ABSTRACT

A COMPARISON OF SHORT TERM OUTCOMES BETWEEN PLANTAR FASCIA SPECIFIC STRETCHING AND NON-SPECIFIC PREFABRICATED FOOT ORTHOTICS IN TREATMENT OF PLANTAR FASCIITIS: A META-ANALYSIS

Background: Ten percent of American adults experience plantar fasciitis in their lifetime regardless of physical activity levels or demographics. National costs from 1 million annual medical visits range form $192-$376 million dollars.

Objective: To find a cost-effective-patient-compliant conservative treatment for plantar fasciitis in adults.

Hypothesis: Plantar fasciitis specific stretches (PFSS) will demonstrate greater short term decreases in overall pain in treating plantar fasciitis compared to non-specific prefabricated foot orthotics (NSPFO).

Study Design: Meta-analysis following PRISMA guidelines.

Data Sources: PubMed, PEDro, and Cochrane Online Library

Study Selection: Random Controlled Trials or clinical trials, medically diagnosed for plantar fasciitis, healthy adults 18 yr or older, 2-3 months follow-up periods, published in the English language from 2001 to present, and either the Foot Function Index or Foot Health Status Questionnaire outcome measures.

Results: The null-hypothesis was accepted indicating NSPFO have greater short term decreases in plantar fasciitis pain than PFSS. A large combined effect size of 3.99 with heterogeneity of results (Q variance of 70.35 and p-value <.05 (4.97 E-17)) indicate inconclusive results for effectiveness of PFSS. A large combined 1.55 effect size with homogeneity between studies (Q variance of 1.55 and p-value >.05 (p=0.535)) indicate consistent effectiveness with NSPFO.
Conclusion: PFSS had a larger effect size compared to NSPFO; however, high variability between PFSS studies indicates statistical inconsistencies resulting in inconclusive results. The most cost-effective, although with poor patient compliance, intervention for adult patients with plantar fasciitis are NSPFO as indicated with homogeneity and large effect size of the synthesized data.

Leng Noou Yang
May 2015
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PLANTAR FASCIA SPECIFIC STRETCHING AND NON-SPECIFIC PREFABRICATED FOOT ORTHOTICS IN
TREATMENT OF PLANTAR FASCIITIS:
A META-ANALYSIS

by
Leng Noou Yang

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submitted in partial
fulfillment of the requirements for the degree of
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APPROVED

For the Department of Physical Therapy:

We, the undersigned, certify that the project of the following student meets the required standards of scholarship, format, and style of the university and the student's graduate degree program for the awarding of the doctoral degree.

__________________________
Leng Noou Yang
Project Author

__________________________
Jenna Sawdon-Bea (Chair)        Physical Therapy

__________________________
Deborah Walker                   Physical Therapy

__________________________
James R. Jimenez                  Community Physical Therapist

For the University Graduate Committee:

__________________________
Dean, Division of Graduate Studies
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BACKGROUND

An estimated 10% of the United States adult population will experience plantar fasciitis in their lifetime regardless of physical activity levels.\(^1,2\) Of the 10%, 1 million medical visits are made annually seeking treatment with estimated medical costs ranging between $192-$376.\(^3\) Although seen within adults of all ages, races, and ethnicities, plantar fasciitis is most commonly observed in middle-aged, obese females and young male athletes. The number of women affected by plantar fasciitis is double that of men, with higher incidence occurring between the ages 40 and 60 years. Spondyloarthropathies, such as ankylosing spondylitis, increases risks earlier at 20-40 years.\(^4,5\)

Plantar fasciitis is a self-limiting condition caused by degenerative irritation of the proximal medial calcaneal tubercle insertion of the plantar fascia resulting in heel pain during dynamic weight bearing activities.\(^3\) Though no definitive etiology has been found, causes of plantar fasciitis range from biomechanical pathologies, such as pes planus and leg length discrepancies, to increasing age, obesity, overuse, and a variety of systemic diseases. Key clinical presentations are palpatory tenderness and pain at the medial calcaneal origin spanning the medial longitudinal arch along the plantar surface of the foot. Symptoms are commonly aggravated with first steps of the day after a night’s rest or after long periods of sitting.\(^2\)

The plantar fascia originates from the calcaneus posteromedially, blending with fibrous digital sheaths at the distal phalanges. It encompasses intrinsic foot musculature as well as associated tendons, providing dynamic support of the medial and lateral arches of the foot. Essential neurovascular structures embedded within extensions of the plantar fascia are the medial and lateral plantar nerves and
vessels. These are vital in providing neuromuscular input and essential nourishment to intrinsic foot structures, particularly at the plantar surface. Aside from providing structural support for vast intrinsic foot structures, the plantar fascia also provides tension similar to the windlass mechanism for static and dynamic stabilization as well as shock absorption by the foot-ankle complex in weight bearing activities.6

Unaddressed failure of dynamic foot stabilizers results in repetitive injury and pain. Dynamic foot stabilizers include intrinsic foot muscles such as the lumbricals and abductor hallucis as well as associated tendons such as tendons from the posterior tibialis and peroneous longus. Mechanical overload of the plantar fascia and its osteoligamentous enthesis on the calcaneal tuberosity results in plantar heel pain. More specifically, biomechanical dysfunctions from anatomical faults, obesity, or daily activities impose constant tension-loads on the windlass mechanism and plantar fascia during weight bearing activities.7 Failure of intrinsic foot musculature providing dynamic stability may cause neural and vascular entrapments via the abductor hallucis and medial head of the quadratus plantae resulting in plantar heel pain.5

Concurrent chronic degenerative changes of collagen fibers with or without inflammatory conditions are occurring as a result of micro-trauma along the fascia or calcaneal enthesis. These changes in fibroblastic proliferation have been observed in fascia biopsies cultured from plantar fascia release surgeries. Additionally, avascular characteristics of fibrocartilages within normal enthesis zones further reduce flow of nutritional blood as well as reparative cellular organisms to the fascia and calcaneal enthesis.4,8 Myofascial adhesions following these changes further contribute to secondary entrapments. As a result,
osteophytes begin to develop in an attempt to restore and modify force loading on functional joint surfaces leading to calcaneal bone spurs.\textsuperscript{8}

Plantar fasciitis is a self-limiting condition in which 80\% of cases resolve spontaneously within 12 months. Five percent of cases may require invasive plantar fascia release procedures in the event of failed conservative measures. Affected populations will seek medical treatment due to frustrations with progressive plantar pain, antalgic gait patterns, and restrictions to routine daily activities.\textsuperscript{5} Although this condition may have multifactorial etiologies, its diagnosis is relatively straightforward: subjective complaints of pain along the proximal plantar fascia and its origin at the calcaneal tuberosity medially.

Common interventions for plantar fasciitis include cryotherapy, rest and activity modification, conventional physical therapy, splints and orthotics, pharmacologic therapy, extracorporeal shock-wave therapy, fasciotomy, and percutaneous procedures.\textsuperscript{4} Of the interventions listed, pharmacologic therapy, extracorporeal shock-wave therapy, fasciotomy, and percutaneous procedures are not within the scope of a physical therapist and are not reviewed in this background.

Plantar fasciitis is more likely to occur in individuals spending considerable amounts of time on their feet daily, with risks increased for obese individuals.\textsuperscript{2-4,9} Regardless, 80\% of plantar fasciitis cases resolve spontaneously within 12 months, therefore, logically speaking, rest and activity modification are ideal cost-effective interventional approaches. However, majority of United States occupations require workers to be on their feet throughout the average 8 hour work day. According to the Bureau of Labor Statistics, 61\% of Americans are employed in manual labor or service occupations.\textsuperscript{10} Additionally, approximately 21 million Americans work multiple jobs.\textsuperscript{10} Therefore, adequate rest and activity modification for the general population within the U.S. is not always feasible.
Obesity affects 34.9% of the adult population within the United States, often contributing to biomechanical pathologies within the ankle foot complex. In a systematic review on Body Mass Index (BMI) and musculoskeletal foot disorders, Butterworth et al.\textsuperscript{11} identified 25 articles reporting an association between BMI and musculoskeletal foot disorders. Their findings indicate strong associations between increased BMI and plantar heel pain and non-specific foot pain.\textsuperscript{11}

General interventions addressing musculoskeletal foot disorders include night splints, orthotics, and conventional physical therapy.\textsuperscript{9} Night splints are generally worn with the intention of providing a passive stretch to the plantar flexors throughout the night during sleep. However, potential issues of poor patient compliance yield inconsistent results.\textsuperscript{12} Orthotics consist of heel pads or cups, pronation spring control braces, low-dye taping, prefabricated orthotics, and custom-made casted orthotics. Heel cups and heel pads are made from several different materials including rubber, viscoelastic, silicon, and felt or foam. These orthotics increase heel pad thickness to reduce peak pressures and pain during heel strike.\textsuperscript{7} Prefabricated foot orthotics are made from materials similar to those found in heel cups or pads, but span the entire foot and are categorized as functional or accommodative.\textsuperscript{13} Prefabricated functional foot orthotics correct abnormal foot and abnormal lower extremity function. Prefabricated accommodative foot orthotics relieve pressure from painful or injured areas on the bottom of the foot. They are available over the counter with differing rigidity depending on the targeted outcome, however they are not as specific or personalized as custom made insoles. Custom-made casted orthotics are made by specialists, typically an orthotist or podiatrist. Development of custom orthotics requires the patient’s ankle/foot complex to first be positioned in a non-weight bearing anatomical
neutral position. Once the neutral foot position is determined, the patient stands full weight bearing and performs several weight-shifting as well as closed-chained movements such as partial squats, full squats and trunk rotations so adjustments can be noted for development of the orthotic. The patient’s foot is then repositioned in subtalar neutral and a mold is casted. The casted mold will then be customized with the measurements taken to fit the patient’s dynamic range. In regards to costs, prefabricated orthotics range from $20-$70 and are readily available over the counter vs. $300+ for custom orthotics that generally take 2-3 weeks to produce.

In a systematic review conducted on plantar heel pain, specifically plantar fasciitis, Landroff and Menz\textsuperscript{12} found casted custom made insoles improved function after 3 months of continuous use compared to sham orthotics, but no significant difference in pain reduction were found. Additionally, custom orthotics were not significantly better in relieving pain or improving function compared to prefabricated orthotics.\textsuperscript{12,14} Furthermore, difficulties interpreting results of studies revealed inconclusive evidence confirming whether heel pads, heel cups, or night splints reduced heel pain.\textsuperscript{12} Crawford et al\textsuperscript{15} compared 4 interventions for plantar heel pain: stretching exercises alone; Achilles tendon stretching and plantar fascia stretching; custom-made orthotics plus stretching exercises; and 3 different types of heel pads (prefabricated shoe inserts) made from silicone, rubber, or felt, plus stretching exercises. Results revealed heel pads plus stretching significantly reduced pain at 8 weeks compared to custom-made orthotics plus stretching.\textsuperscript{15}

Typical stretches assigned in clinical settings to address plantar fasciitis are Achilles stretches (also known as gastroc and soleous stretches). However, a Random Control Trial (RCT) of 101 chronic proximal plantar fasciitis subjects demonstrated greater reductions in morning heel pain (first step pain) at 8 weeks
with plantar fascia stretching with a heel pad vs. Achilles stretching with heel pad.\textsuperscript{12,15,16} Studies comparing a stretching-only protocol to orthotic use combined with stretching revealed similar results at improving pain. Additionally, inclusion of a heel pad during the study’s stretching exercise period yielded even better outcomes with pain and function compared to orthotics and stretching alone or combined.

Currently there is little research comparing prefabricated foot orthotics to plantar fascia specific stretching targeting static and dynamic stabilizers supporting arches of the foot. This meta-analysis will compare plantar fascia specific stretching (PFSS) versus non-specific prefabricated foot orthotics (NSPFO) to find the best cost-effective-patient-compliant conservative interventional approach to treat plantar fasciitis in the adult population. As mentioned earlier, several statistics and current research indicate strong correlations between obesity, occupation, and the prevalence or risk of plantar fasciitis. These factors need to be taken into consideration as patient compliance is key to improving recovery rates. Therefore this meta-analysis will test the hypothesis that individuals with plantar fasciitis will demonstrate a greater short term decrease in overall pain with plantar fascia specific stretches compared to non-specific prefabricated foot orthotics. Therefore the null-hypothesis would be non-specific prefabricated foot orthotics have greater short term decreases in pain than plantar fascia specific stretching.
METHODS

Search Strategy

Study design and criteria were based on the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines. The following databases were searched systematically: PubMed, Physiotherapy Evidence Database (PEDro), PubMed and Cochrane Online Library with reference lists of the yielded articles reviewed and consideration for the meta-analysis. PubMed and Cochrane search results were exported into EndNote X7 and screened for duplications as well as filtered with key search terms for articles to be included in this meta-analysis. The following search terms were used: Plantar Fasciitis, Plantar Fasciitis AND Foot Health Status Questionnaire, Plantar Fasciitis AND Foot Function Index, Plantar Fasciitis AND Stretch, Plantar Fasciitis AND Orthotic, Plantar Fasciitis AND Foot Health Status Questionnaire AND Stretch, Plantar Fasciitis AND Foot Health Status Questionnaire AND Orthotic, Plantar Fasciitis AND Foot Function Index AND Stretch, Plantar Fasciitis AND Foot Function Index AND Orthotic. Titles, abstracts, and full text articles were included in the search and reviewed by 1 reviewer.

Inclusion and Exclusion Criteria

For inclusion, articles screened were required to meet the following inclusion criteria: Random Control Trials (RCTs), controlled clinical trials, PEDro scores of 4 or better, published peer-reviewed journals from 2002 to the present in the English language, sample sizes of 30 or more participants, medical diagnosis of plantar fasciitis, medically diagnosed chronic plantar fasciitis, healthy adults 18 years and older, 2-3 month follow-up data, and outcome measures utilizing the Foot Function Index or Foot Health Status Questionnaire.
Excluded from this meta-analysis were articles with populations of any history of foot/ankle fractures, ankle fusions, vascular or peripheral neuropathic co-morbidities, reconstructive surgeries (ankle/foot hardware); acute ankle/foot injury (sprains, trauma related); immunological co-morbidities; and Pregnancies.

Type of Interventions

For this meta-analysis, studies with Plantar Fascia-Specific Stretching (PFSS) protocols based on DiGiovanni et al’s\textsuperscript{18} studies will serve as the stretching intervention being compared to Non-Specific Prefabricated Foot Orthotics (NSPFO). Rationale for selecting NSPFO for comparison is based on cost and current studies indicating similar effectiveness between the custom orthotics and NSPFO. The Canadian Agency for Drugs and Technologies in Health (CADTH) conducted a systematic review on 4 systematic reviews that included orthotic devices and compared prefabricated versus custom orthotics to assess clinical and cost-effectiveness of each. Although no evidence was found on cost-effectiveness between the 2 groups, conclusion of the review with available evidence suggests custom and prefabricated orthotics have similar interventional outcome effectiveness.\textsuperscript{19}

Outcome Measures

Two highly validated outcome measures utilized to assess and compare the interventions are the Foot Function Index (FFI) and Foot Health Status Questionnaire (FHSQ).\textsuperscript{20} Evidence to substantiate validity was by Landorf and Keenan\textsuperscript{20} who found that the FFI and FHSQ are 2 of the most commonly used foot-specific health-related quality-of-life (HRQoL) assessment tools utilized internationally. The FFI was found to be generally less responsive to change, particularly with Activity Limitations, but was nevertheless significant with Pain
and Disability as well as the overall score of the FFI. In comparison, the FHSQ’s 4 domains of Pain, Function, Footwear, and General Foot Health were all found to have significant improvements.\(^{20}\)

When comparing stretches and heel pad vs. prefabricated orthotics, items 1 and 2 of the pain subscales of the FFI will be used as an outcome measure to assess improvements with pain. Items 1 and 2 of the FFI pain subscales are Pain at Worst and Pain with the First Step which are the common subjective reports with plantar fasciitis. With the prefabricated orthotics group, the FHSQ will be utilized as the outcome measure with emphasis on the Pain Subscale. The FFI and FHSQ variables obtained from the articles eligible for this meta-analysis will be compared 2-3 month ranges from baseline; 2-3 month ranges are chosen as a comparison marker because this meta-analysis is intended to find the best cost-effective short term treatment for plantar fasciitis, reduce the costs of overall clinical visits, and changes in tissue healing typically occur in 6-8 weeks. This increases chances that results are due to interventions and not acute spontaneous recovery.

**Quality Appraisal and Assessment of Methodologic Quality**

One independent reviewer assessed the articles for inclusion and exclusion criterias as well as for quality of the studies through use of the Physiotherapy Evidence Database (PEDro). The PEDro scale is based on the Delphi list developed by Verhagen and colleagues for quality assessment of RCTs for conducting systematic reviews.\(^{21}\) These criteria were used to screen each article meeting the inclusion criteria. The PEDro scale is intended to allow its users to quickly identify internal validity of RCTs or CCTs archived on the PEDro
database (criteria 2-9), and have quality statistical information for interpretable results (criteria 10-11).\textsuperscript{21}

**Assessment of Risk of Bias**

Risks of bias of all articles included in this meta-analysis were independently reviewed by 1 reviewer for baseline characteristics (study sample sizes, age, gender ratio, BMI), methodology of the studies, and attrition rates.

**Data Analysis**

Gathered FFI and FHSQ variables were calculated for comparison with Borenstein M et al’s\textsuperscript{22} program Meta-Analysis: Fixed effect vs. random effects ver. 2007 from www.Meta-Analysis.com with Microsoft Office Excel. All other statistical calculations not utilized within this program are conducted with protocols and equations following the Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0\textsuperscript{23}. Heterogeneity of studies are determined by $Q$ statistic $K<N-1$. Variances among the studies were calculated from the extracted data with a confidence interval of 95%, p-value was set at .05. The higher the $Q$ value and the lower the p-value, the greater the variances are between studies, and vice versa. According to Borenstein et al, a p-value less than .05 will require use of a random effects model statistical analysis, while a p-value greater than .05 will require use of an effect size 1 group model for statistical analysis.

The interventional effect sizes and combined effect sizes were based on Cohen’s $d$ to analyze magnitudes of treatments. An effect size.30-.49 is considered a small effect size, .50-.79 is moderate, and $\geq .80$ is considered a large effect size. Forest Plots are generated with Excel will compare effect sizes of each study as well as combined effect sizes of all studies being analyzed. FFI and FHSQ’s scoring systems are scored on different spectrums; the FFI showing improvements with
decreasing variables from baseline figures, and the FHSQ showing improvements with increasing values from baseline. Due to these differing spectrums, separate effect sizes and forest plots were generated for each outcome measure. Expected results should depict negative values for the FFI and positive values for the FHSQ variables.
RESULTS

Study Selections

A total of 1,289 records were identified through PubMed, PEDro, and Cochrane Library. Key terms used for the search are plantar fasciitis AND orthotics, Plantar fasciitis AND exercise, Plantar fasciitis AND intrinsic foot exercises, Plantar Fasciitis AND short foot exercises, Plantar Fasciitis AND Foot Function Index, Plantar fasciitis AND stretches, Orthotics AND Foot Function Index, and Orthotics AND Foot Health Status Questionnaire. These records were imported into EndNote X7 to filter for duplicates as well as inclusion and exclusion criteria with the key terms noted. From that, 131 duplicate articles were removed and 1,142 articles were excluded for not meeting inclusion and exclusion criteria. Sixteen articles were assessed for eligibility in which ultimately only 4 articles were appropriate.

Four RCTs assessing effectiveness of similar stretching protocols and appropriate follow-up periods with the same outcome measures, the FFI or FHSQ, met the inclusion criteria: DiGiovanni et al in 2003\textsuperscript{18} and 2006\textsuperscript{22}, Rathleff et al\textsuperscript{24}, and Rompe et al\textsuperscript{25}. All 4 studies reported subjects keeping exercise logs, however none were analyzed and compliance were solely based on subjective reports. All 4 articles utilized items 1 and 2 of the FFI pain subscale as outcome measures. Two of the 4 articles, DiGiovanni et al 2003 and 2006, are excluded from this meta-analysis because only percent changes and not actual post-follow-up mean scores were reported while the latter is a long-term follow-up of the same study.

Four RCTs evaluating the effects of prefabricated orthotics and meeting inclusion criteria were found: Baldassin et al\textsuperscript{26}, Landorf et al\textsuperscript{27}, Pfeffer et al\textsuperscript{16}, and Rome\textsuperscript{13} et al, Baldassin et al\textsuperscript{26} and Pfeffer et al\textsuperscript{16} utilized modified FFI outcome
measures, and Pfeffer et al\textsuperscript{16}’s study was done in 1999, therefore they were excluded from this meta-analysis. Both Landorf et al\textsuperscript{27} and Rome\textsuperscript{13} et al utilized the FHSQ as their outcome measures and met all of the inclusion criteria. A description of the studies included in this meta-analysis is available in Table 1, and an article search flow diagram is available in Figure 1.

Results of Individual Studies and Synthesis of Results

Study Characteristics

It is important to note that the intent of this meta-analysis is to compare PFSS and readily available NSPFO that can be obtained in a short amount of time (preferably over the counter). In the PFSS studies, Rathleff et al\textsuperscript{24} reported 24 subjects for their stretching group and instructed them to perform the PFSS stretches for 3 months. Rompe et al\textsuperscript{25} reported 54 subjects in their stretching group whom performed the same but slightly modified stretch for 2 months. In the NSPFO studies, subjects in Rome et al’s\textsuperscript{13} 22 accommodative orthotic subjects and 26 functional orthotic subjects wore their orthotics for 2 months. Landroff et al’s\textsuperscript{27} 44 prefabricated orthotic subjects wore theirs for 3-12 months. Because Rome et al’s\textsuperscript{13} study compared 2 different kinds of prefabricated foot orthotics, accommodative and functional, both variables were included as separate sets of data for this meta-analysis, and both prefabricated orthotics were made from the same company. The FFI and FHSQ’s scoring systems are on differing spectrums, the lower the score the better for the FFI while the larger the scoring total the better for the FHSQ. For this Meta-Analysis, Rathleff et al\textsuperscript{24} only reported on FFI items 1 & 2; Pain with the first step and pain at worst, while Rompe et al\textsuperscript{25} reported on items 1-7 of the pain subscale of the FFI. Both Landorf et al\textsuperscript{27} and Rome et al\textsuperscript{13} reported on Pain and Function subscale totals of the FHSQ. Formulas
obtained from Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 was utilized to calculate combined total mean and standard deviations for the FFI pain subscale variables of items 1 and 2, pain at worst and pain with the first step, from Rathleff et al\textsuperscript{24} and Rompe et al’s\textsuperscript{25} studies. All baseline values used for data analysis are indicated in Table 2.

**Risk of Bias Within Studies**

The studies meeting the inclusion criteria for PFSS, Rathleff et al and Rompe et al, have PEDro scores of 6 and 8 respectively. Both studies contained random and concealed allocations with baseline comparability, an intention-to-treat analysis, between-group comparisons, and point estimates as well as variability. Both studies did not blind subjects and therapists, and Rathleff et al did not blind their assessors or have an adequate follow-up period. Both studies utilized the pain subscales of the FFI (only reporting on items 1 and 2). Studies meeting the inclusion criteria for NSPFO, Landorf et al\textsuperscript{27} and Rome et al\textsuperscript{13}, had PEDro scores of 9 and 4 respectively. Both utilized the pain subscale of the FHSQ as their primary outcome measure. Both studies had random allocation, baseline comparability, between-group comparisons, and point estimates and variability within their studies. Both studies did not blind the therapist in their methodology. Rome et al did not blind their subjects or assessors, did not have adequate follow-up, or an intention-to-treat analysis. Detailed PEDro evaluation scores are available in Table 3.

**Plantar Fascia-Specific Stretching**

The plantar fascia-specific stretching protocol analyzed in this meta-analysis was developed by DiGiovanni et al\textsuperscript{18}. This protocol was utilized by Rathleff et al\textsuperscript{24} and Rompe et al\textsuperscript{25} in their RCTs in which they compared plantar
fascia-specific stretching to High-load strength training and Radial Shock Wave Therapy respectively\textsuperscript{24,25}. Data were extrapolated from baseline and 2-3 month follow-up periods in the stretching groups of each study for analysis. The stretching protocol required the stretch to be performed in sitting by crossing the affected leg over the contralateral leg. With the ipsilateral hand on the affected side, the fingers are positioned across the base of the toes on the plantar surface distal to the metatarsophalangeal joints. The next step is to pull the toes back towards the shin until a stretch in the arch of the foot is felt (Figure 2). Palpation of the plantar fascia during stretching was encouraged to ensure tension is established in the plantar fascia. The protocol states to perform the stretch 10 times, for 10 seconds, 3 times per day. If there is presence of bilateral pain, plantar-specific stretching on both feet was encouraged in the study\textsuperscript{18,24,25}. It is important to note and state that general over the counter soft/gel heel pads were issued in both Rathleff et al\textsuperscript{24} and Rompe et al’s\textsuperscript{25} studies. All heel pads used were not considered a factor of bias in each study’s overall results.

Upon calculations of each study’s effect size, Rathleff et al\textsuperscript{24} reveal an effect size of -1.50 with a confidence interval (CI) of -2.14 and -0.86. Rompe et al\textsuperscript{25} reveal an effect size of -6.51 with a CI of -7.48 and -5.55. A calculated p-value of all results must be greater than .05 to use a fixed effect size 1 group model to generate values and a forest plot for this meta-analysis. However, because the p-value is well below .05, signifying heterogeneity among the studies, a random effects 1 effect size group model was used instead to generate the reported results. The negative values observed on the forest plot (Figure 3 and Table 4) for plantar fascia-specific stretches are because items 1 and 2 in the FFI measures pain on a 0-10 scale with the lower the point value the lower the pain level. Therefore a decrease in point value indicates improvements with symptoms. A large calculated
effect size of -3.99 (CI -8.90-0.92) indicates there is a large relationship between the variables of each study. However, a relatively large Q value of 70.35 with 1 degree of freedom and a p-value of 4.97 E-17 shows high heterogeneity between the studies yielding inconclusive results.

Prefabricated Orthotics

Landroff et al\textsuperscript{27} compared the effectiveness of custom, sham, and prefabricated orthotics\textsuperscript{27}. Prefabricated orthotics in the study are three-quarter length Formthotics constructed from firm-density polyethylene foam. The design adequately provides arch support by filling the region under the arch while preventing the orthotic from flattening. Selection of this type of prefabricated orthotic is based on a survey designed to determine the most commonly prescribed orthotic by podiatric physicians\textsuperscript{27}. Baseline and 3-month follow-up variables of the prefabricated orthotic group were used for data analysis in this study.

Rome et al\textsuperscript{13} compared 2 types of prefabricated foot orthotics, a functional prefabricated orthotic vs. an accommodative prefabricated orthotic\textsuperscript{13} (see Figure 4). Because these orthotics are readily available over the counter and prefabricated, results of both groups at baseline and 2-month follow-up were included in this meta-analysis. It is important to note that for standardization in Rome et al’s\textsuperscript{13} study, the functional and accommodative foot orthotics compared are manufactured from the same company (Taylor Made Orthotics Ltd., Chesterfield England)\textsuperscript{13}. Prefabricated functional orthotics are full length orthotics made of ethyl vinyl acetate with a 25 shore A top cover and a 4° medial rear foot ethyl vinyl acetate post. The accommodative orthotics are full-length orthotics made of low-density ethyl vinyl acetate with a polyurethane heel pad\textsuperscript{13}. Selection
of orthotics for their study derived from the Australian Podiatry Council’s clinical guidelines for orthotic therapy.

Landroff et al’s\textsuperscript{27} study had an effect size of 1.47 (CI 0.99-1.94) while Rome et al’s\textsuperscript{13} accommodative orthotic group’s effect size was 1.35 (CI 0.86-1.84) and 1.87 (CI 1.34-2.40) for the functional orthotic group. As mentioned earlier, a calculated p-value greater than .05 grants utilization of a fixed effect size 1 group model to generate values and a forest plot for this meta-analysis as this indicates homogeneity among the results. The combined effect size calculated of both studies for prefabricated foot orthotics is 1.55 (CI 1.20-1.89). These values indicate that there is a large relationship between results of each study. Additionally, the calculated Q value of 1.25 with 2 degrees of freedom and a p value of .535 indicate homogeneity among the studies suggesting prefabricated orthotics does have consistent effects on reducing pain with plantar fasciitis. A detailed table and forest plot are available in Table 5 and Figure 5.

**Risk of Bias across Studies**

Risk of bias across studies was not completed due to too few included studies.
DISCUSSION

The intent of this meta-analysis was to compare if plantar fascia specific stretches (PFSS) demonstrated greater short term decreases in overall pain compared to non-specific prefabricated foot orthotics in the treatment of plantar fasciitis. Results of this meta-analysis indicate PFSS has a greater combined effect size of 3.99. However a significance level of 4.97 E-17 with Q variance of 70.3 demonstrates high variability between PFSS studies suggesting inconsistent interventional outcomes. In comparison, NSPFO had a smaller but still large effect size of 1.54 on reducing short term plantar fasciitis pain. With a p-value of .535 and Q variance of 1.2, homogeneity of the synthesized results suggests more consistencies with NSPFO outcomes. Studies meeting PFSS inclusion criteria, Rathleff et al\(^24\) and Rompe et al\(^25\), have PEDro scores of 6 and 8 respectively indicating strong internal validity within the studies. Additionally, both studies report similar baseline averages with the exception of an 8-year difference in mean age between each study’s subject populations. Furthermore both studies utilized DiGiovanni et al’s\(^18\) PFSS protocol for their stretching group’s interventional exercises. However, the synthesis of data revealed a very low p-value, a large effect size, and high variance between studies. Therefore, a question of relevance is what factors are causing the synthesis of data to formulate high heterogeneity and inconsistencies between the studies?

Variables taken into consideration in this meta-analysis are FFI and FHSQ scores at baseline and 2-3 month follow-up periods. Primary outcome measures analyzed are pain subscales of the FFI, only items 1 and 2, and the FHSQ. The primary intent of this meta-analysis is to find an intervention that will reduce short term plantar fasciitis pain, therefore other subscales of the FFI and FHSQ were
omitted from the study. A secondary goal is to find the most cost-effective intervention with patient compliance. As a result from this meta-analysis, although with poor patient compliance as suggested with high attrition rates, the Null Hypothesis was accepted stating NSPFO appears to be the most cost-effective intervention for adult patients with chronic plantar fasciitis.

**Strengths of this Review**

This meta-analysis is the first to compare the efficacy of plantar fascia specific stretching vs. non-specific prefabricated foot orthotics for patients with chronic plantar fasciitis. Comparative data extracted for this meta-analysis are from validated outcome measures: the Foot Function Index (FFI) and the Foot Health Status Questionnaire (FHSQ). Validity analysis of the FFI by Budiman-Mark et al\textsuperscript{28} concludes that the FFI is extensively used internationally and pioneers quantifiable measures of foot health\textsuperscript{28}. Utilization of the FFI can be done in full scales or subscales to assess outcomes in various clinical practice or research studies. It has been adapted and translated into multiple languages, is applicable to all age groups, and has frequently been used as a validation criterion for other foot health measures\textsuperscript{28}. In regards to the FHSQ, analysis by Landorf et al\textsuperscript{20} and Bennett et al\textsuperscript{21} reports that the FHSQ has a high degree of clinical utility for practitioners interested in assessing the foot health of groups of individuals\textsuperscript{20,21}. With accurate quantifiable foot health status surveys, the highlight of the FHSQ is its ability to discriminate between different types of foot problems from minor foot complaints to more severe foot problems. Additionally, Bennett et al\textsuperscript{21} found the FHSQ demonstrates a high degree of content, criterion, construct validity, and test-retest reliability.\textsuperscript{29}
A systematic literature search for comprehensiveness of the trials following PRISMA guidelines ensured accuracy with the methodology. Additional strengths to the study are utilization of RCT studies with PEDro scores of 4, 6, 8, and 9\textsuperscript{21}. Variables assessed in this meta-analysis were pain scores obtained from pain subscales of the FFI and FHSQ. Synthesis of results are calculated with Borenstein et al’s\textsuperscript{22} program Meta-Analysis: Fixed effect vs. random effects ver. 2007 from www.Meta-Analysis.com in Excel to ensure standardizations with data synthesis. All other statistical calculations not conducted within this program are conducted with protocols and equations following the Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0\textsuperscript{23} for standardization of calculations within this meta-analysis.

PFSS studies meeting inclusion criteria are Rathleff et al\textsuperscript{24} and Rompe et al\textsuperscript{25}, both of which have PEDro scores of 6 and 8, respectively, indicating strong internal validity within the studies and only mean age as a difference (8 yr) between each study subject’s baseline measures. These 2 PFSS studies utilized DiGiovanni et al’s\textsuperscript{18} PFSS stretching protocols. Although neither PFSS studies compared nor reported total FFI pain subscale scores at baseline vs. follow-up, Rompe et al\textsuperscript{25} did mention in their discussion that analysis of FFI combined scores pre vs. post interventions found significant improvements in favor of the plantar fascia-specific stretching group at both 2 and 4 months follow-up compared to the control group (Achilles stretching)\textsuperscript{25}. Rationale for this is because both studies believed that only items 1 and 2 of the FFI were pertinent to symptoms of plantar fasciitis.

NSPFO studies meeting inclusion criteria, Landorff et al\textsuperscript{27} and Rome et al\textsuperscript{13}, both have PEDro scores of 4 and 9 with random allocations, baseline comparability, between group comparisons, and point estimates and variability.
Similar to the PFSS studies, subject baselines from both NSPFO studies were similar with very little differences. The NSPFO studies used the highly validated FHSQ pain subscales for comparable outcome measures were utilized.

**Limitations to Study and Outcome Levels**

Several limitations of this meta-analysis should be noted. This review only included 4 RCTs with small sample sizes which may already be analyzed in previous reviews. Systematic reviews of small sample sizes have potential unreliability that may influence bias. Although careful and detailed search strategies have been carried out to screen and locate eligible studies for this meta-analysis, there are no absolute certainties that all applicable trials were found. Screening processes, study selections, calculations, and reporting results all have degrees of bias that should not be ignored. As mentioned earlier, the quality of the studies included in this meta-analysis have PEDro scores of 4, 6, 8, and 9 indicating they range from appropriate to strong studies\(^1\). However, all 4 studies did not blind the therapists. Additionally, studies with lower PEDro scores, Rome et al\(^{13}\) and Rathleff et al\(^{24}\), lacked adequate follow-up, blind assessors, and blind subjects. The lowest PEDro scoring study, Rome et al\(^{13}\), did not conceal allocations or an intention-to-treat analysis. Other factors to consider are sample sizes, attrition rates, baseline measures, modifications with interventional methodology, placebo effects, and manufacture bias. These factors attribute to increased threats to external validity of the studies and may influence hetero/homogeneity of results within this meta-analysis.

**Plantar Fascia-Specific Stretching (PFSS)**

Rathleff et al\(^{24}\) and Rompe et al’s\(^{25}\) PEDro scores indicate strong external validity within the studies. Although the studies had strong external validity, a
relatively high Q (total variance) of 70.35 and a very significant p-value (alpha set at .05) of $4.97 \times 10^{-17}$ indicates high variability between PFSS articles indicating inconclusive results. Several possible factors within this meta-analysis have been identified as sources of heterogeneity between the studies.

First, there is a relatively high variance between each study. Initially, to determine the source of these variations was to refer to averaged means and standard deviations of each study at post-follow-up for any discrepancies of the data. The standard deviation often defines the reasoning behind variances in data. However, Rathleff et al’s study did not report standard deviations at follow-up periods. Standard deviations of the means for items 1 and 2 of the FFI pain subscales are reported at baseline, however only the mean and confidence intervals are reported at follow-up periods. Therefore variations between reported outcome sample means could not be accurately defined.

As mentioned earlier, small sample sizes serves as possible sources of heterogeneity among the PFSS studies. However it is important to recognize the possibility of attrition bias within studies as well. Dumville et al. states that an ideal 5% attrition rate will have little bias on the strength of trial findings. Attrition rates of 20% or more increases a possibility of bias; therefore losses between 5% and 20% may still be a source of bias and should not be ignored. Rompe et al.’s stretching group sample size consists of only 54 subjects with an attrition rate of only 7.41% at 2 months follow-up due to non-compliance with the stretching program. Rathleff et al. reported an attrition rate of 12.5% at 3 months from an even smaller sample size of 24. The 5% difference between attrition rates and the small but doubled sample sized differences between each study groups are significant sources of heterogeneity bias.
Other factors taken into consideration as possible sources of heterogeneity between the PFSS studies are age, BMI, and gender. Of the 3 factors, the only difference found between the subjects of each study are average ages at $45 \pm 8$ yr with Rathleff et al\textsuperscript{24} and $53.1$ yr (confidence interval of 27-70) with Rompe et al\textsuperscript{24}. Very minimal differences were found between average BMI and gender ratio suggesting these ratios had very little heterogeneity bias in the results. The average BMI between the studies are 27.1 and 27.2, respectively, with average percentages of females at 67 vs. 66\%, respectively.

Lastly, both studies utilized DiGiovanni et al’s\textsuperscript{18} PFSS protocol for their stretching group’s interventional exercises. However, heterogeneity bias of significance among the PFSS studies could be modification to DiGiovanni et al’s\textsuperscript{18} plantar-fascia specific stretching protocol by Rompe et al\textsuperscript{24}. As modification to the original protocol, Rompe et al\textsuperscript{24} instructed subjects in their study to position the unaffected side-hand on the heel of the affected foot and imposing an additional longitudinal stretch on the plantar fascia in a direction opposite to the toes; thus increasing tensile forces on the plantar fascia\textsuperscript{24}. Chaudhry et al’s\textsuperscript{31} study exploring the relationship between mechanical forces and deformation of human fascia found that for plantar fascia a normal load of $8359$ N ($852$ kg, $1878$ lbs) and tangential force of $4158$ N ($424$ kg, $935$ lbs) are required to produce just 1\% compression and shear changes within the tissue. Additionally, longitudinal force needed to produce tissue changes are greater and beyond what a manual therapist can produce\textsuperscript{31}. They concluded that adequate forces required to produce tissue changes in dense connective tissues such as the plantar fascia are not possible with manual therapy techniques. What is occurring through manual therapy interventions (compressive or stretching) are reflexive tissue changes in twisting or extension forces within the tissue. Manual therapy on the plantar fascia does not
change tissues structure but stimulates fascial mechanical receptors triggering tonus changes in connected skeletal muscle fibers\textsuperscript{31}. Therefore increasing the tensile load on the plantar fascia potentially influenced heterogeneity between the studies. In addition to factors contributing to heterogeneity, Rompe et al\textsuperscript{24} reported 15 patients in their plantar-fascia stretching group that took diclofenac (or ibuprofen) as rescue medication due to intolerable pain (mean number of tablets taken was 11). This accounts for 28\% of the Rompe et al’s\textsuperscript{24} PFSS test subjects resorting to medication due to a possible inflammatory response to the modification of the stretch. In Rathleff et al’s\textsuperscript{24} study, which did not modify the stretching protocol, there were no reports of medication use for pain relief. The difference of decreased pain as indicated by combined means of items 1 and 2 of the FFI of each study’s base line and follow-up measures is an 8.9 improvement in pain at 2 months follow-up for Rompe et al’s\textsuperscript{25} subjects compared to a 3.5 improvement at 3 months follow-up for Rathleff et al’s\textsuperscript{24} subjects. These findings suggests pain medications taken adversely affected outcome measures in Rompe et al’s\textsuperscript{25} study.

Overall, in regards to PFSS, high internal validity of the studies, strong positive effects with pain reduction, and very similar baseline measures between both study subjects suggests that Rompe et al’s\textsuperscript{25} modification to DiGiovanni et al’s\textsuperscript{18} PFFS protocol may have been the significant source of heterogeneity between the studies. The effectiveness of reducing short term plantar fasciitis pain with DiGiovanni et al’s\textsuperscript{18} PFSS protocol suggests this stretching method could be a valuable tool of consideration in a clinical setting for treatment of chronic plantar fasciitis patients; as long as it is not modified. Modification of this protocol increases risks of aggravating the patient’s symptoms. Further research with greater sample sizes comparing a modified vs. non-modified PFSS method is
recommended to identify if there are significant differences with side-effects and effectiveness between the 2 methods.

Non-Specific Pre-Fabricated Orthotics (NSPFO)

Of the NSPFO articles screened, 2 articles met the inclusion criteria for this meta-analysis. The combined effect size between these studies are 1.55 with strong homogeneity between studies as indicated with a Q variance of 1.25 with 2 degrees of freedom and a p-value (alpha set at .05, CI at 95%) of .535. NSPFO studies demonstrated a larger confidence interval but smaller, yet still large, combined effect size compared to PFSS, indicating consistencies with interventional outcomes. These results are important for physical therapy implications because the prefabricated orthotics used in both studies were all designed with different materials and functional intentions. These findings suggest NSPFO, readily over the counter, can ensure effective and consistent outcome results for treatment of chronic plantar fasciitis.

First, a primary source of homogeneity bias is the placebo effect. In a meta-analysis by Lee et al\textsuperscript{32} on the effects of foot orthoses on self-reported pain and function in patients with plantar fasciitis, reductions in pain is greatest at 6 weeks or less\textsuperscript{32}. Speculations of these findings suggest presence of a placebo effect as there was little difference in pain and function improvements at 6-12 weeks. Baldassin et al\textsuperscript{26}, Landorf et al\textsuperscript{27}, and Landorf and Menz\textsuperscript{14} all report similar results with improved pain reported greater at 2-3 months or less with little differences after\textsuperscript{14,26,27}. Rome et al\textsuperscript{13} reported similar results with the greatest improvements with pain at 3 months or less and a smaller improvement from 3 to 12 months.

In relation to the placebo effect, sample sizes have to be considered. Having large study samples will decrease the risk of placebo bias. Lee et al\textsuperscript{32} reported that
Hrobjartsson and Getzche (2001) conducted clinical trials with continuous outcomes demonstrating beneficial effects with placebos, but these effects decreased when sample sizes increased\textsuperscript{32}. Average sample sizes within Lee et al\textsuperscript{32}’s meta-analysis was relatively small at 29.5\textsuperscript{32}, similar to the average sample size for NSPFO subjects within this meta-analysis at 30.7. As with PFSS studies, attrition bias must be taken into account along with sample sizes. Sample sizes of Rome et al’s\textsuperscript{13} study are 22 subjects with an attrition rate of 40.9% in the accommodative orthotic group and 26 subjects with an attrition rate of 15.3% in the functional orthotic group. Landorf et al\textsuperscript{27} had 44 subjects in their prefabricated orthotic group with an attrition rate of only 2.7%. Rome et al’s\textsuperscript{13} 40.9% attrition rate with their accommodative orthotic group serves as a large source of attrition bias that could have influenced overall results of this study. Rome et al\textsuperscript{13} report attrition rates in their study are due to the accommodative orthotics “losing its function as a cushioning device after 4 weeks” and “the insoles had gone hard and flattened out,” which is commonly seen in clinical practice\textsuperscript{13}.

It is important to restate that for standardization in Rome et al’s\textsuperscript{13} study, functional and accommodative foot orthotics compared are manufactured from the same company which in itself is another source of bias towards homogeneity within this meta-analysis\textsuperscript{13}. Additionally, a lower PEDro score of 4 suggests lower internal validity within Rome et al’s\textsuperscript{13} study in comparison to a higher score of 9 in Landorf et al’s\textsuperscript{27} study. Therefore, due to small sample sizes, attrition rates, the placebo effect, and a large difference between PEDro scores, careful interpretation of the homogeneity and effect sizes of NSPFO studies within this meta-analysis are cautioned.
PFSS vs. NSPFO

Although attrition rates among each of the studies serve as sources of bias of significance, they can also have implications of clinical relevance. A secondary intent of this meta-analysis, although not statistically analyzed, is to find the most patient compliant-cost-effective intervention to treat chronic plantar fasciitis. For this meta-analysis, attrition rates for all NSPFO subjects are 15.2% compared to 8.98% for all PFSS subjects. Attrition rates in this meta-analysis have correlations with patient compliance to self-treatment interventions. According to Lingam and Scott\textsuperscript{33}, highly complex treatment regimens increases risks of non-adherence to self-treatments. Therefore, communication between the practitioner and patient is important. In a meta-analysis on patient adherence, Zolnierek and DiMatteo\textsuperscript{34} found that the odds of patient adherence are 2.16 times higher if a physician communicates effectively. Communication is an important aspect of medical care ensuring development of a therapeutic physician-patient relationship so the patients can be informed about treatment regimens and be encouraged with supportive assistance\textsuperscript{34}. Subjects in the PFSS groups all received clear and specific stretching exercise protocols to follow with specific frequencies and duration of stretches. Additionally they were encouraged to keep exercise logs and were frequently asked by assessors for updates on their symptoms and PFSS exercise. In contrast, NSPFO did not receive the same amount of communication from assessors or practitioners involved in the study. They were randomly allocated to specific orthotic groups and were instructed to either discontinue all other therapeutic activity or continue with regular exercises/rehab regimens.

In addition to attrition rates and correlations with patient compliance in self-administered interventions, BMI and its relation to activity levels need to be taken into consideration. When comparing results of both interventions, major
differences between the 2 studies are average BMIs of the subjects. Average BMI values for the PFSS studies are 27.1 (CI 23.4-31) in Rathleff et al’s\textsuperscript{24} subjects and 27.2 (CI 20-30) in Rompe et al’s\textsuperscript{25} subjects. In the NSPFO group, Rome et al\textsuperscript{13} reports an average BMI of 31.5 ± 6.1 for the accommodative prefab fabricated orthotic group and 29.4 ± 3.9 for the functional prefab fabricated orthotic group, while Landorf et al\textsuperscript{27} reports 32.9 ± 6.1 in his subjects. When averaged, BMI values are 27.4 for PFSS studies and 31.3 for NSPFO. According to the CDC, a BMI ranging from 25.0-29.9 is considered overweight and 30.0 and above is considered obese. The average BMI for PFSS subjects fall into the overweight category while NSPFO fall into the obese category.

Upon further interpretation of BMI influencing bias for both interventions, current research correlates higher BMIs with lower overall levels of physical activity whether it be leisure time physical activity or occupational activity\textsuperscript{35}. As plantar fasciitis is a self-limiting condition, painful symptoms will significantly reduce physical activity levels. An individual with a higher BMI and low activity levels will not want to weight bear on the affected foot. Studies show that overall exercise can reduce musculoskeletal pain significantly. However, the resulting pain further reduces their already lower levels of activity, which in turn delays the recovery process.

With higher BMIs and lower activity levels at baseline, arguments of the placebo effect of the orthotics gains merit. Subjects receiving orthotics may assume they are actually receiving an effective quick fix interventional tool with positive changes. As a result, the orthotic may motivate the individual to return to prior levels of activity. By increasing physical activity, appropriate stresses with corrected alignment and stability of their arches may have attributed to rehabilitative benefits reducing plantar fasciitis symptoms. In a study by Dedieu et
subjects using orthotics demonstrated improved realignment of the calcaneus with respect to the talus, thus increasing stability in static and dynamic stance phases. What they found was that orthotics realigned the calcaneous and osteo-articular structures of the foot. Because prevalence of plantar fasciitis is due to biomechanical foot impairments, the range of deformity of the medial arch is decreased with use of orthotics. As a result, mechanical efforts of the forefoot for propulsion is significantly decreased, requiring less effort and stress on the plantar fascia and its assistance with the windlass mechanism during gait. Dedieu et al concluded that realignment of foot structures restores neuromuscular timing of extrinsic and intrinsic foot muscles and their agonist/antagonistic roles in providing dynamic support in weight bearing activities. Thus, as a secondary effect, the central nervous system and its neuroplastic characteristics adapt to the orthotics, impacting muscular activity timing patterns as well as strengthening of intrinsic foot muscles. In reference to the placebo effect, receiving the orthotic can be assumed as a one-time fix intervention, thus increasing patient confidence to return to prior activity levels which secondarily strengthens and restores normal function of the ankle foot complex.

In regards to BMI and PFSS subjects, their higher levels of activity could serve as limitations to interventional outcomes. Varying types of physical activity for leisure or occupation could impact the time necessary for recovery. Therefore with a lower BMI, the PFSS subjects’ increased and varying activity levels can be another source of heterogeneity bias between PFSS studies. The PFSS subjects may have continually participated in their more-active-lifestyles compared to NSPFO subjects, which can slow down the rehabilitative process. In addition, because these subjects are more active, they may have increased symptoms of pain throughout the day in comparison to NSPFO subjects.
From a cost effectiveness standpoint, the average cost of prefabricated orthotics range from $20-$70. Ring and Simon\textsuperscript{37} found that prefabricated orthotics were an average 38\% cheaper than custom orthotics while providing the same short-term benefit. The APTA states that copayments for physical therapy sessions can be as high as $75 per visit. As of January 2014, the Patient Protection and Affordable Care Act have limited the therapy salary cap to a maximum of $1940 for physical therapy and speech language pathology. According to Clinical Practice Guidelines of the Orthopaedic Section of the APTA and American College of Foot and Ankle Surgeons for treatments of plantar fasciitis, average number of visits are twice a week for 4-6 weeks to 6 months depending on the severity of patient symptoms.\textsuperscript{38-41} If a copay rate was set at $5 per visit, an entire 4-week session can upwards to cost $80 and can get high as $600 with a $75 co-pay. In reducing patient costs associated with therapy visits, fewer physical therapy visits may be necessary as results of this meta-analysis suggests NSPFO is an effective intervention for short term relief of painful plantar fasciitis symptoms. The homogeneity of NSPFO studies and its large effect size suggests prescribing prefabricated foot orthotics for treatment of plantar fasciitis can produce consistent effective outcomes.

Conclusions

This is the first meta-analysis comparing plantar fascia-specific stretching with non-specific prefabricated foot orthotics as interventional approaches for plantar fasciitis. These results provide clinical evidence for treatment of chronic, plantar fasciitis. Outcome measures used to analyze changes in symptoms are pain subscales of the FFI, item 1 (pain at worst) and item 2 (pain with the first step), and FHSQ. Although plantar fascia-specific stretching (PFSS) studies have a large
effect size, heterogeneity between studies indicates high variability and inconsistencies indicating inconclusive results. Additionally, PFSS studies had greater similarities between each study with fewer threats to internal validity in comparison to the NSPFO studies. However, Rompe et al.’s\textsuperscript{25} modification of DiGiovanni et al.’s\textsuperscript{18} PFSS protocol resulted in 28% of participants needing pain control medication, suggesting evidence of an acute exacerbation of symptoms. This is a significant discrepancy among the PFSS studies that may have influenced the heterogenous results. Due to the heterogeneity of PFSS, outcomes of this meta-analysis suggest NSPFO provides effective and consistent short-term pain relief for plantar fasciitis, thus rejecting the alternative hypothesis. Further recommendations for future research should focus on 2 key points: DiGiovanni et al.’s\textsuperscript{18} original PFSS protocol vs. the modified protocol for definitive comparison of which method is better, and upon completion of that study, compare the best PFSS method to NSPFO from multiple manufacturers with larger sample sizes to effectively determine if NSPFO is better than PFSS in treating plantar fasciitis. This will help reduce sources of bias and increase advocacy of cost-effective treatments for plantar-fasciitis in a new age of increasing health care intervention rates.
REFERENCES


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| Rathleff et al*             | 45 ± 8   | 67        | 27.1 (23.4-31.0) | FFI Item 1: 7.5 ± 0.8  
                       |          |           |             |                                      | FFI Item 2: 6.9 ± 2.4        |
|                             |          |           |             |                                      | FFI Item 1&2 Total: 14.4 ± 2.33 |
| Rompe et al*                | 53.1 (27-70) | 66       | 27.2 (20-32) | FFI Item 1: 8.3 ± 0.8  
                       |          |           |             |                                      | FFI Item 2: 7.8 ± 1.0         |
|                             |          |           |             |                                      | FFI Item 1&2 Total: 16.1 ± 1.29 |
| Landorf et al               | 47.3 ± 11.6 | 57      | 32.9 ± 6.1  | FHSQ (Foot Pain): 42.1 ± 20.0        | 3 Months:  
                       |          |           |             |                                      | FHSQ (Foot Pain) : 81.8 ± 22.8 |
| Rome et al (Accommodative)† | 58.3 ± 12.6 | --/--    | 31.5 ± 6.1  | FHSQ (Foot Pain): 30 ± 23.7          | 2 Months:  
                       |          |           |             |                                      | FHSQ (Foot Pain) :62 ± 26.1  |
| Rome et al (Functional)†    | 61.2 ± 14.4 | --/--    | 29.4 ± 3.9  | FHSQ (Foot Pain): 39 ± 18.7          | 2 Months:  
                       |          |           |             |                                      | FHSQ (Foot Pain) 74 ± 25.3   |

*( ) indicates range of variable  
†% of females were not reported  
FFI Item 1 is Pain at Worst; FFI Item 2 is Pain with the First Step
### Table 3. Article PEDro Scoring

<table>
<thead>
<tr>
<th>PEDro Criteria</th>
<th>Rome et al</th>
<th>Rompe et al</th>
<th>Landorf et al</th>
<th>Rathleff et al</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eligibility criteria</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
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<tr>
<td>Random allocation</td>
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<td>1</td>
<td>1</td>
<td>1</td>
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<tr>
<td>Concealed allocation</td>
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<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Baseline comparability</td>
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<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Blind subjects</td>
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<td>0</td>
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<tr>
<td>Blind therapists</td>
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<td>Blind assessors</td>
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<td>Adequate follow-up</td>
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<td>0</td>
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<tr>
<td>Intention-to-treat analysis</td>
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<td>1</td>
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<tr>
<td>Between-group comparisons</td>
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<td>1</td>
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<tr>
<td>Point estimates and variability</td>
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<td>1</td>
<td>1</td>
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<tr>
<td>Total PEDro Score out of 10</td>
<td>4</td>
<td>8</td>
<td>9</td>
<td>6</td>
</tr>
</tbody>
</table>

*Eligibility Criteria are not included in overall scoring*
Table 4. Calculated Effect Size, Lower & Upper CI values for Plantar Fascia-Specific Stretching Studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Time of Follow-up</th>
<th>Effect Size</th>
<th>Lower CI</th>
<th>Upper CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rathleff et al(^{22})</td>
<td>3 months</td>
<td>-1.50</td>
<td>-2.16</td>
<td>-0.84</td>
</tr>
<tr>
<td>Rompe et al(^{23})</td>
<td>2 months</td>
<td>-6.51</td>
<td>-7.48</td>
<td>-5.55</td>
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<tr>
<td>Grand Effect</td>
<td>--/--</td>
<td>-3.99</td>
<td>-8.90</td>
<td>0.92</td>
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</tbody>
</table>

Table 5. Calculated Effect Size, Lower & Upper CI values for Non-Specific Prefabricated Foot Orthotics

<table>
<thead>
<tr>
<th>Study</th>
<th>Time of Follow-up</th>
<th>Effect Size</th>
<th>Lower CI</th>
<th>Upper CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rome et al(^{13}) (Functional)</td>
<td>8 weeks (2 months)</td>
<td>1.87</td>
<td>1.19</td>
<td>2.55</td>
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<tr>
<td>Rome et al(^{13}) (Accommodative)</td>
<td>8 weeks (2 months)</td>
<td>1.35</td>
<td>0.60</td>
<td>2.11</td>
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<tr>
<td>Landof et al(^{25})</td>
<td>3 months</td>
<td>1.47</td>
<td>0.99</td>
<td>1.94</td>
</tr>
<tr>
<td>Grand Effect Size</td>
<td>--/--</td>
<td>1.55</td>
<td>1.20</td>
<td>1.89</td>
</tr>
</tbody>
</table>
FIGURES
Figure 1. PRISMA article search flow diagram
Figure 2. Pantar Fascia-specific stretching protocol developed by DiGiovanni et al\textsuperscript{18}

Figure 3. Forest plot for Plantar-Fascia-Specific Stretching (PFSS)
Figure 4. Functional (left) and accommodative (right) foot orthotics\textsuperscript{13}

Prefabricated Orthotics and Effects on Plantar Fasciitis

Figure 5. Forest plot for Non-Specific Prefabricated Foot Orthotics (NSPFO)
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