J. Phys. Ther. Sci.
19: 41–56, 2007

An Evaluation of Research Evidence for Selected Physical Therapy Interventions for Plantar Fasciitis

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Abstract. To evaluate the strength of research evidence for selected interventions in the management of plantar fasciitis and compare the evidence with current clinical guidelines. A literature search of PubMed and CINAHL from 1995 to 2005 was conducted using articles that involve interventions that physical therapists would administer directly, are English-only, peer reviewed, prospective and retrospective studies, and whose interventions are supported at least two randomized controlled trials. Grouped by treatment category, these articles were evaluated using the American Academy of Cerebral Palsy and Development Medicine classification system. Each category was assessed using the Modified Canadian Task Force grading format, and compared with current clinical guidelines. Twenty-seven articles were reviewed: 6 for night splints, 9 for orthotics/inserts, 9 for extracorporeal shock wave therapy (ESWT), and 3 for stretching. Night splints and stretching received a C; orthotics/inserts received a B, and ESWY received an A. Comparisons between the results and the Brigham and Women's Clinical Guideline for Lower Extremity Musculoskeletal Disorders revealed similar recommendations, except for ESWT. Evidence exists for night splints, orthoses, extracorporeal shock wave, and stretching as interventions for plantar fasciitis. ESWT received the highest grade, although existing guidelines have not mentioned this as an intervention.
Key words: Plantar fasciitis, Research evidence, Clinical guideline

(This article was submitted Aug. 4, 2006, and was accepted Sep. 25, 2006)

INTRODUCTION

Few published studies on treatment—and even fewer high quality, randomized clinical trials (RCTs)—exist for one of the most frequently seen soft-tissue disorders of the foot, plantar fasciitis. Plantar fasciitis, also known as heel pain syndrome and heel spur syndrome[14)], affects the hindfoot, specifically the insertion of the plantar aponeurosis at the medial calcaneal tubercle[5, 14)]. Excessive load or tension to this area which forms an anchor for the longitudinal arch of the foot[14)] produces the signs and symptoms consistent with the disorder. Although plantar fasciitis is traditionally considered an inflammatory disorder by most accounts[5, 23, 47)], one source points to a recent histologic study of recalcitrant cases of the disorder as evidence of the condition being one of a degenerative nature affecting collagen without inflammatory mediation[14)]. This newly acquired knowledge may affect the use of anti-inflammatory treatments for chronic cases of plantar fasciitis[14)]. From a physical therapy standpoint, the benefit of using transcutaneous steroidal medications in these cases

is dubious.

This overuse disorder of the hindfoot affects an estimated 2 million people in the United States per year[14, 36], and accounts for 11 to 15 percent of all foot symptoms necessitating professional care among the adult population[5]. Among athletes, runners comprise the large majority of cases[14]. The incidence seems to peak in people between the ages of 40 and 60 years among the general population[5]. Gender bias does not appear to be a component of this condition[14].

The exact etiology of plantar fasciitis is unknown in most cases[9, 14, 36], though most sources point to overuse secondary to various anatomical, environmental, and biomechanical risk factors[5, 14, 36]. A recent matched case-control study supports the correlation of risk factors associated with plantar fasciitis, in particular obesity, prolonged weight bearing, and limited ankle dorsiflexion[36]. Among these factors, limited ankle dorsiflexion revealed the highest odds ratio[36].

Symptoms of plantar fasciitis usually are insidious[14, 47], with periods of sharp pain commonly experienced upon taking the first steps after arising from bed in the morning or after a period of non-weightbearing[5, 9, 14, 44, 47]. The pain may manifest also as dull discomfort[47] or a deep ache[44], usually localized to the inferior, medial heel[47]. Prolonged weightbearing seems to aggravate the pain, whereas rest tends to decrease the pain[9, 44].

Diagnosis of plantar fasciitis can usually be made on the basis of a history and physical examination[5, 9, 44]. Differential diagnoses may include, but are not limited to, calcaneal stress fractures[23, 44, 47], nerve entrapment[23, 44, 47], and fat pad atrophy[44, 47]. Interestingly, plantar calcaneal bone spurs are often mentioned in the literature in association with plantar fasciitis, though the presence of a heel spur can neither confirm nor rule out the diagnosis of plantar fasciitis[5, 9]; 50% of patients with heel pain do not have a calcaneal spur, and 15% of non-painful heels do exhibit a spur[44].

Imaging techniques, though not routinely used in the clinical setting, may be employed in certain cases to address other potential causes of heel pain when the diagnosis of plantar fasciitis is in question. Plain radiographs, bone scans, ultrasonography, and magnetic resonance imaging are some of the techniques[5] used to visualize the area in question, and among these techniques, magnetic resonance imaging seems to have the highest sensitivity and specificity regarding diagnostic quality[23].

Approximately 80% of patients with plantar fasciitis who are conservatively treated experience resolution of symptoms within 12 months[5]. Only about 5% of diagnosed individuals require surgical intervention[5, 14, 36], which is usually considered only after conservative treatment has failed[5, 9, 14, 44, 47]. Typically, conservative treatments are used for 6–12 months[5, 44] before more aggressive approaches, including surgery, are employed. Conservative treatments for plantar fasciitis include stretching and strengthening exercises[9, 14], night splints[5, 9, 14, 23, 41, 44], massage[9, 23], custom orthotics[5, 9, 14, 23, 41, 44], over-the-counter arch supports[5, 9, 14, 41, 44], taping[5, 9, 14, 23], magnet therapy[5], acupuncture[23], walking casts[5], laser therapy[5], ultrasound[5, 9, 23], cryotherapy[9, 14, 23], iontophoresis[5, 9, 14], and extracorporeal shock wave therapy (ESWT)[5, 14].

Given the vast array of available treatments, clinicians might find implementing an appropriate treatment for their patients with plantar fasciitis to be a daunting task. The purpose of this review is to evaluate the strength of evidence for the treatment of plantar fasciitis within the context of a physical therapy setting. With this premise in mind, the first criterion for inclusion in this review is that the treatment intervention must be one that a physical therapist would be able to apply directly. This would exclude any considerations of surgery, high-energy shock wave therapy which requires the use of anesthesia[8], and corticosteroid injections.

Since randomized controlled trials offer the greatest degree of certainty regarding scientific rigor[20], this study design serves as the second inclusionary criterion for this review. More specifically, among the remaining possible therapies, only those that are supported by at least two published, randomized clinical trials within the last 10 years are included. A search of available literature necessitates exclusion of the following therapies based on this second criterion: laser therapy, ultrasound, cryotherapy, massage, acupuncture, walking casts, and taping.

METHODS

A search of PubMed (1995–2005) was conducted with the following limits: 1) English-only, peer-reviewed journal articles from 1995–2005 and

2) prospective and retrospective studies related to treatment of plantar fasciitis. Articles pertaining to diagnosis, prognosis, case studies, and general reviews were excluded. Case studies were excluded due to their inherent level of bias and low methodological quality. Two search strategies were used. The first involved the "clinical queries" function of PubMed and the second involved a general search strategy. The "clinical queries" search strategy offered by PubMed proved to be a useful means of obtaining several randomized controlled studies related to treatments for plantar fasciitis. After choosing the "treatment" category and typing in "plantar fasciitis," a number of articles surfaced, that number being dependent on the specific methodological search filter.

After using the "clinical queries" search strategy, a comprehensive search of PubMed was used to find any additional articles. The following terms were used in this general search: "plantar fasciitis," and "heel pain," in combination with the aforementioned treatment names, for example, "plantar fasciitis" AND "ultrasound." CINAHL was then accessed and searched in a similar fashion to explore those English-language journals not indexed in PubMed. Additionally, some articles were retrieved using the reference lists from previously obtained articles.

No demographic limitations regarding the subject population were imposed. Also, both acute and chronic manifestations of plantar fasciitis were considered. The outcomes of interest were levels of pain and/or degrees of function in relation to the condition. An economic evaluation of the therapies—although a practical consideration from a clinical standpoint—was beyond the scope of this review. After reviewing the literature, the following treatments met the inclusion criteria: low-energy shockwave therapy, orthotics, night splints, and stretching exercises. Table 1 lists these treatment interventions along with the number of articles meeting the inclusion criteria for each treatment.

The classification system used to evaluate the literature was developed by the American Academy for Cerebral Palsy and Developmental Medicine's (AACPDM) Treatment Outcomes Committee (revised 2004 version). Although the original purpose of the system was to develop evidence tables about treatment outcomes for children with developmental disabilities[1)], an AACPDM committee representative recently acknowledged use of the classification system for evaluating interventions unrelated to developmental conditions (J. Darrah [johanna.darrah@ualberta.ca], e-mail, March 15, 2005).

The system has two parts: the first part deals with the type of study in descending order of methodological strength, and the second part deals with assessing the quality of the study. The first part is based on the work of Sackett[1)]. The second part expands on Sackett's work and allows the reviewer to evaluate the quality of the study beyond just its strength of study design. The two-part system offers a more thorough method of study evaluation than many systems which evaluate study designs only. Table 2 outlines the classification system used in this study.

Following a search of literature that met the inclusion criteria, the articles were independently evaluated based on the AACPDM two-part classification system by two reviewers. Any discrepancies in responses of the evaluations were resolved through discussion to achieve consensus. After evaluation, all of the articles within each treatment category were assessed collectively according to a grading format validated for use in physical therapy and subsequently compared with existing clinical guidelines.

RESULTS

Night splints

Probe et al.[35)] studied 116 patients with plantar fasciitis in a prospective randomized study (Level 1). The average duration of symptoms prior to the study was 19 weeks. Patients in the first group received one month of oral anti-inflammatory medication, shoe recommendations, and Achilles tendon stretching exercises. Patients in the second group received the same treatment but also used a dorsiflexion night splint for 3 months. The results

Table 1. Number of articles representing the interventions that met the inclusionary criteria

Interventions	Articles
Shock wave therapy	9
Orthotics	9
Night splints	6
Stretching exercises	3

Table 2. AACPDM classification system

Part I: Levels of Evidence	
Level	Type of Study
I	Systematic Review of randomized clinical trials (RCT)
	Large RCT (with narrow confidence intervals) (n>100)
II	Smaller RCT's (with larger confidence intervals) (n<100)
	Systematic reviews of cohort studies
	"Outcomes research" (very large ecologic studies)
III	Cohort studies with concurrent control group
	Systematic reviews of case control studies
IV	Case series
	Cohort study without concurrent control group (e.g., with historical control group)
	Case-control study
	Retrospective studies
V	Expert opinion
	Case study or report
	Bench research

Part II: Conduct of Study

The conduct of the study will be judged as "Strong" (S), "yes" to 6 or 7 questions, "Moderate" (M), a score of 4 or 5, and "Weak" (W), a score ≤3. The questions are as follows:

1. Were inclusion and exclusion criteria of the study population well described and followed?
2. Was the intervention well described and was there adherence to the intervention assignment?
3. Were the measures used clearly described, valid and reliable for measuring the outcomes of interest?
4. Was the outcome assessor unaware of the intervention status of the participants (i.e., were there blind assessments?)
5. Did the authors conduct and report appropriate statistical evaluation including power calculations?
6. Were dropout/loss to follow-up reported and less than 20%? For two-group designs, was dropout balanced?
7. Considering the potential within the study design, were appropriate methods for controlling confounding variables and limiting potential biases used?

**Quality assessment only needs to be completed for Level I–III studies.

of the study showed no statistically significant difference between the groups using the Health status data Short Form 36 as the main outcome measure. This study's methodological flaws were the absence of a statement of statistical power, an important measure when reporting a finding of non-significance, and an intention-to-treat analysis.

A randomized clinical trial performed by Batt and colleagues[3] using night splints with a subject sample of 32 patients (Level II) reported success in 30 of 33 treated feet. The control group received a heel cushion, anti-inflammatory medication, and a stretching program. The other group received identical treatment with the addition of a custom-fitted night splint. Patients in the control group who did not respond to treatment after 8–12 weeks were crossed over to the tension night splint group. The investigators concluded that the night splint was effective when used in combination with a heel pad, NSAIDs, and a stretching program. Strengths of the study included appropriate inclusion of a power analysis and relative homogeneity of group demographics. Weaknesses of the study included some subjectivity in the discharge criteria and a dropout/loss rate of 20%. An intention-to-treat analysis was not provided.

Another crossover study was performed two years later by Powell et al[34]. In this six-month study, 37 patients (Level II) with recalcitrant plantar fasciitis were randomized into two treatment groups. Group A wore the night splint for one month and then discontinued use of the splint for one month. Group B wore the splint during the second month only with no other treatment the first month. No additional treatments were allowed during the study. The authors reported

improvement of symptoms in 30 of 37 patients. The authors' inclusion of an intention-to-treat analysis and control for spontaneous improvements strengthened the study. Additionally, the use of only one treatment helped to control for any biases otherwise introduced with other treatments. One weakness of the study was that the authors did not comment on the validity or reliability of the two clinical rating systems that were used as outcome measures.

The three remaining studies that fit the criteria for this treatment were all Level IV studies. Martin et al.[27] performed a retrospective correlational study, using a mailed survey and chart reviews to obtain outcome information from patients with plantar fasciitis. One hundred fifty-seven surveys were returned and analyzed, and the majority of the correlations between treatments (orthoses, heel cups, medication) and outcomes were not strong, with the exception of two correlations associated with use of night splints: 1) In subjects with symptoms greater than 12 months before treatment, the use of a night splint correlated with a good outcome. 2) A significant correlation existed between wearing the night splint as instructed and a good outcome. The authors of this study concluded that early, conservative treatment (within 12 months) using multiple treatments simultaneously after the onset of symptoms correlated with a favorable outcome. The fact that 35.6% of the patients did not return the survey weakened the strength of the study.

Berlet et al.[4] prospectively studied a group of 12 individuals diagnosed with plantar fasciitis using the Ankle Dorsiflexion Dynasplint. Patients were assessed on the presplinting visit and after one month of splint wear using the visual analog pain scale and the Mayo clinical scoring system. Although the majority of patients in this study reported improvements in symptoms, these improvements were not statistically significant based on the aforementioned outcome tools. The low study group number may have contributed to this finding of non-significance. The fact that a trained representative from the manufacturer of the splint fitted the patients suggests that the splint may have limited clinical application in terms of ease of use for both the clinician and the patient. Whether or not the splint application necessitated the expertise of a company representative was not clarified by the authors of the study.

Another cohort study without a concurrent control group was performed by Mizel et al.[28] to determine the effectiveness of a combination treatment of a night splint and a shoe modification consisting of an anterior rocker bottom with a steel shank. Of the 57 patients who completed the study, the majority of patients (77%) exhibited either no symptoms or improved symptoms at an average follow-up of 16 months; however this follow-up interval was considerably longer than those in the previously mentioned studies on night splints, thus calling into question whether or not the results of the study were determined more by the natural healing process than by treatment. No inferences could be made on the effectiveness of the night splint alone given that the study utilized a combination of treatments.

Ryan et al.[40] conducted a systematic review of the literature regarding treatment with night splints. A search of Medline (1966–2000) and CINAHL (1982–2000), as well as reference lists of identified articles was carried out using relevant key terms. Their search produced a total of nine studies fitting the inclusionary criteria. Interestingly, our search, which included a more recent search of the literature, revealed only one additional prospective study on the use of night splints since 2000 (Berlet, 2002), and this study was of low methodological quality. Such a finding suggests a relative paucity of recent studies regarding night splint treatment. The investigators appropriately grouped their findings according to level of methodological quality (case study, retrospective studies, RCTs, etc.) and provided sound analyses in their discussion. We agree with the investigators' speculation that the discrepancy between the findings of Probe et al.[35], who found no effect of the night splint as an adjunct treatment, and the other studies was probably due to the relatively acute nature of the former's study population; all the other studies, in contrast, utilized a study population with more chronic symptoms. No formalized, objective grading tool was used, however, to assess the methodological strength of individual studies or the overall effectiveness of night splint treatment based on review of the articles as a whole.

Table 3 presents a summary of how each article under this treatment intervention fared with the review of evidence. Of the articles reviewed, only those with levels I to III were included.

Table 3. Level I to III studies on night splints

Review criteria	Articles reviewed		
	Probe et al.	Batt et al.	Powell et al.
A. Level of Study Design	I	II	II
B. Quality of the Study	Moderate	Weak	Moderate
• Inclusion and exclusion criteria well described and followed?	Yes	Yes	Yes
• Intervention well described and adhered to?	No	No	Yes
• Measures used clearly described, valid and reliable?	Yes	Yes	No
• Were there blind assessments?	Yes	No	No
• Appropriate statistical evaluation, including power calculations?	No	Yes	Yes
• Dropout/loss to follow-up reported and less than 20%? Dropout balanced?	Yes	No	Yes
• Were appropriate methods for controlling confounding variables and limiting potential biases used?	Yes	No	Yes

Orthotics and inserts

Winemiller and colleagues[46] conducted a randomized, double-blind, placebo-controlled trial involving 101 patients (Level I) with plantar fasciitis to assess the effectiveness of magnetic insoles on this condition. At both 4 and 8 weeks follow-up, although both the magnetic insole and non-magnetic insole groups reported improvement, no significant differences were found between the groups based on either of the primary outcome variables (visual analog scale or categorical response to treatment). Based on their results, the authors concluded that the inclusion of magnets in insoles to be ineffective for the treatment of plantar fasciitis. Strengths of this study included the inclusion of both a power analysis and an intention-to-treat analysis.

Caselli et al.[7] also investigated the effectiveness of magnet therapy for plantar fasciitis in a trial involving 34 patients randomized into one of two groups: the first group wore PPT Firm Molded Insoles with a magnetic foil, and the second group wore the same insole without the foil. After 4 weeks the patients were assessed using the foot function index and pretest and post-test scores were compared. Results of the study closely resembled those of the Winemiller et al.[46], with no significant difference found between groups though both groups reported improvement. The methodological quality of this study could have been made stronger with the inclusion of a power calculation, blinded assessments, and a more thorough presentation of the demographic characteristics of the two groups, in particular the duration of symptoms before treatment, to preserve homogeneity.

The effectiveness of orthoses was examined in a multicenter, prospective study by Pfeffer et al.[31] which involved 236 patients (most with symptom duration of less than 6 months) randomized into five treatment groups: stretching only (control group), and stretching combined with either a silicone heel pad, a felt pad, a rubber heel cup, or a custom-made polypropylene orthotic. Patients were reassessed using the pain subscale of the foot function index after 8 weeks, and based on the study results the authors concluded that the prefabricated inserts, along with plantar fascia and Achilles tendon stretching, were more effective than the custom orthotics. Strengths of this study included thorough statistical analyses—with the exception of the report of a power calculation—and the qualification that patients had not received prior treatments, which helped to control for potential residual effects of other treatments. One weakness of the study was that the investigators failed to perform blind assessments.

Another prospective controlled study conducted by Turlik et al.[45] examined the effectiveness of generic heel pads versus functional foot orthotic devices for the relief of chronic plantar fasciitis.

Sixty patients were randomized into either the heel pad group or an orthotic group and an outcome study was performed after 3 months of treatment. The authors provided a detailed description of the materials and manufacturing process of the orthotics, along with sound rationales for the use of these devices. Results of the study showed that patients who received the custom orthotics reported better outcomes than patients who received the heel pads, with all results being statistically significant. The outcome measure utilized in this study, however, was not clearly defined as a valid, reliable questionnaire and blind assessments were not performed, so the quality of the study was somewhat compromised given these shortcomings.

Lynch and colleagues[24] also conducted a randomized, prospective trial with 85 patients with chronic plantar fasciitis. The patients were randomized into one of 3 groups: Group 1 received anti-inflammatory medications and steroid injections; Group 2 received an accommodative viscoelastic heel cup; and Group 3 received mechanical therapy consisting of customized orthoses. Follow-up visits for all groups occurred at 2 weeks, 4 weeks, 6 weeks and 3 months, and patients were evaluated via a visual analog scale. The mechanical therapy group demonstrated a statistically significant better outcome (70% with either an excellent or fair outcome) compared to the other two treatment groups at the 3-month follow-up (33% for Group 1 and 30% for Group 2). The investigators' exclusionary criterion of not allowing subjects to have received any treatments within one month prior to the beginning of the study strengthened the study. The absences of blinding and an intention-to-treat analysis weakened the quality of the study.

A similar study conducted three years later by Martin et al.[26] involved a randomization of 193 patients with plantar fasciitis into groups receiving either custom orthoses, over-the-counter arch supports, or night splints. Follow-up intervals and the use of the visual analog scale as the primary outcome measure paralleled the study of Lynch et al.[24] Study results showed no statistically significant differences among the treatment groups in overall effectiveness after 3 months of treatment, with all three treatments being almost equally effective in producing an excellent or good outcome. The use of custom orthoses demonstrated a statistically significant greater degree of compliance, thus the authors' recommended the use of custom orthoses. The strength of having a relatively high subject sample was offset slightly by the overall dropout/loss rate, which was greater than 20%.

Seligman et al.[42] published a retrospective study (Level IV) which examined the efficacy of a molded orthotic with a heel pad using verbal and Likert-type scales to record levels of pain. Results of the study showed a statistically significant reduction in pain after 5 weeks of heel pad and orthotic use. The authors provided an extensive description of heel pad and orthotic design; the study was weakened, however, by the absence of a control group, no blinded assessments, and a low study group number (10 patients). Additionally, some patients used the Likert-type scale, whereas others used the pain scale, but no explanation was given as to the reason for these individual differences.

An even more extensive retrospective study (Level IV) was conducted by Gill et al.[15] which compared 411 patients' perceptions of treatment success among 11 treatment methods for patients with predominantly chronic plantar fasciitis; among these treatments, a low-profile plastic heel cup and a Tulli's heel cup were used. Results of the survey showed casting to be the most beneficial in terms of patient response, while the heel cup groups exhibited relatively low effectiveness. While the survey involved a large number of patients, the authors acknowledged several inherent weaknesses in their study, among them the lack of a control for combination treatments.

Gross et al.[16] examined the effects of foot orthotics for chronic plantar fasciitis on 15 patients using a repeated measures design (Level IV). Subjects were timed for a 100-meter walk at a self-selected speed, then they rated the pain they experienced using a visual analog scale and completed the pain and disability sections of the foot function index. After 12 to 17 days from the onset of use of the orthotics, the patients performed the same walk test and rated their pain again using the same measures. Results of the study showed a significant reduction (75%) in disability ratings, which supported the authors' recommendation for the use of semirigid custom orthoses for the management of plantar fasciitis. The absence of a control group, blinding, and quantitative evidence to support the claim that rigid foot orthotics impose

too much stress weakened this study.

A systematic review of literature pertaining to orthoses and plantar fasciitis conducted by Landorf and colleagues[22] consisted of grading criteria for the conduct of studies similar to the system employed by the AACPDM, though no formalized scoring system was used. Because these criteria were similar, the reviewers' critical analyses were also similar. A particularly positive attribute of their review was the presentation of clinically relevant information regarding the studies in a useful table format. Unfortunately, the authors did not mention the search methods or inclusionary criteria used for their review, thus limiting additional comparisons to our review of the literature.

Table 4 lists the level I to III studies included in this treatment intervention. Of the 9 total studies reviewed in this category of treatment interventions, 6 qualified as level I to III studies.

Extracorporeal Shock Wave Therapy

The effectiveness of ESWT on symptom reduction for plantar fasciitis was the subject of a study conducted by Buchbinder et al[6]. One hundred sixty-six patients with predominantly chronic fasciitis were randomized to receive either ultrasound-guided ESWT given weekly for 3 weeks or placebo. Follow-up evaluations were performed at 6 and 12 weeks using several outcome measures, among them a visual analog scale and Short Form-36 Health Survey. At both 6 and 12 weeks of the study, both groups improved, but there were no statistically significant differences in outcomes between the two groups. Based on these results, the authors concluded that ESWT was no better than placebo in the treatment of plantar fasciitis. One weakness of the study concerned the allowance of paracetamol (acetaminophen) use throughout the study, which could have confounded the results. Also, the placebo group actually received a very small dose of ESWT, though whether or not such small dosages can induce physiological changes was not discussed. Aside from these faults, the study exhibited strong methodological quality.

Another methodologically strong study was conducted by Rompe et al.[37], who looked at the effects of low-energy ESWT on 112 patients with chronic plantar fasciitis. Subjects were randomized into two groups: the first received 3 applications of 1,000 impulses of low-energy shock waves, while the second received 3 applications of 10 impulses of low-energy waves. The authors administered 3 treatments at weekly intervals and evaluated the patients at six months using a four-step scoring system (primary outcome measure). Results of this pilot study included a significantly higher rate of "good" and "excellent" outcomes in Group 1 than in Group 2, a result which supported the authors' hypothesis. The study was somewhat weakened by the investigators' use of an unvalidated modified scale.

An earlier prospective, controlled single-blind study by Rompe and colleagues[38] examined the effects of low-energy ESWT in 30 patients with chronically painful heels. Patients were treated 3 times at weekly intervals, receiving either 1,000 impulses of .06 mJ/mm^2 at each session or no dosage at all (secondary to no ultrasound gel being used and the shockwave unit being kept at a distance from the patients' feet). Crossover was performed for those patients in the placebo group not responding by the 6-week follow-up. The investigators performed follow-ups after 3, 6, 12 and 24 weeks with a visual analog scale to assess pain, among other outcome measures. The authors reported a significantly greater decrease in pain and increase in walking ability in the treatment group by follow-up week 3. The crossover group also improved quickly upon receiving the actual treatment. Other than a relatively low subject number, this study's only significant methodological flaw was the absence of an intention-to-treat analysis.

The effects of ESWT on running athletes were examined in a randomized controlled trial performed by Rompe et al[39]. Forty-five running athletes with chronic plantar fasciitis were randomized to receive either three applications of 2,100 impulses of low-energy shock waves at weekly intervals, or sham treatment. A blinded observer performed follow-up examinations at 6 months and 1 year using a visual analog scale as the primary outcome measure. The investigators noted significant differences between groups at both 6 months and 1 year, with the treatment group achieving superior results compared to the sham group. The only significant weakness of this study concerned the inadequate description of the non-operative therapy offered to patients at 6 months.

Cosentino et al.[10] examined the effects of ESWT on 60 patients with chronic heel pain in a single

Table 4. Level I to III studies on orthotics/inserts

	Articles Reviewed					
Review Criteria	Winemiller et al.	Caselli et al.	Pfeffer et al.	Turlik et al.	Lynch et al.	Martin et al.
A. Level of Study Design	I	II	I	II	II	II
B. Quality of the Study	Strong	Weak	Moderate	Moderate	Moderate	Moderate
• Inclusion and exclusion criteria...	Yes	Yes	Yes	Yes	Yes	Yes
• Intervention well described...	Yes	No	Yes	No	No	Yes
• Measures used clearly described...	Yes	Yes	Yes	No	Yes	Yes
• Were there blind assessments?	Yes	No	No	No	No	No
• Appropriate statistical...	Yes	No	No	Yes	Yes	No
• Dropout/loss to follow-up...	Yes	Yes	Yes	Yes	No	No
• Were appropriate methods for...	No	No	Yes	Yes	Yes	Yes

blind randomized controlled trial. Subjects were divided into either the treatment or placebo group and all patients received six treatments, one every 7–10 days. Pain levels were assessed via a visual analog scale at the end of the treatments, and one and three months after the end of the study. A statistical analysis of the results showed a significant decrease in pain levels from baseline for the treatment group but not the placebo group. Furthermore, the investigators demonstrated morphological changes through sonongraphy in the enthesophytosis of nine patients 1 month after the last treatment, specifically a reduction in the diameter of the spurs. The absence of dropouts strengthened the study, while the absence of information about control group treatment simulation weakened it. Another weakness of the study was the lack of variables to control for homogeneity between groups, such as patient weight.

A prospective randomized trial was undertaken by Hammer and colleagues[19] using low-energy ESWT on 47 patients with chronic plantar fasciitis. Patients in the first group received three sessions of ESWT (3,000 shockwaves/session) at weekly intervals, while patients in the second group received conservative treatment consisting of iontophoresis with diclofenac and an oral NSAID. After 12 weeks, patients in group 2 were treated using the ESWT treatment of group 1. Follow-up evaluations at 6, 12, and 24 weeks after completion of the treatments consisted of measuring patient pain under different parameters using a visual analog scale. Patients in group 1 demonstrated a significantly greater reduction in pain at 12 weeks, while those in group 2 did not; after cross-over, the patients in group 2 improved significantly to the point that there were no significant differences between groups at the 6-month follow-up. Although the study's groups exhibited good homogeneity across baseline variables, the study was weakened by the absence of blinding and inadequate information on treatment intervention, specifically information pertaining to dosage and/or frequency of either the NSAIDS or iontophoresis.

Speed et al.[43] examined the effects of moderate dose ESWT on 88 patients with chronic plantar fasciitis in a double blind randomized controlled trial. The subjects received either three ESWT or sham treatments at monthly intervals, with no other treatments allowed during the study. Using a visual analog scale, the investigators assessed foot pain

(start-up, night, and daily) prior to the first treatment, then 3 and 6 months from baseline. Both groups showed significant improvement over the course of the 6-month study, but no significant differences were exhibited between groups based on responses to the outcome measures. The authors speculated that conflicting results among various studies using ESWT might be due to the use of different outcome measures and/or different machines. Strengths of the study included appropriate blinding and analysis of results based on intention-to-treat. Along with the absence of a power calculation, the study was weakened by a questionable biasing of treatment frequency. Whereas this study involved treatments at monthly intervals, other studies[6, 10, 19, 37–39] used weekly intervals; such a discrepancy in treatment frequencies may have biased the results toward non-significant findings.

The efficacy of ESWT on tennis elbow and plantar fasciitis was examined in a study by Hammer and colleagues[18] (Level IV). The plantar fasciitis group involved 44 patients with predominantly chronic symptoms who had received unsuccessful conservative treatment previous to the study. Three times at weekly intervals the plantar fasciitis group received 3,000 shock waves of .12 mJ/mm^2. After a follow-up evaluation at 5 months, pain measured on a visual analog scale decreased significantly in this group (70% reported success rate). In addition to the lack of a control group, this study was weakened by the absence of categorizations for pain; that is, the investigators did not parameterize the visual analog scale according to time of day or with certain activities.

Maier et al.[25] prospectively investigated the effects of EWST on 43 patients with chronic plantar fasciitis, utilizing a VAS and Roles and Maudsley (RM) score as clinical outcome measures as well as MRI to determine any morphologic changes. After a mean follow-up of 19.3 months, evaluation of the subjects revealed a statistically significant decrease in the mean VAS and a majority of the patients experienced a satisfactory clinical outcome based on the RM score. An interesting finding via MRI was that the presence of calcaneal bone marrow edema was very predictive for a satisfactory clinical outcome. The investigators speculated that the increased fluid content of the calcaneus associated with plantar fasciitis was responsible for the increased intraosseus pressure and resultant pain. Aside from these insightful morphologic observations, this study was weakened methodologically through lack of randomization and blinding.

A meta-analysis of literature regarding extracorporeal shock wave therapy for chronic plantar fasciitis was conducted by Ogden et al.[30] This meta-analysis involved a search of published literature from 1990 to 2000 using Medline. Some major differences between the results of the literature search from our review and the search results of this meta-analysis included a greater number of studies reported from their search, a direct result of the inclusion of non-English publications and book format publications as part of their search criteria. Also, some of the studies noted in the analysis involved the use of anesthesia, an exclusionary criterion for purposes of our review of the literature. The reviewers used an alphabetical classification system to evaluate the methodological strength of the articles, with Type A studies being the most methodologically sound studies and Type G studies being the most methodologically troublesome. Of these studies, the reviewers focused on those prospective studies with sufficient follow-up duration (defined as one year or more, Type A through C). Results of their analyses showed a total of 840 patients among 8 studies fitting the categorization of Type A through C trials. The collective data in these trials supported the efficacy of ESWT for the treatment of chronic plantar fasciitis, with a success rate varying from 65 to 88%. Success was defined as a complete or significant reduction in pretreatment symptoms or activity limitations. From this data, the reviewers concluded that ESWT was an effective treatment for chronic plantar fasciitis, in particular high-energy ESWT, given the relatively higher success rates and quicker resolution of symptoms when compared with low-energy ESWT.

Table 5 presents a summary of those level I to III studies included in this treatment intervention. Of the 9 studies reviewed under this treatment intervention category, 7 qualified as level I to III studies.

Stretching/exercises

A prospective, randomized study was undertaken by DiGiovanni et al.[13] to examine the effects of stretching on plantar fasciitis symptoms. All 82 patients with chronic plantar fasciitis received a

Table 5. Level I to III studies on extracorporeal shock wave therapy

Review criteria	Articles reviewed						
	Buch et al.	Rompe et al. 2002	Rompe et al. 1996	Rompe et al. 2003	Cosentino et al.	Hammer et al.	Speed et al.
A. Level of Study Design	I	I	II	II	II	II	II
C. Quality of the Study	Strong	Strong	Strong	Strong	Moderate	Moderate	Moderate
• Inclusion and exclusion criteria...	Yes	Yes	Yes	Yes	Yes	Yes	Yes
• Intervention well described...	Yes	Yes	No	No	No	No	Yes
• Measures used clearly described...	Yes	No	Yes	Yes	Yes	Yes	Yes
• Were there blind assessments?	Yes	Yes	Yes	Yes	Yes	No	Yes
• Appropriate statistical...	Yes	Yes	Yes	Yes	Yes	Yes	No
• Dropout/loss to follow-up...	Yes	Yes	Yes	Yes	Yes	Yes	Yes
• Were appropriate methods for...	No	Yes	Yes	Yes	No	Yes	No

three-week course of celecoxib, prefabricated soft insoles, and an educational video on plantar fasciitis. The investigators randomized the subjects into either a non-weightbearing plantar fascia stretching program (Group A) or a weightbearing Achilles tendon stretching program (Group B). After 8 weeks, the patients were reevaluated using the pain subscale of the Foot Function Index. Analysis of the pain subscale scores of the Foot Function Index revealed significantly better results for group A than group B with respect to the first two items of the scale (worst pain and pain with first steps in the morning), and patients in group A exhibited significantly greater response rates. Among the strengths of the study were the inclusion of appropriate statistical analyses and detailed intervention information. Unbalanced dropout between the two groups weakened the study, as well as the absence of blinding for the assessments (only a blinded analysis of outcomes was reported). Furthermore, the investigators chose to have the ankle dorsiflexion stretch performed in standing instead of in bed before getting up. This difference in stretching position could have biased the outcomes, specifically "worst pain" and pain with "first steps in the morning."

Porter et al.[33] studied the effects of two different modes of Achilles tendon stretching on plantar fasciitis. An asymptomatic control group of 41 people were used as a comparison against 94 subjects who were randomized to perform either sustained Achilles tendon stretches (three minutes, three times daily), or intermittent stretches (five sets, 20 seconds each, twice daily). Every month for 4 months the patients provided information about their pain using subjective questionnaires; additionally, a physical therapist measured ankle dorsiflexion at each evaluation. Results of the study showed that both modes of Achilles tendon stretching increased dorsiflexion (approximately 7 degrees from baseline), which correlated with decreases in pain. No significant differences in outcome were found between treatment groups. A dropout/loss rate of greater than 20% and the absence of a power calculation weakened the study. The investigators also allowed those patients who had altered their shoewear to continue wearing the shoewear, though the type of alteration and the number of patients who had altered their shoes were not mentioned.

A comparison of the effects of a standing Achilles tendon stretching program versus use of a

prefabricated night splint program was conducted by Barry et al.[2] in a retrospective study (Level IV) involving 160 patients with predominantly acute plantar fasciitis treated from 1994 through 2000. Each of the two treatment groups was part of a larger, four-tiered intervention approach, each tier representing a progressively more aggressive intervention strategy. Patients were advanced to the next tier if the preceding tier was ineffective after a certain amount of time; tier 3, for example, involved the use of casting if tier 1 and 2 interventions were not found to be effective after 2 months.

Results of the study showed that use of night splints resulted in a significantly shorter recovery time, fewer follow-up visits, and fewer additional treatments when compared to the Achilles tendon stretching group. The investigators also found that the duration of pain prior to treatment was associated with increased time to recovery and increased number of treatment interventions. Based on their findings, the authors recommended early treatment using the four-tiered treatment approach with night splints instead of stretching. The study's adequate sample was weakened by the fact that the study was retrospective and non-randomized.

Table 6 displays how the level I to III studies under this treatment category fared. This treatment category contains the fewest number of level I to III studies in comparison to the other 3 treatment interventions reviewed.

Studies with multiple treatment interventions

Crawford et al.[12] conducted a systematic review of multiple treatments for plantar fasciitis, the scope of which was considerably larger than our review of the literature. The investigators performed extensive database and literature searches for randomized and quasi-randomized studies published between 1966 and 1997. Results of their search revealed 166 published studies, only 14 of which were randomized controlled trials. Analysis of the literature was based on a quality assessment tool consisting of 21 items of interest, including adequate description of the study population, interventions, and randomization procedures, loss to follow-up, allocation concealment, blinding, and compatibility of outcomes with conclusions.

Although similar to the criteria used in our review, direct comparisons could not be made given that the reviewers reported only overall scores for each study without a listed breakdown of the score for each item of interest. Based on their results, the reviewers concluded that there is limited evidence for the effectiveness of night splints and low-energy ESWT for plantar fasciitis, and no evidence to support the effectiveness of magnetic insoles. The reviewers could not make recommendations regarding the use of orthotics due to no RCTs having been published within the time frame of their search. A comparison of the studies on stretching to those analyzed in our review could not be made because the articles included in our evaluation were published after 1997. The reviewers noted a need for more well-conducted RCTs and a standardization of outcome measures for plantar fasciitis.

DISCUSSION

The overall effectiveness of each intervention was assessed using the Modified Canadian Task Force grading system, 32 which had three levels: Grade A (good evidence to support the recommendations that the intervention be specifically considered), Grade B (fair evidence to support the recommendation that the intervention be specifically considered), and Grade C (poor evidence regarding inclusion or exclusion of a intervention, but recommendations may be made on other grounds). Both the levels of evidence and the relative number of studies within each treatment category were considered in determining the overall grade for each intervention. The grades of recommendation for each treatment intervention, as well as the rationale for the assignments of grades, are outlined in Table 7.

In addition to the assignment of grade for each treatment intervention, a post hoc search of the National Guideline Clearinghouse (NGC), a database of evidence-based clinical practice guidelines, was undertaken to check for any existing guidelines pertaining to plantar fasciitis. The search yielded 3 guidelines[29], only 1 of which was determined to be most pertinent to the field of physical therapy and most specific to the treatment of plantar fasciitis. This determination was made by utilizing the "guideline comparison" feature of the database, the results of which presented the most important features of the guideline (methods of review, grading scales, guideline objectives, outcomes, etc.) in a user-friendly table format. "Lower extremity musculoskeletal disorders. A

Table 6. Level I to III studies on stretching/exercises

Review criteria	Articles reviewed: DiGiovanni et al.	Articles reviewed: Porter et al.
A. Level of Study Design	II	II
C. Quality of the Study	Moderate	Weak
* Inclusion and exclusion criteria well described and followed?	Yes	Yes
* Intervention well described and adhered to?	Yes	Yes
* Measures used clearly described, valid and reliable?	Yes	No
* Were there blind assessments?	No	Yes
* Appropriate statistical evaluation, including power calculations?	Yes	No
* Dropout/loss to follow-up reported and less than 20%? Dropout balanced?	No	No
* Were appropriate methods for controlling confounding variables and limiting potential biases used?	No	No

Table 7. Grades of recommendation for reviewed treatment interventions

Intervention	Grade	Reasons
Night splints	C	Poor evidence based on the relatively low number of methodologically strong studies in support of this treatment
Orthoses/magnetic insoles	B	No evidence to support the use of magnetic insoles and fair evidence to support use of orthoses based on mostly Level I–II studies with "moderate" methodologic strength[21–24]. More studies supported use of custom vs. prefabricated orthoses.
Stretching/exercise	C	Poor evidence based on only two Level II studies in support of this intervention, neither of which is methodologically strong.
ESWT	A	Good evidence based on both the number and methodological strength of studies in support of this intervention

guide to diagnosis and treatment," a guideline developed by Brigham and Women's Hospital in Boston and released in 2003, was the guideline of choice for the following reasons: 1) the intended users included physical therapists, who were not included specifically as part of the target audience in the other 2 guidelines; 2) a physical therapist was a member of the group that authored the guideline, a feature not found in the other 2 guidelines; 3) plantar fasciitis was specifically included as a condition of interest, whereas the other guidelines listed heel spur syndrome and chronic foot pain as conditions of interest, respectively; and 4) the efficacy of interventions on pain was listed as a major outcome for consideration in this guideline, unlike the other guidelines, of which one did not state any outcome measures and the other listed the usefulness of radiologic examinations for differential diagnoses as the main outcome of interest.

The authors of this clinical guideline reported a search of Medline and hand searches as sources of literature collection, with a subsequent subjective review of the literature as the method to assess the quality and strength of evidence. No rating scheme was used to evaluate the strength of evidence. In fact, all three guidelines listed "not applicable" for rating schemes pertaining to both strength of

evidence and strength of recommendations. A summary of the guidelines' major recommendations listed cross-friction massage, ultrasound, iontophoresis, and stretching and strengthening exercises under physical therapy recommendations. Unfortunately, a search of the above interventions using the inclusionary criteria for this study found little to no evidence supporting the majority of the guideline recommendations. No studies were found pertaining to cross-friction massage; only one RCT by Crawford et al.[11] related to ultrasound, and only 2 prospective studies related to iontophoresis[17, 21], only one of which is a RCT. Based on the paucity of recent literature found using our search methods, we cannot recommend these interventions as effective physical therapy treatments for plantar fasciitis.

Interestingly, the authors of this guideline did not mention ESWT as a treatment option. One of the authors of the guideline stated in response to correspondence that there is no evidence currently to support the use of this modality (J. McInnes [jmcinnes@partners.org], e-mail, December 14, 2005). This finding conflicts with our finding that there is evidence to support the use of ESWT, based on our search criteria and grading format. Since their guideline does not include rating schemes for either strength of evidence or strength of recommendations, it is difficult to draw conclusions regarding this discrepancy. Some of the interventions listed in the guideline, however, did coincide with the evidence found in our review of the literature. Medial arch supports (orthoses), night splints, and Achilles tendon/plantar fascia stretching exercises were interventions supported by evidence according to the authors of the guideline, a finding consistent with the analysis of interventions in our review.

CONCLUSION

There is scientific evidence for selected physical therapy interventions—night splints, extracorporeal shock wave therapy, orthoses, and stretching exercises—in the treatment of plantar fasciitis not only according to our search and review criteria, but also according to Brigham and Women's Hospital's plantar fasciitis guideline, with the notable exception of ESWT, which was not recommended by the authors of this guideline. Recommendations for future research include the development of a grading format based specifically on the AACPDM's two-part system for evaluating evidence and a standardized outcome measure for patients with plantar fasciitis to enhance the scientific rigor of study comparisons. Additionally, more well-designed RCTs are needed to further evaluate the efficacy of interventions for plantar fasciitis.

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