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Original Articles

A Clinical Trial on Non-Surgical Spinal Decompression Using Vertebral Axial Distraction Delivered by a Computerized Traction Device

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INTRODUCTION

Hypothesis: Axial traction of the spine produces remission of symptoms in specific conditions that have not responded to traditional manipulative protocols when computerized decompression traction, electrical stimulation and biofeedback exercise stabilization are applied under a controlled regimen.

The study is a pilot project and was not considered by an IRB for the initial phase. Continued investigation is suggested. The equipment for the study was provided by Calhoon Health Products. No fees for treatment were charged to any patients and no subjects were paid to participate in the study.

REVIEW OF THE LITERATURE

There are many studies on traction in the current literature. We have sited 20 indicating a broad interest in this concept and a continued search for alternatives to surgical decompression of the spine. The articles with a brief synopsis are listed at the end with the reference. The primary clinical point of the literature review is that compression of the neuronal elements of the spine seems to be a leading cause or generator of the pain in chronic situations. Decompression has proven effective and various forms of decompression are elaborated. In conclusion from analyzing these articles, vertebral axial distraction can be accomplished several ways and reports of reduction of intradiscal pressure, reduction of disc herniations, and associated symptoms are cited.

CURRENT RESEARCH

A trial was designed to measure the improvement on low back and leg pain and neck and arm pain patients. Patients who had reported symptoms in those areas were notified of the project and invited to participate. Other providers of physical medicine were notified as well and encouraged to have patients with similar unresponsive

conditions inquire. All patients admitted to the study had a lengthy history of pain with multiple episodes of chiropractic manipulation and physical therapy with limited success.

METHODS

A combination of questionnaires were used to compute an intake score for each patient. The score was computed using the formula, the sum of the total score from each questionnaire. Categories of severity were created as follows: 0-150; 151-175; 176-200; and > 200.

Protocols were determined based on total intake score and ranged from 3 to 6 treatment sessions per week. Traction protocols were determined based on patient history and symptoms, chronicity and extent of radicular signs. Treatment frequency was determined by total points: under 150 - 3 days per week, 151 to 175 - 4 days per week, 176 to 200 - 5 days per week and over 200 - 6 days per week.

The Axial Disc Compression Traction Therapy unit, manufactured by Chattanooga, was utilized in this study. Directions contained in the D.T.S. Information manual, copyright 2002 by Jay Kennedy were followed.

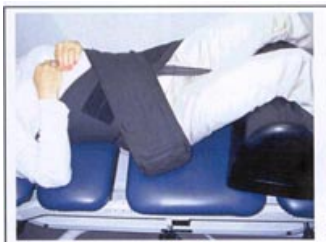
In this study, there were nine men and 5 woman ranging in age between 26-64. The range in chronicity for LB/Leg pain was 6 months to 29 years and neck to arm pain 1 year to 7 years. Exclusion criteria included, those with spinal fusions from hardware implant, those with non-disc related central spinal stenosis, those over age 70 or under age 18.

Intake measurements include modified Oswestry Low Back Pain Disability Questionnaire (Fairbanks, 1980) and the Neck Disability Index (Vernon and Mior, 1988) Activities Discomfort Scale (Turner, 1983) and a quadruple visual analogue pain scale (Yeomans, 2000). Each item was scored and the total recorded and compared to the exit scores. For this project, no objective tests were obtained on intake or exit, only standardized outcomes assessment tools.

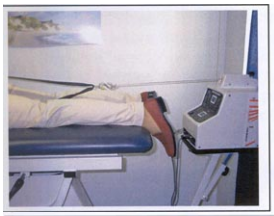
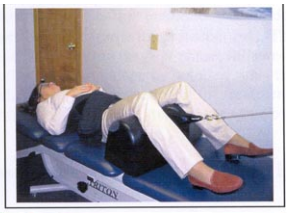
THE PROCEDURE

Patients who qualified to enter into the study were measured and fitted to the traction unit. Both prone and supine protocols were considered for lumbar decompression. The prone position is usually recommended but can be modified per patient ability to tolerate the position. Cervical decompression is done in the supine position. Precise positioning for each patient is critical for outcomes to be optimized A 100% compliance was expected from each subject accepted into the study in order to optimize the statistical analysis.


The specific treatment protocol was determined by the doctor after assessing the intake examination and evaluation. The computer controls the variations in the traction allowing for spinal decompression and attempting to reduce the muscle reaction and subsequent compression that can occur with some types of traditional or conventional traction devices. The preprogrammed patterns for ramping up and down the amount of axial distraction allows for optimal levels of spinal decompression and disc hydration when possible.



Proper patient positioning and specific technique insure expected results.



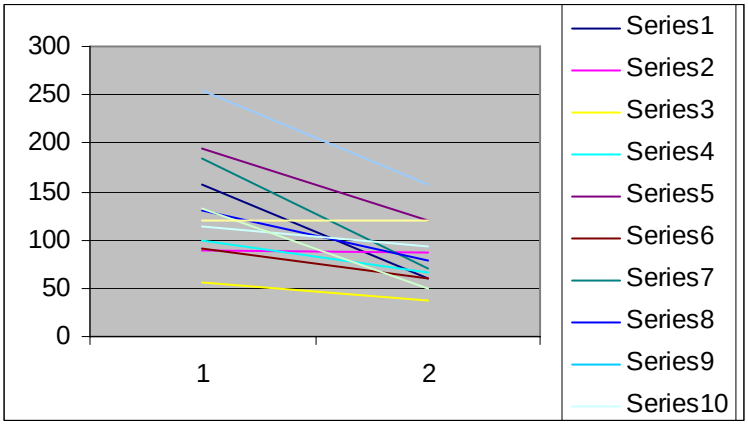
RESULTS

Of the 14 patients that were admitted into the study on May 17, 2004, the group was divided into the neck and arm pain group with 4 patients and the low back and leg pain group with 10 patients.

The three outcomes assessment tools were scored and totaled for each patient on intake and after three weeks of the study.

Spinal Decompression Study Results

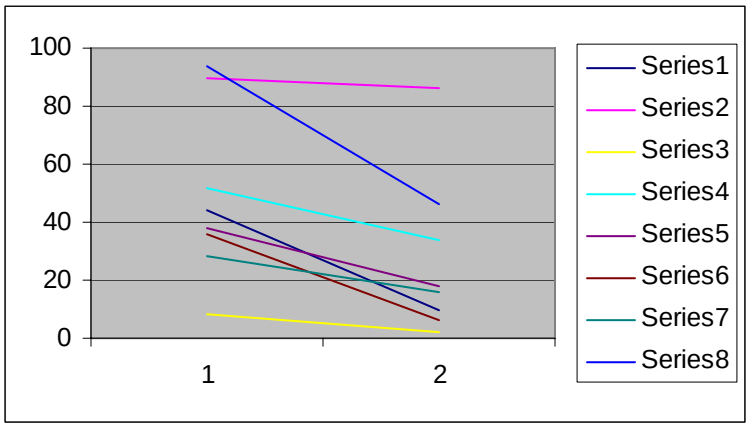
Patient	Complaint	Intake Score	Exit Score	% Measured	% Reported
	Average	135.33	83.17	0.36	63.75
1	Low back and leg	158	60	0.62	75
2	Low back and leg	90	86	0.04	0
3	Low back and leg	56	37	0.34	85
4	Neck and Arm	99	66	0.33	95
5	Low back and leg	194	120	0.38	40
6	Neck and Arm	91	60	0.34	50
7	Low back and leg	185	70	0.62	85
8	Neck and Arm	131	78	0.40	70
9	Neck and Arm	114	94	0.18	70
10	Low back and leg	133	49	0.63	100
11	Low back and leg	119	120	-0.01	10
12	Low back and leg	254	158	0.38	85



Using a single tool, the Revised Oswestry form for low back, it is noted that improvement parallels, in all but one case, the combination of the three tools.

Oswestry Low Back

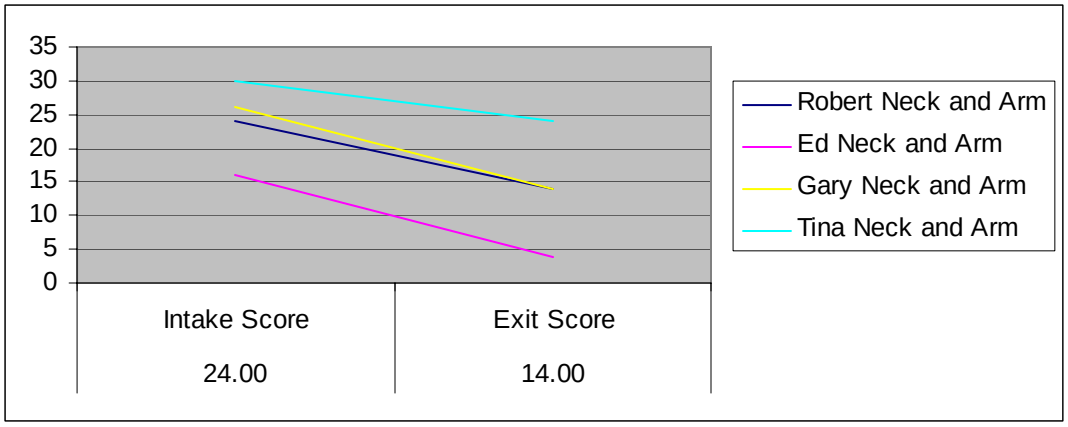
	Average	42.29	24.57	0.53
Patient	**Complaint**	**Intake Score**	**Exit Score**	**%Improvement**
1	Low back and leg	44	10	0.77
2	Low back and leg	90	86	0.04
3	Low back and leg	8	2	0.75
4	Low back and leg	52	34	0.35
5	Low back and leg	38	18	0.53
6	Low back and leg	36	6	0.83
7	Low back and leg	28	16	0.43
8	Low back and leg	94	46	0.51



The neck patients all responded well but not with as high an average as the low back patients.

Neck Oswestry

	Average	24.00	14.00	0.46
Patient	**Complaint**	**Intake Score**	**Exit Score**	
1	Neck and Arm	24	14	0.42
2	Neck and Arm	16	4	0.75
3	Neck and Arm	26	14	0.46
4	Neck and Arm	30	24	0.20



Following the three-week initial phase of the study, the patient sample in this study continued to receive decompression at variable rates based on improvement. The outcome measurements are repeated at one month intervals to determine if the disability levels and perceived improvement parallel each other.

DISCUSSION

It is interesting to note that the measured results parallel the perceived or reported improvement in all but one case. That case would not be included in a long term study due to non-compliance but was included here because that is a regular obstacle in daily clinical practice.

Decompression of the spine is possible using axial distraction as a modality. Study limitations include remission of symptoms may also be linked to electrochemical effects and biomechanical stabilization. All but two of the patients in the study improved at least 30% or more in the first three weeks. Two did not. One drove 2 hours to and 2 hours from treatment sessions and was not expected to achieve much improvement notwithstanding. He did report considerable relief immediately after each session and understood that the driving more than negated any improvements. The other patient who did not measure any improvement did not comply with the protocol as outlined and would have been dismissed from the study due to poor treatment compliance.

Continued follow-up with this patient sample is recommended in Part II of this study at 1, 3, 6 and 12 month results with and without additional treatment. Studies on surgical decompression procedures of the spine are often designed to include a 2-3 year follow-up as well as reporting any associated morbidity during the study time for up to 5 years. Additional patients should be likewise admitted and studied and the 5 year plan should be instituted. Patients will also be instructed in regular use and frequency of the stabilization exercises.

This study utilized an outcomes based research design. Given the significant improvements reported in this study, it is hopeful that a randomized, controlled trial where sham traction (placebo) can be compared to decompression therapy. Also, separate subject groups can also be randomized to electrical stimulation, pelvic stabilization groups, and a combined therapies group.

CONCLUSIONS

Utilizing the outcome measures, this form of decompression reduces symptoms and improves activities of daily living. Long-term benefits were not studied but will be reported in another study. The future study will include regular follow-up measurements to determine if the remission continues with or without recurrence. Also, the future study will investigate whether or not periodic supportive treatment sessions are needed to maintain symptom satisfaction.

A BRIEF SYNOPSIS OF RESEARCH ON LUMBAR/CERVICAL TRACTION

1) Bogduk, N,: The Anatomical Basis for Spinal Pain Syndromes. JMPT 6:Nov.Dec1995. There is no scientific basis for the belief that muscles are a source of chronic pain generation. However controlled studies show how common disc and facet pain is accounting for more than 70% of chronic back pain.

2) Komari H, et al.: The Natural History of Herniated Nucleus with Radiculopathy. Spine 21: 225-229, 1996. A study group of 77 patients verified on pre- and post- traction MRI with signs and symptoms of herniation, received non-surgical intervention including pelvic traction (anything else? If not, delete "including.' If so, include the other treatment approaches). Changes in herniation with good to excellent symptomatic improvements were noted in over 82% utilizing an outcomes based research design. The authors drew the conclusion that improving the disc's circulation or blood supply, accounts for healing of herniation.

3) Onel,D et. al.: CT Investigation of the effects of Traction on Lumbar Herniation. Spine 14: 82-90,1989. A study group of 30 patients with lumbar disc herniations received traction in a CT scanner utilizing a >50% body weight for ~20 min. Hernia retraction was observed in 70% and good clinical improvements were seen in over 93%. The authors concluded improved blood flow was the source of healing. Additionally, they speculated that previous studies that reported traction doesn't create negative intradiscal pressures perhaps used too light a force.

4) Parsons, WB Cumming, JDA: Traction in Lumbar Disc Syndrome. Can Med Jour 77:7-10,1957. A study sample of 100 patients with disc syndrome unresponsive to manipulation were treated with high force traction (+801b). 86% of patients had good to excellent outcomes and 12 had poor outcomes. Most had pain for an extended time durations.

5) Saal, JA Saal, JS: Nonoperative Treatment of Herniated Lumbar Disc w/ Radiculopathy. Spine 14 (4): 431-437, 1989. A study sample of 58 subjects had a conservative program that included traction. Overall 86% had good-excellent results with reduced leg symptoms.

6) Mathews, JA: Dynamic Discography: A Study of Lumbar Traction. Annls of Phys Med, IX (7), 265-279, 1968. A study sample of 3 patients with a ruptured lumbar disc had contrast medium and radiographic images taken during and after a lumbar traction procedure. The protrusions were shown to lessen considerably utilizing 30-minute prone traction sessions and a dimpling of the outer annulus suggested a negative intradiscal force was created.

7) Lidstom, A Zachrisson M: PT of the low back pain and sciatica. Scan J of Rehab Med, 2: 37-42, 1970. Intermittent supine traction with +50% body-weight, for ten, 20 minute sessions with added exercises showed considerable improvement in over 90% of the 62 patients.

8) Hood, LB Chrissman, D: Intermittent Traction in the Treatment of Rupture Disc Plays Ther 48: 21, 1968. A study sample of 40 patients with neurological signs were treated with traction on a friction-free table utilizing 55-70 1bs for 20 minutes. Good to excellent results were seen in 55%.

9) Mathews JA et. al.: Manipulation and traction for Lumbago and Sciatica. Physio Pract 4: 201, 1988. A controlled trial of traction with manipulative techniques. Traction force applied at approximately 100 lbs for 20 minutes resulted in substantial relief in over 85%.

10) Colachis S, Strohm BR: Effects of lntermittant Traction on Vertebral Separation. Arch of Phys Med& Rehab, 50: 251-258, 1969. Subjects were subjected to a supine 'angled' traction force of up to 100 lbs. with x-ray examination. A rope angle of 18 degrees revealed separation greatest at L4-5 (Note: it is speculated that a more acute angle of approximately 10 degrees results in greater separation at L5-S 1). The separation was obvious up to T12-L1 with total elongation of the spine approaching +5mm. The vertebra separation is greater on the posterior vs. anterior aspect of the vertebra.

11) Constatoyannis C, et. al.: Intermittent Cervical Traction for Radiculopathy Due to Large-Volume Herniations. JMPT, 25 (3) 2002. A 3-week trial of intermittent cervical traction to patients with large volume hemiations resulted in complete resolution of symptoms in 4 of 6 patients.

12) Shealy N, Leroy P: New Concepts in Back Pain Management. AJPM (1) 20:239241 1998. The application of supine lumbar traction with adherence to several specific characteristics including progression to a peak force and altering the angle of 'pull' from 10 degrees (L5-S1) to 30 degrees (L3) enhanced distraction at specific levels.

13) Gose E, Naguszewski W&R: Vertebral axial Decompression for Pain associated With Herniated and Degenerated Discs or Facet syndrome: an Outcome Study. Neuro Research, (20) 3, 186-190, 1997. A retrospective analysis of over 770 cases, many assumed to be unresponsive to previous therapies showed a 71% good to excellent success rate with ~20 treatments on the prone VAX-D traction device. All patients were treated prone with 65-95 lbs. of force 3-5 times per week.

14) Weatherall VF: Comparison of electrical activity in the sacrospinalis musculature during traction in two different positions. J Ortho Sports Phys Ther(8):382-390, 1995. The use of EMG electrical activity was shown to be similar in the prone laying position vs. the supine position in a group of patients.

15) Letchuman R, Deusinger RH: Comparison of sacrospinalis myoelectric activity and pain levels in patients undergoing static and intermittent lumbar traction. Spine 18(10): 1361-1365, 1993. This study's objective was used to determine the degree of muscular guarding/contraction of lumbar paraspinals comparing intermittent vs. static traction. Improved comfort was noted greatest in the intermittent traction group.

16) Chin YG, Li FB, Huang CD: Biomechanics of traction for lumbar disc prolapse. Chinese Ortho; Jan(l): 40-2, 1994. Intervertebral pressure was recorded before and during traction. A reported 62% of prolapsed discs showed negative pressure prior to traction. Similarly, 64% reduced IDP with traction and was related to distraction distance. In 19% of prolapsed discs, the pressure actually increased, demonstrating the disruption to the hydrostatic mechanism occurring with complete annular damage and prolapse.

17) Nanno M: Effects of intermittent cervical traction on muscle pain. EMG and flowmetric studies on cervical paraspinals. Nippon Med J; Apr;61(2):137-47, 1994. Cervical intermittent traction was shown to be effective in relieving pain, increasing frequency of myoelectric signals and improving blood flow in the affected muscles.

18) Chung TS, Lee YJ, et al. Reducibility of cervical herniation: evaluation at MRI during cervical traction with a nonmagnetic device. Radiology Dec; 225(3):895900,2002. 29 patients and seven healthy volunteers had intermittent traction while in MR. Substantial increase in vertebral length was seen. Full herniation reduction in 3 and partial in 18 was reported.

19) Dietrich M, et al: Non-linear finite element analysis of formation and treatment of disc herniation. Proc Inst Mech Eng; 206(4):225-31, 1992. The author's analysis shows loads not greater than those occurring in

everyday life can cause loss of stability of the disc and allow lateral nucleus displacement. The model indicates conservative therapy by traction may result in retraction of hernia by about 40%.

20) Ramos G, Martin Wm: Effects of axial decompression on intradiscal pressure. J Neuro 81: 350-353, 1994. Significant negative pressure (-100mm Hg) was recorded at L4/5 disc in three volunteers as axial traction was administered. Negative pressure was recorded at -50 pounds tension perhaps representing a minimal threshold force. Patients were prone and harnessed.

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ATTRIBUTION

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