REVIEW

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Night Splints in Plantar Fasciitis: A Systematic Review

Anna Julia Pereira Bendo, Marcia Izabeli Guimarães Barros, Gladson Ricardo Flor Bertolini, Alberito Rodrigo de Carvalho, Cristiane Buzanello Donin, Márcia Rosângela Buzanello Azevedo

Universidade Estadual do Oeste do Paraná (Unioeste), Cascavel, Paranà, Brazil

CORRESPONDING AUTHOR:
Gladson Ricardo Flor Bertolini
Universidade Estadual do Oeste do Paraná (Unioeste)
Universitaria Street 2069
Cascavel, Paraná, Brazil 85819-110
E-mail: gladsonricardo@gmail.com

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SUMMARY

Introduction. Plantar fasciitis (PF) is a subcalcaneal pain syndrome that affects 10-16% of the world's population. The use of foot and ankle splinting allows the talocrural joints to be in anatomical position, reducing the contracture and tension generated by pain and PF.

Objective. To review the literature on the effectiveness of night splinting in plantar fasciitis.

Materials and methods. Seven databases were used, and EndNote Web and Rayyan reference managers were employed. After exclusion of duplicate articles, Phase 1 - reading of titles and abstracts and Phase 2 - reading of the full texts according to the eligibility criteria by two blinded reviewers (R1 and R2) and discrepancies resolved by the third reviewer (R3). Risk of bias assessment was performed by blinded R1 and R2 with the Cochrane tool, Rob 2.

Results. The references of 258 studies were identified, 144 from the major databases and 114 from grey literature. Finally, three randomized clinical trials were included in this review. A high risk of overall bias was found in the 3 studies included in this review.

Conclusions. It is concluded that the use of the night splint improves pain and function in individuals with plantar fasciitis. However, due to the high risk of bias obtained, there is needed with such a statement, and more primary studies are needed.

Study registration. The project has been registered in PROSPERO under number CRD42021285287.

KEY WORDS

Rehabilitation; plantar fasciitis; foot orthoses; pain management; orthotic devices.

INTRODUCTION

During gait, the foot is responsible for absorbing impact and distributing body weight. At the beginning of the gait (support phase), most of the pressure is in the heel region and in the propulsion phase the pressure passes mostly to the forefoot region (1, 2). Many times, micro traumas in some of the regions with greater weight discharge can generate pain and/or discomfort, as is the case of plantar fasciitis (PF) (3-5).

A PF, also known erroneously as calcaneal spur, is a subcalcaneal pain syndrome common between 40 and 60 years of age, with about 15% of foot lesions in the population (4, 6). Within the affected population, the most frequent age is 40 to 70 years, and the most affected gender is male. Furthermore, athletes, especially runners, also report this orthopedic problem frequently, since during running the pressure distribution is altered (7-9).

The exact cause of this syndrome is unknown, it may result from inflammation in the region of the calcaneal origin of the plantar fascia, which is initiated by excessive traction (10). But it can also be associated with plantar fascia avulsion, stress fracture of the calcaneus, compressive neuropa-

thy of the plantar nerves, plantar calcaneal spur, and plantar fat pad atrophy. The sum of these etiologies can cause pain for the patient (3, 8, 11, 12).

Many treatment techniques are based on decreasing symptoms, stretching, and releasing the triceps sural and fascia that become tensioned, because with the tension of the Achilles tendon and plantar fascia, functional risks are identified that limit dorsiflexion of the foot and toes (3, 13, 14). Treatments can be conservative or nonconservative (15); in most cases conservative treatment is already able to relieve the symptoms. Some treatments include foot orthoses (splint), corticosteroid injections, non-steroidal anti-inflammatory agents, therapeutic ultrasound, extracorporeal shockwaves, stretching exercises, night splints, bandages, and surgical intervention (14, 16-19).

The use of foot and ankle splinting allows the talocrural joint to remain in anatomical position, reducing the contracture and tension generated by pain and PF (20, 21). While the individual sleeps, the foot performs involuntary plantar flexion, resulting in contracture of the posterior leg muscle grouping. Therefore, the use of these orthoses (splints), by placing the joint in an anatomical position, results in a decrease in contracture (10, 21, 22). Therefore, during the night the splint keeps the lower extremity of the affected limb in dorsiflexion and the fingers in extension. The union of these positions allows the fascia to remain at its ideal length for a long period (22, 23). Despite the reports, there is a lack of secondary studies synthesizing the use of the night splint in these cases. Thus, the objective of this study was to review the literature on the effectiveness of night splinting in plantar fasciitis.

MATERIALS AND METHODS

Eligibility criteria

The acronym PICOS was used to formulate the question focused on this study: P – Population (individuals with chronic plantar fasciitis); I – Intervention (night splint); C – Comparison (control group or not using night splint); O – Outcomes: pain (Visual Analog Scale-VAS, which assesses pain changes from baseline to follow-up or the Numeric Rating Scale-NRS) and functionality (Foot Function Index, or other scales and questionnaires that assess pain or functional disability); and S – Study design (randomized clinical trials).

Inclusion criteria

Individuals with chronic plantar fasciitis, men and women, sedentary and athletes, with one or both symptomatic feet, with plantar fasciitis for at least 3 months, age > 18 years. Intervention of night splint use (night splint or orthosis) compared to placebo, simulated treatment, and no treatment, patients reporting plantar fasciitis, heel pain or symptoms (pain in the sole/ankle of the foot not due to other diseases) and pain at the time of recruitment, diagnosed by imaging (ultrasound, MRI) or clinical examination (*e.g.*, signs and symptoms).

Exclusion criteria

Individuals with other diagnoses (such as fascial plantar fibromatosis, plantar nerve injury, fracture, tumor, Morton's syndrome, diabetic diseases such as ulcers, osteoarthritis, rheumatic diseases, neurological diseases, acute or chronic infections, tarsal tunnel syndrome), surgical treatment, and pregnancy. Case studies, cohort studies, systematic reviews, literature reviews, editorials, and animal studies were also excluded.

Information sources

The initial search was conducted using keywords in the PubMed database, with the Medical Subject Headings (MeSH) system, descriptors defined in Health Sciences (DeCS), from the Virtual Health Library (VHL) site and also free terms. Individual search strategies were developed for the databases: PubMed, Embase, The Cochrane Library and The Physiotherapy Evidence Database (PEDro) and in the grey literature: Google scholar, Brazilian Library of Thesis and Dissertations and LIVIVO and at the end of the searches, which were carried out on July 02, 2022, the terms used were grouped in a table together with the number of references found in each base.

Study selection and data collection process

After exporting the databases to a folder named "searches", the references were imported into the EndNote Web reference manager for automatic and manual removal of duplicate articles. Then they were imported into Rayyan QCRI (Qatar Computing Research Institute, DOH, MQ), and again duplicate removal was performed by the first reviewer (AJPB). In this way, the studies that were included in Phase 1 were defined for reading of titles and abstracts, according to eligibility criteria, by two blinded reviewers (AJPB and MIGB). Studies that had a conflict were resolved by the third reviewer (MRB). The final selection, Phase 2, was based on the reading of the full texts by the two reviewers and similarly conflicts were resolved by the third reviewer.

Collected data

The main data collected according to the study characteristics (authors, year of publication, country), sample characteristics (size, mean age and sex), description of the intervention, results and conclusion.

Individual assessment of risk of bias in studies

The risk of bias assessment was performed by blinded reviewers R1 (AJPB) and R2 (MIGB) with the Cochrane tool, Rob 2. And disagreements were resolved by R3 (MRB).

Assessment of the risk of publication bias

Initially, to prevent publication bias, a comprehensive, sensitive search was performed, without restriction on period, language, and with a search of the gray literature. In this way, the risk of publication bias can be mitigated.

RESULTS

The following is a narrative synthesis of the results of the included studies structured around the reported results.

Study selection

All searches were conducted on a single day, December 02, 2021. References for 258 studies were identified, 144 from the major databases (PubMed n = 34, Embase n = 87, Lilacs n = 2, Cochrane n = 21 and Pedro n = 0) and 114 from the grey literature (Google Scholar n = 100, Brazilian Library of Thesis and Dissertations n = 0 and Livivo n = 14).

After removal of the duplicates, the remaining articles for Phase 1 were 102 titles and abstracts, according to the eligibility criteria, and for Phase 2, 23 studies were read in their entirety. Articles included in Phase 2 that did not meet the eligibility criteria were then excluded due to not finding the full article and the intervention not as expected. Three randomized clinical trials were selected and tabulated according to **table I**. **Figure 1** (PRISMA Flowchart 2020) summarizes the complete selection process.

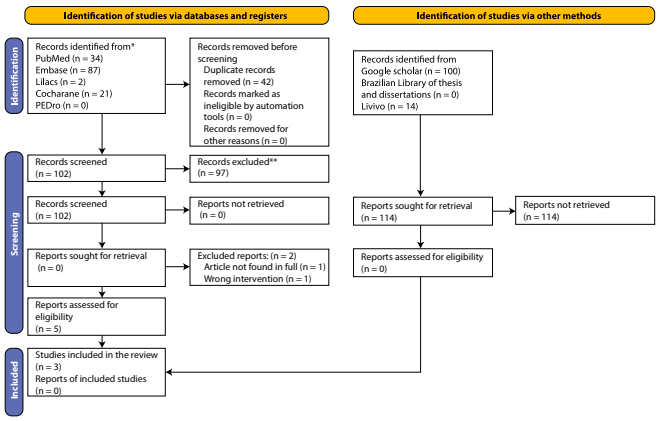

Figure 1. PRISMA 2020 flow chart for new systematic reviews that included searches of databases, registries, and other sources.

Characteristics of the studies

Three randomized clinical trials were included (24-26), one of them of the crossover type (24). The publication date was between 1998 and 2010. In all studies, the sample consisted of men and women with plantar fasciitis with a total of 105 sample units.

Individual study bias analysis

The Cochrane tool, Rob 2 was used for individual assessment of the risk of bias of the three included studies. **Figure 2** presents the results obtained in each of the five domains analyzed by the tool.

The randomization process domain showed two studies with moderate risk of bias (24, 26) and one with low risk of bias (25). The domain deviation from the intended interventions (25, 26) and one with moderate risk of bias (24). Regarding the missing outcome data domain, all three studies showed a low risk of bias (24-26). The domain measurement of missing outcomes showed two studies with low risk (24, 26) and one with moderate risk (25). And finally, in the selection of the reported results domain, all studies presented a high risk of bias (24-26).

Overall, the studies included and subjected to the risk of bias analysis had a high risk of bias.

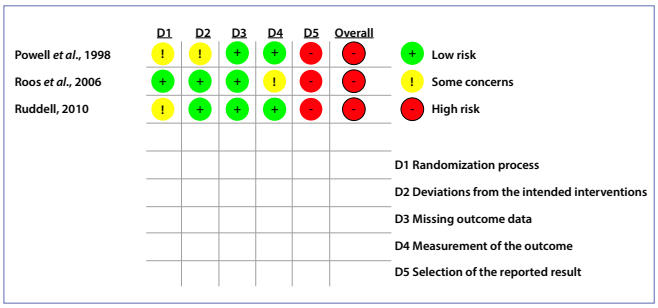

Figure 2. Analysis of the risk of individual bias.

Individual study results

Collection instruments

For measurement of the primary outcome, pain, the VAS scale was used in only one study (26). For the secondary outcome functionality, four different instruments were used: Mayo Clinical Scoring System and Ankle Hindfoot Rating Scale (AOFAS) in the study by Powell *et al.* (24); Foot and Ankle Outcome Score (FAOS) in the study by Roos *et al.* (25) and Foot Function Index (FFI) in the study by Ruddell (26).

Primary outcome – pain intensity

The study by Roos *et al.* (25) did not show significant difference for pain at any moment of evaluation for any of the

Table I. Summary description of the randomized clinical trials included in this review (n = 3).

Eligible studies (Country)	Sample description	Evaluation period	Outcome measure instrument	Results	Conclusion
Powell *et al.*, 1998 (United States) - RCT Crossover	-n = 37 M (n = 8) F (n = 29) -EG (n = 22) night splint month 1 and control month 2 -CG (n = 15) month 1 control and month 2 nights splint	T1: 1 month T2: 2 months T3: 6 months	-Mayo Clinical Scoring System (0-100) -AOFAS (0-100)	**Mayo Clinical Scoring System** / **AOFAS** **EG** / **CG** / **EG** / **CG** T1: 67 / 45 / 81 / 66 T2: 69 / 67 / 84 / 76 T3: 75 / 70 / 91 / 81	Night splints for dorsiflexion provide relief from the symptoms of plantar fasciitis in most patients
Roos *et al.*, 2006 (Sweden) - RCT	-n = 43 M (n = 9) F (n = 34) -G1 (n =13) foot orthosis -G2 (n =15) foot orthosis+night splint -EG (n = 15) night splint	T0: Baseline T1: 6 weeks T2: 12 weeks T3: 26 weeks T4: 52 weeks	-FAOS (3 of 5 ratings) -Pain (0-100) -Symptoms onset (0-100) -Functionality in sport and recreation (0-100)	**FAOS** **Pain** / **Symptoms** / **Functionality in sport and recreation** **G1** / **G2** / **EG** / **G1** / **G2** / **EG** / **G1** / **G2** / **EG** T0: 56 ± 12 / 50 ± 18 / 53 ± 15 / 70 ± 12 / 64 ± 22 / 63 ± 11 / 53 ± 25 / 35 ± 27 / 40 ± 19 T1: 69 ± 19 / 68 ± 14 / 69 ± 18 / 74 ± 19 / 77 ± 20 / 75 ± 12 / 62 ± 30 / 57 ± 20 / 61 ± 19 T2: 76 ± 26 / 76 ± 17 / 70 ± 15 / 76 ± 22 / 78 ± 14 / 76 ± 14 / 62 ± 32 / 59 ± 29 / 63 ± 20 T3: 85 ± 13 / 77 ± 14 / 76 ± 18 / 87 ± 13 / 76 ± 25 / 80 ± 15 / 88 ± 17 / 69 ± 26 / 67 ± 26 T4: 89 ± 16 / 82 ± 16 / 79 ± 20 / 90 ± 12 / 85 ± 14 / 82 ± 17 / 83 ± 22 / 78 ± 23 / 73 ± 26	The night splint+foot orthosis group had no significant improvement over the two groups that received treatments alone
Ruddell, 2010 (Canada) - RCT	-n = 25 M (n = 8) F (n = 17) -CG (n = 12) orthosis that kept the ankle in neutral position -EG (n = 13) night splint that kept ankle in dorsiflexion	T0: baseline T1: 1 month Q2: 2 months T3: 3 months	-VAS (0-10) First steps of the morning Activity of daily living (ADLs) Exercise -FFI (4 ratings) Maximum Pain (0-90) Maximum activity (0-50) Modified Tegner activity scale (1-10) Maximum disability (0-90)	**VAS** **First steps of the morning** / **Exercise** / **DLA's** **CG** / **EG** / **CG** / **EG** / **CG** / **EG** T0: 8.5 ± 0.86 / 8.4 ± 0.79 / 7.0 ± 1.62 / 6.5 ± 2.80 / 6.0 ± 1.46 / 6.1 ± 2.37 T1: 5.1 ± 2.63 / 3.4 ± 2.25 / 5.0 ± 2.82 / 4.0 ± 2.74 / 4.0 ± 2.46 / 3.2 ± 2.10 T2: 3.3 ± 2.58 / 2.4 ± 1.73 / p = 0.575 / 3.3 ± 2.73 / 2.8 ± 2.01 / p = 0.960 / 2.9 ± 2.00 / 2.2 ± 1.78 / p = 0.291 T3: 1.5 ± 1.21 / 1.1 ± 1.22 / 1.9 ± 2.47 / 1.4 ± 1.40 / 1.9 ± 2.09 / 0.98 ± 1.01 **FFI** **Pain maximum** / **Activity maximum** / **Disability maximum** / **Modified Tegner activity scale** **CG** / **EG** / **CG** / **EG** / **CG** / **EG** / **CG** / **EG** T0: 38.83 ± 13.66 / 43.90 ± 21.35 / 9.04 ± 7.88 / 10.65 ± 5.61 / 37.73 ± 21.66 / 49.88 ± 21.35 / 3.33 ± 1.97 / 3.69 ± 1.18 T1: 36.69 ± 18.08 / 32.42 ± 17.88 / 4.70 ± 3.42 / 4.88 ± 4.83 / 31.23 ± 19.31 / 43.79 ± 25.89 / 3.33 ± 1.97 / 3.69 ± 1.18 T2: 27.77 ± 18.66 / 24.94 ± 17.71 / 2.48 ± 2.70 / 3.63 ± 4.33 / 23.95 ± 23.61 / 17.54 ± 16.11 / 3.33 ± 1.97 / 3.69 ± 1.18 T3: 24.05 ± 18.46 / 6.77 ± 13.74 / 4.55 ± 6.08 / 2.88 ± 5.04 / 17.80 ± 17.84 / 7.64 ± 10.95 / 3.33 ± 1.97 / 3.69 ± 1.18	Both the neutral splint and the tension splint showed a similar change in pain level, with one not excelling over the other. The same was observed in the foot function index

RCT: randomized clinical trial; M: male; F: female; VAS: Visual Analog Scale; FAOS: Foot and Ankle Outcome Score; AOFAS: American Orthopaedic Foot and Ankle Society – ankle-hindfoot scale; FFI: Foot Function Index.

three groups. Similarly, Ruddell (26), also did not find significant differences regarding the participants' pain, and this was the only study that evaluated pain by means of the VAS. In contrast to Powell *et al.* (24), who analyzed the pain intensity using a pain domain within the Mayo Clinical Scoring System (MCSS) questionnaire and noted that significant differences were found between the groups and between assessment periods.

Secondary outcome – functionality

In the study carried out by Ruddell (26) the modified Tegner activity scale was used to assess the functionality of the individuals, and it was observed that there was no difference in any group in any of the evaluations. Roos *et al.* (25), applied the Foot and Ankle Outcome Score (FAOS) and found an improvement in functionality at all assessment times. Finally, Powell *et al.* (24), also found improvement in functionality.

Publication bias

Statistics-based analysis of publication bias was not performed due to only three articles being included in this systematic review (27).

DISCUSSION

The present review found, within the consulted databases, only three studies that fit the eligibility criteria stipulated in the published protocol. All included studies (24-26) were at high risk of bias when submitted to the Cochrane tool Rob 2.

The follow-up period ranged from 4 weeks, (one month) to 52 weeks and the only way to compare these evaluation periods would be with the corresponding time, that is, the evaluation with 12-week evaluation. Even so, the comparison would be unfeasible, since the collection instruments used to measure the outcomes analyzed (pain and functionality) presented a great variability, which made it difficult to compare the studies.

In terms of gender, there was a predominance of women (n = 80) compared to men (n = 25). Hill *et al.* (28), besides that, this study also found a relation between the increase in body weight and the manifestation of the symptoms of this syndrome, a fact that was also observed by Powell *et al.* (24). In this same study the authors observed that both the female and male groups had an average weight above the ideal body weight.

The study by Lim *et al.* (21) reported that nighttime dorsiflexion splints, as well as other non-invasive options, relieve the symptoms generated by plantar fasciitis syndrome. However, in the same study, it can be seen that there are other outpatient treatment options (extracorporeal shock waves and corticosteroids injections). Due to the individual response to interventions added to the wide variety of treatments available, it becomes unfeasible to develop a treatment protocol for plantar fasciitis syndrome.

Roos *et al.* (25) conducted a randomized clinical trial with groups receiving treatment alone (foot orthosis and night splint) and combined with other forms of conservative treatment. The group receiving the combined treatment did not show significant differences in the outcome of pain and function. Although the findings of a systematic review conducted in 2020 (29) stated otherwise. More recent studies show that the best treatment option for plantar fasciitis is the union of conservative techniques and the application of them not in isolation.

The only study that conducted a crossover randomized clinical trial to evaluate the benefits of pain and functionality was Powell *et al.* (24). In the one month, in which the experimental group (EG) used the night splint and the control group (CG) did not, there was a positive effect for EG and not for the CG. And in the last evaluation, at 6 months, it was possible to identify that the improvement was sustained even after the end of the splint use. On the contrary, some studies report that the symptoms of plantar fasciitis decrease spontaneously in some patients, and that is why the data collected in a very long follow-up should be carefully analyzed (30).

Through a randomized clinical trial, Turlik *et al.* (31) compared custom orthoses with generic orthoses and obtained positive results with the customized orthoses group. However, Ruddell's (26) study compared the tension splint group with the neutral splint group, and concluded that the maximum pain domain progressively decreased from baseline to the last assessment, the use of a night splint helps to reduce pain, and the dorsiflexion angulation is independent of this improvement. However, in association with the findings of Turlik *et al.* (31), it is considered the importance of verifying the degree of dorsiflexion angulation of the splints, once each individual has different range of motion in the ankle joint.

Due to the great diversity of instruments used for data collection and periods, there is difficulty in comparing studies, which made it impossible to perform meta-analysis. It is also pointed out that given the inclusion criteria, the studies by Batt *et al.* (32) and Probe *et al.* (33) were excluded because the comparator was not only a placebo or no treatment, that is, the use of medication or other forms of treatment - such as physiotherapy -, prevented the articles from entering the analysis.

Although the number of primary studies is small, the use of this conservative method for the treatment of plantar fasciitis showed promise. However, due to the high risk of bias present-

ed in the analyzed studies, it is suggested that more primary studies be performed. And that these studies pay attention to fulfill domain 5 (Risk of bias in the selection of the reported result) of the Cochrane tool, Rob 2, for risk of bias, since the totality of the selected studies received high risk within this domain.

CONCLUSIONS

The use of the night splint shows itself as a useful tool for improves pain and function in individuals with plantar fasciitis.

FUNDINGS

This research received funding from the public sector agency, Fundação Araucária, through a scientific initiation scholarship.

DATA AVAILABILITY

The terms used for the initial search and the articles included in Phase 2 and then excluded - along with other data - are available under reasonable request to the corresponding author.

CONTRIBUTIONS

AJPB, MIGB, GRFB, ARC, CBD, MRBA: project conceptualizaion. AJPB, MIGB, MRBA: database search. AJPB, MIGB: studies analysis. AJPB, MIGB, GRFB, ARC, CBD, MRBA: bias risk analysis and meta-analysis. AJPB, MIGB: manuscript writing. GRFB, ARC, CBD, MRBA: critical revision of the manuscript.

CONFLICT OF INTERESTS

The authors declare that they have no conflict of interests.

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