and a fellow of the International College of Surgeons and the Royal College of Surgeons.

Eric Groteke, DC, CCIC, is a chiropractor and is certified in manipulation under anesthesia. He is also a chiropractic insurance consultant, a certified independent chiropractic examiner, and a certified chiropractic insurance consultant. Groteke maintains chiropractic centers in northeastern Pennsylvania, in Stroudsburg, Scranton, and Wilkes-Barre.

References

1. Eyerman E. MRI evidence of mechanical reduction and repair of the torn annulus disc. International Society of Neuroradiologists; October 1998; Orlando.
2. Narayan P, Morris IM. A preliminary audit of the management of acute low back pain in the Kettering District. Br J Rheumatol. 1995;34:693-694.
3. McDevitt C. Proteoglycans of the intervertebral disc. In: Gosh, P, ed. The Biology of the Intervertebral Disc. Boca Raton, Fla: CRC Press; 1988:151-170.
4. Bogduk N, Twomey L. Clinical Anatomy of the Lumbar Spine. New York: Churchill Livingstone; 1991.

5. Cox JM. Low Back Pain: Mechanism, Diagnosis, and Treatment. 5th ed. Baltimore: Williams & Wilkins; 1990:69-70, 144.
6. Cyriax JH. Textbook of Orthopaedic Medicine: Diagnosis of Soft Tissue Lesions. Vol 1. 8th ed. London: Balliere Tindall; 1982.
7. Nachemson AL. The lumbar spine, an orthopaedic challenge. Spine. 1976;1(1):59-69.
8. Ramos G, Martin W. Effects of vertebral axial decompression on intradiscal pressure. J Neurosurgery. 1994;81:350-353.
9. Shealy CN, Leroy P. New concepts in back pain management: decompression, reduction, and stabilization. In: Weiner R, ed. Pain Management: A Practical Guide for Clinicians. Boca Raton, Fla: St Lucie Press; 1998:239-257.
10. Pal B, Mangion P, Hossain MA, et al. A controlled trial of continuous lumbar traction in back pain and sciatica. Br J Rheumatol. 1986;25:181-183.
11. Weber H. Traction therapy in sciatica due to disc prolapse. J Oslo City Hosp. 1973;23(10):167-176.
12. Yong-Hing K, Kirkaldy-Willis WH. The pathophysiology of degenerative disease of the lumbar spine. Orthop Clin North Am. 1983;14:501-503.
13. Matthews J. The effects of spinal traction. Physiotherapy. 1972;58:64-66.
14. Goldfish G. Lumbar traction. In: Tollison CD, Kriegel M, eds. Inter-disciplinary Rehabilitation of Low Back Pain. Baltimore: Williams & Wilkins; 1989.
15. Onel D, Tuzlaci M, Sari H, Demir K. Computed tomographic investigation of the effect of traction on lumbar disc herniations. Spine. 1989; 14(1):82-90.

A Clinical Trial on Non-Surgical Spinal Decompression Using Vertebral Axial Distraction Delivered by a Computerized Traction Device

Bruce Gundersen, DC, FACO; Michael Henrie, MS II, Josh Christensen, DC. The Academy of Chiropractic Orthopedists Quarterly Journal of ACO - June 2004

Introduction

Hypothesis: Axial traction of the spine produces remission of symptoms in specific conditions that have not responded to traditional manipulative protocols when computerized decompression traction, electrical stimulation and biofeedback exercise stabilization are applied under a controlled regimen.

The study is a pilot project and was not considered by an IRB for the initial phase. Continued investigation is suggested. The equipment for the study was provided by Calhoon Health Products. No fees for treatment were charged to any patients and no subjects were paid to participate in the study.

Review of the Literature

There are many studies on traction in the current literature. We have sited 20 indicating a broad interest in this concept and a continued search for alternatives to surgical decompression of the spine. The articles with a brief synopsis are listed at the end with the reference. The primary clinical point of the literature review is that compression of the neuronal elements of the spine seems to be

a leading cause or generator of the pain in chronic situations. Decompression has proven effective and various forms of decompression are elaborated. In conclusion from analyzing these articles, vertebral axial distraction can be accomplished several ways and reports of reduction of intradiscal pressure, reduction of disc herniations, and associated symptoms are cited.

Current Research

A trial was designed to measure the improvement on low back and leg pain and neck and arm pain patients. Patients who had reported symptoms in those areas were notified of the project and invited to participate. Other providers of physical medicine were notified as well and encouraged to have patients with similar unresponsive conditions inquire. All patients admitted to the study had a lengthy history of pain with multiple episodes of chiropractic manipulation and physical therapy with limited success.

Methods

A combination of questionnaires were used to compute an intake score for each patient. The score was computed using the formula, the sum of the total score from each questionnaire. Categories of severity were created as follows: 0-150; 151-175; 176-200; and > 200.

Protocols were determined based on total intake score and ranged from 3 to 6 treatment sessions per week. Traction protocols were determined based on patient history and symptoms, chronicity and extent of radicular signs. Treatment frequency was determined by total points: under 150 - 3 days per week, 151 to 175 - 4 days per week, 176 to 200 - 5 days per week and over 200 - 6 days per week.

The Axial Disc Compression Traction Therapy unit, manufactured by Chattanooga, was utilized in this study. Directions contained in the D.T.S. Information manual, copyright 2002 by Jay Kennedy were followed.

In this study, there were nine men and 5 woman ranging in age between 26-64. The range in chronicity for LB/Leg pain was 6 months to 29 years and neck to arm pain 1 year to 7 years. Exclusion criteria included, those with spinal fusions from hardware implant, those with non-disc related central spinal stenosis, those over age 70 or under age 18.

Intake measurements include modified Oswestry Low Back Pain Disability Questionnaire (Fairbanks, 1980) and the Neck Disability Index (Vernon and Mior, 1988) Activities Discomfort Scale (Turner, 1983) and a quadruple visual analogue pain scale (Yeomans, 2000). Each item was scored and the total recorded and compared to the exit scores. For this project, no objective tests were obtained on intake or exit, only standardized outcomes assessment tools.

The Procedure

Patients who qualified to enter into the study were measured and fitted to the traction unit. Both prone and supine protocols were considered for lumbar decompression. The prone position is usually recommended but can be modified per patient ability to tolerate the position. Cervical decompression is done in the supine position. Precise positioning for each patient is critical for

outcomes to be optimized A 100% compliance was expected from each subject accepted into the study in order to optimize the statistical analysis.

The specific treatment protocol was determined by the doctor after assessing the intake examination and evaluation. The computer controls the variations in the traction allowing for spinal decompression and attempting to reduce the muscle reaction and subsequent compression that can occur with some types of traditional or conventional traction devices. The preprogrammed patterns for ramping up and down the amount of axial distraction allows for optimal levels of spinal decompression and disc hydration when possible.

Proper patient positioning and specific technique insure expected results.

Results

Of the 14 patients that were admitted into the study on May 17, 2004, the group was divided into the neck and arm pain group with 4 patients and the low back and leg pain group with 10 patients.

The three outcomes assessment tools were scored and totaled for each patient on intake and after three weeks of the study.

Spinal Decompression Study Results

Patient	Complaint	Intake Score	Exit Score	% Measured	% Reported
Average		135.33	83.17	0.36	63.75
1	Low back and leg	158	60	0.62	75
2	Low back and leg	90	86	0.04	0
3	Low back and leg	56	37	0.34	85
4	Neck and Arm	99	66	0.33	95
5	Low back and leg	194	120	0.38	40
6	Neck and Arm	91	60	0.34	50
7	Low back and leg	185	70	0.62	85
8	Neck and Arm	131	78	0.40	70

Using a single tool, the Revised Oswestry form for low back, it is noted that improvement parallels, in all but one case, the combination of the three tools.

Oswestry Low Back

	Average	42.29	24.57	0.53
Patient	Complaint	Intake Score	Exit Score	%Improvement
1	Low back and leg	44	10	0.77
2	Low back and leg	90	86	0.04
3	Low back and leg	8	2	0.75
4	Low back and leg	52	34	0.35
5	Low back and leg	38	18	0.53
6	Low back and leg	36	6	0.83
7	Low back and leg	28	16	0.43
8	Low back and leg	94	46	0.51

The neck patients all responded well but not with as high an average as the low back patients.

Neck Oswestry

	Average	24.00	14.00	0.46
Patient	Complaint	Intake Score	Exit Score	
1	Neck and Arm	24	14	0.42
2	Neck and Arm	16	4	0.75
3	Neck and Arm	26	14	0.46
4	Neck and Arm	30	24	0.20

Following the three-week initial phase of the study, the patient sample in this study continued to receive decompression at variable rates based on improvement. The outcome measurements are repeated at one month intervals to determine if the disability levels and perceived improvement parallel each other.

Discussion

It is interesting to note that the measured results parallel the perceived or reported improvement in all but one case. That case would not be included in a long term study due to non-compliance but was included here because that is a regular obstacle in daily clinical practice.

Decompression of the spine is possible using axial distraction as a modality. Study limitations include remission of symptoms may also be linked to electrochemical effects and biomechanical stabilization. All but two of the patients in the study improved at least 30% or more in the first three weeks. Two did not. One drove 2 hours to and 2 hours from treatment sessions and was not expected to achieve much improvement notwithstanding. He did report considerable relief immediately after each session and understood that the driving more than negated any improvements. The other patient who did not measure any improvement did not comply with the protocol as outlined and would have been dismissed from the study due to poor treatment compliance.

Continued follow- up with this patient sample is recommended in Part II of this study at 1, 3, 6 and 12 month results with and without additional treatment. Studies on surgical decompression procedures of the spine are often designed to include a 2-3 year follow-up as well as reporting any associated morbidity during the study time for up to 5 years. Additional patients should be likewise admitted and studied and the 5 year plan should be instituted. Patients will also be instructed in regular use and frequency of the stabilization exercises.

This study utilized an outcomes based research design. Given the significant improvements reported in this study, it is hopeful that a randomized, controlled trial where sham traction (placebo) can be compared to decompression therapy. Also, separate subject groups can also be randomized to electrical stimulation, pelvic stabilization groups, and a combined therapies group.

Conclusions

Utilizing the outcome measures, this form of decompression reduces symptoms and improves activities of daily living. Long-term benefits were not studied but will be reported in another study. The future study will include regular follow-up measurements to determine if the remission continues with or without recurrence. Also, the future study will investigate whether or not periodic supportive treatment sessions are needed to maintain symptom satisfaction.

References

1. Mackenzie R: Mechanical diagnosis and therapy for disorders of the low back. In Taylor JR, Twomey LT (Eds.): Physical therapy of the low back. Churchill Livingstone, New York, 2000 p.26 & 143.
2. Kushlich SD, Ulstrom RN, Michael CJ: Tissue origin of low back pain and sciatica. Orthop Clin North Am (22): 181,1991.
3. Nachenson AL, Elfstrom G: Intravital dynamic pressure measurements of Lumbar discs. Scand J Rehabil Med 2 Supp 1:1-40, 1970.
4. Yong, Hing K., Kirkaldy-Willis WH:' Pathophysiology of degenerated discs of the lumbar spine. Phila. The Ortho Clinics of N. Am. Vol.(14) #3 July 83, p.p. 493504.
5. Bogduk N., Twomey L.: Clinical anatomy of the Lumbar Spine. ChurchillLivingstone New York. 1992. p.p. 68-69 & 151-173
6. Twomey LT.: Sustained lumbar traction: An experimental study of long spine segments. Spine 1985; (10): 146-149.
7. Judkovich BD.: Lumbar traction therapy-elimination of physical factors that prevent stretch. JAMA 1955; 159.
8. Gose E, Naguszewski L.: Vertebral axial decompression therapy: an outcome study. Neuro Resarch. (20)#3, April 1998.
9. Mathews JA.: Dynamic Discograhy: A study of lumbar traction. Annals of Phy Med, IX (7) 1968, p.p. 265-279.
10. Colachis SC.et al: Effects of intermittent traction on vertebral separation. Arch of Phy Med & Rehab 1972 (50), p.p.251-258.
11. Shealy CN. Borgmeyer V.: Decompression, reduction, stabilization of the Lumbar spine: A cost effective treatment for lumbosacral pain. AJPM 1997, 7(2), 663 -665.
12. Winkle D, et al.: Diagnosis & treatment of the lumbar spine. Aspen: Maryland: 1996 p.p. 303-313.
13. Degenerative disorders of the spine. In: Hochschuler SH, Cotler HB, (Eds.) Rehab of the Spine. Mosby MO. 1993 p.p.464-465 & p.260,
14. Cyriax JH: Illustrated Manual of orthopaedic med, London, Butterworths, 1983 p.p. 30-40.

15. Schiotz E, Cyriax JH: Manipulation, past and present. London, Heinemann, 1975
16. Biomechanics. In: Hochschuler SH, Cotler HB, (Eds.) Rehab of the Spine. Mosby MO.1993 p.p. 146.
17. Kushlich S: Tissue origin of mechanical low back pain and sciatica. In: Hochschuler SH, Cotler HB, (Eds.) Rehab of the Spine. Mosby, MO. 1993 p.p.595-599.
18. Natural history of the lumbar spine. In Taylor JR, Twomey LT,(Eds):Physical Therapy of the Low Back, Churchill Livingstone, New York, 2000, p.p 25-26 & 43-51.
19. Onel D et al. Computed tomographic investigation of the effects of traction on lumbar disc herniations. Spine 1989; 14(1):82-9
20. Hides J, Stokes, M, et al: Evidence of lumbar multifidus wasting ipsilateral to symptoms in patients with low back pain. Spine 1995, 19(2): p. 165
21. Anderson DBJ, Nachemson, AL. Intervertebral disc pressures during traction. Scand J of Rehab Supple 1983; (9):88-91.
22. Colachis S, Strom J: Cervic al traction. Arch Phys Med 1965 (64):815.
23. Harris P: Cervical traction: Review of liturature and treatment guidelines. Phys Ther (57):910, 1977.
24. Braaf MM, Rosner S. Recent concepts in treatment of headache. Headache, (5):3844 1965.
25. Cyriax J: The treatment of lumbar disc lesions. British Medl Jour Dec.23 14341438.
26. McElhannon JE: Physio-therapuetic treatment of myofascial disorders. Anaheim Hills, CA.: James McElhannon.
27. Deyo RA, Loeser JD, Bigos SJ. Herniated lumbar intervertebral disc. Ann Intern Med 1990:(112): 598-603.
28. Breig A, Troup J: Biomechanical considerations in the straight leg raise test. Spine 1979; (4):242.
29. Mazion JM, Haynes LM: Mazion's illustrated reference of orto/neuro/physio diagnostic techniques. Casa Grande, Mazion publisher, 4th ed, 1980
30. Greenstein GM: Clinical assessment of neurological disorders. St. louis, Mosbyyear book, Inc. 1995.
31. Weber H: The natural history of disc herniation and the influence of intervention. Spine 1994 (19): p.p. 2234-2238.
32. Saal JA, Saal JS: The non-operative treatment of HNP with radiculopathy: an outcome study. Spine 1989 (14): p.p. 431-437.
33. Komori H, Shinomiya K, et al., The natural history of HNP with radiculopathy. Spine (21): 225-229, 1996.
34. Quain MB, Tecklin JS,: Lumbar traction: it's effect on respiration. Phys Ther 1985; 65 (9): 1343-6.
35. Krause M, et al: Lumbar traction: evaluation of effects and recommended application for treatment. Man Ther 2000, May;5 (2): 72-81.
36. Gillstrom P, Erickson K,: CT exam of influence of autotraction on herniation of lumbar disc. Arch Orthop Trauma Surg 1985; 104(5):289-93.
37. Beurskens AJ et al: Efficacy of traction for non-specific back pain. Spine 1997 Dec 1 ;(23): 2756-62.
38. Laban MM et al: Intermittant cervical traction: a progenitor of lumbar radicular pain. Arch Phys Med Rehab 1992 Mar;73 (3):295-6.
39. Pellecchia GL: Lumbar traction: a review of the liturature. J Orthop Sports Phys Ther 1994 Nov:20 (5): 262-7.
40. Austin R: Lumbar traction a valid option. Aust J Physio 1998; 44 (4):280.
41. Constantoyannis C, et al: Intermittent cervical traction for radiculopathy due to large-volume herniated discs. JMPT 2002 Mar; 25 (3).
42. Adams M, Bogduk Net al: Biomechanics of back pain. Churchill Livingstone NY, 2002: p,p 163-167
43. Grieve G: Mobilization of the spine. Churchill Livingstone NY, 1991: p.p 273283.
44. Martin M, Ramos G: Effects of vertebral axial decompression on intradiscal pressure. J Neur 81: 350-353, 1994.

45. Richardson C, Jull Get al: Therapeutic exercises for spinal segmental stabilization in low back pain. Churchill Livingstone NY, 1999.
46. Dullerud R, Nakstad P: CT changes after conservative treatment for lumbar disc herniation. Acta Radiol Sept;35(3):415-9, 1994.
47. Quain MB, Tecklin JS: Lumbar traction: its effect on respiration. Phys Ther Sept;65 (9):1343-6, 1985.
48. Mcgill S: Low back disorders (evidence-based prevention and rehabilitation). Human Kinetics, 2002.
49. Hseuh TC, Ju MS: Evaluation of the pulling angle and force on intermittent cervical traction. JFMed Assoc 1991 Dec;90(12): 1234-9
50. Saal JS, Saal JA: Nonoperative management of herniated cervical IVD with radiculopathy. Spine 1996 Aug 15;21(16): 1877-83.
51. Weatherall VF: Comparison of electrical activity in the sacrospinalis musculature during traction in two different positions. J Ortop Sports Phys Ther 1995;(8): 382390.
52. Letchuman R, Deusinger RH: Comparison of sacrospinalis myoelectric activity and pain levels in patients undergoing static and intermittent lumbar traction. Spine 1993;18(10): 1361-1365.