CUSTOMIZED FOOT ORTHOSES IMPROVE THE DYNAMIC PLANTAR LOADING IN PAINFUL PES CAVUS SUBJECTS – NEW ANALYSIS OF A BLINDED, RANDOMIZED TRIAL

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SUMMARY
The purpose of this study was to evaluate the benefit of customized foot orthoses (CFO) in improving dynamics of plantar loading quantified using the Regression Factor (RF) Index. RF index represents the similarity of the statistical distribution of the plantar pressure during stance phase with a Gaussian distribution. As the value increases positively so does the similarity between the pressure and Gaussian distributions. Plantar pressure data from 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. In addition, plantar pressure data were collected on 20 healthy volunteers with no foot pain. Results demonstrated a significant improvement in the active treatment group compared with the control group. Interestingly, results suggest that CFO significantly improve the plantar pressure distribution quantified by RF index (p<0.005), while no difference was observed in the control group (p>0.9). Additionally, the RF index showed that the healthy participants’ dynamic pressure distribution was significantly closer to a Gaussian than participants with painful Pes Cavus. This study suggests that painful Pes Cavus alters the distribution of plantar loading during walking and CFO as an effective therapeutic solution can significantly improve it.

INTRODUCTION
Pes Cavus is a foot type that is characterized by an abnormally high medial longitudinal arch. It is estimated to occur in approximately 10 percent of the population [1]. Custom foot orthoses (CFO) have been described as a treatment for painful Pes Cavus although the mechanism for pain reduction is unclear [2]. The Regression Factor (RF) is novel outcome measure previously introduced as a measure of dynamic plantar loading [3]. The Regression Factor Index is a dynamic plantar loading measure that yields a number between -1 and +1 that illustrates how closely a person’s plantar pressure distribution over time compares with that of a Gaussian distribution. An index of +1 would indicate a perfect agreement between dynamic plantar loading and the normal distribution. Our recent study [3] suggests that this score is independent of gait speed and can be used for screening improvement of dynamic foot loading post foot reconstruction surgery. We hypothesized the RF is an independent outcome measure to determine the effectiveness of CFO for the treatment of painful Pes Cavus.

METHODS
Plantar pressure data from 154 subjects with painful Pes Cavus was retrospectively re-analyzed. Participants were randomized into an active treatment group given custom foot orthoses and a control group given sham insoles. The pressure data for each group was measured using computerized pressure insoles (Pedar®, Novel) under two conditions: 1) shod while wearing orthoses, 2) shod without wearing orthoses. A new toolbox was designed to characterize and quantify the shape of plantar loading distribution during walking. In addition, plantar pressure data was collected on 20 healthy volunteers with no foot pain while walking under both barefoot and shod conditions without wearing any orthoses (mean Age: [24.5± 2.9], BMI: [24.8±3.8]). Plantar pressure was measured using a pressure platform (Emed®, Novel) and the Pedar® system, respectively during barefoot and shod conditions. The shod data from the healthy participants was used as a healthy control group for comparison with the Pes Cavus group. Our outcomes for characterizing plantar loading were 1) the RF index 2) the magnitude of peak pressure (MPP) and 3) the relative location of second peak pressure as a percentage of the stance phase.

Figure 1: Plantar loading and its statistical distribution for a typical participant in the A) Sham treatment group, B) Active treatment group
RESULTS AND DISCUSSION

Figure 1 illustrates the pattern of plantar pressure loading and its distribution in a typical subject in the control (Fig. 1A) and active (Fig. 1B) treatment group. Results demonstrated a significant improvement in the active treatment group in all three outcome measures compared with the control group (Fig. 2). MPP was significantly reduced in both control and active groups (two-tailed, paired, t-test, \( p = 0.02 \) (sham) and \( p < 10^{-6} \) (active)), with a significantly higher reduction on average by 8% in the active group (two-tailed, One Sample, t-test, \( p = 0.02 \), Fig. 2B). The location of second peak pressure as a percentage of stance phase, was significantly later in the active group compared to baseline (two-tailed, paired, t-test, \( p < 0.02 \)) as well as compared to control group by 1.1% (two-tailed, One Sample, t-test, \( p = 0.005 \), Fig. 2C). Interestingly, results suggest that customized foot orthoses significantly improve the plantar pressure distribution quantified by RF index (Fig. 2A), while no difference was observed in the control group (\( p > 0.9 \)). The active group with functional orthoses had a significantly higher RF index compared to the active group without orthoses (two-tailed, paired, t-test, \( p = 0.005 \)) as well as compared to the control group on average by 17% (two-tailed, One Sample, t-test, \( p = 0.005 \)). Additionally, the RF index showed that the healthy control subjects’ dynamic plantar loading distribution was significantly closer to a Gaussian distribution than subjects with painful Pes Cavus. Interestingly, comparison between shod and barefoot in healthy control subjects revealed that despite a significant reduction in MPP while shod, the distribution of plantar pressure remains the same as while barefoot (\( p > 0.2 \)).

CONCLUSIONS

The results of this study suggest that dynamic plantar loading quantified by RF index is negatively altered in painful Pes Cavus as compared with healthy control participants indicating RF index is sensitive to foot posture pathology. RF index was improved significantly for painful Pes Cavus participants wearing custom made foot orthoses compared with those wearing sham orthoses. The improvement in the active group suggests that functional orthoses contribute to a better distribution of peak pressure during dynamic foot loading conditions. The effect size of the RF index to screen improvement due to wearing functional orthoses is much higher than reduction in peak pressure (17% vs. 8%). Wearing sham orthoses significantly reduces peak pressure but doesn’t have any impact on RF Index, suggesting that peak pressure may be biased by the effect of sham but the RF index is not. Further investigation is wanted to both confirm these findings and to investigate the possibility of using the RF index to both evaluate existing treatment options and to develop new ones.

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REFERENCES