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The Effect of Motorized Spinal Decompression Delivered via SpineMED Combined with Physical Therapy Modalities for Patients with Cervical Radiculopathy

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Abstract. [Purpose] The purpose of the present study was to determine the effect of a 4-week course of motorized spinal decompression delivered via SpineMED combined with physical therapy modalities on the treatment of patients with cervical radiculopathy (CRP). [Subjects] A total of 10 patients with CRP (mean age, 34.70 years; age range, 23–48 years) participated in the study. [Methods] A 4-week course of spinal decompression delivered via SpineMED combined with physical therapy modalities was delivered to the patients for 6 days per week for the first two weeks, and four times per week for two additional weeks. The entire treatment consisted of 20 visits over 4-week period. Comparisons of changes in the visual analogue scale (VAS) and neck disability index (NDI) at pre-intervention and at discharge were analyzed using the paired t-test. [Results] There was a significant improvement in the outcome measures of VAS and NDI after 20 sessions of spinal decompression combined with physical therapy modalities. The mean values of discharge for VAS and NDI were reduced by 21% and 14% respectively, as compared with their mean values at pre-intervention. [Conclusion] The results from the present study suggest that the use of motorized spinal decompression delivered via SpineMED combined with physical therapy modalities appears to be a safe and efficacious, noninvasive treatment modality for patients with CRP.
Key words: Cervical radiculopathy, Spinal decompression, Physical therapy

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INTRODUCTION

Neck pain is considered a serious medical problem, which affects approximately 13% to 18% of the general population in industrialized countries, and is second only to low back pain in frequency[1–5)]. Prevalence of chronic neck pain lasting longer than 6 months at one time also ranges from 18.5% in females to 13.2% in males[6)]. Radiculopathy of the cervical spine is defined as a clinical syndrome resulting from damage to the dorsal or ventral nerve root, or both, that originates in the cervical spine as a result of mechanical compression and inflammation of nerve roots in proximity to the intervertebral foramen[7)]. The estimated annual incidence of cervical radiculopathy is approximately 85 per 100,000 people, and it is becoming a serious health problem in industrialized countries[8)] as it has been shown to lead to a high level of morbidity due to its effect on daily activities and quality of life[9–12)].

There are many problems that arise in the cervical

spine which may lead to cervical radiculopathy, including spondylosis, intraspinal or extraspinal tumors, nerve root avulsion secondary to trauma, meningeal or synovial cysts, arteritis, cerebral palsy, vascular abnormalities, or disc herniation due to disc degeneration[13]. Disc herniation, the most common cause of cervical radiculopathy, typically presents as pain in the neck, shoulder, arm, or chest and complaints of weakness, numbness/tingling, paresthesis, and radicular pain depending on the root or roots involved[14]. The most commonly affected level of cervical disc herniation is C6-7, followed by C5-6, and they encompass 90% of all cases[12,13].

Although surgery may be necessary in cases of intractable pain or progression of neurologic deficits in the most severe circumstances, the treatment option for cervical intervetebral disc herniation is essentially noninvasive[15]. Many noninvasive treatment options including cervical traction, anti-inflammatory medication, physical therapy, exercises, chiropractic manipulation and mobilization, or acupuncture are used to reduce neurological symptoms and neck pain related to cervical herniation or to enhance disc physiology and retard or reverse disc degeneration[16–21]. One of these treatment options is axial traction which has been widely used not only by physical therapists but also by neurosurgeons and orthopedists in a variety of clinical settings in an attempt to relieve neck pain by the herniated disc and irritated nerve roots[22–24]. Cervical traction may be applied in various ways such as motorized traction delivered via motorized pulleys, manual traction delivered by a therapist, and gravitational traction delivered through a suspension apparatus[25].

Motorized cervical traction is more frequently used by physical therapists, chiropractors, neurosurgeons, and orthopedists in clinical practice because of its greater standardization and repeatability in trials[25] as compared with other types of traction. There are several benefits for using cervical traction to treat cervical disc herniation. Previous studies[26] have reported decrease of the pressure in the intervetebral disc, unloading of the spinal structure, and relief of the inflammatory reaction of nerve roots with cervical traction due to improvements in circulation to the tissues and reduction of swelling of the tissues, as well as prevention of the formation of adhesions of the dural sleeve[26–28].

When traction is applied, the pull force of traction may elicit the body's protective proprioceptive response to distraction resulting in contraction of the paravertebral muscle, causing reduction of the distraction force[29]. Recently, several spinal decompression systems such as the DRX9000 (Axiom Worldwide, Tampa, FL, USA), vertebral axial decompression (VAX-D) (Vat-Tech, Inc, Palm Harbor, FL, USA), and SpineMED (CERT Health Sciences, LLC, Baltimore, MD, USA), newly developed systems for noninvasive treatment of discogenic neck pain (chronic or acute) have been used in a variety of clinical settings. Studies[30,31] have claimed that the new technologies used by these spinal decompression systems can decrease patients' protective proprioceptive responses to distraction allowing distraction of the spinal segment, thereby reducing intradiscal pressure and symptoms secondary to disc herniation. Other reports[32–34] have demonstrated improvements in visual analogue scale and/or in disability scales in patients with discogenic low back pain (LBP) after treatment with spinal decompression systems such as VAX-D and DRX9000. Although previous studies have reported that symptoms of acute and/or chronic LBP secondary to disc herniation might be relieved by intermittent axial decompression delivered via DRX9000 and VAX-D[32–38], to our knowledge there is no published data available as to the efficacy of motorized spinal decompression delivered via SpineMED to individuals with neck pain secondary to herniated intervetebral disc. Therefore, the purpose of the present study was to determine the effect of the spinal decompression delivered via SpineMED combined with physical therapy modalities such as superficial heat, ultrasound, and interferential current (ICF) on the treatment of patients with cervical radiculopathy.

SUBJECTS AND METHODS

A total of 10 patients with cervical radiculopathy (mean age, 34.70 ± 7.95 years; age range, 23–48 years) volunteered to participate in this study. To be included in this study the subjects met the following criteria. 1) Subjects were required to be between 18 and 60 years old with cervical radiculopathy. 2) Subjects must have been diagnosed with one of the following conditions: herniated disc, bulging or protruding intervetebral

discs verified by magnetic resonance imaging (MRI), computed tomography (CT), or conventional radiograph of the lumbar spine and clinical examination. 3) Subjects were required to have imaging evidence of herniated disc or bulging or protruding intervetebral discs at an involved spinal joint consistent with current symptoms, since structural imaging of herniated disc of MRI and/or CT and symptoms are often poorly associated[39–41]. 4) Subjects must have reported more than mild disability in activities of daily living due to neck pain that constituted a score of 5 to 10 on neck disability index (NDI)[42]. 5) Subjects must have had symptoms of cervical disc herniation for less than 2 months duration at presentation.

Participants were excluded if they had any of the following conditions: 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, use of prescription anticoagulants, corticosteroids, or opiate-based pain medication. Participants were also excluded if they were currently involved in a workers' compensation claim and a legal action regarding their symptoms secondary to neck pain.

All subjects were recruited at a regional spine care center where the current study was performed and examined by a neurosurgeon and a physical therapist with a collective 10 years of experience to check inclusion/exclusion criteria, and to address any questions regarding this study. All subjects signed an informed consent form prior to participating in the study and the local University Institutional Review approved this study. Tables 1 and 2 summarize subject characteristics as well as primary diagnoses and MRI findings of subjects.

The SpineMED spinal decompression system consists of a table and a cervical restraint system designed to comfortably capture the base of the patient's skull for controlled distraction. This cervical restraint system eliminates the variability and inconvenience of a traditional nylon cervical harnesses, and is controlled by a computer to provide cycling distractive forces along the axis of the cervical spine. The SpineMED device also has a disc angle pull adjustment system that is electronically tilted to the angle required to precisely target damaged cervical spine segments so that traction force can be applied to an isolated spinal disc slowly and cycle between brief moments of pulling and relaxing (oscillation) by employing a motor pulley programmed by a computer. The manufacturer claims that the features of this system eliminate the unnecessary treatment of additional segments and any resulting side effects, thus allowing for more efficient treatment and improved clinical results[43].

For treatment procedures, the cervical cradle unit was first electronically tilted to the required angle to target affected segments of the cervical spine. The clinician then positioned the subject lying supine on the SpineMED table with their head positioned in the cervical cradle unit and with the hips and knees flexed and the lower legs supported on a stool. The pull angle setting was 28 degrees for the C5–C6 level and 30 degrees for the C6–C7 level. The initial weight setting was 5–6 lbs for males and 4–5 lbs for females. The pulling weight was increased

Table 1. Subject characteristics

Characteristics	Values
Age (years)	34.70 ± 7.95
Sex (male/female)	3/7
Height (cm)	165.90 ± 9.03
Weight (kg)	60.80 ± 8.57
Side involved: left/right (%)	30/70
Location of pain	%
Pain in neck/scapular only	50
Pain below scapular, above elbow	30
Pain below elbow	20
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	40
Herniated disc and degenerative disc	60
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.

by 1 lbs per session as tolerated and the final pulling weight never exceeded 15 lbs for males and 12 lbs for females. The distraction and relaxation times were set at 60 seconds and 30 seconds respectively, and 50% of the pulling force used during the distraction period was maintained during the relaxation period. Each participant underwent sessions 6 days per week for the first two weeks followed by 4 sessions per week for two additional weeks. The total number of visits totalled 20 times over a 4-week course of therapy and treatment was delivered for 30 minutes in each session. Additionally, 15 minutes of superficial heating (heat pack) were provided followed by 5 minutes of ultrasound treatment (SM-250, Samson Med, Seoul, Korea) using a 1 MHz with a 5-cm^2 sound head at an intensity of 1.5 W/cm^2 in continuous mode and 15 minutes of IFC treatment (SM-850P, Samson Med, Seoul, Korea) at an intensity of 25 mA prior to treatment with SpineMED. Superficial heating, ultrasound, and IFC were all delivered 6 days per week for the first two weeks followed by 4 sessions per week for two additional weeks for a total of 20 sessions.

Subjects who met the inclusion criteria completed an outcome measure questionnaire before the start of intervention. Outcome measures were also surveyed at discharge from the therapy course. Outcome measures were a visual analogue scale (VAS)[44,45] and NDI. Pain intensity in a typical day due to neck pain was determined using an 11-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 been the most commonly used pain scale for people with neck pain and has a test-retest reliability of 0.60 to 0.70[46] and a concurrent validity of 0.76 to 0.84[46]. Reduced ability to manage activities in everyday life due to neck pain was estimated using the 60-point NDI[42]. NDI score was determined by the participant who rated 10 items; each item ranges from 0 (no back pain during activity) to 5 (severe pain during activity). NDI has a test-retest reliability coefficient of 0.89[42] and a concurrent validity of 0.69 to 0.70[42].

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

Table 3. Overall mean (± SD), mean difference (± SD) from outcome measures of post-intervention as compared to pre-intervention measures

Measure	Pre-intervention	Post-intervention
VAS*	6.20 ± 0.63	4.90 ± 0.73
VAS score difference from PI		–1.30 ± 0.94
NDI score*	13.80 ± 1.03	11.90 ± 1.19
NDI score difference from PI		–1.90 ± 0.31

*Significant difference between pre-intervention and discharge ($p<0.01$).
Note. Values are means ± SD (standard deviations).
VAS score range: 0 (no pain) to 10 (worst possible neck pain). NDI score range: 0 (none disability) to 100 (severe disability due to neck pain). VAS: visual analogue scale; NDI: neck disability index; PI: pre-intervention.

RESULTS

All subjects enrolled in the study completed 20 treatment sessions of a combination of spinal decompression therapy and physical therapy. All subjects participating in the study were included in the data analysis. No subjects reported adverse events during the 4-week course of therapy. Statistical analysis found significant differences in the mean measures of VAS and NDI between pre-intervention and discharge for subjects with discogenic neck pain ($p<0.01$). A statistically significant improvement was found for the mean measure of VAS at discharge as compared with the mean measure of VAS at pre-intervention ($p<0.01$). The mean measure at discharge was decreased by 21% as compared with the mean measure of pre-intervention ($p<0.01$). Furthermore, a significant improvement was also noted for the mean measure of NDI at discharge as compared with the mean measure of NDI at pre-intervention ($p<0.01$). The mean measure of discharge was reduced by 14% as compared with the mean measure of pre-intervention ($p<0.01$). Table 3 shows the details of the outcomes after treatment for VAS and NDI.

DISCUSSION

No previous studies have examined the effects of spinal decompression therapy delivered via SpineMED combined with physical therapy modalities for patients with cervical radiculopathy.

This study provides preliminary information on the outcomes after a 4-week course of combined treatment of spinal decompression and physical therapy for patients who suffered from neck pain secondary to disc hernination. Patients in the study reported statistically significant improvements in the mean measures of VAS and NDI after 20 sessions of treatment. Although there is no report in the literature on the efficacy of the intervention of a simultaneous combination of spinal decompression therapy and physical therapy modalities for patients with cervical radiculopathy, a combination of spinal decompression therapy and other treatment protocols has been shown to be beneficial for patients with discogenic LBP[32–34]. Patients with discogenic LBP demonstrated a significant improvement in VAS or disability scales such as the Oswestry Disability Index and the Roland-Morris Disability Questionaire after being treated with a combination of spinal decompression therapy and other treatment methods such as heat, cold, and transcutaneous electrical nerve stimulation.

The most common cause of cervical radiculopathy most likely arises from problems in the intervetebral discs[47], and pain secondary to disc herniation may be due to progressive posterior anular fibrosus breakdown and tearing leading to posterior herniation of the nuclear pulposus which results in pain or damage to the internal disc structure[47]. Previous studies[48,49] have reported that by significantly reducing intradiscal pressure, a spinal decompression system may create a diffusion gradient into the damaged discs allowing nourishment to proceed, ultimately promoting disc metabolism and restoration.

When pressure in the intervetebral disc is greater than capillary pressure in the vertebral body, oxygen diffusion to the disc is impeded, which, in turn, may hinder the healing process of the damaged disc[50], since intervetebral discs are avascular and receive nourishment primarily by diffusion[31]. A previous study[51] reported that pressures inside L4–L5 intervertebral disc were significantly decreased to –150 to –160 mm Hg when spinal decompression via VAX-D was delivered to patients who had a subligamentous herniation at L4-5 and were candidates for percutaneous discectomy. That study indicated that a threshold distraction tension may be necessary to develop negative pressures in the disc, thus the reduction of intradiscal pressure might have therapeutic effects on the herniated disc.

There were several limitations to the current study. First, there was a relatively small sample of patients with cervical pain and radiculopathy. Second, no placebo group, that is, placebo cervical traction, was included in the current study. Third, this study sample consisted of a sample of patients with cervical herniation; thus, our findings can be correlated only with a similar group of patients. Furthermore, in the current study no MRI and/or CT imaging was performed to evaluate the changes in the herniated disc after completing the 4-week course of therapy.

In conclusion, combined treatment of spinal decompression delivered via SpineMED and physical therapy modalities over a 4-week course significantly improved clinical outcome measures of VAS and NDI in patients with cervical radiculopathy. The results from the present study suggest that the use of motorized spinal decompression delivered via SpineMED combined with physical therapy appear to be a safe and efficacious noninvasive treatment modality for patients with cervical pain and radiculopathy. However, we acknowledge that there is a need for randomized controlled trials using a larger patient population to compare spinal decompression therapy and combined therapy using a multidisciplinary treatment approach to the conventional traction treatment.

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