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Original Research Article

Effectiveness of foot orthoses and foot exercises in the management of lower back pain in patients with flexible pes planus – A randomized controlled trial

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Abstract

Background: Lower back pain poses a significant burden on the economy and can be approximated to be around £2.8 billion in countries like the UK. Studies indicate that young Indian adults, aged 18 to 35 years, have a high prevalence of lower back pain (LBP), with rates reported at 42.4% per year and 22.8% per week. We aimed to study the impact of Standardized Foot Orthoses, with and without Foot Exercises, in the management of Chronic Lower Back Pain in people with Pes Planus.

Materials and Methods: The study involved 85 participants who were randomly assigned to two groups, one group (FE, n=42) received foot exercises only, while the other group (FEO, n=43) received both foot exercises and foot orthoses. The level of Lower Back pain was measured using Quebec Disability Scale and Visual Analogue Scale, at the time of inclusion and the conclusion of the duration of eight weeks.

Results: Analysis indicated that participants who received both foot exercises and standard foot orthoses experienced a significantly greater reduction in chronic lower back pain (CLBP), with a large effect size ($d = 0.89$), compared to those who performed foot exercises alone, who showed a medium effect size ($d = 0.46$) ($p < 0.001$, Quebec Scale).

Conclusion: The results indicate that correcting flat foot using foot exercises alone, as well as in combination with foot orthoses, is an effective measure in the management of chronic lower back pain, with the combination demonstrating a superior effect.

Keywords: Foot Orthoses, Lower Back Pain, Pes planus, Foot exercises, Meary's angle.

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1. Introduction

Lower back pain poses a significant economic burden, estimated at around £2.8 billion in countries such as the UK. According to a study by Spencer L. James et al., which assessed 354 medical conditions across 195 countries using Disability-Adjusted Life Years (DALYs), lower back pain ranked as the leading condition in 126 countries.[1,2] The situation in the USA is even more concerning, with annual expenditures for lower back pain management projected to exceed US$100 billion. Notably, about 66% of this economic burden arises from indirect costs, such as lost productivity.[3,4]

A systematic review covering studies from 54 countries estimated the point prevalence of lower back pain at 11.9% (SD 2), while the one-month prevalence was reported at 23.3% (SD 2.9).[5] In India, reports suggest that a large proportion of the population—ranging from 42% to 83%—experiences some form of back problem during their lifetime.[6,7] While some cases resolve spontaneously, others may progress to chronic conditions requiring medical intervention. Among young Indian adults aged 18 to 35 years, the prevalence of lower back pain remains particularly high, with annual and weekly rates of 42.4% and 22.8%, respectively.[6]

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Emerging evidence indicates that flat feet (pes planus) may be associated with lower back pain.[8] Pes planus can cause rotational changes in the lower limbs, potentially altering postural responses and leading to compensatory patterns between the spine and lower extremities.[9] Foot orthoses have been shown to significantly reduce pain associated with adult flat feet, especially in the earlier stages of the condition.[10] Similarly, foot exercises have been observed to relieve pain in cases of flexible flat feet.[11] However, a gap remains in understanding the role of foot orthoses in managing chronic lower back pain.[12-14] To the author's knowledge, no studies have examined the effects of foot exercises on lower back pain, and the evidence regarding standardized foot orthoses[14] remains inconclusive.

Therefore, this study aims to investigate the impact of foot exercises alone, as well as in combination with standardized foot orthoses, on the management of chronic lower back pain. Preserving the medial arch may represent an important initial step in addressing chronic lower back pain in patients with flexible pes planus.

2. Materials and Methods

After obtaining approval from the Institutional Ethical Committee (CDSO: Reg. No. ECR/1365/Inst/TN/2020; dated 7/10/2022), a total of 90 patients were enrolled in this randomized clinical trial and divided into two groups: Foot Exercise (FE, n=45) and Foot Exercise plus Foot Orthoses (FEO, n=45). Since foot exercises represent a relatively novel approach, we aimed to explore the potential of this intervention without the constraints of a traditional control group. All participants provided written informed consent prior to enrollment (**Figure 2**). This study adheres to the CONSORT guidelines (**Figure 1**), and all required information is reported accordingly (see Supplementary Checklist). The trial was prospectively registered with the Clinical Trial Registry of India (CTRI/2023/03/050247; registered on 02/03/2023).

2.1. Participants

The study included patients aged 20–60 years with chronic non-specific lower back pain and unilateral or bilateral flexible flat feet. Flexible flat feet were diagnosed using the wet footprint impression method and the great toe extension test, which helped differentiate them from rigid flat feet.

Exclusion criteria were: pregnancy, previous surgery of the back or lower extremities, serious illness, a positive straight leg raise test, or prior physical therapy (excluding general health-promoting exercises). These criteria were chosen to prevent potential overlapping effects from earlier treatments.

Participants were recruited by trained physicians either directly during hospital visits or via awareness camps conducted in schools, colleges, nurses' quarters, information technology parks, government offices, and similar settings. Screening was performed according to the inclusion and exclusion criteria, including assessment with a wet footprint impression. Informed consent was obtained at this stage, and pregnancy status was reconfirmed to avoid potential harm.

A lateral X-ray of the foot was then performed to determine the degree of flat foot deformity. The primary focus of the study was to assess chronic low back pain (CLBP), measured using two validated tools:

1. 100 mm Visual Analogue Scale (VAS) for pain intensity.[15]
2. Quebec Disability Scale for functional disability.[16] This scale includes 20 daily activities scored from 0 (no difficulty) to 5 (unable to perform).

Scores were recorded at baseline and after the intervention. Participants were allocated to groups by permuted block randomization, with concealment maintained using a predetermined random number list.

2.2. Blinding

Blinding of participants and investigators was not feasible due to the nature of the intervention.

2.3. Interventions

1. Foot Exercises (FE): All patients were taught "short foot exercises"[11] designed to strengthen intrinsic foot muscles. Patients were instructed to raise the medial longitudinal arch, contract the foot along the anterior–posterior axis, and draw the first metatarsal head closer to the heel without flexing the toes. Exercises were performed in three sets of 15 repetitions, starting in the sitting position (Weeks 1–4) and progressing to a double-stance position (Weeks 5–8).
2. Foot Orthoses (FEO group): In addition to the above exercises, participants in the FEO group were provided with standardized silicon-based medial longitudinal arch supports (**Figure 3**). These orthoses could be comfortably used with most shoes or sandals and were provided free of cost. Patients were instructed not to use the orthoses while performing exercises or during sleep, but to wear them throughout the day at work or home.

2.4. Patient safety

Throughout the 8-week intervention, patients were contacted by telephone to monitor adherence to both exercise and orthosis use (in the FEO group). Patients who failed to comply with the prescribed regimen were excluded. Any reported issues were evaluated promptly through re-examination.

2.5. Sample size

Sample size was calculated assuming a one-tailed hypothesis, a 1:1 allocation ratio, a medium effect size (d=0.73), an alpha level of 0.05, and 90% power. This yielded an estimated 42

participants per group. To account for potential dropouts, the total planned sample size was increased to 90. The study was ultimately completed with 85 participants (**Figure 2**).

2.6. Statistical analysis

The study utilized means and standard deviations to present quantitative variables, such as age, gender, BMI, and talo-metatarsal angle, for each group. To assess changes within each group, the study utilized a paired t-test to compare the measurements obtained before and after the intervention and an independent sample t-test to compare the measures across the groups. The statistical analysis was performed using the IBM SPSS Statistics Version 26.0, and statistical significance was defined as a p-value of less than 0.05 in the study. The effect size was calculated using the Rosenthal correlation and classified as low, moderate, strong, or very strong based on the estimated value.

3. Results

The sample initially included 90 patients, consisting of 42 females and 48 males. However, two participants—one from the Foot Orthoses group and the other from the Foot Orthoses plus Exercises group—dropped out due to insufficient pain relief. Additionally, three participants (one from the Foot Exercises group and two from the Foot Orthoses plus Exercises group) were excluded due to failure to adhere to the exercise regimen.

Table 1: Demographic data

Variables		Total sample size (n=85)	FEO group (n=43)	FE group (n=42)
Gender	Male	46 (54.1)	22 (47.8)	24 (52.2)
	Female	39 (45.9)	21 (53.8)	18 (46.2)
Age		36.67±9.14	36.19±9.16	37.7±9.2
BMI		24.09±2.35	24±2.29	24.17±2.44
Left talo-metatarsal angle		18.25±3.15	17.28±3.31	19.24±2.67
Right talo-metatarsal angle		18.2±3.94	17.33±3.79	19.1±3.95

Table 2: Quebec scale for experimental and control group for pre- and post-situation in experimental and control group

Time scale		Mean ± SD	95% CI	Median	Interquartile Range	p-value
Pre	FE group	60.05 ±10.35	56.82-63.27	61	18	0.538
	FEO group	64.49 ±11.11	58.07-64.91	66	15	
Post	FE group	44.10 ±11.72	40.44-47.75	41.5	17	0.001
	FEO group	16.84 ±6.039	14.98-18.70	18	8	

Table 3: VAS scale for experimental and control group for pre- and post-situation in experimental and control group

Time scale		Mean ± SD	95% CI	Median	Interquartile Range	p-value
Pre	FE group	6.10 ±1.16	5.73-6.46	6	2	0.412
	FEO group	6.33 ±1.19	5.96-6.69	7	2	
Post	FE group	4.36 ±1.12	4.01-4.71	4	1	0.001
	FEO group	1.98 ±0.71	1.76-2.19	2	0	

Table 4: Assessment of Quebec scale across groups based on gender

Gender	Time line	FEO group (Mean ± SD)	FE group (Mean ± SD)	p-value
Male	Pre	61.9±9.69	60.04±9.51	0.513
	Post	17.5±6.59	44.54±9.87	0.001
	Change (Pre/Post)	44.41±9.8	15.5±6.93	0.001
Female	Pre	61.05±12.66	60.06±11.66	0.802
	Post	16.14±5.48	43.5±14.09	0.001
	Change (Pre/Post)	44.9±10.39	16.56±9.04	0.001

Table 5: Assessment of VAS scale across groups based on gender

Gender	Timeline	Experimental group (Mean ± SD)	Control group (Mean ± SD)	p-value
Male	Pre	6.08±1.10	6.27±1.12	0.459
	Post	1.95±0.65	4.37±0.97	0.001
	Change (Pre/Post)	4.32±1.21	1.71±0.91	0.001
Female	Pre	6.38±1.28	6.11±1.28	0.746
	Post	2.00±0.77	4.33±1.33	0.001
	Change (Pre/Post)	4.38±1.32	1.78±0.81	0.001

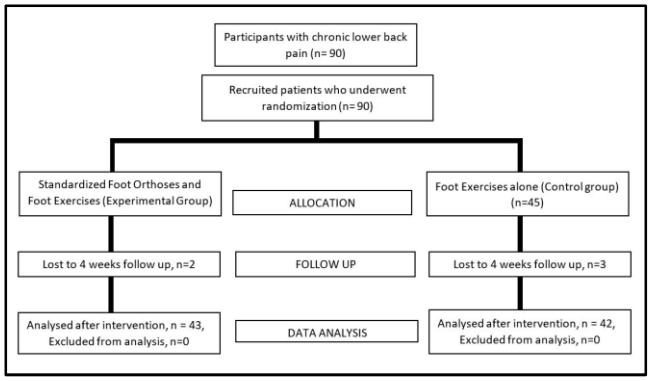

Figure 1: CONSORT flow diagram

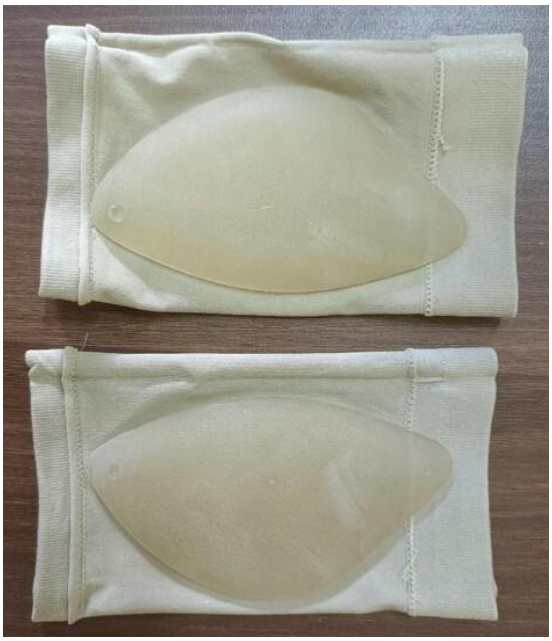

Figure 2: Standardized silicon foot orthoses

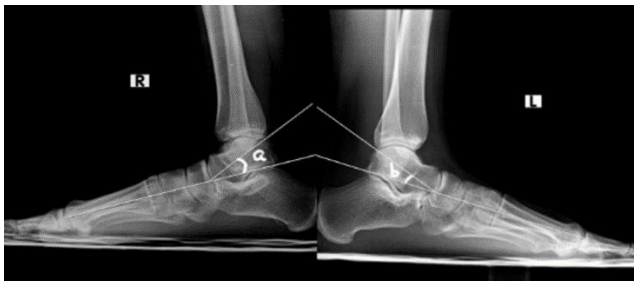

Figure 3: Lateral X-ray of foot (loaded position), with angles **a** and **b** marked on the x-ray conveying the talo-metatarsal angle.

Of the remaining 85 participants, 45.9% identified as female and 54.1% as male, with ages ranging from 22 to 58 years (mean = 36.67, SD ± 9.14). Their mean body mass index (BMI) was 24.09 (SD ± 2.35). The study found that 73% of patients had a bilateral talo-metatarsal angle ≥15, while 37% had only one foot with a talo-metatarsal angle ≥15 (**Figure 3**).

The groups showed no significant differences in age, gender distribution, BMI, or right and left talo-metatarsal angle, as shown in **Table 1**.

Table 1 presents the baseline data and initial distribution of both groups (FEO and FE). Comparisons were made between the initial and final stages of the study for each group. Independent t-tests were conducted for **Table 2** and **3**.

The FEO group showed significant improvements in Quebec Scale scores when comparing initial and final values ($p<0.001$), with a strong effect size ($d = 0.89$). Although the FE group also showed significant improvement compared to initial values ($p<0.001$), the magnitude of the effect size was moderate ($d = 0.46$).

Table 4 and **5** present the impact of gender, but no significant relationship was observed. In addition, comparisons were drawn with the severity of flat foot (judged using the talo-metatarsal angle) and the initial Quebec Disability Scale score, but no correlation was found.

4. Discussion

This is the first randomized controlled trial investigating the efficacy of foot exercises and foot orthoses in managing chronic lower back pain in patients with flexible flat feet. Both treatment groups showed improvement, but the group receiving the additional standardized foot orthoses showed greater improvement (with a larger effect size, $d = 0.89$). The extent of flat foot, as measured by the talo-metatarsal angle, was not found to correlate with the severity of pain on the Quebec Disability Score at recruitment. However, the link between flat foot and back pain was reinforced by the fact that both foot exercises,[11] which aimed to strengthen the intrinsic muscles of the foot, and foot orthoses,[17] which aimed to restore the normal arch, resulted in a reduction in back pain.

Flexible pes planus results in excessive foot pronation. The resulting altered gait has long been hypothesized as a cause of lower back pain.[18] Individuals with flexible pes planus exhibit restricted sagittal plane motion in the rearfoot, which is believed to be counterbalanced by elevated midfoot dorsiflexion, while the hallux is thought to have increased mobility during the push-off phase of the gait cycle.[19] When the subtalar joint pronates, it generates an applied torque that can cause a chain reaction of movements in the lower limb. This chain reaction can result in medial rotation of the femur and tibia, ultimately leading to anterior pelvic tilt.[20-22] All of this leads to increased strain on pelvic muscles such as the gluteus maximus, iliopsoas, and piriformis, which rotate the affected lumbar vertebrae, leading to compensatory scoliosis. This alteration in dynamic forces pulls the lower half of the sacroiliac joint forward and is accompanied by active contraction of the erector spinae to reduce tension on the iliopsoas, hypothetically resulting in muscle fatigue.[23,24]

Numerous studies have demonstrated a positive correlation between the therapeutic impact of customized foot orthoses and alleviation of back pain.[9,25] However, data pertaining to standardized foot orthoses in relation to lower back pain remain inconclusive, and the efficacy of foot exercises in this regard has not been tested until now. The conclusion drawn from this research is that both interventions have a positive impact, with the combination of standardized foot orthoses and foot exercises demonstrating greater efficacy.

The first limitation is that this study focused on flexible pes planus as a potential factor contributing to chronic low back pain, while other factors may also need to be considered. As this was a single-center study including participants from various occupations, a multi-center trial would be required to provide a more comprehensive picture. Age is another confounding factor, given the wide range of individuals included. However, it did not significantly affect the outcomes between the two groups. Another limitation was that patients' compliance with the exercise regimen and use of foot orthoses relied solely on verbal communication, despite our weekly follow-up phone calls.

5. Conclusion

Based on the results, this study concludes that both foot exercises, whether in combination with foot orthoses or done alone, resulted in an improvement in the disability scores. However, the combination showed a more significant impact (larger effect size of d = 0.89) when assessed after an 8-week period.

6. Ethics Statement

1. Ethical Committee Approval was taken before conducting the study with IEC no. ECR/1365/Inst/TN/2020) on 7/10/2022 from Madurai Medical College, Madurai, Tamil Nadu, India.
2. Clinical Trial Registration: Registered in Clinical Trial Registry of India with reference no. CTRI/2023/03/050247 [Registered on: 02/03/2023] - Trial Registered Prospectively.

7. Transparency Statement

The lead author Varunkumar Ramkumar affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

8. Data Availability Statement

The data that support the findings of this study are available on request from the corresponding author.

1. All authors have read and approved the final version of the manuscript and Varunkumar Ramkumar had full access to all of the data in this study and takes complete responsibility for the integrity of the data and the accuracy of the data analysis.

9. Highlights

1. Lower back pain poses a significant burden on the health and economy of a country.
2. High prevalence of lower back pain (LBP) of around 40% annually is being reported among Indian population aged 18 to 35 years.
3. Foot exercises in combination with foot orthoses can be an effective measure in the management of chronic lower back pain**.**

10. Data Availability

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

11. Author Contribution

1. Varunkumar Ramkumar – Conceptualization, Data Collection, Data Analysis, Manuscript writing and editing
2. Thanappan N - Conceptualization, Manuscript writing, review, and editing
3. Maha Iswaryaa C - Manuscript writing and editing
4. Sanjay PS - Manuscript editing, Statistical Analysis
5. Anamika Jayaprakashan - Manuscript writing and editing
6. Sathesh Karthick A- Manuscript writing and editing
7. Alaghu Venkateshan- Conceptualisation
8. Senthil Kumar-Conceptualisation

12. Source of Funding

None.

13. Conflicts of interest

The authors declare no conflict of interest.

14. Acknowledgements

None.

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