

**Special Doctors Report:
THE SIMPLE DRX9000
“PAIN-FREE” TREATMENT FOR SEVERE LOWER BACK PAIN**

Low back pain can have many causes. It is exceedingly frequent and is experienced at some time by up to 80% of the population. The differential diagnosis of low back pain is broad and includes systemic diseases (e.g. metastatic cancer), primary spine disease (e.g. disk herniation, degenerative arthritis) and regional diseases (e.g. aortic dissection) that refer pain to the low back. Treatment is often flawed, frequently painful, and can be exceedingly expensive.

As demonstrated in the literature, the causes of mechanical low back pain probably include degenerative disc disease, degenerative spondylosis with limitation of range of motion, facet arthropathy, relative lateral recess stenosis, pressure changes affecting the thecal and epidural space from disc bulging, subligamentous and/or extruded herniation and segmental instability. Any activity such as sitting, standing and/or lifting that increases axial loading on the spine will exacerbate low back pain.

Anatomically, the spine consists of individual small bones called vertebrae that are stacked on top of one another to form a column. The cushion between each vertebra is called a disk. The problem with a disk is that it can pinch or irritate a nerve from the spinal cord resulting in pain that affects the legs (sciatica). Sciatica can be severe and disabling. If it persists longer than four weeks, worsens and there is no improvement, there is strong physiologic evidence of dysfunction of the spinal segment consisting of the intervertebral disc and its adjoining vertebrae.

This condition needs to be confirmed at the corresponding level and side, by findings on an imaging study (MRI) and warrants an appropriate physician consultation. Primary disc pain can occur with mechanical strain of the annulus allowing nuclear herniations through radial fissures as well as from inflammation following trauma. A healthy disc could become painful if disease in other portions of the spine causes it to bear greater mechanical load and secondarily subject it to excessive strain. It is critical to realize that several mechanisms of causing pain may coexist and that similar disease processes give varying symptoms.

But what type of therapy would be in order to return the patient to a functional level of activity without pain? Diagnostic/treatment variations imply a lack of consensus about appropriate assessment and treatment and suggest that these treatments sometimes are inappropriate or suboptimal. Some patients appear to be more disabled after treatment than before the treatment. Surgery versus conservative trial is the most obvious of such choices. However, surgery is not the only treatment that can lead to increased disability: Methods such as extended bed rest or use of high dose opioids can prolong symptoms and further debilitate patients; although the existing literature has shortcomings, there is sufficient evidence for a number of conclusions about the efficacy and safety of current assessment and treatment methods.

The manipulative techniques, used for mechanical low-back pain associated with facet syndrome or muscle strain, have not been found to be as useful in the management of herniated or degenerative lumbar discs. Similarly, other modalities including ultrasound, electrical stimulation,

short wave therapy, acupuncture, steroids, anti-inflammatory agents and muscle relaxants can fall short of treating underlying problems associated with intervertebral disc lesions. None of these methods relieve pain from neurocompression or from the stimuli associated with prolapsed nucleus pulposus. We reviewed studies on traditional traction that report less than 50% positive outcomes.

Although the use of physical modalities in many forms are useful as adjunct therapy in the treatment of disc pathology they are largely empirical. Nachemson et al have comprehensively outlined changes in intradiscal pressures through various activities. They found that certain spinal motions and positions lower intradiscal pressures so that exercise programs and preventative ergonomic advice are fashioned after these principles.

Research implies that raised intradiscal pressures, in a controlled manner, plays a role in disc lesions and now it is shown that lowering intradiscal pressures, in a controlled manner, plays a role in treating low back pain. New advances centering on the use of decompression, reduction and stabilization produced several important studies on the effect of decompression on intradiscal pressures.

Effects of Intradiscal Pressures

The intervertebral disc and the two zygapophysial joints above and below, form a spinal segment with limited range of movement when isolated. Several spinal segments together, however, can produce large ranges of sagittal and coronal plane movement. The disc provides the main strength and stiffness and consists of a thick annular wall which attaches through cartilaginous plates to the vertebral bodies while the inner nucleus pulposus behaves hydrostatically as a viscous fluid changing shape in response to body position- in effect, acting like a joint.

The nucleus receives axial loads and redistributes the load centripetally to the surrounding annulus, but aging reduces the vascularity of the outer annulus and cartilaginous plates to a few small vessels. The nucleus pulposus is held under tension within an envelope formed by the annulus and cartilage plates, but this envelope is not extensible and maintains turgor by the attraction of water to the proteoglycan macromolecules. Thus, nutrition to this inner nucleus is received by diffusion. Compared to the disc, the zygapophysial joints hold only 10-15% of the load while standing but much larger when flexed or lifting. In other words, they are the guiding and restricting segment during spinal motion and protect the disc from rotational and transitional strains. Thus, back pain may result when these fibrous capsules or synovial folds are irritated. The nucleus of the intervebral disc is contained under pressure and this is a useful index of function.

Nachemson et al ("The lumbar spine: An orthopedic challenge, Spine 1975: "Intravital dynamic pressure measurement of lumbar discs", and "Intervertebral disc pressure during traction", Scand, Journal Rehab. Medicine Supplement, 1 and 9) and Ramos et al "(Effects of vertebral axial decompression and intradiscal pressure", Journal of Neurosurgery, 1994) have studied intradiscal pressures and have concluded that the ability of the disc to withstand comprehensive forces depends on both the integrity of the envelope and the turgor within; that movements such as flexion and lateral bending increase intradiscal pressure while resting pressures are lowest in supine and prone positions, lower in standing than sitting and very low in activities of lumbar extension and rotation. Exercise programs and ergonomic techniques emphasize the maintenance

of a lordosis to maintain decreased pressures helps prevent injury, then a controlled decrease in pressure can directly treat injury.

One of the best studies on intradiscal pressure was conducted by the Department of Neurosurgery and Radiology, Rio Grande Regional Hospital and Health Sciences Center, University of Texas. Intradiscal pressure measurement was performed by connecting a cannula inserted into the patients L4-5 disc space to a pressure transducer. The patient was placed in a prone position on a vertebral axial decompression therapeutic table and the tensionometer on the table was attached. Changes in pressure were recorded at resting state and while controlled tension was applied by the equipment. Intradiscal pressure demonstrated an inverse relationship to the tension applied and tension in the upper range was observed to decompress the nucleus pulposus significantly, to below -100 mm Hg.

The results of this study indicated that it was possible to lower pressure in the nucleus pulposus of herniated lumbar discs to levels significantly below 0 mm Hg when distraction tension was applied according to the protocol described for the decompression therapy.

In an outcome study of 778 patients, Gose et al (Vertebral axial decompression therapy for pain associated with herniation of degenerated discs or facet syndrome: An outcome study, Neurological Research, April 1998) found that decompression therapy was a primary treatment modality for low back pain associated with lumbar disc herniation at single or multiple levels, degenerative disc disease, facet arthropathy and decreased spine mobility; that pain, activity and mobility scores were all greatly improved after therapy.

They demonstrated a success rate ranging from 68% for facet syndrome to 72% for multiple herniated discs and 73% for patients with a single herniated disc. The average successful outcome for all diagnoses was 71%. The authors have concluded that for patients with low back pain decompression therapy should be considered a front line treatment for degenerative spondylosis, facet syndrome, disc disease and nonsurgical lumbar radiculopathy.

The DRX9000 Treatment Program

Many doctor's research has shown that nutrition in the avascular disc depends on diffusion of collagen precursors, nutrients and oxygen through direct channels in the annulus (30%) and the hyaline end plate (70%) in the vertebrae above and below. It is estimated that the cycle of proline uptake and renewal on the normal disc takes approximately 500 days. This inherently slow cycle is additionally compromised in herniated or degenerative discs.

By lowering the intradiscal pressures, the DRX9000 Program greatly facilitates this process and accelerates healing in the disc segment. Maximum clinical improvement occurs when treatment is delivered directly to the affected disc. With the DRX9000 Program, the treating physician can make adjustments in the angle of distraction, positioning of the spine and amounts of force necessary to unload, through distraction and positioning to create the effect of decompression at the specific intervertebral lumbar disc level.

The FDA concluded that the DRX9000 achieves its effects through decompression of the intervertebral discs and facet joints, that is, unloading, due to distraction and positioning. Regular application of the DRX9000 treatments results in remodeling of shortened structures by applying end-range movement to the spine in a controlled manner. Mobilization of the hypomobile joint is used to restore motion.

Limitations of the patient's motion depend on the irritability of the disorder. Decompressing the disc space through positioning of the patient promotes tissue healing, as evidenced through MRI documented reductions in the size and extent of herniations.

Inclusion Criteria for the DRX9000

The following would be inclusion criteria for the DRX9000: (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 therapy; (4) Patients available for four weeks of treatment protocol; and (5) Patient at least 18 years of age.

These indications are ideal candidates for enrollment into the DRX9000 program and have the potential to achieve quality outcomes in the treatment of their back pain: (1) Nerve Compression; (2) Lumbar Disorders; (3) Lumbar Strains; (4) Sciatic Neuralgia; (5) Herniated Discs; (6) Injury of the Lumbar Nerve Root; (7) Degenerative Discs; (8) Spinal Arthritis; (9) Low Back Pain w/ or w/o Sciatica; (10) Degenerative Joint Disease; (11) Myofasciois Syndrome; (12) Disuse Atrophy; (13) Lumbar Instability; (14) Acute Low Back Pain; and (15) Post-Surgical Low Back Pain.

The DRX9000 should be used on patients who have low back pain, with or without radiculopathy who have failed conventional therapy (physiotherapy and chiropractic) and who are considering surgery. Surgery should only be considered following a reasonable trial of the DRX9000 protocols.

Conditions That Are Contraindicated

Patients with the following problems or symptoms are usually excluded from using the DRX9000: pregnancy, prior lumbar fusion, metastatic cancer, severe osteoporosis, spondylolisthesis, compression fracture of lumbar spine below L-1, pars defect, aortic aneurysm, pelvic or abdominal cancer, disc space infections, severe peripheral neuropathy, hemiplegia, paraplegia, or cognitive dysfunction, cauda equina syndrome, tumors, osteod osteoma, multiple myeloma, osteo sarcoma, infection, osteomyelitis, meningitis, virus and disc pathology with a sequestered/free floating fragment.

Time Frame for Patient Change

Often times a patient experiences some relief within the first few (3-7) treatments. Usually by the 12th to 15th treatment all patients have reported significant remission of symptoms. Patients not showing significant improvement by the 15th to 18th session may be referred for further diagnostic evaluation.

DRX9000 Is Not For Everyone

Eighty-to-ninety percent of patients who have been properly selected and comply with the DRX9000 protocol will have good-to-excellent outcomes. Patient's conditions that do not respond quickly to the DRX9000 are often unable to be helped by anything quickly. Patients vary in age, sex and body morphology and may require counseling in weight loss, nutrition and other lifestyle changes.

Also, smoking, previous surgery and chronic use of narcotic or steroid medications, obesity, and large amounts of daily caffeine can have negative influences on the treatment.

Standard DRX9000 Treatment Protocol

Each session on the DRX9000 is approximately 30 minutes long (45 minutes, including set-up and take-off), accompanied by 15 minutes of varied appropriate therapy depending on the physician's assessment and recommendation. The patient comes for 20-25 visits over a 4-6 week period. A complete copy of the DRX9000 treatment protocol can be provided upon request.

Treatment Frequency Can Vary

Treatment frequency is based on diagnosis. For example, a patient with a herniated disc will, on average, be treated daily for two-to-four weeks, then 2-3 times a week for two weeks to be determined by periodic re-evaluations. For a degenerated disc, 3-5 times a week for five weeks and re-evaluation on the first and third week. Patients with facet arthropathy may report a sudden noticeable sensation as facets unlock followed by relief of symptoms. Treatments are then tapered off following this occurrence.

Usually decompression occurs at the therapeutic force of approximately one-half the patient's weight plus or minus poundage as determined by the physician. This window of treatment is altered by factors such as small body frame (less weight) large frame (more weight), acute injury (less weight), etc.

The DRX9000 Program Is Approved

Outcomes of clinical studies on this type of equipment have shown consistent positive results. For example, with orthopedists affiliated with Georgetown University and George Washington University on a scientifically statistical number of patients (initially evaluated by an orthopedic surgeon for diagnosis confirmed by MRI) showed the subsiding of symptoms directly correlated with the progression of treatment. All patients had final evaluations at which time functional range of motion was restored and activities of daily living were resumed; most patients had complete relief of pain. The patients were instructed in biomechanics and modifications were made according to postural changes as outlined in the equipment protocol. All patients who were surgical candidates also had MRI documented findings.

NOTE: One of the most important notations in the studies and reviews of the literature (also

discussed in an earlier study by Shealy, LeRoy et al) was that conventional spinal traction was less effective and biomechanically insufficient for optimal therapeutic outcome (i.e. regular traction does not produce decompression, that is, unloading due to distraction and positioning of the intervertebral discs and facet joints of the lumbar spine).

The DRX9000 Program is not regular spinal traction and does not utilize the conventional traction table. It is also not physical therapy although the protocol does contain elements of physical medicine and it is not to be confused with standard traction.

Decompression Isn't Same as Traction

No. There is a big difference between traction, distraction and decompression. Traction has been around for hundreds, if not thousands of years. The problem with traction, as it is known today, is that it is not always beneficial. In 1998, the Scientific American rated traction to be of little or no value in the examination of efficacious therapies for lower back pain. This finding is consistent with many studies that report traction can often times signal a nociceptive splinting response and put a patient's back muscles in spasms, resisting any attempts to effect a change on the disc proper.

Distraction, a term used to describe a flexion distraction technique, attempts to reposition the spine from the offending lesion. This technique has been shown to be very effective, even though potentially damaging to the person performing the technique and largely dependent on the skill of the technician. Like traction, distraction procedures are limited in the ability to reduce the intradiscal pressure, or produce a negative pressure within the disc imbining fluid, nutrients and creating an environment for repair.

Decompression therefore is an event - a combination of restraint, angle position and equipment engineering. At this writing there is no greater form of decompression available today than Axiom's DRX9000.

FINAL NOTE:

The FDA does NOT consider this device investigational; clinical trials and outcomes studies have been published, in the literature, showing high percentage treatment results for the diagnoses listed. It is a superior version of some of the other types of decompression devices on the market and has produced similar or superior clinical outcomes due especially to the product's design and the treatment protocol. It is also non-invasive and is cost effective for the treatment of the diagnoses listed. The cost per patient can be in the range of \$2500-\$5000 as compared to the surgical procedures costing more than \$30,000 (SurgiCenter facility fees plus procedure costs). Most of the time, the cost of this program is covered by the patient's medical insurance. If not, there are usually financing programs available that can be interest free to the patient.

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