Third Edition 2009

Your BACK PAIN
and how you may
Avoid Surgery
A NON-SURGICAL TREATMENT OPTION

Table of Contents

Overview: Back Pain Facts 2

Anatomy of the Spine 3

About the Disc 4

Diagnosing Back Pain 5

Disc Related Conditions 6

Causes of Back Pain 7

Traditional Treatment Methods 8

What is the DRX9000 True Non-Surgical Spinal Decompression System™? 9-10

DRX9000 Treatment Protocol 11

Guidelines for a Healthy Back 12

Published Research 13

International Research 14

International Medical Advisory Board 15

Resources 16

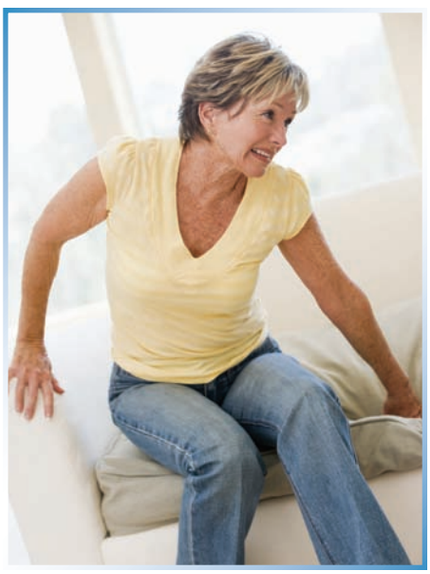
Axiom Worldwide Partners 17

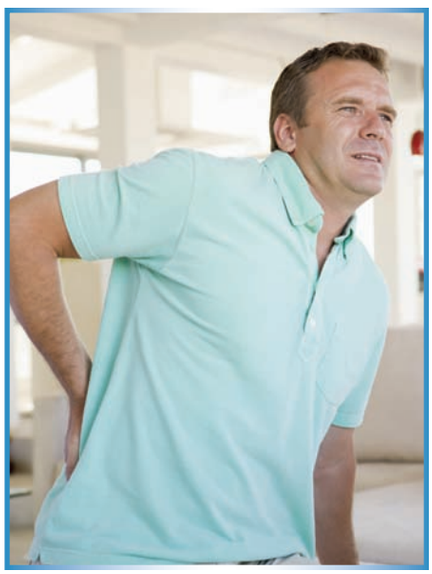
Patient Notes 18

Overview: Back Pain Facts

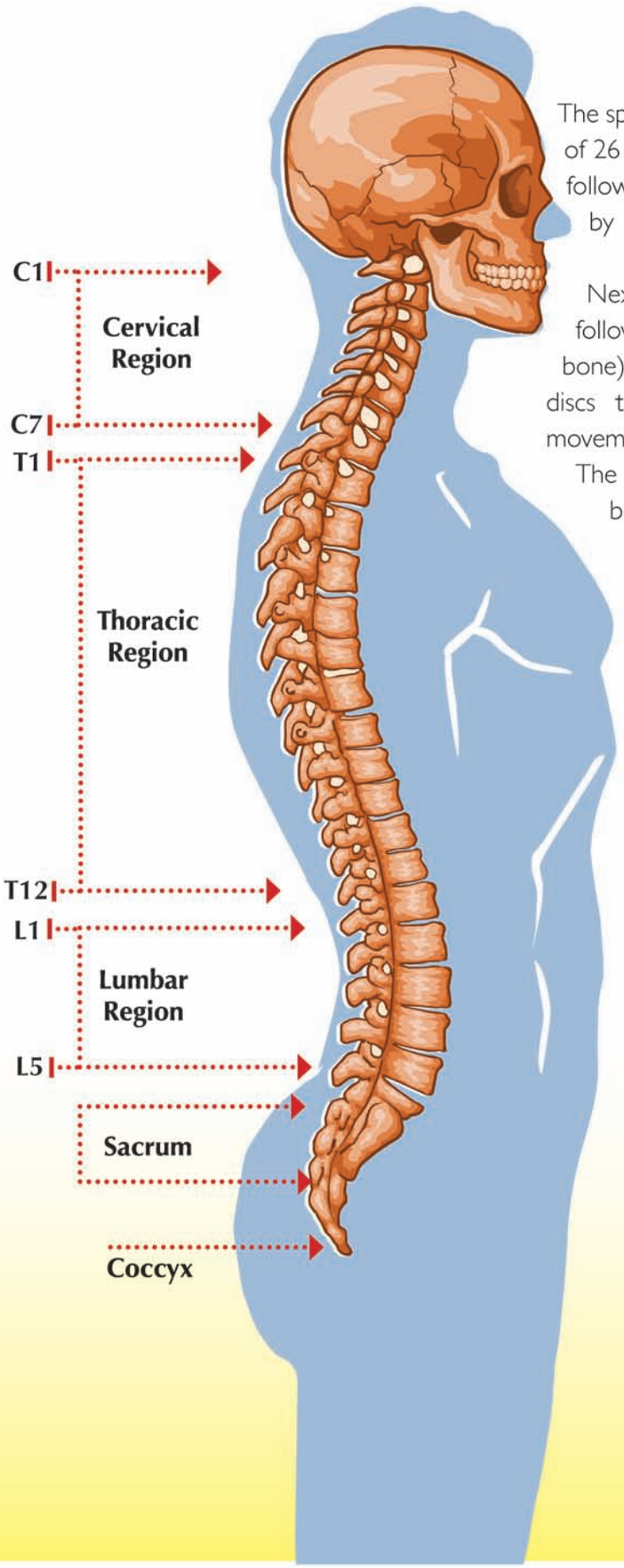
It is estimated that back pain afflicts over 31 million Americans and is the number one cause of activity limitation in young adults.[1] Within a given year, up to 50% of U.S. adults suffer from back pain.[2]

- Americans spend at least $50 billion each year on low back pain and it is the second most common neurological ailment in the United States.[3]
- Low back pain is the second most frequent reason for visits to the physician.[4]
- 80% of people over the age of 30 will experience back problems at some point in their lives. 30% of those will have recurring problems.[5]
- Each year, there are approximately 916,000 spinal surgeries performed in the US.[6]
- The back was involved in almost one fourth of all occupational injuries and illnesses.[7]
- In the United States, back surgery rates increase almost proportionately with the supply of orthopaedic and neurosurgeons.[8]





Anatomy of the Spine



The spine, or vertebral column, is composed of a series of 26 bones. The vertebrae are divided into groups as follows: 7 cervical vertebrae in the neck area, followed by 12 thoracic vertebrae in the middle of the back.

Next are 5 lumbar vertebrae in the lower back, followed by the sacrum and the coccyx (tail bone). Between the vertebrae are intervertebral discs that form strong joints, permit the various movements of the spine, and act as shock absorbers. The disc together with the vertebra above and below it, comprise one spinal motion segment.

The vertebral column is designed to enclose and protect the spinal cord and nerves. As the nerves branch off the spinal cord, they exit the vertebral column and form the peripheral nerves that innervate the body. In addition to protecting the spinal cord and nerves, the spine (or vertebral column) is a strong, flexible rod that allows us to bend forward, backward, and sideways. The entire vertebral column is protected and stabilized by the ligaments (strong fibrous bands) and muscles of the back.

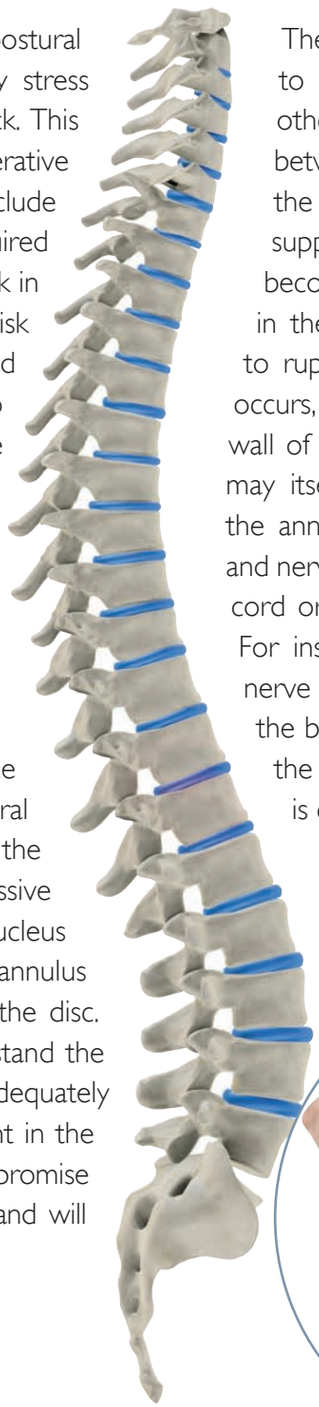
About the Disc

There are many lifestyle issues that contribute to a person's predisposition to experiencing back pain.

Most people go through life with poor postural habits that over time create unnecessary stress on the discs, joints, and muscles of the back. This unnecessary stress speeds up the degenerative process of the spine. Occupations that include frequently carrying heavy loads, being required to work while bent over, or having to work in awkward positions puts you at a higher risk for having a low back injury.[9] To understand how these physical stresses contribute to back pain, it is important to understand the intervertebral disc in more detail.

In their function as shock absorbers, the intervertebral discs are designed to allow movement and withstand the compressive loads transmitted through the spine.

In the center of the disc is a gel-like substance called the nucleus pulposus. There are several rings of tough fibrous tissue surrounding the nucleus called the annulus fibrosus. Compressive loads to the spine are distributed by the nucleus pulposus to the annulus fibrosus. The annulus is the principal load bearing structure of the disc. The annulus fibrosus will be able to withstand the compressive loads as long as the forces are adequately distributed by the nucleus. Any impairment in the structures of the intervertebral disc will compromise its ability to withstand compressive loads and will ultimately cause the disc to fail.



The discs in the lumbar spine are subjected to greater compressive loads than the other discs of the spine; especially the discs between the 4th and 5th lumbar vertebrae; the 5th vertebrae and the sacrum. If the supporting structures that protect the spine become injured or weakened, the pressure in the nucleus may become great enough to rupture the annulus fibrosus. When this occurs, the nucleus pulposus may push on the wall of the annulus fibrosus (bulging disc), or may itself protrude (herniated disc) through the annulus fibrosus, toward the spinal cord and nerves. The pressure exerted on the spinal cord or nerves may cause considerable pain. For instance, when the roots of the sciatic nerve are irritated, the pain can radiate down the buttocks, the back of the thigh, through the calf, and occasionally into the foot. This is called sciatica.

Diagnosing Back Pain

Back pain can interfere with an individual's overall mental state and daily activities such as work, recreation, and relaxation. Back pain can make sleeping difficult or even impossible, causing fatigue, irritability, and a feeling of isolation. For the vast majority of people, back pain can be treated non-surgically.

The type of treatment prescribed for back pain will usually be dictated by the diagnosis of the underlying cause of pain. Diagnosing back pain and choosing a treatment method is determined by reviewing the patient's medical history, performing a physical examination, and prescribing diagnostic tests. Your healthcare provider may want to review a Magnetic Resonance Image (MRI) and an X-ray of your spine to assess the cause of your back pain.

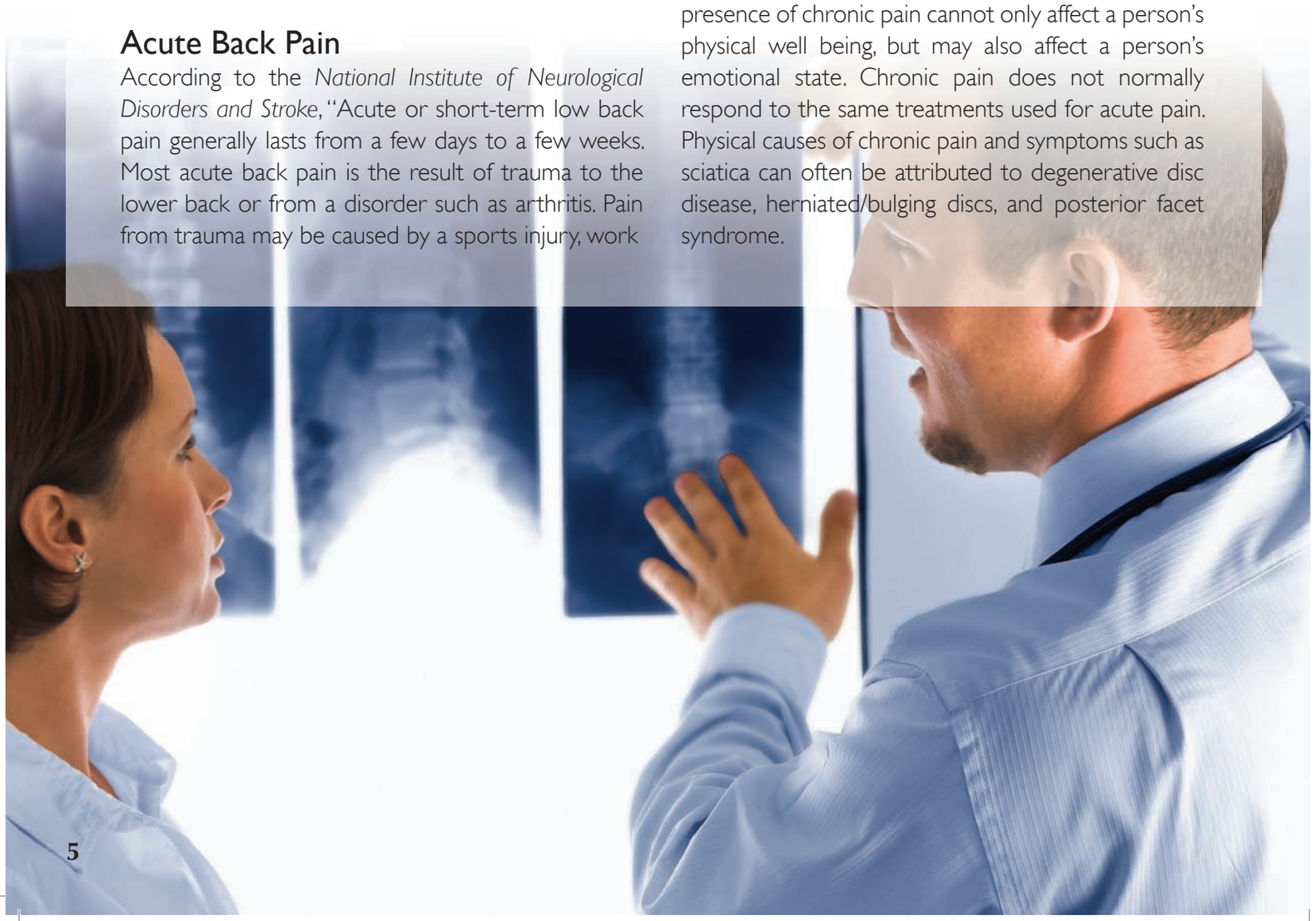
Pain may be defined as either an acute or chronic condition.

Acute Back Pain

According to the *National Institute of Neurological Disorders and Stroke*, "Acute or short-term low back pain generally lasts from a few days to a few weeks. Most acute back pain is the result of trauma to the lower back or from a disorder such as arthritis. Pain from trauma may be caused by a sports injury, work around the house or in the garden, or a sudden jolt such as a car accident or other stress on spinal bones and tissues. Symptoms may range from muscle ache to shooting or stabbing pain, limited flexibility and range of motion, or an inability to stand straight."[10]

Chronic Back Pain

The Mayo Clinic defines chronic back pain as "nonspecific" long lasting, recurrent pain usually present for three months or more. Chronic back pain is nonspecific because in most cases the cause is unknown or difficult to pin down.[11] The constant presence of chronic pain cannot only affect a person's physical well being, but may also affect a person's emotional state. Chronic pain does not normally respond to the same treatments used for acute pain. Physical causes of chronic pain and symptoms such as sciatica can often be attributed to degenerative disc disease, herniated/bulging discs, and posterior facet syndrome.



Disc Related Conditions

It is difficult to create an effective treatment regimen without first identifying the underlying cause of the pain. These conditions may often be treated non-surgically with the DRX9000.™

A **herniated disc** (Figure A) also referred to as a protruding or extruded disc is a condition where a portion of the gel-like center has migrated through the layers of the annulus fibrosus. This can cause mechanical pressure on neighboring structures and trigger chemical reactions resulting in pain and inflammation. These changes will often irritate the nerves, producing numbness or tingling in the legs or feet. Left untreated, this condition may result in life-changing pain and physical disability.

Figure A

Figure B

Degenerative disc disease ***(Figure B)*** is a state of dehydration and deterioration marked by the gradual erosion of the discs ability to distribute and resist mechanical loads. As discs deteriorate, they become more susceptible to injury from physical stress. Degenerative disc disease may also play a contributing role in conditions such as disc bulges, disc herniations, and stenosis.

Facet syndrome: Facets are the posterior joints of the spine that aid in keeping the vertebrae aligned. *(Figure C)* Facet syndrome can result from injury or degeneration of the disc and is characterized by pain, stiffness, and inflammation. The pain generally increases with motion and is relieved by rest.

Sciatica is a condition often associated with a herniated or ruptured disc. When the injured disc compresses one of the spinal nerves leading to the sciatic nerve, it can produce a shock-like pain that travels through the buttocks and down one leg to below the knee. Tingling and numbness are common in this condition. Sciatica can occur suddenly, or develop gradually. The pain and symptoms of sciatica can be intensified by coughing, sneezing, or sitting in the same position for prolonged periods of time.[12]

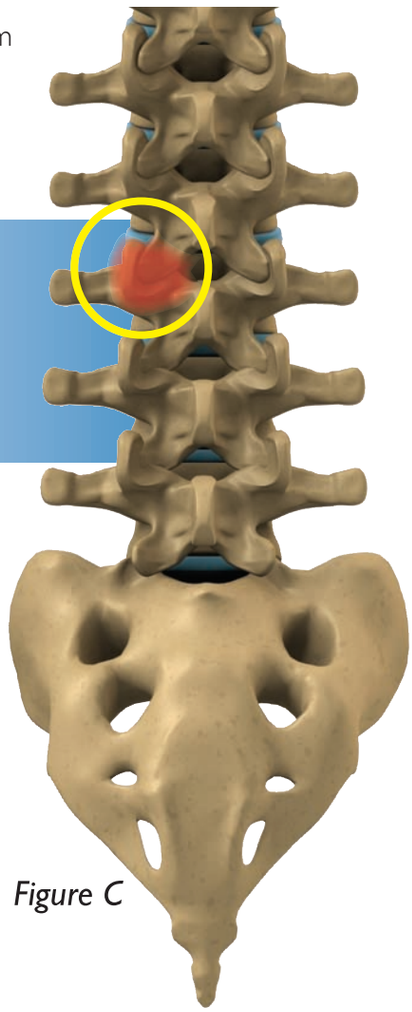


Figure C

Causes of Back Pain

The following lesser known factors may also contribute or aggravate a person's back pain:

OBESITY

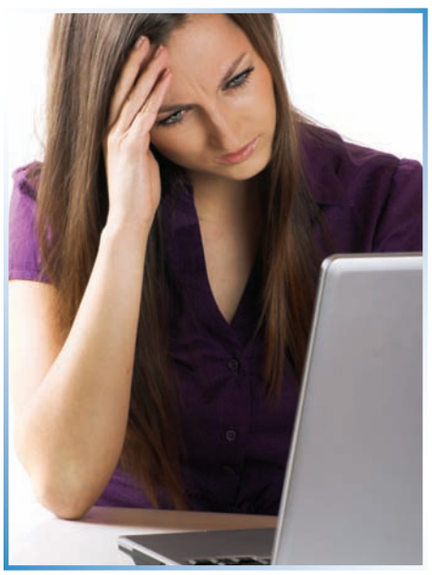
Obesity may contribute to back pain. An association exists between obesity and back pain, in particular with chronic or recurrent low back pain.[13] Even a few extra pounds may affect how a person walks, stands or sits, placing additional strain on the spine.

SPORTS ACTIVITIES

Sports activities can contribute to back pain. Activities like skiing, jogging, golf, and rowing can be stressful on the back. Contact sports, like football and rugby, add additional risk factors of direct injury to other parts of the body. These injuries may indirectly contribute to additional stresses on the back.

STRESS

Stress may also contribute to back pain. Anxiety, depression, and stressful situations may increase a person's risk for back pain. Psychological factors, more specifically stress and depression, may also be contributing factors in chronic low back pain.



Traditional Treatment Methods

- **Bed rest** is sometimes prescribed for patients experiencing back pain, however, prolonged bed rest may be associated with a longer recovery period. It is possible, patients on bed rest may be more prone to develop depression, blood clots in the legs, and decreased muscle tone.[14]

- **Physical therapy** is another common form of treatment for low back pain. The proper use of stretching and stabilization exercises can improve the general function and strength of the spine, but may not address the underlying cause of pain. The proper use of therapeutic exercise is an important component to the successful rehabilitation of the spine, but not before the problem is corrected.

- **Medications**, both oral and injectable, will generally work by temporarily reducing muscle spasm, inflammation, and pain. This treatment method will temporarily alleviate symptoms, but often does not address the underlying cause of pain. Drug dependency is a risk factor, as well as the potential need to prescribe stronger doses of medication to keep up with a patient's increased tolerance. Long term use of certain medications have also been known to result in kidney and/or liver damage.[15]

- **Acupuncture** was first practiced by the Chinese 2,500 years ago and is often used to treat chronic and acute back pain. During acupuncture treatment, the health care provider will insert needles into various points on the body. Some needles penetrate just under the skin, while others may penetrate deeper into muscle tissue. The needles are generally left in place for fifteen to thirty minutes. It is not uncommon in acupuncture to treat back pain by placing needles in the ankles, knees, or fingers.

- **Surgery** is an approach that attempts to correct the source of back pain; however, the benefits of surgery should always carefully be weighed against its risks. Although some patients may report significant pain relief after surgery, there is no guarantee that it will help every individual. Surgery certainly has its place in treating and/or correcting back pain, but it is important to consider the inherent and significant risks associated with surgery and anesthesia.

- **Traction** techniques most commonly used are mechanical or motorized traction, manual traction (traction is exerted by the therapist, using his/her body weight to alter the force and direction of the pull), and auto traction (where the patient controls the traction forces by grasping and pulling bars at the head of the traction table). There are also less common forms, such as underwater (where the patient is fixed perpendicularly in a deep pool, a bar is grasped under the arms and traction applied) and gravitational traction (e.g. bed rest traction, in which the person is fixed to a tilted table or bed, and the force is exerted by their own lower extremities).

What is the DRX9000
True Non-Surgical Spinal Decompression System™

1 What is the DRX9000 True Non-Surgical Spinal Decompression System™?

The DRX9000 True Non-Surgical Spinal Decompression System is designed to provide pain relief for compressive and degenerative injuries of the spine. Through the application of spinal decompressive forces to these injuries, the DRX9000 has given patients relief from back pain and has allowed them to resume the activities they love.

The DRX9000 True Non-Surgical Spinal Decompression System provides relief of pain and symptoms associated with herniated discs, bulging or protruding intervertebral discs, degenerative disc disease, posterior facet syndrome, and sciatica. The therapy is non-invasive and non-surgical.

As it relates to Axiom Worldwide's DRX technology, the theory behind spinal decompression is a process whereby forces are applied to the spine in a manner that maximizes spinal elongation. Spinal elongation is maximized when paraspinal muscles, the muscles that guard the spine from injury, are relaxed. When paraspinal muscles relax, applied spinal decompressive forces spread apart the bony vertebra of the spine. This relieves pressure on nerves and intervertebral discs. Where this spinal elongation occurs, the pressure may drop within the disc which facilitates movement of fluid, carrying nutrients and oxygen inside the disc. Additionally, the reduction in pressure may help draw in herniated disc material, reducing the size of the herniation.

(as seen in figures A and B below)

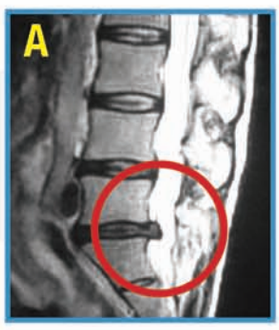
Also see published case reports listed on pg. 13

2 What is spinal decompression and how does the DRX9000 True Non-Surgical Spinal Decompression System work?

Spinal decompression on the DRX9000 involves the application of forces along a treatment curve to elongate the spine without causing the muscles that guard the spine to contract. The technology required to apply spinal decompressive forces is very advanced.

The DRX9000 utilizes high-speed treatment computers to calculate the spinal decompression treatment curve for each patient. A servo-motor / servo amplifier ("servo-motion system") takes the treatment curve and applies the forces to the patient. The servo-amplifier constantly checks (several thousand times per second) and corrects the servo-motor's movement. Measurement devices inside the DRX9000 monitor changes in the decompressive force experienced by each patient.

All of this data is constantly fed back into the treatment computers. The treatment computers constantly calculate corrections and ensure the therapy is true to each patient's treatment curve. This constant monitoring, measuring, and correcting process is called a Nested Closed-Loop Feedback System.



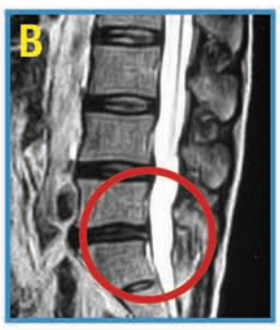


Figure A *shows a disc before treatment on the DRX9000 True Non-Surgical Spinal Decompression System™.*

Figure B *shows the same disc after treatment on the DRX9000 True Non-Surgical Spinal Decompression System™.*

MRI images courtesy of Dr. Terry R. Yochum, DC, DACBR; A Case Study on Spinal Decompression Utilizing the DRX9000™; Terry R. Yochum, DC, DACBR and Chad Maola, DC

3 What can I expect during treatment?

During each 30-45 minute treatment the patient relaxes comfortably on a heavily-padded bed. After being secured into position by an upper and lower body harness, the patient can completely relax by watching a DVD, listening to music, or simply taking a nap. Typically, each 30-45 minute treatment is divided into 18-phases where spinal decompressive forces alternate between a maximum and minimum therapeutic level.

4 Who are the best candidates for treatment?

Patients that may benefit most from the DRX9000 True Non-Surgical Spinal Decompression System may be those with herniated discs, bulging discs, sciatica, degenerative disc disease or facet syndrome.

5 What can I expect during the course of treatment?

Some patients may experience light side effects with this type of therapy. Mild muscular soreness during or after treatment may occur. The sensation would be similar to what a person might experience at the onset of a new exercise regimen. Most patients find this therapy quite comfortable and relaxing. During an average 30-45 minute treatment, most patients experience a gentle stretch in the lumbar spine and tend to fall asleep. Adjunctive therapies that may be prescribed typically include electrical stimulation and cold therapy. Exercise and/or the use of a lumbar support belt may also be prescribed to support the benefits of spinal decompression therapy and improve patient compliance.

DRX9000

TRUE NON-SURGICAL SPINAL DECOMPRESSION SYSTEM™

DRX9000™ Treatment Protocol

The therapeutic protocol* consists of 20 treatments over the course of six weeks. There are three in office phases that will occur during this time.

1

PHASE ONE

Five treatments per week for the first two weeks

During this phase, your healthcare provider may also prescribe:

- Restricted physical activity
- Disc unloader such as the DISC DISTRACTOR™ lumbar support may be prescribed to supplement the effects of decompression
- Adjunctive therapies including electrical stimulation and cold therapy

2

PHASE TWO

Three treatments per week for two weeks

During this phase, your healthcare provider may also prescribe:

- Gentle stretching exercises
- Light activity
- Reduce the use of the DISC DISTRACTOR™ lumbar support
- Adjunctive therapies including electrical stimulation and cold therapy

3

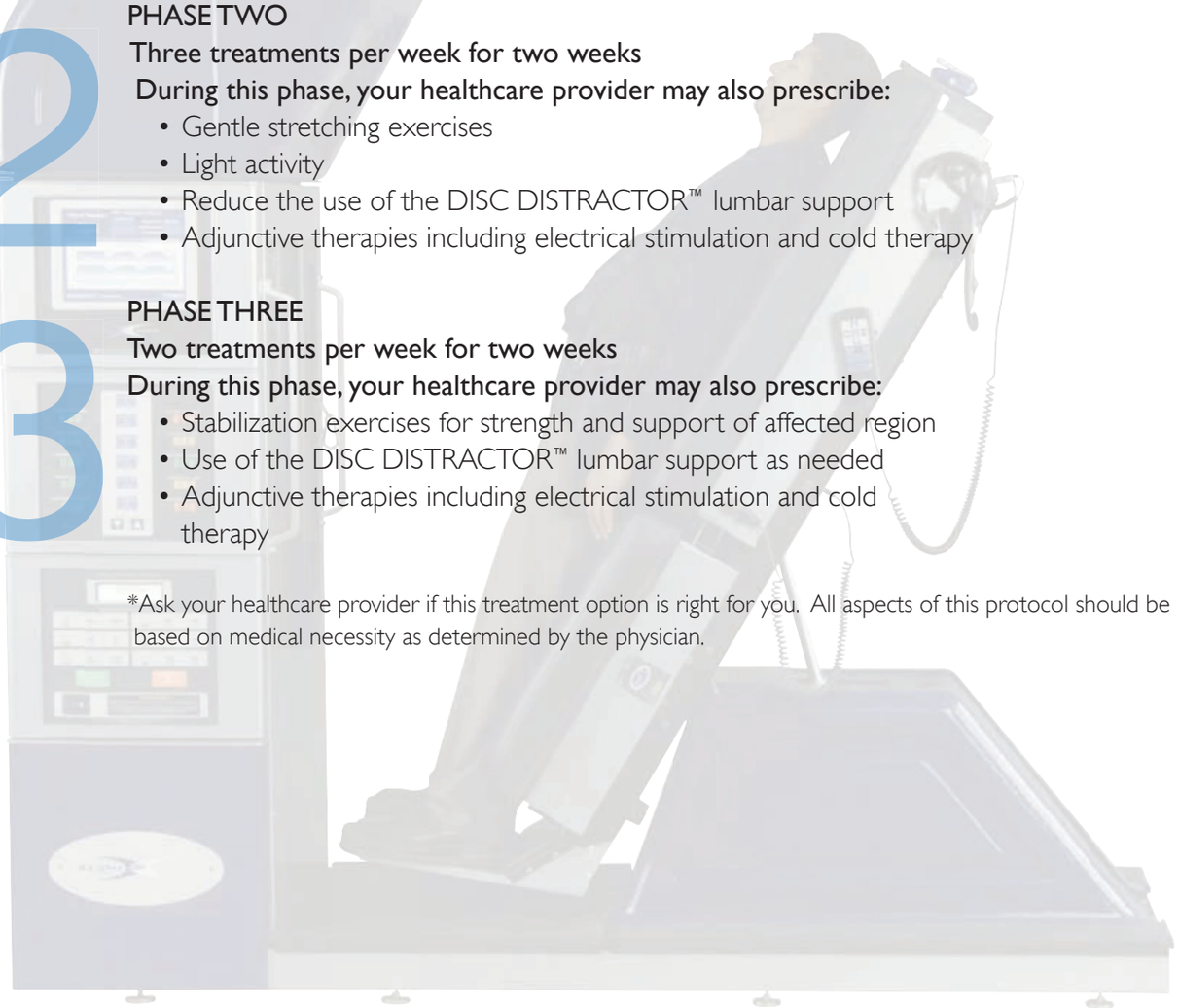
PHASE THREE

Two treatments per week for two weeks

During this phase, your healthcare provider may also prescribe:

- Stabilization exercises for strength and support of affected region
- Use of the DISC DISTRACTOR™ lumbar support as needed
- Adjunctive therapies including electrical stimulation and cold therapy

*Ask your healthcare provider if this treatment option is right for you. All aspects of this protocol should be based on medical necessity as determined by the physician.



Guidelines for a Healthy Back

The following are general guidelines for keeping and maintaining a healthy back.

- Adjust work surfaces to a proper and comfortable height and avoid crossing the legs when seated.
- Avoid slouching, either when seated or standing.
- When standing, keep weight evenly distributed on both feet.
- Push heavy items instead of pulling.
- Lift heavy objects from the knees with a taut abdomen and head slightly tucked to provide good spinal alignment. Practice proper body mechanics at all times.
- Carry objects close to your body.
- Be proactive and look to maintain a healthy weight; extra pounds will regularly tax back muscles.

- Stretch and warm up before exercising or when participating in strenuous activity.

- Maintain a consistent exercise program approved by your healthcare provider.

- When tasking, use a chair with lumbar support, and wear comfortable low-heeled shoes.

- When at rest, reduce the stress on your spine by side-sleeping.

* Consult with your physician to determine if these recommendations are right for you.

Published Research

2008

Management of Low-back Pain with a Non-surgical Decompression System (DRX9000™) – Case Report

European Musculoskeletal Review, Vol 3, Issue 1, 2008

- Joseph V Pergolizzi Jr, MD, *Johns Hopkins University and NEMA Research, Inc,*
- Frank Florio, DC, *Axiom Worldwide, LLC*
- William Martin, MD, *Upper Valley Interventional Radiology,*
- Charlotte Richmond, PhD, *NEMA Research, Inc.*

Management of Discogenic Low-back Pain with a Non-surgical Decompression System (DRX9000™) – Case Report

US Musculoskeletal Review 2008, Vol 3, Issue 1, 14-15, 2008

- Joseph Pergolizzi, MD, *Johns Hopkins University and NEMA Research, Inc,*
- Terry Yochum, DC, DACBR, *Director, Rocky Mountain Chiropractic Radiology Center,*
- Frank Florio, DC, *Axiom Worldwide, LLC,*
- Charlotte Richmond, PhD, *NEMA Research, Inc.*
- Brian S McCain, DC, *Back In Action Spine and Health Centers*

Treatment of 94 Outpatients with Chronic Discogenic Low Back Pain with the DRX9000: A Retrospective Chart Review

Pain Practice, Vol 8, Issue 1, 2008 11-17

- Charlotte Richmond, PhD, *NEMA Research, Inc.,*
- Alex Macario, MD, *Stanford University*
- Joseph Pergolizzi, MD, *Johns Hopkins University and NEMA Research, Inc.*
- Martin Auster, MD, MBA *Johns Hopkins University School of Medicine*

PILOT: Effectiveness & Safety of Non-surgical Spinal Decompression

The Journal of Medicine, December 2008, Vol. 1, Issue 1

- John Leslie, MD, *Mayo Clinic Arizona,*
- Charlotte Richmond, PhD, *NEMA Research, Inc.*
- Alex Macario, MD, *Stanford University*
- Christian Apfel, MD, *University of California at San Francisco*
- Frank Florio, DC, *Axiom Worldwide, LLC*
- Darren Clair, MD, *Vibrance Medical*
- Martin Auster, MD, MBA, *Johns Hopkins University*
- Joseph Pergolizzi, MD, *Johns Hopkins University and NEMA Research, Inc.*

2007

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

US Musculoskeletal Review 2007; 2; 50-52

- Charlotte Richmond, PhD, *NEMA Research, Inc.,*
- Frank Florio, DC, *Axiom Worldwide, LLC*
- Jonathan M. Wilhelm, DC, CCEP, *Big Sky Spine Care*
- Martin Auster, MD, MBA *Johns Hopkins University School of Medicine*

Non-Surgical Spinal Decompression to Treat Chronic Low Back Pain Special Report

Anesthesiology News – PainMedicine News, 2007

Treatment of an L5/S1 Extruded Disc Herniation Using a DRX9000 Spinal Decompression Unit: A Case Report

Chiropractic Economics, Vol. 53: Issue 2, 2007

- Terry R. Yochum, DC, DACBR,
- Chad J. Maola, DC

International Research

2007

Non-surgical Spinal Decompression Treatment of Low Back Pain by Spinal Decompression and Spinal Exercises

Malti Hiranandani, Chief Physiotherapist
The Back and Neck Clinic, Hyderabad, India, 2007

In this clinical trial study, 65 patients received treatment including the DRX9000, moist and ice packs, pain relieving, and muscle strengthening modalities. Several disc disorders were treated such as bulging, protruding, extruded, multi-level degenerative, desiccated, stenotic, and post-surgical recurrence. Spinal decompression was found to effectively treat low back pain.

2006

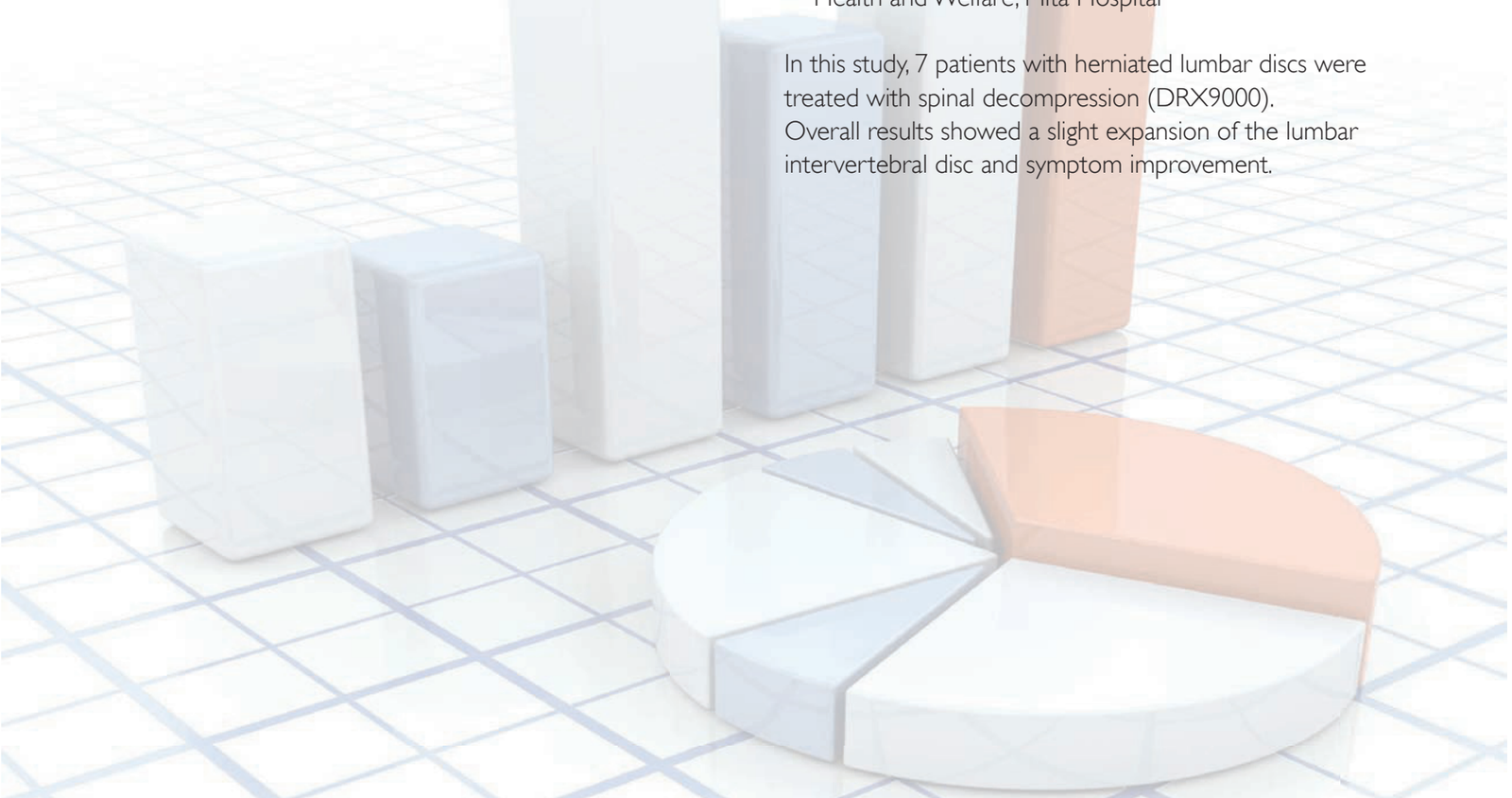
Effects of Spinal Decompression (DRX9000) for Lumbar Disc Herniation

The Journal of Saitama Kenou Rehabilitation, Vol. 6, November 1, 2006.

Naoyuki Oi (1), Akira Itabashi (2), Shusuke Kasano (3), Mitsuru Yamamoto (1), Mutsuo Yamada (1), Yasuyuki Takakura (1), Keigo Kumamoto (1), Tetsuo Suyama (1)

1) Dept. of Rehabilitation Medicine, Saitama Medical University, Saitama Medical Center
2) Saitama Center for Bone Disease
3) Dept. of Rehabilitation Medicine, International University of Health and Welfare, Mita Hospital

In this study, 7 patients with herniated lumbar discs were treated with spinal decompression (DRX9000). Overall results showed a slight expansion of the lumbar intervertebral disc and symptom improvement.



These studies are accessible online at: **www. axiomworldwide.com.**
For more information visit our consumer website at: **www.axiompainsolutions.com**

International Medical Advisory Board

Providing guidance on clinical research endeavors.

Since its inception, Axiom Worldwide's DRX9000™ has shown promising anecdotal results in treating back pain associated with herniated discs, degenerative disc disease, sciatica, and facet syndrome. In response to these encouraging results, Axiom Worldwide established an International Medical Advisory Board in April 2006 to provide guidance on Axiom's current and emerging technologies and their application in treating back pain.

Our International Medical Advisory Board is administered by a steering committee comprised of physicians from Johns Hopkins University School of Medicine, University of California at San Francisco, Mayo Clinic College of Medicine and others.

In addition, the International Medical Advisory Board is instrumental in developing and implementing short and long term clinical trials.

For more information about the International Medical Advisory Board please visit:
www.AxiomWorldwide.com

Changing the way the world treats back pain.

Back pain is a universal problem and Axiom Worldwide is proud to have the DRX9000 True Non-Surgical Spinal Decompression System™ being utilized in over 20 countries.

AXIOM WORLDWIDE

Resources

1. National Committee for Quality Assurance, NCQA News, HEDIS® 2005; Focus is on Health Issues Familiar to Seniors, Working Americans, July 8, 2004.
2. Counseling to prevent low back pain: Section II. In: O'Malley AS, DiGuiseppi C, for the U.S. Preventative Services Task Force. Guide to Clinical Preventative Services: Report of the U.S. Preventative Services Task Force. 2nd Ed. Baltimore, MD: Williams & Wilkins; 1996.
3. National Institute of Neurological Disorders and Stroke, National Institutes of Health, "Low Back Pain Fact Sheet," July 2003.
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- Levin-Gervasi, Stephanie. The Back Pain Sourcebook. 2nd Edition. Lincolnwood, IL: Lowell House, 1998.
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The material in this booklet is for informational purposes only. No medical advice and/or opinion is intended. Only your healthcare provider can determine if Axiom's recommended treatment protocol is right for you. Individual results may vary.

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Axiom Worldwide Partners

Axiom Worldwide has gone to great lengths to establish relationships with innovative technology suppliers that share our vision. For that reason, only components that meet our stringent quality standards are incorporated into any Axiom product.

AXIOM WORLDWIDE IS THE EXCLUSIVE MEDICAL SPINAL DECOMPRESSION EQUIPMENT

PROTECTED BY X-1R CERTIFIED SPACE TECHNOLOGY LUBRICANTS WORLDWIDE

The X-1R Corporation's certified space technology lubricant formulation was developed to improve performance and life of NASA's Space Shuttle Crawler. Axiom engineers worked with X-1R to utilize the certified space lubrication technology in the linear motion devices found in the DRX™ product series. Chief among those linear motion devices are the bearings and railing utilized in the lower floating mattress of the DRX9000™ bed and the ultra-low-profile slide tables providing the linear motion in the DRX9000C™/DRX9500™ Cervical Headrest.

The Space Foundation, in cooperation with NASA, created the Space Certification Program to recognize commercial products that utilize technology either developed for or improved for space exploration. The exclusive X-1R/Axiom Worldwide relationship is recognized by the Space Foundation.

DANAHER MOTION IS THE EXCLUSIVE SERVO MOTION SUPPLIER FOR AXIOM WORLDWIDE MEDICAL SPINAL DECOMPRESSION EQUIPMENT WORLDWIDE

Danaher-Motion's Kollmorgen-brand of servo-amplifier/motor products is utilized by the DRX™ product series to precisely replicate force application instructions from the treatment computer. Danaher-Motion's Thomson-brand matching planetary gearhead devices provide smooth and efficient gearing directly linking the servo-motor to the patient. In 2001, Danaher-Motion engineers helped incorporate the servo-motion system into the DRX9000™. This technology can only be found in the DRX™ product series.

NB IS THE EXCLUSIVE LINEAR MOTION SUPPLIER FOR AXIOM WORLDWIDE MEDICAL SPINAL DECOMPRESSION EQUIPMENT WORLDWIDE

Critical moving components glide along on NB precision bearing technology in the DRX™ product series. All precision linear motion products across the DRX™ platform are lubricated with X-1R's proprietary certified space technology. Application of X-1R lubricants to NB linear motion technology is exclusive to Axiom Worldwide's spinal decompression systems.

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