M.O.T.I.O.N.

Mechanised Orthosis for Children with Neurological Disorders

NORMATIVE DATA COLLECTION

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Canterbury Christ Church University

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FOREWARD

The Canterbury Christ Church University (CCCU) Team led the development, training, and evaluation of Work Package (WP) 2.1.3, an integral part of the Mechanised Orthosis for Children with Neurological Disorders (M.O.T.I.O.N.) project. This report contains an outline of the normative laboratory tests. Dr Sarah Crombie and Victoria Brant, Chailey Clinical Services, Sussex Community NHS Foundation Trust made a significant contribution to this work package.

We would like to acknowledge other CCCU M.O.T.I.O.N. team members for their valuable contribution to this work: Joanna Apps, Dr Maria Stein, Dr Julia Moore, Thomas Kanderakis, Maggie Gurr, Roy Sevit and Rania Kologhassi. Activities of this report took place in cross-border collaboration with project partners from all countries (UK, France, Belgium and Netherlands) and stakeholders from relevant internal and external organisations. We would like to acknowledge M.O.T.I.O.N. partners who have contributed to the development and conduct of the surveys in all project sites:

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UK - Project Partners
- Dr Sarah Crombie and Victoria Brant, Chailey Services, Sussex Community NHS Foundation Trust
- Dr Konstantinos Sirlantzis, University of Kent

EXECUTIVE SUMMARY

The purpose of this report is to produce a normative data set for typically developed (TD) children and children with cerebral palsy (CP).

Key Highlights:

- Ethical approval was granted with substantial help from collaborators at Chailey Clinical Services, Sussex Community NHS Foundation Trust.
- The data presented demonstrate the challenges faced by engineering partners. The CP walking gait is as expected different from the TD child, however the CP data demonstrates a lack of consistency between clinical visits, with large variability evident in the data, and this needs to be considered.
- When shod with ankle foot orthosis (AFO), a more reliable walking gait is present with a reduction in variability of position and velocity across lower limbs.
- These data will support the feasibility work package (WP3.2.3) to ascertain if the addition of power to the ankle foot orthosis (PAFO) changes the acute gait response.
- Beyond the M.O.T.I.O.N project the ambition is to then train participants with the PAFO technology and review outcomes.

CONTENTS

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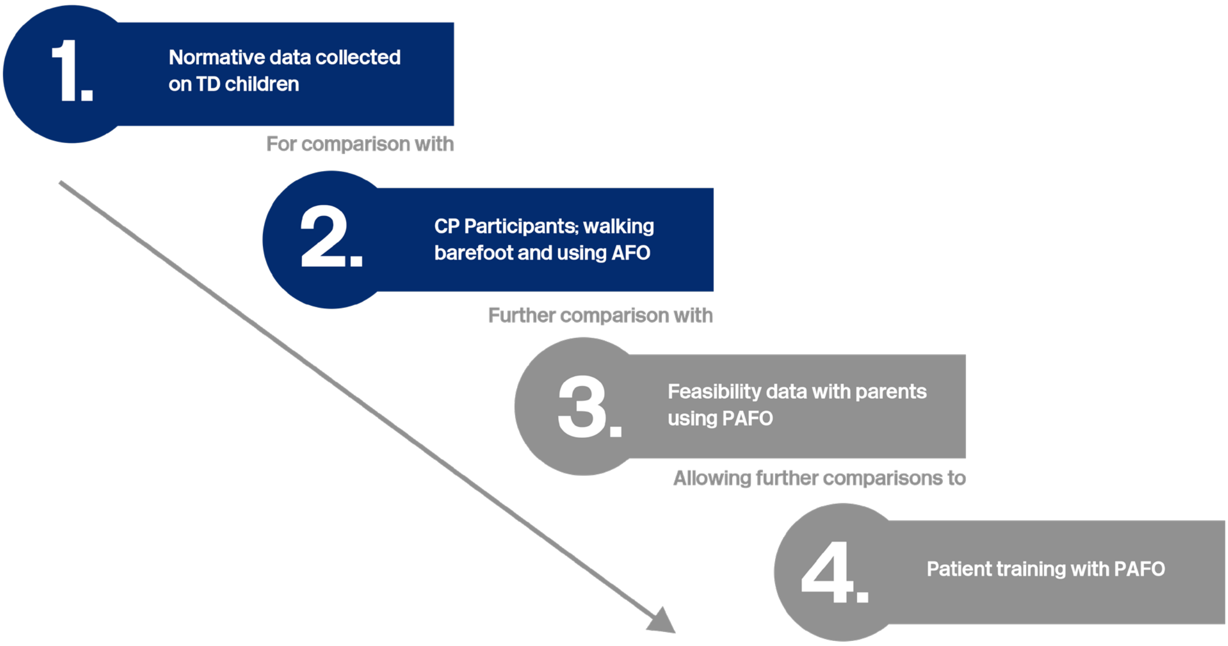
1. NORMATIVE DATA COLLECTION

- The main aims of the M.O.T.I.O.N. normative data collection were to:
- Produce a dataset of normative gait analysis data on typically developed children.
- Produce a dataset of normative gait analysis data on children with cerebral palsy (CP).
- Compare the variability in clinical gait analysis data between two testing sessions for children with CP.
- The data collected would then a) support design and robotic developments for the M.O.T.I.O.N. project, and b) provide data for future research studies concerning diagnosis and treatments for patients with CP.

The data sets provide information on the normal walking gait of TD and CP patient groups. In the CP group the impact of current ankle foot orthosis were investigate, and with repeated trials conducted to assess the variability in clinical gait analysis data between two testing sessions. The ambition for this work package is indicated (part 1 & 2 in blue) in the schematic below.



Work package (and wider) aims of the normative data collection.

Research Design

1.1.1 Participants and recruitment strategy

The sample targeted for the normative study was 15 - 20 participants in both the cerebral palsy (CP) group and the sample of typically developed (TD) children. The aim was for ten participants to complete a second clinical gait analysis assessment for the repeatability study. Patients in the CP group continued to receive routine care during the duration of the study. Participant inclusion and exclusion criteria for the CP group were as follows:

Inclusion criteria:

- Children aged 6-12 years old with cerebral palsy
- Those with diplegia, gross motor function classification system (GMFCS) level II-III or those with hemiplegia, GMFCS level I-II [12]
- Children prescribed with an AFO

- Children with spasticity management using Botulinum Toxin A (BtxA) injection 3 months prior to evaluation; lower extremity surgical procedures 6 months prior to evaluation, hip dislocation; and uncontrolled seizures
- Children with cognitive disorders that may hinder understanding
- Presence of ataxia or dystonia

Potential participants were identified by the direct healthcare team from Chailey Services, Sussex Community NHS Foundation Trust (CCS). Following this, the direct healthcare team contacted the potential participant's caregivers either in routine clinic appointments or via telephone to discuss the study. The direct healthcare team then sent potential participant's caregivers a letter about the study, including the Information Sheet for Parents/Guardians of Participants, Participant Information Sheet for Children and a consent to contact form for the research team at CCS. The letter to caregivers was also supported by a link to an online video explaining the study protocol. This video was targeted for children aged 6-12 years old.

For the TD children the criteria for inclusion aged 6-12 years old, free from any medical conditions and/or orthopaedic injuries that could affect their walking, and that all participants Refrained from any intense exercise for at least 24 hours before the testing session.

1.1.2 Methods of data collection

Testing for CP children took place at CCS, with the trials for TD children taking place at Canterbury Christ Church University. Testing sessions included body measurements, a postural assessment and a walking assessment. Conventional methods for the collection of gait data, population detail and data analysis were considered in generating the protocols (references [1-14]).

Body measurements

Height (cm) was measured with a stadiometer and body mass (kg) with Seca mechanical column scales. Limb lengths were measured with the participant standing and the arms hanging at the side. The following lower extremities measurements were taken: (1) anterior superior iliac spine to the lateral malleolus; (2) anterior superior iliac spine to knee lateral epi-condyle; (3) knee lateral epi-condyle to lateral malleolus. The following upper extremities measurements were taken: (1) acromion process to the tip of the middle finger (dactylion); (2) acromion process to the radiale (the topmost point on the superior edge of the head of the radius of a relaxed arm); (3) radiale to the styloid process of the radius. A segmometer was used to take these measurements.

In addition, the CP children's movement at the ankle, knee and hip were assessed. This was done with the child lying on a therapy plinth. In line with routine clinical practice, a goniometer was used to measure movements at these joints.

Clinical gait analysis

The primary purpose of an Ankle Foot Orthosis (AFO) is to assist in the motion and positioning of the ankle during the gait cycle. Commonly, this assistance is focused in the sagittal plane positioning of the ankle, namely to promote a dorsiflexed position. This benefits the wearer at the beginning of the stance phase, allowing the heel to strike the ground first and promote a functional 1st ankle rocker motion; while also providing clearance in the swing phase to ensure the toes do not drag during the forward swing of gait. Consequently, the analysis of gait in the current project has focused on the motions in the sagittal plane, with the angular motion of the hip, knee and ankle being analysed in the stance and swing phases of gait.

The clinical gait protocol required participants to complete a minimum of 5 trials over a distance of 8m indoors, across a smooth clear walkway at a self-selected velocity. CP children completed this under 2 randomizes conditions, with a minimum of 5 minutes rest between conditions. Condition 1 consisted of wearing their custom designed AFO and shoes that they would normally wear in conjunction with the AFO. The second condition required children to complete the walking task barefooted without any assistance. This protocol was completed on two occasions with a minimum of 1 week between each testing session. TD children completed the barefoot condition only.

Motion patterns in the sagittal plane were measured using inertial measurement units (IMUs) (iSen, STT Systems, Spain) and a digital video camera to provide qualitative monitoring of the participant. IMUs were positioned on the anterior aspect of the thigh and shank, the posterior surface of the trunk above the spineous process of the 5th lumbar and 6th thoracic vertebrae and on the dorsal surface of the foot on both the left and right sides. IMUs were secured in position using elasticated fabric bands to minimize movement artifact and discomfort of participants.

Following completion of the protocol, data was broken down into individual gait cycles (a gait cycle being determined as the duration from initial contact to the following initial contact with the floor on the same side of the body) and sub divided into stance (foot in contact with the ground) and swing (foot off the ground) phases. From these phases maximum and minimum flexion and extension of the knee and hip and dorsiflexion/plantarflexion of the ankle were identified for joint position, angular velocity and angular acceleration. Coefficient of variation scores were then calculated to ascertain the variability of the measures between affected and unaffected sides, AFO and barefoot conditions and between testing sessions for CP children and for the TD children.

Local ethical approval, and NHS approval was granted for these studies (IRAS project ID 288842, reference number 21/PR/0927, CCCU ethics: ETH1920-0278) and for subsequent feasibility studies using the powered ankle foot orthosis. The clinical partners at CCS were fundamental to ethical approval for all studies with CP children.

2 NORMATIVE DATA RESULTS

Thirteen participants completed the trials in the TD group, and 22 in the CP group. From the CP group 16 completed repeat gait walking trials.

2.1 Normative data on TD children

2.1.1 Participant demographics

Participant demographics are shown in Table 1, to the right.

Table 1: Participant demographics for TD children.

	AGE	HEIGHT (cm)	BODY MASS (kg)
P1	10	147	32.5
P2	13	141.7	39.6
P3	10	165.4	51
P4	8	135.6	28.6
P5	6	119.2	21.6
P6	7	126.6	24.8
P7	4	106.8	18
P8	8	131	30
P9	6	122.8	21.4
P10	9	137.8	31
P11	7	121	22.2
P12	11	145.9	34
P13	8	133.9	27.6
mean	8.2	133.4	29.4
SD	2.3	14.4	8.5

2.1.2 Walking gait in TD children

Table 2 below demonstrates the TD data for the ankle, hip and knee during gait phases. Position, velocity and acceleration are reported. The data are presented as maximal and minimal values during stance and swing phases.

Table 2: Normative data for TD children. Mean +/- standard deviation (sd) scores reported.

	POSITION		VELOCITY		ACCELERATION	
ANKLE*	mean	sd	mean	sd	mean	sd
max stance	15.5	6.2	103.8	31.6	1406.5	505.5
max swing	5.2	6.5	197.9	72.0	4698.0	1300.1
min stance	-1.4	6.2	-6.0	51.9	-212.9	855.5
min swing	-4.0	9.2	-22.3	47.7	181.5	624.0
KNEE ^	mean	sd	mean	sd	mean	sd
max stance	20.2	10.4	159.0	55.1	3007.9	1336.3
max swing	65.3	13.7	360.4	88.9	4872.7	1278.6
min stance	8.9	8.3	50.1	52.1	1092.4	961.9
min swing	20.7	57.0	-119.1	75.6	249.9	879.2
HIP$^{\Delta}$	mean	sd	mean	sd	mean	sd
max stance	24.5	8.9	-22.3	29.7	1428.7	840.2
max swing	28.0	10.8	200.1	159.3	2167.2	676.4
min stance	-6.4	7.2	-82.7	30.9	-181.6	450.9
min swing	3.4	7.6	-8.3	74.5	-302.9	365.0

* Ankle data reported as change in angle from participants Anatomical Reference Position (ARP) between the longitudinal of the calf and the vertical axis of the heel, positive angles indicating plantarflexion and negative dorsiflexion.

^ Knee angles reported as a deviation from the participants ARP.

Δ Hip angles reported as change in angle from ARP between the pelvic vertical and the longitudinal of the thigh, positive angles signify hip flexion and negative angles hip extension. Position reported in degrees, Velocity deg.s-1, acceleration deg.s-2.

2.1.3 Variability in gait between limbs for TD children during barefoot walking

The variation between lower limbs for TD children are reported in table 3 below as coefficient of variation scores. Parameters vary in terms of consistency across position, velocity and acceleration. These data are presented for comparison to CP values reported later. There is a tendency toward lower variability in max stance and max swing phases across these three gait parameters.

Table 3: Coefficient of variation (%) for position, velocity and acceleration between lower limbs during walking in TD children.

	POSITION	VELOCITY	ACCELERATION
ANKLE			
max stance	4.8	2.9	1.4
max swing	20.6	0.5	0.1
min stance	32.3	32.7	41.2
min swing	21.3	38.9	1.6
KNEE			
max stance	4.0	6.3	0.8
max swing	4.4	3.4	1.4
min stance	5.8	7.7	4.7
min swing	80.5	2.1	17.5
HIP			
max stance	8.2	22.4	4.0
max swing	1.1	20.7	1.1
min stance	15.2	1.2	9.9
min swing	16.9	32.2	1.0

2.2 Normative data on CP children

2.2.1 Participant demographics

Table 4: Participant demographics for CP children.

	AGE	HEIGHT (cm)	BODY MASS (kg)
P1	9	126.1	26.2
P2	11	139.5	28.2
P3	10	139.4	32
P4	9	125.5	24
P5	8	129.5	32
P6	12	154.8	50.6
P7	9	140	30.2
P8	9	132.5	25.2
P9	11	133.4	26
P10	8	130.5	41.2
P11	9	136.5	52.2
P12	8	125.9	24.4
P13	10	145.8	56.4
P14	7	122.5	22.1
P15	6	118	22.3
P16	11	142.4	37.5
P17	12	154	49.2
P18	7	118.5	19.7
P19	6	123.5	26.8
P20	7	120.9	21.7
P21	8	127.5	30.1
P22	8	127.5	35.6
mean	8.9	132.5	32.4
SD	1.7	10.3	10.7

2.2.2 Barefoot walking gait in CP children who are accustomed to single leg AFO technology

Data presented below in table 5 demonstrates the data for CP children. Data is compared for participants with an affected and unaffected limb. These data are for the barefoot walking condition.

Table 5: Normative data for CP children during barefoot walking.

	POSITION				VELOCITY				ACCELERATION			
	AFF		NONAFF		AFF		NONAFF		AFF		NONAFF	
ANKLE*	mean	sd	mean	sd	mean	sd	mean	sd	mean	sd	mean	sd
max stance	2.4	15.6	15.5	15.5	152.0	75.8	156.1	156.1	1194.4	469.0	1827.4	1827.4
max swing	-6.7	14.0	6.3	6.3	126.0	43.1	183.8	183.8	203.2	325.1	110.3	110.3
min stance	-8.7	14.0	-0.8	-0.8	30.3	34.1	20.7	20.7	250.6	356.6	139.6	102.4
min swing	-18.4	16.2	-4.7	-4.7	-31.6	41.1	-38.1	-38.1	1489.0	676.9	1276.1	1276.1
KNEE ^	mean	sd	mean	sd	mean	sd	mean	sd	mean	sd	mean	sd
max stance	16.2	7.1	25.7	25.7	78.5	48.0	150.7	150.7	2058.4	645.7	2410.6	2410.6
max swing	53.5	9.7	62.1	62.1	344.5	71.1	343.5	343.5	2985.7	1045.4	4368.4	4368.4
min stance	-0.2	3.6	9.0	9.0	-16.6	19.6	36.7	36.7	583.6	369.6	736.1	736.1
min swing	31.3	8.8	32.4	32.4	-101.1	52.2	-71.0	-71.0	-279.6	326.6	-355.2	-355.2
HIP ∆	mean	sd	mean	sd	mean	sd	mean	sd	mean	sd	mean	sd
max stance	15.0	8.6	25.8	25.8	-37.5	27.6	-22.5	-22.5	818.1	297.7	1399.8	1399.8
max swing	26.4	7.4	26.3	26.3	200.4	35.0	222.1	222.1	1759.7	454.0	1673.5	1673.5
min stance	-11.7	5.5	-9.4	-9.4	-84.8	20.0	-80.6	-80.6	-67.7	404.4	-459.4	-459.4
min swing	-3.9	8.4	2.6	2.6	-8.5	27.8	18.8	18.8	-279.6	326.6	-355.2	-355.2

Mean +/- standard deviation (sd) scores reported.

** Ankle data reported as change in angle from participants Anatomical Reference Position (ARP) between the longitudinal of the calf and the vertical axis of the heel, positive angles indicating plantarflexion and negative dorsiflexion.*

^ Knee angles reported as a deviation from the participants ARP.

∆ Hip angles reported as change in angle from ARP between the pelvic vertical and the longitudinal of the thigh, positive angles signify hip flexion and negative angles hip extension. Position reported in degrees, Velocity deg·s^{-1}, acceleration deg·s^{-2}.

2.2.3 Variability (walking gait) between limbs for single AFO CP children during barefoot walking

Table 6 is for comparison with table 3. Variability between affected and unaffected limb is reported as a coefficient of variation (%) during barefoot walking. As expected, during walking barefoot, there is greater variability between limbs compared to TD children, this is evident across the majority of markers presented for the gait analysis

Table 6: Coefficient of variation (%) for position, velocity and acceleration between lower limbs during barefoot walking in CP children with a unilaterally affected limb.

	POSITION	VELOCITY	ACCELERATION
ANKLE			
max stance	102.2	1.8	29.6
max swing	312.8	26.4	41.9
min stance	425.5	26.6	40.2
min swing	215.7	13.3	10.9
KNEE			
max stance	41.4	44.6	11.1
max swing	14.9	0.2	26.6
min stance	128.3	376.1	16.3
min swing	3.8	24.8	16.8
HIP			
max stance	47.4	35.3	37.1
max swing	0.7	7.3	3.6
min stance	25.6	3.5	105.1
min swing	426.9	377.3	16.8

2.2.4 Repeated visits: Coefficient of variation (%) of single AFO gait parameters during barefoot walking

The data in table 7 below shows the high variability when comparing barefoot trials across repeated visits. With large coefficients, detection of small and moderate changes in barefoot walking would be challenging. Often with this type of issue multiple trials required. However, the context of these coefficients will be considered in the feasibility phase of the project.

Table 7: Coefficient of variation (%) for position, velocity and acceleration during barefoot walking for repeated visits of CP children to CCS.

	POSITION		VELOCITY		ACCELERATION	
	AFF	NONAFF	AFF	NONAFF	AFF	NONAFF
ANKLE						
max stance	18.1	6.1	22.2	9.1	19.9	11.6
max swing	67.0	36.3	12.3	27.1	171.2	6.5
min stance	140.8	37.5	50.0	45.2	174.2	7.5
min swing	8.7	37.4	25.8	24.2	32.4	74.3
KNEE						
max stance	27.4	11.9	43.4	7.5	8.2	12.7
max swing	6.0	5.4	2.8	5.0	5.6	7.7
min stance	432.6	101.3	71.3	50.0	29.6	29.1
min swing	11.3	16.7	11.2	19.5	22.0	28.9
HIP						
max stance	45.4	6.0	14.0	31.8	9.5	20.3
max swing	12.2	11.4	7.4	10.3	14.4	14.3
min stance	43.0	7.5	11.6	15.5	128.4	45.0
min swing	1.0	203.4	19.9	350.9	22.0	28.9

2.2.5 Walking gait wearing a single AFO in CP children

The feasibility investigation into PAFO will consider the alterations to walking gait using the powered device in comparison to barefoot walking, and the walking dynamics when compared to AFO shod conditions. The data below are for direct comparison to table 4: data in table 9 is a review of the variability between limbs when participants who require a unilateral AFO are wearing the AFO.

Table 8: Normative data for CP children during single AFO walking. Mean +/- standard deviation (sd) scores reported. Position data reported as deviation from 180 degrees, Velocity $m{\cdot}s^{-1}$, acceleration $m{\cdot}s^{-2}$.

	POSITION				VELOCITY				ACCELERATION			
	AFF		NONAFF		AFF		NONAFF		AFF		NONAFF	
ANKLE	mean	sd	mean	sd	mean	sd	mean	sd	mean	sd	mean	sd
max stance	7.0	4.1	11.9	5.1	64.9	27.5	83.5	21.2	944.6	377.6	1481.7	366.8
max swing	5.2	5.7	9.2	5.8	39.8	21.1	163.2	71.8	234.0	302.2	311.2	191.2
min stance	0.4	2.8	1.7	6.2	4.0	15.1	-17.1	42.6	230.9	178.0	215.0	182.0
min swing	1.8	3.6	-3.4	7.9	-8.7	9.3	-15.8	37.7	-58.2	200.7	-365.1	657.5
KNEE	mean	sd	mean	sd	mean	sd	mean	sd	mean	sd	mean	sd
max stance	18.8	5.9	22.3	12.6	107.4	56.9	162.7	62.9	2408.8	943.5	2592.9	1008.7
max swing	55.1	12.4	56.2	16.0	368.4	99.8	335.0	78.9	3195.5	1396.2	4269.8	1446.4
min stance	2.0	6.1	4.5	8.4	8.3	28.3	43.3	53.4	482.5	296.8	647.0	464.8
min swing	29.7	8.0	24.3	10.8	-60.0	37.1	-75.4	49.1	-152.4	330.9	-213.6	197.8
HIP	mean	sd	mean	sd	mean	sd	mean	sd	mean	sd	mean	sd
max stance	22.0	8.9	27.1	11.6	-25.6	15.7	0.1	23.7	719.4	244.7	1175.1	447.4
max swing	23.1	9.5	23.2	9.2	181.1	50.8	198.5	54.7	1435.4	497.9	1474.9	527.4
min stance	-5.1	6.9	-6.3	8.5	-72.7	19.3	-66.4	20.4	-102.1	152.2	-329.6	321.9
min swing	-1.2	5.6	3.7	7.9	21.8	25.3	6.2	19.1	-152.4	330.9	-213.6	197.8

2.2.6 Variability in walking gait between limbs for single AFO CP children during barefoot walking

During unilateral AFO walking there is a reduction in the variability of position and velocity of when limbs are compared. In comparison to table 6, the CV across position, velocity and acceleration are ~145%, 78% and 26% for barefoot walking respectively (table 6). These numbers are compared to ~86%, 63% and 30% for AFO walking across all markers.

Table 9: Coefficient of variation (%) for position, velocity and acceleration between lower limbs during AFO walking in CP children with a unilaterally affected limb.

	POSITION	VELOCITY	ACCELERATION
ANKLE			
max stance	36.7	17.8	31.3
max swing	38.8	86.0	20.0
min stance	88.6	226.6	5.0
min swing	475.6	40.8	102.6
KNEE			
max stance	11.8	28.9	5.2
max swing	1.4	6.7	20.4
min stance	52.6	96.1	20.6
min swing	14.1	16.1	23.7
HIP			
max stance	14.7	142.2	34.0
max swing	0.4	6.5	1.9
min stance	13.9	6.3	74.5
min swing	283.9	78.6	23.7

2.2.7 Repeated visits: Coefficient of variation (%) of CP gait parameters during single AFO walking

Repeated trials during AFO walking did not appear to reduce the coefficient of variation between visits. A high level of variability is present during both barefoot and AFO trials for repeat visits. See section 2.24, and tables 7 above and table 10 below.

2.2.8 Subsets within the data set: Data from bilateral AFO participants

This section has data from children who wear AFOs on both legs. Table 11 is the data from barefoot walking, and table 12 from dual AFO walking. There are two types of participants recorded in table 11. For participants who are affected by CP in both limbs the columns coded AFFR and AFFL refer to these participants (R and L refer to right and left limbs). The AFF and NONAFF columns refer to those participants who are only affected one side, however these participants also wear dual AFO technology. Table 11 is for barefoot walking, and table 12 is for AFO walking.

Table 10: Coefficient of variation (%) for position, velocity and acceleration during AFO walking for repeated visits of CP children to CCS.

	POSITION		VELOCITY		ACCELERATION	
	AFF	NONAFF	AFF	NONAFF	AFF	NONAFF
ANKLE						
max stance	45.6	42.8	17.3	24.2	18.2	20.8
max swing	205.7	80.3	22.9	32.2	71.0	65.7
min stance	0.2	384.4	10.7	44.6	68.2	58.2
min swing	633.8	-32.1	68.0	75.6	77.2	31.5
KNEE						
max stance	20.7	49.3	22.1	17.4	29.8	19.2
max swing	16.0	16.9	20.7	19.5	23.0	22.5
min stance	107.9	178.7	20.9	44.8	78.6	35.1
min swing	20.7	34.9	55.3	58.1	47.0	261.2
HIP						
max stance	25.3	31.3	45.0	88.4	22.8	45.5
max swing	36.9	33.7	16.6	27.4	29.9	27.3
min stance	17.8	16.8	13.3	27.5	141.6	149.1
min swing	94.4	15.0	69.3	186.1	47.0	261.2

Table 11: Normative data for CP children who require dual AFO, walking barefoot. Mean scores reported.

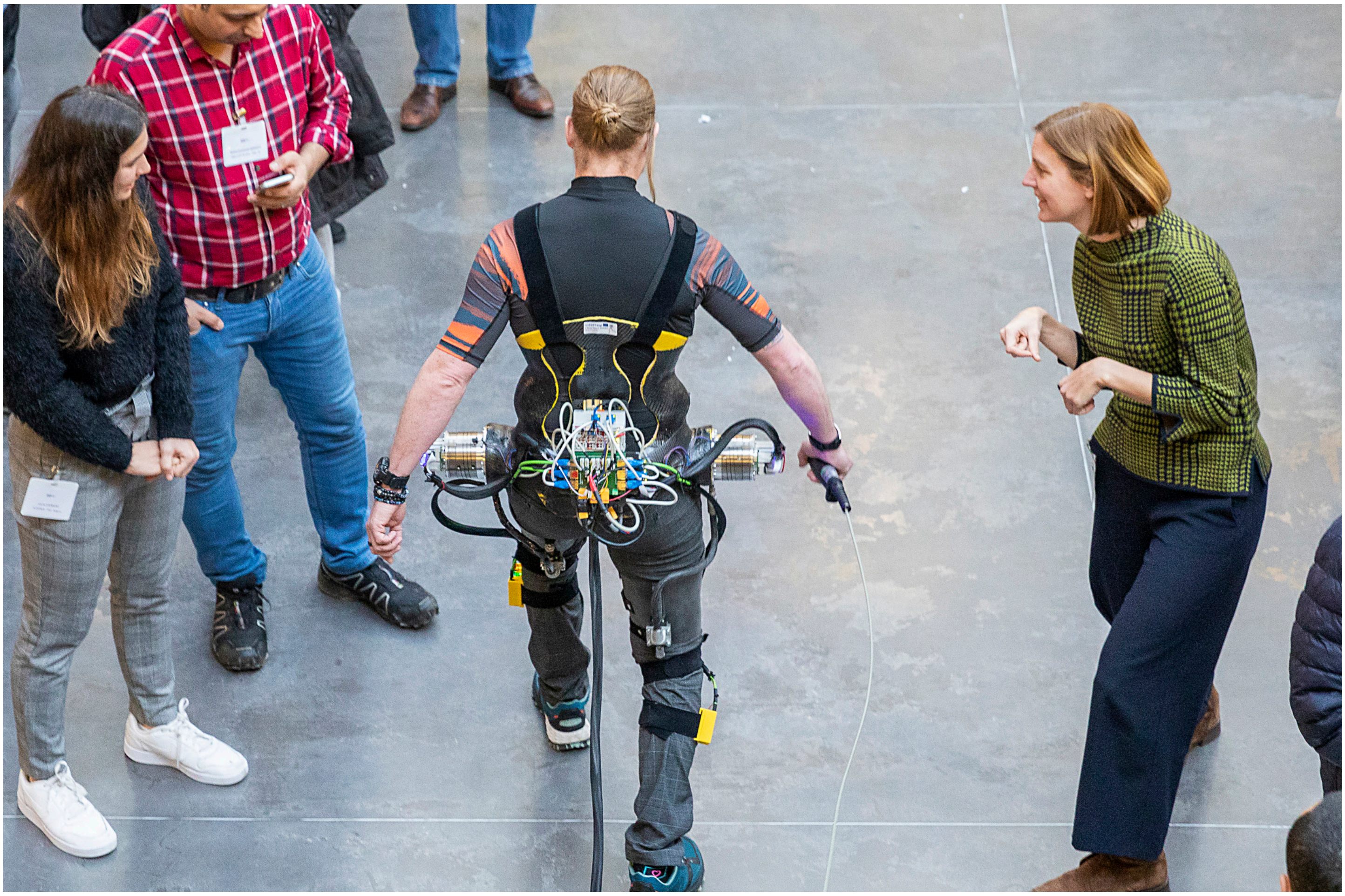
	POSITION				VELOCITY				ACCELERATION			
	AFF	NONAFF	AFFR	AFFL	AFF	NONAFF	AFFR	AFFL	AFF	NONAFF	AFFR	AFFL
ANKLE*												
max stance	12.2	-0.3	11.5	13.3	110.6	96.4	196.6	223.6	1580.4	621.1	1348.4	1755.8
max swing	3.9	-6.5	-6.7	-9.5	161.8	90.7	147.8	143.4	86.1	-69.1	262.9	308.0
min stance	2.0	-3.5	-0.7	-3.3	-2.5	4.3	31.3	24.6	86.1	-69.1	251.7	302.2
min swing	-3.5	-14.0	-14.3	-14.2	-25.4	26.7	-4.3	21.7	1176.9	855.1	1762.3	2194.1
KNEE ^												
max stance	26.7	13.9	24.1	30.1	93.6	40.1	98.1	142.8	2499.6	1350.3	2571.0	2628.5
max swing	54.7	41.9	51.3	56.5	323.1	311.8	302.5	341.7	2955.9	1011.3	2927.1	3825.7
min stance	4.6	-17.4	1.7	2.3	0.2	-91.3	44.8	43.6	618.3	-50.5	582.7	813.8
min swing	35.7	28.6	32.6	34.4	-38.9	-75.7	-67.0	-66.6	-743.9	-420.5	-342.9	-597.2
HIP Δ												
max stance	25.2	11.8	23.5	28.4	-30.0	-34.5	-37.0	-46.8	1369.5	1095.9	1409.4	1920.4
max swing	27.3	22.1	26.3	26.3	170.7	180.4	220.3	249.5	1034.4	786.4	1969.3	2234.8
min stance	-6.9	-18.0	-11.4	-15.2	-75.2	-85.3	-93.3	-93.5	-62.1	241.0	-436.4	-424.2
min swing	1.3	-3.7	-6.4	-4.5	39.4	12.3	34.2	40.1	-743.9	-420.5	-342.9	-597.2

** Ankle data reported as change in angle from participants Anatomical Reference Position (ARP) between the longitudinal of the calf and the vertical axis of the heel, positive angles indicating plantarflexion and negative dorsiflexion. ^ Knee angles reported as a deviation from the participants ARP. Δ Hip angles reported as change in angle from ARP between the pelvic vertical and the longitudinal of the thigh, positive angles signify hip flexion and negative angles hip extension. Position reported in degrees, Velocity deg·s^{-1}, acceleration deg·s^{-2}.*

Table 12: Normative data for CP children who require dual AFO, walking with dual AFO. Mean scores reported.

	POSITION				VELOCITY				ACCELERATION			
	AFF	NONAFF	AFFR	AFFL	AFF	NONAFF	AFFR	AFFL	AFF	NONAFF	AFFR	AFFL
ANKLE*												
max stance	3.0	1.9	7.2	9.3	33.9	32.1	92.2	105.5	425.6	421.0	1073.8	1412.0
max swing	1.2	0.9	0.0	2.4	26.2	32.9	47.3	31.5	170.2	142.3	73.2	118.4
min stance	0.4	-0.1	0.2	-1.1	9.0	-3.2	21.1	2.4	170.2	130.3	77.2	115.5
min swing	-3.3	-2.8	-3.3	0.0	4.3	6.9	-11.6	-12.0	101.0	-20.3	281.7	210.2
KNEE ^												
max stance	24.4	17.3	26.5	28.2	95.2	91.1	159.8	186.5	2046.2	1767.9	2861.9	3501.6
max swing	44.7	34.1	46.5	54.0	286.2	282.7	306.5	373.8	2450.0	2120.3	3696.2	4236.5
min stance	0.3	-5.4	-2.3	1.5	-32.0	-34.7	32.4	52.5	623.6	339.0	803.6	912.5
min swing	28.0	21.2	26.9	25.6	-5.6	-6.3	-31.6	-62.3	-244.0	-346.2	-576.7	-198.4
HIP Δ												
max stance	31.6	26.7	34.4	34.9	-17.3	-28.2	-28.2	-0.8	1191.8	923.5	1538.3	1389.5
max swing	31.7	30.6	35.0	34.6	125.2	127.0	213.1	215.7	1109.7	865.3	1536.5	1611.3
min stance	0.9	-3.8	-11.4	-5.4	-70.7	-79.4	-97.7	-82.0	-244.8	-178.6	-954.3	-470.2
min swing	-3.3	-5.2	-6.5	-4.6	87.6	97.4	75.6	44.5	-244.0	-346.2	-576.7	-198.4

** Ankle data reported as change in angle from participants Anatomical Reference Position (ARP) between the longitudinal of the calf and the vertical axis of the heel, positive angles indicating plantarflexion and negative dorsiflexion. ^ Knee angles reported as a deviation from the participants ARP. Δ Hip angles reported as change in angle from ARP between the pelvic vertical and the longitudinal of the thigh, positive angles signify hip flexion and negative angles hip extension. Position reported in degrees, Velocity deg.s-1, acceleration deg.s-2.*



3. Summary evaluation and graphical presentation of findings

This work package aimed to provide normative data for TD children alongside those with CP. The data collection was fully supported by CCS who provided significant support in the ethics process for this work package, and for feasibility trials (ethical approval is in position for PAFO trials in the UK at this venue). It is apparent that these data would not have been collected with significant partner collaboration, collaborations which were also fundamentally challenged around patient care due to the SARS Covid-19 pandemic.

3.1 Comparisons of variations in walking: TD and CP children

The data set on TD children provides a reference point for movement analysis. The variability (%) between limbs for TD children is ~ 18/14/7 for the position/velocity and acceleration data respectively. This compares to 145/86% for CP children walking barefoot and AFO for position, 78/63% for velocity, and 27/30% for acceleration. These data are presented in figure 1 below. The data from the hip presented here may facilitate support for the hip module development and D3.2.3.

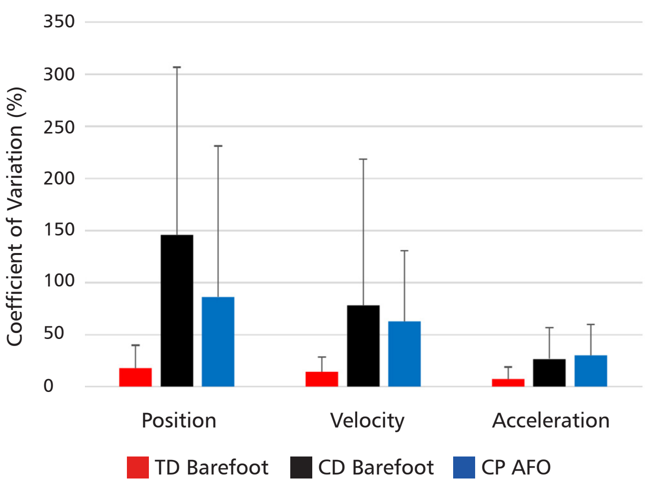


Figure 1: Variability between limbs for all measures, and across all gait phases for TD and CP children.

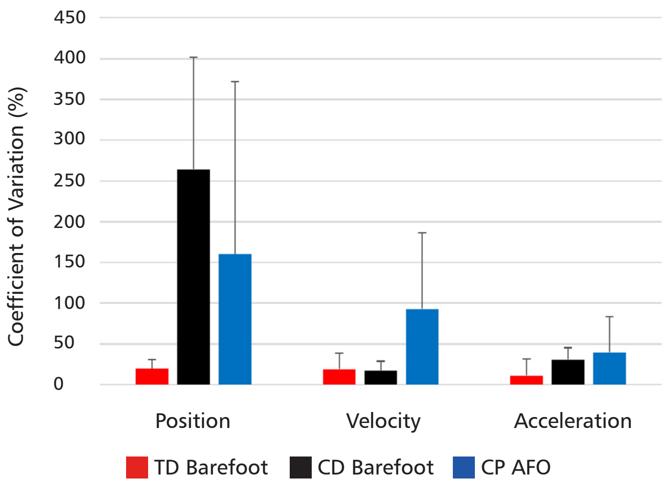


Figure 2: Variability between limbs at the ankle across all gait phases for TD and CP children.

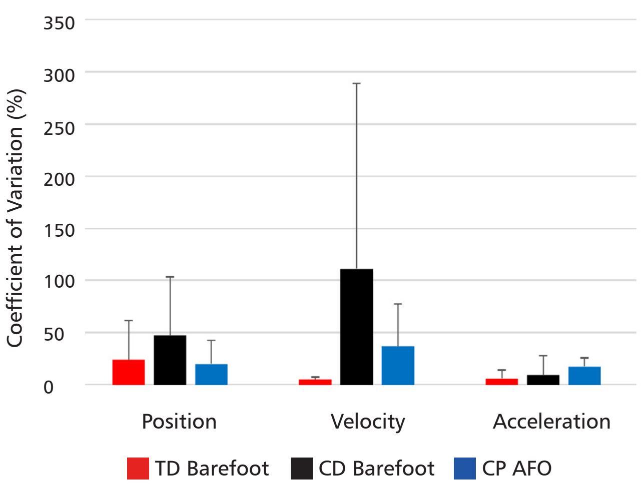


Figure 3: Variability between limbs at the knee across all gait phases for TD and CP children.

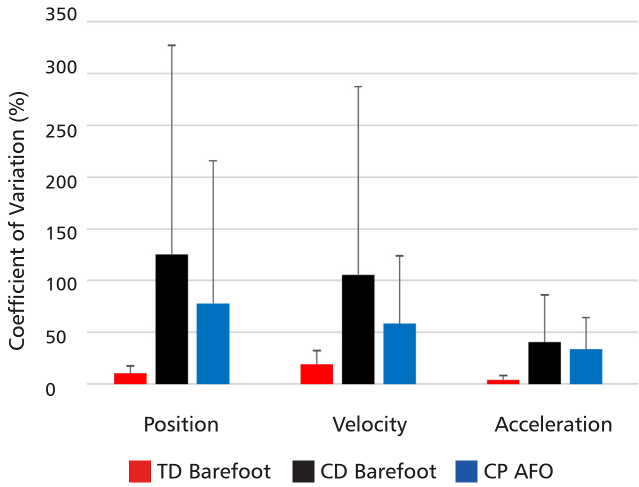


Figure 4: Variability between limbs at the hip across all gait phases for TD and CP children.

Figure 5 below indicates the phase-related nature of the variability. Mid stance and mid swing phases are more variable across participant and trial groups; however this is substantially greater in the CP barefoot trials for minimum stance phase. Use of the AFO reduces variability between limbs during all phases except the minimum swing phase.

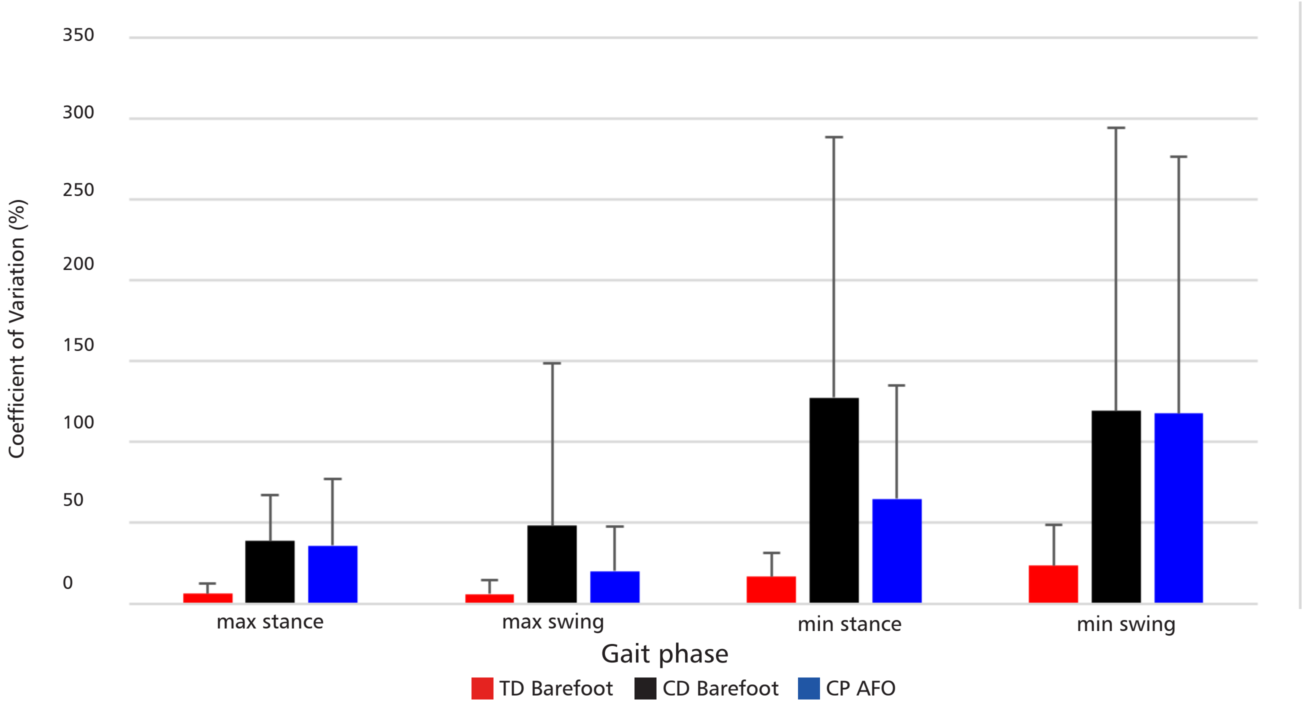


Figure 5: Variability between limbs for TD and CP children: all gait phases.

Figures 6, 7 and 8 demonstrate these data by ankle, knee and hip. At the ankle the variability in the minimal swing phase is elevated wearing AFO when compared to barefoot walking in CP children. At the knee, the minimal stance data indicates the most variability, with a large reduction with AFO technology. At the hip the AFO has substantial impact upon variability during the minimal swing phase.

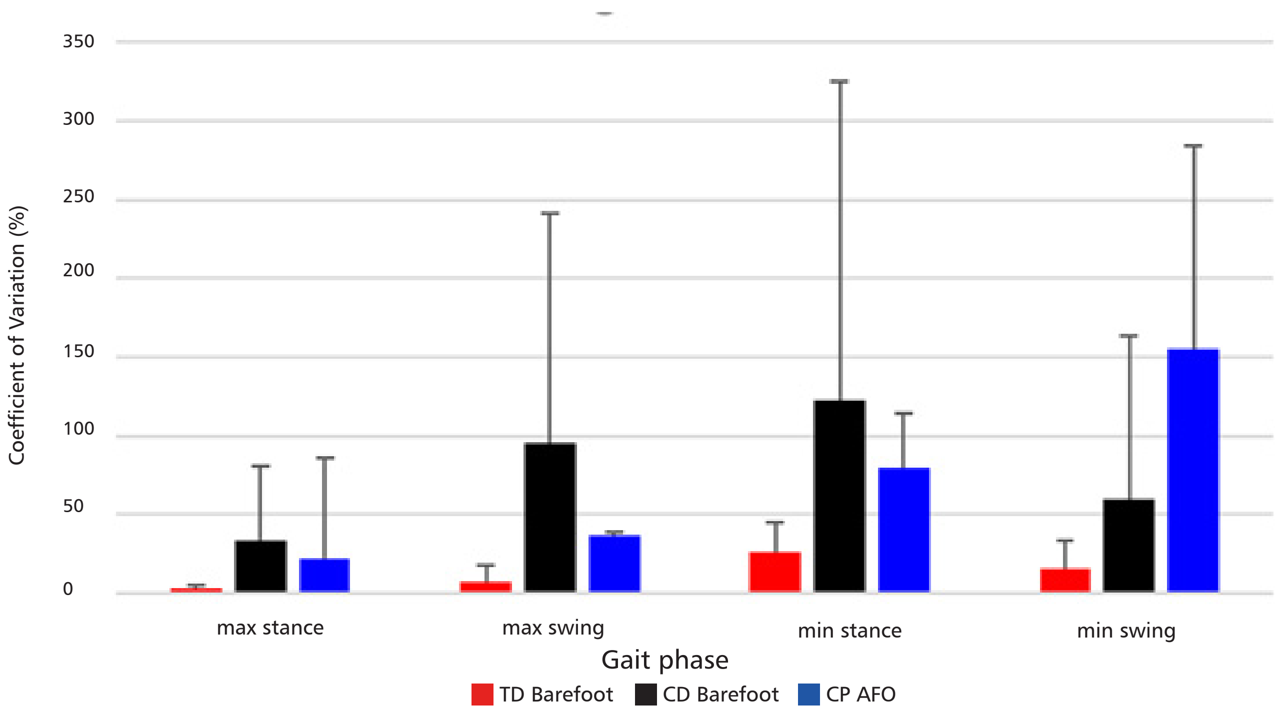


Figure 6 Variability between limbs at the ankle for TD and CP children: all gait phases.

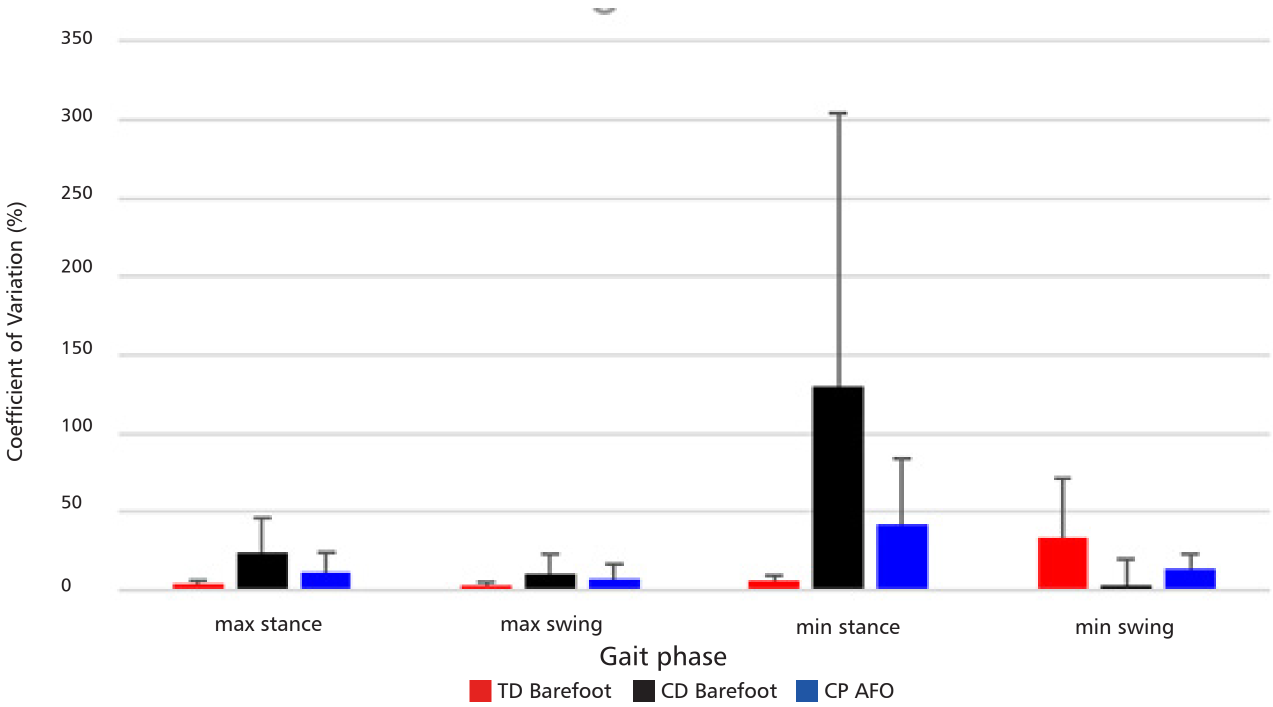


Figure 7: Variability between limbs at the knee for TD and CP children: all gait phases.

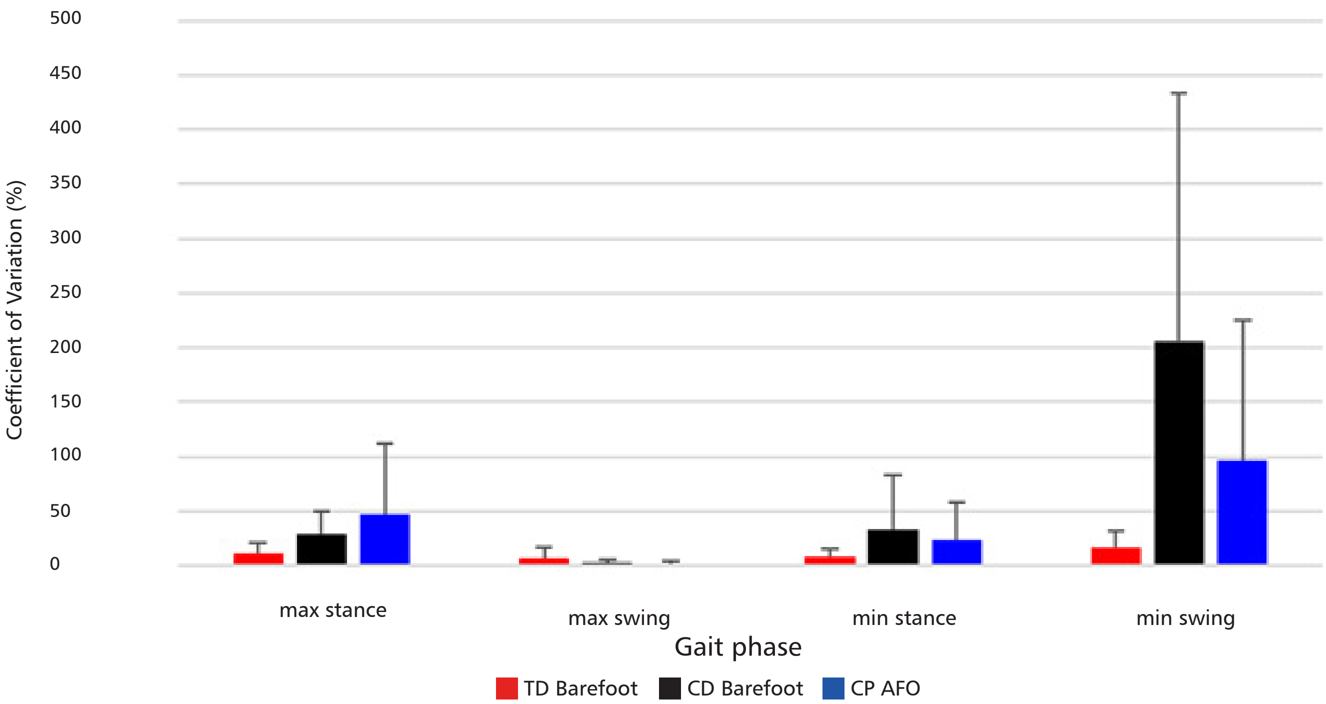


Figure 8: Variability between limbs at the hip for TD and CP children: all gait phases.

The PAFO feasibility trials will allow for direct comparison to these data, and the impact upon walking gait with powered technology. The feasibility work will investigate powered technology in comparison to barefoot and AFO walking, and if powered technology returns CP numbers more aligned with TD walking gait patterns.

3.2 Reliability of repeated trials

Sixteen CP participants visited the CCS venue for a repeat trial with a short period (M = 9.88 days, SD = 6.25) to assess if walking gait markers were consistent walking with and without AFO technology. The expectation was that individualised walking patterns may very substantially between participants, however no data existed on the repeatability of walking patterns. Consistent patterns would allow for specific technology integration, and to identify changes with confidence. The walking gait of CP children is highly variable with repeat visits, Figure 9 below demonstrates the coefficient of variation (%) across gait phases, and there is substantial variability for repeat visits in this client group. Detecting changes will only be possible with relatively large changes to walking gait if research studies utilise conventional forms of data analysis, or recruit an unlikely large sample of CP children.

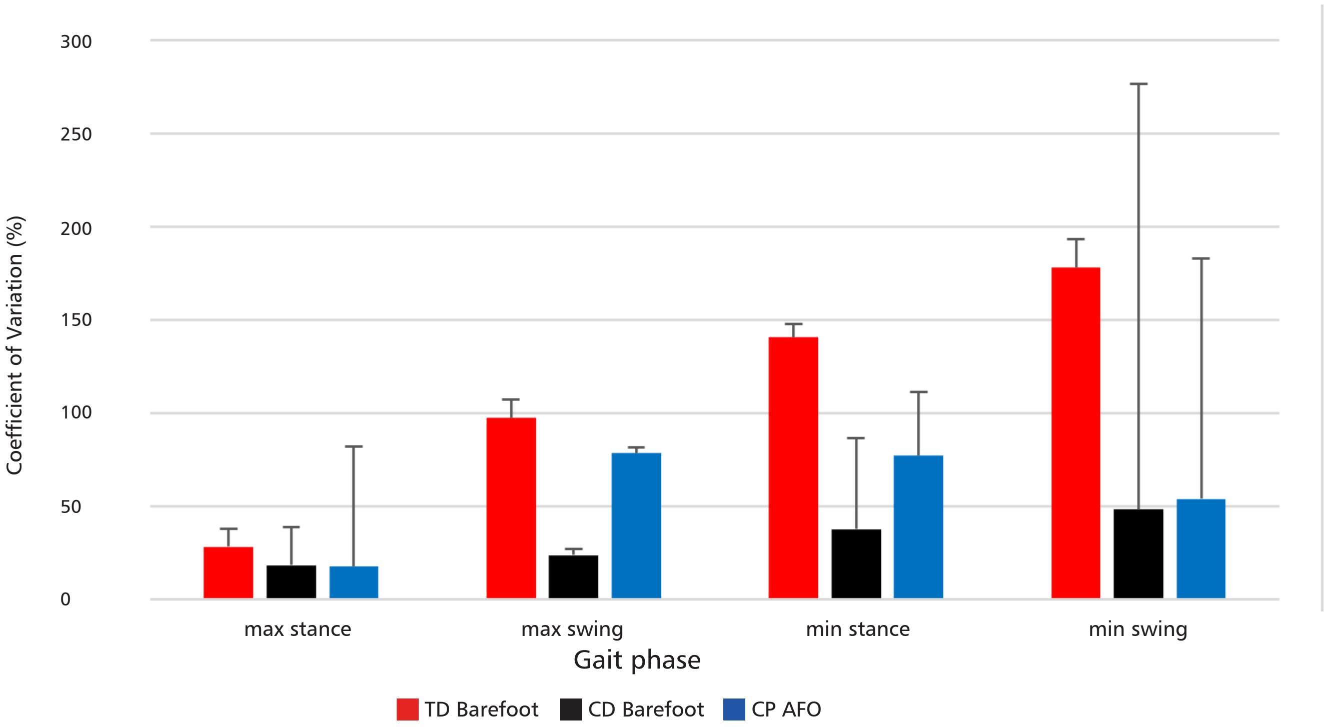


Figure 9 Variability between visits for CP children: all gait phases

4. CONCLUSIONS

The data presented and evaluation fulfil the deliverable for WP2.1.3.

Overall, the data sets demonstrate the challenge the engineers have in altering gait patterns with children with CP. Walking patterns are distinctly different in terms of position of limbs, velocity of movement, and acceleration of limbs between TD and CP children. Coupled with this the movement analysis presented here demonstrates a wide variation within single and repeated measurements on CP children. The current clinically prescribed AFO technology has marked impact upon walking gait. The AFO has a tendency to make walking more consistent, and consistent between limbs within the period of time assessed.

However a further challenge is that the gait patterns appear to be highly variable between visits to the clinic. This work would suggest that moving forwards the feasibility work, and ultimately training utilising PAFO devices needs to accommodate for wide inter and intra individual variation. These data demonstrate the challenge for those designing the PAFO technology in an attempt to bring the CP walking gait closer to that of a TD child.

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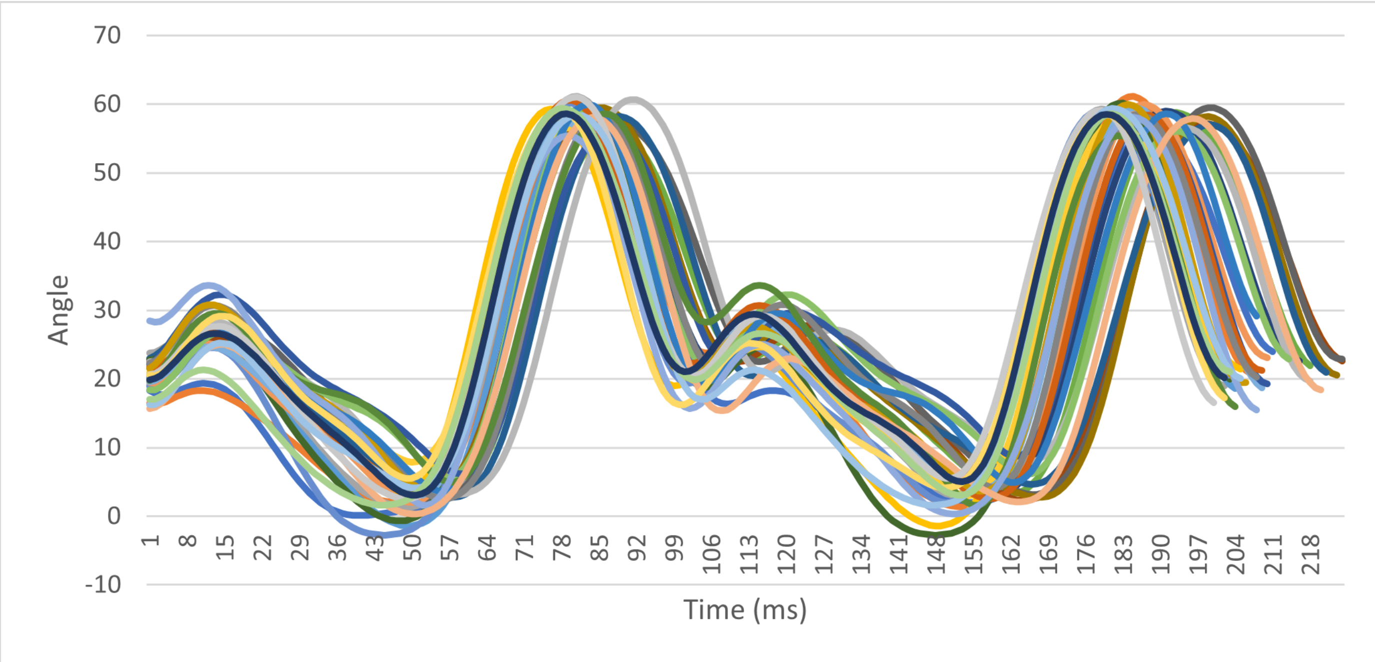
6. APPENDICES

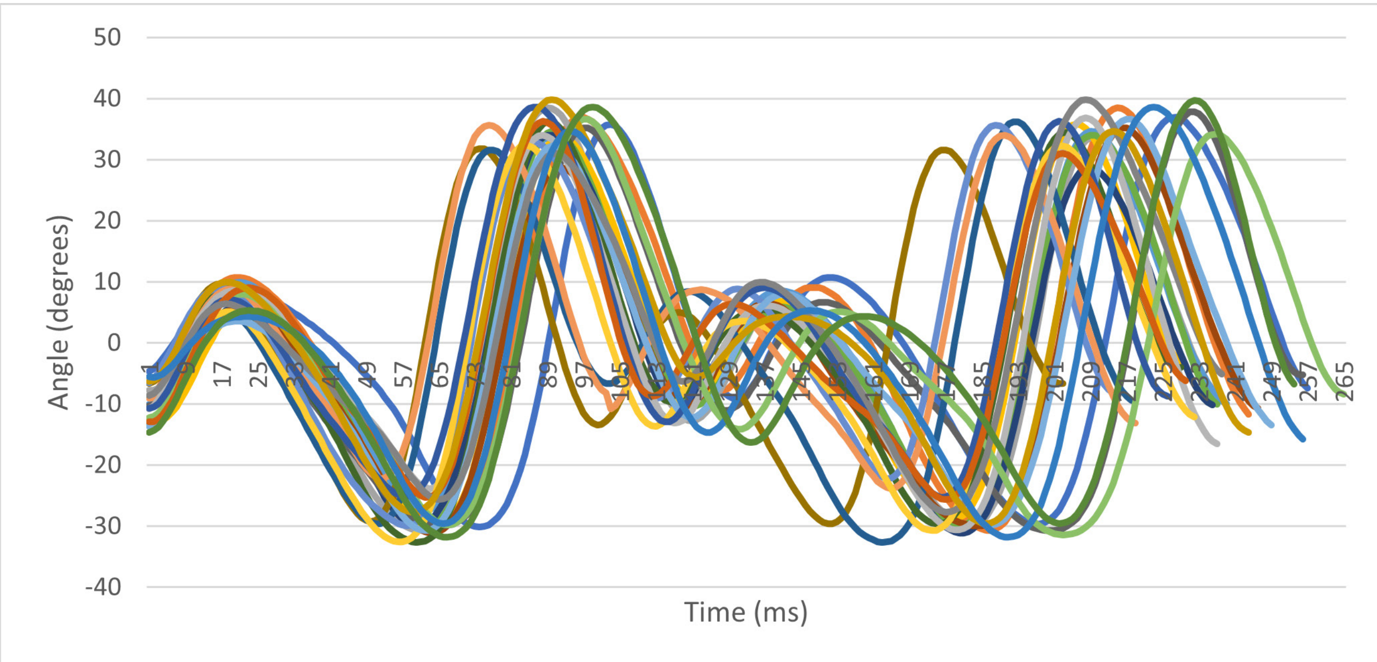
Further analysis & publication plans (Mat)

Further Analysis & Publication Plans

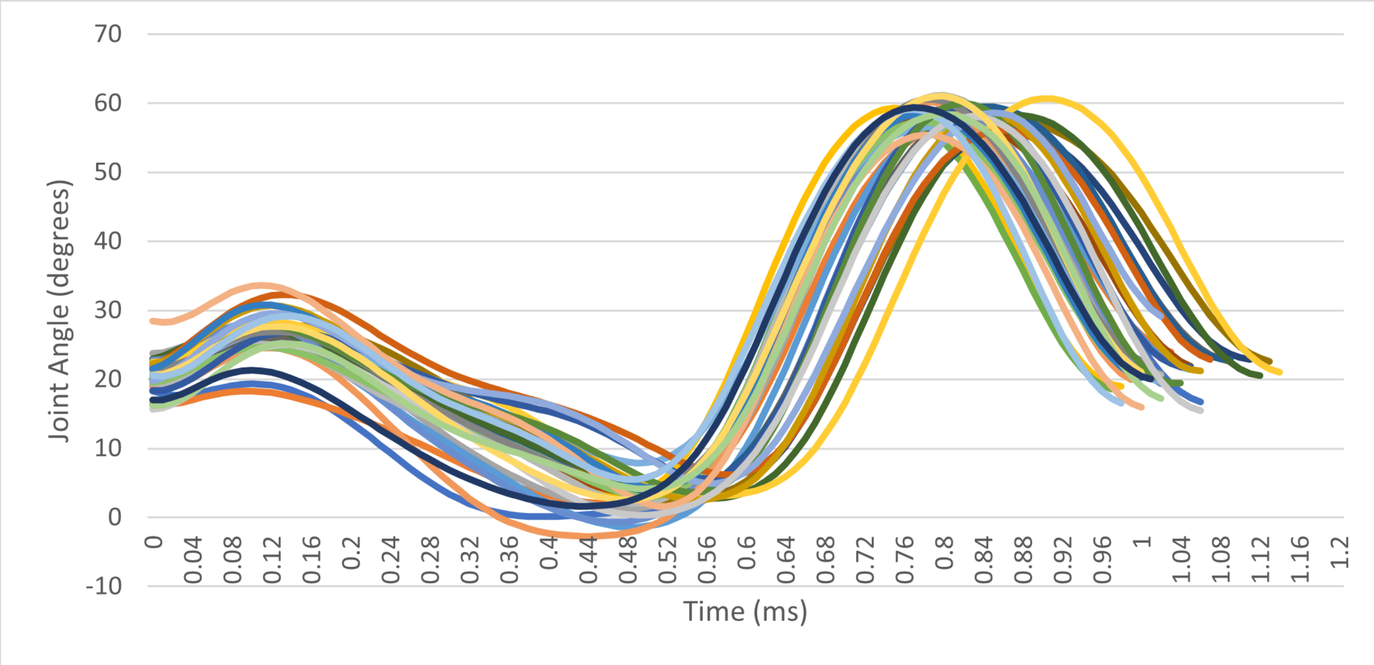
Continuing on from the traditional discrete point analysis which is presented in the main document, where maximum and minimum joint positions, velocities and accelerations are presented, further assessments are to be completed. As while the discrete point analysis will allow a broad assessment of the differences between testing sessions, limbs and even types of AFO. This discounts the temporal component of the gait cycle, as while participants may demonstrate similarities in maxima and minima, the timings of these discrete points are overlooked. This is further compounded by the duration of each gait cycle (time from initial contact to following initial contact on the same side) will naturally vary within participant (as clearly seen in figures A.1 to A.4 below).



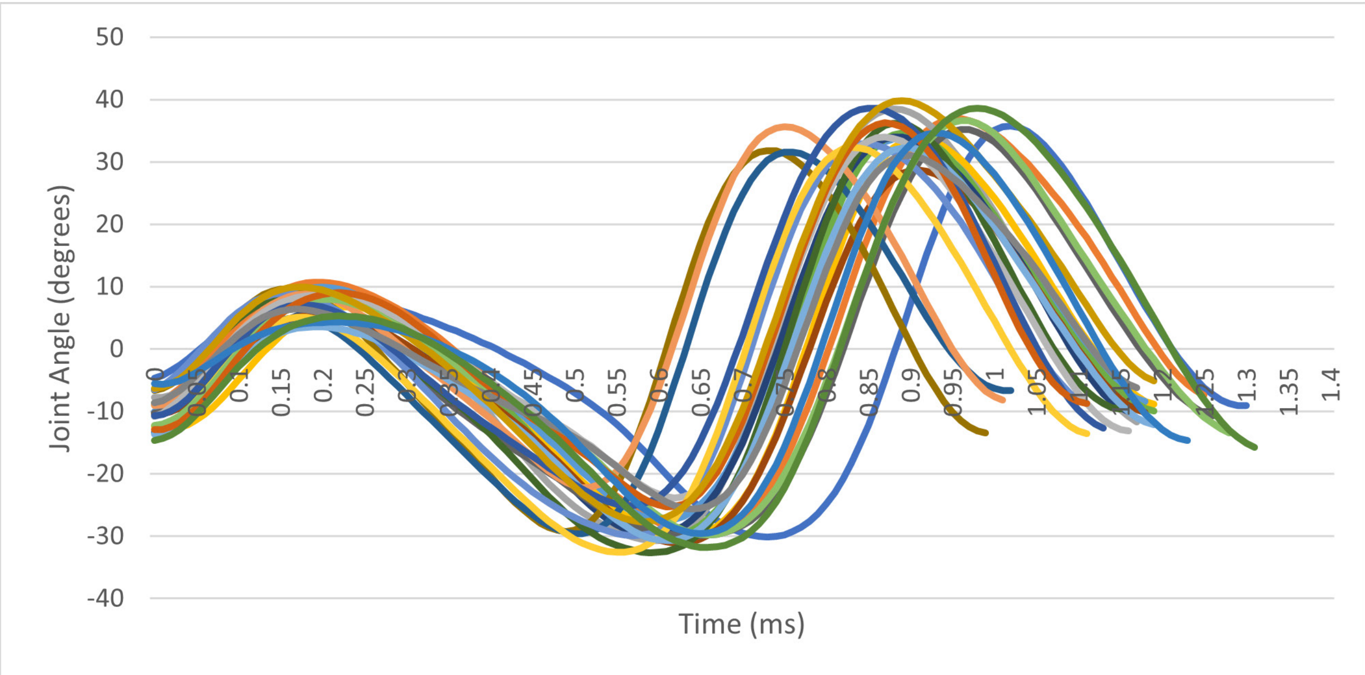
A. 1. Extract of 2 gait cycles of the left knee from the Bare foot trials.



A. 2. Extract of 2 gait cycles of the left knee from the AFO trials.

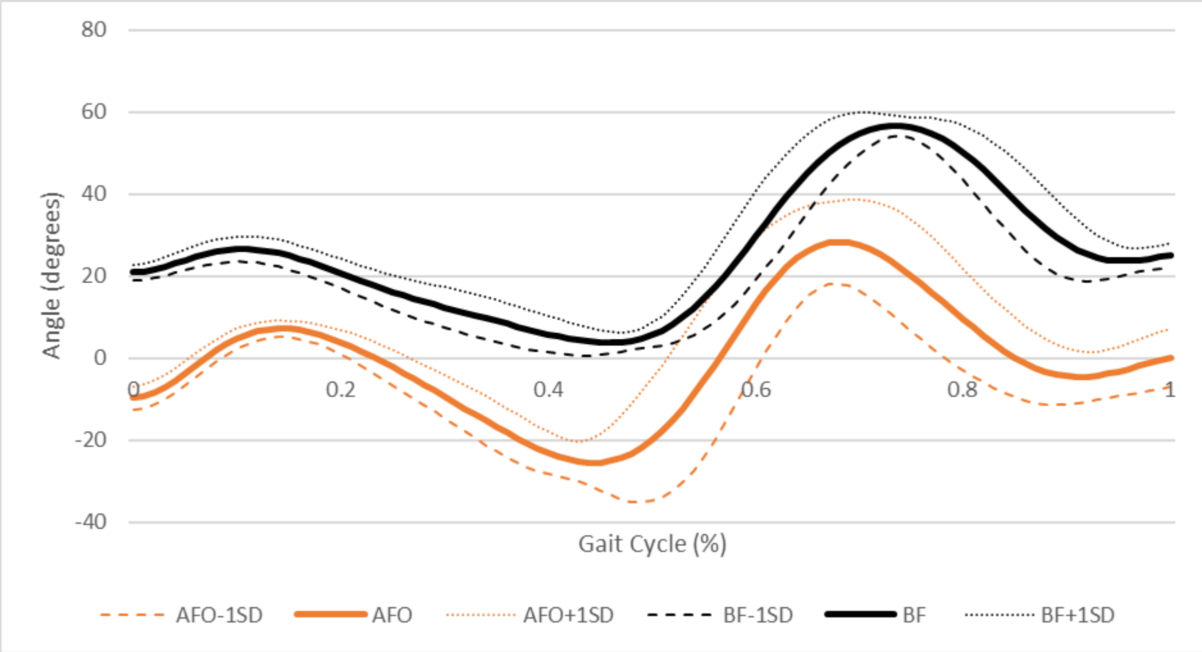


A. 3. Single gait cycle of the left knee from a barefoot trial.



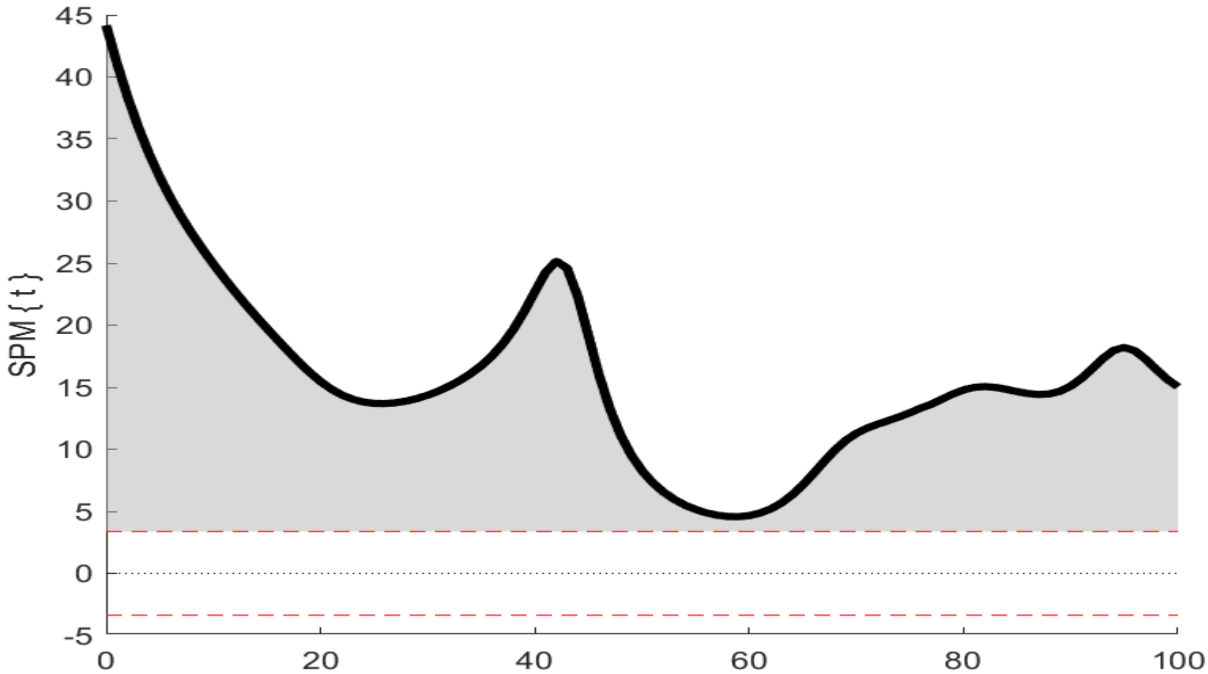
A. 4. Single gait cycle of the left knee from a AFO trial.

To enhance the analysis of the data future work will add a temporal assessment to the discrete point analysis. To complete the intended analysis gait cycles will be normalised to 100% (101 data points) by using interpolation using a spline function to match the durations of the trials (see figure 6.5). Following time normalisation, gait cycles will be used to compare the various conditions (BF vs. AFO; visit 1 vs. visit 2; effected side vs. unaffected) using statistical parametric mapping (SPM) to make time point comparisons across the length of the gait cycle. Figure 6.5 below is a time normalised comparison of the left knee angle between the BF and AFO conditions for a single subject. The mean is identified by the solid lines and the broken lines are the bounds of a single standard deviation.



A. 5. Comparison of the left knee angle between AFO and barefoot conditions, presented as mean±SD.

The output from the SPM analysis (figure 6.6) identifies where significant difference occur across the duration of the gait cycle. The example presented in figure 6.6 demonstrates the comparison of AFO vs. Barefoot for the left knee angle (same data as in figure 6.5) for a single participant. It shows significant differences across the whole gait cycle, as the grey area outside of the dotted red horizontal line signifies a significant difference.



A. 6. SPM output for left knee angle BF vs. AFO.

This SPM approach will be taken forward in future publications where comparisons across the temporal wave will provide further insight into the effects of AFO on walking gait; as well as the variability in the gait cycle across multiple sessions.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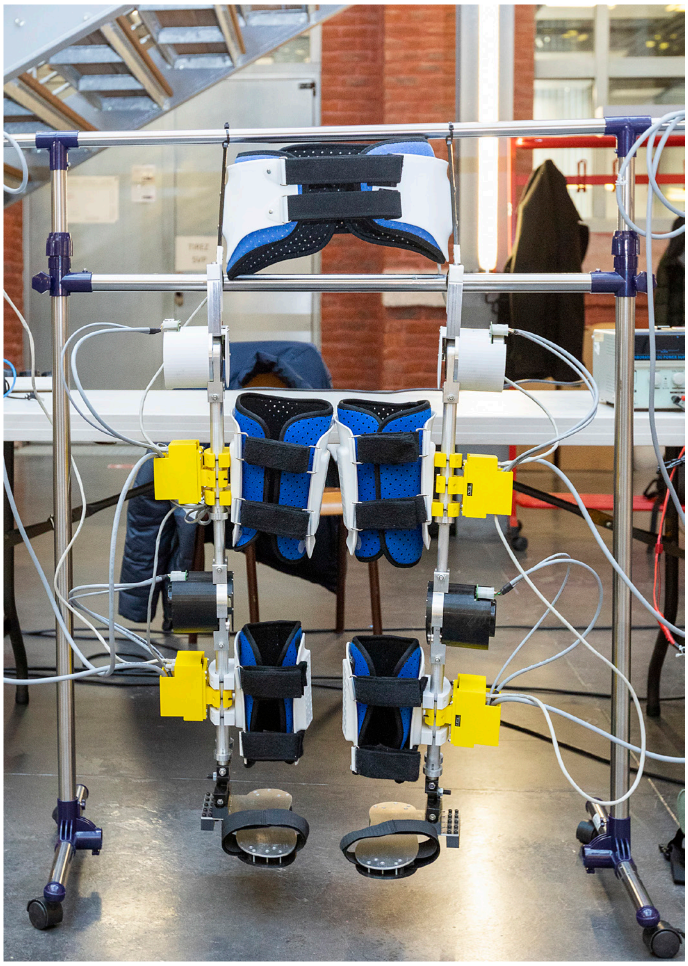


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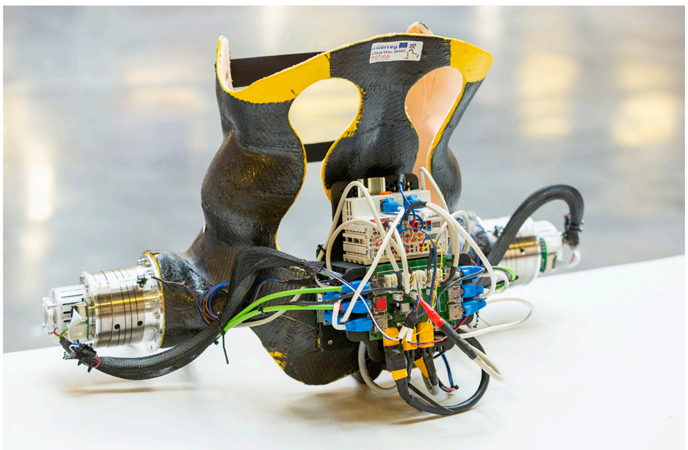

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