

# The Effect of 6 Weeks of Custom-molded Foot Orthosis Intervention on Postural Stability in Participants With $\geq 7$ Degrees of Forefoot Varus

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**Objective:** Postural stability (PS) was assessed in a group of participants with  $\geq 7$  degrees of forefoot varus (FV) after 6 weeks of custom-molded functional foot orthosis (FO) intervention to investigate the effect of FO intervention in a population that may have decreased PS due to their foot structure.

**Design:** A force platform was used to assess right and left single-limb stance position and eyes open and eyes closed condition PS.

**Setting:** PS was assessed in a biomechanics research laboratory.

**Participants:** Twelve participants with  $\geq 7$  degrees of FV (MFV) and 5 participants with  $< 7$  degrees of FV (LFV) participated in the study.

**Interventions:** PS of the MFV group was assessed initially when FOs were received and after 6 weeks of FO intervention. The LFV group PS was assessed during initial and 6-week testing sessions.

**Main Outcome Measures:** The root mean square of the center of pressure velocity was used to quantify single-limb stance PS during no FO and FO conditions.

**Results:** LFV group PS did not change significantly ( $P = 0.829$ ) over the 6-week time period. Significant improvement was, however, reported in the MFV group anteroposterior ( $P = 0.003$ ) and mediolateral ( $P = 0.032$ ) PS at the 6-week assessment versus the initial assessment during both the noFO and FO conditions.

**Conclusions:** Six weeks of FO intervention may significantly improve PS in participants with  $\geq 7$  degrees of FV both when wearing FOs and when not wearing FOs.

**Key Words:** postural sway-postural control, balance-foot structure, orthotics-pronation

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Decreased postural stability (PS) has been revealed after ankle injury<sup>1–9</sup> and in persons with functional ankle instability or recurrent ankle sprains.<sup>10–13</sup> This research has been motivated by the concern that decreased PS after injury may be a risk factor for reinjury. Little research, however, has investigated independent variables that may decrease PS in apparently healthy individuals.<sup>14,15</sup> Identification of these variables may be important as several prospective studies have reported that decreased PS in apparently healthy athletes may be a significant risk factor for sustaining acute injury.<sup>16,17</sup>

A variable recently investigated as a potential source of postural instability is foot structure.<sup>14,15</sup> Root<sup>18</sup> has suggested that the presence of “abnormal” foot postures, such as forefoot varus (FV), result in increased mobility of the subtalar joint (STJ), and/or midtarsal joint (MTJ) during weight-bearing. It may be theorized that increased foot mobility associated with these “abnormal” foot postures may also result in decreased PS. Two studies have recently investigated the effect of foot structure on PS.<sup>14,15</sup> Cobb<sup>14</sup> reported significantly decreased anteroposterior (AP) PS in participants with  $\geq 7$  degrees of FV compared with participants with  $< 7$  degrees of FV. Hertel,<sup>15</sup> however, did not reveal significant PS differences between participants classified with pes planus foot structures compared with those with pes rectus foot structures. The inconsistency in the results between the studies may be related to the parameters used to classify subjects and the variables used to quantify PS and are further discussed in Cobb.<sup>14</sup> If the presence of an increased degree of FV does in fact decrease PS, then identification of intervention methods aimed at improving PS in persons with such foot postures may be warranted.

Functional orthoses (FOs) are often prescribed to treat a variety of lower extremity overuse injuries believed to occur secondary to increased MTJ and STJ mobility associated with “abnormal” foot postures.<sup>19–22</sup> Although the effectiveness of FO intervention in the treatment of

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chronic overuse injury is well accepted clinically,<sup>23-27</sup> the role of FO intervention as a potential preventive measure for acute injury or reinjury is unclear. A potential indication for FO intervention as a preventive measure for acute injury or reinjury may be related to the effect of FO intervention on PS. Two hypotheses have been proposed to explain the benefit of FO intervention on PS. One hypothesis is related to the theory that FO intervention corrects, at least partially, “abnormal” foot postures.<sup>28-30</sup> If a FO acts to “realign” the foot, it may increase joint congruency which may improve foot stability and also PS. The second hypothesis is that FOs provide increased contact area with the plantar surface of the foot that may result in improved mechanoreceptor function and, as a result, improved PS.<sup>4,31</sup>

Several studies have investigated the effect of FO intervention on PS in apparently healthy individuals<sup>32,33</sup> and after acute ankle injury.<sup>4,5,8</sup> Some of the studies have reported significantly improved PS with FO intervention after acute ankle injury,<sup>4,8</sup> whereas others have not.<sup>5</sup> Similarly, investigations of apparently healthy individuals have revealed both significant improvements<sup>32</sup> and no significant change<sup>33</sup> in PS after FO intervention. A factor in the inconsistency between studies may be that none of the investigations classified the foot structure of the subjects receiving FOs. If various foot postures such as FV do result in increased foot mobility that translates into instability and decreased PS, then the effectiveness of FO intervention on PS may be influenced by an individual’s foot structure. To date, only one study has investigated the effect of FO intervention in participants with what may be classified as “abnormal” foot postures.<sup>31</sup> Participants in the study were all classified as excessive pronators based upon the Foot Posture Index. Half of the participants received a prefabricated orthosis and half did not. Bilateral stance PS was assessed at initial and 4-week test periods. No significant AP or mediolateral (ML) PS differences between the groups were reported during the initial assessment. At the 4-week assessment, AP PS did not differ between the conditions, but ML PS was significantly improved in the orthosis group.<sup>31</sup> Although improvements in PS were reported, they were only in the ML direction. However, Cobb<sup>14</sup> revealed significantly decreased AP PS but not ML PS in participants with > 7 degrees of FV compared with those with < 7 degrees of FV. The purpose of the current study, therefore, was to investigate the immediate and extended effect of a custom-molded FO on PS in participants with what may be considered an “excessive” degree of FV. It was hypothesized that FO intervention would improve PS in persons with an “excessive” degree of FV and that over time, as the recipient adjusted to the FO, PS may be further improved.

## METHODS

### Participants

Twelve participants (7 males, 5 females) with  $\geq 7$  degrees of FV (MFV) volunteered for the study (Table 1).

**TABLE 1.** Descriptive Data and Foot Measurements (mean  $\pm$  SD) for Participants With  $\geq 7$  degrees of Forefoot Varus and Participants With  $< 7$  degrees of Forefoot Varus

	$\geq 7$ degrees Forefoot Varus	$< 7$ degrees Forefoot Varus
Age (y)	29.8 $\pm$ 8.4	28.0 $\pm$ 4.0
Mass (kg)	72.7 $\pm$ 9.2	70.4 $\pm$ 18.6
Height (cm)	172.3 $\pm$ 7.9	165.5 $\pm$ 7.2
Forefoot varus (degree)	8.9 $\pm$ 1.7	4.0 $\pm$ 1.3
Navicular differential (mm)	12.2 $\pm$ 3.6	9.7 $\pm$ 4.2
Rearfoot valgus (degree)	9.8 $\pm$ 2.3	5.2 $\pm$ 2.3

None of the participants complained of functional instability, had a history of acute or chronic foot/ankle injury, or used a FO within the 6 months before testing. Ankle functional instability was defined as a frequent feeling of “giving way.” A group of 5 participants (2 males, 3 females) with  $< 7$  degrees FV (LFV), without functional instability or history of acute or chronic foot/ankle injury also volunteered for the study (Table 1). Before testing, all participants provided written informed consent in accordance with institutional guidelines, and the equipment and procedures of the study were explained.

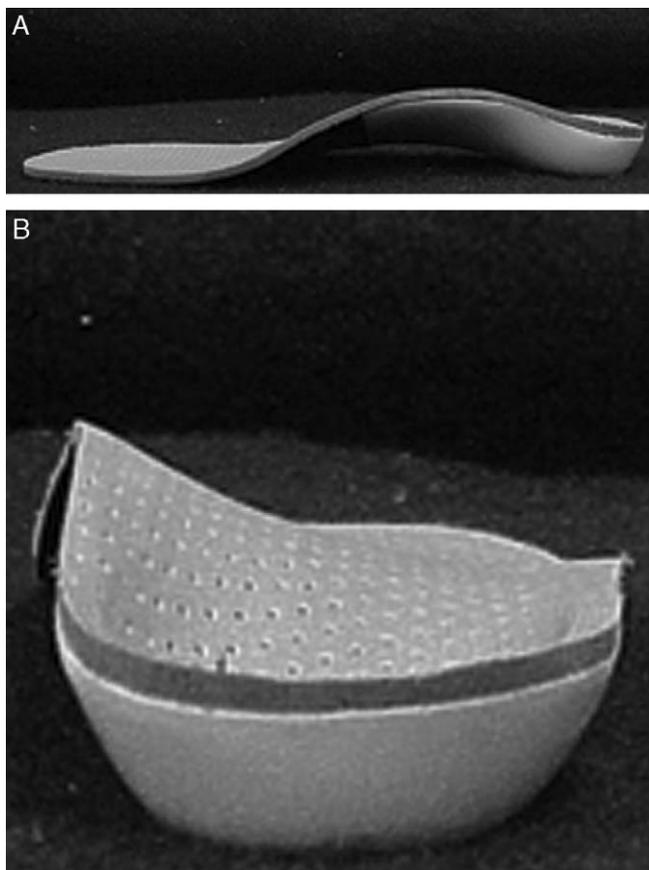
### FV Assessment

FV was assessed according to the method established by Root<sup>34</sup> and modified by Elveru.<sup>35</sup> The measurements were taken with the participant in a prone position with the foot held in STJ neutral position by the examiner. Volunteers with forefoot valgus were not included in the study. The same researcher performed the forefoot measurements 3 times for each foot.<sup>36</sup> The average of the 3 measurements for each foot was used to represent each participant’s FV. Although not used to classify groups, navicular differential,<sup>37</sup> and standing rear-foot varus/valgus<sup>34</sup> measurements were assessed as representative measures of the compensatory increased mobility at the MTJ and STJ associated with the presence of increased FV (Table 1).

After the foot measurements, participants in the MFV group were cast for semirigid custom-molded FOs (Sole Supports, Inc, Lydes, TN). Cast impressions were captured in a foam box using a manufacturer recommended dynamic casting procedure and then shipped to the manufacturer (Sole Supports, Inc, Lydes, TN). The FO used in the current study differed from traditional FOs in that it was constructed from a polyethylene composite material and provided all of its support through the medial longitudinal arch without forefoot or rear-foot posting (Fig. 1).

### Instrumentation

An AMTI Biomechanics Platform (Model OR6-5-2000, Advanced Mechanical Technology, Inc, Newton, MA) sampling at 120 Hz was used to measure 3-dimensional ground reaction forces and moments



**FIGURE 1.** A, Medial view of the custom-molded semi-rigid functional orthosis; B, Posterior view of the custom-molded semi-rigid functional orthosis.

between the participant's foot and the force platform. An AMTI SGA6-4 amplifier (Advanced Mechanical Technology, Inc, Newton, MA) set at a gain of 2000 Hz with a 10.5 Hz second-order critically damped filter was used to process the raw analog data. The Peak Performance Technologies Motus Motion Measurement System (Peak Performance Technologies, Inc, Englewood, CO) was used for analog-to-digital signal conversion and to compute 3-dimensional ground reaction forces and moments.

A program written in Matlab (MathWorks, version 7.0.4) was then used to compute *x*-axis and *y*-axis COP positions from the ground reaction forces and moment data and to compute AP and ML COP velocities using the first central difference method for numerical differentiation.<sup>38</sup> Finally, AP and ML root-mean-square of pressure velocities (RMSCOPVs) were computed to quantify PS<sup>39</sup> using the following formula:

$$\text{RMSCOPV} = \sqrt{\frac{\sum_{i=1}^n \text{COPV}^2}{n}},$$

where *n* is the number of data points (sampling frequency × trial duration) in the trial. The RMSCOPV

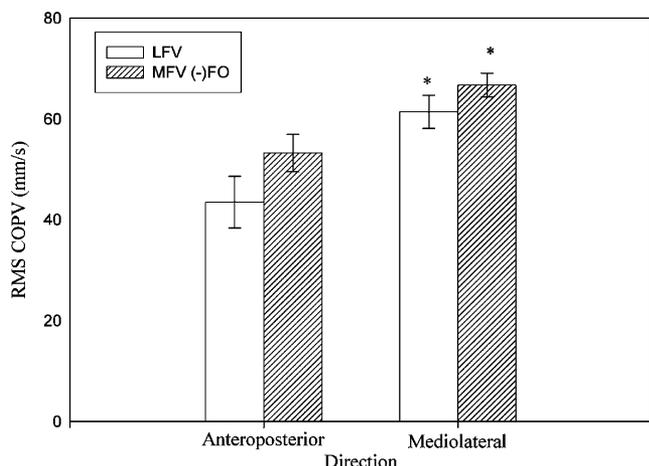
was chosen to represent PS because it has been suggested that the time rate of change in COP position may be more representative of stability than COP position alone.<sup>40</sup>

## Procedures

PS was assessed using the protocol established by Goldie<sup>41</sup> during the following conditions and positions: (1) eyes open right leg stance; (2) eyes closed right leg stance; (3) eyes open left leg stance; and (4) eyes closed left leg stance. The Goldie<sup>41</sup> protocol consists of the performance of 4 consecutive 5-second trials that are subsequently averaged to represent the participant's PS.<sup>41</sup> The testing procedures used in the current study are described in detail in Cobb.<sup>14</sup> During PS assessment, all participants wore the same court shoe (K-Swiss Classic Lo).

MFV group PS was tested during no FO [(−)FO] and FO [(+)FO] conditions. For the (+)FO condition, the insoles of the court shoes were removed, the FOs were inserted, and participants walked for approximately 10 minutes to familiarize themselves with the FO before PS assessment. During PS testing, the order of eye condition (open or closed) and stance position (right single limb or left single-limb stance) testing for both (+)FO and (−)FO trials was counterbalanced to control for fatigue and any learned effect. After completion of the initial testing session, the MFV group was given break-in instructions and logs to record their FO use. The break-in instructions recommended that the FO be worn for 1 hour on the day they were received and that wear then be increased by an hour each day until the FO could be worn for 8 hours without discomfort. The MFV group returned in 6 weeks for follow-up testing and the above procedures were repeated. PS of the LFV group was also assessed during initial and 6-week testing sessions to investigate: (1) PS differences between the MFV and LFV groups at the initial testing session and (2) Whether a learned effect occurred over the time interval.

After the initial and 6-week assessments, the average RMSCOPV of the 4 trials in the AP and ML direction for each condition and position on each visit were used to represent each participant's PS. A doubly multivariate analyses of variance (DM MANOVA)<sup>42</sup> with 2 within-subject factors (limb and eyes) was performed to investigate AP and ML PS differences between the LFV and MFV groups during the initial testing session. A DM MANOVA with 4 within-subject factors (time, insert, limb, and eyes) was then performed to investigate the effect of FO intervention on PS over the 6-week interval in the MFV group. A DM MANOVA with 3 within-subject factors (time, limb, and eyes) was also performed with the LFV group to investigate whether a learned effect occurred between the initial and 6-week testing sessions. Follow-up univariate repeated measures analyses of variance (RM ANOVAs) were performed to investigate significant DM MANOVA omnibus *F* ratios. The significance level for all of the statistical tests was *P* < 0.05.



**FIGURE 2.** AP and ML postural stability [root mean square center of pressure velocity (RMS COPV) ± SEM] of the LFV and MFV groups during the initial test session. \*The MFV group demonstrated significantly decreased AP and ML postural stability compared with the LFV group.

**RESULTS**

**LFV versus MFV Participants**

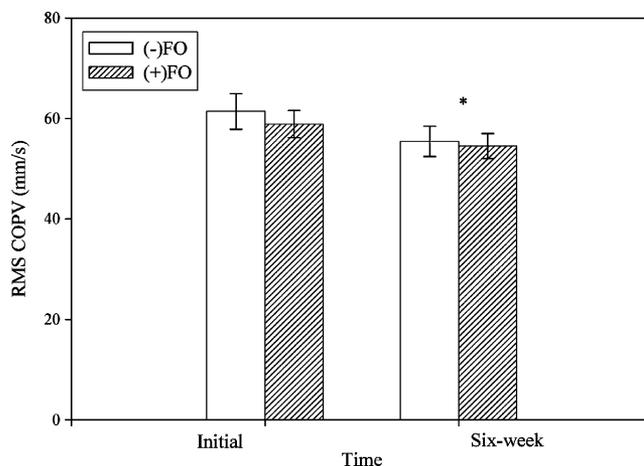
Results of the DM MANOVA revealed a significant between-subject main effect for the group factor ( $F_{2,14} = 4.86, P = 0.025$ ) and a significant within-subject main effect for the eyes factor ( $F_{2,14} = 44.19, P < 0.001$ ). Follow-up RM ANOVAs for the group main effect revealed significant AP ( $F_{1,15} = 8.62, P = 0.01$ ) and ML ( $F_{1,15} = 9.48, P = 0.008$ ) PS differences between the LFV and MFV groups (Fig. 2). Follow-up RM ANOVAs for the eyes main effect revealed significant AP ( $F_{1,15} = 39.11, P < 0.001$ ) and ML ( $F_{1,15} = 89.80, P < 0.001$ ) PS differences between the eyes open and eyes closed conditions. During both the initial and 6-week assessments, PS was significantly better during eyes open versus eyes closed conditions in the AP and ML directions.

**LFV Participants Across Time**

Results of the DM MANOVA revealed no significant within-subject interactions ( $P > 0.05$ ). The only significant within-subject main effect was revealed for the eyes factor ( $F_{2,3} = 28.69, P = 0.011$ ). Follow-up RM ANOVAs for the eyes main effect revealed significant differences between eyes open and eyes closed conditions in both the AP ( $F_{1,4} = 28.33, P = 0.006$ ) and ML ( $F_{1,4} = 61.92, P = 0.001$ ) directions. During both the initial and 6-week assessments, PS was significantly better during eyes open versus eyes closed conditions in the AP and ML directions.

**Participants with ≥ 7 degrees of FV**

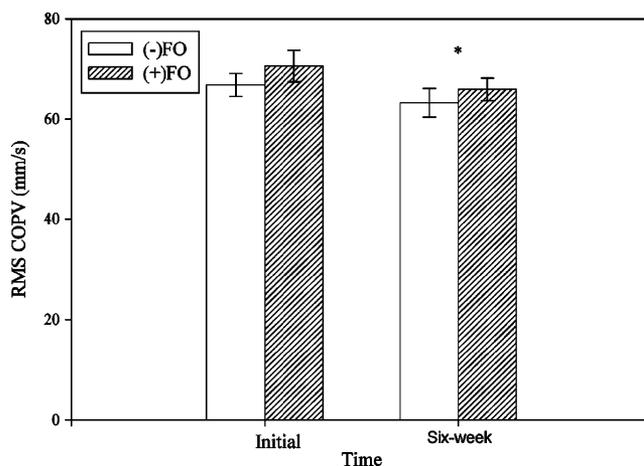
Results of the DM MANOVA investigating the effect of 6 weeks of FO intervention revealed no significant within-subject interactions ( $P > 0.05$ ). Results did reveal significant eye ( $F_{2,10} = 83.94, P < 0.001$ ), insert



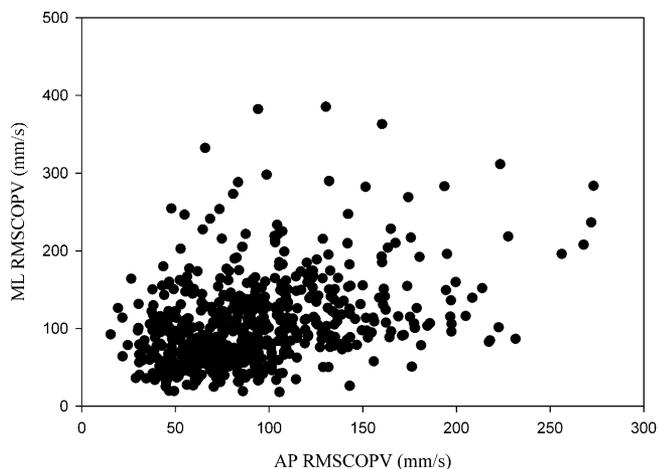
**FIGURE 3.** AP postural stability [root mean square center of pressure velocity (RMS COPV) ± SEM] of participants with ≥ 7 degrees of forefoot varus during no functional orthosis [(-)FO] and functional orthosis [(+)FO] conditions. \*Postural stability was significantly improved at the 6-week test period during both (-)FO and (+)FO conditions.

( $F_{2,10} = 6.70, P = 0.014$ ), and time ( $F_{2,10} = 6.01, P = 0.019$ ) within-subject main effects.

Follow-up RM ANOVAs for the eyes main effect revealed significant differences between eyes open and eyes closed conditions in the AP ( $F_{1,11} = 104.67, P < 0.001$ ) and ML ( $F_{1,11} = 184.36, P < 0.001$ ) directions. Follow-up RM ANOVAs for the insert main effect did not reveal statistically significant differences between the (-)FO and (+)FO conditions for either the AP ( $F_{1,11} = 0.62, P = 0.448$ ) or ML ( $F_{1,11} = 2.15, P = 0.170$ ) directions. Finally, follow-up RM ANOVAs for the time main effect revealed significant differences



**FIGURE 4.** ML postural stability [root mean square center of pressure velocity (RMS COPV) ± SEM] of participants with ≥ 7 degrees of forefoot varus during no functional orthosis [(-)FO] and functional orthosis [(+)FO] conditions. \*Postural stability was significantly improved at the 6-week test period during both (-)FO and (+)FO conditions.

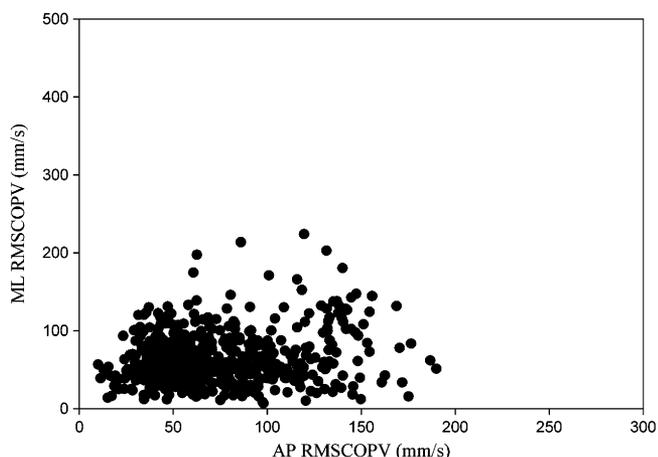


**FIGURE 5.** Representative scatter plot of ML RMSCOPV versus AP RMSCOPV for the initial PS assessment [subject 2 left foot eyes closed position (-)FO condition].

between the initial and 6-week assessments in both the AP ( $F_{1,11} = 13.21$ ,  $P = 0.004$ ) (Fig. 3) and ML ( $F_{1,11} = 5.99$ ,  $P = 0.032$ ) (Fig. 4) directions.

## DISCUSSION

At the initial test session, both AP and ML PS were significantly decreased in the MFV group compared with the LFV group (Fig. 2). The AP PS results are consistent with those of Cobb,<sup>14</sup> but inconsistent with those of Hertel,<sup>15</sup> and the ML PS results are inconsistent with those reported in Cobb<sup>14</sup> and Hertel.<sup>15</sup> Neither Cobb<sup>14</sup> nor Hertel<sup>15</sup> revealed significant ML differences between subjects with  $> 7$  degrees of FV versus  $< 7$  degrees of FV or between subjects classified as having pes planus versus pes rectus foot structures, respectively. Because the groups in the current study and those in Cobb<sup>14</sup> were defined in the same manner, the difference in the ML PS



**FIGURE 6.** Representative scatter plot of ML RMSCOPV versus AP RMSCOPV for the 6 week PS assessment [subject 2 left foot eyes closed position (+)FO condition].

results between the studies is likely the result of differences in the variable used to quantify PS. The current study used the RMSCOPV to quantify PS, whereas Cobb<sup>14</sup> quantified PS using force measures. Differences between the current study and Hertel<sup>15</sup> may once again be related to either the variable used to quantify PS or the parameters used to classify groups.<sup>14</sup> The findings in the current study support the hypothesis that an increased degree of FV may be associated with decreased PS. They also support the suggestion by Karlsson<sup>43</sup> that the different variables used to quantify PS may assess different aspects of standing balance.

With respect to the FO intervention, it was initially hypothesized that MFV group (+)FO condition PS would be improved compared to the (-)FO condition during the initial testing session. It was further hypothesized that as the MFV group accommodated to the FO, their PS would be further improved at the 6-week testing session. The results, however, revealed that the MFV group PS did not change significantly with the introduction of the FO at the initial testing session (Figs. 3, 4). Furthermore, although AP (Figs. 3, 5) and ML (Figs. 4, 6) PS did significantly improve over time, the significant improvement occurred during both the (+)FO and (-)FO conditions. The fact that PS of the LFV group did not change significantly over the 6-week period, however, does suggest the change in the MFV PS was related to the FO intervention.

The only previous study to investigate the effect of FO intervention in a population of participants with “abnormal” foot structure was Rome.<sup>31</sup> Rome<sup>31</sup> reported significantly improved ML PS after 4 weeks of prefabricated FO intervention in participants classified with excessively pronated feet compared to participants classified with excessively pronated feet that did not receive FOs. AP PS, however, did not change significantly over the 4-week test-retest period. Although the current study revealed significant improvements in ML and AP PS over the 6-week test-retest period, the improvement occurred during both the (-)FO and (+)FO conditions. Comparisons of the results between the 2 studies are difficult due to differences in statistical design of the studies. The current study was a completely within-study repeated measures design in which (-)FO and (+)FO conditions were compared for the same participants at the initial and 6-week tests. The Rome<sup>31</sup> study, on the other hand, was a mixed model design in which initial and 4-week FO and no FO conditions were compared between different participants. The fact that both studies revealed significant improvements in ML PS over time that may be attributed to FO intervention suggests that FO intervention may have a beneficial effect on PS in persons with “abnormal” foot structure.

The improvement over time in AP PS in the current study but not in the Rome<sup>31</sup> study may be related to several factors in addition to the differing statistical designs. First, the length of time between the initial test and retest differed between the studies. Perhaps improvements in AP PS secondary to FO intervention do not

occur until sometime after 4 weeks of FO use. Further study with multiple retest periods would be required to definitively answer this question.

Another factor may be differences in the construction of the FOs used in the 2 studies. The custom-molded FO used in the current study provided all of its support through the MLA. The prefabricated FO used by Rome<sup>31</sup> incorporated rear-foot and forefoot posting to control foot function. The support directly under the MLA provided by the custom-molded FO used in the current study, as opposed to indirect control through rear-foot and forefoot posting, may have provided additional support to the MLA through increased arch structure stiffness. As the center of gravity line traveled anteriorly and posteriorly during single-limb stance, the custom-molded FO may have provided greater foot stability. In addition to differences in FO construction, the FOs used in the current study may have provided greater stability because they were custom-molded and fabricated to each participant's foot. The FOs used by Rome<sup>31</sup> were prefabricated and each participant received the same degree of forefoot and rear-foot posting. The unexpected result from the current study was the significant AP and ML PS improvement over the 6-week period during both the (–)FO and (+)FO conditions. Unless the FO intervention also resulted in permanent, or at least transient, change in foot structure over the 6-week time interval, neither of the above mechanisms account for the improvement reported during the (–)FO condition.

Perhaps then, the primary benefit of FO intervention on PS was related to improved mechanoreceptor function secondary to the increased contact area between the FO and the plantar surface of the foot.<sup>4,31</sup> If improved mechanoreceptor function was the mechanism, the results of the current study would suggest that there is an adaptation period during which the improvement in mechanoreceptor function occurs. Furthermore, the improvements in the ML and AP PS during the (–)FO condition suggest that some form of adaptation, independent of the FO contact with the plantar surface of the foot, occurs over time.

## CONCLUSIONS

The current study supports the hypothesis that an increased degree of FV may significantly decrease single-limb stance PS. If decreased PS is a risk factor for sustaining acute injury as has been previously reported,<sup>16,17,44</sup> the significant AP and ML PS improvements that occurred after the 6-week FO intervention period may be clinically relevant.

Before concluding either that: (1) an increased degree of FV is a risk factor for acute injury/reinjury; or (2) the improved PS associated with FO intervention in persons with an increased degree of FV may be an effective preventative measure for acute injury/reinjury, the “threshold” at which decreased PS becomes a significant risk factor must be determined. Further prospective studies are required to determine this “thresh-

old.” A second important clinical implication may be related to the fact that PS did not improve immediately with FO intervention but rather sometime during the 6-week intervention period. If FO intervention were to be used to improve PS and potentially decrease risk of injury/reinjury in persons with  $\geq 7$  degrees of FV, it may be important to begin FO intervention some time before the beginning of the individual's season.

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