New Bracing Concept in the Treatment of Chronic Mechanical Low Back Pain: A Randomized Trial

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ABSTRACT

Objective: *To investigate the results of a new bracing approach on pain and 3D posture alignment in chronic mechanical low back pain (CMLBP).* ***Design:*** *A randomized controlled study with three months follow up.* ***Subjects:*** *Forty patients (age ranged from 40 to 50) selected htiw CMLBP.* ***Interventions:*** *Both groups received infrared radiation additionally the study group received ambulatory training while wearing the thoracolumabar sacral posture corrective orthosis (TLSPCO).* ***Main Outcome Measures:*** *3D orientation in terms of translational and rotational displacements and visual analogue scale (VAS) were measured for all patients at three intervals (before treatment, after 10 weeks of treatment, and at follow up of 3 months).* ***Results:*** *For study group, the results revealed a significant improvement in pain, and 3D thoracolumbar orientation (Rz, Ry, Rx, Ty, and Tx) post treatment (P< 0.05) and maintained at follow up (P > 0.05). For the control group, while there was significant improvement in pain post treatment (P=0.000), there was a significant decline at follow up towards initial baseline values (P=0.000). There was no significant difference for 3 D thoracolumbar orientation. There was a significant difference between groups at post treatment and at follow up adjusted to baseline value of outcome for all measured variables (P < 0.05).* ***Conclusion:*** *TLSPCO is an efficient modality to improve the 3D orientation of thoracolumabr region and pain.*
Keywords: *Mechanical low back pain, Pain, Three dimensional.*

INTRODUCTION

Low back pain (LBP) is among the most common problems a physical therapy faces. It represents a major social and economical burden to society with high recurrence rate up to 90%. Unknown etiology represents eighty five percent or more of etiological factors responsible for the LBP,[33] and so the important question about the precise treatment protocol is almost a subject of debate. The use of conservative orthopedic brace treatment for chronic mechanical low back pain (CMLBP) is one of the most debating subjects. A questionnaire-based survey of physician members of the French Society of Physical Medicine and Rehabilitation (SOFMER) revealed the heterogeneity and the lack of consensus on the indications and the procedures for orthopaedic brace treatment of LBP. It also highlights the Controversy about the values of this type of treatment[24]. It is postulated that this type of treatment is not without critique. Although posture has emerged as one of the important etiological factors reported to be associated with LBP,[36,2,5] most of the previous bracing concept limited their role to immobilization especially in the acute stage to create the best conditions for soft tissue healing and relieving of pain by lowering the nociceptive physical and mechanical input[21]. Moreover, it based on dated concept when the 3D nature of posture were not incorporated into the brace design.

It is postulated that large deviations from ideal postural alignment especially form the trunk which is approximately 60% of body mass[8] has a negative influence on neural, muscular, and vascular tissues, resulting in various spinal disorders[13,31]. And so global posture assessment and correction in view of three dimensional analysis are important aspects that have to be considered in the bracing design if we seek greater and longer lasting improved function. Regarding the objective postural measurement methods, there are several tools available for clinical use. These include simple plumbline measure, photographic techniques[11,35], moiré topography[30], various computer assisted methods including electrogoniometers[26].

There is evidence that this clinical evaluation is an effective tool, but as beneficial as this type of evaluation has proven to be, there are still various shortcomings as the most of these methods are not able to measure trunk posture as rotations and translations in six degrees of freedom as described by Harrison et al.[17]

And so in the current study we used 3D motion analysis system, which is a valid and reliable system[25], provides the managing physiotherapist with a radiation free accurate measurement. Moreover, it provides further information on trunk balance and other 3D features upon which bracing design can be tailored per each patient. Numerous studies showed that mirror Image and mirror image in motion exercises which are prescribed specifically to help normalize the patient's neuromuscular dysfunction and postural deformation through reflecting the patient's posture across different planes are more beneficial than a less personalized program[15,16,22,23]. With these consideration in mind, and to incorporate the findings of 3D postural assessment into the treatment program, we designed an adjustable thoracolumabar sacral posture corrective Orthosis (TLSPCO) which was worn by the patient for short time and have the availability to reflect all transitional displacements and rotational movements of the trunk. Ambulatory exercises were performed by using treadmill while the patient's reverse posture was held by the TLSPCO. Accordingly, the purpose of the current study was to investigate the efficacy of the adjustable TLSPCO on pain and 3D pasture parameters.

Methods

A prospective, randomized, controlled study was conducted at research laboratory of our university. All the patients were conveniently selected from our faculty's outpatient clinic. They were participated in the study after signing an informed consent form prior to data collection.

Study population

Patients were recruited from June 2008 to January 2009 with three months of follow-up. They were screened prior to inclusion by measuring the rotational movements and translational displacements of trunk region, a participant was referred to the study if they had a moderate to severe postural abnormalities according to posture index scale. Patients were included if they had significant posture abnormalities by screening test and CMLBP lasting more than 3 months to avoid acute stage of inflammation. Exclusion criteria included scoliosis, true leg length discrepancy, previous spinal surgery, associated pathologies of lower limbs that may interfere with the global posture as foot, knee and hip deformities. Patients were randomly assigned into two groups of equal number using the roll of a dice, an experimental group (odd number) and a control group (even number). Random permuted blocks of different sizes were employed to achieve a balance of the sample sizes between the two groups. A resident who was blinded to the research protocol and was not otherwise involved in the trial operated the random assignment. The experimental group included 12 females and 8 males (mean age 44±2.6). The control group included 9 females and 11 males (mean age 43.9±3.1). The experimental group received 3D posture correction protocol through adjustable ambulatory TLSPCO. The two groups received infrared radiation to control pain and eliminate the causal role of pain in changing the posture parameters.

Instrumentation

Instrumentation for measurement

The 3D measurement system, Optical Motion Capture

Optical Motion Capture (Qualysis medical AB system), with high precise and robust technology to deliver high quality data to the observer in real-time. The Qualysis Motion Capture software tools make it easy to perform highly complex calculations of all translational and rotational displacement.

Software components

QTrac: data acquisition, tracking and 3D rendering.

QTrac from Qualisys is a comprehensive tool for all the tasks associated with motion capture.

QTrac was specially designed to work with ProReflex line of MCU. The QTrac makes motion measurements quicker and easier than ever before.

QTools: general purpose kinematics analysis tools.

QTools is a versatile analysis package for analyzing 3D data generated by QTrac Since the QTools runs in Excel, it takes advantage of all the reporting facilities of that software, as well as allowing the use of powerful mathematical capabilities to develop customized analyses.

Instrumentation for treatment
TLSPCO

This is a low profile, light weight, thermoplastic orthosis. It is easily applied and removed by the patient. This brace consists of two parts; one part is attached to the lumbosacral region and is considered as a fulcrum on which the other part which is attached to rib cage area will be moved. The two parts are being connected to each other by movable joint which allow the movable part to be adjusted in all translational and rotational movements. The brace would overcorrect the abnormal posture according to the 3D posture analysis data. No other pads or relief areas are used in the orthosis. In the present study we used two version of thoracolumbar brace one for male and another design with anterior opening to be suitable for female (Fig.1,2).

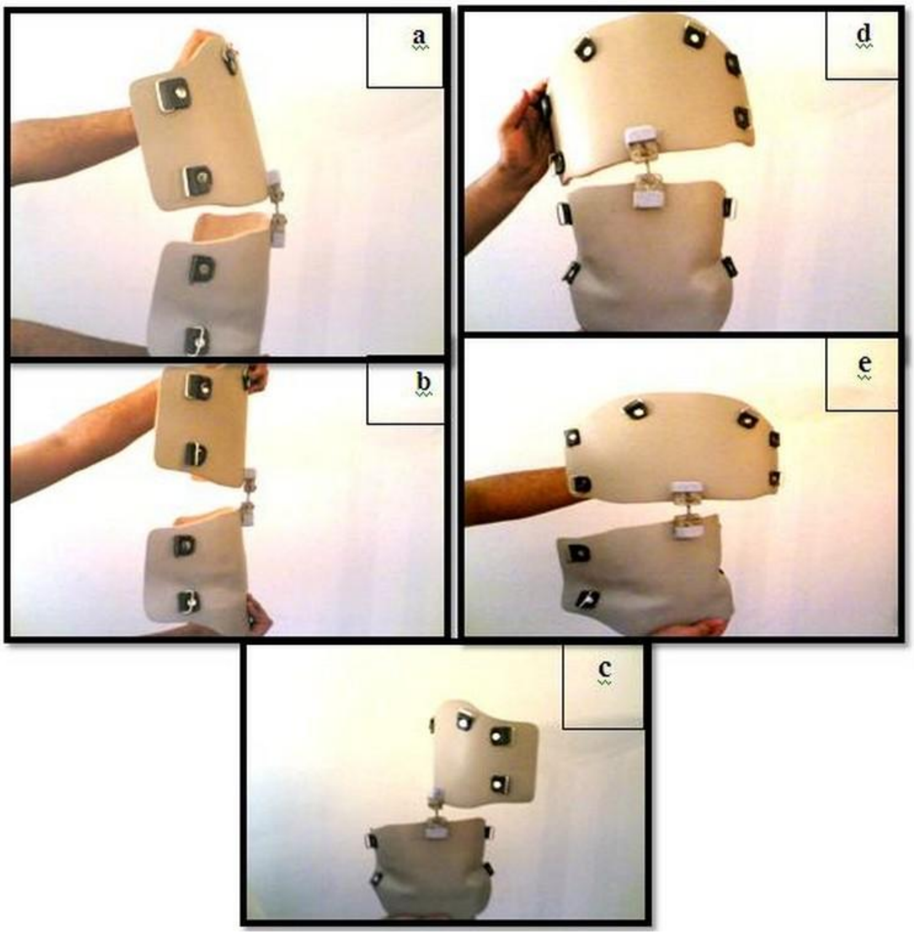

Fig. (1): Anterior part of TLSPCO demonstrating the availability to move in different directions a. Flexion. b. Extension, c. Rotation, d. Side bending, and e. Lateral translation.

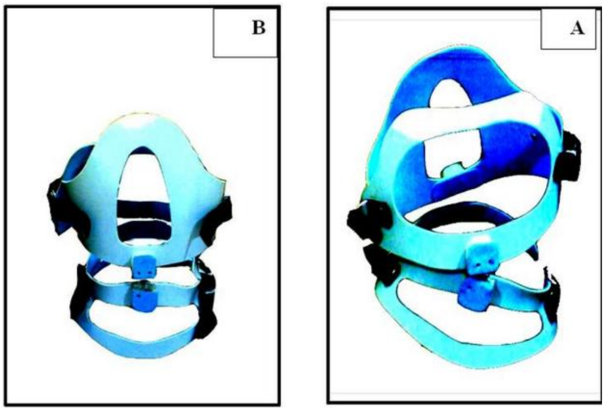

Fig. (2): TLSPCO (female version) a. Anterior view b. Posterior view.

Experimental Procedures

Assessment procedures

Camera set up

Six 120Hz (MCU) were utilized for this study. The height of the three MCU was measured by the tape measurement and adjusted to be 160cm by adjusting the tripod of the three cameras in order to cover the entire field of measurement. The focus and the aperture of each MCU were adjusted to make sure that the camera system is properly working.

System calibration

The camera system was calibrated at the beginning of each measurement session by a reference frame and a T shaped wand. The reference frame (L shape) contains four reflective markers fixed on it and it was used to determine the direction of the global coordinates (X,Y and Z) for the system and according to the position of this reference frame the value of the X Y and Z coordinates, measured in millimeter, of each reflective marker was calculated. The T shaped wand was moved in all directions (X, Y and Z directions) around the reference frame making sure to cover both the upper and lower parts of the volume.

Marker placement procedures

The starting position of the subject was in the erect standing position. The points, over which the markers were fixed, were well cleaned with alcohol to remove sweating and ensure good fixation of markers. The reflective markers were placed on the following landmarks; Right and left acromion processes (RAC&LAC), Epi-sternal notch, xiphoid process, Right and left anterior superior iliac spine (RASIS&LASIS), In the middle of the distance between RASIS and LASIS, Right and left knee, Center of the left and right ankle (talus), In the middle of the distance between center of both heels, In the middle of the distance between RASIS and right posterior iliac spine (RPIS), Lateral malleolus.

Measured items (The postural parameters)

Rotational movements

1- Rotation around Z axis (shoulder girdle – pelvic rotation angle): Was defined as the angle between the shoulder girdle line (line connecting the anterior right acromion (RAC) marker and left acromion marker (LAC) and the pelvic line (line connecting the right anterior superior iliac spine (RASIS) and left anterior superior iliac spine (LASIS) in the axial plane (Fig. 3a).
2- Rotation around X axis (shoulder girdle – pelvic bending angle): It was defined as the angle between the shoulder girdle line (RAC-LAC line) and pelvic line (RASIS-LASIS) in coronal plane (Fig. 3b).
3- Rotation around Y axis (shoulder girdle – pelvic flexion/extension angle): It was defined as the intersection between tow lines: the first line connecting the Right lateral malleolus (RLM) with marker in midpoint between ASIS and PSIS (mid ASIS-PSIS) and the second line connecting RAC with mid ASIS-PSIS in sagittal plane (Fig.3c).

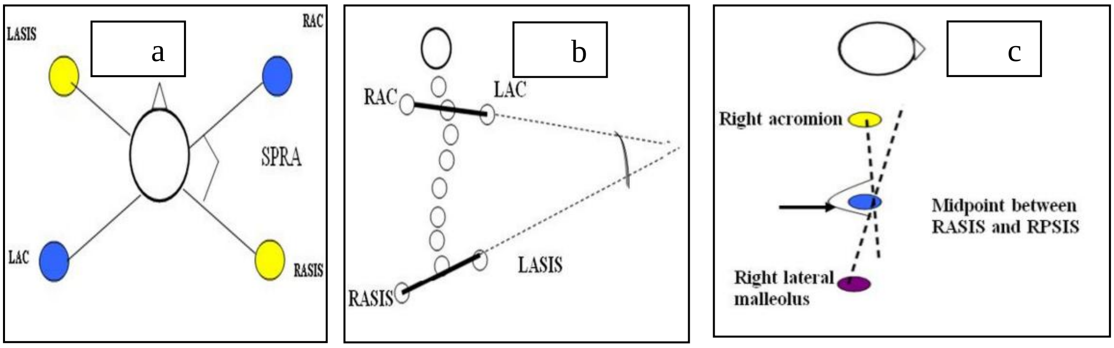

Fig. (3): Schematic representation of shoulder girdle –pelvic rotation angle. b- pelvic bending angle. c- pelvic flexion/extension angle in sagittal plane.

Translational displacement

1- Translation around X axis (left and right side shift of shoulder /pelvic): It was defined as the distance between C7marker and the S1marker in coronal plane.
2- Translation around Y axis (anterorposterior shift of shoulder /pelvic): It was defined as the distance between C7marker and the S1marker in sagittal plane.

Pain assessment

It was performed by using VAS, the patients were asked about the perception of pain using a 10 cm line with 0 (no pain) on one end and 10 (worst pain) on the other end. Patients were asked to place a mark along the line to denote their level of pain.

Treatment procedures

Ambulatory a mirror image functional training

This way of functional training was delivered via the use of TLSPCO with the patient walking at approximately 2-3 miles per hour on a standard, motorized treadmill. After quantifying the complex 3D nature of posture and specifically, the thoracolumbar region through objectively measuring the lateral and anterior or posterior translation distance, axial rotation (shoulder pelvic rotation angle), lateral bending angle and flexion or extension angle (shoulder pelvic flexion or extension angle), these data were incorporated into the brace adjustment through adjusting the movable upper part of the brace into the reverse posture and so we adjust the angulations, translation and rotation simultaneously, and then, the ambulatory exercises for 20 minutes by using treadmill were performed while the patient's mirror image posture was held by the TLSPCO. Based on Harrison et al and Hawes et al., approach, this program was to be repeated 4 times per week for ten weeks (Fig.4).

Fig. (4): Ambulatory training with adjustable TLSPCO.

Sample size determination

To determine the required number of samples in this study, estimates of average mean difference and standard deviation for pain level were collected from a pilot study consisting of 7 patients who received the same program between February 1, 2008, and May 31, 2008. The mean difference value and standard deviation were estimated as 4.7 and 3.6, respectively، a 2-tailed test, an alpha level of 0.05, and a desired power of 90%. These assumptions generated a sample size of 16 subjects per each group. To account for high drop-out rates, the sample size was increased by 25% (40 participants).

Statistical analysis

Descriptive statistics were calculated including mean ± standard deviation (SD) for age, height and weight. The outcome measure of pain and 3D posture parameters in terms of rotational movements and translational displacements were measured using one-way ANOVA to compare measurements made before treatment, after 10 weeks of treatment, and at follow up period of 3 months. Tukey's post-hoc multiple comparisons was implemented when necessary. Analysis of covariance (ANCOVA) at two follow up points for each outcome in which the base line value of the outcome as covariates was used to assess between group differences. (Baseline outcome in the model= baseline value - overall mean baseline value) For all statistical tests the level of significance was set at $P < 0.01$. SPSS (version 10) was used in this study.

RESULTS

Baseline and demographic data

A diagram of subject retention and randomization throughout the study is shown in Fig. 5. The figure show that fifty patients were initially screened, after the screening process forty five patients were eligible to participate in the study and forty completed the study. The clinical and demographic features of the patients at inception are shown in table 1.

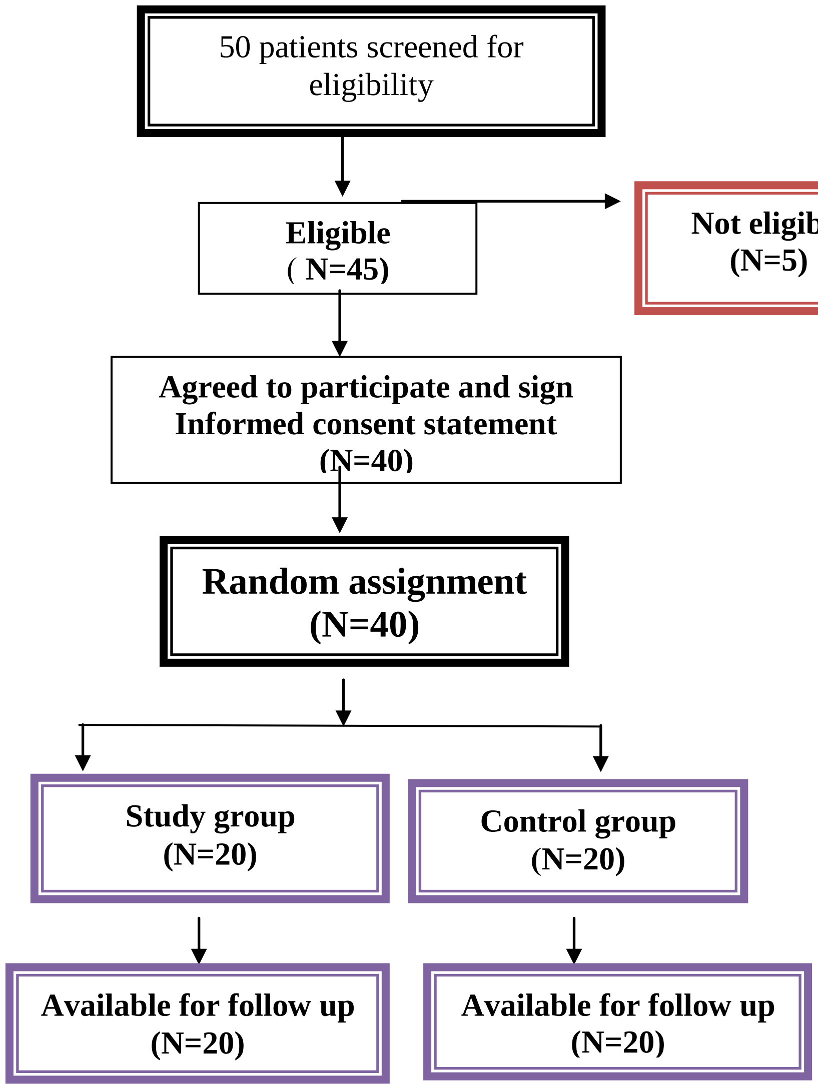

Fig. (5): Flow of study participants.

Table (1): Base line participant characteristics.

	Study group (n=20)	Control group (n=20)
Age	44±2.6	43.9±3.1
High	172±9	175±10
Wight	70±5	69±7
Gender		
Male	8	11
Female	12	9
Employment status		
Employed full time	14	13
Employed part-time	4	6
Unemployed	2	1
Smoke cigarettes currently		
yes	6	8
no	14	12
Race		
white	1	0
nonwhite	19	20
Past use of physiotherapy		
Yes	8	13
No	12	7
History of back pain		
Duration of current pain(wk)	8.5 ±1.7	8.9± 1.7
Duration since first onset(mo)	19±1.3	18±2.6

Values are means ± SD.

Within group analysis

Rotational movements and translational displacements

In contrast to control group where there was not any significant difference for all postural parameters (R z, y, x and T y, x), the results of study group revealed that variation among column means is significantly greater than expected by chance for all the previous postural parameters. The post Test revealed stability of results at follow up Table 2.

Table (2): Within group analysis for 3D postural parameters in both groups.

		Pre- treatment measures	Post 10 weeks measures	Follow up measures	F value	P	Post Hoc Tests		
							P1	P2	P3
Rz	S	7.2± 2.4	3.8± 2.4	4.1± 2.4	9.1	0.001*	0.003*	0.001*	.9
	C	9± 3.4	8.9± 3.4	9.1± 3.6	.01	0.9			
Ry	S	8± 1.9	5.4 ±3.1	5.7 ±3.3	4	0.026*	0.055	0.04*	0.9
	C	7.6 ±3.4	7.8 ±3.6	8.3± 3.7	0.14	0.87			
Rx	S	14.3 ±4.1	7.2 ±3.8	7.7 ±4	15.1	0.000	0.000*	0.000*	0.9
	C	15.2 ±5.2	15.1± 5.3	15.7 ±5.5	0.05	0.9			
Ty	S	9.4± 2	6.2 ±2.6	6.8± 2.4	7.6	0.001*	.01*	0.002*	0.8
	C	9.5 ±2.5	9.8 ±2.6	10.4 ±2.8	0.46	0.63			
Tx	S	69.8±10.9	35.5±21.6	36.9 ±21.9	15.9	0.000*	0.000*	0.000*	0.9
	C	67.8±14.4	68.5 ±13	70.1± 13.4	0.1	0.8			

S: study group C: control group *: significantly different P: probability value for anova table
p1: pre vs follow p2: pre vs post p3: post vs follow

Pain

By using one-way ANOVA, it was found that variation among column means is significantly greater than expected by chance, even for study or control group (F= 137.5 and 25.3 respectively and P< 0.0001 for both groups). The post test revealed stability of results at follow up for study group in comparison with the post treatment (P>0.05). In contrast, there were significant changes in the follow up scores of control group towards initial baseline (P<0.05) (Fig. 6).

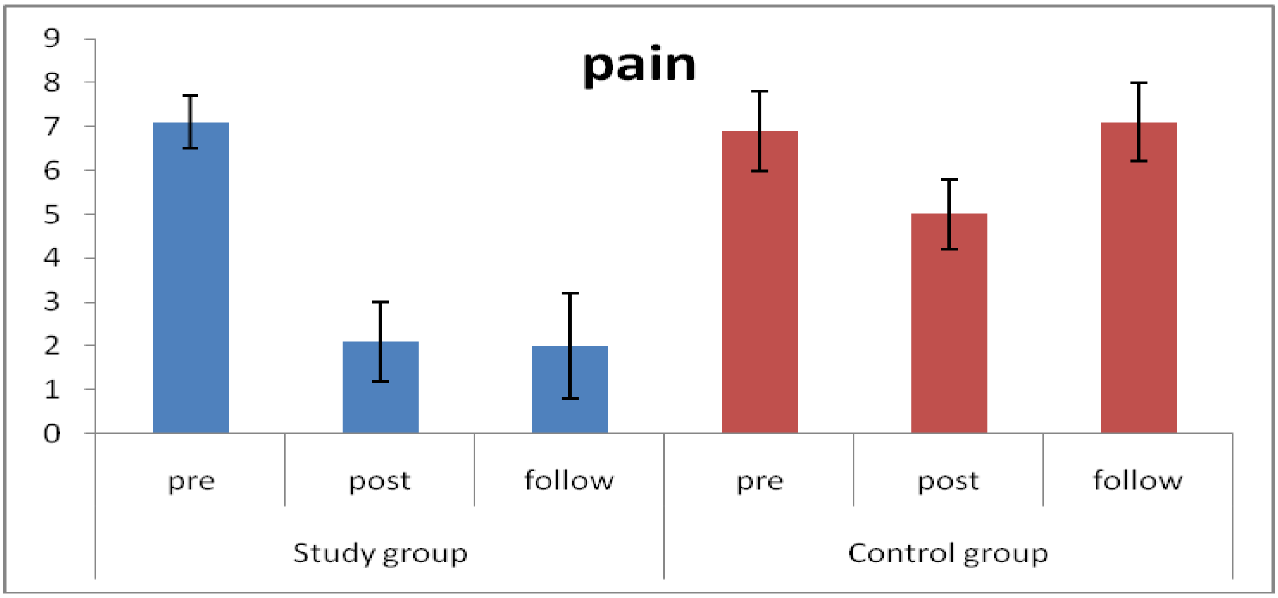

Fig. (6): Pain intensity ratings for both groups versus time of evaluation between group analysis.

The results revealed a statistically significant difference between groups at two intervals of measurements (post treatment and at follow up) adjusted to baseline value of outcome for all measured variables table 3.

Table (3): Between group analysis for 3D postural parameters and pain at two follow up points.

Dependent variables	10 wk Post treatment		ANCOVA [a]		After 3 mo of follow up		ANCOVA [a]	
	Study	control	F	P	Study	control	F	P
RZ	3.8 ±2.4	8.9 ±3.4	103.3	0.000*	4.1±2.4	`9.1±3.6	87.8	0.000*
Ry	5.4±3.1	7.8±3.6	19	0.000*	5.5±3.2	8.3±3.7	18.8	0.000*
Rx	7.3 ±3.8	15.1 ± 5.2	65	0.000*	8.3±3.9	15.7±5.5	15.8	0.001*
Ty	6.28±2.6	9.8±2.6	31.9	0.000*	6.8±2.4	10.4±2.8	29.7	0.000*
Tx	35.4±21.5	68.5±13	42.9	0.000*	36.9±21.9	70.1±13.4	42.5	0.000*
Pain	2.1±0.9	5±0.8	93.4	0.000*	2±1.2	7.1 ±0.9	170.4	0.000*

*: significantly different P: probability value [a]: adjusted to baseline value

DISCUSSION

Many of the studies cited in the literature review, investigated only the immobilization effect of bracing[21,32]. Furthermore, the harmful effects of wearing a brace such as muscle atrophy, stiffness, neuromuscular mismatch and movement phobia are often highlighted in other studies. Although, we were unable to find any literature data on the relationship between spinal posture analysis and the type of the brace in the area of low back pain management, our result concurred with the concept of Biot et al.,[3,4] who magnify the role of posture correction as important aim of physiotherapy and brace use in management of low back pain. This concept make sense and agree with Rigo and Weiss[29,34] who stated that current concept of bracing must take in consideration both the 3D nature of posture and its pathomechanism of progression. Consisted with the previous concept Dubousset claimed that "a modern brace should be able to correct in 3D in order to break the so-called 'vicious cycle' model[9]".

It may be that improving of these posture parameters in the current study attributed to relive of pain and muscle spasm by the traditional treatment in form infrared radiation. However, we found no statistically significant differences in the control group which subjected to traditional treatment only.

The studies which investigating the relation between bracing and posture parameters mainly conducted in the area of scoliosis treatment. Most of these studies acknowledged the negative association between bracing and posture parameters. Weiss reported a case of radiological improvement under brace treatment but combined with increasing of surface trunk rotation and surface lateral deviation[34]. Another study conducted by Rigo failed to demonstrate any significant difference in clinical parameters in terms of lateral deviation, trunk imbalance, pelvic tilt and torsion after using traditional brace[29] in contrast to the previous results, the improvement in the current study concerning the postural parameters in terms of translational displacements and rotational movements in six degree of freedom could be attributed to various reasons: The first reason, the corrective bracing protocol in the current study tailored to each patient according to 3 D postural analysis. In addition, it addresses the neuromuscular as well as the skeletal factors involved in the progression of postural deformity. Overall, treatment of the back disorders based on back posture analysis is an interesting concept often highlighted in many articles. However, this concept were not more than suggestions and recommendations points without any applied strategy as in the suggestion of some researchers to use the back classification (based on precise criteria observed on profile total spine X-rays) to refine the rehabilitation program[6]. Moreover, it often based on 2D spinal analysis and so all the previous studies not addressed the question adequately, nor answered it.

The second reason to expect more effective changes is because the treatment program in this study concentrated on rehabilitation of the spine in a reflexive environment. This interpretation agree with Christensen who reporting about the importance role of rehabilitation in a reflexive environment especially for posture correction exercises as posture is highly controlled by reflex activity[7]. The third reason to expect a more effective change is because moving spinal tissues elongate and remodel more effectively that static spinal tissues.

The other outcome assessment that has been investigated in the present study was the pain. Overall, tneserp eht findings revealed a significant and stable decrease in VAS for study group. This improvement could be attributed to the restoration of normal posture. It seems logical and is generally admitted that spinal function is directly related to spinal structure, mal-alignment in neutral posture, static and especially dynamic function from this malalignment elicits an abnormal stresses and strain in many structures, including the bones,[28] intervertebral discs,[1] facet joints,[37] musculotendinous tissues,[20] and neural elements.[14] which considered as predisposing factors for pain. This result concurred with Troyanovich et al.,[31] and Griegel-Morris et al.,[13] who concluded that large deviations from ideal postural alignment induce stress and strain on spinal tissues, resulting in various pathological disorders.

In contrast to our findings, other studies in the literature which investigated the relationship and impact of posture parameters on LBP reported that postural abnormalities were of minor importance[27,38]. Any contradicted findings between the association of posture and pain in the previous studies might be due to lack of uniform classification and measure as most of the previous research based on 2 D posture analysis, and poor experimental design as all the previous contradicted findings were drawn from a correlational studies which lack the cause and effect relationship.

Concerning pain level outcome in the control group, the immediate reduction of pain might be attributed to physical agent modalities as supported by Gale et al.,[10] who reported the beneficial effects of infrared radiation in reducing chronic back pain by 50% over six weeks. The increase in the pain level at the follow up time could be attributed to the continuous asymmetrical loading from biomechanical dysfunction represented in abnormal 3D posture alignment which results in continuous pathological and histological changes of spinal soft tissues[31].

Certain limitations of the present study are worthy of mention, the patients were not differentiated according to pain intensity and so future studies have to examine the effect of 3D posture correction in different pain category, another concern may arise from Using of two different designs for males and females to match with their body configuration, however, the both designs followed the same mechanical principles and the both have the availability to move in six degrees of freedom. Concerning the initial selection of the patients, they likely represented a convenient sample rather than a random sample of the whole population. Future randomized trials should be conducted on a randomly selected sample of different clinical cases.

Conclusion

This study assists in the understanding the significant role of 3D posture correction in long lasting improved function. Use of adjustable TLSPCO with protocol used in this study results in improvement in pain level and 3D thoracolumbar orientation in terms of translational displacements and rotational movements. Follow up measurement revealed stable improvement in all measured variables for study group. These observed effects should be of value to clinicians and health professionals involved in the treatment of CMLBP disorders.

Clinical message

Using adjustable TLSPCO during ambulatory activities, in addition to infrared radiation is beneficial in long lasting improvement of pain and all 3D thoracolumbar postural parameters in cases of CMLBP.

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الملخص العربي

مفهوم جديد للدعامة في علاج آلام أسفل الظهر الميكانيكية المزمنة :تجربة عشوائية

فى محاولة لدراسة نتائج الدعامة الظهرية بمفهومها الجديد على الألم و الوضع ثلاثى الأبعاد للفقرات الظهرية القطنية وذلك فى حالات آلام أسفل الظهر الميكانيكية المزمنة . تم أختيار 40 مريضا تتراوح اعمارهم ما بين (40 الى 50 سنة) وقد تم تقسيمهم عشوائيا الى مجموعتين متساويتين (مجموعة بحث ومجموعة ضابطة)، استقبل كلا الفريقين الأشعة تحت الحمراء بالإضافة الى ذلك تلقت مجموعة الدراسة التدريبات الحركية في أثناء ارتدائهم الدعامة الظهرية وقد تم قياس الوضع ثلاثى الأبعاد للفقرات الظهرية القطنية من خلال قياس الإنحرافات الدائرية والأزاحية و الألم لجميع المرضى في ثلاث فترات (قبل العلاج وبعد عشرة أسابيع من العلاج ، وبعد ثلاثة أشهر من المتابعة) . لمجموعة الدراسة ، أظهرت النتائج وجود تحسن ملحوظ في الألم و الوضع ثلاثى الأبعاد للفقرات الظهرية القطنية بالنسبة الى كل من الأستدارة حول محور ع ، ص ، س والازاحة حول محور س ، ص بعد العلاج وبعد ثلاثة أشهر . وبالنسبة للمجموعة الضابطة ، فبينما كان هناك تحسن ملحوظ في علاج الألم بعد العلاج ، كان هناك انخفاض كبير في المتابعة بعد ثلاثة شهور نحو القيم الأساسية الأولية ، فى حين لم توجد فروق ذات دلالة احصائية بالنسبة للوضع ثلاثى الأبعاد للفقرات الظهرية القطنية . كما كان هناك فرق كبير بين المجموعتين بعد العلاج وفي المتابعة بالنسبة لجميع المتغيرات المقاسة . وقد دلت النتائج على ان أستخدام الدعامة الظهرية القطنية هي طريقة فعالة لتحسين الوضع ثلاثى الأبعاد للمنطقة الظهرية القطنية والألم .

الكلمات الدالة: آلام أسفل الظهر الميكانيكية – الألم- ثلاثى الأبعاد .