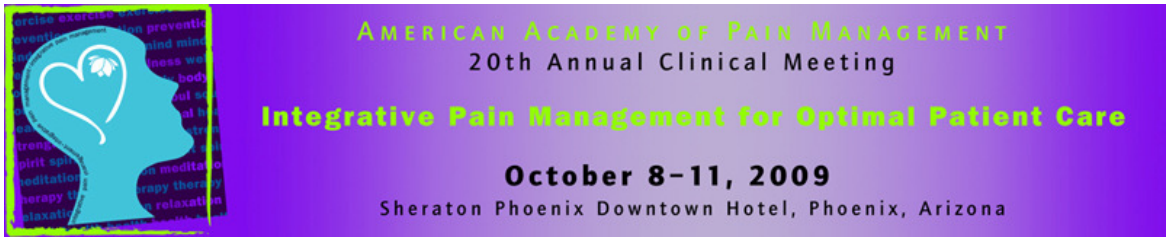


For Presentation at the American Academy of Pain Management 20th Annual Meeting Clinical Meeting

Case Study Report: The Treatment of 100 Cases With Articulating Traction Decompression & Specific Patient Posturing * Including 12 Month Follow-up ♦

Research performed by:
Ryan M. Rosenthal, DC, and Igor Russo, DC **
Advanced Physical Medicine
6931 West North Avenue
Oak Park, IL 60602
contact@advancedphysicalmedicine.org
www.advancedphysicalmedicine.org
877-DRBACKS

Introduction:

This is a practice based retrospective study of the first 100 patients utilizing the Antalgic-Trak® articulating traction decompression system in our practice. As a therapeutic tool, traction decompression is becoming widely used. However, in researching the literature on the subject, only a small group of papers on the subject was found and all had various study limitations. This was also the findings of other authors. [2] The term decompression was coined by Allan Dyer, MD, PhD, who invented and researched the VAX-D treatment device. Dr. Dyer's clinical model uses a logarithmic pattern of decompression to treat the lumbar spine in the prone position. [3,4,5] For the purpose of this study, we refer to our treatment as traction-decompression since we did not use the typical traction cycling, nor did we use a VAX-D logarithmic pattern of pull in regards to these subjects. Rather we have combined elements of traction with progressive increasing tension of the tissues through a careful feedback mechanism between the instrument and the patient. Traction as a treatment modality has extensive research and has been used for decades to treat a variety of spinal complaints. It has also been shown that pulling the lumbar spine at 40% to 50% of a subject's body weight is capable of creating vertebral separation [6,7]. We found this level of pulling effective for decompressing and elongating the spine and surrounding tissues. Since we also incorporated instrument assisted passive range of motion therapy, we feel it is important to highlight its benefits. There is strong evidence that periodic moderate stretching to the connective tissues, using varied postures, improves connective tissue health. [8-13] These referenced studies gave us the insight into the utility and benefit of passive range of motion and exercise, and its impact on the treatment of connective tissues damage.

Design:

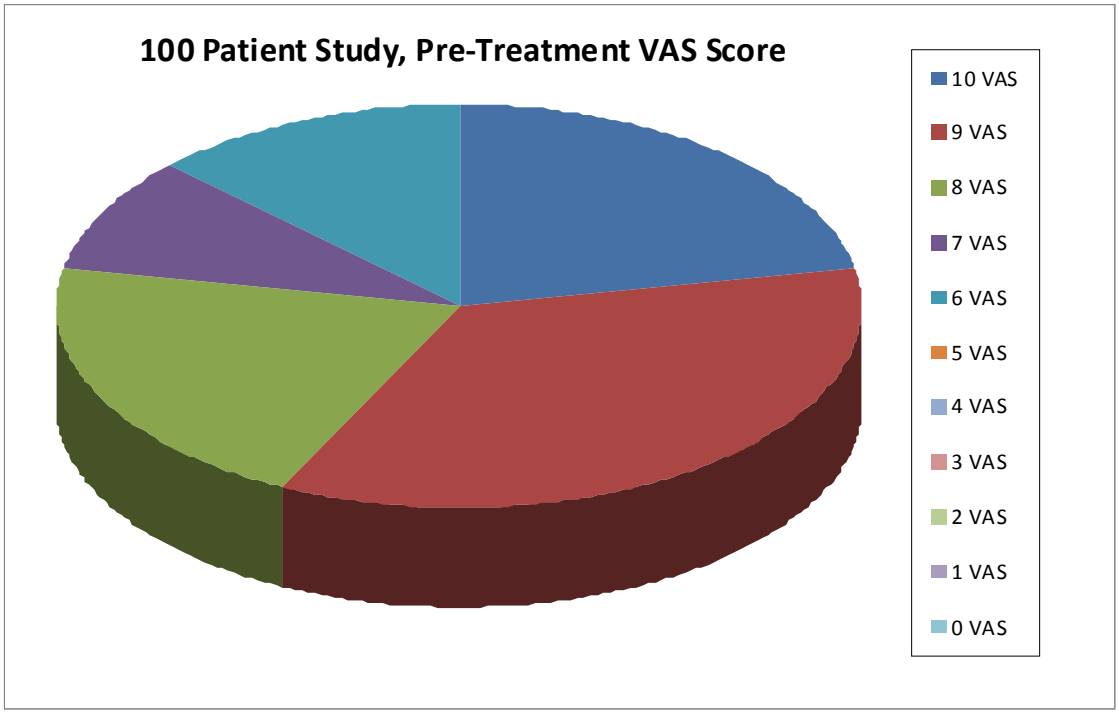
The data compiled will demonstrate the effectiveness of our treatment protocol on low back pain and neck pain with or without a radicular component. The patient outcome data (Table 1) is based on the first group of 100 patients in our practice that were treated using the Antalgic-Trak® for a variety of spinal complaints. There are both male and female subjects, of various ages, with a visual analog scale at the beginning treatments of 6 or higher. All patients received a consultation, and comprehensive physical examination including orthopaedic testing, neurologic assessment, and diagnostic imaging. The entire group received digital x-ray imaging or magnetic resonance imaging of the areas/region of complaint. The results of these imaging studies were relied upon in order to determine the ultimate specific Antalgic-Trak® treatment protocol. Each case received 20 treatment sessions. Subsequently, follow-up data collection was performed 12 months post treatment ♦. VAS were re-measured as was satisfaction of the treatment program on the Antalgic-Trak®.

Overview of the Equipment:

In this study, we used the Antalgic-Trak® instrument which can facilitate traction decompression protocols with specific posture placement of a patient prior to, or during the treatment session. It also enables "passive" spinal range-of-motion facilitated by cervical and lumbar multi-axis articulating joints. The instrument is capable of treating conditions affecting the cervical and lumbar spine. In addition, it is also capable of performing a variety of "auto-cycling" traction and decompression protocols as well as manual mechanical protocols using the cervical and lumbar foot pedals. The Antalgic-Trak® was invented by David B. Bass, DC, AP, DOM, and co-developed by Scott Denny, DC, PhD, AP, DOM. The Antalgic-Trak® is an FDA cleared powered traction device with the following indications for use: disc protrusions, disc herniations, pinched nerves, limited spinal flexibility, muscle spasm, spinal vertebral fixations, spinal facet imbrications, radiculitis, and foraminal encroachment.[1] Using the multi-axis cervical and lumbar articulating sections, we were not limited to "only" straight linear decompression as found in other devices. We were able to provide a variety of spinal postures enabling us to customize how and where the traction decompression pull-forces would move through the spine. Additionally, we utilized other physiological therapeutics to support the treatment effects of the traction decompression and enhance tissue healing. These adjuncts were used throughout the 20 treatment course of customized traction decompression and are discussed later in this presentation.

Subjects:

We treated 100 patients presenting with acute and chronic low back pain, or neck pain, with or without radicular components. 60 Subjects were male, and 40 subjects were female. Patients were chosen according to the acute onset of their symptoms, specifically with a duration of less than 2 weeks and with a chronic onset of symptoms, defined as greater than 6 weeks. Inclusion criteria included spondylolisthesis, spondylosis, spinal disc herniation, spinal disc bulging, spinal stenosis, chronic headaches (migraines) and vertebral segmental dysfunctions (vertebral subluxation) as demonstrated by Digital X-ray or MRI.



Analysis of the 100 subjects Pre Treatment:

- **24 subjects** (24% of the total) reported severe pain or a **VAS of 10** prior to care.
- **39 subjects** (39% of the total) reported severe pain or a **VAS of 9** prior to care.
- **23 subjects** (23% of the total) reported severe pain or a **VAS of 8** prior to care.
- **10 subjects** (10% of the total) reported severe pain or a **VAS of 7** prior to care.
- **4 subject** (4% of the total) reported moderate pain or a **VAS of 6** prior to care.
- **0 subject** (0% of the total) reported moderate pain or a **VAS of 5** or less prior to care

Outcome Measures:

The data presented for the "patient outcomes" were based on the visual analog scale (VAS). The visual analog pain scores were recorded at the initiation of the treatment programs and again at the 20th session.

- VAS of **0:** No Pain
- VAS of **1-3:** Mild Pain (less than 25% of the time subject is awake)
- VAS of **4-6:** Moderate Pain (between 25% and 75% of the time subject is awake)
- VAS of **7-10:** Severe Pain (greater than 75% of the time subject is awake)

Intervention:

In this study, there was no placebo group used to compile data. Individuals normally do not begin therapy if they are “symptom-free”. The FDA adopted Federal Regulations 21,860.7, which states that “such use of a placebo or the withholding of treatment would be inappropriate or contrary to the interest of the patient.”

Our treatment protocol consisted of a total of twenty, 30-minute sessions. **Scheduling of each session consisted of 5-times a week for the first two weeks, three times a week for the next two weeks, and twice a week for the final 2-weeks, for a total of 6 weeks.** The protocol remains the same for every presentation, regardless of the severity or complexity of the condition.

Depending upon the patient’s presentation of symptoms, examination findings, diagnostic study and postural relationships, multi-axial decompression was utilized with a technique called KDM (Kinetic Decompression Mobilization). This procedure allowed us to lock the patient’s spine into specific postures. Varying the spine’s postures enable the pulling forces to reach into areas of the spine and surrounding tissues that common straight linear decompression can potentially miss. These postures (including lateral flexion and rotation) help open the intervertebral foramen to reduce nerve root compressions at impingement levels while simultaneously performing traction decompression. Additionally we employed "range of motion" techniques that involve moving the spine through various postures while the spine is distracted during the decompression cycling.

The instrument creates a soothing decompression within the disc by gently stretching and improving the spacing between the spinal segments. This also improves intersegmental function as well as increasing vertebral segment range of motion. The goal of each treatment is specific for the protocols we are using to make the necessary corrections.

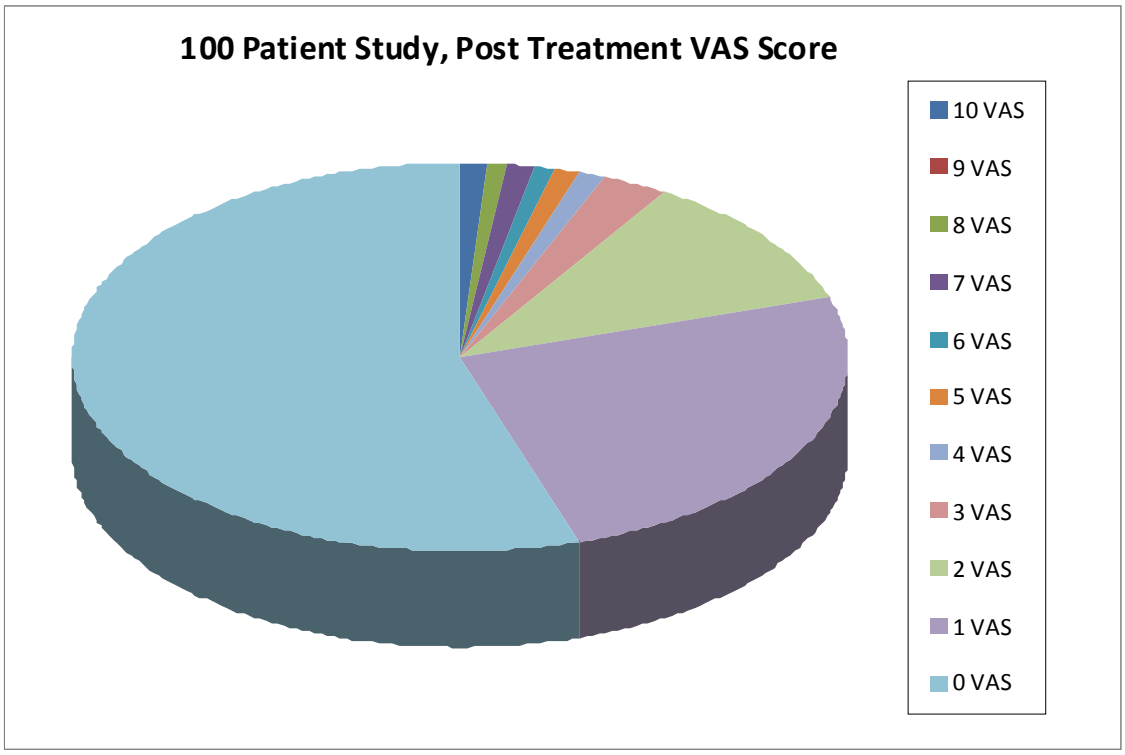
- A spondylolisthesis can be reduced by translating the pelvic seat anterior and flexing the seat to approximate the knees towards the chest before beginning a series of traction-decompression sessions.
- Bulging, protruded and herniated discs can be drawn into their pre-pressured borders by creating negative intradiscal pressure using a series of closely scheduled 30-minute sessions.

Adjunctive Therapeutics:

Each treatment is followed by 10 minutes of ice (heat is utilized after the 5th visit) combined with electrical muscle stimulation (intensity will vary according to patient comfort levels), 2 minutes of cold laser directly at the level of the affected disc and bilaterally at the disc’s corresponding transverse processes (used to decrease edema and reduce scar tissue formation) and kineseotape is applied at the level of dysfunction to consolidate unstable musculature.

Results:

The outcomes, which can be found in table 1, indicate that our study group achieved approximately 95% success in eliminating pain, or reducing the pain to minimal levels in a variety of conditions. The study group included patients who were diagnosed with: pain associated with herniated and bulging discs, facet syndrome, sciatica, osteoarthritis (DJD) and radiculopathy of the upper and lower extremity.



Analysis of the 100 subjects Post Treatment:

- **55 subjects** (55% of the total) experienced **complete pain relief** with their treatment.
- **40 subjects** (40% of the total) reported mild pain or a **VAS of 1 - 3** following the course of care.
- **1 subject** (1% of the total) reported moderate pain or a **VAS of 4** following the course of care.
- **1 subject** (1% of the total) reported moderate pain or a **VAS of 5** following the course of care.
- **1 subject** (1% of the total) reported moderate pain or a **VAS of 6** following the course of care.
- **1 subject** (1% of the total) reported severe pain or a **VAS of 7** following the course of care.

  (NOTE: Case 54 had a starting VAS of 10 and went onto surgery)
- **1 subject** (1% of the total) reported severe pain or a **VAS of 8** following the course of care.

  (NOTE: Case 53 had a starting VAS of 10 and went onto surgery)

Analysis of the Subjects with a VAS of 1 – 3:

- **25 subjects** (62.5%) reported a **VAS score of 1**
- **11 subjects** (27.5%) reported a **VAS score of 2**
- **4 subjects** (10%) reported a **VAS score of 3**

Analysis of Subjects with VAS of 0 - 1:

- **80 subjects** (80% of the total group) reported **VAS score of 0 – 1**

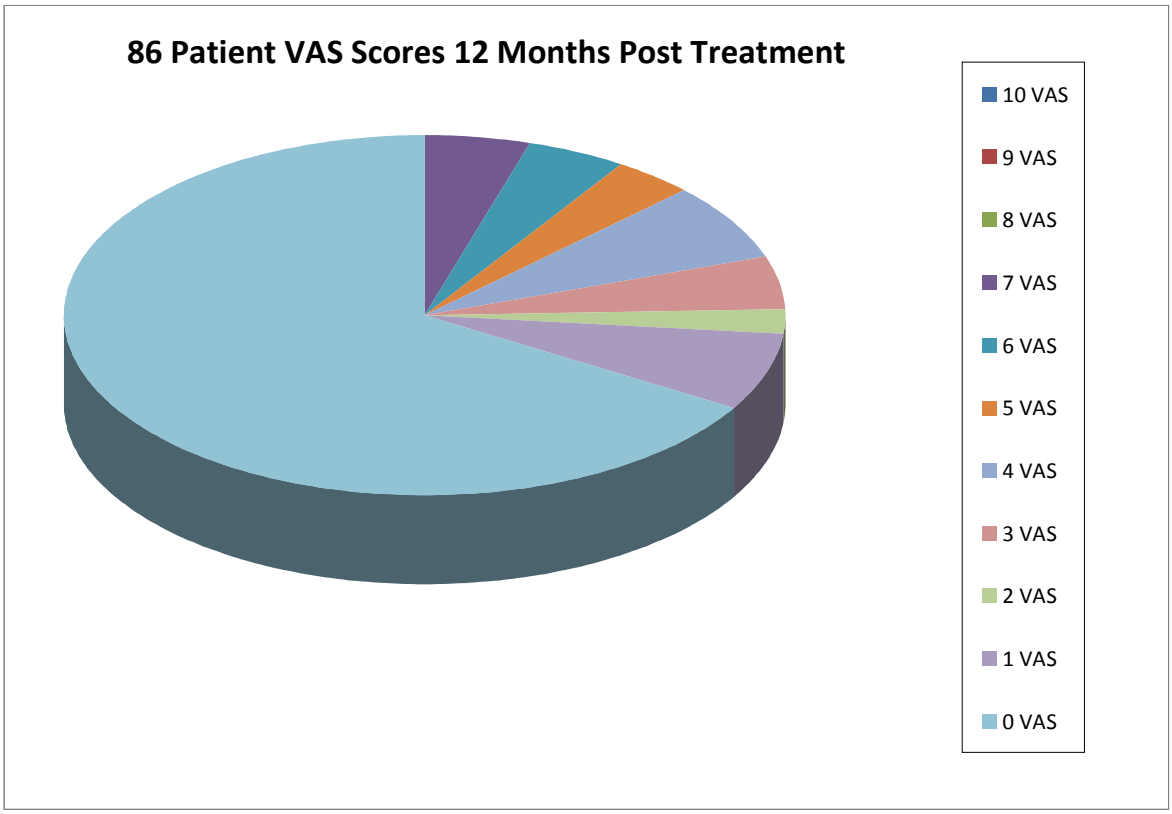
Analysis of Subjects with VAS of 0 - 3:

- **95 subjects** (95% of the total group) reported complete and/or significant pain relief, a **VAS score of 0 – 3.**

Thus, the overwhelming majority of patients benefited from this treatment. Only 5% of the 100 subjects reported a VAS score higher than 4 post treatment program. There were 0 subjects who reported worsening of their pain as a result of treatment, and only 2 subjects went on to have spine surgery (Case 53 and 54). The success of this study is noted by the decrease in all patients' pain level according to their VAS score. Whether a patient went from a VAS of "10" to a VAS of "0" substantiated that multi-axial traction decompression helped all patients, to a great extent. Many articles exist today referencing the positive effects of decompression therapy.

12 Month Follow-up Data:

The original 100 patients were contacted via telephone and surveyed within 12 to 14 months post treatment. 86 subjects (86%) were reached. The remainder could not be contacted due to a variety of reasons including, i.e., change of phone number, relocated their residence, etc. The available subjects were asked to rate their current VAS score and specifically asked if they were satisfied, unsatisfied or unsure about their satisfaction as it related to their Antalgic-Trak® treatment experience. The results are as follows:



Analysis of the 86 subjects – One Year Post Treatment:

- **57 subjects** (66% of the total) experienced **complete pain relief** with their treatment.
- **12 subjects** (14% of the total) reported mild pain or a **VAS of 1 - 3** following the course of care.
- **6 subject** (7% of the total) reported moderate pain or a **VAS of 4** following the course of care.
- **3 subject** (3% of the total) reported moderate pain or a **VAS of 5** following the course of care.
- **4 subject** (5% of the total) reported moderate pain or a **VAS of 6** following the course of care.
- **4 subject** (5% of the total) reported severe pain or a **VAS of 7** following the course of care

Analysis of the subjects with a VAS of 1 – 3 One Year Post Treatment:

- **6 subjects** (7%) reported a **VAS score of 1**
- **2 subjects** (2%) reported a **VAS score of 2**
- **4 subjects** (5%) reported a **VAS score of 3**

Analysis of Subjects with VAS of 0 – 1- One Year Post Treatment:

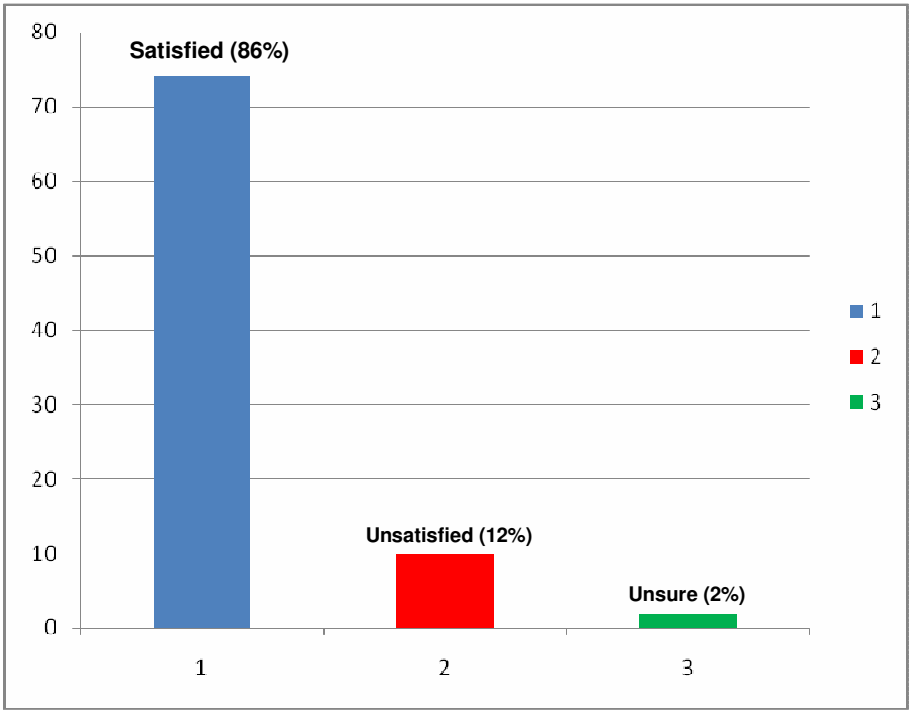
- **63 subjects** (73% of the total group) reported **VAS score of 0 – 1**

Analysis of Subjects with VAS of 0 – 3 - One Year Post Treatment:

- **69 subjects** (80% of the total group) reported complete or significant pain relief, a **VAS score of 0 – 3.**

Analysis of the 86 subjects One Year Post Treatment Satisfaction:

- **74 subjects** (86% of the total) reported they were satisfied.
- **10 subjects** (12% of the total) reported they were unsatisfied.
- **2 subject** (2% of the total) reported they were unsure.



As revealed in the one year post treatment follow-up data, the majority of the patients surveyed maintained significant relief of their spinal condition. 80% of those surveyed maintained a visual analog pain score between 0-3. The satisfaction level revealed that the majority of the patients were “satisfied” with their treatment (86%).

Discussion:

Decompression therapy has been utilized since 1992. It was not until 2005 that the Antalgic-Trak® was introduced. In our opinion, the capabilities of this new treatment instrument allowed us to overcome the limitations of other treatment products which perform spinal traction decompression. Due to the Antalgic-Trak's® unlimited positioning capabilities (Kinetic Decompression Mobilization) and its "range of motion" technique, we are now capable of positioning the patient's spine in a manner to reduce the stress on a facet on the corresponding nerve. We believe this is a breakthrough in traction decompression technology. By distracting the spine in a variety of postures, we are now able to reach into areas of the spine (such as the intervertebral foramen) that basic straight axial decompression cannot reach. The multi-axis feature allows for coupled movements, simulating "ball and socket" motion allowing for a variety of postural combinations. We feel this is critical in producing the outcomes noted in this paper.

In our opinion, decompression, rather than ordinary traction should be the ultimate choice for pain reduction and restoration of spinal integrity. It is believed that traction fails in most cases involving intervertebral disc syndrome because it causes muscular stretch receptors to fire which then causes paraspinal muscles to contract. This is historically a major problem observed in practice. The Antalgic-Trak®, unlike conventional systems, is able to "slowly and progressively" load and release the tractioning pull-forces. This "slow loading" prevents the muscle fibers from firing. In addition, the Antalgic-Trak's® posturing features enable the user to more effectively focus pulling forces through numerous vertebral levels. The objective is to create an improved intradiscal vacuum effect resulting in nutrients and fluids being to be drawn back into the disc, allowing for improved disc hydration. [14]

Conclusion:

Post one year follow-up data suggests Antalgic-Trak® treatment is a valid tool in treating various spinal conditions. The results are based upon successful treatment outcomes and a high level of patient satisfaction. Based upon this preliminary observational study we feel that a larger study should be performed utilizing a control group to see how our treatment protocol performs in comparison to other therapy modalities.

***** The original data was first presented as a scientific poster presentation at the 19th Annual Clinical Meeting of the American Academy of Pain Management in Nashville, TN, in September of 2008.

♦ 12 Month / one year- follow-up data was collected between 12 - 14 months post treatment with the Antalgic-Trak®.

** Conflict of Interest/Financial Disclosure: Neither Dr. Rosenthal, nor Dr. Russo, or anyone affiliated with Advanced Physical Medicine has received any compensation in any manner for this research.

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