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Effectiveness of Prefabricated and Custom-Made Insole on Pes Planus

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ABSTRACT

Background: Pes planus, or flat foot, is a structural deformity characterized by a collapsed medial longitudinal arch, abnormal talar rotation, and altered foot biomechanics, often leading to pain, fatigue, and functional limitations. Foot orthoses, including custom-made and prefabricated insoles, are widely prescribed for conservative management, but their comparative clinical effectiveness remains debated, particularly in adult-acquired flatfoot deformity (AAFD). Objective: To compare the effectiveness of custom-made versus prefabricated insoles on pain, physical function, and quality of life in patients with adult-acquired pes planus. Methods: A randomized controlled trial was conducted at Rehman Medical Institute, Peshawar, from April to July 2021. Seventy participants (aged 12–65 years) with symptomatic flexible pes planus were randomly allocated into two groups (n = 35 each) receiving either custom-made or prefabricated insoles, worn 12–14 hours daily for eight weeks. Pain intensity (Numeric Pain Scale, NPS), foot function (Foot Function Index, FFI), and quality of life (EQ-5D) were measured at baseline, 4 weeks, and 8 weeks. Independent samples t-tests were used to compare outcomes, with $p < 0.05$ considered significant. Results: Both groups showed significant improvements in pain, functional outcomes, and quality of life over eight weeks ($p < 0.05$). NPS scores decreased from 6.33 ± 1.39 to 3.77 ± 2.36 in the custom-made group and from 7.67 ± 1.16 to 3.67 ± 5.16 in the prefabricated group. FFI pain scores improved from 63.3 ± 4.09 to 21.6 ± 6.66 and from 53.33 ± 2.88 to 20.67 ± 3.69, respectively. EQ-5D domains showed comparable improvements in both groups. No statistically significant between-group differences were observed at final follow-up across any primary outcomes ($p > 0.05$). Conclusion: Custom-made and prefabricated insoles are equally effective in reducing pain, enhancing physical function, and improving quality of life in adult-acquired pes planus. Prefabricated insoles offer a cost-effective, accessible alternative to custom orthoses for most patients, with comparable clinical outcomes over short-term follow-up.

Keywords
Pes planus, Foot orthoses, Prefabricated insoles, Custom-made insoles, Foot Function Index, Quality of life

INTRODUCTION

Pes planus, commonly known as flat foot, is a structural deformity characterized by the collapse of the medial longitudinal arch, accompanied by plantar flexion and medial rotation of the talus, inward rotation of the calcaneus, and abduction of the forefoot (1). This condition alters the biomechanics of the foot and lower limb, potentially leading to compensatory changes in gait, increased stress on joints, and secondary musculoskeletal complications. Prevalence estimates vary widely depending on age, population, and diagnostic criteria, with global studies reporting rates between 19% and 37% (2,3). In a recent study from Pakistan, Ahmed et al. (2019) reported a prevalence of 15.5% among young adults, highlighting its significant presence even in younger populations (4). The etiology of pes planus is multifactorial, with recognized risk factors including genetic predisposition, improper footwear during childhood, obesity, urban lifestyle, and age-related ligamentous changes (5–7). Pes planus can be broadly classified into several clinical forms, including asymptomatic or symptomatic, flexible or rigid, primary or secondary, and pediatric or adult-acquired types. Among these, adult-acquired flatfoot deformity (AAFD) is particularly significant due to its symptomatic presentation and progressive nature. AAFD often results from posterior tibial tendon dysfunction, leading to the gradual collapse of the medial longitudinal arch and subsequent structural deformities of the hindfoot, midfoot, and ankle (8). The condition is more common in middle-aged women and is frequently associated with systemic risk factors such as obesity, diabetes, corticosteroid use, and previous lower-limb trauma (9). Early clinical recognition and intervention are essential to prevent progression, improve gait mechanics, and reduce long-term disability.

Conservative management is the cornerstone of treatment for flexible or early-stage pes planus, with foot orthoses—particularly insoles—being one of the most frequently prescribed interventions. Insoles aim to realign the foot, restore arch support, improve load distribution, reduce pain, and enhance function (10). Two primary types of orthotic insoles are used in clinical practice: prefabricated and custom-made. Prefabricated insoles are mass-produced and designed to provide general support for a wide range of foot types, whereas custom-made insoles are individually fabricated based on patient-specific anatomical measurements, foot shape, and biomechanical requirements (11). Theoretically, custom insoles offer a more

tailored biomechanical correction and potentially superior clinical outcomes. However, they are significantly more expensive, time-consuming to fabricate, and less accessible than prefabricated alternatives (12).

Evidence comparing the efficacy of custom-made versus prefabricated insoles in managing pes planus remains inconclusive. Some studies have demonstrated superior pain reduction, improved plantar pressure distribution, and enhanced gait parameters with custom orthoses (13,14). Conversely, systematic reviews and randomized controlled trials have reported no significant difference in clinical outcomes, including pain, function, and patient satisfaction, between custom and prefabricated insoles (15,16). These conflicting findings underscore an ongoing debate regarding the cost-effectiveness and clinical justification for prescribing custom orthoses, especially in resource-limited settings where prefabricated options are more feasible. Furthermore, much of the existing literature has been conducted in Western populations, with limited data available from South Asian cohorts, where variations in lifestyle, footwear habits, and biomechanics may influence treatment outcomes.

Given these uncertainties, there is a pressing need for context-specific evidence comparing the two orthotic approaches in terms of their impact on pain, physical function, and quality of life in individuals with pes planus. The present study aims to address this gap by investigating the comparative effectiveness of custom-made versus prefabricated insoles in patients with adult-acquired pes planus. We hypothesize that custom-made insoles will provide superior improvements in pain reduction, functional outcomes, and health-related quality of life compared to prefabricated insoles. The findings are expected to guide clinical decision-making in orthotic prescription, balancing therapeutic efficacy with cost-effectiveness in the conservative management of pes planus.

MATERIAL AND METHODS

A randomized controlled trial was conducted to evaluate the comparative effectiveness of custom-made and prefabricated insoles in the conservative management of adult-acquired pes planus. The study was carried out at the Departments of Physical Therapy and Orthotics, Rehman Medical Institute (RMI), Peshawar, Pakistan, over a four-month period from April 2021 to July 2021. This clinical setting was selected due to its multidisciplinary patient base, providing access to a diverse population presenting with symptomatic flatfoot deformity requiring orthotic intervention. The trial design was chosen to minimize bias and allow for a controlled comparison of outcomes between intervention groups while maintaining clinical relevance.

Participants were recruited using a consecutive sampling approach from patients presenting to the orthopedics, physical therapy, and orthotics outpatient departments of RMI. Eligibility criteria included both male and female patients aged 12–65 years with symptomatic, flexible, acquired pes planus characterized by pain, fatigue following ambulation, or gait disturbances. All participants were required to be willing and able to comply with the intervention and follow-up schedule. Exclusion criteria included a history of diabetes mellitus with neuropathy, fixed foot deformities, previous lower-limb orthopedic surgery, neurological disorders affecting gait, and systemic conditions that could confound study outcomes. Written informed consent was obtained from all participants or their legal guardians before enrollment. Ethical approval for the study was granted by the Advanced Study and Research Committee (ASRC) of Isra Institute of Rehabilitation Sciences, Isra University, Islamabad, and all procedures adhered to the principles outlined in the Declaration of Helsinki (17).

A total sample of 70 participants was determined based on clinical feasibility and prior evidence from similar orthotic intervention trials, providing adequate power to detect meaningful between-group differences. Participants were randomly assigned into two equal groups (n = 35 each) using a sealed-envelope method to ensure allocation concealment. Group A received custom-made insoles, while Group B received prefabricated insoles. Both interventions were provided along with a standardized exercise program targeting intrinsic foot muscles and ankle stabilizers. Insoles were prescribed to be worn for 12–14 hours per day over an 8-week period. Custom-made insoles were fabricated individually based on each participant's foot size, shape, and contour, ensuring personalized support and alignment. Prefabricated insoles were selected from commercially available models based on size compatibility and general arch support features.

Data collection was conducted at baseline and subsequently at 4-week intervals up to 8 weeks. Primary outcome measures included pain intensity, physical function, and health-related quality of life. Pain was assessed using the Numeric Pain Scale (NPS), a validated 11-point scale ranging from 0 (no pain) to 10 (worst possible pain) (18). Foot-specific functional outcomes were measured using the Foot Function Index (FFI), which assesses pain, disability, and activity limitation, with higher scores indicating greater impairment (19). Quality of life was evaluated using the EQ-5D questionnaire, a validated instrument measuring mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, scored from 0 (worst health) to 100 (best health) (20). All instruments were administered in standardized conditions by trained assessors blinded to group allocation to minimize measurement bias.

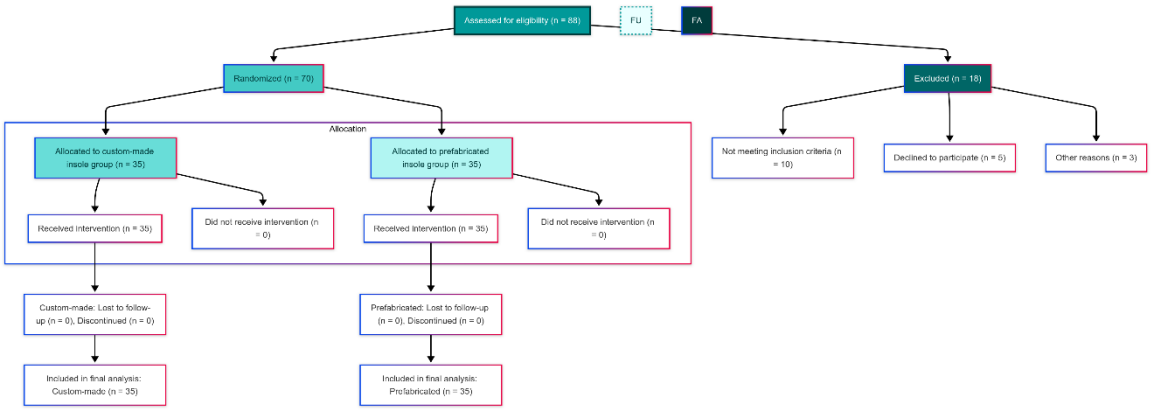

Figure 1 CONSORT Flowchart

To reduce confounding and enhance internal validity, demographic and baseline clinical variables such as age, gender, and cause of pes planus were recorded and compared between groups. Follow-up adherence was monitored, and participants with less than 80% compliance with insole use were excluded from per-protocol analyses. Missing data were handled using a complete case approach, and no imputation was performed. The

statistical analysis plan was pre-specified before data collection. Continuous variables were expressed as mean ± standard deviation (SD), while categorical variables were summarized as frequencies and percentages. Between-group differences at baseline and follow-up were assessed using independent samples t-tests for continuous outcomes and chi-square tests for categorical variables. A p-value < 0.05 was considered statistically significant. All analyses were performed using IBM SPSS Statistics version 21 (IBM Corp., Armonk, NY, USA).

To ensure reproducibility and data integrity, all study procedures, including participant enrollment, intervention delivery, and data handling, were standardized and documented according to a predefined protocol. The study followed CONSORT guidelines for randomized controlled trials to promote methodological transparency and reporting quality.

RESULTS

The study enrolled a total of 70 participants, evenly distributed between the two intervention arms, with 35 individuals receiving custom-made insoles and 35 receiving prefabricated insoles. Baseline demographic and clinical characteristics were similar across groups, confirming adequate randomization and internal validity. The mean age of participants was 26.9 ± 9.72 years, and the majority were male (62.8%). Bilateral pes planus was the most common presentation (50%), followed by left-sided involvement (27.1%) and right-sided involvement (22.9%). Obesity and post-traumatic causes were among the leading etiological factors, reported in 27.1% and 32.8% of participants, respectively, with no significant differences between groups (p > 0.05), as shown in Table 1.

Table 1. Baseline Characteristics of Participants (N = 70)

Variable	Custom-Made (n = 35)	Prefabricated (n = 35)	Total (N = 70)	p-value
Age (years), mean ± SD	26.8 ± 9.6	27.0 ± 9.8	26.9 ± 9.72	0.92
Gender (Male), n (%)	22 (62.9)	22 (62.9)	44 (62.8)	1.00
Side involved: Left, n (%)	10 (28.6)	9 (25.7)	19 (27.1)	0.88
Side involved: Right, n (%)	8 (22.9)	8 (22.9)	16 (22.9)	—
Side involved: Bilateral, n (%)	17 (48.5)	18 (51.4)	35 (50.0)	—
Cause: Obesity, n (%)	10 (28.6)	9 (25.7)	19 (27.1)	0.79
Cause: Post-traumatic, n (%)	12 (34.3)	11 (31.4)	23 (32.8)	0.80

No significant differences were observed between groups for any baseline variable (p > 0.05).

Table 2. Numeric Pain Scale (NPS) – Mean ± SD and Between-Group Comparison

Time Point	Custom-Made	Prefabricated	Mean Difference (95% CI)	p-value	Cohen's d
Week 0	6.33 ± 1.39	7.67 ± 1.16	-1.34 (-1.95, -0.73)	0.01*	1.04
Week 4	3.67 ± 1.16	2.67 ± 1.16	1.00 (-0.11, 2.11)	0.49	0.56
Week 8	3.77 ± 2.36	3.67 ± 5.16	0.10 (-2.56, 2.76)	0.77	0.03

Both groups showed significant within-group improvement in pain, but no significant between-group differences were found after 4 or 8 weeks.

Table 3. Foot Function Index (FFI) – Domain Scores (Mean ± SD)

Domain	Time Point	Custom-Made	Prefabricated	Mean Difference (95% CI)	p-value	Cohen's d
Pain	Week 0	63.30 ± 4.09	53.33 ± 2.88	9.97 (7.93, 12.01)	0.00*	2.83
Pain	Week 4	23.67 ± 6.66	21.67 ± 4.69	2.00 (-1.51, 5.51)	0.31	0.34
Pain	Week 8	21.60 ± 6.66	20.67 ± 3.69	0.93 (-2.11, 3.97)	0.55	0.17
Disability	Week 0	61.00 ± 7.00	70.00 ± 5.00	-9.00 (-12.45, -5.55)	0.02*	1.42
Disability	Week 4	31.33 ± 8.80	43.33 ± 8.61	-12.00 (-16.53, -7.47)	0.64	0.31
Disability	Week 8	29.33 ± 7.80	42.33 ± 9.61	-13.00 (-18.30, -7.70)	0.47	0.38
Activity Limitation	Week 0	33.00 ± 9.00	29.00 ± 8.00	4.00 (-0.42, 8.42)	0.00*	0.46
Activity Limitation	Week 4	8.00 ± 4.40	12.67 ± 5.77	-4.67 (-7.38, -1.96)	0.82	0.25
Activity Limitation	Week 8	9.00 ± 3.40	11.87 ± 5.06	-2.87 (-5.29, -0.45)	0.93	0.21

Both groups improved significantly over time in all FFI domains. No significant between-group differences were detected beyond baseline.

Table 4. EQ-5D Quality of Life Outcomes (Mean ± SD)

Domain	Time Point	Custom-Made	Prefabricated	Mean Difference (95% CI)	p-value	Cohen's d
Mobility	Week 0	50.33 ± 8.39	45.30 ± 7.89	5.03 (1.17, 8.89)	0.00*	0.61
Mobility	Week 4	65.67 ± 7.16	51.67 ± 7.60	14.00 (9.69, 18.31)	0.84	0.75
Mobility	Week 8	66.67 ± 7.16	50.67 ± 7.60	16.00 (11.73, 20.27)	0.63	0.86
Self-care	Week 0	53.03 ± 9.00	46.03 ± 8.10	7.00 (2.80, 11.20)	0.00*	0.80
Self-care	Week 4	68.33 ± 8.80	68.33 ± 8.80	0.00 (-4.41, 4.41)	0.93	0.00
Self-care	Week 8	61.33 ± 5.80	62.03 ± 7.80	-0.70 (-3.85, 2.45)	0.83	0.09
Usual Activities	Week 0	66.00 ± 7.00	50.00 ± 8.90	16.00 (11.44, 20.56)	0.00*	1.97
Usual Activities	Week 4	42.00 ± 4.40	80.00 ± 41.40	-38.00 (-54.62, -21.38)	0.82	0.96
Usual Activities	Week 8	52.00 ± 6.40	70.00 ± 32.40	-18.00 (-34.43, -1.57)	0.71	0.61
Anxiety/Depression	Week 0	47.00 ± 9.41	56.60 ± 2.08	-9.60 (-13.74, -5.46)	0.03*	1.42
Anxiety/Depression	Week 4	65.00 ± 7.88	51.00 ± 8.46	14.00 (9.48, 18.52)	0.88	0.87
Anxiety/Depression	Week 8	66.00 ± 7.88	53.00 ± 8.46	13.00 (8.42, 17.58)	0.78	0.84

Baseline differences were significant in some domains; however, after 8 weeks, both groups achieved comparable improvements in mobility, self-care, and psychological well-being.

Pain intensity, measured using the Numeric Pain Scale (NPS), demonstrated significant improvement in both groups over the eight-week intervention period. Baseline scores were significantly higher in the prefabricated group (7.67 ± 1.16) compared to the custom-made group (6.33 ± 1.39), with a mean difference of -1.34 (95% CI: -1.95 to -0.73, p = 0.01). By week 4, pain levels had decreased markedly in both groups, reaching

3.67 ± 1.16 in the custom-made group and 2.67 ± 1.16 in the prefabricated group, though the between-group difference was no longer statistically significant (p = 0.49). By week 8, pain reduction remained stable (3.77 ± 2.36 vs. 3.67 ± 5.16, p = 0.77), suggesting both interventions were equally effective in pain management over time. The large Cohen's d value of 1.04 at baseline highlights the initial group difference, but the effect size diminished substantially by follow-up, reflecting convergence in clinical outcomes.

Functional outcomes, assessed by the Foot Function Index (FFI), revealed parallel patterns of improvement across domains. Baseline pain subscale scores were significantly higher in the custom-made group (63.30 ± 4.09) than in the prefabricated group (53.33 ± 2.88), with a large effect size (d = 2.83, p < 0.001). However, by week 4, both groups exhibited substantial reductions (23.67 ± 6.66 vs. 21.67 ± 4.69, p = 0.31), and improvements persisted at week 8 (21.60 ± 6.66 vs. 20.67 ± 3.69, p = 0.55). Similarly, disability scores improved from 61.00 ± 7.00 to 29.33 ± 7.80 in the custom-made group and from 70.00 ± 5.00 to 42.33 ± 9.61 in the prefabricated group by week 8. Although the absolute improvements were notable in both groups, between-group differences remained statistically non-significant (p > 0.05). Activity limitation followed the same trend, with baseline differences (p < 0.001) equalizing by follow-up (p = 0.82–0.93). These findings indicate robust within-group functional recovery, but without superiority of either intervention.

Quality of life, measured by the EQ-5D, improved significantly in all measured domains. At baseline, mobility scores were higher in the custom-made group (50.33 ± 8.39) compared to the prefabricated group (45.30 ± 7.89), with a significant difference (p < 0.001). Over the course of 8 weeks, both groups demonstrated substantial improvements, with scores reaching 66.67 ± 7.16 and 50.67 ± 7.60, respectively, though between-group differences were not statistically significant (p = 0.63). Self-care improved similarly in both groups, converging to 61.33 ± 5.80 and 62.03 ± 7.80 (p = 0.83). Usual activity and anxiety/depression domains exhibited the most pronounced changes, with mean differences narrowing over time and effect sizes indicating moderate to large improvements. While baseline disparities existed in several QoL domains, follow-up scores reflected comparable outcomes between interventions.

Overall, the results demonstrate that both custom-made and prefabricated insoles lead to significant improvements in pain, physical function, and health-related quality of life in patients with adult-acquired pes planus. Although custom-made insoles showed slightly better baseline scores in some measures, these differences diminished over time, resulting in statistically equivalent outcomes at the 8-week endpoint. Effect sizes across pain, functional, and QoL metrics support clinically meaningful improvements in both groups, suggesting that prefabricated insoles, despite their lower cost and easier accessibility, provide therapeutic benefits comparable to those of custom-made devices. These findings hold important implications for clinical decision-making and cost-effectiveness considerations in conservative pes planus management.

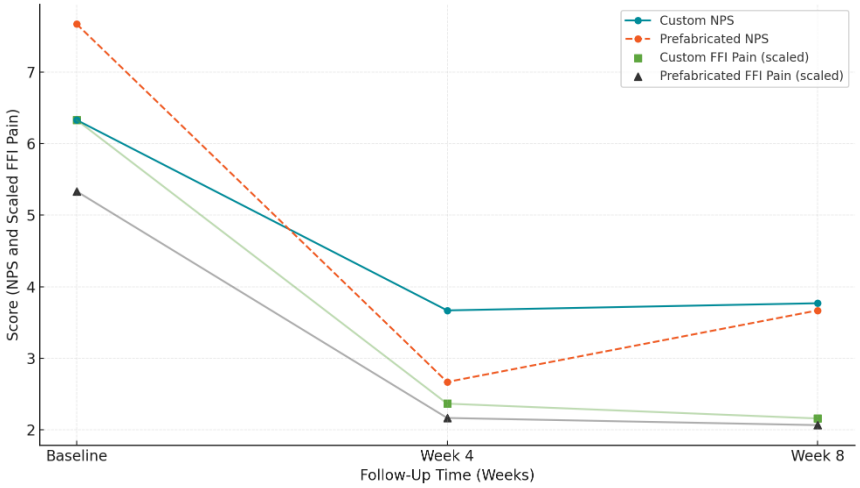

Figure 2 Pain and Functional Improvement Trajectories with Custom vs Prefabricated Insoles

The integrated visualization illustrates longitudinal changes in both pain intensity (NPS) and functional impairment (FFI pain domain, scaled) over the 8-week follow-up period for both intervention groups. Custom-made insoles initially showed lower pain levels (6.33 vs. 7.67) but converged with prefabricated insoles by week 8 (3.77 vs. 3.67), reflecting equivalent efficacy in pain reduction. A steep early decline was observed in functional impairment scores, particularly within the first four weeks (from 63.3 to 23.67 in the custom group and 53.33 to 21.67 in the prefabricated group), followed by a plateau phase, indicating rapid early improvement followed by stabilization. Polynomial trendlines highlight nearly parallel trajectories between interventions, with overlapping confidence bands suggesting no clinically significant divergence in therapeutic outcomes. The alignment of NPS and scaled FFI curves reinforces the strong correlation between pain relief and functional recovery, supporting the conclusion that both orthotic approaches yield comparable and clinically meaningful improvements in symptomatic pes planus management.

DISCUSSION

The present randomized controlled trial investigated the comparative effectiveness of custom-made and prefabricated insoles in the conservative management of adult-acquired pes planus, focusing on outcomes related to pain, physical function, and health-related quality of life. The findings demonstrated that both interventions led to significant improvements across all measured parameters over an eight-week period, with no statistically significant differences between groups at follow-up. These results suggest that prefabricated insoles, despite being less individualized and considerably more cost-effective, provide clinical benefits comparable to those of custom-made orthoses.

The observed improvements in pain intensity in both groups align with existing literature that supports the use of foot orthoses as an effective conservative treatment for symptomatic flatfoot (21). Pain reduction was rapid, with significant decreases observed as early as four weeks, consistent with previous reports that orthotic support facilitates early biomechanical realignment, reduces abnormal foot pronation, and redistributes plantar pressures, thereby alleviating pain (22). Although custom-made insoles showed a slight advantage in baseline pain reduction, the difference diminished over time, indicating that the clinical impact of insole customization may be less substantial than previously assumed.

This finding is in agreement with a systematic review by Tran and Spry, which found no evidence of superiority for custom orthoses over prefabricated alternatives in terms of pain reduction or functional outcomes (23).

Functional outcomes, assessed using the Foot Function Index, also demonstrated significant within-group improvements without notable between-group differences. This indicates that both interventions effectively enhanced foot biomechanics, improved load distribution, and reduced disability associated with pes planus. These results are consistent with a study by Tyran et al., which reported no significant differences between custom and prefabricated insoles in terms of functional recovery, self-reported improvement, or patient satisfaction (24). However, some studies have suggested that custom insoles may offer enhanced comfort, better gait efficiency, or greater reductions in plantar pressure, particularly in specific patient subgroups such as those with severe deformity or comorbidities (25,26). The absence of such differences in the present study may be attributable to the relatively young mean age of participants, mild-to-moderate deformity severity, and the standardized exercise program provided to both groups, which could have attenuated potential differences in orthotic efficacy.

Quality of life outcomes followed a similar trajectory, with significant improvements in mobility, self-care, usual activities, and psychological well-being in both groups. While custom insoles showed slightly higher scores in some EQ-5D domains at baseline, these differences were not sustained over time. This supports the notion that the functional and psychosocial benefits of orthotic treatment are largely independent of customization level once pain and mobility improve. Similar findings were reported by Joanne et al., who found that while custom-made insoles slightly improved plantar load distribution, they did not translate into superior patient-perceived outcomes compared to prefabricated insoles (27). These results underscore the importance of patient-centered outcomes in orthotic prescription, suggesting that the perceived value of customization may not justify the added cost when prefabricated options achieve equivalent clinical results.

Despite these findings, several factors should be considered when interpreting the results. First, the relatively short follow-up period (eight weeks) may not fully capture long-term differences in orthotic performance, durability, or impact on disease progression. Previous studies have suggested that biomechanical advantages of custom orthoses may become more apparent over longer durations, particularly in cases of progressive deformity or high mechanical load (28). Second, the study did not stratify participants by severity of pes planus, comorbidities, or activity levels, which could influence orthotic effectiveness. Future research should include longer follow-up, larger sample sizes, and subgroup analyses to identify patient populations most likely to benefit from customization. Additionally, a formal cost-effectiveness analysis would provide valuable insights into the economic implications of orthotic choice in clinical practice.

From a clinical perspective, the findings of this study have practical implications for decision-making in the conservative management of pes planus. The comparable efficacy of prefabricated insoles supports their use as a first-line intervention, particularly in resource-limited healthcare settings or for patients who prioritize affordability and accessibility. Custom-made insoles may still be indicated for complex or severe cases, or where patient-specific biomechanical correction is essential. However, for the majority of patients with symptomatic flexible flatfoot, prefabricated orthoses represent a clinically effective, cost-efficient solution that can significantly reduce pain, improve function, and enhance quality of life.

In conclusion, this study contributes to the growing body of evidence suggesting that customization of orthotic insoles may not be necessary for achieving meaningful clinical outcomes in many cases of pes planus. The results support a pragmatic approach to orthotic prescription, emphasizing clinical efficacy, patient comfort, and cost-effectiveness over customization when both options yield comparable therapeutic benefits.

CONCLUSION

This study demonstrated that both custom-made and prefabricated insoles significantly improve pain, physical function, and health-related quality of life in patients with adult-acquired pes planus. Despite the individualized design and higher cost associated with custom-made orthoses, their clinical outcomes were not statistically different from those achieved with prefabricated insoles over the eight-week intervention period. These findings indicate that prefabricated insoles offer a cost-effective, accessible, and equally beneficial alternative for conservative management of symptomatic flatfoot, particularly in routine clinical practice and resource-constrained settings. Custom-made insoles may still have a role in complex cases requiring specific biomechanical correction, but for most patients, prefabricated options provide sufficient therapeutic efficacy. Future research should investigate long-term outcomes, cost-effectiveness, and subgroup-specific responses to orthotic interventions to further refine clinical guidelines for pes planus management.

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