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FUNCTIONAL COMPARISON OF CONVENTIONAL AFOs WITH THE DYNAMIC RESPONSE AFO

By:

Mitchell Ruble, B.S.

A Thesis submitted to the

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Requirements for the Degree of Master of Science

Milwaukee, Wisconsin

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ABSTRACT

FUNCTIONAL COMPARISON OF CONVENTIONAL AFOs WITH THE DYNAMIC RESPONSE AFO

Mitchell Ruble, B.S.

Marquette University, 2016

Ankle foot orthoses (AFOs) are commonly prescribed to provide stability and foot clearance for patients with weakened or injured musculature. The Dynamic Response AFO (DRAFO) was designed to improve proprioception at heel strike. The design includes a rigid outer shell with a cut out heel and a soft inner lining; it is typically aligned in plantarflexion and may incorporate external heel wedges. The objective of this study was to investigate the effects of the DRAFO design features and contrast its biomechanical function with that of conventional locked and articulating AFOs. The research hypotheses were: 1) DRAFO-assisted gait parameters (e.g. ankle plantarflexion during early stance, cross-over times of the shank and thigh vertical angles during stance, step width, dorsi activity duration during stance, and center of pressure progression during loading response) will approximate the no AFO condition and 2) DRAFO-assisted gait parameters (e.g. ankle and knee kinematics, cross-over times of the shank and thigh vertical angles during stance, peak foot progression angle, step width, stance phase dorsiflexion activity duration, and mediolateral motion of the center of pressure) will differ from the locked and articulating AFOs.

Ten young healthy subjects were recruited for gait analyses during level treadmill walking; four AFO conditions were contrasted. After five minutes of AFO and treadmill acclimation, each subject walked for two minutes at the self-selected walking speed on a level treadmill. Acquired data included lower extremity joint and segment kinematics, dorsiflexion and plantarflexion muscle activity, and treadmill kinetic data.

Ambulation in the DRAFO demonstrated significantly greater knee flexion and ankle plantarflexion than with conventional AFOs, the foot progression angle was reduced in the DRAFO relative to the no AFO condition, the center of pressure progression for the DRAFO was more medial than that observed during the no and articulating AFO conditions, and the time to transition from an inclined to a reclined shank during swing was delayed. These findings suggest that the plantarflexed alignment, external heel wedges, and perhaps the soft heel features of the DRAFO design affect lower limb joint and segment kinematics, while the rigid structure provides stability to the ankle and subtalar joints.

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Mitchell Ruble, B.S.

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Chapter 1: Introduction and Motivation

Ankle foot orthoses (AFOs) are assistive rehabilitative devices used to treat pathologic gait due to stroke, brain diseases such as cerebral palsy (CP), and muscular diseases such as muscular dystrophy [1]. AFOs may be prescribed to provide: rest, immobilization, protection, control, assistance/resistance of movement, and/or anatomical correction of the ankle and subtalar joints [1, 2]. One common problem addressed by AFOs is drop foot, caused by weak dorsiflexors, which may adversely affect foot clearance during swing phase [3-6]. Common compensatory mechanisms include pelvic hike, circumduction, and vaulting [7], the use of which can lead to additional pathologies and potentially increased energy expenditure. AFOs stabilize the foot in a neutral or flexed position thereby assisting toe clearance during swing phase and minimizing the need for compensatory mechanisms.

Specific AFO prescription is conducted on an individual basis, taking into consideration the functional needs and physical limitations of the patient. For example, weakness of the gastrocnemius-soleus muscle group may require more proximal AFO trimlines and increased rigidity to control tibial motion and potential knee instability during stance; weakness of the pretibial muscles often require dorsiflexion assists or neutral ankle positioning to facilitate toe clearance during swing [2]. AFO prescription and design variations include the level of control of the ankle, foot plate length, orthotic stiffness or rigidity of the foot plate/ankle joints/uprights, proximal trimline, fabrication material, rigid/free/assisted ankle joints, orthotic alignment, and inclusion of supplemental inserts [1, 2].

Although several studies investigated the effects of AFO design parameters on functional outcomes and gait, no study has as yet investigated the Dynamic Response AFO (DRAFO), an alternative AFO design with a flexible heel to enhance proprioception during stance. In addition

to its unique semi-rigid design, the alignment of the DRAFO also varies from that of traditional AFO designs.

The purpose of this study was to use motion analysis to contrast three different AFO designs during treadmill walking for able-bodied subjects. Specifically, this study compared the DRAFO to both a locked and an articulated plastic AFO. The resultant lower extremity gait kinematics, ground reaction force kinetics, and EMG were contrasted for these three AFO designs, as well as for the no AFO condition. The specific aims of this study were to investigate the effect of AFO design on: 1) lower limb kinematics during stance and swing, 2) kinetics during stance, and 3) dorsiflexion and plantar flexion muscle activity during both stance and swing during treadmill walking. The specific research hypotheses (see Table 1.1) investigated in this study were

1) DRAFO-assisted gait parameters (e.g. early plantarflexed ankle angle, swing phase shank and thigh segment angle cross-over times, step width, early stance phase dorsiflexion activity, and center of pressure progression during loading response) will approximate that of the no AFO condition
2) DRAFO-assisted gait parameters (e.g. ankle and knee kinematics, stance phase shank and thigh segment angle, step width, stance phase dorsiflexion activity, and center of pressure progression during loading response) will differ from that for articulating and rigid AFOs.

Table 1.1 Research hypotheses regarding the DRAFO and no AFO and DRAFO versus conventional AFO conditions for various gait parameters.

Research Measure	Hypothesis 1 DRAFO ≈ no AFO	Hypothesis 2 DRAFO ≠ conventional AFOs
Soft heel of DRAFO		
Ankle kinematics (loading response)	≈	≠
Ankle kinematics (stance)		≠
Center of pressure progression (loading response)	≈	≠
Step width	≈	≠
Dorsiflexion activity (stance)	≈	≠
External heel wedges		
Shank segment cross over time (stance)		≠
Thigh segment cross over time (stance)		≠
Shank segment cross over time (swing)	≈	
Thigh segment cross over time (swing)	≈	
Plantarflexed alignment		
Knee kinematics (stance and swing)		≠
Ankle kinematics (swing)		≠

2: BACKGROUND AND LITERATURE REVIEW

Background content and review of the literature relevant to this study are summarized in this chapter. Topics include review of AFOs and human gait for normal, pathologic and AFO treated individuals.

2.1 AFOs

To understand the impact of AFOs on gait, the respective AFO treatment objectives and design variables of AFOs are reviewed.

2.1.1 AFO Treatment Objectives

AFOs are rehabilitation devices used to assist gait during stance and/or swing phase. AFOs compensate for spasticity/weakness in the plantar/dorsiflexors and help provide both stability and foot clearance throughout gait. There are four potential treatment objectives for AFOs: 1) help re-establish an appropriate base of support, 2) control rate, excursion, and direction of segmental movement, 3) improve energy efficiency, and 4) help to position the foot for clearance and weight acceptance [2]. AFOs can restore the plantar base of support which can improve balance and stability, increase AFO limb single support duration, increase contralateral limb step length, and decrease peak plantar pressures, which in turn may facilitate increased activity [2]. By controlling the tibial motion throughout gait, AFOs can help to re-align the lower extremity (LE) and facilitate weight transfer from stance to swing. AFOs have been prescribed to reduce foot drop and improve foot clearance during swing phase for individuals with dorsiflexor

paresis, reducing compensatory gait deviations such as circumduction and vaulting [2, 4]. The AFO can assist foot positioning during loading response so as to restore initial heel contact.

2.1.2 AFO Design Variables

There are various AFO designs to improve gait. For example, the rigid polypropylene AFO (Figure 2.1a) constrains the ankle to limit dorsiflexion or plantar flexion during stance [2]. The design facilitates foot clearance during mid-swing and provides foot-ankle stabilization during loading response [2]. The polypropylene material reduces mass with respect to metal designs; the reduced mass may permit prolonged patient activity without fatigue, although the overall strength of the AFO is reduced.

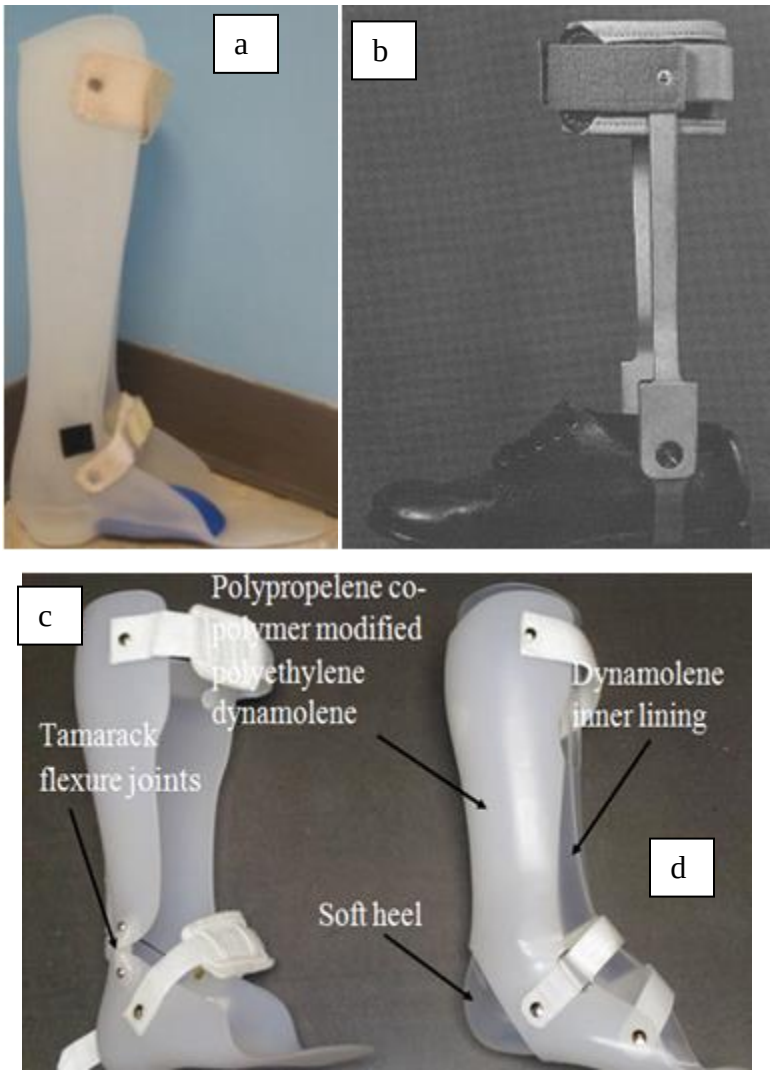

Figure 2.1: Rigid polypropylene AFO (a), articulated bi-channel metal AFO (b), articulating polypropylene AFO (c), and DRAFO (d) (adapted from [2, 8]).

To permit ankle motion, articulated AFOs may also be prescribed. The articulated bichannel adjustable ankle locking AFO (Figure 2.1b) is indicated for patients with limb volume changes and the potential for functional improvements [2]. The bichannel ankle joints permit both locked (various orientations) and constrained (variable ranges of motion) options [2]. However, this metal AFO requires permanent integration with the shoe and therefore adversely affects cosmesis [2]. Articulated plastic AFOs (Figure 2.1c) may also be prescribed to permit

ankle motion in subjects who demonstrate healthy balance during gait and require less durability and control than provided by metal AFOs.

An alternative non-articulated AFO, the Dynamic Response AFO or DRAFO (Figure 2.1c), manipulates gait throughout stance phase and assists independent standing balance [9]. The DRAFO is composed of two separate components: a plastic rigid outer shell and a flexible plastic inner lining. The rigid outer shell, which includes a heel cutout, fixes the ankle in a plantar flexed position; heel lifts are then incorporated to vertically align the tibia during mid-stance. This rigid shell provides protection and stability for the ankle and subtalar joints during gait. The inner lining, which encompasses the foot, ankle and posterior calf, protects the heel; its compliance provides increased proprioceptive feedback during heel contact and loading response [9].

2.2 Normal, Able-Bodied Gait

To understand how AFOs affect gait, normal, no AFO gait is first reviewed. Specifically, the phases of gait, LE kinematics, LE muscle activity during gait, and ground reaction force (GRF) and joint kinetics of normal, able-bodied gait are presented.

2.2.1 Phases of Gait Cycle

The gait cycle is defined as two successive heel strikes (HS) of the ipsilateral limb. The gait cycle can be divided into two periods: stance and swing. Stance duration, which extends from ipsilateral HS to ipsilateral toe off (TO), is approximately 62% of the total gait cycle. Swing phase, defined as ipsilateral TO to ipsilateral HS, has a duration of approximately 38% of the gait cycle. The gait cycle can be further into five sub-phases of stance (initial contact - IC,

loading response - LR, mid stance - MSt, terminal stance - TSt, pre-swing - PSw) and three sub-phases of swing (initial swing - ISw, mid swing - MSw, and terminal swing - TSw), as illustrated in Figures 2.2 and 2.3 [10].

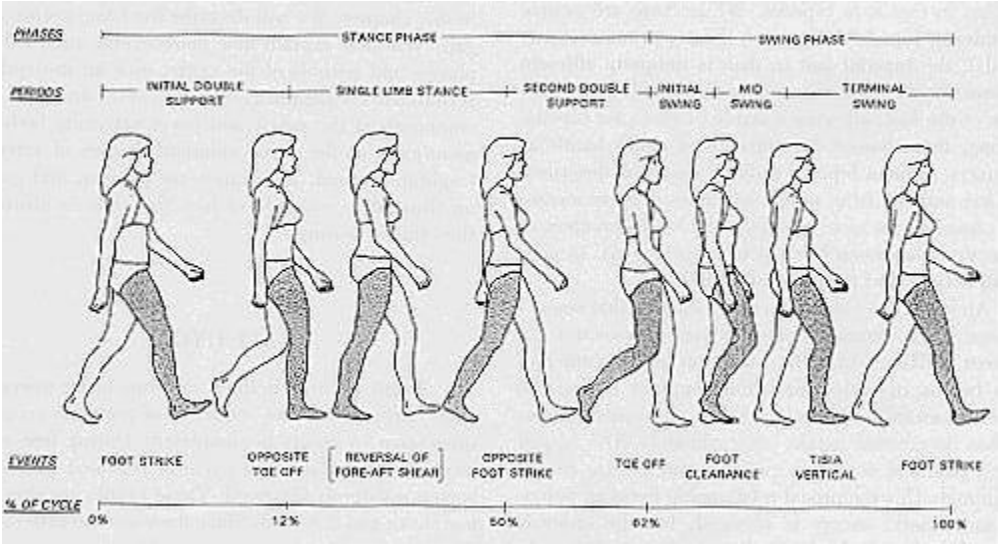

Figure 2.2: Gait cycle and relevant HS and TO events for able-bodied gait (adapted from [11]).

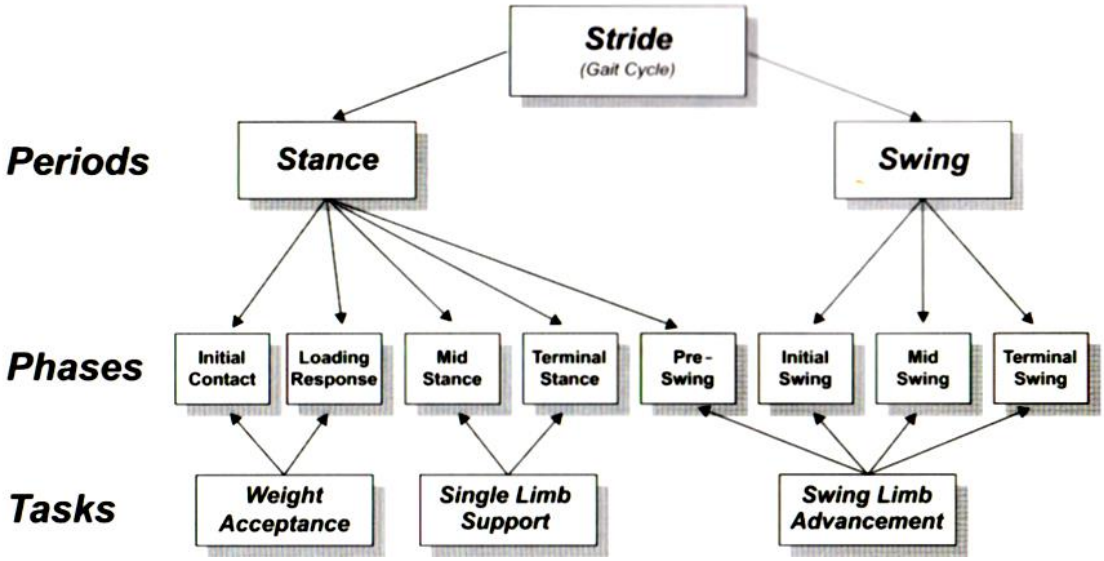

Figure 2.3: Stance and swing sub-phases of gait (adapted from [10]).

Weight Acceptance

Stance begins with weight acceptance, a challenging sub-phase that provides shock absorption, initial limb stability, and preservation of progress [10]. Weight acceptance includes IC and LR. IC (0-2% gait cycle) begins when the foot makes contact with the floor. During LR (2-12% gait cycle), body weight is transferred from the contralateral to the ipsilateral limb. At the end of LR, body weight is fully supported by the ipsilateral limb, initiating the first single limb support (SLS) phase.

Single Limb Support

SLS includes both mid and terminal stance. This phase begins contralateral limb TO through contralateral limb HS; the ipsilateral limb assumes full weight-bearing responsibility. MSt (12-31% gait cycle) is defined from contralateral TO until ipsilateral mid- or fore-foot weight-bearing, providing forward progress and ipsilateral stability [10]. TSt (31-50% gait cycle) prepares for the transition to double limb support (DLS) and contralateral limb weight acceptance. TSt begins with ipsilateral heel rise to just prior to contralateral HS.

Swing Limb Advancement

Swing limb advancement (SLA) includes PSw, initial swing, mid swing, and terminal swing. Pre-swing (50-62% gait cycle), the final sub-phase of stance, includes contralateral HS through ipsilateral TO during which weight is being transferred from the ipsilateral to contralateral limb. The ipsilateral limb pushes off from the ground, providing propulsion to initiate swing [10]. Initial swing (62-75% gait cycle) is defined from ipsilateral foot off to until the foot is opposite the contralateral stance foot [10]. Mid-swing (75-87% gait cycle) then occurs

until the ipsilateral tibia is vertical [10]. Finally, terminal swing (87%-100% gait cycle) continues until the ipsilateral swing foot strikes the floor [10].

2.2.2 Lower Extremity Kinematics during Able-Bodied Gait

Lower extremity kinematics during gait can be described for each of the respective LE joints: ankle, knee and hip. Ankle motion includes alternating periods of plantar and dorsiflexion (Figure 2.4). During IC and LR, the ankle is plantar flexed. This progression from initial heel contact to weight acceptance is often described as the first rocker [10] during which the shank-foot complex rotates about the heel. During early through TSt, the tibia rotates about the ankle (second rocker), with the ankle transitioning to a dorsiflexed position; peak dorsiflexion occurs at TSt. As the contralateral limb makes contact with the ground and weight is re-distributed during PSw, the ipsilateral ankle begins to plantar flex. During this transition (third rocker with mid- and hind-foot rotation about the metatarsal heads), peak ankle plantar flexion occurs. Ankle plantar flexion then decreases during swing via dorsiflexor muscle activity to provide foot clearance [10].

Sagittal plane knee motion ranges from 0 to 60° flexion during able-bodied gait (Figure 2.5). There are two primary periods of knee flexion, during the transition from LR to MSt to assist in shock absorption and weight acceptance and from TSt to initial swing to provide limb clearance.

Sagittal plane hip motion ranges from approximately 30° flexion to 10° extension (Figure 2.6). During IC, the hip is flexed; the hip gradually extends until PSw. The hip then flexes during swing to advance the limb forward to prepare the limb for IC [10].

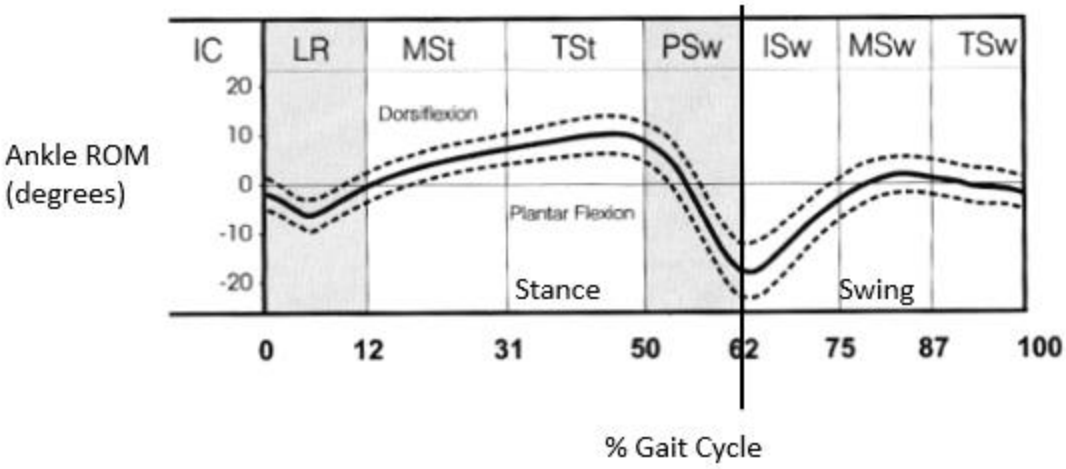

Figure 2.4: Sagittal plane ankle range of motion (+: dorsiflexion) during both stance and swing (adapted from [10]). The sub-phases of stance (IC, MSt, TSt, PSw) and swing (ISw, MSw, TSw) are also noted.

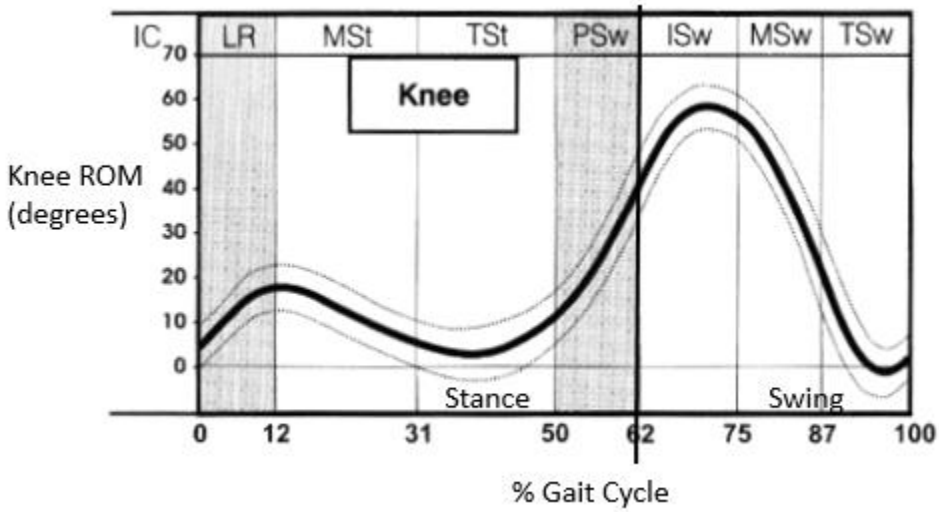

Figure 2.5: Sagittal plane knee ROM (+: flexion) for able-bodied gait (adapted from [10]).

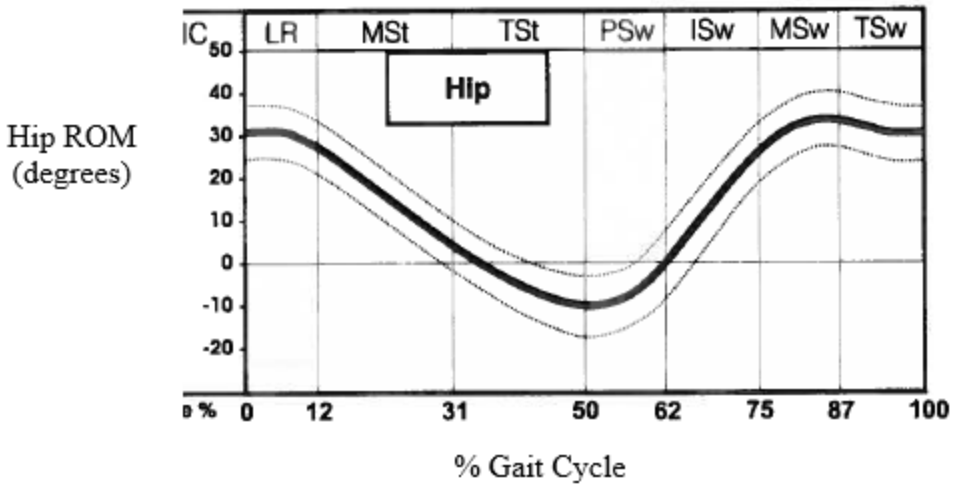

Figure 2.6: Sagittal plane hip ROM (+: flexion) for able-bodied gait (adapted from [10]).

Foot progression angle (FPA), a kinematic measure that has been used to investigate knee moment in children and adults, varies between young able-bodied men (toe out of 7°, [10]) and women (toe out of 5 [10]. Another study reported mean FPA for adult men is 13-13.7° [12]. AFOs have been shown to increase internal FPA in children with diplegia, but not impact children with hemiplegia [13]. A shift towards an internal FPA may help to reduce the second peak knee moment and thereby reduce risk of knee osteoarthritis.

A final kinematic or spatial parameter of gait is step width. This measure has been used to study stability during walking. Similar to FPA, step width also varies with gender, ranging from 7 cm for young, able-bodied women to 8 cm for men [10]. Narrower step width indicates greater stability for a patient as they have a smaller base of support to work with, while a larger step width indicates instability. AFOs are prescribed to increase stability, and thereby decrease step width.

2.2.3 Lower Extremity Muscle Activity during Able-Bodied Gait

Lower extremity muscle activity during gait occurs primarily during the transitions from stance to swing and swing to stance, acting to accelerate and/or decelerate the respective limb segments. Key muscle groups include the dorsiflexors and plantarflexors of the ankle, the hamstrings and quadriceps of the knee (and hip), and the hip flexors and extensors.

The ankle dorsiflexors include the tibialis anterior (TA), extensor digitorum longus (EDL), extensor hallucis longus (EHL), fibularis longus (FL), and peroneus tertius (PT); the ankle plantarflexors include the soleus, gastrocnemius, tibialis posterior, flexor digitorum longus, flexor hallucis longus, peroneus longus, and peroneus brevis. Dorsiflexion activity during gait occurs during LR to decelerate the foot and prevent foot slap and provide foot clearance during swing ([10], Figure 2.6). The plantar flexors are active during mid- to terminal stance to provide push off of the stance leg in preparation for swing ([10], Figure 2.7).

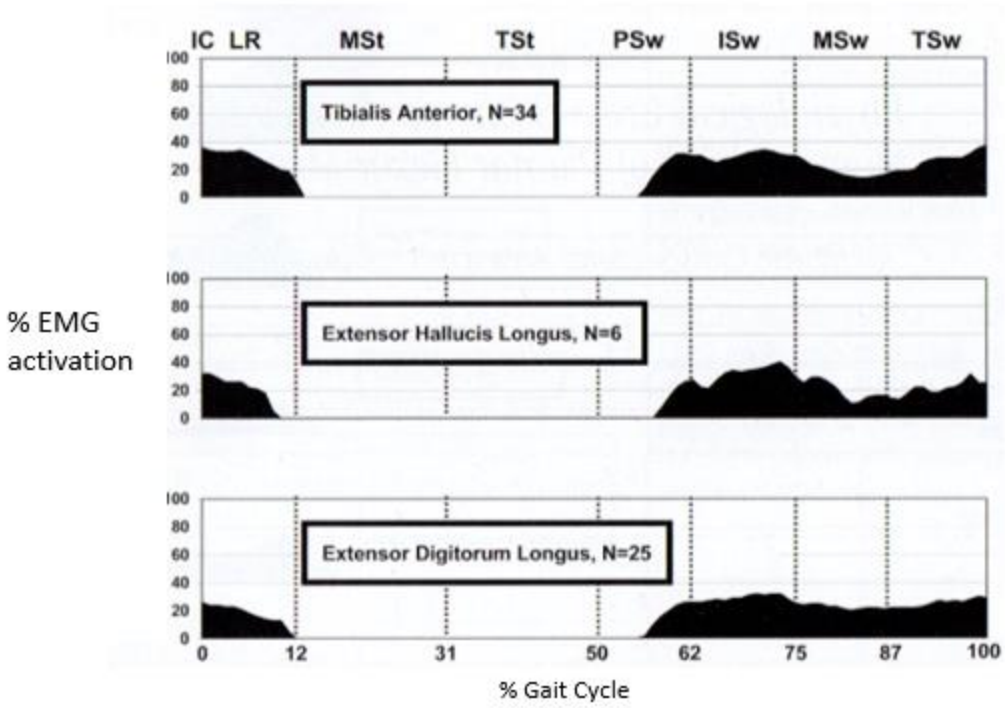

Figure 2.7: Surface EMG activity of the ankle dorsiflexors during able-bodied gait (adapted from [10]). (IC, LR, MSt, TSt, PSw, ISw, MSw, TSw)

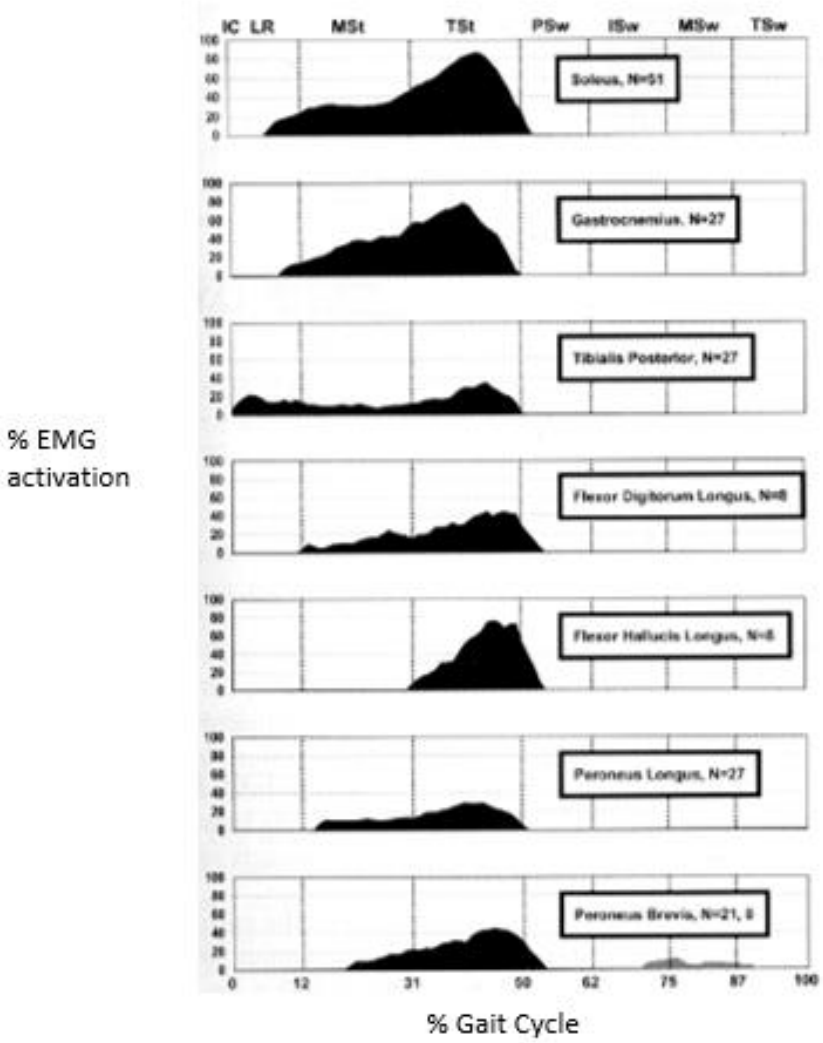

Figure 2.8: Surface EMG activity of the plantar flexors during able-bodied gait (adapted from [10]).

The knee extensor muscles consist of the vastus intermedius, vastus lateralis, vastus medialis, and rectus femoris (Figure 2.9). The knee flexors consist of the biceps femoris, popliteus, gastrocnemius, semimembranosus, semitendinosus, gracilis, and sartorius (Figures 2.10, 2.11, 2.12). The knee extensors are active during early stance and terminal swing to provide stability to the knee and prepare for weight bearing, respectively. The knee flexors are active during initial and mid-swing to assist with clearance.

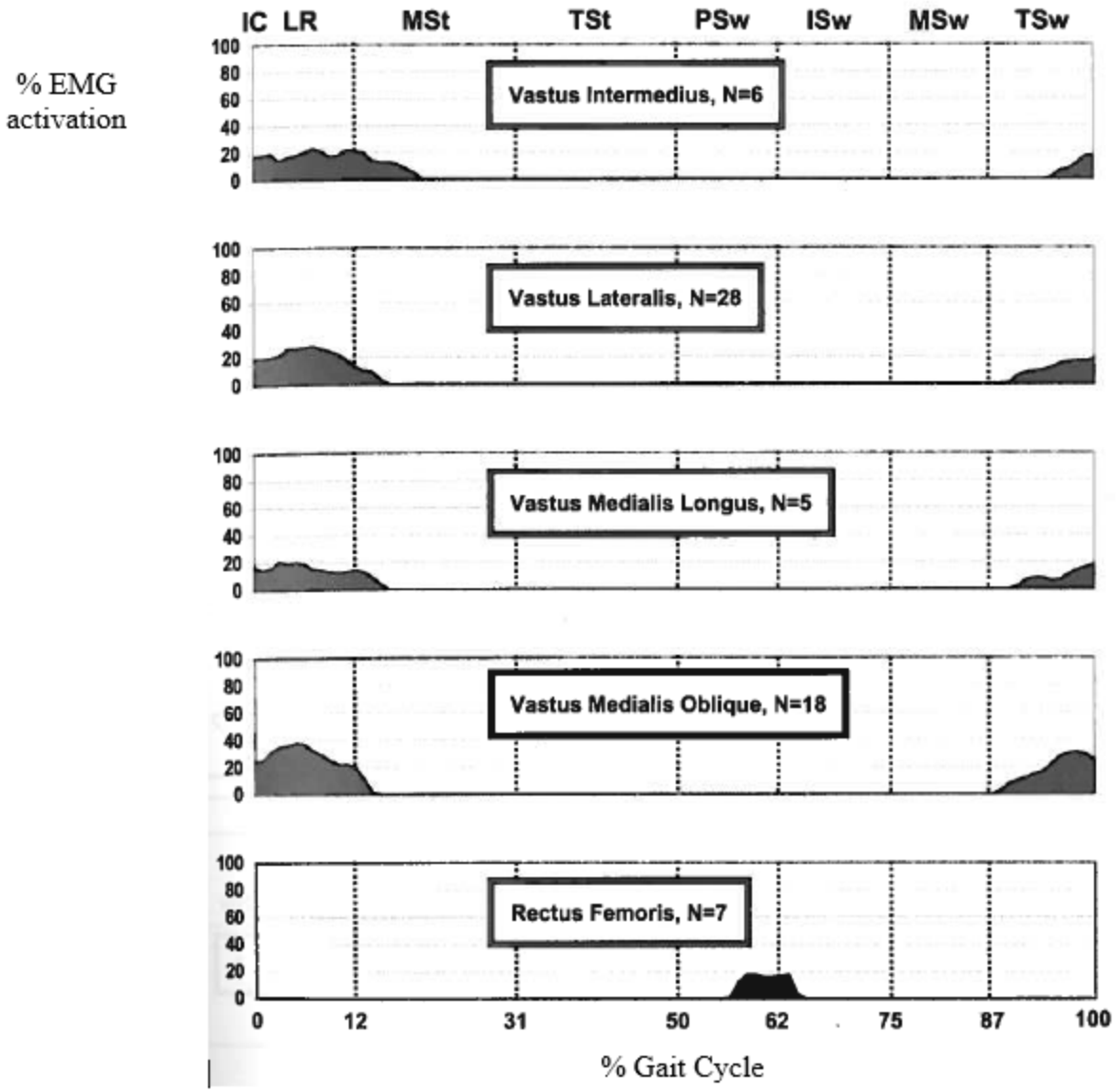

Figure 2.9: Surface EMG activity of the knee extensors during able-bodied gait (adapted from [10]).

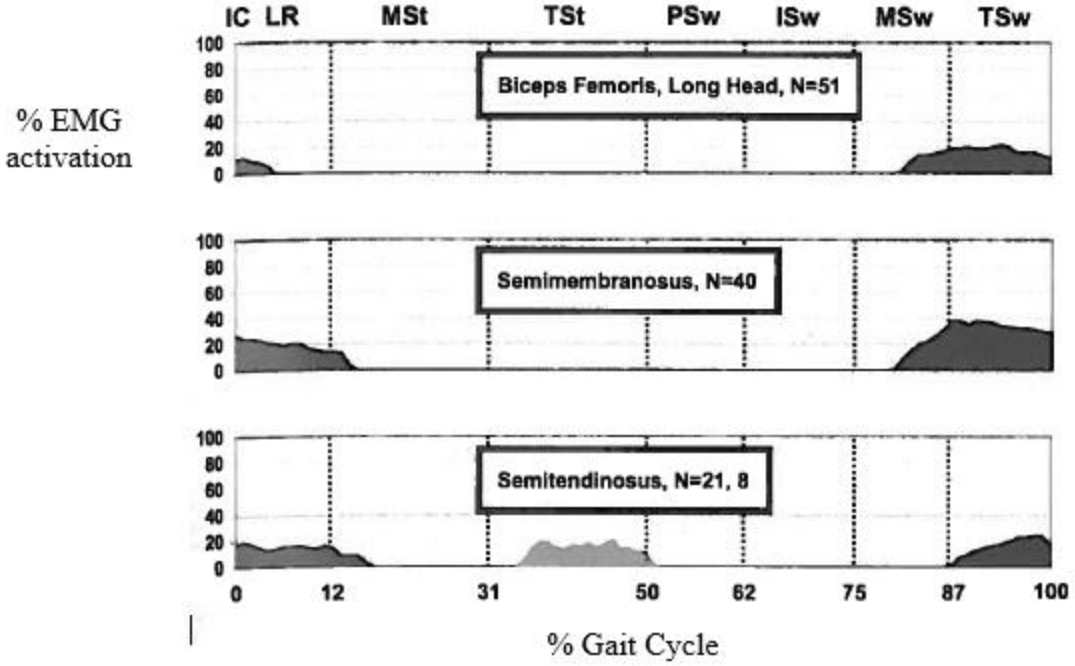

Figure 2.10: Surface EMG activity of the hamstrings during able-bodied gait (adapted from [10]).

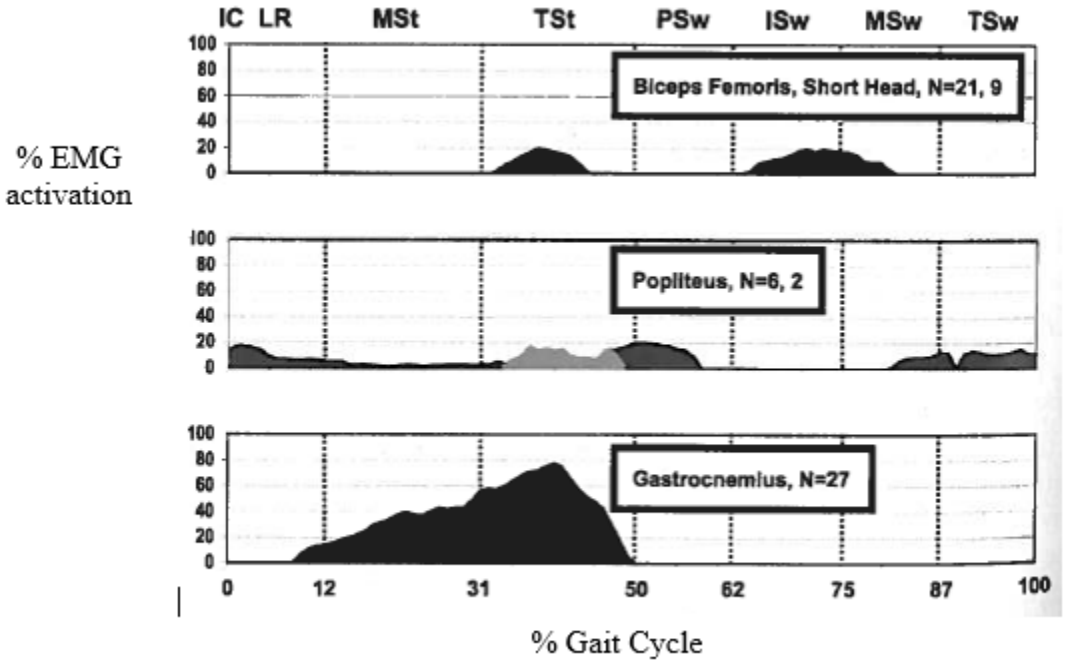

Figure 2.11: Surface EMG activity of the knee flexors during able-bodied gait (adapted from [10]).

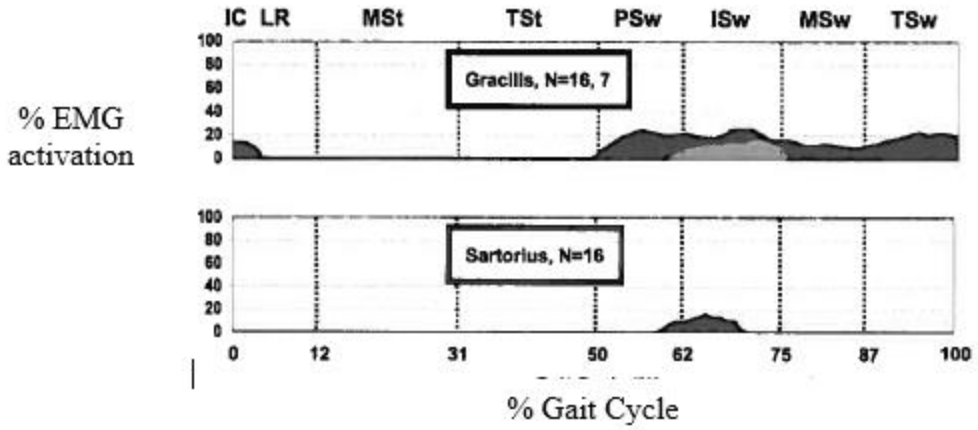

Figure 2.12: Surface EMG activity of the gracilis (knee extensor) and sartorius (hip and knee flexor) during able-bodied gait (adapted from [10]).

The hip extensor muscles consist of the hamstrings (semimembranosus, biceps femoris, and semitendinosus), adductor magnus, and gluteus maximus (Figure 2.13). These muscles are active from terminal swing through LR to advance the lower limb in preparation for stance. The hip flexors include the gracilis, rectus femoris, sartorius, and iliacus; these muscles are active primarily from late stance through early swing (Figure 2.15) to keep the trunk stable during SLS.

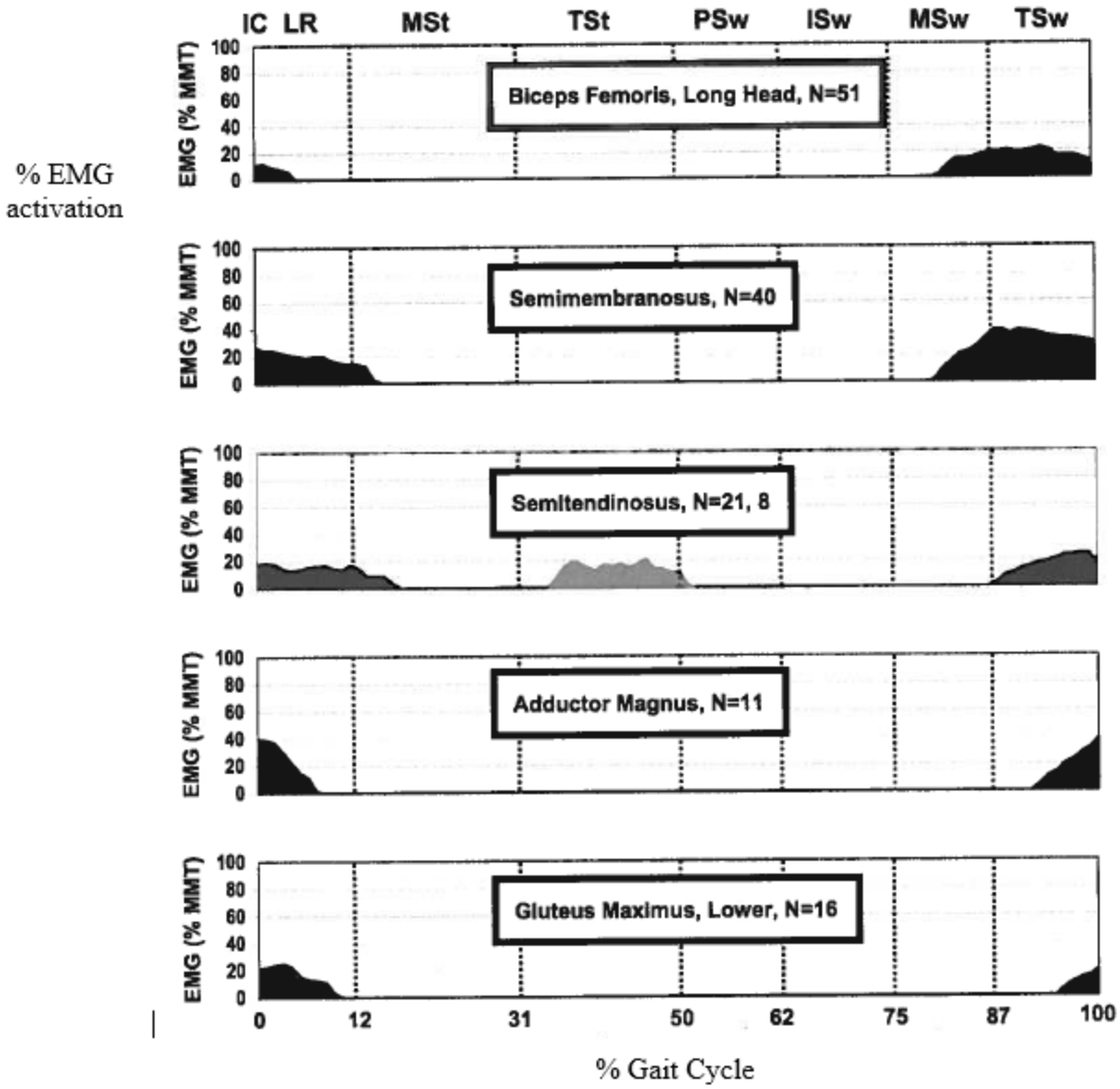

Figure 2.13: Surface EMG activity of the hip extensors during able-bodied gait (adapted from [10]).

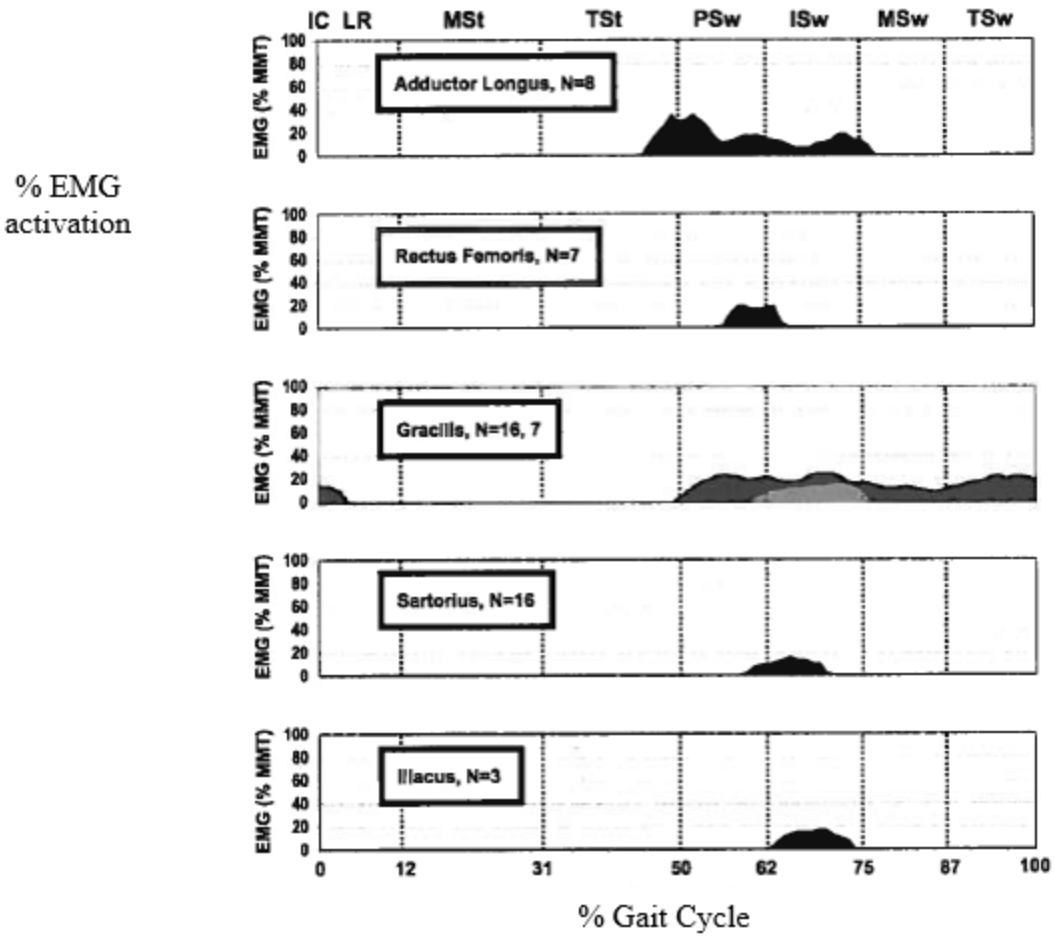

Figure 2.14: Surface EMG activity of the hip flexors during able-bodied gait (adapted from [10]).

2.2.4 Ground Reaction Force Kinetics during Able-Bodied Gait

The kinetics of gait are quantified in terms of the GRF or superior-inferior, medial-lateral, and fore-aft forces under the foot. These forces are located at the center of pressure (COP, Figure 2.15). Both the GRFs and the progression of the COP are used to characterize the kinetics of able-bodied gait and differentiate pathologic gait.

The superior-inferior or vertical GRF during able-bodied gait is characterized by two peaks (approximately 110% body weight), separated by a valley (Figure 2.16). The first peak occurs between LR and MSt and is attributed to weight transfer during SLS [10]. The second

peak, F_3, occurs during TSt and is attributed to plantarflexion push off and the downward acceleration of the center of gravity (COG) as the body weight falls over the forefoot rocker. The valley or local minima occurs due to the rise of the COG as the body rolls over the ipsilateral stance foot.

The medial-lateral and fore-aft forces are smaller in magnitude. The peak medial-lateral force occurs during LR, a braking response of the body [10]. The fore-aft GRFs peak during early stance with an anterior force due to body weight loading. During TSt, the fore-aft forces are posterior reflecting push off or propulsion into swing [10].

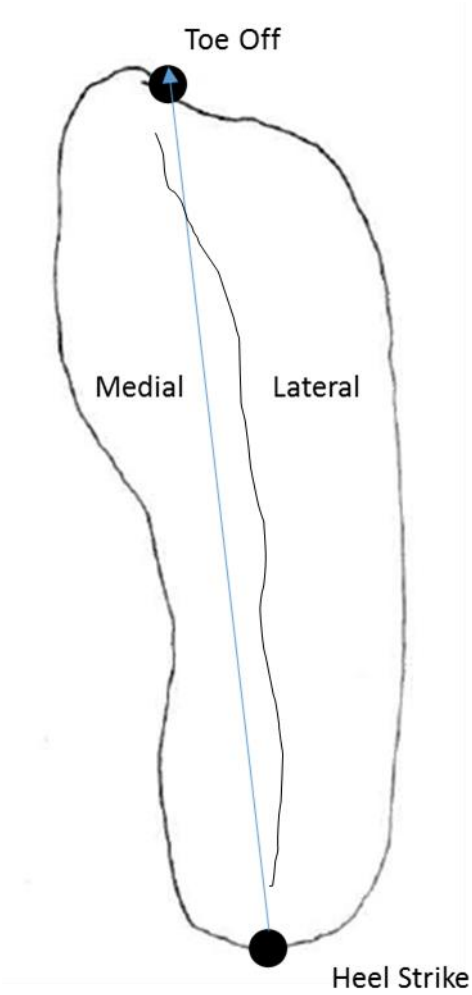

Figure 2.15: COP progression projected onto the right foot from HS-TO. The long axis of the foot (blue line), from the posterior heel to the second metatarsal head, is also shown (adapted from [10]).

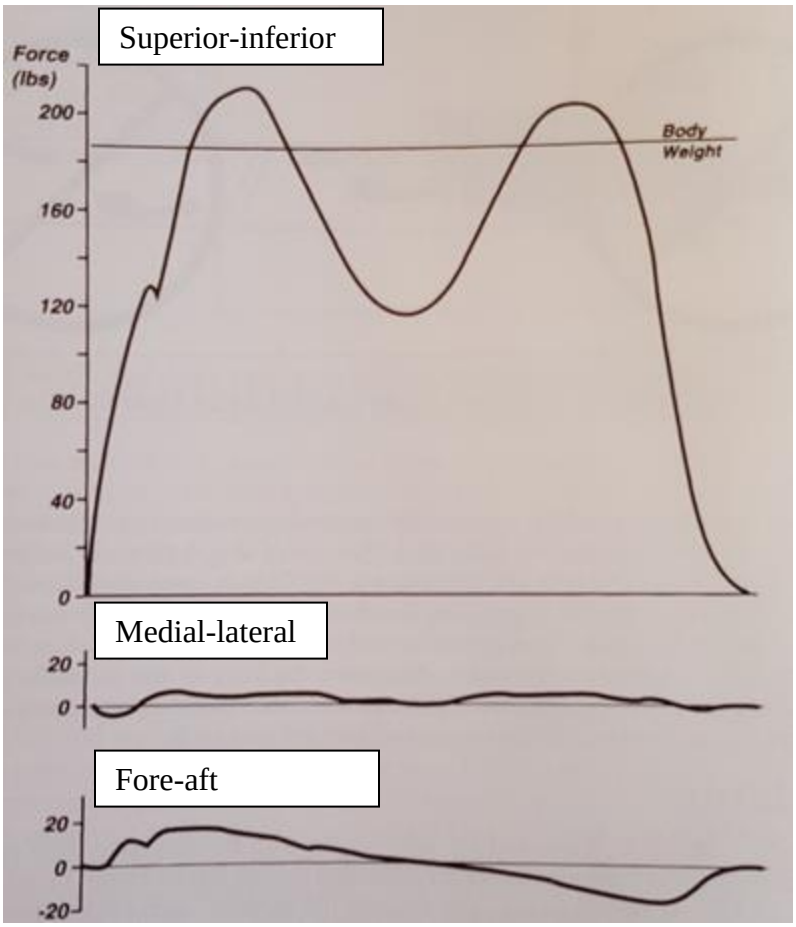

Figure 2.16: GRFs: superior-inferior (top), medial-lateral (middle), and fore-aft (bottom) directions (adapted from [10]).

2.3 AFO-treated Gait

AFOs are used to compensate for weak dorsiflexors, hyperactive plantarflexors, or impaired lower extremity function. The rigid plantar structure of AFOs provides a stable base of support for the foot. AFOs have been shown clinically to restore function, increase walking speed, decrease energy cost ([14], Table 2.1), reduce knee hyperextension ([15], Table 2.2), or increase peak knee extensor moments ([16], Table 2.2). Motion analysis research studies have demonstrated decreased kinematic pathologies, decreased spasticity in terms of EMG activity, and reduced pathologic GRFs with AFO use.

2.3.1 Clinical Functional Outcomes with AFO Use

The efficacy of various AFO designs has been investigated to confirm whether the prescribed AFO addressed the specific treatment objectives and to assess specific functional outcomes, largely with respect to gait (Table 2.1). Clinical tests and metrics have included: the timed up and go test (TUG), stability assessment [Berg Balance scale (BBS)], cadence and self-selected walking speed (SSWS), and metabolic cost (oxygen consumption or energy cost).

The TUG test measures a person's ability to stand up, walk three meters, walk back, and sit down in terms of task completion time. For post-stroke individuals, TUG completion time increased with increasing level of disability [17-19]. TUG time was observed to decrease by 3-6 sec with AFO use [15, 17].

The effects of AFO use on balance and stability during ambulation and various activities of daily living for static and dynamic tasks have been assessed using the BBS (Table 2.1). The BBS assesses balance during 14 tasks relevant to activities of daily living (e.g. sit to stand), with scores ranging from 0 to 4 and higher scores reflecting improved balance and functional independence [20]. Use of a custom metal or plastic AFO resulted in improved BBS scores with respect to the no AFO condition for individuals post-stroke (AFO: 48.0±4.8 vs no AFO: 46.2±5.5) [18]. Wang et al., however, reported no change in BBS scores for post-stroke individuals using standard off-the-shelf plastic, non-articulated AFOs [21]. These differences in functional improvement may be attributed to the specific AFO used.

The effects of AFO use on spatial-temporal parameters such as cadence and SSWS have also been investigated for post-stroke individuals. SSWS has been reported to increase with AFO use relative to the no AFO condition (0.34 m/s vs 0.27 m/s) [14]. The time required to complete

a 10m walk has been shown to decrease with AFO usage for post stroke individuals, again reflecting increased walking speed with AFO use [19].

Finally, the clinical effect of AFO usage on metabolic cost has been measured on individuals with cerebral palsy (CP), as well as post stroke subjects. Metabolic cost has been assessed in terms of both oxygen consumption (volume of oxygen consumed per minute of ambulation) and energy cost (oxygen consumption normalized to distance traveled). Net oxygen uptake and net pulmonary ventilation were reduced (5.9-8.9% and 10.3%, respectively) with AFO use for individuals with CP [22]. Similarly, oxygen consumption decreased from 0.52 to 0.46mL/kg^{-}m with AFO use for post stroke subjects while the physiological cost index decreased from 0.75 to 0.73 [23].

2.3.2 Motion Analysis Investigations of AFO Use

The effect of AFO use on gait has also been investigated using motion analysis (Table 2.2). Ankle orientation in rigid AFOs has been shown to affect joint kinematics and kinetics, with plantarflexed AFOs resulting in decreased knee flexion moment, or increased knee stability during LR for post-stroke individuals [6]. Shorter foot plates decreased ankle dorsiflexion during both stance and swing for able-bodied subjects with AFO use [16]. The effects of AFO alignment (heel wedges) and shoe sole stiffness on knee kinematics have also been investigated. Both the inclusion of a heel wedge and a stiff rocker sole reduced knee hyperextension for a single post stroke subject wearing a plastic, non-articulated AFO [15].

In contrast to traditional kinematic analysis of the ankle, knee, and hip joints, Owen investigated the effects of AFO design on segment kinematics in terms of shank-to-vertical angle (SVA) and thigh-to-vertical angle (TVA) (Figure 2.17 and 2.18). These angles are reported

relative to a global coordinate system (e.g. vertical or gravity reference) rather than a local, segment-based coordinate system. The global reference system was thought to have clinical value with respect to AFO alignment and observational gait analysis. A common clinical misconception is that the shank and thigh are concurrently vertical during MSt (MSt) [24]. Coincident vertical segments would result in knee and ankle instability, requiring forward trunk lean posture or a reclined thigh with trunk lean to impose hip and knee flexion [24]. The SVA during MSt was modified via AFO alignment variations to investigate the effects of AFO alignment and SVA angle on the gait of a post stroke subject. Nominal AFO alignment and footwear resulted in a SVA of 0° (e.g. vertical shank) during MSt. Inclusion of heel wedges resulted in a SVA of 14° (e.g. inclined shank) during MSt, thereby decreasing knee hyperextension during MSt [15].

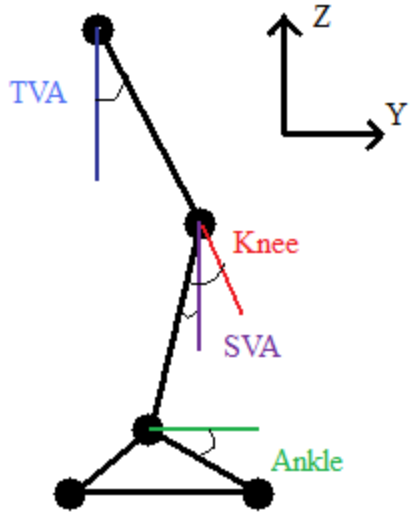

Figure 2.17: Comparison of joint (knee and ankle) and segment (SVA and TVA) angles, defined in local and global coordinate systems, respectively.

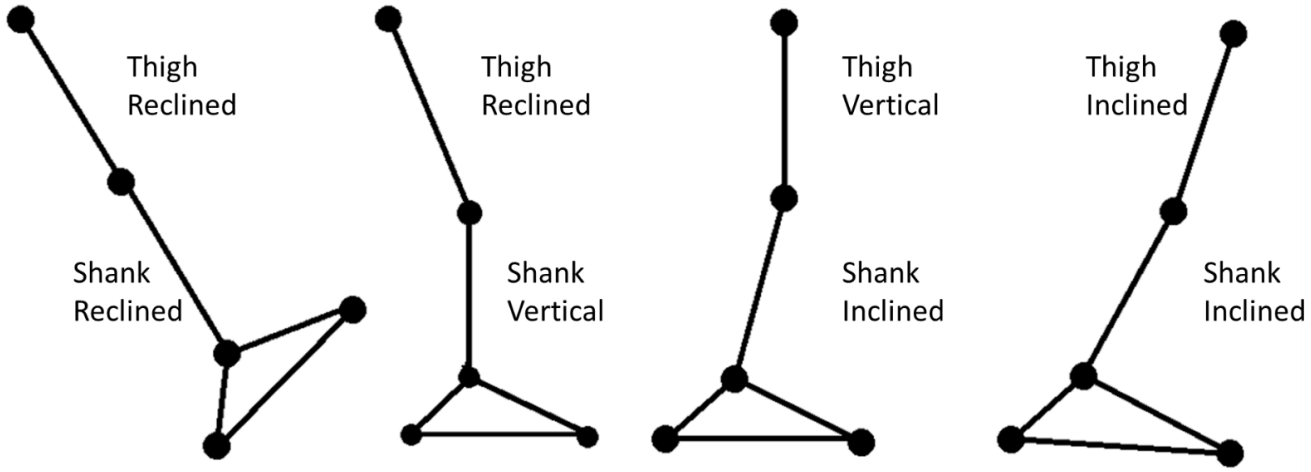

Figure 2.18: Lower limb segment angles from heel strike through toe off, illustrating the shank and thigh segment orientations (e.g. reclined: -, inclined: +).

The effect of AFO design on lower extremity muscle activity has also been investigated, as AFOs are often prescribed to address muscle weakness and/or spasticity [4, 5]. Dorsiflexor activity has been shown to decrease during LR for both post-stroke (7% decrease) and able-bodied (20% decrease) individuals with AFO use, as non-articulated AFOs restrict ankle plantar flexion and minimize the need for dorsiflexor activity during MSt to prevent foot slap [4, 5].

The fixed neutral ankle position in these solid AFOs also reduced dorsiflexor activity during swing for post-stroke subjects [4, 5].

Finally, the effect of AFOs on gait kinetics has been investigated in terms of joint moments and sway of the COP. Full-length foot plates significantly increased peak plantar flexor moment during stance for both post-stroke and able-bodied individuals [16]. COP sway in both the medial-lateral and fore-aft directions was reduced by 23-26% for able-bodied individuals with AFO use during standing balance trials [25].

Table 2.1: Summary of functional outcomes with AFO use as reported in the literature.

Investigators	**Subjects**	**AFO Type**	**Metrics**
Danielsson and Sunnerhagen, 2004 [14]	Hemiparetic (N=10)	Carbon composite AFO	Walking speed, oxygen consumption, heart rate, energy cost
Danielsson, et al,, 2007 [26]	Hemiparetic (N=20) and healthy aged 30-63 (N=16)	Unspecified	Oxygen consumption and energy cost
de Wit, et al., 2004 [17]	Chronic post stroke (N=20)	Polypropylene rigid AFO	Walking speed, TUG
Maltais, et al., 2001 [22]	Splastic diplegic CP (N=10)	Hinged AFO	Oxygen consumption
Ng and Hui-Chan, 2005 [18]	Healthy elderly (N=11), and chronic post stroke (N=10)	Unspecified	Spasticity of plantaflexor, MVIC, 6 minute walk test, TUG test
Simons, et al., 2009 [18]	Acute Stroke (N=20)	Polypropylene rigid AFO or articulated metal AFO	BBS, TUG, 10 m walking test
Wang et al., 2005 [21]	Hemiparetic short term (N=42) and long term (N=61)	Polypropylene AFO	BBS, 10 m walking test

MVC = maximum voluntary contraction

Table 2.2: Summary of research studies assessing AFO function.

Investigators	**Subject**	**AFO Type**	**Metrics**
Cruz and Dhaher, 2009 [3]	Hemiplegic (N=9)	Polypropylene rigid and articulating AFOs	LE kinematics, temporal parameters
Fatone et al., 2009 [16]	Post stroke (N=16), normal (N=12)	Polypropylene articulating AFO	LE Kinetics: knee, ankle moment, LE Kinematics: knee, ankle angles
Geboers et al., 2002 [43]	Normal (N=14) and foot drop (N=29)	Polypropylene rigid AFO or self-selected	Dorsiflexion EMG
Jagadamma et al., 2010 [15]	Hemiplegic (N=1)	Polypropylene rigid AFO	LE Kinetics: knee moment, LE Kinematics: knee angle and SVA
Lairamore et al., 2011 [5]	Post stroke (N=15)	Polypropylene rigid AFO	Dorsiflexion EMG
Silver-Thorn, et al., 2011 [6]	Post stroke (N=8)	Polypropylene rigid AFO	velocity, cadence, step length, LE Kinetics: knee moment
Vistamehr, et al., 2014 [8]	Normal (N=10)	Polypropylene rigid AFO	Propulsive impulses, angular momentum
Warnica, et al., 2014 [25]	Normal (N=18)	Nylon rigid AFO	Kinetics: COP, kinematics: whole body, dorsiflexion and plantarflexion EMG

2.4 Summary

AFOs are assistive devices prescribed to provide support for the foot throughout the gait cycle and to provide proper foot clearance during swing phase. Depending on the impairment, a rigid or an articulating AFO may be prescribed. Rigid AFOs provide greater stability for those with higher levels of impairment or older populations, while the articulating AFOs provide limited movement which may aide recovery and prevent muscle atrophy.

Pathologies requiring AFO intervention have been shown to adversely affect walking speed, balance/stability, kinematics, EMG activity, and kinetics of gait. Pathologies such as stroke and CP can cause dorsiflexion weakness, affecting toe clearance during swing phase. Pathologies and injuries may also lead to compensatory mechanisms, such as hip hiking, vaulting, and circumduction, which can lead to further injuries or increased energy expenditure during gait.

AFO usage has been shown to improve clinical functional outcomes and gait measures compared to no AFO gait in pathologic subjects. AFO usage has been shown to decrease TUG completion times and increase BBS scores, reflecting improved stability when walking with an AFO; walking speed has also been observed to increase with AFO use. Finally, AFO use has reduced compensatory motion of the knee and ankle, decreased dorsiflexor and plantarflexor EMG activity, and reduced COP sway.

Chapter 3: METHODS

This study involved gait analysis of able-bodied individuals during level treadmill ambulation to contrast unassisted versus AFO (non-articulated rigid, articulated and DRAFO designs) gait. The research hypotheses (see Table 1.1) were: 1) DRAFO-assisted gait will approximate that of the non-AFO condition, and 2) DRAFO-assisted gait will differ from that for articulating and rigid AFOs. To test these hypotheses, sagittal plane knee/ankle angles, shank/thigh to vertical angles (SVA/TVA), plantar/dorsiflexion muscle activity duration, and COP progression were contrasted for the various AFO conditions.

This chapter details the procedures for gait analysis including: subject selection, AFO casting/fabrication/fitting, and static/dynamic gait analysis. Details regarding the subsequent data processing for kinematic, EMG, and kinetic data are also included, as are the respective statistical analyses.

3.1 SUBJECT SELECTION

3.1.1 Inclusion Criteria

The study protocol was approved by the Institutional Review Board (IRB) of Marquette University. Ten young healthy subjects, undergraduate and graduate students in biomedical engineering at the University, were recruited. Subject selection criteria were:

- 18-25 years of age,
- normal dorsi-/plantar flexion range of motion and strength, and
- capable of attaining a passive 90° neutral ankle position.

Subjects with prior musculoskeletal injury or deformity of the lower extremities were excluded.

3.1.2 Subject Recruitment

Subjects were recruited via fliers posted in prominent locations in University engineering buildings and by word of mouth. Interested individuals were screened to confirm eligibility. Written informed consent was obtained prior to research participation.

3.2 TESTING PROTOCOL

3.2.1 AFO Casting and Fabrication

During an initial 60 minutes research session, a certified orthotist (Davin Amara, C.O., Bracemasters International, LLC, New Berlin, WI) casted the subject's right leg from the toes to just distal to the knee. The ankle was held at 90° neutral orientation until the cast set. This cast served as a negative mold, and used to create a positive model of the lower leg for fabrication of the custom AFOs. For each subject, two AFOs were fabricated by Bracemasters: an articulating AFO with Tamarack flexion joints with a locked ankle joint option, and the DRAFO aligned at 3° plantarflexion as per clinical guidelines (Figure 3.1). The outer shells of the articulating AFO and DRAFO were fabricated with a polypropylene co-polymer with modified polyethylene dynamolene; the flexible inner lining of the DRAFO was fabricated using dynamolene. When wearing the DRAFO, external lifts were secured to the soles of the subject's shoes to align the shank vertically during MSt.

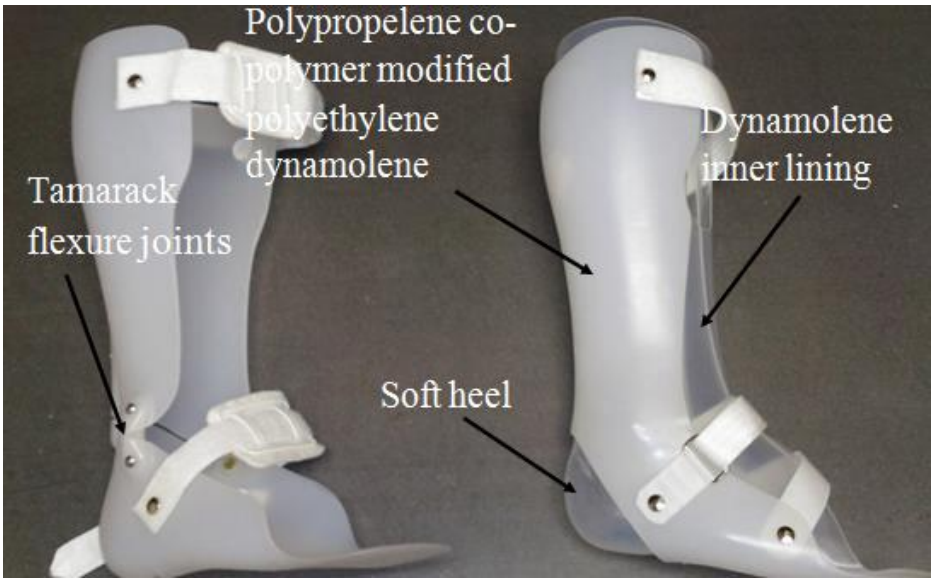

Figure 3.1: Articulating AFO (left) and DRAFO (right).

3.2.2 Gait Analysis

3.2.2.1 Subject Instrumentation and Marker Placement

A second research session, approximately 2 hours in duration, was conducted in Dr. Hyngstrom's Neurolocomotion Lab at Marquette University. Anthropometric measurements of the subject's knee width, ankle width, and leg length were acquired; the subject's height and weight were also recorded [27]. These measurements were requisite input to the Plug-In-Gait (PIG) model (Nexus v 1.8.1, Vicon Motion Systems, Inc, Lake Forest, CA, 2002).

The skin over the subject's anterior shanks and posterior calves was cleaned with rubbing alcohol prior to applying conductive gel and placing bipolar surface EMG electrodes (MA-411 EMG with preamplifier, Motion Lab Systems, Baton Rouge, LA) to acquire tibialis anterior (TA) and gastrocnemius (G) muscle activity. A similar procedure was used to apply a ground electrode over the bony prominence of the subject's proximal tibial flare. These electrodes were

secured with hypoallergenic tape and wrapped with Coban tape (COBAN Technologies, Houston, TX) to minimize potential motion artifact.

Fifteen reflective markers (14mm) were then secured over specific bony landmarks using double sided tape [27]. Marker locations included: the sacrum, as well as right and left anterior superior iliac spines (ASIS), lateral thigh, approximated knee joint center, lateral shank, lateral malleolus, second metatarsal head (on shoe), and heel (on shoe). Four additional markers were placed on each shoe at the medial and lateral midfoot to aid COP referencing (see Figure 3.2). The subject was then secured in an overhead harness system to minimize risk of injury in case of fall.

Nexus (version 1.8.1, Vicon Motion Systems, Inc) was used to capture the kinematic data at 100 Hz. Six to eight (two additional laboratory cameras were added to the motion capture system mid-study) infrared cameras were used to capture the trajectories of the reflective markers. The four EMG channels were sampled at 1000 Hz. The kinetic data from the instrumented, split-belt treadmill (Bertec, Columbus, OH) were sampled at 1000 Hz. All data were synchronously acquired on a single computer.

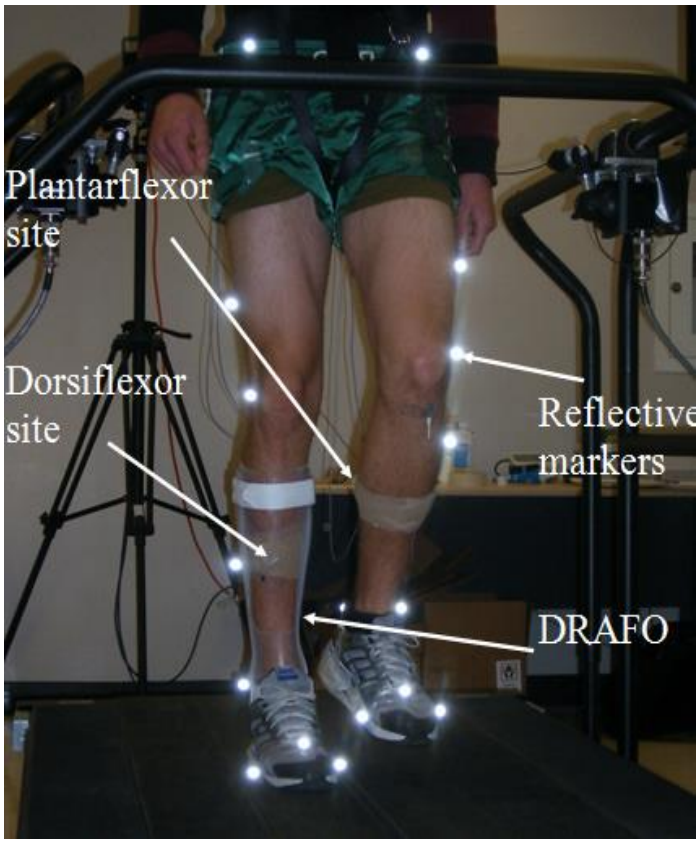

Figure 3.2: Subject wearing the DRAFO, instrumented with reflective markers and surface electrodes, during treadmill walking.

3.2.2.2 Static Trial

Initial static trials were recorded for each subject to validate marker placement, define segments, and acquire maximum voluntary contraction (MVC) EMG activity of the two muscle groups bilaterally. A single MVC of 3-5 seconds was solicited for the right TA, right G, left TA, and left G as the subject stood, dorsiflexing against manual resistance or plantar flexing against the treadmill surface.

A preliminary kinematic PIG model was then created, defining the respective pelvis, thigh, shank, and foot segments in terms of the markers. The pelvis was defined by the two ASIS and sacrum markers. The thigh was defined by the respective ASIS, knee center, and thigh

markers. The shank was defined by the respective knee center, malleolus, and shank markers. Lastly, the foot segment was defined by the respective malleolus, heel and 2nd metatarsal head markers. Marker locations were adjusted as needed, repeating the static trials, prior to dynamic gait trials.

3.2.2.3 Dynamic Gait Trials

Dynamic gait trials were conducted for all test conditions: no AFO condition, followed by randomized testing of the rigid, articulated and DRAFO conditions.

The subject acclimated to the treadmill for approximately 5 minutes, identifying their self-selected walking speed (approximately 1.0 m/s). Marker positions and EMG signals were visually verified during this period. Two minute walking trials at the subject's self-selected walking speed were then conducted; kinematic, EMG and kinetic data were acquired for six 20-second periods. The AFO for the respective test condition was then removed.

The shank and lateral malleolus markers of the right leg were removed. The AFO for the next test condition was then donned. Static trials were repeated for the new AFO condition. The subject acclimated (up to 5 minutes) to the new AFO during overground walking. Dynamic gait trials were then conducted. This procedure was repeated for each of the three AFO conditions.

3.3 KINEMATIC DATA PROCESSING

The kinematic data were first processed using Nexus. The c3d files were imported into a library, prior to reconstruction and editing. Processing steps included correcting mislabeled markers and filling gaps due to marker drop out. Further processing was then conducted using

MatLAB (The Mathworks Inc., Natick, MA) scripts to calculate mean sagittal plane joint angles for the knee and ankle, as well as shank and thigh vertical angles.

3.3.1 Construction of 3D Motion Data

The 2D marker data from each camera were processed through direct linear transformation to create 3D marker motion trajectories. Using the static trial data, the markers were labelled. Marker trajectories were reviewed to identify potential mislabelling, correcting as needed. Marker gaps (less than 50 consecutive frames) due to drop out were filled using spline filtering. Phantom, unlabelled markers were removed. Marker trajectories were smoothed using a Woltring filter.

3.3.2 Calculation of Conventional Lower Extremity Joint Angles

To determine joint angles, limb segments were defined from the various marker sets, as noted in the Static Trials section. The respective joint centers were then identified using the PIG model. The hip joint center was calculated based on leg length and inter-ASIS distance; the knee joint center was calculated using the hip joint center, thigh marker, and knee center marker; the ankle joint center was calculated from the knee joint center, shank marker, and malleolus marker (with ankle offset for the right limb, if an AFO condition) [27].

To facilitate kinematic comparison between AFO conditions, the sagittal plane knee and ankle angles were reviewed to determine the knee and ankle angles during various periods of stance and swing. For the knee, the periods of interest included IC, early stance (0-30% of gait cycle), mid- to late-stance (30-70% gait cycle), and swing. The specific knee metrics were: 1)

knee angle at IC, 2) peak knee flexion during early stance, 3) peak knee extension during mid- to late-stance, and peak flexion during swing. For the ankle, the periods on interest corresponded to the three rockers [e.g., early stance (0-30% gait cycle, heel rocker), mid- to –terminal stance (ankle rocker), late stance (toe rocker)] and swing. The specific ankle kinematic measures were: peak plantarflexion during early stance (first rocker), peak dorsiflexion during mid- to late-stance (second rocker), peak plantarflexion during late-stance (third rocker), and peak dorsiflexion during swing.

3.3.3 Calculation of Non-Conventional Segment Angles, SVA and TVA

Two additional angles were calculated in this study: shank to vertical (SVA) and thigh to vertical (TVA) segment angles, both defined with respect to a global, laboratory-based coordinate system. The SVA refers to the angle between the shank and the global z-coordinate (vertical); similarly, the TVA refers to the angle between the thigh and the global z-coordinate (Figure 2.17). These angles were calculated in MatLAB; the SVA was calculated using the location of the ankle center of rotation and tibial segment orientation; the TVA was calculated using the knee center of rotation and thigh segment orientation. The time at which the SVA and TVA transitioned from extended to flexed positions and vice versa, e.g. crossover time or time (percent gait cycle) when SVA=0° and TVA=0°, were also recorded (Figure 3.3).

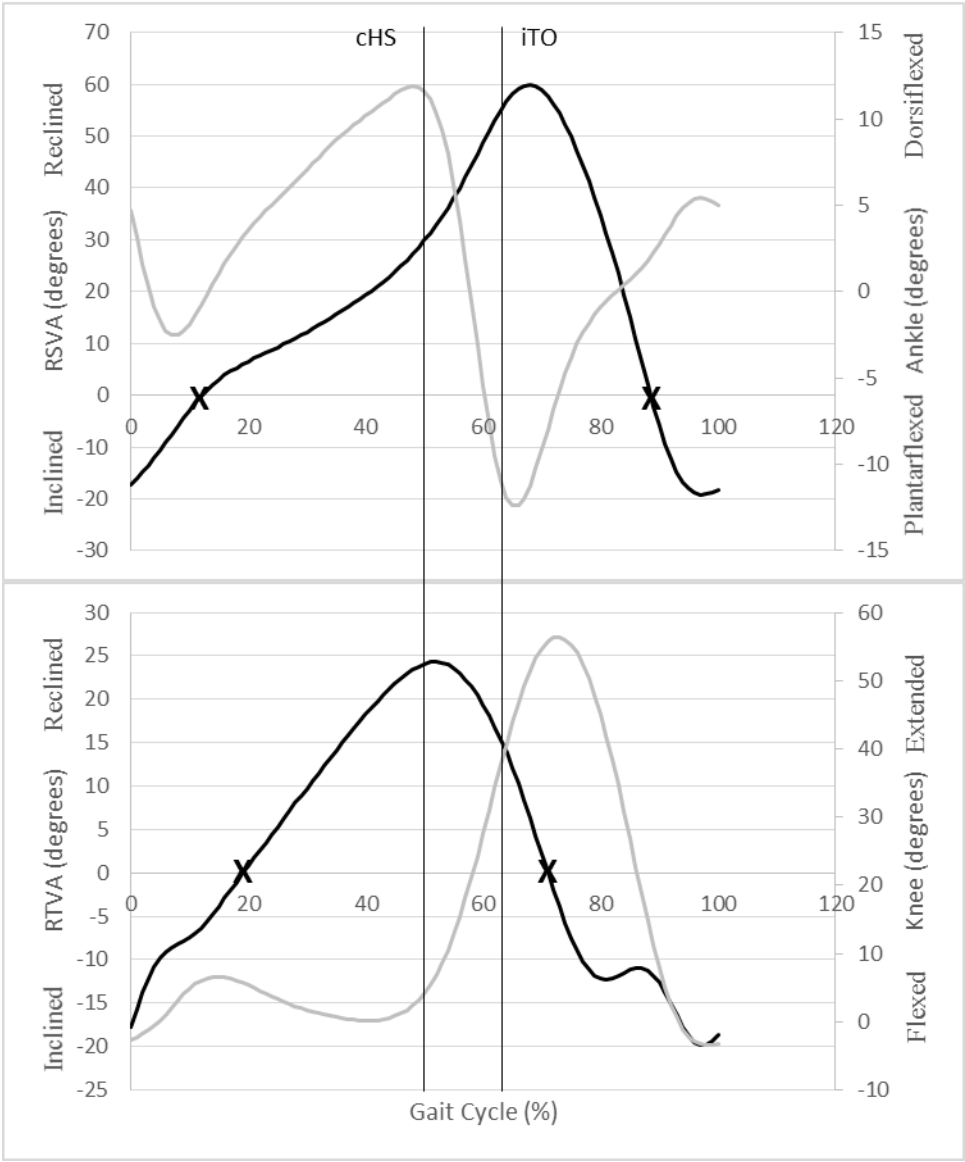

Figure 3.3: Sample kinematic data for subject 3 (no AFO condition) illustrating ankle and knee joint angles (gray), SVA and TVA (black), and SVA and TVA cross-over times (X).

3.3.4 Calculation of Foot Progression Angle

The FPA, the final kinematic parameter investigated in this study, was defined as the angle between forward progression and the long axis of the foot (heel to toe marker) in the

transverse plane. Positive angles were defined as external rotation or toe out; sample data are shown in Figure 3.4.

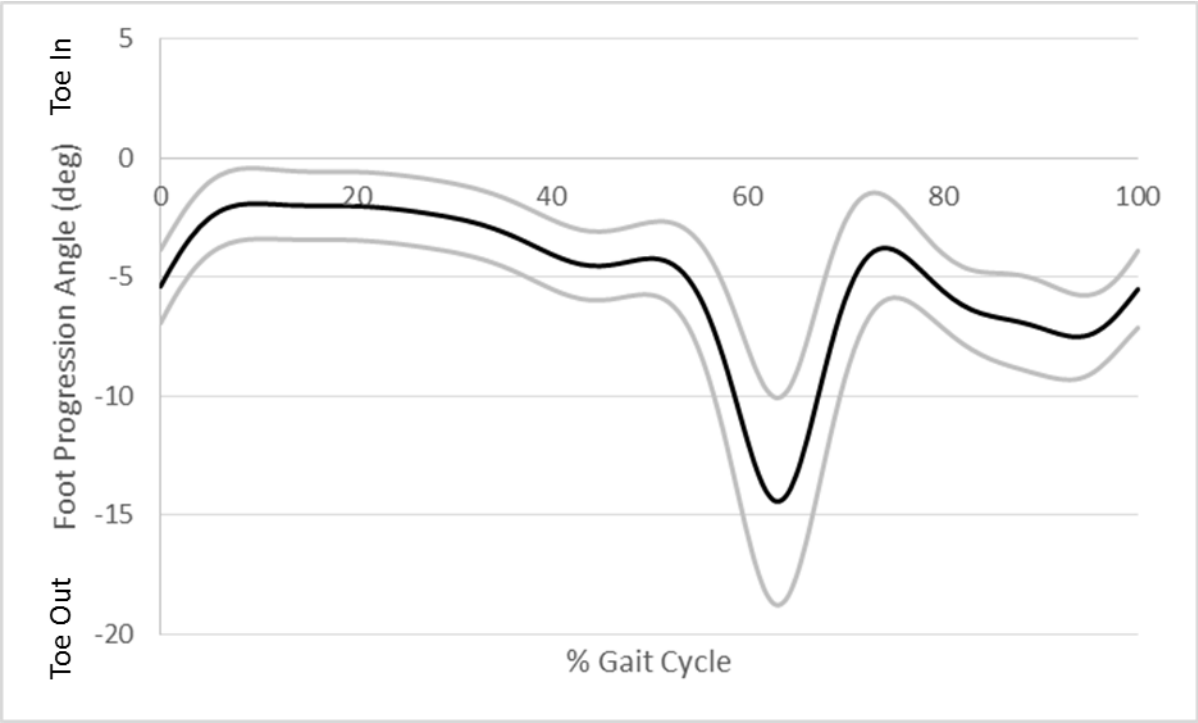

Figure 3.4: Sample foot progression angle, mean (black) and standard deviation (gray), in the transverse plane (subject 5, no AFO condition).

3.4 CALCULATION OF TEMPORAL PARAMETERS

Heel strike (HS) and toe off (TO) events were identified to differentiate stance and swing phases of gait. Specific event detection was based on vertical GRF data from the instrumented treadmill. HS and TO events were defined as the instance when the vertical forces exceeded or fell below 4% of the maximum vertical GRF, respectively. Each gait cycle was defined from successive ipsilateral HS events; stance was defined from successive ipsilateral HS to ipsilateral

TO events and swing was defined as successive ipsilateral TO to ipsilateral HS events (Figure 3.5).

3.4.1 Step Width

Using the HS events and the position of the heel markers, step width was calculated as the mediolateral distance between the heel markers of the left and right feet.

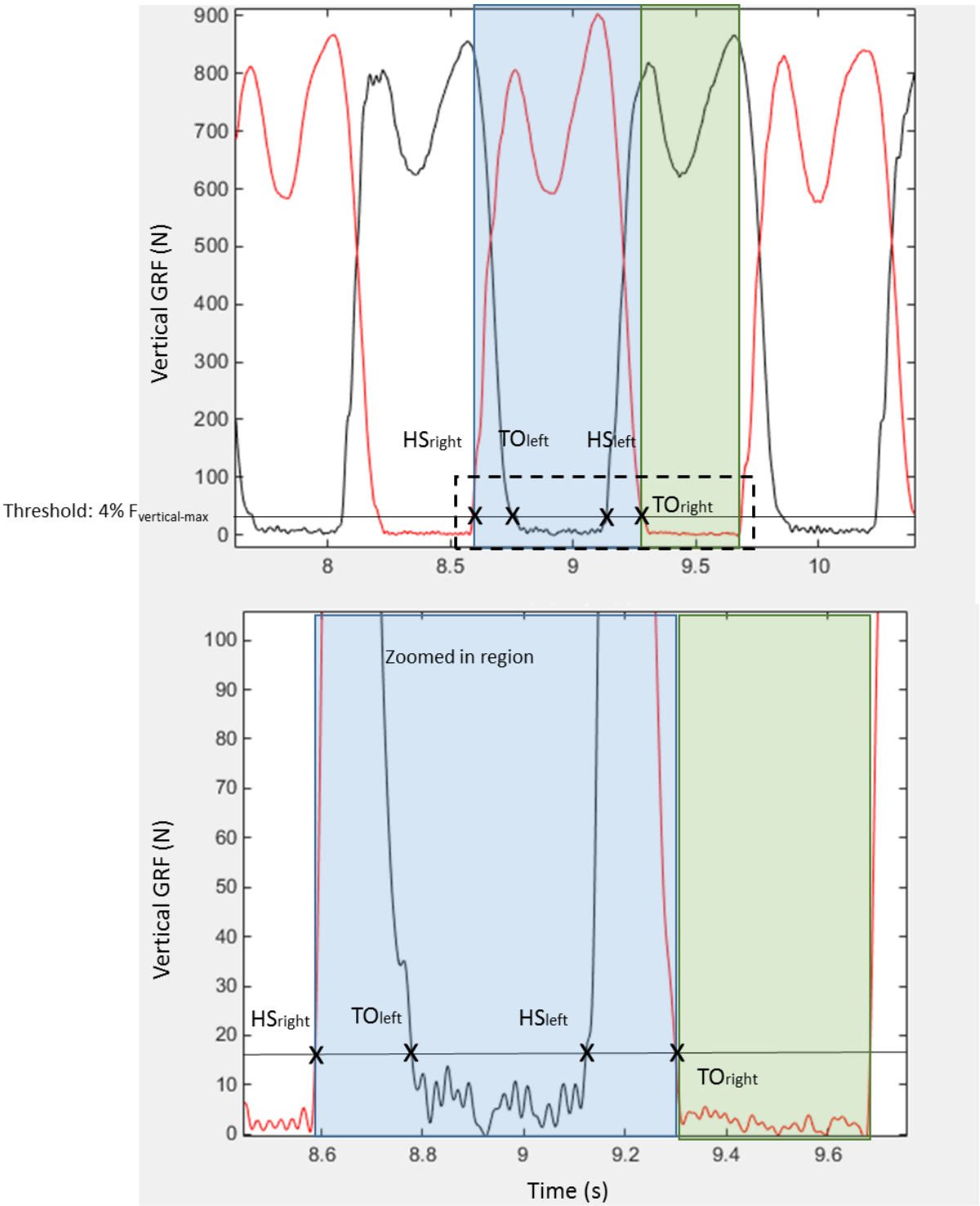

Figure 3.5: Sample vertical GRF data for the right (red) and left (black) limbs for subject 3 (no AFO condition), illustrating HS and TO event detection via a threshold detection algorithm. The blue shaded region is right stance; the green shaded region is right swing.

3.5 EMG DATA PROCESSING

All EMG signal processing was conducted in MatLAB. The TA and G surface EMG data for both limbs were rectified, low pass filtered and segmented into gait cycles based on the HS and TO events; data were then scaled. Finally, EMG data were reviewed during the stance and swing phases of gait to identify the activation periods.

3.5.1 Rectification and filtering of EMG data

The EMG waveform was full-wave rectified (absolute value) and smoothed (second order, low pass, Butterworth filter at 5Hz) to create a linear envelope, Figure 3.6.

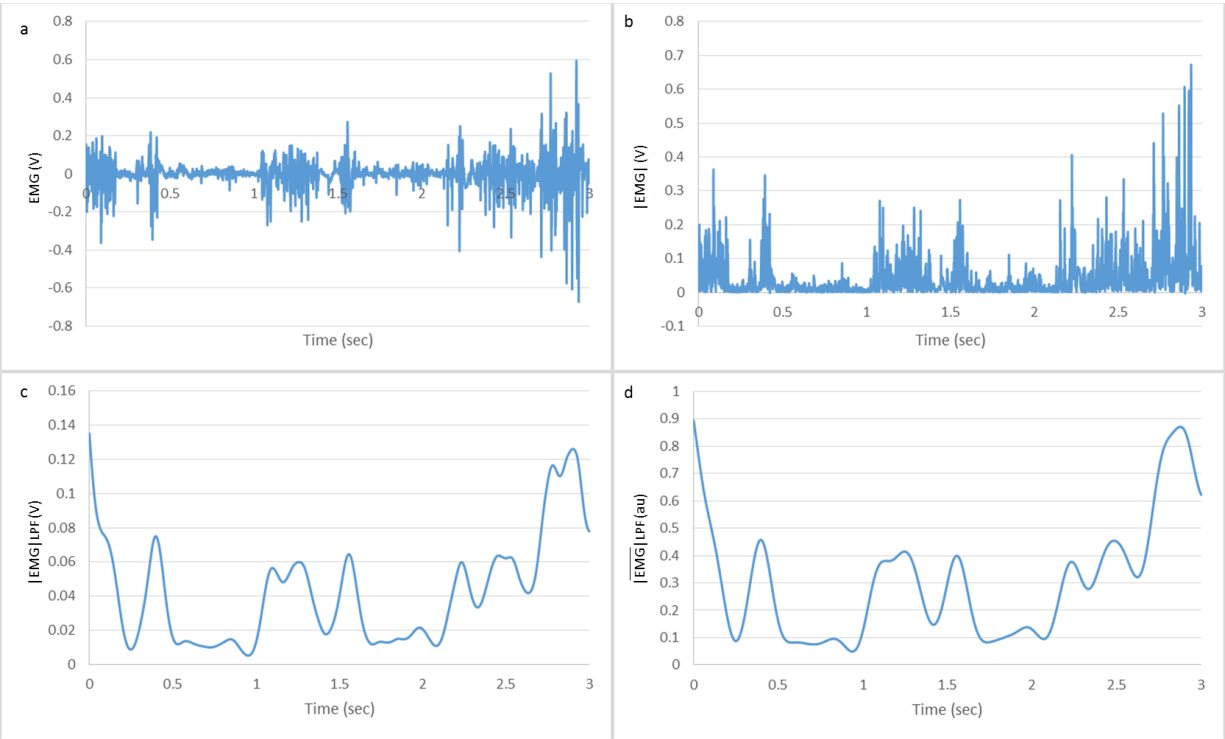

Figure 3.6: EMG post-processing for representative TA data (subject 8 wearing DRAFO): a) raw EMG, b) rectified EMG, c) rectified and low-pass filtered EMG, and d) rectified, filtered, and normalized EMG.

3.5.2 Normalization or scaling of EMG data

The EMG waveforms were then scaled based on the respective EMG magnitude observed during the maximum voluntary contraction (MVC) trial. To determine the MVC magnitude for each subject and muscle, the mean baseline EMG level during off period was subtracted from the mean EMG level during the MVC activation period (Figure 3.7). During the dynamic tasks, the rectified, filtered EMG data were then normalized or scaled based on the respective mean MVC magnitude (Fig 3.6d).

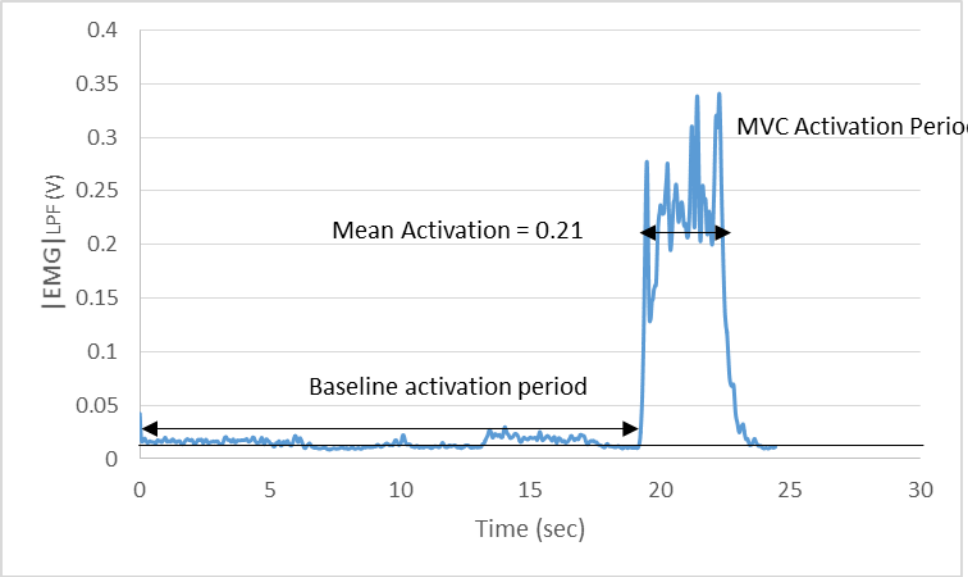

Figure 3.7: MVC trial for dorsiflexion (subject 3, no AFO condition) illustrating mean baseline and mean MVC activation magnitude and duration.

3.5.3. Identification of muscle activation periods

The rectified, filtered, and normalized EMG waveforms were divided into individual gait cycles, stance and swing phases based on synchronously acquired GRF data and the HS and TO events. These EMG subsets were reviewed to identify muscle activation periods based on

amplitude threshold analysis. Periods for which EMG values exceeded this threshold were considered “on” or active; periods for which EMG values were less than the threshold were considered “off” or inactive.

Investigation of the amplitude threshold level (20-40% MVC) was conducted to identify the normalized EMG amplitude threshold for the no AFO condition that resulted in activation periods consistent with able-bodied data [10]. An activation threshold of 20% MVC was selected after comparing dorsiflexor and plantarflexor activation periods for the no AFO condition in this study to Perry’s EMG activity (Figures 2.7, 2.8, 3.8, and 3.9, [10]).

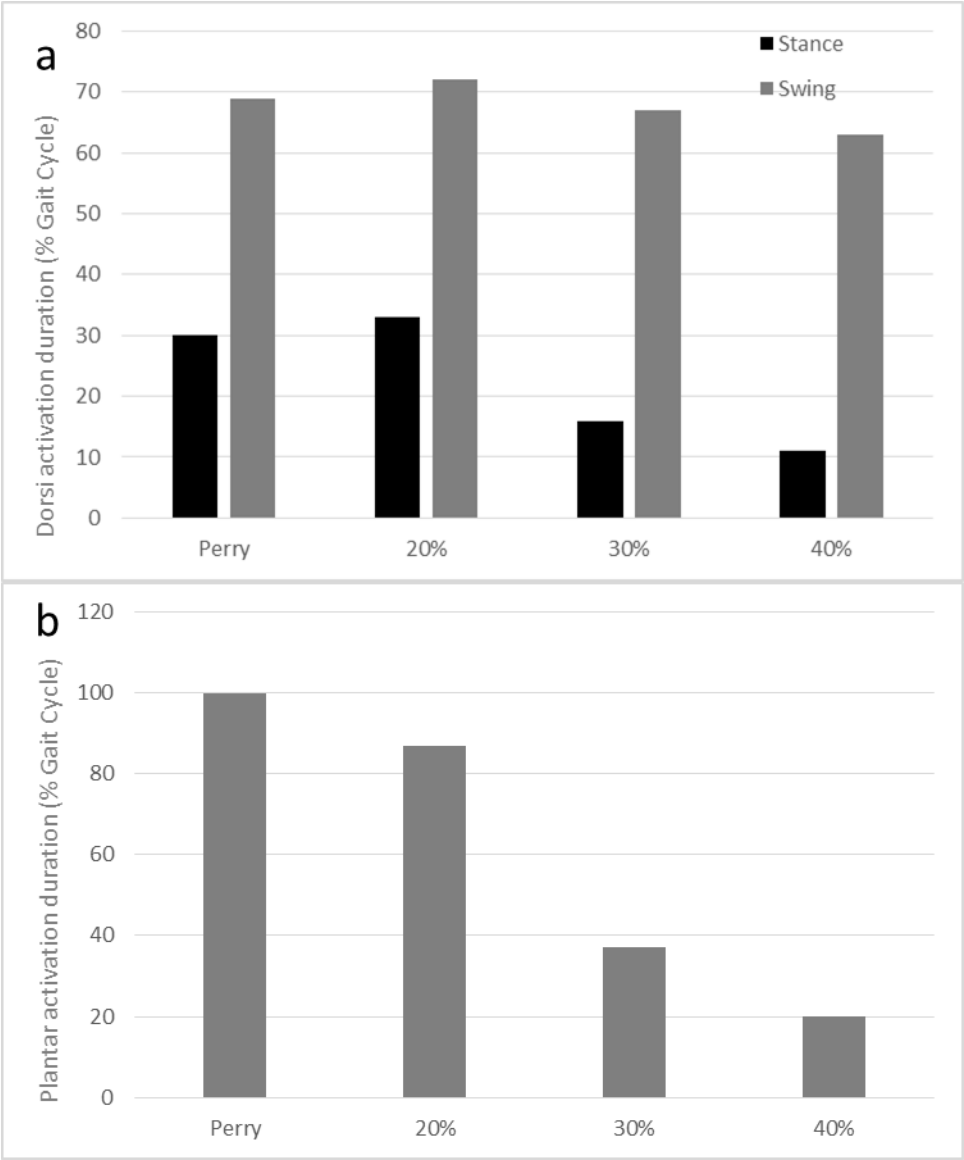

Figure 3.8: Sample activity duration of the dorsiflexors (top - stance: black, swing: dark gray) and plantarflexors (bottom, stance only) for subject 3 (no AFO condition) and for able-bodied persons (Perry), assuming an activation threshold of 20% [10].

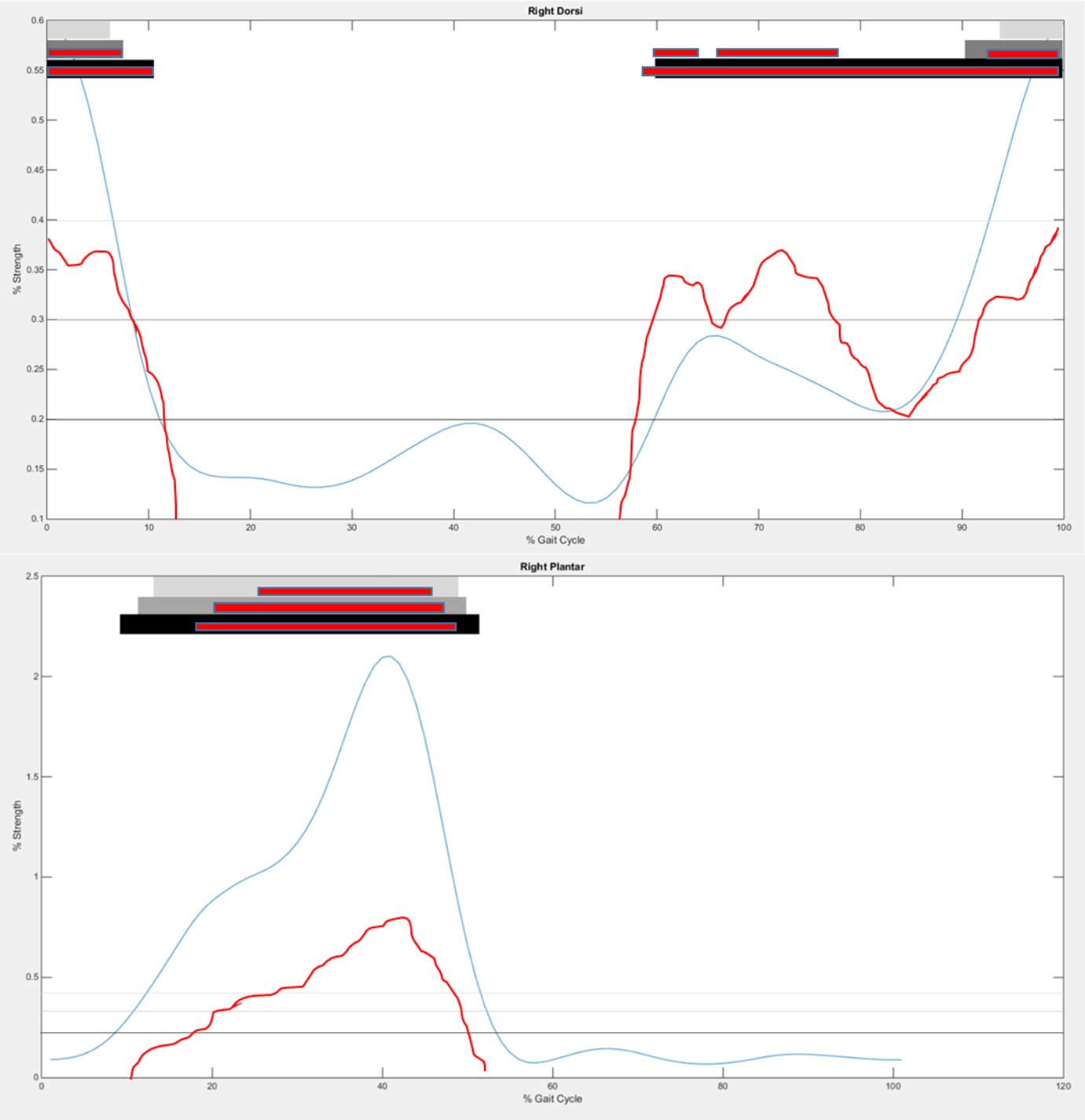

Figure 3.9: Representative dorsiflexion (top) and plantarflexion (bottom) EMG activity time series with corresponding on-periods based on activation thresholds of 20 (black), 30 (gray), and 40% (light gray) for subject 3 (no AFO condition). Also shown is the approximate activation periods for able-bodied subjects from Perry (red) [10].

This activation threshold of 20% MVC was then applied to the bilateral EMG data for both the plantar flexors and dorsiflexors for all gait cycles to differentiate the active and inactive periods, as well as the duration of the activation periods during stance and swing, for each AFO condition for each subject. The total activation period duration during stance (and similarly, during swing) was calculated as the sum of all activation periods during stance for each gait cycle. The mean activation period duration during stance (and similarly, during swing) was calculated across all gait cycles for the respective subject and AFO condition.

3.6 COP DATA PROCESSING

The COP defines the location of the GRF relative to either a global, laboratory-based coordinate system or a local coordinate system such as the foot. Motion of the COP, in terms of the length of the COP trajectory or its anterior-posterior and medial-lateral displacement, is often used to characterize stability during gait or quiet standing. This section details specific kinetic and kinematic data processing to investigate COP progression relative to a local coordinate system defined by the foot, as well as the global, laboratory-based coordinate system.

3.6.1 Calculation of COP progression

The COP of the right and left limbs was initially evaluated using the global, laboratory-based coordinate system of the treadmill, as shown in Figure 3.11. The COP, the location of the GRF vector relative to the treadmill, was defined using Equations 1 and 2 [28]:

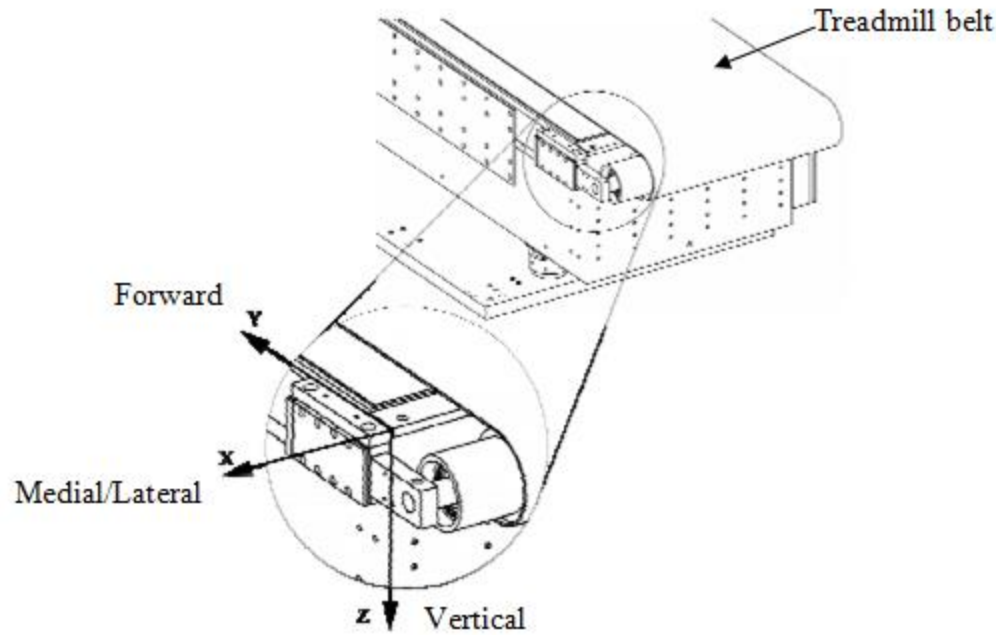

Figure 3.10: Global coordinate system for COP determination (adapted from [28]).

$$x_p = \frac{-h*F_x - M_y}{F_z} \quad (1)$$

$$y_p = \frac{h*F_y - M_x}{F_z} \quad (2)$$

where x_p, y_p are the COP locations in the x-y or transverse plane, h is distance between the treadmill belt and the embedded load cells (e.g. 0.015 mm), and F_i and M_i are the force and moment components.

To express the COP in terms of a local, foot-based coordinate system, a pseudo-foot was defined in terms of the foot markers (Figure 3.11). This pseudo-foot used the heel marker and the medial and lateral shoe markers to define the boundaries of the foot. The alignment of the long-axis of the foot, relative to the global coordinate system, was defined by the angle θ using Equation 3.

$$\theta = \text{atan}\left(\frac{RHeex - RToex}{RToey - RHeey}\right) \quad (3)$$

where R_{Hee} and R_{Toe} refer to the right heel and toe marker positions in the global coordinate system.

To transform the COP from the global coordinate system (x, y) to the local, foot-based coordinate system (x_f, y_f), the above rotation with respect to the angle, θ, was translated from the treadmill origin to the heel (Figure 3.10), as described by Equations 4-5.

$$xf = x * cos(\theta) - y * sin(\theta) \quad (4)$$

$$yf = x * sin(\theta) + y * cos(\theta) \quad (5)$$

To characterize the progression of the COP during stance, the medial-lateral motion relative to the long-axis of the foot was quantified (Fig 3.11 and Fig 3.12). Specifically, at a given instance in stance, the global heel marker position was transformed to the local foot-based coordinate system; the location of the local COP relative to the heel was translated such that the COP was located at the heel at IC. As stance progressed, COP locations with positive x_f values corresponded to COP being lateral to the long axis of the (right) foot; negative x_f corresponded to the COP being medial to the long axis of the (right) foot.

The medial and lateral motion of the COP (e.g. minimum, maximum, range, and mean values) was then calculated for the various sub-phases of stance: LR, MSt, TSt, and PSw for each subject and AFO condition. Outlier values that exceeded the foot width or were in excess of ±2 standard deviations of the mean were excluded from analysis.

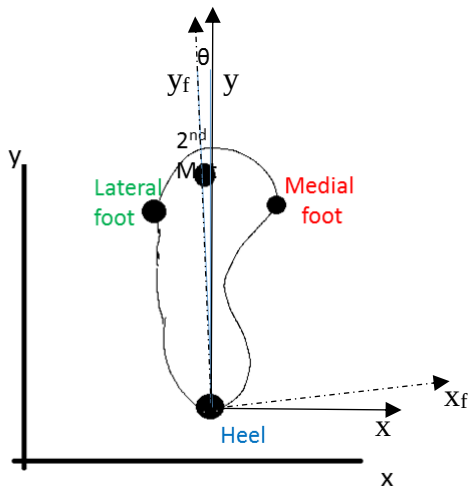

Figure 3.11: Pseudo-foot with medial/lateral shoe, toe, and heel markers in the transverse plane demonstrating the transformation (rotation followed by translation) from the global, treadmill-based coordinate system (x-y or transverse plane) to the local, foot-based coordinate system (x_f-y_f).

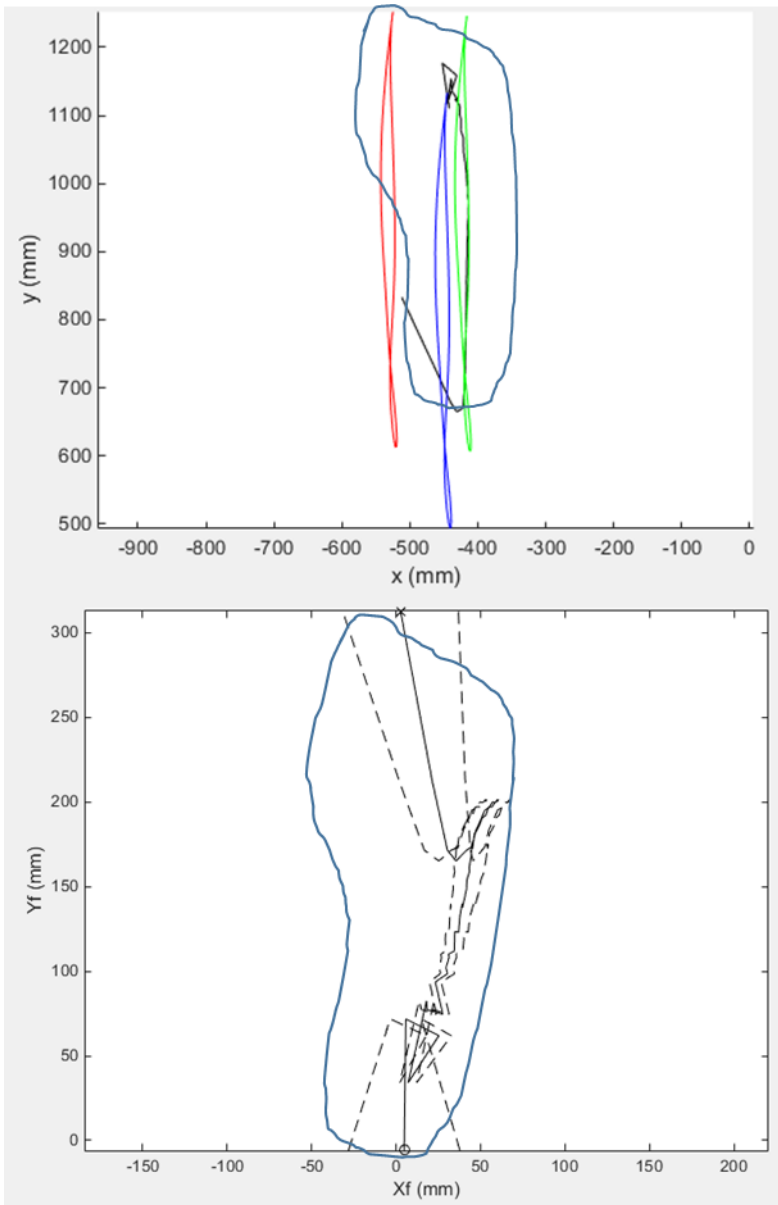

Figure 3.12: (top) Transverse plane motion of the heel (blue), medial (red), and lateral midfoot (green) marker positions during a sample gait cycle (subject 3, no AFO condition); also shown is the COP trajectory (black). The mean motion of the COP relative to the local foot-based coordinate system is shown in (bottom), from heel strike (o) to toe off (x).

3.7 STATISTICAL ANALYSES AND HYPOTHESIS TESTING

Statistical analyses were performed both to assess parameter power and future sample population size, as well as to contrast the measures for the various AFO conditions and investigate the research hypotheses.

3.7.1 Power Testing

Post hoc power analyses were performed for each of the measured kinematic, EMG and kinetic parameters. The post hoc power analyses were performed as two-tailed t tests, with the specific statistical test being "Means: Difference between two dependent means (matched pairs)". The effect size was based on the mean and standard deviation for the respective parameters using a correlation of 0.5. The α value was set at 0.05 and sample size was the number of subjects in this study, n=10 (GPower v 3.1, Heinrich-Heine-Universität Düsseldorf). The respective parameter results were analyzed post hoc to estimate recommended population sizes for future studies.

3.7.2 Hypothesis Testing

The normality of the data parameters (joint and segment angles, EMG activity duration, medial-lateral COP motion) was tested to determine whether subsequent parametric or non-parametric analysis should be conducted to investigate the research hypotheses. Normality testing was conducting using the normality feature of Minitab (v17, Minitab Inc, State College, PA). Normally distributed data were reviewed using the General Linear Model feature to identify significant parameter differences. If observed significant differences in a given

parameter were identified, Tukey's post hoc test was then performed to assess differences between the various AFO conditions and test the corresponding research hypotheses (e.g. Hypothesis 1: ankle kinematics during LR with the DRAFO approximate that of the no AFO condition; Hypothesis 2: ankle kinematics during LR with the DRAFO differ from both the free and rigid AFOs). Similarly, non-normally distributed data were reviewed using Friedman's test. Subsequent post-hoc testing was conducted using Wilcoxon Signed Rank tests to assess differences between the various AFO conditions and test the related research hypotheses.

3.8 SUMMARY

Able-bodied subjects were recruited to contrast various AFO conditions during treadmill walking. Data included kinematic (joint and segment angles, crossover times), EMG (plantar/dorsiflexor activity duration during both stance and swing), and kinetics (medial and lateral motion of the COP during the sub-phases of stance). Data were segmented into gait cycles and respective parameter values were contrasted using statistical analysis to test the research hypotheses, namely that DRAFO-gait approximated no AFO gait and that DRAFO-gait differed from free/rigid-AFO gait.

Chapter 4: RESULTS

Ten young, able-bodied subjects were recruited and completed gait analyses for all test conditions: no AFO, DRAFO, free AFO, and locked AFO. Acquired data included bilateral lower extremity joint and segment kinematics, EMG activity duration of the ankle plantarflexors and dorsiflexors, and GRF and COP data. The various time series were segmented into stance and swing periods, as well as single and double support periods, based on HS and TO events. These data were contrasted for the four AFO test conditions to test the research hypotheses detailed in Table 1.1, namely that the DRAFO condition would approximate the no AFO condition, and that the DRAFO condition would differ from the free and locked AFO conditions.

4.1 SUBJECT INFORMATION

Ten young, able-bodied subjects were recruited as per the selection/exclusionary criteria, and completed level treadmill walking trials and gait analyses in the four AFO test conditions. These subjects and their anthropometric data are summarized in Table 1.

Table 4.1: Summary of subject details and anthropometry.

Subject	**Gender**	**Age (yrs)**	**Height (m)**	**Weight (kg)**	**Lower Limb Length (mm)**
1	F	20	1.52	89.8	830
2	F	20	1.73	53.5	920
3	F	20	1.60	63.5	852
4	M	21	1.80	77.1	936
5	M	19	3.64	65.8	981
6	F	22	1.71	56.3	928
7	F	NA	1.73	65.8	910
8	M	22	1.72	78.9	863
9	F	NA	1.70	86.2	773
10	M	20	1.83	72.6	970

4.2 LOWER EXTREMITY JOINT and SEGMENT KINEMATICS

One objective of this study was to investigate the effects of AFO design on lower extremity joint and segment kinematics. Related measures included knee and ankle joint motion in the three planes, as well as the corresponding thigh and shank segment sagittal plane angles relative to vertical (e.g. TVA and SVA). The related research hypotheses were: 1) DRAFO-assisted gait parameters (e.g. ankle plantarflexion during early stance, cross-over times of the shank and thigh vertical angles during stance, step width, dorsiflexion activity during early stance, and center of pressure progression during LR) will approximate that of the no AFO condition and 2) DRAFO-assisted gait parameters (e.g. ankle and knee kinematics, cross-over times of the shank and thigh vertical cross over times during stance, peak foot progression angle during stance, step width, stance phase dorsiflexion activity duration, and mediolateral motion of the COP) will differ from that for locked and articulating AFOs.

4.2.1 Knee Angle and Thigh to Vertical Angle (TVA)

Representative plots of mean sagittal plane knee angle and TVA across the gait cycle are shown in Figure 4.1. These curves illustrate that the subject demonstrated knee flexion during early stance, with peak knee flexion occurring during swing, as common for able-bodied gait. While few changes in knee angle were observed between the no AFO, free AFO and locked AFO conditions for this subject, the DRAFO affected knee flexion angle at heel strike and during early stance.

To facilitate kinematic comparison between AFO conditions, the sagittal plane knee angle was reviewed to determine peak values and ranges of motion during various periods of

stance (IC, early stance, mid- to late-stance) and swing. The TVA time series was reviewed to identify instances when the TVA was zero, or crossed over from inclined to reclined [Owen, 2010] and vice versa. These peak knee flexion values and TVA cross-over times are summarized in Figures 4.2 and 4.3, respectively.

The mean peak knee flexion at these various periods were normally distributed. Statistical comparison of these measures across AFO conditions using the General Linear Model (GLM) indicated that peak knee flexion differed significantly between AFO conditions for all periods. During IC, peak knee flexion for the DRAFO condition differed significantly from both the no AFO and free AFO conditions. During early stance or LR, peak flexion in the DRAFO condition differed significantly from all other AFO conditions. During mid- to late-stance, the minimum knee flexion with the DRAFO differed significantly from the free AFO condition only. Finally, during swing, no statistically significant differences in peak knee flexion were observed with the DRAFO; the only statistically significant difference in peak knee flexion was between the no AFO and free AFO conditions (see Appendix A).

The TVA cross-over times were also normally distributed. Further statistical comparison using the GLM indicated significant differences in TVA cross-over timings during both stance and swing. Post hoc testing (Tukey) detected differences between the DRAFO and the no AFO, free AFO, and locked AFO conditions for both stance and swing phase ($p < 0.05$, Appendix A).

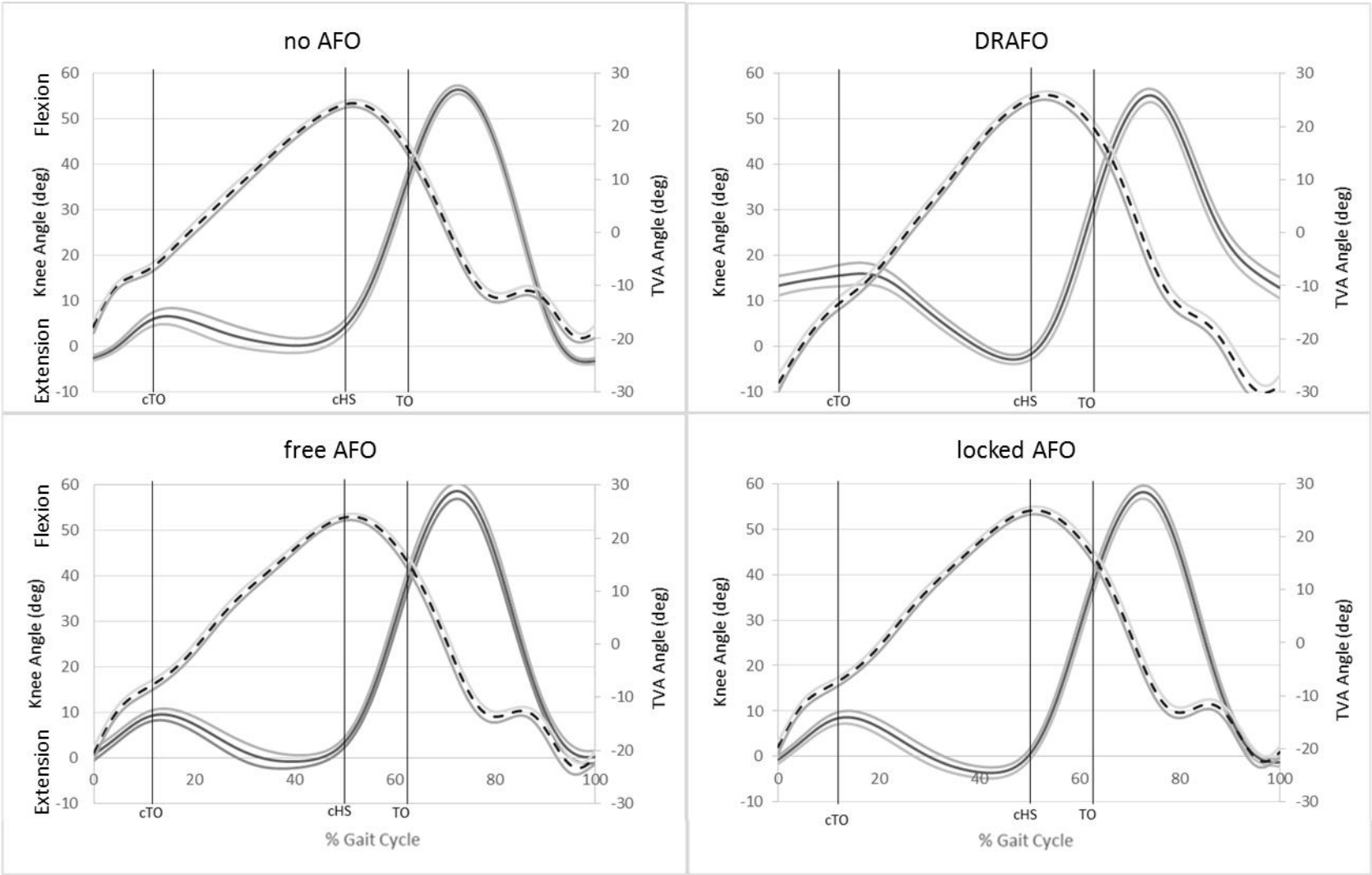

Figure 4.1: Sagittal plane knee angle (solid black) and TVA (dashed black), mean ±1 s.d., as a function of gait cycle for a representative subject (#3) for each of the AFO test conditions. The vertical lines represent contralateral toe off (cTO), contralateral heel strike (cHS) and ipsilateral toe off (iTO). TVA cross-over times are marked with "X".

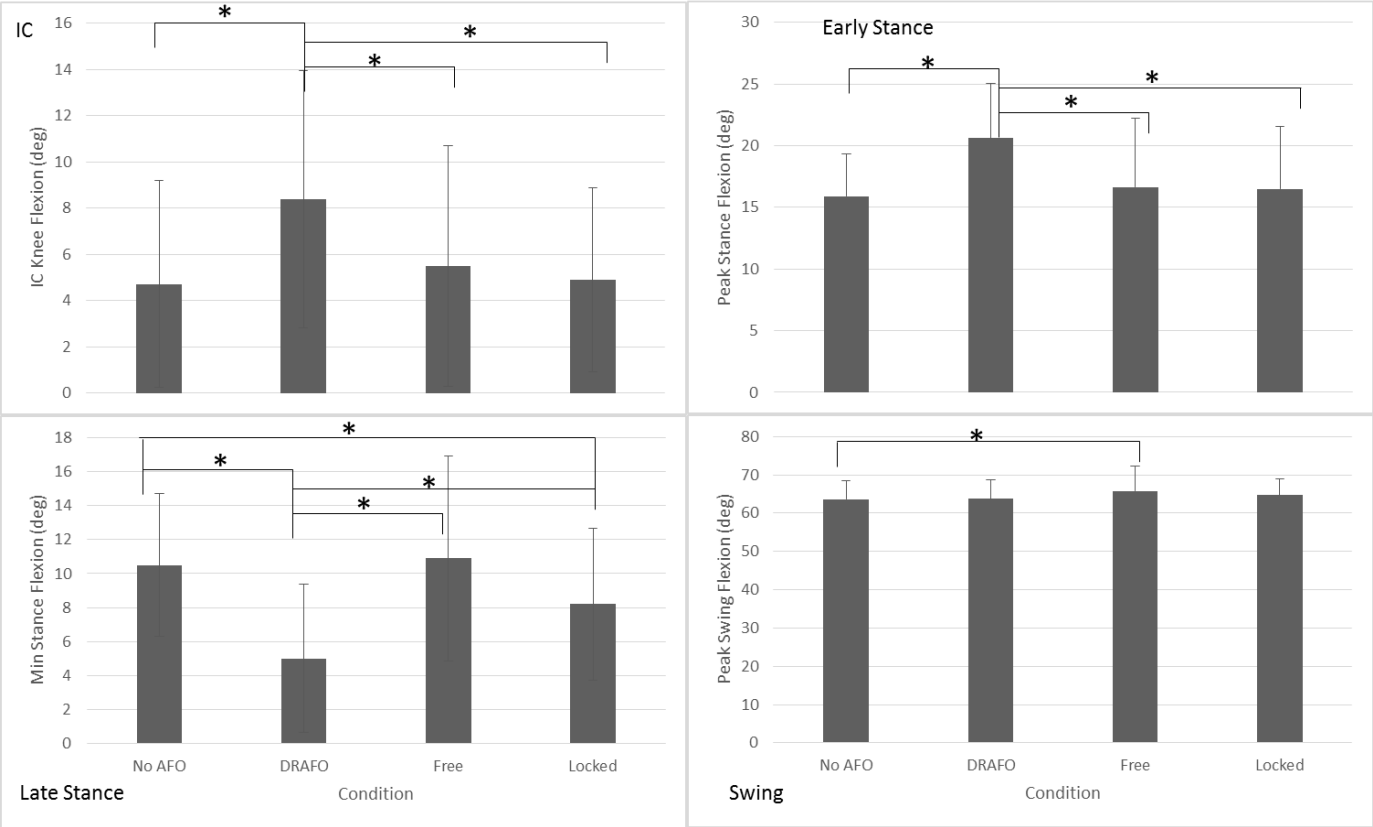

Figure 4.2: Mean peak knee angles across all subjects and gait cycles during IC, early stance (0-30% GC), late-stance (30-70% gait cycle), and swing.

* indicates significance at $p<0.05$ level

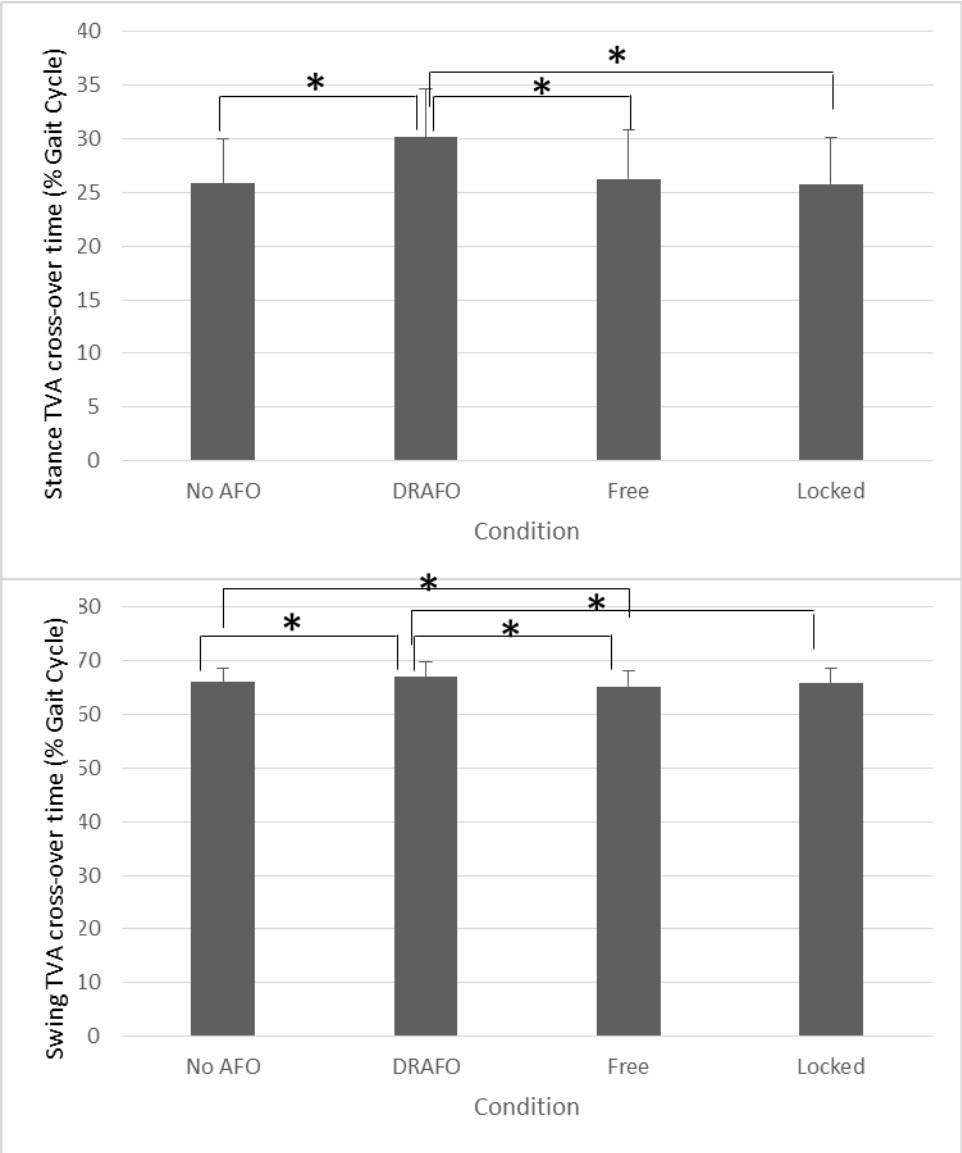

Figure 4.3: Mean TVA cross-over times during stance (top) and swing (bottom).
* indicates significance at $p<0.05$ level

4.2.2 Ankle Angle and Shank to Vertical Angle (SVA)

Representative mean sagittal plane ankle angle and SVA time series waveforms are presented in Figure 4.4. The AFOs reduced the ankle ROM, limiting ankle plantarflexion. Peak dorsiflexion was observed at mid–stance, at contralateral heel contact. The DRAFO condition resulted in delays of both the stance and swing SVA cross-over times.

To facilitate kinematic comparison between AFO conditions, the sagittal plane ankle angle time series were reviewed to determine peak values during early stance (first rocker), mid- to terminal-stance (second rocker), late stance (third rocker), and swing. The SVA time series were reviewed to identify the times at which cross-over (e.g., transition from positive to negative values and vice versa) occurred. These measures are summarized in Figures 4.5 and 4.6 across all subjects and gait cycles for all AFO conditions.

With the exception of swing, the mean peak ankle measures during stance were normally distributed. Statistical comparison of these measures across AFO conditions using GLM indicated that statistically significant differences were observed between AFO conditions ($p < 0.05$). Subsequent post hoc (Tukey) testing indicated that peak plantarflexion during early stance differed between the DRAFO and no AFO and between the locked and free AFO conditions. Peak plantarflexion during early stance with the DRAFO differed from both the locked and free AFO conditions; the no AFO condition differed from the free and locked AFO conditions. Peak dorsiflexion during MSt for the no AFO condition differed from the DRAFO condition; peak dorsiflexion during MSt with the DRAFO condition differed from the free and locked AFO conditions. Peak plantarflexion during late-stance with the no AFO condition differed from the DRAFO and all AFO conditions, as all AFOs minimized ankle plantarflexion to assist with foot clearance. The peak dorsiflexion during swing (non-normally distributed data; tested with Friedman's test and Wilcoxon Sign Rank post hoc testing) indicated statistically significant differences between the DRAFO and no AFO conditions, as well as between the DRAFO and the locked and free AFO conditions (Appendix B).

Stance and swing phase SVA cross-over times were both normally distributed. Statistical comparison of these measures using GLM indicated statistical significance only for SVA cross-

over time during swing ($p < 0.05$). Post hoc testing (Tukey) indicated that the SVA cross-over time with the DRAFO differed from that with no AFO and the free AFO (Appendix B).

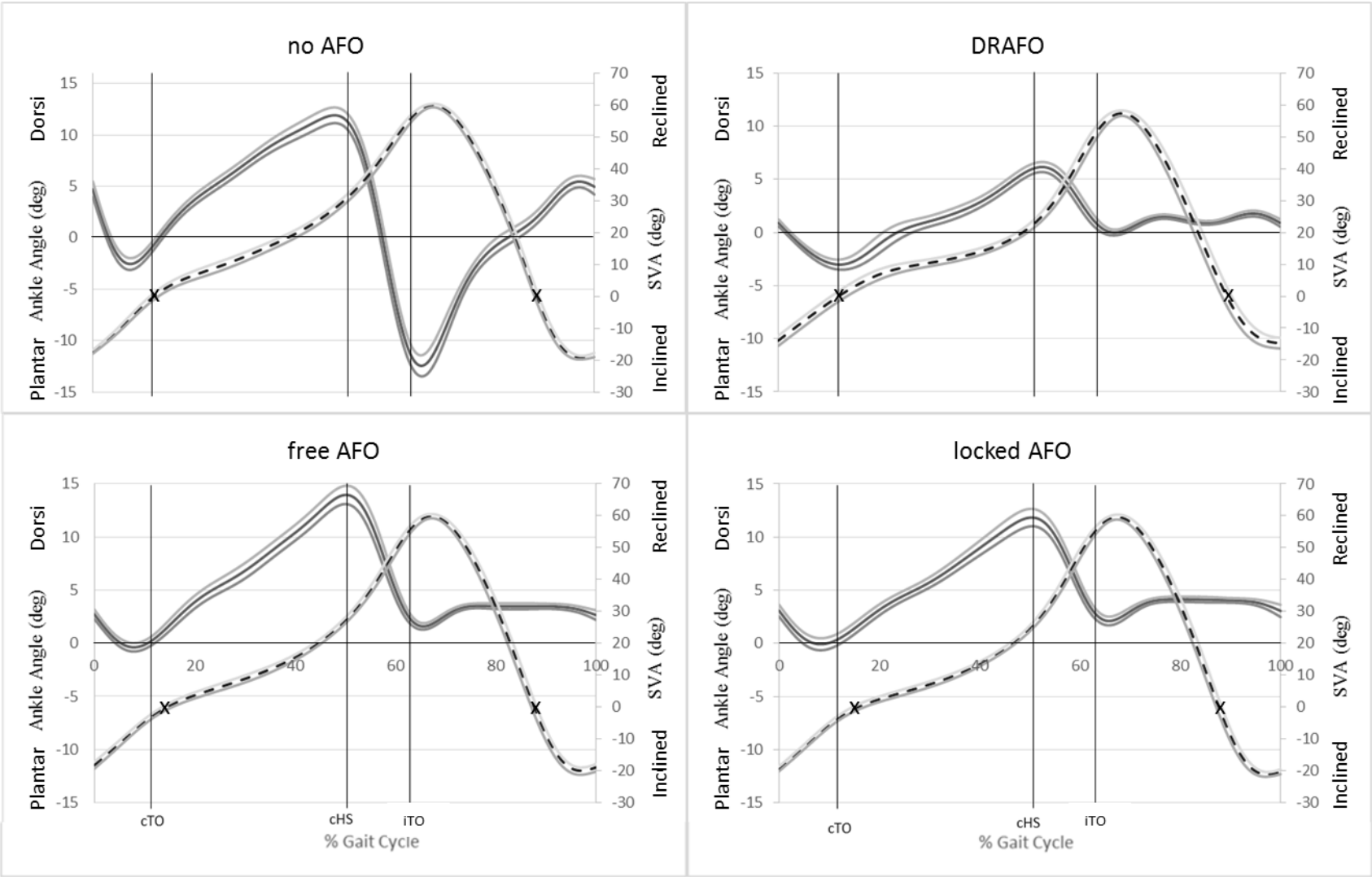

Figure 4.4: Mean sagittal plane ankle angle (solid black) and SVA (dashed black), mean ±1 s.d. (+ ankle angle: dorsiflexion) across all gait cycles for a representative subject (#3) for each of the AFO conditions. The vertical lines represent contralateral toe off (cTO), contralateral heel strike (cHS) and ipsilateral toe off (iTO) events. SVA cross-over times are marked with “x”.

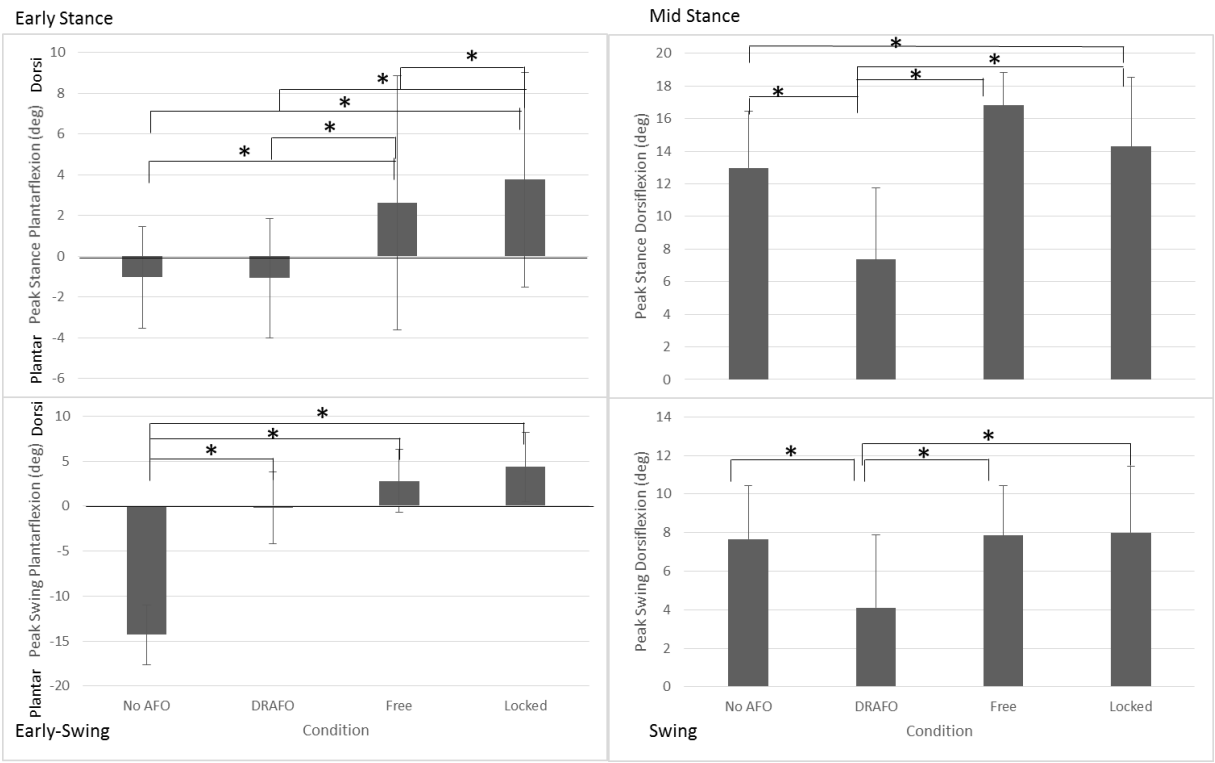

Figure 4.5: Mean peak plantarflexion during early stance, peak dorsiflexion during MSt, peak plantarflexion during late stance/early swing, and peak dorsiflexion during swing.
* significant difference at $p<0.05$ level

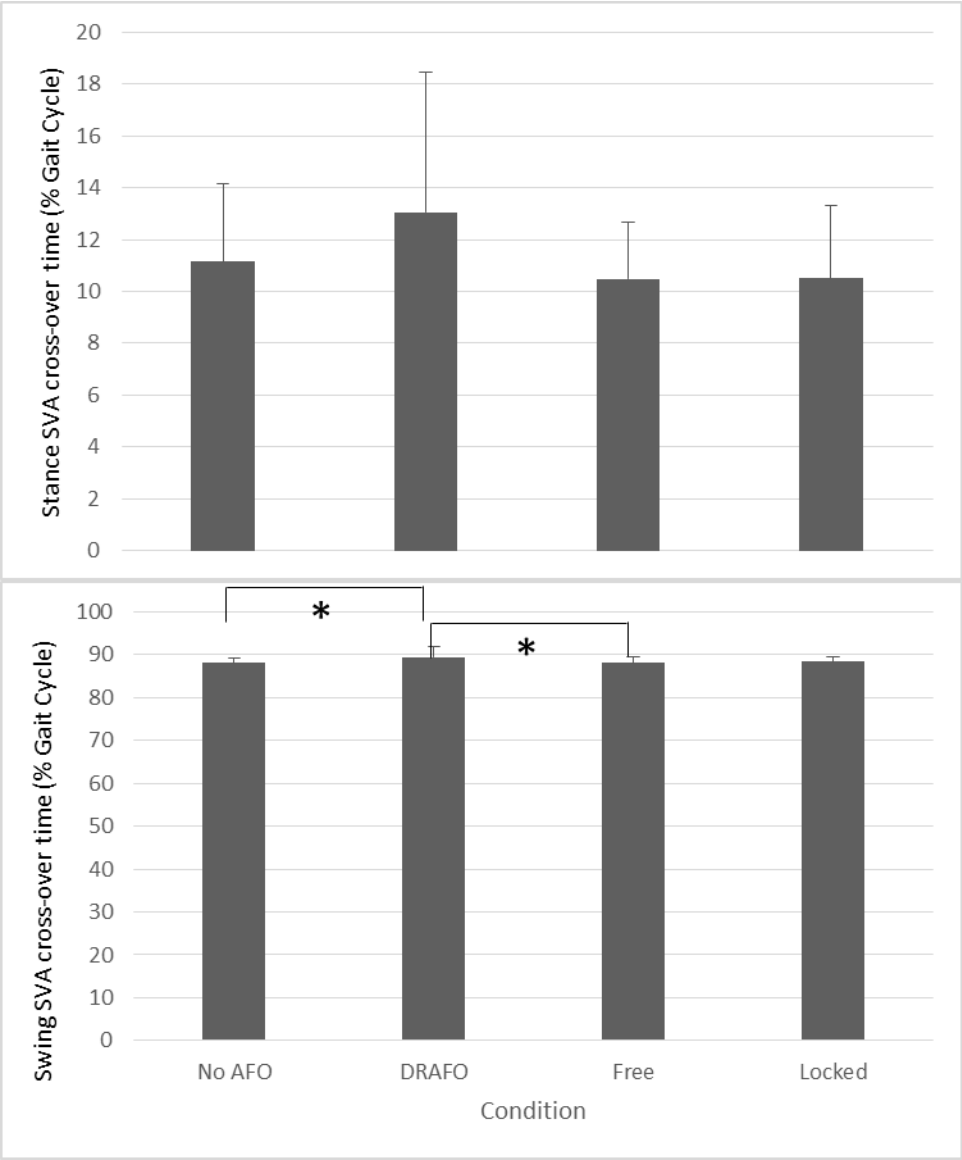

Figure 4.6: Mean SVA cross-over times during stance (top) and swing (bottom).
* indicates significance at $p<0.05$ level

4.2.3 Foot Progression Angle (FPA)

To measure the effect of AFOs on FPA, the minimum and maximum values during stance were calculated and averaged across subjects for each AFO condition (Figure 4.7). As the mean minimum foot progression angles were non-normally distributed, Friedman's test was performed to identify significant differences between AFO conditions; subsequent Wilcoxon

Sign Rank tests were then conducted. Significant differences in the minimum foot progression angle were observed between the no AFO and DRAFO conditions. Similar statistical analysis of the mean maximum foot progression angle (normally distributed, investigated using a GLM) did not indicate significant differences between AFO conditions (Appendix C).

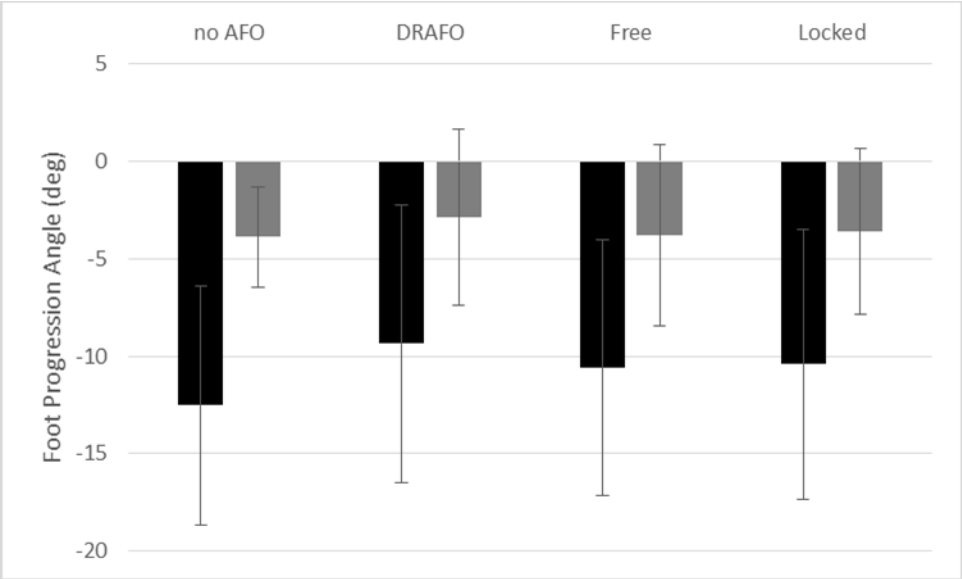

Figure 4.7: Mean minimum (black) and maximum (gray) foot progression angle during stance across subjects for each AFO condition.
* indicates significance at $p<0.05$ level

4.2.4 Step Width

The step width at heel strike was averaged for all gait cycles and subjects for each AFO conditions (Figure 4.8). This measure might provide insight into AFO stability during stance. Step width data were normally distributed significant differences between AFO conditions were investigated using a GLM to determine significance among conditions. No significant differences between AFO conditions were observed (Appendix D).

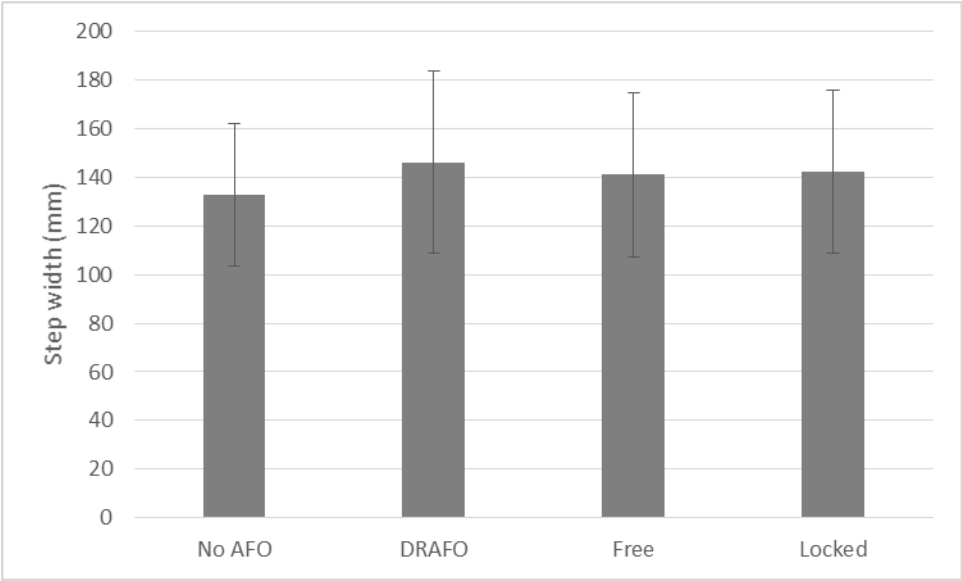

Figure 4.8: Mean step width at heel strike across subjects for each AFO condition.
* indicates significance at $p<0.05$ level

4.3. EMG Activity

A second objective of this study was to compare the EMG activity duration of the dorsiflexors (anterior tibialis) and plantarflexors (gastrocnemeus) for the four AFO conditions to test the hypothesis that EMG activity during stance will not differ between the no AFO and DRAFO conditions but will between the DRAFO and free/locked AFO conditions.

The normalized linear envelope of the respective surface EMGs was contrasted for the four AFO conditions (dorsiflexors: Figure 4.9, plantarflexors: Figure 4.10); the corresponding activation periods (e.g. period for which the normalized EMG exceeded the 20% activation threshold) are also noted. The activity durations during stance and swing across all subjects and gait cycles are contrasted between AFO conditions in Figure 4.11.

The dorsflexion activity duration during swing and plantarflexor activity duration during stance were normally distributed; these EMG data were contrasted between AFO conditions

using the GLM with subsequent Tukey's post hoc testing to investigate potential significant differences between AFO conditions. Dorsiflexor activity duration during stance and plantarflexion activity during swing were non-normally distributed; Friedman's test and Wilcoxon Sign Rank post hoc tests were conducted to investigate potential differences in these muscle activity durations between AFO conditions.

These post-hoc analyses indicated that dorsiflexor activity duration during swing differed significantly between the no AFO and the DRAFO conditions; dorsiflexor activity duration during swing with no AFO also differed from the free and locked AFO conditions. No significant differences in dorsiflexion activity duration were observed during stance. Plantarflexor activity duration during swing also differed significantly between the no AFO and locked AFO condition; no differences in plantarflexor activity duration during stance were observed (Appendix E).

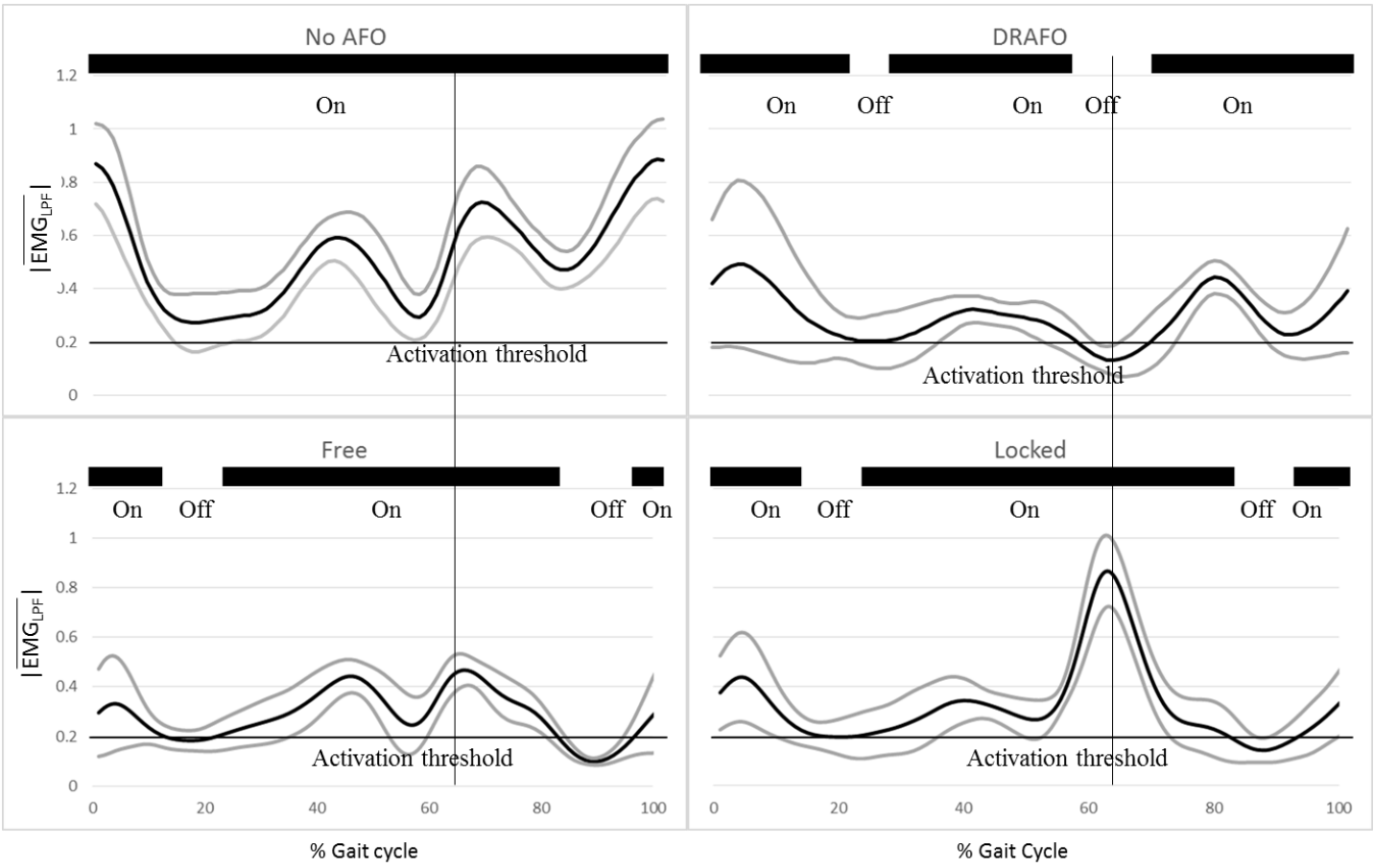

Figure 4.9: Representative normalized linear envelope of dorsiflexor EMG (mean ±1 s.d.) for subject 5 for all AFO conditions. Filled black horizontal bars represent "ON" or activation periods during which activity exceeded the 0.2 threshold. The vertical black line indicates TO, thereby differentiating stance from swing.

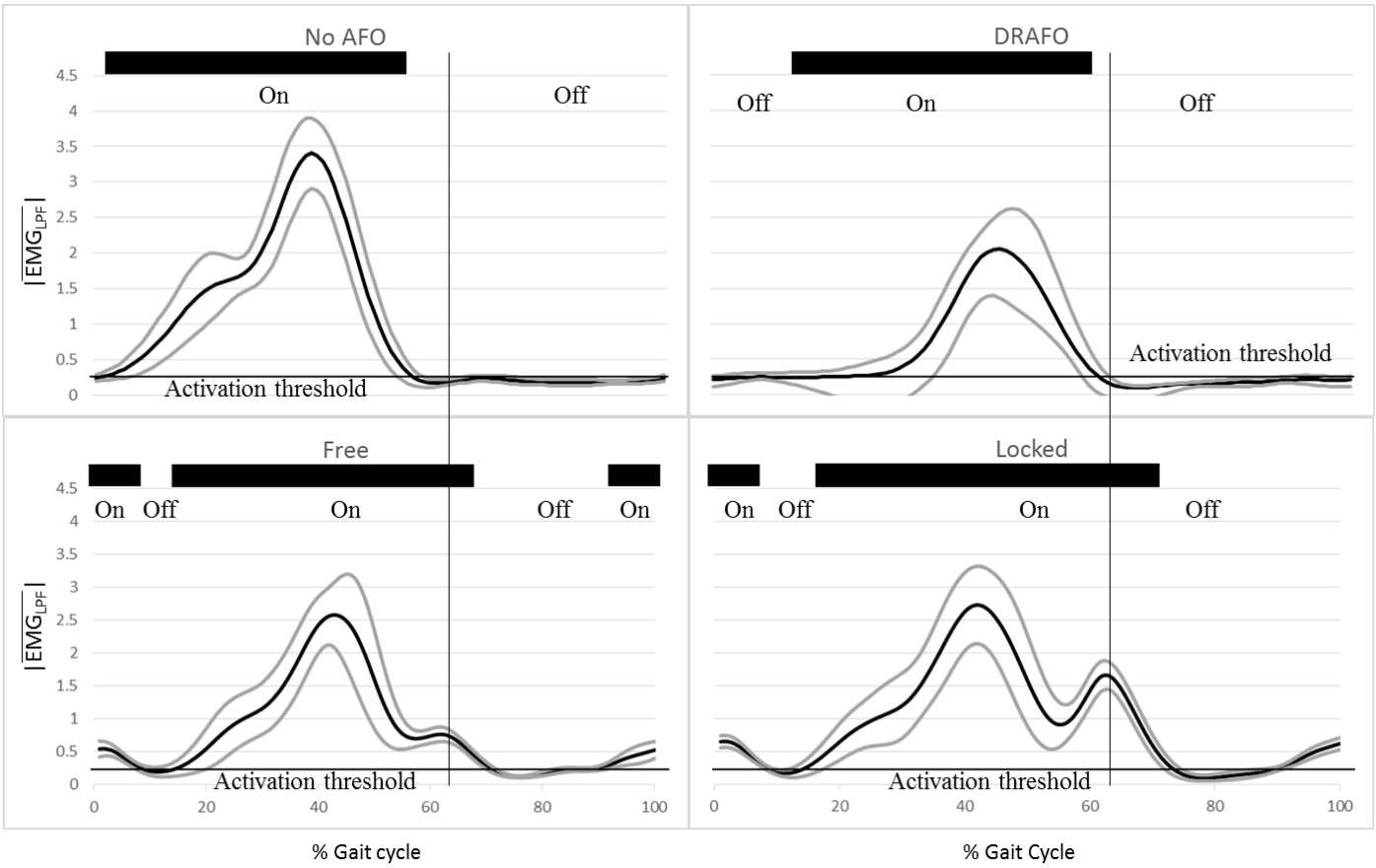

Figure 4.10: Normalized linear enveloped plantarflexor EMG (mean ±1 s.d.) for subject 5 for all AFO conditions. Black bars represent "ON" or activation period. The vertical black line indicates TO, thereby differentiating stance from swing.

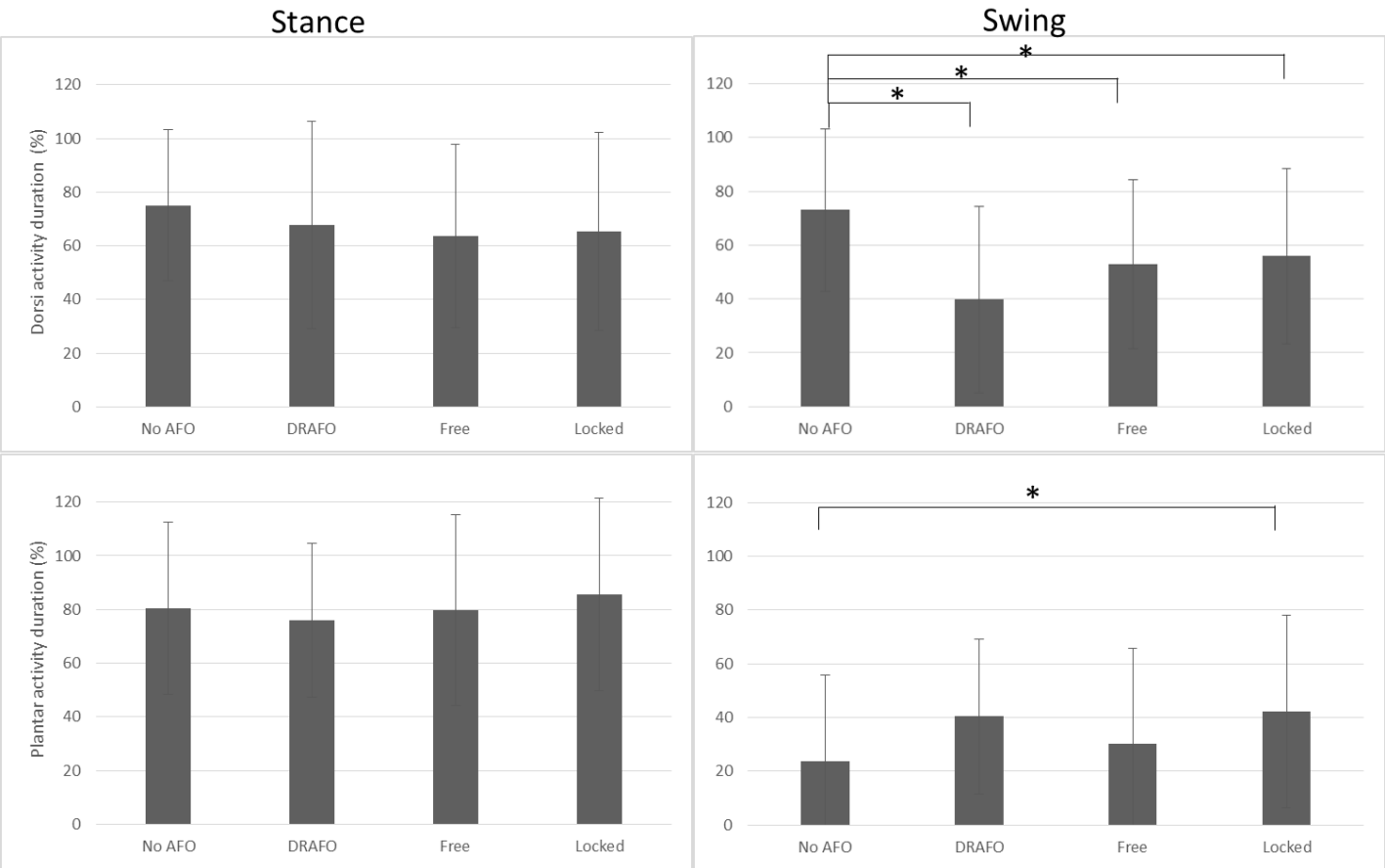

Figure 4.11: Dorsiflexor (top) and /plantarflexor (bottom) activation periods during stance (left) and swing (right) across subjects for all gait cycles.
* significant difference at $p<0.05$ level

4.4 Medial/Lateral Motion of the Center of Pressure (COP)

The final research objective was to contrast the medial-lateral motion of the COP for the four different AFO conditions (see Figure 4.12). The related research hypothesis was that the mediolateral motion of the COP with the DRAFO would approximate the no AFO condition and would differ from that with the free/locked AFO conditions.

The peak medial and lateral motion of the COP relative to the long-axis of the foot are represented in Figures 4.13 and 4.14 for the stance sub-phases, LR, MSt, TSt, and PSw. This COP movement during the various sub-phases was then contrasted between AFO conditions, as

shown in Figure 4.14. As the peak medial and lateral motion of the COP during the various stance sub-phases were normally distributed, these measures were contrasted using the GLM and with subsequent Tukey's post hoc testing to identify potential significant differences between AFO conditions.

During LR, TSt and PSw, the peak medial motion of the COP for the DRAFO condition differed from the no AFO condition. During MSt, the COP motion with the DRAFO differed significantly from both the no AFO and free AFO conditions. The maximum medial motion of the COP during PSw also differed between the DRAFO and free AFO conditions.

Peak lateral motion of the COP relative to the long axis of the foot differed significantly between the DRAFO, no AFO, and free AFO conditions during LR. During MSt and TSt, the peak lateral motion of the COP for the DRAFO condition significantly differed from the no AFO condition. Finally, during TSt, the peak lateral motion of the COP differed between the DRAFO and free and locked AFO conditions. No significant differences in peak lateral motion of the COP were observed between AFO conditions during PSw (Appendix F).

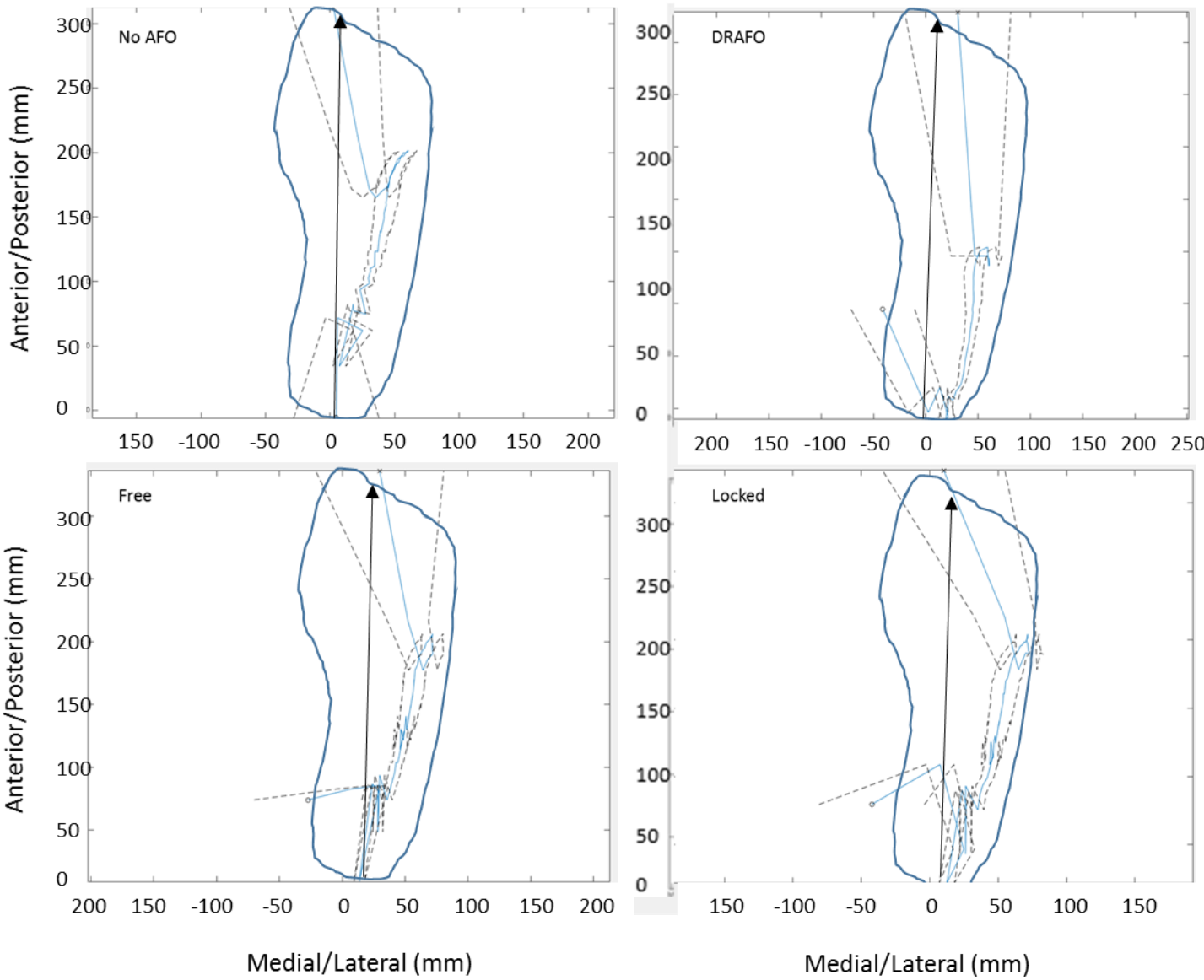

Figure 4.12: Representative mean (blue) and standard deviation (black dashed) motion of the COP in the transverse plane from HS (o) to TO (x) for multiple gait cycles for each AFO condition (subject 3).

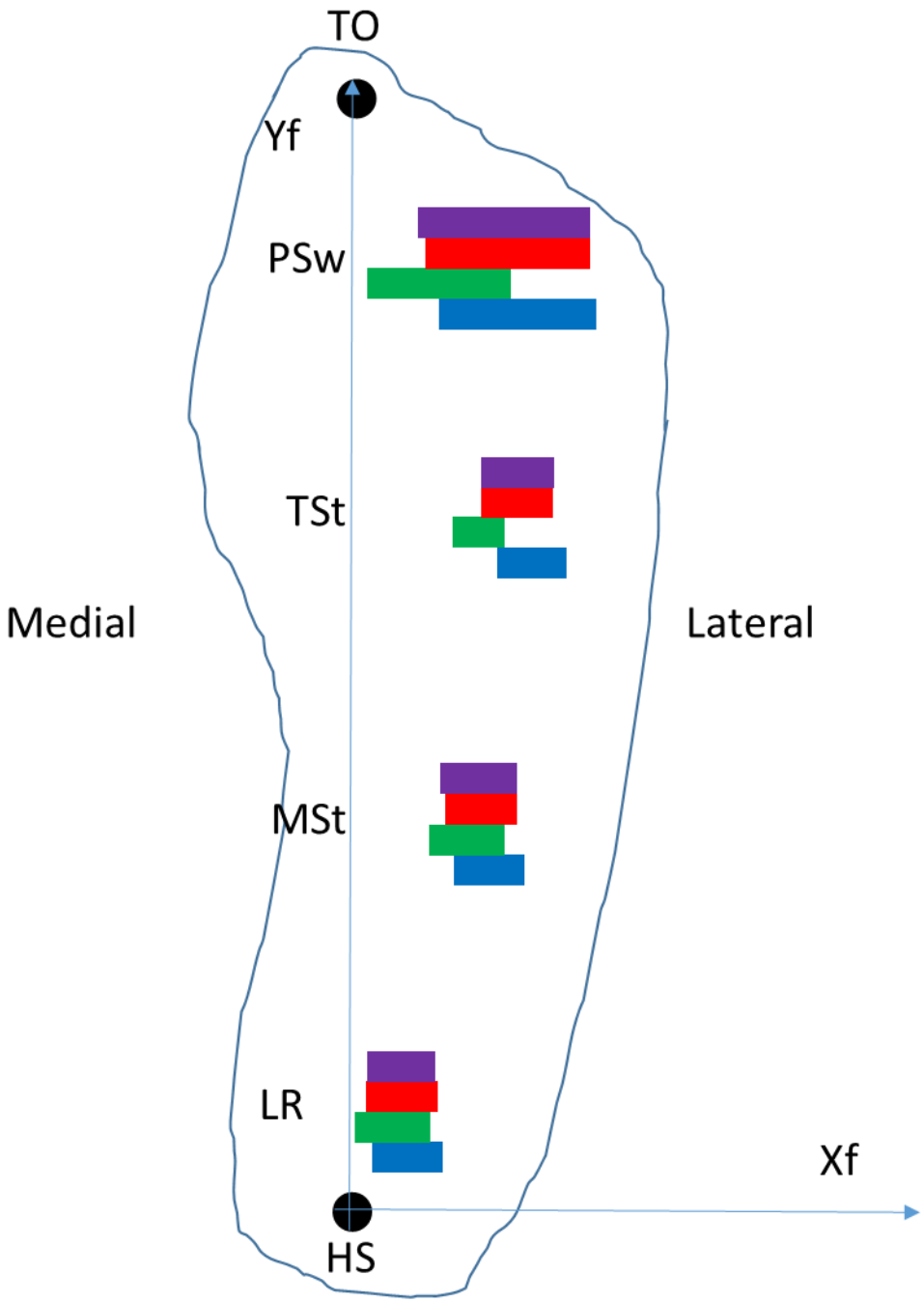

Figure 4.13: Mean mediolateral motion of the COP across all subjects during the various stance sub-phases for each AFO condition (blue = no AFO, green = DRAFO, red = free, purple = locked AFO). For reference, the COP progression from able-bodied subjects is also shown (black circles) [10].

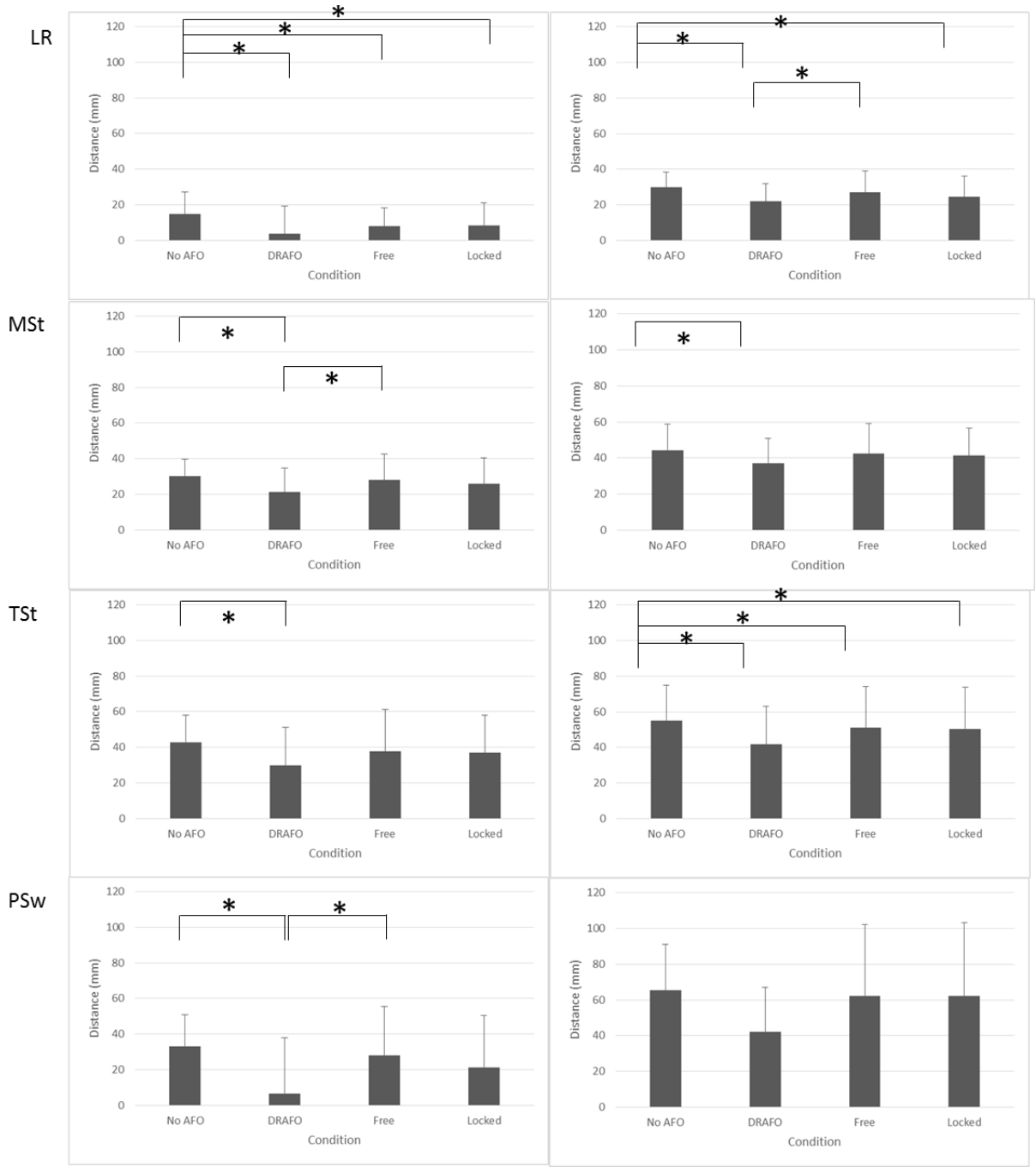

Figure 4.14: Mean motion of the COP relative to the heel-to-toe long axis of the foot during the LR, MSt, TSt, and PSw sub-phases of stance. As all COPs were lateral to the long axis of the foot, these values represent the minimum lateral motion (left) and maximum lateral motion (right) of the COP.
Significant differences ($p<0.05$) between AFO conditions are noted with an *.

4.5 POWER ANALYSIS

A priori power analyses were performed to determine the sample size necessary for the study at pre-defined effect sizes (Table 4.2). Small (0.3), medium (0.5), and large (0.8) effect sizes were investigated. No data regarding ankle angle, EMG activity or COP motion were reported in AFO investigations in the literature; current literature were therefore reviewed to estimate sample size based on reported sagittal plane knee angle [29]. Sample sizes of 5 to 71 subjects were projected for large to small effect sizes, respectively - motivating the initial sample size of 10 subjects included in this study. The respective parameter effect size and power are summarized in Table 4.3.

Table 4.2: A prior power analysis as a function of effect size and the corresponding sample size estimates.

	Effect size	**# subjects**
Small	0.3	71
Medium	0.5	27
Large	0.8	12
sagittal plane knee angle [28]	1.6	5
Early knee flexion [this study]	1.44	7

Effect sizes for knee and ankle kinematics, SVA, and dorsiflexion activity duration were large (d > 0.8) and had power greater than 0.7. The effect sizes for the plantar flexion muscle activity duration and COP motion were medium (d > 0.5) and resulted in powers greater than 0.3 (small) and >0.5 (medium), respectively. A small effect size (d > 0.3) was observed for the TVA cross-over time during stance, with small (~0.2) power. The full power analyses are summarized in Appendix G.

Table 4.3: Post hoc power analysis of select study parameters.

Measure	**Effect size**	**Power**
Knee flexion --- LR	0.92	0.74
Ankle dorsiflexion --- stance	1.44	0.98
TVA cross-over time --- stance	0.41	0.21
SVA cross-over time --- stance	0.99	0.79
Peak FPA	0.47	0.39
Step width	0.39	0.30
Dorsi activity duration --- LR	0.0067	0.05
Plantar activity duration --- stance	0.28	0.13
Peak lateral COP during LR	0.77	0.59

4.6 SUMMARY

Kinematic, EMG, and kinetic data were statistically analyzed in relation to the study hypotheses. Statistically significant kinematic differences were detected between the DRAFO and no AFO conditions. Peak ankle dorsiflexion during both stance and swing phase n, as well as peak plantarflexion during PSw, differed between these conditions. Peak knee flexion throughout the stance differed significantly between the DRAFO and no AFO conditions. In addition, the TVA cross-over time during both stance and swing differed between the DRAFO and no AFO conditions; only the SVA cross-over time during swing differed between AFO conditions. The minimum FPA also differed significantly between the DRAFO and no AFO condition. Swing

phase dorsiflexion activity duration differed significantly between the DRAFO and no AFO condition; no differences in dorsiflexion or plantarflexion activity duration during stance were observed between the DRAFO and no AFO.

Kinematic parameters that differed between the DRAFO and locked or free AFO conditions included: ankle angle at IC, early stance dorsiflexion, swing phase dorsiflexion, and peak knee flexion during stance. The TVA cross-over time for both stance and swing also differed between the DRAFO and AFO conditions, as did the SVA cross-over time during swing (DRAFO and free AFO only). No significant differences in either dorsi or plantar flexion activity duration were found between the DRAFO and AFO conditions. The COP progression differed significantly between the DRAFO and free AFO conditions from LR through PSw.

Chapter 5: DISCUSSION

AFO prescription objectives include: 1) re-establish an appropriate base of support, 2) control rate, excursion, and direction of segment movement, 3) improve energy efficiency, and 4) aid foot positioning for clearance and weight acceptance [2]. As such, use of AFOs may assist patients by returning their gait to normal, or near normal, kinematic patterns. This may reduce incidence of compensatory gait mechanisms, thereby decreasing pain and facilitating safer, more efficient, and more comfortable gait for prolonged durations.

Due to the soft heel, plantar flexed alignment and rigid frame, the specific research hypotheses investigated in this study were: 1) DRAFO-assisted gait parameters (e.g. ankle plantarflexion during early stance, swing phase SVA and TVA cross-over times, step width and LR COP progression) will approximate that of the no AFO condition and 2) DRAFO-assisted gait parameters (e.g. ankle and knee kinematics, stance phase SVA and TVA cross-over times, , step width, stance phase dorsiflexion activity duration, and COP progression during LR) will differ from that for articulating and rigid AFOs. To test these hypotheses, kinematic, EMG and kinetic measures were contrasted for able-bodied subjects wearing various AFOs during level treadmill walking.

This chapter will discuss the resultant knee, ankle and foot kinematics, shank and thigh segment angles, dorsiflexor muscle activity duration, and COP progression data, the respective research hypotheses (Tables 1.1 and 5.1), and corresponding data from prior investigations reported in the literature.

Table 5.1: Summary of gait parameter results in terms of the research hypotheses. (+):hypothesis supported, (-):hypothesis not supported, (~):hypothesis testing inconclusive, (--------):measures not relevant to research hypothesis.

Metric	Hypothesis 1: DRAFO ≈ no AFO	Hypothesis 2: DRAFO ≠ locked AFO DRAFO ≠ free AFO
Ankle Kinematics		
- LR plantarflexion	+	+
- MSt dorsiflexion	----------	+
- TSt-PSw plantarflexion	----------	-
- Swing dorsiflexion	----------	+
Knee Kinematics		
- IC/LR flexion	----------	+
- MSt minimum flexion	----------	+
- TSt-PSw flexion	----------	+
- Swing flexion	----------	-
Step width	+	-
SVA cross-over time		
- Stance	----------	-
- Swing	-	----------
TVA cross-over time		
- Stance	----------	+
- Swing	-	----------
Dorsiflexion activity duration		
- Stance (LR)	+	-
-	----------	----------
COP progression (LR)	-	~

5.1 KINEMATICS

AFOs are commonly prescribed to treat ankle and subtalar joint instability by providing rigid support of the foot and ankle. This support often decreases kinematic pathologies during gait and may reduce joint pain and muscle spasticity. The DRAFO incorporates a heel cut out and flexible inner layer to enhance proprioception to assist in detecting heel strike, and may decrease potential gait pathologies introduced by more traditional rigid AFOs. However, the

rigid frame supporting the ankle and subtalar joints, as well as the plantarflexed alignment of the DRAFO, may contribute to additional gait pathologies or compensatory mechanisms.

5.1.1 Joint Angles

5.1.1.1 Knee Kinematics

During IC, greater knee flexion was observed with the DRAFO condition (8.38±3.43°) than for all other conditions (No AFO: 4.71±4.47, free AFO: 5.48±4.21, locked AFO: 4.89±4.78°). Throughout stance phase, knee flexion in the DRAFO differed significantly from that for the No AFO, locked, and free AFO conditions. For example, during early stance, greater knee flexion was observed with the DRAFO (20.60±4.47°) vs No AFO (15.89±5.57°), locked AFO (16.49±5.07), and free AFO (16.64±4.36) conditions. In contrast, during late stance, the knee was less flexed with the DRAFO (5.00±5.60°) vs No AFO (10.51±5.21), free AFO (10.89±6.05), and locked AFO (8.20±6.63°) conditions. These differences in knee flexion during stance were associated with medium power (>0.7). No significant differences in knee flexion were observed between the DRAFO and other AFO conditions during swing, although modest power was associated with these measures (approximately 0.05).

During able-bodied gait [10], the knee is slightly flexed during IC. The knee flexes further during LR to provide shock absorption. As the shank transitions from a reclined to an inclined position during the second rocker of MSt, the knee begins to extend as the body COM advances over the foot. The knee remains extended throughout TSt, flexing during PSw in preparation for swing. During swing, the knee flexes through mid-swing to provide foot clearance; the knee then extends to prepare the limb for IC and weight acceptance.

For the DRAFO condition, the increased knee flexion observed during IC and MSt may be attributed to the presence of the external heel wedge that increased the effective shank length; the observed increased knee flexion during early stance therefore may simply have been introduced to maintain the overall limb length and minimize vertical motion of the body COM. The increased knee flexion with the DRAFO during early stance, together with the reduced knee flexion during PSw, contributed to greater knee ROM with the DRAFO during stance phase.

Other studies observed increased maximum knee flexion during stance with AFO use [30-32]. Increased heel height and plantarflexed alignment via external heel wedges was found to increase knee flexion and internal knee extensor moments during MSt for young healthy subjects wearing rigid AFOs [30]; these results are consistent with that observed with the plantarflexed DRAFO in the current study. Knee flexion at IC was also observed to increase for individuals with cerebral palsy (CP) wearing rigid AFOs [29]. Desloovere observed increased knee flexion during stance with rigid AFOs; although these AFOs were aligned in a neutral, not plantarflexed, orientation, these results were consistent with that observed in the current study for the conventional AFOs [28].

Clinically, decreased knee flexion during stance may be observed for patient populations with knee joint pain during load bearing (e.g. knee osteoarthritis) [33]. For individuals with genu recurvatum, increased knee flexion is encouraged during early stance via AFO use to prevent further joint deformity; prior studies have shown that increased knee flexion during early stance reduces hyperextension of the knee [34]. The increased knee flexion with the DRAFO (which increased ankle plantarflexion via alignment and the inclusion of the external heel wedges) during early stance may therefore assist both of these patient populations, although the primary benefit may be due to the external heel wedge, not the DRAFO itself. A contraindication for the

DRAFO and/or for use of external heel wedges, includes individuals with weak quadriceps muscles. Increased knee flexion during early stance requires enhanced quadriceps activity to stabilize the increased internal knee flexion moment and prevent knee buckling. As such, increased knee flexion during early stance, may lead to increased energy costs due to the requisite increased quadriceps activity [20].

AFO designs that stabilize the ankle in a neutral position via a rigid (or semi-rigid) structure assist with foot and toe clearance during swing phase. As the DRAFO was aligned in a plantarflexed position, increased knee flexion was expected as a compensatory mechanism. As such, although increased knee flexion during swing is unnecessary for conventional AFOs, it was expected in the DRAFO condition to compensate for the plantarflexed alignment. In this study, peak knee flexion during swing did not differ from the no AFO and the DRAFO and locked AFO conditions. However, greater knee flexion was observed with the free AFO condition (65.78° vs. 63.68°) during swing, as the plantarflexion stop of the free AFO did not fully constrain ankle plantarflexion due to gravity.

Due to both design and alignment differences between the DRAFO and traditional AFOs (e.g., soft heel, external heel wedge and plantarflexed alignment), the DRAFO was expected to increase knee flexion during both stance and swing relative to the conventional AFOs (Hypothesis 2). Greater knee flexion was observed with the DRAFO during early stance, as was reduced knee flexion during late stance relative to these conventional AFOs, supporting the second hypothesis during stance. However, no differences in knee angle were observed between the DRAFO and the free and locked AFO conditions during swing. As such, the second hypothesis was only supported for knee flexion during stance, not for swing.

5.1.1.2 Ankle Kinematics

During early stance, greater plantarflexion was observed in the DRAFO condition (-1.08±3.47°) relative to the slightly dorsiflexed ankle position observed with both the free (2.61±3.31°) and locked (3.75±2.78°) AFO conditions; ankle plantarflexion during early stance however, did not differ between the DRAFO and no AFO conditions. During MSt, dorsiflexion was reduced in the DRAFO (7.36±4.41°) compared to the no AFO condition (12.97±2.94°); ankle dorsiflexion was also reduced with the DRAFO (7.36±4.41°) relative to the free (16.82±3.98°) and locked (14.27±3.79°) AFO conditions. During late stance, plantarflexion was reduced for the DRAFO (-0.21±2.02°) compared to the no AFO condition (-14.32±6.24°). Finally, during swing phase, peak dorsiflexion was reduced for the DRAFO (4.11±4.24°) compared to the no AFO (7.67±5.26°) condition, as well as for the free (7.84±3.84°) and locked AFO (8.00±3.44°) conditions.

For an able-bodied subject [10], greater ankle ROM during ambulation is expected than with any AFO. Ankle motion during able-bodied gait can be described by a neutral ankle position at IC, with gradual plantarflexion and eccentric dorsiflexor activity to prevent foot slap during the first rocker. During MSt through TSt (second rocker), the ankle dorsiflexes as the tibia rolls over the ankle. During PSw, the ankle plantarflexes, providing active push-off in preparation for swing. Finally, during swing, the ankle dorsiflexes to provide foot and toe clearance; this dorsiflexion is then reduced to establish a neutral ankle orientation to prepare for IC.

The effect of AFOs on gait is dependent on 1) dorsi- and/or plantarflexion constraints (e.g., articulated and free, articulated with a plantarflexion stop, or solid/locked) and 2) ankle orientation in the AFO. A solid, non-articulating AFO prohibits both dorsi- and plantarflexion

and aligns the ankle in a neutral position; ankle motion during both stance and swing is therefore expected to be minimal (reduced plantarflexion during early stance, reduced dorsiflexion during MSt-TSt, reduced plantarflexion during PSw, and reduced dorsiflexion during swing). In contrast, an articulated, free AFO theoretically permits some dorsiflexion as well as some plantarflexion. However, articulated, free AFOs often incorporate a plantarflexion stop, minimizing plantarflexion due to gravity during swing.

The traditional AFOs investigated in this study included both a locked AFO and an articulated AFO with a plantarflexion stop. Subject ambulation in these AFOs resulted in the expected ankle kinematics described above. During early stance, these AFO conditions resulted in slight dorsiflexion, rather than plantarflexion, due to the plantarflexion constraints of these designs. These ankle kinematics during early stance are consistent with prior literature involving both healthy and hemiplegic individuals wearing an articulated polypropylene AFO [35], as well as hemiplegic individuals wearing a dynamic, articulated AFO [36]. PSw plantarflexion was also reduced relative to the no AFO condition due to the constrained ankle motion of the locked AFO and the plantarflexion stop of the free AFO, again consistent with prior gait analysis of young, diplegic subjects wearing dorsiflexed, polypropylene AFOs [37]. Contrary to expectations, ankle kinematics during MSt with the conventional AFOs demonstrated greater dorsiflexion than with no AFO condition. The locked AFO resulted in a mere 1° increase in dorsiflexion, which would likely be clinically insignificant; the increased dorsiflexion during MSt with the free AFO may have been attributed to AFO alignment and the unconstrained ankle movement. Increased dorsiflexion during MSt has also been observed for diplegic and hemiplegic individuals ambulating in solid and free AFOs, as well as with a posterior leaf spring (PLS) AFO, compared to control subjects ambulating without an AFO [38].

The DRAFO design, despite the flexible inner liner, is a solid, non-articulating AFO aligned in 3° plantarflexion with additional shank inclination due to the incorporation of external heel wedges. Therefore, the DRAFO was expected to increase ankle plantarflexion during early stance (IC-LR), reduce dorsiflexion during MSt and reduce active plantarflexion during PSw relative to the no AFO condition. The observed DRAFO results were largely consistent with these expectations. During MSt, while ambulating with the DRAFO, more plantarflexion was observed relative to the traditional AFO conditions. However, the DRAFO resulted in reduced plantarflexion relative to the no AFO condition during TSt, perhaps due to the rigid frame restricting ankle motion.

Peak dorsiflexion during swing was reduced for all AFO conditions compared to the no AFO condition, as the AFOs structure does not permit the same level of ankle movement. The DRAFO, due to its plantarflexed alignment and rigid outer shell, was even less dorsiflexed during swing than both the free and locked AFO conditions. The lack of dorsiflexion during swing phase can lead to compensatory adjustments in knee/hip kinematics to provide necessary toe clearance.

The findings in this study indicated that ambulation in the DRAFO resulted in greater plantarflexion throughout LR-MSt and swing phase than in the conventional AFOs, but that ankle angle during early stance (IC-LR) was comparable to that without an AFO. Clinically prescribed AFOs are aligned in a nominal position that provides a pain free range of motion (ROM), yet provides stability during stance and/or acts to decrease ankle/subtalar joint deformity. The plantarflexed alignment of the DRAFO would be contraindicated for patients with pain during ankle plantarflexion.

A second prescription criterion for AFOs is to prevent plantarflexion during swing to reduce risk of tripping. The DRAFO is aligned in a more plantarflexed position than conventional AFOs, which may contribute to compensatory mechanisms (i.e., increased knee and/or hip flexion) to lift the lower limb during swing to provide toe clearance. However, for the conventional AFOs in this study, ankle dorsiflexion during swing did not differ from the no AFO condition, demonstrating that these traditional AFOs provide adequate foot clearance during swing phase. For the DRAFO condition, the ankle was actually plantarflexed during swing, introducing a possible tripping risk. Individuals with unimpaired knee and hip flexors might therefore increase knee/hip flexion to compensate and provide the extra toe clearance needed during swing. For individuals with weak knee/hip musculature, the DRAFO alignment and/or incorporation of external heel wedges may need to be modified to reduce tripping or toe drag.

Ankle kinematics in the DRAFO were not expected to differ from the no AFO condition during early stance. No significant differences in ankle plantarflexion during early stance were observed between the DRAFO and no AFO conditions, supporting Hypothesis 1.

The plantarflexed alignment of the DRAFO condition was expected to differentiate ankle kinematics from that of the conventional AFOs during both stance and swing (Hypothesis 2). During treadmill ambulation in the DRAFO versus the conventional AFOs, increased plantarflexion was observed during early stance and reduced dorsiflexion was observed during MSt, supporting the second hypothesis. The low statistical power was associated with ankle kinematics during early stance, however, may minimize key differences; an expanded subject population may be necessary to ensure identification of significant changes between the AFO designs to effectively investigate the second hypothesis. In contrast, ankle plantarflexion during MSt-PSw did not differ between the DRAFO and conventional AFO conditions, failing to

support the second hypothesis during these latter sub-phases; strong power (0.98) was associated with these measures. Finally, the plantarflexed alignment of the DRAFO was expected to increase plantarflexion during swing relative to the conventional AFOs, a result that was confirmed by this study with medium power (0.55). In summary, the ankle kinematics, with the exception of MSt-PSw, differed between the DRAFO and conventional AFOs, confirming Hypothesis 2 (see Table 5.1).

5.1.2 Segment Angles

The TVA cross-over time was delayed with the DRAFO relative to all other conditions during both stance and swing (DRAFO: stance 30.16±4.49%, swing 67.08±2.68%; no AFO: stance 25.92±4.07%, swing 66.19±2.40%; free AFO: stance 26.29±4.51%, swing 65.25±2.84%; and locked AFO: stance 25.77±4.41%, swing 65.83±2.71% gait cycle). In addition to the comparison of TVA cross-over time as a percentage of gait cycle, these TVA cross-over times were also contrast in actual time (DRAFO: stance 0.36±0.06 sec, swing 0.79±0.07 sec; no AFO: stance 0.30±0.06, swing 0.76±0.07 sec; free AFO: 0.30±0.06 sec, swing 0.75±0.08 sec; locked AFO: 0.30±0.05 sec, swing 0.76±0.08 sec). In actual time, the TVA cross-over time was significantly delayed during stance and swing relative to the other AFO conditions.

SVA cross-over times did not differ significantly different between the four AFO conditions during stance. During swing, however, the SVA cross-over time was significantly delayed with the DRAFO (89.42±2.35% gait cycle, 1.05±0.09 sec) compared to the no AFO (88.08±1.00% gait cycle, 1.01±0.08 sec) and free AFO (88.07±1.41% gait cycle, 1.02±0.09 sec) conditions. These SVA cross-over times during swing were also reviewed in actual time; as for SVA cross-over time in percent gait cycle, the SVA cross-over time with the DRAFO condition

was significantly delayed during swing phase compared to the free and locked AFO conditions. These delays, however, while statistically significant are likely not clinically significant.

Clinical AFO alignment guidelines dictate that the shank be vertical at MSt. A common misconception is that the shank and thigh are vertical at the same time during gait [23]. However, observations from both Owen and the current study indicate that the shank rotates to a vertical position prior to the thigh, e.g. SVA cross-over time precedes TVA cross-over time. For the AFO conditions in the current study, the shank and thigh were never concurrently vertical (e.g. SVA=0° and TVA=0° at the same time). The SVA cross-over time during stance was observed at 10.5 – 11.1% cycle (late LR to early MSt); the TVA cross-over time occurred at 25.8-30.2% gait cycle (late MSt).

5.1.2.1 TVA

The TVA cross-over time during stance was delayed with the DRAFO relative to the no AFO condition. This delay is consistent with the increased knee flexion and ankle plantarflexion observed during early/MSt with the DRAFO. The plantarflexed DRAFO alignment, together with the external heel wedges, results in an inclined shank during foot flat, contributing to a more reclined thigh and flexed knee throughout stance phase (Figure 4.1). The reclined thigh requires additional time to transition to an inclined position, thereby delaying the stance TVA cross-over time.

Few studies have investigated thigh and shank segment kinematics via TVA and SVA measures. Owen demonstrated that thigh segment transitioning from a reclined to inclined position assists forward progression of the trunk [Owen, 2010]. Accelerated stance TVA cross-over times therefore reflect decreased SLS duration and potential instability during MSt.

The delayed stance TVA cross-over time with the plantarflexed DRAFO may perhaps be attributed to a more reclined thigh and inclined shank from IC through stance TVA cross-over (Figure 4.1). The delayed stance TVA cross-over time was approximately 5% gait cycle relative to both the no AFO and conventional AFO conditions. The inclined shank and reclined thigh move the knee center of rotation posteriorly, resulting in a more stable internal knee extension moment during early stance and potentially prolonged stance and SLS duration. However, this delay is likely not clinically significant as it is less than 2% gait cycle or approximately 60 msec. A more inclined thigh may correspond to increased hip extension during late stance, requiring increased hip flexor activity and energy costs to lift the limb into swing.

The heel wedges and plantarflexed alignment of DRAFO was only expected to affect SVA cross-over time and forward progression during stance. As such, the DRAFO was not expected to alter TVA cross-over time during swing relative to the no AFO condition (Hypothesis 1). However, these DRAFO design were expected to affect the TVA cross-over time during stance between the DRAFO and the conventional AFOs (Hypothesis 2). Significant differences in TVA cross-over time during swing were observed between the DRAFO and no AFO condition, failing to support Hypothesis 1. Significant differences in TVA cross-over time during stance were found between the DRAFO and conventional AFOs, supporting Hypothesis 2. These modest differences of approximately 1-5% gait cycle (less than 60 msec) were associated with low power (see Appendix G), and should therefore be confirmed with future testing of both an expanded population of able-bodied subjects and a clinical population that are candidate for AFOs.

5.1.2.2 SVA

Analysis of segment, rather than joint, angles may assist determination of AFO alignment and understanding of the effects of AFOs on gait [13, 23, 30]. MSt has been identified as a challenging phase of the gait cycle as it reflects single limb support. The shank position during MSt: 1) contributes to knee stability affecting the position of the knee center of rotation relative to the weight-line and GRF, 2) affects forward progression of the thigh, pelvis, and trunk (trunk glide: relatively stationary shank during MSt with forward momentum advancing the thigh, pelvis, and trunk, and extending the knee, [39]), 3) influences thigh, pelvis, trunk, and head kinematics, 4) controls GRF alignment and alters internal joint moments at the knee and hip, and 5) may influence energy expenditure [23], [37].

The SVA is dependent on heel height [30]; increased heel height (e.g. due to external shoe wedges) results in an inclined shank at foot flat. Increased heel height has been observed to increase knee flexion and the internal knee extension moment during MSt for healthy subjects wearing rigid AFOs [30]. As alignment of the SVA affects knee kinematics, SVA can be used as a potential clinical measure to align AFOs to alter joint kinematics and stability during stance. For example, a SVA of 14° inclination imposed via heel wedges reduced knee hyperextension during MSt for a hemiplegic patient wearing a rigid AFO [13].

The plantarflexed alignment and external heel lifts of the DRAFO were expected to affect SVA cross-over timing relative to the no AFO condition during stance, providing an inclined shank to assist limb advancement through MSt. However, the stance SVA cross-over time did not differ from the no AFO condition, while still providing enhanced knee flexion. Despite the 10° inclination at MSt, the SVA cross-over time during stance with the DRAFO was not advanced relative to the free and locked AFO conditions, indicating that the DRAFO did not

accelerate limb advancement. This unexpected behavior may be due to treadmill, rather than overground, ambulation and minor differences in self-selected walking speed for each AFO condition.

The plantarflexed alignment and external heel wedges of the DRAFO were also expected to affect the swing SVA cross-over time. However, no differences in SVA cross-over time were observed between AFO conditions. The plantarflexed AFO alignment and/or incorporation of heel wedges therefore did not affect swing phase shank kinematics.

Clinically, the SVA cross-over time may be used to understand knee and hip kinematics. Delays in SVA cross-over time during both stance and swing, in combination with knee and hip kinematics, may provide a more holistic view of forward progression of the body COM and swing limb advancement to assist assessment of AFO alignment.

The DRAFO was not expected to alter SVA cross-over time during swing compared to the no AFO condition. The stance SVA cross-over time differed between the DRAFO and no AFO conditions, failing to support the first hypothesis with a high power (0.79).

The plantarflexed alignment and external heel wedges of the DRAFO were expected to affect SVA cross-over time during stance of the DRAFO from the neutrally-aligned conventional AFO conditions (Hypothesis 2). However, despite the high power (0.79) associated with this measure, the stance SVA cross-over time did not differ significantly between the DRAFO and conventional AFO conditions. This lack of support for Hypothesis 2 may be attributed to the healthy subject population; individuals were able to push through the stance-to-swing transition, and fight the AFO.

5.1.3 FPA

FPA characterizes foot placement in the coronal plane, evaluating with the foot is internally (“toe in”) or externally (“toe out”) rotated. FPA is linked to the shank, which may then impact knee and hip biomechanics. AFO alignment may impact foot progression angle as the constrained foot, ankle and subtalar joints may hinder roll-over. “Toe out” may therefore reflect a compensatory mechanism to facilitate roll-over and forward progress. Analysis of foot progression angle therefore extends the biomechanical analysis beyond the sagittal plane.

Statistically significant differences in minimum FPA were observed between the DRAFO and no AFO conditions (DRAFO: -6.02±4.18°, no AFO: -7.79±3.45°). However, no statistical differences in either the minimum or maximum FPA were found between the DRAFO and conventional AFO conditions. The lack of differences between the DRAFO and conventional AFOs, as well as high standard deviations may indicate that the differences are not clinically significant.

The effect of FPA on knee and hip joint kinetics has been investigated as it relates to injury and/or the development of OA [40, 41]. Guo et al. found that FPA with increased toe out reduces the second peak knee adduction moment, and therefore may be a compensatory gait deviation that may benefit individuals with early knee OA by [40]. Lin et al. also investigated the effects of FPA for healthy teenagers; increased toe in resulted in an increased knee adduction moment [40]. Despite differences in subject population, both studies indicate increased toe out reduces the knee adduction moment.

5.1.4 Step Width

AFOs are often prescribed to help stabilize the foot segment in both the sagittal and coronal planes, to enhance stability of the lower extremity during ambulation. Frontal plane stability may be inferred from step width; wider step width or a wider base of support may be indicative of instability. Patients with subtalar joint instability may increase their step width as a compensatory mechanism; step width may then decrease with AFO use as the device may increase the subtalar joint stability. Although gait analysis was only conducted for able-bodied subjects, analysis of step width may reflect potential instability induced by AFO use.

Step width was increased with AFO use relative to the no AFO condition (no AFO: 132.96±29.34mm, DRAFO: 146.23±37.60mm, free: 141.11±33.93mm, locked: 142.36±33.61mm), although these differences were not significant.

While AFOs typically increase frontal (and sagittal) plane stability and decrease step width for individuals with subtalar joint instability due to stroke or CP [42, 43], step width increased with AFO use for the able-bodied subjects who participated in this study. The introduction of AFOs for this healthy population likely decreased comfort and stability, as reflected by the increased step width AFOs particularly with the rigid AFOs (step width with DRAFO > locked AFO > free AFO > no AFO). This finding is consistent with Opara who observed increased step width during overground ambulation in locked metal AFOs in young, able-bodied subjects [44].

The soft heel of the DRAFO was expected to result in step widths that approximated that of the no AFO condition (Hypothesis 1) but differed from the conventional AFOs that incorporate rigid heel structures (Hypothesis 2). In fact, step width did not differ significantly between the DRAFO and no AFO conditions, supporting Hypothesis 1 with a modest power

(0.30). No significant differences in step width were observed between the DRAFO and conventional AFO conditions; Hypothesis 2 was therefore not supported.

5.2 EMG

AFOs are prescribed to stabilize the ankle and subtalar joints during stance, as well as assist the ankle dorsiflexors (e.g. to resist plantarflexion) during swing to provide foot clearance. Rigid AFOs maintain the ankle in a neutral position, restricting dorsiflexion during stance and plantarflexion during swing. Articulating AFOs permit some dorsiflexion, and often incorporate a plantarflexion stop to resist gravity-induced plantarflexion during swing phase. The DRAFO incorporates a rigid shell, thereby approximating a rigid AFO during swing. However, the soft heel permits some plantarflexion during LR.

No statistical differences in dorsiflexion activity duration during stance were observed between test conditions (no AFO: 73.15±28.28%, DRAFO: 39.82±38.69%, free AFO: 52.97±34.29%, and locked AFO: 65.36±36.83% stance duration). However, large variability in dorsiflexion activity duration were observed for all AFO conditions. Despite this variability, statistically significant differences in dorsiflexion activity were observed during swing. Dorsiflexion activity duration for all three AFO conditions was reduced relative to the no AFO condition during swing (no AFO: 73.15±30.19%, DRAFO: 39.82±34.71%, free AFO: 52.97±31.40%, and locked AFO: 55.88±32.60% swing duration). Although no significant differences in dorsiflexion activation duration were observed between the DRAFO and conventional AFOs during swing, dorsiflexion activity duration with the DRAFO was approximately 13% less than that observed for the locked and free AFO conditions.

No significant differences in plantarflexion activity duration during stance were observed between AFO conditions (no AFO: 80.38±11.96%, DRAFO: 75.96±17.65%, free AFO: 79.62±15.78%, and locked AFO: 85.59±14.46% stance duration).

5.2.1 Dorsiflexion Activity

For healthy subjects, dorsiflexion activity occurs primarily during two intervals: 1) from IC to LR, the dorsiflexors eccentrically contract to prevent foot slap and 2) from ISw through TSw to assist with foot clearance. AFOs are frequently prescribed for patients with weak dorsiflexors (and/or spastic plantarflexors).

Individuals with weak dorsiflexors may demonstrate foot slap during early stance or toe drag during swing, inducing potential instability during stance due to rapid foot flat, and potential tripping during swing. AFOs are often prescribed for such individuals to prevent these gait pathologies, and minimize fall risk due to toe drag. AFOs are therefore expected to decrease dorsiflexion activity, if present, during early stance and early to mid-swing.

During stance, no significant differences in dorsiflexion activity duration were observed between AFO conditions. Although the AFOs held the ankle in a constant position (plantarflexed for DRAFO, neutral orientation for locked AFO) or prevented plantarflexion via a plantarflexion stop (free AFO), these healthy subjects continued to activate their dorsiflexors during LR. During swing, ambulation in the AFOs significantly reduced dorsiflexion EMG activity duration, as expected due to AFO design features that reduce gravity-induced foot drop or plantarflexion.

Several studies have investigated the effects of AFOs on stance phase dorsiflexor activity [45, 46]. Decreased dorsiflexion activity during early stance (0-15% gait cycle) was observed for healthy subjects wearing AFOs [38]; decreased dorsiflexor activity throughout the gait cycle was

observed for individuals with peripheral paresis wearing AFOs [38]. Romles et al. also noted decreased magnitude (36%) in dorsiflexor activity at IC for children with hemiplegic CP wearing a hinged AFO [39]. These results are contrary to that observed during stance in the current study, although the current study simply assessed dorsiflexion activity duration throughout stance (and swing), not activity amplitude nor activity duration during the stance sub-phases. A healthy population may still activate the dorsiflexors in early stance phase despite being held in a rigid AFO.

The decreased dorsiflexion activity duration observed during swing with AFO use for able-bodied subjects is consistent with the literature [39] (children with CP), [38] (able-bodied individuals and subjects with peripheral paresis), and [5] (individuals post-stroke). Many AFO designs (e.g., Dynamic Ankle Orthosis, locked AFO, and articulated AFO with plantarflexion stop) have been observed to reduce dorsiflexion activity levels during swing.

Prior studies also investigated both the short- and long-term effects of AFO usage on dorsi- (and plantar-) flexor muscle activity [38]. While rigid AFOs limit the mobility of the ankle and subtalar joints, providing stability, these constraints may lead to muscle atrophy due to inactivity. One study measured the effects of AFOs on the gait of 14 healthy subjects and 29 subjects with peripheral paresis of the dorsiflexors. For the healthy control subjects, AFO use resulted decreased dorsiflexion amplitude during LR, while the paretic subjects with AFOs demonstrated decreased dorsiflexion amplitude throughout the entire gait cycle [38]. Sustained activity of the dorsiflexor muscles may help to retain muscle mass over the long-term, and may be beneficial for patients with potential for musculoskeletal recovery. However, this dorsiflexion activity during stance may reflect an inefficient system for which energy expenditure might be reduced if the dorsiflexion activity decreased with AFO use.

The soft heel of the DRAFO was expected to permit ankle plantarflexion during LR, thereby necessitating dorsiflexor activity to prevent foot slap. As such, dorsiflexion activity duration during stance with the DRAFO was expected to approximate the no AFO condition (Hypothesis 1). No significant differences in dorsiflexion activity duration during stance were observed between the DRAFO and no AFO conditions; Hypothesis 1 was therefore supported [with low power, likely attributed to the high variability in EMG activity (Appendix G)].

As the soft heel of the DRAFO likely increases dorsiflexion activity during LR, dorsiflexion activity duration during stance was expected to differ from that with the conventional AFOs, particularly for the locked AFO that prohibits ankle plantarflexion during LR (Hypothesis 2). However, no differences in dorsiflexion activity duration during stance were observed between the DRAFO and conventional AFO conditions; therefore, Hypothesis 2 was not supported during stance phase, although the associated power was low (<0.01, Appendix G) due to high variability in EMG and small study population.

5.2.2 Plantarflexion Activity

Plantarflexion activity for able-bodied subjects typically occurs during stance only, from TSt through PSw to provide powered push off to propel the limb into swing. This plantarflexion activity helps stabilize the ankle as the shank rotates over the forefoot (third rocker) [10]. With the potential exception of powered or leaf spring AFO designs, most AFOs do not provide active push off; these passive AFOs simply stabilize the ankle to assist shank rotation over the forefoot rocker. As the plantarflexors are not expected to be active during swing, plantarflexion activity duration was investigated during stance only.

No differences in plantarflexion activity duration during stance were observed with DRAFO relative to the no AFO condition, nor with respect to the conventional AFOs. The DRAFO, with its plantarflexed alignment and external heel wedges, might be expected to affect plantarflexor activity during stance. However, no significant differences in plantarflexion activity duration were found, which may be attributed to: 1) high variability in plantarflexor activity duration, and 2) habitual plantarflexion activity during TSt-PSw for powered push-off, despite the orthotic plantarflexion constraint. Geboers also noted sustained plantarflexion activity for both able-bodied and paretic subjects wearing AFOs during level treadmill walking [38].

AFOs are not typically prescribed to address pathological plantarflexion activity, unless spastic plantarflexion activity is observed and it affects foot clearance during swing. Excessive plantarflexion activity may be treated with an AFO with a plantarflexion stop (free, articulated AFO) or a rigid ankle joint (locked AFO or DRAFO), thereby preventing powered push-off during late swing and assisting foot clearance during swing.

5.3 KINETICS

The COP quantifies the location of the GRF and may be used to investigate plantar loading patterns and load progression during the various sub-phases of stance. The COP can be used to assess balance and dynamic stability, contrasting the medial-lateral motion of the COP relative to the long-axis of the foot in the DRAFO and no AFO conditions, as well as for the DRAFO compared to the conventional AFOs. As the DRAFO has a soft heel, proprioception may be enhanced during IC and LR, resulting in COP progression that more closely mimics the no AFO condition, particularly during early stance.

During LR, the COP progression of the DRAFO was more medial than for the no AFO condition with similar range of motion, as quantified by the peak medial/min lateral position (DRAFO: 3.63±15.76mm, no AFO: 14.78±12.51mm) and peak lateral position (DRAFO: 21.91±10.08mm, no AFO 29.80±8.53mm). During MSt, the DRAFO COP progression was also more medial than for the no AFO condition (peak medial position: DRAFO = 21.08±13.63mm, no AFO = 30.30±9.57mm; peak lateral position: DRAFO = 36.99±13.92mm, no AFO = 44.23±14.42mm). Similar differences were noted during both TSt (peak medial: DRAFO = 29.79±21.50mm, no AFO = 42.88±15.18mm; lateral peak: DRAFO = 41.54±21.47mm, no AFO = 55.01±19.92mm) and PSw (peak medial only: DRAFO = 6.57±31.39mm, no AFO = 33.16±17.77mm).

During LR, the COP for the DRAFO was also significantly more medial than for the free AFO condition (peak lateral: DRAFO = 21.91±10.08mm, free AFO = 26.87±12.13mm). The COP with the DRAFO was also more medial than the free AFO condition during MSt (peak medial: DRAFO = 21.08±13.63mm, free AFO = 28.01±14.63mm). Similar observations were made during both TSt and PSw, for which the COP for the DRAFO was again more medial than that for the no AFO and Free AFO condition: TSt (peak lateral: DRAFO = 41.54±21.47mm, free AFO = 50.94±23.12mm) and PSw (peak medial (DRAFO = 6.57±31.39mm, free AFO = 28.12±27.21mm).

5.3.1 COP Progression

During level, treadmill walking for able-bodied subjects, the COP is initially located at the center of the heel during IC, progressing forward toward the toes at TO [47]. The progression of COP moves laterally with respect to the long-axis of the foot from the heel, from IC through

MSt, before moving towards the long axis of the foot, with a location medial to this axis during PSw [Figure 2.15]. In the current study, however, the COP progression for the DRAFO condition relative to that observed for the no AFO condition was consistently more medial to the long axis of the foot.

The COP relative to the long axis of the foot was more medial for the DRAFO (and free AFO condition) relative to the no AFO condition, from LR through PSw. The more medial COP progression may be attributed to wearing a rigid AFO device, and although increased stability would indicate that step width would be decreased, no significant differences were found in step width between conditions. It is also possible that the wedges may have induced a more pronated/inverted foot than in the conventional AFO conditions, although the wedges were only intended to affect sagittal plane stability. More lateral COP progressions have been postulated to increase stability or dynamic balance; both Balmaseda (able-bodied subjects wearing AFOs) [48] and Wang (hemiparetic subjects wearing rigid AFOs) [20] observed more lateral COP progression with AFOs relative to the no AFO condition. In contrast to the current study, these studies reflected impaired balance with AFO use, necessitating the wider base of support and more lateral COP progression trajectory.

The soft heel of the DRAFO was expected to increase proprioception during IC and LR, resulting in COP progression during IC through LR that more closely approximates the no AFO condition (Hypothesis 1); these effects were not expected in the latter sub-phases of stance (e.g. MSt-PSw). However, COP progression differed between the DRAFO and no AFO conditions during LR; Hypothesis 1 was not supported with modest to high power (0.32-0.92, Appendix G).

The soft heel and posterior heel wedge of the DRAFO were expected to differentiate COP progression for the DRAFO relative to the conventional AFOs during IC through LR

(Hypothesis 2). The COP progression with the DRAFO differed from the locked AFO during LR; differences in COP progression were also observed during a *portion* of LR with the free AFO condition. As such, Hypothesis 2 was largely supported with medium power (>0.5, Appendix G).

5.4 STUDY LIMITATIONS

This study made several assumptions that influenced study design, testing, data processing, and data analysis. For example, research subjects were restricted to young able bodied subjects. The use of this homogeneous population permitted analysis of AFO effects, free from potential variability due to neuromusculoskeletal impairment, pathologies and aging. This subject population likely exhibited less variability, thereby increasing the power associated with the study parameters (e.g., knee, ankle, shank, and thigh kinematics, dorsi-/plantar-flexion muscle activity duration, and COP progression). As such, these results may not directly translate to patient populations with specific neural, muscular and/or skeletal pathologies. These patient populations would likely exhibit greater heterogeneity and parameter variance, requiring greater population sizes for sufficient power.

Another factor regarding the experimental design that may have influenced the observed results was that subjects wore the same shoes for all conditions; larger shoes were not donned to accommodate AFO bulk. While the shoe constraint minimized potential variability due to differences in heel height and sole/upper compliance, the tight fit in the AFO conditions may have reduced ankle mobility and introduced discomfort. Footwear and footwear fit have been shown to impact COP [49]. Despite the potential impact of footwear and shoe fit on COP progression, consistent footwear was thought to be a more important study design consideration.

A final experimental factor that may have affected the results was that ambulation trials were restricted to level treadmill walking, rather that overground or non-level terrain gait. Studies have shown that level treadmill versus overground ambulation may result in several changes; treadmill walking has been observed to reduce dorsiflexion, decrease internal knee extensor moment during early and late stance, increase hip extensor moment (early stance and swing), decrease dorsiflexion activity during stance, and increase braking and vertical GRFs [50]. Lower extremity joint and segment kinematics, however, are largely the same for level treadmill vs overground walking, and therefore the joint and segment kinematic findings were likely not affected by the treadmill ambulation. The advantage of treadmill ambulation is that the subject's velocity is controlled, although their cadence and step length may vary. As study parameters were contrasted between AFO conditions and all trials were conducted at approximately the same walking velocity on a level treadmill, observed differences between AFO conditions might extend to overground walking at similar walking speeds.

Motion capture was based on reflective markers placed on the skin and AFO to track segments and joint motion. While skin motion likely introduced minimal error to the joint and segment kinematics (e.g. less than 4.4° [51]), marker placement on the AFO to approximate ankle position may not accurately approximate the joint, and does not mimic the motion of the actual ankle. As knee and ankle motion, as well as SVA and TVA motion were based on at least one marker positioned on the skin, kinematic errors likely did not affect key findings. The lateral offset of the malleoli markers on the right AFO-limb were addressed during kinematic data processing, as anthropometric measures at the malleoli were taken both with and without the AFO.

One factor that likely influenced data analysis was the use of a single MVC trial to scale the EMG activity. With only one MVC trial, estimates of peak EMG amplitudes may have been in error. As such, the MVC might not assess the true MVC, and errors may have been introduced in both scaling and activity duration calculations.

Another potential data analysis error involved the calculation of the TVA and SVA. These segment angles were based on sagittal plane location of only two markers per segment. Therefore, errors in sagittal plane motion of these markers, due to skin motion or other factors, may influence the accuracy of these calculations. Calculation of SVA and TVA using an additional marker or marker triad might improve the accuracy of these measures and the associated SVA and TVA cross-over times.

5.5 FUTURE STUDY

Based on this study, further testing is recommended to fully contrast ambulation in the DRAFO and traditional AFOs. Future research might investigate the impact (e.g., stability, SSWS, SLS duration, shank inclination velocity) of increased knee flexion in the DRAFO for subjects with cerebral palsy, hemiplegia with knee osteoarthritic, and genu recurvatum. Such studies should include a subject population of at least 12 subjects, based on power analyses conducted with the current data. In addition to kinematic (inclusive of step width, FPA, and other coronal and transverse plane parameters), EMG, and kinetic measures, clinical measures such as the TUG, BBS and comfort questionnaire should be included to gain further insight into the effects of the DRAFO's soft heel, plantarflexed alignment, and external heel wedges.

As the functional outcomes of the DRAFO are likely influenced by its effective alignment, future work might also investigate posterior heel wedges of various heights to help develop prescription and fitting guidelines for the DRAFO.

5.6 SUMMARY

The design features of the DRAFO, namely the soft heel, plantarflexed alignment, external heel wedges, and solid ankle, resulted in several kinematic differences between the DRAFO and no AFO conditions during stance. These kinematic differences included: increased knee flexion and plantarflexion, as well as delayed thigh cross-over time, with the DRAFO. The DRAFO also resulted in reduced dorsiflexion EMG activity during swing phase – as did the conventional AFOs. Finally the DRAFO moved the lateral COP progression more medially when compared to the no AFO condition. These design features of the DRAFO were expected to result in several gait parameters (e.g., ankle plantarflexion during early stance, cross-over times of the shank and thigh vertical angles during stance, step width and COP progression during LR) that would more closely approximate the no AFO condition, as posed by Hypothesis 1. Hypothesis 1, however, was only supported for a subset of these gait parameters, namely ankle kinematics during LR, step width, and dorsiflexion activity duration during stance.

The DRAFO's altered alignment and addition of the heel wedge were also expected to result in differences from conventional AFOs for specific gait metrics (e.g., ankle and knee kinematics, cross-over times of the shank and thigh vertical angles during stance, peak FPA, step width, stance phase dorsiflexion activity duration, and mediolateral motion of the center of pressure), as postulated by Hypothesis 2. Hypothesis 2 was also supported for a subset of gait

parameters, specifically knee kinematics during stance, ankle kinematics from LR through MSt as well as during swing, and TVA cross-over time during stance.

The observed increased knee flexion during stance with the DRAFO may enhance shock absorption during LR and minimize potential knee joint pain during weight acceptance, possibly benefiting those who suffer from knee OA; the increased knee flexion during stance may also benefit patients with genu recurvatum. The DRAFO's soft heel and more plantarflexed ankle may also assist weight acceptance and the first rocker, assisting foot flat. However, the delayed TVA cross-over time with the DRAFO may be attributed to the increased knee flexion during stance, and may result in prolonged stance. Finally, more medial COP progression with the DRAFO and conventional AFOs may reflect increased stability or dynamic balance in these AFOs, although no differences in step width were observed between any AFO conditions.

Chapter 6: CONCLUSION

AFOs are commonly prescribed to compensate for spasticity/weakened muscles in the plantar/dorsiflexors, provide stability during stance and assist with foot clearance during swing. Rigid AFOs maximize stability during stance and provide assistance with clearance during swing, fully restricting the mobility of the ankle and subtalar joints. The sole function of articulating AFOs is to provide frontal plane stability during stance.

The DRAFO is a rigid AFO that includes a soft inner shell and a rigid polypropylene outer shell with heel cutout. As both rigid AFOs and articulating AFOs with a plantarflexion stop provide support for the plantar surface, ankle and subtalar joints, proprioception during stance is reduced. The inclusion of the heel cutout and soft liner of the DRAFO may increase proprioception during LR. Additional design features of the DRAFO include a plantarflexed alignment with supplemental external heel wedges to incline the shank during MSt; together these features may accelerate forward progression of the body COM during stance relative to conventional AFOs.

The purpose of this study was to contrast the DRAFO relative to the no AFO condition, and relative to conventional AFOs during level treadmill ambulation. The specific variables analyzed in this study included: kinematic measures (ankle and knee joint angles in the sagittal plane, SVA and TVA cross-over time, step width, and FPA), muscle activity duration (dorsiflexors and plantarflexors), and COP progression. The specific research hypotheses investigated in this study were:

1) Gait parameters (e.g ankle plantarflexion during LR, swing phase SVA and TVA cross-over times, dorsiflexion activity duration during stance, step width, and COP progression during LR) with the DRAFO will approximate that of the no AFO condition.

2) Gait parameters (e.g. ankle and knee kinematics, stance phase SVA and TVA cross-over times, foot progression angle, step width, stance phase dorsiflexion activity duration, and COP progression during LR) with the DRAFO will differ from that for articulating and rigid AFOs.

The design features of the DRAFO, namely the soft heel, plantarflexed alignment, external heel wedges, and solid ankle, resulted in several kinematic differences between the DRAFO and no AFO conditions during stance. These kinematic differences included: increased knee flexion and ankle plantarflexion, as well as delayed thigh cross-over time, with the DRAFO. The DRAFO also resulted in reduced dorsiflexion EMG activity during swing phase – as did the conventional AFOs. Finally the DRAFO had a more medial peak COP progression when compared to the no AFO condition, although the COP progression for all conditions was lateral to the long axis of the foot. These design features of the DRAFO were expected to result in several gait parameters (e.g., ankle plantarflexion during early stance, cross-over times of the shank and thigh vertical angles during stance, step width and COP progression during LR) that would more closely approximate the no AFO condition, as posed by Hypothesis 1. Hypothesis 1, however, was only supported for a subset of these gait parameters, namely ankle kinematics during LR, step width, and dorsiflexion activity duration during stance.

The DRAFO's altered alignment and addition of the heel wedge were also expected to result in differences from conventional AFOs for specific gait metrics (e.g., ankle and knee kinematics, cross-over times of the shank and thigh vertical angles during stance, peak foot progression angle, step width, stance phase dorsiflexion activity duration, and mediolateral motion of the center of pressure), as postulated by Hypothesis 2. Hypothesis 2 was also supported for a subset of gait parameters, specifically knee kinematics during stance, ankle

kinematics from LR through MSt as well as during swing, and TVA cross-over time during stance.

Joint and segment kinematics provide insight into how individuals walk; gait pathologies due to musculoskeletal impairment and/or orthotic intervention often induce compensatory mechanisms. In this investigation of young, able-bodied subjects during treadmill ambulation at self-selected walking speeds, the DRAFO resulted in increased knee flexion during early/MSt and swing, with increased extension during late stance. Greater stance flexion during LR may reduce joint loading, while potentially increasing knee extensor activity to counter the corresponding internal knee flexion moment. As expected, the plantarflexed alignment the DRAFO resulted in greater ankle plantarflexion throughout gait, relative to conventional AFO conditions. This increased plantarflexion, together with the external heel wedges and soft heel, however, more closely approximated the no AFO condition, providing a more natural initiation of the gait cycle. Increased plantarflexion may also be beneficial during PSw, assist the 3rd rocker in preparation for swing. During swing, however, increased plantarflexion likely hinders foot clearance and may result in compensatory kinematics, although increased knee flexion was not observed. As the design features of the DRAFO were in the sagittal plane, no frontal or coronal plane effects were expected. However, the DRAFO altered the minimum FPA compared to the no AFO condition. This alteration may affect knee kinematics and kinetics in the frontal and transverse planes.

EMG activity can provide insight into musculature use and can help to better understand the effects of the DRAFO on dorsi/plantarflexion activity duration. Increased activity duration might be indicative of increased energy expenditure and potential risk of muscle fatigue. The soft heel of the DRAFO was expected to approximate dorsiflexion activity duration of the no

AFO condition, with the ankle dorsiflexors acting to prevent foot slap during LR. The rigid frame of the DRAFO, like that of the conventional AFOs, was expected to minimize dorsiflexion activity during swing. Contrary to expectations, dorsiflexion activity in the DRAFO did not approximate the no AFO condition. In addition, none of the AFOs reduced dorsiflexion activity during swing; this anomaly is likely attributed to habit and muscle memory as all subjects were healthy. Muscle activity duration with the DRAFO therefore does not reflect any functional advantage relative to conventional AFOs, although this finding should be further investigated with a clinical population.

The progression of the COP, together with step width and FPA, were investigated as potential measures of stability during gait. The soft heel of the DRAFO was expected to improve proprioception during LR, resulting in COP progression that approximated the no AFO condition, thereby differing from that of conventional AFOs. However, the COP progression during LR remained similar to that of the conventional AFOs. The potential advantages of the soft heel are therefore unknown, or may have been masked by the plantarflexion alignment.

To further investigate the potential effects of the DRAFO on stability, both step width and FPA were measured. Significant differences were found between the DRAFO and no AFO conditions, but these changes were likely not clinically significant. However, further research into FPA and its effects on the knee moment are warranted. No significant differences in step width were found between AFO conditions, the effects of stability on the DRAFO are uncertain.

There are several study limitations that must be taken into consideration. The subject population was small (10 subjects) and consisted solely of young, able-bodied subjects, thereby affecting analysis of muscle activity duration. Finally, ambulation trials were performed on a level treadmill, providing constant velocity analysis within the trials, but which may differ from

overground walking and ambulation over non-level terrain. Additionally, the self-selected velocity of some subjects varied between conditions which may have affected the analysis of TVA, SVA and muscle activity duration as a percent of the gait cycle.

Despite these limitations, the study provides insight into the effects of various DRAFO design features (soft heel, plantarflexed alignment, external heel wedges, and rigid frame) on gait compared to both the no AFO and conventional AFO conditions. Of the measures investigated, only ankle and knee joint kinematics differed between the DRAFO and conventional AFOs. The increased ankle plantarflexion with the DRAFO better approximated normal kinematics during LR, and may provide a more effective lever arm for the 3rd rocker in preparation for swing. The DRAFO also increased knee flexion during early and late stance, as well as during swing. This may reduce lower limb loading during early stance, but may increase energy expenditure due to increased quadriceps effort during early stance to counter the internal knee flexion moment and increased hip and/or knee flexor activity during swing to assist toe clearance. These results support DRAFO use for individuals with lower limb joint pain and perhaps mild genu recurvatum.

Future analysis of the DRAFO might address optimization of alignment and external heel wedge height, muscle activity of the quadriceps and hamstrings, COP progression, COP progression velocity, and energy consumption to further investigate the impact of the DRAFO design features on ambulation. The subject population might be extended to include clinical populations that are candidates for AFO treatment intervention.

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Appendix A: Statistical analysis of peak knee flexion angle and TVA cross-over times.

	IC	Early stance	Late stance	Swing
Normality	0.38	0.815	0.927	0.565
GLM	**0.003**	**<0.001**	**<0.001**	**0.03**
Friedman's Test	XXXX	XXXX	XXXX	XXXX
no AFO - DRAFO	**<0.05**	**<0.05**	**<0.05**	>0.05
no AFO – free	>0.05	>0.05	>0.05	**<0.05**
no AFO - locked	>0.05	>0.05	**<0.05**	>0.05
DRAFO - free	**<0.05**	**<0.05**	**<0.05**	>0.05
DRAFO - locked	**<0.05**	**<0.05**	**<0.05**	>0.05

	TVA Stance	TVA Swing	TVA Stance (sec)	TVA Swing (sec)
Normality	0.683	0.297	0.738	**0.011**
GLM	**<0.001**	**<0.001**	**<0.001**	XXXX
Friedman's Test	XXXX	XXXX	XXXX	**0.008**
No AFO - DRAFO	**<0.05**	**<0.05**	**<0.05**	**0.019**
No AFO - free	<0.05	**<0.05**	>0.05	0.541
No AFO - locked	<0.05	>0.05	>0.05	0.919
DRAFO - free	**<0.05**	**<0.05**	**<0.05**	**0.006**
DRAFO - locked	**<0.05**	**<0.05**	**<0.05**	**0.032**

Appendix B: Statistical analysis for peak sagittal plane ankle angle and SVA cross-over times.

	Stance plantar	Stance dorsi	Late plantar	Swing dorsi
Normality	0.467	0.799	0.724	**0.007**
GLM	**<0.001**	**<0.001**	**<0.001**	XXXX
Friedman's Test	XXXX	XXXX	XXXX	**0.008**
no AFO - DRAFO	>0.05	**<0.05**	**<0.05**	**<0.05**
no AFO - free	**<0.05**	**<0.05**	**<0.05**	>0.05
no AFO - locked	**<0.05**	>0.05	**<0.05**	>0.05
DRAFO - free	**<0.05**	**<0.05**	>0.05	**<0.05**
DRAFO - locked	**<0.05**	**<0.05**	>0.05	**<0.05**

	SVA Stance	SVA Swing	SVA Stance (sec)	SVA Swing (sec)
Normality	0.675	0.315	0.986	**0.014**
GLM	0.17	**0.009**	**0.037**	XXXX
Friedman's Test	XXXX	XXXX	XXXX	**0.017**
no AFO - DRAFO	XXXX	**<0.05**	>0.05	0.032
no AFO - free	XXXX	>0.05	>0.05	0.61
no AFO - locked	XXXX	>0.05	>0.05	0.476
DRAFO - free	XXXX	**<0.05**	>0.05	**0.006**
DRAFO - locked	XXXX	>0.05	>0.05	**0.019**

Appendix C: Statistical analysis for foot progression angle

	Min FPA	Max FPA
Normality	**0.005**	0.481
GLM	XXXXX	**0.454**
Friedman's Test	**0.045**	XXXXX
no AFO - DRAFO	**<0.05**	XXXXX
no AFO - free	>0.05	XXXXX
no AFO - locked	>0.05	XXXXX
DRAFO - free	>0.05	XXXXX
DRAFO - locked	>0.05	XXXXX

Appendix D: Statistical analysis of step width

	Step width
Normality	0.775
GLM	0.092
Friedman's Test	XXXX
no AFO - DRAFO	XXXX
no AFO - free	XXXX
no AFO - locked	XXXX
DRAFO - free	XXXX
DRAFO - locked	XXXX

Appendix E: Full statistical information for EMG (dorsi/plantar) activity duration

	Dorsi Stance	Dorsi Swing	Plantar Stance
Normality	0.193	0.086	0.372
GLM	0.220	**<0.001**	0.077
Friedman's Test	XXXXX	XXXXX	XXXXX
no AFO - DRAFO	XXXXX	**<0.05**	XXXXX
no AFO - free	XXXXX	**<0.05**	XXXXX
no AFO - locked	XXXXX	**<0.05**	XXXXX
DRAFO - free	XXXXX	>0.05	XXXXX
DRAFO - locked	XXXXX	>0.05	XXXXX

Appendix F: Full statistical information for COP progression

	LR Min	LR Max	MST Min	MST Max	TST Min	TST Max	PSw Min	PSw Max
Normality	0.398	0.324	0.334	0.312	0.472	0.567	0.948	0.241
GLM	**<0.001**	**0.001**	**0.001**	**0.036**	**0.004**	**0.003**	**0.003**	0.143
Friedman's Test	XXXX	XXXX	XXXX	XXXX	XXXX	XXXX	XXXX	XXXX
no AFO - DRAFO	**<0.05**	**<0.05**	**<0.05**	**<0.05**	**<0.05**	**<0.05**	**<0.05**	XXXX
no AFO - free	**<0.05**	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05	XXXX
no AFO - locked	**<0.05**	**<0.05**	>0.05	>0.05	>0.05	>0.05	>0.05	XXXX
DRAFO - free	>0.05	**<0.05**	**<0.05**	>0.05	>0.05	**<0.05**	**<0.05**	XXXX
DRAFO - locked	>0.05	>0.05	>0.05	>0.05	>0.05	<0.05	>0.05	XXXX

Normality testing, statistical significance testing (GLM/Friedman's), and post-hoc power testing for knee COP progression throughout stance phase (LR-PSw)

Appendix G: Full power/effect size information for all variables

Measure	Specific Phase	Effect size	Power
Knee Angle			
	IC	0.91	0.72
	LR	0.92	0.74
	MSt	1.02	0.82
	Sw	0.0065	0.05
Ankle Angle			
	Stance plantar	0.013	0.05
	Stance dorsi	1.44	0.98
	Swing plantar	2.56	0.99
	Swing dorsi	0.74	0.55
TVA Crossing			
	Stance	0.41	0.21
	Swing	0.66	0.46
SVA Crossing			
	Stance	0.99	0.79
	Swing	0.35	0.17
Dorsi Activity			
	Stance	0.0067	0.05
	Swing	1.02	0.91
Plantar Activity			
	Stance	0.28	0.13
Medial COP			
	LR	0.78	0.59
	MSt	0.74	0.55
	TSt	0.64	0.44
	PSw	1.19	0.92
Lateral COP			
	LR	0.79	0.61
	MSt	0.52	0.32
	TSt	0.65	0.45
	PSw	0.96	0.77
FPA			
	Min	0.47	0.39
	Max	0.26	0.19
Step width			
	Mean	0.39	0.30