Impact of a Modified Lumbar Belt, with and without Customized Insoles, in Comparison to Standard Prefabricated Belts on Low Back Pain and Functional Disability in Patients with Pronated Feet: Randomized Clinical Trial

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ABSTRACT

Background: Chronic Low Back Pain (LBP) remains a pervasive global health concern. Foot Pronation (FP), by affecting anatomical alignment, has been identified as a contributing factor to nonspecific chronic LBP. Patients with chronic LBP often exhibit impaired proprioception, which may aggravate symptoms.

Objective: This study aimed to evaluate the efficacy of a modified lumbar belt, independently and in combination with custom-made insoles, in alleviating back pain and disability in patients with FP. Outcomes were also compared with those of a standard prefabricated belt.

Material and Methods: A randomized clinical trial was conducted involving 45 individuals diagnosed with nonspecific chronic LBP and FP. Using block randomization, participants were allocated to four groups: (1) prefabricated belt, (2) modified belt, (3) custom-made insole, and (4) modified belt combined with insole. Pain and disability were assessed at baseline and after six weeks using the Visual Analog Scale (VAS) and the Oswestry Disability Index (ODI).

Results: All groups demonstrated significantly greater pain reduction compared to the standard belt group. However, no significant difference in pain reduction was observed among the insole, modified belts, and combined groups. The greatest improvement in disability was observed in the combined group, significantly surpassing all others. Custom-made insoles alone also led to a notable reduction in disability compared to the standard belt.

Conclusion: The modified lumbar belt proved more effective than the prefabricated version in managing pain and disability among patients with FP. Combined use with custom-made insoles further enhanced outcomes, highlighting the benefit of integrated interventions.

Keywords

Low Back Pain; Spinal Orthosis; Rehabilitation; Pronation; Foot Orthoses

Introduction

Low Back Pain (LBP) is a widespread musculoskeletal disorder that affects a significant proportion of the global population, with an estimated lifetime prevalence of 70-85% [1]. It is the leading

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cause of disability among individuals under the age of 45 and ranks as the second most common reason for physician visits, the fifth leading cause of hospital admissions, and the third most frequent indication for surgical procedures [2-5]. Approximately 11-12% of the population suffers from functional disability due to LBP [6].

Non-specific chronic low back pain refers to back pain that lasts over 12 weeks with no identifiable pathology, such as radiographic abnormalities or blood test indicators [7, 8], which approximately 90-95% of all LBP cases have suffered from that pain [9]. This condition not only imposes a substantial economic burden on healthcare systems but also significantly diminishes patients' quality of life.

A key factor in LBP patients is proprioception, which helps postural control and stability. Two systematic reviews suggest that proprioception is impaired in individuals with LBP, and this deficit correlates with pain intensity [9, 10]. Research also indicates that lumbar belts may enhance proprioception by stimulating sensory feedback, potentially contributing to pain reduction [11, 12].

Furthermore, Foot Pronation (FP), characterized by excessive inward rolling of the foot during walking or standing, has been identified as a potential contributor to nonspecific chronic LBP. By altering the biomechanical alignment of the lower extremities, FP can lead to increased pelvic tilt, lumbar hyperlordosis, and muscular tension, ultimately contributing to spinal instability and pain. Insoles are a commonly recommended treatment for FP to improve postural alignment and potentially reduce LBP [13].

Considering that the wrong biomechanics of the foot and its effect on all higher areas, the simultaneous presence of a disorder in the lower limb, and the lack of proprioception, may cause a vicious cycle. During this cycle, the disorder in the foot causes defects in the position of the back and pelvis. On the other hand, due to the presence of proprioceptive disorders, the body will not be able to recognize and correct positional problems. As a result, stress and strain in the lumbar and pelvis areas will increase abnormally, and back pain will occur. Due to the presence of pain and its inhibiting effect on the transmission of proprioceptive messages [14], the proprioceptive disorder will more increase, resulting in ultimately increasing defects of the back and pelvis.

Lumbar belts can enhance proprioception by providing sensory feedback, thereby improving spinal stability and reducing pain. Similarly, custom insoles are designed to correct foot alignment, thereby addressing the underlying biomechanical abnormalities associated with FP. However, the efficacy of combining these interventions remains underexplored.

This study aimed to evaluate the effects of a modified lumbar belt, both independently and in combination with custom insoles, on pain and functional disability in patients with FP and chronic LBP, in comparison to standard prefabricated belts.

Material and Methods

Subjects

This study, as a randomized clinical trial, was conducted between 2022 and 2023 at multiple clinical sites, including Shahid Rajaei, Shahid Motahari, Imam Reza Clinic in Shiraz, and Imam Reza Hospital in Lar. At this stage, the purposes were to inform each participant about the study´s aim, the required commitment, its duration and the potential benefits and risks associated with the interventions. In the case of voluntary acceptance and signing of the consent form by the patient, their personal information was recorded, they were asked to fill out the Oswestry Disability Index questionnaire, and then allocation to the intervention group was done. Block randomization was used for proper and random allocation to the groups of the belt, insole, modified belt, and insole with modified belt (B C C D D A

D A C A B B A D C B A B D C C B D A A C B D B A D C C A C B B D D A C A C B D B A D D A C B). Based on the created block randomization arrangement, symbol A was used for allocation in the belt group, symbol B for insole group, symbol C for the modified belt group, and symbol D for insole and the modified belt group. In case of unwillingness to participate in the study, standard treatment was performed for the patient. None of the patients were aware of other types of orthotic treatment in this study.

Ethical consideration

Ethical approval was obtained from the University of Social Welfare and Rehabilitation Sciences, Tehran, Iran, and the trial was registered with the Iranian Registry of Clinical Trials (IRCT20220403054393N1).

Participants

A total of 45 individuals diagnosed with nonspecific chronic LBP and FP were enrolled. Some inclusion and exclusion criteria were considered in this study.

Inclusion criteria were as follows: 1) the presence of non-specific back pain according to the doctor's diagnosis and foot pronation in one or two feet, 2) age 30-50 years, 3) chronic LBP lasting >12 weeks, 4) Visual Analog Scale (VAS) pain score ≥3, and 5) Body Mass Index (BMI) 18.5-30.

Exclusion criteria were also as follows: 1) the simultaneous use of other treatments (physiotherapy, medication, injections, etc.), 2) recent spinal or lower limb injuries/surgeries, 3) pregnancy or childbirth in the last six months, 4) leg length discrepancy >5 mm, 5) any mobility disorder that affects the ability to participate in the study, 6) the history of sprained ankle, and 7) gait abnormalities (e.g., rigid pronation, genu varum, lameness).

Intervention

The study was conducted in four phases, as follows:

1. Design and fabrication of a silicon pad

At first, a mold in the shape of an isosceles triangle similar to the sacrum was made to cover the sacral and lumbar regions. The mold was perforated to increase tactile stimulation and proprioception (Figure 1). Then, the mold was filled with silicone, and the silicone pad was embedded into a prefabricated lumbar

Figure 1: Mold filled with silicone

Figure 2: Modified belt with silicone pad

belt (Figure 2).

2. Baseline assessment

After the selection of the participants, the VAS score for the average amount of back pain in the last week was registered by them, and they were also asked to answer the questions of the Oswestry disability index. Then, participants were randomly assigned to one of four groups: 1. prefabricated lumbar belt, 2. modified lumbar belt, 3. customized insole, and 4. modified lumbar belt + customized insole. After group allocation, participants in the insole or insole+ modified belt groups underwent foot scanning and measurement. Then, they returned home while their custom insoles were being fabricated. After one week, the patients could receive their completed insoles. Participants in the other two groups received their assigned orthoses immediately, and the intervention phase began for them. The premade and modified belt, which was considered for each patient based on the recorded size of the hip circumference in the area between the anterior superior iliac spine and the trochanter, was closed for them at the place above the pubic bone. The force introduced by the belt was equal to 50 Newton [15], which was measured by a tension dynamometer, and the correct closing place was marked on the belt. We asked the patient to close the belt in the specified place and come back for readjustment in case of size or weight change.

3. Intervention implementation

If assigned to the insole group, participants underwent foot scanning using a PT-SCAN pressure analysis system. Custom insoles were designed using CAD-CAM technology. For this purpose, we used the pressure scan PT-SCAN model 4452F40 of Paya Fanavaran Ferdowsi company with resistive sensor technology, made in Iran. The number of sensors is 2288 in a 44×52 matrix, and the measurement area is 40×40 cm^2 (1.4 sensors per square centimeter). Other features of the device include a data resolution of 12 bits, a pressure range of 0.5 to 100 PSI, and a data acquisition frequency of 200 to 400 Hz. The obtained computer scan was evaluated for each patient individually, and a special insole was designed for him using PT insole design computer software. The medial wedge was 4 degrees from the midline to the medial edge of the sole, and based on the size of the patient's foot, it was considered 6 to 8 cm long in the design [16]. The length of the internal longitudinal arch was also considered depending on the size of the patient's foot and the size recorded for him from the talus bone to the head of the first metatarsal, and its height was 15 mm [17]. The metatarsal pad was placed 5 mm behind the head of the second to fourth metatarsals, and its size was such that it covered the three central metatarsals. The width and length of this pad were fitted according to the size of each patient's foot [18]. The height of the metatarsal pad gradually increased from the edges to the middle, up to 6 mm at the middle point. It should be noted that this height is acceptable at a high rate for the metatarsal pad according to the study conducted to measure the tolerance of the pad in patients [19].

In the end, the obtained information was given through G-codes to the device related to Paya Fanavaran company, made in Iran, which did the work of cutting the insoles on the 2/3-thick foam block (Figure 3). After the

Figure 3: Custom-made insole

insole was prepared, the patient would return to the clinic.

At the time of delivery of each of the orthoses, we asked the patients to walk, stand, and sit for 10 minutes with the prescribed orthoses in the clinic so that they could report any problem or discomfort. After ensuring the comfort of the patients and their understanding of how to use the device, they were asked to use prescribed orthoses continuously for 6 weeks, during daily activities, for at least 8 hours during the day, and then return to the center. A notebook was provided to the patients, and they were asked to write down the hours of using each of the received orthoses every day.

4. Follow-up assessment (after six weeks)

Participants completed a post-intervention VAS and Oswestry Disability Index (ODI) questionnaire.

The satisfaction with the treatment was also recorded on a 0–10 scale.

Statistical analysis

Data were analyzed using SPSS software (version 26). Analysis of Covariance (ANCOVA) was employed to compare post-intervention outcomes while adjusting for baseline values. Multiple comparisons were conducted using the Bonferroni test. A *P*-value of <0.05 was considered statistically significant.

Results

In this study, a telephone interview was conducted with 271 individuals, 142 of whom were eligible to participate in the study. Of these, 83 individuals came for face-to-face interviews. After the investigations and taking into account the including and excluding criteria, 52 individuals were qualified to conduct this study. These numbers were assigned to the belts, insoles, modified belts, and insoles with modified belts based on a block randomization arrangement. A total of 45 individuals came back after 6 weeks and completed the study (seven lost to follow-up) (Figure 4). The mean and standard deviation of the subjects' basic characteristics are reported in Table 1. In addition, the mean and standard deviation of

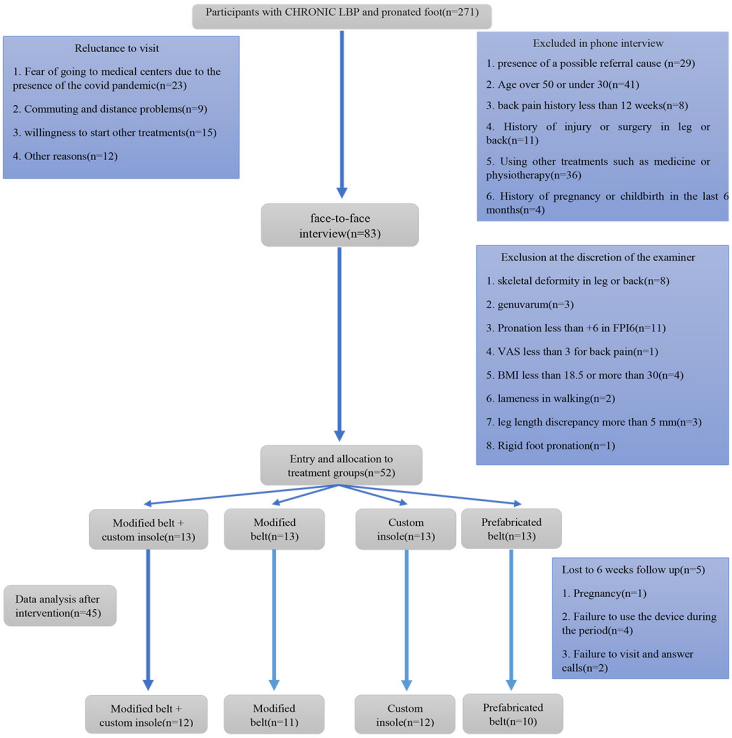

Figure 4: CONSORT flow chart (LBP: Low Back Pain, VAS: Visual Analog Scale, BMI: Body Mass Index)

the level of satisfaction, pain, and function in the pre-test and post-test in different treatment groups are shown in Table 1.

Levene's test showed that the variances of individuals' satisfaction in different groups were the same (Leven's statistic =2.006, df1=3, df2=41, *P*-value=0.128). The analysis of variance of the satisfaction variable showed a significant difference between the average satisfaction of individuals in different groups (df=3, F=8.64, *P*-value<0.001).

A Scheffe's posthoc test showed that mean satisfaction differences were significant between the simple belt and custom insole groups and also with the custom insole + modified belt groups. Both the custom insole and the custom insole + modified belt group had more satisfaction than the simple belt group. In addition, the custom insole + modified belt group had more satisfaction than the custom insole group (Table 2).

ANCOVA was used to examine the pain intensity and disability of patients after various treatments by adjusting for the effect of initial pain and disability separately. ANCOVA showed a significant difference in pain and disability in different treatment groups after the interventions and the adjustment of the effect of the initial pain and disability intensity (Table 3). The coefficient of determination of the pain model was equal to 65%, and in the disability model, it was equal to 51%.

For multiple comparisons, Bonferroni test was used (Table 4). The results showed that the amount of pain reduction in all groups was significantly higher than in the simple belt, but the severity of pain reduction in the three groups of insoles, modified belts, and the simultaneous use of insoles and modified belts was not significantly different. The findings also showed that the average disability in the group using the insole and the modified belt at

Table 1: Mean ± standard deviation of basic characteristics, pain, and pronated foot variables in the subjects

Groups	no	Age	BMI	FP	VAST1	VAST2	ODIT1	ODIT2	Satis faction T2
Simple belt	10	42.60±6.32	24.51±2.15	6.50±0.52	6.80±0.91	5.40±1.17	20.60±2.01	11.60±1.43	5.10±2.18
Custom insole	12	44.92±4.10	25.08±2.56	6.42±0.51	6.33±0.65	3.67±0.65	20.00±2.82	9.83±1.58	7.00±1.47
Modified belt	11	43.45±5.42	24.95±1.37	6.45±0.68	6.73±0.90	3.91±0.70	20.45±2.65	10.18±1.25	6.09±1.04
Custom insole + modified belt	12	45.08±4.99	25.13±1.98	6.58±0.66	6.42±0.99	3.00±0.85	20.33±2.42	8.17±1.19	8.08±0.79

BMI: Body Mass Index, FP: Foot Pronation, VAS: Visual Analogue Scale, ODI: Oswestry Disability Index, T1: pre-test, T2: post-test (after six weeks)

Table 2: Average satisfaction comparison in different intervention groups with Scheffe's post-hoc test

Group(I)	Group(J)	Mean difference(I-J)	Std. Error	*P*-value
Simple belt	Custom insole	-1.90	0.61	0.03
	Modified belt	-0.99	0.62	0.48
	Custom insole + modified belt	-2.98	0.61	<0.001
Custom insole	Modified belt	0.90	0.60	0.52
	Custom insole + modified belt	-1.08	0.58	0.34
Modified belt	Custom insole + modified belt	-1.99	0.60	0.02

Table 3: Analysis of covariance for post-intervention measures by adjusting the primary measures of the variables

Variables	Source of variation	df	Sum of Squares	F	*P*-value
VAST2	VAS.T1	1	10.17	20.54	<0.001
	group	3	26.07	17.55	<0.001
	Error	40	19.80		
ODIT2	ODI.T1	1	8.43	4.89	0.03
	group	3	63.94	12.37	<0.001
	Error	40	68.93		

VAS: Visual Analogue Scale, ODI: Oswestry Disability Index, T1: pre-test, T2: post-test (after six weeks), df: Degree of freedom, F: F statistic, Statistically Significant (*P*-value<0.05).

Table 4: Multiple comparison of mean adjusted variants in different treatment groups

Group(I)	Group(J)	variables	Mean	Mean difference(I-J)	Std. error	*P*-value
Simple belt VAS mean = 5.26 ODI mean = 11.55	Custom insole	VAS	3.79	*1.46	0.30	<0.001
		ODI	9.89	*1.65	0.56	0.03
	Modified belt	VAS	3.81	*1.44	0.30	<0.001
		ODI	10.16	*1.39	0.57	0.11
	Custom insole + modified belt	VAS	3.07	*2.18	0.30	<0.001
		ODI	8.16	*3.38	0.56	<0.001
Custom insole	Modified belt	VAS	3.79	-0.01	0.29	1.00
		ODI	9.89	-0.26	0.54	1.00
	Custom insole + modified belt	VAS	3.07	0.71	0.28	0.10
		ODI	8.16	*1.72	0.53	0.01
Modified belt	Custom insole + modified belt	VAS	3.07	0.73	0.29	0.10
		ODI	8.16	*1.99	0.54	0.00

VAS: Visual Analogue Scale, ODI: Oswestry Disability Index, Std. error: standard error, *: statistically significant difference (*P*<0.05)

the same time significantly reduced compared to the other three groups, and the use of the insole significantly reduced the amount of disability more than the use of a simple belt.

Discussion

This study is conducted to evaluate the effects of a modified lumbar belt, both independently and in combination with custom insoles, on pain and functional disability in patients with FP and chronic LBP, in comparison to standard prefabricated belts.

All intervention groups demonstrated significant reductions in pain intensity compared to the prefabricated belt group (*P*-value<0.001). However, no significant differences in pain reduction were observed among the insole, modified belts, and combined intervention groups. The intensity of pain reduction in the simultaneous use of insoles and padded belts was greater than the use of either of these two items alone. The use of insoles also reduced the intensity of pain more than the use of padded belts.

The greatest improvement in functional disability was observed in the group using both

the modified belt and custom insole, with a mean ODI score reduction of 3.38±1.19, significantly greater than the other groups (*P*-value<0.001). The custom insole group also showed a significant reduction in disability compared to the prefabricated belt group (*P*-value=0.03).

The modified belt, designed with silicone-textured pads, was more effective than the standard prefabricated belt, likely due to its ability to enhance proprioceptive feedback and improve spinal stability. These results align with previous studies demonstrating the benefits of lumbar support in pain management and postural control.

The results of this study are consistent with previous research demonstrating the efficacy of custom insoles in improving functional ability and reducing pain in patients with FP [20, 21]. Similarly, the use of lumbar belts has been shown to reduce pain and disability in chronic LBP patients [22-24]. However, this study is the first to directly compare the effects of custom insoles, modified lumbar belts, and their combined use in patients with FP and Chronic Low Back Pain (CLBP). We considered the use of prefabricated belts as the standard treatment for comparison with other groups. In a study, it was stated that the use of a belt with lumbar support had a greater effect on reducing pain than a belt without lumbar support [25]. In this study, the authors hypothesized that the greater effectiveness of the lumbar support belt was due to its increased support. However, other studies have shown that soft belts are more effective in reducing back pain than rigid ones [26], making this theory unlikely. It is possible that the heated plastic lumbar support, which was molded to the patient's body, enhanced pain reduction by improving body contact and proprioception.

According to the results of this study, the use of insoles has a greater effect than the use of a standard belt alone, which seems completely logical due to the correction and elimination of the cause of pain.

The improved outcomes observed with the modified lumbar belt may be attributed to its ability to enhance proprioceptive feedback, which is often impaired in patients with chronic LBP. The textured silicone pad in the modified belt likely provides additional sensory input, helping patients better perceive and correct their posture. Similarly, custom insoles address the biomechanical abnormalities associated with FP, reducing stress on the lumbar spine and pelvis. The combination of these interventions appears to maximize their benefits by simultaneously correcting lower limb alignment and enhancing lumbar proprioception [9-12, 27, 28].

For better control of the results, the belt was worn above the pubic bone, and a pressure of 50 newtons was used in all subjects [15].

The average foot pronation of the subjects was 6.49 with a standard deviation of 0.589, which is similar to previous studies [20].

According to Scheffe's post-hoc test, patient satisfaction was significantly higher in the group using both the custom insole and the modified lumbar belt compared to the standard belt group. This finding underscores the importance of patient-centered outcomes in evaluating the effectiveness of orthotic interventions. The higher satisfaction levels may reflect the greater pain relief and functional improvement experienced by patients in this group. We believed that daily activities, associated with devices, such as insoles and lumbar belts are more beneficial than inactivity, leading to managing pain more effectively while preventing the negative consequences of reduced mobility.

While this study provides valuable insights, it has some limitations. The sample size, though adequate for detecting significant differences, was relatively small. Future studies with larger cohorts and longer follow-up periods are needed to confirm these findings. Additionally, the study did not assess the long-term effects of these interventions or their impact on other outcomes, such as quality of life or

return to work. Further research could also explore the mechanisms underlying the observed effects, particularly the role of proprioception in pain reduction.

Conclusion

This study demonstrates that the modified lumbar belt and custom insoles are effective interventions for reducing pain and functional disability in patients with chronic LBP and FP. The modified belt outperformed the standard prefabricated belt, and the combination of the modified belt and custom insoles yielded the greatest improvements in disability and patient satisfaction. These findings advocate for the integration of both spinal and lower limb interventions in the management of chronic LBP associated with FP.

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Authors' Contribution

MA. Mardani conceived the idea and contributed to the study design. A. Biglarian participated in designing the methodology and statistical analysis. MA. Mardani, M. Arazpour, and B. Delshad were responsible for the design and fabrication of the orthoses. Data collection was carried out by B. Delshad and R. Musavi. The analysis and interpretation of the results were conducted by A. Biglarian, MA. Mardani, M. Arazpour, B. Delshad, and R. Musavi. The draft manuscript was prepared by MA. Mardani, A. Biglarian, M. Arazpour, B. Delshad, and R. Musavi. All authors reviewed, revised, and approved the final version of the manuscript.

Ethical Approval

The study protocol was approved by the Ethics Committee of the University of Social Welfare and Rehabilitation Sciences (IR.USWR.REC.1400.305).

Informed Consent

Written informed consent was obtained from all participants prior to enrollment.

Funding

None

Conflict of Interest

None

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