Spinal Decompression: Measurement of Treatment Outcomes.

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Key Words: Spinal Decompression, Spinal Pain Treatment, Non-surgical Treatment, Lumbar Spine, Cervical Spine

Running Head: Spinal Decompression

Number of Words:

Abstract

Objective: Approximately 80% of all adults will experience severe back pain during their lives and 50% of all adults at some time in their lives will experience neck and upper extremity pain. Decompression (unloading through distraction and positioning) of the cervical spine can be accomplished through a variety of modalities. The effectiveness of one such approach is the focus of this investigation.
Design: Retrospective Chart Review.
Setting: Outpatient Treatment Center, Westminster, Maryland
Patients: A consecutive sample of 156 patients who presented with a complaint of lumbar pain and 37 adult patients who presented with a complaint of cervical pain.
Intervention: A computerized commercially available, FDA Cleared decompression table (K051013). Patients received treatments 5 days a week for periods of either 20 or 25 treatments determined by the practitioner.
Main Outcome Measures: Changes in Visual Analog Pain Scores over time, improvements in activities of daily living, and improvements in functioning.
Results: Both lumbar and cervical patients reported significant improvements in all targeted outcome measures with the greatest reduction occurring within the first 5 days of treatment (first week.) Lumbar patients score differences from the start of treatment to the end of treatment for measurement were significant for Activities of Daily Living, Pain Visual Analog Scale, Oswestry Score (all, $p < 0.0001$) and Change in Disability Status (Chi Square = 14.1, $p<0.0027$) (Table 3.) Improvement in the Pain Visual Analog Scale was not different between post-surgical and non-post-surgical patients, $F=1.23$, $df = 24$, p 0.224.) Outcome differences were not explained by differences in presence, absence or location of herniation or degenerative disc. For cervical patients there were statistically significant improvements from time of treatment entry to completion of treatment for: Standing, Getting In/Out of Car, Driving, Dressing, House Cleaning/Yard Work, Working at One's Job, and Pain During Sleeping. The proportion of cervical patients reporting that they were taking pain medications dropped from 64% at the time of entry into treatment to 35% by the end of treatment.
Conclusions: Spinal decompression strategies for the relief of patients back pain, whether at the lumbar or cervical level remains under investigation. There have been multiple calls for well designed randomized control trials to investigate the effectiveness of decompression. The data reported here suggests that in such studies mechanical spinal decompression will demonstrate significant improvements in specific patient outcomes.

Introduction

Approximately 80% of all adults will experience severe back pain during their lives and 50% of all adults at some time in their lives will experience neck and upper extremity pain.[1] Millions of people live with chronic back pain each day. Excessive loading of the spine through changes in our lifestyle and extended periods of sitting while driving or working at a desk cause premature degeneration of intervertebral discs, and repeated injury of the disc annulus.[2] With all of this unnatural positioning and loading of the human spine, there is little wonder that severely damaged discs almost never heal.

Nutrition in the avascular disc depends on osmotic diffusion of collagen precursors such as proline, nutrients and oxygen. Diffusion of the collagen precursors into the avascular disc pass through direct channels in the annulus (30%) and the hyaline end plate in the vertebrae above and below (70%).[3] It is estimated that the cycle of proline uptake and renewal in the normal disc (necessary for collagen synthesis and repair) takes approximately 500 days. This inherently slow cycle is additionally compromised in the deranged disc. Lowering intradiscal pressures greatly facilitates this process and accelerates healing in the disc segment.[4]

Physical therapy programs can be very effective in treatment and improvement of symptoms. [5, 6] Of the various interventions, traction used to produce spinal decompression[7] has been considered a treatment of choice.[8, 9] The benefits of decompression of the vertebrae have includes relief of tonic muscle contraction and unloading the spine,[10] reducing nerve root compression,[11] and increasing overall mobility.[12]

Decompression (unloading through distraction and positioning) of the spine can be accomplished through a variety of active and passive modalities. While there are reports of effectiveness investigations of motorized traction devices[13], there have been specific calls for increased numbers of investigations to demonstrate the effectiveness of motorized traction

systems.[14] The effectiveness of one these systems is the focus of this investigation. This data will form the basis for decision making in the design of a randomized controlled trial of mechanical decompression.

Methods

This study is a pilot project representing two retrospective consecutive series of patients. One group treated for low back pain and one group treated for cervical pain. Patients were from a single practice.

All treatments were undertaken using the SpineMED® Decompression table (CERT Health Sciences LLC.) The SpineMED® table uses a computerized system and proprietary design to provide controlled intermittent distraction. (Figure 1) In addition to the provision of treatments for low back pain, the system also provides for isolation of the cervical spine for treatment. (Figure 2)

All data were extracted from patient medical records by an independent data extractor and from structured data reporting forms. Data was entered into a Microsoft Access™ database and were analyzed using SAS-PC for Windows v. 9.1.3™. Descriptive statistics were used to report demographic and other similar data. Paired t-tests were used to test pre-treatment post-treatment differences for continuous variables. Chi Square was used to test for differences in categorical variables and Analysis of Variance for changes in group data.

Data gathered included:

- Presentation / Chief Complaint
- Patient demographic information (age, gender)
- Patient post surgical status, if any
- Evidence of disk herniation or degenerative disc disease

- Symptom duration
- Daily (during treatment) Visual Analog Pain Scale measurements
- Patient Treatment Plan information
- Extremity Motor Functions
- Deep Tendon Reflexes
- Extremity Sensory
- Cervical Orthopedic / Vascular Tests
- MRI results
- Oswestry Neck Disability Scale
- On-going Visual Analog Pain Scales and Pain Drawings

Results

Lumbar Results

Data from a total of 156 consecutive lumbar treatment patients was analyzed. Demographic data from these patients is shown in Table 1. Most patients had herniations or degenerative disc disease at the L4-L5 and L5-S1 levels. Score differences from the start of treatment to the end of treatment for measurement of Activities of Daily Living all of which showed statistically significant improvements ($p < 0.0001$) (Figure 3), the Pain Visual Analog Scale (significant improvement ($p < 0.0001$) (Figure 4), Oswestry Score (significant improvements, $p < 0.0001$) (Table 2) and Change in Disability Status (significant change $\text{Chi Square} = 14.1$, $p<0.0027$) (Table 3.) The improvement in the Pain Visual Analog Scale was not different between post-surgical and non-post-surgical patients, $F=1.23$, $df = 24$, p 0.224) Outcome differences were not explained by differences in presence, absence or location of herniation or degenerative disc.

Cervical Results

Data were gathered from a total of 37 patients (Table 4.) Most patients had herniations or degenerative disc disease at the C5-C6 and C6-C7 levels. Only three patients had had prior spine surgery. Patients' reported impact of their condition on activities of daily living showed statistically significant improvements from time of treatment entry to completion of treatment for: Standing, Getting In/Out of Car, Driving, Dressing, House Cleaning/Yard Work, Working at One's Job, and Pain During Sleeping. (Table 5) Figure 5 shows the trend in Visual Analog Pain scores over the treatment period for all participants. The proportion of patients reporting that they were working regular hours changed from 47% at entry into treatment to 53% at the time of completion of treatment. The proportion of patients reporting that they were taking pain medications dropped from 64% at the time of entry into treatment to 35% by the end of treatment.

Discussion

Clearly significant improvements were seen for both lumbar and cervical treatment patients using this decompression modality. Lumbar patients reported significant improvements in all patient oriented evidence that matters: improved ability to conduct activities in daily living; significantly decreased pain scores; significantly improved disability status; and significantly improved functional status. Cervical patients showed significant improvement in most activities of daily living; significant improvement in reported pain status, and a reduction in the number and frequency of medications used by the end of treatment (medication use was not consistently captured for lumbar patients and was therefore not included in this analysis.)

Spinal decompression strategies for the relief of patients back pain, whether at the lumbar or cervical level remains under investigation. There have been multiple calls for well designed randomized control trials to investigate the effectiveness of decompression.[13,14] The data

reported here suggests that in such studies mechanical spinal decompression will demonstrate significant improvements in specific patient outcomes.

Table 1. Demographic Data for Lumbar Patients (N=156)

Variable		
Percent Males		50.6%
Mean Age (sd) Males		53.8 yrs ± 13.5 yrs
Mean Age (sd) Females		55.0 yrs ± 13.9 yrs
Herniations L1-L2 L2-L3 L3-L4 L4-L5 L5-S1		 14 (8.9%0 19 (12.1%) 28 (17.9%) 60 (38.4%) 43 (27.5%)
Degenerative Disc Disease L1-L2 L2-L3 L3-L4 L4-L5 L5-S1		 26 (16.6%) 40 (25.6%) 61 (39.1%) 77 (49.3%) 65 (41.7%)
History of Spine Surgery		56 (35.9%)
Mean Time Since Surgery		6.5 years
Presence Hardware Fixation		0
History Postural Hypotension		5 (3.3%)
Seizures / Epilepsy		3 (1.9%)
History Heart Disease		17 (11.1%)
History Connective Tissue Disease		4 (2.6%)

Table 2. Differences in Oswestry Analysis Lumbar

Difference from Baseline in Oswestry Disability Index:

	Mean / SD	T test	P
Baseline	33.0 / 14.3	4.99	0.0001
Final Measure	13.0 / 14.0		

Tables 3. Change in Disability Status Lumbar Patients

	Minimal Disability	Moderate Disability	Severe Disability	Extreme Disability
Baseline	8 (25.0%)	11 (34.3%)	12 (37.5%)	1 (3.1%)
Final Measure	21 (65.6%)	9 (28.1%)	2 (6.2%)	0 (0.0%)

Chi Square = 14.1, $p<0.0027$

Table 4. Demographic Data for Cervical Patients (N = 37)

Variable		
Percent Males		37.8%
Mean Age (sd) Males		46.2 yrs ± 14.8 yrs
Mean Age (sd) Females		51.2 yrs ± 10.6 yrs
Herniations		
C1-C2		0
C2-C3		2 (5.6%)
C3-C4		6 (16.6%)
C4-C5		3 (8.3%)
C5-C6		13 (36.1%)
C6-C7		13 (36.1%)
Degenerative Disc Disease		
C1-C2		0
C2-C3		4 (11.1%)
C3-C4		16 (44.4%)
C4-C5		14 (38.9%)
C5-C6		26 (72.2%)
C6-C7		21 (58.3%)
History of Spine Surgery		3 (8.57%)
Mean Time Since Surgery		7.5 years
Presence Hardware Fixation		0
History Postural Hypotension		2 (5.71%)
Seizures / Epilepsy		0
History Heart Disease		4 (11.4%)
History Connective Tissue Dx		1 (2.86%)

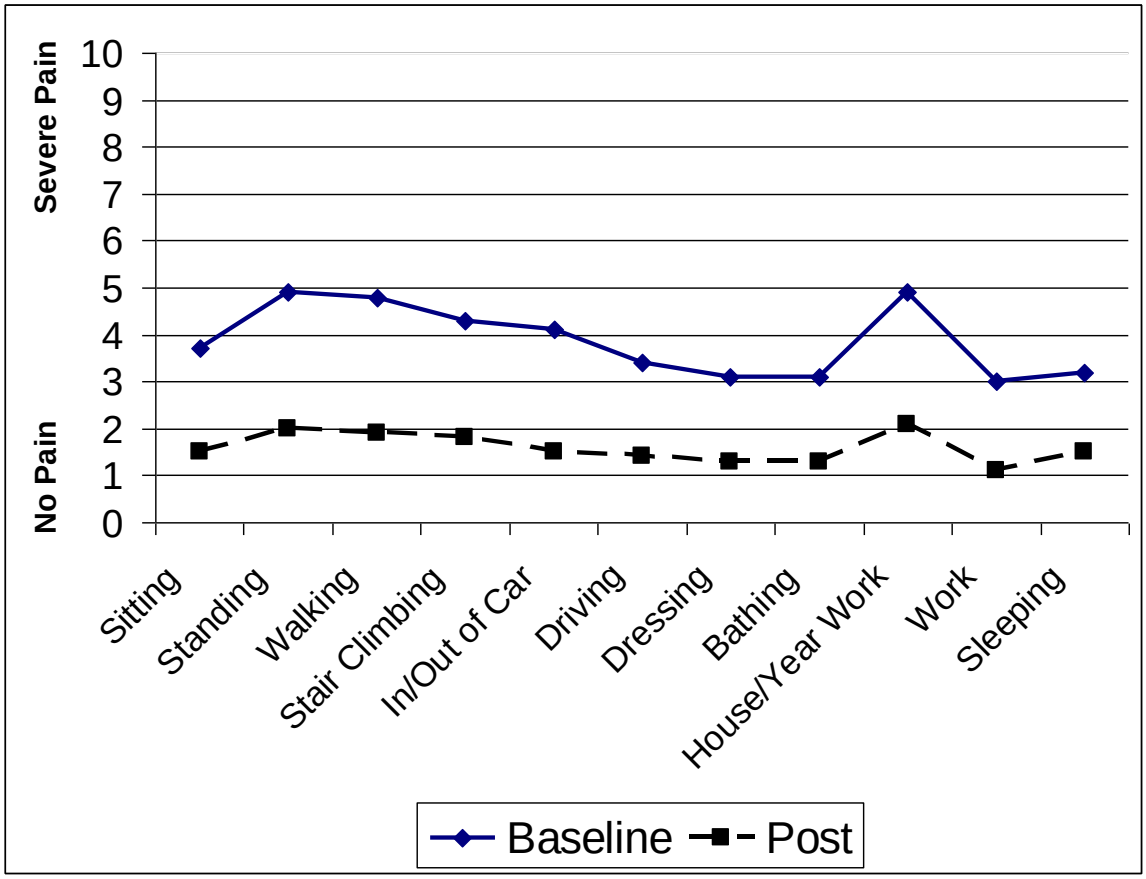
Table 5. Activities of Daily Living. Scores range from 0 = No Pain / No Difficulty to 10 = Can Not Perform / Severe Pain.

Area of Daily Activity	PreScores (Mean ± SD)	PostScores (Mean ± SD)	Significance Pr > |t|
Mobility			
Sitting	2.65 ± 2.81	2.01 ± 2.87	ns
Standing	3.55 ± 3.22	1.92 ± 2.76	0.04
Walking	3.26 ± 3.39	1.88 ± 3.08	ns
Stair Climbing	3.00 ± 3.37	1.73 ± 2.58	ns
In/Out of Car	3.50 ± 3.13	1.82 ± 2.50	0.03
Driving	3.75 ± 3.18	2.13 ± 2.76	0.04
Functions			
Dressing	3.26 ± 2.49	1.78 ± 2.56	0.03
Bathing	2.60 ± 2.28	1.73 ± 2.58	ns
House Cleaning/Yard Work	4.13 ± 3.26	2.23 ± 2.79	0.02
Work	3.50 ± 3.05	1.09 ± 2.01	0.007
Pain Sleeping	4.18 ± 3.24	2.36 ± 3.21	0.04

Figure 1. SpineMED® Table (Photo courtesy CERT Health Sciences LLC)

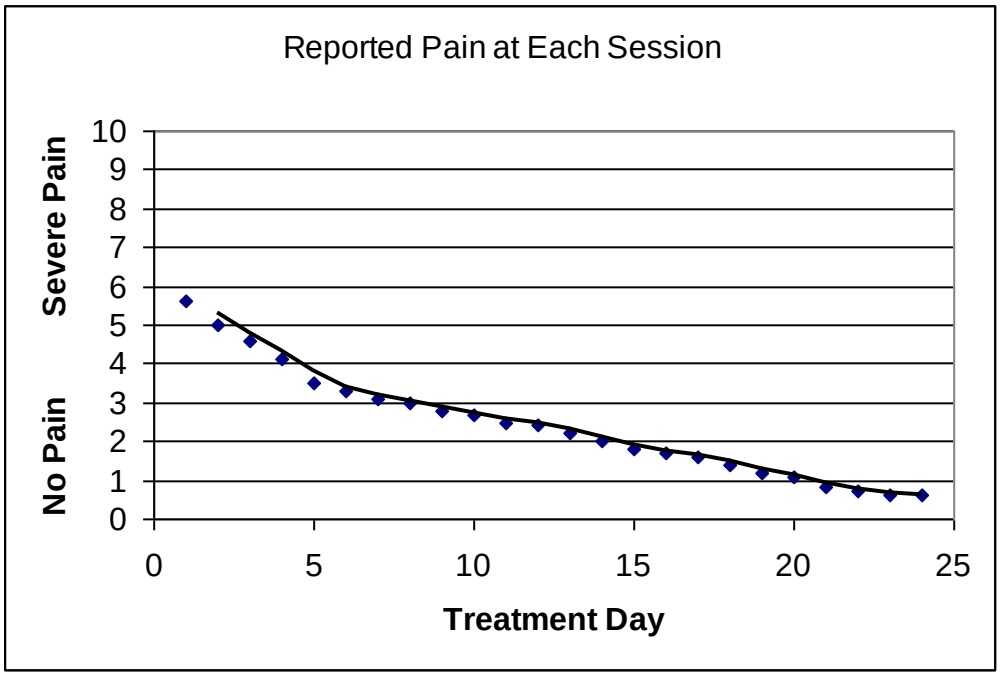
Figure 2. Patient in cervical spine treatment position. (Photo courtesy CERT Health Sciences LLC)

Figure 3. Differences for Activities of Daily Living Scale Pre-treatment to Post-Treatment, Lumbar Patients



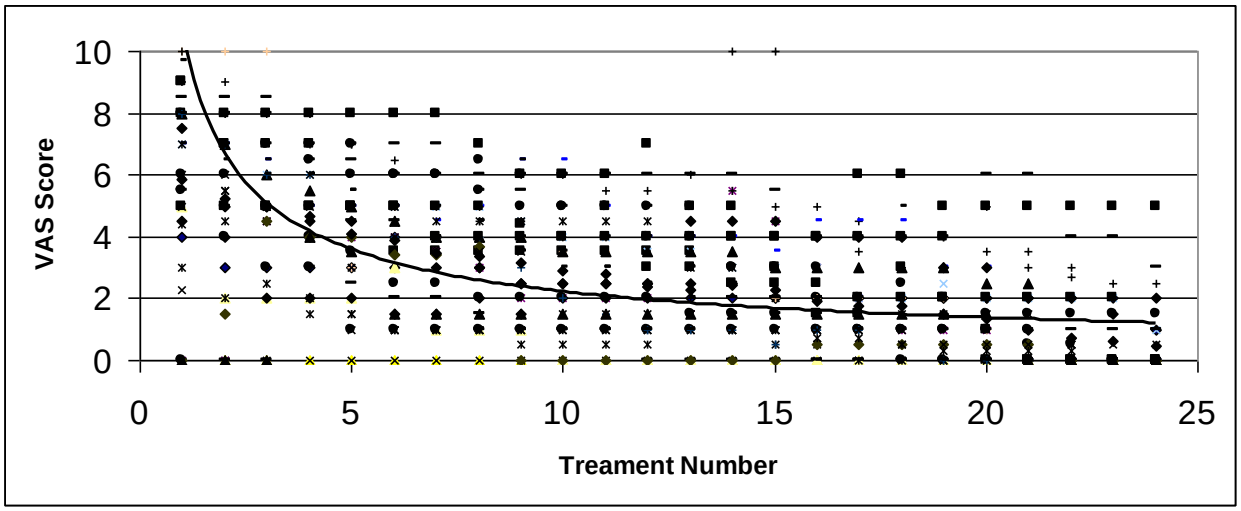
Activity	Baseline Mean	Post Mean	t value	p
Sitting	3.7	1.5	6.98	0.0001
Standing	4.9	2	8.54	0.0001
Walking	4.8	1.9	8.69	0.0001
Stair Climbing	4.3	1.8	7.09	0.0001
In/Out of Car	4.1	1.5	8.84	0.0001
Driving	3.4	1.4	6.22	0.0001
Dressing	3.1	1.3	5.94	0.0001
Bathing	3.1	1.3	5.66	0.0001
House/Year Work	4.9	2.1	7.34	0.0001
Work	3.0	1.1	5.72	0.0001
Sleeping	3.2	1.5	5.11	0.0001

Figure 4. Improvement in Pain Visual Analog Scale – Lumbar Patients



Improvement is the same for post surgical and non-post surgical patients, F=1.23, df = 24, p 0.224)

Figure 5. Cervical patients reported pain status – Visual Analog Pain Scale.



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