

Abstract

WESTBROOK, AUDREY ELIZABETH. Testing the Functionality of a Vibrotactile Ankle Foot Orthosis to Prevent Foot Drop and Assist Push-off. (Under the direction of Gregory S. Sawicki).

Given the extreme importance of locomotion in our everyday lives, it is imperative that aging and impaired populations with locomotor deficits be provided with the tools to regain function and improve overall quality of life. Two common walking-related problems in impaired populations are the inability to clear the foot as they swing the leg forward (foot drop) and the impaired capacity to propel the body forward. A key factor contributing to these symptoms may be the inadequate ankle joint control on a weakened limb. We have developed a novel ankle foot orthosis (AFO) with built-in vibrotactile biofeedback to provide dynamic feedback to encourage activation of ankle muscles during select phases of walking. The goal of this project, therefore, is to test the effectiveness of this vibrotactile AFO for correcting the symptoms related to foot drop and/or weakened push-off in a healthy population.

The AFO was designed to be as transparent to the user as possible having minimal interference with gait kinematics, and lightweight enough to minimize metabolic penalty of adding mass to the user's limb. For the foot drop condition, the intervention involves the use of ankle angle biofeedback in healthy controls in an attempt to coerce the user into a more dorsiflexed (i.e. lifted) position through recruitment of their tibialis anterior muscle. The AFO emits a vibration and beep in order to indicate a danger zone (risk of falling), and therefore is to be avoided by the user. When the user feels a vibration and hears a tone, they

attempted to dorsiflex their ankle to the best of their ability, exaggerating the effects that we would like to see in an impaired population.

For the push-off condition, the intervention uses the same ankle angle biofeedback in combination with heel sensors in the base of the AFO to encourage ankle plantarflexion to enhance push-off in healthy controls by providing the user with a beep at the appropriate moment to utilize their ankle muscles. Rather than providing assistance at the ankle angle like many powered devices, we are asking the user to proactively recruit more soleus muscle activity through the use of the biofeedback.

To test the efficacy of the AFO, we performed an inverse dynamics analysis on the gait patterns of the healthy controls walking at 1.25 m/s and compared conditions between No AFO, AFO with no biofeedback, and AFO with the biofeedback turned on. For the foot drop study (Chapter 1) results indicated that this AFO successfully improves gait function with reference to foot drop, as dorsiflexion angles and tibialis anterior muscle activity were increased. However compensations at the knee and hip joint were required to achieve these increases, making the metabolic cost of walking go up by 27%.

For the push off study (Chapter 2) results indicated that the AFO also successfully improves gait function with reference to plantarflexor weakness, as positive ankle joint power and soleus muscle activity were increased. Like the foot drop study, compensations at the knee and hip joint were required to achieve these increases, making the metabolic cost of walking go up by 16%.

This information lays the groundwork for future testing on this vibrotactile biofeedback AFO to prevent foot drop and assist push-off in impaired populations. If future testing finds that impaired populations can recruit muscle activity that they are not using on a daily basis, much like the healthy controls did here, therapies can focus on improved locomotor functions without the use of assistive technology.

© Copyright 2015 by Audrey Westbrook

All Rights Reserved

Testing the Functionality of a Vibrotactile Ankle Foot Orthosis to Prevent Foot Drop and
Assist Push-Off

by
Audrey Westbrook

A thesis submitted to the Graduate Faculty of
North Carolina State University
in partial fulfillment of the
requirements for the degree of
Master of Science

Biomedical Engineering

Raleigh, North Carolina

2015

APPROVED BY:

Dr. Gregory Sawicki,
Committee Chair

Dr. Michael Lewek

Dr. Helen Huang

Biography

Audrey is from Bentonville, NC and attended high school at South Johnston in Benson, NC. She graduated cum laude from North Carolina State University with a Bachelor of Science in Biomedical Engineering with an emphasis in biomechanics and a Bachelor of Science in Mechanical Engineering. She won first place in the Biomedical Senior Design Competition, as well as first place in the Mechanical Senior Design Competition. In 2012, Audrey began to pursue her M.S. at the Joint Department of Biomedical Engineering at North Carolina State University and the University of North Carolina, Chapel Hill.

Acknowledgements

I would like to first thank my friends and family for the support they have showed me through my years of school, both as an undergraduate student and a graduate student. Thank you to Greg Sawicki for mentoring me the past two years, and helping me become the best researcher I can be. Thank you to all of the members of the Human PoWeR Lab (Kota Takahashi, Michael Browne, Rich Nuckols) for all the help you've provided through this project. I also want to thank all the members of my senior design team (Adam Willson, Tojan Rahhal, Kristen Lasater, Whitney Barnette, and Andrew DiMeo) who started this project with me. And finally, a special thanks to Bruce Wiggin. You brought me into the PoWeR Lab as an undergraduate and showed me my passion for rehabilitation engineering. I owe you for all of this!

Table of Contents

List of Tables	v
List of Figures	vi
CHAPTER 1:.....	1
Testing the Functionality of a Vibrotactile Ankle Foot Orthosis to Prevent Foot Drop	1
Introduction	1
Material and Methods.....	5
Results	16
Discussion	37
Conclusion.....	42
CHAPTER 2:.....	44
Testing the Functionality of a Vibrotactile Ankle Foot Orthosis to Assist Push-off.....	44
Introduction	44
Materials and Methods	48
Results	59
Discussion	80
Conclusion.....	84
Overall Discussion and Conclusions	84
References	89
Appendix	94

List of Tables

Table 1: Ankle Foot Orthosis Mass Distribution - Foot Drop.....	6
Table 2: Foot Drop Participant Data	9
Table 3: List of Dependent Variables – Foot Drop	10
Table 4: Ankle Foot Orthosis Mass Distribution – Push Off	49
Table 5: Push Off Participant Data.....	52
Table 6: List of Dependent Variables – Push Off	53

List of Figures

Figure 1: Vibrotactile Ankle Foot Orthosis to Prevent Foot Drop	7
Figure 2: Time Series Graph - Foot Drop	11
Figure 3: Mean Ankle Joint Angles, Moments, and Powers	17
Figure 4: Mean Knee Joint Angles, Moments, and Powers	20
Figure 5: Mean Hip Joint Angles, Moments, and Powers.....	23
Figure 6: Average Positive, Negative, and Net Ankle Joint Powers	25
Figure 7: Average Positive, Negative and Net Knee Joint Powers	27
Figure 8: Average Positive, Negative, and Net Hip Joint Powers.....	29
Figure 9: Average TA Muscle Activity.....	32
Figure 10: Net Metabolic Power	35
Figure 11: Vibrotactile Ankle Foot Orthosis to Assist Push-Off.	50
Figure 12: Time Series Graph – Push Off.....	54
Figure 13: Mean Ankle Joint Angle, Moments, and Powers.....	60
Figure 14: Mean Knee Joint Angles, Moments, and Powers	63
Figure 15: Mean Hip Joint Angles, Moments, and Powers.....	66
Figure 16: Average Positive, Negative, and Net Ankle Joint Powers	68
Figure 17: Average Positive, Negative and Net Knee Joint Powers	70
Figure 18: Average Positive, Negative, and Net Hip Joint Powers.....	72
Figure 19: Average Soleus Muscle Activity.....	75
Figure 20: Net Metabolic Power	78
Figure 21: Paretic Limb Soleus Activity of Stroke Survivor	95
Figure 22: Paretic Limb Ankle Joint Angles, Moments, and Powers of Stroke Survivor.....	97
Figure 23: Paretic Limb Positive, Negative, and Net Ankle Joint Powers of Stroke Survivor	99
Figure 24: Paretic Limb Knee Joint Angles, Moments, and Powers for Stroke Survivor.....	101
Figure 25: Paretic Limb Positive, Negative, and Net Knee Joint Powers of Stroke Survivor	103
Figure 26: Paretic Limb Hip Joint Angles, Moments, and Powers for Stroke Survivor	105
Figure 27: Paretic Limb Positive, Negative, and Net Hip Joint Powers of Stroke Survivor	107
Figure 28: Net Metabolic Power of Stroke Survivor.....	109
Figure 29: Non-paretic Limb Ankle Joint Angles, Moments, and Powers for Stroke Survivor	111
Figure 30: Non-Paretic Limb Positive, Negative, and Net Ankle Joint Powers of Stroke Survivor..	113
Figure 31: Non-paretic Limb Knee Joint Angles, Moments, and Powers for Stroke Survivor.....	115
Figure 32: Non-Paretic Limb Positive, Negative, and Net Knee Joint Powers of Stroke Survivor ...	117
Figure 33: Non-Paretic Limb Hip Joint Angles, Moments, and Powers.....	119
Figure 34: Non-Paretic Limb Positive, Negative, and Net Hip Joint Powers of Stroke Survivor.....	121

CHAPTER 1:

Testing the Functionality of a Vibrotactile Ankle Foot Orthosis to Prevent Foot Drop

Introduction

Often, people forget the importance of one of the simplest tasks we do every day: walking. In aging and impaired populations, activities of daily living are often limited due to locomotion deficiencies such as walking speed [1]. One of the main focuses of rehabilitation engineering is to improve walking in aging populations through the use of strength training, exercise programs, or physical therapy. In the more modern age, however, approaches often involve the use of assistive devices to enhance walking capabilities. An example of a device like this is an ankle exoskeleton. While providing locomotor efficiency at the ankle joints, exoskeletons are often cumbersome and can add a lot of mass to the lower limbs, therefore increasing the metabolic cost of walking [2].

Another potential solution to locomotion problems is the use of biofeedback. Biofeedback can be used in many ways to alter the gait parameters of a user. Some of these include use of ground reaction forces, muscle activity from electromyography, or joint position to provide visual, auditory, or vibratory biofeedback [3]. In a rehabilitation setting, biofeedback has the capability to improve the control and learning of damaged physiological functions and can show moderate to large effects immediately following treatment [4]. For example, De Nunzio et al. shows that through trunk vibration biofeedback in Parkinson's

patients, stride length, cadence and velocity of gait can be improved [5]. Furthermore, walking exercises that include auditory rhythmic biofeedback have been shown to be an effective way to improve temporal stability during walking in impaired populations [6]. And if only one gait parameter is being changed, research studies have shown that providing real time biofeedback is overall an effective method for gait retraining [7].

However, biofeedback is not always utilized in some of the ways it should. When focusing on lower limb biofeedback, the majority of the literature involves the use of ground reaction forces or electromyography (EMG). Research studies do suggest that EMG biofeedback has the ability to increase muscle strength and show a recovery of impairments such as foot drop [8]. However, the use of EMG signals as a biofeedback source is not always the most reliable method, as other studies have found no significant improvements between EMG biofeedback and traditional physical therapy [9], making the efficacy of EMG biofeedback unclear. We believe that biofeedback intervention should be focused on joint position, or more specifically, the ankle joint position, based on the knowledge that the majority of mechanical energy for walking is supplied by muscles that cross the ankle joint [10]. In many impaired populations, a contributor to the high energetic cost of walking comes from plantar flexor weakness at the ankle [2]. Therefore, by focusing biofeedback rehabilitations on the ankle specifically, we can hope to target ankle joint positions that provide the most efficient gait, contributing to lower cost of walking in impaired populations.

A common locomotion problem for many with neuromuscular impairments at the ankle is foot drop, which is the inability to dorsiflex (i.e. lift their toe) during swing. This

condition reduces the mechanical work output at the ankle and further causes the hip and knee to compensate, reducing the individual's metabolic economy and greatly increasing the risk of fall. While currently there are several devices designed to assist drop foot prevention, no devices are designed as a rehabilitation aid, to train individuals to prevent foot drop without direct intervention by a medical device or orthotic. Some of the devices currently on the market utilize functional electrical stimulation (FES), in which they electrically stimulate the peroneal nerve to increase dorsiflexion, such as the Bioness. It sends in low-level stimulation to the peroneal nerve through a wireless software system. Other devices that address foot drop are AFOs that brace the foot in a 90 degree position during walking, effectively reducing chance of fall, however do not make walking any easier for the user.

The problem with the current devices on the market is the limitation to retrain a person's gait. While stimulating ankle dorsiflexor and plantarflexor muscles during the swing phase of gait has the capability to reduce foot drop [11] and work well with regard to obstacle performance [12], it lacks the long term goals of one day walking without an assistive device. Similarly, an AFO that simply braces the limb provides a crutch to the patient. Without the brace, they have a high risk of fall, as they become dependent on its functionality. The same goes for FES technologies, as without the stimulation to either the peroneal nerve, or the muscles themselves, foot drop would continue to occur.

This study investigates the capability of a vibrotactile biofeedback Ankle Foot Orthosis (AFO) (Patent Pending: US20130296741 A1) to return the patient to the life they had before the neuromuscular impairment. Instead of having the weakened limb either braced

or electrically stimulated while walking, this option gives them the chance to retrain to a normal, healthy gait. This intervention involves the use of ankle angle biofeedback in an attempt to assist the user in retraining their muscles to avoid foot drop. The AFO emits a vibration and beep in order to indicate a danger zone (risk of falling), and therefore is to be avoided by the user. So when the user feels a vibration and hears a tone, they will attempt to dorsiflex (i.e. lift) their foot to the best of their ability, in turn mitigating the problem of foot drop. Once full gait is restored using the biofeedback, the patient will not have to wear any type of brace at all. Using the ankle angle as the only gait parameter to be altered, the effectiveness of this type of rehabilitation is hypothesized to be very efficient. It is also hypothesized that this intervention could lead to considerable metabolic energy savings through continued training; an outcome that could improve the quality of life for clinical populations, such as people with post-stroke hemiparesis who spend up to 50% more metabolic energy while walking [13].

However for the purposes of this study, a healthy population is utilized in order to test the feasibility of the brace as a gait altering device before testing on an impaired population. Therefore, instead of taking an unhealthy gait and attempting to correct it, we will be taking an otherwise healthy gait, and attempting to force the user into an exaggerated ankle angle position in which they are more dorsiflexed than usual. We hypothesize that when the vibrotactile biofeedback is turned on, users will exhibit significant increases in dorsiflexion at the ankle by compensating at other joint locations and using their dorsiflexor muscles more. Additionally, we expect the metabolic cost of walking to increase as the user will be walking in a manner that is unfamiliar to them.

Material and Methods

AFO Fabrication

Before testing, a custom fabricated, unilateral carbon fiber/fiber glass composite ankle foot orthosis (AFO) was created for eight healthy participants (Figure 1). For an impaired population, the AFO will be used for the limb with weakened muscles, but for the purposes of this study, the leg used was at the discretion of the participant. Each AFO contained hinge joints to allow free motion in the sagittal plane during all phases of the gait cycle to present less risk to the user than the more common powered AFOs. This AFO instead asks the user to control their own muscles based on cues from vibrotactile biofeedback to encourage proactive rehabilitation.

Each AFO includes a Fio V3 Arduino Microcontroller that controls the biofeedback through the user of a buzzer and a vibration motor. A magnetic encoder is used to detect ankle angle in real-time as a way to alert the user to the position of their foot relative to the ground while walking. Pressure sensors in the bottom of the AFO were placed in order to detect specific phases of the gait cycle while walking. A combination of signals from the magnetic encoder at the ankle joint and from the pressure sensors on the bottom of the AFO are used to control the timing of the biofeedback. Table 1 below shows a breakdown of the weight of the AFO for a US size 8 shoe and a US size 12 shoe. While heavier in mass than traditional 90 degree AFOs due to the addition of the hinge joints, it remains virtually transparent to the user, making it possible to walk without hindrance.

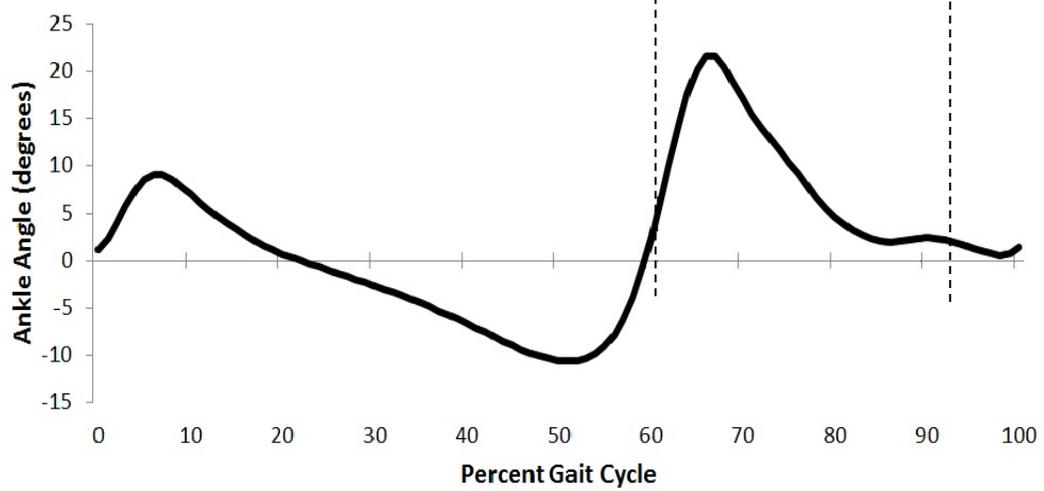
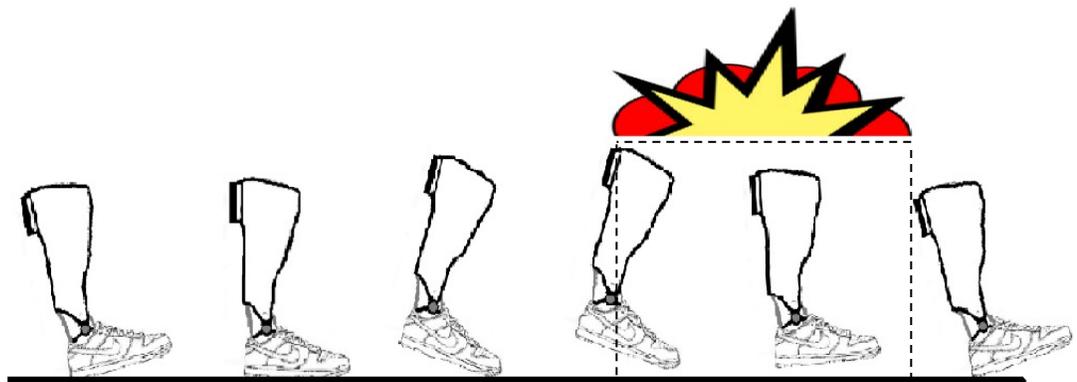
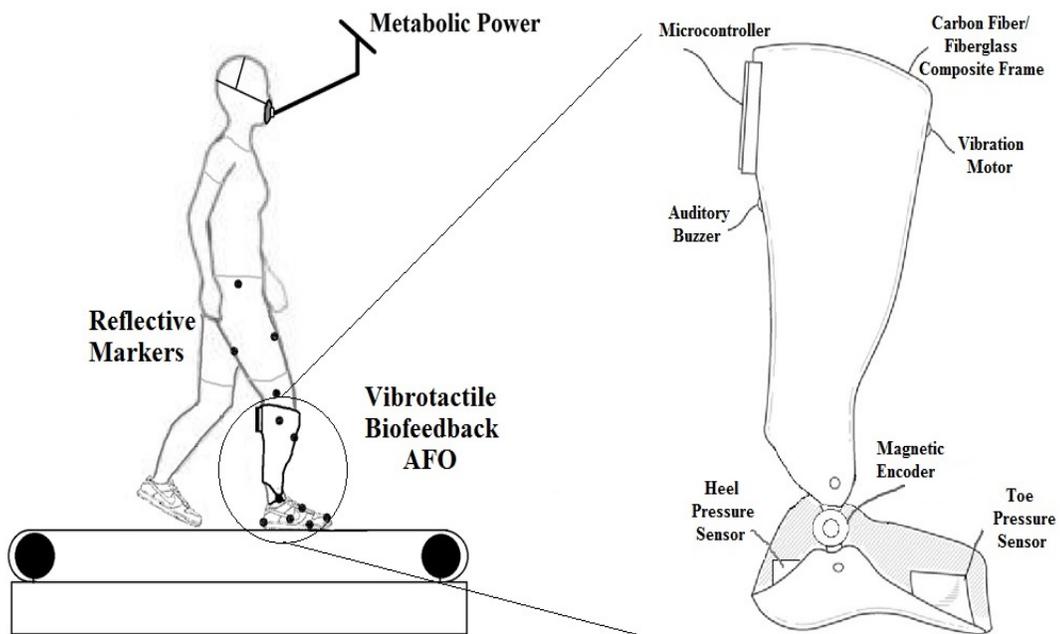
Table 1: Ankle Foot Orthosis Mass Distribution - Foot Drop

Segment	US Size 8	US Size 12
Carbon Fiber Foot Section	20.9	30.4
Aluminum Joints (x2)	59.4	59.4
Carbon Fiber Shank Section	88.7	95.4
Microcontroller	65.4	65.4
<u>Total Mass</u>	<u>234.4</u>	<u>250.6</u>

When set to indicate foot drop, the AFO emitted a vibration and a tone as a negative response to the user dropping their foot to a dangerous position, putting them at a risk of fall. In the healthy population used in this study, however, the negative response was set at a position that forced the user to walk with their toe more dorsiflexed (i.e. lifted) than normally comfortable. By forcing an otherwise healthy gait to an abnormal posture, we believe that biofeedback alone can help retrain an unhealthy gait to be more symmetrical.

Figure 1: Vibrotactile Ankle Foot Orthosis to Prevent Foot Drop

The left panel shows the testing methods including reflective markers and metabolic power collection. The right panel shows an in depth description of the AFO including microcontroller, vibration motor, auditory buzzer, pressure sensors, and magnetic encoder locations. The bottom panel shows an ankle angle over a full gait cycle from heel strike (0%) to heel strike (100%) with a depiction of the timing that the biofeedback comes on.



Experimental Protocol

Eight healthy participants who were able to walk without assistance (mean \pm s.d., age = 23.63 ± 3.29 years; mass = 74.72 ± 10.82 kg; height = $1.75 \pm .08$ m) signed an institutional review board (IRB) approved consent form to participate in this study. A more in depth listing of the subject characteristics can be found in Table 2 below. All procedures were approved by the University of North Carolina, Chapel Hill and North Carolina State University IRB and followed the procedures outlined by the Declaration of Helsinki.

Table 2: Foot Drop Participant Data

Participant	Age (years)	Mass (kg)	Height (meters)
1	31	74.84	1.854
2	21	79.37	1.676
3	24	97.52	1.803
4	21	61.23	1.778
5	21	68.04	1.676
6	24	68.04	1.626
7	24	72.57	1.702
8	23	76.20	1.823
Mean \pm SD	23.63 ± 3.29	74.72 ± 10.82	$1.75 \pm .08$

All trials were completed on an instrumented treadmill (BERTEC, Columbus, OH, USA) at a speed of 1.25 m/s and lasted for seven minutes. Each participant was asked to walk for three different conditions with the vibrotactile biofeedback AFO. In a randomized order, the participant was asked to walk for seven minutes with (1) No AFO, (2) AFO with

no biofeedback, (3) AFO with the biofeedback turned on. In an impaired population, foot drop is often classified as the inability to lift the foot up to or past 10 degrees of plantarflexion [14].

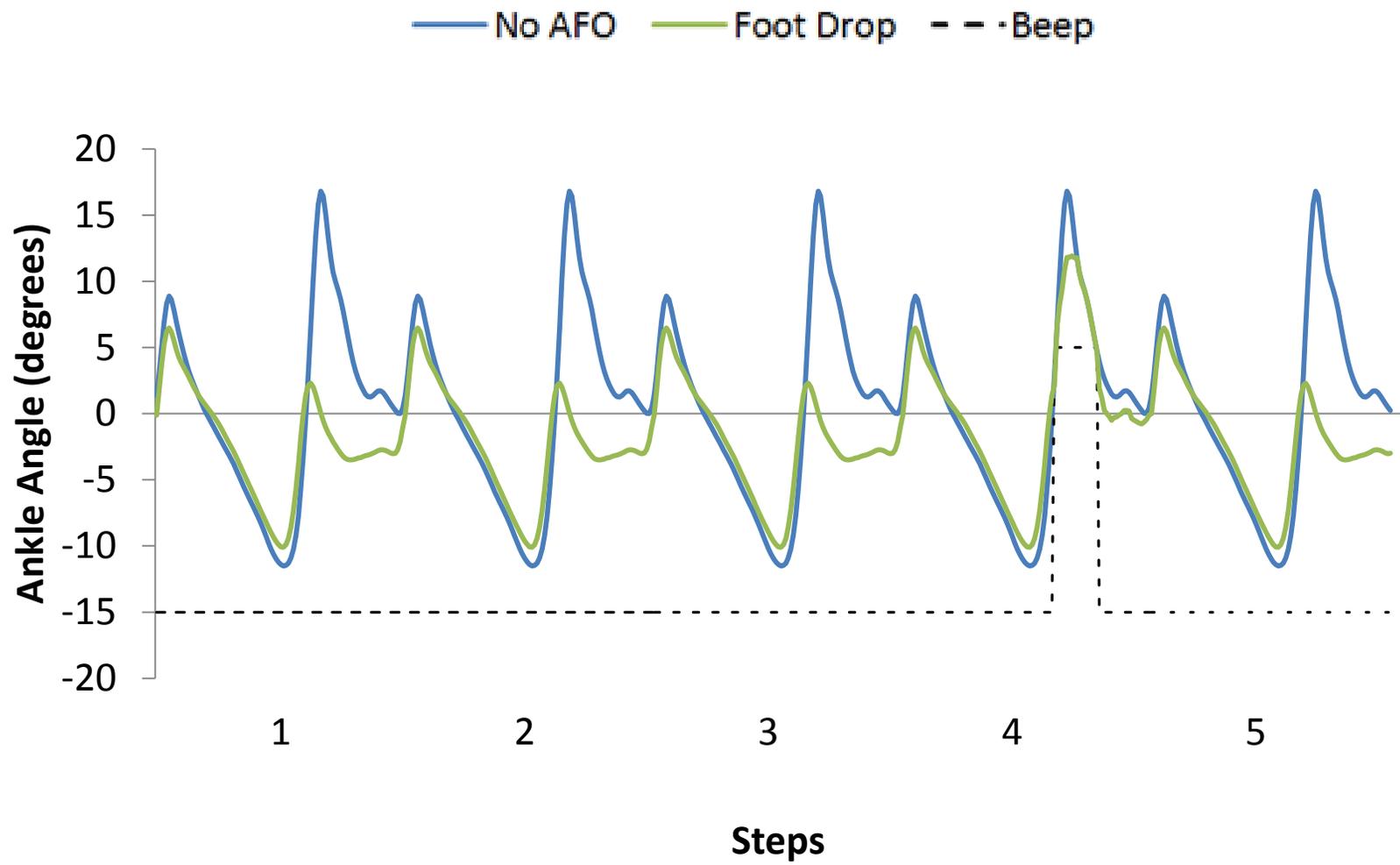
Therefore, for the purposes of testing the AFO in a healthy population, the biofeedback was programmed to come on before the ankle angle reached 5 degrees, encouraging the ankle to be in a more dorsiflexed or lifted position. Figure 2 below shows a time series graph of a typical user wearing the AFO for 5 strides. With the feedback turned on to come on at 5 degrees of plantarflexion in swing, the user must keep their ankle in a more dorsiflexed position. Stride 4 in the figure below indicates what would happen in the user were to drop their toe above 5 degrees of plantarflexion, making the beep come on as an indication to keep the toe more lifted. Table 3 below shows both the primary and secondary variables observed and reported in the results below.

Table 3: List of Dependent Variables – Foot Drop

<i>Primary</i>	<i>Secondary</i>		
Tibialis Anterior Activity	Ankle Moment	Knee Moment	Hip Moment
Ankle Angle	Ankle Power	Knee Power	Hip Power
Metabolic Cost	Knee Angle	Hip Angle	

Figure 2: Time Series Graph - Foot Drop

Example ankle joint angles (degrees) for a healthy participant during walking at 1.25 m/s plotted over a stride from heel strike (0%) to heel strike (100%) of the same limb for 5 strides. The blue line represents a participant walking normally with no AFO, the green line represents the participant walking in the AFO with active biofeedback, and the dashed black line represents the timing of the biofeedback “beep” during walking. The beep does not come on until the 4th stride, as the user plantarflexed above 5 degrees.



Kinetics and Kinematics

Prior to gait analysis, anthropometric data was collected. All trials were completed using an instrumented treadmill (BERTEC, Columbus, OH, USA) set at 1.25 m/s. An eight camera motion analysis system (VICON, Oxford, UK) was utilized to capture the position of 31 reflective markers attached to the legs and pelvis of the user at 120 Hz. To calibrate a seven segment model composed of two thighs, two shanks, two feet, and one pelvis, a static standing trial was collected. The raw marker positions were filtered using a second-order low pass Butterworth filter with a cut-off frequency of 8 Hz. Joint angle for the ankle, knee, and hip were computed in three dimensions as the orientation of the distal segment with reference to the proximal segment.

Force data was recorded at 960 Hz during walking using two force platforms underneath the split-belt BERTEC treadmill, while ensuring that each foot hit the correct treadmill belt while walking. By doing so, we make certain that the individual limb was contributing to the correct limb calculations. The raw force analog data were filtered with a second order low pass Butterworth filter with a cut-off frequency of 35 Hz. Inverse dynamic analyses were used to compute net joint moments, which were then multiplied by joint angular velocities to calculate powers for the ankle joint. Calculations of kinetics and kinematics were performed using a combination of Visual 3D software (C-Motion Inc., Germantown, MD, USA), Microsoft EXCEL, and MATLAB (MathWorks, Natick, MA, USA).

Electromyography

Electromyography (EMG) data was collected using surface electrodes to monitor the activity of the lower leg muscles during walking using a wired electromyography system (SX230, Biometrics Ltd., Newport, UK). Activity was recorded for the tibialis anterior (TA) muscle and the soleus muscle (SOL) for all collected trials on the limb that was wearing the AFO. The muscles activity was calculated by band-pass filtering (20-460 Hz) in hardware and then conditioned by rectifying, and low-pass filtering with a cutoff frequency of 6 Hz. EMG data was quantified by integrating with respect to time and normalized by the peak values.

Calculation of Positive and Negative Mechanical Work

To calculate the sum of the average of the positive (equation 1) and negative (equation 2) mechanical work values in the joints (\bar{P}_j), the total sum of work done by the lower limb joints (W_j) was divided by the stride time (τ_{stride}). Stride-averaged joint power data for the ankle, knee, and hip were individually integrated with respect to time over discrete periods of positive and negative work using the trapezium method [15]. All values of positive and negative work at each joint were summed over each individual stride, representing the work done by the limb both with and without the AFO.

$$\bar{P}_j^+ = \frac{W_j^+}{\tau_{stride}} \quad (1)$$

$$\bar{P}_j^- = \frac{W_j^-}{\tau_{stride}} \quad (2)$$

Metabolic Measurement and Efficiency

The flow rate for oxygen intake and carbon dioxide outtake were recorded using a portable metabolic system (OXYCON MOBILE, VIASYS Healthcare, Yorba Lina, CA, USA). The last two minutes of a five minute standing trial were used to obtain a net metabolic measurement. By doing so, the rate of metabolic energy consumption (W) was calculated while standing, and then subtracted from the average flow rate during the last two minutes of the seven minute walking trials at 1.25 m/s. A visual inspection of the oxygen consumption rate during the collections confirmed that the participants were at steady-state. The Brockway equation [16] was used to convert the flow rates for oxygen and carbon dioxide to metabolic power and to normalize them to the subject's body mass (W/kg).

Statistical Analysis

For this study, kinematic and kinetic data were averaged over 10 strides. Group means were then computed and to test for differences in outcome variables between conditions, and ANOVA with a Bonferroni adjustment was used. Pair-wise comparisons between the limb wearing the AFO were made when the biofeedback was turned off and then turned on.

Results

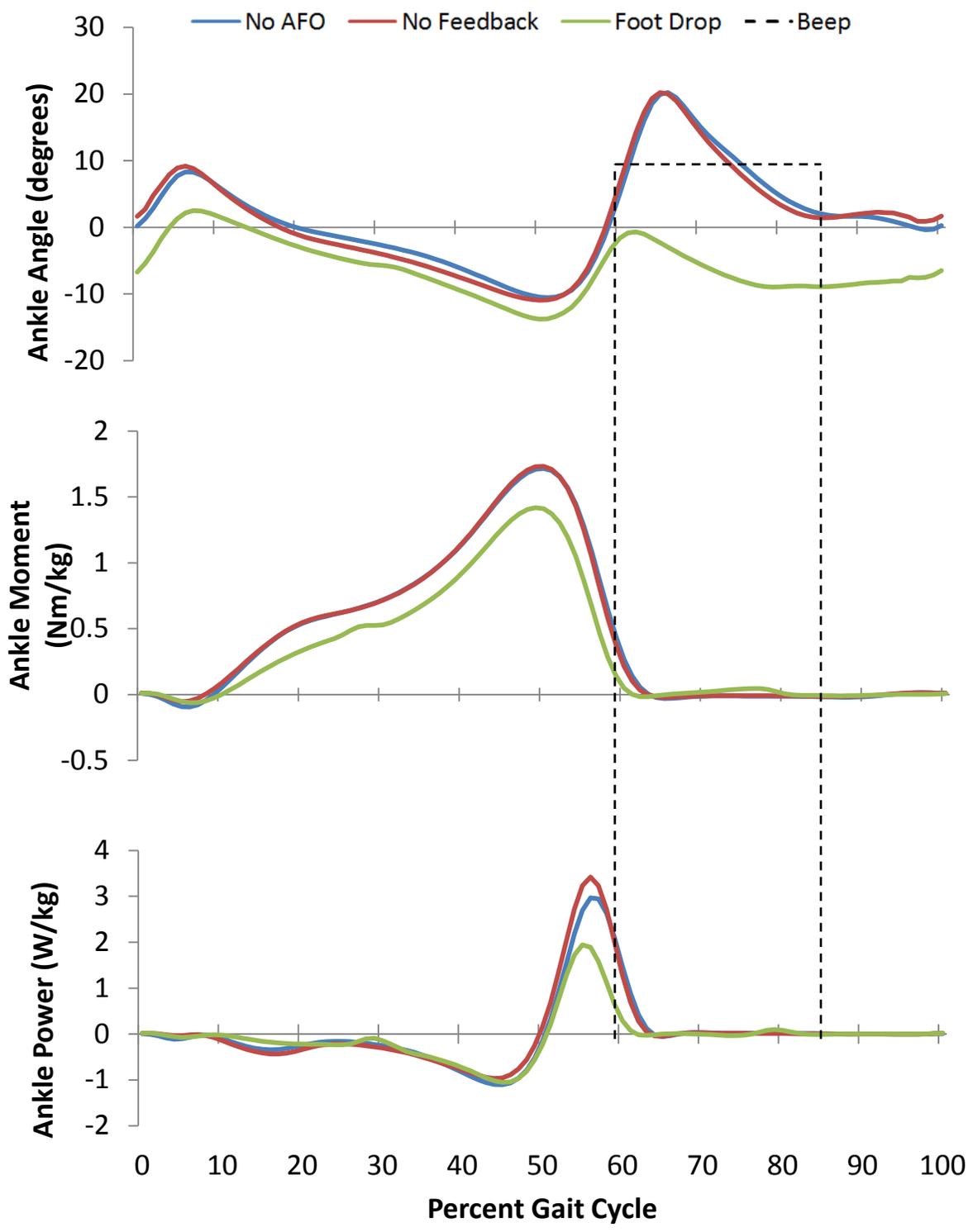
Angles, Moments, and Powers

The results obtained in this study include the joint angles, moments and powers for the leg while walking at a speed of 1.25 m/s. This was collected while the user was walking normally, while the user was walking with the AFO turned off, and then while the AFO was turned on and providing biofeedback.

At the ankle, ANOVA testing showed a main effect for the following conditions: Peak ankle dorsiflexion ($p = 0.000001$); Peak positive ankle power ($p = 0.0004$); Total positive ankle power ($p = 0.0005$). Paired T-tests to determine statistical significance between specific conditions are reported below. On average, the participants showed significant increases in peak dorsiflexion during swing of 20.94 degrees (t-test: $p = 0.00008$) when comparing the AFO trial to that of No AFO. No significant changes were seen when comparing No AFO to the AFO-No Biofeedback trials (Figure 3). When comparing changes between ankle moment and power, no significant changes were present between No AFO and AFO-No Biofeedback, however when the AFO was turned on, slight decreases (1.72 Nm/kg vs. 1.44 Nm/kg) were seen in ankle moment, contributing to significant losses in peak positive ankle power (3.15 W/kg vs. 2.04 W/kg) (t-test: $p = 0.009$) at this time (Figure 3) when comparing to No AFO trials. The participants produced less total positive ankle power during the AFO-Biofeedback trials compared to No AFO trials (0.24 W/kg vs. 0.14 W/kg) (t-test: $p = 0.009$), however no significant changes in total negative ankle power were seen (Figure 6).

Figure 3: Mean Ankle Joint Angles, Moments, and Powers

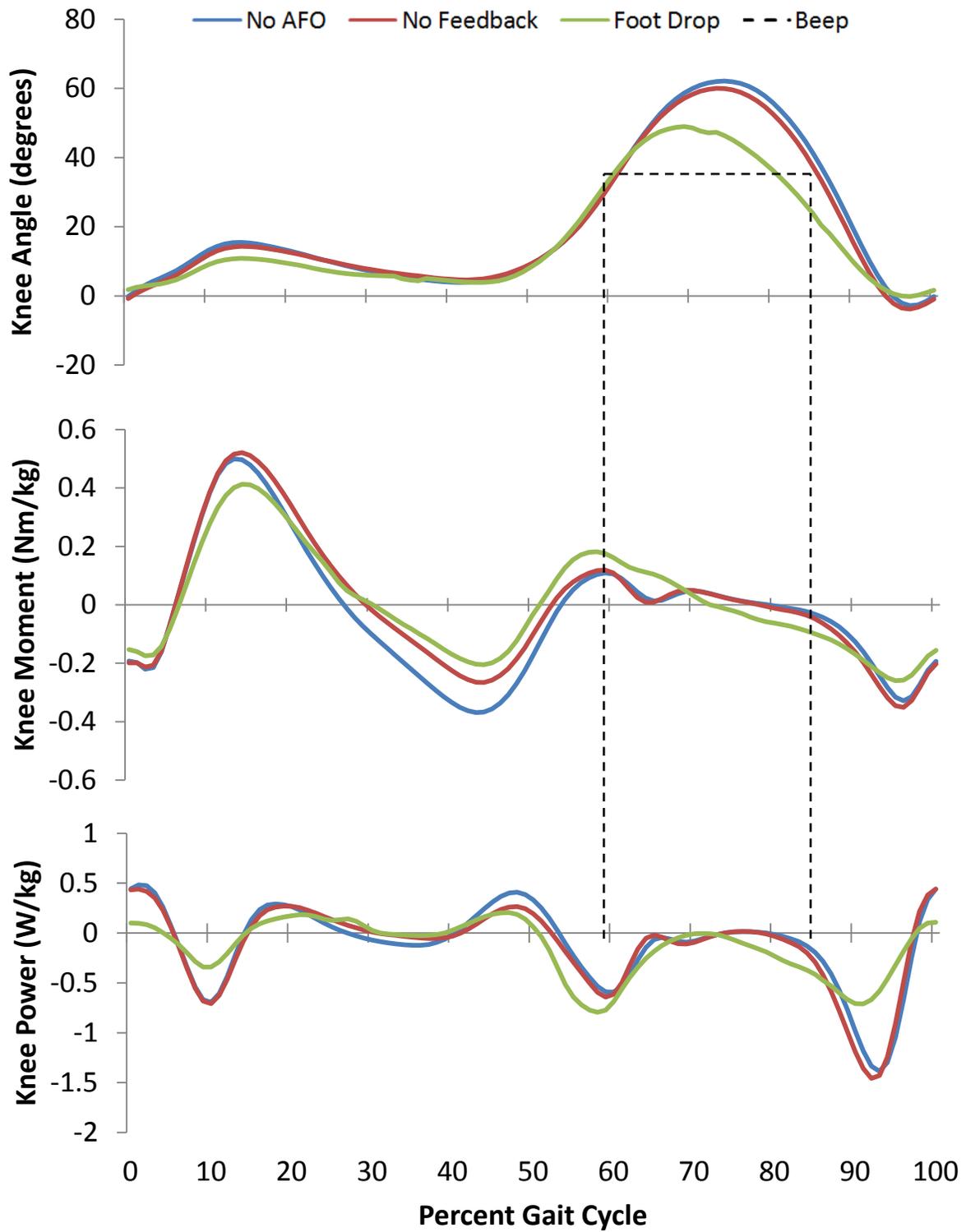
Mean ankle joint angles (degrees), moments (Nm/kg), and powers (W/kg) for healthy participants during walking at 1.25 m/s. Ankle angle (top panel), ankle moment (middle panel) and ankle power (bottom panel) are plotted over a stride from heel strike (0%) to heel strike (100%) of the same limb. The blue line represents the participant walking normally with no AFO, the red line represents the participant walking in the AFO with the biofeedback turned off, the green line represents the participant walking in the AFO with active biofeedback, and the dashed black line represents the timing of the biofeedback “beep” during walking.



At the knee, ANOVA testing showed a main effect for the following conditions: Peak knee flexion at mid stance ($p = 0.0002$); Peak knee flexion at initial swing ($p = 0.0008$); Peak power at terminal stance ($p = 0.0019$); Peak flexor moment at terminal stance ($p = 0.0022$). Paired T-tests to determine statistical significance between specific conditions are reported below. Average knee angles between the No AFO and AFO-No Biofeedback trials showed no significant changes, however between No AFO and AFO trials, average decreased peak knee flexion of 4.61 degrees (t-test: $p = 0.009$) was seen at mid stance as well as average decreased peak knee flexion of 12.49 degrees (t-test: $p = 0.007$) at initial swing (Figure 4). When observing knee moment and power, the only significant change between No AFO and AFO-No Biofeedback trials was a loss of power at terminal stance (0.44 W/kg vs. 0.28 W/kg) (t-test: $p = 0.011$), however when comparing No AFO to trials with biofeedback turned on, more changes were observed. Decreased extensor moments were observed during loading response (0.51 Nm/kg vs. 0.43 Nm/kg) causing a decrease in peak power absorption of the knee at this time (-0.75 W/kg vs. -0.45 W/kg). Decreases in flexor moments were observed during terminal stance (-0.38 Nm/kg vs. -0.21 Nm/kg) (t-test: $p = 0.015$) and during terminal swing (-0.317 Nm/kg vs. -0.27 Nm/kg). These losses correlate with lower power absorption of the knee at the same locations in the gait cycle (Terminal Stance: 0.44 W/kg vs. 0.28 W/kg) (Terminal Swing: 0.45 W/kg vs. 0.22 W/kg). Increases in extensor moment were observed during pre-swing (0.12 Nm/kg vs. .21 Nm/kg), correlating to increased peak power absorption at the knee at that time (-0.66 W/kg vs. -0.91 W/kg) (Figure 4). This contributed to average total positive power decreases (0.09 W/kg vs. 0.08 W/kg) between No AFO and AFO trials (Figure 7).

Figure 4: Mean Knee Joint Angles, Moments, and Powers

Mean knee joint angles (degrees), moments (Nm/kg), and powers (W/kg) for healthy participants during walking at 1.25 m/s. Knee angle (top panel), knee moment (middle panel) and knee power (bottom panel) are plotted over a stride from heel strike (0%) to heel strike (100%) of the same limb. The blue line represents the participant walking normally with no AFO, the red line represents the participant walking in the AFO with the biofeedback turned off, the green line represents the participant walking in the AFO with active biofeedback, and the dashed black line represents the timing of the biofeedback “beep” during walking.



At the hip, ANOVA testing showed a main effect for the following condition: Peak extensor moment at mid swing ($p=0.0002$). Paired T-tests to determine statistical significance between specific conditions are reported below. When comparing No AFO to AFO-No Biofeedback trials, there were not significant hip angle changes during walking. However at initial ground contact, slight increases in peak flexion of the hip were observed (21.44 degrees vs. 25.12 degrees) when comparing No AFO to AFO trials. In addition, slight increases in peak flexion during late swing (24.57 degrees vs. 27.01 degrees) were also observed as well as lower peaks of hyperextension of the hip during pre-swing (-12.74 degrees vs. -10.16 degrees) (Figure 5). When observing hip moments and powers, no significant changes were observed between No AFO and AFO-No Biofeedback trials. However, between No AFO and trials with biofeedback, lower peaks in extensor moments at initial contact were observed (0.56 Nm/kg vs. 0.50 Nm/kg), causing lower spikes of power generation (0.47 W/kg vs. 0.64 W/kg) at this time. In addition, a significant loss in controlling extensor moment during mid swing was observed (0.01 Nm/kg vs. -0.094 Nm/kg) (t-test: $P=0.002$), causing an increase in peak hip power output at this time (0.76 W/kg vs. 0.96 W/kg) (Figure 5). Average total positive and negative hip power showed no significant changes between all trials, however slight increases in positive power (0.18 W/kg vs. 0.20 W/kg) and decreases in negative power (-0.19 W/kg vs. -0.16 W/kg) were seen when comparing No AFO to AFO-Biofeedback trials (Figure 8).

Figure 5: Mean Hip Joint Angles, Moments, and Powers

Mean hip joint angles (degrees), moments (Nm/kg), and powers (W/kg) for healthy participants during walking at 1.25 m/s. Hip angle (top panel), hip moment (middle panel) and hip power (bottom panel) are plotted over a stride from heel strike (0%) to heel strike (100%) of the same limb. The blue line represents the participant walking normally with no AFO, the red line represents the participant walking in the AFO with the biofeedback turned off, the green line represents the participant walking in the AFO with active biofeedback, and the dashed black line represents the timing of the biofeedback “beep” during walking.

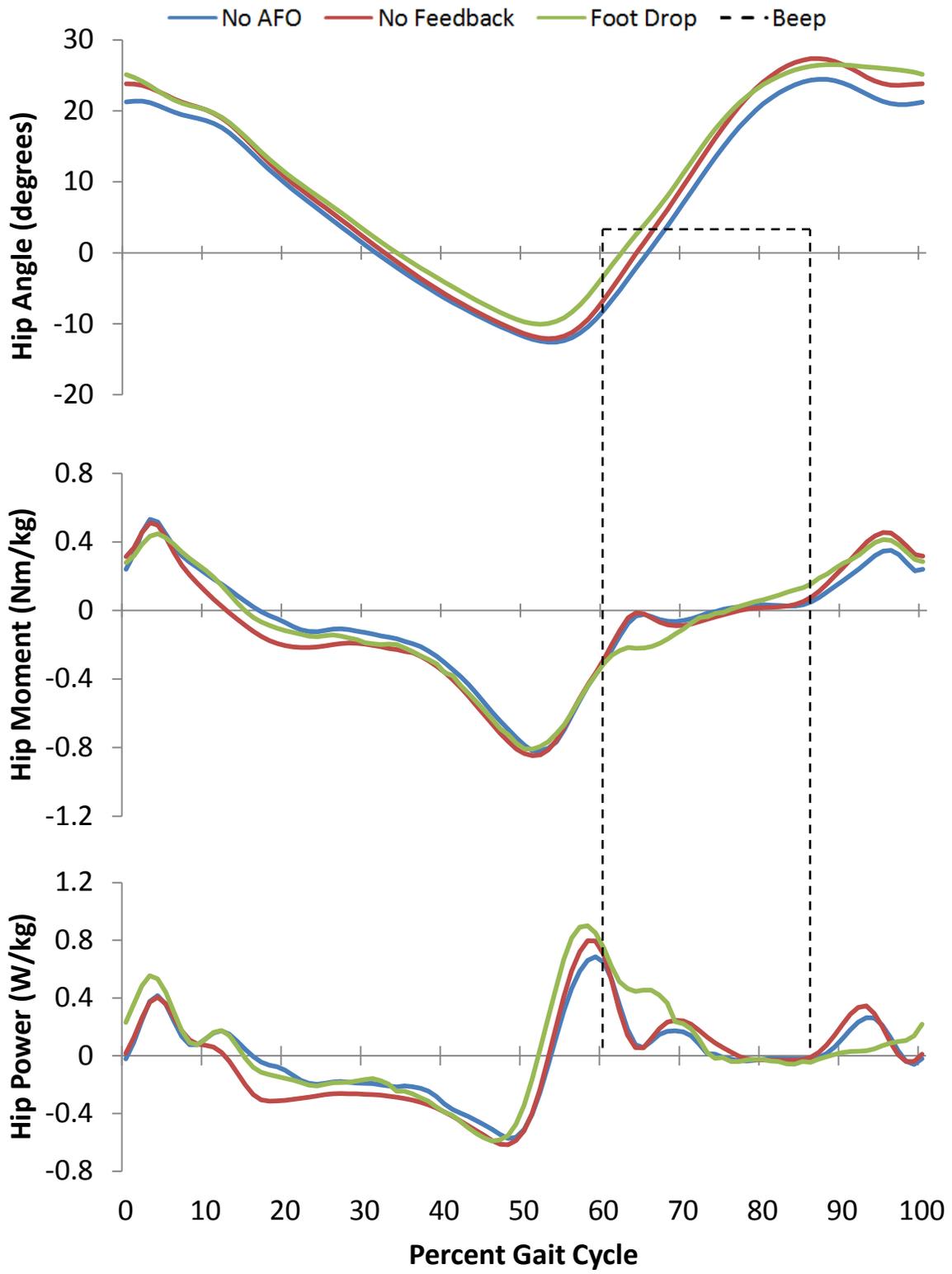


Figure 6: Average Positive, Negative, and Net Ankle Joint Powers

Average positive, negative, and net ankle joint powers (W/kg) for healthy participants walking at 1.25 m/s. Positive power (top panel), negative power (middle panel), and net power (bottom panel) are plotted below. The blue bar represents the participant walking normally with no AFO, the red bar represents the participant walking in the AFO with the biofeedback turned off, and the green bar represents the participant walking in the AFO with active biofeedback.

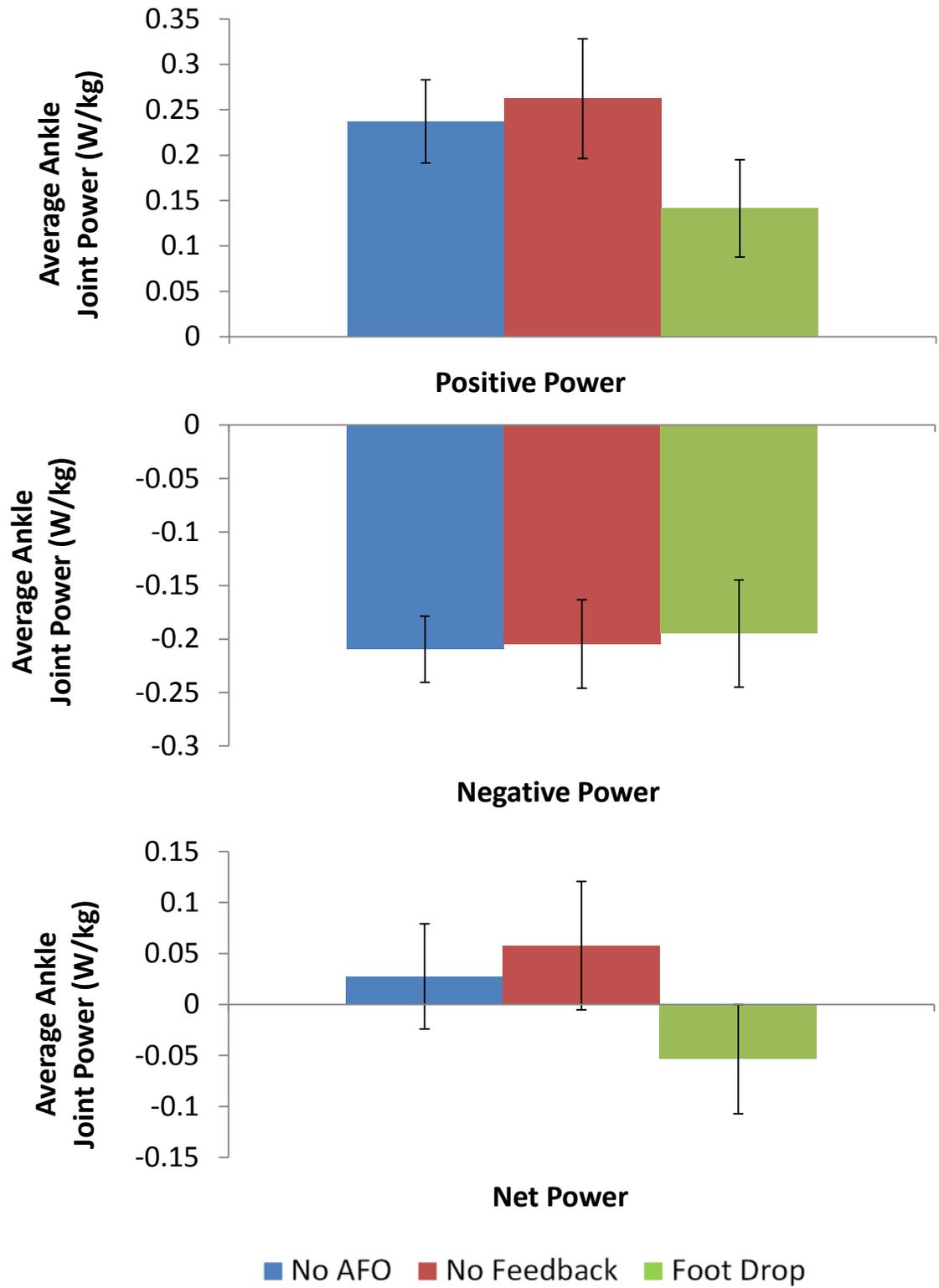
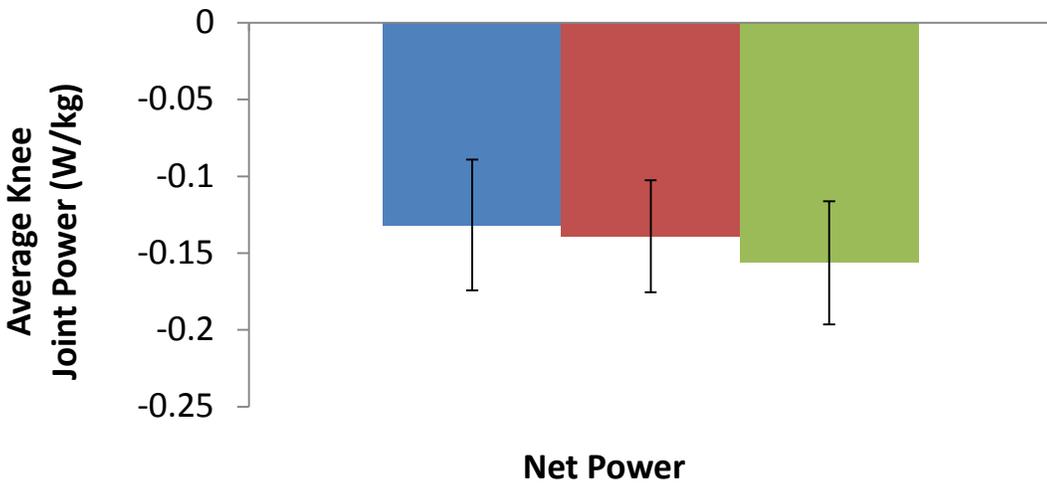
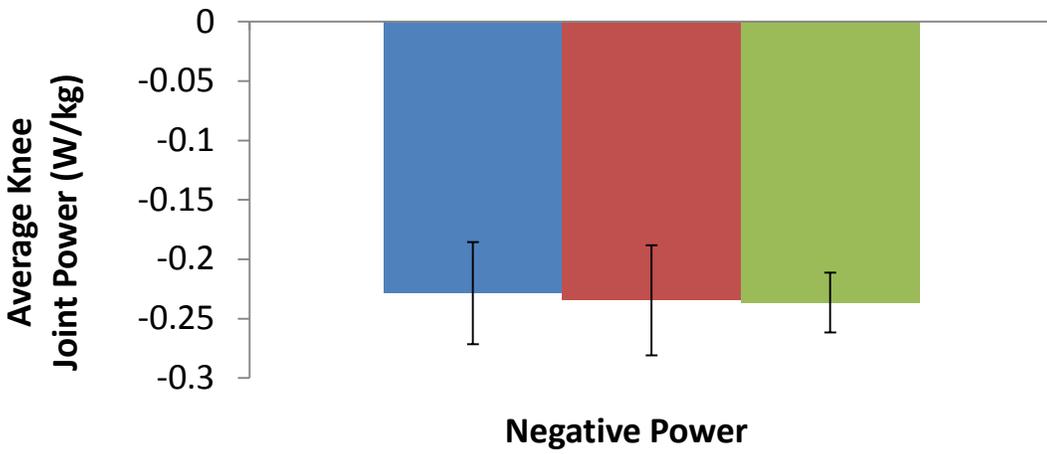
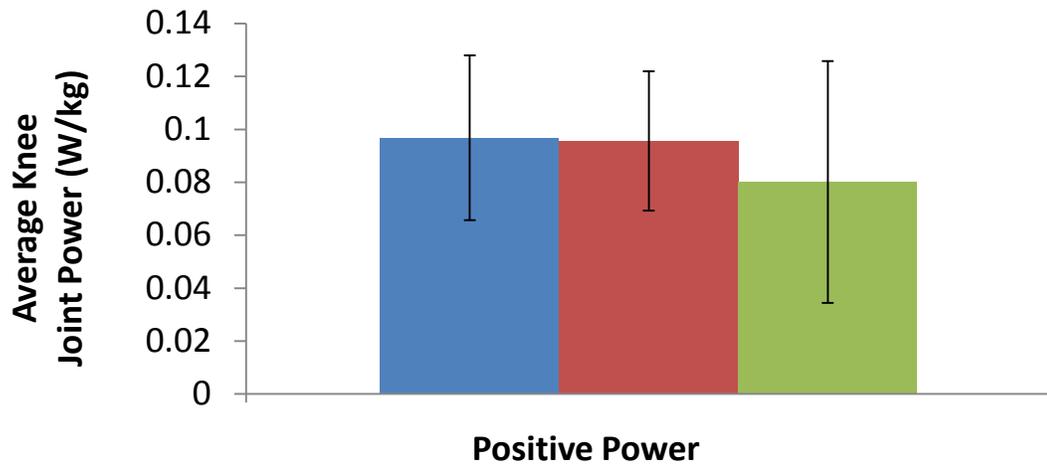


Figure 7: Average Positive, Negative and Net Knee Joint Powers

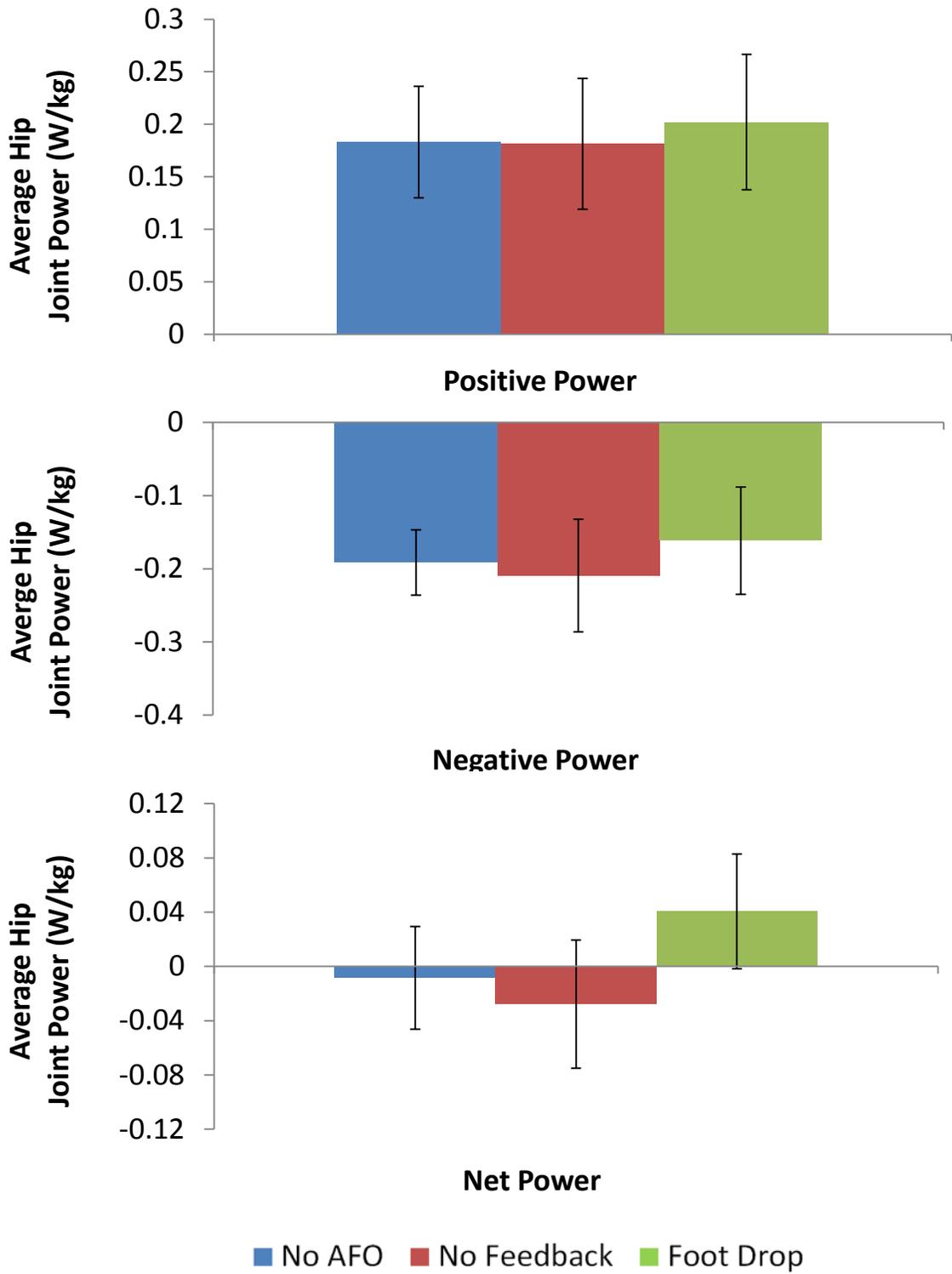
Average positive, negative, and net knee joint powers (W/kg) for healthy participants walking at 1.25 m/s. Positive power (top panel), negative power (middle panel), and net power (bottom panel) are plotted below. The blue bar represents the participant walking normally with no AFO, the red bar represents the participant walking in the AFO with the biofeedback turned off, and the green bar represents the participant walking in the AFO with active biofeedback.



■ No AFO ■ No Feedback ■ Foot Drop

Figure 8: Average Positive, Negative, and Net Hip Joint Powers

Average positive, negative, and net hip joint powers (W/kg) for healthy participants walking at 1.25 m/s. Positive power (top panel), negative power (middle panel), and net power (bottom panel) are plotted below. The blue bar represents the participant walking normally with no AFO, the red bar represents the participant walking in the AFO with the biofeedback turned off, and the green bar represents the participant walking in the AFO with active biofeedback

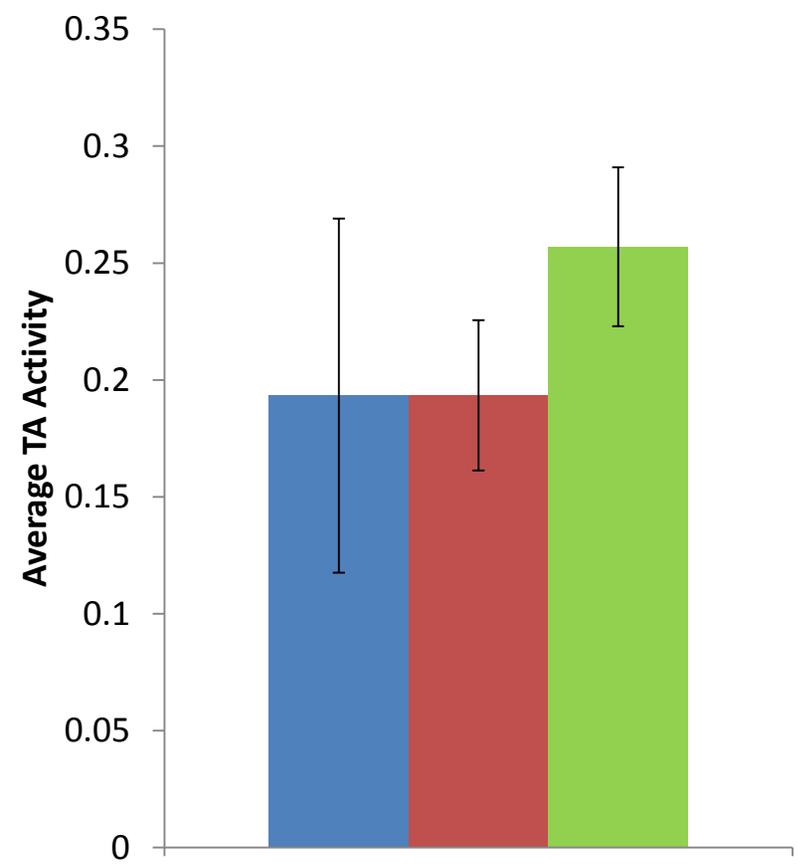
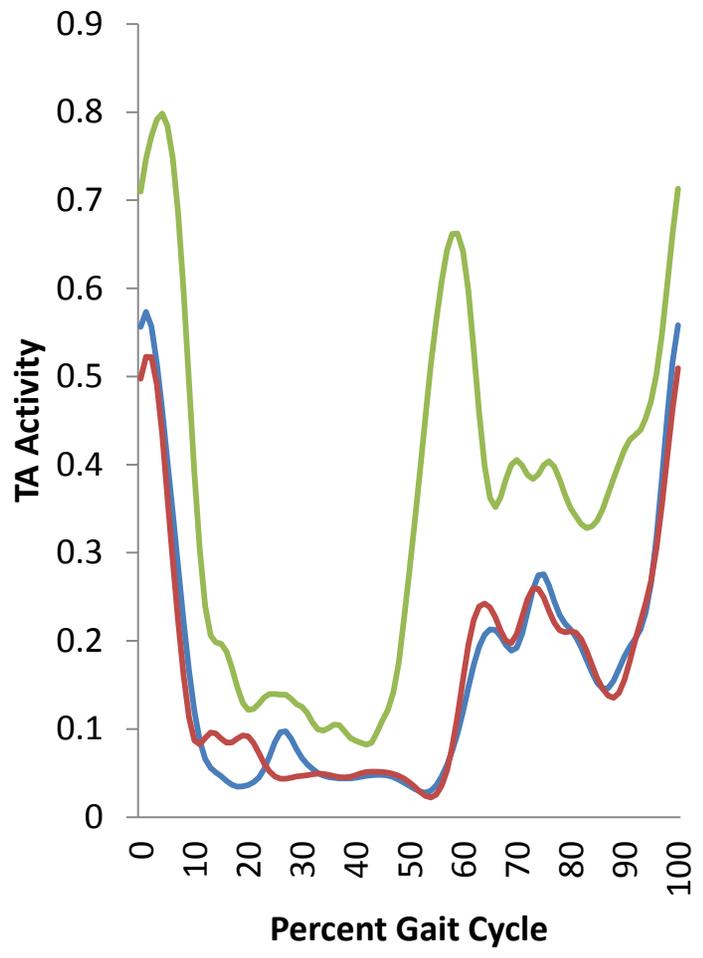


Electromyography

Electromyography (EMG) data was collected for this study during walking at 1.25 m/s. This was collected while the user was walking normally, while the user was walking with the AFO turned off, and then while the AFO was turned on and providing biofeedback. When biofeedback was provided and the user was attempting to keep their foot at a more dorsiflexed position, increases in tibialis anterior (TA) muscle activity were seen (0.19 vs. 0.26) (Figure 9) when comparing to the No AFO trials. No significant changes were seen when comparing TA muscle activity between No AFO and AFO-No Biofeedback.

Figure 9: Average TA Muscle Activity

Average tibialis anterior (TA) muscle activity plotted over a full stride from heel strike (0%) to heel strike (100%) (left panel) and average power plotted for each condition (right panel). The blue line/bar represents the participant walking normally with no AFO, the red line/bar represents the participant walking in the AFO with the biofeedback turned off, and the green line/bar represents the participant walking in the AFO with active biofeedback.



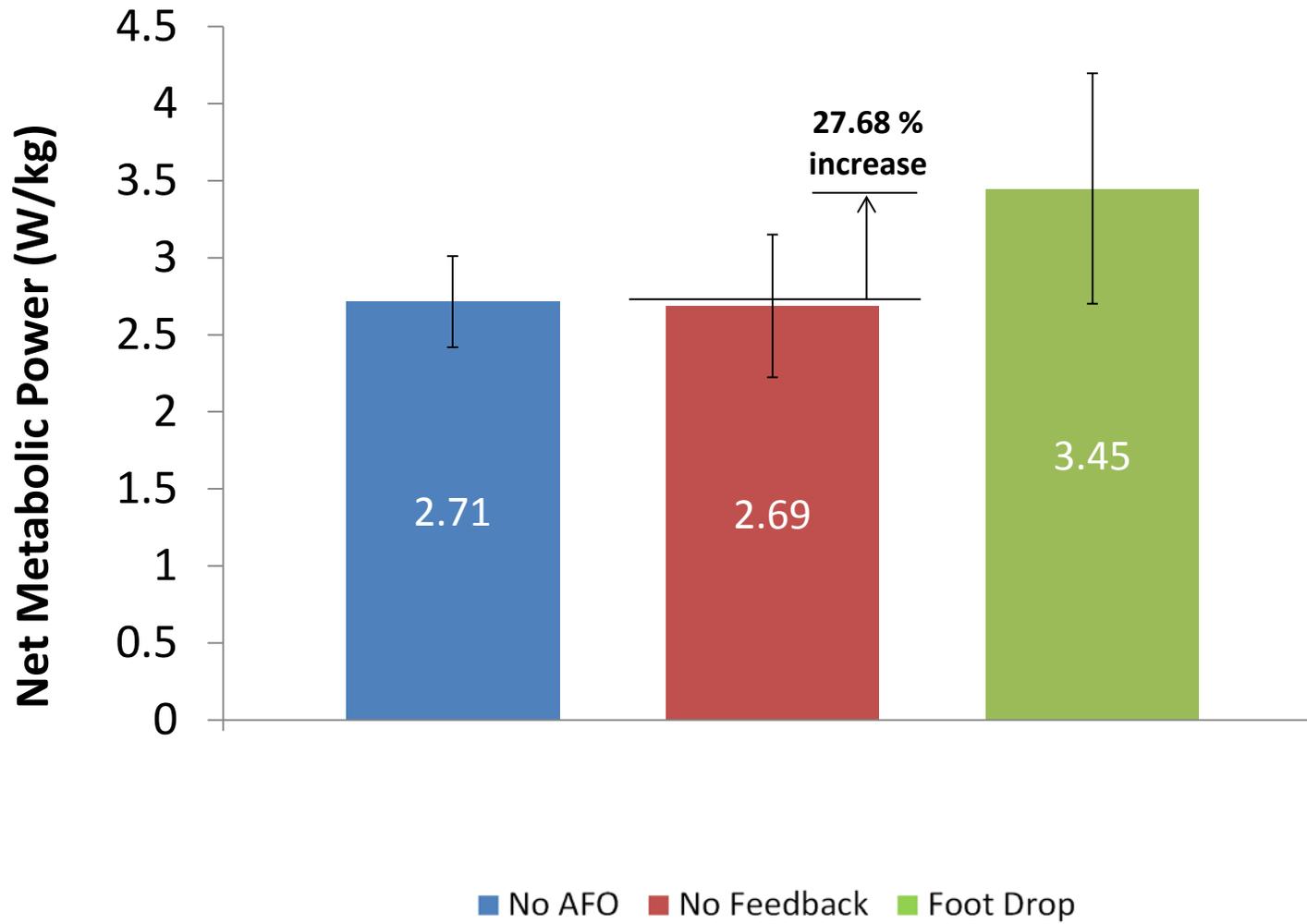
■ No AFO ■ No Feedback ■ Foot Drop

Net Metabolic Power and Efficiency

Net metabolic power (W/kg) for the participants was collected for this study during walking at 1.25 m/s. This was collected while the user was walking normally, while the user was walking with the AFO turned off, and then while the AFO was turned on and providing biofeedback. Each trial was collected for seven minutes and the averages of the last two minutes of walking are shown in Figure 10 below. After donning the AFO without turning the biofeedback on, there was a very slight decrease of -1.31% (2.71 W/kg vs. 2.69 W/kg) in net metabolic power, but not enough to be statistically significant. After turning on the biofeedback and encouraging the participants to keep their toe more lifted (dorsiflexed) than usual, an average increase of 27.68% (2.71 W/kg vs. 3.45 W/kg) was recorded.

Figure 10: Net Metabolic Power

Net metabolic power (W/kg) for healthy participants (n=8) during walking at 1.25 m/s. The blue bar represents the participant walking normally with no AFO, the red bar represents the participant walking in the AFO with the biofeedback turned off, and the green bar represents the participant walking in the AFO with active biofeedback.



Discussion

The aim of this study was to develop a working Ankle Foot Orthosis (AFO) with a dynamic biofeedback mechanism to assist individuals who exhibit foot drop by alerting the user to an increasing risk of injury through auditory and vibratory cues. As a way to test the effectiveness of the AFO prior to collection on impaired populations, 8 healthy subjects (mean \pm s.d., age = 23.63 ± 3.29 years; mass = 74.72 ± 10.82 kg; height = $1.75 \pm .08$ m) were utilized for testing. When set to indicate foot drop, the AFO emitted a vibration and a tone as a negative response to the user dropping their foot to a dangerous position, putting them at a risk of fall. In the healthy population used in this study, however, the negative response was set at a position that forced the user to walk with their ankle more dorsiflexed (i.e. lifted) than normally comfortable. By forcing an otherwise healthy gait to an abnormal posture, we hypothesized that when the vibrotactile biofeedback was turned on, users would exhibit significant increases in tibialis anterior (TA) muscle activity as well as increased dorsiflexion at the ankle by compensating at other joint locations and using their dorsiflexor muscles more. Additionally, we expected the metabolic cost of walking to increase as the user was walking in a manner that was unfamiliar to them.

In support of the hypothesis, the data from this study showed overall increases in muscle function related to the problems of foot drop. The TA muscle is the main dorsal flexor of in the foot and its contraction is what causes dorsiflexion, or toe lift, while walking [17]. The inability of impaired populations to utilize this muscle is one of the main causes of foot drop. The electromyographic (EMG) signals of the TA muscles in this study indicate

that wearing the AFO with the biofeedback turned on significantly increases TA muscle activation in the limb with the AFO.

Due to the increased TA activity in trials with the biofeedback response turned on, significant increases in dorsiflexion were observed as a result. Given the results that healthy individuals can change their gait patterns using the embedded biofeedback, it gives us hope that an impaired population can attempt to do the same. With training, a person suffering from foot drop can hope to increase their dorsiflexion by utilizing their TA muscles more than they normally would, thereby increasing toe clearance during swing phase. Studies have shown that there is a more direct potential relationship between toe clearance and tripping than between other gait parameters and tripping [18] making increases in dorsiflexion at the ankle an important parameter to study.

Though users walking in the biofeedback AFO did show promising results of TA activity and dorsiflexion at the ankle, there were several compensations made to the user's kinematics and kinetics. The ankle power data from this study shows that wearing the AFO with the biofeedback response turned on resulted in decreased positive ankle power at push-off. This suggests that the concentric burst of propulsive plantarflexor activity during pre-swing was lower when the biofeedback was turned on [19]. A typical AFO has these same effects due to the non-compliant nature of an AFO that locks the ankle angle at 90 degrees [20]. The AFO used in this study attempts to eliminate this problem with the use of a hinge joint that no longer restricts movement while walking. However, as these decreases in ankle power are seen, it is believed that because the user was attempting to keep the toe at a more

dorsiflexed position, they were not pushing off from the ground as hard as they normally would. With more training, and continued wear with the biofeedback, we are hopeful that this ankle power decrease would become non-existent. However, additional testing must be completed before this can be confirmed.

In addition to ankle power decreases, other compensations at the knee and hip joints were observed when the user was walking at a more dorsiflexed position. At the knee, some of the more significant changes observed were a decrease in peak knee flexion at mid swing phase, as well as decreased flexor moments and power absorption during late swing. Additionally, slight increases in extensor moments during pre-swing were observed, attributing to increased peak power absorption in the knee at the same moment [21]. These changes suggest that the user was walking at a less crouched position, and not utilizing all of the power output that the knee can provide, essentially “turning the knee down” in order to keep their ankle in a more dorsiflexed position. At the hip, the most noteworthy compensations were losses in flexor moments during pre-swing, causing increases in bursts of power generation at the hip at that time. This indicates that with the losses in ankle propulsion power during the foot drop condition, limb advancement was less passive, forcing the user to utilize more hip power generation to achieve momentum [21].

Metabolic energy expenditure was measured across each trial in order to determine the cost of walking in the vibrotactile AFO, both with and without biofeedback. With no biofeedback turned on, a 1.31% decrease in metabolic cost was seen on average over the 8 participants. The AFO was designed to be incredibly lightweight (Average: 242.5 grams) so

to be virtually transparent to the user, therefore this decrease in metabolic cost is likely due to added stability in the frontal plane, as studies show that an energy cost can be decreased using balance control [22]. With the biofeedback turned on and the users walking at a more dorsiflexed position, an average increase in metabolic cost of 27.68% was seen. This supports our hypothesis as we expected the cost of walking to increase while in an unfamiliar position, as enforced gait patterns can elicit substantially higher metabolic energy cost [22].

The significant amount of compensations needed for the user to walk at a more dorsiflexed position leads to many unanswered questions about this type of rehabilitation. First is a question of the type of biofeedback as well how we are giving instructions to use it. As a question of instruction, the user was asked to walk in a way that they would not hear a beep or feel a vibration from the AFO. In order to do so, they had to activate their TA muscle and keep their toe lifted; otherwise they were given negative biofeedback in the form of a beep/vibration. Studies have shown that motor skill learning is most sufficient when biofeedback and instructions are given externally rather than internally [23]. Therefore, as we are asking the user to not allow the AFO to beep (external biofeedback) rather than asking them to simply lift their foot within each step (internal biofeedback), we believe this form of instruction is appropriate. In terms of type of biofeedback, there is a question of whether or not modality of the biofeedback could affect the results. For example, if we included visual biofeedback of some kind, would the results be better? Or would that, in combination with the vibrotactile biofeedback, involve too much cognitive demand?

In elderly populations, numerous physical or cognitive challenges are encountered when using health information technology [24], making it necessary that rehabilitation technologies not be too demanding. When using biofeedback in older adults, studies have shown that older adults can benefit from extrinsic cues of body position using biofeedback, but when secondary tasks are added, performance is often decreased [25]. Therefore we believe that the task of keeping the toe lifted to avoid vibrotactile biofeedback requires little cognitive demand, however if other modalities of biofeedback are added in an elderly or impaired population, performance could be lessened. However further studies should be conducted to confirm this assumption.

Due to losses in ankle power in the foot drop condition of this study, we wonder if we should utilize the biofeedback at joints other than the ankle. In impaired populations, toe clearance is often inhibited by a lack of knee flexion during swing [26]. As the biggest issue of foot drop is a lack of toe clearance, increases in knee flexion could be another option to prevent falls, bringing into question whether or not we should be focusing the biofeedback at the knee joint. Furthermore, a study on foot drop following stroke found a lack of evidence for dorsiflexor impairment as the problem for toe clearance. Instead, they argued that limb advancement comes from compensations at the knee and hip to avoid falls [27]. However, Greene and Granat's study of knee and ankle flexion on ground clearance in paraplegic gait concluded that knee flexion alone is not sufficient to overcome toe clearance, and that a combination of dorsiflexion and knee flexion is necessary to prevent falls [28]. Therefore, we believe that increasing dorsiflexion through this vibrotactile ankle foot orthosis could be an

effective method towards rehabilitation for those who suffer from foot drop. However, encouraging dorsiflexion alone may be better served in populations who only suffer from damage to the dorsiflexor muscles, rather than on populations like stroke survivors who suffer from many other gait dysfunctions besides foot drop. Though further studies are necessary to confirm these assumptions.

While these results are promising, there is the question of how these results may differ for someone who actually suffers from foot drop. Intiso et al. looked at the effects of biofeedback to improve control of foot drop in stroke survivors through EMG, finding that muscle recruitment of the tibialis anterior muscle is possible through training and physical therapy [8]. We are hopeful that ankle angle biofeedback can provide the same results in an impaired population. By providing the user the position of their ankle in real time within a step, we hope that they will be able to improve tibialis anterior function and subsequently, their amount of dorsiflexion. The data from this study of healthy controls helps to lay the groundwork for further testing on a population that suffers from foot drop in order to determine if our assumptions are correct.

Conclusion

In this study, we analyzed the effect of a vibrotactile biofeedback ankle foot orthosis to help prevent foot drop through the use of healthy controls to test the functionality of the biofeedback. We found that when the biofeedback was set to a degree that forced the user to keep their toe more lifted than usual, TA muscle activity was significantly increased, thereby

increasing dorsiflexion at the ankle. However compensations at other joints were made in order to achieve these results, increasing metabolic demand from the user. Further testing is necessary to determine if continued wear of the AFO and practice with the biofeedback could eliminate some of these compensations. Furthermore, testing of the AFO in a population that suffers from foot drop is necessary to see its full potential as a rehabilitation aid.

CHAPTER 2:

Testing the Functionality of a Vibrotactile Ankle Foot Orthosis to Assist Push-off

Introduction

Often, people forget the importance of one of the simplest tasks we do every day: walking. In aging and impaired populations, activities of daily living are often limited due to locomotion deficiencies such as walking speed [1]. One of the main focuses of rehabilitation engineering is to improve walking in aging populations through the use of strength training, exercise programs, or physical therapy. In the more modern age, however, approaches often involve the use of assistive devices to enhance walking capabilities. An example of a device like this is an ankle exoskeleton. While providing locomotor efficiency at the ankle joints, exoskeletons are often cumbersome and can add a lot of mass to the lower limbs, therefore increasing the metabolic cost of walking [2].

Another potential solution to locomotion problems is the use of biofeedback. Biofeedback can be used in many ways to alter the gait parameters of a user. Some of these include use of ground reaction forces, muscle activity from electromyography, or joint position to provide visual, auditory, or vibratory biofeedback [3]. In a rehabilitation setting, biofeedback has the capability to improve the control and learning of damaged physiological functions and can show moderate to large effects immediately following treatment [4]. For example, DeNunzio et al. shows that through trunk vibration biofeedback in Parkinson's

patients, stride length, cadence and velocity of gait can be improved [5]. Furthermore, walking exercises that include auditory rhythmic biofeedback have been shown to be an effective way to improve temporal stability during walking in impaired populations [6]. And if only one gait parameter is being changed, research studies have shown that providing real time biofeedback is overall an effective method for gait retraining [7].

However, biofeedback is not always utilized in some of the ways it should. When focusing on lower limb biofeedback, the majority of the literature involves the use of ground reaction forces or electromyography (EMG). Research studies do suggest that EMG biofeedback has the ability to increase muscle strength and show a recovery of impairments such as foot drop [8]. However, the use of EMG signals as a biofeedback source is not always the most reliable method, as other studies have found no significant improvements between EMG biofeedback and traditional physical therapy [9], making the efficacy of EMG biofeedback unclear. We believe that biofeedback intervention should be focused on joint position, or more specifically, the ankle joint position, based on the knowledge that the majority of mechanical energy for walking is supplied by muscles that cross the ankle joint [10]. In many impaired populations, a contributor to the high energetic cost of walking comes from plantar flexor weakness at the ankle [2]. Therefore, by focusing biofeedback rehabilitations on the ankle specifically, we can hope to target ankle joint positions that provide the most efficient gait, contributing to lower cost of walking in impaired populations.

In addition to foot drop, another common locomotion problem for many with neuromuscular impairments at the ankle is a lack of propulsive power at push-off. This

condition causes decreased average power in the ankle joints and plantarflexor weakness while walking. This makes the propulsive phase of gait more difficult, reducing the individual's metabolic economy and greatly increasing the risk of fall. In order for humans to have fully efficient gait, coordinated ankle propulsion is necessary [10]. As previously mentioned, some common methods to help remedy this weakness are strength training and physical therapy. However other methods include powered devices such as exoskeletons that attempt to provide power to the ankle joint. While there are studies that show powered exoskeletons using a tethered power source can reduce the metabolic cost of walking by 6% [29], there continue to be several downsides to this type of treatment.

More often than not, this type of treatment is confined to a laboratory or rehabilitation facility due to the external power required for the exoskeleton to work. Additionally, the motors required to apply significant ankle torque are bulky and high in mass, making it difficult to walk before the power is even turned on. We feel that it is important for an intervention to aid people with neuromuscular deficiencies to enhance participation in society, making the idea of a portable device the most optimal option. Franz et al. investigated the capability of biofeedback in older adults with propulsive deficits, finding that this population has “considerable and underutilized propulsive reserve available” [30], making real-time biofeedback a promising method of rehabilitation.

This study investigates the capability of the same vibrotactile biofeedback Ankle Foot Orthosis (AFO) (cite patent) used in Chapter 1 to encourage ankle plantarflexion to enhance push-off in neuromuscularly impaired patients, attempting to improve their quality of life.

Rather than providing assistance at the ankle angle like many powered devices, we are asking the user to proactively retrain their own muscles through the use of the biofeedback. Hinge joints are utilized so to not hinder the users walking in any way, as an assistive device often helps in one level of movement, while hindering in another. This intervention involves the use of ankle angle biofeedback in an attempt to teach the user at what point in the gait cycle they should be using their ankle muscles the most. The AFO emits a vibration and beep just as the user's heel leaves the ground, reminding them at this point to activate their plantarflexor muscles, propelling them forward. Once full gait is restored using the biofeedback, the patient will not have to wear any type of brace at all. Using the ankle angle as the only gait parameter to be altered, the effectiveness of this type of rehabilitation is hypothesized to be very efficient. It is also hypothesized that this intervention could lead to considerable metabolic energy savings through continued training; an outcome that could improve the quality of life for clinical populations, such as people with post-stroke hemiparesis who spend up to 50% more metabolic energy while walking [13].

However for the purposes of this study, a healthy population is utilized in order to test the functionality of the brace as a gait altering device before testing on an impaired population. We will see if an otherwise healthy gait has the capability to activate their plantarflexor muscles more, and increase power at the ankle using only the provided biofeedback. We hypothesize that when the vibrotactile biofeedback is turned on, users will exhibit significant increases in plantarflexion (i.e. more pointed toe) and power output at the ankle by compensating at other joint locations and using their plantarflexor muscles more.

Additionally, we expect the metabolic cost of walking to increase as the user will be walking in a manner that is unfamiliar to them.

Materials and Methods

AFO Fabrication

Before testing, a custom fabricated, unilateral carbon fiber/fiber glass composite ankle foot orthosis (AFO) was created for eight healthy participants (Figure 11). For an impaired population, the AFO will be used for the limb with weakened muscle activity, but for the purposes of this study, the leg used was at the discretion of the participant. Each AFO contained hinge joints to allow free motion in the sagittal plane during all phases of the gait cycle to present less risk to the user than the more common powered AFOs. This AFO instead asks the user to control their own muscles based on cues from vibrotactile biofeedback to encourage proactive rehabilitation.

Each AFO includes a Fio V3 Arduino Microcontroller that controls the biofeedback through the user of a buzzer and a vibration motor. A magnetic encoder is used to detect ankle angle in real-time as a way to alert the user to the position of their foot relative to the ground while walking. Pressure sensors in the bottom of the AFO were placed in order to detect specific phases of the gait cycle while walking. A combination of signals from the magnetic encoder at the ankle joint and from the pressure sensors on the bottom of the AFO are used to control the timing of the biofeedback. Table 4 below shows a breakdown of the weight of the AFO for a US size 8 shoe and a US size 12 shoe. While heavier in mass than

traditional 90 degree AFOs due to the addition of the hinge joints, it remains virtually transparent to the user, making it possible to walk without hindrance.

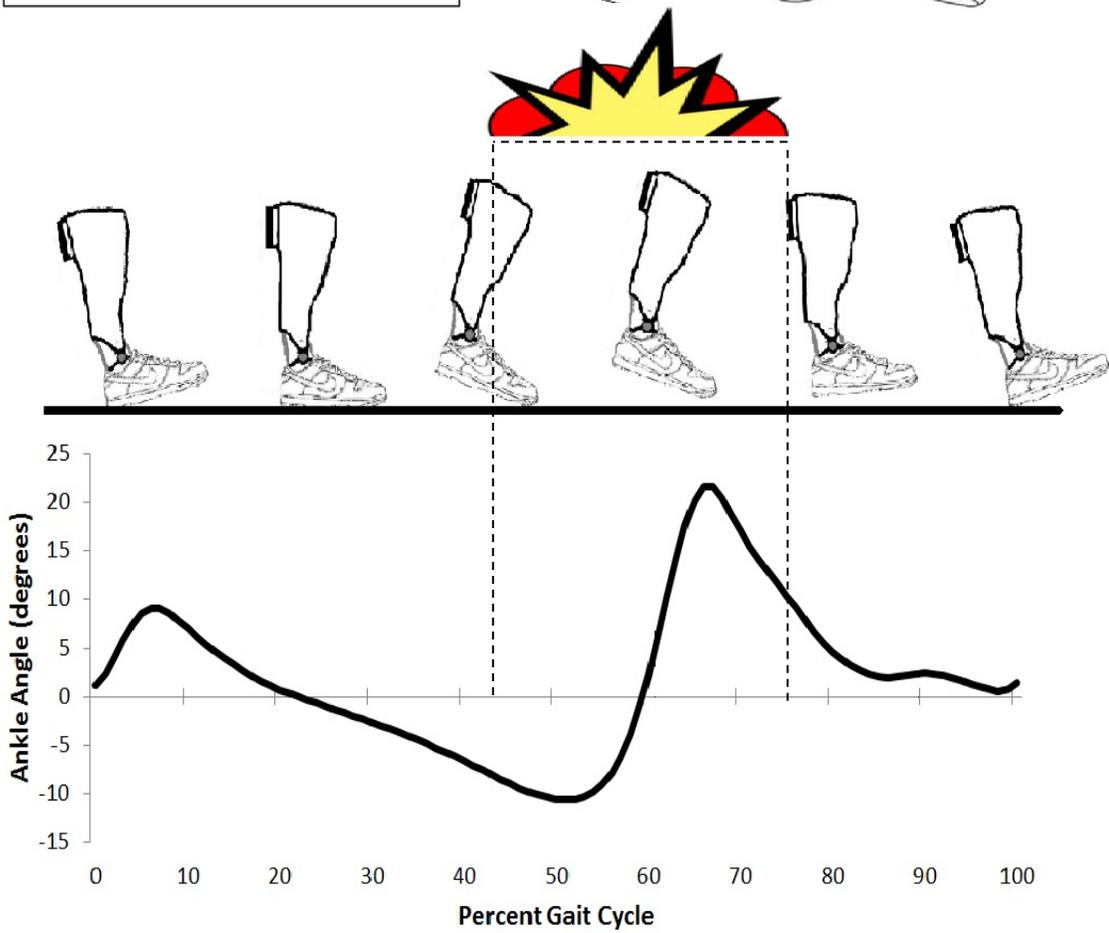
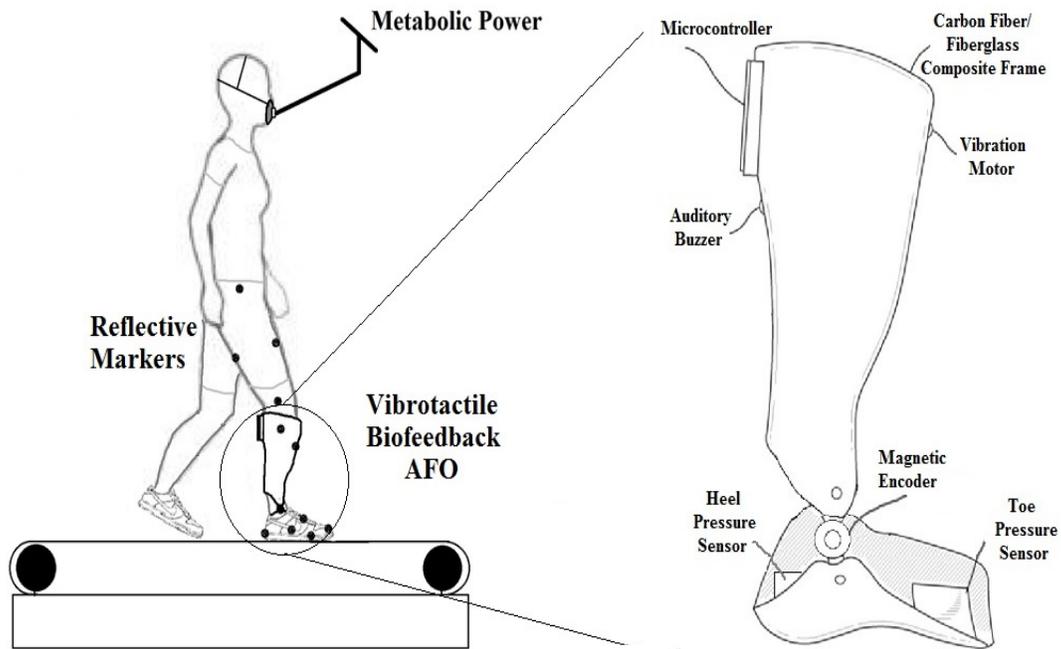
Table 4: Ankle Foot Orthosis Mass Distribution – Push Off

Segment	US Size 8	US Size 12
Carbon Fiber Foot Section	20.9	30.4
Aluminum Joints (x2)	59.4	59.4
Carbon Fiber Shank Section	88.7	95.4
Microcontroller	65.4	65.4
<u>Total Mass</u>	<u>234.4</u>	<u>250.6</u>

When set to enhance ankle propulsion, the AFO emitted a vibration and a tone as a reminder of the appropriate time to attempt to push-off from the ground. Rather than providing direct assistance to the ankle muscles, the brace gave the user a vibration and tone at the appropriate time in the gait cycle, letting them know when to activate their muscles for push-off. Most devices to aid in propulsion use either motors or pneumatic devices. The idea behind this device was to ask the user to rely solely on their own muscles, and by simply using biofeedback, attempted to proactively retrain the ankle muscles to work harder in the healthy population. By doing so in an impaired population, we can hope to do the same, and therefore restore functional gait to the user.

Figure 11: Vibrotactile Ankle Foot Orthosis to Assist Push-Off.

The left panel shows the testing methods including reflective markers and metabolic power collection. The right panel shows an in depth description of the AFO including microcontroller, vibration motor, auditory buzzer, pressure sensors, and magnetic encoder locations. The bottom panel shows an ankle angle over a full gait cycle from heel strike (0%) to heel strike (100%) with a depiction of the timing that the biofeedback comes on.



Experimental Protocol

Eight healthy participants who were able to walk without assistance (mean \pm s.d., age = 23.63 ± 3.29 years; mass = 74.72 ± 10.82 kg; height = $1.75 \pm .08$ m) signed an institutional review board (IRB) approved consent form to participate in this study. A more in depth listing of the subject characteristics can be found in Table 5 below. All procedures were approved by the University of North Carolina, Chapel Hill and North Carolina State University IRB and followed the procedures outlined by the Declaration of Helsinki.

Table 5: Push Off Participant Data

Participant	Age (years)	Mass (kg)	Height (meters)
1	31	74.84	1.854
2	21	79.37	1.676
3	24	97.52	1.803
4	21	61.23	1.778
5	21	68.04	1.676
6	24	68.04	1.626
7	24	72.57	1.702
8	23	76.20	1.823
Mean \pm SD	23.5 \pm3.42	74.72\pm10.82	1.75\pm.08

All trials were completed on an instrumented treadmill (BERTEC, Columbus, OH, USA) at a speed of 1.25 m/s and lasted for seven minutes. Each participant was asked to walk for three different conditions with the vibrotactile biofeedback AFO. In a randomized order, the participant was asked to walk for seven minutes with (1) No AFO, (2) AFO with no biofeedback, (3) AFO with the biofeedback turned on. For the purposes of testing the AFO in a healthy population, the biofeedback was programmed to come on just as the users

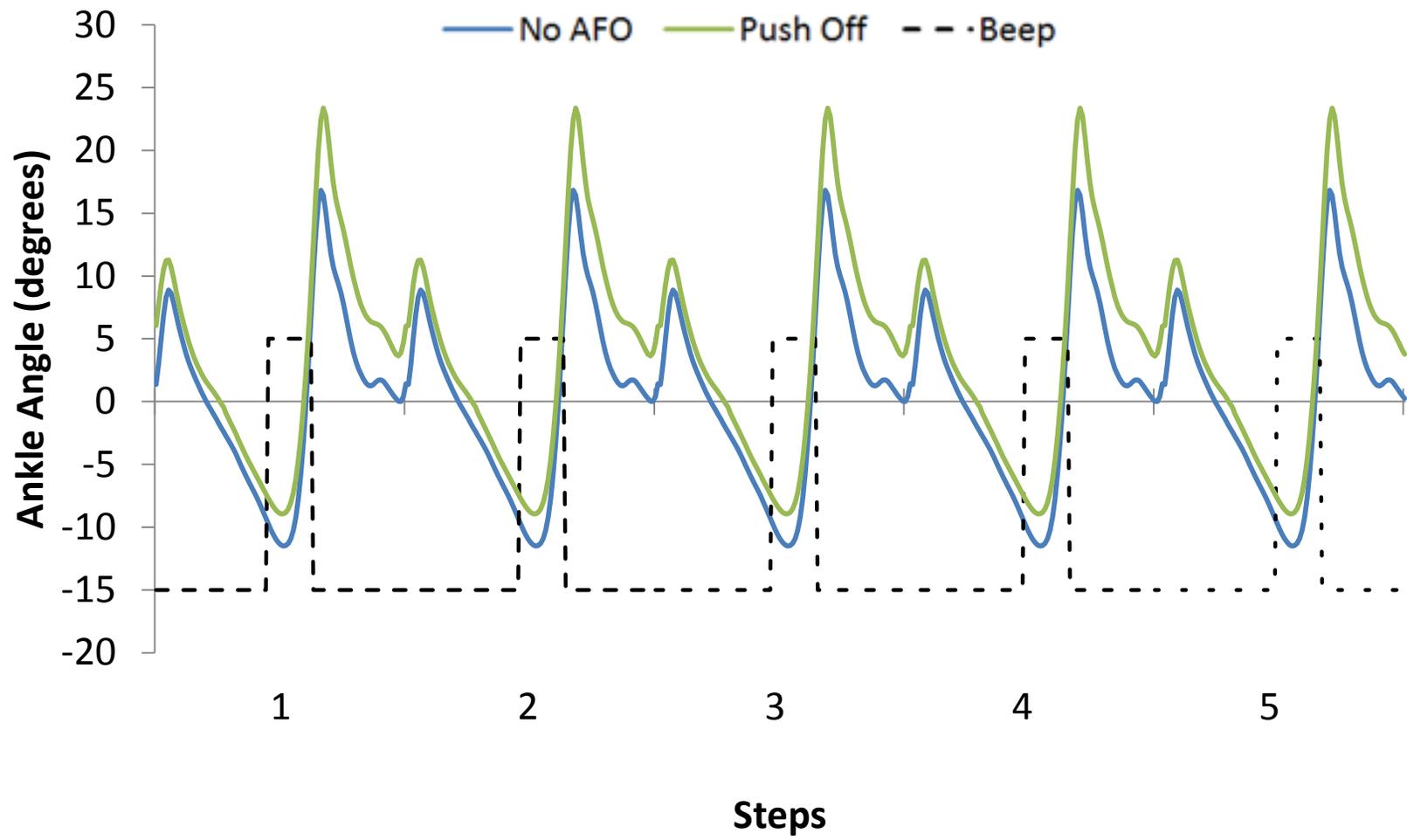
heel left the ground, encouraging them to use more of their ankle muscles, and push-off from the ground harder at that time. Figure 12 below shows a time series graph of a typical user wearing the AFO for 5 strides. With the feedback turned on to come on as the user's heel leave the ground, the user would attempt to push-off harder, typically causing a more plantarflexed ankle angle. Table 6 below shows both the primary and secondary variables observed and reported in the results below.

Table 6: List of Dependent Variables – Push Off

Primary	Secondary	
Soleus Activity	Ankle Moment	Hip Angle
Ankle Angle	Knee Angle	Hip Moment
Ankle Power	Knee Moment	Hip Power
Metabolic Cost	Knee Power	

Figure 12: Time Series Graph – Push Off

Example ankle joint angles (degrees) for a healthy participant during walking at 1.25 m/s plotted over a stride from heel strike (0%) to heel strike (100%) of the same limb for 5 strides. The blue line represents a participant walking normally with no AFO, the green line represents the participant walking in the AFO with active biofeedback, and the dashed black line represents the timing of the biofeedback “beep” during walking at every step as the user’s heel leaves the ground.



Kinetics and Kinematics

Prior to gait analysis, anthropometric data was collected. All trials were completed using an instrumented treadmill (BERTEC, Columbus, OH, USA) set at 1.25 m/s. An eight camera motion analysis system (VICON, Oxford, UK) was utilized to capture the position of 31 reflective markers attached to the legs and pelvis of the user at 120 Hz. To calibrate a four segment model composed of two thighs, two shanks, two feet, and one pelvis, a static standing trial was collected. The raw marker positions were filtered using a second-order low pass Butterworth filter with a cut-off frequency of 8 Hz. Joint angle for the ankle, knee, and hip were computed in three dimensions as the orientation of the distal segment with reference to the proximal segment.

Force data was recorded at 120 Hz during walking using two force platforms underneath the split-belt BERTEC treadmill, while ensuring that each foot hit the correct treadmill belt while walking. By doing so, we make certain that the individual limb was contributing to the correct limb calculations. The raw force analog data were filtered with a second order low pass Butterworth filter with a cut-off frequency of 35 Hz. Inverse dynamic analyses were used to compute net joint moments, which were then multiplied by joint angular velocities to calculate powers for the ankle joint. Calculations of kinetics and kinematics were performed using a combination of Visual 3D software (C-Motion Inc., Germantown, MD, USA), Microsoft EXCEL, and MATLAB (MathWorks, Natick, MA, USA).

Electromyography

Electromyography (EMG) data was collected using surface electrodes to monitor the activity of the lower leg muscles during walking using a wired electromyography system (SX230, Biometrics Ltd., Newport, UK). Activity was recorded for the tibialis anterior (TA) muscle and the soleus muscle (SOL) for all collected trials on the limb that was wearing the AFO. The muscles activity was calculated by band-pass filtering (20-460 Hz) in hardware and then conditioned by rectifying, and low-pass filtering with a cutoff frequency of 6 Hz. EMG data was quantified by integrating with respect to time and normalized by the peak values.

Calculation of Positive and Negative Mechanical Work

To calculate the sum of the average of the positive (equation 1) and negative (equation 2) mechanical work values in the joints (\bar{P}_j), the total sum of work done by the lower limb joints (W_j) was divided by the stride time (τ_{stride}). Stride-averaged joint power data for the ankle, knee, and hip were individually integrated with respect to time over discrete periods of positive and negative work using the trapezium method [15]. All values of positive and negative work at each joint were summed over each individual stride, representing the work done by the limb both with and without the AFO.

$$\bar{P}_j^+ = \frac{W_j^+}{\tau_{stride}} \quad (1)$$

$$\bar{P}_j^- = \frac{W_j^-}{\tau_{stride}} \quad (2)$$

Metabolic Measurement and Efficiency

The flow rate for oxygen intake and carbon dioxide outtake were recorded using a portable metabolic system (OXYCON MOBILE, VIASYS Healthcare, Yorba Lina, CA, USA). The last two minutes of a five minute standing trial were used to obtain a net metabolic measurement. By doing so, the rate of metabolic energy consumption (W) was calculated while standing, and then subtracted from the average flow rate during the last two minutes of the seven minute walking trials at 1.25 m/s. A visual inspection of the oxygen consumption rate during the collections confirmed that the participants were at steady-state. The Brockway equation [16] was used to convert the flow rates for oxygen and carbon dioxide to metabolic power and to normalize them to the subject's body mass (W/kg).

Statistical Analysis

For this study, kinematic and kinetic data were averaged over 10 strides. Group means were then computed and to test for differences in outcome variables between conditions, and ANOVA with a Bonferroni adjustment was used. Pair-wise comparisons between the limb wearing the AFO were made when the biofeedback was turned off and then turned on.

Results

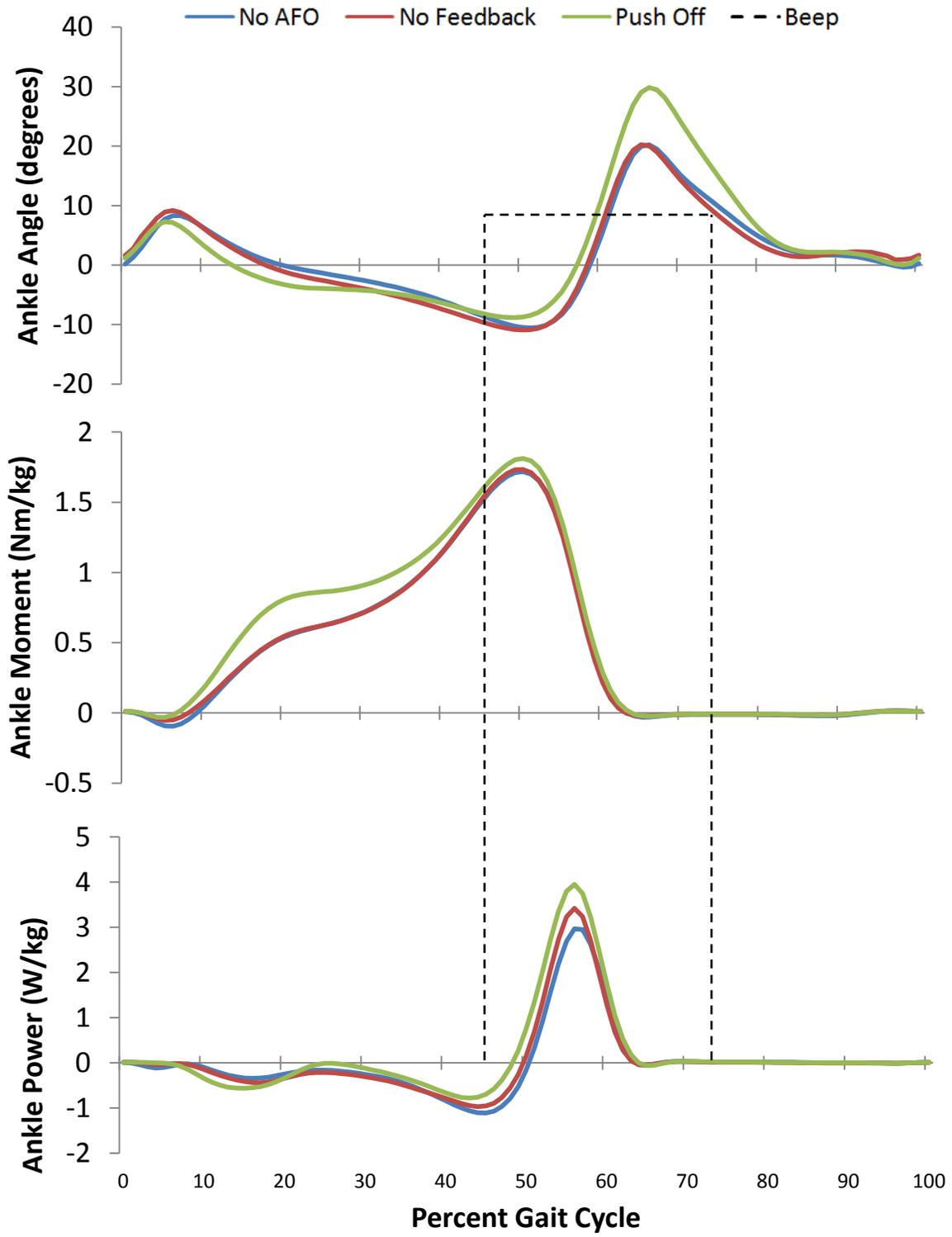
Angles, Moments, and Powers

The results obtained in this study include the joint angles, moments and powers for the leg while walking at a speed of 1.25 m/s. This was collected while the user was walking normally, while the user was walking with the AFO turned off, and then while the AFO was turned on and providing biofeedback.

At the ankle, ANOVA testing showed a main effect for the following conditions: Peak ankle plantarflexion ($p = 0.0001$); Peak positive ankle power ($p = 0.0006$); Total positive ankle power ($p = 0.0004$). Paired T-tests to determine statistical significance between specific conditions are reported below. On average, the participants showed significant increases in peak plantarflexion of 9.68 degrees (t-test: $p = 0.0001$) when comparing the AFO trial to that of No AFO. No significant changes were seen when comparing No AFO to the AFO-No Biofeedback trials (Figure 13). When comparing changes between ankle moment and power, no significant changes were present between No AFO and AFO-No Biofeedback, however when the AFO was turned on, slight increases in peak ankle moment (1.72 Nm/kg vs. 1.81 Nm/kg) were seen, contributing to significant increases in peak ankle power as well (3.15 W/kg vs. 4.07 W/kg) (t-test: $p = 0.018$) (Figure 13). The participants produced more total positive ankle power when the AFO was turned on than when compared to No AFO trials (0.24 W/kg vs. 0.36 W/kg) (t-test: $p = 0.001$) however no significant changes in total negative ankle power were seen (Figure 16).

Figure 13: Mean Ankle Joint Angle, Moments, and Powers

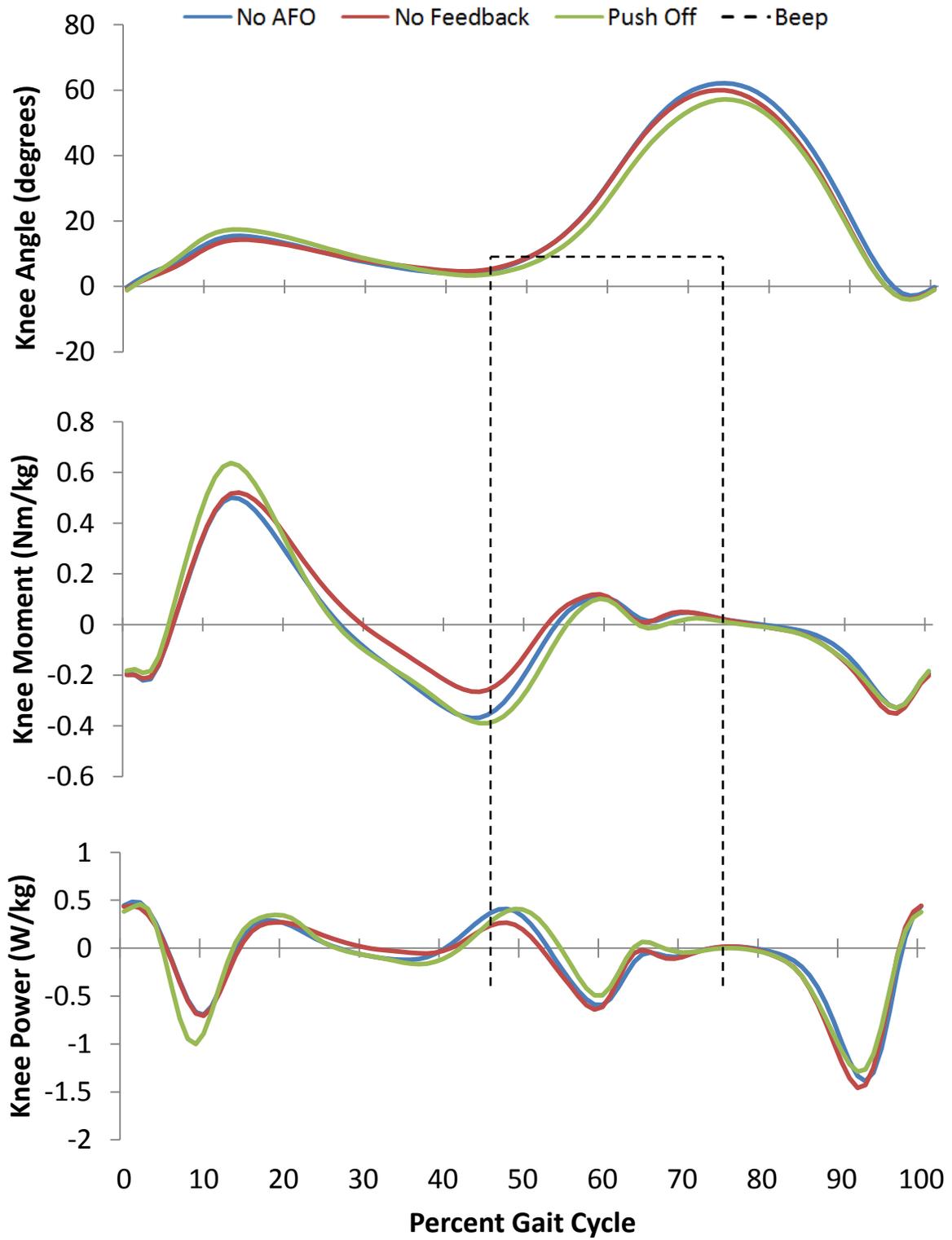
Mean ankle joint angles (degrees), moments (Nm/kg), and powers (W/kg) for healthy participants during walking at 1.25 m/s. Ankle angle (top panel), ankle moment (middle panel) and ankle power (bottom panel) are plotted over a stride from heel strike (0%) to heel strike (100%) of the same limb. The blue line represents the participant walking normally with no AFO, the red line represents the participant walking in the AFO with the biofeedback turned off, the green line represents the participant walking in the AFO with active biofeedback, and the dashed black line represents the timing of the biofeedback “beep” during walking.



At the knee, ANOVA testing showed a main effect for the following conditions: Peak knee flexion ($p = 0.002$); Total positive knee power ($p = 0.0001$). Paired T-tests to determine statistical significance between specific conditions are reported below. Average knee angles between the No AFO and AFO-No Biofeedback trials showed no significant changes, however between No AFO and AFO trials, decreased peak knee flexion of 5.16 degrees (t-test: $p = 0.011$) (Figure 14) was seen. When observing knee moment and power, there were minimal changes between No AFO and AFO-No Biofeedback trials that include some loss in flexor moment during terminal stance (-0.38 Nm/kg vs. -0.40 Nm/kg), contributing to a loss of power generation at that time (0.44 W/kg vs. 0.34 W/kg). With the biofeedback turned on, increased extensor moments were observed during loading response (0.51 Nm/kg vs. 0.64 Nm/kg) causing an increase in peak power absorption of the knee at this time (-0.75 W/kg vs. -1.09 W/kg). Average total positive knee power was significantly increased when comparing No AFO and AFO-Biofeedback trials (0.09 W/kg vs. 0.11 W/kg) (t-test: $p = 0.015$), however no significant changes in average total negative knee power were observed (Figure 16).

Figure 14: Mean Knee Joint Angles, Moments, and Powers

Mean knee joint angles (degrees), moments (Nm/kg), and powers (W/kg) for healthy participants during walking at 1.25 m/s. Knee angle (top panel), knee moment (middle panel) and knee power (bottom panel) are plotted over a stride from heel strike (0%) to heel strike (100%) of the same limb. The blue line represents the participant walking normally with no AFO, the red line represents the participant walking in the AFO with the biofeedback turned off, the green line represents the participant walking in the AFO with active biofeedback, and the dashed black line represents the timing of the biofeedback “beep” during walking.



At the hip, ANOVA testing showed a main effect for the following condition: Peak extensor moment at initial swing ($p = 0.0042$). Paired T-tests to determine statistical significance between specific conditions are reported below. When comparing hip angle between the three trials, no significant differences were observed, however slight changes in peak flexion were seen after donning the AFO at loading response (21.44 degrees vs. 23.49 degrees) and in mid swing (24.57 degrees vs. 26.42 degrees) (Figure 15). Changes in hip moments and powers were also observed after donning the AFO with no biofeedback. Most noteworthy is the increase in average peak power generation as weight is shifting to the opposite limb (0.76 W/kg vs. 0.83 W/kg). With the AFO turned on and providing biofeedback, losses in extensor moment attributed to losses in power generation for the hip during transition from loading response to mid stance were observed (0.47 W/kg vs. 0.33 W/kg). At initial swing, significant increases in peak extensor moment were observed (0.01 Nm/kg vs. 0.08 Nm/kg) (t-test: $p=0.006$) attributing to losses in bursts of power generation at that time (0.26 W/kg vs. 0.17 W/kg) (Figure 15). Average total positive hip power showed decreases when comparing No AFO to trials with the biofeedback, but this change was not enough to be significant (0.18 W/kg vs. 0.13 W/kg) (Figure 18).

Figure 15: Mean Hip Joint Angles, Moments, and Powers

Mean hip joint angles (degrees), moments (Nm/kg), and powers (W/kg) for healthy participants during walking at 1.25 m/s. Hip angle (top panel), hip moment (middle panel) and hip power (bottom panel) are plotted over a stride from heel strike (0%) to heel strike (100%) of the same limb. The blue line represents the participant walking normally with no AFO, the red line represents the participant walking in the AFO with the biofeedback turned off, the green line represents the participant walking in the AFO with active biofeedback, and the dashed black line represents the timing of the biofeedback “beep” during walking.

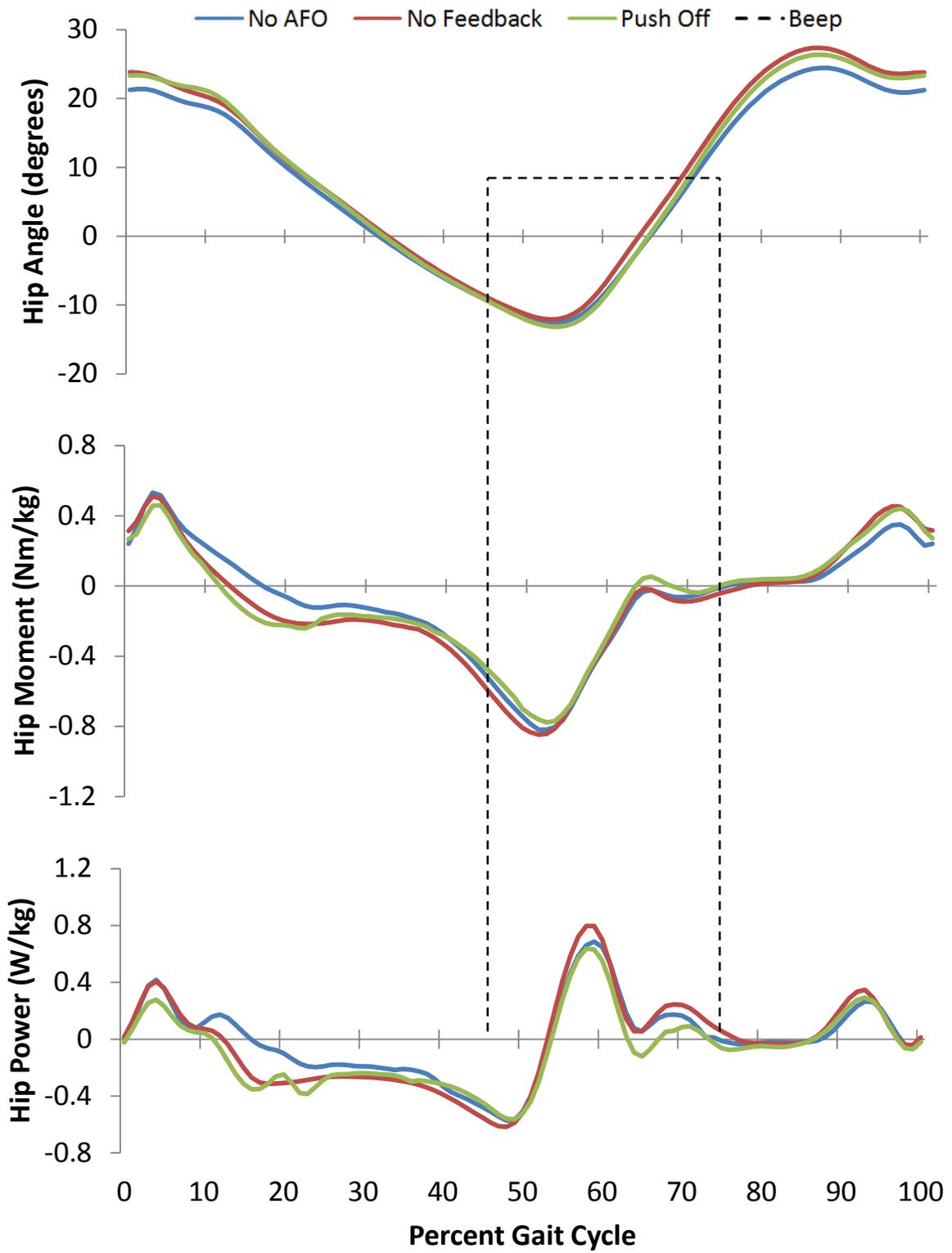
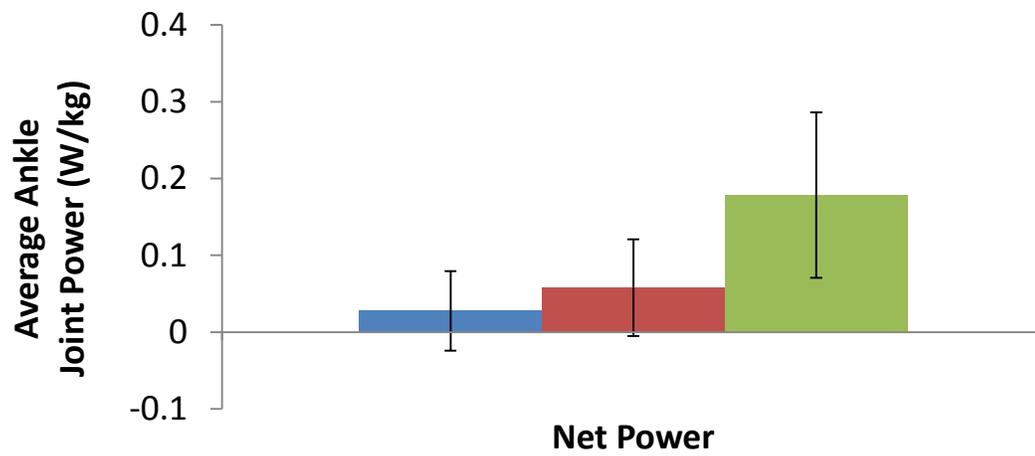
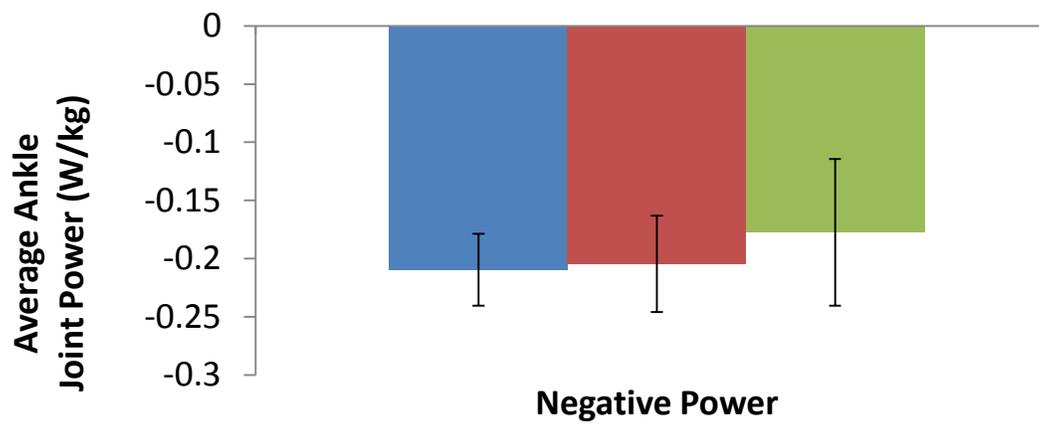
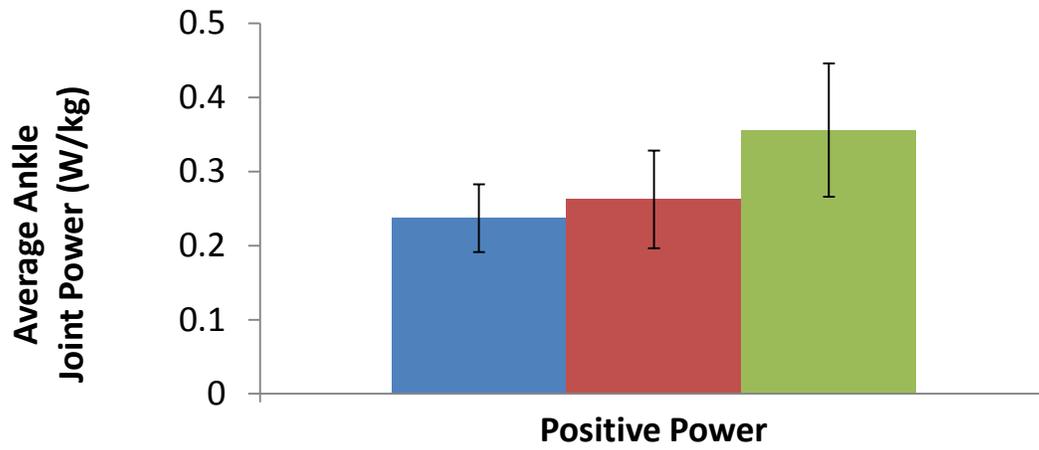


Figure 16: Average Positive, Negative, and Net Ankle Joint Powers

Average positive, negative, and net ankle joint powers (W/kg) for healthy participants walking at 1.25 m/s. Positive power (top panel), negative power (middle panel), and net power (bottom panel) are plotted below. The blue bar represents the participant walking normally with no AFO, the red bar represents the participant walking in the AFO with the biofeedback turned off, and the green bar represents the participant walking in the AFO with active biofeedback.



■ No AFO ■ No Feedback ■ Push Off

Figure 17: Average Positive, Negative and Net Knee Joint Powers

Average positive, negative, and net knee joint powers (W/kg) for healthy participants walking at 1.25 m/s. Positive power (top panel), negative power (middle panel), and net power (bottom panel) are plotted below. The blue bar represents the participant walking normally with no AFO, the red bar represents the participant walking in the AFO with the biofeedback turned off, and the green bar represents the participant walking in the AFO with active biofeedback.

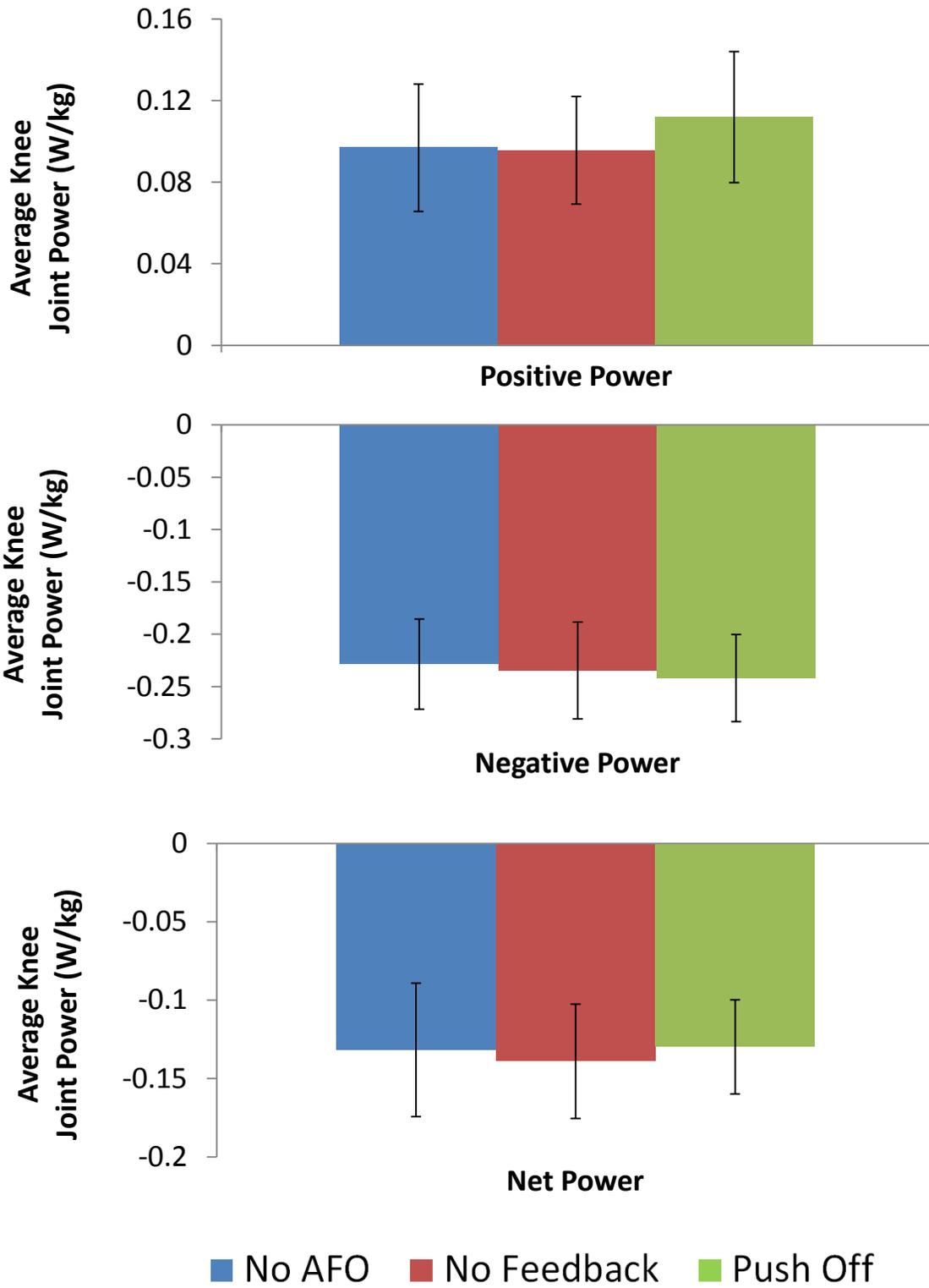
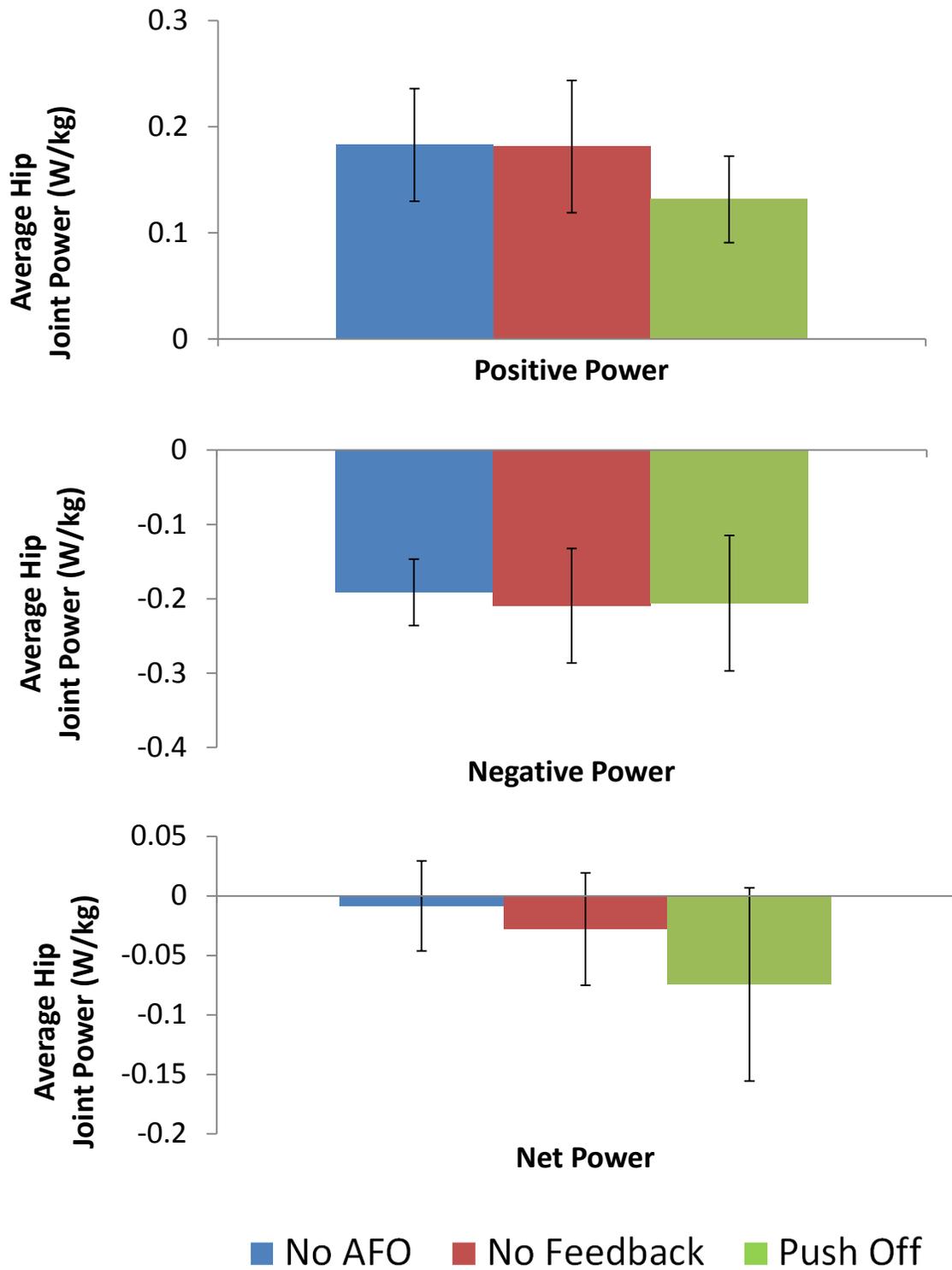


Figure 18: Average Positive, Negative, and Net Hip Joint Powers

Average positive, negative, and net hip joint powers (W/kg) for healthy participants walking at 1.25 m/s. Positive power (top panel), negative power (middle panel), and net power (bottom panel) are plotted below. The blue bar represents the participant walking normally with no AFO, the red bar represents the participant walking in the AFO with the biofeedback turned off, and the green bar represents the participant walking in the AFO with active biofeedback.

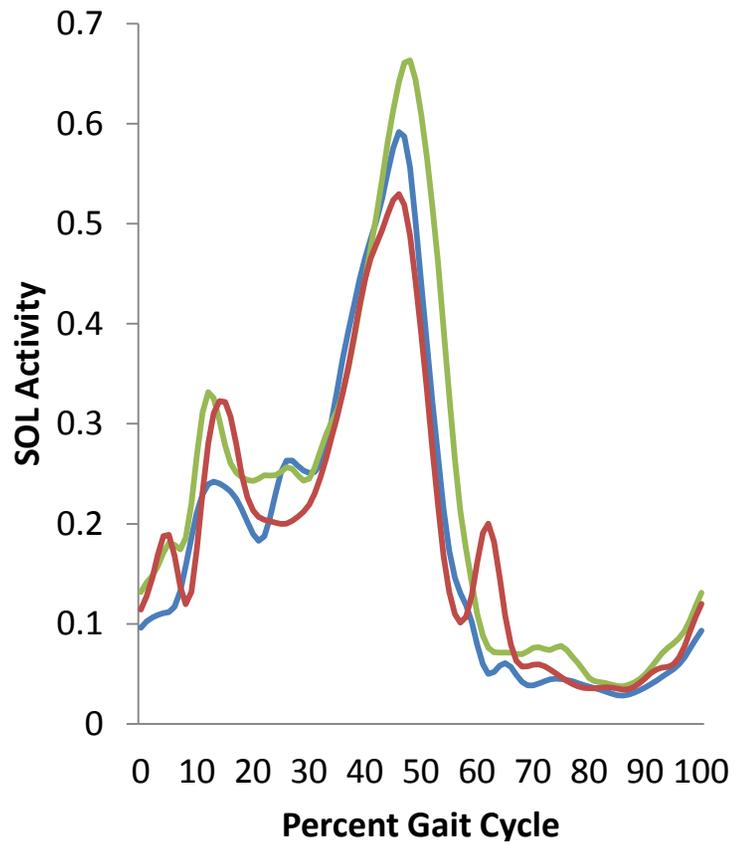


Electromyography

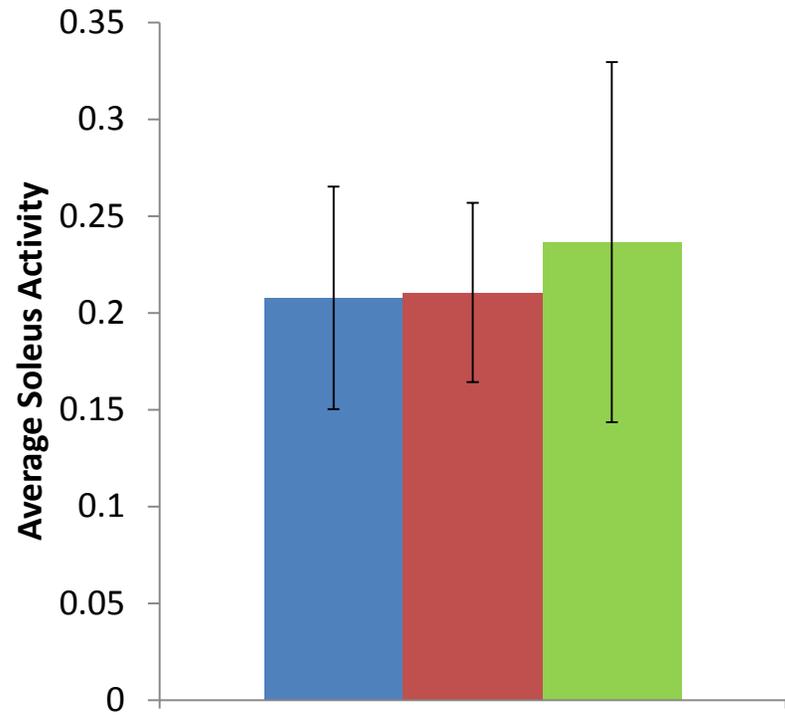
Electromyography (EMG) data was collected for this study during walking at 1.25 m/s. This was collected while the user was walking normally, while the user was walking with the AFO turned off, and then while the AFO was turned on and providing biofeedback. When biofeedback was provided and the user was attempting to push-off harder from the ground using their ankle muscles, increases in average soleus (SOL) muscle activity were seen (.21 vs. .23) (Figure 19) when comparing to the No AFO trials. No significant changes were seen when comparing SOL muscle activity between No AFO and AFO-No Biofeedback.

Figure 19: Average Soleus Muscle Activity

Average soleus (SOL) muscle activity plotted over a full stride from heel strike (0%) to heel strike (100%) (left panel) and average power plotted for each condition (right panel). The blue line/bar represents the participant walking normally with no AFO, the red line/bar represents the participant walking in the AFO with the biofeedback turned off, and the green line/bar represents the participant walking in the AFO with active biofeedback.



■ No AFO ■ No Feedback ■ Push Off

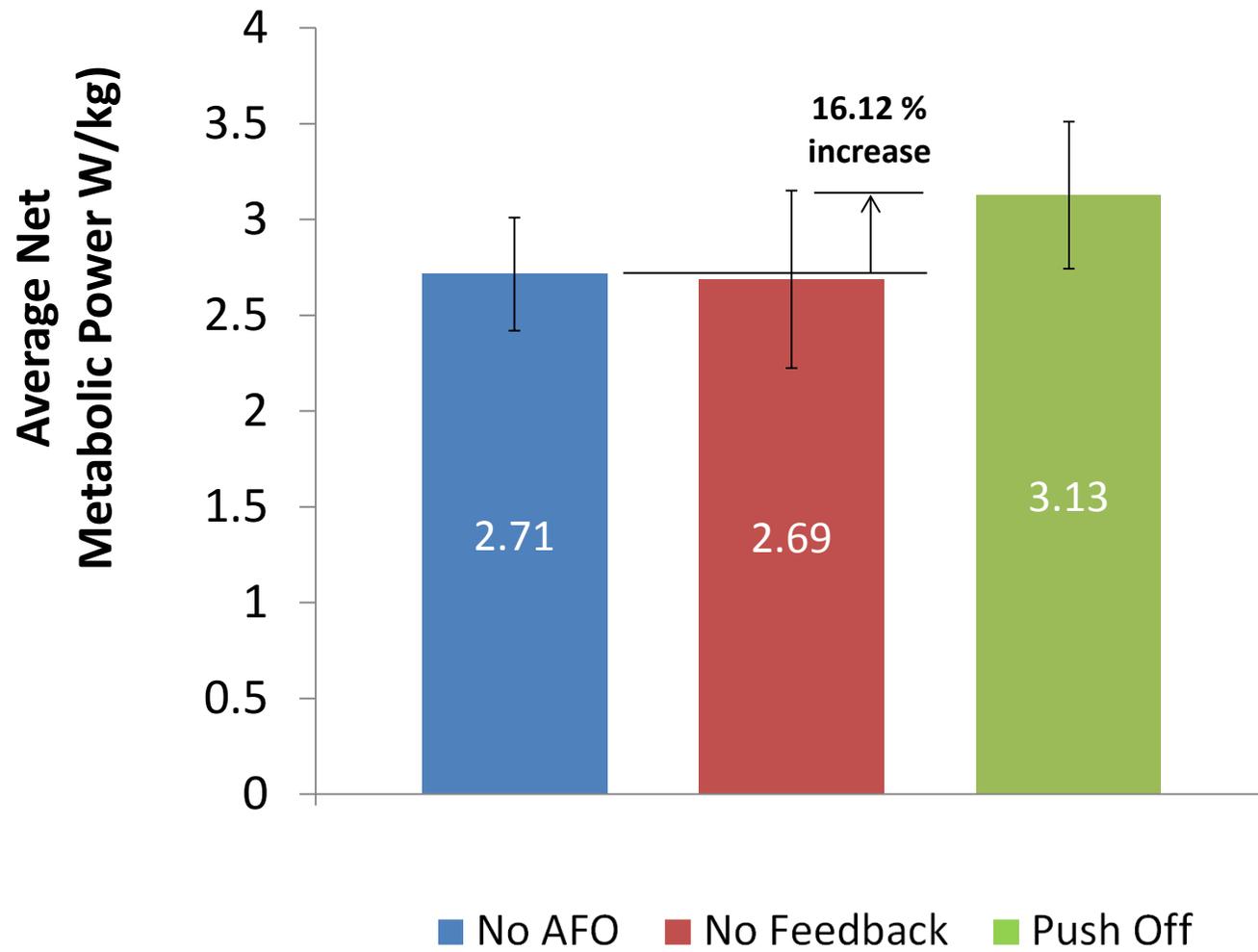


Net Metabolic Power and Efficiency

Net metabolic power (W/kg) for the participants was collected for this study during walking at 1.25 m/s. This was collected while the user was walking normally, while the user was walking with the AFO turned off, and then while the AFO was turned on and providing biofeedback. Each trial was collected for seven minutes and the averages of the last two minutes of walking are shown in Figure 20 below. After donning the AFO without turning the biofeedback on, there was a very slight decrease of -1.31% (2.71 W/kg vs. 2.69 W/kg) in net metabolic power, but not enough to be significant. After turning on the biofeedback and encouraging the participants to push-off harder from the ground using their ankle muscles, a significant average increase of 16.12% (2.71 W/kg vs. 3.13 W/kg) was recorded.

Figure 20: Net Metabolic Power

Net metabolic power (W/kg) for healthy participants (n=8) during walking at 1.25 m/s. The blue bar represents the participant walking normally with no AFO, the red bar represents the participant walking in the AFO with the biofeedback turned off, and the green bar represents the participant walking in the AFO with active biofeedback.



Discussion

The aim of this study was to develop a working Ankle Foot Orthosis (AFO) with a dynamic biofeedback mechanism to assist individuals with ankle propulsion deficiencies by indicating to the user the appropriate moment in the gait cycle to use their plantarflexor (i.e. push-off) muscles through auditory and vibratory cues. As a way to test the effectiveness of the AFO prior to collection on impaired populations, 8 healthy subjects (mean \pm s.d., age = 23.63 ± 3.29 years; mass = 74.72 ± 10.82 kg; height = $1.75 \pm .08$ m) were utilized for testing. When set to enhance ankle propulsion, the AFO emitted a vibration and a tone as a reminder of the appropriate time to activate their plantarflexor muscles, occurring just as the user's heel left the ground. The idea behind this device was to ask the user to rely solely on their own muscles, and by simply using biofeedback, attempted to proactively retrain the ankle muscles to work harder in the healthy population. By asking the user to utilize more ankle plantarflexor muscles, we hypothesized that when the vibrotactile biofeedback was turned on, users would exhibit significant increases in soleus activity and in positive ankle power output by compensating at other joint locations and using their plantarflexor muscles more. Additionally, we expected the metabolic cost of walking to increase as the user was walking in a manner that was unfamiliar to them.

In support of the hypothesis, significant increases in positive peak ankle power at push-off were observed while wearing the AFO with biofeedback, suggesting a higher burst of propulsive plantarflexor activity at that time [19]. In addition, an average increase of 9.68 degrees in plantarflexion was observed when utilizing the biofeedback. Restricted

plantarflexion range in older adults is often a factor in reduced propulsive mechanisms [31], making this a promising result for rehabilitation of impaired populations. By successfully producing more plantarflexed positions at push-off, in turn resulting in increased push-off power, we are hopeful that these results can be replicated in populations with decreased plantarflexor power.

Soleus EMG activity of the healthy controls was recorded for each trial of this study. While wearing the AFO with no feedback, increases in soleus activity were observed possibly due to the added stability given to the user while wearing it. Most AFOs decrease soleus activity by locking the ankle in a 90 degree position [32]; however the hinge joints utilized in our design have eliminated that problem. When comparing the user's soleus activity when walking with the biofeedback to that of normal walking, increases in soleus activity were also seen, though not to the extent of trials with the feedback turned off. This suggests that when the user was attempting to push-off harder with the timing of the biofeedback, they were using some increased muscle activity, but compensations at other joints were large factors in the observed increased ankle power.

Compensations at both the knee and hip joints were observed when the user was attempting to push-off harder. We saw slight decreases in peak knee flexion during swing, indicating that the user was walking with a straighter leg than without the biofeedback. Additionally, increased extensor moments in mid stance were exhibited, attributing to increased stability during stance before push-off [21]. This increased stability also attributed to increased negative power absorption at the knee prior to push-off. Changes observed at the

hip were more substantial, as significant losses in power generation of the hip during transition from loading response to mid stance were seen. Furthermore, losses in bursts of power generation occurred in the hip joint as weight was shifting to the opposite limb. In a healthy population, limb advancement is sometimes passive as a result of the ankle's propulsive mechanics [21], therefore these compensations indicate that the user was essentially downgrading power generation in the hip joint, causing passive limb advancement and redistributing that power to be focused at the ankle joint.

Metabolic energy expenditure was measured across each trial in order to determine the cost of walking in the vibrotactile AFO, both with and without biofeedback, just as it was in Chapter 1 of this report. Just as the foot drop study reported, an average decrease of 1.31% in metabolic cost was seen after donning the AFO with no feedback due to the transparency of the brace and added stability in the frontal plane [22]. With the biofeedback turned on and the users pushing off at the timing of the beep/vibration, an average increase in metabolic cost of 16.12% was seen. This supports our hypothesis as we expected the cost of walking to increase while in an unfamiliar position, as enforced gait patterns can elicit substantially higher metabolic energy cost [22], though we are hopeful that with continued training this percentage can be lowered.

The same questions from the foot drop study of this paper arise for the push-off condition as well, though our same arguments remain true. We feel that giving the user a vibration/beep just before push-off serves as an external biofeedback source, rather than asking the user to simply push off harder (internal biofeedback), making this a more effective

method of training [23]. Furthermore, we believe that the modality of the biofeedback is appropriate, as additions of other types of feedback could be too cognitively demanding [25], and asking to change more than one gait parameter could be detrimental to productive relearning [7].

While these results are promising, there is the question of how these results may differ for someone who has deficits in propulsive power while walking. Franz et al.'s study of biofeedback in older adults found that propulsive forces and push-off muscle activity can be improved in older adults when provided feedback [30], giving hope to our study that an impaired population can emulate some of the results seen here. By providing the user the correct timing to push-off within each step, we hope that they will be able to improve plantarflexor mechanisms, reducing the metabolic cost of walking. The data from this study of healthy controls helps to lay the groundwork for further testing on a population that suffers from foot drop in order to determine if our assumptions are correct. In the Appendix of this report, we have included pilot data from one stroke survivor walking in the biofeedback AFO that shows similar trends to that of the healthy subjects in this report. While the user was wearing the AFO and attempting to push-off with the timing of the biofeedback, she exhibited increases in plantarflexor muscle activity (Figure 21), increases in plantarflexion (Figure 22) and propulsive ankle power (Figure 22), as well as lowered metabolic cost of walking (Figure 28). Data from other joints and the non-paretic limb is provided as well, in order to look for other compensations that may have caused this decrease in metabolic cost. As it is only one participant, there is no statistical evidence to support the data, therefore additional testing of impaired populations is necessary.

Conclusion

In this study, we analyzed the effects of a vibrotactile biofeedback ankle foot orthosis to help assist push-off during walking through the use of healthy controls to test the functionality of the biofeedback. We found that when the biofeedback was set to convey the appropriate moment to utilize plantarflexor muscles, propulsive ankle power and plantarflexion was increased due to increases in soleus muscle activity and decreases in overall hip power output. However, as these compensations to push-off harder were unfamiliar to the users, increased metabolic demand was observed. Further testing is necessary to determine if continued wear of the AFO and practice with the biofeedback could eliminate some of these compensations. Furthermore, testing of the AFO in a population that suffers from propulsion deficiencies is necessary to see its full potential as a rehabilitation aid.

Overall Discussion and Conclusions

Overall, the goals of this study were to investigate the capability of a vibrotactile biofeedback Ankle Foot Orthosis (AFO) to help those with neuromuscular impairments related to foot drop or propulsion deficiencies at the ankle. For the first framework of foot drop prevention, healthy controls were provided with biofeedback in the form of a vibration and tone if they dropped their toe past 5 degrees of plantarflexion. In order to avoid the beep and vibration while walking, the user had to lift their toe more than normally comfortable,

resulting in increased tibialis anterior muscle activity and dorsiflexion of the ankle during the swing phase of gait. However compensations such as decreased ankle power and increased hip power to achieve these results lead us to believe that this type of rehabilitation will be best served for those who suffer from foot drop not accompanied with other neuromuscular impairments. For example, users who also have impairments such as propulsion deficits accompanied with foot drop (i.e. stroke survivors) will continue to have these propulsive deficits if only focusing on keeping their toe lifted. Instead, populations similar to that of stroke survivors should focus more on knee flexion to achieve toe clearance, while populations with injuries causing foot drop without other added deficiencies could benefit from wearing this AFO by strengthening their tibialis anterior muscle and increasing ankle dorsiflexion.

In the second framework of propulsion deficiencies at the ankle, healthy controls were provided with a vibration and tone at the moment before push-off to indicate the appropriate moment to utilize their plantarflexor muscles. They were asked to time their push-off at the moment of the beep/vibration and at that moment, attempt to push-off harder from the ground than they normally would. In doing so, increases in propulsive ankle power and soleus muscle activity were observed as well as decreases in peak hip power, indicating that users could recruit ankle push-off power for limb advancement that they were not already using by downgrading power at the hip. If an impaired population, such as those with hemiparesis following stroke can attempt to replicate these results, we are hopeful that gait symmetry could be restored, and quality of life improved. Furthermore, if a user with both

propulsive deficits and foot drop were to utilize this AFO, both push-off power and problems with toe clearance from foot drop can hope to be restored, as studies have shown that increased push-off can lead to greater knee flexion and toe clearance [27].

Both of these frameworks show promise to help those with impairments while walking, however there remain many unanswered questions due to the limitations of this study. The first is to address the actual need for the AFO. As the novelty of this rehabilitation lies in the biofeedback, it is not necessary that the beep and vibration come in the form of an AFO. While this AFO is extremely lightweight and nearly transparent to the user, it still may be beneficial to instead detect ankle angle and foot pressures through small sensors imbedded into fabric, rather than bracing both the ankle and calf. Though with the minimal decrease in metabolic cost while wearing the AFO with no biofeedback, we believe the added stability in the frontal plane may be beneficial to impaired populations, though further studies are necessary to confirm this.

Another limitation to this study is the inability to determine whether users were making changes in their gait within each step, or if they were using the biofeedback to change their entire gait pattern as a whole. Further studies could answer this question by taking the biofeedback away within trials, and seeing if the changes in their gait patterns hold true without it. For the foot drop condition, we believe that users would not keep their toe as lifted without the biofeedback from the AFO. However for the push-off condition, there is a possibility that simply telling the user to push-off harder will make them continue the pattern, even without the biofeedback. However, without the constant reminder, ankle power would

likely return to normal, though further testing is necessary to confirm this assumption. The lack of continued wear of the AFO in this study is also a limitation that must also be addressed in further studies. We do not know the long term effects of wearing this vibrotactile AFO, however we strongly believe that it is with continued use that the effects will be best utilized for both foot drop and propulsion deficits.

Future studies should also look into the possibilities of hybrid approaches of assistance and biofeedback together. With the knowledge that ankle exoskeletons can assist push-off power [29] and the promising effects of biofeedback shown in this study, it is possible that a combination of the two could be most beneficial. Studies should provide assistance in dorsiflexion for those with foot drop while also providing real time biofeedback of their ankle position, slowly downgrading each with continued wear to see the long term effects. For users with propulsive deficits, plantarflexion assistance should be provided while also using biofeedback to indicate the appropriate moment to push-off harder. Much as before, downgrading the assistance and biofeedback can show the long term results of such a study. In addition, the effects of wearing this AFO could prove beneficial to aging population who do not yet have gait impairments. By using this AFO as a preventative measure, rather than waiting for a problem to occur, perhaps older adults can maintain their muscle function longer.

In conclusion, we believe this report lays the groundwork for future testing on a vibrotactile biofeedback AFO to prevent foot drop and assist push-off in impaired populations. This work could bring insight to the rehabilitation field through biofeedback if it

is found through further testing that impaired populations can recruit muscle activity that they are not using on a daily basis.

References

- [1] Langlois JA, *et al.*, Characteristics of older pedestrians who have difficulty crossing the street. *American Journal of Public Health*. 1997; 3: 393-397.
- [2] Sawicki GS, Lewis CL, Ferris DP. It pays to have a spring in your step. *Exercise and sport sciences reviews*. 2009; 37(3):130.
- [3] Stanton R, Ada L, Dean CM, & Preston E, Biofeedback improves activities of the lower limb after stroke: A systematic review. *Journal of Physiotherapy*. 2011; 57: 145-156.
- [4] Tate JJ, Milner CE, Real-Time Kinematic, Temporospacial, and Kinetic Biofeedback During Gait Retraining in Patients: A Systematic Review. *Physical Therapy*. 2010; 90: 1123-1134.
- [5] De Nunzio AM *et al.*, Alternate rhythmic vibratory stimulation of trunk muscles affects walking cadence and velocity in parkinson's disease. *Clinical Neurophysiology*. 2010; 121(2): 240-247.
- [6] Del Olmo MF, & Cudeiro J, Temporal variability of gait in parkinson disease: Effects of a rehabilitation programme based on rhythmic sound cues. *Parkinsonism & Related Disorders*. 2004; 11(1): 25-33.
- [7] Shull P, *et al.*, Quantified Self and Human Movement: A review on the clinical impact of wearable sensing and feedback for gait analysis and intervention. *Gait and Posture*. 2013; 40(1): 11-19.

- [8] Intiso D, Rehabilitation of Walking with Electromyographic Biofeedback in Foot-Drop After Stroke. *Stroke*. 1994, 25: 1189-1192.
- [9] Moreland J, & Thomson MA, Efficacy of electromyographic biofeedback compared with conventional physical therapy for upper-extremity function in patients following stroke: A research overview and meta-analysis. *Physical Therapy*. 2014; 74: 534-543.
- [10] Kuo AD, Donelan JM, Ruina A, Energetic consequences of walking like an inverted pendulum: Step-to-step transitions. *Exerc Sport Sci Rev*. 2005; 33: 88-97
- [11] Kesar T *et al.*, Functional Electrical Stimulation of Ankle Plantarflexor and Dorsiflexor Muscles: Effects on Poststroke Gait. *Stroke*. 2009; 40(12): 3821-3827.
- [12] Swigchem R, *et al.*, Effect of Peroneal Electrical Stimulation Versus an Ankle-Foot Orthosis on Obstacle Avoidance Ability in People with Stroke-Related Foot Drop. *Physical Therapy*. 2012; 92: 398-406.
- [13] Bregman DJ, Spring-like Ankle Foot Orthoses reduce the energy cost of walking by taking over ankle work. *Gait Posture*. 2012; 35: 148-153.
- [14] Vinci P, & Perelli S, Footdrop, foot rotation, and plantarflexor failure in charcot-marie-tooth disease. *Archives of Physical Medicine and Rehabilitation*. 2002; 83: 513-516.
- [15] Farris DJ, Sawicki GS. The mechanics and energetics of human walking and running: A joint level perspective. *J R Soc Interface*. 2012; 9: 110-118

- [16] Brockway JM. Derivation of formulae used to calculate energy expenditure in man. *Hum Nutr Clin Nutr.* 1987; 41: 463-471
- [17] Qaqish J, *et al.*, Foot Type and Tibialis Anterior Muscle Activity during Stance Phase of Gait. *International Journal of Physiotherapy and Rehabilitation.*, 2013; 1(1): 19-29.
- [18] Shultz BW, Lloyd, JD, Lee WE, The effects of everyday concurrent tasks on overground minimum toe clearance and gait parameters. *Gait & Posture.* 2010; 32: 18-22.
- [19] Thompson D, Energy and Power During the Gait Cycle. Available from the Internet: <<http://moon.ouhsc.edu/dthomps/gait/epow/pow1.htm>>
- [20] Nair P, *et al.*, Stepping with an ankle foot orthosis re-examined: A mechanical perspective for clinical decision making. *Clinical Biomechanics.* 2010; 25: 618-622.
- [21] Perry J, and Burnfield JM, "Hip." *Gait Analysis: Normal and Pathological Functions.* SLACK Inc, 2010; 103-119.
- [22] Wezenberg D, De Haan A, Van Bennekhom CAM, & Houdijk H, Mind your step: Metabolic energy cost while walking an enforced gait pattern. *Gait & Posture.* 2011; 33: 544-549.
- [23] Shea CH, & Wulf G, Enhancing motor learning through external-focus instructions and feedback. *Human Movement Science,* 1999; 18: 553-571.

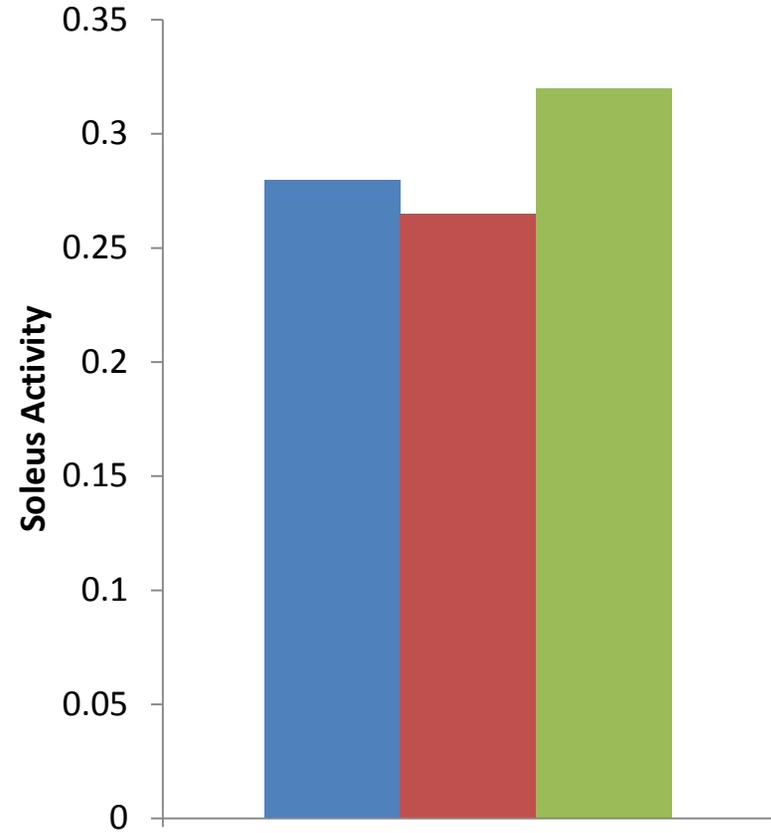
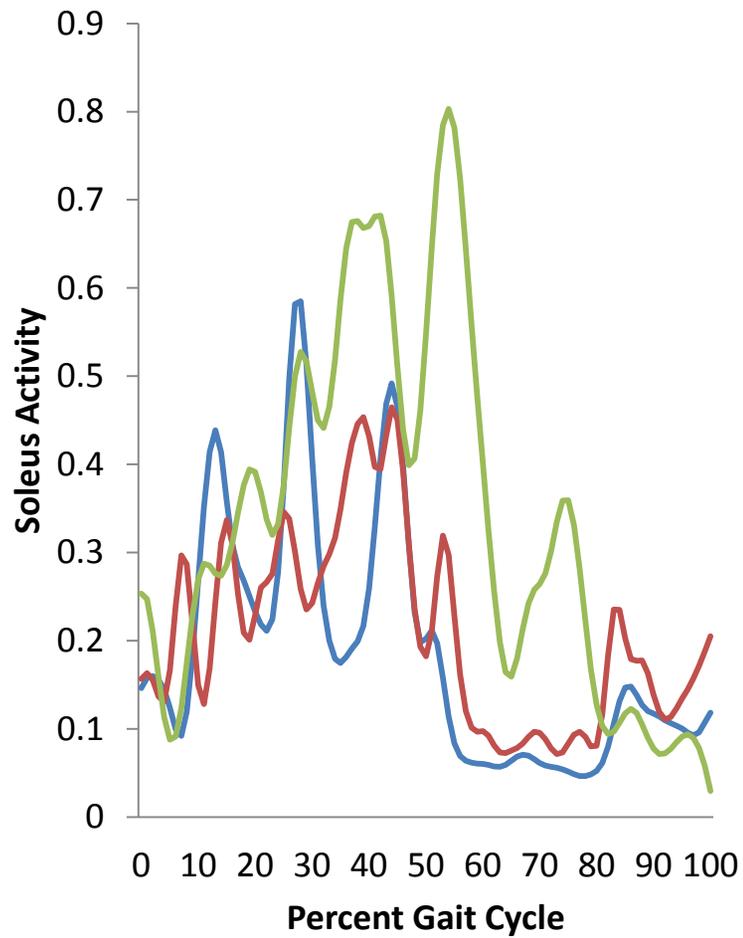
- [24] Joe J, & Demiris ,. Older adults and mobile phones for health: A review. *Journal of Biomedical Informatics*. 2013; 46: 947-954.
- [25] Haggerty S, Jiang L, Galecki A, & Sienko K, Effects of biofeedback on secondary-task response time and postural stability in older adults. *Gait & Posture*. 2012; 35: 523-528.
- [26] Sutherland DH, Davids JR, Common gait abnormalities of the knee in cerebral palsy. *Clinical Orthopaedics*. 1993; 288: 139–147.
- [27] Little VL, McGuirk TE, & Patten C, Impaired limb shortening following stroke: What’s in a name? *PLoS ONE*. 2014 9(10).
- [28] Greene PJ, & Granat MH, The effects of knee and ankle flexion on ground clearance in paraplegic gait. *Clinical Biomedhanics*. 2000; 15: 536-540.
- [29] Malcolm P, Derave W, Galle S, De Clercq D, A Simple Exoskeleton That Assists Plantarflexion Can Reduce the Metabolic Cost of Human Walking. *PLoS ONE*. 2013; 8(2).
- [30] Franz JR, Maletis M, & Kram R, Real-time feedback enhances forward propulsion during walking in old adults. *Clinical Biomechanics*. 2014; 29: 68-74.
- [31] Kerrigan DC, *et al.*, Biomechanical gait alterations independent of speed in the healthy elderly: Evidence for specific limiting impairments. *Archives of Physical Medicine and Rehabilitation*, 79, 317-322.

- [32] Geboers JF *et al.*, Immediate and long-term effects of ankle-foot orthosis on muscle activity during walking: A randomized study of patients with unilateral foot drop. *Archives of Physical Medicine and Rehabilitation*. 2002; 83: 240-245.

Appendix

Figure 21: Paretic Limb Soleus Activity of Stroke Survivor

Soleus (SOL) muscle activity of the paretic limb of a stroke survivor walking at 0.7 m/s plotted over a full stride from heel strike (0%) to heel strike (100%) (left panel) and average power plotted for each condition (right panel). The blue line/bar represents the participant walking normally with no AFO, the red line/bar represents the participant walking in the AFO with the biofeedback turned off, and the green line/bar represents the participant walking in the AFO with active biofeedback.



■ No AFO ■ No Feedback ■ Push Off

Figure 22: Paretic Limb Ankle Joint Angles, Moments, and Powers of Stroke Survivor

Ankle joint angles (degrees), moments (Nm/kg), and powers (W/kg) of the paretic limb of a stroke survivor walking at 0.7 m/s. Ankle angle (top panel), ankle moment (middle panel) and ankle power (bottom panel) are plotted over a stride from heel strike (0%) to heel strike (100%) of the same limb. The blue line represents the participant walking normally with no AFO, the red line represents the participant walking in the AFO with the biofeedback turned off, the green line represents the participant walking in the AFO with active biofeedback, and the dashed black line represents the timing of the biofeedback “beep” during walking.

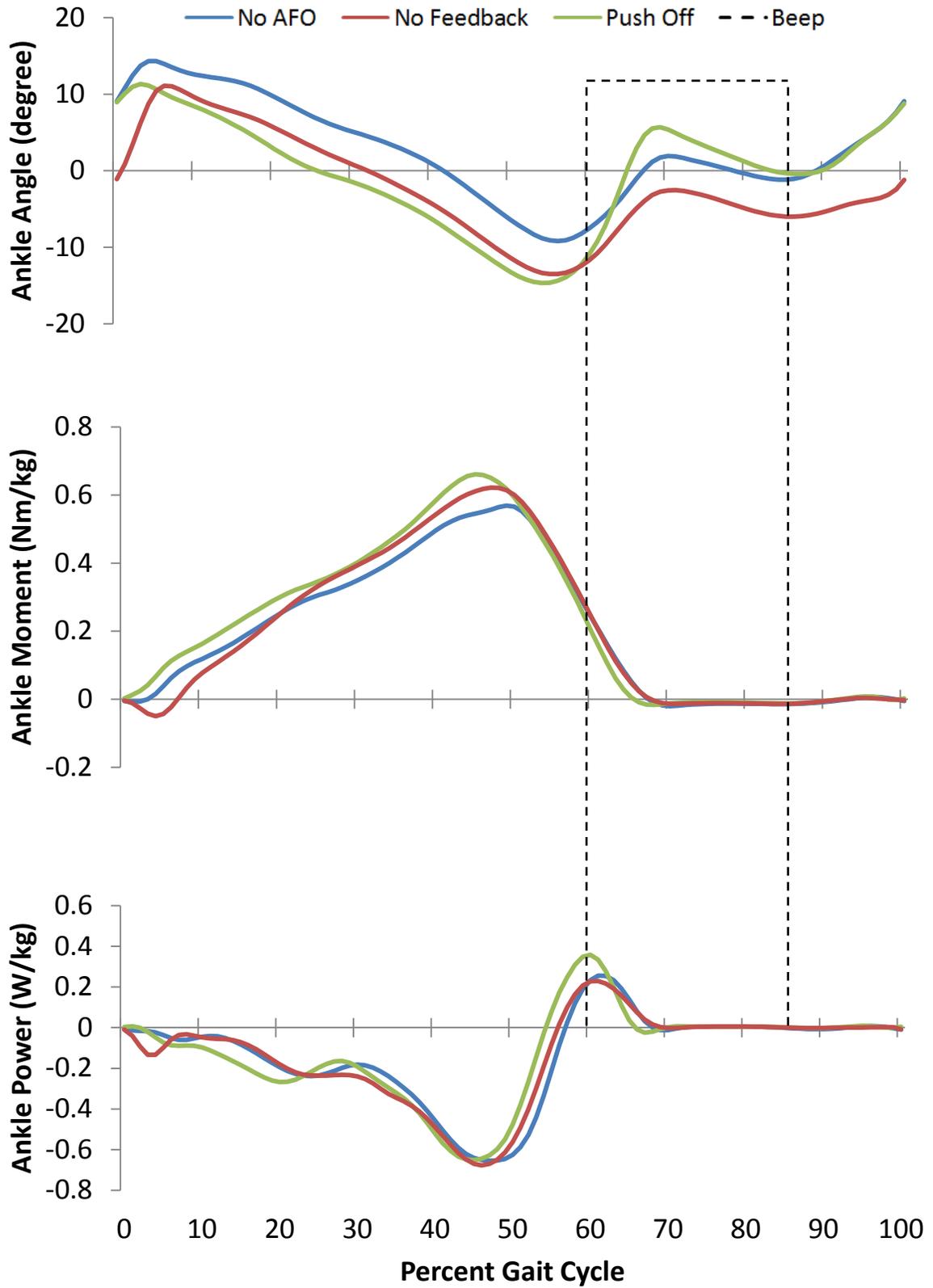
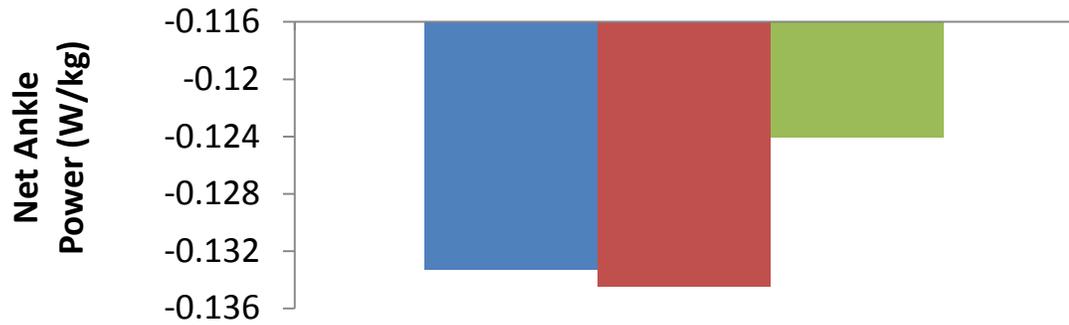
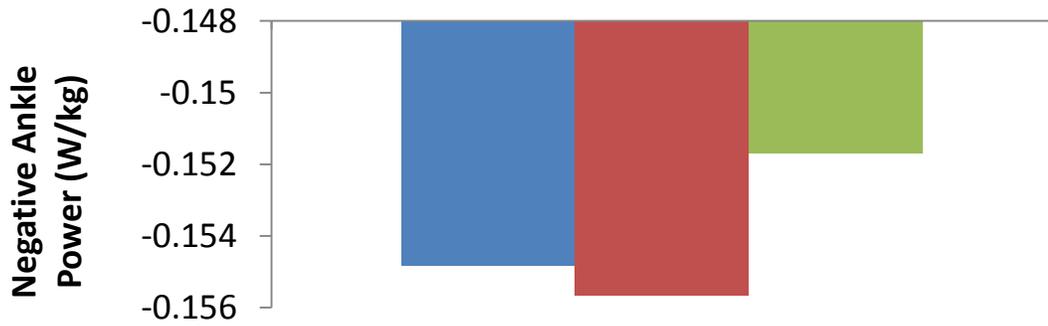
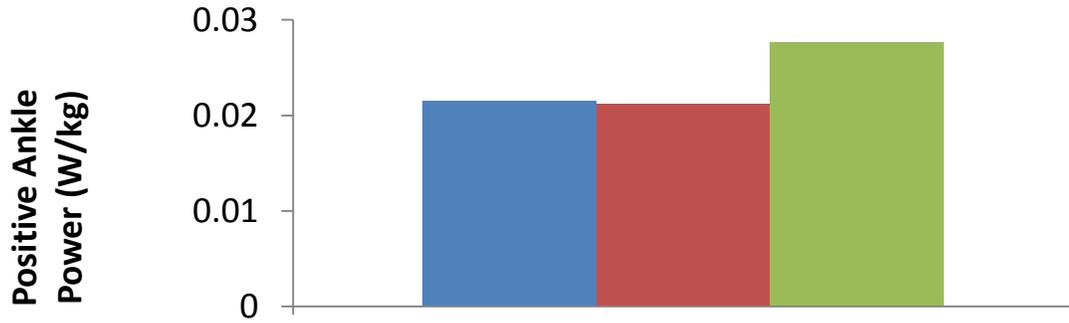


Figure 23: Paretic Limb Positive, Negative, and Net Ankle Joint Powers of Stroke Survivor

Average positive, negative, and net ankle joint powers (W/kg) of the paretic limb of a stroke survivor walking at 0.7 m/s. Positive power (top panel), negative power (middle panel), and net power (bottom panel) are plotted below. The blue bar represents the participant walking normally with no AFO, the red bar represents the participant walking in the AFO with the biofeedback turned off, and the green bar represents the participant walking in the AFO with active biofeedback.



■ No AFO ■ No Feedback ■ Push Off

Figure 24: Paretic Limb Knee Joint Angles, Moments, and Powers for Stroke Survivor

Knee joint angles (degrees), moments (Nm/kg), and powers (W/kg) of the paretic limb of a stroke survivor walking at 0.7 m/s. Knee angle (top panel), knee moment (middle panel) and knee power (bottom panel) are plotted over a stride from heel strike (0%) to heel strike (100%) of the same limb. The blue line represents the participant walking normally with no AFO, the red line represents the participant walking in the AFO with the biofeedback turned off, the green line represents the participant walking in the AFO with active biofeedback, and the dashed black line represents the timing of the biofeedback “beep” during walking.

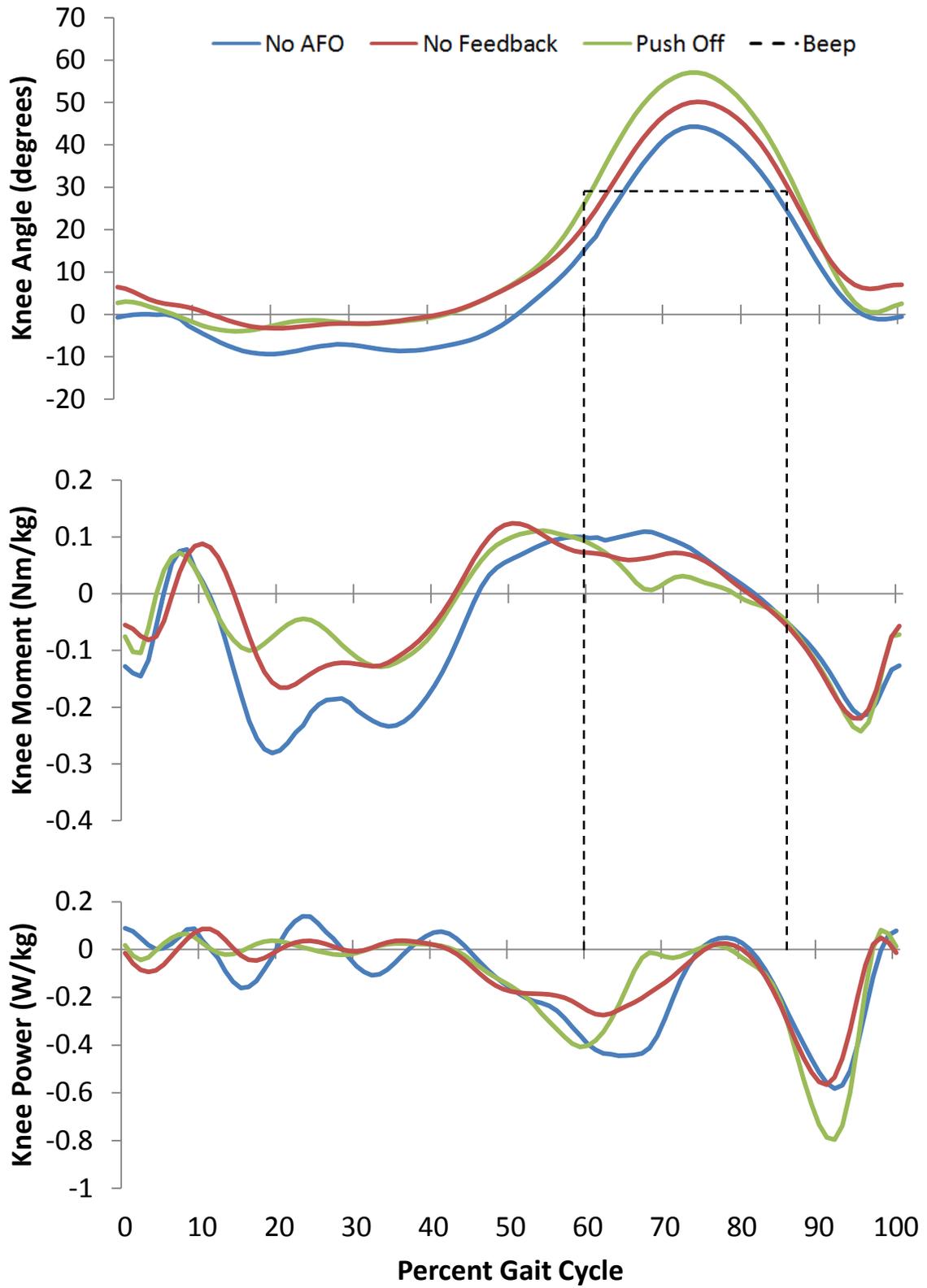


Figure 25: Paretic Limb Positive, Negative, and Net Knee Joint Powers of Stroke Survivor

Average positive, negative, and net knee joint powers (W/kg) of the paretic limb of a stroke survivor walking at 0.7 m/s. Positive power (top panel), negative power (middle panel), and net power (bottom panel) are plotted below. The blue bar represents the participant walking normally with no AFO, the red bar represents the participant walking in the AFO with the biofeedback turned off, and the green bar represents the participant walking in the AFO with active biofeedback.

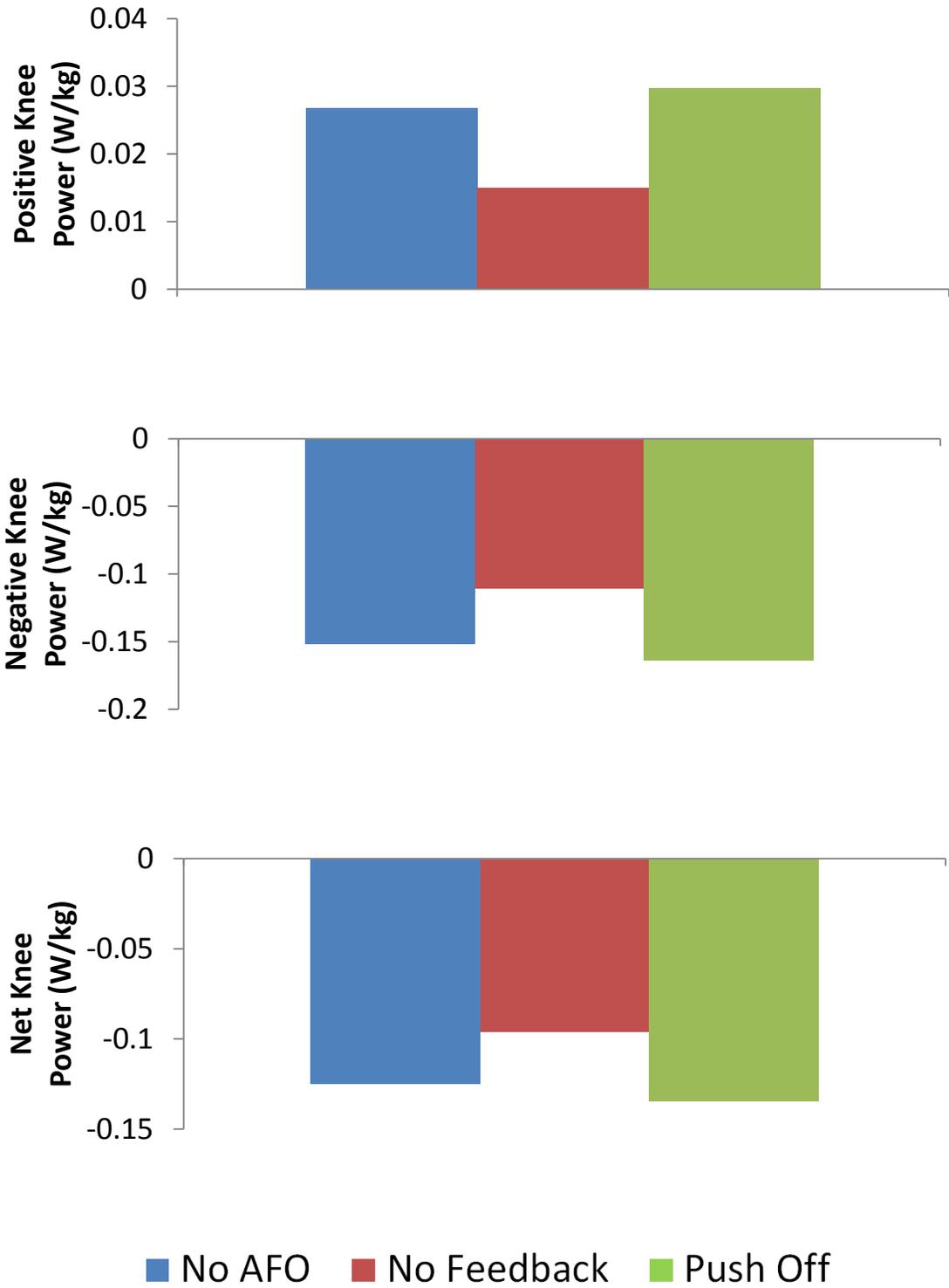


Figure 26: Paretic Limb Hip Joint Angles, Moments, and Powers for Stroke Survivor

Hip joint angles (degrees), moments (Nm/kg), and powers (W/kg) for the paretic limb of a stroke survivor during walking at 0.7 m/s. Hip angle (top panel), hip moment (middle panel) and hip power (bottom panel) are plotted over a stride from heel strike (0%) to heel strike (100%) of the same limb. The blue line represents the participant walking normally with no AFO, the red line represents the participant walking in the AFO with the biofeedback turned off, the green line represents the participant walking in the AFO with active biofeedback, and the dashed black line represents the timing of the biofeedback “beep” during walking.

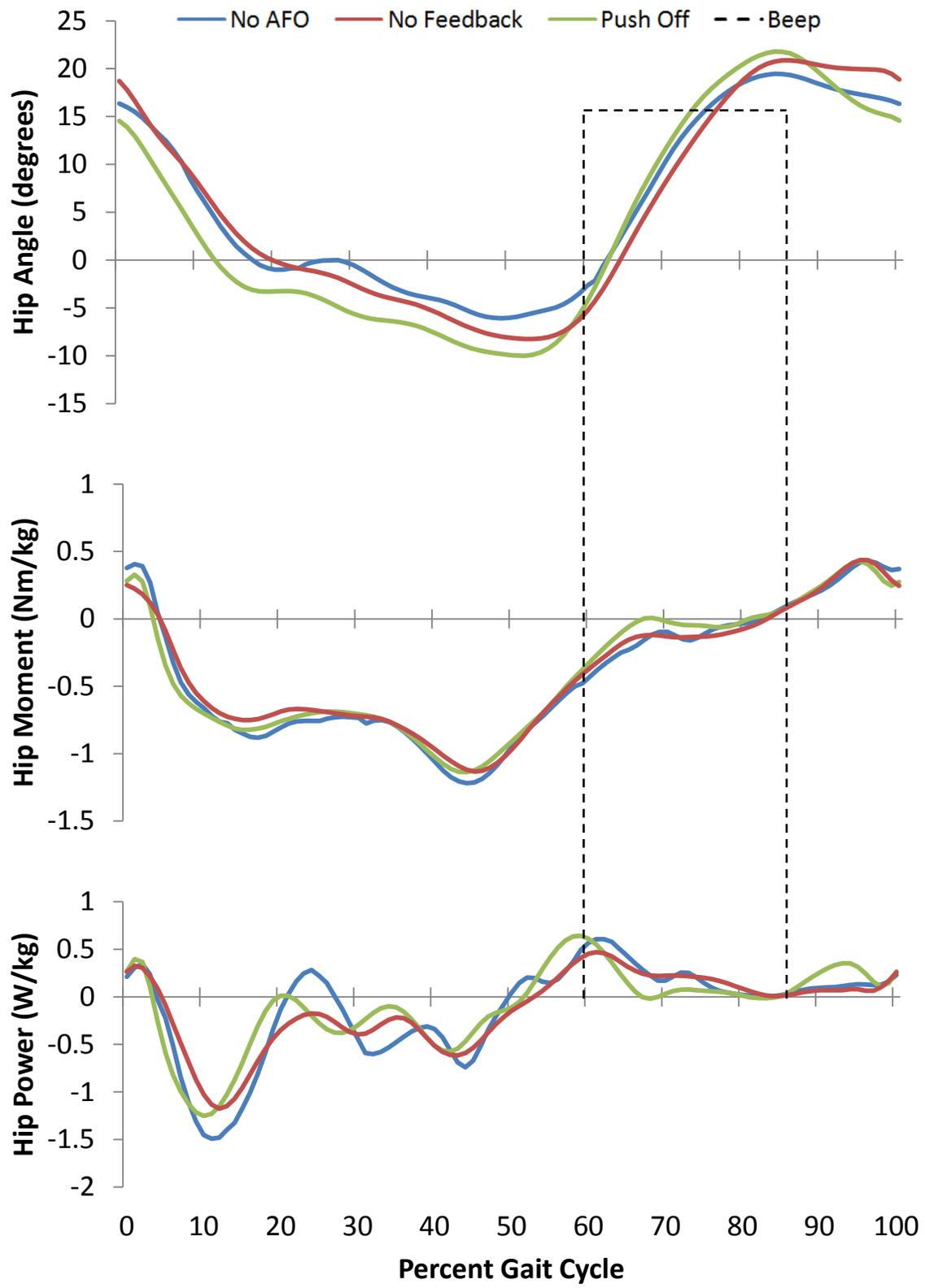
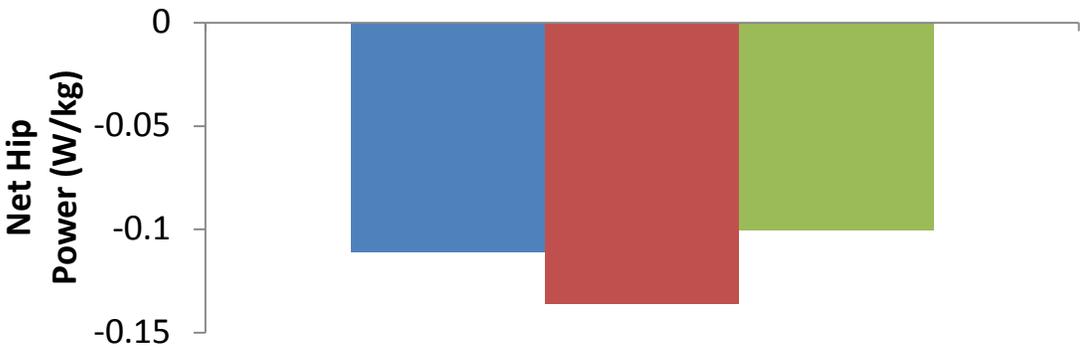
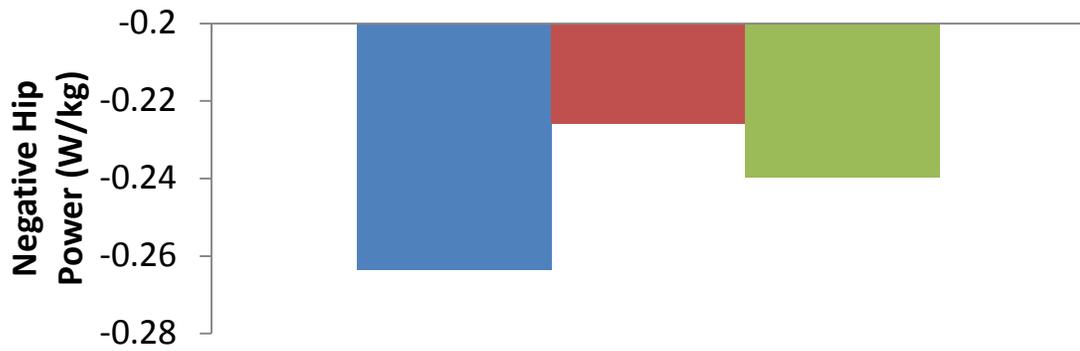
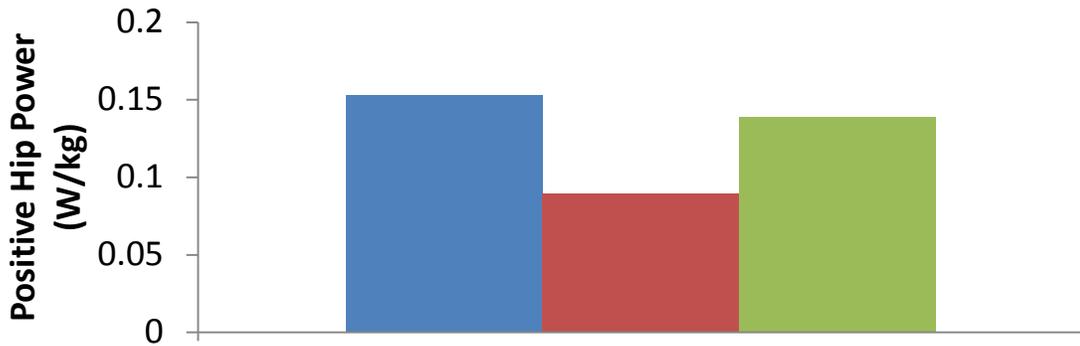


Figure 27: Paretic Limb Positive, Negative, and Net Hip Joint Powers of Stroke Survivor

Average positive, negative, and net hip joint powers (W/kg) for the paretic limb of a stroke survivor walking at 0.7 m/s. Positive power (top panel), negative power (middle panel), and net power (bottom panel) are plotted below. The blue bar represents the participant walking normally with no AFO, the red bar represents the participant walking in the AFO with the biofeedback turned off, and the green bar represents the participant walking in the AFO with active biofeedback.



■ No AFO
 ■ No Feedback
 ■ Push Off

Figure 28: Net Metabolic Power of Stroke Survivor

Net metabolic power (W/kg) for a stroke survivor during walking at 0.7 m/s. The grey bar represents the participant walking normally with no AFO, the black bar represents the participant walking in the AFO with the biofeedback turned off, and the red bar represents the participant walking in the AFO with active biofeedback.

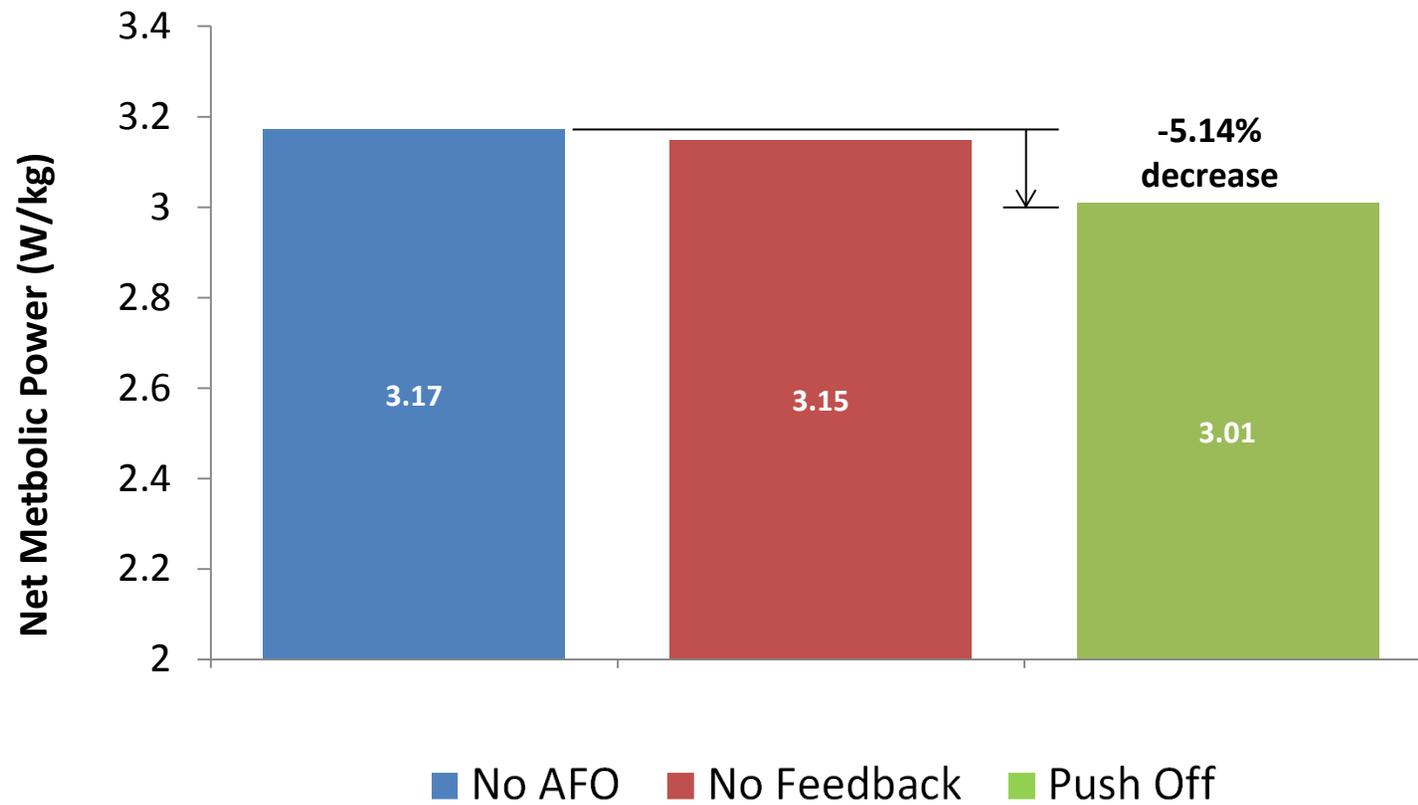


Figure 29: Non-paretic Limb Ankle Joint Angles, Moments, and Powers for Stroke Survivor

Ankle joint angles (degrees), moments (Nm/kg), and powers (W/kg) for the non-paretic limb of a stroke survivor during walking at 0.7 m/s. Ankle angle (top panel), ankle moment (middle panel) and ankle power (bottom panel) are plotted over a stride from heel strike (0%) to heel strike (100%) of the same limb. The blue line represents the participant walking normally with no AFO, the red line represents the participant walking in the AFO with the biofeedback turned off, and the green line represents the participant walking in the AFO with active biofeedback.

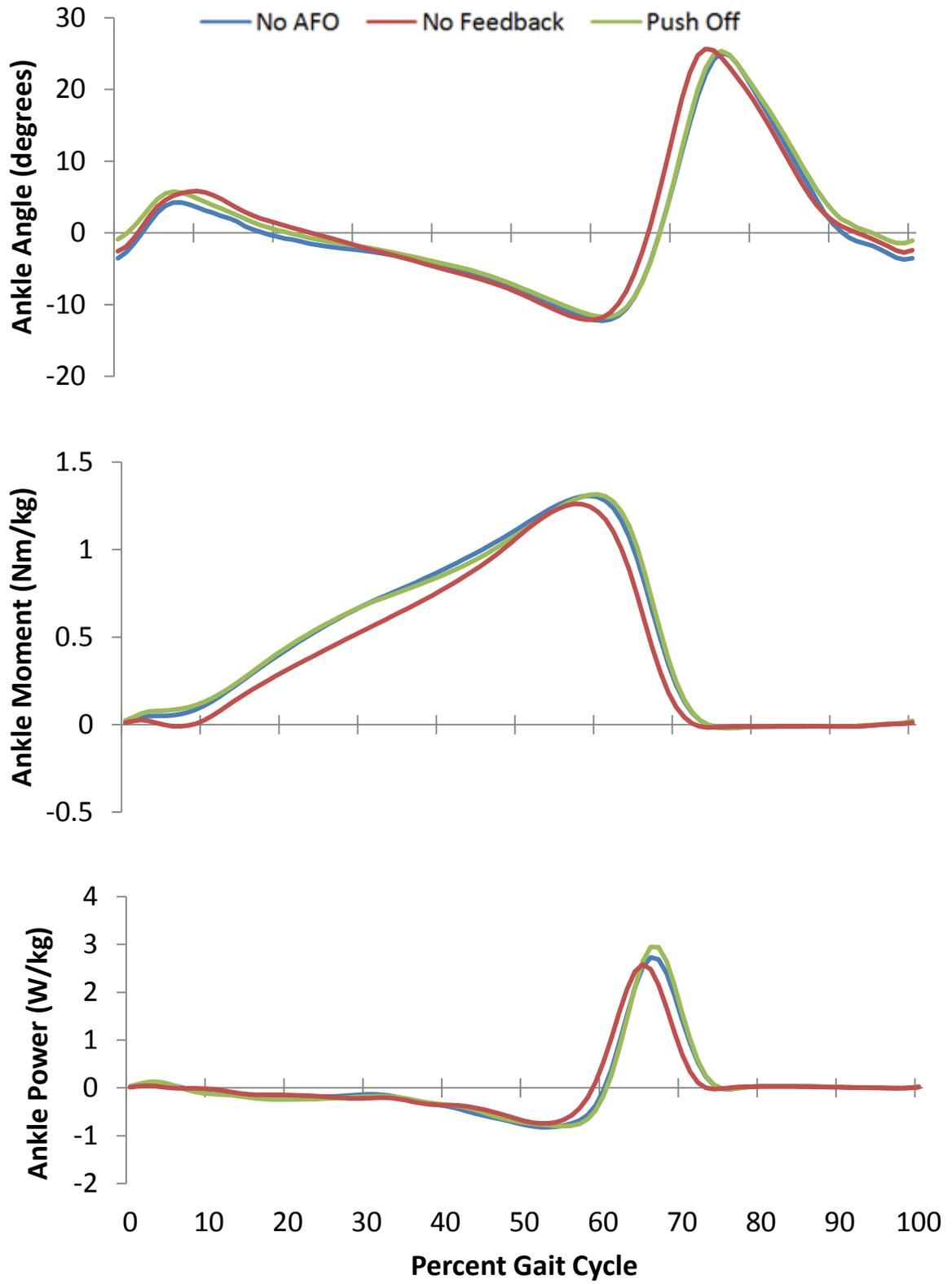
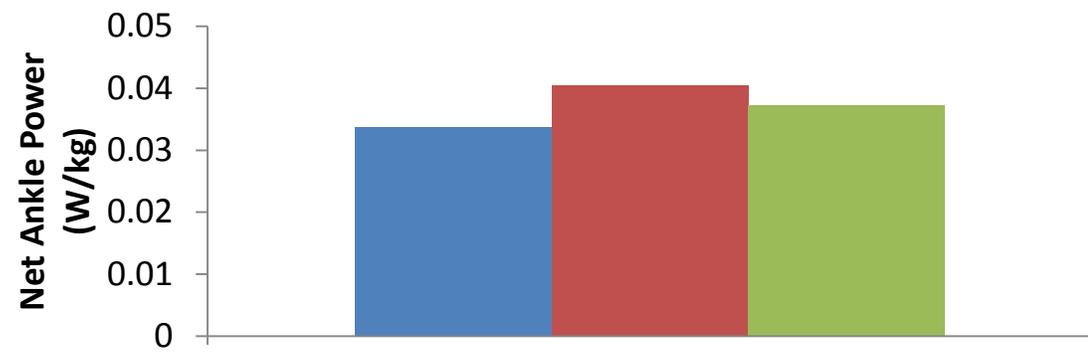
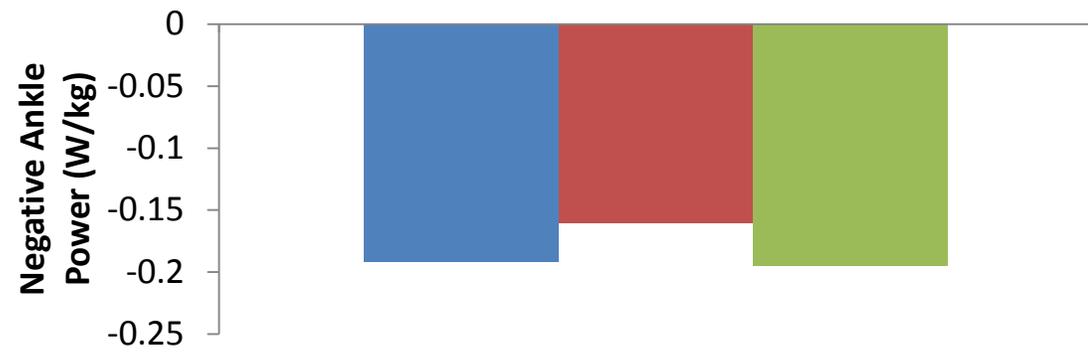
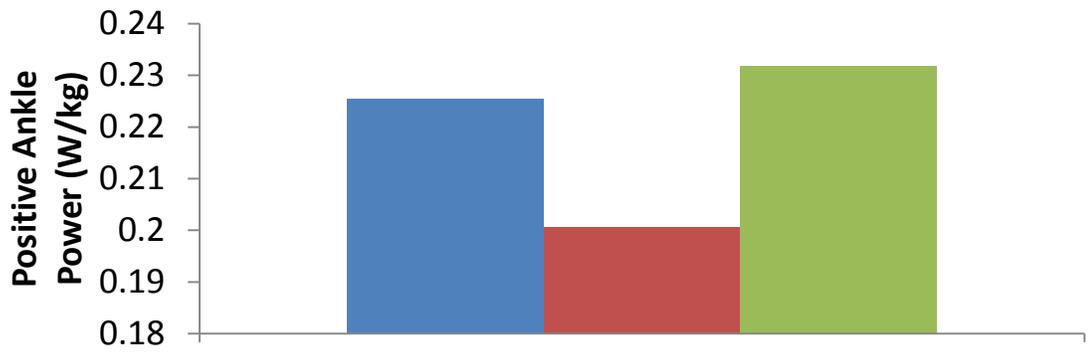


Figure 30: Non-Paretic Limb Positive, Negative, and Net Ankle Joint Powers of Stroke Survivor

Average positive, negative, and net ankle joint powers (W/kg) of the non-paretic limb of a stroke survivor walking at 0.7 m/s. Positive power (top panel), negative power (middle panel), and net power (bottom panel) are plotted below. The blue bar represents the participant walking normally with no AFO, the red bar represents the participant walking in the AFO with the biofeedback turned off, and the green bar represents the participant walking in the AFO with active biofeedback.



■ No AFO ■ No Feedback ■ Push Off

Figure 31: Non-paretic Limb Knee Joint Angles, Moments, and Powers for Stroke Survivor

Knee joint angles (degrees), moments (Nm/kg), and powers (W/kg) of the non-paretic limb of a stroke survivor during walking at 0.7 m/s. Knee angle (top panel), knee moment (middle panel) and knee power (bottom panel) are plotted over a stride from heel strike (0%) to heel strike (100%) of the same limb. The blue line represents the participant walking normally with no AFO, the red line represents the participant walking in the AFO with the biofeedback turned off, and the green line represents the participant walking in the AFO with active biofeedback.

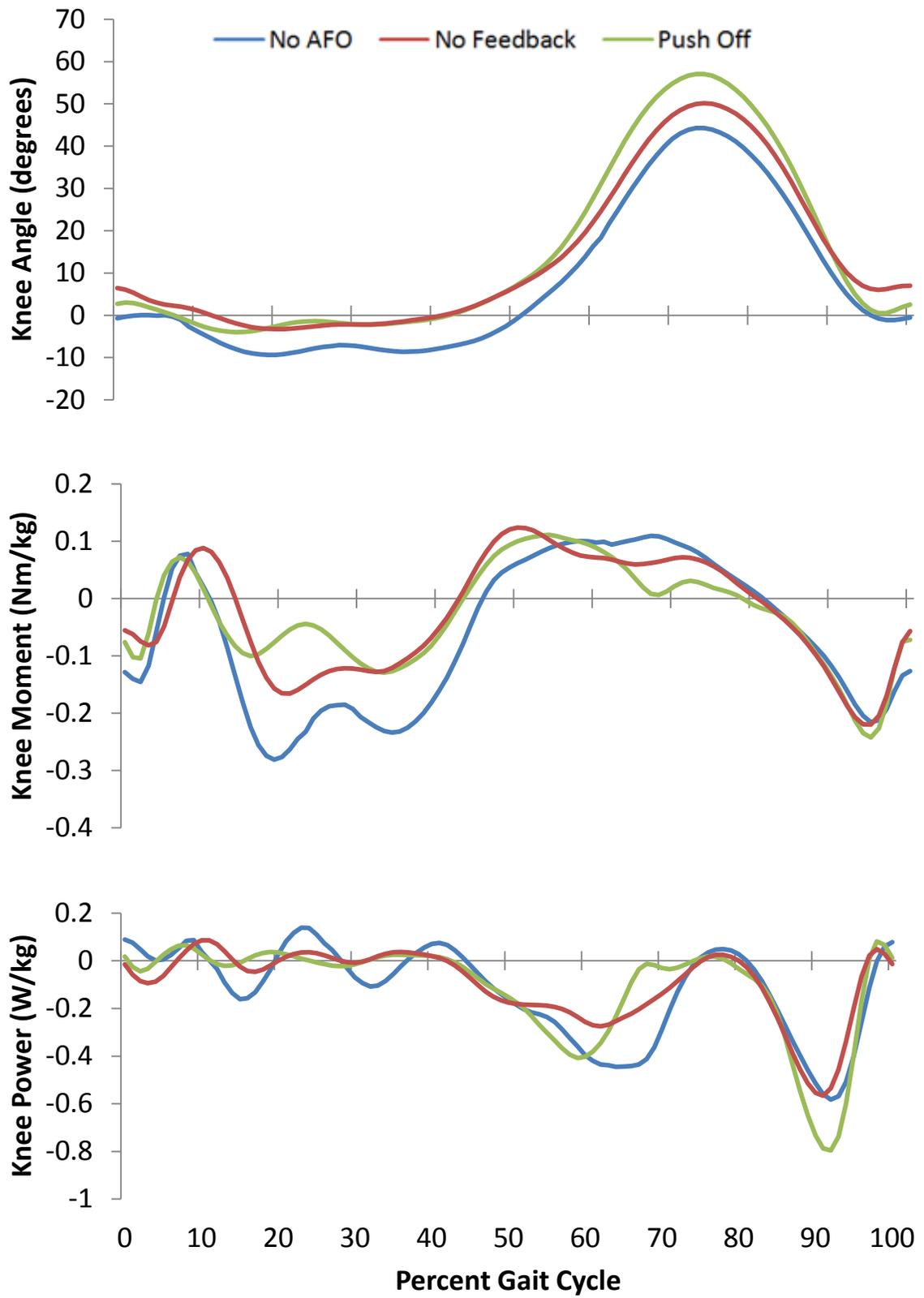
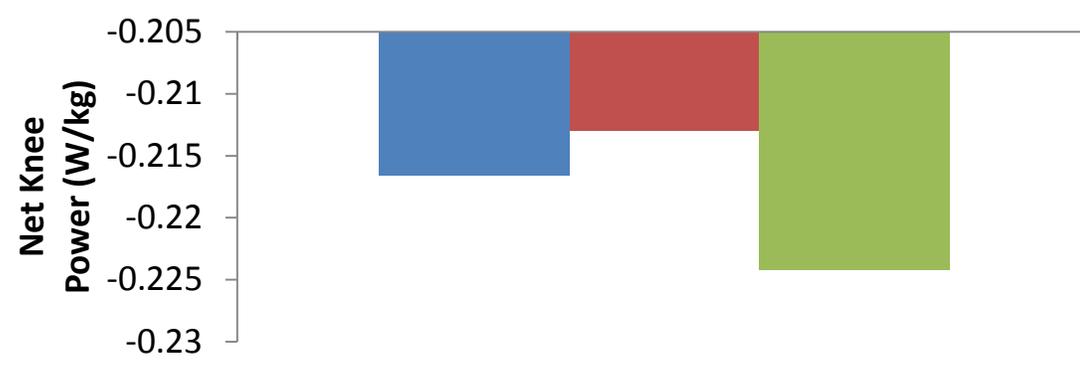
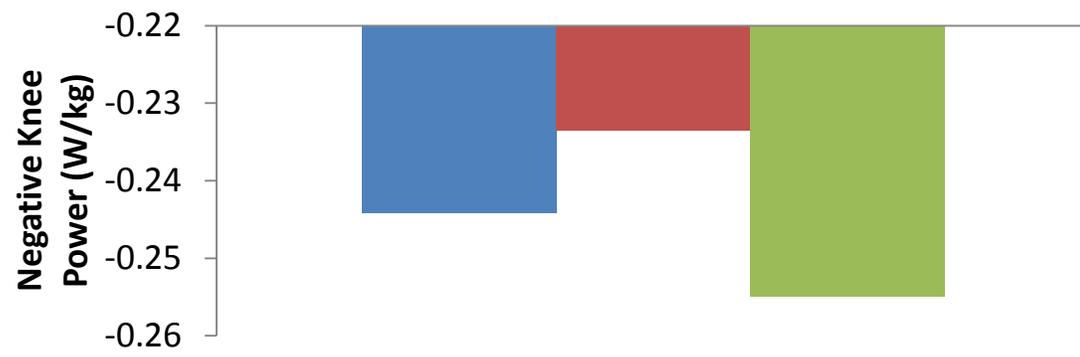
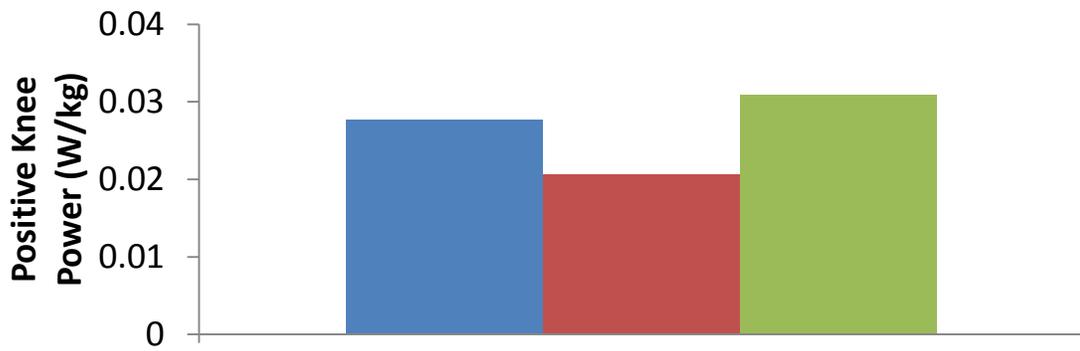


Figure 32: Non-Paretic Limb Positive, Negative, and Net Knee Joint Powers of Stroke Survivor

Average positive, negative, and net knee joint powers (W/kg) of the non-paretic limb of a stroke survivor walking at 0.7 m/s. Positive power (top panel), negative power (middle panel), and net power (bottom panel) are plotted below. The blue bar represents the participant walking normally with no AFO, the red bar represents the participant walking in the AFO with the biofeedback turned off, and the green bar represents the participant walking in the AFO with active biofeedback.



■ No AFO ■ No Feedback ■ Push Off

Figure 33: Non-Paretic Limb Hip Joint Angles, Moments, and Powers

Hip joint angles (degrees), moments (Nm/kg), and powers (W/kg) of the non-paretic limb of a stroke survivor during walking at 0.7 m/s. Hip angle (top panel), hip moment (middle panel) and hip power (bottom panel) are plotted over a stride from heel strike (0%) to heel strike (100%) of the same limb. The blue line represents the participant walking normally with no AFO, the red line represents the participant walking in the AFO with the biofeedback turned off, and the green line represents the participant walking in the AFO with active biofeedback.

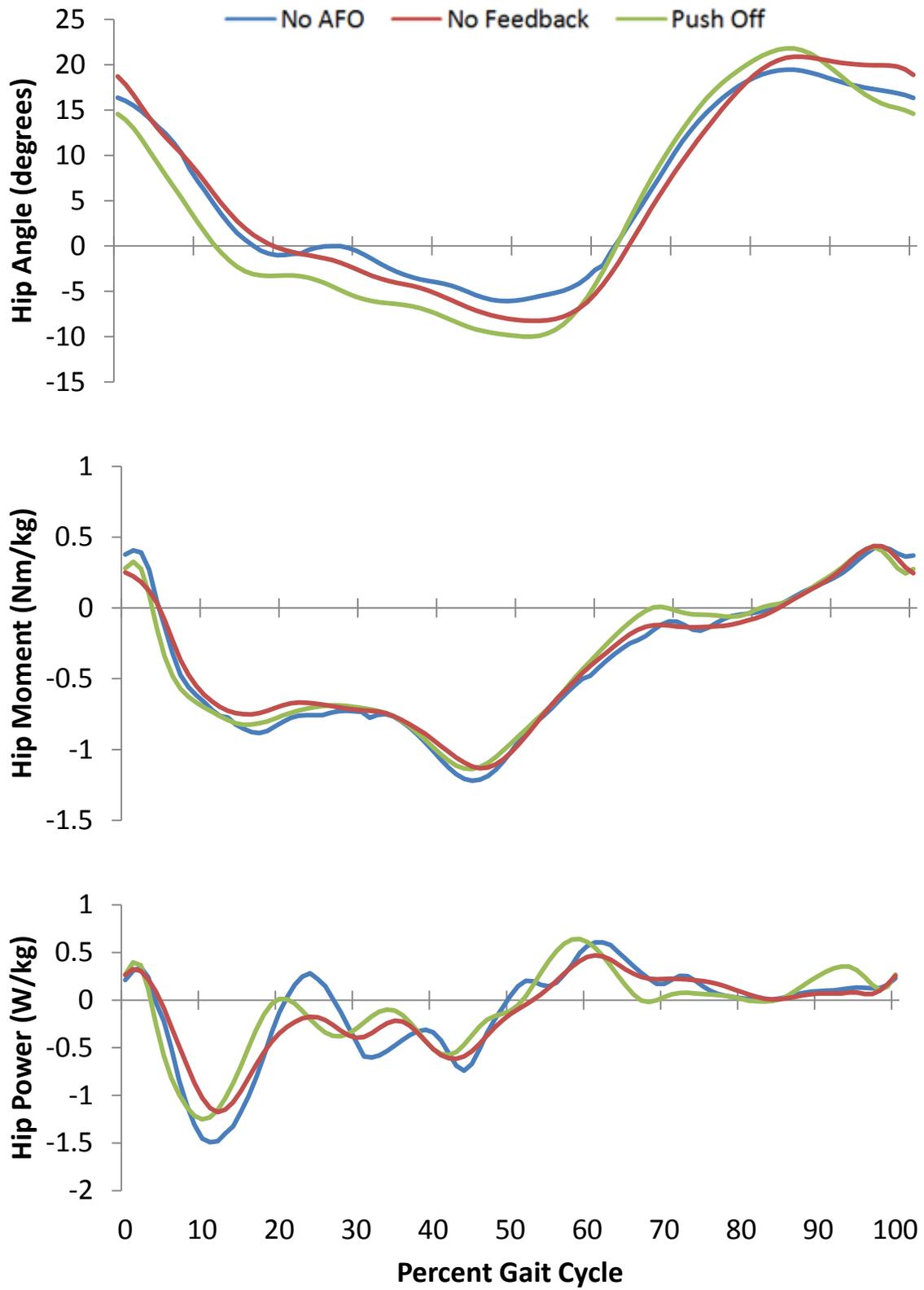
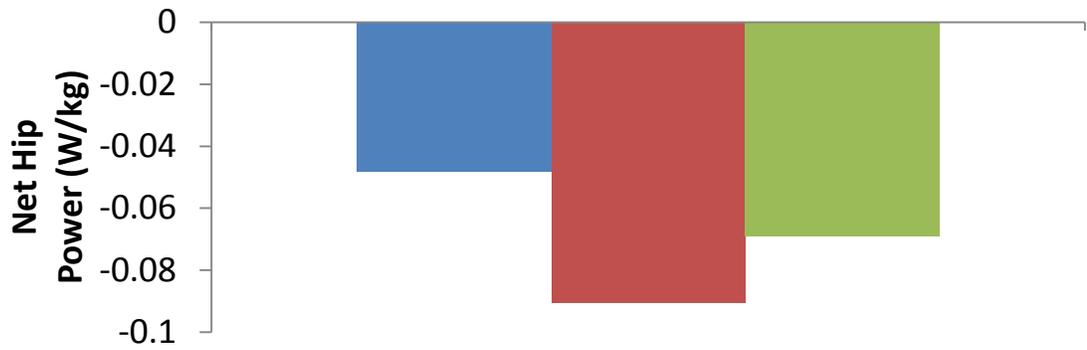
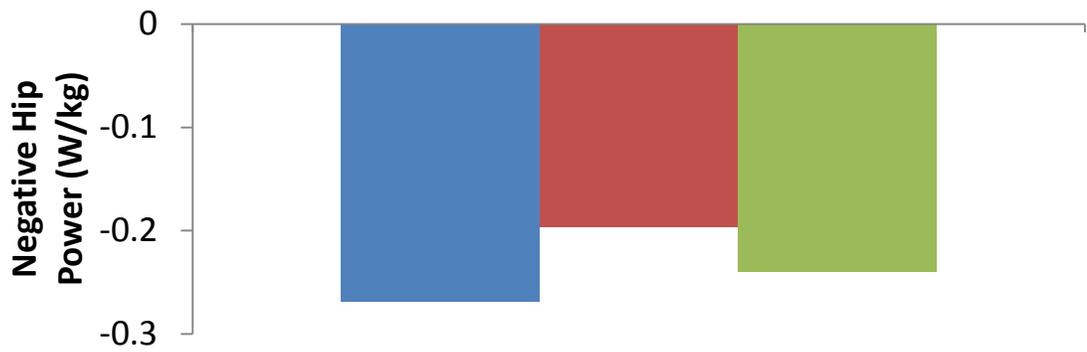
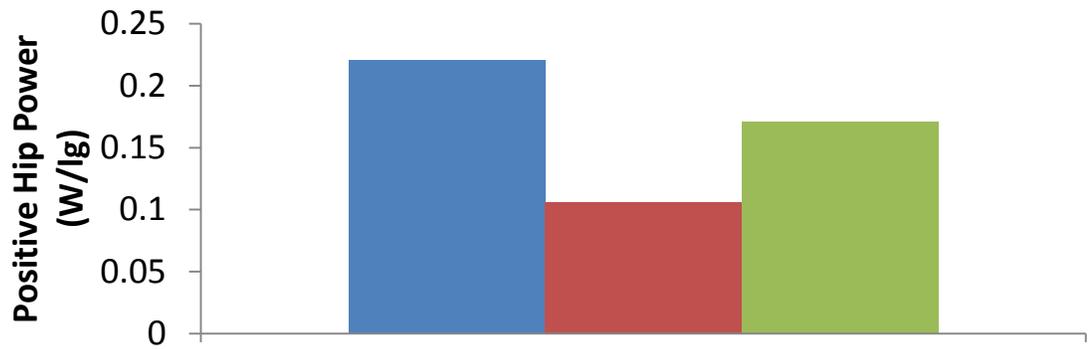


Figure 34: Non-Paretic Limb Positive, Negative, and Net Hip Joint Powers of Stroke Survivor

Average positive, negative, and net hip joint powers (W/kg) of the non-paretic limb of a stroke survivor walking at 0.7 m/s. Positive power (top panel), negative power (middle panel), and net power (bottom panel) are plotted below. The blue bar represents the participant walking normally with no AFO, the red bar represents the participant walking in the AFO with the biofeedback turned off, and the green bar represents the participant walking in the AFO with active biofeedback.



■ No AFO ■ No Feedback ■ Push Off