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Effect of Molded Lumbosacral Orthosis on Postural Sway and Pain in Subjects with Chronic Non-Specific Low Back Pain: A Prospective Study

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Abstract

Study design: Prospective pre-post quasi experimental study design (Level of Evidence-IV).

Objectives: Objective was to find the effectiveness of Molded LSO on postural sway and Pain in subject with NSCLBP.

Background of the data: In orthotic treatment molded Lumbosecral orthosis (LSO) application is still controversial topic in Non-specific Chronic Low Back Pain (NSCLBP). Many studies are concentrated upon postural balance and pain with Spinal orthosis in NSCLBP have significant interrelationship but spinal orthosis with postural balance improvement have no strong evidence but this is an attempt to check the effect on COP and Pain using orthosis. This study will stabilized a clinical report on NSCLBP in terms with COP-sway and Pain in Indian scenario.

Materials and methods: 30 subjects with NSCLBP were included in this study by convenient sampling method. The Postural sway parameters (COP, RMS & Range) in mediolateral (Ax) and anterio-posterior (Ay) direction measured using Kistler force plate in Eye open (EO) and Eye Close (EC) condition and pain using VAS. All the measurements was acquired as baseline (pre) with and without molded LSO, and after (Post) 4 weeks following onset of Molded LSO use.

Results: There was significant difference between pre and post with & without Molded LSO postural sway in mediolateral (Ax) and anterio-posterior (Ay) of COP in both EO and EC condition, (p \leq 0.05). RMS was in without brace EC and EO and with brace EO in Ay and was in Ax, EO without brace and EC and EO with brace (p \leq 0.05). Range in Ay EO without brace, and in with brace EO were Ax in EO with brace (p \leq 0.05). VAS score mean differences were decreased in without and with braces but statistically not significant within groups.

Conclusion: As per present perspective clinical evident report it going to conclude that molded Lumbosacral Orthosis have a significance impact on positive influences for reducing postural sway and pain in short term orthotic treatment protocol. It have positive impact on static postural balance and pain with saliently maintaining the lower COG alignment and unloading lumbar spine by using molded Lumbosacral Orthosis in subjects. One center prospective short term clinical report cannot indiscriminate the positive impact of molded Lumbosacral Orthosis in NSCLBP. So the molded Lumbosacral Orthosis can be recommended as a RCT study on this prospect for short term use orthotic plan in NSCLBP.

Keywords: Molded lumbosecral orthosis •Non-specific chronic low back pain • Postural sway

Abbreviations: LBP: Low back pain • LBP: Low back pain • NSCLBP: Non-specific chronic low back pain • COP: Centre of pressure • LLD: Leg length Discrepancy • BMI: Body mass index • VAS: Visual analogue scale • SPSS: Statistical package for the social science • LSO: Lumbosacral orthosis • NILD: National Institute For Locomotor Disabilities • OPD: Out Patient Department • EO: Eye Open • EC: Eye Close • RMS: Root mean square • M: Male • F: Female

Introduction

Non-specific chronic low back pain is an unknown etiological phenomenon of back pain and the common pain management provides as per the severity of this diseases [1,2]. Indian population of LBP is varying in between 6.2% to 92% from the overall population [3]. Non-specific low back pain does not affects the any structural changes in muscle, bone and other soft tissues that have the common symptoms of pain and loss of function, limitation of activities and restricted participation [4]. Commonly the back spinal and lower extremity muscles participates in human postural structure to makes stand and maintain postural balance that is for long term and it is an significant cause of back pain [5,6].

Normal symptomatic phenomenon of pain in NSCLBP may cause by the physical forces and Stresses on spinal soft tissues especially in muscle and ligaments compression affects spinal Cord nerve route structure [7].

No such special clinical test is there for investigating the NSCLBP, only some classical method is use like

1. Previous history of pain.

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- 2. Dermatomal radiation.
- 3. More pain on coughing.
- 4. Sneezing or straining.
- 5. Positive straight leg raising and

6. Crossed straight leg rising can be used to predict nerve root compression on MRI; by this findings we can confirm the diagnosis of specific/nonspecific causes of low back pain [8,9].

NSCLBP and postural balance and Spinal orthosis have significant interrelationship but spinal orthosis with postural balance improvement have no strong evidence [10].

Standard Molded LSO design may soft or rigid provides transfer the load from trunk muscles, immobilize the spinal range of motion, increase intraabdominal pressure, restrict mobility of the spinal column, and assist muscle during various human activities [11-13]. Molded LSO also provides for the early intervention to prevent the onset of LBP primary and secondary prevention or to prevent LBP progression [14].

In the long-term use of Molded LSO other clinical side effects appears as like

- 1. Somatosensory system.
- 2. Decreases the mobility and stability of the waist.
- 3. Decrease muscle strength, coordination capability and
- 4. A change in proprioception [15,16].

Spinal braces on NSCLBP are still a controversial topic in orthotic treatment protocol. Last decades orthotic clinical evidence based practice worked out in effect of moulded LSO on COP-Sway with pain on separate aspect [10,16-18], but this is an attempt to find the effects of molded LSO on COP-sway and pain compactly in NSCLBP. This study wants to stabilize a clinical report on non-specific Chronic LBP in terms with COP-sway and Pain in Indian scenario for better orthotic prescription.

Materials and Methods

A sample of convenience of 30 persons with NSCLBP was take part in this study. Demographic data of the subject was collected in the demographic data collection form. This includes age, sex, height, weight, cause. This clinical study was studied at Department of Prosthetics and Orthotics, National Institute for Locomotor Disabilities (Divyangjan), B.T. Road, Bon-Hooghly, Kolkata, west Bengal, 700090, Study population was used patients with low back pain report to the general out Patient Department (OPD) of NILD, Study Period of 12 months and Study Design Prospective Quasi Pre-Post Experimental study design. Inclusion criteria was patient with non-specific chronic (12 weeks or more) LBP, Age group 30-60 [19], able to ambulate without any walking aid, First time user, Patients with cognitive efficient.

The study was approved by the Ethical Committee of National Institute for Locomotor Disabilities (Divyangjans), Kolkata, India, for the period 28th February 2018 to 27th April 2019.

Dependent variable was Postural sway and Independent Variable Molded LSO.

The study procedure was explained to the selected individual. The informed consent was obtained from the individual, when they agree to participate in study. Then first Pre data (Base line) of COP and Pain was taken in without molded LSO. After the clinical orthotic adaptation pre data was collected and after 4 weeks the post data was taken after successful orthotic follow up trail. COP postural sway data was taken in eye open and eye close condition in with and without orthosis. The subject is asked to place two feet on the affixed foot prints (not self-selected foot placement)

such that the central cross mark on the foot prints would be on the middle of subject's foot positioning. This actually helps to place the subject's feet just over the central x-y- axis. The upper extremity of subject should be aligned perfectly. Special instruction was given to subject to adopt a naturally straight posture and look straight head towards visual reference. In each subject, a 0.5-minute test will be taken in both eye open and eye closed in static position. In each test (eye open and eye close) 5 minutes time interval should be given to the subject. Pre data (Without Brace) taken were Patients asked to stand on a force plate in two different condition; eye open and eye close. Sessions was identical for pre and post fitment. During sessions a Force plate were used to see the effect of Molded LSO on balance in subject with Non-specific chronic LBP (Figures 1-4).

Pain was assessed by questionnaire Visual analogue scale (VAS). Effectiveness of the Molded LSO was analyzed between pre and post used of orthosis by Mean of paired t-test. The data obtained from this procedure were analyzed using SPSS software by paired t-test. Raw data were exported from computer stored Kistler force plate into Microsoft excel and final data analysis was performed in SPSS VERSION 24.0 (SPSS Inc, Chicago, Illinios) and Graph Pad Prism version 5. Data p- Value \leq 0.05 was considered for statistically significant in this current study.

Kistler 3D force plate

Force plate is biological instrument that provides the gold standard ground reaction force and COP data to quantify balance, gait and other parameters of biomechanics. The gold standard high accuracy piezoelectric force plate (Type 9260AA6, Serial Number 4464611; Kistler Instruments Winterthur, Switzerland) was used in this study.

Visual Analogue Scale (VAS)

Worldwide VAS scale was standardized by Boonstra et al. [20] for clinical finding of pain intensity in LBP. It is currently used in evidence based practice for the measuring of pain concentration in NSLBP [21]. It was also guided by symposium activity in IRSSD (International Research Society of Spinal Deformities) annual scientific meeting in 2016. It have also clinical evidence for using the VAS scale in Indian NSLBP population, Pande et al. [22] was used this assessment tool for finding pain severity over Indian population.

Kistler 3D Force Plate and VAS scale were validate in this prospect with pilot study and original research work in this study set up with the affiliation with The West Bengal University of Health Sciences, Kolkata.

Design Molded Lumbosacral Orthosis

This custom fabricated molded lumbosacral orthosis (LSO) is a circumferential brace design controlling the lumbosacral spinal area. Specific measurements and a cast is taken for the entire patient and used as a mold in fabricating the brace.

Materials used to fabricate the brace are 3 mm polypropylene. The LSO (anterior corset and posterior solid sections) is a very versatile orthosis and recommended for low back pain and other spinal conditions. The design affords excellent adjustability of pressure and comfortable fit. The anterior overlap corset design consists of a single opening anteriorly with Velcro closures. The exterior frame control anterior, posterior Flexion and lateral rotation of lumbar spine. The molded posterior section with a corset-type front is providing solution for the individual to adjust the abdominal pressure. It is highly adjustable and comfortable to wear. This lumbosacral orthosis may produce a greater increase in lumbar stiffness and might lead to the generation of intra-abdominal pressure. This, in turn might change the forces exerted on the different lumbar structures that provide proprioceptive information, maintain stability by reducing load on the trunk and restrict mobility (extension).

Trimline

Anterior superior up to sternal notch, anterior Inferior 30 mm above pubic symphysis to just below ASIA providing sufficient Clarence for sitting lateral Superior up to 12th rib, lateral inferior 30 mm above Grater Trochanter, posterior Superior 50 mm below the inferior angle of scapula, Posterior inferior as low as possible not interfering with setting clearance, no additional pressure pad was used. Pressure system was applied during the time of orthotic modification.



Figure 1. Subject on force platform in lab room with equipment's.



Figure 2. Subject on force platform with brace in eye closed condition.



Figure 3. Subject on force platform without brace in eye closed condition.



Figure 4. Subject on force platform without brace in eye open condition.

Results

The results for the postural sway were presented in Table 1 and VAS results were presented in Table 2. Postural sway in respect to COP-AP/ML, mean, RMS, Range have the significant differences in with and without brace pre-post eye closed and eye open conditions in subjects with NSCLBP (Figures 5-7).

Table 1. Significance, mean and SD differences of COP-AP/ML parameters within			
groups pre post with without brace conditions.			

Post-COP-Ax-WtBEO- -0.004751667 0.000479387 17.60785217 0.052 Pre-COP-Ax-RMS-WtBEO 11.78493333 11.16078081 0.052 Post-COP-Ax-Range-WtBEO 459.315 510.2250785 0.198 Pre-COP-Ax-Range-WtBEO 317.6341483 281.0046663 0.0001 Pre-COP-Ax-Range-WtBEO 0.0243015 0.001009475 0.0001 Post-COP-Ax-WBEO 0.0042801 0.000804282 0.0001 Pre-COP-Ax-RMS-WBEO 7.913166667 17.61372793 0.0001 Pre-COP-Ax-Range-WBEO 359.5434333 327.8134776 0.001 Pre-COP-Ax-Range-WBEO 202.903 140.7531701 0.0001 Pre-COP-Ax-Range-WBEO 202.903 140.7531701 0.001 Pre-COP-Ax-RMS-WIBEC 10.0181054 0.000688271 0.0081 Pre-COP-Ax-RMS-WIBEC 14.54795 13.01291961 0.001 Pre-COP-Ax-RMS-WIBEC 14.54795 13.01291961 0.001 Pre-COP-Ax-Range-WIBEC 505.12 457.8502125 0.0001 Pre-COP-Ax-Range-WIBEC 505.12 457.8502125 </th <th>Parameters</th> <th>Mean</th> <th>SD</th> <th>Significance</th>	Parameters	Mean	SD	Significance
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Post-COP-Ax-RMS-WtBEC 14.54795 13.01291961 Pre-COP-Ax-Rnage-WtBEC 638.941 711.2367732 0.452 Post-COP-Ax-Range-WtBEC 505.12 457.8502125 0.0001 Pre-COP-Ax-WBEC 0.000574867 0.000709121 0.0001 Post-COP-Ax-WBEC 0.003058933 0.000671998 0.045 Pre-COP-Ax-WBEC 23.1285 17.93259139 0.045 Pre-COP-Ax-RMS-WBEC 15.8006 14.39118137 0.045 Pre-COP-Ax-Range-WBEC 420.2970667 395.7869936 0.943 Post-COP-Ax-Range-WBEC 425.8103333 259.5187762 0.001 Pre-COP-Ay-WtBEO -0.004687367 0.000511011 0.001	Post-COP-Ax-WtBEC	0.002008067	0.000405272	
Pre-COP-Ax-Rnage-WtBEC 638.941 711.2367732 0.452 Post-COP-Ax-Range-WtBEC 505.12 457.8502125 0.0001 Pre-COP-Ax-WBEC 0.000574867 0.000709121 0.0001 Post-COP-Ax-WBEC 0.003058933 0.000671998 0.001 Post-COP-Ax-WBEC 23.1285 17.93259139 0.045 Pre-COP-Ax-RMS-WBEC 15.8006 14.39118137 0.045 Pre-COP-Ax-Range-WBEC 420.2970667 395.7869936 0.943 Post-COP-Ax-Range-WBEC 425.8103333 259.5187762 0.001 Pre-COP-Ay-WtBEO -0.004687367 0.000511011 0.001	Pre-COP-Ax-RMS-WtBEC	22.3676	22.27677268	0.083
Post-COP-Ax-Range-WtBEC 505.12 457.8502125 Pre-COP-Ax-WBEC 0.000574867 0.000709121 0.0001 Post-COP-Ax-WBEC 0.003058933 0.000671998 0.001 Pre-COP-Ax-WBEC 23.1285 17.93259139 0.045 Pre-COP-Ax-RMS-WBEC 15.8006 14.39118137 0.943 Pre-COP-Ax-Range-WBEC 420.2970667 395.7869936 0.943 Pre-COP-Ax-Range-WBEC 425.8103333 259.5187762 0.001 Pre-COP-Ay-WtBEO -0.004687367 0.000511011 0.001	Post-COP-Ax-RMS-WtBEC	14.54795	13.01291961	
Pre-COP-Ax-WBEC 0.000574867 0.000709121 0.0001 Post-COP-Ax-WBEC 0.003058933 0.000671998 0.001 Pre-COP-Ax-WBEC 23.1285 17.93259139 0.045 Pre-COP-Ax-RMS-WBEC 15.8006 14.39118137 0.045 Pre-COP-Ax-Range-WBEC 420.2970667 395.7869936 0.943 Pre-COP-Ax-Range-WBEC 425.8103333 259.5187762 0.001 Pre-COP-Ay-WtBEO -0.004687367 0.000511011 0.001 Post-COP-Ay-WtBEO -0.010826333 0.000620077 0.001	Pre-COP-Ax-Rnage-WtBEC	638.941	711.2367732	0.452
Post-COP-Ax-WBEC 0.003058933 0.000671998 Pre-COP-Ax-RMS-WBEC 23.1285 17.93259139 0.045 Post-COP-Ax-RMS-WBEC 15.8006 14.39118137 0.045 Pre-COP-Ax-Range-WBEC 420.2970667 395.7869936 0.943 Post-COP-Ax-Range-WBEC 425.8103333 259.5187762 0.001 Pre-COP-Ay-WtBEO -0.004687367 0.000511011 0.001	Post-COP-Ax-Range-WtBEC	505.12	457.8502125	
Pre-COP-Ax-RMS-WBEC 23.1285 17.93259139 0.045 Post-COP-Ax-RMS-WBEC 15.8006 14.39118137 0.045 Pre-COP-Ax-Range-WBEC 420.2970667 395.7869936 0.943 Post-COP-Ax-Range-WBEC 425.8103333 259.5187762 0.001 Pre-COP-Ay-WtBEO -0.004687367 0.000511011 0.001 Post-COP-Ay-WtBEO -0.010826333 0.000620077 0.001	Pre-COP-Ax-WBEC	0.000574867	0.000709121	0.0001
Post-COP-Ax-RMS-WBEC 15.8006 14.39118137 Pre-COP-Ax-Range-WBEC 420.2970667 395.7869936 0.943 Post-COP-Ax-Range-WBEC 425.8103333 259.5187762 0.943 Pre-COP-Ay-WtBEO -0.004687367 0.000511011 0.001 Post-COP-Ay-WtBEO -0.010826333 0.000620077 0.001	Post-COP-Ax-WBEC	0.003058933	0.000671998	
Pre-COP-Ax-Range-WBEC 420.2970667 395.7869936 0.943 Post-COP-Ax-Range-WBEC 425.8103333 259.5187762 0.001 Pre-COP-Ay-WtBEO -0.004687367 0.000511011 0.001 Post-COP-Ay-WtBEO -0.010826333 0.000620077 0.001	Pre-COP-Ax-RMS-WBEC	23.1285	17.93259139	0.045
Post-COP-Ax-Range-WBEC 425.8103333 259.5187762 Pre-COP-Ay-WtBEO -0.004687367 0.000511011 0.001 Post-COP-Ay-WtBEO -0.010826333 0.000620077 0.001	Post-COP-Ax-RMS-WBEC	15.8006	14.39118137	
Pre-COP-Ay-WtBEO -0.004687367 0.000511011 0.001 Post-COP-Ay-WtBEO -0.010826333 0.000620077	Pre-COP-Ax-Range-WBEC	420.2970667	395.7869936	0.943
Post-COP-Ay-WtBEO -0.010826333 0.000620077	Post-COP-Ax-Range-WBEC	425.8103333	259.5187762	
	Pre-COP-Ay-WtBEO	-0.004687367	0.000511011	0.001
Pre-COP-Ay-RMS-WtBEO 7.105616667 4.969122137 0.0051	Post-COP-Ay-WtBEO	-0.010826333	0.000620077	
	Pre-COP-Ay-RMS-WtBEO	7.105616667	4.969122137	0.0051

Post-COP-Ay-RMS-WtBEO	15.20993333	14.03885589	
Pre-COP-Ay-Range-WtBEO	739.2486667	790.6448002	0.011
Post-COP-Ay-Range-WtBEO	295.444	192.552021	
Pre-COP-Ay-WtBEC	-0.067887433	0.000717208	0.0001
Post-COP-Ay-WtBEC	-0.000495867	0.000417048	
Pre-COP-Ay-RMS-WtBEC	36.30143333	32.73326181	0.032
Post-COP-Ay-RMS-WtBEC	54.4554	46.49278136	
Pre-COP-Ay-Rnage-WtBEC	936.7165667	667.8991435	0.1
Post-COP-Ay-Range-WtBEC	687.5466667	408.9976205	
Pre-COP-Ay-WBEC	-0.073763933	0.000666412	0.0001
Post-COP-Ay-WBEC	0.000023833	0.000279926	
Pre-COP-Ay-RMS-WBEC	38.41886667	35.97339814	0.123
Post-COP-Ay-RMS-WBEC	25.60746667	18.64012969	
Pre-COP-Ay-Range-WBEC	743.5820667	915.4506714	0.87
Post-COP-Ay-Range-WBEC	772.9613333	462.3767193	
Pre-COP-Ay-WBEO	0.0257916	0.000673752	0.0001
Post-COP-Ay-WBEO	-0.012870833	0.000567258	
Pre-COP-Ay-RMS-WBEO	35.92373333	28.3705835	0.011
Post-COPA-y-RMS-WBEO	19.87163333	23.0373656	
Pre-COP-Ay-Range-WBEO	786.5886667	711.4927989	0.0001
Post-COP-Ay-Range-WBEO	157.6812667	157.6812667	

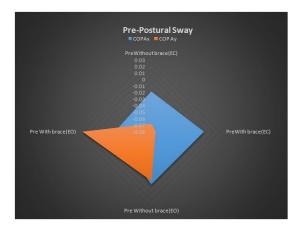


Figure 5. Pre-postural sway (COP- Ax & Ay) with & without Brace.

 Table 2. Significance, mean and SD differences of VAS parameters within groups pre post with without brace conditions.

Parameters	Mean	SD	P-Value
Pre without Brace	7.016667	1.004088	2.16706

Post without Brace	2.866667	0.812334	
Pre with Brace	5.733333	0.860955	1.32943
Post with Brace	2.233333	0.673132	

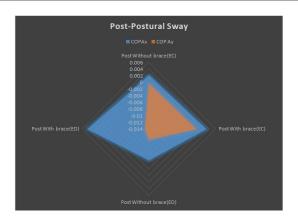


Figure 6. Post-postural sway (COP- Ax & Ay) with & without Brace.

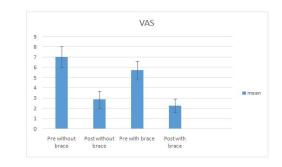


Figure 7. VAS score with and without brace in pre-post.

Discussion

This study is investigated to analyze the effect of molded lumbosacral orthosis on COP-AP/ML postural sway and pain in subjects with non-specific chronic low back pain. Present study have a specific objectives for this prospective to establish a orthotic clinical evidence base practice report on reducing pain and COP-AP/ML sway using molded Lumbosecral Orthosis (LSO) in subjects with non-specific chronic low back pain (NSCLBP).

Current evident result of this study found that COP-Ax (ML) mean is significantly decreased in eye open (EO) post condition without molded LSO, p=0.001. RMS of COP-Ax (ML) is no significant differences. Range of COP-Ax (ML) also has no significant differences in pre post condition. COP-Ay (AP) mean is significantly increased in EO post condition without molded LSO (p=0.001). RMS value is significantly increased (p=0.005). Range is significantly decreased (p=0.01). With brace COP-Ax (ML) mean is significantly increased in EO post condition (P=0.005). Range is significantly increased in EO post condition (p=0.001). RMS is significantly decreased (p=0.01). With brace COP-Ax (ML) mean is significantly increased in EO post condition (p=0.0001). RMS is significantly decreased in EO post condition (p=0.0001). RMS is significantly decreased in EO post condition (p=0.0001). RMS is significantly decreased (p=0.01). Range significantly decreased (p=0.001). RMS is significantly decreased (p=0.001). Finding outcome shows statically significant changes of COP-AP/ML in respect to RMS and Range value which signifies provisions for positive improvement of closed postural sway with brace in EO condition.

Result of this study also found that COP-Ax (ML) mean is significantly increased in eye close (EC) post condition without molded LSO (p=0.0001). RMS of COP-Ax (ML) has no significant differences in pre & post condition. Range of COP-Ax (ML) has no significant differences. COP-Ay (AP) mean is significantly decreased in EC post condition without molded LSO, p=0.0001. RMS value is significantly increased, p=0.03. Range of COP-Ay (AP) is no

significant differences. With brace COP-Ax (ML) mean is significantly increased in EC post condition, p=0.0001. RMS is significantly decreased, p=0.045. Range is no significant differences. With brace COP-Ay (AP) mean is significantly increased in EC post condition, p=0.0001. RMS is no significant differences. Range is no significant differences. With brace EC condition COP sway significantly increased in AP-sagittal plane, with decreased RMS and range value. Apparently the COP-AP sway is increased but in long term it may have a positive chance to improve COP-AP balance in NSCLBP. Other hand, COP-ML apparently decreased with long term brace there may be chance to improve balance as COP RMS and range not significantly changes in this study.

Alexander Ruhe et al. established that NSLBP patients showed an increased COP mean displacement and this difference was significant and decreased postural stability. It is suggest that there is a relationship between NSLBP in duration of treatment protocol with COP excursions in AP/ML [23]. This is in accordance of this study and in present study it is observed that there is significant difference in mediolateral (Ax) and anterio posterior (Ay) COP displacement in subjects without brace before (Mean (Ax) 0.0181 ± 0.00068), (Mean (Ay)0.0678 ± 0.00071) and after (Mean (Ax)0.0020 ± 0.00040), (Mean (Ay) -.00049 \pm .000417) the treatment (p \leq 0.001) in eye close condition. Sinaki et al. reported that wearing a spinal kypho-orthosis can improve balance and walking quality at baseline, they found significant differences between the osteoporotic-kyphotic group and the control group in balance (P=.002). After a 4-week intervention, comparison of the baseline data of the experimental group and follow-up results showed a significant change in balance (P=0.003) [24]. In this current evident clinical result is reported that postural sway is improved in AP (p=0.001) which may improve balance in NSLBP. This established clinical evidenced based outcome is supported our result that there is significant difference in mediolateral (Ax) and anterio-posterior (Ay) COP displacement in subjects with brace before (Mean (Ax) 0.00057 ± 0.0007091), (Mean (Ay)-0.07376 ± .000666) and after (Mean (Ax) 0.0030 ± 0.00067), (Mean (Ay) 0.000023 ± 0.00028) the treatment application ($p \le .001$) in eye close condition.

The findings of current study is not convenient with the findings of the Cholewicki et al. observed and reported that molded LSO have no significance differences in static condition on COP deviations (p=0.13). They applied the LSO on healthy group and same group used as a control group. In this present study the molded LSO has been applied to Chronic LBP patients and a positive result has been found in static balance on postural sway in AP and ML [25].

It is seen that in present study there is significant difference in mediolateral (Ax) and anterio-posterior (Ay) COP displacement in subjects without brace before (Mean (Ax) 0.00123 \pm 0.00080), (Mean (Ay) -0.0047 \pm 0.00051) and after (Mean (Ax)-0.0048 \pm 0.00048), (Mean (Ay)-0.0108 \pm 0.00062) the treatment application (p \leq .001) in eye open condition. In our perspective short term clinical study evident for significant difference in COP-AP/ML (p \leq .001) deviations in NSCLBP after using molded LSO. Alexander et al. reported differences in static balance reactions for CLBP and healthy subject. Specifically, with eyes open, showed significant difference in anterior/posterior excursion (p= 0.015) and in eye close (p=0.009), Mediolateral (Ax) sway in eye close (p=0.000) but there are no significant difference in eye open Ax (p=0.066) [26].

Here in this present study it is observed that use of molded LSO decrease the pain as well as COP sway (p=0.001, 0.0001 respectively). Azadinia et al. and Salavati et al. reported NSLBP have improvement in postural stability at closed eyes conditions (P= 0.003) in the control group which are used LSO and the routine physiotherapy in compression to the group which are given only routine physiotherapy. They used Force platform (9260 AA, Kistler, Switzerland) to collect COP data along the X and Y-axes, representing mediolateral (ML) and anterio-posterior (AP) directions, respectively. In there within group study using LSO, they found statistically significant difference (p=0.03)in NSCLBP using orthosis in anterio-posterior (Ay) sway of the COP in eye open and in eye close condition (p=0.04), there mediolateral (Ax) sway is significant in eye open (p=0.03) and non-significant in eye close (p=0.09) [27,28].

In current study anterio-posterior (Ay) sway in EO& EC and mediolateral (Ax)in eye open is supported but it is not supporting mediolateral (Ax)in eye close. This is in accordance to our study for using 3D force plate. But this current evident result shows significant COP-AP/ML deviations on LSO in NSLBP without physiotherapy plan. Jie Mi et al. found There was no significant difference in sway (EO: 0.44 \pm 0.10 vs. 0.41 \pm 0.16, p=0.598) or (EC: 0.55 \pm 0.23 vs. 0.47 \pm 0.14, p=0.174) after using the LSO by NSLBP subjects [29].

The finding in this current study there is significant difference in mediolateral (Ax) and anterio-posterior (Ay) COP displacement in subjects with NSLBP with brace before (Mean -0.0243 ± 0.001), (Mean 0.0258 ± 0.00067) and after (Mean 0.0042 ± 0.0008), (Mean -0.013 ± 0.00057) the treatment ($p \le 0.001$) in eve open condition. As in our perspective pre-post COP-AP/ML deviations significantly (p=0.0001) changed in LSO. Apparently post result supported through pre result. Della Volpe et al. showed a significant increase in average RMS of COP in AP direction for CLBP group (0.34 _0.03 mm, F=19.9, p < 0.0001) as compared to the healthy group (0.27-0.02 mm). Post testing revealed significant differences for corresponding to the dynamic stance conditions [30]. Where Maki et al. also found significant increase (P < 0.004) in the medial ± lateral (RMSz) in the frontal plane during spontaneous sway in a blind folded population of elderly who were prone to falling compared to a non-falling elderly population [31]. This study agreement with the findings of current study where significant difference in anterio-posterior (Ay) RMS before (Mean 24.66 ± 17.61), and after (Mean 7.91 ± 10.26), the treatment (p=0.0001) in eye open condition where without brace before (Mean 36.30 ± 32.73) and after (54.45 ± 46.49) the treatment (p=0.032) in eye close condition and before (Mean 7.10 \pm 4.96) and after (15.2 ± 14.0) the treatment (p=0.0051) in eye open condition. But not agreement with the finding of current study were there is no significant difference in with brace before (Mean 38.41 ± 35.97) and after (25.60 ± 18.64) the treatment (p=0.123) in eye close condition.

Brumagne et al. reported that significance reduced postural stability in the CLBP group during more challenging standing conditions, the between-group difference in COP RMS AP was 1.8 mm (p=0.046) [16]. On the other hand, Della Volpe et al. found that there is no significant increase in mean RMS of COP in ML (Ax) direction for the CLBP group as compared to the healthy group [30].

It is also seen in this current study that there is no significant difference in mediolateral (Ax) RMS without brace before (Mean 18.91 ± 17.60), and after (Mean 11.78 ± 11.160), the treatment (p=0.52) in eye open condition, before (Mean 22.36 ± 22.27), and after (Mean 14.54 ± 13.0), the treatment (p=0.083) in eye close condition, where with brace before (Mean 35.92 ± 28.37), and after (Mean 19.87 ± 23.0), the treatment (p=0.011) in eye open condition, and before (Mean 23.12 ± 17.93), and after (Mean 15.8 ± 14.39), the treatment (p=0.045) in eye close condition.

Sian MacRae et al. demonstrated that the antero-posterior Centre of pressure parameter data for chronic low back pain and asymptomatic participants during different standing conditions, Firm surface eyes-open, eyes-closed; and compliant surface, eyes-open, eyes-closed. Found there were no differences in COPRMSE AP for any of the four standing conditions (F [2.35, 70.38] r=1.39, p=0.26, I]2=0.04) [32].

Where as in current findings there is also no such significant difference in anterio-posterior (Ay) RMS with brace before (Mean 38.41 ± 35.97) and after (25.60 \pm 18.64) the treatment (p=0.123) in eye close condition. But significant difference before (Mean 24.66 \pm 17.61), and after (Mean 7.91 \pm 10.26), the treatment (p=0.0001) in eye open condition, in without brace before (Mean 36.30 \pm 32.73) and after (54.45 \pm 46.49) the treatment (p=0.032) in eye close condition and before (Mean 7.10 \pm 4.96) and after (15.2 \pm 14.0) the treatment (p=0.0051) in eye open condition. Munoz et al. reported that a lumbar lordos is brace improved the quality of balance

performance in patients suffering from lumbar pain. A 51% reduction in mean COP displacement was found when patients wearing a brace stood on a force platform with eyes closed [33]. It is also seen in current study where the mean difference in AP/ML postural sway is decreasing after the use of LSO in eye close condition.

Where it is seen in current study that there is no significant difference in mediolateral (Ax) Range in subjects with non-specific chronic low back pain without brace before (Mean 459.3 ± 510.22), and after (Mean 317.63 ± 281.0), the treatment (p=0.198) in eye open condition. Were in current study also no significant difference in mediolateral (Ax) and anterio-posterior (Ay) Range in subjects with non-specific chronic low back pain with brace before (Mean 420.3 ± 395.78), (Mean 743.58 ± 915.45) and after (Mean 425.81 ± 259.51), (Mean 772.96 ± 462.37) the treatment (p=0.943, 870) in eye close condition. Jie Mi et al. investigated postural control in patients with NSLBP had deficits with greater center of pressure (COP) sway Range when standing on firm surface with eyes open (p=0.002); with eyes closed (p=0.002) in compression to the healthy control [29], were it is seen that in current study there is no significant difference in mediolateral (Ax) and anterio-posterior (Ay) Range in subjects with non-specific chronic low back pain without brace before (Mean 638.94 ± 711.23), (Mean 936.71 ± 667.89) and after (Mean 505.12 ± 457.85), (687.54 ± 408.99) the treatment (p=0.452, 0.10) in eve close condition may be due to the investigate the difference between healthy and NCLBP patient but in current study in this result showing the effect in pre post condition after using the brace for 4 weeks.

Heta Haresh Thakkar et al. found that the significant difference in postural sway between normal and CLBP sufferers in posterior and left lateral direction (P <0.05). The CLBP group showed reduction in dynamic excursion distances (SEBT) in all direction as compared to control group, except on right anteromedial, anterolateral and right and left posterior direction [34], were in current study there is significant difference in mediolateral (Ax) and anterio-posterior (Ay) Range in subjects with non-specific chronic low back pain with brace before (Mean 359.54 ± 327.81), (Mean 786.58 ± 711.49) and after (Mean 202.90 ± 140.75), (Mean 157.68 ± 106.77) the treatment (p \leq 0.01) in eye open condition.

There were no significant differences but it have the mean differences without any post side effect symptoms on pain in subjects with non-specific chronic low back pain before (Mean 7.02 \pm 1.00) and after 4 weeks (2.87 \pm 0.81) without brace (p=2.16706) and with the brace before (Mean 5.73 \pm 0.86) and after 4 weeks (2.23 ± 0.67) (p=1.32943). Pain was decreased after wearing the orthosis but none significantly. The findings of the present study is in agreement with the findings of the Jong-II Kang et al, where they found that pain decreased in nonspecific chronic low back pain after wearing the lumbosacral orthosis (VAS P<0.01). It is considered that the mechanical characteristics of lumbosacral orthosis decrease pain by increasing the stability of the spine and pelvis [35]. Another study by Redford et al, they reported that lumbosacral orthosis reduces low back pain by limiting the trunk movement and decreasing the load on the waist by transmitting forces applied to IV disc to soft tissue surrounding the abdomen [36]. Million et al. divided their subjects into a group wearing a lumbosacral corset and a group not wearing the corset. They showed that pain decreased in group wearing the lumbosacral corset and it is supporting this study's findings [37].

Sinaki et al. reported that kypho-orthosis can increase decrease low back pain significantly (P=0.001) by increasing the strength of the back extensor muscle patients with and at risk of falls [24]. Deepak et al. High prevalence (78.75%) of depression among chronic pain patients without any difference in chronic facet pain and chronic low back pain of any origin, there was strong relation between pain severity and depression (r=0.86) [38]. Carl L. Herndon et al. found For all NSLBP patients the average NRS pain ratings decreased by 65.5% from pre to (local anesthetic injections 2 ml 1% lidocaine, preservative free) post-injection (p < 0.0001). 48% (N= 12) of the patients reported full pain relief (NRS pain ="0"), whereas 52% (N= 13) reported pain Postural control is an action of maintaining, achieving or restoring a state of its COP-COM sway within the base of support during posture or activity. Current clinical tests of balance assess different components of balance ability in eye open and eye close condition. In present study clinical assessments based on understanding of balance and postural control strategies in subject with non-specific chronic low back pain and outlines of the concept of postural control strategies in different conditions are improved. Postural control strategies depend upon support or change-in-support. In this study balance analyze in subjects with non-specific chronic low back pain in the terms of postural (COP) sway, LSO was used as the support of spine and lower back in subject with non-specific chronic low back pain to improve quality of life.

Conclusion

As per present perspective clinical evident report it is going to conclude that molded LSO have a significance impact on positive influences for reducing postural sway and pain in short term orthotic treatment protocol. It have positive impact on static postural balance and pain with saliently maintaining the lower COG alignment and unloading lumbar spine by using molded LSO in subjects. One center prospective short term clinical report cannot indiscriminate the positive impact of molded LSO in NSLBP. So the molded LSO can be recommended as a RCT study on this prospect for short term use orthotic plan in NSCLBP.

References

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