

# Short- and Long-Term Influences of a Custom Foot Orthotic Intervention on Lower Extremity Dynamics

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**Objective:** The objective of the current study was to analyze the influence of a short-term and long-term custom foot orthotic (CFO) intervention on the lower extremity dynamics in a group of female runners with a history of overuse running knee injury.

**Design:** Descriptive laboratory study.

**Setting:** University of Massachusetts Biomechanics Laboratory, Amherst, MA.

**Participants:** This study included a group of female recreational runners (15 to 40 km per week) who had a history of overuse running knee injury in the 6 months leading up to the study.

**Intervention:** Semi-rigid, custom foot orthoses manufactured from a neutral suspension cast and designed to meet the specific needs of each subject. Subjects wore the custom foot orthoses during all running activities for a period of 6 weeks.

**Main Outcome Measures:** Three-dimensional ankle and knee dynamics were collected while subjects performed over-ground running trials with and without a CFO intervention. Data were collected before and after a 6-week CFO intervention during all running activities.

**Results:** For ankle parameters, short-term intervention led to significant decreases in maximum values for rearfoot eversion angle and velocity, impact peak, and loading rate. Ankle inversion impulse was also significantly decreased during the loading phase. At the knee, maximum knee external rotation moment was significantly increased when subjects wore the custom foot orthoses.

**Conclusions:** The 6-week intervention led to subjective changes, including a significant decrease in pain. An improvement in symptoms did occur with the 6-week intervention. In addition, dynamic results revealed that custom foot orthoses have an immediate effect on dynamics and that this influence occurs only when orthoses are worn in the footwear. The short-term CFO intervention led to significant decreases in rearfoot kinematics (maximum eversion angle and velocity) but no changes observed in knee kinematics. The kinetic analysis revealed that these subjects exhibited significant

decreases in maxima for ankle inversion moment and angular impulse during the loading phase, impact peak, and vertical loading rate with short-term, CFO intervention. At the knee, the CFO condition led to increases in knee external rotation moment maxima and angular impulse.

**Key Words:** custom foot orthoses, joint moment, rearfoot motion, overuse running injury

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Custom foot orthoses (CFOs) are typically prescribed as part of a treatment program for a number of running related overuse injuries.<sup>1</sup> Several studies have been conducted over the past 25 years to investigate the efficacy of this intervention in producing positive clinical outcomes<sup>2–4</sup> and to analyze the influence custom foot orthoses have on lower extremity dynamics.<sup>5–11</sup> It is generally accepted in the literature that custom foot orthotic intervention produces positive clinical outcomes for patellofemoral pain syndrome,<sup>4</sup> plantar fasciitis,<sup>3</sup> and a variety of other running injuries.<sup>2</sup> However, what remains unclear is how this therapeutic modality influences the dynamics of the lower limb to produce the positive clinical outcomes.

Prior research has assessed lower extremity dynamics in the following subjects: 1) those who are not typically candidates for the intervention (ie, healthy subjects)<sup>10,13</sup>; 2) those who have worn orthoses previously for an uncontrolled period of wear<sup>11</sup>; and 3) those who were injured and for whom only subjective measures have been analyzed.<sup>4</sup> We recognize the need to investigate healthy subjects and to create an understanding of how the intervention influences lower extremity dynamics, which can then be used to study effects in a clinical sample of runners. By studying healthy subjects, pain can be controlled as a confounder and the results may help researchers make inferences about how the intervention influences a clinical sample. However, individuals who require CFOs as a therapeutic modality must also be studied.

The majority of quantitative studies have focused on analyzing rearfoot kinematics. More recently, researchers have investigated the three-dimensional (3D) lower extremity kinematics and kinetics in healthy runners,<sup>13</sup> healthy runners classified as *pronators*,<sup>10</sup> and in a group of runners who were prescribed foot orthoses for a running-related injury.<sup>11</sup> Data for these studies were collected at the time of dispense (short-term intervention) or after a runner had worn the device for some

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uncontrolled period of time (long-term intervention). Muen-dermann et al<sup>12</sup> reported that foot orthotic intervention results in consistent immediate effects on lower extremity dynamics over a 3-week period. However, this study included healthy subjects and its primary purpose was to determine whether a baseline reading of immediate effects was consistent between days. This was an essential initial step before an analysis of long-term CFO intervention effects.

A question that often arises is whether the influence of this intervention in a clinical sample is realized in the short term upon dispense or if there are further adaptations that occur with a prescribed period of wear (long term). Therefore, the purpose of the current study was to analyze the influence of short-term and long-term CFO interventions on the lower extremity dynamics in a group of female runners with a history of overuse running knee injury. It was hypothesized that 1) short-term CFO intervention would lead to significant decreases in rearfoot dynamic variables<sup>13</sup> and 2) long-term (6-week) CFO intervention would lead to dynamic changes exhibited when the subjects ran in a shoe-only (SHOD) condition.

## METHODS

### Subjects

This study included a group of female recreational runners who had a history of overuse running knee injury in the 6 months leading up to the study (height:  $1.64 \pm 0.07$  m; mass:  $61.6 \pm 6.27$  kg). All subjects were 18- to 35-year-old females who ran 15 to 40 km per week. Only runners classified as rearfoot strikers from their vertical ground reaction force record were included in the study. Although the relationship between structural characteristics and dynamic function is not well understood,<sup>14,15</sup> no subjects exhibited leg-length discrepancy, rigid forefoot varus deformity, gastrocnemius equinus, structural hallux limitus, or rigidus. Approval for the participation of human subjects in this investigation was obtained from the Human Subjects Review Committee at the University. An a priori sample size prediction was performed using SAS version 8.2 and data from the literature.<sup>5,16</sup> A sample size of 12 was estimated for a minimal statistical power of  $\geq 0.80$  and  $\alpha = 0.05$ .

### Experimental Setup

During individual overground running trials, 3D kinematic data were collected using an eight-camera, Qualisys ProReflex system (Gothenburg, Sweden) interfaced to a microcomputer. An AMTI force platform (Advanced Mechanical Technology, Watertown, MA) was embedded, flush with the surface of the floor, in a 20-m runway. The force platform was interfaced via an A/D converter to the same microcomputer used for the camera system to synchronize the data. The sampling frequency of the kinematic data for all running trials was 240 Hz and for the kinetic data was 1920 Hz.

Running speed was monitored using two photocells positioned 5.94 m apart; one was positioned in advance of the force platform and the second following the force platform. Only running trials at 4.0 m/s ( $\pm 5\%$ ) were accepted.<sup>10</sup>

Prior to each testing session, a right-handed global coordinate system (GCS) was defined and calibrated. The

origin of the GCS was positioned on the AMTI force platform. The right-handed GCS was oriented such that the z-axis was vertical, the y-axis was in the anteroposterior (A-P) direction or in the direction of motion, and the x-axis was in the mediolateral (M-L) direction.

### Protocol

Each subject received a biomechanical evaluation and was casted for the custom foot orthoses using the neutral suspension cast technique. Negative impressions were sent to Paris Orthotics Lab (Vancouver, BC, Canada) where they were laser-scanned, digitally cast dressed (AOMS, Sharp Shape, Cupertino, CA), and a multidensity fiberboard positive cast was created using a computer numerically controlled milling machine. The custom foot orthotic design was a semi-rigid, functional foot orthosis with a thermoplastic (3 mm copolymer or polypropylene) orthotic shell. Thermoplastic orthotic shells were vacuum-pressed and finished at Paris Orthotics Lab. Orthotic shell material selections were based on subject body weight. The device was intrinsically posted to calcaneal vertical and inverted an additional 5 degrees. Foot orthoses also included an extrinsic ethyl vinyl acetate (EVA) rearfoot stabilizer with nylon strike plate. The heel cup depth was 18 mm and a minimum cast dressing was used. Lastly, a full-length, EVA (Microcel Puff) top cover was added for additional cushioning.

Prior to data collection, retro-reflective markers were positioned on each subject. These markers included both calibration and tracking markers. Calibration markers were positioned on the left and right greater trochanters, right-side medial and lateral femoral condyles, right-side medial and lateral maleoli, and the 1st and 5th metatarsal heads. Tracking markers were securely positioned to define the pelvis (L5/S1 joint line, anterior superior iliac spine, iliac crest), thigh (rigid array of four markers), leg (rigid array of four markers), and calcaneus (rigid triad). Calibration markers were removed after the calibration trial while the tracking markers remained for all running trials.

Data were collected on two occasions: at the time of CFO dispense (Week 0) and after 6 weeks of prescribed orthotic intervention. The CFO intervention was introduced to each individual running program in a graduated fashion in a manner that has been advocated clinically. During Week 1, orthoses were only worn while walking and 1 hour of wear was added daily. In the following week, each subject gradually introduced the orthosis to their running program. Lastly, during Weeks 3 to 6, subjects were instructed to wear the orthoses during all running activity. Prior to the 6-week data collection, each subject was asked to complete an Orthotic Evaluation Form adapted from Saxena et al.<sup>4</sup> It was hoped that the inclusion of such a questionnaire would shed light on whether the intervention produced a positive clinical outcome.

Following the calibration stance trial, each subject performed 5 acceptable overground running trials for the SHOD condition and an additional 5 running trials for the shoe and custom CFO condition in a randomized manner. All running trials were performed in the New Balance 801 running shoe so that a calcaneal marker set could be positioned directly on the skin. An acceptable trial was one in which the subject

contacted the force platform with a normal stride and within the required time.

## Data Reduction

Kinematic data for the stance phase of each overground running trial were digitized using QTM software (Qualisys, Inc., Gothenberg, Sweden). Synchronized raw kinematic and kinetic signals were exported from QTM in a C3d format and processed using Visual 3D software (C-Motion, Inc., Rockville, MD). Raw kinematic and kinetic data were low-pass filtered using a fourth order, zero-lag Butterworth digital filter. For the kinematic data, a cut-off frequency of 12 Hz for the low-pass filter was selected based on a residual analysis technique recommended by Winter<sup>17</sup> while the kinetic data were filtered with a cut-off of 75 Hz.

The 3D segmental and joint kinematics, internal joint moments and vertical ground reaction forces were calculated using the Visual 3D software. The 3D segment and joint angles were calculated using an X (flexion/extension), Y (abduction/adduction), Z (longitudinal rotation) Cardan rotation sequence.<sup>18</sup> Joint angles were reported as movement of the distal segment relative to the proximal segment. Segment angles were reported relative to the laboratory coordinate system.

A Newton-Euler inverse dynamics approach was employed to calculate the joint kinetics. The inverse dynamics approach requires three sources of information: 1) segment inertial parameters; 2) kinematic data; and 3) ground reaction forces. The foot, leg and thigh segments were modeled as frusta of a right cone and the pelvis was modeled as a cylinder. The anthropometric properties, including segment mass, moment of inertia, and center of mass from the subject weight and height, were derived from Dempster's anthropometric data.<sup>19</sup> Segment lengths were defined by the standing calibration markers. Joint centers were defined as the midpoint between the standing calibration markers for ankle and knee. Internal joint moments about the ankle and knee were calculated and reported in the coordinate system of the proximal segment. Both the kinematic and kinetic data were interpolated to 101 data points, with each data point representing 1% of the stance phase.

## Statistical Analysis

Parameters describing the kinematics of the foot, ankle, leg, and knee, moments of the ankle and knee joints, and ground reaction forces related to each hypothesis were determined for each subject/trial. All hypotheses were statistically analyzed using a condition (CFO and SHOD) × session (Week 0 and Week 6) × subjects repeated measures analysis of variance. Analyses of planned comparisons were conducted with paired samples t-tests. Significance is indicated by  $\alpha < 0.05$  and an observed power  $\geq 0.80$ . In addition, effect size (ES) was calculated for each parameter.<sup>20</sup> Cohen<sup>20</sup> proposed that ES values of 0.2 represent small differences and 0.5 represent moderate differences.

## RESULTS

Prior to the data collection after 6 weeks of intervention, each subject in the Treatment Group completed an Orthotic Evaluation Form. The results revealed that the intervention produced an improvement in symptoms (symptoms decreased by 73.1%) and there was a significant decrease (ES = 0.92;  $P < 0.001$ ) in pain from an initial 6.00 ( $\pm 1.73$ ) score at Week 0 to 1.73 ( $\pm 1.42$ ) at Week 6 (0 = no pain; 10 = severe pain).

There were no significant interactions or main effects for Session for any of the ankle kinematic variables (Table 1). However, there were significant Condition main effects for maximum rearfoot eversion angle (ES = 0.56;  $P = 0.003$ ) and velocity (ES = 0.75;  $P < 0.001$ ). These parameters were significantly decreased for the CFO condition.

There were no significant Condition × Session interactions or Session main effects for any of the ankle kinetic variables (Table 1). Significant Condition main effects were found for the ankle inversion moment (ES = 0.34;  $P = 0.04$ ), ankle inversion impulse during the loading phase (ES = 0.48;  $P = 0.008$ ), vertical impact peak (ES = 0.44;  $P = 0.01$ ), and vertical ground reaction force loading rate (ES = 0.69;  $P < 0.001$ ). All variables were significantly reduced for the CFO condition when compared to the SHOD condition.

For the knee parameters, there were no significant Condition × Session interactions or Session main effects for any of the parameters (Table 2). There was a significant Condition main effect for the maximum internal external

**TABLE 1.** Ankle and Ground Reaction Force Parameters (n = 12)

Parameters	Week 0		Week 6	
	SHOD	CFO	SHOD	CFO
Maximum rearfoot eversion angle	-6.20 ± 4.80	-4.64 ± 4.20	-5.20 ± 4.88	-4.32 ± 4.74
Maximum calcaneal eversion angle	-0.65 ± 3.95	0.73 ± 3.90	-0.82 ± 3.54	1.75 ± 4.18
Maximum tibial adduction angle	5.00 ± 3.40	5.55 ± 2.92	4.98 ± 2.99	5.53 ± 2.71
Maximum rearfoot eversion velocity	-214.37 ± 79.46	-175.71 ± 73.14	-247.92 ± 108.96	-210.34 ± 94.17
Maximum ankle inversion moment	0.78 ± 0.25	0.73 ± 0.18	0.87 ± 0.32	0.80 ± 0.32
Ankle inversion impulse	0.56 ± 0.18	0.47 ± 0.16	0.66 ± 0.31	0.53 ± 0.30
Maximum impact peak	1.93 ± 0.22	1.82 ± 0.20	1.88 ± 0.23	1.78 ± 0.25
Maximum loading rate	96.05 ± 29.43	84.02 ± 23.95	94.24 ± 26.85	74.68 ± 15.98

Data are means ± SD. Angles are in degrees, velocity in degrees/s, moments in N-m/kg of body mass, impulse in Nm-s/kg of body mass, force in BW, loading rate in BW/s.

**TABLE 2.** Knee Parameters (n = 12)

Parameters	Week 0		Week 6	
	SHOD	CFO	SHOD	CFO
Maximum knee internal rotation angle	2.77 ± 4.45	2.57 ± 4.59	5.86 ± 5.52	5.17 ± 6.16
Maximum tibial internal rotation angle	6.88 ± 4.26	5.50 ± 4.75	8.55 ± 5.48	8.41 ± 5.37
Maximum femoral internal rotation angle	-1.28 ± 5.22	-1.96 ± 5.82	-2.85 ± 6.61	-2.05 ± 7.23
Maximum knee adduction angle	4.46 ± 3.89	4.70 ± 4.50	3.71 ± 4.50	4.36 ± 3.60
Maximum knee flexion angle	-44.70 ± 5.80	-45.07 ± 5.59	-42.81 ± 5.77	-42.38 ± 5.41
Maximum knee external rotation moment	-0.43 ± 0.14	-0.47 ± 0.13	-0.38 ± 0.20	-0.39 ± 0.19
Knee external rotation impulse	-0.51 ± 0.21	-0.55 ± 0.19	-0.44 ± 0.30	-0.44 ± 0.30
Maximum knee abduction moment	-1.00 ± 0.34	-1.05 ± 0.37	-0.95 ± 0.35	-1.01 ± 0.31
Knee abduction impulse	-1.44 ± 0.49	-1.49 ± 0.45	-1.35 ± 0.43	-1.42 ± 0.38
Maximum knee extension moment	1.72 ± 0.41	1.74 ± 0.40	1.60 ± 0.54	1.60 ± 0.52
Knee extension impulse	1.99 ± 0.58	1.94 ± 0.45	1.79 ± 0.68	1.76 ± 0.65

Data are means ± SD. Angles are in degrees, moments in N-m/kg of body mass, impulse in Nm-s/kg of body mass.

rotation knee moment (ES = 0.68; *P* = 0.001). The variable was significantly greater for the CFO condition.

**DISCUSSION**

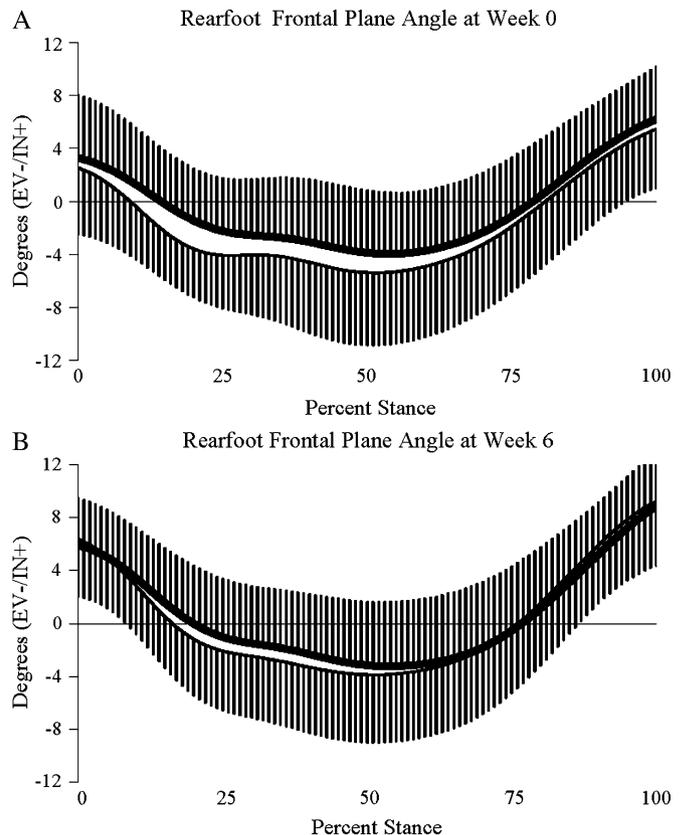
The purpose of this study was to analyze the influence of immediate short-term and long-term CFO interventions on the lower extremity dynamics in a group of female runners with a history of overuse running knee injury. The immediate short-term influence referred to the dynamic changes measured immediately at the time of orthotic dispense, while the long-term influence referred to the changes that occur after a prescribed period of wear (6 weeks). In the current investigation, a group of runners with a history of overuse lower extremity injury participated in a prescribed period of wear. Prior to the data collection after 6 weeks of intervention, each subject in the Treatment Group completed an Orthotic Evaluation Form, the results of which revealed that the intervention produced an improvement in symptoms and a decrease in pain. These findings are consistent with Saxena et al,<sup>4</sup> who reported that 76.4% of subjects reported an improvement in symptoms with a 2- to 4-week CFO intervention.

Maximum rearfoot eversion angle was significantly decreased (Fig. 1). This finding is consistent with values reported in the literature; however, results are typically highly variable and changes are small in magnitude.<sup>10,11,13</sup> Rearfoot eversion velocity was significantly decreased for the CFO condition (Fig. 2). Smith et al<sup>6</sup> were among the first to report this finding. Maximum rearfoot eversion velocity is a variable that has been frequently associated with overuse running injury, although the direct relationship has yet to be established.<sup>21,22</sup>

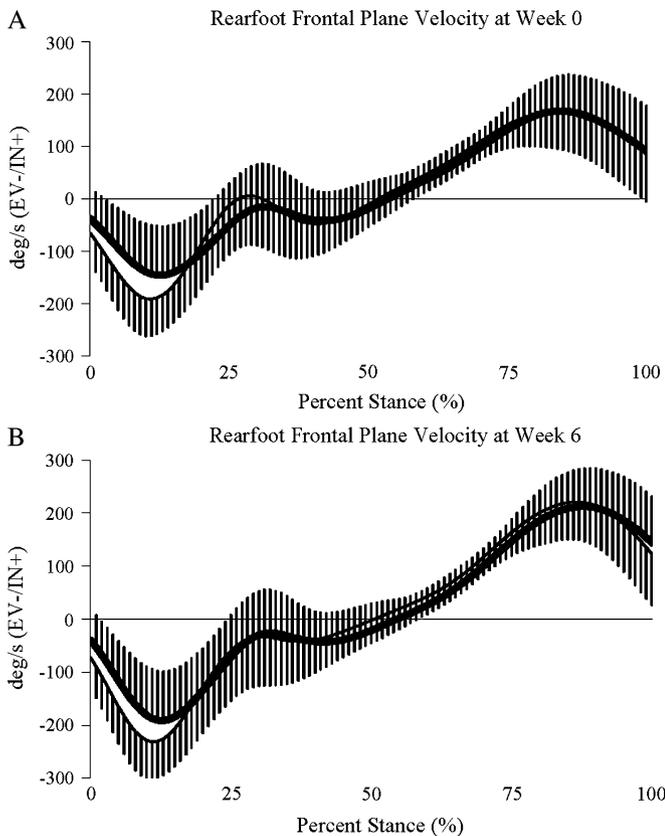
The current sample of runners did not exhibit increases in maximum knee adduction angle as reported by Williams et al.<sup>11</sup> This may be due to the design of the CFO intervention employed. Williams et al<sup>11</sup> used a Blake inverted orthosis, which typically includes a high degree of intrinsic varus (inversion) cast dressing. The devices in their study were posted at 15 to 25 degrees of varus (inversion) and thus were far more aggressive than the orthoses employed in the current study (5 degrees varus or inversion). Given that the

CFO intervention used in the current study produced positive clinical outcomes at the knee, it appears that improved symptoms cannot be explained by changes in knee kinematics alone.

There were no significant Condition × Session interactions or Session main effects for any of the kinetic variables.



**FIGURE 1.** Ensemble average of rearfoot frontal plane joint angles at Week 0 (A) and Week 6 (B). The SHOD (thin line) and CFO (thick line) conditions were measured across the stance phase.



**FIGURE 2.** Ensemble average of rearfoot frontal plane joint velocity at Week 0 (A) and Week 6 (B). The SHOD (thin line) and CFO (thick line) conditions were measured across the stance phase.

However, there were significant Condition main effects for maximum ankle inversion moment, ankle inversion impulse, vertical impact peak, vertical loading rate, and maximum knee external rotation moment. Significant decreases in maximum ankle inversion moment have been reported in three recent studies.<sup>10,11,13</sup> It has been suggested that if custom foot orthoses reduce the ankle inversion moment (Fig. 3), the stress placed on the biological tissues responsible for resisting rearfoot eversion or subtalar joint pronation will be reduced. Although it is unclear how this relates to overuse running injuries at the knee, this may have a great deal of relevance in individuals who have adult acquired flatfoot and specifically posterior tibialis tendon dysfunction.<sup>23</sup>

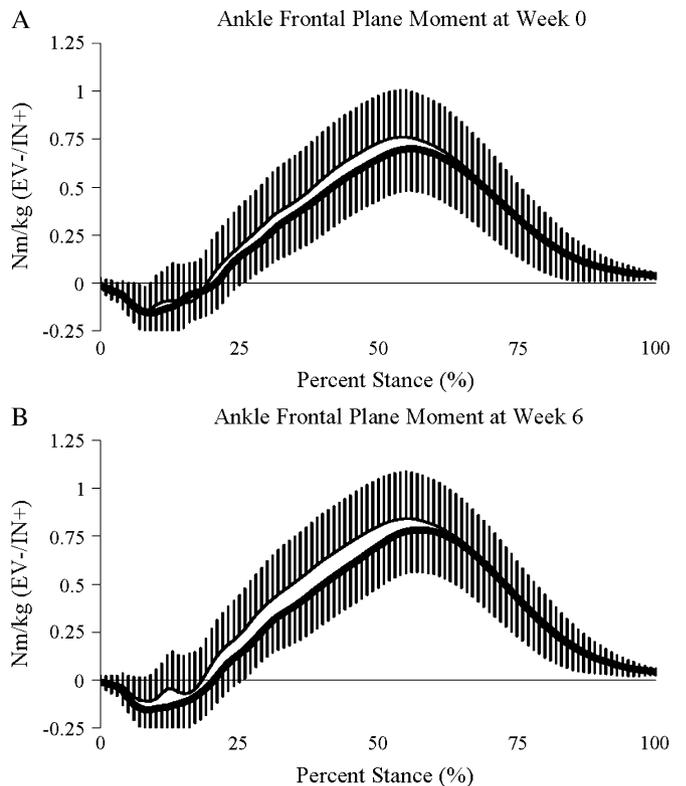
To analyze the magnitude of the internal ankle inversion moment further, ankle inversion impulse was quantified and statistically analyzed. Devita et al<sup>24</sup> and Stefanyshyn et al<sup>25</sup> have recently analyzed angular impulse at the knee. DeVita et al<sup>24</sup> have suggested that the quantification of angular impulse provides the researcher with information about the total contribution of a joint moment toward producing movement. Statistical analysis of the ankle inversion angular impulse revealed that the amount of ankle inversion angular impulse was significantly decreased for the CFO condition during the loading phase of the stance phase. In contrast, there were no differences during the propulsive phase. This finding

provides further evidence that custom foot orthoses have an effect on ankle kinetics during the loading phase when the orthosis is in contact with the foot. Specifically, foot orthoses may play a role in reducing the loads associated with rearfoot eversion during the loading phase.

The current sample of injured runners also exhibited significant increases in maximum knee external rotation moment with the CFO intervention. This finding is also supported by Muendermann et al<sup>10</sup> and it has been suggested that this moment is produced by biological tissues to resist knee internal rotation. Increasing the magnitude of the peak moment with a CFO intervention in individuals who have a knee injury seems to be somewhat counterintuitive.

Maximum vertical loading rate is a variable that has been associated with running injuries.<sup>22</sup> Significant decreases in maximum vertical loading rate with a CFO intervention have been previously reported by Muendermann et al.<sup>10</sup> Although the relationship between maximum loading rate, and overuse injury has not been clearly established, it has been speculated that these variables may be deleterious if magnitudes exceed the physiologic tolerance level for an individual runner.<sup>22</sup> Results from the current sample of injured female runners suggest that custom foot orthoses may be beneficial in reducing maximum impact peak and vertical loading rate.

The second research aim was to determine whether the long-term (6-week) CFO intervention in the Treatment group would lead to significant changes in lower extremity dynamics.



**FIGURE 3.** Ensemble average of ankle frontal plane moment at Week 0 (A) and Week 6 (B). The SHOD (thin line) and CFO (thick line) conditions were measured across the stance phase.

It was hypothesized that a long-term CFO intervention would lead to significant differences in dynamic variables when comparing results from Week 0 to Week 6. The absence of any interactions or Session main effects suggests that the observed differences in dynamics occur with short-term intervention. The results from the current sample of injured runners suggest that custom foot orthoses influence dynamics immediately upon dispense and only when they are worn in the running shoe. It does not appear from these results that there is an accommodative period during which changes in dynamics occur over a 6-week intervention. The data revealed that there were nonsignificant decreases in maximum knee external rotation moment ( $ES = 0.26$ ;  $P = 0.08$ ) and knee external rotation angular impulse ( $ES = 0.20$ ;  $P = 0.13$ ) with the 6-week intervention. Furthermore, the magnitude of differences was felt to be small and not clinically relevant.

### CONCLUSION

The purpose of the current study was to analyze the influence of a short-term and long-term CFO intervention on the lower extremity dynamics in a group of female runners with a history of overuse running knee injury. The 6-week intervention led to subjective changes including a significant decrease in pain and an improvement in symptoms did occur with the 6-week intervention. In addition, dynamic results revealed that custom foot orthoses have an immediate effect on dynamics and that this influence occurs only when orthoses are worn in the footwear. The absence of any Session main effects in this study indicates that there were no long-term effects with a 6-week intervention on ankle and knee dynamics. The short-term CFO intervention led to significant decreases in rearfoot kinematics (maximum eversion angle and velocity) but no changes observed in knee kinematics. The kinetic analysis revealed that these subjects exhibited significant decreases in maximum ankle inversion moment and angular impulse, impact peak, and vertical loading rate with the CFO intervention. At the knee, the CFO condition led to increases in knee external rotation moment maxima and angular impulse. However, these adaptations occurred at the dispense of the CFO and were maintained during the 6-week period after dispense.

These results suggested that custom foot orthoses influenced several variables during the loading phase. The current study revealed significant decreases in vertical loading rate, maximum rearfoot eversion velocity, and ankle inversion angular impulse during the loading phase with CFO intervention. All of these variables occur in the initial 50% of the stance phase and have been associated with running injuries. The relationship between observed positive clinical outcome at the knee and the dynamic influence of the intervention remains unclear. It is plausible that CFO intervention is beneficial to individuals in differing manners. That is, single subject designs might further our knowledge by revealing what is beneficial to an individual who suffers from a specific injury.

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