SUMMARY OF STUDY

Subjects' Conditions

- Patients with low back pain
- Patients of all ages, gender, and ethnicity
- Mean Pain Level of 6.88 out of 10

Prior to Treatment

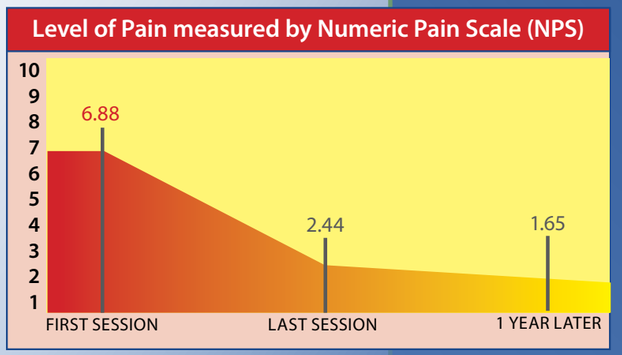
- 45% of patients had previous treatments
- Previous treatments involved acupuncture, back surgery, epidural block, pain medication, conventional physical therapy

Treatment Protocol

- 20 Treatments over 4-6 Weeks

Post Treatment

- The mean pain level for the first session was 6.88 out of 10
- The mean pain level for the last session was 2.42 out of 10
- The mean pain level 1 year after last treatment was 1.65 out of 10
- 76% decrease in pain one year after the last therapy session



This chart shows a mean NPS of 6.88 at the beginning treatment. After treatment, mean NPS is reduced to 2.44. After 1 year patients continue to improve with a mean NPS of 1.65

NORMAN SHEALY, MD, PhD is a neurosurgeon, psychologist, and founding president of the American Holistic Medical Association. For over three decades, he has been at the forefront of alternative medicine and alternative health care. He holds ten patents for innovative discoveries in medicine, has published more than 300 articles, and authored more than 24 books. He is the co-founder of the American Board of Scientific Medical Intuition, and perhaps the world's foremost medical expert on medical intuition.

Individual results may vary. These statements have not been evaluated by the FDA. All spinal decompression devices currently registered with the FDA have received their 51O K clearance by claiming their device is substantially similar to predicate traction devices.

ProMED Pain Rehabilitation Institute
Non-Surgical Disc and Laser Center

(630) 226-5754

ProMedPainRehab.com

RESEARCH

3 Medical Doctors Show Disc Decompression Led to a

76% Decrease in Pain

Even 1 Year After the Last Therapy Session AND When Other Therapies Already Failed

This chart shows a mean NPS of 6.88 at the beginning treatment. After treatment, mean NPS is reduced to 2.44. After 1 year patients continue to improve with a mean NPS of 1.65

ProMED Pain Rehabilitation Institute
Non-Surgical Disc and Laser Center

LONG-TERM EFFECT ANALYSIS OF IDD THERAPY® IN LOW BACK PAIN: A RETROSPECTIVE CLINICAL PILOT STUDY

C. Norman Shealy, MD, PhD, Nirman Koladia, MD, and Merrill M. Wesemann, MD
AJPM Vol. 15 No. 3 July 2005

INTRODUCTION

Low back pain is one of the most common problems treated by orthopedic surgeons. Eighty percent of adults will experience significant low back pain sometime during their life. Second to the common cold, problems caused by the lower back are the most frequent cause of lost workdays in adults under the age of 45 (1).

OBJECTIVES

The objectives of this study were (i) to produce a follow-up to the Shealy and Borgmeyer Study (3), (ii) to evaluate long- term benefits of IDD Therapy® treatment, and (iii) to determine any benefits of IDD Therapy® in comparison to other treatment options. In 1997, Shealy and Borgmeyer presented a significant new approach to the management of back pain (3). Their preliminary results suggested that decompressive mobilization of the lumbar spine was beneficial in 86% of patients with ruptured intervetebral disc and 75% of those with facet arthrosis (3). The present study served as a follow-up to the previous study.

IDD Therapy®, as previously explained, is a modality that utilizes a technology designed to conjoin the successful protocols originally set forth by Shealy, with an expanded physical therapy component to address the pathogenesis of low back pain conditions. We expected therefore, the treatment benefits should continue after the sessions are over, this study aimed to find out the level of such long term benefits obtained. There is anecdotal observation amongst IDD Therapy® clinicians that IDD Therapy® treatment benefits many patients who have failed with other treatment modalities, including traction, vertebral axial decompression, conventional physical therapy, NSAIDs and corticosteroids. This study also aimed to serve as a pilot to evaluate this observation.

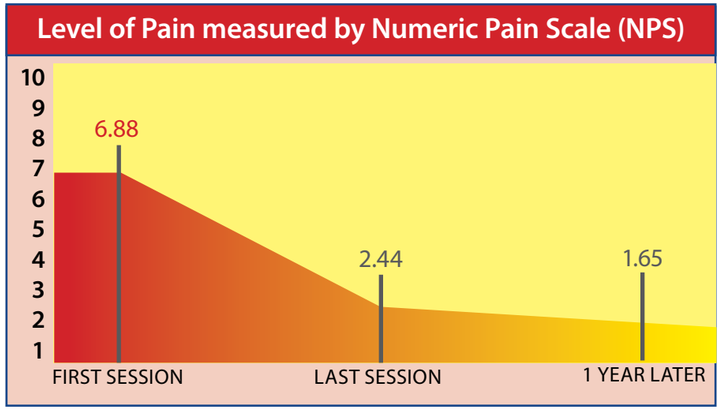
METHODOLOGY

Patient selection. The investigation presented was a pilot study to establish the maintenance of the therapeutic effect of IDD Therapy® at one-year follow-up. The authors expected that the private practice sample chosen would not be very different from a randomized sample. The ideal random sample for IDD Therapy® treatment would be patients suffering from low back pain. The patients were selected from a private practice clinic from a group of patients who may otherwise have been re- ferred for conventional physical therapy rehabilitation and who, instead, were prescribed a computer directed regimen with IDD Therapy® technology best suited to their specific pathologies. This sample should closely represent the ideal sample because IDD Treatment is prescribed to patient suffering from low back pain, with or without previous treatments. A bias would be potentially manifested if the patients presenting to this clinic were significantly different from the general population of such patients, which in the authors' opinion, is but a slight possibility considering the setup and location of the medical practice.

Inclusion/exclusion criteria. Patients with low back pain, with/without previous failed attempts with other treatments, were included in the study. The study included patients of all ages, gender, and ethnicity. Patients with severe osteoporosis, vertebral fractures, spondylolisthesis (grade 2 or higher), unstable post-surgical conditions, any kind of surgical hardware, vertebral fusion (within 6 months), and spinal instability were excluded. Patients who could not provide a legal consent were also excluded.

Protocol. The included patients were administered the appropriate IDD Therapy® treatment protocol; administered via the IDD Therapy® approved equipment. The parameters of the protocol involve treatment time, treatment intensity, and positioning angle (4). These parameters are set on the basis of pathology, vertebral level indicated, and patient characteristics (4). Twenty treatment sessions are recommended within a 4-6 week range, provided that early evaluation is showing a positive patient response. Patients with protocol deviations were dropped-out of the study (see also, Results).

Pain scale and endpoints. The pain scale selected for this study was the numeric pain scale (NPS) (5). Each patient was asked to delineate her/his pain intensity from 0-10 (0- no pain, 10-most unpleasant pain imaginable) on the administered NPS. The first NPS evaluation was administered before the first session of IDD Therapy® treatment. After completion of the full regiment, the second NPS was administered and designated last session. After an average of one year subsequent to the last treatment, the patients were again administered the NPS for the third time.



This chart shows a mean NPS of 6.88 at the beginning treatment. After treatment, mean NPS is reduced to 2.44. After 1 year patients continue to improve with a mean NPS of 1.65

RESULTS

The study was initiated with 35 patients. Two (2) patients were dropped from the study because they could not complete the treatment. Therefore, the total number of patients completing this treatment was 33. Nine (9) patients could not be contacted for the 1-year follow-up. This left 24 patients that could be assessed for the 1-year duration effect analysis.
Of the 24 patients (17 female and 18 males), the mean age was 73.49 years (SD = 6.87). The last treatment sessions were completed between November 8, 2002 and March 5, 2004. The date of the first session was 4-6 weeks before the last session for each patient. The date for 1-year duration effect analysis was May 18, 2004. The mean duration for the study group was 362.00 days, or approximately 1 year (SD = 148.48). The average number of sessions per patient was 19.24 (SD = 5.44).

The mean pain level (Figure 1) for the first session was 6.88 (0-10 NPS, SD = 2.47). The mean pain level for the last session and 1- year duration effect analysis were 2.42 (SD = 2.18) and 1.65 (SD = 2.47), respectively. Therefore, the mean improvement for the first session to last session was 4.46 ($p<0.01$), and the mean improvement from the first session to 1-year duratio n effect analysis was 5.23 ($p<0.01$), a 0.77 improvement over the last session. This correlates to a reported 76% decrease in pain one year after the last therapy session.

The vertebral levels were L1 through S1. Previous treatments involved acupuncture, back support, back surgery, chiropractic, epidural block, pain medication, conventional physical therapy, and trigger point therapy. Forty-five percent (16/35) of the patients had previous treatments before being enrolled into the present study.

CONCLUSIONS

The study results have revealed an improvement of 4.46 points (on the NPS) from the first session to last session. An overall improvement of 5.23 points occurred from the last treatment session to the 1-year duration effect analysis. Improvement from the last treatment session to the date of the 1- year duration effect analysis was 0.77 points. A direct conclusion that can be drawn from the data is that improvement in pain continues after the treatment sessions are completed.

Disclosure. The authors have a proprietary interest in IDD Therapy®.