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Consistent Immediate Effects of Foot Orthoses on Comfort and Lower Extremity Kinematics, Kinetics, and Muscle Activity

Anne Mündermann[1,3], Benno M. Nigg[1], R. Neil Humble[2], and Darren J. Stefanyshyn[1]

[1,2]University of Calgary; [3]Stanford University

In order to accommodate patients to new foot orthoses over time, two steps are required: The first is to obtain a baseline reading of the immediate effects across several weeks to ensure consistency. The second step is to look at changes with progressively longer wear periods similar to what occurs in general practice. This study addressed the first step. The purpose of this study was to determine whether the baseline reading of the immediate effects of foot orthoses on comfort and lower extremity kinematics, kinetics, and muscle activity is consistent between days. Participants were 21 recreational runners who volunteered for the study. Three orthotic conditions (posting, custom-molding, posting and custom-molding) were compared to a control (flat) insert. Lower extremity kinematic, kinetic, and EMG data were collected for 108 trials per participant and condition in 9 sessions for each person for running at 4 m/s. Comfort for all orthotic conditions was assessed in each session using a visual analog scale. Statistically significant session effects were detected using repeated-measures ANOVA ($\alpha = .05$). Three of the 93 variables had a significant session effect. A significant interaction between orthotic condition and session was observed for 6 of the 93 variables. The results of this study showed that the effects of foot orthoses on comfort, lower extremity kinematics, kinetics, and muscle activity are consistent across a 3-week period when the wear time for each condition is restricted. Thus, foot orthoses lead to immediate changes in comfort, kinematics, kinetics, and muscle activity with limited use. These immediate effects of foot orthoses on comfort, kinematics, kinetics, and muscle activity are consistent between days.

Key Words: footwear modifications, adaptation, repeatability, running, human locomotion

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[1]Human Performance Lab, Faculty of Kinesiology, and [2]Division of Podiatry, Faculty of Medicine, University of Calgary, Calgary, AB Canada T2N 1N4; [3]Dept. of Mechanical Engineering, Durand 205, Stanford University, Stanford, CA 94305-3030.

Introduction

Foot orthoses are used for many activities and for several reasons. For instance, recreational runners often use custom-molded foot orthoses in order to prevent running related injuries, rehabilitate from injuries, increase comfort, and/or improve performance. Other proposed functional qualities of foot orthoses include aligning the skeleton and providing improved cushioning (Lockard, 1988), improving sensory feedback (Robbins & Gouw, 1991), reducing muscle activity (Nawoczenski, Cook, & Saltzman, 1995), and reducing joint moments (Crenshaw, Pollo, & Calton, 2000). Until recently, the effects of foot orthoses on skeletal alignment were controversial (e.g., Eng & Pierrynowski, 1994; Stacoff, Reinschmidt, Nigg, et al., 2000) and little was known about the effects on other variables. However, a recent study provided some evidence that foot orthoses do affect these variables. For example, foot orthoses have been shown to affect lower extremity kinematics, impact loading, and joint moments (Mündermann, Nigg, Humble, & Stefanyshyn, 2003b).

Although not measured, clinicians typically use subjective comfort to determine the appropriateness of foot orthoses. Patients are usually instructed to increase the wear time per day slowly over a 2- to 3-week period to break in their foot orthoses gradually until they feel fully comfortable (Doxey, 1985; Lockard, 1988). This clinical rule is based on the assumption that comfort of foot orthoses changes during the break-in period. Indeed, a recent study found that comfort of shoe inserts made from material similar to foot orthoses may change during a 3-week period (Mündermann, Nigg, Stefanyshyn, & Humble, 2002). It has also been reported (Mündermann, Nigg, Humble, & Stefanyshyn, 2003a) that differences in comfort between foot orthoses are related to changes in lower extremity kinematics, kinetics, and muscle activity. Consequently, it is speculated that the effects of foot orthoses on lower extremity kinematics, kinetics, and muscle activity also change over time. However, to our knowledge, no conclusive evidence has been provided as to whether patients accommodate to foot orthoses.

In order to address the issue of accommodation of patients to new foot orthoses over time, two steps are required: The first step is to obtain a baseline reading of the immediate effects across several weeks to ensure consistency. The second step is to look at changes with progressively longer wear periods similar to what occurs in general practice. Without addressing the first step, however, one could not be sure the changes, or lack of changes, that were measured following longer wear periods were due to longer term accommodation or whether they were due to extended data collection periods. While several studies have quantified within-day and between-day repeatability (Diss, 2001; Ferber, McClay Davis, Williams, & Laughton, 2002; Kadaba, Ramakrishnan, Wootten, et al., 1989) and inter- and intraindividual variability (Bates, Osternig, Sawhill, & James, 1983; Devita & Skelly, 1990; De Wit, De Clercq, & Aerts, 2000) of kinematic, kinetic, and electromyographic data during running, information on the repeatability of immediate effects of footwear interventions on lower extremity biomechanics is lacking. Therefore this study was undertaken to address the first step of identifying the accommodation process to foot orthoses.

The purpose of this study was to determine whether the baseline reading of the immediate effects of foot orthoses on comfort and lower extremity kinematics, kinetics, and muscle activity is consistent between days. It was hypothesized that the immediate effects of foot orthoses on comfort and lower extremity kinematics, kinetics, and muscle activity are consistent over a 3-week period.

Methods

Twenty-one volunteers, all recreational runners, participated in this study (12 F, 9 M; see Table 1). All gave informed written consent according to the guidelines of the University of Calgary's ethics committee. They were initially screened for miles run per week (15–40 km per week). All were classified as pronators, based on 2-D measured foot eversion during running at 4 m/s in the control condition on a treadmill (angle between heel bisection line and shank bisection line: >13°; Clarke, Frederick, & Hamill, 1984). All runners were clinically assessed by one of the authors (R.N. Humble, DPM). Joint range of motion and strength and flexibility of the lower extremity muscles had to be within normal values, and leg length discrepancy had to be less than 0.5 cm. Participation in the study required that the runners be pronators with foot varus deformity as etiology. The inclusion criteria in this study matched the general criteria for the prescription of foot orthoses by podiatrists.

All experiments were performed using running sandals (Model: Bryce Canyon; The Rockport Co., Canton, MA). The original inserts of both running sandals were removed and replaced bilaterally by each of four insert conditions: control; posting; molding; posting and molding (Table 2). Removal of the original insert of

Table 1 Characteristics of the 21 Participants (*M* ± *SD*)

Maximum foot eversion in frontal plane, Control condition (°)	16.2	± 3.2
Age (years)	25.4	± 5.6
Weight (kg)	64.2	± 7.0
Height (cm)	170.2	± 6.7

Table 2 Material and Geometric Components and Weight of Foot Orthotic Conditions

Insert condition	Bottom layer	Shape	Posting
Control insert	EVA[a] (3 mm)	Flat	None
Medial post (posting)	EVA[a]	Flat	6 mm (medial)
Neutral shell[b] (molding)	Polypropylene shell	Custom-molded	None
Custom orthoses[b] (posting & molding)	Polypropylene shell	Custom-molded	6 mm (medial)

Note: Top layer of all conditions consisted of 3 mm Spenco©
[a] Ethylene vinyl acetate (Solflex [Shore C: 50-55], Phoenix, AZ); [b] Paris Orthotics Ltd., Vancouver, Canada.

the running sandal resulted in a rim (approx. 5.0 mm) around the outside of the upper sole, preventing the foot orthosis from sliding between the foot and the sandal. The top layer of all orthotic conditions consisted of 3-mm Spenco (Spenco Medical Corp., Waco, TX). The posting condition consisted of a full length medial wedge. Plaster casts of both feet in a non-weight-bearing, subtalar neutral position were taken from each participant. Custom-molded orthoses were fabricated to positive molds obtained from the negative casts.

Subjects completed 2 weeks of their regular running schedule in the control condition (running sandal + control insert). Following this initial phase, each was tested three times a week for 3 weeks (9 sessions per runner). In each of the 9 sessions the participants ran 200 m on an indoor track with each of the four insert conditions to assess comfort. They were then set up for biomechanical testing at the Human Performance Laboratory at the University of Calgary. The four insert conditions were tested in random order. However, before testing each of the three orthotic conditions, participants ran 50 m in the control condition. Kinematic, kinetic, and electromyographic (EMG) data were collected for 12 running trials at 4.0 ± 0.2 m/s (heel-toe running, 48 trials per runner per session, total = 9,072 trials). The experimental design of collecting data for each runner on 9 different days allowed us to test the hypothesis that the effects of foot orthoses on comfort and lower extremity kinematics, kinetics, and muscle activity are consistent over a 3-week period.

Comfort was assessed using a 15-cm visual analog scale. Before each of the three orthotic comfort assessments (O_i), participants assessed comfort of the control condition (C). The resulting testing order was C-O_1-C-O_2-C-O_3. The experimental conditions were tested in random order. The comfort scale and protocol used in this study have been described in detail elsewhere (Mündermann et al., 2002). One comfort rating for each orthotic condition was obtained for each participant and session.

Three reflective skin markers of 12.7-mm diameter were attached to each of the three segments of the right lower extremity: thigh, shank, and foot. Additional joint markers were placed on the anterior superior iliac spine and greater trochanter, the lateral epicondyle and patella center, and the lateral malleolus and insertion of the Achilles tendon to determine hip, knee, and ankle joint centers, respectively. Joint coordinate systems (Cole, Nigg, Ronsky, & Yeadon, 1993) were constructed using the positional information of the segment and joint markers during a standing trial in the control condition. Kinematic data were collected using seven high-speed cameras (240 Hz; Motion Analysis Corp., Santa Rosa, CA). 3-D marker traces were reconstructed using Expert Vision 3-D analysis software (Motion Analysis Corp.). Ground reaction forces were measured using a force plate (2400 Hz; Kistler AG, Winterthur, Switzerland) which was placed in the center of the runway level with the ground.

Kinematic and kinetic data were filtered using a zero-lag quadratic low-pass Butterworth filter with a cutoff frequency of 12 Hz and 50 Hz, respectively. 3-D lower extremity kinematics and kinetics were calculated using KinTrak software (University of Calgary) employing an inverse dynamics approach. The angle, force, and moment curves were normalized to touch-down and toe-off, resulting in 101 data points per curve per trial. Extreme point values were determined from these curves (see Nomenclature), normalized to the average for the control condition and averaged for each condition, session, and participant.

Nomenclature

Kinematic, Kinetic, and EMG Variables Included in Statistical Analysis

Symbol	Definition
$\beta_{ev, max}$	Maximum eversion angle about longitudinal axis of foot segment
$\Delta\beta_{ev}$	Difference between initial foot eversion and max. foot eversion
$\beta_{inv, max}$	Max. inversion angle about longitudinal axis of foot segment
$\Delta\beta_{inv}$	Diff. between final foot inversion and max. foot inversion
β_{tot}	Diff. between max. foot inversion and max. foot eversion
θ_{max}	Max. internal tibia rotation angle about the cross axis of ankle joint
$\Delta\theta$	Diff. between initial internal tibia rotation and max. internal tibia rotation
α_{init}	Ankle dorsiflexion angle at heel-strike
$\alpha_{plantar, max}$	Max. plantarflexion angle about mediolateral axis of ankle joint
$\alpha_{dorsi, max}$	Max. dorsiflexion angle about mediolateral axis of ankle joint
α_{tot}	Diff. between max. ankle plantarflexion and max. ankle dorsiflexion about mediolateral axis of ankle joint
γ_{max}	Max. knee flexion angle about mediolateral axis of knee joint
$\Delta\gamma_{max}$	Diff. between max. knee flexion angle and initial knee flexion angle about mediolateral axis of knee joint
$\beta'_{ev, max}$	Max. angular eversion velocity about longitudinal axis of foot segment
$\beta'_{inv, max}$	Max. angular inversion velocity about longitudinal axis of foot segment
θ'_{max}	Max. angular internal tibia rotation velocity about cross axis of ankle joint
$M_{inv, ankle}$	Max. moment about long axis of foot
$M_{flex, ankle}$	Max. moment about mediolateral axis of ankle joint
$M_{extrot, knee}$	Max. moment about rotation axis of knee joint
$M_{abd, knee}$	Max. moment about abduction/adduction axis of knee joint
$M_{ext, knee}$	Max. moment about mediolateral axis of knee joint
$t_{Minv, ankle}$	Time point of max. moment about long axis of foot
$t_{Mflex, ankle}$	Time point of max. moment about mediolateral axis of ankle joint
$t_{Mextrot, knee}$	Time point of max. moment about rotation axis of knee joint
$t_{Mabd, knee}$	Time point of max. moment about abduction/adduction axis of knee joint
$t_{Mext, knee}$	Time point of max. moment about mediolateral axis of knee joint
$F_{z, impact}$	Impact peak of vertical ground reaction force
$F_{z, active}$	Active peak of vertical ground reaction force
$G_{z, max}$	Maximum loading rate of vertical ground reaction force
$S_{m, glob, pre}$	Global EMG intensity of each of the 7 muscles[†] during pre-heel-strike interval
$S_{m, high, pre}$	EMG intensity in high-frequency band of each of 7 muscles during pre-heel-strike interval
$S_{m, low, pre}$	EMG intensity in low-frequency band of each of 7 muscles during pre-heel-strike interval
$S_{m, glob, post}$	Global EMG intensity of each of 7 muscles during post-heel-strike interval
$S_{m, high, post}$	EMG intensity in high-frequency band of each of 7 muscles during post-heel-strike interval

(continued)

Nomenclature (*Cont.*)

$S_{m, low, post}$	EMG intensity in low-frequency band of each of 7 muscles during post-heel-strike interval
$S_{m, glob, propulsion}$	Global EMG intensity of each of 7 muscles during propulsion phase
$S_{m, high, propulsion}$	EMG intensity in high-frequency band of each of 7 muscles during propulsion phase
$S_{m, low, propulsion}$	EMG intensity in low-frequency band of each of 7 muscles during propulsion phase

Note: †The 7 lower extremity muscles tested were: TA = tibialis anterior; PL = peroneus longus; GM = gastrocnemius medialis; BF = biceps femoris; VL = vastus lateralis; RF = rectus femoris; VM = vastus medialis.

Myoelectric signals were recorded from seven lower extremity muscles of the right leg. Bipolar surface electrodes (Ag-AgCl) were placed on the vastus lateralis and medialis, rectus femoris, biceps femoris (long head), tibialis anterior, peroneus longus, and gastrocnemius medialis muscles. Each electrode was 10 mm in diameter with an intra-electrode distance of 22 mm. A ground electrode was placed on the tibial tuberosity. Placement of the electrodes was marked to ensure similar placement for all 9 sessions. The electromyographic signals (EMG) were preamplified at source and recorded using a BioVision system (BioVision, Wehrheim, Germany) at 2,400 Hz. Timing of heel-strike and toe-off for one step per trial was taken from the ground reaction force data. Electromyographic data for each trial were checked for crosstalk by cross-correlating the raw EMG signals between muscles. The correlation coefficients for all muscle combinations of accepted trials were smaller than 0.500.

Wavelet analysis was used to resolve the EMG signals simultaneously into their intensity in time and frequency space (von Tscharner, 2000). The intensity obtained using this wavelet analysis represents a close approximation of the power of the EMG signal. The wavelet analysis consisted of three steps: (a) computation of the wavelet-transformed EMG signal using a filter bank of wavelets including intensity and damping factors; (b) computation of the intensity of the wavelet-transformed signal by adding its square and the square of its time derivative divided by the center frequency for each wavelet; and (c) application of a Gauss filter to the wavelet-transformed signal to eliminate oscillations resulting from interference as described by Wakeling et al. (Wakeling, von Tscharner, Nigg, & Stergiou, 2001).

A filterbank of 11 wavelets was used (von Tscharner, 2000) and a wavelet domain was defined as the EMG intensity over time corresponding to each of the 11 wavelets. A low-frequency band was defined as frequencies between 25 and 82 Hz, and a high-frequency band was defined as frequencies between 142 and 300 Hz. The choice of Wavelet Domains 2 and 3 as a representation of the low-frequency band, and Wavelet Domains 6 to 8 as a representation of the high-frequency band, allowed for a clear distinction between low- and high-frequency bands. Global EMG intensity was defined as the sum of EMG intensities for Wavelet Domains 1 through 8.

Myoelectric signals measured using surface electrodes are attenuated by the soft tissues such as fat overlying the muscle to be measured. To account for these intersubject differences and to allow for comparisons of orthotic effects between participants and sessions, the global, low, and high intensities were normalized for each person and session so that the maximum of the total intensity for the control condition had a value of 1. The primary functions of muscle activity vary throughout the stance phase of running. For instance, before heel-strike the foot is not in contact with the ground and there is no feedback information from the ground reaction force; thus the EMG intensity in this interval is controlled by a feed-forward mechanism. The main functions of muscle activity prior to heel-strike are to stabilize the joints of the lower extremity and to tune the muscles of the lower extremity to minimize possible soft tissue vibrations resulting from the impact of the heel on the ground (Nigg, 1997).

EMG intensity after heel-strike is initially also controlled by a feed-forward mechanism. However, EMG intensity during this interval may also contain stretch-reflex related responses whereby the impact of the foot on the ground at heel-strike acts as a signal into the body. EMG intensities for the rest of the stance phase are primarily related to muscle forces that accelerate and support the body. Therefore global, low, and high intensities were finally averaged over the pre-heel-strike interval (50 ms before heel-strike), the post-heel-strike (50 ms after heel-strike), and Phase 3 (30 to 100% of stance phase), resulting in nine EMG variables per muscle (see Nomenclature). Due to technical problems with the ground reaction force measurements, Participant 1 was eliminated from this study. Therefore the results and discussion sections are based on data for 20 participants.

Differences in comfort ratings and kinematic, kinetic, and EMG variables for the three orthotic conditions relative to the control condition were compared between sessions using repeated-measures ANOVA with the significance level set at $\alpha = .05$. Orthotic conditions and session numbers were used as factors in the analysis of variance.

Results

Results of the ANOVAs for comfort ratings, kinematic, kinetic, and EMG variables are listed in Tables 3 to 5. Of the 93 variables, 54 showed significant orthotic effects. A significant session effect was observed for 3 of the 93 variables. A significant interaction between orthotic condition and session was found for 6 of the 93 variables ($p < .05$). Average differences for 9 variables between the orthotic condition and the control condition for all sessions are shown in Figure 1. For instance, the differences between the effects of the three orthotic conditions on maximum internal tibia rotation and maximum external rotation moment at the knee joint were small and not consistent for all sessions. However, other variables including comfort, impact force, and maximum loading rate showed similar orthotic effects for all sessions. For other variables including foot eversion, maximum foot eversion velocity, and total peroneus longus intensity during the post-heel-strike interval, the effects of the two molded conditions were consistently different from the isolated posting condition for all sessions. However, for these variables the values for the molding and the posting and molding conditions were similar for each session, with neither condition being consistently greater for all sessions.

Table 3 ANOVA *P*-Values to Detect Significant Differences in Comfort and Kinematic and Kinetic Variables Between Conditions and Sessions

Variable	Orthotic condition	Session	Condition × Session
Comfort	**<.001**	.994	.677
$\beta_{ev, max}$	**<.001**	.998	.657
$\Delta\beta_{ev}$	**<.001**	.669	.719
$\beta_{inv, max}$	**<.001**	.810	.688
$\Delta\beta_{inv}$	**.006**	.160	.786
β_{tot}	**.001**	.971	.603
θ_{max}	.425	.197	.801
$\Delta\theta$	.055	.265	**.046**
α_{init}	.110	.293	.514
$\alpha_{plantar, max}$	**<.001**	.816	.687
$\alpha_{dorsi, max}$	**.002**	.428	.672
α_{tot}	**<.001**	.276	.845
Υ_{max}	**.008**	.695	.166
$\Delta\Upsilon_{max}$	**<.001**	.180	.711
$\beta'_{ev, max}$	**<.001**	.671	.358
$\beta'_{inv, max}$	**<.001**	.835	.374
θ'_{max}	**.012**	.548	.616
$M_{inv, ankle}$	**<.001**	.914	.830
$M_{flex, ankle}$	**<.001**	.133	.254
$M_{extrot, knee}$	.058	.637	.981
$M_{abd, knee}$	.173	.962	.331
$M_{ext, knee}$	**<.001**	.598	.327
$t_{Minv, ankle}$	.085	.372	.591
$t_{Mflex, ankle}$	**<.001**	.598	.282
$t_{Mextrot, knee}$	**<.001**	.833	.640
$t_{Mabd, knee}$	**<.001**	.710	.826
$t_{Mext, knee}$	**<.001**	.147	.059
$F_{z, impact}$	**<.001**	.418	.399
$F_{z, active}$	.556	.740	.197
$G_{z, max}$	**<.001**	.876	.448

Note: Significant results shown in bold, $p < .05$

Table 4 ANOVA *P*-Values to Detect Significant Differences in EMG Intensity of 3 Shank Muscles Between Conditions and Sessions

Variable	Orthotic condition	Session	Condition × Session
$S_{ta, glob, pre}$	**<.001**	.594	.973
$S_{ta, high, pre}$	**<.001**	.597	.947
$S_{ta, low, pre}$	**.026**	.753	.808
$S_{ta, glob, post}$	**<.001**	.714	**.037**
$S_{ta, high, post}$	**<.001**	.746	.687
$S_{ta, low, post}$	**.001**	.757	.081
$S_{ta, glob, propulsion}$	.113	.922	**.035**
$S_{ta, high, propulsion}$	**<.001**	.820	.808
$S_{ta, low, propulsion}$	**.010**	.905	.417
$S_{pl, glob, pre}$	.138	.387	.852
$S_{pl, high, pre}$	.652	.186	.765
$S_{pl, low, pre}$	.182	.149	.679
$S_{pl, glob, post}$	**<.001**	.859	.897
$S_{pl, high, post}$	**.004**	.472	.904
$S_{pl, low, post}$	**<.001**	.980	.838
$S_{pl, glob, propulsion}$	.381	**.049**	.051
$S_{pl, high, propulsion}$	.244	.172	.161
$S_{pl, low, propulsion}$	**.034**	.305	.338
$S_{gm, glob, pre}$	**.013**	.922	.680
$S_{gm, high, pre}$	**.011**	.940	.685
$S_{gm, low, pre}$	**.026**	.968	.805
$S_{gm, glob, post}$	**<.001**	.629	.675
$S_{gm, high, post}$	**<.001**	.667	.713
$S_{gm, low, post}$	**.001**	.669	.699
$S_{gm, glob, propulsion}$	.689	.228	.072
$S_{gm, high, propulsion}$	.438	.385	.210
$S_{gm, low, propulsion}$	**.019**	.169	.188

Note: Significant results shown in bold, $p < .05$

Table 5 ANOVA *P*-Values to Detect Significant Differences in EMG Intensity of 4 Thigh Muscles Between Conditions and Sessions

Variable	Orthotic condition	Session	Condition × Session
$S_{bf, glob, pre}$	.307	.185	.261
$S_{bf, high, pre}$	.408	.235	.103
$S_{bf, low, pre}$	.380	.261	.226
$S_{bf, glob, post}$	**.001**	.957	.460
$S_{bf, high, post}$	**.020**	.913	.234
$S_{bf, low, post}$	**.001**	.944	.603
$S_{bf, glob, propulsion}$	.677	.436	.200
$S_{bf, high, propulsion}$	.432	.533	.760
$S_{bf, low, propulsion}$	.295	.822	.208
$S_{vl, glob, pre}$	**.015**	.777	.385
$S_{vl, high, pre}$	**.043**	.200	.650
$S_{vl, low, pre}$	**.011**	.698	.698
$S_{vl, glob, post}$	.126	.526	.174
$S_{vl, high, post}$	.055	.059	.114
$S_{vl, low, post}$	.644	.821	.098
$S_{vl, glob, propulsion}$	**<.001**	**.012**	**.001**
$S_{vl, high, propulsion}$	.056	**.032**	.068
$S_{vl, low, propulsion}$	.692	.412	**.016**
$S_{rf, glob, pre}$	.183	.437	.155
$S_{rf, high, pre}$	.485	.554	.290
$S_{rf, low, pre}$	.074	.510	.251
$S_{rf, glob, post}$	.175	.163	.481
$S_{rf, high, post}$	.845	.322	.464
$S_{rf, low, post}$	.272	.301	.576
$S_{rf, glob, propulsion}$	**.016**	.168	**.008**
$S_{rf, high, propulsion}$	.099	.271	.056
$S_{rf, low, propulsion}$	.715	.089	.092
$S_{vm, glob, pre}$	**.028**	.994	.587
$S_{vm, high, pre}$	**.014**	.966	.781
$S_{vm, low, pre}$	**.017**	.957	.893
$S_{vm, glob, post}$	.713	.641	.625
$S_{vm, high, post}$	.793	.440	.755
$S_{vm, low, post}$	.932	.750	.539
$S_{vm, glob, propulsion}$	**.001**	.216	.058
$S_{vm, high, propulsion}$	.057	.167	.762
$S_{vm, low, propulsion}$	.489	.670	.254

Note: Significant results shown in bold, $p < .05$

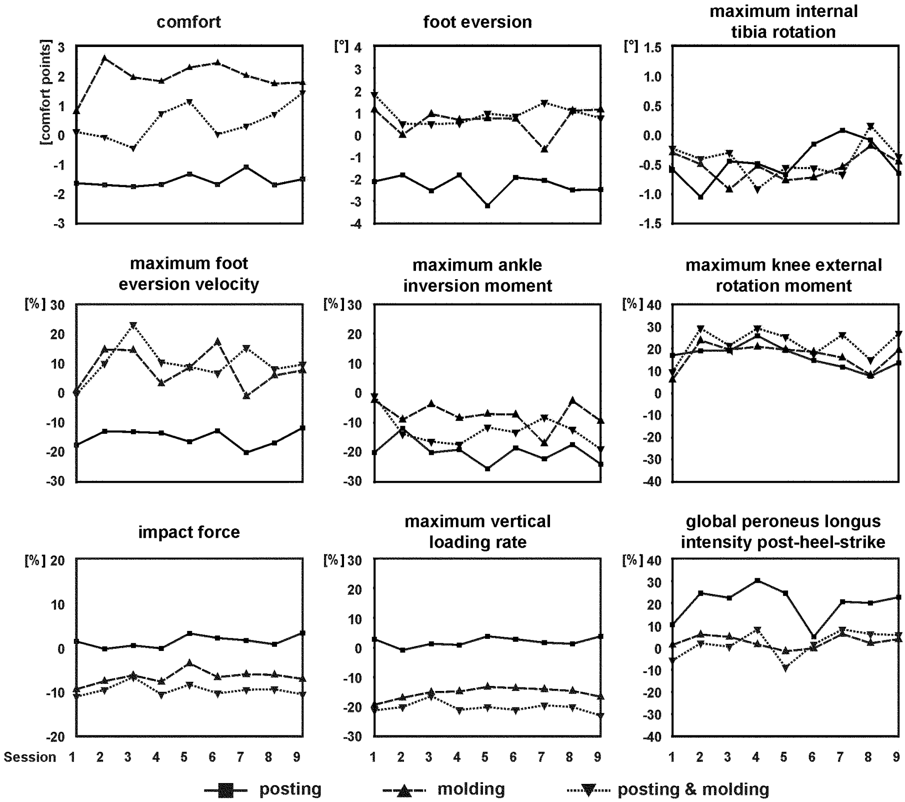

Figure 1 — Average differences in comfort, kinematic, kinetic, and EMG variables compared to control condition for Sessions 1 to 9 (comfort: 1 rating per Participant × Condition × Session; kinematic, kinetic and EMG variables: 12 trials per Participant × Condition × Session). Differences are shown in percent where appropriate.

Discussion

The major findings of this study were as follows:

- Different effects on comfort, kinematics, kinetics, and muscle activity for three different orthotic designs were observed.
- The effects of foot orthoses on comfort, kinematics, kinetics, and muscle acitivity were similar in nine experimental sessions throughout a 3-week period.

Thus the results of this study do support the hypothesis that the immediate effects of foot orthoses on comfort and lower extremity kinematics, kinetics, and muscle activity are consistent over a 3-week period. These major findings are discussed in detail below.

The fact that immediate effects of foot orthoses on comfort, kinematics, kinetics, and muscle activity were observed showed that the body can quickly adjust to foot orthoses. In the current study the participants only used the foot orthoses during the experimental sessions, corresponding to a wear time of approximately 15 minutes per session and orthotic condition, to guarantee the same general experimental conditions for all runners. Furthermore, the control condition was used as a baseline condition within each session. If participants had worn one of the orthotic conditions outside the experimental sessions, then this orthotic condition might have become the baseline that all other conditions were compared to, either consciously or unconsciously.

Participants were tested in three sessions per week. Compared to clinically suggested initial wear times of at least 1 hour per day, the wear time in the current study was very short. In addition, compared to a clinical setting in which the body is exposed to only one orthotic condition, in this study the runners used all orthotic conditions in each experimental session. Thus, while this study showed that the body immediately adjusts to foot orthoses, it is still unclear whether the effects of foot orthoses change during a clinically suggested accommodation period. It is possible that the structural properties and/or the surface texture of foot orthoses change with wear. Such changes in the orthotic properties over time may affect lower extremity biomechanics mechanically by altering the lower extremity geometry or physiologically by modifying the input signal into the sensorimotor system (Nigg, Nurse, & Stefanyshyn, 1999).

Placing foot orthoses in a shoe may result in altered sensory feedback leading to changes in gait kinetics and muscle activation patterns (Nurse & Nigg, 2001). However, to date it is unknown whether such effects are transient or whether they are dependent on footwear awareness. Initially, changing between orthotic conditions may be consciously perceived as disturbance of the foot/shoe interface reflected in different perceptions of comfort, as found in this study. These alterations in perception of comfort may fade if an orthotic condition is worn for a longer period.

Differences in kinematics, kinetics, muscle activity, and comfort assessments were found in this study. These differences were determined by the orthotic conditions and did not change over time. However, previous studies have shown that between-day repeatability of kinematic, kinetic, and EMG data is lower than within-day repeatability (e.g., Kadaba et al., 1989). Large intersubject variability has been reported for kinematic and kinetic variables, especially in the frontal and transverse plane (McClay & Manal, 1999). The variability in kinematic, kinetic, and EMG data between experimental sessions is due in part to inherent physiological variability as well as to the variability introduced by the experimental setup.

In the current study, markers and electrodes were carefully placed to minimize such variability by marking the placement on the skin in the first session, and applying the markers on the marked locations in all consecutive sessions. The fact that values for the orthotic conditions were compared to values for the control condition in each session eliminated most of the systematic errors due to the experimental setup and due to intersubject variability. This assumption is supported by the fact that differences in comfort, kinematics, kinetics, and muscle activity between orthotic conditions were in most cases greater than differences between sessions. Thus, from a methodological viewpoint, the effects of foot orthoses on these variables are repeatable between days. As the immediate effects of foot orthoses were consistent between days, the first assessment of foot orthotic effects is a true representation of the general immediate effects of foot orthoses on lower extremity biomechanics.

The results of this study showed that the baseline reading of the immediate effects of foot orthoses on comfort, kinematics, kinetics, and muscle activity is consistent between days. This is a very important finding as it constitutes the basis for future research addressing the second step of identifying the accommodation process to foot orthoses. Based on the knowledge obtained in this study, it can be assumed that changes, or lack of changes, which might be measured following longer wear periods, will be primarily due to a longer period of accommodation rather than to extended data collection periods. Thus, future studies can now quantify the effects of foot orthoses with progressively longer wear periods similar to what occurs in general practice. Moreover, since the effects of foot orthoses on lower extremity biomechanics can be measured reliably, changes in these variables can now be related to clinical outcomes measured in terms of pain and/or frequency of injury.

In summary, the current study showed that the effects of foot orthoses on comfort, lower extremity kinematics, kinetics, and muscle activity are consistent across a 3-week period when the wear time for each orthotic condition is restricted. Thus, foot orthoses lead to immediate changes in comfort, kinematics, kinetics, and muscle activity with limited use. These immediate effects of foot orthoses are consistent between days. This study, then, had laid the foundation for future studies to examine the changes in comfort, lower extremity kinematics, kinetics, and muscle activity with the use of foot orthoses over the initial clinical wear period; to identify possible mechanisms of accommodation to foot orthoses; and to relate biomechanical effects of foot orthoses to clinical outcome assessed as pain or frequency of injury.

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