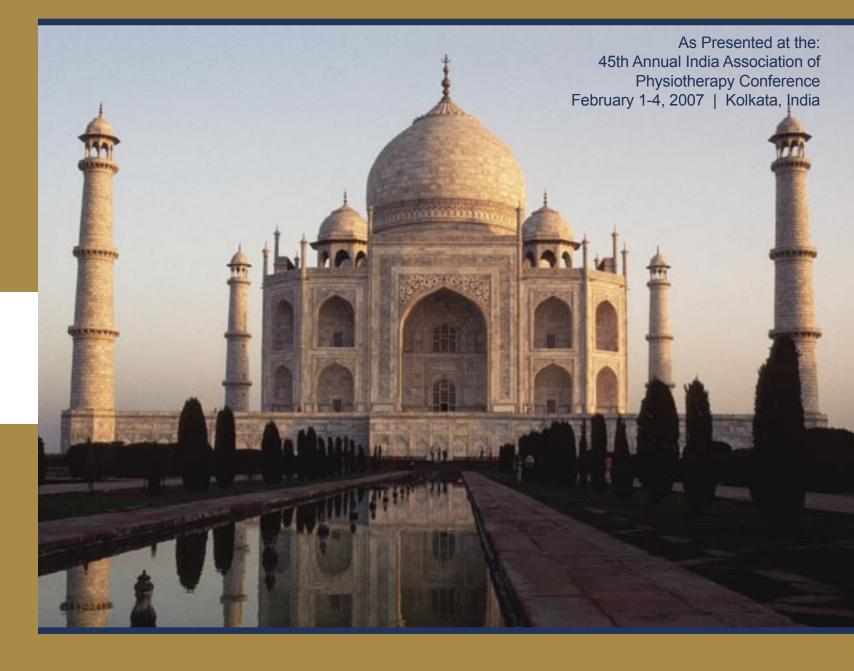


The forgoing study was not sponsored by Axiom Worldwide. However, the author of the study, Malti Hiranandani, is affiliated with Axiom Worldwide's distributor in India. Axiom has made no determination of and makes no representations as to the adequacy of the design, scope or manner in which the study was conducted. The study does not have control groups making it difficult to determine how much of the benefit described in the report was placebo or spontaneous recovery and how much was due to treatment on the DRX9000 $^{\infty}$. Further studies utilizing more precise controls are necessary to draw such conclusions. Axiom Worldwide's referencing the presentation of the study should not be construed to mean that Axiom Worldwide endorses the study or represents that the study establishes any conclusive success rate or the efficacy of the device. The information is offered simply to demonstrate the exciting activity ongoing with the DRX9000 $^{\infty}$. As always, individual patient's experiences with the DRX9000 $^{\infty}$ may vary and patients should always consult with their physician to determine whether treatment on the DRX9000 $^{\infty}$ makes sense for them.

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



9423 Corporate Lake Drive
Tampa, Florida 33634
Tel: 813-249-6444 Fax: 813-249-6445
www.AxiomWorldwide.com



Malti Hiranandani, Chief Physiotherapist- The Back and Neck Clinic, Hyderabad

MKT0004-REVA

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

This paper on the efficacy of treatment of back pain was presented in the Annual All India Physiotherapy conference held at kollkata on Feb 1-4, 2007.

It is based on the study of patients treated at back and neck clinic using the spinal decompression equipment known as DRX9000™

This paper is presented by Ms. Malti Hiranandani, Chief physiotherapist working with back and neck clinic. It was awarded as the best paper in musculoskeletal branch of physiotherapy.

INTRODUCTION

Low back pain is the third common problem present worldwide. Trauma, tumors, infections, degenerative, mechanical are the common causes of low back pain. The changing trends of work, life-style patterns, anxiety, and stress are the precipitating factors for low back pain.

The intervertebral disc is responsible for a significant number of lumbar/leg pain and neck/arm pain syndromes. Compression increases intradiscal pressure leading to annular compromise and possible extrusion of nuclear material. The treatment whether surgical or conservative should involve the reduction of compression forces on disc and thereby prevent further progression of symptoms.

A U.S. based concept of decompression of the spine is introduced to treat back pain as an effective non-surgical non-invasive method. Since the disc is an avascular structure, it doesn't receive fresh blood and oxygen with every beat of the heart. It requires "diffusion" created by motion and 'decompression' to restore nutrients and enhance healing.

Decompression is defined as reduction in pressure (intradiscal). Recumbent positions (both prone and supine) decrease intradiscal pressures in comparison to standing and sitting. However focused, axial mechanical+Y translation traction, (creating 'decompression' i.e. unloading due to distraction and positioning) has been shown to

reduce disc pressure and enhance the healing response even further. There is a reduction in intradiscal pressure which has a profound effect on the healing process via increased contact with the blood supply and fibroblast migration-this is phasic effect. This is in addition to the pain relief created neurologically by stretching soft tissue (e.g. stretch receptors, mechanoreceptors etc.) making decompression therapy a logical and viable addition to a "passive" pain care regimen. Studies verify the significant reduction of intradiscal pressures into the negative range. to approximately minus 150 -200mm/Hg which results in the non-surgical decompression of the disc and nerve root. By significantly reducing intradiscal pressure, spinal disc decompression promotes retraction of the herniation into the disc and facilitates influx of oxygen, protein and other substrates. The promotion of fibro elastic activity stimulates repair and inhibits leakage of irritant sulphates and carboxylates from the nucleus. This treatment uses 20 treatment sessions using DRX 9000 Spinal Decompression

Vacuum Effect in spinal decompression accomplishes two things. From a mechanical stand point, disc material that has protruded or herniated outside the normal confines of the disc can be pulled back within the disc by the vacuum created within the disc. Also, the vacuum within the disc stimulates in growth of blood supply, secondarily stimulating a healing response. This results in pain reduction and proper healing at the injured site.

- Herniated disc
- Degenerative disc

- Post-surgical patient

Relative contra-indications

- Disc fragmentation
- Severe arthritis
- Osteoporosis
- Pars defect
- Spondylolisthesis
- Paralaysis

unit with extensive back care.

Decompression treatment Indications

- Sciatica
- Facet syndrome

- Calcification
- Surgical spinal appliances

DATA SOURCE & METHODOLOGY

Study Design-Clinical trial study.

Methodology - 75 individuals with low back pain from age group of 25 to 75 years old are selected for the study.

Evaluation and assessment tools - reflex hammer, large goniometer, measuring tape

Treatment Tools - moist packs, DRX 9000, pain relieving and muscle strengthening modalities, ice packs, therabands and swiss ball.

PATIENTS TREATED ARE 75			
Number of Bulged discs	17	Protruded discs	15
Extruded discs	5	Degenerated/multi-level	16
Post surgery recurrence	7	Dessicated discs	5
Stenotic (soft tissues)	5	Discontinued	10

Framework of Analysis and Findings

The analysis framework used on the primary data is detailed

- 1. Paired sample t-test was done to see the effectiveness of the treatment on the respondents.
- 2. The data was taken from the respondents before and after the treatment which is a fairly accepted and robust method to assess the efficacy of the treatment
- 3. Different tests were performed with the help of paired samples t-test to assess the significant difference before and after the treatment.
- 4. Data was collected pertaining to VAS, slumps and SLR apart from the demographic details of the respondents.

BEFORE & AFTER VAS

To assess the efficacy of the treatment, subjective scores from the respondents were taken within the framework of Visual Analogous scale before and after the treatment. This is a subjective feeling of pain by the patient on a scale of 0-10. The hypotheses proposed were:

Null Hypothesis ==> H0: There is no significant difference between the means of before VAS scores and after VAS scores

Alternate Hypothesis ==> H1: There is a significant difference between the means of before VAS scores and after VAS scores

The probability-value for this test is 0.00000. Also, the observed difference of means comes out to be 5.160 which falls in the rejection zone, at a significance level of 5%. Hence, we reject the null hypothesis. Alternately, we accept that there is a significant difference between the before and after VAS scores.

This implies that, as per the perception of the respondents there is a significant difference in their status before and after the treatment. Alternately, it can be inferred that from the perspective of respondents, the treatment was

*BEFORE & AFTER LEFT SLUMPS

To assess the efficacy of the treatment, scores from the respondents were taken for their right slumps before and after the treatment. This is also a test to confirm whether the back pain is related to the disc or not. The hypotheses proposed were:

> Null Hypothesis ==> H0: There is no significant difference between the means of before right Slumps and after right Slumps

> Alternate Hypothesis ==> H1: There is a significant difference between the means of before right Slumps and after right Slumps

The probability-value for this test is 0.001. Also, the observed difference of means comes out to be 0.208 which falls in the rejection zone, at a significance level of 5%. Hence, we reject the null hypothesis.

Alternately, we accept that there is a significant difference between the before and after right Slumps. This implies that there is a significant difference in the right Slumps before and after the treatment at 95% confidence level. Hence, it can be inferred that the treatment was effective for the right Slumps, as there is a statistically significant difference in the condition of right Slumps before and after the treatment.

Before and After Left Slumps

To assess the efficacy of the treatment, scores from the respondents were taken for their left Slumps before and after the treatment. This is also a test to confirm whether the back pain is related to the disc or not. The hypotheses proposed were:

> Null Hypothesis ==> H0: There is no significant difference between the means of before left Slumps and after left Slumps

Alternate Hypothesis ==> H1: There is a significant difference between the means of before left Slumps and after left Slumps

The probability-value for this test is 0.002. Also, the observed difference of means comes out to be 0.170 which falls in the acceptance zone, at a significance level of 5% Hence, we reject the null hypothesis. Alternately, we accept that there is a significant difference between before and after left Slumps.

This implies that there is a significant difference in the left Slumps before and after the treatment at 95 % confidence level. Hence, it can be inferred that the treatment was effective for the left Slumps, as there is a statistically significant difference in the condition of left Slumps before and after the treatment

* EDITORS NOTE: Utilized as an orthopedic physical assessment tool, the slump test is a dural tension test which evaluates lesions affecting the neuromeningeal structures. This is performed with the patient in the seated position with the cervical and thoracic spines flexed as the clinician passively raises the left and/or right leg. Back pain indicates a positive test.

SUMMARY OF FINDINGS

- From the perspective of respondents, the treatment was
- The treatment was effective for the right and left Slumps.
- The treatment was effective for the VAS scores

The decompression is followed by extensive spinal stabilization exercises, posture care, ergonomics and assistive devices. These exercises strengthen the extensors muscles and ligaments.

LITERATURE REVIEW

- Traditional traction has proven to be less effective and biomechanically inadequate to produce optimal therapeutic
- One study by Mangion et al concluded that any benefit derived from continuous traction devices was due to enforced immobilization rather than actual traction
- Weber compared patients treated with traction to a control group that had simulated traction and demonstrated no significant differences. Research confirms that traditional traction does not produce spinal decompression.
- Matthews 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.
- Goldfish speculates that the degenerated disc may benefit by lowering intradiscal pressure, affecting the nutritional state of the nucleus pulposus.
- · Onel et al reported the positive effects of distraction on the disc with contour changes by computed tomography imaging dramatically drop into a negative range.

In summary, spinal decompression is effective for the treatment of low back pain. It is evident from both subjective and objective examination results. Spinal stabilazation exercises and back care form the integral part of treatment.