

Conservative Treatment of Pain and Disability due to Spinal Degenerative Changes using Controlled Biofeedback Decompression Mechanical Axial Traction

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Abstract

Background: Conservative care for degenerative spinal conditions includes several modalities of treatment. Thus, the traction distinguishes as it is capable to elicit the body's protective proprioceptive response to distraction, reducing intradiscal pressure and minimizing symptoms secondary to disc herniation and axial pain.

Objectives: This work aims to determine the clinical effects of a short treatment course of motorized axial spinal decompression for patients with pain and physical impairment, caused from either lumbar or cervical degenerative disc pathology with no immediate surgical indication.

Methods: A prospective, non-randomized, single center, case series study from patients with both axial and irradiated symptoms from cervical or lumbar spine. Subjects were submitted to a traction protocol using a motorized mechanical axial decompression system (SpineMED®, LAS Brasil, SP). Clinical outcomes as VAS and ODI for lumbar patients 17 and NDI for cervical patients were also collected.

Results: Clinical outcomes improved along the treatment. AP-VAS scores showed an overall reduction of 59% ($p < 0.001$), while IP-VAS scores improved in 56% in the last session ($p < 0.001$). Average ODI showed statistical significance at last session (28 to 18; $p = 0.014$). Average NDI also showed statistical significance at last session (30 to 20; $p < 0.001$). Despite some minor adverse events, no major complication occurred during treatment.

Conclusion: This present spinal decompression treatment significantly improved patient's clinical outcomes, indicating that this modality of treatment is a safe and effective noninvasive alternative for patients with cervical or lumbar axial pain and radiculopathy.

Keywords: Spine; Conservative treatment; Radiculopathy; Pain; Traction

Introduction

Conservative care for mid to long-term degenerative spinal conditions with axial and irradiated pain generally includes pharmacological treatment, physical rehabilitation, or injections [1]. Mechanical traction is an old treatment modality, which had been decreased in use facing other modern technologies, or utilized in combination with other treatment modalities, such as manual therapy, exercises, heat or electrotherapy [2]. Patients with chronic axial spinal pain, defined as a referred pain in the axial skeleton and considered as a syndrome with both nociceptive and neuropathic pain components [3], reported improvement in symptoms with reduction of the axial load in the spine [4]. Previous studies have shown decrease of pressure in the intervertebral disc after traction, unloading of the spinal structure, and alleviating the inflammatory reaction of the nerve roots [2,5].

The objective of this work was to determine the effect of a short treatment course of motorized axial spinal decompression for patients with pain and physical impairment, caused from either lumbar or cervical degenerative disc pathology with no imminent surgical indication. In that goal, this work aims to report clinical outcomes, drop-offs and adverse events.

Methods

This is a prospective, non-randomized, single center, case series study. Patients were enrolled from January to June 2014. All patients signed an informed consent to participate in this study and gave their permission for the publication these data. Cases indicated for conservative treatment were referred by local spine surgeons mainly

due to axial and irradiated symptoms from cervical or lumbar spine. Cases were evaluated with inclusion/ exclusion criteria. Inclusion criteria: non-acute sciatica and/or peripheral radicular symptoms (> than four weeks) due to herniated or bulging disc, persistent pain from degenerated discs not responding to clinical treatment, and mechanical low back pain. Exclusion criteria: spinal instability, pars defects, unstable spondylolisthesis, gross osteoporosis, spinal tumor, arthrodesis at the index or adjacent levels, pregnancy, and patients under the age of 15 years old.

Selected participants were submitted to 20-25 sessions of treatment, 30 minutes each in duration, typically administered 3-5 times per week over a 4-6 week period. The procedure is performed with the patient fully clothed, and must be carried out in a pain free fashion. It was utilized a computer controlled motorized mechanical axial decompression system (SpineMED®, LAS Brazil, SP). The system consists of a table, with lumbar and cervical comfortable capture apparatus, that is controlled by a computer to provide cycling distractive forces along the axis of the spine. The device has angle adjustment that is electronically tilted to apply the traction force to

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an isolated spinal disc. The computer controlled biofeedback response adjusts distractive forces at an astounding rate of 20 milliseconds (the human neurological response is approximately 50 milliseconds), so can distract the spine without eliciting reflex muscle contractions or spasms (reflex arc bypasses) that impair smooth axial distraction.

The starting distractive lumbar force to be used for the patient was calculated according to the body weight. The protocol is composed of a series of two force phases per cycle, which consisted of a 60 second "Maximum Tension" distraction phase (high force), and a 30 second "Minimum Tension" relaxation phase (low force) for an approximate total period of 30 minutes. For the high force, the distractive tension was calculated as $\text{Body weight} \times 1/4 - 4.5 \text{ KG}$. For the low force, the distraction tension was set as $\text{High force tension} \times 1/2 + 3.5 \text{ KG}$. The decompression started from a beginning force of zero KG and slowly built up to the maximum force [6]. Each workout must be increased 2-4 Lbs for women and 3-5Lbs for men, always based on the patient's clinical status.

The initial cervical treatment was 5-6 Lbs for males and 4-5 Lbs for females. The pulling weight was increased by 1 Lbs per session and final pulling weight never exceeded 15 Lbs for males and 12 Lbs for females [7].

The patient is placed in supine position on the table. Treatments were carried out individualized by the characteristics of each patient by a quick set up into the computer. For lumbar treatment (Figure 1), the upper torso is captured through the lower margin of the ribcage by a comfortable attaching system incorporated to the fixed section of the table. The pelvic support gently rest over the patient's iliac crest, and is electronically tilted to rotate the pelvis, and apply the distraction forces directly to the skeletal structure. For cervical procedures (Figure 2), the cervical unit is first electronically tilted to the angle required to target specific segments of the cervical spine through flexion. The patient is then placed on the table with their head positioned in the cervical cradle unit. The patented Cervical Restraints are designed to comfortably capture the base of the patient's skull for direct and controlled distraction.

Clinical outcomes were obtained at baseline (before treatment), at the 10th session, and at the final session. The primary outcome was pain relief. Axial lumbar and cervical pain were assessed using a Visual Analogue Scale (AP-VAS). Irradiated pain (legs or arms) was assessed by VAS (IP-VAS). Secondary outcomes were related to daily activities and return to work. Physical function was assessed by Oswestry Disability Index (ODI) questionnaire.

The minimum clinically important difference (MCID) was also used

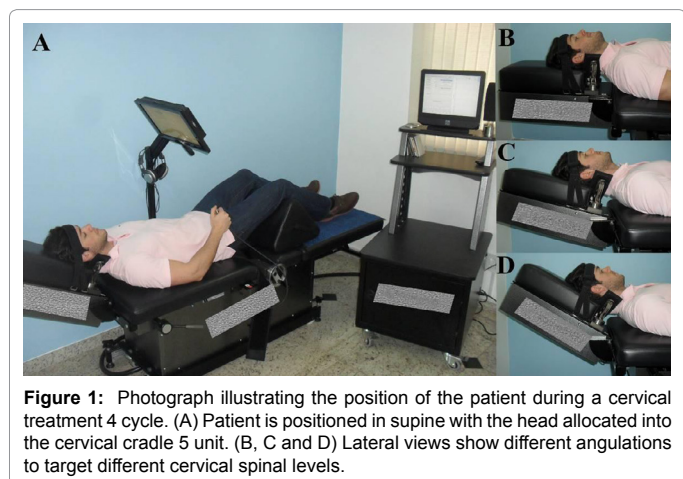


Figure 1: Photograph illustrating the position of the patient during a cervical treatment 4 cycle. (A) Patient is positioned in supine with the head allocated into the cervical cradle 5 unit. (B, C and D) Lateral views show different angulations to target different cervical spinal levels.



Figure 2: Photograph illustrating the position of the patient during a lumbar treatment cycle. (A) Patient is positioned in supine with the torso and iliac crest attached. (B, C and D) Lateral views of the lumbar unit show different angulations to target different lumbar spinal levels.

as an additional method to analyze self-assessed clinical outcomes. MCID represents a threshold clinical change that is considered meaningful enough to the patient to justify the intervention and its associated cost and risk. Accordingly to Norman et al., [8] it was used a distribution-based approach to estimate and apply the MCID values. Questionnaires scores that overcome MCID values were considered clinically meaningful. Paired t-test was used to compare two mean values, and statistical significance was set for alpha equal to 0.05 or 5%.

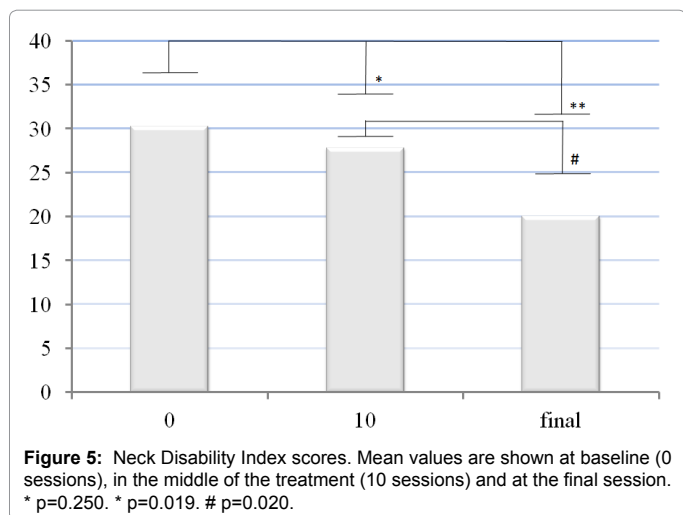
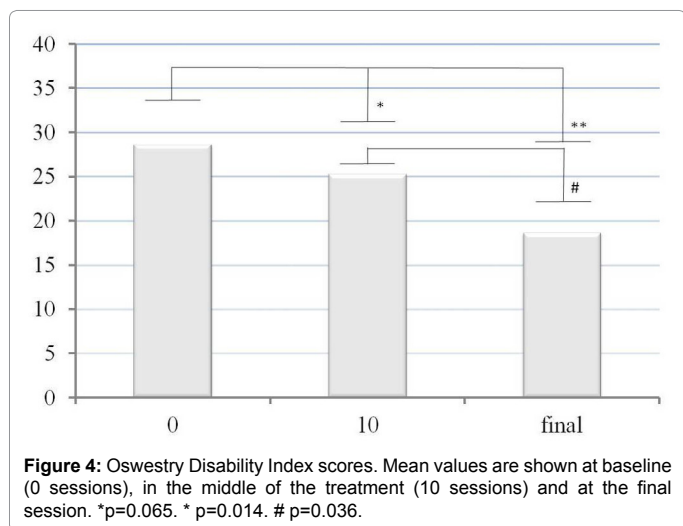
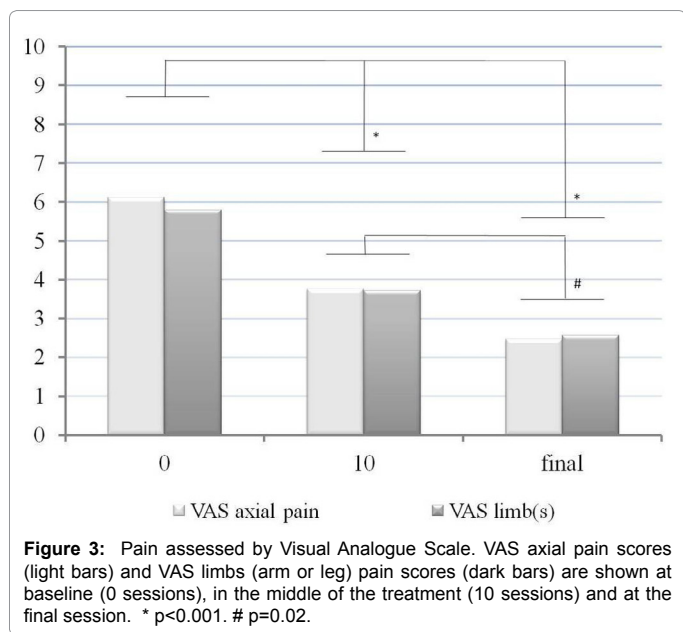
Results

Demographic, clinical presentation and radiological findings are shown in Table 1. The sample was composed of 18 lumbar and 9 cervical cases. The gender ratio was 66% / 33% (male / female), with a mean age of 49 years old (26-94, range). Axial (back or neck) pain was present in all cases, in exception of one C5C6 herniated nucleus pulposus case (HNP) that presented only arms paresthesia and carpal tunnel syndrome. In lumbar cases, 50% had irradiated symptoms along with LBP. In cervical cases, only 2 cases (22%) had isolated neck pain. Affected disc levels included C3 to C7 in cervical spine and from L2 to S1 in lumbar spine. For the lumbar treatments, 16 out of 18 cases had L4L5 as one of the symptomatic levels. In the cervical cases, 7 out of 9 had C5C6 as one of the pathological players.

Clinical outcomes (pain and disability) were quantified in self-assessed questionnaires and improved along treatment (Figures 3-5). AP-VAS scores showed a 39% improvement at the first checkpoint (10th session; $p < 0.001$) further improving to a 59% reduction at last session ($p < 0.001$). IP-VAS scores was also significantly lowered at the 10th session (36% improvement; $p < 0.001$) and was further lowered until the last session, when a 56% improvement was observed ($p < 0.001$). Average ODI scores presented a statistical tendency ($p = 0.065$), diminishing from 28 to 24 at the 10th session point (15% reduction). Nevertheless, at the last session this reduction was magnified to 36% (28 to 18; $p = 0.014$). Average NDI scores did not present a statistical reduction ($p = 0.250$), diminishing from 30 to 28 at the 10th session point (8% reduction). Nevertheless, at the last session this reduction was increased to 34% (30 to 20; $p = 0.020$). In addition to comparison of average scores, the self-assessed outcomes were also submitted to analysis of the MCID in order to evaluate if the changes overcome the threshold for an important clinical change. MCID values were 1.0 points for AP-VAS scores, 1.6 points for IP-VAS scores, 6.7 points for ODI scores and 4.1 points for NDI scores. All decreases in clinical outcomes overcame MCID values, in exception the ones obtained in ODI and NDI at the 10th session. Four out of 27 cases had not been

#	Age	Gender	Pathology	Symptoms	Radiology	# of sessions	Frequency	Previous treatments	Adverse events (session #)	Unsuccessful treatment or drop-off
1	94	M	Lumbar	LBP + neurogenic claudication	Central stenosis from L2-L5	20	daily	-	-	-
2	39	M	Lumbar	LBP	L4L5 and L5S1 DDD	25	daily	Physiotherapy, hydrotherapy, pilates, and radiofrequency	-	-
3	42	M	Lumbar	LBP + gluteal pain	L4L5 bulging disc; L5S1 HNP	23	daily	Hydrotherapy	-	-
4	66	M	Lumbar	LBP + leg pain and numbness	L2-L4 spondylolisthesis; L4L5 and L5S1 HNP	23	daily	Physiotherapy and postural education	-	-
5	36	M	Lumbar	Dynamic LBP	L5S1 DDD	2	daily	Hydrotherapy	muscle spasms (1;2)	drop-off
6	45	M	Lumbar	LBP	L3L4 and L4L5 bulging disc	24	daily	-	-	-
7	41	M	Lumbar	LBP e irradiated pain to ASIC	L4L5 and L5S1 bulging disc	24	daily	Physiotherapy	-	-
8	51	F	Lumbar	LBP + leg pain + neurogenic claudication	L4L5 central stenosis and L5S1 bluding disc	25	daily	Physiotherapy, exercising, postural education, hydrotherapy, and acupuncture	-	no relief after treatment - surgical procedure
9	35	M	Lumbar	LBP + leg pain	L4L5 HNP, and L5S1 DDD	25	daily	-	-	-
10	88	F	Lumbar	LBP	L4L5 and L5S1 HNP	20	daily	Physiotherapy and hydrotherapy	-	-
11	26	M	Lumbar	LBP + gluteal pain	L5S1 DDD and bulging disc	25	daily	Fisioterapia, acupuncture, postural education , and NSAIDs	-	poor relief after treatment - surgical procedure
12	58	M	Lumbar	LBP	L4L5 HNP	20	daily	Hydrotherapy	-	-
13	49	M	Lumbar	LBP	L4L5 DDD	20	daily	Physiotherapy, pilates, injections, and acupuncture	-	-
14	57	F	Lumbar	LBP + leg pain	L4L5 HNP, degenerative scoliosis	25	daily	Physiotherapy and acupuncture	-	-
15	57	M	Lumbar	LBP	Bulding disc from L2 to S1	8	daily	Physiotherapy, pilates, and acupuncture	-	treatment interrupted by personal reasons
16	30	M	Lumbar	LBP	L4L5 HNP	25	3 times/week	Osteopatya, isostretching, and exercising	-	-
17	64	M	Lumbar	LBP + leg pain	L4L5 DDD	25	daily	Laminectomy (20 years ago), NSAIDs, and pain killers	-	-
18	46	F	Lumbar	LBP + leg pain	L4L5 DDD, and L5S1 HNP	20	daily	Physiotherapy and acupuncture	-	-
19	41	M	Cervical	Cervical pain + arm pain	Bulging disc from C3 to C6	25	daily	Physiotherapy	-	-
20	42	M	Cervical	Cervical pain + arm pain	C3C4 and C4C5 DDD; C5C6 and C6C7 HNP	25	daily	Physiotherapy and hydrotherapy	dizziness and vertigo (20)	-
21	41	F	Cervical	Cervical pain	C5C6 and C6C7 degenerative spondylolisthesis	25	daily	-	-	-
22	73	F	Cervical	Arms paresthesia + bilateral CTN	C5C6 HNP	20	daily	-	dizziness and vertigo (13)	-
23	47	F	Cervical	Cervical pain + arm pain	C5C6 HNP	21	daily	Physiotherapy, postural education, and acupuncture	dizziness and vertigo (6)	-
24	65	F	Cervical	Cervical pain + arm pain	C5C6 HNP	18	daily	Physiotherapy, postural education, injections, and NSAIDs	dizziness and vertigo (15)	rotator cuff surgery - drop-off
25	35	F	Cervical	Cervical pain + shoulder pain	C4C5 and C5C6 DDD and HNP	23	daily	Physiotherapy	-	-
26	35	M	Cervical	Cervical pain + rotator cuff lesion	C6C7 HNP	20	3 times/week	Physiotherapy	-	-
27	31	M	Cervical	Cervical pain + arm pain	C6C7 foraminal stenosis	20	3 times/week	Physiotherapy	-	-

Table 1: Demographic, clinical presentation and radiological data.



working before the treatment, and three of them (75%) returned to work during treatment or as soon as the treatment was completed.

Adverse events and unsuccessful treatments are detailed in Table 1. Five out of 27 patients (19%) had minor adverse events. Four patients treated for cervical disc (44% of cervical of subgroup) conditions experienced temporary dizziness and/or vertigo. These occurrences took place by the time that patient had substantial pain relief, and then abandoned cervical and head antalgic positioning (low cervical spine flexion and upper cervical spine extension). The average time to clearance of these symptoms was 2.3 weeks (1-3, range).

During the study, there were 4 drop-offs (14%). One patient (#5) with dynamic LBP tried two sessions, but experienced back pain and muscle spasm after the treatment, deciding to interrupt the study protocol. Two lumbar patients (#8 and #11) decided to go to surgery due to unsatisfactory pain relief after the entire treatment. One patient (#15) decided to discontinue the treatment due to personal reasons, and only received 8 sessions.

Discussion

This work followed patients with back or neck pain with or without irradiated symptoms, due to degenerative spine conditions, treated with motorized axial spinal decompression. Axial and irradiated pain decreased in the initial stage of treatment, and physical disability in daily activities was gradually improved, as it would be expected [7]. Despite some minor adverse events, such dizziness and vertigo, no major complication occurred during the study protocol.

History and Traction Modalities

Spinal traction has been utilized since Hippocrates [9], but its efficacy has not been elucidated [10]. Yet, there are some controversies about its physiological basis and application benefits for the patient. Accordingly to Piercy et al. [11], traction is conceptually a longitudinal stretching force applied to the spine. Kendal et al. [12] has defined it as a therapeutic force placed in order to perform an elongation and stretching of the periarticular structures, and can be carried out manually or through a traction machine. As the spine movement is globally distributed between each spinal segment, it is expected that the lymphatic and blood flow increases by the reduction of nerve root compression, leading to a better nutritional status and removing inflammatory debris, thereby alleviating irradiated pain [13]. Thereby, this present device enhances intervertebral vascularization, nutrition and regeneration by diminishing intradiscal pressure that favors the gradient difference and provides hydration of the intervertebral disc.

Differently from other traction mechanisms, the SpineMED® device is capable to target the levels to be tractioned. Moreover, the continuous monitoring of the traction force, and the responsiveness of muscle spasms attenuated by an infra-red radiation that minimizes the extent of contraction of lumbar muscles (bypassing reflexes) in rest during traction cycles, leads to a reduction in intervertebral disc pressure [14] and an improvement of patients' clinical symptoms [7].

Clinical Indications

Randomized clinical trials have failed to find consistent data for various treatment approaches usually utilized in physical therapy strategies including exercise, manual therapy, and traction [15]. Several authors have indicate that when a more subgroups of patients with low back pain (LBP) are studied, the power of clinical results are enhanced, but most researches utilize an heterogeneous group of patients with LBP that mask the benefits of this present technique [16].

Surveys [17-20] indicate that the presence of sciatica is the primary condition to a subgroup for which traction is most beneficial. In addition, patients who also have signs of nerve root impingement, a positive straight leg raise test, or fail to show centralization of symptoms during examination seems to likely benefit from mechanical traction [21]. These findings corroborate with worse clinical results found in patient (#5) that presented dynamic LBP and experienced back pain and muscle spasm after only two sessions, leading to the interruption of his treatment.

Clinical Outcomes and Return to Work

Results following small groups, heterogeneity, different modalities, combination of treatments, and non-standardized indications can be pointed out as weak points of the studies with traction modalities, and seems to blur the consensus about traction efficacy [2,22]. Differently, this paper shows good clinical results in self-assessed questionnaires, regardless of the patient's surgical history or clinical symptoms. AP-VAS scores showed an overall reduction of 59% ($p < 0.001$), while IP-VAS scores was improved in 56% at the last session ($p < 0.001$). Average ODI scores presented no a statistical tendency reduction ($p = 0.065$) at the 10th session visit, but showed a statistical significance at the last session (28 to 18; $p = 0.014$). Average NDI scores presented no statistical reduction ($p = 0.250$) at the 10th session visit, but showed a statistical significance at the last session (30 to 20; $p = 0.020$). Even when the self-assessed outcomes were submitted to analysis of the MCID, all clinical outcomes overcame the threshold for an important clinical change, in exception to the ones obtained in ODI and NDI at the 10th session. Besides, four patients were incapable of working before the treatment, with 75% of them returning to work during the treatment or as soon as the treatment was completed. In this way, changes in health behaviors and increasing the conservative treatment options have the potential of reducing medical care costs as well as generating greater satisfaction among patients, doctors, and care managers [23].

The dropout rate in this series was 14% (4 patients), but due to a small number of subjects, it was not possible to elucidate the real impact of dropouts in the overall analysis of the results. However, this probably represents the therapeutic limitation of the device, being these patients those who have not achieved satisfactory results with this treatment modality, and opted for more aggressive treatments.

Complications

The most frequent complication found in this series of cases is a temporary dizziness and/or vertigo, present in 44% of patients from cervical subgroup. The vertebrobasilar system is responsible for the irrigation of the labyrinth, the vestibulocochlear nerve and the auditory and vestibular pathways of the brainstem and cerebellum [24]. Several cervical conditions lead to vertebrobasilar insufficiency due to its compression and decreased blood flow in its territory of irrigation, which can cause the onset of labyrinthine symptoms such as dizziness, vertigo, imbalance, falls, hearing loss, tinnitus and weakness in the extremities [25]. By the way, these findings took place by the time that patient had substantial pain relief, and then abandoned cervical and head antalgic positioning. As the irritation on the cervical proprioceptors from muscle spasms and trigger points decreased, the symptoms were alleviated. The average time for resolution of symptoms was 2.3 weeks (1-3, range), and patients remained asymptomatic throughout the entire evaluation.

Limitations

In this survey patients filled out several self-assessed questionnaires

(VAS, ODI, NDI). These tools limit the results of our study and questionnaire-based studies in general, due to the comprehension of the questions by patients. Other issue is the fact that with a limited number of subjects, it is not possible to elaborate a more sophisticated statistical evaluation. Thus, neither the dropouts nor the intention of treatment analysis could be performed. However, the results found in this study bring to patients, physicians and care managers an initial pathway in the conservative treatment of cervical and lumbar axial pain through a controlled biofeedback decompression mechanical axial traction device.

Conclusion

This present spinal decompression treatment provided by the computer controlled motorized mechanical axial decompression system over a 4-6 week period has been proved to significantly enhance clinical outcomes of VAS and ODI/NDI self-assessment questionnaires. The results indicate that this modality of treatment is a safe and effective noninvasive alternative for patients with cervical or lumbar axial pain and radiculopathy. However, this work represents an analysis of single center experience based on a small case series with no after-treatment follow-up, so conclusions are limited to the study design drawbacks. Due to this study design, a general analysis is beneficial to give the authors and readers the clinical results of an initial experience but due to the small number of patients, it is not possible to divide into subgroup (such as cervical and lumbar treatments) to have further inferences. To bypass these limitations and provide reliable data, this article does not extrapolate its findings.

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