

A RETROSPECTIVE DATA ANALYSIS OF

**The Effectiveness Of
Decompression Therapy
In Patients With Herniated
Nucleus Pulposus/Degenerative
Joint Disease, Facet Syndrome
And Sciatica.**

**TECHNICAL REPORT
June 2004**

Amy K. Dicke-Bohmann, Ph.d.,
Jonathan A. Bohmann, Ph.d.,
Jack Aldridge Ph.d.,
William Squires Ph.d.,
Andrew Rutledge DC.



A RETROSPECTIVE DATA ANALYSIS OF

The Effectiveness Of Decompression Therapy In Patients With Herniated Nucleus Pulposus/Degenerative Joint Disease, Facet Syndrome And Sciatica.

TECHNICAL REPORT

June 2004

Amy K. Dicke-Bohmann, Ph.d.,

Jonathan A. Bohmann, Ph.d.,

Jack Aldridge Ph.d.,

William Squires Ph.d.,

Andrew Rutledge DC.

INTRODUCTION

Physicians are charged with attending patients suffering from mechanical back pain each day in their practices. When symptoms persist, despite comprehensive management protocols, doctors and patients are frequently discouraged. The options available to practitioners have varied greatly and so have the results. Expenditures for low back pain are also of great concern. In 1998 an estimated \$90.7 billion dollars was incurred by individuals with back pain in the United States (Luo et al. 2003).

Clinic outcome studies have reported use of certain spinal decompression systems with successful pain control ranging from 75% to 86%. These advances are of special interest to those practitioners who manage both acute and chronic low back pain and dysfunction. A recent study group categorized by MRI finding, undergoing decompression therapy with evidence of single

and multiple disc herniation found 86% of patients reported a complete resolution of pain. Lordex decompression/stabilization protocol incorporates a design substantially equivalent to those used in the studies described above. The *good to excellent* response showed 91.7% of patients reporting pain reduction which has been attributed to the Lordex System's ability to target specific segments, and effectively decompress the spine and stabilize the supporting musculature.

MEASURING PAIN REDUCTION USING VISUAL PAIN ANALOGS

A visual pain analog (VPA) was used to measure perceived pain in patients. The VPA measurement technique measures patients' perceptions of pain on a 10-point scale. This self-report technique provides unique information to the literature because patient's experience pain to differing

degrees, and they want to perceive less pain. Measuring pressure on the spine does not necessarily provide information on the actual pain perceived by the patient.

A precedent has been set to use such a subjective method in both the psychological and medical fields. A VPA scale was used to measure perceived after patients with painful diabetic neuropathy were given a low dose of gabapentin. Patients demonstrated a reduction in pain using the scale (Gorson, Schot, Herman, Ropper, & Rand, 1999).

The scale has been used specifically for leg and back pain in a study on lumbosacral radicular pain. Measurements were made on VPA scale after patients experienced radiofrequency lesioning of dorsal root ganglia (Geurts, van Wijk, Wynne, Hammink, Buskens, Lousberg, Knape, & Groen, 2003).

Visual pain analog scales have been used in published research as early as 1987, when the scale was used to assess chronic pain in hemophiliacs (Chioniere & Melzack, 1987) and soon afterward in patients with rheumatoid arthritis (Tack, 1990).

Most recently, VPA scales have been used to assess pain in cognitive studies. Pain was measured by VPA scales, and then correlated with a patients' tendencies to catastrophize (Jones, Rollman, White, Hill, & Brooke, 2003); the scales have also been used in studies where pain was reduced using virtual reality (Hoffman, Garcia-Palacios, Kapa, Beecher, & Sharar, 2003).

In the present study, VPA scales were used to assess pain at the beginning of the study, before the Lordex procedure was introduced, and again at the end of the study, after patients had exposure to the Lordex method. It is hypothesized that patients given the Lordex procedure will report less pain at the end of the study than they reported at the beginning.

METHOD

PARTICIPANTS

Data were analyzed from 121 participants, of which 74 were male, 46 were female, and one participant did not indicate sex; the age range of the participants was 26 to 77. In addition, 16 participants had experienced a back surgery in the past. Diagnosis varied and included lumbar disc syndrome, degenerated disc disease, herniated disc, stenosis, sciatica and facet syndrome.

MATERIALS

Materials included the Lordex LDU machine, the Lordex RX1 Machine, therapist-assisted Stretch Flex Program, consultations with the doctors, and a visual pain analog (VPA) in which patients rated their perceived pain on a scale from 0 (none) to 10 (extreme).

PROCEDURE

Participants used the VPA to describe their perceived pain before treatment. Then they participated in the Lordex protocol. This involved approximately twenty one-hour sessions over a period of six weeks to eight weeks. Sessions are scheduled daily for the first five days, and the remaining five to seven weeks of sessions occur three times a week. Participants are asked to avoid alcohol, excessive sugar, and caffeine.

Each session includes three phases. Phase one involves a thirty-minute session on the Lumbar Decompression Unit (LDU). Participants experience alternating cycles of 45 seconds of decompression therapy and 15 seconds of rest per minute. Phase two involves the Restoration Exercise (RX-1) machine. When on the RX-1 the participant engages in resisted strength training

in order to properly (re)train the extensor muscle mass through high intensity muscle specific therapeutic exercise. By isolating the lumbar extensor muscles and reducing contribution to the kinetic activity by the hamstrings, quadriceps and gluteals, the greatest amount of neuromuscular re-education and strength restoration can occur. The literature suggests that disuse atrophy is a precursor to mechanical lumbar instability, therefore the introduction of an overload stimuli enhances stabilization of the lumbar spine by increasing overall strength. Increased strength in the lumbar is achieved by increasing the resistance in each session. Phase three involves a basic stretching and home exercises for the patient to practice. Some of these include hamstring and gluteal stretches, mild transverse abdominal training, and lumbar roll stretch.

DATA ANALYSIS

The first two VPA scores were averaged into a VPA 1 score and the last two VPA scores were averaged into a VPA2 score. These scores were subjected to a Wilcoxon T-test, a nonparametric repeated measure test for significant differences between two testing sessions.

OVERALL ANALYSIS

The mean from Time 1 for all participants was 4.9483 out of a possible 10 on the self-report pain measure, with a standard deviation of 1.8529. The mean for Time 2 for all participants was 1.6963, with a standard deviation of 1.98463. The mean and standard deviation for both times are summarized in Figure 1.

Figure 1

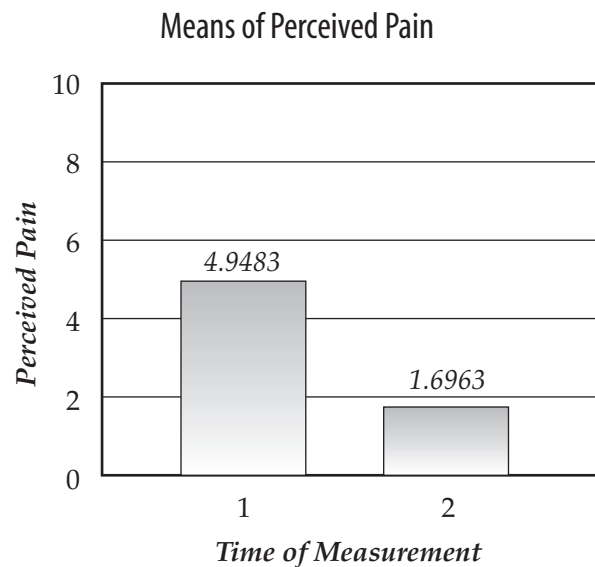


Table 1

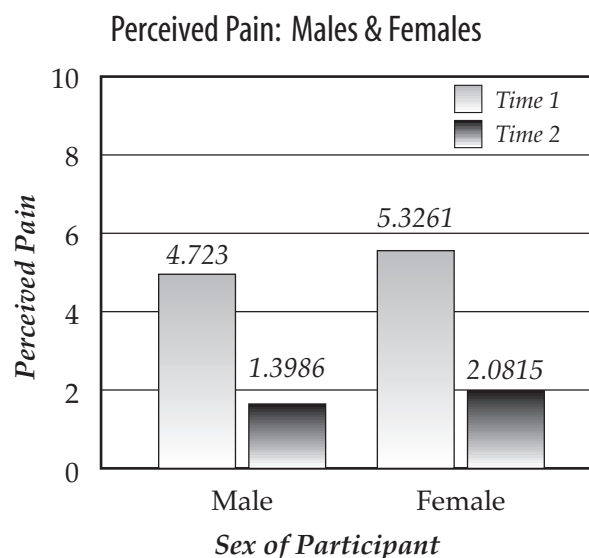
	Time1		Time 2	
	Mean	SD	Mean	SD
All Participants	4.95	1.85	1.7	1.98
Males	4.72	1.97	1.4	1.79
Females	5.33	1.62	2.08	2.23
HNP/myelopathy	4.84	1.59	2.25	2.13
Stenosis	5.64	2.36	1.5	2.47
LDS	5.04	1.97	1.65	1.59

The data were analyzed with a Wilcoxon-T matched pairs signed ranks test due to the nonparametric repeated measures type of data provided. The results from the test were significant, $T(114)=50.5$, $p<.0001$. The perceived pain at Time 2 was significantly reduced compared to the perceived pain at Time 1.

SEX

Males and females were analyzed separately in order to determine whether the significant result could be replicated with each sex. As summarized in Figure 2, the males reported more pain in Time 1 ($M=4.723$; $SD=1.97092$) than Time 2 ($M=1.3986$; $SD=1.78652$). A Wilcoxon-T test demonstrated a significant result [$T(69)=30.5$, $p<.0001$]. The females also reported more pain in Time 1 ($M=5.3261$; $SD=1.61664$) than in Time 2 ($M=2.0815$; $SD=2.22988$). A Wilcoxon-T test also found that the females reported significantly less pain in Time 1 than Time 2 [$T(44)=0$, $p<.0001$].

Figure 2

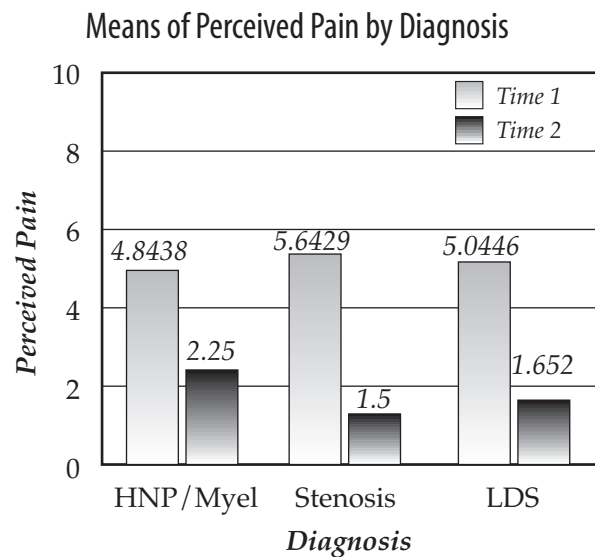


DIAGNOSIS

Three different diagnoses were analyzed separately. A summary of means for participants with the HNP/Myelopathy diagnosis, the Stenosis diagnosis, and the LDS diagnosis are found in Figure 3. Participants diagnosed with HNP/myelopathy reported significantly less pain at Time 2 ($M=2.25$; $SD=2.12916$) than at Time 1

($M=4.8438$, $SD=1.5887$) [$T(15)=0$, $p<.0001$]. In addition, participants diagnosed with stenosis reported significantly less pain at Time 2 ($M=1.5$; $SD=2.46644$) than at Time 1 ($M=5.6429$, $SD=2.35786$); [$T(7)=0$, $p<.02$]. And, participants diagnosed with LDS reported significantly less pain at Time 2 ($M=1.652$; $SD=1.95159$) than at Time 1 ($M=5.0446$, $SD=1.9726$); [$T(54)=20.5$, $p<.0001$].

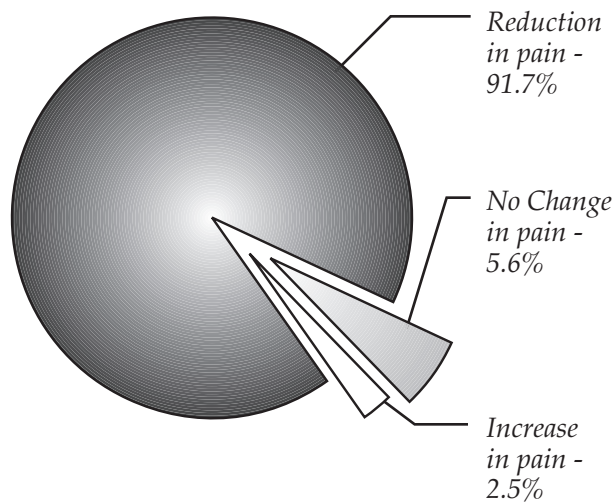
Figure 3



DISCUSSION

The purpose of this study was to evaluate the finding of the Lordex Lumbar Spine Pain Management Program and examine the positive clinical outcomes for herniated disc, degenerative joint disease, facet arthrosis, sciatica and spinal stenosis. Two machines are incorporated into the Lordex System protocol; the (LDU) Lordex Decompression Unit and the (RX-1) Lumbar Restoration Extension Machine. A Spinal Hygiene Machine was made available to the patient at the completion of the protocol to assist in long-term maintenance of improvement.

Participants' Change in Pain from Time 1 to Time 2



A significant reduction in pain was observed from the beginning of the treatment to the end of the treatment. All participating groups including males, females, and patients of varying disorders reported a reduction in self-reported pain. The reduction in pain was experienced by 91.7% of the patients. A small percentage, 5.8%, experienced no change in pain, and only 2.5% experienced an increase in pain. It is possible that this non invasive treatment option could be an ideal alternative to back surgery for many patients who experience acute or chronic back pain.

The LDU design involves a patient lying supine with there lumbar region over a split table to reduce gravitational resistance, a knee pad to allow flexion of the hips during treatment, segmental control of the angle to be treated by controlling elevation of the table, non-slip pelvic restraint and wing jacket TM chest harness to hold the upper and lower portions of the patient. The LDU utilizes a standard traction protocol of 50% of the patient's body weight minus ten pounds for the first session. The following session the patient underwent a traction of 50% body weight, and then every session thereafter 50% plus ten pounds. The

modifications to these units allow the patient to either relax by sleeping or reading during the session. After the first phase is completed the patient will exit the LDU go right over to the RX-1 for the exercise portion. The lumbar exercise is performed by patient placement on the machine with the feet received on a platform, the patient iliac crest height to be positioned slightly above the fulcrum of the movable arm piece, the height of the femurs to be parallel to the seat, then the femur guided back into the acetabulum by use of a tightening wheel in order to stabilize the pelvis. The patient undergoes 20 minutes of supervised extension movements producing both an eccentric and concentric contraction of the lumbar muscles. The patient is advised to perform both the eccentric and concentric movement for approximately for 7 seconds each, for total of 14 seconds per repetition. The patient must then perform approximately 60 – 80 repetitions of constant load extension exercise. Following the these two phases the participant will be instructed on basic stretching protocols for home use. The extent of these exercises will vary based on need, but overall is considered an adjunct to the Lordex protocol.

This basic protocol produced a 91.7% positive response in patients in 122 patients. Each patient, after a few therapy sessions, reported a perceptible increase in their lumbar strength. This study did not measure those changes directly. Other studies have shown similar correlating results. In one study and randomized trial of combining manipulation with stabilization exercise was compared to physician consultation for chronic low back pain. The results showed a greater reduction in self assessed pain levels with a short, specific treatment program utilizing exercise than with a medical consultation. (Niemisto 2003) Low back pain can affect the muscle recruitment for spinal stability which in turn affects the mechanical function of the spine. (van Dieen 2003).

The Lordex protocol is a noninvasive, nonsurgical therapy that is focused on the exercise of the lumbar musculature whether a patient is pre or post-operative. 16 of the patients in this study were post-operative based on the history provided. Many of the patients that had not had surgery were able to avoid any invasive procedures after the series of treatments. Other studies have shown how exercise when compared to surgical intervention can be just as effective in the results. A comparison of chronic low back pain patients who underwent cognitive intervention and exercise programs improved significantly in muscle strength versus another group which underwent lumbar fusion. (Keller 2003) The stability of the spine as an indicator for spinal function has been shown to be invaluable in other publications as well. The Lordex system appears to be effective in improving spinal function and decreasing pain.

REFERENCES

- Choiniere, M., & Melzack, R. (1987). Acute and chronic pain in hemophilia. *Pain*, 31(3), 317-331.
- Geurts, J. W. M., van Wijk, R. M. A. W., Wynne, H. J., Hammink, E., Buskens, E., Lousberg, R., Knappe, J. T. A., & Groen, G. J. (2003). Radiofrequency lesioning of dorsal root ganglia for chronic lumbrosacral radicular pain: A randomised, double-blind, controlled trial. *Lancet*, 361(9351), 21-26.
- Gorson, K. C., Schot, C., Herman, R., Ropper, A. H., & Rand, W. M., 1999. Gabapentin in the treatment of painful diabetic neuropathy: A placebo controlled, double blind, crossover trial. *Journal of Neurology, Neurosurgery and Psychiatry*, 66(2), 251-252.
- Hoffman, H. G., Garcia-Palacios, A., Kapa, V., Beecher, J., & Sharar, S. R. (2003). Immersive virtual reality for reducing experimental ischemic pain. *International Journal of Human Computer Interaction*, 15(3), 469-486.
- Jones, D. A., Rollman, G. B., White, K. P., Hill, M. L., & Brooke, R. I. (2003). The relationship between cognitive appraisal, affect, and catastrophizing in patients with chronic pain. *Journal of Pain*, 4(5), 267-277.
- Tack, B. B. (1990). Self-reported fatigue in rheumatoid arthritis. *Arthritis Care and Research*, 3(3), 154-157.
- Keller MD, Anne et al. (2004). Trunk muscle strength, Cross-sectional Area, and Density in Patients With Chronic Low Back Pain Randomized to Lumbar Fusion or Cognitive Intervention and Exercises. *Spine*, 29(1), 3-8.
- Niemisto MD, Leena et al. (2003). A Randomized Trial of Combined Manipulation, Stabilizing Exercises, and Physician Consultation Alone for Chronic Low Back Pain. *Spine*, 28(19), 2185-2191.
- Van Dieen MD, Jaap et al. (2003). Trunk Muscle Recruitment Patterns in Patients With Low Back Pain Enhance the Stability of the Lumbar Spine. *Spine*, 28(8), 834-841.
- Leinonen MD, Ville et al. (2003). Lumbar Paraspinal Muscle Function, Perception of Lumbar Position, Postural Control in Disc Herniated-Related Back Pain. *Spine*, 28(8), 842-848.
- Hida MD, Shinichi et al. (2003). Intraoperative Measurements of Nerve Root Blood Flow During Discectomy for Lumbar Disc Herniation. *Spine*, 28(1), 85-90.
- Luo PhD, Xuemei et al. (2003). Estimates and Patterns of Direct Health Care Expenditures Among Individuals With Back Pain in the United States. *Spine*, 29(1), 79-86.
- Byerly, T.L., Byerly, K.A., Sognier, M.A., Squires, W.G. *Prediction of Muscle Performance During Dynamic Repetitive Movement. Aviation, Space, And Environmental Medicine* (Vol. 74, No. 1). January 2003.