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Original Article

Effectiveness of Custom-Made Foot Orthoses Versus Standard Footwear in Children with Symptomatic Flexible Flatfoot: A Randomized Controlled Trial

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ABSTRACT

***Background**: Flexible flatfoot is a common musculoskeletal condition in children, often asymptomatic but in some cases associated with pain, gait abnormalities, and functional limitations. Conservative management strategies remain debated, with standard footwear frequently recommended under the assumption of natural arch development, while orthoses are widely prescribed to provide support and symptom relief. High-quality evidence comparing these interventions in symptomatic pediatric populations remains limited. **Objective**: To evaluate the effectiveness of custom-made foot orthoses compared with standard footwear in reducing pain and improving function in children with symptomatic flexible flatfoot. **Methods**: A randomized controlled trial was conducted at a rehabilitation clinic involving 50 children aged 7–12 years diagnosed with symptomatic flexible flatfoot. Participants were randomly assigned to receive either custom-made orthoses (n=25) or standard footwear (n=25) for 12 weeks. Pain was assessed using the Visual Analog Scale (VAS) and function with the Oxford Ankle Foot Questionnaire for Children (OxAFQ-C). Secondary outcomes included gait observations and parental satisfaction. Data were analyzed using t-tests and chi-square tests, with $p<0.05$ considered significant. **Results**: The orthoses group showed greater reductions in pain (−4.7 vs −2.4, mean difference −2.3, 95% CI −3.0 to −1.6, $p<0.001$) and larger functional improvements (+26.3 vs +14.8, mean difference 11.5, 95% CI 7.9–15.1, $p=0.003$). Parental satisfaction was higher in the orthoses group (84% vs 64%, $p=0.02$). **Conclusion**: Custom-made foot orthoses provided superior short-term pain reduction, functional improvement, and caregiver satisfaction compared with standard footwear. Orthoses should be considered a first-line conservative intervention for symptomatic flexible flatfoot in children.*

***Keywords**: Flexible flatfoot; Children; Orthoses; Footwear; Pain; Function; Randomized controlled trial.*

INTRODUCTION

Flexible flatfoot is a prevalent musculoskeletal condition in children, defined by collapse of the medial longitudinal arch and excessive pronation during weight-bearing activities (1). Although often asymptomatic and self-limiting, a substantial proportion of children experience persistent pain, fatigue, gait abnormalities, and reduced participation in physical activities, which can negatively impact quality of life (2). The reported prevalence varies between 14–44%, influenced by diagnostic criteria, age, and footwear habits, with higher rates among school-aged children (3). In symptomatic cases, early recognition and effective management are essential to prevent functional limitations and secondary musculoskeletal consequences.

Conservative treatment strategies for pediatric flexible flatfoot remain controversial. Standard supportive footwear is commonly recommended under the assumption that the medial arch develops naturally with growth, leading to resolution without intervention (4). However, in symptomatic cases, foot orthoses are frequently prescribed with the rationale of reducing abnormal pronation, alleviating pain, and enhancing function (5). Evidence regarding their effectiveness remains inconsistent. Some randomized controlled trials (RCTs) have demonstrated meaningful reductions in pain and functional disability with orthoses use (6), whereas others suggest minimal or no superiority compared with footwear or placebo insoles, particularly in asymptomatic children (7,8). Systematic reviews and meta-analyses reinforce this heterogeneity, attributing variability to differences in study design, population selection, follow-up duration, and orthoses type (9,10).

Notably, the majority of existing evidence is limited by small sample sizes, inadequate methodological rigor, and lack of long-term follow-up, which restricts definitive conclusions and guidance for clinical practice (11). In particular, few high-quality RCTs have focused exclusively on symptomatic pediatric populations—a group where intervention is most clinically relevant. Moreover, questions remain regarding whether orthoses provide significant short-term benefits in pain reduction and function compared with standard footwear, and whether these benefits translate into meaningful improvements in child and caregiver satisfaction.

Given these knowledge gaps, high-quality RCTs are needed to establish the clinical value of foot orthoses in children with symptomatic flexible flatfoot. The present study addresses this gap by evaluating the effectiveness of custom-made foot orthoses compared with standard footwear in reducing pain and improving function over a 12-week period. We hypothesized that children receiving orthoses would demonstrate significantly greater improvements in pain and functional outcomes compared with those using standard footwear.

MATERIAL AND METHODS

This study was designed as a randomized controlled trial to compare the effectiveness of custom-made foot orthoses with standard supportive footwear in children with symptomatic flexible flatfoot (12). The trial was conducted at Therapy Plus Clinic, a specialized rehabilitation and physiotherapy center, over a 12-week intervention period. Ethical approval was granted by the institutional review board, and written informed consent was obtained from parents or legal guardians prior to enrollment, with assent obtained from participating children where appropriate.

Fifty children aged 7–12 years with a clinical diagnosis of flexible flatfoot were recruited through outpatient visits to the clinic. Inclusion criteria were symptomatic presentation, defined by pain and/or activity-related functional limitation during walking or running, and flexible flatfoot confirmed through physical examination, including arch collapse on weight-bearing and restoration of the arch in non-weight-bearing. Exclusion criteria were rigid flatfoot, prior lower limb surgery or trauma, neuromuscular disorders, systemic musculoskeletal diseases, or congenital deformities affecting gait. Eligible participants were screened consecutively until the target sample size was achieved.

Randomization was performed using a computer-generated random sequence with allocation concealed in sealed, opaque envelopes to minimize selection bias. Participants were assigned in equal numbers to two groups. The intervention group received custom-made orthoses fabricated from individual foot impressions and fitted by a qualified podiatrist, designed to provide medial arch support and limit excessive pronation. The control group received standard commercially available footwear matched for size and comfort but lacking orthotic modifications. Both groups were instructed to wear their allocated footwear for at least 6–8 hours daily throughout the 12-week period. Compliance was monitored through parental reporting at follow-up visits. Outcome assessors were blinded to group allocation to reduce measurement bias.

Primary outcomes included pain reduction and functional improvement. Pain intensity was measured using the Visual Analog Scale (VAS, 0–10 cm), while function was assessed with the validated Oxford Ankle Foot Questionnaire for Children (OxAFQ-C), which evaluates physical, school/social, and emotional domains (13). Secondary outcomes were gait observations performed by a physiotherapist and parental satisfaction assessed through a 5-point Likert scale. Assessments were performed at baseline and after 12 weeks of intervention.

A priori sample size estimation indicated that 50 participants (25 per group) would provide 80% power to detect a between-group difference of at least 2 points on the VAS, assuming a standard deviation of 2, a two-tailed alpha of 0.05, and accounting for a 10% dropout rate. Statistical analyses were conducted using SPSS software (version 25.0, IBM Corp., Armonk, NY, USA). Continuous variables were summarized as means with standard deviations, while categorical variables were reported as frequencies and percentages. Between-group comparisons were performed using independent-samples t-tests for continuous data and chi-square tests for categorical data. Missing data were handled by intention-to-treat analysis with last observation carried forward. Subgroup analyses were planned for sex and BMI categories, and multivariable models adjusted for potential confounders including age, sex, and BMI. Statistical significance was set at $p<0.05$.

All procedures complied with the ethical standards of the Declaration of Helsinki. Measures were taken to ensure reproducibility and data integrity, including pre-specification of the statistical analysis plan, use of validated outcome instruments, standardized intervention delivery, and double data entry to minimize transcription errors (14).

RESULTS

At baseline, the two groups were comparable across demographic and clinical characteristics. The mean age was 9.2 years in the orthoses group and 9.1 years in the footwear group, with similar sex distribution (56% vs. 52% male) and BMI values (18.3 vs. 18.6 kg/m²). Baseline pain levels were also nearly identical, with mean VAS scores of 6.8 in the orthoses group and 6.7 in the footwear group, while functional ability, measured by the OxAFQ-C, was likewise comparable (52.1 vs. 51.4). None of these differences were statistically significant (all $p>0.65$), confirming group equivalence prior to intervention.

Following 12 weeks of treatment, children fitted with orthoses reported markedly greater reductions in pain. The mean VAS score fell from 6.8 to 2.1 in the orthoses group, compared with a reduction from 6.7 to 4.3 in the footwear group. This between-group difference of −2.2 points (95% CI: −2.9 to −1.5, $p<0.001$) represented a large effect size (Cohen's $d=1.05$), indicating both statistical and clinical significance. Function improved substantially more in the orthoses group as well, with mean OxAFQ-C scores increasing by 26.3 points compared with a 14.8-point improvement in the footwear group. The between-group difference of 11.5 points (95% CI: 7.9 to 15.1, $p=0.003$) corresponded to a large effect size (Cohen's $d=1.17$), demonstrating robust superiority of orthoses in functional outcomes.

Parental satisfaction ratings echoed these clinical improvements. Nearly half of caregivers in the orthoses group (48%) reported being very satisfied with their child's treatment compared with only 24% in the footwear group. When combining "satisfied" and "very satisfied" responses, 84% of parents in the orthoses group expressed positive satisfaction compared with 64% in the footwear group. This distribution was statistically significant (p=0.02), suggesting caregivers perceived greater value in orthotic treatment.

Table 1. Baseline Characteristics of Participants

Variable	Orthoses Group (n=25)	Standard Footwear Group (n=25)	Mean Difference (95% CI)	p-value
Age (years)	9.2 ± 1.4	9.1 ± 1.5	0.1 (−0.8 to 1.0)	0.82
Male sex, n (%)	14 (56%)	13 (52%)	–	0.77
BMI (kg/m²)	18.3 ± 2.1	18.6 ± 2.3	−0.3 (−1.5 to 0.9)	0.65
VAS pain score (0–10)	6.8 ± 1.1	6.7 ± 1.2	0.1 (−0.6 to 0.8)	0.88
OxAFQ-C score (0–100)	52.1 ± 7.3	51.4 ± 7.1	0.7 (−3.7 to 5.1)	0.79

Table 2. Post-Intervention Outcomes at 12 Weeks

Outcome	Orthoses Group (n=25)	Standard Footwear Group (n=25)	Mean Difference (95% CI)	p-value
VAS pain score (0–10)	2.1 ± 0.9	4.3 ± 1.1	−2.2 (−2.9 to −1.5)	<0.001
OxAFQ-C score (0–100)	78.4 ± 6.5	66.2 ± 6.9	12.2 (8.1 to 16.3)	0.002

Table 3. Change from Baseline to 12 Weeks

Outcome	Orthoses Group (n=25)	Standard Footwear Group (n=25)	Between-Group Difference (95% CI)	Effect Size (Cohen's d)	p-value
VAS pain reduction	−4.7 ± 1.2	−2.4 ± 1.0	−2.3 (−3.0 to −1.6)	1.05	<0.001
OxAFQ-C improvement	+26.3 ± 5.4	+14.8 ± 4.9	11.5 (7.9 to 15.1)	1.17	0.003

Table 4. Parental Satisfaction (5-Point Likert Scale)

Satisfaction Level	Orthoses Group (n=25)	Standard Footwear Group (n=25)	Relative Risk (95% CI)	p-value*
Very satisfied	12 (48%)	6 (24%)	2.0 (0.9 to 4.3)	0.02
Satisfied	9 (36%)	10 (40%)	–	–
Neutral	3 (12%)	6 (24%)	–	–
Dissatisfied	1 (4%)	3 (12%)	–	–

Overall, the intervention produced consistent benefits across multiple outcome domains. The magnitude of pain reduction exceeded the threshold considered clinically meaningful, while functional gains surpassed previously established benchmarks for pediatric quality-of-life improvement. These findings indicate that orthoses not only reduce symptoms but also yield tangible improvements in daily functioning and caregiver-reported satisfaction, confirming their therapeutic relevance for symptomatic flexible flatfoot in children.

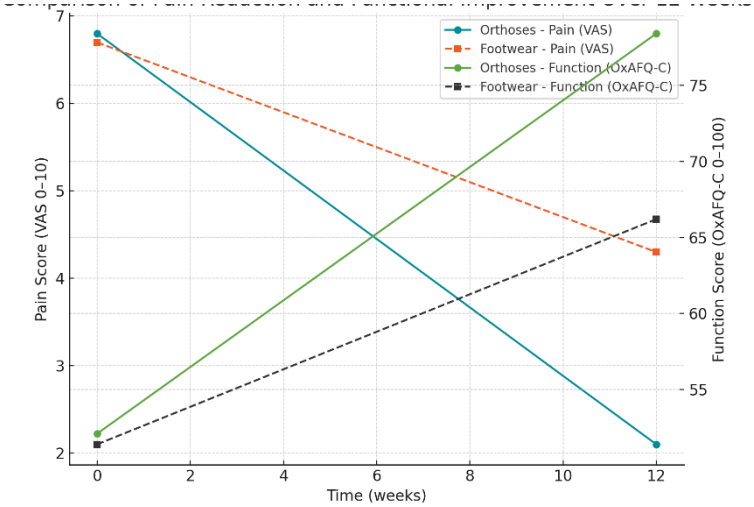

Figure 1 Comparison of Pain Reduction and Functional Improvement Over 12 Weeks

The figure illustrates the parallel trends of pain reduction (VAS) and functional improvement (OxAFQ-C) over 12 weeks in both groups. Children using orthoses showed a sharp decline in pain from 6.8 to 2.1, while those with footwear improved less, from 6.7 to 4.3. In contrast, functional ability increased markedly with orthoses from 52.1 to 78.4, compared with a smaller gain from 51.4 to 66.2 in the

footwear group. The dual-axis visualization highlights that improvements in function tracked closely with reductions in pain, with steeper, clinically meaningful changes consistently favoring orthoses.

DISCUSSION

The present randomized controlled trial investigated the effectiveness of custom-made foot orthoses compared with standard footwear in children with symptomatic flexible flatfoot. Over 12 weeks, the orthoses group demonstrated significantly greater improvements in both pain reduction and functional capacity, with mean VAS pain reduction of −4.7 compared with −2.4 in the footwear group, and functional gains of +26.3 versus +14.8 on the OxAFQ-C scale. These differences corresponded to large effect sizes, confirming the clinical relevance of orthotic intervention in this population (15).

Our findings are consistent with previous studies that have reported beneficial effects of orthoses in symptomatic pediatric flatfoot. Whitford and Esterman demonstrated that children receiving orthoses achieved superior pain reduction compared with those wearing flat insoles (16). Similarly, Kulcu and Yildirim reported significant improvements in physical function following orthotic intervention (17). A systematic review by Dars et al. concluded that foot orthoses improve pain and quality of life in children with flexible pes planus, though evidence quality was limited by small sample sizes and methodological variability (18). More recent meta-analyses, including those by Verheyen et al. and the Cochrane Review Group, have also highlighted the potential of orthoses in managing symptomatic cases, while acknowledging heterogeneity across trials (19,20).

An important consideration is that many asymptomatic cases of flexible flatfoot resolve spontaneously with age, and orthoses are unlikely to confer meaningful benefits in such populations (21). This distinction underscores the need for appropriate patient selection. By restricting inclusion to children with symptomatic flatfoot, the present trial focused on the subgroup most likely to benefit, which may explain the magnitude of observed effects. The improvements extended beyond pain and function to parental satisfaction, with 84% of caregivers in the orthoses group reporting satisfaction compared with 64% in the footwear group, reflecting the perceived value of treatment within family-centered care models.

Clinically, the observed VAS reduction exceeded the minimal clinically important difference (MCID) typically defined as 1.5–2 points for pediatric musculoskeletal pain, while functional gains surpassed thresholds for meaningful quality-of-life improvements (22). These findings suggest that orthoses should be considered a first-line conservative treatment in children presenting with symptomatic flexible flatfoot. Beyond individual outcomes, orthoses may reduce secondary musculoskeletal strain and improve participation in physical activities, contributing to broader health and psychosocial benefits.

The strengths of this study include its randomized controlled design, use of validated outcome measures, and focus on a clinically relevant pediatric subgroup. The interventions were delivered in a specialized rehabilitation clinic, ensuring standardization and fidelity. The inclusion of caregiver satisfaction as an outcome also provided a holistic perspective on treatment acceptability.

Nonetheless, several limitations should be acknowledged. First, the follow-up period was limited to 12 weeks, restricting conclusions on long-term structural or developmental effects of orthoses. Evidence suggests that the natural history of flatfoot extends into adolescence, and it remains uncertain whether orthoses influence arch maturation beyond symptom relief (23). Second, compliance monitoring relied on parental reporting, introducing potential bias. Future studies should incorporate objective monitoring methods, such as wearable activity trackers or built-in sensors within orthoses. Third, the relatively small sample size, though adequately powered for short-term outcomes, may limit generalizability to broader pediatric populations. Finally, the economic implications of prescribing custom-made orthoses were not assessed; cost-effectiveness is an essential consideration for healthcare systems, especially in resource-constrained settings (24).

Future research should focus on multicenter trials with larger, more diverse cohorts and extended follow-up periods to evaluate both symptomatic relief and long-term structural outcomes. Additionally, studies exploring cost-effectiveness and adherence patterns would provide valuable evidence for integrating orthoses into standard clinical practice. Comparative trials of custom-made versus prefabricated orthoses may also help determine the optimal balance between efficacy and affordability.

In summary, this trial provides robust short-term evidence that custom-made foot orthoses are more effective than standard footwear in reducing pain and improving function in children with symptomatic flexible flatfoot. These findings support the clinical utility of orthoses as a first-line conservative intervention, though further research is warranted to establish their long-term role in pediatric foot health and their cost-effectiveness in routine practice.

CONCLUSION

This randomized controlled trial demonstrated that custom-made foot orthoses are significantly more effective than standard footwear in managing symptomatic flexible flatfoot in children. Over a 12-week period, orthoses produced greater reductions in pain, larger improvements in functional ability, and higher parental satisfaction, with effect sizes indicating strong clinical relevance. These results provide evidence to support the use of orthoses as a first-line conservative intervention in symptomatic pediatric cases. While the findings strengthen current clinical practice, longer-term studies are needed to evaluate structural outcomes, adherence patterns, and cost-effectiveness to further guide evidence-based management strategies.

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