Elsevier Editorial System(tm) for Clinical Biomechanics Manuscript Draft

Manuscript Number: CLBI-D-12-00182R2

Title: Evaluation of combined prescription of rocker sole shoes and custom-made foot orthoses for the treatment of plantar fasciitis

Article Type: Research Paper

Keywords: plantar fasciitis, rehabilitation, shoes

Corresponding Author: Prof Daniel Tik-Pui Fong, BSc, MSc, PhD

Corresponding Author's Institution: The Chinese University of Hong Kong

First Author: Daniel Tik-Pui Fong, BSc, MSc, PhD

Order of Authors: Daniel Tik-Pui Fong, BSc, MSc, PhD; Kai-Yip Pang; Mandy Chung; Aaron Hung; Kai-Ming Chan

Abstract: Background: It is a routine practice to prescribe a combination of rocker shoes and custom-made foot orthoses for patients with plantar fasciitis. Recently, there has been a debate on this practice, and studies have shown that the individual prescription of rocker shoes or custom-made foot orthoses is effective in treating plantar fasciitis. The aim of this study was to evaluate and compare the immediate therapeutic effects of individually prescribed rocker sole shoes and custom-made foot orthoses, and a combined prescription of them on plantar fasciitis.

Methods: This was a cross-over study. Fifteen patients with unilateral plantar fasciitis were recruited; they were from both genders and aged between 40 and 65. Subjects performed walking trials which consisted of one 'unshod' condition and four 'shod' conditions while wearing baseline shoes, rocker shoes, baseline shoes with foot orthotics, and rocker shoes with foot orthotics. The study outcome measures were the immediate heel pain intensity levels as reflected by visual analogue scale pain ratings and the corresponding dynamic plantar pressure redistribution patterns as evaluated by a pressure insole system. Results: The results showed that a combination of rocker shoes and foot orthoses produced a significantly lower visual analogue scale pain score (9.7 mm) than rocker shoes (30.9 mm) and foot orthoses (29.5 mm). With regard to baseline shoes, it also significantly reduced the greatest amount of medial heel peak pressure (-33.58%) without overloading other plantar regions when compared to rocker shoes (-7.99%) and foot orthoses (-28.82%).

Discussion: The findings indicate that a combined prescription of rocker sole shoes and custom-made foot orthoses had greater immediate therapeutic effects compared to when each treatment had been individually prescribed.

Cover letter

Dear editor,

REF: Submission of manuscript "Evaluation of combined prescription of rocker sole shoes and custom-made foot orthoses for the treatment of plantar fasciitis"

The authors would like to submit this paper as a "Research Paper". We declare that each author were fully involved in the study and preparation of the manuscript and that the material within has not been and will not be submitted for publication elsewhere. None of the authors has any commercial relationships which may lead to a conflict of interest.

For corresponding please contact Prof Daniel Tik-Pui Fong at Department of Orthopaedics and Traumatology, Faculty of Medicine, The Chinese University of Hong Kong, Hong Kong, China. (email: dfong@ort.cuhk.edu.hk)

Best regards
Kai-Yip Pang
Daniel Fong
Mandy Man-Ling Chung
Aaron See-Long Hung
Kai-Ming Chan

12th March 2012

Reviewers' comments:

Reviewer #1:

The authors have put considerable efforts in answering the questions. I still feel that the article needs edition by an English (native) speaker.

Thank you for your comments. This paper has been submitted to our university's academic editor for professional editing. An acknowledgement has also been added in Line 26-28.

With respect to the scientific value of the manuscript, I have no major remarks. Below you will find some final (minor) remarks which should be addressed in order to increase the readability of the paper.

Line 44-48: To my opinion the methods part is still not adequately organized and lacks good English vocabulary.

Thank you for your comments. We have reorganized the methods (Line 44-51) and also submitted the paper to our university's academic editor for professional editing.

Line 199: The authors have still not given an adequate definition of Peak Pressure (PP). Is the PP defined as the maximum pressure in the area considering the sensor with the peak value or making the sum of all sensors in the selected area. This is a critical point as FO will alter dramatically the contact area. Moreover, the fact that the authors are using pressure related parameters, it is imperative to mention the dimensions of the sensors.

The peak pressure is defined as the maximum pressure measured in any one sensor within the masked regions. Therefore, it is not the sum of all the sensors in the selected area.

The Novel Pedar system was used in our study. Each pair of Pedar insole was selected according to the subject's shoe size. In each Pedar insole, there are 84-99 embedded sensors. Further technical data of the insoles were obtained from the manufacturer and are shown below.

This information is added in Line 198-206.

Technical data

insole sizes	22 to 49 (european)
sensor thickness (mm)	1.9
thickness of leads	1.5
number of sensors	84 - 99
pressure range (kPa)	15 - 600
hysteresis (%)	< 7
resolution (kPa)	2.5
offset temperature drift (kPa/K)	< 0.5
frequency response (0-100 Hz)	< 2dB
min. bending radius (mm)	20
pressure change due bending (kPa)	< 20

Figure 1: Impossible to evaluate the added value of this table as poor readability due to resolution problems.

Sorry for the trouble. The figure has very good resolution when we downloaded the high resolution image from the generated pdf file. To further improve the figure quality, we have separated the single figure into five separate graphs.

Table 1: It is uncommon to provide not only the mean and standard deviation for specific demographic parameters but also the range. Normally, adequate selection of descriptive statistical parameters should reduce the amount of data.

We have removed the range from Table 1.

1	<u>Title Page</u>
2	Title:
3	Evaluation of combined prescription of rocker sole shoes and custom-made foot
4	orthoses for the treatment of plantar fasciitis
5	
6	Authors:
7	Daniel Tik-Pui FONG, ^{1,2} Kai-Yip PANG, ^{1,2} Mandy Man-Ling CHUNG, ^{1,2} Aaron
8	See-Long HUNG, 1,2 Kai-Ming CHAN 1,2
9	
10	Affiliation:
11	¹ Department of Orthopaedics and Traumatology, Prince of Wales Hospital, Faculty
12	of Medicine, The Chinese University of Hong Kong, Hong Kong, China.
13	² The Hong Kong Jockey Club Sports Medicine and Health Sciences Centre, Faculty
14	of Medicine, The Chinese University of Hong Kong, Hong Kong, China.
15	
16	Corresponding author:
17	Dr Daniel Tik-Pui FONG
18	Email: dfong@ort.cuhk.edu.hk
19	Phone: (852) 2632 3535
20	Fax: (852) 2646 3020
21	Address: Department of Orthopaedics and Traumatology, Prince of Wales Hospital,
22	Faculty of Medicine, The Chinese University of Hong Kong, Hong Kong, CHINA.
23	
24	Acknowledgements:
25	This research project was made possible by resources donated by The Hong Kong
26	Jockey Club Charities Trust. The authors sincerely thank Dr. David John
27	Wilmshurst, Academic Editor of the Research Administration Office of The Chinese
28	University of Hong Kong, for the effort in English proofreading.
29	
30	Keywords: plantar fasciitis; rehabilitation; shoes
31	
32	Word count: 271 (abstract); 3,439 (main text)
33	
34	No. of Figures: 1
35	
36	No. of Tables: 4
27	
37	

Abstract

38

39 Background: It is a routine practice to prescribe a combination of rocker shoes and 40 custom-made foot orthoses for patients with plantar fasciitis. Recently, there has 41 been a debate on this practice, and studies have shown that the individual prescription of rocker shoes or custom-made foot orthoses is effective in treating 42 43 plantar fasciitis. The aim of this study was to evaluate and compare the immediate 44 therapeutic effects of individually prescribed rocker sole shoes and custom-made 45 foot orthoses, and a combined prescription of them on plantar fasciitis. 46 Methods: This was a cross-over study. Fifteen patients with unilateral plantar 47 fasciitis were recruited; they were from both genders and aged between 40 and 65. 48 Subjects performed walking trials which consisted of one 'unshod' condition and 49 four 'shod' conditions while wearing baseline shoes, rocker shoes, baseline shoes 50 with foot orthotics, and rocker shoes with foot orthotics. The study outcome 51 measures were the immediate heel pain intensity levels as reflected by visual 52 analogue scale pain ratings and the corresponding dynamic plantar pressure 53 redistribution patterns as evaluated by a pressure insole system. Results: The results 54 showed that a combination of rocker shoes and foot orthoses produced a significantly lower visual analogue scale pain score (9.7 mm) than rocker shoes 55 56 (30.9 mm) and foot orthoses (29.5 mm). With regard to baseline shoes, it also significantly reduced the greatest amount of medial heel peak pressure (-33.58%)

without overloading other plantar regions when compared to rocker shoes (-7.99%)

and foot orthoses (-28.82%).

60 Discussion: The findings indicate that a combined prescription of rocker sole shoes

and custom-made foot orthoses had greater immediate therapeutic effects compared

to when each treatment had been individually prescribed.

Introduction

Plantar fasciitis is a musculoskeletal overuse disorder with high prevalence. It affects people irrespective of gender, age, ethnicity, or physical activity (Singh *et al.*, 1997). It has been estimated that about 10% of the population, particularly those aged between 40 and 65 years, are affected at some time during their lives (Riddle *et al.*, 2004; Taunton *et al.*, 2002). Plantar fasciitis is characterized by localized pain or tenderness under the medial heel during palpation or weight-bearing, and it results in the limitation of physical activity (Tisdel *et al.*, 1999). To date, the etiology of plantar fasciitis is still poorly understood, and it remains unknown in approximately 85% of cases (Schepssis *et al.*, 1991). The literature suggests that its risk factors are multi-factorial, and they can be categorized as environmental, anatomical, and mechanical. Risk factors hitherto identified include a decreased ankle joint range of

77 motion, obesity, and occupations that require prolonged standing (Riddle *et al.*, 78 2003).

79

80

81

82

83

84

85

86

87

88

89

90

91

92

93

94

There is no single universally accepted method for treating plantar fasciitis. The condition frequently responds to a wide range of conservative treatments that demonstrate variable levels of efficacy from 46% to 98% (Tisdel et al., 1999; Schepssis et al., 1991; Crawford & Thomson, 2003; Lynch et al., 1998; Wolgin et al., 1994). Many studies have, however, indicated a higher success rate with mechanical therapies than with other conservative forms and their efficacy is usually greater than 70% (Lynch et al., 1998; Wolgin et al., 1994; Martin et al., 2001; Walter et al., 2004). Over the years, there has been an extensive debate regarding the most effective form of mechanical treatment. Rocker shoes and Custom-made Foot Orthoses (FO), known as pedorthic devices, have frequently been advocated to manage the mechanical factors which precipitate the development of plantar fasciitis. It has been a routine practice to prescribe them in combination (Hutchins et al., 2009; Janisse & Janisse, 2008). However, the justification for this was based on the phenomena of subjective pain relief and symptom resolution. To date, scientific evidence to confirm these observations is equivocal.

95

Rocker shoes, which are a type of therapeutic footwear with an external modification of the outsole contour (Hutchins et al., 2009), are routinely prescribed to relieve the high-pressure plantar regions of the foot (Brown et al., 2004). The shoes' basic clinical function is to 'rock' the foot from heel-strike to toe-off, thus altering the motion and the force distribution patterns (Schie et al., 2000). A variety of designs accommodating different pathological needs are available. Three of the most commonly prescribed rocker soles are the toe-only, negative heel, and double rocker (Janisse & Janisse, 2008). Previous investigations have consistently demonstrated that prescribing rocker shoes on their own (i.e., without the inclusion of FO) could reduce the heel pressure by 10% to 30% (Brown et al., 2004; Schie et al., 2000; Praet & Louwerens, 2003) without adversely the affecting ambulatory ability (Long et al., 2004; Myers et al., 2006; Van Bogart et al., 2005). Its average efficacy on plantar fasciitis treatment ranged from 59% to 72% (Hutchins et al., 2009). The literature has not verified whether the inclusion of custom-made FOs could be a further enhancement of the rocker shoes' intrinsic offloading functions.

111

112

113

114

96

97

98

99

100

101

102

103

104

105

106

107

108

109

110

Despite the development of custom-made FOs, the functional approach is still firmly established as the paradigm of design and fabrication in the field of podiatry (Root, 1994). It emphasizes the importance of dynamic interrelationships between the foot

joints during gait. The biomechanical principles in which FO works have remained contentious (Pratt, 2000). However, custom-made FOs have been extensively shown to have favorable therapeutic outcomes for plantar fasciitis on their own in non-rocker shoes (Crawford & Thomson, 2003; Lynch *et al.*, 1998; Walter *et al.*, 2004). The average efficacy ranged from 50% to 70% with a 20% to 30% reduction of medial heel pressure (Lynch *et al.*, 1998; Martin *et al.*, 2001; Pratt, 2000; Roos *et al.*, 2006; Landorf & Keenan, 2000). To date, there has been no quantitative study to characterize the offloading property of FO in rocker shoes.

Conclusively, the individual prescription of rocker shoes and custom-made FOs has been shown to be effective in treating plantar fasciitis. It is critical to quantitatively justify their continued combined prescription in order to prevent the delivery of an item which is of insignificant benefit to patients. Therefore, the purpose of this study has been to explore the combined therapeutic effect of rocker shoes and custom-made FOs on plantar fasciitis.

Methods

132 Subjects

A power analysis with a power of 0.8 and an α of 0.05 justified 15 subjects would be

sufficient to show a significant pressure reduction of 30%. This effect size was based on previous study findings of rocker sole shoes on pressure relief at the medial heel region (Brown *et al.*, 2004; Praet & Louwerens, 2003) and on the assumption of clinically meaningful change for patients to experience pain relief (Farrar *et al.*, 2000; Williamson & Hoggart, 2005). Written informed consent was obtained from all subjects before their admission to the study. Ethical approval was obtained from the Joint Chinese University of Hong Kong (New Territories East Cluster) Clinical Research Ethics Committee.

Fifteen Chinese patients (3 males, 12 females) with chief complaints of unilateral plantar fasciitis (6 rights, 9 lefts) were recruited from a private pedorthic clinic during their first visit over 2.5 months. Their demographics are presented in Table 1.

The subject inclusion criteria were: (1) being aged between 40 and 65 years old (Riddle *et al.*, 2004; Taunton *et al.*, 2002); (2) being referred by orthopaedic doctors as having a confirmed diagnosis of plantar fasciitis; (3) having a persistent complaint of plantar heel pain during ambulation and on the day of data collection; (4) exhibiting abnormal foot pronation; and (5) having the ability of independent non-aided heel—toe walking and being able to follow verbal instructions. Subjects

were excluded if they had a history or physical findings of: (1) traumatic injury in the last six months; (2) previous plantar fascia surgery; (3) heel pain of neural origin, fat pad atrophy and bursitis; (4) other associated pain at back, knee, or ankle and foot affecting ambulation; and (5) biomechanical conditions contra-indicated either for FO or rocker shoes (Long *et al.*, 2004; Myers *et al.*, 2006; Van Bogart *et al.*, 2005).

Materials

Each subject was well-fitted by the same certified pedorthist with two pairs of testing shoes (baseline shoes, rocker sole shoes) and two pairs of testing inserts (flat insoles, custom-made FOs). The baseline shoes were of an ordinary healthy style. The rocker shoes were similar in all aspects to the baseline shoes except that the sole was designed with a toe-only rocker profile. In accordance with the recommendations of Schie *et al.* (2000), the rocker angle was 15° and the rocker axis was positioned at 60% and oriented at 80° to the long axis of the shoes. Flat insoles were made of 3-mm poron covered with a layer of fabric. Custom-made FOs, in the Rootian functional approach, were fabricated by the Ezped Foot Orthotic CAD/CAM System (Hong Kong) which was associated with a 3-D laser scanner. It was an exact replication of a plaster technique by which a pair of 3-D electronic

casts in a non-weightbearing subtalar neutral position was captured and rectified (Table 2). All FOs were prescribed in 3-mm polypropylene topped with 3-mm poron and fabric cover. Both testing inserts were fabricated by a foot orthotic laboratory in Hong Kong which was accredited by the Prescription Foot Orthotic Laboratory Association (PFOLA) in the USA.

Experiment

This was a cross-over study in which every subject performed walking trials in each of the five test conditions. These conditions consisted of: (1) an 'unshod' condition (barefoot), and four 'shod' conditions using (2) Baseline Shoes with flat Insoles (BSI), (3) Baseline Shoes with custom-made foot Orthoses (BSO), (4) Rocker Shoes with flat Insoles (RSI), and (5) Rocker Shoes with custom-made foot Orthoses (RSO). A cross-over design was chosen in order to minimize the within-group variability and to lower the subject attrition; this was because these could potentially create errors in the study.

The study outcome measurements were the ratings of medial heel pain intensity associated with plantar fasciitis at the first step and during gait reflected by the visual analogue scale (VAS) and their corresponding dynamic plantar pressure

redistribution evaluated by a pair of pressure insoles (Novel Pedar System, Germany). Both the VAS pain score and plantar pressure insoles were well documented as being valid and reliable for clinical pain rating (Williamson & Hoggart, 2005; Bijur *et al.*, 2001) and shoe–foot interface plantar pressure evaluation (Putti *et al.*, 2007). Similar outcome measures have been used in other plantar fasciitis studies (Wearing *et al.*, 2003; Wearing *et al.*, 2007).

Measurement

The VAS pain score questionnaire was administered immediately after each test condition (Dixon & Bird, 1981; Williamson & Hoggart, 2005). Each subject was asked to make the respective marks on the same questionnaire to minimize the variability of VAS scoring for repeated measures (Rosier *et al.*, 2002; Scott & Huskisson, 1979). The VAS pain score has been shown to be linear with ratio properties (Price *et al.*, 1983), and thus it is statistically robust for parametric statistical analysis if the distribution of data is Normal or transformable to Normal (Dexter & Chestnut, 1995). The dynamic variation of bipedal plantar pressure distributions of all 'shod' conditions was used to supplement the objectivity of the VAS pain ratings. There were 99-sensors embedded in each insole which recorded data at a sampling rate of 100 Hz. Each insole was divided into 10 anatomical regions, which were automatically masked by the system as medial heel (M01).

lateral heel (M02), medial mid-foot (M03), lateral mid-foot (M04), 1st metatarsal head (M05), 2nd and 3rd metatarsal heads (M06), lateral metatarsal heads (M07), hallux (M08), 2nd and 3rd toes (M09) and lateral toes (M10). Peak plantar pressure was evaluated in each region during the stance phase. The peak plantar pressure is defined as the maximum pressure measured by any one sensor within the masked regions.

Test Protocol

All data for a given subject were collected on the same day. Each subject performed three heel—toe walking trials for each test condition on a 6-meter long, straight, carpet-covered linoleum concrete walkway. Because plantar pressure and perceived pain intensity are associated with the walking speeds (Willson & Kernozek, 1999), the subjects were instructed to walk naturally at their own self-selected speeds. Consistency of walking speed was monitored in all trials by counting the time required for six steps (Brown *et al.*, 1996). A trial was discarded if the walking was not performed in a smooth natural gait, in a straight line, or with inconsistent speeds.

The evaluation always began with an unshod walking condition followed by four shod walking conditions in a randomized sequence outputted by a random-number

generator program. All participants were blinded for the test conditions which were prepared in a separate room. Between successive test conditions, the subjects were given: (1) a five-minutes rest, extended on request, in order to avoid the pain being aggravated during tests and carried over to the next test condition; (2) the VAS pain level questionnaire immediately after each test condition; and (3) sufficient practice walking trials to become accustomed to the next test condition at the desired speed before data capture.

<u>Analysis</u>

The recordings of all walking trials were displayed, processed, edited and analyzed by the associated software (Novel Pedar System, Germany). To negate the acceleration and deceleration effects, the data of the first step and the last step of each trial of the involved side were trimmed out. Four sequential steps were then selected and their peak pressures during stance were averaged in each of the 10 anatomical regions. Data from all trials, all test conditions, and all subjects were pooled together for statistical analysis.

For both VAS-immediate pain ratings and pressure data, if the Shapiro-Wilk normality test was passed, repeated measures one-way ANOVA with Bonferroni

correction post-hoc pairwise comparisons was conducted to explore any significant difference (p < 0.05) between the test conditions. Otherwise, non-parametric Friedman one-way ANOVA was employed. All statistical tests were conducted by SPSS 16 with significance level at p < 0.05.

Results

The self-selected walking speed of the subjects ranged from 96 to 120 steps per minute. The p-values of the Shapiro-Wilk normality test of all data sets of VAS-immediate pain ratings and regional peak pressures in all test conditions were greater than 0.05. This indicated that the parametric statistical analyses were eligible. The percentage changes of the VAS-immediate pain ratings, with respect to barefoot walking, of the four 'shod' conditions and the results of repeated measures one-way ANOVA with Bonferroni correction post-hoc pairwise comparisons are shown in Table 3.

Descriptive statistics and the results of repeated measures one-way ANOVA and Bonferroni corrected post-hoc test on peak pressures for each of the 10 anatomical regions in four shod conditions are shown in Table 4. It was found that, except in the region of the 2nd and 3rd toes, the rest of the other nine regions demonstrated a

significant difference in peak pressures between the four shod conditions. With respect to BSI, the percentage changes of peak pressures for each of the 10 anatomical regions in RSI, BSO, and RSO are compared graphically in Figure 1.

Discussion

In this study, the immediate therapeutic effects on plantar fasciitis among rocker shoes, FO and a combination thereof were evaluated and compared. Clinically, it was more accurate to use a percentage reduction in the VAS pain ratings (rather than the raw changes) as a means of comparing treatment (Williamson & Hoggart, 2005). It was verified that a 33% reduction was a clinically meaningful change for patients to experience pain relief (Farrar *et al.*, 2000). The immediate reduction of pain intensities of RSI, BSO, and RSO were found respectively to be 52.5%, 54.6%, and 85.1% with respect to barefoot walking. All three reductions were greater than 33%; however, RSO got a further 30% reduction in pain intensity compared to BSO and RSI. Critically, statistical findings indicate that rocker shoes combined with FOs produce significantly greater immediate pain relief in the medial heel than individual prescription of rocker shoes and FOs.

As a mechanical treatment in plantar fasciitis, it was expected that the pedorthic

device could relieve overloads or undesirable pressures at the medial heel during gait and, in turn, reduce the pain associated with plantar fasciitis. For the peak pressures at medial heel, their means were 145.81, 112.80, and 105.25 kPa for RSI, BSO, and RSO, respectively. The combination of rocker shoes and FOs demonstrated significantly greater offloading in medial heel pressure than when rocker shoes and FOs are used separately. The results of the VAS pain ratings were objectively supported by peak pressure data.

The only difference between baseline shoes and rocker shoes was their outsole profiles. Comparative analysis on the patterns of dynamic regional peak pressure was therefore conducted to explore the plantar pressure redistribution behavior of the rocker soles. The findings revealed a significant reduction in peak pressures across the forefoot and medial heel regions. Such consistent reductions were then balanced by elevated plantar pressure in the mid-foot. This observation was in agreement with previous studies (Hutchins *et al.*, 2009). However, it was noted that the rocker shoes were more effective in reducing pressure in the forefoot than in the heel. The significant decreases of forefoot pressure ranged approximately from 13% to 25%, whereas there was only an 8% decrease in medial heel pressure. In the literature, heel pressure reductions generally ranged from 10% to 30% (Brown *et al.*,

2004; Long et al., 2004; Myers et al., 2006; Van Bogart et al., 2005). However, direct comparisons in terms of pressure values were not reliable because of two fundamental reasons. Firstly, the design of rocker sole profiles employed in previous studies varied considerably in the rocker angles. Secondly, subjects in most of the previous studies were either asymptomatic or diabetic neuropathic individuals who were all pain-free. Therefore, the values so obtained were not representative. It was a merit of this study to recruit subjects whose demographics most reflect those that are commonly referred for pedorthic treatment (Taunton et al., 2002). Furthermore, it should be noted that the current findings highlight profound pressure elevation across the mid-foot after rocker shoes had been prescribed. This has important clinical implications for future rocker shoes prescription; this is because it may be a potential source of irritation or even pain particularly for patients who suffer from mid-foot pathologies.

318

319

320

321

322

323

305

306

307

308

309

310

311

312

313

314

315

316

317

By comparing the dynamic regional peak pressures between BSO and BSI, the effects of the inclusion of FOs on the redistribution of the shoe—foot interface plantar pressure were examined. The results demonstrated that the FOs used in this study were able to significantly reduce the medial heel pressure by 28.82%. This finding is comparable to those in previous studies, which demonstrated a reduction in medial

heel pressure from 20% to 30% (Pratt, 2000; Roos et al., 2006; Kandorf & Keenan, 2000). In contrast to a rocker sole acting as a powerful forefoot offloader, FOs worked as a strong heel offloader. FOs significantly reduced medial heel and lateral heel pressure by nearly 30% and 28%, whereas the rocker sole reduced it by only 8% and 5%. Another fundamental difference between their behaviors was the strategy of pressure redistribution at mid-foot. A rocker sole demonstrated significant pressure increases of 18.5% and 14.4% at medial mid-foot and lateral mid-foot, respectively. Conversely, FOs decreased medial mid-foot and lateral mid-food pressure significantly by 15.1% and 19.4%; this was because of the increased contact area of mid-foot via the custom-casted contour of the orthotics (Kogler et al., 1996). Thus, rocker soles and FOs possessed their own strengths and drawbacks in accordance with their pressure redistribution behaviors. Rocker soles reduced the pressures in the heel and forefoot by redistributing the pressure to mid-foot, thereby potentially overloading that region. On the other hand, FOs reduced the pressure at mid-foot by redistributing the pressure to the forefoot, and this may potentially cause forefoot overloads.

340

341

342

324

325

326

327

328

329

330

331

332

333

334

335

336

337

338

339

The comparative analysis of regional peak pressure between RSO and BSI was equivalent to characterizing the interactive redistribution behavior of rocker soles

and FOs in combination. To date, the literature has focused chiefly on the interaction of FOs and medical shoes, which were non-rocker-soled, on the plantar pressure distribution of diabetic patients with or without neuropathy (Ashry *et al.*, 1997; Lord & Hosein, 1994; Lotta *et al.*, 2007; Tsung *et al.*, 2004).

The study findings reveal that RSO served as a powerful offloader both of the heel and the forefoot pressure during gait. As compared to rocker behavior, RSO was a stronger forefoot offloader with less risk of mid-foot overloads when compared to a rocker sole acting alone. Referring to orthotics behavior, further decreases in forefoot pressure would likely be caused by the effects from FO. In other words, the rocker behavior of RSO was enhanced because of theinclusion of the FO. As compared to orthotics behavior, RSO reduced more pressure at the heel than FO. Similarly, referring to the rocker behavior, such a decrease could be the contribution of the rocker shoes. Due to presence of a rocker sole, RSO acted as a stronger heel offloader than when FO was used alone. At the same time, a satisfactory redistribution of forefoot pressure was possible.

In conclusion, these findings suggest that the RSO utilized the pressure redistribution benefits both of the rocker sole and FO. The rocker sole reduced

forefoot plantar pressure by redistributing the plantar pressure to the mid-foot, which was reduced by the FO. Insignificant pressure difference across the mid-foot was thus elucidated. Additional studies should be conducted on the details of their interactive biomechanics.

Only the immediate effect of a combination of rocker shoes and FOs was evaluated by using a subjective VAS pain score. Because of the meaningful findings, further studies on its efficacy in the treatment of plantar fasciitis are justified. In future studies, randomized controlled trials should also be conducted to assess the long-term effects of the combined prescription of rocker sole shoe and custom-made FO.

Conclusion

The statistical results show that the combination of rocker shoes and FOs produce a significantly lower VAS pain score (9.7 mm) than rocker shoes (30.9 mm) and FOs (29.5 mm). With respect to baseline shoes, it also significantly reduced the greatest amount of medial heel peak pressure (-33.58%) without overloading other plantar regions when compared to rocker shoes (-7.99%) and FOs (-28.82%). RSO was a safer mechanical modality of plantar fasciitis. Therefore, the practice of combined

prescription of custom-made FOs and rocker sole shoes was justified to provide greater immediate therapeutic effects on plantar fasciitis.

383
384

References

386

- 387 Ashry, H.R., Lavery, L.A., Murdoch, D.P., Frolich, M., & Lavery, D.C.
- 388 Effectiveness of diabetic insoles to reduce foot pressures. J. Foot Ankle Surg.
- 389 1997; 36: 268–271.
- 390 Bijur, P.E., Silver, W., & Gallagher, E.J. Reliability of the visual analog scale for
- measurement of acute pain. Acad. Emerg. Med. 2001; 8: 1153–7.
- 392 Brown, D., Wertsch, J.J., Harris, G.F., & Klein, J. Effect of rocker soles on plantar
- 393 pressures. Arch Phys. Med. Rehabil. 2004; 85: 81–6.
- 394 Brown, M., Rudicel, S., & Esquenazi, A. Measurement of dynamic pressures at the
- shoe-foot interface during normal walking with various foot orthoses. Foot
- 396 Ankle Int. 1996; (3): 152–6.
- 397 Crawford, F. & Thomson, T. Interventions for treating plantar heel pain (review).
- 398 *The Cochrane Database Syst. Rev.* 2003; (3): CD000416.
- 399 Dexter, F. & Chestnut, D.H. Analysis of statistical tests to compare visual analog
- scale measurement among groups. *Anesthesiology*. 1995; 82: 892–902.
- 401 Dixon, J.S. & Bird, H.A. Reproducibility along 10-cm vertical visual analogue scale.
- 402 Ann. of the Rheum. Dis. 1981; 40(1): 87–9.
- 403 Farrar, J.T., Portenoy, R.K., Berlin, J.A., Kinman, J.L., & Strom, B.L. Defining the
- clinically important difference in pain outcome measures. *Pain*. 2000; 88:

- 405 287–94.
- 406 Hutchins, S., Bowker, P., Geary, N., & Richards, J. The biomechanics and clinical
- 407 efficacy of footwear adapted with rocker profiles: evidence in literature. *The*
- 408 Foot. 2009; 19(3): 165–70.
- Janisse, D.J. & Janisse, E. Shoe modification and the use of orthoses in the treatment
- of foot and ankle pathology. J. Am. Acad. Orthop. Surg. 2008; 16(3): 152–8.
- 411 Kogler, G.F., Solomonidis, S.E., & Paul, J.P. Biomechanics of longitudinal arch
- 412 support mechanism in foot orthoses and their effect on plantar aponeurosis
- 413 strain. Clin. Biomech. 1996; 11: 243–52.
- Landorf, K.B. & Keenan, A.-M. Efficacy of foot orthoses: what does the literature
- 415 tell us? J. Am. Podiatr. Med. Assoc. 2000; 90(3): 149–58.
- 416 Long, J.T., Sirota, N., Klein, J.P., Wertsch, J.J., Janisse, D., & Harris, G.F.
- Biomechanics of the double rocker sole shoe: gait kinematics and kinetics.
- 418 Conf. Proc. IEEE Eng. Med. Biol. Soc. 2004; 7: 5107–10.
- 419 Lord, M. & Hosein, R. Pressure redistribution by molded inserts in diabetic footwear:
- 420 a pilot study. J. Rehabil. Res. Dev. 1994; 31(3): 214–21.
- Lotta, D.J., Hastings, M.K., Commean, P.K., Smith, K.E., & Mueller, M.J. Effect of
- Footwear and Orthotic Devices on Stress Reduction and Soft Tissue Strain of
- the Neuropathic Foot. Clin Biomech. (Bristol, Avon) 2007; 22(3): 352–9.

- Lynch, D.M., Goforth, W.P., Martin, J.E., Odom, R.D., Preece, C.K., & Kotter, M.W.
- Conservative treatment of plantar fasciitis: a prospective study. *J. Am. Podiatr.*
- 426 *Med. Assoc.* 1998; 88(8): 375–80.
- 427 Martin, J.E., Hosch, J.C., Goforth, W.P., Murff, R.T., Lynch, D.M., & Odom, R.D.
- 428 Mechanical treatment of plantar fasciitis: a prospective study. J. Am. Podiatr.
- 429 *Med. Assoc.* 2001; 91(2): 55–62.
- 430 Myers, K.A., Long, J.T., Klein, J.P., Wertsch, J.J., Janisse, D.J., & Harris, G.F.
- Biomechanical implications of the negative heel rocker sole shoe: gait
- kinematics and kinetics. *Gait Posture*. 2006; 24(3): 323–30.
- 433 Praet, S.F. & Louwerens, J.W. The influence of shoe design on plantar pressures in
- 434 neuropathic feet. *Diabetes Care*. 2003; 26(2): 441–5.
- 435 Pratt, D.J. A critical review of the literature of foot orthoses. J. Am. Podiatr. Med.
- 436 *Assoc.* 2000; 90(7): 339–41.
- 437 Price, D.D., McGrath, P.A., Rafii, A., & Buckingham, B. The validation of visual
- analogue scales as ratio scale measures for chronic and experimental pain. *Pain*.
- 439 1983; 17: 45–56.
- Putti, A.B., Arnold, G.P., Cochrane, L., & Abboud, R.J. The Pedar in-shoe system:
- repeatability and normal pressure values. *Gait Posture*. 2007; 25: 401–5.
- Riddle, D.L., Pulisic, M., Pidcoe, P., & Johnson, R.E. Risk factors for plantar

- fasciitis: a matched case-control study. J. Bone Joint Surg. Am. 2003; 85-A:
- 444 872–7. (Erratum in: *J. Bone Joint Surg. Am.* 2003; 85-A: 1338)
- 445 Riddle, D.L., Pulisic, M., & Sparrow, K. Impact of demographic and
- impairment-related variables on disability associated with plantar fasciitis. Foot
- 447 *Ankle Int.* 2004; 25: 311–7.
- Roos, E., Engstrom, M., & Soderberg, B. Foot orthoses for the treatment of plantar
- 449 fasciitis. Foot Ankle Int. 2006; 27(8): 606–11.
- Root, M.L. Development of the functional orthosis. Clin. Podiatr. Med. Surg. 1994;
- 451 11(2): 183–210.
- Rosier, E.M., Iadarola, M.J., & Coghill, R.C. Reproducibility of pain measurement
- and pain perception. *Pain*. 2002; 98: 205–16.
- 454 Schepssis, A.A., Leach, R.E., & Gorzyca, J. Plantar fasciitis: etiology, treatment,
- surgical results, and review of the literature. Clin. Orthop. Relat. Res. 1991;
- 456 266: 185–97.
- 457 Schie, C.V., Ulbrecht, J.S., Becker, M.B., & Cavanagh, P.R. Design criteria for rigid
- 458 rocker shoes. Foot Ankle Int. 2000; 21(10): 833–44.
- 459 Scott, J. & Huskisson, E.C. Accuracy of subjective measurements made with or
- without previous scores: an important source of error in serial measurement of
- 461 subjective states. *Ann. Rheum. Dis.* 1979; 38: 558–9.

- Singh, D., Angel, J., Bentley, G., & Trevino, S.G. Fortnightly review: Plantar fasciitis.
- 463 *BMJ*. 1997; 315: 172–5.
- Taunton, J.E., Ryan, M.B., Clement, D.B., McKenzie, D.C., Lloyd-Smith, D.R., &
- Zumbo, B.D. Plantar fasciitis: a retrospective analysis of 267 cases. *Phys. Ther.*
- 466 *Sport.* 2002; 3(2): 57–65.
- Tisdel, C.L., Donley, B.G., & Sferra, J.J. Diagnosing and treating plantar fasciitis: a
- 468 conservative approach to plantar heel pain. Clin. J. Med. 1999; 66(4): 231–5.
- Tsung, B.Y.S., Zhang, M., Mak, A.F.T., & Wong, M.W.N. Effectiveness of insoles
- on plantar pressure redistribution. J. Rehabil. Res. Dev. 2004; 41: 767–74.
- 471 Van Bogart, J.J., Long, J.T., Klein, J.P., Wertsch, J.J., Janisse, D.J., & Harris, G.F.
- Effects of the toe-only rocker on gait kinematics and kinetics in able-bodied
- 473 persons. *IEEE Trans. Neural Syst. Rehabil. Eng.* 2005; 13(4): 542–50.
- Walter, J.H., Ng, G., & Stoltz, J.J. A patient satisfaction survey on prescription
- custom-molded foot orthoses. J. Am. Podiatr. Med. Assoc. 2004; 94(4): 363–7.
- Wearing, S.C., Smeathers, J.E., Sullivan, P.M., Yates, B., Urry, S.R., & Dubois, P.
- 477 Plantar fasciitis: are pain and fascial thickness associated with arch shape and
- 478 loading? Phys. Ther. 2007; 87(8): 1002–8.
- Wearing, S.C., Smeathers, J.E., & Urry, S.R. The effect of plantar fasciitis on
- vertical foot-ground reaction force. Clin. Orthop. Relat. Res. 2003; 409:

481 175-85. Williamson, A. & Hoggart, B. Pain: a review of three commonly used pain rating 482 scales. J. Clin. Nurs. 2005; 14: 798-804. 483 Willson, J.D. & Kernozek, T.W. Plantar loading and cadence alterations with fatigue. 484 Med. Sci. Sports Exer. 1999; 31(12): 1828-33. 485 Wolgin, M., Cook, C., & Graham, C. Conservaative treatment of plantar heel pain: 486 long term follow-up. Foot Ankle Int. 1994; 15(3): 97–102. 487 488 489

Figure and Table Legends

490

- 491 Figure 1a—e: Dynamic plantar pressure redistribution between test conditions. BSI:
- Baseline shoes with flat insoles; RSI: Rocker shoes with flat insoles; BSO: Baseline
- shoes with custom-made foot orthoses; RSO: Rocker shoes with custom-made foot
- orthoses. (M01: Medial heel, M02: Lateral heel, M03: Medial mid-foot, M04:
- 495 Lateral mid-foot, M05: 1st Metatarsal head, M06: 2nd and 3rd Metatarsal heads,
- 496 M07: Lateral metatarsal head, M08: Hallux, M09: 2nd and 3rd Toes, M10: Lateral
- 497 toes.) * = statistical significant difference with p < 0.05.
- Table 1: Subjects demographics of the study
- Table 2: The standard of cast rectification
- Table 3: VAS-immediate pain ratings of the test conditions
- Table 4: Dynamic regional peak pressure (kPa) of the 'shod' conditions

Table 1: Subjects demographics of the study

	Mean (S.D.)
Age (yr)	50.6 (5.3)
Weight (kg)	64.3 (24.9)
Height (cm)	158.7 (7.2)
Shoe size (Eur)	38.2 (2.5)
Duration of symptoms (months)	11.0 (2.5)

Table 2: The standard of cast rectification

Type of rectification	Standard	
Medial addition	2-mm	
Lateral expansion	3-mm	
Heel cup height	Posterior:13-mm	
	Medial: 13-mm	
	Lateral: 13-mm	
Extrinsic rearfoot posting	Up to the level of sustantaculum tali	
(EVA: 80)		
Intrinsic forefoot posting	5-mm and 3-mm beyond the 1 st and 5 th	
	metatarsophangeal joints respectively	

Table 3: VAS-immediate pain ratings of the test conditions

Test Conditions ^a	est Conditions ^a Mean S.D.		% $\Delta VAS_{(barefoot)}^{b}$ Statistical analysis p -value ^c		Bonferroni ^d	
BF	65.0	15.57		< 0.05	BF>A, BF>B, BF>C, BF>D	
(A) BSI	49.1	11.19	24.5	< 0.05	A>B, A>C, A>D	
(B) RSI	30.9	11.30	52.5	< 0.05	B>D	
(C) BSO	29.5	13.63	54.6	< 0.05	C>D	
(D) RSO	9.7	6.10	85.1			

^a BF = Barefoot; (A) BSI = Baseline shoes; (B) RSI = Rocker shoes; (C) BSO = Baseline shoes with FO; (D) RSO = Rocker shoes with FO

 $^{^{\}rm b}$ % $\Delta {\rm VAS}$ (barefoot): percentage change of VAS pain rating compared with barefoot

^c Repeated measures one-way ANOVA test of the test conditions

 $^{^{}d}Results \ of \ Bonferroni \ corrected \ post \ hoc \ test \ showing \ significant \ difference \ between \ conditions \ with \ p < 0.05$

Table 4: Dynamic regional peak pressure (kPa) of the 'shod' conditions

Anatomical Regions	(A) BSI (SD)	(B) RSI (SD)	(C) BSO (SD)	(D) RSO (SD)	Statistical analysis p-value ^b	Bonferroni ^c
M01 Medial Heel	158.47 (31.80)	145.81 (28.85)	112.80 (24.77)	105.25 (21.40)	< 0.05	A>B, A>C, A>D, B>C, B>D, C>D
M02 Lateral Heel	182.90 (41.59)	174.08 (39.28)	131.80 (29.53)	125.70 (26.42)	< 0.05	A>C, A>D, B>C, B>D
M03 Medial mid-foot	105.91 (26.31)	125.50 (30.39)	89.93 (18.65)	100.08 (24.33)	< 0.05	A <b, a="">C, B>C, B>D</b,>
M04 Lateral mid-foot	122.18 (21.92)	139.79 (30.98)	98.54 (20.24)	108.25 (27.14)	< 0.05	A <b, a="">C, B>C, B>D</b,>
M05 1 st Met head	175.07 (24,60)	152.34 (20.18)	156.27 (31.08)	128.22 (20.65)	< 0.05	A>B, A>C, A>D, B>D, C>D
$M06$ $2^{nd} & 3^{rd}$ Met heads	203.60 (29.72)	166.01 (28.19)	195.92 (37.92)	162.42 (38.58)	< 0.05	A>B, A>D, B <c, C>D</c,
M07 Lateral met heads	143.78 (40.90)	123.07 (30.44)	148.89 (40.43)	121.11 (35.90)	< 0.05	A>B, A <c, a="">D, C>D</c,>
M08 Hallux	214.99 (71.46)	180.16 (57.10)	212.60 (91.38)	173.65 (59.35)	< 0.05	A>B, A>D, C>D
M09 2 nd & 3 rd Toes	118.75 (30.45)	107.72 (50.45)	123.33 (34.40)	108.37 (27.56)	No significant difference	
M10 Lateral toes	82.14 (31.73)	61.71 (25.11)	81.47 (26.12)	63.54 (26.68)	< 0.05	A>B, A>D, B <c, C>D</c,

(A) BSI = Baseline shoes; (B) RSI = Rocker shoes; (C) BSO = Baseline shoes with FO; (D) RSO = Rocker shoes with FO

^b Repeated measures one-way ANOVA test of the four 'shod' conditions

 $^{^{\}rm c}$ Results of Bonferroni corrected post hoc test showing significant difference between conditions with p < 0.05

Figure 1a Click here to download high resolution image

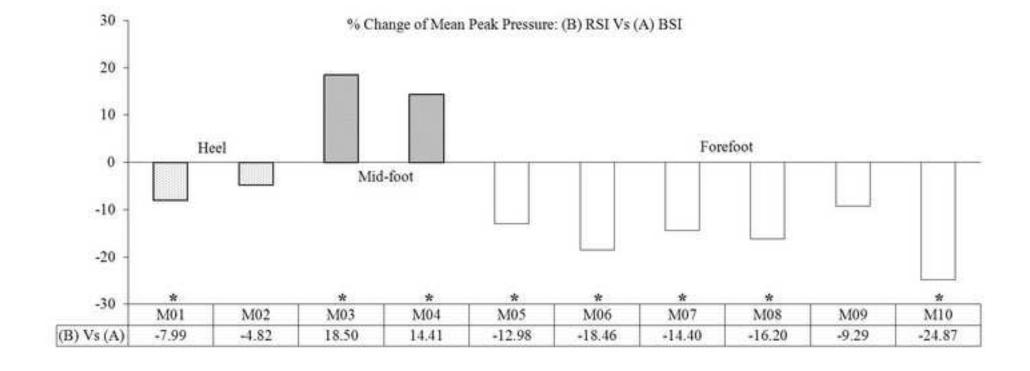


Figure 1b Click here to download high resolution image

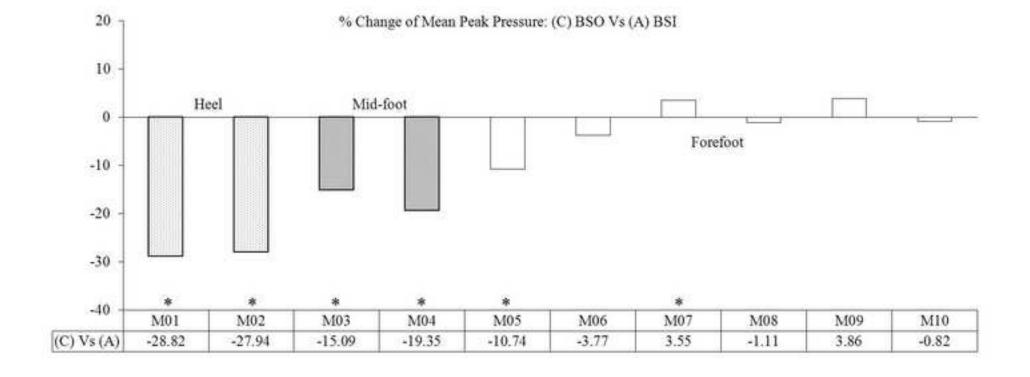


Figure 1c Click here to download high resolution image

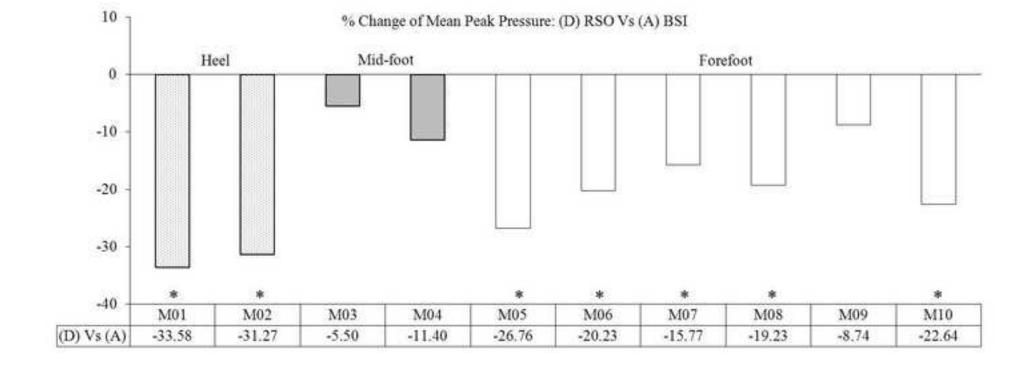


Figure 1d Click here to download high resolution image

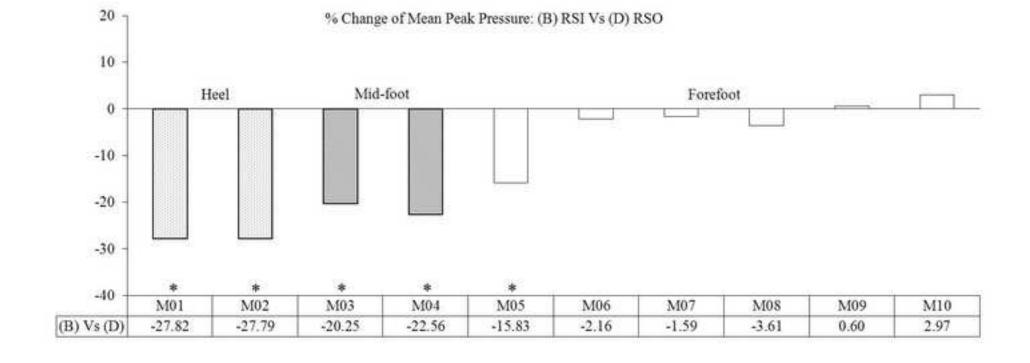


Figure 1e Click here to download high resolution image

