



The influence of ankle-foot orthosis stiffness on walking performance in individuals with lower-limb impairments



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ABSTRACT

Background: Passive-dynamic ankle-foot orthoses utilize stiffness to improve gait performance through elastic energy storage and return. However, the influence of ankle-foot orthosis stiffness on gait performance has not been systematically investigated, largely due to the difficulty of manufacturing devices with precisely controlled stiffness levels. Additive manufacturing techniques such as selective laser sintering have been used to successfully manufacture ankle-foot orthoses with controlled stiffness levels. The purpose of this study was to use passive-dynamic ankle-foot orthoses manufactured with selective laser sintering to identify the influence of orthosis stiffness on walking performance in patients with lower-limb neuromuscular and musculoskeletal impairments.

Methods: Thirteen subjects with unilateral impairments were enrolled in this study. For each subject, one passive-dynamic ankle-foot orthosis with stiffness equivalent to the subject's clinically prescribed carbon fiber orthosis, one 20% more compliant and one 20% more stiff, were manufactured using selective laser sintering. Three-dimensional kinematic and kinetic data and electromyographic data were collected from each subject while they walked overground with each orthosis at their self-selected velocity and a controlled velocity.

Findings: As the orthosis stiffness decreased, ankle range of motion and medial gastrocnemius activity increased while the knee became more extended throughout stance. Minimal changes in other kinematic, kinetic and electromyographic quantities were observed.

Interpretation: Subjects effectively compensated for changes in ankle-foot orthosis stiffness with altered gastrocnemius activity, and the stiffness levels analyzed in this study had a minimal effect on overall walking performance.

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1. Introduction

Ankle-foot orthoses (AFOs) are commonly prescribed to help improve gait in patients with various lower-limb neuromuscular and musculoskeletal impairments (Owens et al., 2011). AFOs can improve gait by mechanically compensating for weakness of the plantarflexor and dorsiflexor muscles, which have been shown to be important contributors to body support, forward propulsion and mediolateral balance in walking (Neptune et al., 2001; Liu et al., 2006; Pandy et al., 2010; Allen and Neptune, 2012). Passive-dynamic AFOs (PD-AFOs) are a category of AFOs that rely on design characteristics, such as stiffness, to improve gait performance through elastic energy storage and return (ESAR). Although several studies have demonstrated the beneficial effects of PD-AFOs on pathological gait compared to walking without an AFO (Danielsson and Sunnerhagen, 2004; Desloovere et al., 2006; Van Gestel et al., 2008; Patzkowski et al., 2012) or with more traditional

AFOs (Desloovere et al., 2006; Bartonek et al., 2007; Van Gestel et al., 2008; Wolf et al., 2008; Patzkowski et al., 2012), few studies have examined the influence of PD-AFO stiffness characteristics on walking performance.

Two studies that have investigated the influence of AFO stiffness on walking performance found that stiffness can affect the energy cost of walking (Bregman et al., 2011) and influence joint kinematics (Kobayashi et al., 2011, 2013). In addition, recent studies that have varied the stiffness characteristics of ankle-foot prosthetic devices used by transtibial amputees, which function similarly to PD-AFOs by providing some level of body support and forward propulsion, found that as stiffness decreased the prosthesis contributed less to body support. The decreased stiffness of the prosthesis necessitated an increase in the activity of muscles that contribute to body support, specifically the vasti and rectus femoris (Fey et al., 2011; Ventura et al., 2011a,b), which resulted in increased knee extensor moments (Fey et al., 2011; Ventura et al., 2011b). These studies also showed that as stiffness decreased, the prosthesis' contribution to forward propulsion increased resulting in a decrease in the hamstring muscle activity which normally contributes to forward propulsion (Fey et al., 2011; Ventura et al., 2011a,b). Fey et al. (2011) also found that as stiffness decreased,

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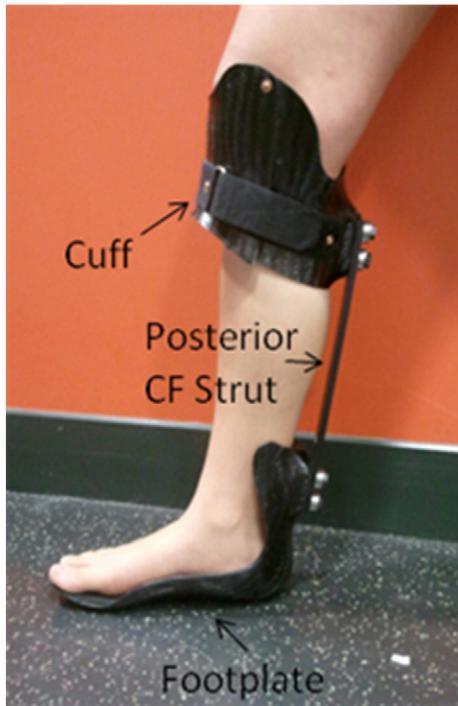


Fig. 1. Clinically prescribed carbon fiber (CF) PD-AFO (Intrepid Dynamic Exoskeletal Orthosis (IDEO), Brooke Army Medical Center, San Antonio, TX, USA).

prosthesis energy storage in early and mid-stance and energy return in late stance increased. However, the designs of PD-AFOs and ankle-foot prostheses are fundamentally different, and no study has systematically investigated whether similar results exist when PD-AFO stiffness is varied.

Performing such studies can be challenging due to the difficulty of manufacturing custom AFOs with precisely controlled stiffness levels. Previous studies have modified stiffness through fluid mechanics (Yamamoto et al., 2005; Yokoyama et al., 2005; Kobayashi et al., 2011), springs (Yamamoto et al., 1999), elastic components (Bleyenheuft et al., 2008) and design features (Desloovere et al., 2006), but these techniques provided stiffness levels that were either difficult to precisely control or limited to discrete levels of resistance at the AFO hinge. An alternative approach is to use advanced additive manufacturing techniques such as selective laser sintering (SLS), which enable more precise control of design characteristics such as stiffness. SLS has recently been used to successfully manufacture PD-AFOs (Faustini et al., 2008; Schrank and Stanhope,

2011), traditional AFOs (Creylman et al., 2013), foot orthoses (Pallari et al., 2010; Salles and Gyi, 2013), prosthetic sockets (Faustini et al., 2006; Rogers et al., 2007, 2008), prosthetic feet (Fey et al., 2011) and prosthetic ankles (Ventura et al., 2011a,b).

Therefore, the overall goal of this study was to use SLS-manufactured PD-AFOs to identify the influence of PD-AFO stiffness on walking performance in individuals with lower-limb neuromuscular and musculoskeletal impairments. We hypothesize that as PD-AFO stiffness decreases: 1) sagittal plane ankle joint range of motion (RoM) and work will increase in the PD-AFO limb; 2) the PD-AFO's contribution to body support will decrease and corresponding knee joint extensor moments and work and the activity of muscles that contribute to body support will increase to compensate; and 3) the PD-AFO's contribution to forward propulsion will increase and hip joint extensor moments and work and the activity of muscles that contribute to forward propulsion will decrease to compensate. Through testing these hypotheses, this study will help guide the development of more effective PD-AFO designs and quantitative prescription criteria for subject-specific devices.

2. Methods

Subject-specific PD-AFOs with different stiffness levels were created using SLS. Each subject's clinically prescribed PD-AFO was a modular, carbon fiber (CF) design consisting of a footplate, tibial cuff and a connecting posterior strut (Intrepid Dynamic Exoskeletal Orthosis (IDEO), Brooke Army Medical Center, San Antonio, TX, USA; Fig. 1). The PD-AFO stiffness was modified by altering the geometry of the posterior strut. A SLS strut with stiffness equivalent to the CF strut was designed and manufactured for each patient as well as SLS struts that were 20% more compliant and 20% more stiff than the CF strut. This range was selected to represent typical modifications to the IDEO stiffness that can occur during the clinical prescription process. The stiffness of each SLS strut was verified post-build by performing a three-point-bend test and destructive testing to measure the maximum deflection and ultimate strength was also performed on duplicate struts to ensure their structural integrity. The struts were then evaluated on subjects through a comprehensive biomechanical gait assessment during overground walking to quantify the influence of PD-AFO stiffness on walking performance. From this point forward the PD-AFOs will be referred to as AFOs for brevity.

2.1. Subjects

Thirteen active military personnel with unilateral lower extremity injuries, consistent with those previously reported (Bedigrew et al., 2014), and resulting ankle muscle weakness participated in the study

Table 1
Characteristics for subjects with unilateral neuromuscular and musculoskeletal impairments due to various limb salvage procedures and resultant ankle muscle weakness. L indicates a left-side impairment and R indicates a right-side impairment.

	Mean	Std dev	Max	Min		# Male	# Female						
Age (years)	29.4	5.8	40.0	21.0	Gender	13	0						
Height (m)	1.80	0.08	1.95	1.64									
Body mass (kg)	88.2	10.8	113.6	75.5	Affected limb	# Right	# Left						
Leg length (m)	1.01	0.07	1.14	0.91		6	7						
	Subject												
	1	2	3	4	5	6	7	8	9	10	11	12	13
Neuropathy	R					L			R				R
Paresis		R											
Tissue loss			R					R	R				
Fracture(s)				L	L	L	L			L	L	L	
Osteoarthritis				L									
Equinovarus									R				
Shrapnel											L		
Vascular injury											L		

(Table 1). All subjects were active and had experienced high-energy lower-leg trauma (e.g., motor vehicle accidents or blast injuries) requiring limb salvage procedures. Nine of the thirteen subjects were able to perform pain-free maximum voluntary isometric ankle contractions on a dynamometer (Biodex Medical Systems, Inc., Shirley, NY, USA). All nine of these subjects experienced deficits in their ankle torque values relative to their uninvolved limb (plantarflexor torque: 49.96% mean deficit; dorsiflexor torque: 34.85% mean deficit). Each subject had been prescribed a subject-specific IDEO (Patzkowski et al., 2012) by their orthopedic surgeon (based on available ankle RoM, intensity of activities and subject preference) and provided institutionally approved written informed consent prior to their participation in this study. All subject data were collected in the Military Performance Laboratory at the Center for the Intrepid in Fort Sam Houston, TX.

2.2. Design and manufacture of the SLS AFOs

Due to the design of the IDEO AFO, the stiffness of each subject's clinically prescribed CF IDEO was due to the deformation of the posterior strut component (Patzkowski et al., 2012). Therefore, a SLS framework was used to create subject-specific AFO struts of varying stiffness (for details, see Harper et al., 2014). This framework has been shown to produce high-quality SLS AFO struts that are biomechanically equivalent to stiffness-matched CF AFO struts (Harper et al., 2014). The primary steps in this SLS framework include: (1) determining the stiffness of the subject's clinically prescribed CF IDEO posterior strut through mechanical testing in a three-point-bend configuration with a support span of 160 mm, (2) using computer-aided design and a predictive model to develop subject-specific struts that were 20% more stiff, 20% more compliant and equivalent to the CF strut stiffness, (3) using SLS to manufacture the struts using Nylon 11 (PA D80-ST, Advanced Laser Materials, LLC, Temple, TX, USA), which has high ductility and low damping compared to other SLS materials (Faustini et al., 2008), (4) verifying the stiffness of each SLS strut through mechanical testing in the same three-point-bend configuration used to determine the stiffness of the CF strut, (5) mechanically testing tensile specimens to verify the material properties of the SLS build, and (6) destructively testing duplicates of each SLS strut to ensure their structural integrity. The SLS struts were used in subsequent biomechanical testing if 1) they were within 5% of the desired stiffness, 2) the duplicate struts did not fracture during destructive testing, and 3) all tensile specimens indicated that the material had appropriate ductility and strength.

2.3. Experimental walking protocol

Subjects underwent three biomechanical gait assessments, one for each AFO strut (nominal SLS strut, 20% more stiff SLS strut and 20% more compliant SLS strut), in randomized order. Clubmaker™ lead tape (Golfsmith, Austin, TX, USA) was attached to the nominal and compliant struts to normalize the weight to the stiff SLS strut. Before testing each AFO, a certified orthotist attached the strut to the cuff and footplate to ensure proper alignment. Subjects were given a minimum of 30 min to acclimate to each AFO (Geboers et al., 2002; Smith and Martin, 2011) and wore the same make and model of footwear across conditions.

For each AFO condition subjects walked overground at their self-selected velocity (SS) and a controlled Froude velocity (FR, 0.16) based on leg length (Vaughan and O'Malley, 2005). At FR, auditory cues (Biofeed Trak, Motion Analysis Corp., Santa Rosa, CA, USA) based on the forward progression of a marker on the 7th cervical vertebra were used to provide speed feedback to the subjects. Ground reaction force (GRF) data were collected from 5 embedded AMTI forceplates (1200 Hz, AMTI, Inc., Watertown, MA, USA). A 26-camera optoelectronic motion capture system (120 Hz, Motion Analysis Corp., Santa Rosa, CA, USA) and a 6 degree-of-freedom body segment marker set with 57 reflective markers were used to collect 3D whole body kinematics (Wilken et al., 2012). In addition, a digitization process was used to

identify 20 bilateral anatomical bony landmarks (C-motion, Inc., Germantown, MD, USA).

Surface electromyographic (EMG) data were collected at 1200 Hz (Motion Laboratory Systems, Inc. Baton Rouge, LA, USA) bilaterally from 7 muscles: soleus, medial gastrocnemius, tibialis anterior, rectus femoris, biceps femoris long head, vastus medialis and gluteus medius. Electrodes were not applied if the AFO interfered with their placement or if there was insufficient remaining muscle mass.

2.4. Kinematics and kinetics

All kinematic and kinetic analyses were performed in Visual3D (C-Motion, Inc., Germantown, MD, USA). A 13-segment model was created and scaled to each subject's body mass (including the IDEO) and height (Dempster, 1955) using anatomical landmarks to define joint centers and joint coordinate systems according to the International Society of Biomechanics standards (Grood and Suntay, 1983; Wu and Cavanagh, 1995; Wu et al., 2002). Marker trajectory data were interpolated with a cubic polynomial, and GRF and marker trajectory data were low-pass filtered using a 4th-order Butterworth filter with cutoff frequencies of 50 and 6 Hz, respectively. Joint kinematics were determined using Euler angles with pelvis, hip, knee and ankle kinematics defined using Cardan rotation sequences (Grood and Suntay, 1983; Baker, 2001; Wu et al., 2002). Net joint moments and powers were calculated using inverse dynamics and expressed in the proximal segment's coordinate system. The moments and powers were normalized by subject body mass while GRFs were normalized by subject body weight. GRFs as well as sagittal plane joint angles, moments and powers corresponding to five complete gait cycles for each limb (gait events defined by Zeni et al., 2008) were time-normalized to 100% of the gait cycle and exported for further analysis in Matlab (MathWorks, Inc., Natick, MA, USA).

The gait cycle was divided into six regions (Fig. 2). Within each region peak values were identified for each kinematic and kinetic variable of interest and joint work and GRF impulses were calculated. Work at the ankle, knee and hip was computed as the time integral of the corresponding joint power. GRF impulses were computed as the time integral of the anteroposterior (A/P), mediolateral (M/L) and vertical GRFs. In addition, to minimize any bias due to variations in AFO strut alignment and to obtain a normalized measure of AFO deflection, the AFO limb ankle angle during swing (unloaded neutral angle) was subtracted from the AFO limb ankle angle across the gait cycle. For each subject, the variables of interest were averaged across all gait cycles for each combination of AFO stiffness and velocity.

2.5. Electromyography (EMG)

In Visual3D, the EMG data were demeaned, bandpass filtered with cutoff frequencies of 20 Hz and 400 Hz and smoothed with a 50 ms sliding RMS window. The processed EMG data were time-normalized to 100% of the gait cycle and exported for further analysis in Matlab. To account for biomechanical testing of AFO conditions occurring on different days, for each muscle, EMG data were normalized by the peak EMG magnitude during the FR speed collected on the same day (Yang and Winter, 1984). Integrated EMG (iEMG) quantities were calculated for each muscle as the time integral of the corresponding normalized EMG within each of the six regions of the gait cycle. For each subject, iEMGs were averaged across all gait cycles for each combination of AFO stiffness and walking velocity and then normalized by the full gait cycle iEMG magnitude for the nominal stiffness condition.

2.6. Statistical analyses

Statistical analyses were performed using SPSS (SPSS, Inc., Chicago, IL, USA) to test the three hypotheses. To test the first hypothesis that the AFO limb ankle RoM and work would increase as AFO stiffness

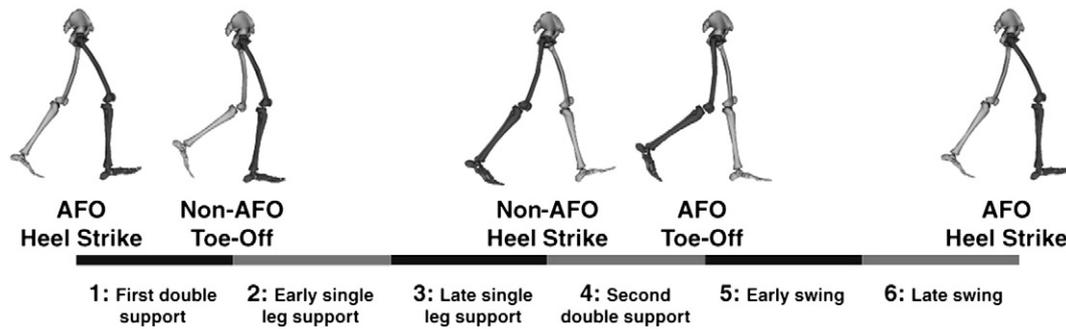


Fig. 2. The six regions evaluated in the AFO limb gait cycle: 1) first double support (AFO heel-strike to non-AFO toe-off), 2) early single-leg support and 3) late single-leg support (non-AFO toe-off to non-AFO heel-strike divided into two equal sections), 4) second double support (non-AFO heel-strike to AFO toe-off), 5) early swing, and 6) late swing (AFO toe-off to AFO heel-strike divided into two equal sections).

decreased, peak ankle angles and moments during the full gait cycle and ankle joint work in each of the six regions of the gait cycle were analyzed using separate two-factor (AFO stiffness level, limb) ANOVAs.

To test the second hypothesis that the AFO's contribution to body support would diminish and knee joint work and knee extensor moments would increase to compensate as AFO stiffness decreased, vertical GRF impulses during the stance phase of the gait cycle (Regions 1–4), peak knee angles and moments during the full gait cycle and knee joint work in each of the six regions of the gait cycle were analyzed using separate two-factor (AFO stiffness level, limb) ANOVAs.

The final hypothesis that the AFO's contribution to forward propulsion would increase, and thus hip joint work and hip extensor moments would decrease as AFO stiffness decreased was tested by analyzing the braking and propulsive GRF impulses during the stance phase of the gait cycle (Regions 1–4), peak hip angles and moments during the full gait cycle and hip joint work in each of the six regions of the gait cycle using separate two-factor (AFO stiffness level, limb) ANOVAs.

In addition, medial and lateral GRF impulses were assessed during the stance phase of the gait cycle (Regions 1–4) using separate two-factor (AFO stiffness level, limb) ANOVAs. For all ANOVAs, the AFO stiffness factor consisted of three levels (nominal, 20% more stiff and 20% more compliant) while the limb factor consisted of two levels (AFO and non-AFO). Significant main or interaction effects resulting from all ANOVAs were adjusted using a Huynh–Feldt correction. For significant interaction effects, post-hoc pairwise comparisons were evaluated with a Bonferroni correction for multiple comparisons. The unadjusted criterion for statistical significance was set at $P < 0.05$. Limb main effects were not reported.

3. Results

Kinematic, kinetic and EMG data followed similar trends in both the SS and FR conditions. In addition, walking velocities were not significantly different between the SS (1.28 m/s) and FR (1.27 m/s) conditions ($P = 0.776$). Therefore, to minimize redundancy, the SS results are presented here while the FR results are included as Supplemental Material for completeness. In addition, ensemble averaged time-series plots for the SS condition are included in the Supplemental Material for reference.

3.1. SLS-manufactured AFO struts

The SLS framework successfully generated struts matching the desired stiffness levels within 5%, as determined using a three-point-bend configuration with a support span of 160 mm for all 13 subjects. In addition, all duplicate struts passed the destructive testing without failure. Forces ranging from 4854 N (Subject 10, compliant strut) to 13,072 N (Subject 11, stiff strut) were achieved during the destructive testing as the struts plastically deformed. The SLS struts ranged in stiffness from 402 N/mm (most compliant) to 1216 N/mm (most stiff) with

mean (standard deviation) values of 628 (157) N/mm (compliant), 785 (196) N/mm (nominal) and 932 (226) N/mm (stiff) across subjects.

3.2. Kinematics and kinetics

Altering AFO strut stiffness had a minimal effect on walking kinematics and kinetics. There were no differences in hip joint angles (Table 2) although peak knee flexion in Region 2 significantly decreased in the compliant condition relative to the nominal and stiff conditions (Region 2: AFO main effect, $P = 0.008$, compliant to nominal, $P = 0.031$, compliant to stiff, $P = 0.026$). In addition, peak plantarflexion in Region 1 significantly increased in the compliant condition relative to the nominal condition (Region 1: AFO main effect, $P = 0.005$, compliant to nominal, $P = 0.028$), and peak dorsiflexion in Region 4 significantly decreased

Table 2

Mean (standard deviation) peak joint angles and joint moments of the AFO and non-AFO limbs at the self-selected velocity (SS) for each AFO stiffness condition.

		Compliant	Nominal	Stiff
<i>Joint Angles (°)</i>				
Plantarflexion \blacklozenge	AFO	-6.59 (2.25)	-6.03 (1.75)	-5.96 (2.32)
	Non-AFO	-3.30 (2.42)	-1.29 (2.16)	-2.72 (2.78)
Dorsiflexion \blacksquare	AFO	6.55 (2.33)	5.86 (1.88)	5.68 (2.18)
	Non-AFO	14.94 (3.01)	16.40 (3.59)	14.23 (3.10)
Plantarflexion \blacklozenge	AFO	-0.79 (0.63)	-0.50 (0.45)	-0.56 (0.55)
	Non-AFO	-16.60 (6.07)	-15.13 (5.59)	-15.98 (3.75)
Knee flexion \blacktriangle	AFO	13.38 (7.62)	15.71 (6.00)	17.17 (7.83)
	Non-AFO	13.65 (5.66)	16.29 (4.41)	15.11 (6.74)
Knee flexion \blacktriangle	AFO	59.81 (5.69)	61.28 (4.87)	61.84 (5.11)
	Non-AFO	60.58 (3.83)	62.99 (5.04)	61.21 (5.44)
Hip extension	AFO	-4.77 (5.44)	-3.44 (6.56)	-3.15 (2.86)
	Non-AFO	-6.25 (4.95)	-5.21 (5.96)	-6.02 (3.70)
<i>Joint moments (Nm/kg)</i>				
Dorsiflexion	AFO	0.37 (0.11)	0.38 (0.08)	0.39 (0.09)
	Non-AFO	0.27 (0.11)	0.22 (0.10)	0.26 (0.08)
Plantarflexion	AFO	-1.48 (0.23)	-1.50 (0.22)	-1.47 (0.26)
	Non-AFO	-1.42 (0.19)	-1.48 (0.20)	-1.38 (0.18)
Knee flexion	AFO	0.44 (0.18)	0.44 (0.14)	0.42 (0.17)
	Non-AFO	0.63 (0.15)	0.65 (0.14)	0.62 (0.14)
Knee extension	AFO	-0.43 (0.22)	-0.47 (0.21)	-0.57 (0.23)
	Non-AFO	-0.44 (0.26)	-0.49 (0.23)	-0.47 (0.29)
Knee flexion	AFO	0.46 (0.17)	0.41 (0.19)	0.35 (0.17)
	Non-AFO	0.45 (0.16)	0.42 (0.11)	0.44 (0.07)
Hip extension	AFO	-0.96 (0.36)	-0.97 (0.25)	-0.96 (0.33)
	Non-AFO	-1.17 (0.29)	-1.26 (0.29)	-1.21 (0.25)
Hip flexion	AFO	0.67 (0.26)	0.67 (0.23)	0.68 (0.24)
	Non-AFO	0.61 (0.20)	0.58 (0.17)	0.63 (0.21)

\blacklozenge Denotes a significant difference between compliant and nominal AFO struts.

\blacktriangle Denotes a significant difference between compliant and stiff AFO struts.

\blacksquare Denotes a significant difference between nominal and stiff AFO struts.

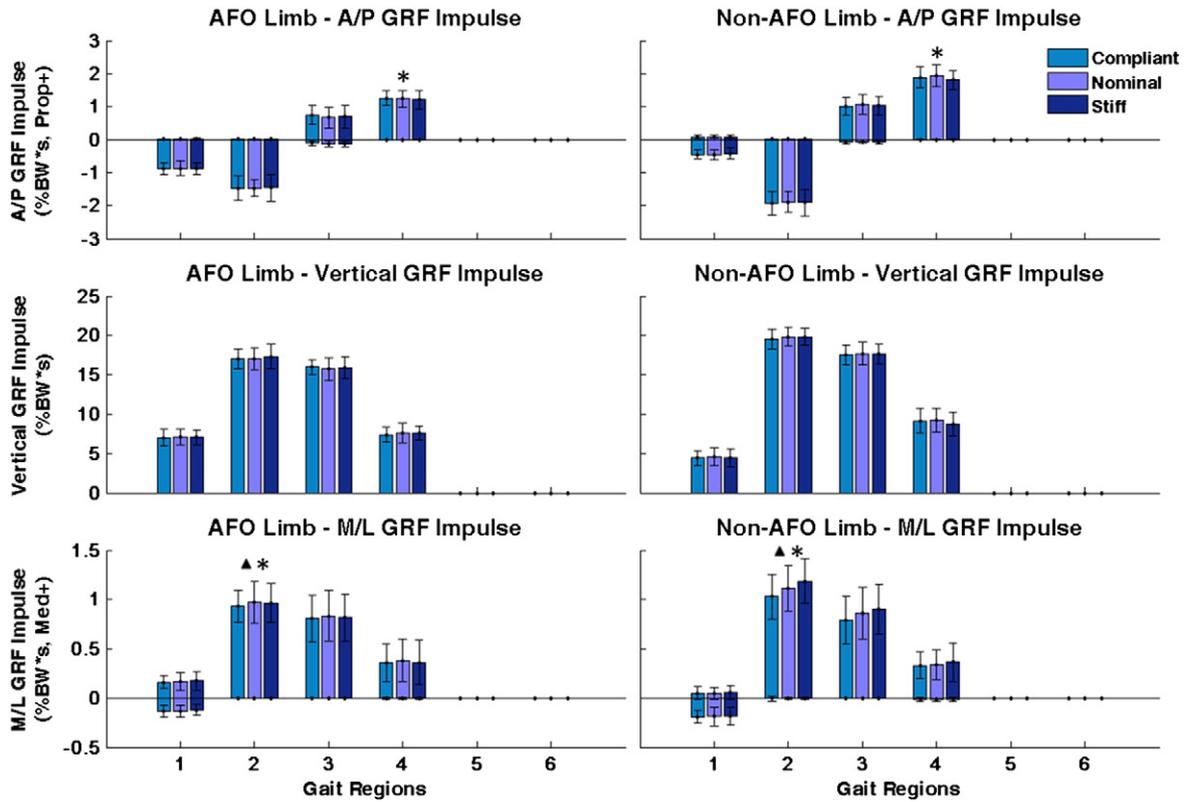


Fig. 3. Mean (standard deviation bars) ground reaction force (GRF) impulses across subjects for the AFO and non-AFO limbs at the self-selected velocity (SS) across the six evaluated regions of the gait cycle: 1) first double support, 2) early single-leg support, 3) late single-leg support, 4) second double support, 5) early swing, and 6) late swing. Significant AFO main effects are depicted with an asterisk (*) while significant differences between AFO struts are indicated with the following symbol: compliant and stiff (▲). Positive values represent propulsive, vertical and medial GRF impulses.

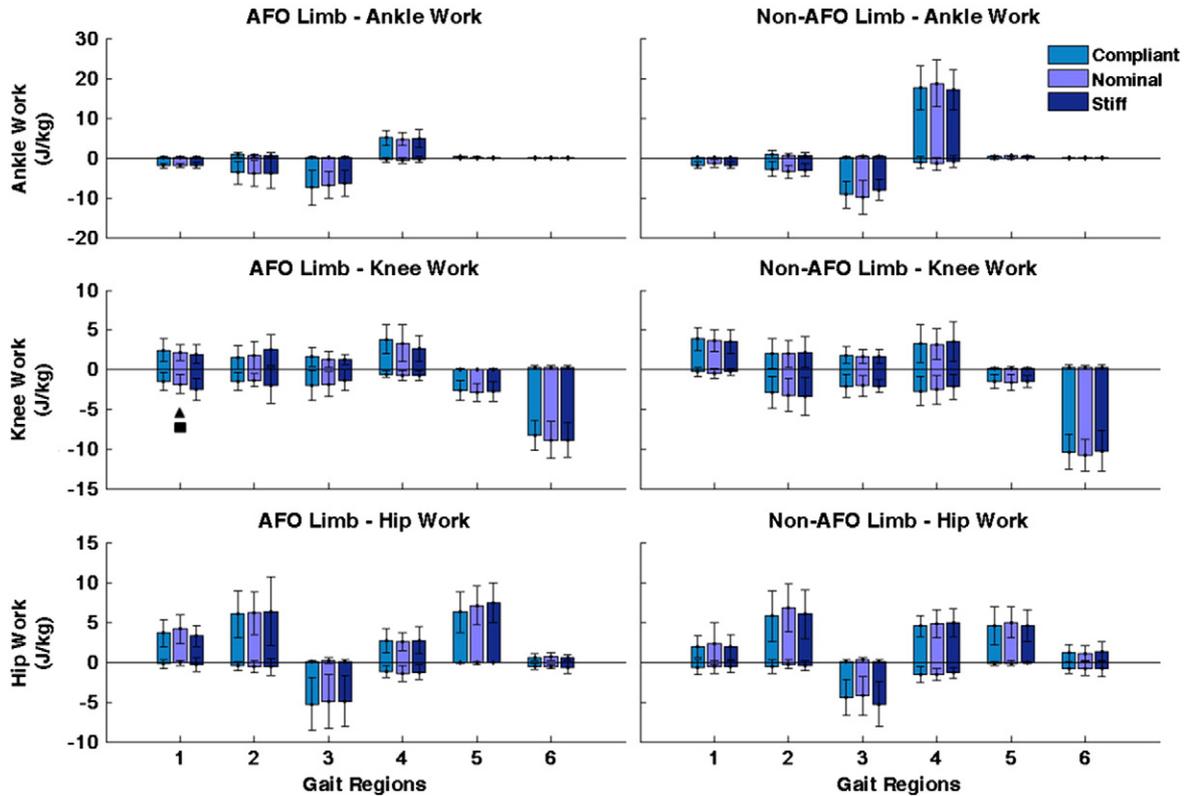


Fig. 4. Mean (standard deviation bars) joint work across subjects for the AFO and non-AFO limbs at the self-selected velocity (SS) across the six evaluated regions of the gait cycle: 1) first double support, 2) early single-leg support, 3) late single-leg support, 4) second double support, 5) early swing, and 6) late swing. Significant differences between AFO struts are indicated with the following symbols: compliant and stiff (▲), and nominal and stiff (■).

in the stiff condition relative to the nominal condition (Region 4: AFO main effect, $P = 0.032$, nominal to stiff, $P = 0.045$).

Only the propulsive (Region 4: AFO main effect, $P = 0.039$) and medial (Region 2: AFO main effect, $P = 0.018$) GRF impulses (Fig. 3) were influenced by AFO stiffness with the medial GRF impulse significantly increased in the stiff condition relative to the compliant condition (Region 2: compliant to stiff, $P = 0.003$). There were no differences in joint moments (Table 2). Joint work (Fig. 4) was only affected at the knee (Region 1: AFO main effect, $P = 0.034$) with negative

knee work significantly increased in the AFO limb in the stiff condition relative to the nominal and compliant conditions (Region 1: leg*AFO interaction effect, $P = 0.001$, compliant to stiff, $P = 0.003$, nominal to stiff, $P = 0.035$).

3.3. Integrated EMG

Altering AFO strut stiffness had almost no effect on the integrated EMG quantities (Fig. 5). One exception occurred during Region 3, where

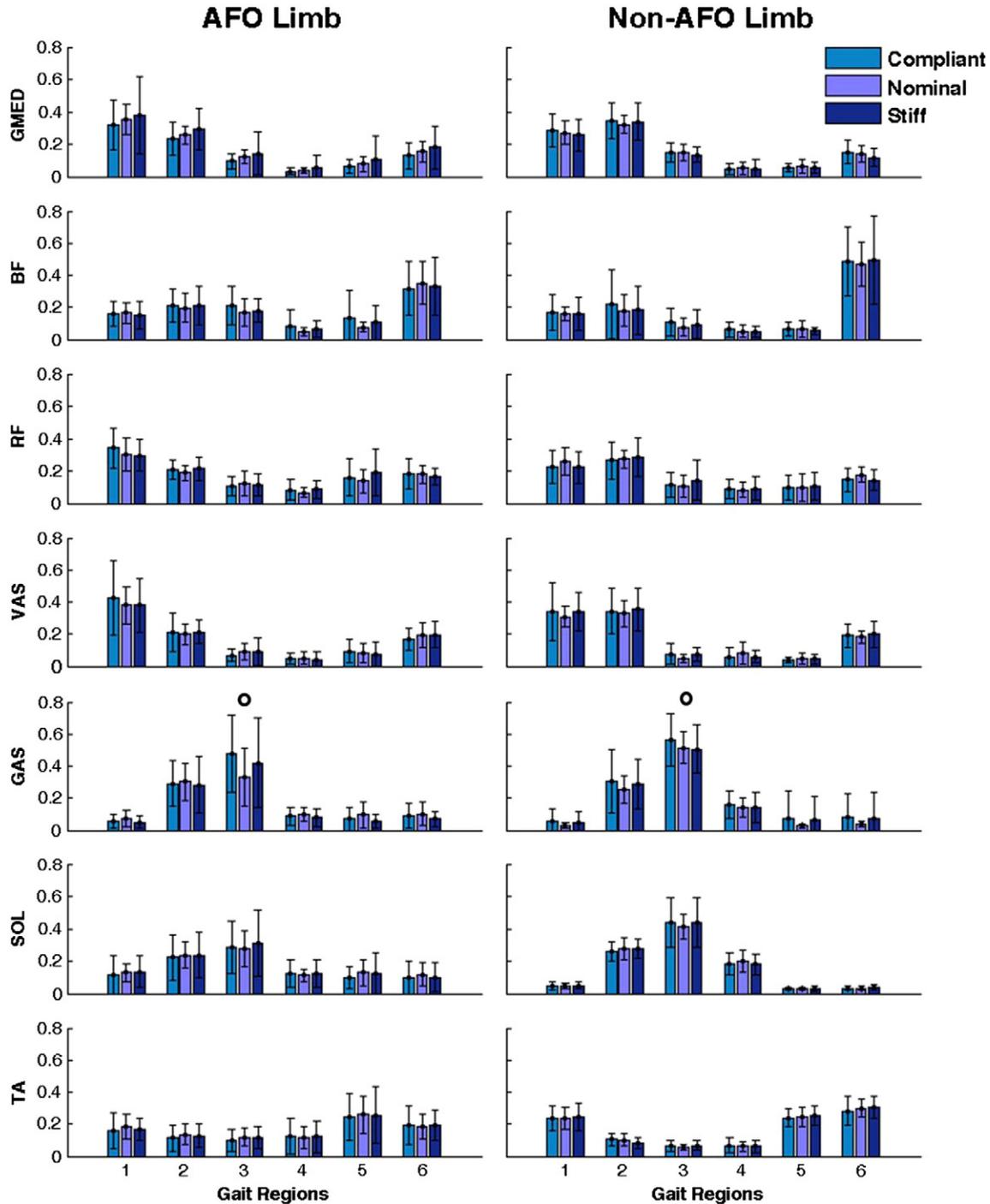


Fig. 5. Mean (standard deviation bars) integrated electromyographic (iEMG) quantities across subjects for the AFO and non-AFO limbs at the self-selected velocity (SS) across the six evaluated regions of the gait cycle: 1) first double support, 2) early single-leg support, 3) late single-leg support, 4) second double support, 5) early swing, and 6) late swing. Significant differences between AFO struts are indicated with the following symbol: compliant and nominal (O). Muscle abbreviations are as follows: gluteus medius (GMED), biceps femoris long head (BF), rectus femoris (RF), vastus medialis (VAS), medial gastrocnemius (GAS), soleus (SOL), and tibialis anterior (TA).

the medial gastrocnemius increased its activity in the compliant condition relative to the nominal condition (Region 3: AFO main effect, $P = 0.006$, compliant to nominal, $P = 0.006$). However, no other changes in muscle activity were identified.

4. Discussion

The goal of this study was to use SLS-manufactured PD-AFOs to identify the relationships between AFO stiffness and walking performance in patients with various lower-limb neuromuscular and musculoskeletal impairments. Consistent with previous prosthetic foot–ankle studies (Fey et al., 2011; Ventura et al., 2011a, b), the SLS framework enabled the successful generation of AFO struts with highly controlled stiffness characteristics.

The hypothesis that ankle RoM and work would increase as stiffness decreased was only partially supported. Unexpectedly, no significant changes in ankle joint work or moments were observed (Fig. 4, Table 2) as AFO stiffness decreased. However, as stiffness decreased ankle RoM increased. This was largely consistent with recent studies examining the influence of AFO (Kobayashi et al., 2011, 2013) and prosthetic foot (Fey et al., 2011) stiffness on gait performance in which investigators found significant increases in the ankle RoM of the AFO or prosthetic limb as stiffness decreased.

The hypothesis that as AFO stiffness decreased, the corresponding contribution to body support would decrease and the knee extensor moment, knee work and muscle activity would increase, was only partially supported. Activity of the medial gastrocnemius increased in late single-leg support when it is known to provide body support (Neptune et al., 2001; Anderson and Pandey, 2003; Liu et al., 2006). It is likely that increased activity of the medial gastrocnemius compensated for the decrease in body support provided by the compliant AFO and eliminated the need for other compensations. This compensatory increase in medial gastrocnemius activity is consistent with previous work showing that as healthy subjects hop with an AFO, which acts to increase the overall ankle stiffness, they maintain a constant leg stiffness by decreasing their medial gastrocnemius activity (Ferris et al., 2006). This result is also partially consistent with previous studies in individuals with lower-limb amputations which showed that as prosthesis stiffness decreased, the prosthesis contributed less to body support (Fey et al., 2011; Ventura et al., 2011a, b). However, these studies noted an increase in the activity of the knee extensor muscles (Fey et al., 2011; Ventura et al., 2011a, b), which have been previously shown to contribute to body support in unimpaired walking (Kepple et al., 1997; Anderson and Pandey, 2003; Neptune et al., 2004; Liu et al., 2006; McGowan et al., 2009) while the present study found an increase in medial gastrocnemius activity. Thus, it appears that the subjects in the present study were able to compensate for the diminished body support with the medial gastrocnemius while lower-limb amputees, who do not have a fully functional medial gastrocnemius, compensate for the diminished body support with the knee extensor muscles.

No significant changes in the contribution to forward propulsion were observed as stiffness decreased. In addition, no changes were observed at the hip as a result of altering AFO stiffness. Thus, the hypothesis that the AFO's contribution to forward propulsion would increase and hip extensor moments, hip work and the activity of muscles that contribute to forward propulsion would decrease to compensate was not supported. These results differ from recent gait studies in individuals with amputations that found that as stiffness decreased the prosthesis contributed more to forward propulsion (Fey et al., 2011; Ventura et al., 2011a, b). These differences between studies suggest that subjects ambulating with an AFO may utilize different compensatory mechanisms when stiffness is altered compared to amputees. This difference is likely due to the fact that subjects ambulating with a unilateral AFO have two intact limbs, although one is impaired, and may compensate for changes in AFO stiffness with the impaired ankle muscles (c.f., individuals with amputations).

One interesting result occurred in the medial GRF. As AFO stiffness decreased, the medial GRF impulse during early single-limb stance decreased. In addition, in the AFO limb there was a trend of decreased gluteus medius activity as stiffness decreased during first double support (significant at FR – see Supplemental Material). This is consistent with a previous study that found the gluteus medius to be a primary contributor to the medial GRF (Pandey et al., 2010). In addition, a decreased hip abductor moment has been shown to be strongly correlated with an increased range of whole-body angular momentum (Silverman et al., 2012), which is a measure of dynamic balance during walking. This relationship suggests that decreases in AFO stiffness may have an influence on frontal plane balance control. This is consistent with a recent study that found a strong correlation between increased prosthesis stiffness and increased dynamic balance control (Nederhand et al., 2012). The influence of AFO stiffness on measures of dynamic balance warrants further investigation.

Although the results of this study provide insights into the influence of AFO stiffness on gait in individuals with various neuromuscular and musculoskeletal impairments, some potential limitations exist. One potential limitation is that the SLS struts may not have captured all of the functional characteristics of the subject's CF strut. However, a previous study that assessed walking with a CF strut versus a stiffness-matched SLS strut found very few differences in biomechanical gait measures (Harper et al., 2014), all of which were less than the minimal detectable change values established within the literature (Wilken et al., 2012). An additional limitation is that the contribution of the AFO to the ankle joint moments and work could not be separated from the biological contributions. Future work should seek to quantify the contribution of the AFO to the total joint moment to further understand the compensatory mechanisms used.

Another potential limitation is that device acclimation period was not strictly controlled as subjects were given time to acclimate to each new stiffness condition until they felt comfortable for testing. However, a previous study assessing both healthy subjects and subjects with foot-drop found that changes in lower-limb muscle activity occur almost immediately in response to donning an AFO and do not accumulate over time (Geboers et al., 2002), and another study investigating amputees showed that changes in temporal parameters and joint kinematics due to altered inertial properties of the prosthesis occurred almost immediately (Smith and Martin, 2011). In the present study, all subjects took a minimum of 30 min to acclimate to each new stiffness condition. Thus, we expect that adaptations to each new stiffness level were complete by the time of testing. Lastly, our subject population consisted of active military personnel who had experienced traumatic injuries. Aside from their injuries, these subjects were in good physical condition and were otherwise healthy. As a result, this subject population may not be representative of the entire population of AFO users, and future work should assess the effect of AFO stiffness in different patient populations.

5. Conclusions

In summary, subjects effectively compensated for changes in AFO stiffness with altered gastrocnemius activity, and the stiffness levels analyzed in this study had a minimal effect on overall walking performance. This suggests that orthotists may not need to precisely control the stiffness level and may instead prescribe the AFO stiffness based on other factors such as patient perception and comfort. However, evidence was found to suggest that the control of frontal plane balance may be influenced by AFO stiffness and that further work is needed to investigate this relationship.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <http://dx.doi.org/10.1016/j.clinbiomech.2014.07.005>.

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