Examining the Degree of Pain Reduction Using a Multielement Exercise Model with a Conventional Training Shoe Versus an Ultraflexible Training Shoe for Treating Plantar Fasciitis

Michael Ryan, PhD; Scott Fraser, BSc, PT; Kymberly McDonald, BSc; Jack Taunton, MD, MSc

Abstract: Plantar fasciitis is a common injury to the plantar aponeurosis, manifesting as pain surrounding its proximal insertion at the medial calcaneal tubercle. Pain is typically worse in the morning when getting out of bed, and may subside after the tissue is sufficiently warmed up. For running-based athletes and individuals who spend prolonged periods of time on their feet at work, plantar fasciitis may become recalcitrant to conservative treatments such as ice, rest, and anti-inflammatory medication. Exercise-based therapies have received only limited attention in the literature for this common problem, yet they are becoming increasingly validated for pain relief and positive tissue remodeling at other sites of similar soft-tissue overuse injury. This study reports on pain outcomes in individuals experiencing chronic plantar fasciitis whiles wearing a shoe with an ultraflexible midsole (Nike Free 5.0) (FREE) versus a conventional training (CON) shoe in a 12-week multielement exercise regimen, and after a 6-month follow-up. Adults with ≥ 6-month history of painful heel pain were recruited and randomly assigned to wear 1 of the 2 shoes. All subjects completed the same exercise protocol. A visual analogue scale item tracked peak pain in the preceding 24 hours taken at baseline, 6- and 12-week points, and at the 6-month follow-up. Twenty-one subjects completed the program (9 FREE; 12 CON). Both groups reported significant improvements in pain by the 6-month follow-up, and the FREE group reported an overall reduced level of pain throughout the study as a result of lower mean pain scores at the midpoint and post-test compared with the CON group. The exercise regimen employed in this study appears to reduce pain associated with chronic plantar fasciitis, and in doing so, the Nike 5.0 shoe may result in reductions in pain earlier than conventional running shoes.

Keywords: plantar fasciitis; Nike 5.0; running shoes

Michael Ryan, PhD[1]
Scott Fraser, BSc, PT[2]
Kymberly McDonald, BSc[1]
Jack Taunton, MD, MSc[1]

[1]University of British Columbia, Vancouver, British Columbia, Canada; [2]Allan McGavin Physiotherapy Clinic, Vancouver, British Columbia, Canada

Correspondence:
Michael Ryan, PhD,
University of British Columbia
3055 Wesbrook Mall,
Vancouver, British Columbia,
V6T 1Z3 Canada.
Tel: 604-506-2253
Fax: 604-822-9058
E-mail: mryan76@gmail.com

Introduction

Plantar fasciitis—also known as "painful heel syndrome" or "chronic plantar heel pain"—is a common injury among athletes in running-based sports and professions that require prolonged periods of weight bearing. It is reported to account for 15% of all adult foot complaints requiring professional consultation, and in a survey of 2002 running injuries, plantar fasciitis was the third most prevalent injury.[1,2] It primarily affects individuals aged > 40 years, and common symptoms include morning pain, pain on standing after periods of inactivity, and pain with running subsiding after warm-up and returning later in the workout.[3]

In the interests of supporting the medial longitudinal arch, lessening stress on the plantar fascia and addressing any exacerbating foot alignments, foot orthoses are often one of the first treatment options for patients experiencing plantar fasciitis. Evaluating the effectiveness of foot orthotic therapy is not without considerable challenge considering large degree of variance between orthotic materials, provider specifications, and impression methods, as well as differences between study methodologies. Therefore, it is not surprising that the evidence for the effectiveness of foot orthoses against plantar fasciitis is equivocal. Roos et al[4] reported a significantly greater improvement in pain scores in patients with plantar fasciitis treated with foot orthoses versus night splint. In a randomized, single-blind controlled trial testing a custom orthosis, prefabricated insole and sham insole, there was no difference between any of the groups in pain scores after a 12-month follow-up.[5] A Cochrane systematic review reports that it is unclear whether custom foot orthoses are effective at reducing the pain associated with plantar fasciitis.[6]

Depending on the efficacy of repeated conservative treatments, injections of a corticosteroid may follow in recalcitrant cases. Several authors have reported on the efficacy of steroid injections; however, there is limited evidence for this treatment without consistent results from well-designed randomized controlled trials.[7–9] Results from steroid injections must also be weighted against the risks of plantar fascial rupture.[10,11]

Although orthotic insoles help to lessen stress on the plantar fascia, and cortisone injections limit pain caused by inflammation, neither of these treatments contribute to improvements in the strength and flexibility of the intrinsic structures of the foot, which is a treatment element identified as important in the nonoperative management of plantar fasciitis.[12]

Physiotherapy treatments, specifically those involving exercises, stretching, and ultrasound analgesia, can be an excellent method in providing targeted and progressive levels of strain to injured soft tissue, which may help stimulate appropriate remodeling.[13] A physiotherapy regimen will often incorporate balance training or dynamic stretches to improve overall posture and increase flexibility and activation of lower-limb muscle groups; however, the effects of these physiotherapy interventions have not been formally investigated for a patient group with plantar fasciitis. Exercise-based treatments (usually focusing on eccentric elements) have been increasingly well documented in the literature at the Achilles tendon, infrapatellar tendon, and common elbow extensor tendon for their therapeutic benefits of pain reduction and positive tissue remodeling, as demonstrated with ultrasonographic evidence of tissue normalization and an increase in collagen type I production.[14–18]

This study aims to report a case series for a physiotherapy regimen encompassing static, dynamic, and tissue-specific stretches, as well as balance exercises directed at improving the pain levels in individuals experiencing plantar fasciitis. Furthermore, this study examines whether individuals performing the exercises in shoes with a soft, ultraflexible midsole (Nike Free 5.0) (Figure 1) will have a greater improvement in pain than individuals wearing conventional running shoes.

Figure 1. The Nike Free 5.0. Originally designed to assist track and field runners perform barefoot training exercises with the cushion and protection of a shoe, the Free 5.0 achieves its high degree of flexibility from a series of clefts made to the mid-sole/out-sole of the sole.

Methods

Subjects

All subjects (aged 18–60 years) were recruited from advertisements in local newspaper media and had signed informed consent before participating in this study in accordance with the Clinical Ethics Research Board of the University of British Columbia. Diagnosis of plantar fasciitis was made by a physiotherapist (S. Fraser) with > 15 years experience in orthopedics and sports medicine in an outpatient clinic setting. Diagnosis was based on tenderness to pressure at the origin of the plantar fascia on the medial tubercle of the calcaneus coupled with sharp shooting inferior foot pain made worse with activity and/or on rising in the morning. Radiographs documenting calcific changes at the plantar fascia origin were not performed. Individuals were excluded if they presented with comorbidities of the lower extremity, foot, or ankle, including posterior tibialis tendinopathy, chronic ankle instability, cuboid syndrome, plantar nerve entrapment, peroneus longus tendinopathy, or stress fracture. Subjects must have been symptomatic for at least 6 months and were excluded if there was a history of systemic inflammatory disease, connective tissue disease, or previous local trauma to the legs or feet.

After baseline interview, all subjects were randomly assigned via a random number generator into 1 of 2 groups: 1) a group wearing a novel ultra-flexible shoe (Nike Free

5.0) (FREE); 2) a group in which the subjects wore their own conventional running shoes (CON). All shoes in the CON group were confirmed to be classified as either a neutral-supportive or stability running shoe with similar sole and upper characteristics, namely thermoplastic midfoot shank and heel counter, and with reinforced cushioned material in the heel midsole. The Nike Free 5.0 achieves its high degree of flexibility from a series of 8 cross-sectional and 3 longitudinal clefts that run the width and length of the mid/out-sole of the shoe, respectively, which is approximately 1 cm overalls less midsole thickness and the absence of a heel counter.

After subjects were randomly assigned, they reported their injury and treatment history followed by a physical examination by one of the authors (S. Fraser) documenting resting calcaneal standing position, frontal and sagittal plane midfoot alignment on the rearfoot, passive Hallux range of motion, and a functional assessment of talocrural joint range of motion. Of the 21 subjects, 7 (4 FREE, 3 CON) were using anti-inflammatory medication prior to enrollment, and all of 21 subjects had agreed to forgo their medication usage during the investigation. Two subjects (both FREE group) used steroid-based inhalers for periodic asthmatic episodes. All subjects were encouraged to not undertake concurrent treatments during the process of the investigation.

Exercise Regimen

Subjects were instructed on the exercises of the rehabilitation protocol. These exercises were for static and dynamic stretching and balance improvement, and were performed 4 times/week over a 12-week period. These exercises included:

- Karaoke: lateral side-step movement involving crossing 1 foot over the next for 5 sets of 15 cross-overs in each direction.
- Balance walking, or walking along a straight line on the ground, for 5 sets of 30 strides.
- Forefoot extension exercise in which the subject stands feet shoulder width apart with 1 foot ahead of the other, and then contracting only calf muscles of the back leg, then lifts the heel of the back leg until the metatarsophalangeal joint of that foot is maximally extended. The subject is instructed to concentrate on maintaining balance on the back leg over the first and second metatarsophalangeal joints throughout movement for 5 sets of 15 repetitions.
- Standing one-legged balance exercise: performed initially with eyes open, then with mastery exhibited by being able to hold balance and not touch the ground with contralateral leg performed with eyes closed, then on an unstable surface with and without eyes open for 1 minute.
- Ankle inversion/eversion exercise: foot is placed sideways at the edge of a step. After stabilizing the remainder of the foot and leg, the ankle is inverted and everted to the limits of the range for 3 sets of 15 repetitions.
- Gastrocnemius and soleus stretching: while standing in a neutral position and the knee extended, the foot is placed on top of a ramp or phone book, elevating the forefoot on the rearfoot (talocrural dorsiflexion) and being held for 3 sets of 30 seconds each. Next, the foot is again placed on top of a phone book with the knee flexed approximately 15° to 20°, and held for 3 sets of 30 seconds each.
- Tissue-specific plantar fascia stretch: in a sitting position, the right foot is crossed over the left while one hand passively extends the right forefoot. The left hand then applies light-to-moderate pressure in 3- to 5-second intervals along the length of the medial longitudinal arch. Same procedure is then repeated for the left foot.

Detailed instruction for each exercise was given and subjects needed to demonstrate mastery (confirmed by physiotherapist SF) of at least the preliminary technique prior to involvement in the study. Subjects performed all of the above exercises, except for the tissue-specific plantar fascia stretch, wearing their footwear. Subjects in the FREE group were instructed to only wear their Nike Free 5.0 shoes during their exercise sessions. Compliance with the physiotherapy regimen was confirmed with a training log that subjects were required to submit on a weekly basis, and each subject was contacted by telephone every week to ensure clarity and execution of the exercise regimen.

A visual analogue scale (VAS) (100 mm) questionnaire was used as the outcome measure for pain assessment assessing peak pain experienced in the previous 24 hours.[19] Measurements were taken during interviews with subjects at the baseline testing, midprogram, at the conclusion of the 12-week treatment protocol, and at the 6-month follow-up.

All data were entered in a personal computer and analyzed using PASW statistical software (Version 17.0.2; SPSS Inc., Chicago, IL). Initial comparisons of between-group

baseline variables of age, height, weight, body mass index (BMI), and symptom duration were compared using independent samples t-tests. A 2-way analysis of variance (ANOVA) test was conducted to determine whether there was a significant main effect for footwear condition and time, in addition to an interactive effect, for the VAS item for pain. A preliminary Shapiro–Wilks test of the VAS values from this study population reported a significant departure from normality; therefore, Mann–Whitney U tests were performed at each of the 4 time intervals to determine whether a significant difference existed for each VAS item between footwear groups. The significance level for this study was set at a P value of 0.05.

Results

A total of 24 subjects were recruited. Over the course of the study, 3 subjects dropped out. Two subjects experienced an increase in foot pain and 1 dropped out of the program. All 3 of these subjects were part of the FREE group. There were no differences in compliance to the exercise regimen between the groups based on the number of exercise sessions completed over the 12-week program.

Twenty-one subjects (9 FREE and 12 CON) completed the 12-week program. Ten subjects reported bilateral symptoms, which were addressed by taking the average pain score between feet at each time interval and assigning that as the individual patient score.[20] Table 1 outlines descriptive statistics for baseline variables between groups. Four of the subjects in the FREE group reported prolonged standing at work averaging 9 hours per day, and 8 subjects in CON group reported prolonged standing at work averaging 7.9 hours per day. Because of the presence of 2 of the subjects in the FREE group having disproportionately greater symptom durations (123 and 108 months, respectively), the FREE group had a significantly greater overall symptom duration.

On average, each study participant had attempted 2 previous treatments. The most frequently attempted previous treatment were orthotics (used by 81% of subjects), followed by exercises (33% of subjects) and massage (23% of subjects). Other treatments included chiropractic care, taping, therapeutic ultrasound, acupuncture, viscoelastic gel heel cups, fascial release, ice massage, laser, and night splint.

Results from the 2-way ANOVA report a significant overall main effect for footwear ($P < 0.05$) and time ($P < 0.001$). There was no significant interactive effect for footwear and time observed ($P > 0.10$). Results from the Mann–Whitney U test report that at the baseline test there were no differences in pain across the footwear groups; however, there were apparent trends suggestive of a difference in the pain score between the footwear groups at the midpoint and post-test time points (Figure 2). There were no significant differences for pain levels at follow-up between groups.

Discussion

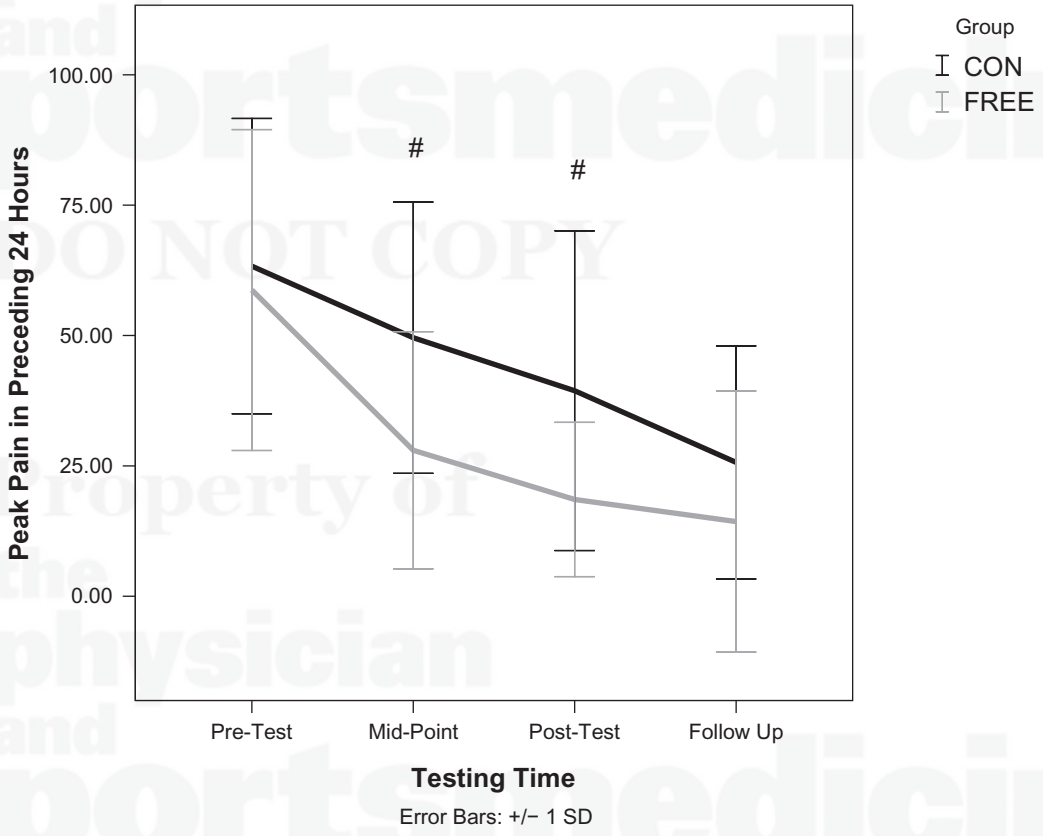
The physiotherapy regimen used in this investigation resulted in a significant reduction in pain associated with plantar fasciitis in both groups observed (main effect for time). In addition, the subjects performing the exercises wearing the Nike Free 5.0 had significantly lower pain scores throughout the study period than the subjects using conventional training shoes (main effect for shoe condition). Because there was not a significant interaction effect across shoe and time, we are unable to statistically report that the FREE group experienced a disproportionate decrease in pain throughout the observation period in this study. However, it is worth mentioning that the main effect for shoe is likely attributed to the trend for lower mean scores reported in the FREE group at the 6- and 12-week points (P values = 0.062 and 0.076 for the mid-point and post-test, respectively) (Figure 2). Over the 12-week period of the study, the CON group showed a 30% reduction in peak pain, whereas the FREE group had a 63% pain reduction. In one case, in which a subject in the FREE group had a previously unsuccessful surgical release of their plantar

Table 1. Overview of Baseline Variables Between Groups

Group	Number of Subjects	Age (μ ± SD)	Weight (μ ± SD)	Height (μ ± SD)	BMI (kg/m^2) (μ ± SD)	Symptom Duration (μ ± SD)
Control (CON)	12	39 ± 8	87 ± 12	170 ± 7	28 ± 9	12 ± 8[a]
Intervention (FREE)	9	42 ± 7	82 ± 18	167 ± 9	29 ± 5	33 ± 44[a]

[a]Represents a significant difference between groups ($P < 0.05$).
Abbreviations: BMI, body mass index; CON, conventional; FREE, Nike Free 5.0; SD, standard deviation.

Figure 2. Graph illustrating relationship between the visual analogue scale item for peak pain in the preceding 24 hours across both shoe conditions over time.



#Indicates a trend for a difference between the two shoe conditions at that time point.
Abbreviation: SD, standard deviation.

fascia, there was an 87% reduction in their pain score (VAS from 74.5–10). The implications of pain relief in a population with longstanding (> 6-month symptom duration) plantar fasciitis are sizeable considering half of our study population was required to stand for > 7 hours per day, which is a risk factor often impeding the success of conservative treatments or resulting in a higher degree of injury recurrence.

Although the Nike Free 5.0 is not considered a strict replica for a barefoot condition, the increased flexibility of the sole may contribute to similar stresses being applied to the foot, particularly from the standpoint of allowing increased range of motion at the forefoot compared with conventional running footwear. As a result of the increase in sole flexibility, the foot could better engage its windlass mechanism during toe-off, resulting in greater strain on the intrinsic soft-tissue structures from an increase in the mechanical work of the foot coupled with greater storage and release of elastic components.[21,22] Increasing load in a controlled setting has been well documented as a successful treatment option for chronic soft-tissue injuries of the Achilles insertion and midportion, infrapatellar, and common elbow extensor tendons.[23–27]

We speculate that the clinical success experienced ultimately in both footwear groups performing the multielement exercise regimen in the present study is a result of 1 or a combination of the following 3 therapeutic effects. Firstly, the static and tissue-specific stretching exercises for the calf and plantar fascia provide a stimulus for increases in flexibility, as well as sustained low levels of stress on the relevant tissues. Both exercises have been proven to increase ankle flexibility and decrease pain in this patient population.[28–30] The second effect comes from a positive tissue remodeling stimulus secondary to the small controlled stresses applied to the plantar intrinsic muscle/tendon/ligament complex through the dynamic range of motion exercises of the foot and ankle. A previous case

report on a directed program of targeted exercises to increase range of motion and progressively increase sport-specific stress on the plantar fascia reported favorable clinical outcomes.[31] Lastly, 2 exercises were aimed at addressing overall posture and balance to minimize postural contributions to loading of the plantar fascia and increased calf tension (secondary to forward sway). Similar balance exercises incorporating semi-compressible foam rollers have shown to significantly improve dynamic balance.[32]

There are several limitations to consider for the present study. An intention-to-treat analysis was not performed, which may be justified in certain circumstances despite the drop outs reported for the following reasons: 1) the baseline values for the pain scores from the excluded subjects were statistically similar to the overall group; 2) the drop outs occurred early in the study before any follow-ups had been conducted; 3) imputation is not justified when missing data would compromise the overall analysis; and 4) the data presented herein are intended to introduce a concept, and should not be interpreted as a definitive trial examining treatment efficacy.[33]

The mechanism(s) behind the treatment effect in this study remain speculative. The results of this investigation would be strengthened by including measures to understand the nature of the treatment effect, such as by documenting isokinetic strength at the talocrural, subtalar, and first metatarsophalangeal joints. Balance or agility testing would determine whether there were reported improvements in standing or dynamic posture. Electromyography of such foot and lower leg muscles as gastrocnemius, soleus, flexor hallucis longus and brevis, peroneus longus/brevis, and flexor digitorum longus/brevis to determine whether the increased forefoot extension range of motion, either alone or in combination with the soft durometer midsole, translates into greater strength and/or activation of relevant muscle groups.

Although the absence of any notable recurrence in pain throughout the population at the 6-month follow-up is promising, ultimately a 12- or 24-month follow-up period is needed to confirm the positive long-term treatment benefit. There is a potential for a treatment bias within the present study because only 1 of the 2 groups investigated received a new shoe, which may be mitigated in future projects by providing both groups with new footwear. However, both groups received the same exercise regimen and the same degree of instruction. While the present study is an introductory approach to quantifying a exercise regimen of this nature, future studies in this area should include additional disease-specific outcome measures, such as the Foot Function Index.[34] Diagnostic imaging via ultrasound or magnetic resonance imaging was not conducted prior to subject enrollment, therefore, we can not be certain of the standardization of disease pathology across our population and, in particular, the presence of heel spur.

From a clinical perspective, the 2 individuals who had dropped out because of an increase in foot pain in the FREE group could represent a potential complication from using a flexible soled shoe in this treatment approach. It appears there may be a significant advantage in terms of responsive pain relief wearing a shoe such as the Nike Free 5.0; however, this should be balanced against the relatively lower risk of their symptoms deteriorating.

Conclusion

The outcomes of the present study report that a 12-week multielement exercise regimen that incorporates static and dynamic stretching and balance exercises significantly improves the pain in patients experiencing chronic plantar fasciitis. Furthermore, it appears that carrying out this exercise regimen wearing shoes with a more flexible sole, such as the Nike Free 5.0 shoe, may result in earlier pain relief than conventional running shoes.

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Conflict of Interest Statement

Michael Ryan, PhD and Jack Taunton, MD, MSc disclose conflicts of interest with Nike, Inc. Scott Fraser, BSc, PT and Kymberly McDonald, BSc disclose no conflicts of interest.

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