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Original Research Article

THE EFFICACY OF CUSTOMIZED ORTHOTIC DEVICES IN MANAGING PLANTAR FASCIITIS: A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Background: Plantar fasciitis is one of the most common causes of heel pain, often resulting in significant discomfort and functional limitation. While conservative treatments such as rest, stretching, and anti-inflammatory medication provide relief in many cases, the role of orthotic support remains central to long-term symptom management. Customized orthotic devices are designed to provide individualized support and may offer superior outcomes compared to standard prefabricated insoles. **Objective:** To evaluate the clinical effectiveness of customized orthotic devices in comparison to standard insoles in reducing pain and improving function in patients with plantar fasciitis, using validated assessment tools over a defined follow-up period.

Material and Methods: In this randomized controlled trial, adult patients diagnosed with plantar fasciitis were randomly allocated into two groups: one receiving customized orthotic devices and the other receiving standard over-the-counter insoles. Baseline assessment included the Foot Function Index (FFI) and Visual Analog Scale (VAS) for pain. Follow-up evaluations were conducted at 4, 8, and 12 weeks. Outcome measures included changes in pain severity, foot function, and patient satisfaction.

Results: A total of 100 participants were enrolled, with 50 in each group. Both groups showed significant improvement from baseline, but the customized orthotic group demonstrated greater reductions in VAS pain scores and higher improvements in FFI at all follow-up intervals. By the 12-week mark, mean VAS scores reduced by 70 percent in the customized group versus 48 percent in the standard group. Patient satisfaction was significantly higher among those using customized orthoses.

Conclusions: Customized orthotic devices are more effective than standard insoles in reducing pain and improving foot function in patients with plantar fasciitis. Their use should be considered as a preferred conservative option, especially in individuals with persistent symptoms or biomechanical abnormalities.

Keywords: Plantar Fasciitis; Customized Orthotics; Heel Pain; Foot Biomechanics; Randomized Controlled Trial; Foot Function Index; VAS Score; Conservative Treatment; Arch Support; Insole Therapy.

INTRODUCTION

Plantar fasciitis is among the most prevalent causes of heel pain in adults and is responsible for up to 15 percent of all foot complaints requiring medical attention. The condition is characterized by inflammation and microtears of the plantar fascia a thick, fibrous band that supports the medial longitudinal arch—primarily at its insertion on the calcaneus.[1] It typically presents with insidious onset of pain that is worst during the first steps after waking or prolonged rest and improves with gradual activity. Although traditionally associated with middle-aged individuals and athletes, it also affects a wide demographic including sedentary

individuals, especially those with biomechanical abnormalities or prolonged standing occupations.[2]

The pathophysiology of plantar fasciitis involves repetitive strain, overuse, and altered load distribution across the foot's arch, leading to chronic inflammation and degenerative changes rather than an acute inflammatory process. Common risk factors include obesity, excessive foot pronation, tight Achilles tendons, leg length discrepancy, and inadequate footwear. The condition is usually self-limiting but can become chronic and functionally disabling if not addressed appropriately.[3]

Conservative management remains the first-line approach and includes rest, stretching exercises, oral non-steroidal anti-inflammatory drugs, activity modification, and supportive footwear. Among these, orthotic interventions—particularly the use of shoe inserts or insoles play a pivotal role in redistributing plantar pressures, improving foot biomechanics, and reducing tension on the plantar fascia.[4,5] While off-the-shelf (standard) insoles offer general cushioning and arch support, their one-size-fits-all design may not cater to individual anatomical variations or biomechanical requirements.

Customized orthotic devices, fabricated based on foot morphology, gait pattern, and pressure distribution analysis, are designed to offer targeted support and correction. These devices aim not only to relieve symptoms but also to address the underlying biomechanical imbalances contributing to chronic stress on the plantar fascia. Despite their increasing popularity and theoretical advantages, the clinical superiority of customized orthoses over standard prefabricated insoles remains a subject of ongoing investigation.[6,7]

Multiple studies have explored the effectiveness of orthotic therapy in plantar fasciitis with mixed conclusions, often limited by heterogeneity in sample size, duration of follow-up, and outcome measurement tools. Some evidence suggests that customized orthotics yield better long-term results in reducing heel pain and improving foot function, while other studies report comparable outcomes between customized and standard insoles, especially in the short term.[8] Additionally, cost considerations and patient adherence are important factors influencing their widespread use.

In this context, a need exists for well-designed, randomized trials evaluating the comparative efficacy of customized orthotic devices versus standard insoles using validated assessment tools and clinically meaningful outcomes. This study was conducted to bridge that gap by assessing pain reduction, functional improvement, and patient satisfaction in a defined population with plantar fasciitis over a 12-week follow-up period. By objectively comparing both interventions, the study aims to guide clinical decision-making and optimize conservative treatment strategies for plantar fasciitis.

MATERIALS AND METHODS

This randomized controlled trial was conducted in the outpatient department of orthopedics and physical medicine at a tertiary care hospital over a period of six months. The study included adult patients aged 25 to 60 years who presented with clinical symptoms of plantar fasciitis, including heel pain of at least four weeks' duration, localized tenderness at the medial calcaneal tubercle, and pain exacerbated by weight-bearing after rest. Diagnosis was confirmed clinically and supported by ultrasonographic findings where necessary.

Patients with a history of recent lower limb trauma, foot or ankle fractures, prior foot surgeries, inflammatory arthropathy, systemic connective tissue disorders, or neurological deficits affecting gait were excluded. Those with known rigid foot deformities, such as pes cavus, or non-mechanical causes of heel pain were also excluded. Informed consent was obtained from all participants.

A total of 100 eligible patients were randomized into two equal groups using a computer-generated random number sequence. Group A received customized orthotic insoles, fabricated after individual biomechanical assessment including foot scanning, arch indexing, and gait pattern analysis. These insoles were designed to match the patient's foot contours and provide arch support tailored to plantar pressure zones. Group B received standard prefabricated insoles, commonly available over-the-counter, designed to provide generic cushioning and arch support. Both groups were advised to wear the insoles during waking hours and continue regular activities of daily living. Participants were instructed to avoid other new treatments for plantar fasciitis during the study period.

Baseline data were collected, including demographic variables (age, sex, BMI, occupation), duration of symptoms, and previous treatments received. The primary outcome measures were:

- Visual Analog Scale (VAS) score for pain (0 to 10)
- Foot Function Index (FFI), a validated composite score assessing pain, disability, and activity limitation

Secondary outcomes included patient-reported satisfaction and compliance with orthotic use. Follow-up assessments were conducted at 4 weeks, 8 weeks, and 12 weeks. At each visit, VAS and FFI scores were recorded. Final evaluation at 12 weeks included a global patient satisfaction score rated on a 5-point Likert scale (very dissatisfied to very satisfied).

Statistical analysis was carried out using standard software. Continuous variables such as age, VAS, and FFI scores were presented as mean ± standard deviation, while categorical variables were presented as frequencies and percentages. Between-group comparisons were made using independent t-tests for continuous variables and Chi-square test for

categorical variables. Repeated measures ANOVA was used to compare changes in VAS and FFI scores over time within and between groups. A p-value of less than 0.05 was considered statistically significant.

The study was conducted in accordance with ethical guidelines, and necessary institutional approvals were obtained prior to enrollment.

RESULTS

A total of 100 patients diagnosed with plantar fasciitis were enrolled and randomized equally into two groups of 50 each. All participants completed the 12-week follow-up without loss. The average age of patients was 44.2 years, with a slight female predominance. The baseline characteristics of both groups were comparable in terms of age, BMI, symptom duration, and foot involvement. Both interventions resulted in significant pain reduction and functional improvement, but patients using customized orthotics showed greater improvement across all outcome measures.

Table 1 presents the age-wise distribution of patients in each group, showing the highest frequency in the 41–50 year age bracket.

Table 1: Age Distribution of Study Participants (N = 100)

Age Group (years)	Customized Group (n)	Standard Group (n)	Total (n)	Percentage (%)
25–30	6	7	13	13.0
31–40	12	11	23	23.0
41–50	19	21	40	40.0
51–60	13	11	24	24.0
Total	**50**	**50**	**100**	**100.0**

Table 2 displays the sex distribution, with a slightly higher number of female participants in both groups.

Table 2: Sex Distribution of Study Participants (N = 100)

Sex	Customized Group (n)	Standard Group (n)	Total (n)	Percentage (%)
Male	22	20	42	42.0
Female	28	30	58	58.0
Total	**50**	**50**	**100**	**100.0**

Table 3 outlines the distribution based on symptom duration. Most participants had symptoms for 2 to 6 months.

Table 3: Duration of Symptoms Before Enrollment (N = 100)

Symptom Duration	Customized Group (n)	Standard Group (n)	Total (n)	Percentage (%)
1–2 months	8	6	14	14.0
2–6 months	29	31	60	60.0
>6 months	13	13	26	26.0
Total	**50**	**50**	**100**	**100.0**

Table 4 presents the side of foot involvement. Right foot was slightly more affected in both groups.

Table 4: Side of Foot Involvement (N = 100)

Affected Side	Customized Group (n)	Standard Group (n)	Total (n)	Percentage (%)
Right	27	29	56	56.0
Left	23	21	44	44.0
Total	**50**	**50**	**100**	**100.0**

Table 5 summarizes the mean VAS pain scores at baseline, confirming that both groups had comparable pain levels before starting treatment.

Table 5: Baseline VAS Pain Scores

Parameter	Customized Group	Standard Group	p-value
Mean VAS ± SD	7.8 ± 1.0	7.7 ± 0.9	0.64

Table 6 shows the change in VAS pain scores over the 12-week follow-up period. While both groups showed significant reduction in pain, the customized orthotic group demonstrated a more pronounced and consistent improvement at all intervals.

Table 6: VAS Pain Score Progression Over Time

Time Point	Customized Group (Mean ± SD)	Standard Group (Mean ± SD)	p-value
Baseline	7.8 ± 1.0	7.7 ± 0.9	0.64
4 Weeks	5.1 ± 1.2	6.0 ± 1.4	0.01
8 Weeks	3.4 ± 1.1	4.6 ± 1.3	0.001
12 Weeks	2.3 ± 1.0	4.0 ± 1.2	<0.001

Table 7 outlines the Foot Function Index (FFI) scores over the follow-up period. Lower FFI scores indicate better foot function. The customized group demonstrated significantly better improvement from week 4 onward.

Table 7: Foot Function Index (FFI) Progression

Time Point	Customized Group (Mean ± SD)	Standard Group (Mean ± SD)	p-value
Baseline	68.2 ± 7.4	67.5 ± 6.9	0.57
4 Weeks	52.7 ± 8.2	58.4 ± 7.7	0.006
8 Weeks	39.8 ± 6.9	49.2 ± 7.5	<0.001
12 Weeks	28.4 ± 5.8	42.6 ± 6.3	<0.001

Table 8 compares the proportion of patients achieving clinically meaningful pain relief (defined as ≥50% reduction in VAS score) at the end of 12 weeks. The customized orthotic group had a significantly higher response rate.

Table 8: Proportion of Patients with ≥50% Pain Reduction at 12 Weeks

Outcome	Customized Group (n)	Standard Group (n)	Total (n)	Percentage (%)
≥50% Pain Reduction	41	28	69	69.0
<50% Pain Reduction	9	22	31	31.0
Total	**50**	**50**	**100**	**100.0**

Table 9 shows patient satisfaction ratings at 12 weeks based on a 5-point Likert scale. A larger proportion of patients using customized orthotics reported being very satisfied or satisfied with treatment.

Table 9: Patient Satisfaction at 12 Weeks

Satisfaction Level	Customized Group (n)	Standard Group (n)	Total (n)	Percentage (%)
Very Satisfied	22	11	33	33.0
Satisfied	19	17	36	36.0
Neutral	6	14	20	20.0
Dissatisfied	3	6	9	9.0
Very Dissatisfied	0	2	2	2.0
Total	**50**	**50**	**100**	**100.0**

Table 10 summarizes the compliance with orthotic usage, as recorded in patient self-reported diaries. Compliance was marginally better in the customized orthotic group.

Table 10: Compliance with Orthotic Use Over 12 Weeks

Compliance Level	Customized Group (n)	Standard Group (n)	Total (n)	Percentage (%)
High (≥8 hrs/day)	38	32	70	70.0
Moderate (4–7 hrs/day)	10	13	23	23.0
Low (<4 hrs/day)	2	5	7	7.0
Total	**50**	**50**	**100**	**100.0**

DISCUSSION

Plantar fasciitis remains one of the most frequently encountered musculoskeletal complaints in orthopedic and rehabilitation clinics, often leading to prolonged discomfort, restricted mobility, and reduced quality of life. Conservative treatment continues to be the mainstay of therapy, with orthotic intervention being a cornerstone in biomechanical offloading of the plantar fascia. This study aimed to evaluate whether customized orthotic devices offer superior clinical benefit over standard prefabricated insoles in adult patients diagnosed with plantar fasciitis.[9]

The randomized trial involving 100 participants demonstrated that both customized and standard orthoses resulted in significant pain reduction and functional improvement over a 12-week period. However, the customized orthotic group exhibited significantly better outcomes across multiple objective and subjective parameters. This suggests that individualized biomechanical correction may provide incremental therapeutic advantage over generic support in managing plantar fasciitis.[10]

Pain reduction, as measured by VAS score, was greater in the customized group throughout the study period, with a mean reduction of 5.5 points by the end of 12 weeks, compared to 3.7 points in the standard group. While both groups started with comparable baseline VAS scores, the customized group showed more rapid and consistent pain relief. This could be attributed to the tailored contouring of customized orthotics, which more precisely aligns with the plantar arch and redistributes pressure during stance and gait phases.[11]

The Foot Function Index (FFI), a validated tool for assessing pain, disability, and activity limitation, also revealed significantly better scores in the customized group. By week 12, the mean FFI score in the customized group had decreased by approximately 40 points, compared to a 25-point reduction in the standard group. These findings reinforce the hypothesis that individualized support not only reduces pain but also promotes restoration of normal foot function and mobility.[12]

The proportion of patients achieving clinically meaningful pain relief (≥50% reduction in VAS) was notably higher in the customized orthotic group (82%) compared to the standard group (56%). This observation is clinically relevant, as patient-perceived improvement plays a critical role in compliance and satisfaction with conservative therapy. Patient satisfaction ratings, too, were significantly more favorable in the customized

group, with 82% reporting themselves as very satisfied or satisfied by the end of the study, versus 56% in the standard group.[13]

Compliance with orthotic usage was generally high in both groups, but slightly better in those using customized orthoses. This may be due to enhanced comfort and fit provided by custom devices, leading to better tolerance and adherence to daily use. This observation aligns with findings from previous studies where customized orthoses were associated with greater perceived comfort and durability, influencing patient behavior positively.[14]

Existing literature presents mixed findings regarding the superiority of customized orthotics. Some trials report no significant difference between custom and prefabricated insoles, particularly in the short-term. However, most of these studies either had small sample sizes, lacked long-term follow-up, or did not use standardized assessment tools. The current study, by including a well-powered sample and using validated outcome measures over a consistent follow-up period, adds robust data supporting the efficacy of customized devices.[15]

The therapeutic mechanism by which orthotics alleviate symptoms in plantar fasciitis is multifactorial. Customized orthotics are designed to correct abnormal pronation, reduce strain on the plantar fascia, and normalize plantar pressure distribution. These biomechanical modifications likely contribute to the observed clinical improvements. Moreover, addressing individual anatomical variations such as leg length discrepancy or arch abnormalities provides additional functional benefit that standard insoles may not offer.[16]

Despite the clear advantages seen in this study, certain limitations should be acknowledged. The follow-up period was limited to 12 weeks, and long-term durability or recurrence rates were not assessed. Furthermore, while self-reported compliance was recorded, objective monitoring (such as wearable sensors) was not used. The study also did not incorporate cost-effectiveness analysis, which is an important consideration when recommending custom devices in clinical practice.

Nonetheless, the findings strongly support the role of customized orthotic devices in the conservative management of plantar fasciitis, especially in patients with moderate to severe symptoms, biomechanical abnormalities, or those who fail to improve with standard interventions. These results advocate for a more personalized approach to orthotic therapy, moving beyond the one-size-fits-all model.

CONCLUSION

Customized orthotic devices are more effective than standard prefabricated insoles in managing plantar fasciitis, offering superior improvements in pain reduction, foot function, and patient satisfaction over a 12-week period. Their individualized design enables better biomechanical correction and targeted support, making them especially beneficial for patients with persistent symptoms or specific anatomical variations. Incorporating customized orthoses as a primary component of conservative therapy should be strongly considered in cases where personalized intervention is feasible and appropriate.

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