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Selective Laser Sintered Versus Carbon Fiber Passive-Dynamic Ankle-Foot Orthoses: A Comparison of Patient Walking Performance

Selective laser sintering (SLS) is a well-suited additive manufacturing technique for generating subject-specific passive-dynamic ankle-foot orthoses (PD-AFOs). However, the mechanical properties of SLS PD-AFOs may differ from those of commonly prescribed carbon fiber (CF) PD-AFOs. Therefore, the goal of this study was to determine if biomechanical measures during gait differ between CF and stiffness-matched SLS PD-AFOs. Subject-specific SLS PD-AFOs were manufactured for ten subjects with unilateral lower-limb impairments. Minimal differences in gait performance occurred when subjects used the SLS versus CF PD-AFOs. These results support the use of SLS PD-AFOs to study the effects of altering design characteristics on gait performance. [DOI: 10.1115/1.4027755]

Introduction

Individuals with various lower-limb neuromuscular and musculoskeletal impairments often experience ankle muscle weakness [1]. Ankle muscle weakness negatively affects walking ability as the ankle plantarflexor and dorsiflexor muscles have been shown to be important contributors to body support, forward propulsion, leg swing initiation, mediolateral balance control, and foot clearance during swing [2–5]. As a result, AFOs are commonly prescribed to improve gait in individuals with impairments by mechanically compensating for ankle weakness and resulting loss of function [6]. Studies have shown traditional AFOs, designed primarily to provide appropriate foot support, have had a number of positive effects on gait including improving toe clearance during swing (e.g., Refs. [7,8–10]), improving spatiotemporal parameters of gait (e.g., Refs. [7–9,11,12–14]), decreasing the energy cost of walking (e.g., Refs. [7,8]), promoting heel strike (e.g., Refs. [7,9,12]), facilitating forward progression (e.g., Ref. [13]), and improving mediolateral stability (e.g., Ref. [10]) and balance (for review, see Ref. [15]).

PD-AFOs are a category of AFOs that rely on design characteristics to improve gait performance through elastic energy storage and return [16]. One design characteristic that can influence the function and performance of the PD-AFO is the material used to manufacture the orthosis. CF PD-AFOs, in particular, have been shown to provide beneficial effects on pathological gait compared to walking without an AFO [1,17–19] or with traditional AFOs [1,18–21]. However, few studies have examined the influence of other design characteristics on gait performance.

One challenge to performing such studies is the difficulty of manufacturing custom AFOs with precisely controlled design characteristics. One approach is to use SLS, which is an additive manufacturing technique that facilitates more automated fabrication of custom PD-AFOs and provides precise control of specific design characteristics. SLS has recently been used to create PD-AFOs [16,22], traditional AFOs [23], foot orthoses [24,25], and prosthetic sockets [26–28], feet [29], and ankles [30,31]. Since SLS AFOs can be manufactured within precisely controlled design specifications, they can be used to achieve similar spatiotemporal parameters and ankle kinematics to traditional, polypropylene designs [23]. However, some mechanical properties of SLS PD-AFOs, such as energy dissipation, can differ from CF PD-AFOs [16] and no study has directly compared the gait performance of a CF versus an SLS PD-AFO. Therefore, the goal of this study was to identify the influence of a CF versus a stiffness-matched SLS PD-AFO on various biomechanical measures during overground walking. We hypothesized that there would be no difference in walking performance across the PD-AFOs manufactured with the different materials. The results of this study will help determine the validity of using SLS PD-AFOs to study the effects of altering design characteristics on gait performance and extending those results to the prescription and design of subject-specific PD-AFOs.

Methods

Subjects. Ten active subjects with ankle muscle weakness as a result of a range of unilateral lower extremity injuries (e.g., motor vehicle accidents and blast injuries) participated in this study (Table 1). An orthopedic surgeon had prescribed each subject a subject-specific intrepid dynamic exoskeletal orthosis (IDEO) [1], which is a modular CF PD-AFO consisting of a footplate, cuff, and posterior strut (Fig. 1). Each subject provided institutionally approved written informed consent prior to their participation in this study. All data were collected in the Military Performance Laboratory at the Center for the Intrepid in Fort Sam Houston, TX. From this point forward, we will refer to the PD-AFO simply as an AFO for brevity.

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 deformation of the posterior strut

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Table 1 Characteristics for subjects with unilateral neuromuscular and musculoskeletal impairments due to various lower extremity injuries

	Mean	Std. Dev.	Max	Min		No. of male	No. of female
Age (years)	28.7	6.0	40.0	21.0	Gender	10	0
Height (m)	1.78	0.07	1.92	1.64			
Body mass (kg)	86.0	8.5	97.3	75.5		No. of right	No. of left
Leg length (m)	1.00	0.07	1.14	0.91	Affected limb	5	5

Fig. 1 Clinically prescribed CF PD-AFO (IDEO, Brooke Army Medical Center, Fort Sam Houston, TX)

component [1]. Due to observed variations in the modulus of elasticity that made theoretical stiffness predictions difficult, the stiffness of the CF strut was determined using a three-point-bend configuration and a mechanical testing machine with a 5000 N uniaxial load cell (Instron, Norwood, MA). A load of 890 N (200 lbf) was applied at a rate determined by the ASTM standard D790 with a support span of 160 mm. This load represented the peak vertical ground reaction force (GRF) that occurs during walking in an average subject. The applied load and resulting deflection were used to calculate the stiffness.

To match the stiffness characteristics of the CF AFO while satisfying other design constraints (e.g., length and cuff and footplate attachment sites), the strut geometry for the SLS AFO was modified to a channel beam design and the stiffness was varied by altering the strut dimensions. A generic SLS strut was designed in Solidworks (SolidWorks, Waltham, MA) and finite element analysis simulations were performed to identify and minimize through iteration stress concentrations within the strut under physiologic loads. A predictive model for stiffness was developed by manufacturing and testing a series of SLS struts with varying dimensions. Using the predictive model, the generic AFO strut computer aided design (CAD) model was modified in Solidworks for each subject to match the length and stiffness characteristics of their prescribed CF strut.

The Solidworks CAD files were then exported to a Vanguard HiQ/HS Sinterstation (3D Systems, Inc., Rock Hill, SC) where the SLS AFO struts were manufactured using Nylon 11 (PA D80-ST, Advanced Laser Materials, Temple, TX), which has high ductility and low damping compared to other SLS materials (see Ref. [16] for details). A duplicate of each strut was built adjacent to the original to ensure uniform material properties for destructive testing (see below). In addition, tensile specimens, designed according to the ASTM standard D638, were manufactured throughout the build volume to assess the quality and uniformity of the SLS part material properties throughout the build.

After the SLS struts were manufactured, mechanical testing was performed on each strut in the same three-point-bend configuration used to test the CF struts to verify its stiffness. Tensile testing was performed on each tensile specimen to assess their material properties using ASTM standard D638. Destructive testing of each duplicate strut was performed using a three-point-bend configuration on a mechanical tester with a 100 kN uniaxial load cell (MTS ReNew/Instron, Eden Prairie, MN). The strut was loaded at 500 mm/min (maximum rate of the mechanical testing machine) until it fractured or was plastically deformed beyond the ultimate flexural strength. If the duplicate strut did not fracture during destructive testing and all tensile specimens indicated the parts had appropriate ductility and strength, then the paired strut was deemed ready for use in the overground walking trials.

Experimental Walking Protocol. The experimental protocol was a crossover design in which the subjects underwent two biomechanical gait assessments in randomized order, one with the CF strut and one with the stiffness-matched SLS strut. Clubmaker™ lead tape (Golfsmith, Austin, TX) was affixed to the CF strut to match the weight of the SLS strut. Prior to testing each AFO, a certified orthotist attached the strut to the cuff and footplate and ensured proper alignment. Subjects wore the same make and model of footwear in each condition and were given a minimum of 30 min to acclimate to each AFO [32,33].

Subjects walked overground at their self-selected velocity (SS) and a controlled Froude velocity (FR), which is based on leg length [34]. GRF data were collected from 5 embedded AMTI forceplates (1200 Hz, AMTI, Inc., Watertown, MA). A 6 degree-of-freedom body segment marker set with 57 reflective markers and a 26-camera optoelectronic motion capture system (120 Hz, Motion Analysis Corp., Santa Rosa, CA) were used to collect 3D whole body kinematics [35].

Spatiotemporal Parameters, Kinematics, and Kinetics. Using Visual3D (C-Motion, Inc., Germantown, MD), marker trajectory data were interpolated using a cubic polynomial and the GRF and marker trajectory data were filtered using a 4th-order Butterworth filter with cutoff frequencies of 50 and 6 Hz, respectively. A 13-segment model consisting of a head, torso, pelvis, two upper arms, two lower arms, two thighs, two shanks, and two feet was created and scaled to each subject's body mass and height [36]. Anatomical landmarks were used to define joint centers as well as joint coordinate systems using the International Society of Biomechanics standards [37–39]. Joint kinematics were computed using an Euler angle approach with pelvis, hip, knee, and ankle kinematics defined using the Cardan rotation sequences determined previously [38–40]. Net internal joint moments and powers were calculated using inverse dynamics and expressed in the proximal segment's coordinate system. GRFs were normalized by subject body weight and joint moments and powers were normalized by subject body mass. GRFs as well as sagittal plane joint angles, internal moments, and powers corresponding to five complete gait cycles with each limb beginning with a forceplate strike (gait events defined by Ref. [41]) were time-normalized to 101 points and exported for further analysis in MATLAB (MathWorks,

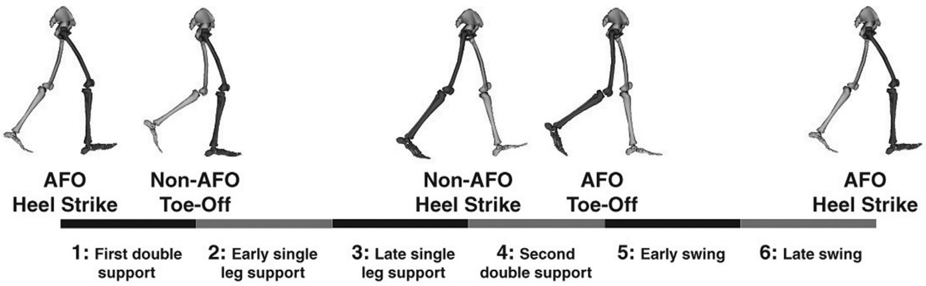

Fig. 2 The six regions evaluated in the AFO limb gait cycle: (1) first double support (AFO heel-strike to non-AFO toe-off), (2) early single-leg support and (3) late single-leg support (non-AFO toe-off to non-AFO heel-strike divided into two equal sections), (4) second double support (non-AFO heel-strike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

Inc., Natick, MA). Spatiotemporal gait parameters were also calculated in Visual3D and exported to MATLAB for further processing.

For analysis, the gait cycle was divided into six regions (Fig. 2). For each region of the gait cycle, 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 within each of the six regions of the gait cycle. GRF impulses were computed as the time integral of the anterioposterior (A/P), mediolateral (M/L), and vertical GRFs within each of the six regions of the gait cycle. In addition, the AFO limb ankle angle during swing was subtracted from the overall AFO limb ankle angle to minimize any bias due to variations in AFO strut alignment. For each subject, variables of interest, including spatiotemporal parameters, were averaged across all gait cycles for each combination of AFO condition and velocity.

Statistical Analyses. Statistical analyses were performed using SPSS (SPSS, Inc., Chicago, IL) to test the hypothesis that there would be no difference in gait performance across the AFOs manufactured with different materials. Spatiotemporal parameters across the gait cycle along with peak joint angles, peak joint moments, and joint work in each of the six regions of the gait cycle, and braking (negative), propulsive (positive), medial (positive), lateral (negative), and vertical GRF impulses in each region of the stance phase of the gait cycle (regions 1–4) were analyzed using two-factor (two AFO struts, two limbs) ANOVAs. Significant main or interaction effects resulting from these 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 $p < 0.05$. Leg main effects were not reported.

Results

Spatiotemporal, kinematic, and kinetic data followed similar trends in both the SS and FR conditions. In addition, walking velocities were not significantly different between the SS and FR conditions. Therefore, to minimize redundancy, the SS results are presented here while the FR results are included as supplemental material.

SLS-Manufactured AFO Struts. The SLS framework successfully generated struts matching the stiffness of the CF struts within $\pm$ 5% as determined using a three-point-bend configuration with a support span of 160 mm. In addition, all duplicate struts passed the destructive testing in the three-point-bend configuration without failure. Forces ranging from 4,854 N (subject 10) to 12,278 N (subject 6) were achieved during the destructive testing as the struts plastically deformed. The SLS struts ranged in stiffness from 490 N/mm to 932 N/mm with mean $\pm$ standard deviation values of 716 $\pm$ 167 N/mm.

Spatiotemporal Parameters. Overall, the spatiotemporal parameters were unaffected by AFO material (Fig. 3) with no significant differences identified.

Kinematics and Kinetics. Altering AFO strut material had a minimal effect on gait kinematics and kinetics. There were no differences in knee and hip angles (Fig. 4), although the peak ankle plantarflexion in regions 1 and 5 was significantly less in the SLS condition compared to the CF condition (region 1: AFO main effect, $p = 0.025$; region 5: AFO main effect, $p = 0.004$), particularly in the non-AFO limb (region 1: leg*AFO interaction effect, $p = 0.034$, CF to SLS, $p = 0.007$; region 5: leg*AFO interaction effect, $p = 0.048$, CF to SLS, $p = 0.015$). In addition, peak ankle dorsiflexion of the AFO limb during late single-leg stance and preswing was significantly lower in the SLS condition (leg*AFO interaction effect, $p = 0.004$, CF to SLS, $p = 0.017$). There were no differences in the GRF impulses in either the AFO or non-AFO limbs (Fig. 5).

Similarly, there were no differences in the ankle, knee, or hip joint moments, with the exception of a significantly larger peak hip extensor moment for the SLS condition in region 1 (Fig. 6: AFO main effect, $p = 0.040$). There were no differences in ankle or knee work, although there were minor differences at the hip (Fig. 7). In region 2, positive hip work was significantly increased in the SLS condition compared to the CF condition (AFO main effect, $p = 0.046$).

Discussion

The goal of this study was to determine if there are differences in specific biomechanical measures during walking when subjects use a CF versus a stiffness-matched SLS PD-AFO. The results generally supported our hypothesis that there would be no difference in gait performance with the different materials. Changes in walking performance that did arise were less than the minimal detectable change values established within the literature [35], and thus may be of little functional relevance. Spatiotemporal parameters did not differ between AFO conditions (Fig. 3), and although differences were observed in the joint kinematics (Fig. 4), all were less than the minimal detectable change values [35]. These results are in agreement with a recent study on subjects with unilateral foot drop that found no significant differences in spatiotemporal parameters and minimal differences in joint kinematics between SLS and polypropylene AFOs [23]. However, the AFOs worn in that study were not passive-dynamic [23] and comparisons to the present work are therefore difficult.

Although some kinematic differences were observed between AFO materials, kinetic differences were less evident (Figs. 5–7).

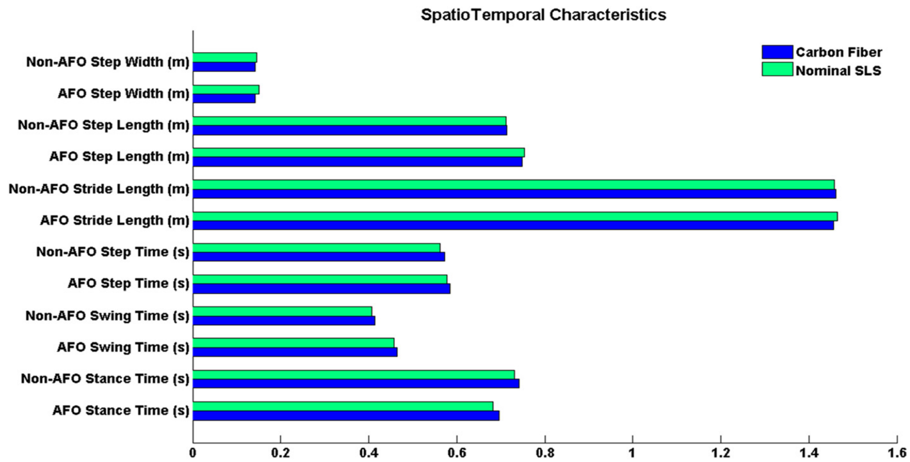

Fig. 3 Mean spatiotemporal parameters across subjects for the AFO and non-AFO limbs at the SS. No significant differences between AFO conditions were identified.

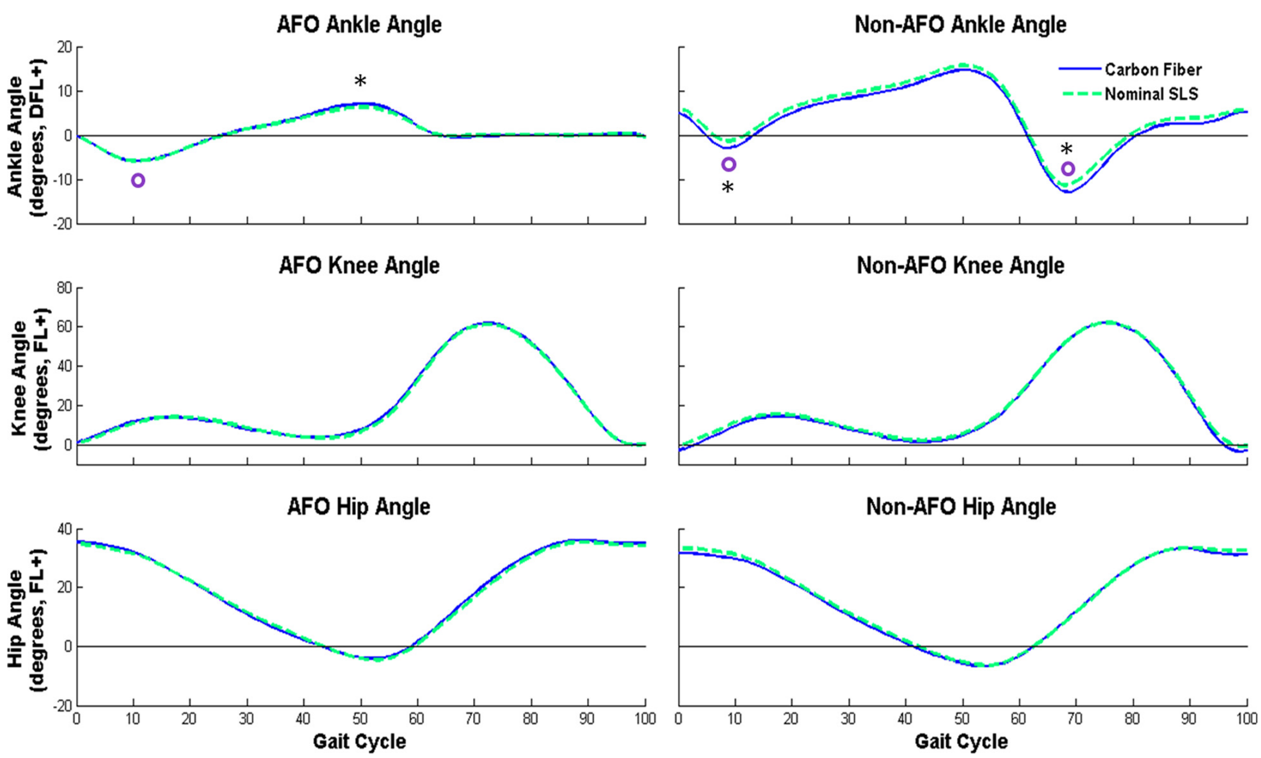

Fig. 4 Ensemble averaged joint angles for the AFO and non-AFO limbs at the SS across the gait cycle. Significant AFO main effects are depicted with an open circle (○) while significant differences between the CF and SLS AFOs within a leg are depicted with an asterisk (*). Positive values represent ankle dorsiflexion, knee flexion, and hip flexion.

In both limbs, the peak hip extensor moment and positive hip work during early gait were greater in the SLS condition; however, these differences were only identified during specific regions of the gait cycle and were relatively small with changes in the hip extensor moment less than the minimal detectable change value [35]. This is consistent with a recent study comparing the use of a CF prosthetic foot to a stiffness-matched SLS prosthetic foot that identified very few changes in spatiotemporal, kinematic, and kinetic gait parameters [42]. Overall, these findings support the use of SLS prosthetics and orthotics to replicate the functional characteristics of CF prosthetics and orthotics during gait.

Although the results indicate there is no difference in gait performance between a CF and a stiffness-matched SLS PD-AFO, there are some potential limitations of this study that should be addressed. One potential limitation is that the subject population was limited to highly active individuals with various unilateral lower extremity injuries. However, because the subject population was fairly heterogeneous in terms of injuries, which included fractures, neuropathies and tissue losses, and since our goal was to observe relative differences in biomechanical quantities between the two AFO material conditions, we believe that the results of this study are robust and may extend to other patient populations. Another potential limitation is that patient perception of the SLS AFO and resulting compensations, rather than device material, may have contributed to the changes in gait performance observed. Future work is needed to differentiate between these effects. One final limitation is that changes in muscle activity across AFO material conditions were not assessed. As a result, it is possible that although spatiotemporal, kinematic, and kinetic parameters remained largely unchanged, muscle activity,

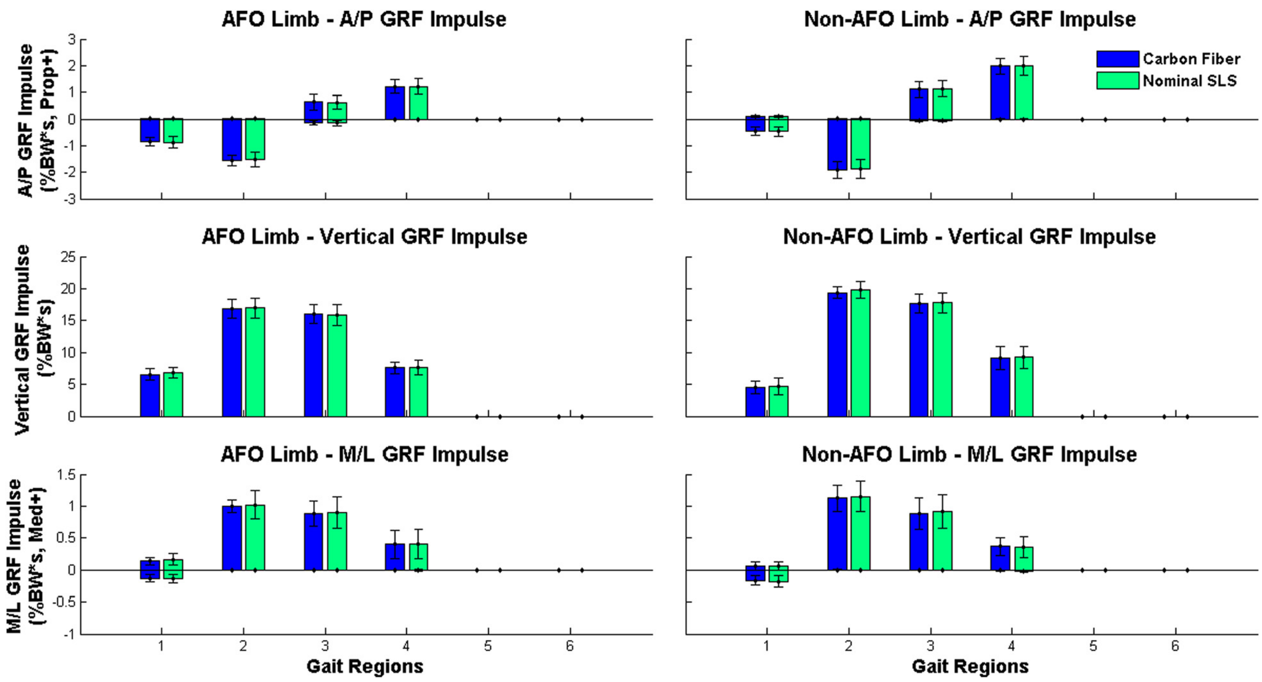

Fig. 5 Mean (standard deviation bars) GRF impulses across subjects for the AFO and non-AFO limbs at the SS across the six evaluated regions of the gait cycle: (1) first double support, (2) early single-leg support, (3) late single-leg support, (4) second double support, (5) early swing, and (6) late swing. No significant differences between AFO conditions were identified. Positive values represent propulsive, vertical, and medial GRF impulses.

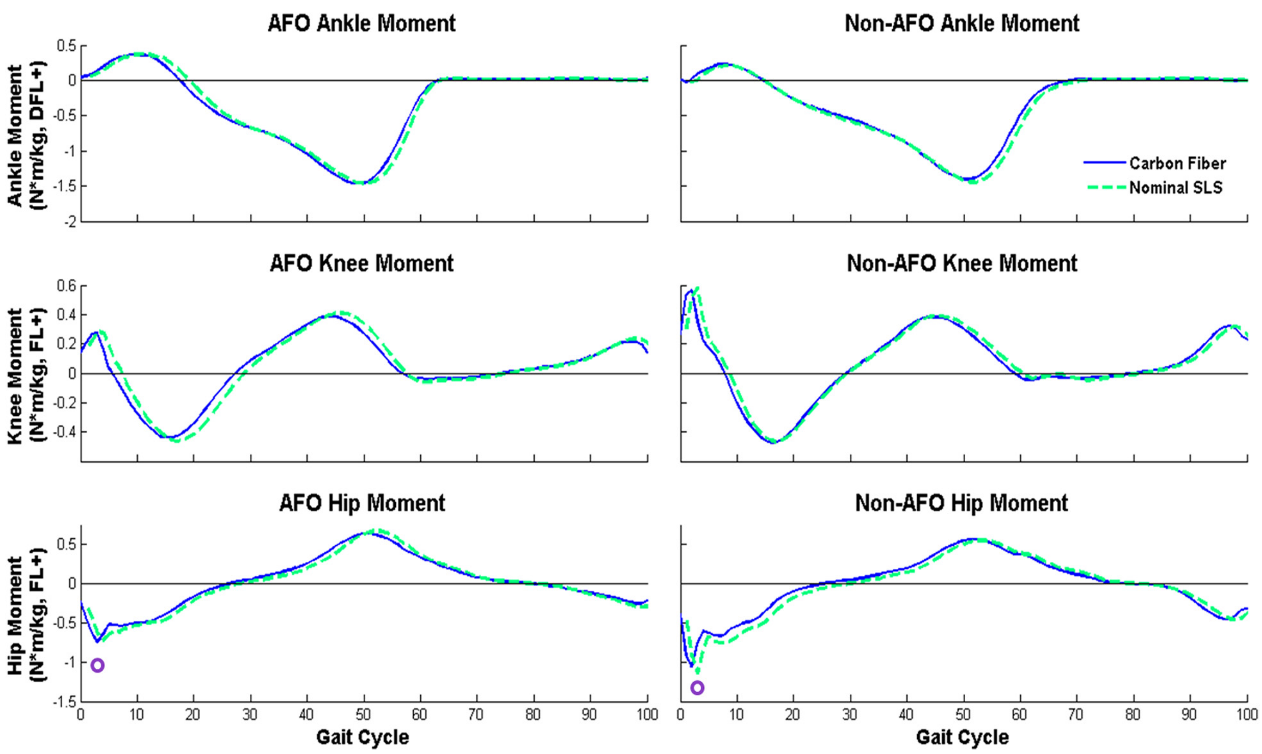

Fig. 6 Ensemble averaged joint moments for the AFO and non-AFO limbs at the SS across the gait cycle. Significant AFO main effects are depicted with an open circle (O) while significant differences between the CF and SLS AFOs within a leg are depicted with an asterisk (*). Positive values represent ankle dorsiflexor moments, knee flexor moments, and hip flexor moments.

specifically muscle cocontraction, may have been altered. Future work should focus on analyzing individual muscle activity to determine if individual muscle compensations occurred that were not evident in the net joint moment and work quantities.

Overall, the SLS design and manufacturing framework was able to successfully generate PD-AFOs that replicated the stiffness characteristics of the CF strut and resulted in minimal changes in gait performance. Those changes in gait performance

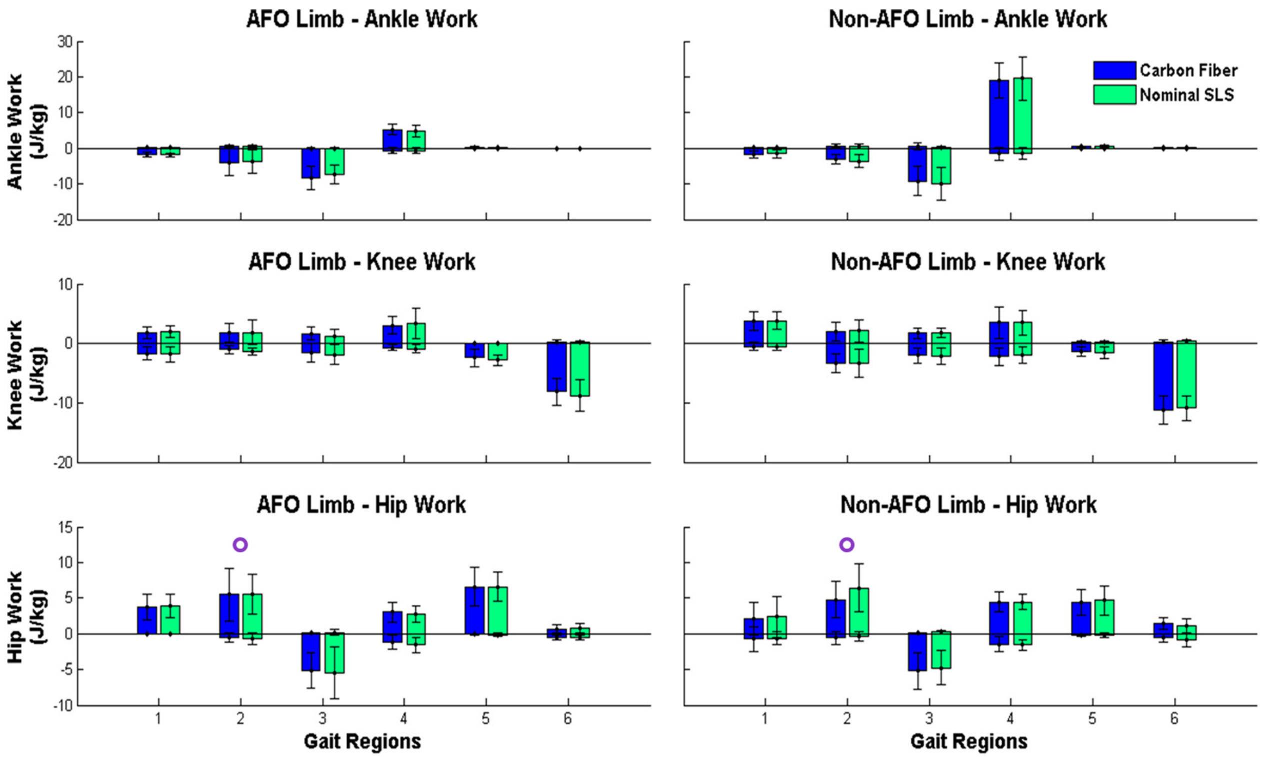

Fig. 7 Mean (standard deviation bars) joint work across subjects for the AFO and non-AFO limbs at the SS across the six evaluated regions of the gait cycle: (1) first double support, (2) early single-leg support, (3) late single-leg support, (4) second double support, (5) early swing, and (6) late swing. Significant AFO main effects are depicted with an open circle (O) while significant differences between the CF and SLS AFOs within a leg are depicted with an asterisk (*).

that did arise were less than the minimal detectable change values established in literature [35], and thus ultimately our hypothesis that there would be no difference in gait performance across AFO materials was largely supported. The results of this study help validate the use of Nylon 11 SLS PD-AFOs to study the effects of altering design characteristics on gait performance. By enabling these studies to be performed, SLS PD-AFOs can ultimately aid in establishing effective prescription and design criteria for subject-specific PD-AFOs to help improve rehabilitation outcomes.

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