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Dynamic Plantar Loading Index: Understanding the benefit of Custom Foot Orthoses for Painful Pes Cavus

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Abstract

The purpose of this study was to evaluate a new method showing how custom foot orthoses (CFO) improve dynamics of plantar loading. The method is based on the probability distribution of peak pressure time series and is quantified using the Regression Factor (RF). RF is a least square regression slope between the experimentally observed plantar pressure magnitude probability distribution and a modeled Gaussian shape. Plantar pressure data from a randomized controlled trial of 154 participants with painful Pes Cavus were retrospectively re-analyzed. The participants were randomized to an active treatment group given CFO or a control group given sham orthoses. The location of 2nd Peak pressure as a percentage of stance time (P_{Loc2}) and its magnitude (P_{M2}) was also calculated. In addition, plantar pressure data were collected on 23 healthy volunteers with normal foot alignment and no foot pain. Results demonstrated Pes Cavus had a significantly lower RF than healthy participants (0.30 v. 0.51; $p < 10^{-7}$). P_{M2} was reduced in both active and control groups. However, RF and the P_{Loc2} were only changed in the active group ($p < 0.005$) without any significant change in the control group ($p > 0.5$). This study suggests that painful Pes Cavus alters the shape of probability distribution of plantar loading during walking and CFO are an effective therapeutic solution that can significantly improve it. Further use of the RF index and 2nd peak pressure location as an outcome measure for treatment of foot and ankle deformities is suggested.

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Keywords

Pes Cavus; custom foot orthoses; randomized controlled trial; gait; orthotic devices; outcome assessment (health care)

Introduction

Pes Cavus is a foot type characterized by an abnormally high medial longitudinal arch. It is estimated to occur in approximately 10 percent of the population.(Sachithanandam and Joseph, 1995) The most common etiologies for this deformity are neurologic, traumatic, residual clubfoot, and idiopathic.(Younger and Hansen, 2005) It has been estimated that approximately 60 percent of patients with pes cavus experience foot pain.(Burns et al., 2005)

A recent Cochrane systematic review on treatments for painful pes cavus describes the effect of custom foot orthoses (CFO), off-the-shelf orthotic devices, and commercially available athletic footwear.(Burns et al., 2007) The authors concluded that one randomized controlled trial supported significant pain relief from CFO over sham orthoses.(Burns et al., 2007; Burns et al.) CFO significantly reduced approximately 75% of foot pain regardless of etiology.(Burns et al., 2006) However, the exact mechanism by which this is accomplished remains elusive.(Burns et al., 2006; Crosbie and Burns, 2008)

It is generally thought that one of the functions of CFO is to reduce plantar pressure magnitudes by redistributing them throughout the plantar surface.(Redmond et al., 2000) Unfortunately, this has not proven to be a reliable measure of the effectiveness of this treatment. (Burns et al., 2006) One potential reason is that peak pressure can be altered by gait speed and body mass index (BMI).(Morag and Cavanagh, 1999; Najafi et al., 2010a; Wrobel et al., 2003) Frequently, patients with painful foot deformity alter their gait strategy by reducing gait speed or limiting the time spent in certain phases of stance in order to reduce pain and/or pressure in symptomatic regions of the foot (e.g., antalgic gait).(Crosbie and Burns, 2008) If pain is reduced post intervention, measurements of plantar pressure magnitudes may exceed those seen pre-intervention due to an increased gait speed or a less antalgic gait, historically viewed as a negative outcome. (Najafi et al., 2010a)

Recently, a novel dynamic plantar loading outcome measure has been proposed called the Regression Factor (RF) Index. (Najafi et al., 2010a) It was described in healthy participants and patients with Charcot osteoarthropathy. The Regression Factor is calculated by the least square regression slope between the experimentally observed plantar pressure magnitude probability distribution and a Gaussian distribution with the same mean, standard deviation, and magnitude. An index close to +1 interpreted as a better agreement between dynamic plantar loading and the Gaussian distribution. Healthy participants have demonstrated an RF=0.46 while Charcot patients have a negative value. (Najafi et al., 2010a) After surgical reconstruction, the Charcot patient's RF approximated healthy participants. Preliminary testing demonstrated this measure to be independent of gait speed. (Najafi et al., 2010a)

It is not known if the RF index is different in patients with pes cavus and whether it is responsive to CFO intervention. Therefore, the aim of this study was to perform a secondary analysis of a large randomized sham-controlled trial applying the RF to the CFO and sham orthoses condition. Additionally, we explored the timing and magnitude of the second plantar pressure peak as CFO has previously been described to influence ankle torque. (MacLean et al., 2006)

Methods

Participants

The original trial data were obtained from the principal investigator (JB) and the methods were described previously. (Burns et al., 2006) In brief, after institutional ethics approval and informed consent, 154 participants (56% male; Age=50±14 years; BMI=27.8±6.1 kg/m²) with painful pes cavus were enrolled on the basis of reaching a threshold Foot Posture Index (FPI) (Redmond et al., 2006) of -2 or less. (Redmond et al., 2008) FPI is a diagnostic tool that evaluates the multi-segmental and multi-planar aspects of the foot using six criteria that together enable the foot to be scored along a continuum of cavus (supinated) to planus (pronated) features. (Redmond et al., 2006) The six components provide an aggregate score ranging from -12 for highly cavus to +12 for highly planus foot alignment. The FPI has demonstrated acceptable intra- and inter-rater reliability in children and adults. It has been independently validated against radiographic parameters and three-dimensional gait, and it provides a more complete description of foot structure than other clinical measures. (Cain et al., 2007; Menz and Munteanu, 2005; Redmond et al., 2006)

Figure 1 illustrates the flowchart of recruitment and the protocol of re-analyzing the data. Participants were randomly assigned to two groups: A control group that was given sham orthoses (3mm latex foam) and an active treatment group that was given custom foot orthoses (standard prescription of a direct milled 3mm polypropylene). Both groups were casted in identical fashion. The person who re-analyzed the data was blinded to the type of intervention.

Additionally, twenty-three healthy participants (55% male; Age=25±3; BMI=24.8±3.8 kg/m²) without foot pain were recruited. They answered similar general health surveys and their FPI was also ascertained. Those who had a FPI of -2 or less were excluded. The local Institutional Review Board approved this aspect of the study and all participants signed an informed consent prior to testing.

Plantar Pressure Assessment and outcome calculation

For both studies, plantar pressure assessment was performed using computerized pressure insoles (Pedar[®], Novel-Germany) in the participant's habitual shoes (Fig. 2B). For participants with painful pes cavus, their regular shoe insole was removed and replaced by the randomly allocated orthoses (custom or sham) and the pressure insole was applied between the foot and the allocated orthoses i.e. on top of the orthoses. Participants walked a minimum of 40 steps at their self-selected walking speed on a 10m walkway. The sampling frequency was 50 Hz. (Burns et al., 2006) Additionally, plantar loading during barefoot condition was measured using a pressure platform (Emed[®], Novel) in healthy volunteers with sample frequency of 400Hz (Fig 2.A). In healthy participants, gait velocity was controlled during both shod and barefoot condition using a validated gait analyzer system based on body sensor (Physilog[®], BioAGM, Switzerland). (Aminian et al., 2002; Aminian et al., 2004; Najafi et al., 2009) Figure 2 illustrates the experimental setup for healthy participants during barefoot and shod tests.

A new toolbox was designed (see Appendix), to characterize and quantify the shape of peak plantar pressure time-series during walking (Fig. 2 and Fig. 3). Three outcomes were extracted using this toolbox including 1) the RF index 2) the magnitude of 2nd peak pressure (P_{M2}) and 3) the relative location of 2nd peak pressure as a percentage of the stance phase (P_{Loc2}). Previously, CFO have been shown to influence the ankle moment, thus motivating our attention to the location and amplitude of 2nd peak pressure. (MacLean et al., 2006; MacLean et al., 2008) For the barefoot condition, the gait speed estimated using Physilog

was verified to ensure achieving gait steady state (Lindemann et al., 2008; Najafi et al., 2010b) without any significant speed reduction while touching the pressure platform.

The data were scaled to 100 samples using a linear interpolation scheme to moderate the effect of gait velocity (stance duration). Then a Gaussian distribution with the same mean, variance, and maximum probability magnitude as the actual data was fitted for each foot and trial using a linear regression model, producing the RF index (see Appendix). The normal distribution evaluated the probability of observing low, medium or high pressures at any point during stance. For instance, very low and high pressures were expected but usually occur very rapidly (at heel contact and toe off) and therefore account for only a small percentage of the stance phase. These pressures therefore make up the tail ends of the distribution. There was a greater probability of seeing medium pressures during stance and these intermediate pressures made up the central part of the normal distribution. Since the magnitude, standard deviation, and mean values of two distributions are identical, the RF index is expected to range from -1 to $+1$ and as the value increases positively so does the similarity between the actual and modeled pressure probability distributions. (Najafi et al., 2010a)

Statistical analyses

Each set of data were then analyzed using a new toolbox designed using Matlab™ program (Fig. 2 and Fig. 3) for RF Index, P_{M2} , P_{Loc2} , and stance duration. Considering the unilateral nature of foot pathology, the right and left foot for each participant were considered as an independent measure. A paired student's t test was performed for intra-subject comparison (e.g. with and without orthoses and barefoot v. shod condition). A two sample student's t test assuming equal variance was calculated between groups. Multivariate and multiple linear regression test was used for testing the effects of confounding factors including age, gender, BMI, and stance duration (assuming as proxy of gait velocity) on three outcomes of this study. Additionally, the correlation between each of the measured outcomes and BMI as well as stance duration were examined using Pearson correlation of coefficient. Statistical significance was set at 0.05.

Results

Pes Cavus vs. Healthy Participants (Table I)

Two healthy participants and one pes cavus participant were excluded from the final data analysis because their recorded pressure data during shod condition were too noisy. An additional healthy participant was excluded because of having FPI of less than -2 .

Results suggest that all three outcomes are significantly different between pes cavus and healthy group after adjusting for age, BMI, gender, and stance duration ($p < 10^{-3}$). Table I summarizes the comparison between healthy group and pes cavus group. In pes cavus, the RF index was significantly reduced on average by 41% ($p < 10^{-7}$, average difference(diff)=0.21, 95% CI=[0.14, -0.30]) compared to the healthy group (Fig 3A). No significant correlation was observed between RF index and stance duration ($r=0.08$, $p=0.3$), indicating that RF index is speed independent. The P_{M2} in pes cavus was significantly higher than healthy group on average by 51% ($p < 10^{-7}$, diff=135kPa; 95% CI=[105, 166] kPa). Additionally, the P_{Loc2} happened earlier in pes cavus compared to the healthy group on average by 5.8% ($p < 10^{-7}$, diff=-4.8%; 95% CI=[-5.8, -3.7]%). In other words, the forefoot loaded earlier. Stance duration was also significantly longer in pes cavus compared to the healthy group on average by 8.6% indicating that the pes cavus participants walked slower.

Comparison between barefoot and shod conditions in Healthy Participants

The average P_{M2} was significantly reduced by 66% when wearing shoes without orthoses compared to barefoot condition (267 ± 65 kPa in shod v. 785 ± 247 kPa in barefoot condition, $p < 10^{-6}$, $\text{diff} = -518$ kPa; 95% CI = $[-594, -444]$ kPa). On the same note, wearing shoes significantly shifted the P_{Loc2} ($82.9 \pm 2.5\%$ in shod v. $81.3 \pm 5\%$ in barefoot, $p = 0.01$, $\text{diff} = 1.6\%$, 95% CI = $[0.4, 3.3]\%$). However, after adjusting for stance duration, the difference for P_{Loc2} was not significant ($p = 0.08$). Interestingly, no significant difference was observed for the RF index between shod and barefoot condition, suggesting that regular shoes do not influence the probability distribution of plantar loading.

Sham vs. Active treatment groups in Pes Cavus (Tables II and III)

Tables II and III summarize the comparison between active and control groups for pes cavus participants. The average of FPI was -4.3 ± 2.8 . At baseline, while wearing standardized control shoe shoes with no foot orthoses, there were no significant differences observed between the control and active groups for any of the measures (Table II), suggesting effective randomization. Figure 3 illustrates a typical pattern of plantar loading pre and post usage of CFO. The active CFO group demonstrated a significantly higher RF index (44%; $p < 10^{-7}$) compared to baseline (with shoes and no orthoses), while no improvement was observed in the control group (Fig 4A and Table III). Both the control and active groups showed a decrease in P_{Loc2} compared to baseline (Fig. 4B) although the magnitude of reduction was higher in the active group than in the control group (8%; $p = 0.02$). The P_{Loc2} was significantly later in the active group compared to baseline as well as compared to control (1.1%; $p < 0.005$) (Fig 4C). Stance duration did not change significantly between the active and control group as well as compared to baseline suggesting that gait speed did not change between the groups. Interestingly, although sham orthoses significantly reduced the peak pressure magnitude, there was no significant change in the RF Index and the 2nd peak pressure location ($p > 0.2$). On the same note, after adjusting for the stance duration, using the P_{M2} no longer remains significant between two groups ($p = 0.22$), while both RF index and P_{Loc2} remain significant between control and active groups ($p < 0.01$).

No significant correlation existed between the P_{Loc2} and the ankle dorsiflexion lunge test data ($r = 0.08$, $p = 0.16$) or stance duration ($r = -0.07$, $p = 0.18$). This suggests that the occurrence of the 2nd peak is independent of stance duration and ankle flexibility. Similarly, we didn't observe a significant correlation between the P_{Loc2} and its magnitude ($r = -0.09$, $p = 0.09$) suggesting that the magnitude of plantar loading doesn't impact its location as a percentage of stance time.

Discussion

Our results show a significant change in the RF index for the CFO group compared to the control group (44%; $p < 10^{-7}$) in people with pes cavus. The direction of the change after using CFO in the active group trended towards healthy participants with normal foot alignment. We found that participants with pes cavus have a significantly lower RF than healthy participants (0.30 v. 0.51; $p < 10^{-7}$). These findings may give empiric support for a preferred movement path proposed by Nigg, et al. (Nigg, 2001)

To the best of our knowledge, it is novel to explore the timing and magnitude of the 2nd plantar pressure peak. Previously, CFO been shown to influence ankle moment, thus motivating our attention to this measure. (MacLean et al., 2006) While equinus and pseudo-equinus have been theorized as compensation strategies or consequences of pes cavus, their effect to date has mostly been an epidemiological observation. Wrobel and colleagues

reported that people with ankle equinus, defined in non-weightbearing, demonstrated significant associations in only three out of eleven kinetic measures after multivariate adjustment.(Wrobel et al., 2004) Burns and colleagues improved on the robustness of equinus ascertainment by assessing it in a weight-bearing posture with the lunge test.(Burns et al., 2006) The 2nd peak pressure magnitude in pes cavus was significantly higher than healthy participants on average by 51%. This may be described in part by the pes cavus group had a significantly higher BMI by 8%. Stance duration was also significantly longer in pes cavus compared to the healthy group on average by 8.6% indicating that the pes cavus participants walk slower. The RF index improved in pes cavus wearing CFO as the 2nd pressure peak occurred later in stance. Interestingly this parameter is also independent of BMI, peak pressure magnitude, stance duration, and lunge test but is significantly improved by wearing functional foot orthoses. Therefore, the 2nd peak as a percentage of stance appears to be a more robust measure of the compensatory gait strategy due to pes cavus (and may or may not be moderated by equinus) than non-weight-bearing assessment (Wrobel et al., 2004) or weight-bearing assessment using the lunge test.(Burns et al., 2006)

A leading theory for the benefit of CFO in people with painful pes cavus has been the redistribution of plantar pressures leading to decreased peak pressure magnitudes.(Burns et al., 2006; Crosbie and Burns, 2008) However, absolute plantar pressure magnitudes across the whole foot are dependent on a number of factors that vary between patients as well as between trials, such as gait speed and BMI.(Najafi et al., 2010a) It has therefore been impossible to set a threshold for peak pressures above which patients begin to experience pain or deformity. A better alternative for investigating the redistribution of plantar pressures is a measure of dynamic plantar loading. We found the 2nd peak as a percentage of stance and the RF index, was independently associated with the potential benefit of CFO in painful pes cavus. The RF Index is a dynamic plantar loading measure estimated from fitting a person's plantar pressure probability distribution to a Gaussian distribution.(Najafi et al., 2010a) In other words it is a direct measure of what has been thought to be the key to how custom made foot orthoses work (by redistributing plantar pressures). In addition, the RF index as a measure of dynamic plantar loading is not dependent on other variables such as gait speed, BMI, and peak pressure magnitude. It is also not regionally biased by isolated analysis using regional masks. Interestingly, although sham orthoses significantly reduced the peak pressure magnitude, it did not have any effect on RF Index and 2nd pressure peak location, indicating that while extra padding can reduce plantar pressures, it has no effect on dynamic plantar loading.

There are limitations to this analysis. This re-analysis maintained the randomization scheme and we controlled for potential confounders such as age, BMI, stance duration, and lunge test. It is possible other moderating variables such as pain response may be present. Also, two different plantar pressure measurement systems, testing techniques, and sampling frequencies were used between healthy participants and pes cavus. These differences may alter the magnitude of difference observed between the two populations although the estimates are very similar to our prior work.(Najafi et al., 2010a) The theoretical range of the RF was described as ranging from -1 to +1. However, the theoretical distributions to which the experimental distributions were compared are not constrained to have positive pressures. Additionally, since the plantar surface of the foot contains soft tissue, a perfect normal distribution is physiological unattainable. Therefore, the RF may be more constrained than what is theoretically possible. In this study to quantify the similarity between experimental and modeled Gaussian distribution, a linear regression model was proposed. This approach may not necessary indicate that the experimental data adheres to a Gaussian distribution. In an exploratory effort, we used Lilliefors test for testing whether the distributions in each group can be assumed as Gaussian. Results suggest that Kstat is significantly lower in healthy group than pes cavus with p-values often less than 0.05 in pes

cavus group and higher than 0.05 in healthy group ($kstat=0.12\pm0.02$ and $p=0.02\pm0.05$ in pes cavus group v. $kstat=0.10\pm0.03$ and $p=0.09\pm0.13$ in healthy group; $p<0.005$). These results suggest that the healthy group PPM distribution more closely adheres to normality. The results also suggest that the pes cavus group adheres to normality, just not as closely as the healthy group. However, since the statistical values are very similar, this implies that there is not a very large absolute difference in normality between healthy and pes cavus groups. Additionally, Lilliefors test failed to show significant improvement post usage of orthoses in the active groups though a moderate but not significant improvement toward normal distribution was observed in the active group. Additional studies study should be addressed to explore probability distribution of other plantar loading parameters such as mean pressure trajectory or ground reaction force.

Conclusion

Dynamic plantar loading quantified by RF index, magnitude and location of 2nd peak pressure were altered in participants with painful pes cavus as compared with healthy participants. Furthermore, dynamic plantar loading improved significantly for participants with pes cavus wearing custom made foot orthoses compared with those wearing sham orthoses. Wearing sham orthoses significantly reduced peak pressure but didn't affect the RF Index or the location of the 2nd peak pressure. Further consideration is suggested for the use of the RF index and 2nd peak pressure location as outcome measures in therapeutic and surgical approaches to foot and ankle deformities.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.
Flowchart of patient recruitment and data analysis

Figure 2.

Experimental setup – A) Plantar pressure during barefoot condition was measured using a pressure platform (Emed[®], Novel). The gait velocity was controlled using a gait analyzer system based on body worn sensor to ensure achieving steady state walking when touching the platform. (B) A novel toolbox was designed to extract the three proposed outcomes and visualized the results. (C) Emed-Novel program was used to extract the magnitude of plantar pressure during stance as an input for the toolbox explained in Fig 2B, (D) The plantar pressure during shod condition was measured using computerized pressure insoles (Pedar[®], Novel-Germany), (E) A novel toolbox was designed to extract the three outcomes of the study for each foot, (F) Pedar-Novel program was used to extract the magnitude of plantar pressure during shod condition as an input for the toolbox explained in Fig. 2E)

A Typical Participant in the Control Group
Pre using CFO

A Typical participant in the Active Group
Post Using CFO

Figure 3.
Plantar pressure distribution in a typical Pes Cavus individual (A) before wearing CFO and (B) after wearing CFO

Figure 4.

(A) While wearing orthoses, RF index was significantly improved in the active group without any change in the control, (B) Magnitude of plantar pressure was reduced in both control and active groups while wearing orthoses, (C) The relative location of the second plantar pressure peak was significantly improved in the active group, while the improvement was not significant in the control group. (*:p<0.05, **:p<0.005)

Table 1

Comparison between healthy control and participants with Pes Cavus

	N	BMI [kg/m ²]	FPI	RF Index	2nd Peak Magnitude, [kPa]	2nd Peak Location [% of Stance]	Stance, Mean [s]
Normal Foot Posture	20*2	24.8±3.8	3.2±2.3	0.51±0.15	267.7±63.9	82.9±2.5	0.70±0.05
Pes Cavus	153*2	27.8±6.1	-4.4±2.7	0.30±0.16	403.5±94.6	78.1±3.3	0.76±0.08
Percentage of Change	-	-12%	-	-41%	51%	5.8%	-8.6%
p-Value		0.03	<10 ⁻⁷	<10 ⁻⁷	<10 ⁻⁷	<10 ⁻⁷	<10 ⁻⁴
Mean Difference and its 95% CI		3kg/m ² [0.3,5.3]]	7.9 [6.9,8.5]	0.21 [0.14,0.30]	-135.8kPa [-166,-105]	4.8% [3.7,5.8]	-0.06s [-0.03,.08]

Table II
Comparison between Control (Sham) and Active treatment groups in participants with Pes Cavus

	Age [Years]	Sex [%Male]	Height [cm]	Body Mass [kg]	BMI [kg/m ²]	FPI Left Foot	FPI Right Foot
Active #74	50±14	51%	172±9	82±19	27.9±5.8	-4.3±2.5	-4.3±2.5
Control # 79	50±14	60%	172±10	82±20	27.4±6.0	-4.3±2.7	-4.7±2.7
P-Value Active v. Sham	0.80	0.24	0.67	0.86	0.63	0.96	0.32
Mean Difference and its 95%CI	0 years [-4,5]	[-.3,.1]	0cm [-35,23]	0kg [-6,7]	0.3kg/m ² [-1,2]	0 [-.9,.9]	0.4 [-.4,1.2]

Table III
Comparison between active and control groups with and without orthoses in participants with Pes Cavus

	Shod without orthoses				Shod with orthoses			
	RF Index	2 nd Peak Mag. [kPa]	2 nd Peak Location [% of stance]	Stance duration [s]	RF Index	2 nd Peak Mag. [kPa]	2 nd Peak Location [% of stance]	Stance duration [s]
Active	0.30±0.15	405±90	78.3±3.2	0.75±0.07	0.46±0.15	348±97	79.3±2.9	0.74±0.08
Control	0.30±0.15	402±98	78.0±3.3	0.76±0.10	0.32±0.16	376±102	78.4±2.8	0.76±0.09
% of Change	-	-	-	-	44%	-8%	1.1%	-2.6%
p-Value	0.77	0.75	0.39	0.20	<10 ⁻⁷	0.02	<0.005	0.17
Mean difference and its 95% CI	0 [-0.03,.04]	3kP [-18,25]	0.3% [-4,1.1]	-0.01s [-0.03,.01]	0.14 [.09,.20]	-28kPa [5,50]	0.9% [0.3,1.6]	-.02s [-.3,-.01]