RESEARCH PAPER

CLINICAL EFFECTIVENESS OF A NOVEL MODIFIED ORTHOTIC INSERT FOR PLANTAR FASCIITIS: A PROSPECTIVE INTERVENTIONAL STUDY

Dr. Vinoth Kumar S[1*], **Dr. Nitesh Kumar Rathi**[1], **Dr. Kruthikaa Rajindran**[1]

[1*]Department of Orthopaedics, Saveetha Medical College and Hospital, Saveetha Institute of Medical and Technical Sciences (SIMATS), Chennai, Tamil Nadu, India

[1]Junior Resident (Dr. Vinoth Kumar S, Dr. Kruthikaa Rajindran) | ORCID: https://orcid.org/0009-0008-6002-6567

[1]Head of the Department (Dr. Nitesh Kumar Rathi)

[1]ORCID: https://orcid.org/0009-0004-9505-4120

***Corresponding Author:** Dr. Vinoth Kumar S, Junior Resident, Department of Orthopaedics, Saveetha Medical College and Hospital, Saveetha Institute of Medical and Technical Sciences (SIMATS), Chennai, Tamil Nadu, India | ORCID: https://orcid.org/0009-0008-6002-6567

ABSTRACT

Background

Plantar fasciitis is one of the most common causes of inferior heel pain in adults and is frequently associated with prolonged standing, obesity, repetitive mechanical loading, and altered foot biomechanics. Conservative management remains the cornerstone of treatment, with orthotic inserts playing an important role in reducing plantar fascia strain and improving functional outcomes.

Objective

To evaluate the effectiveness of modified orthotic inserts in reducing heel pain among patients with plantar fasciitis using validated pain assessment scales.

Methods

A prospective interventional pre–post study was conducted on 30 patients aged 18–65 years with clinically diagnosed plantar fasciitis and heel pain of at least four weeks' duration. Patients with previous foot trauma, inflammatory arthritis, neurological gait disorders, prior foot surgery, or recent corticosteroid injection were excluded. All participants received modified orthotic inserts designed to provide medial longitudinal arch support, heel cushioning, plantar pressure redistribution, and shock absorption. Pain intensity was assessed before intervention and after four weeks using the Visual Analog Scale (VAS) and Numeric Pain Rating Scale (NPRS). Statistical analysis was performed using the paired t-test for normally distributed difference scores and the Wilcoxon signed-rank test where this assumption was not met, with $p < 0.05$ considered statistically significant.

Results

The mean age of participants was 45.93 ± 8.51 years, with a predominance of females, manual labourers, and overweight or obese individuals. After four weeks of orthotic use, the mean VAS score significantly decreased from 7.60 ± 0.97 to 3.57 ± 1.30, representing a mean reduction of 4.03 ± 0.65 (53.1%; $t = 33.884$, $df = 29$, $p < 0.001$). Similarly, the mean NPRS score decreased from 7.90 ± 1.06 to 3.60 ± 1.40, corresponding to a mean improvement of 4.30 ± 0.75 (54.4%; $p < 0.001$). A strong positive correlation was observed between improvements in VAS and NPRS scores. Subgroup analysis demonstrated no significant differences in pain reduction according to gender or body mass index, indicating consistent treatment effectiveness across patient groups.

Conclusion

Modified orthotic inserts provide significant short-term pain relief in patients with plantar fasciitis by improving arch support, heel cushioning, shock absorption, and plantar load distribution. As a simple, safe, non-invasive, and cost-effective intervention, they represent an effective first-line conservative treatment. Their incorporation into a comprehensive management programme including stretching exercises, footwear modification, weight management, and activity modification may further optimize clinical outcomes.

Keywords

Plantar fasciitis; Heel pain; Modified orthotic inserts; Foot orthoses; Conservative management; Visual Analog Scale (VAS); Numeric Pain Rating Scale (NPRS); Plantar fascia; Biomechanics; Pain reduction.

How to cite this article: Kumar VS, Rathi NK, Rajindran K. Clinical effectiveness of a novel modified orthotic insert for plantar fasciitis: a prospective interventional study. Int J Drug Deliv Technol. 2026;16(74s): 422-430. DOI: 10.25258/ijddt.16.74s.49

INTRODUCTION

Plantar fasciitis is recognized as one of the most common causes of inferior heel pain in adults, accounting for a significant proportion of musculoskeletal complaints encountered in orthopaedic and rehabilitation practice [1]. It is estimated to contribute to nearly 10% of running-related injuries and is highly prevalent among middle-aged individuals, particularly those who are overweight or engaged in occupations requiring prolonged standing or repetitive weight-bearing activities. The condition is clinically characterized by sharp, stabbing pain localized to the medial calcaneal tuberosity, which is typically most severe during the first steps taken in the morning or after periods of rest. This classical "first-step pain" phenomenon is considered a hallmark feature and plays a crucial role in clinical diagnosis.

Despite the suffix "-itis," plantar fasciitis is now widely understood to be a degenerative rather than an inflammatory condition. Histopathological studies have demonstrated features such as collagen disorganization, fibroblast proliferation, myxoid degeneration, and neovascularization, with minimal or no evidence of inflammatory cell infiltration [2]. Consequently, the term "plantar fasciosis" is often considered more appropriate. The pathophysiology primarily involves repetitive microtrauma to the plantar fascia, leading to a failed healing response and progressive tissue degeneration. This paradigm shift from inflammation to degeneration has important implications for treatment strategies, emphasizing mechanical offloading and tissue rehabilitation rather than solely anti-inflammatory approaches.

The plantar fascia itself is a thick fibrous aponeurosis that originates from the medial tubercle of the calcaneus and extends distally to insert into the proximal phalanges [3]. It is divided into medial, central, and lateral bands, with the central band being the most clinically significant. Functionally, the plantar fascia plays a critical role in maintaining the medial longitudinal arch of the foot, absorbing shock during gait, and facilitating efficient energy transfer through the windlass mechanism. During toe dorsiflexion, the plantar fascia tightens, elevating the arch and enabling effective propulsion. Any disruption in this biomechanical system, such as excessive pronation or arch collapse, increases tensile stress on the fascia, predisposing it to injury [4].

Several risk factors have been identified in the development of plantar fasciitis, including obesity, prolonged standing, abnormal foot biomechanics (such as pes planus or pes cavus), tightness of the Achilles tendon, and sudden increases in physical activity. Chronic overload leads to increased thickness of the plantar fascia, often exceeding 4 mm as observed on ultrasound imaging. These risk factors highlight the multifactorial nature of the condition, involving both intrinsic anatomical factors and extrinsic mechanical stresses [5]. Diagnosis of plantar fasciitis is primarily clinical, based on characteristic symptoms and physical examination findings. Patients typically present with localized tenderness at the medial calcaneal tubercle and may demonstrate a positive Windlass test, wherein dorsiflexion of the toes reproduces pain. Imaging modalities such as X-ray, ultrasound, and MRI may be used in selected cases to confirm the diagnosis or rule out differential conditions such as calcaneal stress fractures, tarsal tunnel syndrome, fat pad atrophy, or S1 radiculopathy [6]. Ultrasound is particularly useful in demonstrating increased plantar fascia thickness, while MRI can reveal oedema at the calcaneal origin.

he prognosis of plantar fasciitis is generally favourable, with approximately 80–90% of patients experiencing improvement with conservative management. Most cases resolve within 6 to 12 months, although some may become chronic and persist beyond one year. Early intervention, patient compliance, and weight reduction are key factors associated with better outcomes [7]. Given its high prevalence and potential for chronicity, plantar fasciitis represents a significant burden on healthcare systems and underscores the importance of effective, evidence-based management strategies.

Conservative treatment remains the cornerstone of management, with a strong emphasis on biomechanical correction. Among the various modalities, modified orthotic inserts have gained considerable attention as a first-line intervention. These devices are designed to reduce mechanical strain on the plantar fascia, redistribute plantar pressures, support the medial longitudinal arch, and improve overall foot biomechanics. Orthotic modifications may include medial arch support, deep heel cups, silicone heel pads, and posting corrections to address specific biomechanical abnormalities. By addressing the underlying mechanical overload, orthoses play a crucial role in both symptom relief and prevention of recurrence. The mechanism of action of orthotic inserts is multifactorial. They help in reducing peak plantar pressures, limiting excessive pronation, and enhancing load distribution across the foot. Additionally, they improve gait biomechanics, thereby reducing repetitive stress on the plantar fascia [8]. Evidence from randomized controlled trials and systematic reviews supports their effectiveness in achieving short-term pain reduction and moderate functional improvement. Interestingly, studies have shown no clear long-term superiority of custom-made orthoses over prefabricated ones, suggesting that cost effective prefabricated inserts may be an appropriate initial choice.

In addition to orthotic therapy, other conservative modalities include activity modification, stretching exercises targeting the plantar fascia and Achilles tendon, short-term use of non-steroidal anti-inflammatory drugs (NSAIDs), and footwear modification. Adjunct therapies such as night splints, extracorporeal shockwave therapy (ESWT), corticosteroid injections, and platelet-rich plasma (PRP) injections may be considered in refractory cases [9]. However, these interventions vary in terms of evidence, cost, and risk profile, with orthotic inserts and stretching remaining the most consistently recommended first-line approaches. Recent trends in research and clinical practice indicate a growing interest in advanced orthotic technologies, including CAD/CAM-designed orthoses, 3D-printed inserts, and pressure-mapping based customization [10]. These innovations aim to enhance the precision and effectiveness of biomechanical correction. At the same time, there is increasing recognition of the importance of combining orthotic therapy with structured rehabilitation programs, including strengthening and load management strategies.

In conclusion, plantar fasciitis is a common yet complex condition characterized by degenerative changes in the plantar fascia due to repetitive mechanical overload. Its management requires a comprehensive understanding of foot biomechanics and a multifaceted approach targeting both symptoms and underlying causes. Modified orthotic inserts have emerged as a key component of conservative treatment, offering a safe, cost-effective, and evidence-based solution for alleviating heel pain and improving functional outcomes. As research continues to evolve, the integration of biomechanical insights with advanced orthotic technologies and rehabilitation strategies holds promise for optimizing patient care and reducing the burden of this prevalent condition.

AIM AND OBJECTIVES

Aim

To evaluate the effectiveness of modified orthotic inserts in reducing heel pain in patients with plantar fasciitis by addressing underlying biomechanical abnormalities.

Objectives

- To assess the reduction in heel pain following the use of modified orthotic inserts in patients with plantar fasciitis, using the VAS and NPRS.
- To describe the demographic and clinical characteristics (age, gender, occupation, BMI, symptom duration) of patients presenting with plantar fasciitis in this cohort.

METHODOLOGY

Study Design

The present study was conducted as a prospective interventional (pre-post) study to evaluate the effectiveness of modified orthotic inserts in patients with plantar fasciitis. The study aimed to assess pain reduction following intervention.

Study Setting

The study was carried out in the Department of Orthopaedics/Physiotherapy at a tertiary care hospital. Patients attending the outpatient department (OPD) with complaints of heel pain suggestive of plantar fasciitis were included in the study.

Study Duration

The study was conducted over a period of 6–12 months, during which patient recruitment, intervention, follow-up, and data analysis were completed.

Participants

Inclusion Criteria

Patients were included in the study if they: were aged between 18 and 65 years; had clinically diagnosed plantar fasciitis; presented with heel pain for at least 4 weeks; and were willing to participate and provide informed consent.

Exclusion Criteria

Patients were excluded if they: had a history of foot trauma or fracture; had inflammatory joint diseases (e.g., rheumatoid arthritis); had neurological disorders affecting gait; had previous foot surgery; or had received a steroid injection in the past 3 months.

Study Sampling

A convenience sampling method was used to recruit eligible participants from the outpatient department. Patients meeting the inclusion criteria were enrolled consecutively until the desired sample size was achieved.

Study Sample Size

A total of 30 participants were included in the study.

Study Parameters

The following parameters were assessed: pain intensity using the Visual Analog Scale (VAS) and Numeric Pain Rating Scale (NPRS); duration of symptoms; and demographic variables (age, gender, occupation, BMI).

Study Procedure

After obtaining informed consent, 30 patients with clinically diagnosed plantar fasciitis presenting with heel pain were enrolled in the study. Baseline pain intensity was assessed using the Visual Analog Scale (VAS) and Numeric Pain Rating Scale (NPRS).

All participants were provided with modified orthotic inserts and instructed to place them inside their footwear and use them during daily activities.

Patients were followed up after 4 weeks, and pain intensity was reassessed using VAS and NPRS. The effectiveness of the orthotic inserts was evaluated by comparing baseline and post-intervention pain scores.

Study Data Collection

Data were collected using a structured proforma that included patient demographics, clinical findings, and outcome measures. Pain scores were recorded at baseline and follow-up visits. All data were documented systematically and entered into a database for analysis.

Data Analysis

The collected data were analysed using IBM SPSS Statistics [version not specified in source data — to be inserted by authors]. Continuous variables were expressed as mean ± standard deviation. Normality of the distribution of paired differences was assessed prior to analysis; where this assumption was met, pre- and post-intervention comparisons were performed using the paired t-test (used for VAS), and where it was not met, the Wilcoxon signed-rank test was used (used for NPRS). A p-value of <0.05 was considered statistically significant.

Ethical Considerations

The study was conducted after obtaining approval from the Institutional Ethics Committee (IEC-Reference Number: 041/03/2025/IEC/SMCH). Written informed consent was obtained from all participants prior to enrolment. Confidentiality of patient data was maintained throughout the study. Participants were informed about their right to withdraw from the study at any stage without affecting their treatment

FIGURE 1 : PRODUCT TOP VIEW

FIGURE 2 : PRODUCT BOTTOM VIEW

Orthotic Insert Description

The modified orthotic insert evaluated in this study was developed specifically to reduce mechanical loading of the plantar fascia while remaining economical and suitable for routine clinical use.

Structural Components

The insert consisted of the following:

- Base Layer (size-specific, measured individually): Thermoplastic polyurethane (TPU), semi-rigid construction, full-length support.

- Middle Layer: High-density memory foam for pressure redistribution and shock absorption.
- Heel Region: Increased heel cushioning, with peak impact forces reduced by extending cushioning into the midfoot and forefoot regions.
- Arch Region: Anatomically contoured medial longitudinal arch support for improved load transfer during gait.
- Bottom Layer: Anti-slip silicone foam for improved footwear stability and comfort.

The overall design was intended to improve foot biomechanics by supporting the medial longitudinal arch, reducing plantar fascia strain, redistributing plantar pressure, and enhancing shock absorption through improved cushioning across the forefoot, midfoot, and hindfoot.

Intervention

Each participant received one pair of modified orthotic inserts. Patients were instructed to: wear the inserts inside closed footwear; use them during all weight-bearing activities; continue normal daily activities; avoid barefoot walking; and continue using the inserts for four consecutive weeks.

All participants received standardized advice regarding plantar fascia stretching, Achilles tendon stretching, appropriate footwear, and weight reduction when applicable.

No corticosteroid injections, PRP injections, extracorporeal shockwave therapy/ultrasound therapy, or surgical interventions were administered during the study period.

RESULTS

Table 1: Distribution of Study Participants According to Age Group

Age Group	**n**	**%**
28–35 years	3	10.0
36–45 years	12	40.0
46–55 years	10	33.3
56–65 years	5	16.7
Total	**30**	**100.0**

Mean Age ± SD: 45.93 ± 8.51 years

The age-wise distribution of the 30 study participants shows the largest proportion (40.0%) belonging to the 36–45 years age group, followed by the 46–55 years group (33.3%), with a mean age of 45.93 ± 8.51 years. This distribution reflects the well-established epidemiological pattern of plantar fasciitis predominantly affecting middle-aged adults engaged in sustained weight-bearing activities. Although the inclusion criteria permitted participants aged 18–65 years, no enrolled participant fell into the 18–27-year range; the observed sample spanned 28–65 years.

Table 2: Distribution of Study Participants According to Occupation

Occupation	**n**	**%**
Manual Labourer	13	43.3
Office Worker	6	20.0
Homemaker	4	13.3
Healthcare Worker	4	13.3
Teacher	3	10.0
Total	**30**	**100.0**

The occupational distribution shows manual labourers forming the largest category (43.3%), followed by office workers (20.0%), homemakers (13.3%), healthcare workers (13.3%), and teachers (10.0%). The predominance of manual labour occupations underscores the significant role of prolonged mechanical foot stress as a predisposing factor for plantar fasciitis in this study cohort.

Table 3: Distribution of Study Participants According to Duration of Symptoms

Duration of Symptoms	**n**	**%**
1–3 months	15	50.0
4–6 months	6	20.0
7–12 months	9	30.0
Total	**30**	**100.0**

The symptom duration distribution shows half the participants (50.0%) presenting within 1–3 months of onset, followed by 30.0% with 7–12 months and 20.0% with 4–6 months. This mixed cohort of early-onset and chronic cases enables a comprehensive assessment of orthotic efficacy across varying chronicity levels of plantar fasciitis.

Table 4: Correlation Between VAS Improvement and NPRS Improvement After 4 Weeks

Variable	**Mean Improvement ± SD**	**Pearson r**	**t-statistic / p-value**
VAS Improvement	4.03 ± 0.65	—	—
NPRS Improvement	4.30 ± 0.75	—	—
Correlation (VAS vs NPRS improvement)	—	0.840	t = 8.176, p < 0.001; 95% CI [0.687, 0.921]

A strong, statistically significant positive correlation was observed between VAS and NPRS improvement scores (Pearson r = 0.840, t = 8.176, p < 0.001; 95% CI: [0.687, 0.921]). This finding supports the concurrent validity of VAS and NPRS as complementary instruments for measuring intervention-related analgesia in this study cohort.

Table 5: Summary of Primary Outcome Measures — Pre- and Post-Intervention Comparison

Outcome	**Baseline Mean ± SD**	**4 Weeks Mean ± SD**	**Mean Reduction**	**% Reduction**	**Statistical Test / p-value**
VAS Score	7.60 ± 0.97	3.57 ± 1.30	4.03 ± 0.65	53.1%	Paired t-test: t=33.884, df=29, p<0.001
NPRS Score	7.90 ± 1.06	3.60 ± 1.40	4.30 ± 0.75	54.4%	Wilcoxon signed-rank: V=465, p<0.001

A consolidated summary confirms statistically significant reductions in both VAS (53.1%, paired t-test: t = 33.884, p < 0.001) and NPRS (54.4%, Wilcoxon signed-rank test: V = 465, p < 0.001) pain scores at 4 weeks. The concordant findings across two independently validated pain scales, supported by very large effect sizes (Cohen's dz = 6.19 for VAS and 5.74 for NPRS, calculated as mean difference ÷ SD of difference scores), provide evidence for the short-term analgesic effect of modified orthotic heel inserts in the management of plantar fasciitis.

DISCUSSION

The present prospective interventional study evaluated the clinical effectiveness of a novel modified orthotic insert in reducing heel pain among patients with plantar fasciitis. Thirty clinically diagnosed patients were followed for four weeks after receiving orthotic inserts designed to provide medial arch support, heel cushioning, and improved plantar pressure distribution. The findings demonstrated a highly significant reduction in pain measured by both the Visual Analog Scale (VAS) and Numeric Pain Rating Scale (NPRS), consistent with biomechanical correction through orthotic intervention as an effective conservative treatment strategy.

The demographic profile of the present study revealed a mean age of 45.93 ± 8.51 years, with the majority of participants belonging to the 36–45-year age group (40%), followed by the 46–55-year group (33.3%). These findings are comparable with the study by Martin et al., who reported that plantar fasciitis predominantly affects middle-aged adults owing to cumulative mechanical stress and age-related degenerative changes within the plantar fascia [11]. Similarly, Riddle and Schappert observed that the highest prevalence of plantar fasciitis occurs between the fourth and sixth decades of life, supporting the age distribution observed in the present study [12]. Degenerative changes in collagen fibres, repetitive microtrauma, and reduced tissue elasticity with advancing age likely explain this increased susceptibility.

Occupational analysis showed that 43.3% of participants were manual labourers, indicating that prolonged standing and repetitive weight-bearing activities are important contributors to plantar fasciitis. Similar observations were reported by Irving et al., who identified occupations requiring prolonged standing as major risk factors because continuous mechanical loading increases tensile strain on the plantar fascia [13]. The findings also agree with Ribeiro et al., who demonstrated that repetitive occupational loading predisposes individuals to plantar fascia degeneration and chronic heel pain [14]. Thus, occupational biomechanics remain an important consideration in both prevention and treatment.

Half of the participants (50%) presented within three months of symptom onset, whereas 30% had symptoms for 7–12 months. This distribution suggests that both acute and chronic plantar fasciitis respond favourably to orthotic therapy. Landorf, Keenan, and Herbert similarly reported that orthotic devices provide significant pain relief irrespective of symptom duration by correcting abnormal foot biomechanics and reducing repetitive stress on the plantar fascia [8]. Early intervention, however, has been associated with faster symptom resolution and reduced progression to chronic degeneration.

The primary outcome of this study was the significant reduction in heel pain after four weeks of orthotic use. The mean VAS score decreased from 7.60 ± 0.97 to 3.57 ± 1.30, representing a 53.1% reduction, while the mean NPRS score decreased from 7.90 ± 1.06 to 3.60 ± 1.40, corresponding to a 54.4% reduction. Both improvements were highly statistically significant ($p < 0.001$). These findings support the analgesic effect of modified orthotic inserts observed in this uncontrolled, single-arm cohort.

Comparable results have been reported by Landorf et al., whose randomized controlled trial demonstrated significant short-term improvement in heel pain with prefabricated and customized orthoses compared with sham inserts [8]. Likewise, Baldassin et al. reported marked reductions in pain scores following orthotic treatment over six weeks, concluding that biomechanical correction effectively decreases plantar fascia strain and improves patient comfort [15]. The magnitude of pain reduction observed in the present study is broadly consistent with these findings, though the present study lacked a control or sham-orthotic group, which limits attribution of the improvement to the device itself versus natural history or placebo effect.

The effectiveness of orthotic inserts can be explained through their proposed biomechanical action. The modified inserts used in this study incorporated medial arch support and heel cushioning, intended to redistribute plantar pressure, improve shock absorption, limit excessive pronation, and decrease tensile stress on the plantar fascia during gait — though plantar pressure and gait were not directly measured in this study. Cheung and Ng demonstrated that orthotic devices significantly reduce peak plantar pressures and improve pressure distribution during walking, leading to reduced mechanical overload on the plantar fascia [10]. Similarly, Bonanno et al. reported that foot orthoses improve lower-limb biomechanics and decrease stress across the plantar fascia, resulting in substantial pain relief [16].

An important observation in the present study was the strong positive correlation between improvements measured using VAS and NPRS (Pearson's $r = 0.840$; $p < 0.001$). This indicates good agreement between the two pain assessment tools and is consistent with the consistency expected of patient-reported outcomes. Similar correlations between VAS and NPRS have been documented by Hawker et al., who concluded that both scales are reliable, sensitive, and largely interchangeable instruments for assessing musculoskeletal pain in clinical research [17]. The concurrent validity demonstrated in the present study is consistent with this prior work.

The statistical analysis demonstrated very large treatment effects. The paired t-test for VAS showed $t = 33.884$ ($p < 0.001$), while NPRS improvement, assessed using the Wilcoxon signed-rank test because

the difference scores did not meet normality assumptions, also reached high statistical significance. These findings indicate that the observed improvement was unlikely to be attributable to chance. However, the calculated effect sizes (Cohen's dz = 6.19 and 5.74) are markedly larger than those typically reported in the orthotic literature and should be interpreted cautiously, as they may in part reflect the small sample size, the absence of blinding, and the absence of a comparator arm. Whittaker et al., in a systematic review, concluded that foot orthoses produce significant but generally moderate short-term pain reduction and functional improvement in patients with plantar heel pain, which contextualizes the unusually large effect observed here [9].

The present study also observed that pain reduction was comparable across different BMI categories and between genders, suggesting that orthotic inserts may provide clinical benefit across different body habitus in this sample. Although obesity is a recognized risk factor for plantar fasciitis due to increased plantar loading, the biomechanical support provided by orthotic devices appeared sufficient to achieve pain reduction across different body habitus in this cohort. Previous studies have similarly reported that while obesity increases disease incidence, it does not necessarily diminish the therapeutic response to orthotic treatment [13,16].

The favourable outcomes observed in this study emphasize the importance of trialling conservative management before considering invasive interventions such as corticosteroid injections, platelet-rich plasma therapy, extracorporeal shock wave therapy, or surgical plantar fascia release. Orthotic inserts are inexpensive, non-invasive, reusable, and generally associated with minimal adverse effects, which may make them suitable for routine outpatient practice; however, patient compliance and satisfaction with the inserts used in this study were not formally assessed and cannot be reported as a study finding.

The strengths of the present study include its prospective design, standardized intervention, and use of two validated pain assessment scales that demonstrated good agreement. The consistent statistical significance across multiple outcome measures adds confidence to the pain-reduction finding. Nevertheless, several limitations should be acknowledged. The study included only 30 participants from a single centre, limiting generalizability. The design was a single-arm pre–post study without a control, placebo, or sham-orthotic comparison group, and without blinding — both of which limit causal inference and may inflate the apparent effect size. The follow-up period of four weeks evaluated only short-term outcomes. Functional outcomes, plantar pressure analysis, gait assessment, imaging evaluation of plantar fascia thickness, patient compliance, patient satisfaction, and the differential contribution of individual design features (e.g., arch support versus cushioning) were not assessed, despite compliance/satisfaction and design-feature analysis having originally been listed as study objectives. Cost and fabrication-time figures mentioned in the original conclusion (₹1,500 per pair; two-day fabrication) were likewise not part of the formal study data collection and are better characterized as manufacturing notes rather than study outcomes. Future randomized controlled trials with larger, multi-centre samples, blinding or sham comparators, longer follow-up, and objective biomechanical analyses are required to determine the long-term effectiveness and durability of modified orthotic inserts.

Overall, the findings of the present study provide clinical evidence that modified orthotic inserts are associated with significant short-term reduction in heel pain in patients with plantar fasciitis. These results are broadly consistent with contemporary literature and support further investigation of modified orthotic inserts as part of the conservative management of plantar fasciitis, ideally in a controlled trial design. Their simplicity, low apparent cost, and non-invasive nature make them an attractive candidate for a first-line treatment option, particularly when combined with stretching exercises, footwear modification, weight management, and patient education — pending confirmation in adequately controlled studies.

CONCLUSION

This study found that modified orthotic inserts were associated with short-term reduction of plantar fasciitis–related heel pain in a small, single-arm cohort. Among 30 predominantly middle-aged participants, statistically significant reductions were observed in both VAS and NPRS pain scores after 4 weeks, with more than 50% improvement ($p < 0.001$). Pain reduction was consistent across gender and BMI categories in this sample. The customized design was intended to address individual foot biomechanics and plantar pressure distribution, although biomechanical measures (e.g., plantar pressure mapping, gait analysis) were not directly assessed in this study.

Manufacturing notes provided by the study team indicate the inserts could be produced at an approximate cost of

₹1,500 per pair and fabricated within two days; these figures were not part of the formal outcome data and should be treated as preliminary, unverified estimates rather than study findings. Similarly, claims regarding patient comfort, compliance, and improved ability to perform daily activities were not measured using a validated instrument in this study and are not reported as findings here.

Overall, modified orthotic inserts appear to be a safe and low-cost conservative intervention for plantar fasciitis warranting further evaluation. Larger randomized controlled studies with a control or sham-orthotic arm, blinding where feasible, longer follow-up, and formal assessment of functional outcomes, patient compliance, satisfaction, recurrence, and comparison with other conservative treatment modalities are recommended before broader clinical adoption can be firmly supported.

REFERENCES :

1. Buchbinder R. Plantar fasciitis. N Engl J Med. 2004;350(21):2159–2166.
2. Lemont H, Ammirati KM, Usen N. Plantar fasciitis: a degenerative process (fasciosis) without inflammation. J Am Podiatr Med Assoc. 2003;93(3):234–237.
3. Hicks JH. The mechanics of the foot. II. The plantar aponeurosis and the arch. J Anat. 1954;88(Pt 1):25–30.
4. Wearing SC, Smeathers JE, Urry SR, Hennig EM, Hills AP. The pathomechanics of plantar fasciitis. Sports Med. 2006;36(7):585–611.
5. Irving DB, Cook JL, Menz HB. Factors associated with chronic plantar heel pain: a systematic review. J Sci Med Sport. 2006;9(1–2):11–22.
6. Goff JD, Crawford R. Diagnosis and treatment of plantar fasciitis. Am Fam Physician. 2011;84(6):676–682.
7. Thomas JL, Christensen JC, Kravitz SR, et al. The diagnosis and treatment of heel pain: clinical practice guideline. J Foot Ankle Surg. 2010;49(3 Suppl):S1–S19.
8. Landorf KB, Keenan AM, Herbert RD. Effectiveness of foot orthoses to treat plantar fasciitis: a randomized trial. Arch Intern Med. 2006;166(12):1305–1310.
9. Whittaker GA, Munteanu SE, Menz HB, et al. Foot orthoses for plantar heel pain: a systematic review and meta-analysis. Br J Sports Med. 18. ;63(S11):S240–S252.
2018;52(5):322–328.
10. Cheung JT, Ng GY. Biomechanical effects of foot orthoses on plantar pressure distribution. Clin Biomech (Bristol, Avon). 2008;23(5):622–628. [Note: the original manuscript cited this journal/volume/issue/page range under two different titles ("Efficacy of customized foot orthoses in plantar pressure redistribution and plantar fasciitis management" and this title); authors should verify the correct title against the original source.]
11. Martin RL, Davenport TE, Reischl SF, et al. Heel pain—plantar fasciitis: revision clinical practice guidelines. J Orthop Sports Phys Ther. 2014;44(11):A1–A33.
12. Riddle DL, Schappert SM. Volume of ambulatory care visits and patterns of care for patients diagnosed with plantar fasciitis. Foot Ankle Int. 2004;25(5):303–310.
13. Irving DB, Cook JL, Young MA, Menz HB. Impact of occupational standing and obesity on plantar heel pain. J Sci Med Sport. 2007;10(5):283–289.
14. Ribeiro AP, João SMA, Dinato RC, et al. Biomechanical factors associated with plantar fasciitis. Clin Biomech (Bristol, Avon). 2011;26(5):490–495.
15. Baldassin V, Gomes CR, Beraldo PS. Effectiveness of prefabricated and customized foot orthoses in plantar fasciitis. Foot Ankle Int. 2009;30(8):726–733.
16. Bonanno DR, Landorf KB, Munteanu SE, et al. Effectiveness of foot orthoses for plantar heel pain: systematic review and meta-analysis. Br J Sports Med. 2017;51(2):86–96.
17. Hawker GA, Mian S, Kendzerska T, French M. Measures of adult pain: Visual Analog Scale and Numeric Rating Scale. Arthritis Care Res (Hoboken). 2011