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Abstract

Background: Children with cerebral palsy (CP) experience an increased energy cost in relation to their impaired walking ability. This increased energy cost is connected to kinematic deviations, as well as deviations in the muscle activation pattern. Energy preserving walking is therefore an important treatment goal, and an ankle-foot orthosis (AFO) is a commonly used orthotic device to enhance this. Adjusting the shank- to vertical angle (SVA) with a five- millimeter heel wedge has further demonstrated a crucial impact on pathological deviations that arises among children with CP.

Aim: To investigate the effect of ankle- foot orthosis and ankle-foot orthosis alignment with a 5 mm heel wedge on energy cost during walking in children with CP. Secondary aims are to examine possible changes in spatiotemporal gait parameters, kinematics, and muscle activity.

Methods: Seven children with CP (mean age 10.86 ± 3.14) performed three walking tests to estimate their energy cost during walking. Additionally, they conducted a 3D gait analysis to assess kinematics and muscle activity during walking. Both test procedures were performed in three different conditions, consisting of 1) Walking with shoes, 2) Walking with their neutral aligned AFO (AFOn), and 3) Walking with an adjusted AFO (AFOa). The aligned adjustment was implemented using a 5 mm wedge placed between the footplate and the sole of the shoe.

Results: Energy cost was reduced when walking with AFOn compared to shoes (5.55 j/kg/m and 5.91 j/kg/m, respectively). AFOa demonstrated a significantly reduced time in single support, and a significantly longer time in double support compared to shoes ($p=0.04$ and $p=0.03$). Time in single support was significantly shorter for the affected leg in all three conditions ($p=0.00$). Kinematic data of the hip joint revealed a significantly increased hip extension in single support (SS) for the affected leg when walking with shoes compared to AFOa ($p=0.04$). In the swing phase (SW), there was a significant reduction in hip flexion when walking with AFOa and AFOn compared to shoes for the affected leg ($p=0.01$ and $p=0.00$). Similar for the unaffected leg, a significantly reduced hip flexion in SW was apparent when comparing AFOa to shoes ($p=0.04$). For the ankle joint, AFOa demonstrated significantly increased dorsiflexion ($p=0.04$) at initial contact (IC) compared to AFOn. Significant findings were also found in SW for the affected leg when comparing shoes to AFOn and AFOa ($p=0.00$ and $p=0.00$, respectively).

Conclusion: The use of the neutral aligned AFO significantly reduced energy cost during walking as compared to walking with shoes. Further, both AFO conditions revealed significant changes compared to walking with shoes in the kinematics of the ankle and hip joint.

Sammendrag

Bakgrunn: Barn med cerebral parese (CP) opplever en økt energikostnad i forbindelse med deres reduserte gangevne. Denne økte energikostnaden er forbundet med kinematiske avvik og avvik i muskelaktiveringsmønster. En effektiv og økonomisk gange er derfor et viktig behandlingsmål hos barn med CP, og en ankel- fot ortose (AFO) er et vanlig brukt ortopedisk verktøy for å stimulere til dette. Justering av vinkelen på leggen i forhold til det vertikale, ved bruk av en fem millimeter hælkile, har vist en essensiell påvirkning på patologiske avvik som forekommer blant barn med CP.

Formål: Å undersøke effekten av ankel-fot ortoser, samt ankel-fot ortose justering med en 5 mm hælkile på energikostnaden under gange. Sekundærformål for studien er å kartlegge mulige endringer i spatiotemporale gangparameter, kinematikk og muskelaktivitet.

Metode: Syv barn med CP (gjennomsnittsalder 10.86 ± 3.14) utførte tre gangtester for å estimere deres energikostnad under gange. I tillegg utførte de en 3D ganganalyse for å vurdere kinematikk og muskelaktivitet under gange. Begge testprosedyrer ble utført ved bruk av tre ulike kondisjoner, bestående av 1) Gange med sko, 2) Gange med deres nøytrale AFO innstilling (AFOn), og 3) med den justerte AFO innstillingen (AFOa). Justeringen ble implementert ved å bruke en 5 mm hælkile som ble plassert mellom fotbladet og skosålen.

Resultat: Energikostnad ble redusert når man sammenlignet gange med AFOn med sko (5.55 j/kg/m og 5.91 j/kg/m). Det ble funnet en signifikant forskjell i tid i singel support og dobbel support fasen, hvor AFOa hadde en kortere tid i singel support (SS), og en lengre tid i dobbel support (DS) sammenlignet med sko ($p=0.04$ and $p=0.03$). Lengden i singel support fasen var signifikant kortere for den affiserte foten enn den friske foten for alle tre kondisjonene ($p=0.00$). Kinematiske data for hofteleddet viste en signifikant større hofteekstensjon i SS for den affiserte foten ved gange med sko sammenlignet med AFOa ($p=0.04$). I svingfasen (SW) ble det funnet en signifikant reduksjon i hoftefleksjon ved gange med AFOn og AFOa sammenlignet med sko for den affiserte foten ($p= 0.00$ og $p=0.01$). Den friske foten viste en signifikant redusert hoftefleksjon i SW når man sammenlignet AFOa med sko ($p=0.04$). For ankelleddet demonstrerte AFOa en signifikant høyere dorsalfleksjon ved første hælistett for den affiserte foten, sammenlignet med AFOn ($p=0.04$). I svingfasen viste også AFOn og AFOa en signifikant høyere dorsalfleksjon sammenlignet med sko ($p=0.00$).

Konklusjon: Gange med den nøytralt justerte AFOen viste en signifikant redusert energikostnad sammenlignet med sko. Videre viste begge AFO kondisjonene signifikante endringer i kinematikken i ankel- og hofteleddet sammenlignet med sko.

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Last but not least, a particular thanks to all the children who participated in this study for their countless effort, and to their families for taking the time to come.

Abbreviations

CP	Cerebral Palsy
TD	Typically Developing
AFO	Ankle- Foot Orthosis
AFOn	Neutral AFO alignment
AFOa	Adjusted AFO alignment with a 5 mm heel wedge
SVA	Shank To Vertical Angle
sEMG	Surface Electromyography
GMFCS	Gross Motor Function Classification System
ECS	Energy Consumption
EC	Energy Cost
AL	Affected Leg
HL	Healthy Leg
3DGA	3D- Gait Analysis

Table of content

1.Background

Cerebral Palsy (CP) is the most common cause of physical disability in childhood and is caused by malformation or damage to the brain either before, during, or within a short time after birth (1). It describes a group of permanent disorders that affects the development of movement and posture, causing activity limitations (2). Children with CP may experience varying degrees of restrictions related to their motor abilities, dependent on their level of mobility according to the Gross Motor Classification System (GMFCS). GMFCS- level I- II indicates minimal disability with total independence of assistive walking devices. Limb involvement is also a determinant for motoric ability among children with CP, where hemiplegia, meaning that one side of the body is affected, is most common for those classified with a GMFCS-level I- II (3). Although children with hemiplegic CP are able to walk independent without any assistive devices, impaired walking along with various gait abnormalities is a common feature within this group (4). Increased energy cost during walking appears as a common constraint, and it is found that children with CP increase their energy cost up to three times during walking, compared to typically developing (TD) children (5). This increased energy cost is found to be connected to deviations in the kinematics and muscle activity (6). Therefore, energy conservative walking is an important treatment goal for children with CP (7).

An ankle-foot orthosis (AFO) is a commonly used orthotic device to decrease energy cost during walking in children with CP (8). It is a device worn on the lower part of the leg to provide direct control of the motion and alignment of the ankle and foot and is generally prescribed for patients with hemiplegic CP (8, 9). It aims to produce a more normal gait pattern by blocking pathological movements of the joint on the affected side (11). A variety of AFO types are available, but the patients' neurobiomechemical deficit, is the key consideration when deciding which AFO to prescribe (11, 12). AFO optimization, based on the neurobiochemical deficit, is a process called tuning. Tuning involves modifying the characteristics of the footwear or adjusting the angle of the tibial inclination of the AFO (14). The tibial inclination angle is also called the shank to vertical angle (SVA) and can be adjusted by removing or adding wedges under the heel. Such alterations will result in kinematic changes at the ankle, knee, and hip, which may contribute to an improved energy cost during walking (5, 9, 14).

Manipulation of the SVA through adding wedges under the heel has demonstrated crucial improvements on kinematic gait deviations that arise among children with CP, which further is suggested to affect the energy cost (16). One typical gait deviation among children with CP embraces the inability of dorsiflexion in the ankle joint. This deviation does often leads to excessive plantar flexion at initial contact and in the swing phase of the gait cycle, disrupting the normal heel-toe progression of gait (17). This abnormality is known as drop-foot. It occurs as a result of weakness or underactivity of the tibialis anterior muscle, with a simultaneous hyperactivity of the gastrocnemius and soleus muscle (11, 17, 18). The use of an additional heel wedge inside the AFO is shown to increase the ankle dorsiflexion, in addition to alter the muscle activity. Furthermore, changing the SVA by adding heel wedges has shown favourable changes in energy conservation by improving kinematic deviations of the knee joint (16). In resemblance to the gait deviation at initial contact for the ankle joint, there is found an increased knee flexion at initial contact. This deviation is a result of quadriceps femoris weakness as it works to extend the knee joint, or spasticity of the hamstrings muscles (20). In the hip joint, similar kinematic deviations are shown. An increased hip flexion during stride can be present, with an inability to adequately extend the joint. These abnormalities can be described by hip flexor contracture or overactivity as well as hip extensor weakness (15).

It is found that children with CP have a disordered timing of muscle activity, partly explaining the high energy cost found during walking in this group (5,15,16). This disordered timing can somewhat be explained by a simultaneous co-contraction, based on the increased demand for joint stability and movement accuracy during walking for children with CP (23). Researchers have found that an AFO may have a considerable effect on ankle plantar flexor activity, in addition to reducing the immediate ankle dorsiflexor activity found in those with CP (22). Using dynamic electromyography (EMG) to provide information concerning muscle activity will, therefore, be of great importance when determining possible causes of altered energy cost when walking with and without an AFO.

In resemblance to muscle activity, there is found a close connection between improvements in spatiotemporal gait parameters and energy cost with the use of AFOs during walking (24). It is found that both gait speed, cadence, step length, and stride length can be increased with the use of AFOs (24). Additionally, gait symmetry can be improved, with increased time in single support and a decreased time in double support on the affected side (10). While the AFO imposes a direct mechanical constraint on the ankle joint, it will further counteract on both the knee- and hip joint (25). Therefore, this counteraction will have significant fluctuations in all gait abnormalities that appear during walking for children with CP. However, there are limited research on the complexity of SVA manipulation and its impact on energy cost through alterations in gait kinematics and muscle activation (19,20,21,22).

As previously mentioned, manipulation of the SVA through adding wedges under the heel have suggested a reduced energy cost through improving kinematic deviations, and alter the muscle activity in children with hemiplegic CP (16). It is further found that a five- millimeter heel wedge will increase the SVA about two degrees, which will move the hip forward approximately 30 mm. These findings were based on average-sized adults, and it is found that children even need a more increased SVA than what traditionally have been used (10). The primary aim of this study is, therefore, to investigate the effect of ankle-foot orthosis and ankle-foot orthosis alignment on energy cost during walking in children and adolescents with cerebral palsy. Secondary aims are to examine the possible changes in spatiotemporal gait parameters, kinematics, and muscle activity. The hypothesis for the study is that the use of AFO and AFO alignment will lower the overall energy cost, in resemblance to reduce the muscle activity, ankle plantarflexion, knee flexion and hip flexion of the affected leg in children with hemiplegia.

2.Material and Methods

2.1 Participants

Eight children and adolescents (from now on called children) were recruited to participate in this study, but only data from seven participants were used, due to missing data (Table 1). The participants were recruited through Trøndelags Ortopediske Verksted (TOV), and the study took place at St.Olavs Hospital in Trondheim. All participants were between the age of 5-17 and were diagnosed with hemiplegic CP with a corresponding Gross Motor Classification System (GMFCS) level I-II. To be eligible for inclusion, they had to be able to receive and understand verbal instructions and to walk consistently for at least five minutes without any assistant devices. All participants were prescribed an AFO through TOV, whereas five participants had the original ToeOFF, while two participants wore a customized hinged thermoplastic AFO. A written consent was signed by both parents before any child was tested, and they were informed that they could withdraw from the study at any time without giving a reason. The study protocol was approved by the Regional Committee for Medical and Health Research Ethics.

Table 1: Descriptive data presented as number (n) or mean ± standard deviation (SD) for the participants

N	**7**
Unilateral right/left	4/3
Gender, female/male (n)	4/3
Age, years (mean ± SD)	10.86 ± 3.14
Height, cm (mean ± SD)	144.14 ± 16.59
Weight, kg (mean ± SD)	35.97 ± 12.24
Leg length affected side, mm (mean ± SD)	748.42 ± 103.94
Leg length healthy side, mm (mean ± SD)	761.42 ± 105.35

2.2 Equipment and procedure

The participants went through a testing protocol consistent of four different test settings:

1) Anthropometrical measurements

2) Surface electromyography (sEMG) placement

3) Walking tests to estimate energy cost during walking

4) 3D- gait analysis (3DGA) to evaluate kinematics with simultaneous sEMG recordings.

The protocol was conducted at two different locations, in which the oxygen consumption procedure required a longer pathway to sustain continuous walking. All testing was performed with three different conditions, consisting of walking with shoes, walking with their neutral aligned AFO (AFOn), and walking with an adjusted AFO (AFOa). The adjusted AFO (AFOa) was implemented using a five-millimeter wedge placed between the footplate and the sole of the shoe. The five-millimeter alignment change was chosen based on typical adjustment introduced to average- sized adults (10).

Before testing, the children were introduced to the protocol, using pictures to explain and illustrate the procedures. They were given ten minutes to familiarize themselves with the equipment, including seeing and holding the Metamax mask that they were going to use under the oxygen consumption test.

2.2.1 Anthropometrics

During anthropometric testing, the participants were barefoot and wore their own preferable clothes. A stadiometer (Seca, Hamburg, Germany) was used to measure height, and a digital scale was used to measure weight. Measuring tape and caliper were further used to measure leg length, ankle width, ankle width with AFO, knee width, and width from ASIS to ASIS (anterior superior iliac spine). These measurements were further applied into the Plug-in Gait lower body model in Vicon Nexus (30).

2.2.2 sEMG placement

First, skin preparations were conducted, including cleaning and shaving the skin if necessary. Ambu BlueSensor N electrodes (Ambu AS, Ballerup, Denmark) were further placed according to SENIAM (Surface ElectroMyoGraphy for the Non-Invasive Assessment of Muscles) recommendations for electrode placement, bilaterally on the following five muscles: Tibialis Anterior (TA), Soleus (SOL), Gastrocnemius Medialis (GM), Rectus Femoris (RF) and Hamstring Medialis (HM) (31). Both the electrodes and the transmitters were placed to fit inside the AFO and secured using medical tape. The sEMG recordings were amplified by a 1000 gain with a sampling frequency at 1000 Hz. The signals were visually inspected and had to be considered sufficient before proceeding in the test protocol.

Figure 1: sEMG placement

2.2.3. Walking tests to estimate energy cost

Energy cost during walking was estimated using data collected from a portable indirect calorimeter, Metamax II (CORTEX Biophysik GmbH, Leipzig, Germany). Based on air inhaled through a Cortex face mask with a disposable flow turbine and a small mixing chamber, it provided respiratory values for each 10th seconds (23). Calibration of the equipment was performed before each test, using ambulant air, a reference gas (15% O_2 and 5% CO_2), and a 3-liter cylindrical pump that calibrated the flow turbine (Hans-Rudolph, Shawnee, KS). Time and heart rate during the walking test were collected using Polar M400 (Polar Electro Oy, Finland) that measured heart rate through a supplementary chest strap with an attached heart rate monitor. Distance travelled over the walking tests were measured using a standardized measuring wheel with a 1.0-meter circumference.

To estimate energy cost during walking, the participants executed three walking tests. They were instructed to walk back and forth a 35-meter long hallway, first for five minutes (5MWT), then three minutes (3MWT1), and finally three minutes (3MWT2) with a two minutes relaxation period between each test. The 5MWT were always executed first, to secure that all the energy cost measurements would be in a steady-state manner. The conditions, on the other hand, differed between the participants based on pre-defined randomization. It was emphasized that they had to walk at as they usually did, without talking, as a way to secure the accuracy of the measurements. When signalized, the participants started walking. At the end of the pathway, they were told to turn around and to continue walking. They were also asked if they felt OK, and based on pre-defined instructions, they responded with either a “thumb up” or a “thumb down.” If they gave a “thumb down,” the test would immediately stop, and the mask would be detached. Heart rate and oxygen measurements were started simultaneously. Two testers walked behind the participant, one with the distance wheel while the other held the equipment and recorded the time. One additional tester was located near the computer to secure the data quality. The same tester did the condition changes between the tests, that based on pre-defined randomization either was 1: Shoes only, 2: AFOn or, 3) AFOa.

Figure 2: Equipment setup for the walking tests

2.2.4 3DGA and sEMG collection

Kinematics were assessed using 3-dimensional gait analysis (3DGA, Vicon Motion Systems, Ltd, Oxford, UK), and surface electromyography (sEMG) were collected using Myon (Myon AG, Baar, Switzerland) wireless surface EMG-system. Ten cameras with a sampling frequency of 200 Hz and three AMTI force plates (Watertown, USA) with a sampling frequency of 1000 Hz were positioned along an 11-meter walkway. Before testing, Vicon´s Active Wand was used to calibrate the system, to enable the cameras to capture movements throughout the capture volume. Additional calibration of the force plates was executed, based on a calibration matrix that provided values for the position relative to the room (Fx, Fy, and Fz) (32). Sixteen reflective markers (14 mm) were attached to the anatomical landmarks as specified by the Vicon Plug- in- Gait, lower body model (33). Three additional reflective markers from the upper body model were placed on the 7th cervical vertebrae (C7) as well as on the right- and left shoulder (RSHO and LSHO) (34). The participants were instructed to walk back and forth on the 11-meter marked pathway, at a self-preferred speed. Testing was completed when three force plate hits on both right, and the left leg was achieved for all three conditions.

2.3 Data analysis

2.3.1 Energy cost

Respiratory exchange ratio (RER) calculated as VCO_2/VO_2, and mixed venous oxygen saturation (sVO2) were extracted from MetaSoft (Cortex Biophysic 2005) and exported to Excel 2016 version (Microsoft Inc, Redmond, WA, USA). Data from the walking tests were plotted for visual inspection, and the most stabile 60-seconds with less than 10% variation in VO2 and ventilation, and less than 5% variation in RER were defined as steady-state (35).

Energy cost expressed as J/kg/m were calculated using energy consumption (ECS) divided by speed (m/min)(36):

- $EC\ (J/kg/m) = \text{ECS}\ /\text{Walking Speed}$

Where ECS expressed as J/kg/min was calculated using relative VO_2, and RER:

$ECS\ (J/kg/min) = \ ((4.96 * \text{RER}) + 16.04) * \ VO_2\ /\text{kg}$

Whereas relative VO_2 was calculated using the earlier collected weight:

- $Relative\ VO_2(\text{mL/kg/min}) = (VO_2/\text{weight}) * 1000$

2.3.2 Kinematics and spatiotemporal gait parameters

The kinematic data were processed using Nexus software (Oxford Metrics, Oxford, UK) to define gait cycles, detect events, and calculate spatiotemporal gait parameters. A customized Matlab program (R2019a, MathWorks, Inc., Natick, MA, USA) was used for processing the c3d-files exported from Nexus. The script divided the gait cycle into four phases based on the detected end of double support 1 (DS1), single support (SS), and double support 2 (DS2), dividing the gait cycle into DS1, SS, DS2, and swing phase (SW). The script extracted joint angles for hip flexion/extension, knee flexion/extension, and ankle dorsi/plantar flexion for the different phases throughout the gait cycle, for both healthy and affected leg. Nexus´ Plug-in Gait setup model used the angles between two adjacent segments in a specific plane for the computation of joint angles (37). The rotation around the mobile axis, named Euler angles, were then applied to decompose the three-dimensional rotation, in which the rotation around the x-axis (tilt) was done first, followed by Y (obliquity), and lastly, Z (rotation) (38). Joint angles at each percentage of the gait cycle were then time-normalized to 0-100% of the gait cycle. An average of 2-5 trials for all three conditions for each participant was used in the analysis. The spatiotemporal gait parameters step length (m), cadence (steps/min), walking speed (m/s), time in single support, and time in double support was calculated for all three conditions for each participant, for both healthy and affected leg. Walking speed, cadence, and step length was normalized using the following equations (39):

- $Normalized\ walking\ speed = \ speed/\sqrt{((leg\ length)/1000 \times 9.81 m/s^2}$
- $Normalized\ cadence = cadence/\sqrt{((leg\ length)/1000 \times 9.81 m/s^2)}$
- $Normalized\ step\ length = step\ length/leg\ length$

2.3.3 Surface electromyography

The raw sEMG-signals from each limb were sampled at 1000 Hz and filtered with an 8th order Butterworth band-pass filter ranging from 30 Hz to 300 Hz. After visually inspecting the data, an sEMG root mean square (RMS) value was calculated with a window width of 50 ms for all EMG channels and each percentage of the gait cycle. The gait cycle was divided into the same four phases as for the kinematic data (DS1, SS, DS2, and SW). After visually inspecting the data for intra-subject variability, absolute sEMG-RMS of 2-5 trials for all three conditions were averaged for each participant and time-normalized to the gait cycle.

2.4 Statistical analysis

2.4.1 Energy cost

Statistical analysis for the energy cost data was performed using IBM SPSS statistics version 26 (SPSS, Inc., Chicago, IL). Due to the small sample size, data were pooled for females and males. Owing the small sample size, a parametric Paired- Samples T-tests were used to determine differences in energy cost across the three conditions: Shoes-AFOn, Shoes- AFOa, and AFOn- AFOa. The level of significance was set at $p<0.05$ for all statistical analyses. An additional post-hoc analysis was conducted to exclude potential differences in walking speed between the conditions.

2.4.2 Kinematics and spatiotemporal gait parameters

Statistical analysis for the kinematics was carried out using Matlab (R2019a, Mathworks, Inc., Natick, Ma, USA). Averages from the hip, knee, and ankle joint angles were calculated and displayed for each percentage of the gait cycle, with a 95% confidence interval (CI). A paired sample t-test (ttest_paired) using Statistical Parametric Mapping (SPM) in Matlab (Wellcome

Department of Cognitive Neurology, London, UK) was conducted to estimate paired differences between the conditions: Shoes- AFOn, Shoes- AFOa and AFOn-AFOa. For each percentage of the gait cycle, differences between the conditions were defined as significant when $p<0.05$. SPM was applied as no abstraction of the originally sampled time series needed to be executed in order to statistically analyze the data (40).

Differences in spatiotemporal gait parameters between healthy and affected leg, as well as differences between conditions (Shoes, AFOn and AFOa), were tested using a two-way ANOVA with post-hoc paired tests in IBM SPSS (Version 26, SPSS, Inc., Chicago, IL). The spatiotemporal gait parameter of interest was set as the dependent variable, leg, and condition as a fixed effect, and subject as a random effect.

2.4.3 Surface electromyography

Statistical analyses for the electromyographic data were performed using Matlab (R2019a, Mathworks, Inc., Natick, Ma, USA). Average absolute sEMG-RMS amplitudes per percentage of the gait cycle were calculated and displayed, with an additional 95% CI. Between- group differences (Shoes- AFOn, Shoes- AFOa, and AFOn-AFOa) were tested using the same paired t-test in SPM as for the kinematic data (ttest_paired). SPM was appropriate for this analysis because multi-muscle EMG time-series are highly correlated, and time depended, which of traditional statistical analysis of scalars fails to account for (41). Muscle activity was determined as significantly different between the conditions if $p<0.05$.

2.4.4. Correlation analysis of significant changes

A pairwise post- hoc Pearson correlation analysis was performed where significant changes in energy cost appeared by the test in section 2.4.1, and significant changes in gait kinematics, spatiotemporal gait parameters, and surface EMG found by statistically testing in section 2.4.2 and 2.4.3, respectively. Correlations were defined as significant if $p<0.05$.

3.Results

Seven hemiplegic patients were included, with data from both affected and unaffected leg.

3.1 Energy cost

There was a significant effect on energy cost when walking with the neutral aligned AFO as compared to shoes. While walking with shoes demonstrated a mean energy cost of 5.91 j/kg/m, walking with the neutral aligned AFO presented an energy cost of 5.55 j/kg/m. No significant differences were detected in terms of walking speed between the three conditions.

Table 2: Mean values for energy cost when walking with shoes, AFOn and AFOa with paired comparisons

Condition	Mean	Comparisons	95% CI
Shoes	5.91	Shoes-AFOn	**.01156 - .71058**
AFOn	5.55	Shoes-AFOa	-.155799 - .79238
AFOa	5.59	AFOn-AFOa	-.32718 - .23943

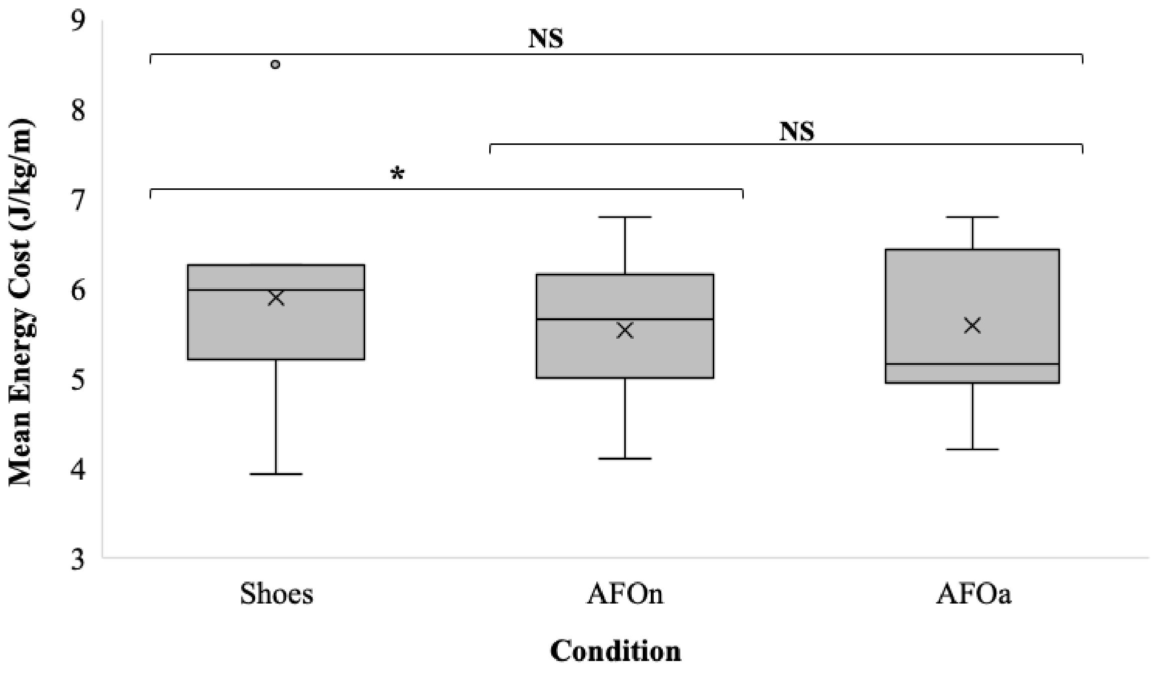


Figure 3: Box-plot illustrating the distribution and central tendency of the energy cost data
*Abbreviations: X= mean values, NS= No significant differences, *=Statistically significance (p <0.05), AFOn= Neutral AFO alignment, AFOa= Adjusted AFO alignment*

3.2 Spatiotemporal gait parameters and kinematics

Table 3 displays spatiotemporal gait characteristics for both healthy and affected leg, walking with shoes, AFOn, and AFOa. Significant differences were observed in terms of time in single support between healthy- and affected leg and the three conditions. The duration of single support was shorter for the affected leg in all three conditions (p=0.00). There was also a significantly shorter time in single support when walking with AFOa compared to shoes (p=0.04). Similar differences were detected for the time in double support, where AFOa demonstrated a significantly longer time in double support as compared to walking with shoes (p=0.03).

Table 3: Mean spatiotemporal gait parameters measured during walking with shoes, AFOn and AFOa

	Shoes		**AFOn**		**AFOa**		**P-value**	
	AL	HL	AL	HL	AL	HL	Legs	Conditions
Norm. walking speed (m/s)	0.42	0.42	0.40	0.39	0.40	0.40	.80	.36
Norm. cadence (steps/min)	43.62	42.97	41.80	41.62	41.47	41.53	.91	.79
Norm. step length (m)	0.81	0.77	0.77	0.77	0.78	0.77	.70	.88
Time in single support (%)	37.05†	40.44†	36.38	38.59	36.27†	37.96†	**.00***	**.04***
Time in double support (%)	21.32†	22.47†	23.93	24.08	24.78†	24.67†	.64	**.03***

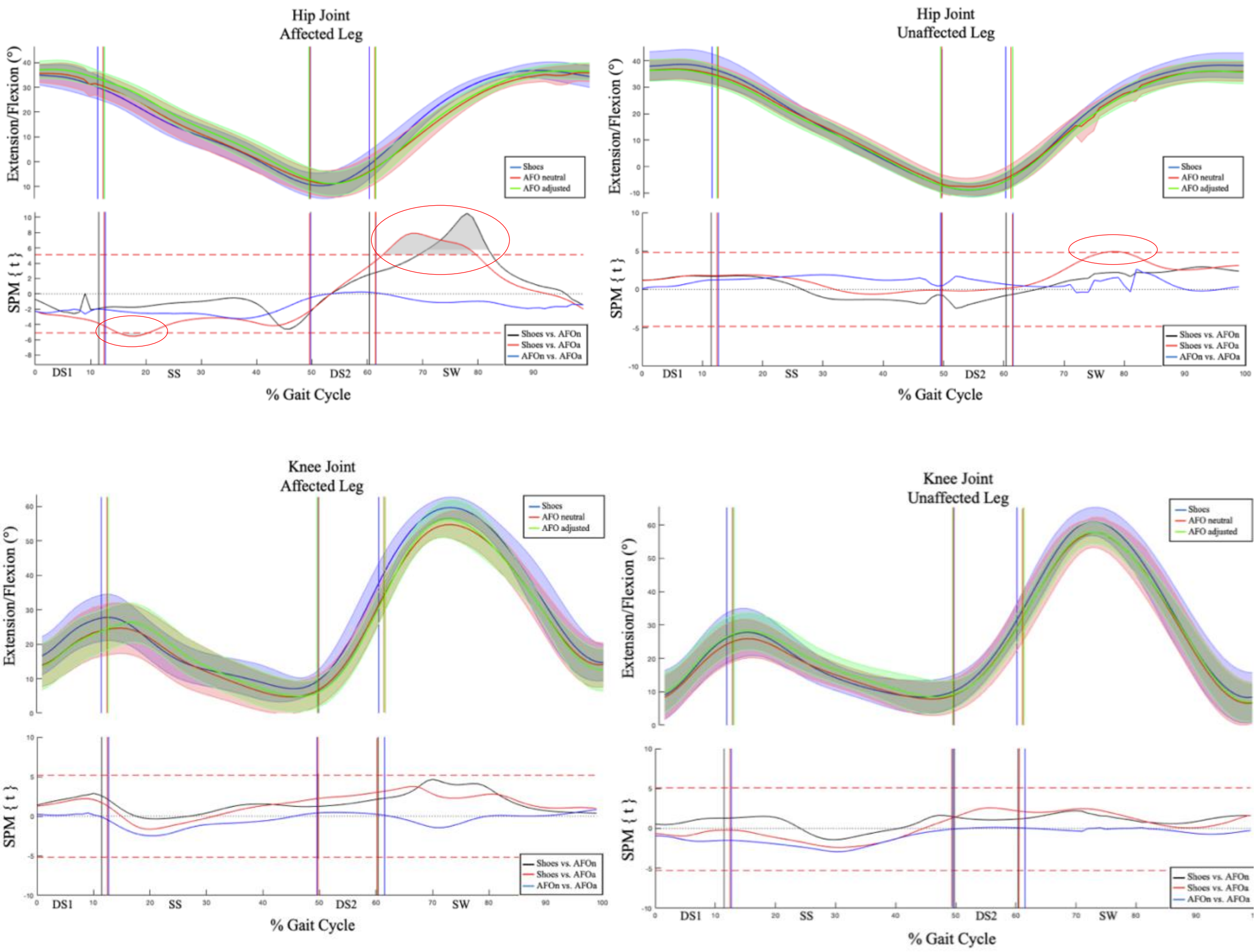
Abbreviations: AFOn= Neutral AFO alignment, AFOa= Adjusted AFO alignment, AL= Affected Leg, HL= Healthy Leg
*=Significant differences (p<0.05). †AFOa significant different from shoe condition

Values derived from kinematic data collected with and without AFOs are shown in Table 4. Figure 4 illustrates the angle of the hip, knee, and ankle joint when walking with shoes, AFOn, and AFOa with supplementary mapping of possible significant differences between the conditions. Significant differences in the hip joint for the affected leg were found when comparing shoes to AFOa, with a significantly increased hip extension in single support (SS) when walking with shoes (p=0.04). In the swing phase (SW), there was found a significant reduction in hip flexion when walking with AFOn and AFOa compared to shoes (p=0.00 and p=0.01, respectively). Walking with AFOa also reduced hip flexion in swing phase for the unaffected leg (p=0.04). For the ankle angle, significant differences were observed at initial contact (IC) for the affected leg when comparing the two AFO-conditions, with AFOa demonstrating significantly increased dorsiflexion (p=0.04). Significant findings were also found in swing phase for the affected leg when comparing shoes to AFOn and AFOa, with the two AFO conditions demonstrating a significantly increased dorsiflexion (p=0.00 and p=0.00, respectively).

Table 4: Joint kinematics walking with shoes, AFOn and AFOa for affected and unaffected leg

	Shoes (Mean ± SD)		AFOn (Mean ± SD)		AFOa (Mean ± SD)	
Kinematics (degrees)	**AL**	**HL**	**AL**	**HL**	**AL**	**HL**
Ankle plantarflexion (IC)	-5.24 ± 7.75	3.47 ± 13.60	2.24 ± 3.65*	5.59 ± 6.64	4.67 ± 3.43*	6.95 ± 3.88
Ankle plantarflexion (SW)	-22.15 ± 11.59	-16.73 ± 13.68	-1.10 ± 3.16*	-13.82 ± 11.32	0.56 ± 4.14*	-12.84 ± 7.28
Knee flexion (IC)	16.62 ± .7.39	9.03 ± 13.68	13.93 ±8.29	8.32 ± 8.61	13.46 ± 8.95	9.80 ± 8.03
Peak knee flexion	60.78 ± 3.35	61.86 ± 5.52	56.28 ± 4.84	59.76 ± 5.30	57.41 ± 6.51	58.53 ± 4.40
Peak Hip Flexion	38.55 ± 4.04*	39.13 ± 6.21*	36.83 ± 4.19*	37.21 ± 4.97	37.76 ± 3.77*	36.89 ± 5.49*

Abbreviations: AFOn= Neutral AFO alignment, AFOa= Adjusted AFO alignment, AL= Affected Leg, HL= Healthy Leg, IC= Initial Contact, SW= Swing Phase, *=Statistically significant (p <0.05)



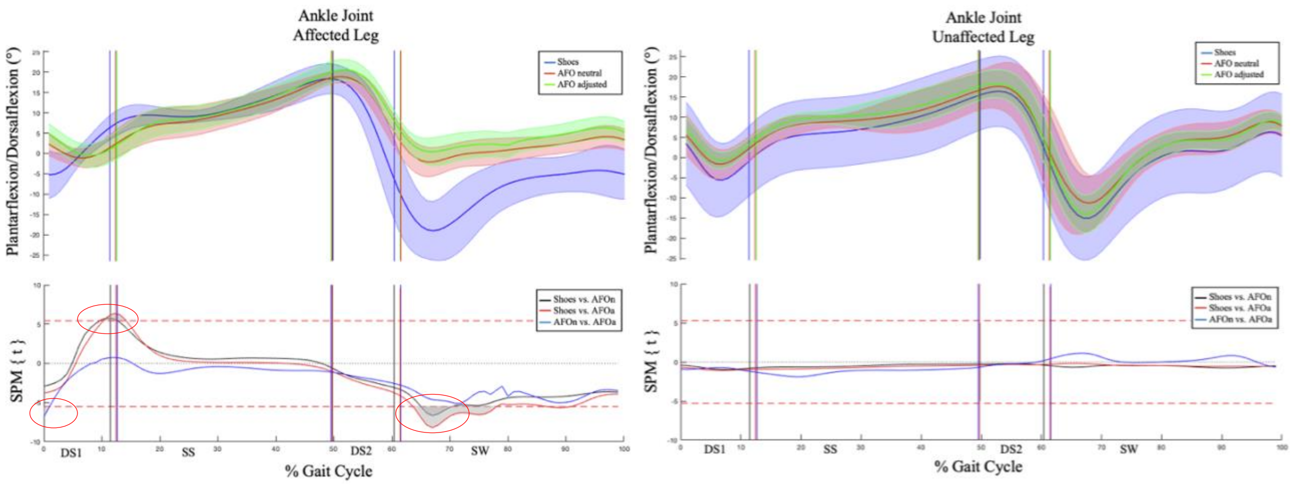
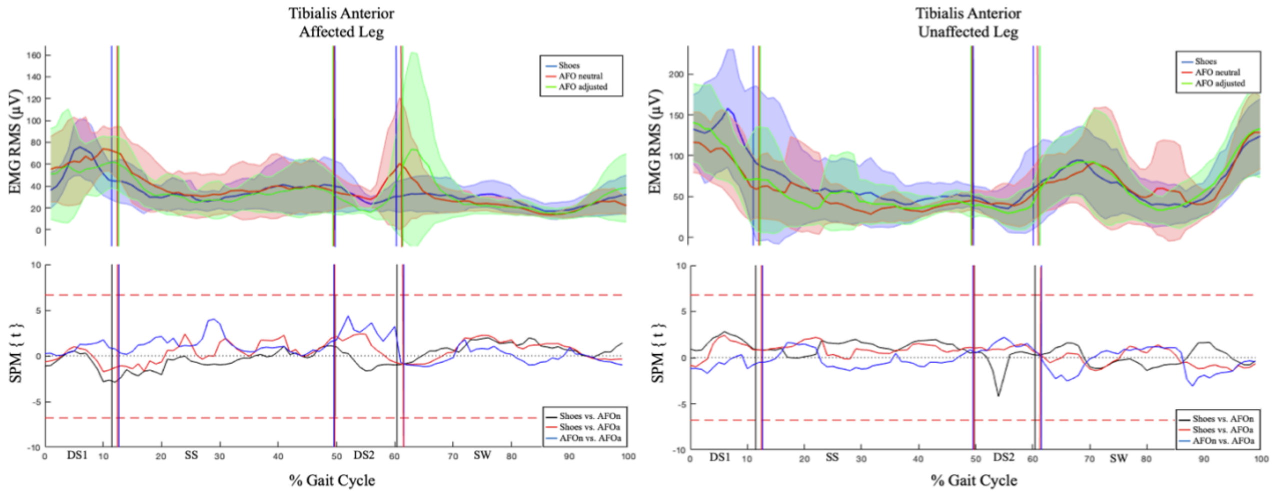
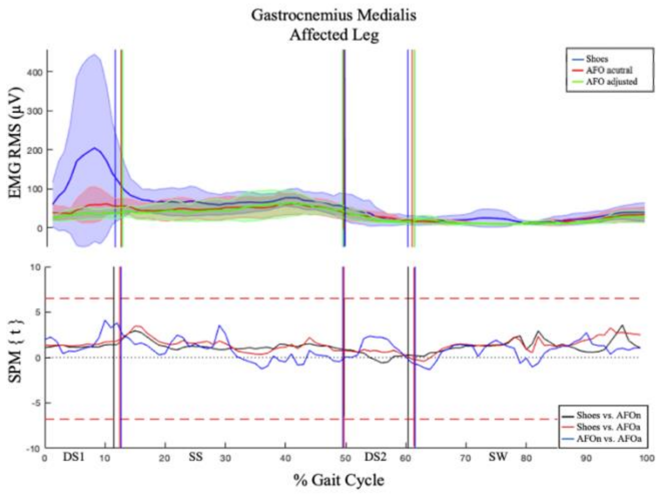


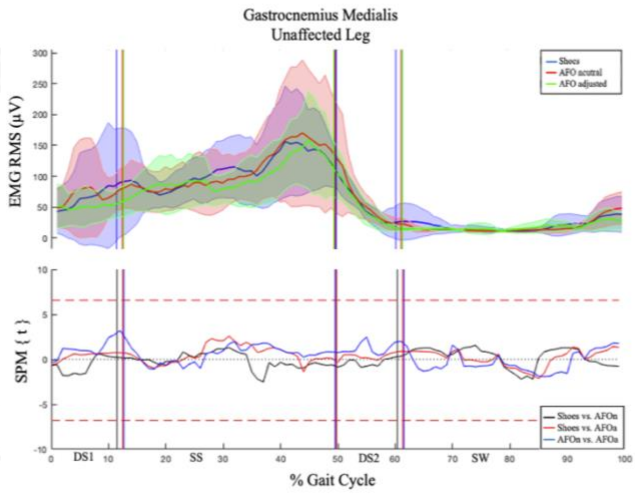
Figure 4: Average values (mean ± 95% CI) with following statistical mapping for both affected and unaffected leg for the hip, knee and ankle joint. The blue line represent the average angle when walking with shoes, red with the neutral aligned AFO and green with the adjusted AFO. In the statistical mapping graph the black line represents differences in angles when walking with shoes compared to AFOn, red line between shoes and AFOa, and the blue line between AFOn and AFOa. The red dotted line represents the t-value corresponding to alpha level .05. The vertical lines in all graphs splits the gait cycle into four phases, based on the end of double support 1, single support and double support 2 for each condition.

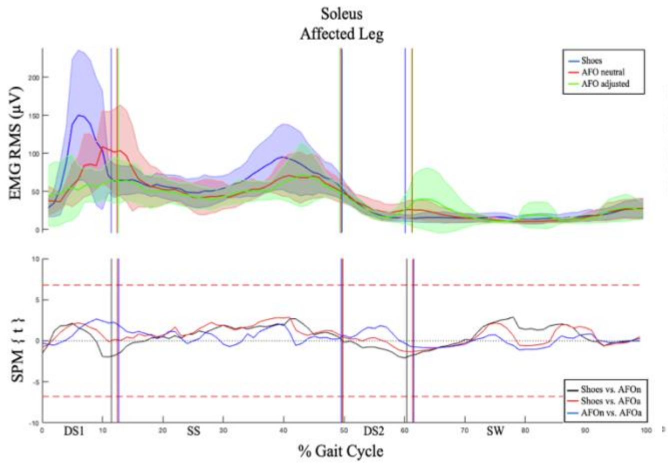
3.3 Surface Electromyography

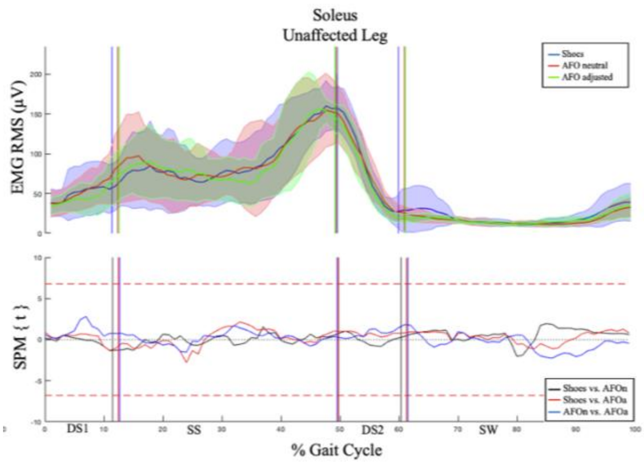
Data on the muscle activity of Tibialis Anterior, Gastrocnemius Medialis, Soleus, Rectus Femoris, and Hamstrings Medialis are shown in Figure 5. No significant differences in muscle activity were detected in any of the muscles when comparing the muscle activity of the affected and unaffected leg when walking with shoes, the neutral AFO, and the adjusted AFO.

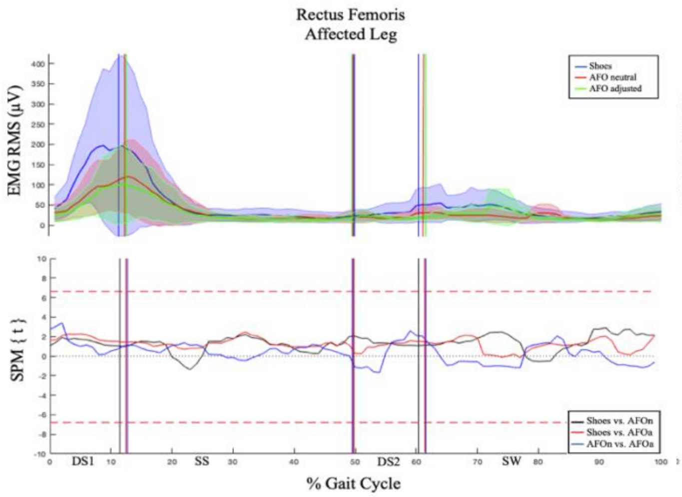


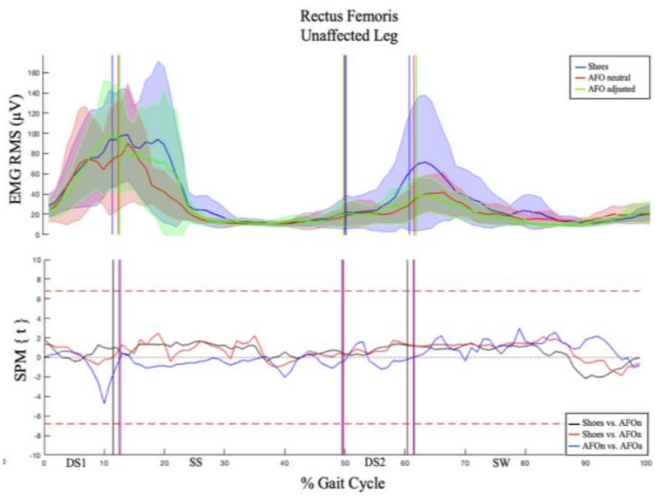

Gastrocnemius Medialis
Affected Leg
Shoes
AFO acutral
AFO adjusted
EMG RMS (μV)
SPM { t }
Shoes vs. AFOn
Shoes vs. AFOa
AFOn vs. AFOa
DS1
SS
DS2
SW
% Gait Cycle


Gastrocnemius Medialis
Unaffected Leg
Shoes
AFO neutral
AFO adjusted
EMG RMS (μV)
SPM { t }
Shoes vs. AFOn
Shoes vs. AFOa
AFOn vs. AFOa
DS1
SS
DS2
SW
% Gait Cycle


Soleus
Affected Leg
Shoes
AFO neutral
AFO adjusted
EMG RMS (μV)
SPM { t }
Shoes vs. AFOn
Shoes vs. AFOa
AFOn vs. AFOa
DS1
SS
DS2
SW
% Gait Cycle


Soleus
Unaffected Leg
Shoes
AFO neutral
AFO adjusted
EMG RMS (μV)
SPM { t }
Shoes vs. AFOn
Shoes vs. AFOa
AFOn vs. AFOa
DS1
SS
DS2
SW
% Gait Cycle


Rectus Femoris
Affected Leg
Shoes
AFO neutral
AFO adjusted
EMG RMS (μV)
SPM { t }
Shoes vs. AFOn
Shoes vs. AFOa
AFOn vs. AFOa
DS1
SS
DS2
SW
% Gait Cycle


Rectus Femoris
Unaffected Leg
Shoes
AFO neutral
AFO adjusted
EMG RMS (μV)
SPM { t }
Shoes vs. AFOn
Shoes vs. AFOa
AFOn vs. AFOa
DS1
SS
DS2
SW
% Gait Cycle

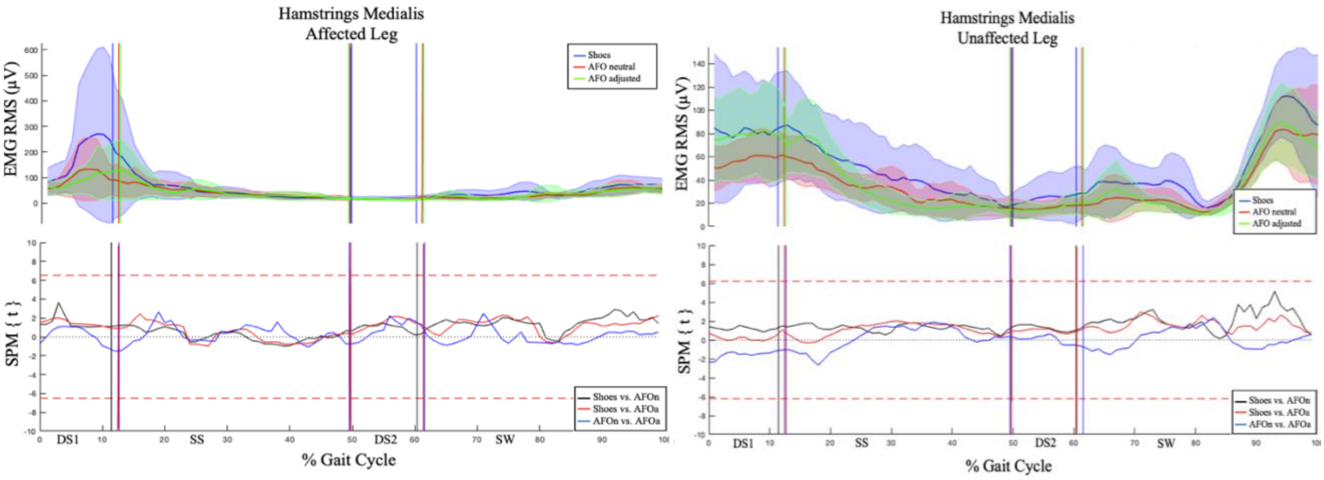


Figure 5: Average absolute sEMG-RMS (mean ± 95% CI) with following statistical mapping for both affected and unaffected leg for all muscles. In the sEMG-RMS graph the blue line represent the average absolute EMG-RMS when walking with shoes, red with the neutral aligned AFO and green with the adjusted AFO. In the statistical mapping graph the black line represents differences in muscle activity when walking with shoes compared to AFOn, red line between shoes and AFOa, and the blue line between AFOn and AFOa. The red dotted line represents the t-value corresponding to alpha level .05. The vertical lines in all graphs splits the gait cycle into four phases, based on the end of double support 1, single support and double support 2 for each condition.

3.4 Correlation analysis

Table 5 provides the Pearson correlation coefficient and significance level of the pairwise post- hoc Pearson correlation analysis executed on the variables where significant differences between the conditions occurred. No relationship was detected between the significant changes in energy cost during walking with AFOn and changes in spatiotemporal gait parameters and the kinematics.

Table 5: Pearson Correlation analysis to investigate possible relationship between significant changes

	EC Shoes		**EC AFOn**		**EC AFOa**	
	r	P-value	r	P-value	r	P-value
Time SS (%)	.000	1.000	.038	.898	-.076	.797
Time DS (%)	-.305	.289	-,0.15	.958	.020	.945
Ankle PF IC	.275	.342	.025	.932	-.044	.880
Ankle PF SW	.084	.776	-.133	.649	-.304	.290
Hip Flexion SW	.317	.270	.055	.851	-,084	.775

Abbreviations: EC= Energy Cost, r= Pearson correlation coefficient, AFOn= Neutral AFO alignment, AFOa= Adjusted AFO alignment, SS= Single Support, DS= Double Support, PF= Plantarflexion, IC= Initial Contact, SW= Swing Phase, *=Statistically significant (p <0.05)

4.Discussion

The primary aim of this study was to investigate the effect of AFO and AFO alignment on energy cost during walking in children with CP. Secondary outcomes were to assess possible changes in spatiotemporal gait parameters, kinematics, and muscle activity. The main result shows that the use of AFO reduces the energy cost during walking compared to walking with shoes. However, no significant differences were demonstrated with the use of a five-millimeter heel wedge placed between the footplate and the sole of the shoe. In this discussion, changes in energy cost will be discussed with respect to changes in spatiotemporal gait parameters, kinematics, and muscle activity.

4.1 Energy cost

Compared to walking with shoes only, the overall mean energy cost was significantly lower when walking with AFOn. This reduction was due to a decrease in energy consumption, as walking speed did not significantly change between the different conditions. Brehm et al., and Buckon et al. (26,20), who also evaluated the effect of different AFO designs on energy cost, revealed similar results. Brehm et al. did, however, in their study, find that the change in energy cost was primarily due to varying underlying impairments among the participants, such as spasticity. Our results do also indicate a variation regarding the response of AFO use, but due to the small sample size, such sub-analyses could not be executed. Furthermore, the small sample size may suggest a challenge using the mean value of energy cost to compare the three conditions. The energy cost of the shoe condition demonstrates one outlier, indicating an inter-variability between the included subjects. One single outlier may have a significant effect on the mean in this study, in which the study population is small. Therefore, it is essential to take this into account before drawing any conclusions in which one condition is more energy conserving than any other.

4.2 Spatiotemporal gait parameters

As for the spatiotemporal gait parameters, significant differences were observed in terms of time in single support, where the time was shorter for the affected leg for all three conditions. However, these changes were detected when comparing shoes to the adjusted AFO, with AFOa having a significantly shorter time in single support. Similar findings were observed when looking into time in double support, where AFOa demonstrated a significantly longer time in double support compared to walking with shoes. These findings are the direct opposite of what Balaban et al. (6) report in their study, where they found that the use of AFO significantly increased time in single support and decreased time in double support. One possible reason for our findings may be the self-sufficient gait pattern that the participant showed when walking with shoes. Potential differences in self-sufficient gait patterns will also affect the energy cost of walking, so further research should, therefore, assess the participants´ need for AFOs when determining possible effects of gait parameters on their energy cost.

On the contrary, several of the spatiotemporal gait parameters indicated a decrease in differences between healthy and affected leg when walking with both AFOn and AFOa. Normalized cadence, normalized step length, time in single support, and time in double support demonstrated a reduced difference between affected and healthy leg when walking with the two AFO conditions. In agreement with this, Hayek et al. (43) proposed in their study that the use of AFOs improves stability on the affected side for children with hemiplegic CP. Furthermore, Maltais et al. (29) suggested that an appropriate AFO can provide lower energy costs through improved stability.

4.3 Kinematics

In the present study, kinematic changes observed at the ankle joint were as expected and in agreement with previous studies comparing AFO use in children with CP (8, 42, 43). Lam et al. (44) reported in their research that the use of AFOs provided a better pre-positioning of the ankle joint at initial contact. Our results imply comparable enhancement, with increased dorsiflexion at initial contact of 7.48° when walking with AFOn, and 9.91° when walking with AFOa, respectively. Moreover, a significantly increased dorsiflexion of the ankle joint was detected in the swing phase when walking with the two AFO conditions, with the use AFOn increasing ankle dorsiflexion with 21.05° and AFOa with 22,71° as compared to walking with shoes. Buckon et al. (27) reported similar findings for the ankle joint, with an additionally decreased knee hyperextension during stance using AFOs. Hayek et al. (43) support these findings and report that solid AFOs (SAFOS) significantly reduced knee flexion with 7,5° at initial contact compared to barefoot walking. Our results do also demonstrate reduced knee flexion at initial contact when comparing the two AFO conditions with shoe-walking, with reduced knee flexion of 2.69° with AFOn, and 3.16° with AFOa, respectively.

However, no significant differences can be reported in the kinematics of the knee joint across the three walking conditions.

Although no significant changes were detected in knee joint kinematics, our findings may indicate that the use of AFOs influences the compensatory responses at proximal joints secondary to distal joint abnormalities (45). When looking into the kinematics of the hip joint, a significant difference was found in single support when comparing shoes to AFOa, with an increased extension when walking with shoes. On the contrary, for the swing phase, walking with shoes induced a significantly increased hip flexion for the affected leg. The two AFO conditions significantly reduced the hip flexion during swing phase with 1.72° for AFOn and 0.79° for AFOa, respectively. For the healthy leg, a similar tendency occurred, with a significantly reduced hip flexion of 2.24° when comparing walking with shoes to AFOa. Our results indicate that the use of AFOs can optimize the ability to adequately extend the hip joint during the swing phase of the gait cycle (46). Correctly pre-positioning of the foot with the use of AFOs, did in this study, lead to increased dorsiflexion in the ankle joint throughout the entire gait cycle. These modifications were further applicable to the statistically significant reduced hip flexion during swing, both for the affected and unaffected leg. Nonetheless, no correlation was found when investigating the possible relationship between these kinematic changes and the decreased energy cost. Conversely, Ballaz et al. (47) reported a strong correlation between energy expenditure index and ankle/knee range of motion. It is, however, important to emphasize that we only executed kinematic measurements of the lower extremity, while the energy cost measurements took the entire body into account.

4.4 sEMG

Because the use of AFOs results in a more normal positioning of the foot, this can result in increased stability with a corresponding decrease in muscle activity. It is thought that these changes further will result in a reduced energy cost during walking (48). Our findings did, however, not reveal any significant differences in muscle activity across the three conditions. While the present observations refer to the possible relationship between changes in energy cost and muscle activity, it is highly relevant to emphasize the limitation of only measuring sEMG of the lower extremity in this study.

Some changes were, however, detected by the use of AFOs, although not significant. The change of movement pattern (toe- to- heel gait to heel- to- toe gait) when wearing the two AFO conditions, affected the role of Tibialis Anterior (TA) as a dorsiflexor. A decreased peak activity at initial contact was observed by the use of AFOs. As previously mentioned, the AFOs controls the foot position relative to the shank and thereby prevent the foot from dropping. Hence, the dorsiflexors are not required, as their function has been replaced by the AFOs. Romkes et al. (49) reported similar findings, with a reduced TA activity at initial contact with the use of hinged AFOs (HAFOs). Similar to TA, the first burst (first 15% of the gait cycle) of the plantar flexors muscles Gastrocnemius Medialis (GM) and Soleus (SOL) were reduced when wearing AFOs. Since GM is a biarticular muscle that influences both ankle and knee function, it is likely to link this reduced muscle activity to the reduced excessive plantarflexion and reduced knee flexion found at initial contact. Comparable, for Hamstrings Medialis (HM) that flexes the knee joint and Rectus Femoris (RF) that flexes the hip joint, a reduced muscle activity appeared within the first 15% of the gait cycle with the use of AFOs. This reduction could partly be explained by the change of movement pattern that appears with the use of AFOs, from a toe-to-heel to heel- to- toe gait pattern. It is, however, hard to distinguish between possible spastic activity and activity due to the biomechanical needs of toe walking.

When investigating the total muscle activity throughout the gait cycle, Romkes et al. (49) found that the activity of TA did not change during the gait cycle as a whole when walking with HAFOs, compared to barefoot walking. Lam et al. (44) support these findings, with AFO-use increasing the RMS-value of TA as compared to barefoot walking. Our results substantiate these results, which may indicate that the use of AFOs will increase the effectiveness of the calf muscles, and prevent muscle weakness while leading to a decreased energy cost by correctly positioning the foot. However, due to non-significantly changes in muscle activity across the three conditions, no correlation analyses were conducted to detect the possible relationship between changes in muscle activity and energy cost.

4.5 Methodological considerations and future research

The present study had several limitation which is avenues for further research, but first I will highlight the use of indirect calorimetry as a strength of this study, in which this method is considered as the gold standard for measuring VO_2 (50). However, a potential limitation with the oxygen consumption test is that the protocol defined steady- state after five minutes of walking for all the participants. It is found that the steady- state of oxygen consumption can occur after two minutes of submaximal walking in children with CP, but some test procedures use walking times up to ten minutes (51, 22, 52). It is acknowledged that the protocol of the current study could have been improved by the inclusion of a practice walk, but this was omitted to reduce the burden on the participants.

Secondly, in the current study, we focused on changes in energy cost during walking, which is considered as a relatively simple task. There is found a strong relationship between energy cost and walking for children diagnosed with a GMFCS-level III- IV, so when investigating the possible effect of AFOs on energy cost for hemiplegic children with a GMFCS-level I- II, more challenging tasks may have induced more reality-based situations (53). Similar for changes in muscle activity, more intensive tasks could have initiated greater differences between the conditions, indicating potential challenges for participation in daily life. This needs to be taken into account when interpreting these laboratory-based results to clinical practice (54). Monitoring of walking activity performance within the context of day-to- day life in children with CP who are ambulatory could possibly exclude the sources of errors that may occur during clinical lab-assessment (55).

Thirdly, another possible limitation of this study that warrants a long-term study outside the laboratory, was the application of a new orthosis alignment. An adaptation period of the aligned AFO could interpret a more accurate effect on energy cost, as previous research has suggested an adaptation period of four weeks (56).

Moreover, I will highlight the limitation of not having a standardized neutral AFO alignment across the participants, as the neutral alignment was determined based on the orthopedists' recommendation and the patient's preference. As a result, this study did not contain sufficient details on the materials and designs of the AFOs, or the prescription process of the AFOs to each subject with regard to their clinical presentation (57). Additionally, our results did not contain sufficient information about the SVA across the different orthoses, which is a limitation among several studies investigating the effect of SVA manipulation (16). The lack of a definitive assessment process will therefore prevent generalization and replication of the clinical setting, as we cannot conclude with any specific inclination to be more beneficial than any other.

Furthermore, the motion capture was based on reflective markers placed on the skin and AFO to track joint motion. Research has found that marker placement on the AFO may not precisely estimate the joint, as it does not mimic the motion of the actual ankle (58). However, as knee and ankle motion, as well as the SVA was based on several markers positioned on the skin, such kinematic errors are not likely to affect the main findings. Besides, anthropometric measures were taken at the malleoli, both with and without the AFO, as a way to avoid this possible error.

However, some limitations may be present regarding the sEMG that were collected concurrently with the motion capture. Placement and visual inspection of the sEMG-signals was done prior to the walking tests, and there could possibly have occurred a change in the sEMG- signals during this time. Additionally, the data used for sEMG- analysis were collected after 11 minutes of walking, and it is found that fatigue can occur among children with CP already after five minutes of walking (59). Future research should, therefore, aim to avoid determination of muscle activity after elapsed distances for more than five minutes.

Lastly, I will highlight the apparent limitation in sample size, which is characteristic of most studies involving children with CP. Due to the small sample size, no power-analyses were conducted, which is considered as a fundamental step in the assessment of clinical research (60). Future research should, therefore, aim to replicate these findings in an adequately powered trial. Another challenge regarding the study sample was the clinical heterogeneity of this study. Individual differences might have affected the diversity of the results, based on the variation in gait observed in children with hemiplegic CP (6). This could possibly confound the effect of AFO use on energy cost, kinematics, spatiotemporal gait parameters, and muscle activity.

4.6 Conclusion

The use of the neutral aligned AFO significantly reduced energy cost during walking as compared to walking with shoes. Further, both AFO conditions revealed significant changes compared to walking with shoes in the kinematics of the ankle and hip joint, particularly for the dorsiflexion range. Nonetheless, no changes in energy cost were detected with the use of an additional five- millimeter heel wedge. A further avenue for research should aim to recruit a bigger sample size in which information regarding material and design of the AFOs are specified. The effect of AFO and AFO alignment on energy cost, kinematics, spatiotemporal gait parameters and muscle activity can then be replicated to a clinical setting in which children with hemiplegic CP can benefit from.

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