

A Multimodal Treatment Approach using Spinal Decompression via SpineMED, Flexion-Distraction Mobilization of the Cervical Spine, and Cervical Stabilization Exercises for the Treatment of Cervical Radiculopathy

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Abstract. [Purpose] The aim of the present study was to determine whether a multimodal treatment approach using spinal decompression via SpineMED and spinal mobilization as well as cervical stabilization exercises would benefit patients with neck pain with radiculopathy. [Subjects] A total of 10 patients with cervical radiculopathy ranging in age from 19 to 46 with an average age of 35.50 years participated in this study. [Methods] Patients received treatment in 85 minute sessions, 6 days per week for the first two weeks, and 4 days per week for two additional weeks. Treatment protocol consisted of spinal decompression via SpineMED and flexion-distraction mobilization of the cervical spine as well as cervical stabilization exercises. Physical therapy modalities including superficial heat, ultrasound, and interferential current were also delivered prior to administration of SpineMED. Differences between patients' pre-intervention and discharge outcome measures, pain on a visual analogue scale (VAS) and neck disability index (NDI), were examined using a paired t-test. [Results] Mean measures of patients' VAS and NDI demonstrated significant improvement after being treated with 20 sessions of combined treatment. [Conclusion] Findings of the present study provide significant evidence to support the efficacy of a multimodal treatment approach using spinal decompression via SpineMED and spinal mobilization as well as cervical stabilization exercises. A multimodal approach might be an asset in the management of cervical spine disorders.

Key words: Cervical radiculopathy, Spinal decompression, Multimodal treatment

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INTRODUCTION

Neck pain with radiculopathy is defined as an abnormal condition of the nerve root that originates in the cervical spine due to mechanical compression and inflammation of the nerve root or roots in proximity to the intervertebral foramen¹⁾. Approximately 13% to 18% of the general population in industrialized countries are affected by neck pain with radiculopathy²⁾, and cervical radiculopathy produces a high level of morbidity, affecting daily activities of living and quality of life^{3–6)}.

Disc herniation is the most common cause of cervical radiculopathy which typically presents with pain often described as sharp, achy, or burning in the neck, shoulder, arm, or chest, depending on the root or roots affected, usually in a myotomal distribution⁷⁾. Neck pain with radiculopathy also presents with loss of motor function,

reflex changes, and sensory changes such as numbness/tingling and paresthesia or dysesthesia⁷⁾. C6–7 is the most common level of disc herniation followed by C5–6, and together they encompass 90% of all cases^{6,8)}.

Noninvasive treatment options for neck pain with disc herniation of the cervical spine include cervical traction, anti-inflammatory medication, physical therapy, exercises, spinal manipulation and mobilization, or acupuncture in order to reduce neurologic symptoms and neck pain^{9–14)}. One of the treatment options is traction (axial traction) and it has been widely used among clinicians attempting to relieve neck pain by reducing the pressure within the intervertebral disc and unloading the structures of the neck soft tissues¹⁵⁾. Intermittent traction is beneficial for preventing the formation of adhesions of the dural sleeve through gentle stretching and relaxation of the soft tissues of the cervical spine^{16,17)}. There are several ways to apply force

for cervical traction: motorized traction delivered via a motorized pulley (motorized traction), manual traction delivered manually by a therapist, and gravitational traction delivered through a suspension apparatus¹⁸.

Several spinal decompression systems have been newly developed for noninvasive treatment of neck pain with radiculopathy. These include SpineMED (CERT Health Sciences, LLC, Baltimore, MD, USA), DRX9000 (Axiom Worldwide, Tampa, FL, USA), and vertebral axial decompression (VAX-D) (Vat-Tech, Inc, Palm Harbor, FL, USA). When conventional traction is applied, the pull force of traction may elicit the body's protective proprioceptive response to distraction in which back muscles resist the distraction, thereby reducing the distraction force¹⁹. It is the manufacturers' claim that the new technology adopted by spinal decompression systems can decrease the patient's protective proprioceptive response to distraction in the paravertebral muscles of the spine thus, allowing distraction of the affected spinal unit, thereby reducing pressure within the damaged disc and symptoms related to disc herniation^{20,21}.

Manual therapy techniques (spinal mobilization and spinal manipulation) are also commonly used in therapeutic regimes for patients with cervical radiculopathy. These techniques are used to reduce pain by affecting the pain processing system²² and reflex inhibition, and increasing range of motion of the spinal segment²³. Spinal mobilization is defined as the application of manual force to the spinal segments within the limit of passive range of joint motion, and involves low-velocity (non-thrust) passive motion within the patient's control to stop²⁴. Flexion-distraction mobilization which uses specially designed treatment tables is the one of the most common forms of therapy for the treatment of neck pain with or without arm pain and is beneficial for the treatment of acute neck pain²⁵.

Conservative management of neck pain with cervical radiculopathy also includes therapeutic exercises that target the improvement of neck stability. Neck stabilization exercises are commonly prescribed by clinicians to protect damaged cervical structures from further injury, recurrent pain episodes, and degenerative change, as well as reduce the intensity of the pain and disability due to neck pain²⁶⁻³⁰. Neck stabilization exercises incorporate various methods such as stretching, isometric/static or dynamic strengthening, and resistance or endurance training as well as proprioceptive exercises. Previous studies³¹⁻³⁴ have provided strong evidence that exercise therapy for the treatment of chronic/mechanical neck disorders is likely to reduce pain as well as the disability it causes and increase the neck's range of motion.

Although cervical radiculopathy is a common problem in the adult population in industrialized countries, its management varies widely and there is insufficient evidence to confirm the effectiveness of the various interventions described above. Thus, the aim of the present study was to determine whether a multimodal treatment approach using spinal decompression via SpineMED and spinal mobilization as well as cervical stabilization exercises would benefit patients suffering from neck pain with

radiculopathy.

SUBJECTS AND METHODS

Patients who participated in the current investigation were treated between August 2009 and January 2010. A total of 10 patients with cervical radiculopathy ranging in age from 19 to 46 with an average age of 35.50 ± 4.50 years participated in this study; 70 % of the patients were female and 30 % were male.

Inclusion criteria for patients in the current study were as follows: 1) Subjects were included if they were between 18 and 60 years old and had cervical radiculopathy. 2) Subjects must have been diagnosed with one of the following conditions: herniated disc, bulging or protruding discs confirmed by magnetic resonance imaging (MRI) or computed tomography (CT) of the cervical spine. 3) Subjects must have shown imaging evidence of herniated disc, or bulging or protruding discs at an involved spinal joint consistent with their symptoms, since structural imaging of herniated disc of MRI and/or CT and symptoms are often poorly correlated^{35,36}. 4) Subjects must have demonstrated at least mild disability in activities of daily living due to neck pain, constituting a score of 5–10 on the neck disability index (NDI)³⁷. 5) Subjects must have had symptoms related to disc herniation in the cervical spine for less than a 2-month duration at presentation.

We excluded subjects who presented with a history of cervical spine surgery, pregnancy, severe osteoporosis, recent cervical vertebral compression fracture, local spinal osteomyelitis, meningitis, aortic aneurysm, primary malignant or metastatic spinal neoplasm, hemiplegia, paraplegia, cognitive dysfunction, or disc pathology with sequestration, or were using prescription anticoagulants, corticosteroids, or opiate-based pain medication. Additionally, we also excluded subjects who were currently involved in a workers' compensation claim or legal action regarding their symptoms secondary to intervertebral disc herniation of the cervical spine.

We recruited all subjects by referral from a neurosurgeon working in a local spine care center where the current study was performed. The subjects were screened by the same neurosurgeon and a physical therapist who had a collective 10 years of experience to check inclusion/exclusion criteria, and to address any questions regarding this study. Prior to participating in the study all the participants gave their written consent and our local University Institutional Review approved the present study. Subject characteristics and primary diagnosis as well as MRI findings of subjects are summarized in Tables 1 and 2.

The SpineMED spinal decompression system consists of a table and a cervical restraint system which captures the base of the patient's skull to provide cycling distractive forces along the axis of the cervical spine. A disc angle pull adjustment incorporated in the SpineMED device could be tilted to the angle required to precisely target affected cervical spine segments enabling the distractive force to be applied to a single spinal disc.

For administration of the SpineMED device therapy, the

Table 1. Subject characteristics

Characteristics	Values
Age (years)	35.5 ± 4.5
Sex (male/female)	3/7
Height (cm)	167.2 ± 7.1
Weight (kg)	63.5 ± 7.2
Side involved: left/right (%)	40/60
Location of pain	%
Pain in neck/scapular only	50
Pain below scapular, above elbow	10
Pain below elbow	40
Duration of symptoms (months)	%
Less than 2	100
Previous history of NP (% yes)	0

Note: Values are means ± SD (standard deviations); N = 10; NP: Neck pain.

Table 2. Primary diagnosis and MRI findings of participants

Category	Values (%)
Primary diagnosis	
Herniated disc	30
Herniated disc and degenerative disc	70
Disc involved confirmed from MRI	
C5–C6	70
C6–C7	30
Changes in disc confirmed from MRI	
Protrusion and disc space narrowing	100

Note: MRI: magnetic resonance imaging.

cervical restraint system was first electronically tilted to the angle indicated by the manufacturer to target the damaged cervical spine segment. Then, the treating clinician positioned the subject supine on the SpineMED table with his or her head positioned in the restraint system and with the hips and knees flexed and the lower legs supported on a stool. The typical pull angle used was 28 degrees for the C5–C6 level and 30 degrees for the C6–C7 level, and the initial pulling force was set as 5–6 lbs for males and 4–5 lbs for females. The pulling force for cervical distraction was raised in increments of 1 lb per session as tolerated and the final pulling force was 15 lbs for males and 12 lbs for females. Additionally, the time for distraction and relaxation was set at 60 seconds and 30 seconds respectively, and during the relaxation period half of pulling force applied in the distraction period was maintained. Treatment was delivered for 30 minutes, 6 days per week for the first two weeks, and 4 days per week for two additional weeks. Thus, the total number of visits was 20 times over a 4-week course of therapy. Heat pack therapy was delivered for 15 minutes to provide superficial heating to the patients followed by 5 minutes of ultrasound treatment (SM-250, Samson Med, Seoul, Korea) using a 1 MHz, 5-cm² sound head at an intensity of 1.5 W/cm² in continuous mode and 15 minutes of interferential current treatment (SM-850P, Samson Med, Seoul, Korea) at an intensity of 25 mA before administration of SpineMED.

All participants also received flexion-distraction mobilization which was performed on a specially designed treatment table (MF 90, Wellness System, Seoul, Korea) with a moveable headpiece which allows the clinician to manually move the patient through passive flexion and extension of the cervical spine. The treating clinician positioned the participant prone on the treatment table with the cervical head piece, and then placed one hand over the cervical region at the level of interest for stabilization, applying a gentle and steady force through the contact hand in the caudal direction and posterior to anterior direction, while the clinician used the other hand on the handle of the headpiece to control the desired range of motion. The total treatment time of each session was 5 minutes, and treatment took place 6 days per week for the first two weeks and 4 times per week for two additional weeks; the entire treatment for mobilization of the cervical spine consisted of 20 sessions over a 4-week period.

All patients were additionally given some form of adjunctive cervical stabilization exercises using a sling device (Redcord, Staboo, Norway) designed to improve the dynamic stability of the cervical spine through retraining of the co-contraction pattern of the cervical muscles, and to mobilize the damaged cervical spine segment. Each participant was treated with cervical exercise 6 times per week for the first two weeks, and 4 times per week for two additional weeks. Thus, the entire cervical exercise session totaled 20 sessions over a 4-week course of therapy and the total treatment time of each session was 15 minutes.

Outcome measures, pain on a visual analogue scale (VAS)^{38,39} and NDI, were evaluated before the initiation of intervention and after discharge from intervention. All subjects completed initial and post-treatment VAS and NDI assessments. Numerical pain intensity on a typical day secondary to neck pain was rated using a 10-point VAS with a score of 0 (no neck pain during a typical day) to 10 (worst possible neck pain during a typical day). VAS has a test-retest reliability of 0.60 to 0.70⁴⁰ and a concurrent validity of 0.76 to 0.84⁴⁰. Reduced ability to manage activities in everyday life secondary to neck pain was estimated using the 50-point NDI (0 being no overall neck pain and 50 being the most severe neck pain)³⁷. The NDI score was determined by the patient who rated 10 items, each ranging from 0 (no back pain during activity) to 5 (severe pain during activity). NDI has a test-retest reliability coefficient of 0.89³⁷ and a concurrent validity of 0.69 to 0.70³⁷.

The paired t-test was used to examine the differences between pre-intervention and discharge VAS and NDI. A p value less than 0.05 ($p < 0.05$) was considered a statistically significant. The dependent variables were VAS and NDI scores. The independent variable was time of the pre-intervention and discharge measurements. The software package SPSS 14.0 KO (SPSS, Chicago, IL, USA) was used for statistical analyses.

RESULTS

All subjects enrolled in the study received 20 sessions of conservative treatment consisting of spinal decompression

therapy, cervical flexion-distraction mobilization, and cervical stabilization exercises. Data of all subjects was used in the statistical analysis. There were no adverse events reported during the 4-week course of therapy.

All patients who participated in this study reported a clinically meaningful improvement in pain and function (see Table 3) after being managed with a combination of spinal decompression via SpineMED and spinal mobilization, as well as cervical stabilization exercises. Reduction in pain perception and disability index in maintaining activities of daily living were found to be statistically significant ($p<0.01$). There was statistically significant difference in the measurement of VAS between pre-intervention and discharge ($p<0.01$). The mean measure of discharge was 49% of the mean measure of pre-intervention (see Table 3). Furthermore, there was also a statistically significant difference in NDI between pre-intervention and discharge ($p<0.01$). The mean measure of NDI at discharge was 76% of the mean measure of pre-intervention (see Table 3). More details concerning the outcomes after treatment for VAS and NDI are provided in Table 3.

DISCUSSION

Although spinal decompression devices such as SpineMED or spinal mobilization or exercise have been widely promoted for the treatment of neck pain and radiculopathy secondary to disc herniation, studies on the efficacy of these treatment modalities are lacking. We believe that this study provides the first data pertaining to the efficacy of a multimodal approach consisting of spinal decompression via SpineMED and cervical spine mobilization as well as cervical stabilization exercises for the treatment of the cervical radiculopathy. In addition, findings from this study may be used to estimate the average number of treatments needed to reduce patient pain in the management of herniated discs of the cervical spine.

In this study, the patients reported a significant improvement in the mean measures of pain level and functional activities after being treated in 20 sessions of combined treatment. These findings correlate well with those of Beattie et al.⁴¹⁾ and Macario et al.⁴²⁾ as well as Gose et al.⁴³⁾ who reported significant improvements in VAS and/or a disability scale for patients with discogenic low back pain (LBP) after being managed with spinal decompression therapy in combination with other treatment modalities such as heat, cold, and transcutaneous electrical nerve stimulation. However, their study subjects were patients with discogenic LBP, not cervical radiculopathy, and the present study used a multimodal treatment approach as the intervention instead of a single specific treatment for the management of herniated disc.

One common cause of cervical radiculopathy is herniated intervertebral discs⁴⁴⁾, which stimulate pain or damage to the internal disc structure⁴⁴⁾. A previous study⁴⁵⁾ experimentally demonstrated that an increase in pressure within the intervertebral disc of a cadaver could cause annular rupture and disk herniation. This finding suggests that reducing

Table 3. Overall mean (\pm SD) of outcome measures at discharge compared with pre-intervention measures

Measure	PI	Discharge
VAS*	6.10 ± 0.73	3.00 ± 0.81
VAS score difference from PI		-3.10 ± 0.56
NDI score*	13.90 ± 1.37	10.60 ± 1.71
NDI score difference from PI		-3.30 ± 0.67

*Significant difference between pre-intervention and discharge ($p<0.01$).

Note. Values are mean \pm SD (standard deviation). VAS score range: 0 (no pain) to 10 (worst possible neck pain). NDI score range: 0 (no disability) to 50 (severe disability due to neck pain). VAS: visual analogue scale; NDI: neck disability index; PI: pre-intervention.

intradiscal pressure may play an important role in relieving pain related to disc herniation and promotion of healing in damaged discs. When pressure within the disc is greater than capillary pressure in the vertebral body as a result of a herniated disc, oxygen diffusion to the disc is impeded, which, in turn, may hinder the process of repairing the damaged disc⁴⁶⁾, since discs have no blood supply and mostly receive nutrients by diffusion²¹⁾. Previous experiments^{47,48)} showed that a spinal decompression system may promote displacement of fluid to a damaged disc by significantly lowering pressure within the disc using an unique type of traction which produces distractive tension to the affected spine without eliciting reflex paravertebral muscle contractions²¹⁾. Thus, the spinal decompression system may allow the flow of nutrients into the damaged discs, leading to rehydration of dried-out discs, promotion of disc metabolism and restoration^{47,48)}.

In the present study, in addition to spinal decompression and exercises, all of the patients received instrument-assisted flexion-distraction mobilization over a 4-week period of therapy that addressed symptoms of neck pain secondary to herniated disc. Improvements in VAS and NDI scores were noted after application of this treatment modality with other treatment protocols. Although studies on cervical flexion-distraction treatment are lacking, several possible explanations are suggested for the mechanical, physiological, and anatomical effects of this technique on the herniated disc. Flexion-distraction procedures redistribute mechanical loads normally in the affected spinal segment reducing irritation of associated joints⁴⁹⁾. As a result of redistributing mechanical load in the spinal joint, the process of healing of the damaged intervertebral disc is facilitated in nociceptive pain generators with dissipation of pathologic stress⁴⁹⁾. In addition, flexion-distraction procedures have also been demonstrated to increase the central canal diameter in the cervical spine⁵⁰⁾ and the lumbar disc spaces as well as facet joints⁵¹⁾, and decrease disc protrusion in the lumbar and/or cervical spine^{52,53)} as well as intradiscal pressure^{51,52)}. Furthermore, flexion-distraction procedures can decrease hypertonicity of the multifidi muscles that are assumed to play an important role in the maintenance of dysfunction and pain related to the herniated disc⁵⁴⁾.

Patients were also prescribed a cervical stabilization exercise program incorporating stretching, isometric/static or dynamic strengthening, and endurance training exercises using a sling device for the treatment of neck pain and radiculopathy. The neck pain and disability index clearly favored application of neck muscle training in combination with SpineMED and spinal mobilization. Differences in pre- and post-intervention VAS and NDI score were statistically significant. In the past, passive physical therapy and rest were the mainstream management of chronic neck pain⁵⁵). Thus, stressful exercises such as strengthening and endurance exercises or stretching exercises were avoided since pain often accompanies the initiation of stressful exercises, which was thought to worsen the condition of the neck pain. Several studies have shown strong evidence that neck strengthening training is beneficial for chronic neck pain as well as the disability it causes when frequency and intensity of training are applied appropriately^{56–59}). In addition, neck strength and range of motion can be improved through resistance training³¹). The findings of the current study as well as previous studies clearly suggest that an exercise training program should be included in the management of neck pain and radiculopathy.

This study had several limitations. There was a relatively small sample of patients and no control group. Thus, it was difficult to determine what changes in outcome measures actually resulted from treatment, placebo effect or spontaneous resolution. The study sample consisted of a sample of patients with cervical pain and radiculopathy secondary to herniated disc; thus, our findings can be generalized only to a similar group of patients. It is not known if the multimodal approach used in the current study would also be effective for managing patients who have different characteristics from our group of patients. No follow-up information was collected, so it was not possible to determine whether the observed improvements were temporary or permanent. Furthermore, there were no MRI and/or CT images taken post-treatment to evaluate the changes in the herniated disc after completing the 4-week course of therapy.

In conclusion, the findings of the present study provide significant evidence in support of the efficacy of a multimodal treatment approach using spinal decompression via SpineMED and cervical spine mobilization as well as cervical stabilization exercises over a 4-week period of therapy for patients with neck pain and radiculopathy secondary to herniated disc. The findings of this clinical trial and those of previous studies support the use of spinal decompression therapy, flexion-distraction mobilization of the cervical spine, and an exercise training program for the neck. Therefore, the multimodal treatment approach might be an asset in the management of the cervical spine disorders. It is our opinion that a well designed randomized controlled trial using a larger patient population needs to be performed to further enhance these conclusions regarding effectiveness of multimodal treatment approaches for discogenic neck disorders.

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