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

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Abstract: Background: It is a routine practice to prescribe a combination of rocker shoes and custommade 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: <u>dfong@ort.cuhk.edu.hk</u>)

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	
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29	
30	Keywords: plantar fasciitis; rehabilitation; shoes
31	
32	Word count: 271 (abstract): 3 /39 (main text)
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38 Abstract

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

57	significantly reduced the greatest amount of medial heel peak pressure (-33.58%)
58	without overloading other plantar regions when compared to rocker shoes (-7.99%)
59	and foot orthoses (-28.82%).
60	Discussion: The findings indicate that a combined prescription of rocker sole shoes
61	and custom-made foot orthoses had greater immediate therapeutic effects compared
62	to when each treatment had been individually prescribed.
63	
64	
65	Introduction
66	Plantar fasciitis is a musculoskeletal overuse disorder with high prevalence. It
67	affects people irrespective of gender, age, ethnicity, or physical activity (Singh et al.,
68	1997). It has been estimated that about 10% of the population, particularly those
69	aged between 40 and 65 years, are affected at some time during their lives (Riddle et
70	al., 2004; Taunton et al., 2002). Plantar fasciitis is characterized by localized pain or
71	tenderness under the medial heel during palpation or weight-bearing, and it results in
72	the limitation of physical activity (Tisdel et al., 1999). To date, the etiology of
73	plantar fasciitis is still poorly understood, and it remains unknown in approximately
74	85% of cases (Schepssis et al., 1991). The literature suggests that its risk factors are
75	multi-factorial, and they can be categorized as environmental, anatomical, and
76	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).

80	There is no single universally accepted method for treating plantar fasciitis. The
81	condition frequently responds to a wide range of conservative treatments that
82	demonstrate variable levels of efficacy from 46% to 98% (Tisdel et al., 1999;
83	Schepssis et al., 1991; Crawford & Thomson, 2003; Lynch et al., 1998; Wolgin et al.,
84	1994). Many studies have, however, indicated a higher success rate with mechanical
85	therapies than with other conservative forms and their efficacy is usually greater
86	than 70% (Lynch et al., 1998; Wolgin et al., 1994; Martin et al., 2001; Walter et al.,
87	2004). Over the years, there has been an extensive debate regarding the most
88	effective form of mechanical treatment. Rocker shoes and Custom-made Foot
89	Orthoses (FO), known as pedorthic devices, have frequently been advocated to
90	manage the mechanical factors which precipitate the development of plantar fasciitis.
91	It has been a routine practice to prescribe them in combination (Hutchins et al., 2009)
92	Janisse & Janisse, 2008). However, the justification for this was based on the
93	phenomena of subjective pain relief and symptom resolution. To date, scientific
94	evidence to confirm these observations is equivocal.

96	Rocker shoes, which are a type of therapeutic footwear with an external
97	modification of the outsole contour (Hutchins et al., 2009), are routinely prescribed
98	to relieve the high-pressure plantar regions of the foot (Brown et al., 2004). The
99	shoes' basic clinical function is to 'rock' the foot from heel-strike to toe-off, thus
100	altering the motion and the force distribution patterns (Schie et al., 2000). A variety
101	of designs accommodating different pathological needs are available. Three of the
102	most commonly prescribed rocker soles are the toe-only, negative heel, and double
103	rocker (Janisse & Janisse, 2008). Previous investigations have consistently
104	demonstrated that prescribing rocker shoes on their own (i.e., without the inclusion
105	of FO) could reduce the heel pressure by 10% to 30% (Brown et al., 2004; Schie et
106	al., 2000; Praet & Louwerens, 2003) without adversely the affecting ambulatory
107	ability (Long et al., 2004; Myers et al., 2006; Van Bogart et al., 2005). Its average
108	efficacy on plantar fasciitis treatment ranged from 59% to 72% (Hutchins et al.,
109	2009). The literature has not verified whether the inclusion of custom-made FOs
110	could be a further enhancement of the rocker shoes' intrinsic offloading functions.

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,
114 1994). It emphasizes the importance of dynamic interrelationships between the foot

115	joints during gait. The biomechanical principles in which FO works have remained
116	contentious (Pratt, 2000). However, custom-made FOs have been extensively shown
117	to have favorable therapeutic outcomes for plantar fasciitis on their own in
118	non-rocker shoes (Crawford & Thomson, 2003; Lynch et al., 1998; Walter et al.,
119	2004). The average efficacy ranged from 50% to 70% with a 20% to 30% reduction
120	of medial heel pressure (Lynch et al., 1998; Martin et al., 2001; Pratt, 2000; Roos et
121	al., 2006; Landorf & Keenan, 2000). To date, there has been no quantitative study to
122	characterize the offloading property of FO in rocker shoes.
123	
124	Conclusively, the individual prescription of rocker shoes and custom-made FOs has
125	been shown to be effective in treating plantar fasciitis. It is critical to quantitatively
126	justify their continued combined prescription in order to prevent the delivery of an
127	item which is of insignificant benefit to patients. Therefore, the purpose of this study
128	has been to explore the combined therapeutic effect of rocker shoes and
129	
	custom-made FOs on plantar fascilitis.

131 Methods

132 <u>Subjects</u>

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

134	sufficient to show a significant pressure reduction of 30%. This effect size was based
135	on previous study findings of rocker sole shoes on pressure relief at the medial heel
136	region (Brown et al., 2004; Praet & Louwerens, 2003) and on the assumption of
137	clinically meaningful change for patients to experience pain relief (Farrar et al.,
138	2000; Williamson & Hoggart, 2005). Written informed consent was obtained from
139	all subjects before their admission to the study. Ethical approval was obtained from
140	the Joint Chinese University of Hong Kong (New Territories East Cluster) Clinical
141	Research Ethics Committee.
142	
143	Fifteen Chinese patients (3 males, 12 females) with chief complaints of unilateral
144	plantar fasciitis (6 rights, 9 lefts) were recruited from a private pedorthic clinic
145	during their first visit over 2.5 months. Their demographics are presented in Table 1.
146	
147	The subject inclusion criteria were: (1) being aged between 40 and 65 years old
148	(Riddle et al., 2004; Taunton et al., 2002); (2) being referred by orthopaedic doctors
149	as having a confirmed diagnosis of plantar fasciitis; (3) having a persistent
150	complaint of plantar heel pain during ambulation and on the day of data collection;
151	(4) exhibiting abnormal foot propation: and (5) having the ability of independent

152 non-aided heel-toe walking and being able to follow verbal instructions. Subjects

153	were excluded if they had a history or physical findings of: (1) traumatic injury in
154	the last six months; (2) previous plantar fascia surgery; (3) heel pain of neural origin,
155	fat pad atrophy and bursitis; (4) other associated pain at back, knee, or ankle and
156	foot affecting ambulation; and (5) biomechanical conditions contra-indicated either
157	for FO or rocker shoes (Long et al., 2004; Myers et al., 2006; Van Bogart et al.,
158	2005).

160 <u>Materials</u>

161 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 162 insoles, custom-made FOs). The baseline shoes were of an ordinary healthy style. 163 164 The rocker shoes were similar in all aspects to the baseline shoes except that the sole 165 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 166 axis was positioned at 60% and oriented at 80° to the long axis of the shoes. Flat 167 insoles were made of 3-mm poron covered with a layer of fabric. Custom-made FOs, 168 in the Rootian functional approach, were fabricated by the Ezped Foot Orthotic 169 170 CAD/CAM System (Hong Kong) which was associated with a 3-D laser scanner. It 171 was an exact replication of a plaster technique by which a pair of 3-D electronic

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

178 Experiment

179 This was a cross-over study in which every subject performed walking trials in each 180 of the five test conditions. These conditions consisted of: (1) an 'unshod' condition 181 (barefoot), and four 'shod' conditions using (2) Baseline Shoes with flat Insoles 182 (BSI), (3) Baseline Shoes with custom-made foot Orthoses (BSO), (4) Rocker Shoes 183 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 184 185 variability and to lower the subject attrition; this was because these could potentially 186 create errors in the study.

187

188 The study outcome measurements were the ratings of medial heel pain intensity 189 associated with plantar fasciitis at the first step and during gait reflected by the 190 visual analogue scale (VAS) and their corresponding dynamic plantar pressure

191	redistribution evaluated by a pair of pressure insoles (Novel Pedar System,
192	Germany). Both the VAS pain score and plantar pressure insoles were well
193	documented as being valid and reliable for clinical pain rating (Williamson &
194	Hoggart, 2005; Bijur et al., 2001) and shoe-foot interface plantar pressure
195	evaluation (Putti et al., 2007). Similar outcome measures have been used in other
196	plantar fasciitis studies (Wearing et al., 2003; Wearing et al., 2007).
197	Measurement
198	The VAS pain score questionnaire was administered immediately after each test
199	condition (Dixon & Bird, 1981; Williamson & Hoggart, 2005). Each subject was
200	asked to make the respective marks on the same questionnaire to minimize the
201	variability of VAS scoring for repeated measures (Rosier et al., 2002; Scott &
202	Huskisson, 1979). The VAS pain score has been shown to be linear with ratio
203	properties (Price et al., 1983), and thus it is statistically robust for parametric
204	statistical analysis if the distribution of data is Normal or transformable to Normal
205	(Dexter & Chestnut, 1995). The dynamic variation of bipedal plantar pressure
206	distributions of all 'shod' conditions was used to supplement the objectivity of the
207	VAS pain ratings. There were 99-sensors embedded in each insole which recorded
208	data at a sampling rate of 100 Hz. Each insole was divided into 10 anatomical
209	regions, which were automatically masked by the system as medial heel (M01),

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

217 <u>Test Protocol</u>

218 All data for a given subject were collected on the same day. Each subject performed 219 three heel-toe walking trials for each test condition on a 6-meter long, straight, 220 carpet-covered linoleum concrete walkway. Because plantar pressure and perceived 221 pain intensity are associated with the walking speeds (Willson & Kernozek, 1999), 222 the subjects were instructed to walk naturally at their own self-selected speeds. 223 Consistency of walking speed was monitored in all trials by counting the time 224 required for six steps (Brown et al., 1996). A trial was discarded if the walking was 225 not performed in a smooth natural gait, in a straight line, or with inconsistent speeds. 226

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

229	generator program. All participants were blinded for the test conditions which were
230	prepared in a separate room. Between successive test conditions, the subjects were
231	given: (1) a five-minutes rest, extended on request, in order to avoid the pain being
232	aggravated during tests and carried over to the next test condition; (2) the VAS pain
233	level questionnaire immediately after each test condition; and (3) sufficient practice
234	walking trials to become accustomed to the next test condition at the desired speed
235	before data capture.
236	
237	Analysis
238	The recordings of all walking trials were displayed, processed, edited and analyzed
239	by the associated software (Novel Pedar System, Germany). To negate the
240	acceleration and deceleration effects, the data of the first step and the last step of
241	each trial of the involved side were trimmed out. Four sequential steps were then
242	selected and their peak pressures during stance were averaged in each of the 10
243	anatomical regions. Data from all trials, all test conditions, and all subjects were
244	pooled together for statistical analysis.
245	
246	For both VAS-immediate pain ratings and pressure data, if the Shapiro-Wilk
247	normality test was passed, repeated measures one-way ANOVA with Bonferroni

248	correction post-hoc pairwise comparisons was conducted to explore any significant
249	difference (p < 0.05) between the test conditions. Otherwise, non-parametric
250	Friedman one-way ANOVA was employed. All statistical tests were conducted by
251	SPSS 16 with significance level at $p < 0.05$.
252	
253	Results
254	The self-selected walking speed of the subjects ranged from 96 to 120 steps per
255	minute. The p-values of the Shapiro-Wilk normality test of all data sets of
256	VAS-immediate pain ratings and regional peak pressures in all test conditions were
257	greater than 0.05. This indicated that the parametric statistical analyses were eligible.
258	The percentage changes of the VAS-immediate pain ratings, with respect to barefoot
259	walking, of the four 'shod' conditions and the results of repeated measures one-way
260	ANOVA with Bonferroni correction post-hoc pairwise comparisons are shown in
261	Table 3.
262	
263	Descriptive statistics and the results of repeated measures one-way ANOVA and
264	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 theregion of the 2nd and 3rd toes, the rest of the other nine regions demonstrated a

267	significant difference in peak pressures between the four shod conditions. With
268	respect to BSI, the percentage changes of peak pressures for each of the 10
269	anatomical regions in RSI, BSO, and RSO are compared graphically in Figure 1.
270	
271	Discussion
272	In this study, the immediate therapeutic effects on plantar fasciitis among rocker
273	shoes, FO and a combination thereof were evaluated and compared. Clinically, it
274	was more accurate to use a percentage reduction in the VAS pain ratings (rather than
275	the raw changes) as a means of comparing treatment (Williamson & Hoggart, 2005).
276	It was verified that a 33% reduction was a clinically meaningful change for patients
277	to experience pain relief (Farrar et al., 2000). The immediate reduction of pain
278	intensities of RSI, BSO, and RSO were found respectively to be 52.5%, 54.6%, and
279	85.1% with respect to barefoot walking. All three reductions were greater than 33%;
280	however, RSO got a further 30% reduction in pain intensity compared to BSO and
281	RSI. Critically, statistical findings indicate that rocker shoes combined with FOs
282	produce significantly greater immediate pain relief in the medial heel than individual
283	prescription of rocker shoes and FOs.
284	

285 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.

293

294 The only difference between baseline shoes and rocker shoes was their outsole 295 profiles. Comparative analysis on the patterns of dynamic regional peak pressure 296 was therefore conducted to explore the plantar pressure redistribution behavior of 297 the rocker soles. The findings revealed a significant reduction in peak pressures 298 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 299 300 agreement with previous studies (Hutchins et al., 2009). However, it was noted that 301 the rocker shoes were more effective in reducing pressure in the forefoot than in the 302 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 303 304 literature, heel pressure reductions generally ranged from 10% to 30% (Brown et al.,

305	2004; Long et al., 2004; Myers et al., 2006; Van Bogart et al., 2005). However,
306	direct comparisons in terms of pressure values were not reliable because of two
307	fundamental reasons. Firstly, the design of rocker sole profiles employed in previous
308	studies varied considerably in the rocker angles. Secondly, subjects in most of the
309	previous studies were either asymptomatic or diabetic neuropathic individuals who
310	were all pain-free. Therefore, the values so obtained were not representative. It was
311	a merit of this study to recruit subjects whose demographics most reflect those that
312	are commonly referred for pedorthic treatment (Taunton et al., 2002). Furthermore,
313	it should be noted that the current findings highlight profound pressure elevation
314	across the mid-foot after rocker shoes had been prescribed. This has important
315	clinical implications for future rocker shoes prescription; this is because it may be a
316	potential source of irritation or even pain particularly for patients who suffer from
317	mid-foot pathologies.

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

324	heel pressure from 20% to 30% (Pratt, 2000; Roos et al., 2006; Kandorf & Keenan,
325	2000). In contrast to a rocker sole acting as a powerful forefoot offloader, FOs
326	worked as a strong heel offloader. FOs significantly reduced medial heel and lateral
327	heel pressure by nearly 30% and 28%, whereas the rocker sole reduced it by only
328	8% and 5%. Another fundamental difference between their behaviors was the
329	strategy of pressure redistribution at mid-foot. A rocker sole demonstrated
330	significant pressure increases of 18.5% and 14.4% at medial mid-foot and lateral
331	mid-foot, respectively. Conversely, FOs decreased medial mid-foot and lateral
332	mid-food pressure significantly by 15.1% and 19.4%; this was because of the
333	increased contact area of mid-foot via the custom-casted contour of the orthotics
334	(Kogler et al., 1996). Thus, rocker soles and FOs possessed their own strengths and
335	drawbacks in accordance with their pressure redistribution behaviors. Rocker soles
336	reduced the pressures in the heel and forefoot by redistributing the pressure to
337	mid-foot, thereby potentially overloading that region. On the other hand, FOs
338	reduced the pressure at mid-foot by redistributing the pressure to the forefoot, and
339	this may potentially cause forefoot overloads.

341 The comparative analysis of regional peak pressure between RSO and BSI was342 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).

347

348 The study findings reveal that RSO served as a powerful offloader both of the heel 349 and the forefoot pressure during gait. As compared to rocker behavior, RSO was a 350 stronger forefoot offloader with less risk of mid-foot overloads when compared to a 351 rocker sole acting alone. Referring to orthotics behavior, further decreases in 352 forefoot pressure would likely be caused by the effects from FO. In other words, the 353 rocker behavior of RSO was enhanced because of theinclusion of the FO. As 354 compared to orthotics behavior, RSO reduced more pressure at the heel than FO. 355 Similarly, referring to the rocker behavior, such a decrease could be the contribution 356 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 357 358 redistribution of forefoot pressure was possible.

359

360 In conclusion, these findings suggest that the RSO utilized the pressure 361 redistribution benefits both of the rocker sole and FO. The rocker sole reduced

362	forefoot plantar pressure by redistributing the plantar pressure to the mid-foot, which
363	was reduced by the FO. Insignificant pressure difference across the mid-foot was
364	thus elucidated. Additional studies should be conducted on the details of their
365	interactive biomechanics.
366	
367	Only the immediate effect of a combination of rocker shoes and FOs was evaluated
368	by using a subjective VAS pain score. Because of the meaningful findings, further
369	studies on its efficacy in the treatment of plantar fasciitis are justified. In future
370	studies, randomized controlled trials should also be conducted to assess the
371	long-term effects of the combined prescription of rocker sole shoe and custom-made
372	FO.
373	
374	Conclusion
375	The statistical results show that the combination of rocker shoes and FOs produce a
376	significantly lower VAS pain score (9.7 mm) than rocker shoes (30.9 mm) and FOs
377	(29.5 mm). With respect to baseline shoes, it also significantly reduced the greatest
378	amount of medial heel peak pressure (-33.58%) without overloading other plantar
379	regions when compared to rocker shoes (-7.99%) and FOs (-28.82%). RSO was a
380	safer mechanical modality of plantar fasciitis. Therefore, the practice of combined

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

386 **References**

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490 **Figure and Table Legends**

491	Figure 1a-e: Dynamic plantar pressure redistribution between test conditions. BSI:
492	Baseline shoes with flat insoles; RSI: Rocker shoes with flat insoles; BSO: Baseline
493	shoes with custom-made foot orthoses; RSO: Rocker shoes with custom-made foot
494	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.
498	Table 1: Subjects demographics of the study
499	Table 2: The standard of cast rectification

- 500 Table 3: VAS-immediate pain ratings of the test conditions
- 501 Table 4: Dynamic regional peak pressure (kPa) of the 'shod' conditions

	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 1: Subjects demographics of the study

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

Test Conditions ^a	Mean	S.D.	% $\Delta VAS_{(barefoot)}^{b}$	Statistical analysis <i>p</i> -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		

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

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

^b % Δ VAS (barefoot): percentage change of VAS pain rating compared with barefoot

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

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

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
$\frac{M09}{2^{nd} \& 3^{rd} Toes}$	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,

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

(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









