

Comparative Trial of the Foot Pressure Patterns between Corrective Orthotics, Formthotics, Bone Spur Pads and Flat Insoles in Patients with Chronic Plantar Fasciitis

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Abstract

Introduction: The objective of the study is to compare the efficacy of flat insoles, bone spur pads, pre-fabricated orthotics and customised orthotics in reducing plantar contact pressure of subjects with plantar fasciitis. **Materials and Methods:** This is a controlled non-blinded comparative study conducted in a tertiary medical institute. Thirty subjects with unilateral plantar fasciitis between the ages of 20 and 65 years were recruited at the sports medicine clinic. The contact pressures and pressure distribution patterns in both feet for each subject were measured with sensor pressure mats while standing. Repeat measurements were made with the subjects wearing shoes, flat insoles, bone spur heel pads, pre-fabricated insoles and customised orthotics on both feet. The asymptomatic side was used as the control. Contact pressure measurements of the symptomatic and asymptomatic feet and power ratio of the pressure distribution pattern of the rearfoot were then compared. **Results:** Contact pressure was higher on the asymptomatic side due to unequal distribution of weight. Bone spur heel pads were ineffective in reducing rearfoot pressure while formthotics and customised orthotics reduced peak rearfoot pressures significantly. The power ratio of the rearfoot region decreased with the use of formthotics and customised orthotics. **Conclusion:** Pre-fabricated orthotics and customised orthotics reduced rearfoot peak forces on both sides while bone spurs heel pad increase rearfoot peak pressures. Pre-fabricated and customised orthotics are useful in distributing pressure uniformly over the rearfoot region.

Ann Acad Med Singapore 2009;38:869-75

Key words: Biomechanics, Heel pain

Introduction

Plantar fasciitis accounts for an estimated one million visits per year to the doctor in the United States,¹ and makes up approximately 25% of all foot injuries in runners.² Although the majority of the cases resolve within 10 months, 10% develop chronic plantar fasciitis.³ The pathomechanics of plantar fasciitis is assumed to be due to excessive tensile loading, exacerbated by abnormal biomechanics of the legs such as pes planus, leg length discrepancy, and tightness of calf muscles.^{4,5}

Treatment includes rest, anti-inflammatory medication, shoe inserts, night splints, stretching, iontophoresis,

corticosteroid injections, extracorporeal shockwave therapy and surgery. There is no evidence that any specific mode of treatment is particularly effective.⁶

Orthotics is thought to relieve symptoms by reducing strain in the fascia.^{7,8} While this has been borne out in cadaveric studies,^{9,10} the clinical efficacy of orthotics can vary.

Plantar fasciitis may result when the plantar fascia enthesis fail to adapt to compressive, bending or shearing forces¹¹ rather than tensile forces as suggested by Warren.¹² Thus orthoses that reduce compressive loads on the plantar fascia may address the root cause of plantar fasciitis.

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Materials and Methods

Recruitment

Thirty subjects between the ages of 20 and 65 years old diagnosed with plantar fasciitis at the Changi Sports Medicine Centre (CSMC) were included. Diagnosis was based on a combination of history, clinical findings (pain upon palpation of the calcaneal tuberosity with reproduction of symptoms) and ultrasonographic findings (thickening of the plantar fascia >4mm or thickness of >2mm difference from the contra-lateral side).^{13,14} Those with a history of inflammatory arthritis, heel pain due to other conditions, e.g. fat pad syndrome, bilateral plantar fasciitis or previous surgical release^{15,16} were excluded. Assessment of the condition (patient biobata, level of habitual physical activity, occupation and previous corticosteroid injection) was performed using a standardised protocol. The severity of pain was measured using a 10 point Visual Analogue Scale (VAS) (Fig. 1). The functional limitation was categorised on the Roles and Maudsley Scale, which has been validated in previous studies on plantar fasciitis.^{17,18}

The patients were fitted with customised orthotics manufactured by a podiatric laboratory in Biolab, Australia, (Fig. 2) and consisted of a semi-rigid acrylic orthotic shell and a firm foam heel post applied inferiorly to the rearfoot region. A plantar fascia aperture was milled into the orthotic at the heel region for the symptomatic side, and a plantar fascia accommodative groove was milled into the shell of the orthotic.

Data Acquisition

Recordings were taken using sensor mats that were

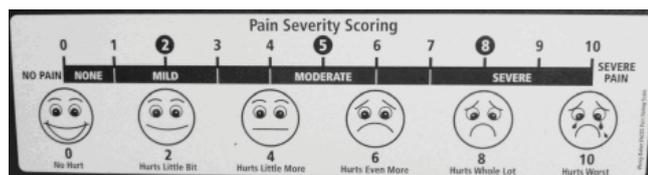


Fig. 1. Visual analogue scale



Fig. 2. Picture of insoles. From left to right: flat insoles, bone spurs heel pad, formthotics and customised orthotics with heel aperture.

trimmed to size, with the patients wearing shoes without insoles, with flat insoles, with bone spur pads, with formthotics and lastly with orthotic insoles for the symptomatic foot. The measurements were repeated for the asymptomatic side as controls. The choice of insoles was based on prescription practises of podiatric physicians.¹⁹

The formthotics were prefabricated full length firm-density polyethylene foam inserts (Foot Science International, Christchurch, New Zealand) made with sufficient thickness to fill the arch area and support for the medial longitudinal arch of the foot. The bone spur pads (Brown Medical Industries, Spirit Lake, Iowa) were constructed of viscoelastic polymer and were designed with indented areas to alleviate high pressure over the calcaneus as shown in Figure 2. The flat insoles were 6 mm soft (120 kg/mm²) ethyl vinyl acetate foam inserts with no additional cushioning.

The pressure sensor system collects pressure information using pressure sensors and renders the data as “movie” in a real time window. Each sensor consists of 954 resistive sensing elements arranged in a rectangular grid with a spatial density of 4 elements per cm². The software used was the Research Foot Version 5.24 by Tekscan, USA.

Before each recording was taken, the subjects were asked to walk approximately 20 steps to get accustomed to the insoles. They were then asked to localise the pain they experience. The location of the pain was correlated with the high-pressure zones shown on the pressure map. To minimise bias, patients were not informed of the specific area of interest in the pressure measurements and were instructed to adopt the most natural stance when measurements were taken. Measurements were taken with the subjects standing still with their feet shoulder-width apart and looking at a fixed point on a wall.

The foot pressure scans were converted to greyscale and cropped down to the fixed area in the heel. The cropped images were processed in MATLAB where Fast Fourier Transformation (FFT) was performed. This shows the relative strengths of frequencies in the image data and the highest frequency power were selected for analysis. The power ratio (proportion of the highest frequency power to the total power of the image) was one of the parameters extracted.

Outcome Measures

The outcome measures, nominated a priori were:

Total Peak Pressure	(N/cm ²)
Forefoot Peak Pressure	(N/cm ²)
Rearfoot Peak Pressure	(N/cm ²)
Total Plantar Force	(N)

Forefoot Plantar Force Percentage	(%)
Rearfoot Plantar Force Percentage	(%)
Total Contact Area	(cm ²)
Forefoot Contact Area Percentage	(%)
Rearfoot Contact Area Percentage	(%)
Power ratio heel area of the affected foot	

The outcome measures were analysed according to a pre-planned protocol. The data collected from the feet with plantar fasciitis as well as that for the asymptomatic sides were grouped (shown below) and the mean values calculated and subjected to the Analysis of Variance (ANOVA) Test, with the threshold for statistical significance set at $P < 0.05$.

- Group A – Contact pressure without insoles
- Group B – Contact pressure with flat insoles
- Group C – Contact pressure with bone spur pads
- Group D – Contact pressure with formthotics
- Group E – Contact pressure with orthotic insoles

We determined the sample size of 30 prior to conducting the trial. The sample size provides a 90% probability of detecting an effect between the different insoles of 1.0 N/cm². The sample size calculation assumed a standard deviation (SD) of 5.00 N/cm². Comparisons were pain between orthotic devices of the same side as well as between the symptomatic and asymptomatic limbs.

Results

Thirty subjects were recruited. The distribution of subjects according to gender and the Roles and Maudsley Score are shown in Tables 1 and 2, respectively, with approximately equal distribution between both genders. The average VAS score of the subjects on presentation was 5.94 ± 1.6 out of a maximum of 10. The majority of the subjects fell into categories 3 and 4 (Fig. 3). The level of habitual activity was categorised (Table 3) and the results are displayed below in Figure 4.

The occupation of the subjects with plantar fasciitis is displayed in Figure 5 with half engaging in regular physical activity. Of these, 41.0% has had previous cortisone injections to treat their plantar fasciitis. The duration of symptoms at the point of presentation was 31.3 weeks (1 to 144). The subjects were also assessed for their foot type during static stance and categorised into neutral, low medial arch or high medial arches, the results of which are represented in Figure 6.

The average plantar fascia thickness was $5.88 \text{ mm} \pm 1.30$ on the affected side versus $3.86 \text{ mm} \pm 1.25$ on the contra-lateral side. The contact pressure measurements for the

asymptomatic foot and the side with plantar fasciitis are summarised below in Tables 4 and 5, respectively.

Of the 10 outcome measures, all except the total plantar force were found to be statistically significant, with a confidence level of more than 95%.

The rearfoot peak pressure value is almost similar to the total peak pressure value (Table 5). The predilection to distribute the body weight onto the heels may be a contributing factor in the pathogenesis of the disease. This is at odds with other studies, which show that regional loading of the foot remain unaltered in plantar fasciitis.²⁰⁻²³ The total forces on the symptomatic side are significantly lower than the asymptomatic side for all groups. This may be due to subjects preferentially distributing more of the weight to the painless side while standing. This would also account for the higher peak forces at both forefoot and rear

Table 1. Range of Age, Gender, Height, Weight and Body Mass Index (BMI) in Subjects with Plantar Fasciitis

	Male subjects with plantar fasciitis	Female subjects with plantar fasciitis
Age (y)	53.31 ± 6.24	32.43 ± 7.86
Gender	16 (53.3%)	14 (46.7%)
Height (m)	1.608 ± 0.034	1.655 ± 0.102
Weight (kg)	68.55 ± 16.4	75.79 ± 18.8
BMI	26.15 ± 4.03	27.49 ± 5.03

Table 2. Roles and Maudsley Score

Score	Definition	Description
1	Excellent	No pain, full movement and full activity.
2	Good	Occasional discomfort, full movement and full activity.
3	Fair	Some discomfort after prolonged activity, need for further treatment.
4	Poor	Pain limiting activities, need further treatment.

Table 3. Habitual Physical Activity

Classification	Description
Sedentary	No participation in exercise or physical activity of at least 20 minutes per occasion.
Occasional exercise	Participation in any form of exercise or physical activity of at least 20 minutes per occasion, for less than thrice a week.
Regular exercise	Participation in any form of exercise or physical activity of at least 20 minutes per occasion, for at least thrice a week.

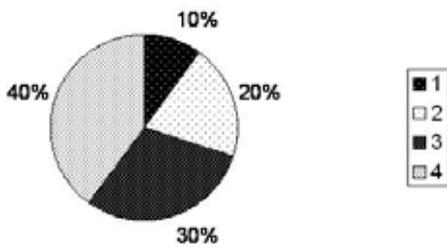


Fig. 3. Pie chart on the Roles and Maudsley Score.

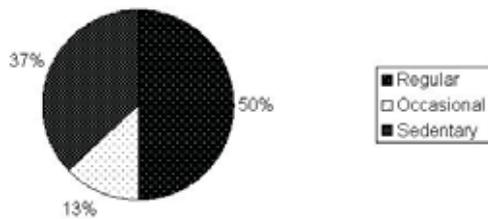


Fig. 4. Pie chart on habitual physical activity.

foot across all orthoses on the asymptomatic side versus the symptomatic sides.

When comparing between devices within each side, the rearfoot peak pressures with bone spur pads were marginally lower when compared to that when wearing shoes without insoles and higher than that when wearing flat insoles (Tables 4 and 5). The contact area percentage was also lowest when wearing the bone spurs pad. Unlike the other inserts, the bone spur pads were not full length inserts and cushions only the calcaneal region, thus reducing the contact area. The bone spur pads do not offer any support to the medial longitudinal arch of the foot and thus cannot reduce tensile forces on the plantar fascia. While the bone spur pad is soft, it compresses upon vertical loading. As a result, the pressure remains concentrated at the heel region. This might explain why heel pads have been ranked the least effective of 11 treatments for plantar fasciitis.²⁴

Compared to measurements without shoe inserts, rearfoot peak pressure with the other shoes inserts is lower, with the largest decrease seen in the use of formthotics and customised orthotics for both the symptomatic and asymptomatic sides. The contoured nature of the formthotics and customised orthotics provide greater contact area with the sole, allowing plantar forces to be more evenly distributed and resulting in lower peak rearfoot pressure. The percentage rearfoot contact area is highest for both sides with the customised orthotics followed by the formthotics. The inserts also offer support to the medial longitudinal arch thus reducing fascia tension especially for those with low-arch feet.^{25, 26}

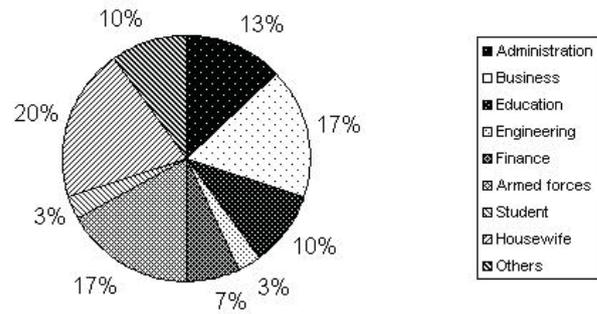


Fig. 5. Distribution of subjects with plantar fasciitis according to occupation.

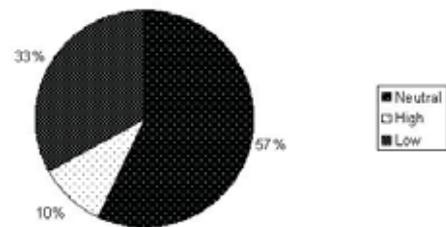


Fig. 6. Distribution of the subjects with plantar fasciitis according to foot types.

When comparing the power ratio of the rearfoot between similar devices (formthotics and customised orthotics) between sides (Tables 6), the ratio is lower on the symptomatic side, consistent with the lower peak foot pressures on the symptomatic side. Comparison between devices on the same side reflects a trend similar to that of peak rearfoot pressure with the lowest values seen in the formthotics and customised orthotics.

The power ratio is the ratio of the highest frequency power (corresponding to high-pressure areas) over the total power and represents the amount of variation in the greyscale images of the contact pressure measurements. Hence, reduction in the power ratio denotes a more uniform distribution of load in the high pressure regions of the rearfoot.

Discussion

The plantar fascia arises predominantly from the medial process of the calcaneal tuberosity and attaches distally, through several slips, to the plantar surface of the forefoot form.²⁷ It is divided into 3 bands, namely: medial, lateral and central, the latter of which is the major component.

Recent histological studies suggest that the plantar fascia is histologically distinct from tendons and ligaments.^{28, 29} Plantar fasciitis involves predominantly the proximal insertion of the aponeurosis (entheses)^{30, 31} The entheses consist of 4 zones: dense fibrous collagenous tissue, uncalcified fibrocartilage, calcified fibrocartilage and

Table 4. Results of Statistical Analysis of Contact of Foot Pressure Parameters of the Asymptomatic Foot

	Without insoles	With flat insoles	With bone spur pads	With formthotics	With orthotics	<i>P</i>
Total peak pressure value (N/cm ²)	12.004 ± 6.96	10.963 ± 5.48	12.588 ± 7.01	8.759 ± 3.03	7.704 ± 2.70	0.0075
Forefoot peak pressure value (N/cm ²)	5.775 ± 2.90	6.729 ± 7.79	6.767 ± 3.51	4.467 ± 3.03	4.021 ± 1.83	0.091
Rearfoot peak pressure value (N/cm ²)	11.433 ± 7.27	10.608 ± 5.74	11.708 ± 7.24	8.158 ± 3.11	7.504 ± 2.83	0.026
Total plantar force (n)	370.44 ± 131	370.46 ± 141	348.32 ± 131	332 ± 127	321.32 ± 129	0.61
Forefoot plantar force percentage (%)	29.252 ± 16.5	29.49 ± 16.1	34.965 ± 19.1	22.407 ± 17.7	23.843 ± 14.0	0.079
Rearfoot plantar force percentage (%)	70.888 ± 16.7	70.505 ± 16.1	64.952 ± 19.1	77.636 ± 17.7	76.158 ± 14.0	0.076
Forefoot plantar force (N)	111.08 ± 86.6	113.79 ± 87.3	126.00 ± 102	83.741 ± 89.6	79.768 ± 70.4	0.29
Rearfoot plantar force (N)	259.77 ± 105	256.64 ± 110	222.32 ± 111	248.29 ± 88.2	241.55 ± 99.9	0.73
Total contact area (cm ²)	94.473 ± 28.1	101.39 ± 30.1	83.817 ± 26.9	97.921 ± 29.8	102.84 ± 29.1	0.05
Forefoot contact area percentage (%)	40.638 ± 9.48	40.061 ± 9.91	45.513 ± 11.3	30.955 ± 14.3	33.083 ± 11.5	<0.0001
Rearfoot contact area percentage (%)	59.354 ± 9.48	59.958 ± 9.94	54.515 ± 11.3	69.002 ± 14.3	66.915 ± 11.5	0.0001

bone.^{32,33} The prevalence of fibrocartilage insertions in areas which experience stress in more than one degree of freedom³⁴⁻³⁶ suggests that entheses are specifically adapted to shearing and bending forces. The presence of fibrocartilage in greater quantities in the deep surface of tendon insertion³⁶ and the high concentrations of proteoglycans and glycosaminoglycans within fibrocartilage entheses^{11,37} suggest that the enthesis plays a role in redistribution of compressive forces. This suggests a role in shear, bending and compressive forces in the pathogenesis of plantar fasciitis.

The pathogenesis of plantar fasciitis is not well understood. There is no compelling histological evidence of inflammation; rather degenerative changes predominate.³⁶ Hence, plantar fasciitis may well represent fascial degeneration^{30,38} similar to a tendinopathy. In particular, the fibrocartilage enthesis is prone to degenerative changes^{39,40} such as cartilage fissuring and ossification, typically involving the deep fibres.^{40,41} The bone spurs may represent an attempt of the body to buttress bending forces at the deep fibres rather than a result of excessive traction.

While the aetiology of plantar fasciitis is multifactorial, mechanical overloading is thought to be an important factor. Orthoses are commonly thought to exert their therapeutic effect by reducing these tensile forces.^{7,8} However, systemic reviews have shown the effectiveness of orthoses in the treatment of plantar fasciitis to be poor.⁴² This may be

due to their failure to address compressive forces rather than their inefficacy in relieving plantar fascia strain. Our current study demonstrates that the customised orthotics as well as pre-fabricated insole is effective in reducing peak rearfoot contact pressure. In addition, the lower power ratio in the heel region of the symptomatic side denotes a more uniform distribution of pressure over the rearfoot region avoiding areas of high pressure which can compress upon the enthesis. This is particularly important in view of the current finding of elevated rearfoot pressure in subjects with plantar fasciitis with forces in the rearfoot approaching that of peak total pressure.

There are some limitations to our study. Firstly, the study design allows us to make only biomechanical inferences which are valid only for the static weight-bearing. It does not account for forces that are generated in dynamic situations. Further biomechanical studies with subjects engaged in walking and running will be necessary to elucidate the differences in force attenuation by different orthotic devices would be necessary. The clinical efficacy of the orthotics with the rearfoot aperture needs to be validated with another prospective trial against sham orthotics. Be that as it may, the current design may be of particular use in patients whose occupation entails extended periods of standing. Extrapolation of the data to real life condition must also take into account local social customs. For instance, 20% of the subjects were housewives where the efficacy of orthoses

Table 5. Results of Statistical Analysis of Contact of Foot Pressure Parameters of the Symptomatic Foot

	Without insoles	With flat insoles	With bone spur pads	With formthotics	With orthotics	P
Total peak pressure value (N/cm ²)	10.779 ± 3.94	10.308 ± 2.58	11.300 ± 2.63	8.429 ± 1.97	7.688 ± 2.00	>0.0001
Forefoot peak pressure value (N/cm ²)	5.7208 ± 2.63	5.667 ± 2.35	6.558 ± 3.13	4.271 ± 2.44	3.867 ± 1.76	0.0013
Rearfoot peak pressure value (N/cm ²)	10.358 ± 4.15	9.738 ± 3.26	10.450 ± 3.25	7.900 ± 2.36	7.300 ± 2.40	0.0008
Total plantar force (N)	352.75 ± 126	354.69 ± 133	325.56 ± 101	308.37 ± 105	311.08 ± 99.9	0.46
Forefoot plantar force percentage (%)	30.682 ± 17.0	31.803 ± 18.2	36.367 ± 19.2	23.912 ± 19.9	22.954 ± 16.5	0.063
Rearfoot plantar force percentage (%)	69.323 ± 17.0	69.773 ± 19.1	63.633 ± 19.2	76.088 ± 19.9	77.048 ± 16.5	0.08
Forefoot plantar force (N)	109.83 ± 80.4	118.75 ± 87.2	121.23 ± 80.0	76.997 ± 72.9	75.335 ± 65.7	0.095
Rearfoot plantar force (N)	242.90 ± 98.9	239.69 ± 94.2	204.33 ± 81.1	231.38 ± 87.8	235.75 ± 76.7	0.57
Total contact area (cm ²)	93.267 ± 24.5	102.73 ± 27.9	82.291 ± 25.2	95.678 ± 25.2	102.06 ± 28.6	0.05
Forefoot contact area percentage (%)	40.553 ± 11.5	40.148 ± 10.7	47.909 ± 10.3	32.008 ± 15.9	31.484 ± 13.3	>0.0001
Rearfoot contact area percentage (%)	59.408 ± 11.4	59.853 ± 10.7	52.902 ± 10.1	67.990 ± 15.9	68.513 ± 13.3	>0.0001

Table 6. Results of the Power Ratio of Greyscale Images of Rearfoot Pressure Measurements for the Asymptomatic Foot

	Without insoles	With flat insoles	With heel pads	With formthotics	With orthotics	P
Symptomatic side	1.585 ± 1.16	1.237 ± 0.972	1.357 ± 0.509	1.199 ± 0.560	1.094 ± 0.350	0.23
Asymptomatic side	1.769 ± 1.14	1.323 ± 1.15	1.589 ± 0.669	1.291 ± 0.753	1.119 ± 0.430	0.086

may be limited in our local context where it is customary to omit footwear at home. Similarly, differences between prevailing sartorial norms of the different genders, e.g. the habitual use of high heel shoes may have subtly influenced the static stance and hence the pressure measurements.

Due to the protracted nature of the condition in which the majority of the patients taking up to 10 months to recover and with 10% of them developing chronic disease, orthotics can still fill a useful role in the physician's armamentarium in the temporary relief of symptoms.³ The current study provides a biomechanical rationale for the efficacy of customised and pre-fabricated orthotics in the treatment of plantar fasciitis seen in previous studies.

Acknowledgement

The authors like to thank Ms Tan Peck Ha, Senior Lecturer of the School of Biomedical Engineering, for her invaluable guidance in obtaining the pressure measurements for the subjects in this study.

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