

The Efficacy of Lumbar Extension Traction of Sagittal Alignment in Mechanical Low Back Pain: A randomized controlled trial

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ABSTRACT

Objective: This study was conducted to investigate the effect of lumbar extension traction on the pain, function and whole spine sagittal balance as represented in lumbar curvature, thoracic curvature, C7 plumb line, and sacral slope. **Design:** A randomized controlled study with six months' follow-up. **Patients:** Eighty patients with chronic mechanical low back pain (CMLBP) and definite hypolordosis were randomly assigned to traction or a control group. **Interventions:** The control group (n=40) received stretching exercises and infrared radiation, whereas the traction group (n=40) received lumbar extension traction in addition to stretching exercises and infrared radiation three times a week for 10 weeks. **Main outcome measures:** Back pain rating scale, Oswestry Disability Index, and radiological spine sagittal balance parameters in terms of lumbar lordosis, thoracic kyphosis, sacral slope, and positioning of C7 plumb line were measured for all patients at three intervals (before treatment, after 10 weeks of treatment, and at six months follow-up). **Results:** There was a significant difference between the traction and control groups adjusted to baseline value of outcome at 10 weeks post treatment with respect to lumbar lordotic curve ($P=0.000$), thoracic kyphosis ($P=0.013$), sacral slope ($P=.001$), C7 plumb line distance ($P=0.001$), while there was no significant difference with respect to pain ($P=0.29$) and Oswestry Disability Index (ODI) ($P=0.1$). At 6-months follow-up, there were significant differences between both groups for all the previous variables ($P<0.05$). **Conclusions:** Lumbar extension traction in addition to stretching exercises and infrared radiation improved spine sagittal balance parameters and decreased pain and disability in CMLBP.

Keywords: Traction, Mechanical low back pain, Randomized Controlled Trial.

INTRODUCTION

Various studies point to the fact that loss of the lordotic lumbar curve has been identified as a major risk factor for

low back pain^{1,16,42}. This abnormal posture results in degenerative changes in the muscles, ligaments, bony structures and neural elements⁴¹. It is also believed that lumbar lordosis contributes significantly to maintaining spinal balance³⁷. Many studies argue that loss of lumbar lordosis is one of the most contributing factors for fixed sagittal imbalance^{3,35}, that justify the growing interest of lumbar lordosis as an important clinical outcome in the treatment of spinal disorders¹⁰.

Harrison et al's work in this area was pioneering in its reference to the possibility of lumbar sagittal curve correction with 2 way lumbar traction¹⁸. To date, no published randomized controlled trial addressed the issue of lumbar curve correction by this type of traction. Only two non-randomized trials were conducted pertaining to the cervical and lumbar regions^{18,19}. Despite the importance of these studies, all attempts to assess the efficacy of this type or other types of traction on the restoration of the sagittal curve¹⁷, have generally relied on radiographs to determine the global or segmental magnitude of the lordosis, and questionnaires to assess pain, while ignoring the assessment of global sagittal balance that is recognized as an important aspect to be considered in the rehabilitation of spinal disorders^{12,24}.

To my knowledge, no randomized study has quantified the effect of lumbar lordosis correction on spine sagittal balance or other clinical outcomes in cases of chronic mechanical low back pain (CMLBP). Specifically, despite the widespread inclusion of postural correction in therapeutic interventions, there is limited experimental data to support its effectiveness. Accordingly, the aim of the present study was to investigate the effects of lumbar extension traction on pain, disability and whole spine sagittal balance as represented in lumbar curvature,

thoracic curvature, C7 plumb line, and sacral slope.

METHODS

A prospective, randomized, controlled study was conducted at the Farouk Hospital. All of the patients were conveniently selected from the outpatient clinic. The patients signed an informed consent form prior to data collection.

Study population

Patients were recruited from December 2009 to October 2010 with six months of follow-up. The patients were screened prior to inclusion by measuring the Cobb angle. If the angle was less than 40°, the patient was referred to the study. Patients were included if they had CMLBP with symptoms lasting longer than 3 months to avoid the acute stage of inflammation. The patients were randomly assigned to either the treatment group (n=40) or the control group (n=40). An independent person who was blinded to the research protocol and was not otherwise involved in the trial operated the random assignment by picking one of the sealed envelopes which contained numbers chosen by random number generator. Exclusion criteria included spinal canal stenosis, rheumatoid arthritis,

osteoporosis, inability to tolerate the lumbar extension position, scoliotic deformity and any lower extremity deformity that may interfere with global alignment. A diagram of patients' retention and randomization throughout the study is shown in figure 1. The figure shows that 130 patients were initially screened. After the screening process, 84 patients were eligible to participate in the study and 80 completed the first follow up, and 71 of them completed the study.

The patients in both groups received stretching exercises and infrared radiation to control pain and eliminate the causal role of muscle spasms and/or tightness in changing the magnitude of lumbar lordotic curve. During the infrared application, the patients were asked to adopt prone position where the area to be treated (the low back) was adequately exposed. The lamp was positioned at distance ranged from (50-75cm). The radiation strikes the surface at or near right angle to achieve maximum penetration. The duration of application was fifteen minutes per session 3 times a week for 10 weeks³³. Stretching exercises were performed for the erector spinae muscles and hamstring muscles. Each movement was held for 30 seconds, and each exercise was repeated 3 times. The stretching program was performed 3 times a week for 10 weeks²⁶.

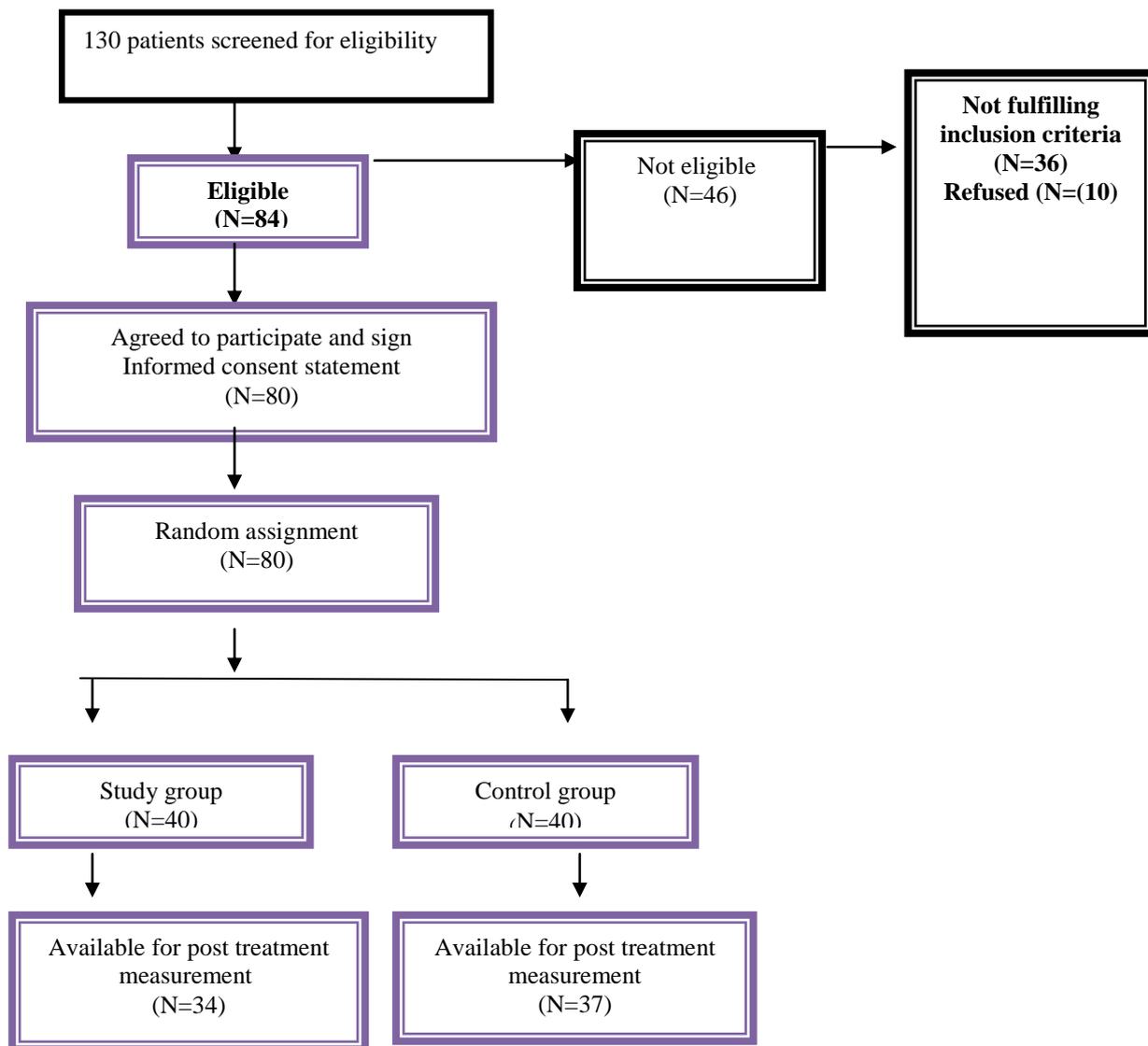


Fig. (1): Flow of study participants.

The traction group additionally received lumbar extension traction. All the traction procedures were done according to Harrison et al's protocol¹⁸. The only exception was the use of a computerized traction unit (Electronica Ragania 356, Alfatrac 1, Italy), that ensured gradual increase and decrease of the traction force to be more comfortable. In this type of 3-point bending traction, each subject lied in a supine position; an anterior pull was applied by a posterior padded strap between the upper torso and lower pelvis, which placed under the patient's low back, at the level of lumbar curve. The tension in the strap was the transverse force (part 1 of 3-point bending) and was adjusted to each patient's tolerance. whereas the second strap at the level of the femur heads (part 2 of 3-point bending) constrained the femurs to permit increased

forward rotation of the pelvis and the third strap placed at the upper torso (part 3 of 3-point bending) (Fig. 2). The patients were having traction three times a week for ten weeks. The traction began at three minutes/session, increased by one minute/session to 20minutes. After they became familiar with the traction, patients were encouraged to use the maximum tolerable force. The patients in both groups were instructed to avoid any other exercise programs that could interfere with the results.



Fig. (2): Extension traction.

The main outcome variable was the lumbar lordotic curve. The secondary outcome measures included other sagittal balance parameters, disability, and back pain. For measuring lumbar lordotic curve and other sagittal balance parameters, a 36-in lateral X-ray film including the entire spine were obtained before treatment, 10 weeks afterwards and at 6 months of follow-up. All X-ray films were obtained with the patient standing with arms crossed and knees fully extended to minimize any compensatory mechanisms may affect the whole sagittal balance. The following items were measured: lumbar curve (L1–L5) (using the Cobb method), thoracic curve (T5–T12), sacral slope, and the C-7 plumb line. The extent of lumbar lordosis was measured from the superior endplate of L-1 to the inferior endplate of L-5. The thoracic curvature was measured from the superior endplate of T-5 to the inferior endplate of T-1. Sacral slope defined as the angle between the horizontal and the sacral plate (Fig. 3). As computer and manual measurements of spinopelvic parameters have been shown to have high intra- and interobserver reliability¹⁴, all

measurements were performed digitally using surgimap software.

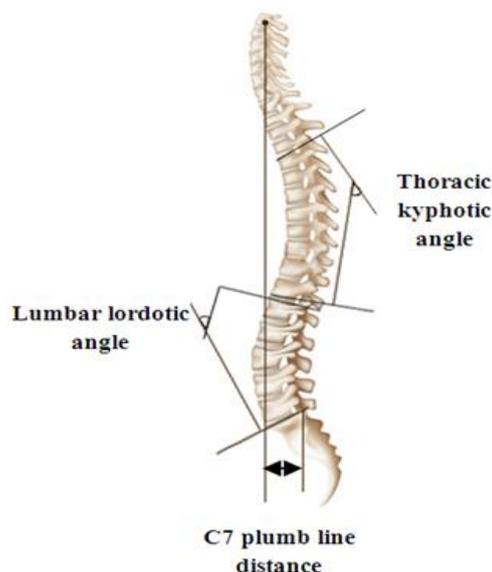


Fig. (3): Sagittal alignment.

In addition to radiological assessment, pain intensity and disability were also measured for all patients at three measurement intervals (before treatment, 10 weeks afterwards and at 6 months of follow-up). The back pain was measured by the visual analogue scale (VAS), which is considered as a valid and reliable scale used to measure the patient pain intensity³⁸. The scale is composed of 0-10 numbers. The Patients were asked to place a mark along the line to denote their pain level; 0 reflecting "no pain" and 10 reflecting the "worst pain".

Disability was measured using the Oswestry Disability Index (ODI). It consists of 10 items that refer to activities of daily living that might be disrupted by low back pain. The items are: 1. pain intensity, 2. personal care, 3. lifting, 4. walking, 5. sitting, 6. standing, 7. sleeping, 8. sex life, 9. social life, and 10. traveling. Each with 1 of 6 possible answers provided. The total score is transferred onto a scale ranging from 0 to 100, where 0 indicates no disability and 100 indicates worst possible disability³⁴. The outcome assessor, who also applied the treatment intervention programs, was not masked during the study.

Sample size determination

A prior power calculations indicated that 27 patients were needed in each group to detect a difference in lumbar lordotic angle between the groups at 90% power, a 5% significance level, a 2-tailed test, and an expected effect size of $d = 0.9$ based on pilot research consisted of 10 patients who received the same program between June 1, 2009, and September 31, 2009. The mean change and standard deviation were estimated as 5.2 and 5.7, respectively. To account for high drop-out rates, the sample size was increased by 40%.

Data Analysis

To compare the traction group and the control group, Statistical analysis was based on the intention-to-treat principle, and P-values less than 0.05 were considered significant. Multiple imputations were used to handle missing data. To impute the missing

data multiple regression models were constructed including variables potentially related to the fact that the data were missing and also variables correlated with that outcome. Stata was used (Stata Corp, College Station, Texas, USA). Analysis of covariance (ANCOVA) at two follow-up points (after 10 weeks of treatment and at follow-up of six months) was performed for all variables, the baseline value of the outcome as covariates was used to assess between group differences. (baseline outcome in the model = baseline value – overall mean baseline value).

RESULTS

Base line participant characteristics

The clinical and demographic features of the patients at inception are presented in Table 1.

Table (1): Baseline participant demographics.

	Study group (n=40)	Control group (n=40)
Age (y)	46.3±2.05	45.9±2.1
Height(cm)	172±9	175±10
Weight(kg)	75±9	80±10
Gender (%)		
Male	22(55%)	23(57.5%)
Female	18(45%)	17(42.5%)
Employment status		
Full time	25(62.5%)	18(45%)
Part-time	11(27.5%)	10(25%)
Unemployed	4(10%)	12(30%)
Smoke cigarettes currently		
Yes	12	19
No	28	21
Previous back pain treatment (yes: no)		
Surgery	0	0
Medication	29	30
Physical therapy	5	7
Other	6	3

SD, standard deviation, the values are mean (SD) for age, height, weight, duration of current pain, and duration since first onset.

Between group analysis

Results are summarized and presented as mean (SD) in table 2. After 10 weeks of treatment, the analysis of covariance (ANCOVA) revealed a significant difference between the traction and control groups adjusted to baseline value of outcome for all the following variables; lumbar lordosis ($F=33.4$, $P=0.000$), thoracic kyphosis ($F=7.1$, $P=0.013$), ascral slope ($F=15.3$, $P=0.001$), C7 plumb line ($F=14.7$, $P=0.001$), while there was

no significant difference for pain ($F=1.2$, $P=0.29$) and ODI ($F=2.5$, $P=0.1$). At six-month follow-up, the analysis showed that there were still significant differences between the traction and control groups for all the measured variables; lumbar lordosis ($F=39.4$, $P=0.000$), thoracic kyphosis ($F=32.8$, $P=0.0001$), ascral slope ($F=15.4$, $P=0.001$), C7 plumb line ($F=14.5$, $P=0.001$), pain ($F=9.8$, $P=0.004$), ODI ($F=13.1$, $P=0.001$).

Table (2): Mean and standard deviations of sagittal balance parameters, pain, disability.

Dependent variables	Pre-treatment values		10 weeks Post treatment		P	After 6 months of follow up		P
	Study	control	Study	control		Study	Control	
Lumbar lordosis	13.9±3.1	13.7±2.9	20.1±3.8	15.2±3.6	0.000*	18.3±3.6	14.7±3.0	0.000*
Thoracic kyphosis	31.4±4.1	30 ±4.8	34.3±4.2	29.7±5.4	0.013*	33.9±3.9	29.9± 4.8	0.0001*
Plumb line	39.8±6.7	38.7±6.6	36.3±7.1	37.9±6	0.001*	36.7± 6.9	38.1±6.1	0.001*
Sacral slope	23.5±3.4	24.3±2.5	25.5±3.3	24.7±2.3	0.001*	25.23.2	24.5±2.6	0.001*
Pain	6±1	5.5±1.7	3.2±1.4	3.5±1.2	0.29	2.6±1.1	3.5±1.2	0.004*
ODI	32.4±3.1	31.1±4.8	21.8±3.1	23.4±3.4	0.1	23.8±2.7	27.1±3	0.001*

*: significantly different P: probability value of ANCOVA

DISCUSSION

This study demonstrates that the group received lumbar extension traction in addition to traditional treatment in form of stretching exercises and infrared radiation showed more improvement than the control group in spine sagittal balance, pain, and disability based on the decrease in C7 plumb line distance, pain intensity, ODI and increase in lumbar lordotic angle, sacral slope and kyphotic angle. Furthermore, after six months, these significant changes were maintained. This study provided objective evidence that, pain, disability and global sagittal balance in terms of lumbar curvature, thoracic curvature, C7 plumb line, and sacral slope and not just the lumbar lordotic curve is affected by lumbar extension traction.

The traction group's statistically significant increase in the lumbar lordosis are in accordance with the findings of Harrison et al who conducted a nonrandomized controlled trial to evaluate the effect of 3-point bending traction and reported the possibility of lumbar lordotic curve correction after 8 to 10 weeks of treatment¹⁸. These results were also supported by another study by the same authors pertaining to the cervical spine. That study reported improvements in the cervical sagittal curve after 2-way traction¹⁹. In the current study, it may be that relieving of muscle spasm and or tightness by the traditional treatment in form of stretching exercises and infrared radiation was responsible for improving the lumbar lordotic curve. However, there are no statistically significant differences in the

control group, which received only traditional treatment. This finding while supported by Helliwell et al.,²¹ who found that the straightening of cervical curve and muscle spasm were not correlated to each other in patients presenting with neck pain, contradicted by another study of Gilbert et al., who confirmed the strong relation between hypolordosis and paraspinal muscle spasm in their retrospective chart review¹¹. This discrepancy may be attributed to the lack of a causal relationship in the previous studies.

Concerning the sagittal thoracic curve, the findings revealed that lumbar extension traction had significant and stable effect on increasing thoracic kyphotic angle. The explanation behind these findings may be attributed to the resultant changes in the lumbar lordotic angle and the interdependence between lumbar and thoracic curve. This explanation has been confirmed by Jackson and Hales who investigated the association between lumbar and thoracic curve²³. Similarly, it makes sense and agrees with the concept of Carlson⁴ and Sato et al.,³⁶ who highlighted the compensatory interdependence exists between body segments, specifically between lumbar lordosis and thoracic kyphosis.

In contrast to previous findings, Berthonnaud et al., reported the weak correlations between the thoracic and lumbar areas. This contradiction cannot be directly compared with the current study because this study was a correlational design and not a true experimental design; that is, they look for a degree of association between variables without the ability to ascribe cause or effect².

The current results also have shown that there is a significant and stable increase in sacral slope after application of lumbar extension traction. This result is consistent with the concept of many studies that highlighted the strong association between lumbar lordosis and sacral slope^{44,45}. In the same line, Loder²⁹ postulated that the amount of a person's pelvic parameters correlated strongly with the amount of one's L1-L5 lordosis. Similarly, Van Royen et al.,⁴³ and Skalli et al.,³⁹ highlighted the strong association between changes in spinal alignment and pelvic posture.

Concerning the C7 plumb line, it is generally admitted that Spinal balance is conceived as the result of an optimal lordotic positioning of the vertebrae above a correctly oriented pelvis; restoration of lumbar and pelvic parameters are therefore the possible explanation for significant change in C7 plumb line. This interpretation of the findings can be made under the concept of Hammerberg and Wood who reported a significant correlation between the position of the C7 plumb line and lumbar lordosis¹⁵. Additionally, the role of pelvic orientation was supported by many authors who reported that Modifications of sagittal spinal curvatures are closely linked to pelvic orientation^{7,27}.

It may be stretching exercises, were responsible for improving the posture parameters. However, we found no statistically significant differences in the control group, which received only traditional treatment. Up to my knowledge, there is a lack of knowledge concerning the impact of stretching exercises on posture deviations correction. Of interest, there are arguments in literature over whether stretching exercises alone or in combination with resistance training will produce postural changes^{22,32}.

The back pain intensity was also significantly improved in the traction group compared with the control group. Overall, the findings are in agreement with those of other studies, that investigated the association between sagittal alignment and back pain.^{18, 20, 25} On the other side, the findings of the current study stand in contrast with those of other studies, that referred to the lack of association between lumbar lordosis and pain^{28,31}. The

reasons for these differences may be related both to the initial selection of patients with relatively small number, and to the fact that all these studies were correlational studies and not true experimental studies; that is, they look for a degree of association between variables without the ability to ascribe cause or effect.

The reduction of pain in the control group, that received stretching exercises and infrared radiation, is in agreement with the findings of Cleland et al who reported the beneficial effects of stretching exercises in management of non-radicular low back pain⁶. In addition to previously mentioned reasons, I believe that using of thermal agent was a contributing factor for pain relieve as supported by Gale et al who demonstrated the effectiveness of infrared radiation in chronic low back pain.⁹ The transient nature of pain reduction for control group could be attributed to the constant stress and strain on the tissues developed to counteract the tendency of the upper trunk to move forwards as the center of gravity line moves more anteriorly in relation to the spinal column in hypolordotic subject as postulated by Glassman et al.,¹³.

Considered the functional outcome, the improvement of functional parameters is in agreement with the findings of Miyakoshi et al., who reported that lumbar lordosis restoration is considered as an important factor for improving spinal function³⁰. In contrast, a systematic review of Christensen and Hartvigsen does not support the association between sagittal spinal curves and health including daily function and pain⁵. This contradiction may be attributed to different reasons: First, low methodological quality of included studies, the systematic review of Christensen and Hartvigsen included all types of sagittal plane curvature measurement methods, we found that several studies were using the flexicurve (flexible ruler) to measure lumbar lordosis via sagittal skin contour. Of interest, flexicurve measurement of lumbar lordosis is not externally valid and not useful for making legitimate decisions regarding the state of lumbar lordosis⁴⁰. The second reason concerned with the vague inclusion and exclusion criteria for patient selection.

In regards to the functional improvement in the control group after 10 weeks of

treatment, it seems logical and is generally admitted that exercise based therapies are a logical approach to improve function,⁸ while the significant decline in the functional status at 6 months of follow-up may be attributed to the continuous asymmetrical loading from biomechanical dysfunction represented in the abnormal spinal posture, that results in continuous pathological and histological changes of spinal soft tissues.

Unique contribution of this study is that it evaluated the independent effect of structural rehabilitation in form lumbar lordosis correction on the whole spine sagittal balance, pain, and disability, which to my knowledge, has not been previously reported. In conclusion, the findings of the current study serve to reinforce the importance of using structural rehabilitation in form of restoring the normal lumbar lordotic curvature in management of chronic low back pain. Of interest, restoring of normal curve introduces yet another treatment option to a list that already includes physical agent modalities, manual therapies such as massage and myofascial stretch. Its unique appeal lies in its long lasting effect. These observed effects should be of value to clinicians and health professionals involved in the treatment of spinal disorders.

However, the analysis of the current study has some potential limitations, each of which points toward directions of future study. The primary limitation was the invasive nature of the radiological assessment and repeated exposure to x ray at three intervals. Furthermore, due to the type of intervention, it was not possible to blind the physiotherapist who provided interventions. Concerning the initial selection of the patients, they likely represented a convenient sample rather than a random sample of the whole population. The control group did not receive the same form of time consuming treatment.

Conclusion

The results of the present study show that the lumbar extension traction in addition to stretching exercises and infrared radiation have positive impact on lumbar lordotic curve, pain intensity, disability, and whole spine

sagittal balance parameters in CMLBP. Follow up measurement revealed stable improvement in all measured variables. These observed effects should be considered by clinicians and health professionals involved in the treatment of lumbar disorders.

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الملخص العربي

عالية الشد ثنائي الاتجاه على الالم و توازن العمود الفقري الكلي في حالات الالم أسفل الظهر الميكانيكية المزمنة: تجربة عشوائية

في محاولة لدراسة تأثير الشد ثنائي الاتجاه على الالم ، الأداء الوظيفي و معلمات توازن العمود الفقري الكلي ممثلة في تقعر الفقرات القطنية ، تحذب الفقرات الصدرية ، انحدار الفقرات العجزية ، الخط الراسي من الفقرة العنقية السابعة . تم اختيار ثمانون مريضاً يعانون من الالم أسفل الظهر الميكانيكية المزمنة وقصور واضح في زاوية انحناء الفقرات القطنية . وقد تم تقسيمهم عشوائياً الى مجموعتين متساويتين مجموعة البحث ومجموعة ضابطة . استقبلت المجموعة الضابطة الأشعة تحت الحمراء وتمارين التمدد في حين تلقت مجموعة البحث الشد ثنائي الاتجاه بالإضافة إلى الأشعة تحت الحمراء و تمارين التمدد . تم العلاج ثلاث مرات في الأسبوع لمدة عشرة أسابيع . وتم قياس الالم، الأداء الوظيفي بواسطة مؤشر العجز (أوسويستري) ، والمعلمات الإشعاعية لتوازن العمود الفقري من حيث تقعر الفقرات القطنية ، تحذب الفقرات الصدرية ، انحدار الفقرات العجزية ، والخط الراسي من الفقرة العنقية السابعة لجميع المرضى في ثلاث فترات (قبل العلاج ، وبعد 10 أسابيع من العلاج ، وبعد 6 أشهر من المتابعة) . أظهرت النتائج وجود فرق كبير بين المجموعتين بعد 10 أسابيع مقارنة بالقيم الأساسية بالنسبة إلى تقعر الفقرات القطنية ، تحذب الفقرات الصدرية ، انحدار الفقرات العجزية ، الخط الراسي من الفقرة العنقية السابعة بينما لم يكن هناك اختلاف كبير فيما يتعلق بالالم والأداء الوظيفي . وبعد 6 أشهر من المتابعة أظهرت النتائج وجود فرق كبير بين المجموعتين لجميع المتغيرات . وقد دلت النتائج على ان الشد ثنائي الاتجاه بالإضافة إلى الأشعة تحت الحمراء وتمارين التمدد أدى إلى تحسين معلمات توازن العمود الفقري الكلي وانخفاض الالم والعجز في حالات الالم أسفل الظهر الميكانيكية المزمنة .