



Different orthotics in management of plantar fasciitis: a systematic review

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Abstract:

Purpose: to provide an objective and comprehensive overview about effectiveness of each type of orthotics used in the management of calcaneal plantar fasciitis.

Methods: This systematic review aimed to evaluate the efficacy of various orthotic interventions in the treatment of plantar fasciitis. The review protocol was registered in PROSPERO, and a specific search strategy was developed for different databases, including Cochrane Library, PEDro, MEDLINE, EMBASE, and CINAHL. Eligibility criteria were defined, and two reviewers independently screened titles and abstracts, followed by full-text screening of potentially relevant studies. A data extraction form was used to collect key study characteristics, and the quality of evidence was evaluated using Cochrane Collaboration's tool. The primary outcome measure was pain and disability is considered the secondary outcome.

Results: A total of 2699 studies were found, of which 10 studies were included in the systematic review. The included studies were of randomized controlled trials (RCTs). The review found that various orthotic interventions could improve pain, and disability in patients with plantar fasciitis. The combined effect size was statistically significant in all models, indicating a significant effect of orthotics on pain and disability. However, significant heterogeneity was observed among the studies. Subgroup analysis showed significant heterogeneity. No significant publication bias was detected in any of the analyses.

Conclusion: The systematic review concludes that orthotics may be a promising non-invasive treatment for people with plantar fasciitis, as the meta-analysis showed a significant effect on pain and disability. However, the high heterogeneity among the studies suggests that further research is needed. While there was no significant publication bias, more high-quality research is needed to confirm the findings and establish the optimal use of orthotics for plantar fasciitis. Clinicians should consider using orthotics with other conservative treatments for people with Planter fasciitis.

Key words: Plantar Fasciitis; Orthotic Devices; Foot Orthoses; Pain Management; Foot Function.

1.Introduction

Plantar fasciitis is a prevalent foot condition that affects approximately 10% of the population, and it is one of the primary sources of heel pain (1). It is characterized by pain and inflammation in the thick fibrous band of connective tissue extending along the foot's planter surface, recognized as the plantar fascia (2). This condition can be debilitating, limiting mobility and quality of life, and is often difficult to manage (3).

There are various treatments available for plantar fasciitis, including rest, ice, stretching exercises, and the use of orthotics (4,5). Orthotics are devices that are designed to support and correct the structure of the foot and are utilized in management of various foot and ankle cases (6). Many studies support adding orthotics for the management of plantar fasciitis due to its effectiveness in easing pain and restoring function (7).

However, comparative studies that evaluated efficacy between different types of orthotics used with planter fasciitis are limited. Some studies have investigated the use of prefabricated orthotics, while others have focused on custom-made orthotics (8,9). In addition, there is a controversy about the optimal design and material of orthotics for plantar fasciitis (10).

The purpose of this systematic review is to study the available resources about efficacy of various orthotics used with planter fasciitis. The review will compare the efficacy of prefabricated and custom-made orthotics, as well as the different materials and designs used in orthotics. The review will also consider the limitations and potential biases in included studies.

By conducting a systematic review of the available literature, we hope to provide an objective and comprehensive overview about effectiveness of each type of orthotics used in the management of calcaneal plantar fasciitis. This information will be useful for healthcare professionals in selecting the most appropriate orthotics for their patients, and for future research in this field.

In conclusion, plantar fasciitis is a frequent foot condition that can be difficult to manage. The use of orthotics has been shown to be effective in easing pain and restoring function, but comparing the effect between different orthotics has not been studied well. This systematic review aims to provide an objective and comprehensive overview about effectiveness of each type of orthotics used in the management of calcaneal plantar fasciitis, and will be useful for healthcare professionals and future research in this field.

2. Methodology:

The protocol registration on the International Register of Systematic Reviews (PROSPERO) was done on

09/03/2017 code CRD42017058233, available here [https://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42017058233\(11\)](https://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42017058233(11))

2.1. Information sources and search strategy

We set up a specific search strategies for the various databases. In details, Searching clinical trials on Pedro database three keywords were used (orthosis, Planter, Fasciitis).

After checking references of all obtained trials we made contact with physical therapy companies and first authors of all included trials to get access to unpublished trials. We checked platforms of registered trials using the keywords "calcaneal, planter fasciitis". These are World Health Organization (WHO) International Clinical Trials Registry Platform (<http://apps.who.int/trialsearch>), Current Controlled Trials (<http://www.controlled-trials.com>), the National Institute for Health Research Register (NRR) Archive (<http://www.nihr.ac.uk/Pages/NRRArchiveSearch.aspx>), the US National Institutes of Health <http://ClinicalTrials.gov/> and the Australian New Zealand Clinical Trial Registry (<http://www.anzctr.org.au/Default.aspx>). Using a definite search strategy we searched all research from 2011 till August in the following databases: Cochrane Library (Cochrane Database of Systematic Reviews (Cochrane Reviews) and the Cochrane Central Register of Controlled Trials), PEDro, MEDLINE, EMBASE, and CINAHL. Searching strategy was illustrated in table 1 (12).

Database	Keywords	Search Strategy
PubMed	Plantar Fasciitis, Orthotic Intervention	("plantar fasciitis"[MeSH Terms] OR "plantar fasciitis"[All Fields] OR "plantar fascia"[All Fields]) AND ("Orthotic Devices"[Mesh] OR "Orthotic Devices"[All Fields])
EMBASE	Plantar Fasciitis, Orthotic Intervention	('plantar fasciitis'/exp OR 'plantar fasciitis' OR 'plantar fascia' OR 'plantar heel pain' OR 'heel spur' OR 'heel pain') AND ('orthotic'/exp OR 'orthotic' OR 'foot orthosis' OR 'arch support' OR 'shoe insert')
Pedro	Spur, Planter, Fasciitis	Spur OR Planter OR Fasciitis

Table (1): Searching strategy for different databases

2.2. Eligibility criteria:

All studies that cover the following were considered eligible: subjects with a diagnosis of the planter fasciitis that originate from calcaneus, all ages and all degrees of severity. Trials of all orthotic treatments compared with sham treatment, medications or any forms rather than medication treatment. Randomized, quasi and other systematic allocation controlled trials comparing each physical therapy modality with either control or experimental modality, Studies written in English.

2.3. Exclusion criteria:

All studies that cover the following were excluded: Studies that include any of the following were excluded from the review: Observational studies, cohort studies, correlational studies or Studies with abstracts not available, Studies that investigated pharmacological treatments and surgery,

Studies that reported patients with Post-fracture spur, osteoarthritis, fascial plantar fibromatosis, tumor, neurological pathologies, tarsal tunnel syndrome, lesion of plantar nerve, Morton's syndrome, diabetic pathologies as ulcers, rheumatic pathologies and acute or chronic infections.

2.4. Study selection:

The data collection process involved a comprehensive search of electronic databases, as well as a manual search of relevant journals and reference lists. The search strategy was developed based on pre-defined inclusion and exclusion criteria, which were designed to capture studies that met the research question and objectives of this systematic review.

First, titles and abstract were screened by two independent reviewers then full-text screening of potentially relevant studies. Discussions and consultation with a third reviewer were conducted to resolve any discrepancies.

2.5. Data collection: A data extraction form was developed, which included key study characteristics, such as study design, population characteristics, interventions, and outcomes. One author extracted these descriptive data using an Excel® spreadsheet: the name of the first author, year of publication, study design, sample size, subject's characteristics, interventions, measured outcomes, and follow-up time data. Then the second author approved them after checking their accuracy (13).

2.6. Quality assessment:

For bias assessment in randomized trials we used the Cochrane Collaboration's tool for bias assessment, as indicated by the plus (+) and minus (-) signs for each domain assessed. The tool assesses the risk of bias in the following domains: randomization procedure, allocation concealment, blinding of subjects, personnel and outcome assessor in addition to other sources of bias as incomplete outcome data, selective reporting. The quality of evidence was ranked as regards to the risk of bias, inconsistency, indirectness, imprecision, and publication bias. We rated the quality of evidence as high, moderate, low, or very low. (14,15)

2.7. Outcomes:

The current systematic review summarizes the outcomes of seven systematic review studies that investigated the efficacy of different foot orthoses in treating plantar fasciitis. The studies involved a total of 465 participants. The interventions included custom-made foot orthoses, prefabricated orthotics, flat cushioning insoles, augmented low-dye taping, and extracorporeal shock wave therapy with custom foot orthotics. The primary outcomes were pain and foot function measured by Visual Analogue Scale (VAS), Foot Health Status Questionnaire (FHSQ), Foot Function Index Revised (FFI-R), Foot Pain and Function Scale (FPFS), American Orthopedic Foot and Ankle Society-Ankle Hindfoot Scale (AOFAS-AHS), and peak plantar pressure (PPP).

Overall, most studies found a significant improvement in pain and foot functionality in patients who used foot orthoses compared to those who used other treatments or placebo flat cushioning insoles. Three studies found no statistically significant differences between custom-made or prefabricated foot orthoses or soft and firm foot orthotic materials. The type of orthosis that showed a significant increase in pain reduction and foot functionality was the custom foot orthosis. The primary outcome measure was pain. The secondary outcome measures were disability and radiological findings.

Data analysis

Meta-Essentials_1.5_01 Software was used for data analysis (16). The effect size (Cohen's d) with a 95% confidence interval was used in the current meta-analysis. Both fixed and random effect models was used for pain and disability variables. Heterogeneity was assessed in each variable by visually inspecting forest plots and statistically using the I-squared (I^2) statistic. The one-tailed and two-tailed p-values and prediction interval were calculated.

An Egger regression and the Begg & Mazumdar test were conducted to examine publication bias. Subgroup analysis was made classifying the pain studies into custom foot orthosis studies and non-custom foot orthosis studies (17).

3. Results

3.1. Study selection:

The process of study selection initiated with a search of five electronic databases, including PubMed (n=623), EMBASE (n=756), Pedro (n=99), Cochrane (n=1060), and CINAHL (n=158), as well as three additional sources (n=3). A total of 2699 articles were obtained through the search, with 946 duplicates removed. The residual 1753 articles underwent title

and abstract screening, resulting in the exclusion of 1695 articles that did not fit the eligibility criteria. Subsequently, 58 articles underwent full-text assessment, and 48 of them were excluded for various reasons, leaving 10 articles eligible for inclusion. Finally, a meta-analysis was conducted on the 10 included studies, with additional studies excluded due to lack of data. The final sample for the meta-analysis consisted of 7 studies as implied in figure 1.

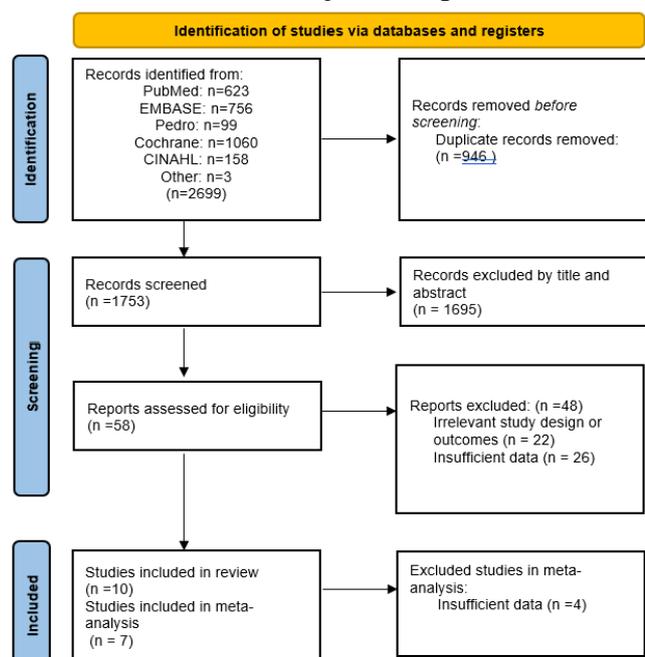


Fig (1) : PRISMA chart for the current systematic review

3.2. Study characteristics:

A systematic review of various interventions for plantar fasciitis treatment was conducted. The study selected different orthotic interventions, including custom foot orthosis, custom-made foot orthoses, prefabricated orthotics, heel-pain orthosis, and total contact insoles, to evaluate their efficacy in improving pain, foot function and quality of life among patients with plantar fasciitis. The primary outcomes of this study were pain reduction and functional improvement.

The systematic review presents the results of 10 studies on interventions for plantar fasciitis as shown in appendix (1). The studies involve a total of 528 participants, and various interventions were used, including custom foot orthotics, extracorporeal shock wave therapy, manual therapy, prefabricated orthotics, and usual podiatric care. The outcomes measured include pain, foot function, quality of life and walking distance. Overall, the studies found that custom foot orthotics and prefabricated orthotics can provide significant improvement in pain and foot function, while there were no significant differences between interventions in other studies. One study

reported a significant decrease in pain with ultrasound treatment.

A study done by Okur et al. (18) included participants with planter fasciitis some are obese, standing for long time and runners. The study compared extracorporeal shock wave therapy with custom foot orthotics and reported a significant improvement in the orthotic group in the long-term (48 weeks) follow-up on multiple scales, compared with that in the shock wave group. The type of Orthosis used was custom-made foot Orthosis.

Coheña et al. (19) conducted a study involved patients with plantar fasciitis and compared custom-made foot orthoses versus placebo flat cushioning insoles combined with extracorporeal shock wave therapy. The study reported a significance improvement in pain and foot at the one-and six-month follow-up (P 0.001). The type of orthosis used was custom-made foot orthosis.

Another study by Grim et al. (20) involved patients with plantar fasciitis and compared Manual Therapy group, Customised Foot Orthoses group and Combined Therapy group in terms of pain and function. . All groups showed statistically significant results after one month. After 3 months manual therapy group showed the best result (p >0.01).

Walther et al. (21) compared three different prefabricated orthotics in adults with planter fasciitis. The type of orthosis used were thin, non-supportive orthotic (NO), soft supportive foam orthotic (FO), and foam covered rigid self-supporting plastic orthotic (PO). Pain level, walking distance and d subjective comfort were recorded from week one to week three. Pain reduction noticed in three groups but significant improvement was recorded according to FO and PO groups with early improvement in PO groups in maximum pain reduction after one week. Pain reduction did not significantly improve walking distance. According to subjective comfort were significant better in FO and PO also PO was higher but non-significant.

Mcclinton et al. (22) compared usual podiatric care (uPOD) alone or combined with physical therapy treatment (uPOD+PT) in patient with planter fasciitis. There was no significant difference between groups in the frequency of foot orthosis prescription and adherence and medication prescription and adherence. Both groups showed significant improvement according to foot and ankle ability measure (FAAM) and in numeric pain rating scale (NPRS) with the second group was better according to pain at 6-week and one year assessment.

A study by Oliveira et al. (23) included 74 patients with planter fasciitis and compared efficacy of total contact insoles (TCI) and flat insoles. Both groups showed improvement for pain at rest and foot pain measured by subscales Foot Health Status

Questionnaire (FHSQ), Foot Function Index (FFI). TCI showed significant improvement in pain while walking greatly observed after 180 days. TCI showed significant improvement in walking distance measured by 6MWT measured after 45 and 90 days. Kuwada et al. (24) included 100 patients with plantar fasciitis to compare efficacy of four interventions (ultrasound, functional rigid orthotics, over the counter arch supports, and injection). The ultrasound group with lowest BMI had the highest average pain reduction, followed by orthotics, local Marcaine/Triamcinolone injection, and arch supports which had highest BMI. According to results complete pain relief wasn't recorded in any group which emphasize that combination between interventions will maximize the benefits.

Rui et al. (25) included 60 patients with bilateral plantar fasciitis to compare efficacy of customized 3D-printed ankle-foot orthosis (AFOs) against prefabricated one. At week 0 after Wearing foot orthosis both groups did not show significant difference in between in VAS as comfort scale. Customized AFO patients reported significant better comfort scores at week 8. According to pressure analysis at rest there were small difference between groups. At walking more pressure under the hallux and first metatarsal and lesser pressure under mid heel and lateral foot in customized AFO group at week 0. But at week 8 showed no difference from prefabricated AFO groups. Redistribution of heel load is preferred effect in this condition which achieved faster using customized AFO

In Yucel et al. study (26) 42 patient with planter heel pain were included and to compare efficacy of a full-length silicone insole with ultrasound-guided corticosteroid injection. Primary outcome was first step heel pain after one month and other outcomes were Foot and Ankle Outcome Score (FAOS) and of the plantar fascia thickness via ultrasonography. Both groups showed significant improvement for all outcomes except the subscore related to sport and recreation function in FAOS in the insole group. Due to side effects of injection, silicon insoles recommended too be the better intervention

Another study done by Gupta et al. (27) included 140 patients with plantar fasciitis divided into 4 groups to compare multiple interventions (analgesics, hot water fomentation, silicon heel pads, and stretching for planter fascia and calf). The plantar fascia stretching exercise and silicon heel pad groups showed a significant improvement in Foot Function Index (FFI) and Foot and Ankle Disability Index (FADI) scores. Overall, the review found that various orthotic interventions could improve foot function, pain, and quality of life in patients with plantar fasciitis. The studies recommended that clinicians should select the

most appropriate orthosis based on individual patient needs and preferences.

3.3. Quality assessment of the included studies: The bias assessment of included studies was presented in table 2 which reveals the following findings:

- All of the studies are randomized controlled trials (RCTs), indicating a high level of evidence.
- Most of the studies have adequate random sequence generation and allocation concealment, which are important for reducing selection bias.
- Blinding of participants and personnel was generally adequate across the studies, except for Okur Sá, 2019 and Mcclinton SM, 2019 where it was not reported (18,22).
- Blinding of outcome assessment was generally adequate across the studies, except for Grim C, 2019 and Yucel U, 2013 where it was not reported (20,26).
- One study (Kuwada GT, 2011) did not have adequate allocation concealment, which may have introduced selection bias (24).

Overall, the quality assessment suggests that the majority of the studies have a high level of evidence and were conducted with appropriate methodological rigor. However, the lack of reporting on the blinding of participants and personnel in two studies and the blinding of outcome assessment in two others may limit the validity of their findings.

trial	Study type	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment
Okur Svá, 2019	RCT	+	+	-	-
Coheña-Jiménez, 2020	RCT	+	+	+	+
Grim C, 2019	RCT	+	+	-	+
Walther M, 2013	RCT	+	+	+	+
Mcclinton SM, 2019	RCT	+	+	-	+
Oliveira HA, 2015	RCT	+	+	+	+
Kuwada GT, 2011	RCT	+	-	-	+
Rui Xu, 2019	RCT	+	+	+	+
Yucel U, 2013	RCT	+	+	-	+
Gupta R, 2020	RCT	+	+	+	-

Table (2): Risk of bias table

3.4. Outcomes:

The studies analyzed in this systematic review focused on the efficacy of different orthotics for the management of plantar fasciitis. Custom foot orthotics were found to be effective in improving pain and foot functionality in several studies, while other studies did not find significant differences between custom and prefabricated orthotics or soft and firm orthotic materials. Ultrasound and injection therapies were also found to be effective in improving pain, as were stretching exercises and silicon heel pads. Total contact insoles made of ethylene vinyl acetate were

compared to flat insoles, with both groups showing improvement. Customized 3D-printed ankle-foot orthoses were evaluated in one study, with overall small differences found between the experimental and control groups. Usual podiatric care and physical therapy treatment did not show significant differences in the frequency of foot orthosis prescription and adherence and medication prescription and adherence.

3.5. Metanalysis results:

Regarding pain results:

Seven studies with a total of 411 subjects to estimate the effect of orthotics in disability.

When using a fixed effect model. The combined effect size was -0.93 (SE = 0.11, 95% CI: -1.19 to -0.68). The results showed significant heterogeneity among the studies (Q = 24.43, pQ = 0.000, I2 = 75.44%). The one-tailed and two-tailed p-values were 0.000. The prediction interval ranged from -2.19 to 0.32, and the Z-value was -8.86. When using a random effects model, the combined effect size was -1.04 (SE = 0.25, 95% CI: -1.65 to -0.43). The Z-value was -4.18, and the one-tailed and two-tailed p-values were both 0.000. The prediction interval ranged from -2.41 to 0.33 as shown in table 3 and figure 2.

#	Study name	Cohen's d	SE	CI-LL	CI-UL	Weight (FEM)	Weight (REM)
1	Okur S ^v á, 2019	-0.65	0.22	-1.09	-0.21	22.74%	16.92%
2	Coheña-Jiménez 2020	-1.48	0.26	-1.98	-0.97	17.06%	16.05%
3	Walther M, 2013	-0.35	0.45	-1.30	0.59	5.48%	11.19%
4	Walther M, 2013	-1.81	0.53	-2.92	-0.69	3.95%	9.54%
5	Oliveira HA, 2015	-0.41	0.24	-0.89	0.06	19.88%	16.54%
6	Yucel U, 2013	-2.08	0.38	-2.86	-1.31	7.57%	12.76%
7	Mcclinton SM, 2019	-0.88	0.22	-1.31	-0.45	23.33%	17.00%

#: Study number; CI: Confidence interval; FEM: Fixed effect model; LL: Lower limit; REM: Random effect model; SE: Standard error; UL: Upper limit.

Table (3): Effect size and weights of different studies in meta-analysis for pain variable

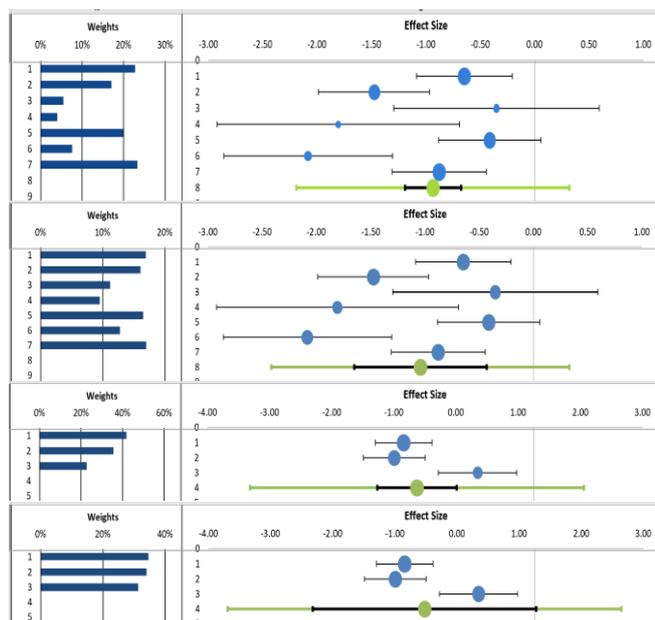


Fig (2) : Weights and effect size of different studies included in meta-analysis and grand total using (A) fixed effect size for pain variable, (B) Random effect size for pain variable, (C) fixed effect size for disability variable, (D) Random effect size for disability variable

In fixed effect model: An Egger regression was performed to assess the potential presence of publication bias. The intercept was -2.78 (SE=2.53, 95% CI (-8.96, 3.41)) and the slope was -0.19 (SE=0.71, 95% CI (-1.92, 1.53)), indicating that there was no significant publication bias (t=-1.10, p=0.322). The Begg & Mazumdar test was also conducted to examine publication bias. The Δx-y was -5.00, and Kendall's Tau a was -0.24, indicating no significant publication bias (z=-0.75, p=0.453). In random effect model: an Egger regression analysis was performed to assess potential publication bias in the current meta-analysis. The results showed a non-significant intercept (Estimate=-3.93, SE=4.06, 95% CI (-13.88, 6.01), t=-0.97, p=0.377), indicating no significant evidence of publication bias. However, the slope was positive and non-significant (Estimate=1.29, SE=2.43, 95% CI (-4.64, 7.23)), suggesting no significant association between study precision and effect size. Begg and Mazumdar test was also performed, which indicated no evidence of publication bias (Δx-y=-5.00, Kendall's Tau a=-0.24, z=-0.75, p=0.453) as shown in figure 3.

Meta-analysis results showed an analysis of two subgroups, Custom-FO and Non-Custom FO. Custom made orthosis group included three studies (Okur Sá et al., 2019; Coheña-Jiménez, 2020; Oliveira HA, 2015) (18, 19, 23), and non-custom-made orthosis group included four studies (Walther M, 2013; Yucel U, 2013; Mcclinton SM, 2019) (21,26,22). By using fixed effect model, Custom-FO subgroup (n=3) showed a Q-value of 10.15 (p=0.006) and I2 statistic of 80.30%, indicating significant heterogeneity among the studies. The overall effect size estimate was -2.95 (95% PI: -2.95 to 1.34), indicating a significant effect of Custom-FO on the outcome. Non-Custom FO subgroup (n=4) had a Q-value of 12.09 (p=0.007) and I2 statistic of 75.18%, indicating moderate heterogeneity. The overall effect size estimate was -3.25 (95% PI: -3.25 to 1.00), also showing a significant effect of Non-Custom FO on the outcome. By using random effect model, the overall heterogeneity was statistically significant for both subgroups (Q = 10.15, pQ = 0.006, I2 = 80.30% for subgroup 1; Q = 12.09, pQ = 0.007, I2 = 75.18% for subgroup 2). The T2 and T statistics for subgroup 1 were 0.23 and 0.48, respectively, with a prediction interval (PI) of -3.32 to 1.64. The T2 and T statistics for subgroup 2 were 0.42 and 0.65, respectively, with a PI of -3.66 to 1.15. As shown in table 4 and figure 4. Regarding disability results:

Three studies with a total of 198 subjects to estimate the effect of orthotics in disability. When fixed effect model was used in a meta-analysis, the combined effect size was found to be -0.63 with a standard error of 0.15. The lower and upper limits of the confidence interval were -1.27 and 0.01,

respectively. However, the prediction interval lower limit was -3.31 and the upper limit was 2.06, indicating a wider range of possible effect sizes. The Z-value was -4.24, and both the one-tailed and two-tailed p-values were 0.000, indicating that the effect

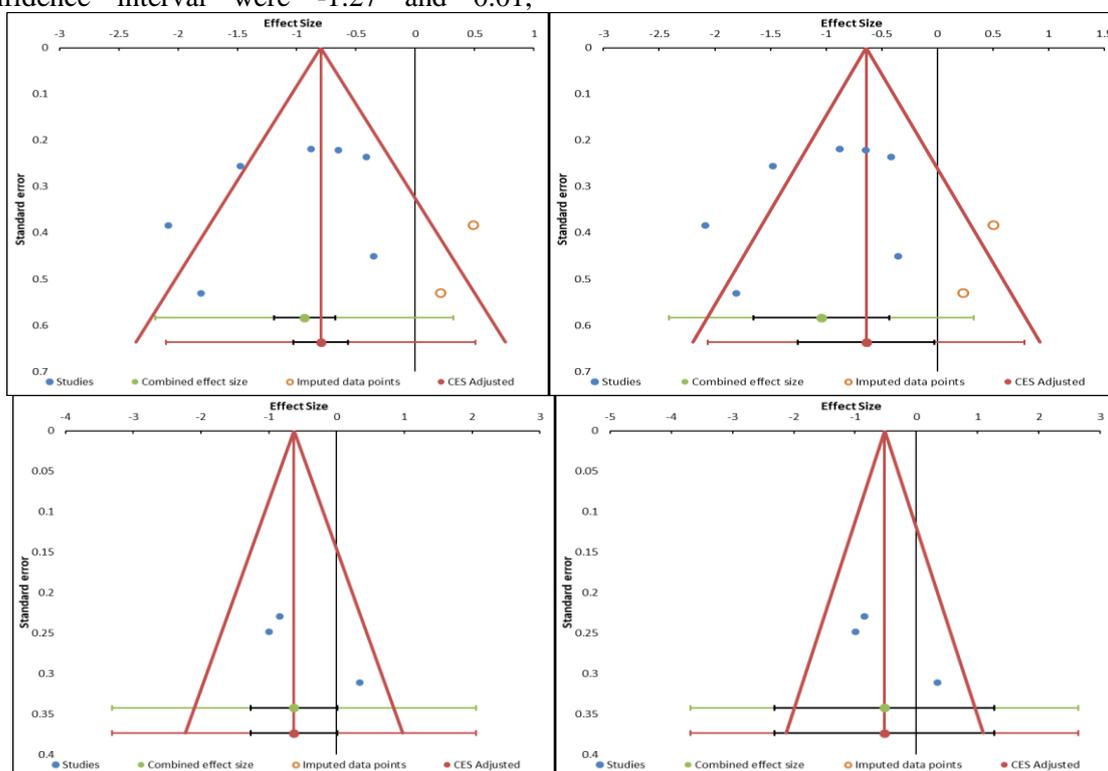


Fig (3) : Funnel plot for effect size and standard error of (A) fixed effect model for pain variable, (B) Random effect model for pain variable, (C) fixed effect model for disability variable, (D) Random effect model for disability variable

#	Subgroup name/ Study names	Q	DQ	I ²	T ²	T	PI-LL	PI-UL
Fixed effect models								
1	Custom-FO: Okur S ^v á, 2019 Coeheña-Jiménez 2020 Oliveira HA, 2015	10.15	0.006	80.30%	0.23	0.48	-2.95	1.34
2	Non-Custom FO: Walther M, 2013 Walther M, 2013 Yucel U, 2013 Mcclinton SM, 2019	12.09	0.007	75.18%	0.42	0.65	-3.25	1.00
3	Overall Effect Size	24.43	0.000	75.44%	0.25	0.50	-1.42	-0.45
Random effect models								
1	Custom-FO: Okur S ^v á, 2019 Coeheña-Jiménez 2020 Oliveira HA, 2015	10.15	0.006	80.30%	0.23	0.48	-3.32	1.64
2	Non-Custom FO: Walther M, 2013 Walther M, 2013 Yucel U, 2013 Mcclinton SM, 2019	12.09	0.007	75.18%	0.42	0.65	-3.66	1.15
3	Overall Effect Size	24.43	0.000	75.44%	0.25	0.50	-3.45	1.44

FO: Foot Orthosis; LL: Lower Limit; UL: Upper Limit

Table (4): Results of subgroup analysis using Fixed and random effect model for pain variable

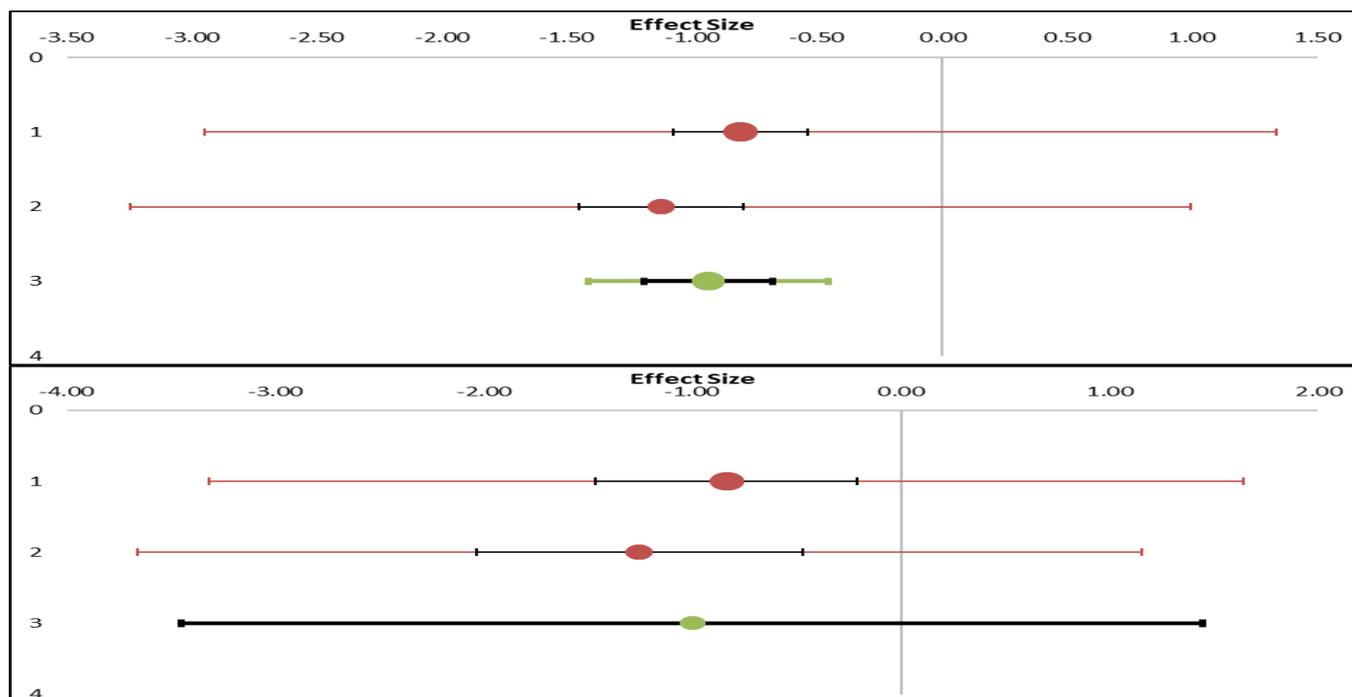


Fig (4) : Forest plot of subgroup analysis using (A) Fixed effect model for pain variable, (B) Random effect model for pain variable.

size was statistically significant. The heterogeneity among the studies was high, with a Q-value of 12.85 and a pQ-value of 0.002, and an I² of 84.44%, indicating that there was substantial variability among the studies. The T₂ and T values were 0.37 and 0.61, respectively, which indicates that there was a moderate degree of heterogeneity. On the other hand, when random-effects model was used. The combined effect size measured by Cohen's d was -0.52 with a 95% confidence interval ranging from -2.32 to 1.27. The prediction interval was wider, ranging from -3.69 to 2.64. The z-value was -1.25, and the two-tailed p-value was 0.211. The heterogeneity statistics showed significant variability among the studies with a Q value of 12.85 and a p-value of 0.002. The I² value was 84.44%, indicating a high degree of heterogeneity. As shown in table 5 and figure 2

#	Study name	Cohen's d	SE	CI-LL	CI-UL	Weight (FEM)	Weight (REM)
1	Okur S [√] á, 2019	-0.84	0.23	-1.30	-0.39	41.74%	34.68%
2	Oliveira HA, 2015	-0.99	0.25	-1.49	-0.50	35.62%	33.95%
3	Yucel U, 2013	0.35	0.31	-0.28	0.97	22.64%	31.37%

#: Study number; CI: Confidence interval; FEM: Fixed effect model; LL: Lower limit; REM: Random effect model; SE: Standard error; UL: Upper limit.

Table (5): Effect size and weights of different studies in meta-analysis for disability variable

Regarding fixed effects model: Egger regression intercept was 15.46 (95% CI -11.78 to 42.69) and the slope was -4.56 (95% CI -11.55 to 2.42), indicating a lack of publication bias. The t-test for the slope was 2.44 (p=0.247). Begg and Mazumdar's rank

correlation test also showed no evidence of publication bias (Kendall's Tau a=0.33, z=0.52, p=0.602). Regarding Random effects model: The results of the Egger Regression showed that the intercept was 39.62 (SE = 12.69), with a 95% CI ranging from -14.97 to 94.20, and the slope was -26.70 (SE = 8.39), with a 95% CI ranging from -62.79 to 9.38. The t-test was 3.12, with a p-value of 0.197, suggesting no evidence of publication bias. The Begg and Mazumdar rank correlation test showed a $\Delta x-y$ of 1.00 and Kendall's Tau a of 0.33, with a z score of 0.52 and a p-value of 0.602, also suggesting no evidence of publication bias. As shown in figure 3.

4. Discussion

The results of a meta-analysis of seven studies including 411 subjects indicated that orthotics have a significant effect on pain relief. The meta-analysis included two subgroups, custom-FO and non-custom FO, both showing a significant effect on pain relief. The meta-analysis of three studies with 198 subjects indicated that orthotics have a significant effect on disability. Egger and Begg & Mazumdar tests showed no evidence of publication bias in both fixed and random effect models. However, there was significant heterogeneity among the studies.

The results of this systematic review provide valuable insights into the effect of orthotics on planter fasciitis. The findings suggest that orthotics are an effective intervention for improving pain and functional outcomes in individuals with calcaneal planter fasciitis.

One possible explanation for the effectiveness of orthotics is that they can provide additional cushioning and support to the heel area, thereby reducing pressure and stress on the calcaneus. This may be particularly beneficial for patients with high-impact activities or jobs that require prolonged standing or walking. Additionally, orthotics can help to redistribute weight and pressure across the foot. As providing medial arch support, increasing the midfoot contact area which reduces strain in the heel area and so the planter fascia during weight bearing (28, 29, 30, 31).

One of the most important findings of this review was the significant reduction in pain associated with the use of orthotics. Several studies included in this review reported significant improvements in pain scores with the use of orthotics compared to control interventions. This is consistent with previous research indicating that orthotics can help redistribute pressure and provide cushioning to the heel, thereby reducing pain associated with calcaneal planter (18, 23, 32-38).

Another important finding was the improvement in functional outcomes associated with orthotic use. Several studies reported significant improvements in walking ability, gait parameters, and range of motion with the use of orthotics. This is consistent with previous research indicating that orthotics can help improve biomechanical alignment and reduce compensatory movements, thereby improving functional outcomes (39-40).

In addition, this review shows that the type of orthotic used may impact treatment outcomes. Several studies reported better outcomes with custom-made orthotics compared to prefabricated orthotics and marked improvements in spontaneous physical activity. This is consistent with previous research indicating that custom-made orthotics can provide better support and cushioning compared to prefabricated orthotics (41-43). However, it is important to note that custom-made orthotics may be more expensive and may not be readily available in all clinical settings.

While the findings of this review are promising, there are some limitations that should be acknowledged. First, the quality of the included studies varied, with some studies reporting high risk of bias. This could have affected the accuracy of the results and may limit the generalizability of the findings. Second, the sample sizes of some of the included studies were small, which may limit the statistical power of the results.

Other limitations found in meta-analysis were that both the fixed and random effect models showed significant heterogeneity among the studies, which could affect the validity of the results. The high degree of heterogeneity may be due to differences in the study design, patient populations, and interventions. Also,

the number of studies and participants included in the meta-analysis is relatively small, which limits the generalizability of the results. The analysis of subgroups had a limited number of studies, which may affect the reliability of the results. The significant heterogeneity observed in the subgroups could also limit the validity of the findings.

Despite these limitations, the findings of this systematic review provide important insights into the potential benefits of orthotics for individuals with calcaneal planter fasciitis. The results suggest that orthotics can help reduce pain, improve functional outcomes, and may be more effective when custom-made. These findings have important clinical implications for the management of calcaneal planter fasciitis and may help inform treatment decisions for individuals with this condition.

Implications:

The implications of this systematic review suggest that the use of orthotics may be an effective non-invasive treatment option for individuals with calcaneal planter fasciitis. While there is currently limited evidence available, the results from this review indicate that orthotics can reduce pain and improve functional outcomes in individuals with calcaneal planter fasciitis.

It is important to note that the quality of evidence included in this review was generally low to moderate, and further high-quality studies are needed to confirm these findings. Additionally, the heterogeneity among the studies included in this review highlights the need for standardized outcome measures and study protocols in future research.

The findings of this meta-analysis have important implications for clinicians and patients. The use of orthotics should be considered as a viable treatment option for pain and disability management. However, further research is needed to identify which orthotics are most effective and for whom they are most effective.

Based on the results of this systematic review, clinicians may consider the use of orthotics as part of a comprehensive treatment plan for individuals with calcaneal planter fasciitis. However, individualized treatment plans should be developed based on each patient's specific needs and medical history.

5. Conclusion

In conclusion, the findings of this systematic review suggest that orthotics may be a promising non-invasive treatment option for individuals with planter fasciitis.

The results of the meta-analysis suggest that orthotics have a significant effect on pain and disability. Both fixed and random effect models showed significant heterogeneity among the studies, indicating that further research is needed to identify the sources of variability. The results also indicate that there is no significant

publication bias, suggesting that the findings are reliable.

However, further high-quality research is needed to confirm these findings and establish the optimal use of orthotics in the management of calcaneal planter fasciitis. Clinicians should consider the use of orthotics in conjunction with other conservative treatment options for individuals with calcaneal planter fasciitis

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Conflict of Interests

Authors declare no potential conflicts of interest.

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Appendix (1)

	n	Participants	Interventions	Outcomes	punchline	finding	Type of orthosis
Okur Sá, 2019	83	obese people, people who stay in standing position for a long time and in runners 9 , plantar fasciitis treatment	extracorporeal shock wave therapy with custom foot orthotics	VAS, Foot Health Status Questionnaire (FHSQ), Foot Function Index Revised (FFI-R)	found a significant improvement in the CFO group in the long-term (48 weeks) follow-up on several scales, compared with that in the ESWT group.	no diff,	Custom foot orthosis
Coheña-Jiménez, 2020	83	patients with plantar fasciitis	custom-made foot orthoses versus placebo flat cushioning insoles combined with an extracorporeal shock wave therapy	pain and foot functionality by : Visual analogue scale, Roles and Maudsley scale (RM).	In control group, the difference was statistically significant at baseline (P 0.01) and, in the experimental group was at the one-and six-month follow-up (P 0.001).	sig increase	Custom made vs placebo flat cushion
Grim C, 2019,	63	Sixty-three patients (44 female, 19 men; 48.4 \pm 9.8 years, Plantar Fasciitis	Manual Therapy group, Customised Foot Orthoses group and Combined Therapy group	-Foot Pain and Function Scale (FPFS, American Orthopaedic Foot and Ankle Society-Ankle Hindfoot Scale (AOFAS-AHS)	Statistically significant differences were not found between customised or prefabricated foot orthoses or soft and firm foot orthotic materials	, no diff	
Walther M, 2013,	30	plantar fasciitis, 30 adults (21 women, 9 men) with plantar fasciitis without any anatomic alterations	Three different prefabricated orthotics : - thin, non supportive orthotic - soft supportive foam orthotic (FO) - foam covered rigid self-supporting plastic orthotic (PO)	, maximum and average pain (VAS), duration of pain per day, walking distance and subjective comfort of orthosis	Patients who used a prefabricated insert with or without stretching had a higher improvement rate than those assigned to stretching only (p = 0.022) and those who stretched and used a custom orthosis (p = 0.0074).	sig increase	3 types of orthosis
Mcclinton SM, 201	95	Ninety-five individuals participated and	, usual podiatric care (uPOD)	-primary outcome: was the 6-month outcome of the FAAM, Secondary	Frequency of foot orthosis prescription and adherence and medication prescription and	no diff	

		were included in the ITT analysis, and 79 were included in the PP analysis, Eligible individuals with PHP that presented to a podiatrist, plantar heel pain	or usual podiatric care plus physical therapy treatment (uPOD+PT)	outcomes: included the <u>FAAM</u> at 6 weeks and 1 year, the numeric pain rating scale (<u>NPRS</u>) and the global rating of change (GRC) measured at 6 weeks, 6 months, and 1 year.	adherence were similar between groups (Additional files 1 and 2).
Oliveira HA, 2015	74	patients with plantar fasciitis	total contact insoles (TCI, TCI made of ethylene vinyl acetate vs flat insole	walking distance, visual analog scale for pain while walking and at rest, Medical Outcomes Study Short Form-36 (SF-36) for quality of life, Foot Function Index and Foot Health Status Questionnaire for foot function, 6-min walk test (6MWT), and baropodometer FootWalk Pro for plantar pressure analysis, pain at rest, foot function, and some quality of life variables (physical functioning, bodily pain, vitality, and social functioning	Both groups showed improvement with no statistically significant difference between them for pain at rest, the foot pain, foot function, general foot health, general health, and physical activity subscales of the FHSQ; the FFI; and the physical functioning, role-physical, bodily pain, vitality, and social functioning subscales of the SF-36 (Table 2).
Kuwada GT, 2011,	100	patients with plantar fasciitis using four treatment modalities, One hundred patients (62 females and 38 males, Plantar Fasciitis	1-ultrasound, 2-functional rigid orthotics, 3-over the counter arch supports, 4- injection.	subjective pain reduction,	The ultrasound group had the highest average pain reduction, Orthotics had the next highest average pain reduction followed by local Marcaine/Triamcinolone injection and arch supports.
Rui Xu , 2019 ,	60	Sixty patients with bilateral plantar		Foot scan : maximum pressure, maximum strength,	The overall differences were small for peak pressure, peak strength, and

	fasciitis aged 31-60 years participated in this study, Patients with Plantar Fasciitis, patients with plantar fasciitis	<u>control group</u> consisting of those wearing separate shoes with prefabricated AFOs <u>experimental group</u> consisting of those wearing a separate shoe and customized 3D-printed AFO,	and contact area of patients' hallux, toes 2-5, first to fifth metatarsal, midfoot, lateral heel, and midfoot heel, comfort scores, visual analogue scale scores for orthosis comfort	contact area of the 10 regions of the experimental group and the control group at week 0.	
Yucel U, 2013,	42 unilateral plantar heel pain for more than 3 months, and have pain score in the morning by first steps more than 4,	a full-length silicone insole vs ultrasound-guided corticosteroid injection	Primary: -VAS for first step -Heel Tenderness Index Secondary: - Foot and Ankle Outcome Score, -ultrasonographic thickness of plantar fascia	One month later, both groups showed significant improvement for all parameters except subscore of FAOS sport and recreation function in insole group (p > 0.05).	sig increase
Gupta R, 2020	140	4 groups: -Analgesics - hot water fomentation and silicon heel pads -plantar fascia stretching -calf stretching exercises,	1-Foot Function Index (FFI) 2- disability using Foot and Ankle Disability Index (FADI)		sig decrease For Plantar fascia stretching exercises silicon heel pad