

Magnetic Resonance Imaging Findings after Treatment with a Non-surgical Spinal Decompression System (DRX9000™)—Case Report

a report by

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Spinal decompression systems such as the DRX9000™ (Axiom Worldwide, Tampa, FL) have been launched into clinical practice in the last 10 years for the treatment of low-back pain (LBP). These systems were developed to provide a non-invasive intervention for the treatment of LBP of discogenic origin. They also address some of the problems associated with simple traction such as fatigue (both patient and therapist), the patient's inability to tolerate the force or position, triggering of muscle spasm, and the exacerbation of pain.

The US Food and Drug Administration (FDA)-cleared DRX9000 True Non-surgical Spinal Decompression System™ (see Figure 1) applies spinal distraction forces by using a sensitive computerized feedback mechanism to provide relief of LBP and symptoms associated with herniated discs, bulging or protruding inter-vertebral discs, degenerative disc disease, posterior facet syndrome, and sciatica. The DRX9000 uses a split-table design to reduce friction between the patient and the device. The patient lays supine; a chest and shoulder support system controls the upper body and a knee rest is used to eliminate pelvic rotation. The apparatus has built-in air bladders, disc-angle-pull adjusters, and harnesses, and it can increase the decompression force more slowly in the latter part of the therapy. The DRX9000 uses a motor pulley to deliver mechanized segmental distraction, which can be delivered in a static or oscillatory fashion for a pre-selected duration; the location of lumbar spinal disease determines the best pull-angle settings.

The DRX9000 aims to relieve pain by enlarging intra-discal spaces, reducing herniation, and decreasing intra-discal pressure during treatment. A retrospective chart audit of 94 patients provided preliminary data that chronic LBP may improve with DRX9000 spinal decompression.¹ A prospective trial on 18 patients found that pain improved significantly after DRX9000 treatment, requiring fewer analgesics and resulting in better function.² In view of such findings, corresponding radiographic data may be helpful to explain improvement in pain and function after DRX9000 treatment.



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Presentation of Case

A 33-year-old male was seen at an outpatient facility with persistent LBP of six-year duration that was progressively worsening and interfering with work and daily life, including walking. The patient was 73 inches tall and weighed 212 pounds. He had undergone previous chiropractic treatment and physical therapy with little benefit. The earliest available records revealed a medical consultation and magnetic resonance imaging (MRI) in June 2001 for a complaint of LBP radiating into his right buttock after

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jogging. The patient indicated at that time that he had been experiencing pain and stiffness for approximately one year. The patient reported that his symptoms were aggravated with bending, putting on his socks, running, coughing, and sneezing. The MRI performed in June 2001 demonstrated loss of hydration at L2/L3, L3/L4, and L4/L5, with loss of disc height at L4/L5 and L5/S1. Disc protrusions were identified at L3/L4 and L4/L5. Hypertrophic facet changes were noted at multiple levels.

MRI of the lumbar spine performed on August 4, 2006 (see Figure 2) prior to treatment with the DRX9000 revealed mild to moderate degenerative disc disease of the lumbar spine with loss of disc signal at most levels, as well as disc bulges identified at L3/L4, L4/L5, and L5/S1. Prior to initial treatment, the patient reported an overall pain level of 6 on a 0–10 scale; this pain occurred 75% of the time. The patient underwent 20 treatments on the DRX9000 over a six-week period. Treatment was administered five times per week for the first two weeks and three times per week for a further two weeks, then tapered to two sessions per week for the last two weeks. Treatment length varied between 28 and 35 minutes. Initial parameters began at a maximum decompressive force of 90 pounds with a minimum force of 45 pounds. Final treatment parameters were 115 pounds at maximum decompressive force with a minimum force of 57 pounds. The decompressive force was increased in increments of five to 10 pounds based on patient response. The angle of treatment force ranged from 15 to 20°. Adjunctive therapies included ice, electric stimulation, and light rehabilitation activities. At his final DRX9000 treatment, the patient reported a pain level of 0. Follow-up MRI (see Figure 3) of the same patient performed on October 10, 2006 showed an increase

in intra-discal signal on T2-weighted sagittal images at L2/3, L3/4, L4/5, and L5/S1, reflecting an improvement in disc morphology. The incidental small annular tears were unchanged.

Discussion

In adults, LBP is not uncommon. Approximately 66% of adults will suffer LBP at least once in their lifetime³ and, following the first episode, 25–60% of patients will report recurrence of LBP, some within as little as one year.⁴ Back pain, one of the most frequent reasons for seeking medical care,^{5,6} is the most common reason for work disability among American men, often resulting in early retirement.^{7,8} Mechanical back pain, which accounts for 97% of all LBP, is attributed to injury to the lumbosacral muscles and ligaments, facet joint or sacroiliac joint arthropathy, or discogenic disease due to degenerative changes.⁹ Discogenic pain, most probably due to internal disc degeneration, affects the lower back, buttocks, and hips.⁹

Although most LBP spontaneously resolves, treatment, whether through self-care or under the supervision of a healthcare practitioner, is often needed. Treatment for LBP should be individualized¹⁰ and is variable, depending on the diagnosis and the type of healthcare practitioner providing care.¹¹ Treatment options can be divided into pharmacological, non-surgical, or surgical therapies. Initially, the patient should be evaluated to rule out the need for urgent surgical intervention; however, there is conflicting evidence as to the benefits of surgery.^{12,13} Pharmacological therapy includes acetaminophen and non-steroidal anti-inflammatory drugs (NSAIDs); if pain persists, prescription medications such as muscle relaxants¹⁴

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and opioids¹⁵ may be needed. Non-surgical, non-pharmacological treatment consists of many alternatives, such as back exercise,¹⁶ back school,¹⁷ acupuncture,¹⁸ manipulation,¹⁹ or traction.²⁰ However, when conservative methods fail, surgery may be needed to reduce the pressure in the intervertebral spaces (decompression).

A recent review of clinical trials evaluating the efficacy of spinal decompression systems concluded that currently available data in the peer-reviewed press are too limited to determine whether spinal decompression provides benefits to individuals with LBP over other non-surgical treatments.¹⁰ Previous studies include weak and inconsistent methodologies because of designs that included different sample sizes, clinical patient inclusion criteria, regulatory oversight levels, protocol lengths, and post-therapy follow-up. Investigators used inappropriate end-point measures and poor outcome markers, reported negative results inadequately, and neglected to include placebo controls. Since that review, two studies evaluating the DRX9000 have emerged.¹² The first study is retrospective and analyzes the treatment of 94 patients from September 2005 to March 2006 with the DRX9000.¹ The mean pre-DRX9000

Figure 1: The DRX9000



pain score was 6.05 (0–10 scale) and decreased to 0.89 after the final DRX9000 session. No adverse events were noted. Results suggest that chronic LBP improved after treatment, with patients requiring fewer analgesics and achieving better function. The authors acknowledge the inconclusiveness of these findings as their study design was retrospective and did not include control groups. The second study, a prospective, multicenter, non-randomized, phase II pilot study to evaluate the effectiveness and safety of the DRX9000 for the active treatment of chronic LBP, followed subjects from January 5, 2007 to April 27, 2007. Twenty patients with chronic LBP—based on a diagnosis of

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musculoskeletal or mechanical LBP, herniated discs, bulging or protruding discs, degenerative disc disease, or pain from failed back surgery more than six months previously—underwent a series of 20 DRX9000 treatments (each session lasting 28 minutes) for six weeks, with five sessions per week in the first two weeks tapering to two sessions per week in the last two weeks. Adjunctive treatment included ice after DRX9000 sessions, lumbar stretching exercises, and analgesics as required. Assessments of pain, analgesic use, functionality, satisfaction, activities of daily living, and safety were collected through examinations, questionnaires, and patient diaries. Eighteen evaluable study participants (33.3% female; 83.3% white; mean age 46.6 years;

Figure 2: Pre-DRX9000 Magnetic Resonance Imaging



Figure 3: Post-DRX9000 Magnetic Resonance Imaging



77.8% employed) had a mean pain score of 6.4 on a 0–10 scale prior to the first DRX9000 treatment; this decreased to 0.8 after the final DRX9000 treatment. Sixteen out of the 18 subjects (88.9%) reported an improvement in back pain and better function as measured by activities of daily living. On a 0–10 satisfaction scale, patients gave the DRX9000 an average score of 8.1. No patient required any invasive therapies (e.g. epidural injections, surgery). Overall, the pain of patients decreased by 50% after two weeks of DRX9000 treatment. Patients required fewer analgesics and experienced better function. No safety issues were identified with the multimodal treatment routine.

Our case report demonstrates the positive hydrating effect that the DRX9000 treatment has on the inter-vertebral disc.

For LBP of discogenic origin, the goal of therapy is to expand the intervertebral space and reduce disc protrusion and intra-discal pressure,^{21–23} which are the goals of DRX9000 treatment. MRI is useful to quantify the volume and hydration variation of the inter-vertebral disc.²⁴ Therefore, the use of MRI to explain improvement in pain and function after DRX9000 treatment may be beneficial.

Our case report demonstrates the positive hydrating effect that the DRX9000 treatment has on the inter-vertebral disc. Further prospective clinical studies are needed to further validate clinical and radiographic improvement in patients with chronic LBP. ■

Acknowledgment

This case report has been underwritten with a grant from Axiom Worldwide, LLC, Tampa, FL.

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