

A Prospective Study on Maximalist Athletic Shoes as Part of a Comprehensive Approach to the Medical Management of Early-Stage Plantar Fasciitis

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Abstract

Plantar fasciitis (PF) is the most common musculoskeletal disorder of the foot and has significant impact on quality-of-life. The vast majority of cases respond to conservative treatment, which includes wearing supportive shoes. Highly cushioned, maximalist athletic shoes are thought to reduce stress and strain of impact forces and may suggest a possible benefit in the management of early plantar fasciitis. 38 patients with clinical heel pain and ultrasonographic confirmation of PF (>4.0 mm) were randomized to either a maximalist athletic shoe (HOKA Bondi 6) or standard athletic shoe (New Balance 880v9) in conjunction with standard of care (SOC) for a period of 12 weeks. Pain assessment and ultrasonographic measurements were made pre- and post-treatment. Those who wore maximalist shoes as part of SOC reported a significant decrease ($p=0.003$) in their pain Visual Analog Scores (VAS, mean decrease of 6 points) as compared to standard athletic shoe group (mean VAS decrease 4.12 points). A greater mean decrease in plantar fascia thickness from pre-treatment to post-treatment was observed for the maximalist group (1.46 mm) than the standard group (1.14 mm), but this did not reach statistical significance. 95% of patients randomized to maximalist group reported that the shoes helped in their recovery process, as compared to 76% of patients randomized to standard group. This study tested the effect of highly cushioned maximalist athletic shoes as compared to standard running shoes part of a comprehensive approach to the medical management of plantar fasciitis. We conclude that highly cushioned maximalist athletic shoes, such as the HOKA Bondi 6, may be considered as part of standard of care for management of plantar fasciitis.

Keywords: Plantar fasciitis; Heel pain; Maximalist shoes; Athletic shoes; Hoka

Introduction

Plantar Fasciitis (PF) is the most common musculoskeletal disorder of the foot encountered by healthcare professionals and has significant impact on quality-of-life [1,2]. In the United States, one in ten people will experience complaints associated with plantar fasciitis in their lifetime [3]. While the exact pathology of PF is unknown, repetitive microtrauma associated with persistent load bearing caused by excessive stress at the calcaneal attachment of the plantar fascia has been shown to be a risk factor for heel pain [4-6].

Clinically, patients complain of pain in the plantar medial or central heel, which is worse with the first few steps in the morning or after a period of rest [7]. The pain gradually improves with activity, but then worsens at the end of the day due to increased weight-bearing [8].

Compared to healthy patients, patients with plantar fasciitis (PF) exhibit significant differences in foot kinematics and kinetics. Individuals with PF have a greater total rearfoot eversion and greater maximum 1st metatarsophalangeal joint dorsiflexion, which may create increased load on the fascia and increase pain [9]. Patients with PF compensate through increased contact time of the midfoot and forefoot, increased midfoot and forefoot impulse, delayed time to the mid-stance vertical ground reaction force valley, and decreased peak force at terminal stance [10,11].

Plantar heel pain patients are likely to have a thickened plantar fascia with associated fluid collection and have fascial thickness values >4.0 mm on musculoskeletal ultrasound [12,2]. Histopathologically, patients with chronic PF show changes to the nature of the tissue, with collagen fiber disorientation, mucoid ground substance production, and calcification within the fascia. This prolonged degenerative process

is termed “fasciosis” rather than “fasciitis” [13]. Radiographically, heel spurs are present in approximately 50% of patients with plantar fasciitis, but they do not correlate with symptoms and can also be found in asymptomatic people [14,15].

The vast majority of cases of plantar fasciitis respond to conservative treatment, which address both the mechanical and inflammatory issues. Mechanically, a combination of stretching protocols, activity modifications, rest, foot orthoses, heel cups, heel lifts, strappings, manual physical therapy, and night splints are used. To address inflammation, oral non-steroidal anti-inflammatory medication (NSAIDs), and icing are employed [16-18]. Additional treatment with steroid injections [19], platelet rich plasma injections [20], and shockwave therapy [21] may be used when initial conservative care fails. Surgery is reserved for those patients who are refractory to the above treatments [5].

Viscoelastic heel cushions [22,23] and utilization of running shoe cushioning [4,14,24] has become a standard method for managing impact loading and consequent injuries due to stress and exercise. Footwear manufacturers have customarily classified their shoes by

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their level of stability, namely neutral, stability or motion-control, with degrees of pronation and supination dictating shoe selection. Newer classifications are defined by heel-toe drop, which highlight differences between heel elevation and forefoot elevation of the midsole, expressed as minimalist, traditional/neutral, or maximalist [16]. Minimalist shoes are defined by a highly flexible sole and upper that weighs 200g or less, a heel stack height of 20mm or less and a heel-toe differential of 7mm or less [25]. Traditional shoes have a heel-toe drop less than 10mm [16]. Although there is no standard definition for what constitutes maximalist running shoes [26], there are termed as such because they provide a highly cushioned midsole in both the rearfoot and forefoot, as compared to a traditional running shoe [26,27].

The aim of this study was to determine if maximalist running shoes can be used as part of a comprehensive management protocol for plantar fasciitis, and if it has a measurable impact over standard supportive running shoes.

Materials and Methods

This study was submitted to and approved by the Western Institutional Review Board (#20192587). Informed consent was reviewed and signed by each of the participants, and the rights and privacy of the subjects were protected as per standard protocol. The patient population was comprised of patients over 18 years old who had heel pain for 1-6 months, with a PF width at the plantar medial tubercle of the calcaneus on musculoskeletal ultrasound <4.0 mm [28,29,2]. Exclusion criteria for this study were direct trauma, systemic inflammatory disease, connective tissue disease, lumbar spine disc herniation, suspected history of secondary orthopedic ailments, heel pain lasting over 6 months, and normal musculoskeletal ultrasound findings. The inclusion-exclusion criteria are summarized in Table 1. The patients were randomized using Research Randomizer (www.randomizer.org) into one of two treatment groups: maximalist athletic shoe (HOKA Bondi 6) + standard of care (SOC) or standard athletic shoe (New Balance 880v9) + SOC. The HOKA Bondi 6 are one of the more cushioned road athletic shoes in the HOKA portfolio based on stack height. It has a midsole made of compression molded ethylene-vinyl acetate (EVA) and a rocker design with a curved midsole. Additionally, it has a 4.0 mm heel-to-toe drop. The New Balance 880v9 was chosen as the comparator standard shoe for this study because it has the characteristics of a traditional, sturdy, neutral shoe with a two-layer EVA midsole, moderate cushioning of under 30mm stack height, and a 10mm heel-to-toe drop.

45 patients/48 cases of plantar fasciitis met the criteria to be enrolled in the trial and were randomly assigned to one of the two treatment groups as described above. Study participants were given a voucher for one of the two treatment athletic shoes to be professionally fitted at an athletic shoe store. SOC included home physical therapy stretches, use of a night splint, ice water soaks for 5 minutes nightly, and an oral NSAID such as ibuprofen, naproxen, or meloxicam for 10-14 days. Demographic data, including body mass index (BMI), was assessed at their baseline visit. Higher BMI has been shown to be associated with plantar fascia disease [30]. The study period lasted a total of 12 weeks.

Patients were evaluated clinically at baseline, 6 weeks, and then again at 12 weeks. A pre- and post-treatment musculoskeletal ultrasound of the plantar fascia and pain rating on a Faces visual analog scale was performed at initiation and completion of the trial. Ultrasonography is a cost-effective, point-of-service, non-invasive study that can visualize the thickening of the plantar fascia, hypoechoic changes, and perifascial fluid collections [31-33]. The proximal plantar fascia was assessed with a 12-MHz linear array ultrasound transducer (Butterfly IQ+, Guilford, CT, USA). The thickness of the plantar fascia was measured 1 cm from the proximal end of the fascia near its insertion into the calcaneus (Image 1). All ultrasound imaging and interpretation were performed by the senior author (RF).

Of the group that was randomized to standard comparator + SOC, three patients discontinued intervention due to severe pain, and a steroid injection was administered. Of the group that was randomized to maximalist shoes + SOC, four participants did not receive allocated intervention due to COVID-19 restrictions; one participant was lost to follow up due to hospital admission for a respiratory infection; and two patients discontinued intervention due to fit issues with the shoes. A summary of the clinical trial design is presented in Figure 1.

Demographic variables collected included sex, laterality of the plantar fasciitis, age, and BMI. Outcome measures collected included pre- and post- treatment ultrasound measurement of plantar fascia thickness, pre- and post-treatment VAS pain scores, and asking patients if they thought that the shoes helped in the management of their plantar fasciitis. All survey response variables were reported as n (%) for categorical data and mean ± standard deviation for numerical data. P-values were derived from Welch two sample t-test for comparison of continuous variables or Fisher's Exact Test for fraction of cases reporting benefit from shoes.

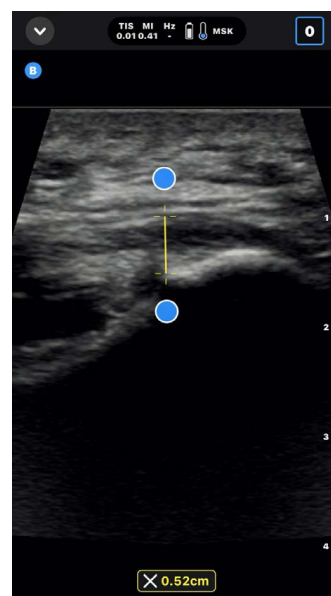


Image 1: Measuring PF thickness and quality on ultrasound.

Table 1: Inclusion/Exclusion Criteria.

INCLUSION	EXCLUSION
i. Age >18	i. direct trauma
ii. Unilateral heel pain for 1-6 months	ii. systemic inflammatory disease,
iii. PF diagnosed on musculoskeletal ultrasound as >4.0mm	iii. connective tissue disease,
	iv. lumbar spine disc herniation suspected history of secondary orthopedic ailments
	v. heel pain >6 months,
	vi. normal MSK U/S findings

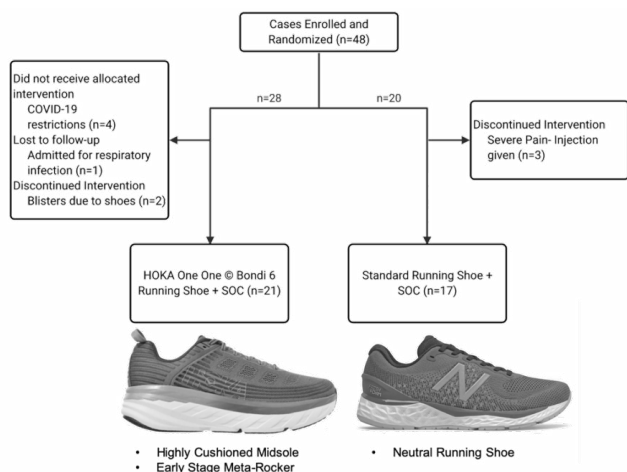


Figure 1: Trial Design. Summary of participation throughout the study (n = number of plantar fasciitis cases). HOKA Shoe shown is the HOKA Bondi 6. Standard athletic shoe shown is New Balance 880v9. Participants were randomized to either intervention in combination with standard-of-care management.

Table 2: Demographics, expressed as n (%) or as the average ± SD.

	HOKA	New Balance
	n (%) or average	± SD
Sex		
Female	12 (57%)	12 (71%)
Male	9 (43%)	5 (29%)
Laterality		
Left	11 (52%)	9 (53%)
Right	10 (48%)	8 (47%)
Age	51.8 ± 10.7	49.5 ± 16.6
BMI	26.5 ± 4.84	31.6 ± 7.33

Table 3: Outcome Measures. Measures are reported as n (%) or as the average ± SD. P- values were derived from Welch's two sample t test for continuous data or Fisher's Exact Test for fraction of cases reporting benefit from shoes. (U/S: ultrasound; VAS: Visual Analog Scale).

	HOKA	New Balance	p-value
	n (%) or average ± SD		
Pre-Treatment U/S	5.65 ± 1.04	5.73 ± 1.14	0.831
Post-Treatment U/S	4.20 ± 0.890	4.59 ± 0.859	0.171
Decrease in U/S	1.46 ± 0.879	1.14 ± 1.01	0.309
Pre-VAS	7.38 ± 1.50	7.94 ± 1.20	0.209
Post-VAS	1.38 ± 1.36	3.82 ± 1.70	0.00004
Decrease in VAS	6.00 ± 1.87	4.12 ± 1.80	0.003
Shoes Helped	20 (95%)	13 (76%)	0.152

Results

Demographic distribution of sex, laterality, age, and BMI were roughly equal in both experimental groups, as shown in Table 2. Outcome measures were also reported for each experimental group (Table 3). While a greater mean decrease in plantar fascia thickness from pre-treatment to post-treatment was observed for the maximalist treatment group (1.46 mm) than the standard comparator group (1.14 mm), this difference did not reach statistical significance (Figure 2). However, the decrease in the pain VAS scores from pre-treatment to post-treatment was statistically significant (Figure 3). Patients who were randomized to the maximalist shoes + SOC reported an average improvement in their pain VAS scores by 6 points, whereas the patients who were randomized to the standard running shoes + SOC only reported pain improvement by an average of 4.12 points (p=0.003).

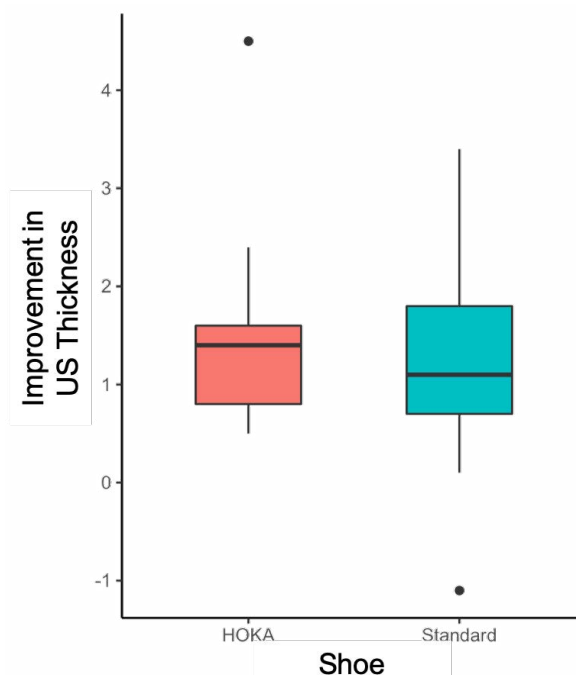


Figure 2: Box plot of ultrasound (U/S) thickness improvement. Comparison of decrease in U/S thickness from measured baseline between HOKA and New Balance running shoes, measure in millimeters. Paired Welch's t-test: p-value = 0.309.

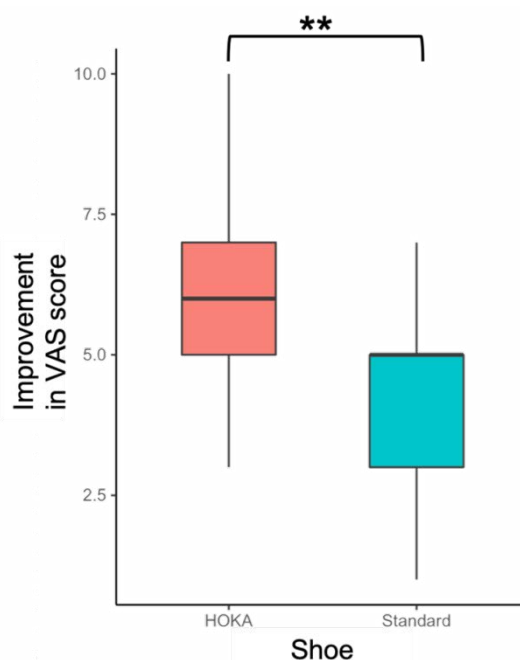


Figure 3: Box plot of visual analog scale (VAS) pain score improvement, assessed on a scale of 1-10. Comparison of decrease in VAS score from reported baseline between HOKA and New Balance running shoes. Paired Welch's t-test: p-value=0.003.

Additionally, 95% of patients randomized to maximalist shoes reported that the shoes helped in their recovery process, as compared to 76% of patients randomized to standard athletic shoes (Figure 4).

Discussion

This study looked at the effect of highly cushioned maximalist

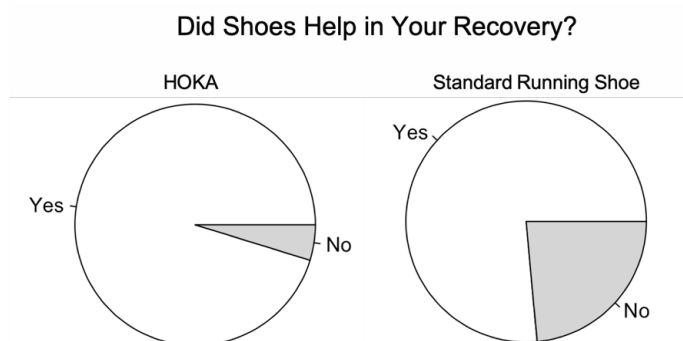


Figure 4: Pie charts of patient-reported benefit from shoes. Comparison of perceived shoe helpfulness between HOKA and New Balance athletic shoes. Fisher's Exact test: p-value=0.152.

athletic shoes as part of a comprehensive approach to the medical management of plantar fasciitis. The presented results fill an important knowledge gap, demonstrating that, within the conditions of this study, wearing highly cushioned maximalist athletic shoes relieved patients' plantar fasciitis pain.

Patients in both treatment groups were predominantly female, around 50 years old, and overweight to obese, with no bias for laterality of the impacted foot. This aligns with the risk factors of plantar fasciitis in the normal population [6].

Harutaichun et al [31] studied the differences in lower-extremity kinematics between male military personnel with and without plantar fasciitis. They found that the plantar fasciitis group showed significant differences in motion in the multi-segment foot, ankle, knee, and hip from the control group during various subphases of the stance phase.

The patients who wore HOKA Bondi 6 shoes in addition to receiving SOC reported a significant decrease in their pain VAS scores compared to the control group ($p=0.003$). The highly cushioned midsole in both the rearfoot and forefoot of maximalist shoes appears to play a meaningful role in managing impact loading and relieving pressure off the plantar fascia in a way which more effectively reduced pain than traditional athletic shoes.

In addition, most patients reported belief that shoes comprised a valuable part of their foot health in the recovery from plantar fasciitis, as patients in 87% of all cases reported that shoes helped in their recovery process, with 95% of cases reporting that the HOKA shoes helped and 76% reporting that standard athletic shoes helped.

Changing thickness of the plantar fascia has been shown to be a valid objective measurement to assess the effectiveness of a new or existing treatment protocol [28,26]. In our study, the decrease in thickness of the plantar fascia as assessed by ultrasound from pre-treatment to post-treatment showed no statistically significant difference between the two groups. However, the data does show a trend toward greater reduction in thickness among the HOKA shoe group. A power analysis was performed to estimate required sample size to confirm statistical significance of the observed effect in a potential follow-up study. Taking the difference in observed mean of the two groups as a constant effect size, it would require a minimum sample of 138 patients in each group to see a statistically significant p-value (assessed at $p \leq .05$, Cohen's $d \leq 0.80$).

Hannigan and Pollard [26] compared the vertical ground-reaction force and ankle kinematics between maximalist and traditional shoes before and after a 6-week acclimation period to the maximalist shoe. They determined that running shoes did not change running

biomechanics, as average vertical loading rate and vertical impact peak of the vertical ground-reaction force were still elevated as compared to a traditional shoe after this period. Our study evaluated the outcome of shoe selection in addition to SOC for active plantar fasciitis in a general population and did not select out sedentary versus active participants. Running and walking mechanics differ, especially in those with a known musculoskeletal painful condition, and may account for the differences between these studies. Ogden [34] compared minimalist and maximalist cushioned running shoes and found statistically significant decreases in all plantar loading variables under the total foot and forefoot in the maximalist shoe when compared to a minimalist shoe [35-37].

Limitations of our study included the fact that blinding was not possible due to logo on the shoes, which may influence patient's reporting of subjective measurements. There are numerous multifactorial etiologies for plantar fasciitis. We attempted to limit the study group via the inclusion/exclusion criteria listed in Table 1, but undoubtedly, there were additional unknown causes of PF that were not able to be selected out in this study. The study also used a comparator running shoe to serve as a control. There was an expectation that patients in the standard running shoe + SOC group would improve, and that using a comparator shoe was not a "true control." The study team attempted to reduce potential bias by ensuring both treatment groups received SOC in addition to the assigned shoe intervention. It was expected that both groups would improve with SOC, and that statistical measurements would be able to delineate if there was a difference between groups. This was a single site study with a relatively small sample size ($n=38$ analyzed) and can be repeated in a larger scale multi-site clinical trial to maximize enrollment. The lead investigator performed the ultrasound measurements, and was not blinded to the treatment group, which may introduce additional bias.

Despite the limitations of our investigation, we believe that the results of this study could be useful to help facilitate future addition of highly cushioned maximalist athletic shoes to mitigate plantar fasciitis pain as part of a comprehensive approach to the medical management of plantar fasciitis.

We present here a comparative study on the effect of highly cushioned maximalist athletic shoes as part of a comprehensive approach to the medical management of plantar fasciitis. The patients in this trial who wore maximalist shoes in addition to receiving SOC for plantar fasciitis reported a significant decrease in their pain VAS scores over the control group. These findings could be built upon in a large-scale clinical trial to assess if the observed improvement in ultrasound-measured plantar fascia width is statistically significant as well, as our sample size was too small to accurately assess that difference. Nevertheless, the observed improvement in reported pain indicates that highly cushioned athletic shoes, such as Hoka Bondi 6, may be considered as an added intervention for noninvasive pain treatment of early-stage plantar fasciitis.

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