Dramatic Results Without Surgery

Case Study: Severe Herniated Disc

Two years ago, Terence M. ruptured a disc while lifting a box from the trunk of his car. As a result, he lost the use of his right leg and suffered relentless, excruciating pain. Desperate for relief, he went to see Harvey Kleinberg, DO, an Osteopathic Physician and Physical Medicine and Rehabilitation Specialist for over 35 years. Dr. Kleinberg used Non-Surgical Spinal Decompression Therapy to alleviate Terence's pain and restore his lost function.

"When patients have injuries, you want to make them feel better as quickly as possible, and that is what Spinal Decompression Therapy is capable of doing for many patients," Dr. Kleinberg said.

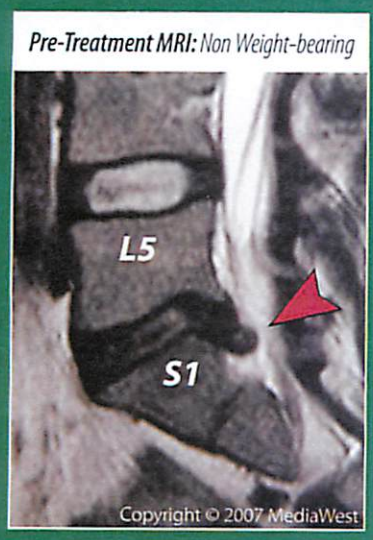
Dr. Kleinberg prescribed a treatment plan of three 30-minute sessions a week, which eventually tapered off as the pain began to subside. Patients usually undergo about 20 to 25 treatments, and easy maintenance can keep people from ever having a repeat injury again.

"My pain was excruciatingly horrible," Terence said. "I thought I'd never be able to be up and about again. My pain was gone in two weeks. I was feeling so good, I couldn't wait to go back to work."

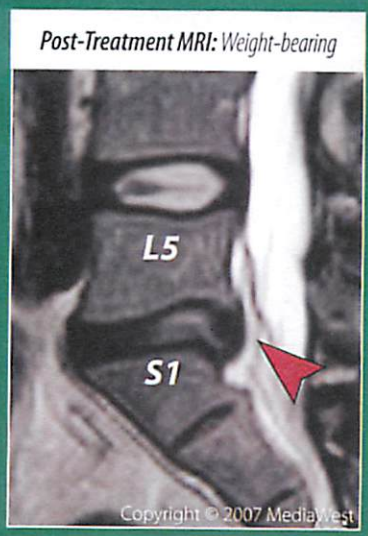
"I Was a Pain Doctor In Pain!"

Dr. Kleinberg knows first-hand how unbearable back pain can be—he suffered from herniated discs three years ago. "I had undergone three laminectomies, but continued to suffer from severe sciatica one year after the third surgery. Due to the severity of my problem, it took 29 treatments for a total elimination of pain. It's been three years now, and I'm still pain-free!" Because Spinal Decompression Therapy alleviated his back pain, he is determined to inform people about this non-surgical treatment for herniated or degenerative discs.

"No one should have to suffer from pain for the rest of their lives if there is a treatment outside of surgery that can offer them relief with no risk involved," Dr. Kleinberg said.



Pre-Treatment MRI: Non Weight-bearing



Post-Treatment MRI: Weight-bearing

Pre- and Post-MRIs: *Spinal Decompression in Action!*

Shown in this box are pre- and post-MRIs of a Non-Surgical Spinal Decompression Therapy patient who had a herniated disc much like that of Dr. Kleinberg's patient, Terence. The red arrows point to the injured disc, before and after treatment. Before treatment, the disc protrudes into the spinal canal, impinging painfully on sensitive nerves. After treatment, the once-extruded disc material has been literally "sucked" back into place! The result was a return to normal functioning.*

* Individual patient results may vary.

A Negative Pressure Is Created

Effects of Vertebral Axial Decompression on Intradiscal Pressure: G. Ramos M.D., W Martin M.D.; Journal of Neurosurgery 1994

ABSTRACT: The object of the study was to examine the effect of vertebral axial decompression on pressure in the nucleus pulposus of the lumbar discs. Intradiscal pressure measurement was performed by connecting a cannula inserted into the patients L4-L5 disc space to a pressure transducer. Changes in intradiscal pressure were recorded at resting state and while controlled tension was applied by the equipment to a pelvic harness. **Intradiscal pressure was decreased to below -100 mm HG.**

Journal of Neurosurgery: *Effects of Vertebral Axial Decompression' on Intradiscal Pressure. September 7994. Vol. 87, NO.3. Gustavo Ramos, MD; William Martin, MD.*

Outcome: *VAX-D'" creates a negative intradiscal pressure force up to -160* mm *Hg.*

American Journal of Pain Management: *Decompression, Reduction, and Stabilization of the Lumbar Spine: A Cost Effective Treatment for Lumbosacral Pain. April 7997. Vol. 7, NO.2. C. Norman Shealy, MD, PhD; Vera Borgmeyer, RN,* MA.

Outcome: *The authors compared the pain-relieving results of traditional mechanical traction (74 patients) with a decompression device (25 patients). The decompression system gave "good" to "excellent" relief in 86% of patients with ruptured discs and 75% of those with facet arthrosis. The traction yielded no "good" to "excellent" results with ruptured discs and only 50% "good" to "excellent" results in patients with facet arthrosis.*

No Benefit To Traction

Evidence does not demonstrate traction to be effective in the treatment of patients with acute low back problems.

Bigos S, Bowyer O, Braen G, et al. Acute low back pain in adults. Clinical Practice Guideline No 14. AHCPR Publication No. 95-0642. Rockville, MD: Agency for Health Care Policy and Research; December 1994

Increase In Disc Height/Decrease Herniation

Case Study Reveals an Increase in Disc Height and a Decrease in Size of Disc Herniation After Treatment with Spinal Decompression

True non-surgical Spinal Decompression Therapy was developed to provide a non-invasive option for discogenic low back pain. Researchers of a case report published in Volume 2 Issue 1 of the European Musculoskeletal Review State, Evidence based data that show the promising effects of spinal decompression on the safe and effective treatment of LBP continue to accumulate. The report titled, *Management of Low Back Pain with a Non-surgical Decompression System Case Report* reveals the pre and post treatment MRI findings of a 69 year old male with low back pain. Prior to treatment the patient reported experiencing low back pain radiating into both legs. When asked to describe his pain intensity on a scale of 0-10 the patient **rated his pain a 10**. The patient underwent 22 treatments over a seven week period. Utilizing the same pain intensity scale the patient reported a **pain level of 1 post treatment**. Four month after the initial treatment a **follow up MRI revealed decreased herniation size and increased disc height at multiple lumbar levels.**

Success Rates of 80% to 90%

John Leslie M.D. , and the Mayo Clinic 18th Annual Meeting American Academy of Pain Management, Tampa Fl Sept. 5 2007

- Multi-center, phase II, non-randomized pilot study utilizing spinal decompression.
- Designed to evaluate the effectiveness and safety of spinal decompression in the treatment of chronic lower back pain.
- Patients enrolled - average of ten years of chronic back pain.
- After two weeks of treatments of spinal decompression- 50% reduction in pain scores
- Upon completion of the entire six week protocol success rate of 88.9% was documented.

American Journal of Pain Management: *Long-term Effect Analysis of /DO THERAPY· ** in Low Back Pain: A Retrospective Clinical Pilot Study. July 2005. Vol. 75, NO.3.* C. *Norman Shealy, MD, PhD; Nirman Koladia, MD; Merrill* M. *Wesemann, MD.*

Outcome: *Of 24 study participants, each reported consistent pain relief and continual improvement of symptoms one year later. Improvement in pain continued after the treatment sessions were completed.*

Practical Pain Management: *Technology Review: 100 THERAPY·. April 2005. Vol. 5, Issue 3.* C. *Norman Shealy, MD, PhD.*

Outcome: *The treatment leads to satisfactory pain relief and improved quality of life in up to 88% of patients-many of whom have failed other "conventional" approaches. Based on the author's review of recent study results, /DO THERAPY'"appears to be the current optimal recommendation for most lumbar pain syndromes.*

Journal of Neuroimaging: *MRI Evidence of Nonsurgical,Mechanical Reduction, Rehydration and Repair of the Herniated Lumbar Disc. April 7998. Vol. 8, NO.2. Edward L. Eyerman, MD.*

Outcome: *All but 3 of 20 patients reported significant pain relief and complete relief of weakness and immobility, when present. This study also shows a correlation between the improvement on the MRI and the reported improvement in pain.*

Journal of Neurological Research: *Vertebral Axial Decompression for Pain Assoc with Herniated* or *Degen Discs* or *Facet Syndrome: An Outcome Study. April 7998. Vol. 20, NO.3. E. Gose, PhD; W Naguszewski, MD; R. Naguszewski, MD.*

Outcome: *Pain, activity and mobility scores greatly improved for 71%of the 778 patients studied. The authors consider VAX-D'" to be a primary modality for low back pain due to lumbar herniations, degenerative disc disease, and facet arthropathy. The authors concluded that post-surgical patients with persistent pain or "Failed Back Syndrome" should try VAX-D before further surgery.*

Long Term Success

Decompression Reduces Chronic Back Pain: A four year Study; R. Odell M.D., D Boudreau D.O., Anesthesiology News March 2003

ABSTRACT: Excellent 4 year study results have been reported in a small series of patients with chronic discogenic low back pain with a spinal decompression device. Of the 23 patients who responded, 52% had a pain level of zero, 91% were able to resume their normal daily activities, and 87% were working or retired without having back pain as the cause of retirement.
SUMMARY: Among 23 patients, 71% showed more than 50% reduction in pain immediately after treatment and 86% showed a 50% or better showed a pain reduction at 4 years. "After 4 years 52% showed a pain level of zero. Thus pain relief not only improved but lasted." Reported R. Odell M.D.

***The Anesthesiology News* (2003) Reported:**

- 4 Year Study
- 91% of People Resume Normal, Daily Activities
- **Over 80% showed 50% or Better Pain Reduction at the End of the 4 Year study.**
- Greater than 50% Still Had a Pain Level of Zero. This means the results lasted.

CLINICAL STUDIES ON THE EFFECTIVENESS OF SPINAL DECOMPRESSION THERAPY

"Eighty-six percent of ruptured intervertebral disc (RID) patients achieved 'good' (50-89% improvement) to 'excellent' (90-100% improvement) results with decompression. Sciatica and back pain were relieved." "Of the facet arthrosis patients, 75% obtained 'good' to 'excellent' results with decompression."

C. Norman Shealy, MD, PhD, and Vera Borgmeyer, RN, MA.
Decompression, Reduction, and Stabilization of the Lumbar Spine: A Cost-Effective Treatment for Lumbosacral Pain. American Journal of Pain Management Vol. 7 No. 2 April 1997

"Serial MRI of 20 patients treated with the decompression table shows in our study up to 90% reduction of subligamentous nucleus herniation in 10 of 14. Some rehydration occurs detected by T2 and proton density signal increase. Torn annulus repair is seen in all."

Eyerman, Edward MD. Simple pelvic traction gives inconsistent relief to herniated lumbar disc sufferers. Journal of Neuroimaging. Paper presented to the American Society of Neuroimaging, Orlando, Florida 2-26-98.

"Results showed that 86% of the 219 patients who completed the therapy reported immediate resolution of symptoms, while 84% remained pain-free 90 days post-treatment. Physical examination findings showed improvement in 92% of the 219 patients, and remained intact in 89% of these patients 90 days after treatment."

Gionis, Thomas MD; Groteke, Eric DC. Surgical Alternatives: Spinal Decompression. Orthopedic Technology Review. 2003; 6 (5).

"All but two of the patients in the study improved at least 30% or more in the first three weeks." "Utilizing the outcome measures, this form of decompression reduces symptoms and improves activities of daily living."

Bruce Gundersen, DC, FACO; Michael Henrie, MS II, Josh Christensen, DC. A Clinical Trial on Non-Surgical Spinal Decompression Using Vertebral Axial Distraction Delivered by a Computerized Traction Device. The Academy of Chiropractic Orthopedists, Quarterly Journal of ACO, June 2004

Intervertebral Differential Dynamics Therapy
A New Direction for the Initial Treatment of Low Back Pain

a report by Dennis McClure, MD, and Bethany Farris, MD, Private Practice, Dayton, Ohio

(Originally published in *US Musculoskeletal Review* 2006)

Patients with back pain usually present a neurosurgeon or spine specialist with an abnormal magnetic resonance imaging (MRI), while their referring physician tells them they have a degenerated disc causing their pain. Throughout my years of practice, it has become apparent to me that patients with back pain want to know why they are having pain, the cause of their back pain and how to effectively treat their back pain in order to avoid surgery. In addition to improving pain, another goal in treatment is to improve flexibility, as well as quality of life, in the safest and most effective manner prior to recommending more invasive procedures for treating the patient's pain due to degenerative disc disease. It is a misconception by the public that surgery 'fixes' a person's back pain. If this were true, we would never see patients with failed back syndrome.

There has been no established uniform or conservative management to effectively treat low back pain.

In November 2003, I introduced Intervertebral Differential Dynamics (IDD) Therapy to my neurosurgical practice. IDD Therapy® is a noninvasive spinal rehabilitation treatment developed by Norman Shealy, MD, PhD, and is delivered by the Accu-SPINA® spinal care device. IDD Therapy provides computer-directed physio-therapeutic treatment to the lumbar and cervical intervertebral discs and facet joints, with a course of treatment consisting of 20 sessions of 25 to 30 minutes, spread over a six-week period. IDD Therapy protocols allow for the controlled distraction of targeted vertebrae to mobilize the joint and to create a negative pressure inside the intervertebral disc. This negative pressure leads to the diffusion of fluid and nutrients into the disc to stimulate its metabolism and promote hydration and healing. The negative pressure can also lead to the retraction of a herniated nucleus pulposus. IDD Therapy treatment further delivers a passive exercise element to release spasmodic behavior and to reeducate supporting soft tissues. Since introducing IDD Therapy to the practice I have treated over 1,200 patients. Initial studies of IDD Therapy indicated success rates of 86% and 76% one year post-treatment. Our results of treatment are similar to the initial reports of IDD therapy; in fact, in some cases we believe they are higher. We present our results of over 415 patients who have been analyzed so far in looking at success rates that contribute to variables affecting the outcome of IDD Therapy.

Dennis McClure, MD, has been in private practice in Dayton, Ohio, since 1995. He was certified by the American Board of Neurological Surgery in 1988 and served in the US Air Force from 1984. He is a lifetime member of the American Association of Neurological Surgeons. Dr. McClure obtained his MD from Indiana University in 1978 and completed neurosurgery training at the University of Wisconsin Hospitals (Madison) in 1984.

Questions and Direction

After treating patients for two years, it seemed apparent that most of them reported significant recovery of back pain after completing IDD Therapy. This raised several important questions. What are the reasons patients do not improve with IDD Therapy? What factors about these patients led to a good prognosis with treatment? What factors led patients to experience different severities of pain prior to and after treatment?

Understanding the answers to these questions was crucial for us to quantify and improve the quality of treatment we could give to our patients. We therefore employed a research analyst to answer these questions and analyze the data extracted from the patients' files, which included medical history, assessment measures (taken and recorded upon initial evaluation), diagnoses, treatment parameters and follow-up measures.

Preliminary Analyses and Results

This preliminary analysis was conducted by analyzing the success from self-reports given by the patient on follow-up. Success with IDD Therapy was rated by patients after treatment (2-4 weeks, and 12 months) (see Table 1).

In the preliminary analysis we defined success as an improvement rating of 2 or 3. A patient must report a 50% decrease or greater in pain in order to be considered a success in this analysis. Data from the past 415 patients completing treatment was analyzed between two months and two years after completion of the course of IDD Therapy treatment, at an average time of one year post-treatment. Any patient failing to give an improvement rating was excluded. Success rates were examined according to diagnosis assigned prior to treatment (see Table 2).

Of particular interest are lumbar surgical candidates, that is, those patients who had been advised to undergo surgery and who came to the practice for a second opinion or patients who I might have previously operated on. This group showed a success rate of 92%. This is quite an exciting find, considering the next alternative for these patients would have been surgery. Although

the sample size for cervical and post-laminectomy patients was limited, the success rates are promising for these groups as well.

Having determined initial success rates of treatment led us to inquire about variables influencing the outcome of treatment. In particular, what makes patients have these exciting success rates and more importantly, what variables affect the outcome of treatment for patients who did not benefit from IDD Therapy? We contacted the lumbar surgical candidates for additional follow-up information at 12 months. Out of 129 patients, 84 were contacted. The data for these patients was analyzed and the results are follows:

- Effects of Gender—females reported significantly higher pain after treatment, ($p<.00.58$)

- Effects of Age (90% confidence interval)—there was a significant increase in pain after treatment as age increased, ($p<.0955$).

- Effects of Time—patients who reported initial success (rating of 2 or 3) directly after treatment continued to have a significant reduction in pain at the time of the follow-up (anywhere from two months to two years after completing treatment) ($p<.0001$).

- Effects on Activity Level—patients who reported success (reduction in pain) after treatment also reported improvement in other aspects of their life, including a significant increase in capacity to live a more active lifestyle, ($p<.0001$).

- Factors that had no effect on outcome measures included body mass index, number of diagnoses, number of serious illnesses, number of prior treatments, and angle of distraction.

- Flexibility measuring forward bending and straight leg-raising improved by 60% post-treatment.

These results were encouraging and led us to examine other aspects related to pain prior to and after treatment. More specifically, psychological processes and attitudes, and how they may affect IDD Therapy.

Depression and Attitude Study and Results

To more accurately assess improvement and factors affecting it, a study was designed to assess patients prior to and post-treatment. Participants gave consent and took a battery of surveys prior to treatment, including a pain assessment, a self-rated depression inventory and an attitude assessment. After patients completed treatment, they took the pain assessment again, and results were analyzed. Analyses are based on a sample size of 50 patients.

The first important finding was that patients who reported higher pain prior to treatment showed significantly higher rates of depression, ($p<.0071$), which gave us important insight into psychological aspects of a patient's health affecting their perception of pain. Second, patients with negative attitudes (skeptic or cynic) reported slightly higher pain prior to treatment, although not enough to be statistically significant in a one-way analysis of variance (ANOVA). These findings suggest that conceptual treatment of pain should take a more holistic approach.

This study also replicated the effect of age from the previous analysis. Patients in this sample showed that, as age increases, pain after treatment also significantly increased ($p<.0110$). Number of prescription medications also had a significant effect on the outcome of treatment. Patients taking more medication report significantly higher pain after treatment ($p<.0143$). Patients on more prescription medications are in overall poorer health prior to treatment. If this holds true, it would also reinforce the idea of treating back pain using a more holistic approach. This would allow us to address and treat additional aspects of patients' health such as psychological, physical and spiritual areas, resulting in better improvement in pain from IDD Therapy, and overall quality of life.

It is also worth noting that, while different factors may significantly affect the outcome of IDD Therapy, the sample had a significant decrease in pain according to a matched pairs test, ($p<.0001$). In addition, although depression significantly affected reported pain prior to treatment, patients with depression significantly improved after treatment ($p<.0001$).This leads me to believe that IDD Therapy not only decreases pain, but also lifts depression associated with pain. Overall, the success rate was 88.2% for this sample, which fell between the ranges of success found in our initial estimates of 79-92% success.

Table I: Patient-rated Success of IDD Therapy

Improvement Rating	Interpretation	Pain Adjustment
0	No improvement	0-24% decrease
1	Minimal improvement	25-49% decrease
2	Moderate improvement	50-79% decrease
3	Excellent improvement	80-100% decrease

Future Studies—Anger and Stress

In light of supporting a more holistic approach to pain, we have begun to look at back pain in broader terms than the physical pain our patients experience. We have also started to examine the severity of impairments as a consequence of the pain, and how this affects patients' daily lives. We began to assess and examine the influence of other factors, such as stress and anger levels, on the outcome of IDD Therapy. So far, 65 patients have participated in this most recent study, called the Anger and Stress Study. The results are preliminary, as most patients have not completed the follow-up portion of this study. Our preliminary findings include:

- Number of Daily Activities Affected by Pain—Patients who report high numbers of daily activities affected by pain score significantly higher on the anger assessment ($p<.0002$), significantly higher on the depression scale ($p<.0001$), and report significantly higher pain ($p<.0007$).

- Stress Effects—Patients who score high on the Social Readjustment Scale score significantly higher on the anger assessment ($p<.0001$).

- Anger Effects—Patients who score high on the anger assessment score significantly higher on the depression scale ($p<.0002$).

- Depression Score Effects—Patients who score high on the depression scale report significantly higher pain prior to treatment ($p<.0037$).

Conclusions

A number of implications can be made from the analyses above. However, since these are preliminary in nature, we will not elaborate on the potential meaning from each analysis. Instead, we hope to convey information by moving the conception and treatment of back pain in a new direction, one that uses safer, non-invasive treatments such as IDD Therapy for the initial treatment of low back pain, recognizing the complexity of our patients and treatment through a more holistic approach. ■

Figure 1: MRI Examples

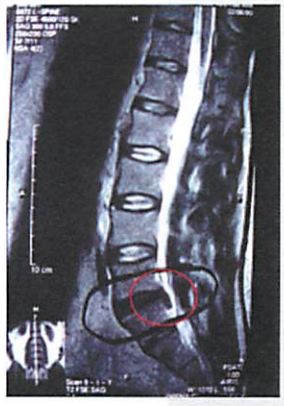


Figure 1a: Pre-treatment MRI (02/02/05)

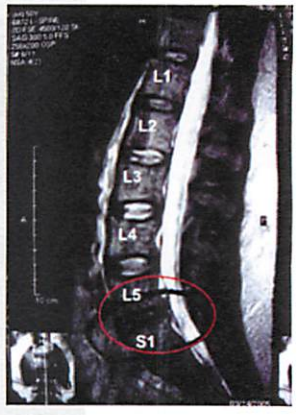


Figure 1b: Post-treatment MRI (03/14/05)

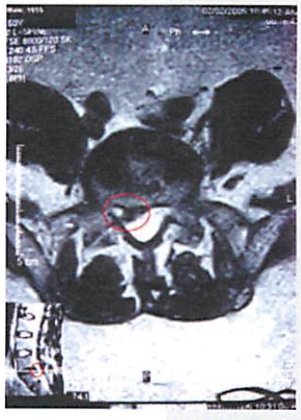


Figure 1c: Pre-treatment MRI (02/02/05)

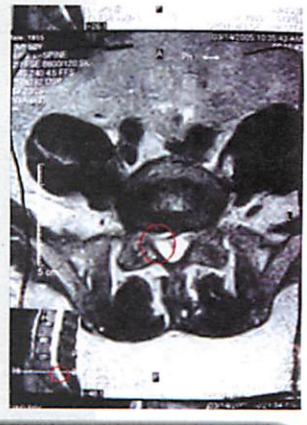


Figure 1d: Post-treatment MRI (03/14/05)

Table II: Success Rates According to Diagnosis Prior to Treatment

Diagnosis type	Reported success rate (%)	Sample size (n)
Lumbar back pain	79	330
Surgical lumbar candidates	92	129
Cervical pain	84.7	33
Post-laminectomies	79	52

Research Proves Spinal Decompression

Reduces Disc Herniation Size up to 90% In a Majority of Patients

While Decreasing Pain 90%

"I had piercing pain down my right leg from a disc herniation"

"I first came in with a Lumbar Disc Herniation after a weight lifting injury. The pain was pinching and piercing down my right leg. It caused abnormal nerve sensations and led to a decrease in life enjoyment. I had a significant amount of numbness and tingling radiating down my leg as well. On a scale of 1 to 10, the pain

Subjects' Condition

- Herniated Discs
- Degenerated Discs
- Torn Annulus

Prior to Treatment

- Pain in back and down the leg
- Numbness in legs
- Weakness

5-Week Protocol

- 20 treatments
- Force of Pull = 1/2 body weight plus 10 lbs
- Force alternated with 30 seconds of relaxation to 50 pounds

Post Treatment

- Over 90% reduction of nucleus herniation in 71% of patients
- Torn annulus repair is seen in all
- Virtually all subjects have sufficient relief of pain to return to work
- 71% had significant pain relief and complete relief of weakness
- 90%+ had numbness in

was a 7. ***I tried Chiropractic care, pain meds, exercise and an inversion table.*** *Seriously, nothing helped. I decided to take matters in my own hands, and found Spinal Decompression online. My first concerns were if the treatment would work for me and if I would need to come in for the rest of my life.* ***My recovery process has been both fast and enjoyable.*** *As a result of my treatment,* ***I now enjoy daily exercise, time with family and can finally sleep soundly at night!*** *The only drawback is that now I can no longer use my back pain as an excuse to miss family reunions. I would highly recommend Spinal Decompression."*
~ Chase G.

the leg disappear

- 86% had "good" to "excellent" relief of Sciatic and back pain
- 28% had rapid relief in as few as 3 treatments
- 85% improved clinically
- Only 6% recurrence rate at 1 year

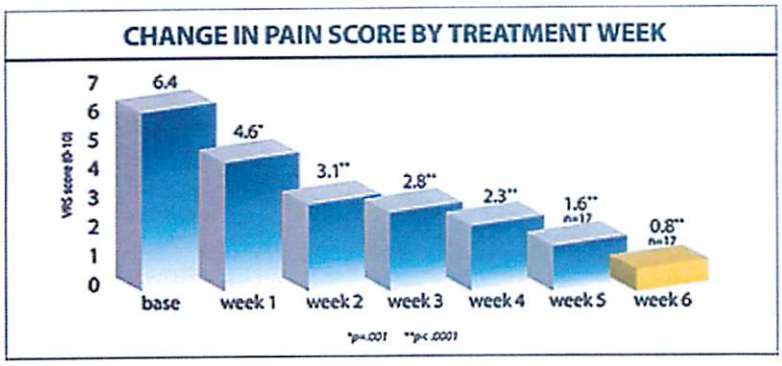
Source: *CT MRI Neurosonology PET SPECT Brain Mapping, Journal of Neuroimaging, Volume 8 / Number 2, April 1998.*

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.

Dr. Leslie of the Mayo Clinic Proves Spinal Decompression to be Up to 88.9% Effective for NECK and BACK PAIN !

Subjects' Condition

- Herniated Discs
- Bulging Discs
- Degenerative Discs
- Failed Back Surgery
- Facet Syndrome



"I can do just about anything now"

"I was suffering from Herniated Discs in my lower back. The pain was the worst pain I have ever felt in my life. It was so bad that I could not sit in the chair in the front lobby waiting to meet the Doctor for the consultation. I was actually lying on the floor when we met because that was the only relief from the constant pain. ***On a scale of 0–10, my pain was an 11!*** *(Seriously!) The pain ran down my right leg often causing loss of feeling in my right foot affecting my walking. I have had back pain for most of my adult life including surgery in 2001 which was expensive and only helped temporarily. I had tried nearly every treatment known for backs since 2001.* ***I tried epidurals/steroid shots, physical therapy, massage, back surgery, exercise, inversion table and pain medication.*** *I took prescription painkillers until the prescription ran out, then about 12–16 Advil a day.* ***Spinal Decompression has been the only treatment that has significantly helped.*** *I am running again, I am back working out at the gym, I can do just about anything now. I don't feel limited anymore and I look forward to playing sports again."*

~ Daniel M.

Prior to Treatment

- Average Pain Score 6.4 Out of 10
- Pain Greater Than 6 Months

6 Week Treatment Protocol

- 20 Treatments

Post Treatment

- Average Pain Decreased to 0.8 Out of 10
- Decreased Pain
- Improved Function
- Required Fewed Analgesics After Treatment
- No Safety Issues or Adverse Effects

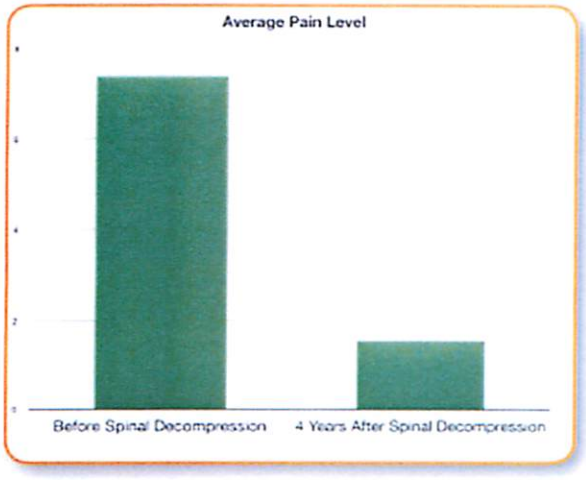
Study Team: *John Leslie, MD, Charlotte Richmond, PhD, Alex Macario, MD, Christian Apfel, MD, Frank Florio, DC, Darren*

Clair, MD, Martin Auster, MD, Joseph Perfolizzi, MD; Mayo Clinic Arizona, 2NEMA Research, Stanford University, University of California at San Francisco, Axiom Worldwide, Vibrance Medical, Johns Hopkins University

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.

Research Proves Spinal Decompression's "Excellent" Long Term Effectiveness

Even 4 Years Later!



Subjects' Condition

- Herniated Discs
- Degenerated Discs

Prior to Treatment

- Average pain level 7.41 out of 10

Directly After Treatment

- Average pain level 3.41 out of 10

4 Years Later

- 52% had a pain level of zero
- 91% were able to resume their normal daily activities

"5 years later and still no pain"

"When I had Spinal Decompression treatments 5 years ago I was suffering from severe pain in my lower back and right leg. On a scale from 1–10, ***my pain was a 10.*** *I was also experiencing some tingling and numbness associated with the pain.* ***I just wanted the pain to go away.*** *I tried epidurals/steroid shots, physical therapy, traditional chiropractic, massage, exercise and pain medication. I was taking about four pain pills a day. I found a Spinal Decompression Clinic on the internet and wondered if spinal decompression would work for me and if I would have to continue the treatment for the rest of my life? As a result of the spinal decompression* ***I am able to walk, sit and stand pain free****. And I am back to work with no problems.* ***The pain in my back and my leg is completely gone.*** *I would recommend spinal decompression to everyone."*

~ Gilbert R.

- 87% were working or retired without having back pain as the cause of retirement.

SUMMARY: 71% showed more than 50% reduction in pain immediately after treatment and 86% showed a 50% or better showed a pain reduction at 4 years.

Source: *Anesthesiology News, Volume 29, Number 3, March 2003, Robert H. Odell Jr., MD. Ph.D., Boudreau D. DO.*

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.

Medical Doctors From Stanford and John Hopkins University Show Patients Rate Spinal Decompression 8.98 out of 10 in Satisfaction

Subjects' Condition

- Herniated Discs
- Degenerated Discs

Prior to Treatment

- Average Pain Score 5.99 out of 10
- Pain lasting great than

And 100% Would Recommend Spinal Decompression

"Only 6 weeks later my back and leg feel wonderful"

"I had a herniated disc at L3 and L5, according to my MRI. ***My right side was in excruciating pain from my disc pushing on my sciatic nerve.*** *My foot was numb and tingly all the time.* ***I was in the E.R. every weekend. I was taking all kinds of pain pills, was in a wheelchair for 2 months and used a walker for 1 month.*** *I knew the pills could cause damage to my liver and kidneys but I didn't know what else to do. They were also becoming very addictive and that made me scared.* ***I was three days from having back surgery*** *when I saw an ad in the newspaper. I came down to the office and the Doctors explained everything. The Dr's put me on the Decompression Table and* ***only 6 weeks later my back and leg feel wonderful. No***

12 weeks

Treatment Protocol

- 23 DRX sessions Over 8 Weeks
- Lumbar stretching exercises and ice or muscle stimulation

Post Treatment

- Pain decreased from Average 5.99 to .87 out of 10
- NSAID and Opioid use went from 65% of patients to <5%
- Patients reported a mean 90% improvement in back pain
- Better function as measured by activities of daily living.
- Patients rated the DRX9000 an 8.98 out of 10 in Satisfaction
- No patient required more invasive therapies (e.g. surgery)
- 100% Would recommend DRX to someone else

Source: *Alex Macario, MD, MBA, Standford University; Sunil J. Panchal, MD, COPE Foundation,*

more pain pills for me. I cannot say enough about Spinal Decompression! I recommend it to anyone with back or neck pain."
~ Hilma S.

Florida Pain Management; Charlotte Richmond, PhD, Nema Research, Biomedical Research & Education Foundation; Joseph V. Pergolizzi, Jr., MD, Johns Hopkins University & Nema Research

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 510 K clearance by claiming their device is substantially similar to predicate traction devices.

CAUTION **Pain Medications—Special Advisory Warning:** *It may be time to reconsider how you manage your pain medication intake. In the U.S., 60 million adults take Over-The-Counter (OTC) pain relievers every day or for several days per week.[1] Ongoing use can lead to serious health risks or even death.*

OTC pain drugs should be taken at the lowest effective dose for no more than 10 days.[2]

Non-Steroidal Anti-Inflammatory Drugs (NSAIDs): This class of drug is the most commonly used medication in the world. OTC NSAIDs include **ibuprofen** (Advil™ and Motrin™), **naproxen** (Aleve™), and **aspirin**. NSAIDs are used primarily to treat inflammation, pain, and fever, by blocking prostaglandin production. However, prostaglandins are needed to create mucosal protection for the lining of the stomach, and, if blocked, serious damage can occur. NSAIDs also inhibit platelets that help with blood coagulation and homeostasis, and can interfere with kidney function. There is no risk-free NSAID dose (includes low-dose aspirin).

BLACK BOX WARNINGS *The FDA's most serious warning must now appear on all PRESCRIPTION and OTC NSAID packaging.[3] This marks the first time ever that an OTC drug has been required to have a Black Box Warning.[4] High doses of OTC brands can be just as dangerous as prescription formulations.*

- *NSAIDs (except aspirin) may cause an increased risk of heart attack, blood clots, and stroke, which can be fatal. Risks may increase with duration of use. Cardiovascular conditions such as high blood pressure may also increase the risk.[3]*
- *NSAIDs increase the risk of serious gastrointestinal (GI) adverse events including inflammation, bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal and most often occur without warning symptoms.[3]*

NSAID-Induced PUBs, *known together as* **Perforations** *(erosions of the stomach and small intestinal lining),* **Ulcers,** *and* **GI Bleeds,** *cause over 100,000 hospitalizations annually.[5] Chronic NSAID use (90+ days) showed serious damage to the small intestine in 70% of the subjects.[6] Patients over 60 with perforations have a 30% chance of dying.[7]*

Compared to non-users, NSAID users' risk for PUBs increases by:
2.5 times when taking low-dose aspirin.[4]
3 times when taking OTC ibuprofen or naproxen.[4]
10 times when taken with alcohol.[8]
12 times when combined with anti-depressants (SSRIs).[9]
13 times with previous Peptic Ulcer Disease or GI Bleed.[1]
13 times when used with anticoagulants (bloodthinners).[1]
15 times when used with Corticosteroids.[10]
25–30 times when two NSAIDs are used together.[1,7]

Acetaminophen (APAP): Tylenol™, Datril™, and others do not have anti-inflammatory effects like NSAIDs but are commonly taken for chronic pain. Used in over 600 medications.[11]

- *Annually, acetaminophen (APAP) toxicity kills nearly 500 people and causes 56,000 ER visits, 2,600 hospitalizations, and 100,000+ calls to Poison Control Centers.[12]*
- *Overdose of acetaminophen is the leading cause of* **Acute Liver Failure (ALF).** *ALF may feel like flu symptoms over several days.[11] Coma and death can rapidly occur in one-third of ALF cases.[13]*
- *ALF can occur using the maximum 4 grams (gm) per day dose for five or more consecutive days.[12] 10% of ALF victims used 2–4 daily gm.[12]*
- *APAP causes half of all ALFs. Of these cases, 38% had combined two or more APAP-containing preparations.[13]*
- *Alcohol used with more than 2 gm of APAP can cause ALF.[13]*

Bigger Doses Don't Mean Better Relief

The analgesic ceiling effect of a drug refers to the dose beyond which there is no additional pain relief. Taking higher than the recommended dose does not yield additional pain relief, but may increase side effects. The ceiling per dose for the following meds are Ibuprofen, 400 mg; Acetaminophen, 1000 mg; Naproxen, 500 mg; Pure Opioids, no ceiling; Combination Opioids with APAP (less than 4 gm/24 hours to avoid ALF).[14,15]

Opioids: These powerful prescription narcotics are extremely addictive and may cause permanent physical changes in the brain. Commonly prescribed opioids are oxycodone (OxyContin®), hydrocodone (well-known brands Vicodin® and Lortab® contain acetaminophen), and methadone.

- *The #1 selling U.S. drug is hydrocodone. With 135 million prescriptions, the U.S. uses 99% of the world's hydrocodone.[16]*
- *Hydrocodone caused 62% of accidental APAP-induced ALFs.[13,17]*
- *Prescription opioid-related deaths exceed the total deaths involving heroin and cocaine.[17]*
- *There were 22,400 accidental overdose deaths with opiate prescriptions vs. 17,000 homicides in 2005 in the U.S.[17]*
- *More people in the 45–54 age group die of unintentional opioid drug overdose than from motor vehicle accidents.[17]*

References listed on page 21

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PAIN MANAGEMENT
The journal with the practitioner in mind.

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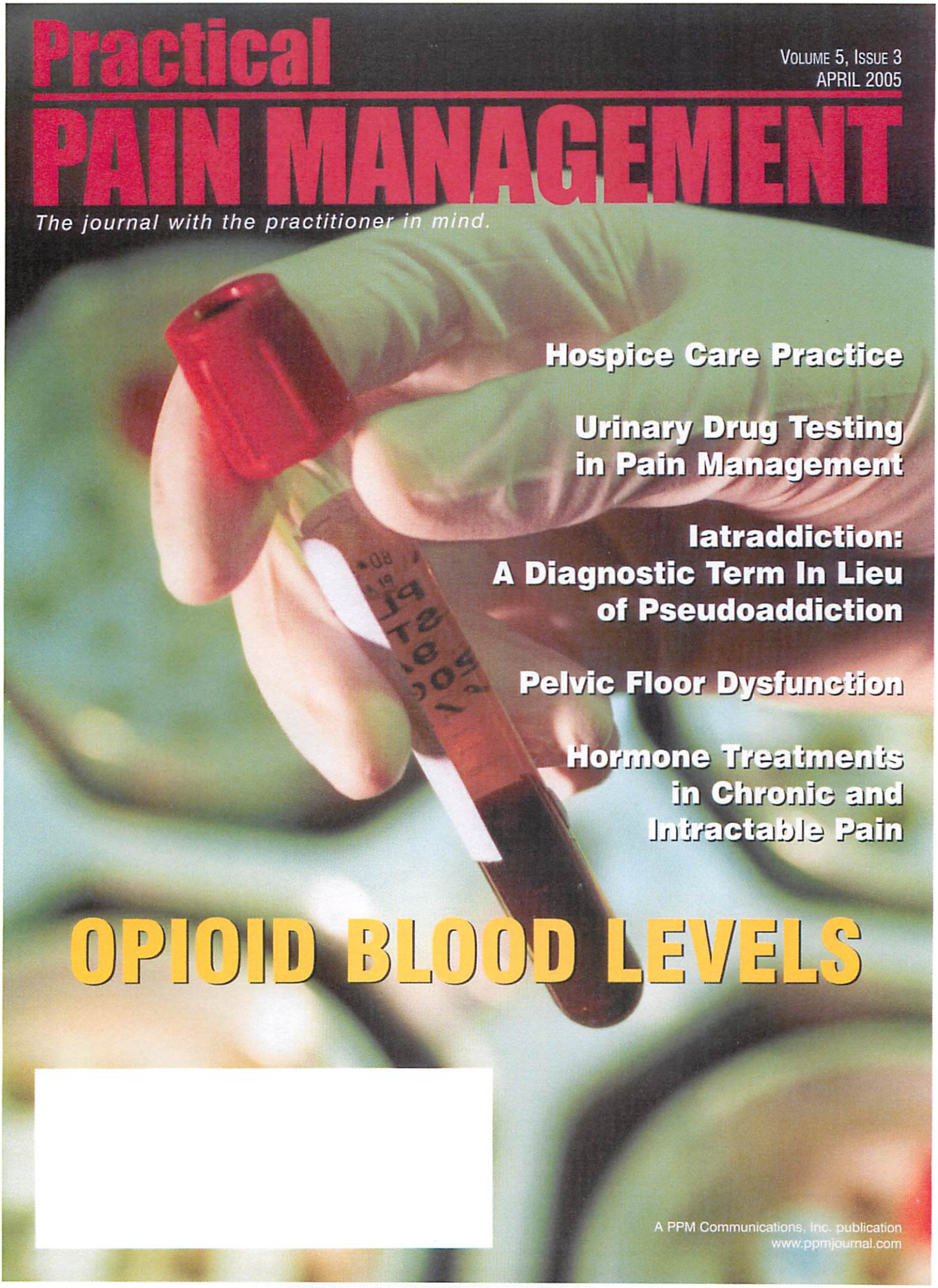

Hospice Care Practice

Urinary Drug Testing in Pain Management

Iatraddiction: A Diagnostic Term In Lieu of Pseudoaddiction

Pelvic Floor Dysfunction

Hormone Treatments in Chronic and Intractable Pain

OPIOID BLOOD LEVELS

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Intervertebral Differential Dynamics Therapy

By C. Norman Shealy, MD, PhD

The author reviews the evolution of back pain technology and presents results of a study utilizing differential dynamics rehabilitation.

The annals of medicine offer countless examples of widely used diagnostic and treatment protocols that represented the standard of care for the time. Through clinical observation and data analysis, physicians are able to identify necessary refinements for improving outcomes. In essence, an evolution takes place yielding better refined, more effective standards of care.

Consider for example, the standard of care established over six decades ago for diagnosing ruptured intervertebral discs, namely Pantopaque® myelography. Although it provided excellent radiological contrast, twenty-five percent of patients developed adhesive arachnoiditis after a single myelogram — leading to progressive disability far worse than the ruptured disc. Fortunately, MRI replaced the more risky Pantopaque myelogram, giving rise to a more refined standard of care. The MRI, a more specific diagnostic approach, proved highly effective and much less traumatic to the patient.

Now consider one of the standards of care for low back pain. Although some form of spinal traction/distraction was used for centuries, the results were erratic and inconsistent, so that most spinal specialists began to abandon this approach in the 1960's.[1] Then Burton and Nida introduced the concept of gravity lumbar reduction therapy.[2] They literally strapped patients upright in a harness for eight hours a day, for one to four weeks, with results best in patients with ruptured discs. However, the complication of hypotension and eight hours of immobilization doomed this radical approach.

Back to the Drawing Board

In 1996, the author was asked by an emerging company to evaluate a pneumatic traction/distraction device that reputedly "decompressed" the lumbar spine. The author was shocked to see patients required to hold themselves in the prone position manually with their arms and hands overhead for 30 minutes of considerable distraction. Five, of six patients interviewed, reported significant shoulder discomfort. The author's attempt on this device resulted in a subluxation of the right shoulder, resulting in several weeks of shoulder pain. Even more troubling was the observation that the prone position actually increased lumbar lordosis — clearly undesirable for optimal spinal dynamics. It occurred to this author that it was definitely no great improvement over the old Hippocratic technique of strapping a patient upright on a door that was dropped out a window!

Optimal Mechanisms

The author evaluated the mechanisms considered optimal for lumbar decompression, reduction and stabilization. Working with several models, x-ray confirmation, and manual palpation, the following conclusions were reached for optimal mechanical distraction of the lumbar spine:

1. split table separation,
2. flexion of the knees,
3. flexion of the lumbar spine to raise the angle and distraction segmentally,
4. comfort and non-slippage of the pelvic restraining belt,
5. comfort and non-slippage of the chest restraint,
6. concomitant use of TENS, heat, ice and myofascial release,
7. a graduated limbering, strengthening and stabilization exercise program,
8. angle of distraction ranging from 10 to 30 degrees.

In the author's review and experience, as of a decade ago, no single device incorporated all these major factors that are important in achieving clinical results. Yet using these guidelines led to vertebral distraction of 7 to 15 millimeters and good to

excellent pain relief. Of 14 patients having MRI-confirmed ruptured discs with surgery recommended, only one subsequently required surgery. Of eight patients with degenerative disc disease or facet arthrosis, six achieved good to excellent pain relief.[3]

Device Evolution

Continuing evolution of the technology discussed above has led to further improvements now being incorporated in new generation devices utilizing computer-directed physical therapy of the lumbar spine, along with refinements of treatment protocols employing differential dynamic rehabilitation.

Treatment objectives include freeing a locked facet joint, correcting spinal misalignment which has rendered it dysfunctional, relieving pressure on a nerve root, or bulging disc, stimulating inhibition of annular fluids, restoration and rehabilitation of normal spinal function and the underlying musculature that is typically compromised.

Comfort during the treatment has improved as well as the ability to focus therapeutic force on specific vertebral levels with optimum mobilization, manipulation, and clinical relief. The ability to utilize multiple primary waveforms, as well as a secondary oscillatory waveform designed more specifically to apply a neuromuscular component, further illustrate the progression evolution of this rehabilitative therapy. Active tracking of applied forces, the ability to individualize treatment according to patient needs and the ability to quantify patient response to the treatment regimen pre- and post-therapy sessions further improves therapeutic results.

The device used in the following study was the Accu-SPINA™, manufactured by North American Medical, and utilizing the 'Intervertebral Differential Dynamic (IDD®) Therapy' protocol.

Study Results

The author was able, as an independent consultant, to review results currently being reported from ten clinics comprising a cohort of over 500 patients. Improvement rates of 65 to 88% confirm the author's earlier findings regarding differential dynamic rehabilitation. Most importantly, the latest study demonstrates not only an average 65% decrease in pain at completion of IDD therapy, but average pain reduction of 76% one year after treatment (see Figure 1, courtesy of North American Medical).

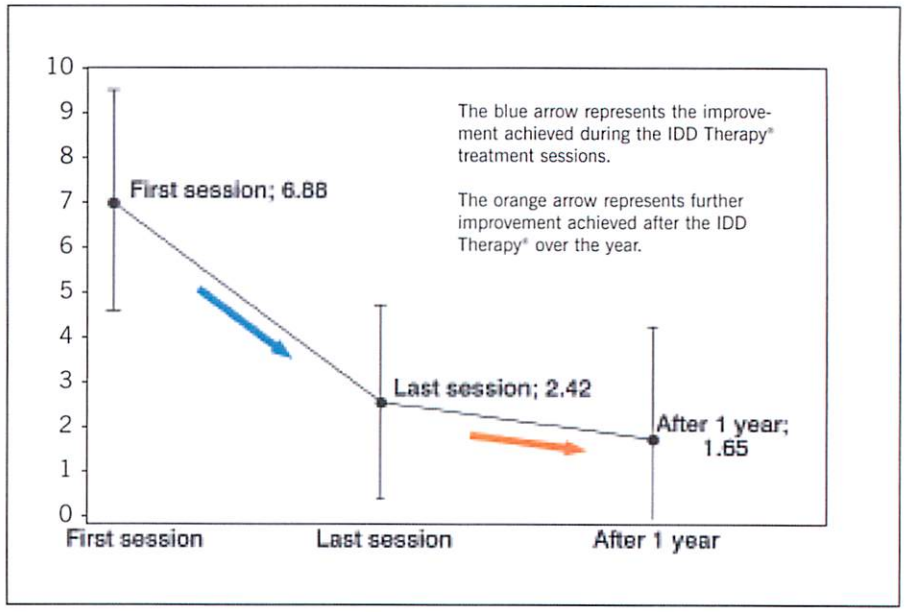

FIGURE 1. *The chart shows mean NPS of 6.88 at the beginning of IDD Therapy® treatment after the completion of treatment the mean NPS is reduced to 2.42 (last session). After a duration of one year the patients continue to improve and the mean NPS is 1.65.*

Current exploration of vibration, distraction, oscillation and other adjunctive mobilization adjustments offer even greater potential for the future of inter-vertebral differential dynamics rehabilitation.

Summary

During the past decade, computerized technology has markedly increased successful outcomes of non-surgical physical therapeutic mobilization for spinal pain, including ruptured discs, as well as locked and degenerative facet pain syndromes. Specific individual spinal segment dynamic mobility leads to satisfactory pain relief and improved quality of life in up to 88% of patients — many of whom have failed other "conventional" approaches. Based on author's review of recent study results, inter-vertebral differential dynamic rehabilitation appears to be the current optimal recommendation for most lumbar pain syndromes. ■

C. Norman Shealy, MD, PhD, is a neurosurgeon, trained at Massachusetts General Hospital, after medical school at Duke University. He has taught at Harvard, Western Reserve, University of Wisconsin, University of Minnesota, Forest Institute of Professional Psychology. He currently serves as President of Holos University Graduate Seminary, which offers doctoral programs in Spiritual Healing and Energy Medicine. Dr. Shealy introduced the concepts of Dorsal Column Stimulation and Transcutaneous Electrical Nerve Stimulation (TENS), both now used worldwide. In 1971, he founded the first comprehensive, holistic clinic for pain and stress management. The Shealy Institute became the most successful and most cost-effective pain clinic in the U.S., with 85% success in over 30,000 patients. The Shealy protocols for management of depression, migraine, fibromyalgia and back pain are increasingly being integrated into hospitals and individual practices. The Shealy Wellness Center focuses on these four major chronic problems. Dr. Shealy holds nine patents for innovative discoveries, has published over 300 articles including 22 books, the latest of which is Youthful Aging — Secret of the Fountain. *His free e-newsletter is available at www.norm shealy.net. Holos University information is at www.hugs-edu.org.*

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Beth Israel Deaconess Medical Center
A Harvard Medical School Teaching Affiliate

Welcome Relief for Low Back Pain

J. Stewart
Beth Israel Deaconess Medical Center. Reviewed for medical accuracy by physicians at Beth Israel Deaconess Medical Center (BIDMC), Harvard Medical School

Introduction

"It's a miracle. I feel like a whole new person," raves 61-year old Kathleen Ross about what some believe to be a remarkably effective form of therapy for low back pain called vertebral axial decompression, or VAX-D. "I was in such pain from a chronic slipped vertebra that I couldn't bear to sit. Then lying down was the only way to relieve the pain. I was afraid I'd be this way for the rest of my life."

For years people like Kathleen, who suffer from chronic and acute low back pain, have relied on conventional therapies that included bed rest, manipulation, pain medication, and, in the most severe cases, surgery. Now an increasing number of patients are being referred by their physicians and surgeons to VAX-D therapy.

VAX-D is a noninvasive treatment that is said to work by alternately stretching and relaxing the lower spine, gently "distracting" the lumbar vertebrae and decompressing the intervertebral discs. In most cases, patients find they can now move more and get long- lasting relief from the crippling pain that comes with a variety of lower back problems.

Causes of Low Back Pain

Vertebral axial decompression (VAX-D) is a noninvasive treatment that is said to work by alternately stretching and relaxing the lower spine, gently "distracting" the lumbar vertebrae and decompressing the intervertebral discs. Low back pain is common in western culture, yet according to the North America Spine Society, the relationship between structural defect and pain is not always understood.

Mechanical back pain can come from inflammation caused by injury or irritation, a bulging or herniated disc, or simply the degeneration of discs that comes with aging. Compressive pain occurs when the spinal nerve roots are pinched or the blood supply to the nerve roots is cut off. In both cases pain can be aggravated by activities that increase "axial loading" such as sitting, standing, or lifting. Sometimes too much pressure from overexertion is the problem. Sometimes too little pressure from inactivity is to blame.

VAX-D is said to relieve the pressure between discs and decompress the nucleus within the disc in a controlled manner, which could cause healing to occur in a number of ways. The treatment is increasingly being recommended as front-line therapy in cases of herniated disc, degenerative disc, slipped vertebra, sciatica, posterior facet problems, and spinal nerve disorders, as well as for post-surgical patients who continue to suffer from "failed back syndrome."

Vertebral axial decompression (VAX-D) is a noninvasive treatment that is said to work by alternately stretching and relaxing the lower spine, gently "distracting" the lumbar vertebrae and decompressing the intervertebral discs.

The VAX-D Table

The VAX-D Therapeutic Table was invented by Dr. Allan Dyer, the former Deputy Minister of Health of Ontario, Canada, and was approved by the FDA for use in the United States in 1994. At present, over 180 clinics offer VAX-D therapy throughout the US, and in Canada, Puerto Rico, Mexico and Australia.

The equipment consists of a mechanically controlled two-part table and a logic control system operated by a technician who constantly monitors and records the therapy cycles. Dr. J. Robert Wootton, a Florida-based physician and one of the earliest practitioners of VAX-D therapy in the United States, explains the procedure. "The patient lies face down on the extendable table, the upper body resting over the stationary portion, holding on to adjustable handgrips that can be released at any time for safety. The patient wears a specially fitted pelvic harness, which is attached to a 'tensionometer' at the foot of the table.

"As the table separates hydraulically, the harness gently pulls the lumbar spine downward, decompressing the vertebrae and the intervertebral discs. A typical half-hour session consists of fifteen (15) alternating cycles of distraction and relaxation, lasting 1 minute each. In most cases, the desired results are achieved within 20-30 daily sessions."

The amount of "pull" varies for each patient, depending on the degree of distraction necessary to treat the condition. In the beginning, and during relaxation cycles, the tensionometer maintains 20 pounds of pressure. Then it increases to between 65 and 85 pounds during decompression. A paper graph connected to the machine prints out a continuous record of the intradiscal pressure.

Interestingly, many professional athletes use the VAX-D table, set at 55 pounds of pressure, as a pre-exercise warm-up, according to Dr. Wootton. "The nerves in the lower back supply the legs, so if you take the pressure off the nerves to the legs, you have more power."

The Vacuum Effect

As tension is continuously applied to the harness, the pressure within the discs reaches a threshold at which it changes from a positive to a negative level, indicating decompression, or a vacuum. The precise control provided by the VAX-D table enables the therapist to determine the exact pull required to achieve optimal decompression. Many patients report instant reduction of pain during the session, as well as afterward.

The vacuum effect that is created inside the discs has "far-reaching therapeutic implications," according to Dr. Frank Tilaro, medical director for the Advanced Spinal Institute in Ogden, Utah, and director of clinical research for VAX-D Medical Technologies. "Prior to the introduction of VAX-D, a non-surgical method for disc decompression was unavailable. In numerous studies, conventional traction has never demonstrated a reduction of intradiscal pressure to negative ranges. On the contrary, many traction devices actually caused an increase due to reflex muscle

spasm." The two-part VAX-D table is designed to apply discrete progressive tension to the lumbar spine, without creating reflex muscle contractions in the upper vertebrae.

Dr. Wootton further explains the multiple effects of high-level decompression within the discs. "The powerful negative pressure from the vacuum draws back the herniated disc into its proper orientation, draws nutrient-rich spinal fluid into the disc, and stimulates repair cells, effectively mending the disc." Wootton adds, "VAX-D is the most promising non-surgical medical treatment for lumbar pain to be developed in many years."

Not everyone, however, is a candidate for VAX-D therapy. Contraindications include infection, degenerative arthritis, tumors, osteoporosis, fractures, or any condition that compromises the integrity of the spinal column. Prospective patients should be evaluated by a therapist or physician prior to therapy, and routine spinal X-rays should be taken. A CT scan or MRI may also be necessary to rule out any contraindications. To date, no serious side effects have been reported with VAX-D Therapy.

Long-Term Effects

According to clinical results gathered over the last 4 years, the vast majority of patients experience some degree of recovery with VAX-D therapy, and of those the majority remain in remission. (Some experts caution, however, that no well-designed trials have demonstrated the efficacy of this treatment.) Some patients choose to return for maintenance visits or to enhance the protective benefits of this treatment.

Although the safety and efficacy of VAX-D are said to be high, and the cost is relatively low (approximately 1/12 the cost of surgery), many insurance companies have yet to cover the procedure. This is changing, as VAX-D becomes more widely known.

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DECOMPRESSION IS MORE THAN TRACTION

by Eric Kaplan, D.C., F.I.A.M.A.

As I travel around the country, the great debate continues. Is it traction or is it decompression? There is a large dynamic in tables made and the cost of these tables. Tables range from $12,000 to $150,000, yet some sales people try to tell the consumer they are the same. Hopefully my article will let you decide, allow you to make the decision.

Decompression, first and foremost, has been great for our profession. Never, and I mean never, before have patients in droves come to chiropractors offices and paid cash in advance. This technology is so accepted now, hundreds of MD's are buying decompression tables and treating discs. Yes, once again, while our profession decides the great debate, the MD's are quietly moving into the back business. They are doing this, not with the $10,000 traction machines. They understand pure traction; this has been around for years and, alone, does not work.

Marketing. It's all about Perception

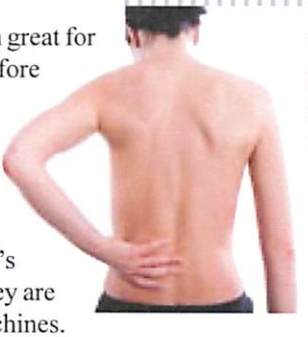
I have always stated, if you want a Rolls Royce Practice, you need to have a Rolls Royce mentality. A KIA will take you from point A to point B, as simply as a Rolls Royce; but quality and perception abound in the Rolls Royce. How your table looks is important to the consumer as well as function. We must not cheapen our profession. Decompression has done, marketing wise, for our profession what the term COSMETIC DENTISTRY has done for dentistry.

The appearance of your equipment is important to the consumer. The other component is the marketing. A personalized infomercial is the key. The generic ones just don't work as well. Consumers like celebrity endorsements as well as real doctor testimonials.

Technology has advanced in every form of medicine, yet chiropractors try to remain as we have one hundred years ago. Some naysayers will say it is diluting chiropractic; I say, it is enhancing our profession. What percentage of your patients have cell phones? How about DVD players, I-Pods TIVO, DVR, or navigation systems in their cars? What about these same patients ten years ago, twenty years ago? Technology has changed our environment. Patients today demand the newest and the best. Decompression has been great for our profession, now we must not cheapen it.

Traction vs. Decompression

Traction has been in use for many years as a physical therapy modality. CPT offers a code for this as 97012. A variety of devices have been utilized to apply traction forces in novel ways, with basic electronic motors with winch and cable mounted on the table or in a separate column, bed traction with weights, split/floating tables, tilt tables, gravity inversion devices etc.



TRACTION fails, in many cases, because it causes muscular stretch receptors to fire, which then causes para-spinal muscles to contract.

There is a big difference between traction and decompression. Traction has been around for hundreds of years. The problem with traction is that it is not always beneficial. Traction offers a straight pull. Consider that the lumbar and cervical spine offer a normal lordotic curvature. A traction device will pull all segments thus disrupting the normal lordotic curve. Quality decompression tables, can isolate the diseased disc by segment and not disrupt the normal lordotic curvature.

Forms of Traction have been around for centuries. In the past many naysayers took a hard line on traction. In 1998, the *Scientific American* rated traction to be of little or no value in the examination of treatments for low back pain. The Quebec Task Force on Spinal Disorders concluded that there was no scientific evidence to support the use of spinal traction in either the diagnosis or treatment of low back pain and discogenic disease. These findings are consistent with many studies that report traction alone can often times signal a pain splinting response and put a patient's back muscles in spasm, resisting any attempts to effect a change in the disc. Traction fails, in many cases, because it causes muscular stretch receptors to fire, which then causes para-spinal muscles to contract. This muscular response often causes an increase in intradiscal pressure, creating more pain. Traction does not create a vacuum effect within the disc, allowing nutrients and oxygen into the disc, therefore, the disc does not heal.

Traction is performed in two distinctly different ways:

1. A continuous pull is exerted on the area concerned and held (called *the rack* and used for back treatment as well as torture in medieval days)
2. An on-off procedure of pull and release called *intermittent traction.*

Spinal Decompression, meanwhile, uses a computerized program with specific parameters, angles and weight of pull customized and retained in the software for each individual. The higher end decompression tables can document and store data by patient, by visit, and provide a printout. This is an important component for research and reimbursement not provided by the less expensive traction tables. True Decompression tables utilize a computerized program with specific times and weights used for each individual. This highly specialized computer modulates the application of distraction forces in order to achieve the ideal effect. The system uses a gentle, curved angle pull which yields far greater treatment results than a less comfortable, sharp angle pull. Distraction must be offset by cycles of partial relaxation.

The system continuously monitors spinal resistance and adjusts distraction forces accordingly. A specific cervical or lumbar segment can be targeted for treatment by changing the angle of distraction. This patented technique of decompression may prevent muscle spasm and patient guarding. Constant activity monitoring takes place at a rate of 10,000 times per second, making adjustments not perceived by the eye as many as twenty times per second via its fractional metering and monitoring system.

Genuine decompression also involves the use of a special pelvic harness that supports the lumbar spine during therapy. Negative pressure within the disc is maintained throughout the treatment session. With genuine decompression, the pressure within the disc space can actually be lowered to about -150 mmHg. As a result, the damaged disc will be rehydrated with nutrients and oxygen.

Some experts have called this procedure *ramping*, which slowly introduces the traction effect to the spine, then holds the segment and gradually increases the weight and pressure. In this manner the procedure can override the body's natural segment at a specific angle to gain the event known as *decompression.* The key to this ramping effect is to offset the body's natural defense mechanism of tightening the muscles in response to the external pulling. This causes a wider spacing of the vertebral discs which, in turn, creates a negative pressure (decompression) on this area. Bulging disc material can actually be pulled back underneath the vertebra and off the spinal cord or nerves they are irritating. Degenerative discs that have lost their height can be opened up to near normal heights, creating increased movement and decreased nerve pressure.

Application must be segment specific, with proper isolation of the segment. In decompression, one size does not fit all.

Should a patient with multiple herniations be treated the same as the patient with a single herniation? Then which herniation should you treat first? Decompression is a science as well as a technique that must be respected.

The problems with many of the earlier and less expensive tables were numerous:

- non-specific for disc levels with its straight-line traction
- required patients to hold on with their hands, causing severe shoulder/arm problems
- inherent muscular resistance failed to achieve direct or

specific decompression of the spinal column and the prone position was very uncomfortable for most patients, especially to women.

Now the engineers of many of the high end companies have solved these problems and improved the outcomes greatly:

- patients are placed supine wearing two harnesses to avoid holding on with their hands and, thus, avoiding the muscular resistance found in other tables.
- the amount of decompression can be targeted to the specific disc level by varying the angle of traction
- computers automatically gauge the amount of decompression for each patient.

True decompression tables, as stated, utilize a procedure called *ramping*, which is slowly documented and graphed by computer, and graduates the traction effect to the spine on a gradual and specific plane. By allowing this slow transition and by isolating the specific segment, the doctor is capable of creating the "Vacuum Effect" of decompression. The gradual ramping procedure allows the override of the body's natural defense mechanism of tightening the muscles in response to the external pulling provided by simple traction of many less expensive table options. Yes, the age old adage is true: "YOU GET WHAT YOU PAY FOR."

Decompression, when instituted properly, causes a wider spacing of the vertebral discs which, in turn, creates a negative pressure, thus the "vacuum effect" we call *decompression.* There are numerous reports and articles written showing that bulging disc material can actually be pulled back underneath the vertebra and off the spinal cord or nerves they are irritating. Degenerative discs that have lost their height can be opened up to near normal heights, creating increased movement and decreased nerve pressure. As you do your homework and do your research, you will find that most of the research studies have been provided by the higher end, TRUE DECOMPRESSION equipment.

One can experience traction without decompression, but not decompression without traction.

Decompression is created by a progressive event—a combination of specific vertebral restraint, specific angle position by level of bulge or herniation, and equipment engineering. One can experience traction without decompression, but not decompression without traction. Traction can be a machine, or just weights attached to your feet hanging over a bed as done in the past at hospitals. Decompression is a progressive event that is obtained by utilizing negative pressure, by vertebrae, on a specific angle, to achieve the "Vacuum Effect" or the event known as *decompression.*

Decompression is an FDA Cleared technology that relieves pain by enlarging the space between the discs. The vertebrae are gently and slowly separated methodically by software attached to the spinal decompression table. As the vertebrae are separated, pressure is slowly reduced within

the disc (intradiscal pressure) until a vacuum is created within the disc. This vacuum effect literally "pulls" or "sucks" the gelatinous center of the disc back into the disc, thereby reducing the disc bulge, or disc herniation, we call this the "Vacuum Effect." Thus, disc bulge reduction removes pressure off the spinal nerves and treats the cause of the problem. This suction or "vacuum effect" allows much needed oxygen, nutrients and fluid into injured and degenerated discs, enabling the healing of the disc to begin.

Genuine spinal decompression is achieved by specific software and equipment that provides ongoing, monitored, gradual and calculated increases in distractive forces to spinal vertebrae, utilizing various degrees of distractive forces and calculated angles for the correct spinal segment. Decompression creates a slow "vacuum effect" within the disc that brings the necessary nutrients and oxygen to enter the disc, allowing the disc to heal. Traction does NOT create a "vacuum effect," which is what allows the disc to re-hydrate and heal and, ultimately, leads to pain relief.

How do you know what your or any table does provide? First, you must look to the FDA documents. If your equipment is approved for traction, it is not appropriate in the eyes of many boards to market for decompression. All machines must file a 510K with the FDA. In this document, they must also provide what the table is being utilized for. You will find the word traction, and *traction* alone, on many of the inexpensive tables. Others utilize decompression. CPT now offers a code for decompression. This code is different than traction. CPT and the FDA recognize the difference. Once again, the difference is in the equipment and the software.

So, where do you begin? In my opinion, follow the FDA; that is their job. Make sure that, if you are marketing decompression, your equipment is FDA Cleared with the language of decompression in the FDA documents.

Decompression creates a slow "vacuum effect" within the disc that brings the necessary nutrients and oxygen to enter the disc, allowing the disc to heal.

Many companies will try to persuade you and say all 510K's are the same. They are not. The language in the 510K must be specific, which is why each table manufacturer must provide detailed documents. The FDA does not simply approve because one table says it is similar to another. Each company must provide specific documents and then answer questions from the FDA. This is not a simple process. Do your homework, make your own decision. But, remember, if you want a Rolls Royce practice, you need Rolls Royce technology.

Dr. Eric S. Kaplan, is CEO of Multidisciplinary Business Applications, Inc. (MBA), a comprehensive coaching firm with a successful, documented history of creating profitable multidisciplinary practices nationwide. Dr. Kaplan is the best selling Author of DYING TO BE YOUNG, *www.dyingtobeyoung.net, and co-developer and President of Discforce the next Generation on Spinal decompression. For more information, call 1-561-626-3004 or visit www.discforce.com.* TAC

Emerging Technologies: Preliminary Findings

Decompression, reduction and stabilization of the lumbar spine: a cost-effective treatment for lumbosacral pain

C. Norman Shealy, MD, PhD and Vera Borgmeyer, RN, MA

AJPM 1997;7:63-65

Introduction

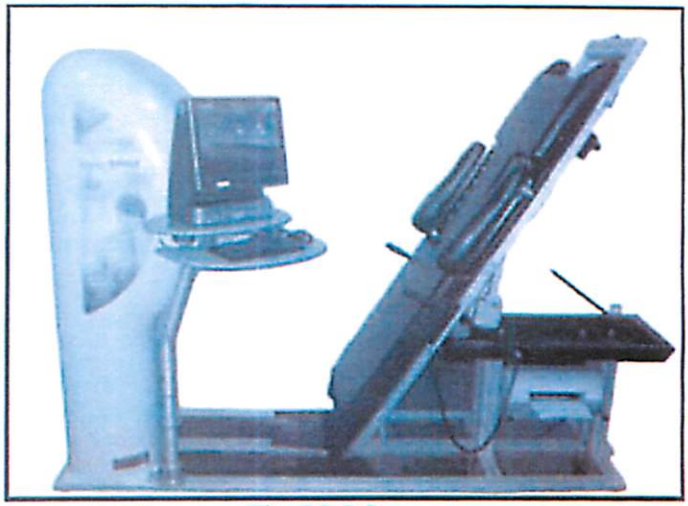
Pain in the lumbosacral spine is the most common of all pain complaints. It causes loss of work and is the single most common cause of disability in persons under 45 years of age. (1). Back pain is the most dollar-costly industrial problem (2). Pain clinics originated over 30 years ago, in large part, because of the numbers of chronic back pain patients. Interestingly, despite patients' reporting good results using "upside-down gravity boots," and commenting on how good stretching made them feel, traction as a primary treatment has been overlooked while very expensive and invasive treatment have dominated the management of low back pain. Managed care is now recognizing the lack of sufficient benefit-cost ratio associated with these ineffective treatments to stop the continued need for pain-mitigating services. We felt that by improving the "traction-like" method, pain relief would be achieved quickly and less costly.

Although pelvic traction has been used to treat patients with low back pain for hundreds of years, most neurosurgeons and orthopedists have not been enthusiastic about it secondary to concerns over inconsistent results and cumbersome equipment. Indeed, simple traction itself has not been highly effective, therefore, almost no pain clinics even include traction as part of their approach. A few authors, however, have reported varying techniques which widen disc protrusion, reduce muscle spasm, separate vertebrae, and/or lengthen and stabilize the spine (3-12).

Over the past 25 years, we have treated thousands of chronic back pain patients who have not responded to conventional therapy. Our most successful approach has required treatment for 10-15 days, 8 hours a day, involving physicians, physical therapists, nurses, psychologists, transcutaneous electrical nerve stimulator (TENS) specialists and massage therapists in a multidisciplinary approach which has resulted in 70% of these patients improving 50-100%. Our program has been recognized as one of the most cost effective pain programs in the US (13). The average cost of the successful pain treatment has been cited as less than half the national average (13).

Our protocol combined traditional, labor-intensive physical therapy techniques to produce mobilization of the spinal segments. This, combined with stabilization, helped promote healing. In addition we used biofeedback, TENS and education to reinforce the healing process. We wanted to produce a simpler and more cost-effective protocol that could be consistently reproduced. The biofeedback and education could be easily replicated. The problem was producing spinal mobilization to the degree that we could decompress a herniated nucleus and relieve pain. Stabilization would come after pain relief.

The DRS System was developed specifically to mobilize and distract isolated lumbar segments. Using a specific combination of lumbar positioning and varying the degree and intensity of force, we produced distraction and decompression. With fluoroscopy, we documented a 7-mm distraction at 30 degrees to L5 with several patients. In fact, we observed distraction at different spinal levels by altering the position and degree of force.



The DRS System

We set out to evaluate the DRS system with outpatient protocols compared to traditional therapy for both ruptured lumbar discs and chronic facet arthroses.

Subjects. Thirty-nine patients were enrolled in this study. There were 27 men and 12 women, ranging in age from 31 to 63. Twenty-three had ruptured discs diagnosed by MRI. Of these, all but four had significant sciatic radiation with mild to moderate L5 or S1 hyperalgesic. All had symptoms of less than on year.

The face arthrosis patients also underwent MRI evaluations to rule-out ruptured discs or other major pathologies. They had experienced back pain from one to 20 years. Six had mild to moderate sciatic pain with significant limitations of mobility.

METHODOLOGY

Patients were blinded to treatment and were randomly assigned to traction or decompression tables. Traction patients were treated on a standard mechanical traction table with application of traction weights averaging on-half body weight plus 10 pounds, with traction applied 60-seconds-on and 60-seconds-off, for 30 minutes daily for 20 treatments. Following the traction, Polar Powder ice packs and electric stimulation were applied to the back for 30 minutes to relieve swelling and spasm and patients were then instructed in use of a standard TENS use to be employed at home continuously when not sleeping. After two weeks, the patients received a total of three sessions with an exercise specialist for instruction in and supervision of a limbering/strengthening exercise program. They were re-evaluated at five to eight weeks after entering the program.

Eighty-six percent of ruptured intervertebral disc (RID) patients achieved "good" (50-89% improvement) to "excellent" (90-100% improvement) results with decompression. Sciatica and back pain were relieved. Only 55% of the RID patients achieved "good" improvement with traction and none "excellent."

Of the facet arthrosis patients, 75% obtained "good" to "excellent" results with decompression. Only 50% of these patients achieved "good" to "excellent" results with traction.

DISCUSSION

Since both traction and decompression patients received similar treatment (except for the differences in the traction table versus the decompression table) with similar weights, ice packs and TENS, the results are quite enlightening. The decompression system is encouraging and supports the considerable evidence reported by other investigators stating that decompression, reduction and stabilization of the lumbar spine relieves back pain. The computerized DRS System spears to produce consistent, reproducible and measurable non-surgical decompression, demonstrated by radiology. Of equal importance, the professional staff facilities required, as well as the time and cost are all significantly reduced. Since the more complex treatment program of the last 25 years has already been shown to cost 60% less than the average pain clinic, the cost of this simpler and more integrated treatment program should be 80% less than that of most pain clinics – a most attractive solution to the most costly pain problem in the U.S. In addition, patients follow a 30-day protocol that produces pain relief yet allows them to continue daily activities and not lose workdays.

SUMMARY

We have compared the pain-relieving results of traditional mechanical traction (14 patients) with a more sophisticated device which decompresses the lumbar spine, unloading of the facets (25 patients). The decompression system gave "good" to "excellent" relief in 86% of patients with RID and 75% of those with facet arthroses. The traction yielded no "excellent" results in RID and only 50% "good" to "excellent" results in those facet arthroses. These results are preliminary in nature. The procedures described have not been subjected to the scrutiny of review nor scientific controls. These patients will be followed for the next six months, at which time outcome-based data can be reported. These preliminary findings are both enlightening and provocative. The DRS system is now being evaluated as a primary intervention early in the onset of low back pain-especially in workers' compensation injuries.

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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.

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 duration 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.

DISCUSSION

Possible explanations of the conclusions drawn from this study regarding prolonged therapeutic effect phenomenon include (i) an etiological solution to the pathology being achieved during the session which slowly leads to the decrease in pain, (ii) the patient adapting to pain over time, or (iii) the patient undergoing other treatments. Further trails should be designed to address these possible theories.

Forty-five percent (16/35) of patients in this study were administered their IDD Therapy® after previous treatments of low back pain. The average improvement of 5.23 points on the NPS suggested that IDD Therapy® benefits patients when other treatment options have failed.

The results of this study beg the questions - could IDD Therapy® computer directed physical therapy protocols lead to prevention of reoccurrence in patients that have been treated by IDD Therapy® protocol equipment, and could these treatment protocols prevent the pathologies of back pain, before the first occurrence. This study involved only 35 patients; a large study should be devised to confirm further the results and address the explanations proposed.

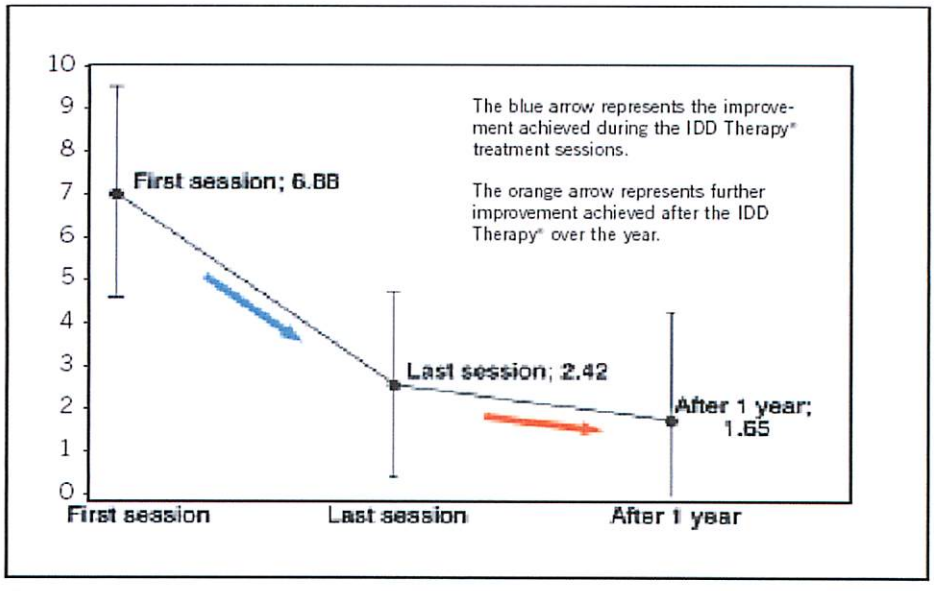

FIGURE 1. *The chart shows mean NPS of 6.88 at the beginning of IDD Therapy® treatment after the completion of treatment the mean NPS is reduced to 2.42 (last session). After a duration of one year the patients continue to improve and the mean NPS is 1.65.*

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

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Long-term back pain after a single-level discectomy for radiculopathy: incidence and health care cost analysis.

Parker SL[1], Xu R, McGirt MJ, Witham TF, Long DM, Bydon A.

Author information

Abstract

OBJECT: The most common spinal procedure performed in the US is lumbar discectomy for disc herniation. Longterm disc degeneration and height loss occur in many patients after lumbar discectomy. The incidence of mechanical back pain following discectomy varies widely in the literature, and its associated health care costs are unknown. The authors set out to determine the incidence of and the health care costs associated with mechanical back pain attributed to segmental degeneration or instability at the level of a prior discectomy performed at their institution.

METHODS: The authors retrospectively reviewed the data for 111 patients who underwent primary, single-level lumbar hemilaminotomy and discectomy for radiculopathy. All diagnostic modalities, conservative therapies, and operative treatments used for the management of postdisectomy back pain were recorded. Institutional billing and accounting records were reviewed to determine the billed costs of all diagnostic and therapeutic measures.

RESULTS: At a mean follow-up of 37.3 months after primary discectomy, 75 patients (68%) experienced minimal to no back pain, 26 (23%) had moderate back pain requiring conservative treatment only, and 10 (9%) suffered severe back pain that required a subsequent fusion surgery at the site of the primary discectomy. The mean cost per patient for conservative treatment alone was $4696. The mean cost per patient for operative treatment was $42,554. The estimated cost of treatment for mechanical back pain associated with postoperative same-level degeneration or instability was $493,383 per 100 cases of first-time, single-level lumbar discectomy ($4934 per primary discectomy).

CONCLUSIONS: Postoperative mechanical back pain associated with same-level degeneration is not uncommon in patients undergoing single-level lumbar discectomy and is associated with substantial health care costs.

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Intervertebral Differential Dynamics Therapy – A New Direction for the Initial Treatment of Low Back Pain

a report by
Dennis McClure *and* **Bethany Farris**

Private Practice

Patients with back pain usually present a neurosurgeon or spine specialist with an abnormal magnetic resonance imaging (MRI), while their referring physician tells them they have a degenerated disc causing their pain. Throughout my years of practice, it has become apparent to me that patients with back pain want to know why they are having pain, the cause of their back pain and how to effectively treat their back pain in order to avoid surgery. In addition to improving pain, another goal in treatment is to improve flexibility, as well as quality of life, in the safest and most effective manner prior to recommending more invasive procedures for treating the patient's pain due to degenerative disc disease. It is a misconception by the public that surgery 'fixes' a person's back pain. If this were true, we would never see patients with failed back syndrome.

There has been no established uniform or conservative management to effectively treat low back pain.

In November 2003, I introduced Intervertebral Differential Dynamics (IDD) Therapy to my neurosurgical practice. IDD Therapy® is a non-invasive spinal rehabilitation treatment developed by Norman Shealy MD, PhD, and is delivered by the Accu-SPINA® spinal care device. IDD Therapy provides computer-directed physio-therapeutic treatment to the lumbar and cervical intervertebral discs and facet joints, with a course of treatment consisting of 20 sessions of 25 to 30 minutes, spread over a six-week period. IDD Therapy protocols allow for the controlled distraction of targeted vertebrae to mobilise the joint and to create a negative pressure inside the intervertebral disc. This negative pressure leads to the diffusion of fluid and nutrients into the disc to stimulate its metabolism and promote hydration and healing. The negative pressure can also lead to the retraction of a herniated nucleus pulposus. IDD Therapy treatment further delivers a passive exercise element to release spasmodic behaviour and to re-educate supporting soft tissues. Since introducing IDD Therapy to the practice I have treated over 1,200 patients. Initial studies of IDD Therapy indicated success rates of 86% and 76% one year post-treatment. Our results of treatment are similar to the initial reports of IDD therapy; in fact, in some cases we believe they are higher. We present our results of over 415 patients who have been analysed so far in looking at success rates that contribute to variables affecting the outcome of IDD Therapy.

Dennis McClure has been in private practice in Dayton, Ohio since 1995. He was certified by the American Board of Neurological Surgery in 1988 and served in the US Air Force from 1984. He is a lifetime member of the American Association of Neurological Surgeons. Dr McClure obtained his MD from Indiana University in 1978 and completed neurosurgery training at University Wisconsin Hospitals-Madison in 1984.

Questions and Direction

After treating patients for two years, it seemed apparent that most of them reported significant recovery of back pain after completing IDD Therapy. This raised several important questions. What are the reasons patients do not improve with IDD Therapy? What factors about these patients led to a good prognosis with treatment? What factors led patients to experience different severities of pain prior to and after treatment?

Understanding the answers to these questions was crucial for us to quantify and improve the quality of treatment we could give to our patients. We therefore employed a research analyst to answer these questions and analyse the data extracted from the patients' files, which included medical history, assessment measures (taken and recorded upon initial evaluation), diagnoses, treatment parameters and follow-up measures.

Preliminary Analyses and Results

This preliminary analysis was conducted by analysing the success from self-reports given by the patient on follow-up. Success with IDD Therapy was rated by patients after treatment (2–4 weeks, and 12 months) (see *Table 1*).

In the preliminary analysis we defined success as an improvement rating of 2 or 3. A patient must report a 50% decrease or greater in pain in order to be considered a success in this analysis. Data from the past 415 patients completing treatment was analysed between two months and two years after

Table 1: Patient-rated Success of IDD Therapy

Improvement rating	Interpretation	Pain adjustment
0	No improvement	0–24% decrease
1	Minimal improvement	25–49% decrease
2	Moderate improvement	50–79% decrease
3	Excellent improvement	80–100% decrease

Table 2: Success Rates According to Diagnosis Prior to Treatment

Diagnosis type	Reported success rate (%)	Sample size (n)
Lumbar back pain	79	330
Surgical lumbar candidates	92	129
Cervical pain	84.7	33
Post-laminectomies	79	52

completion of the course of IDD Therapy treatment, at an average time of one year post-treatment. Any patient failing to give an improvement rating was excluded. Success rates were examined according to diagnosis assigned prior to treatment (see *Table 2*).

Of particular interest are lumbar surgical candidates, that is, those patients who had been advised to undergo surgery and who came to the practice for a second opinion or patients who I might have previously operated on. This group showed a success rate of 92%. This is quite an exciting find, considering the next alternative for these patients would have been surgery. Although the sample size for cervical and post-laminectomy patients was limited, the success rates are promising for these groups as well.

Having determined initial success rates of treatment led us to inquire about variables influencing the outcome of treatment. In particular, what makes patients have these exciting success rates and more importantly, what variables affect the outcome of treatment for patients who did not benefit from IDD Therapy? We contacted the lumbar surgical candidates for additional follow-up information at 12 months. Out of 129 patients, 84 were contacted. The data for these patients was analysed and the results are as follows:

- Effects of Gender – females reported significantly higher pain after treatment, ($p<.0058$)
- Effects of Age (90% confidence interval) – there was a significant increase in pain after treatment as age increased, ($p<.0955$).
- Effects of Time – patients who reported initial success (rating of 2 or 3) directly after treatment continued to have a significant reduction in pain at the time of the follow-up (anywhere from two months to two years after completing treatment), ($p<.0001$).
- Effects on Activity Level – patients who reported success (reduction in pain) after treatment also reported improvement in other aspects of their life, including a significant increase in capacity to live a more active lifestyle, ($p<.0001$).
- Factors that had no effect on outcome measures included body mass index, number of diagnoses, number of serious illnesses, number of prior treatments, and angle of distraction.
- Flexibility measuring forward bending and straight leg-raising improved by 60% post-treatment.

These results were encouraging and led us to examine other aspects related to pain prior to and after treatment. More specifically, psychological processes and attitudes, and how they may affect IDD Therapy.

Depression and Attitude Study and Results

To more accurately assess improvement and factors affecting it, a study was designed to assess patients prior to and post-treatment. Participants gave consent and took a battery of surveys prior to treatment, including a pain assessment, a self-rated depression inventory and an attitude assessment. After patients completed treatment, they took the pain assessment again, and results were analysed. Analyses are based on a sample size of 50 patients.

The first important finding was that patients who reported higher pain prior to treatment showed significantly higher rates of depression, ($p<.0071$), which gave us important insight into psychological aspects of a patient's health affecting their perception of pain. Second, patients with negative attitudes (skeptic or cynic) reported slightly higher pain prior to treatment, although not enough to be statistically significant in a one-way analysis of variance (ANOVA). These findings suggest that conceptual treatment of pain should take a more holistic approach.

This study also replicated the effect of age from the previous analysis. Patients in this sample showed that, as age increases, pain after treatment also significantly increased ($p<.0110$). Number of prescription medications also had a significant effect on the outcome of treatment. Patients taking more medication report significantly higher pain after treatment ($p<.0143$). Patients on more

Figure 1: MRI Example

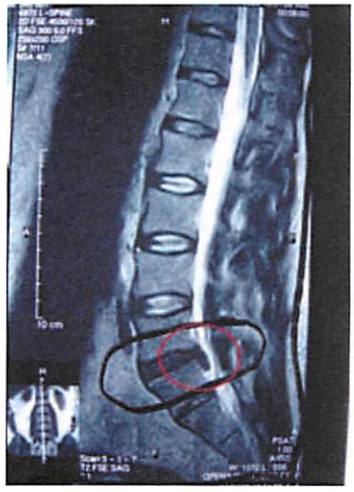

Figure 1a: Pre-treatment MRI (02/02/05)

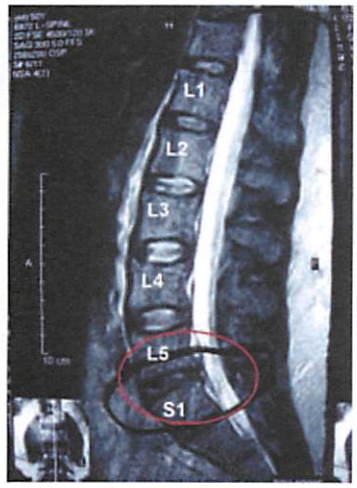

Figure 1b: Post-treatment MRI (14/03/05)

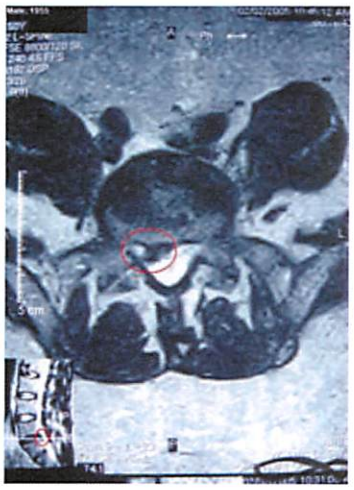

Figure 1c: Pre-treatment MRI (02/02/05)

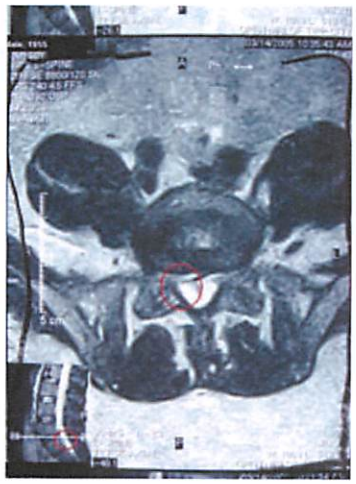

Figure 1d: Post-treatment MRI (14/03/05)

A 50-year-old male with herniated disc at L5-S1. Severe low back pain radiating down into the right leg with straight leg raise of 10° (on the right). Received IDD Therapy in February 2005 and by March 2005 the patient had straight leg raises of 90 degrees and no pain.

prescription medications are in overall poorer health prior to treatment. If this holds true, it would also reinforce the idea of treating back pain using a more holistic approach. This would allow us to address and treat additional aspects of patients' health such as psychological, physical and spiritual areas, resulting in better improvement in pain from IDD Therapy, and overall quality of life.

It is also worth noting that, while different factors may significantly affect the outcome of IDD Therapy, the sample had a significant decrease in pain according to a matched pairs test, ($p<.0001$). In addition, although depression significantly affected reported pain prior to treatment, patients with depression significantly improved after treatment ($p<.0001$). This leads me to believe that IDD Therapy not only decreases pain, but also lifts depression associated with pain. Overall, the success rate was 88.2% for this sample, which fell between the ranges of success found in our initial estimates of 79–92% success.

Future Studies – Anger and Stress

In light of supporting a more holistic approach to pain, we have begun to look at back pain in broader terms than the physical pain our patients experience. We have also started to examine the severity of impairments as a consequence of the pain, and how this affects patients' daily lives. We began to assess and examine the influence of other factors, such as stress and anger levels, on the outcome of IDD Therapy. So far, 65 patients have participated in this most recent study, called the Anger and Stress Study. The results are preliminary, as most patients have not completed the follow-up portion of this study. Our preliminary findings include:

- Number of Daily Activities Affected by Pain: Patients who report high numbers of daily activities affected by pain score significantly higher on the anger assessment ($p<.0002$), significantly higher on the depression scale ($p<.0001$), and report significantly higher pain ($p<.0007$).
- Stress Effects: Patients who score high on the Social Readjustment Scale score significantly higher on the anger assessment ($p<.0001$).
- Anger Effects: Patients who score high on the anger assessment score significantly higher on the depression scale ($p<.0002$).
- Depression Score Effects: Patients who score high on the depression scale report significantly higher pain prior to treatment ($p<.0037$).

Conclusions

A number of implications can be made from the analyses above. However, since these are preliminary in nature, we will not elaborate on the potential meaning from each analysis. Instead, we hope to convey information by moving the conception and treatment of back pain in a new direction, one that uses safer, non-invasive treatments such as IDD Therapy for the initial treatment of low back pain, recognising the complexity of our patients and treatment through a more holistic approach. ■