Gait & Posture 118 (2025) 75–84

Contents lists available at ScienceDirect

Gait & Posture

journal homepage: www.elsevier.com/locate/gaitpost

Orthotic bracing to treat equinus in children with spastic cerebral palsy: Recorded compliance and impact of wearing time

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A B S T R A C T

Aim: Spastic cerebral palsy (SCP) often results in "pes equinus," managed with ankle-foot orthoses (AFOs). Yet, little is known about actual wearing time and the minimum duration for improvement. This study explores orthotic compliance, examining its impact on clinical and gait parameters. The hypothesis anticipates a compliance rate below 50 %, suggesting AFOs worn for over 6 hours enhance ankle dorsiflexion.

Method: In a clinically prospective study, SCP children (ages 5 – 15 years) with equinus underwent gait analysis at recruitment and three months later. Wearing time, measured by sensors, categorised participants into compliant (≥6 hours) and non-compliant (<6 hours) groups.

Results: Data were obtained for 32 participants (21 males, 11 females; mean age 10 years 7 months [SD 3 years]). Among 32 participants, 47 % wore AFOs over 6 hours, showing significant ankle dorsiflexion improvement. Thigh shell wearing time was shorter; only two exceeded 6 hours during the day.

Interpretation: Confirming our hypothesis, compliance was < 50 %, yet AFOs over 6 hours improved ankle dorsiflexion. The study revealed minimal AFO daytime use and thigh shell acceptance. Wearing time significantly impacted equinus deformity, underscoring the need to identify factors influencing compliance for effective measures to extend usage.

1. Introduction

Spastic cerebral palsy (SCP) in children is most frequently linked to the deformity and walking abnormality known as equinus gait [1]. The inability to achieve sufficient ankle dorsiflexion results in initial contact with the forefoot, leading to disproportionate weight-bearing under the metatarsal heads [2]. This can result in the flexion or hyperextension of the knee during walking [3]. In the pelvic region, the equinus deformity can cause retraction [4] and is associated with increased lateral inclination of the upper body [5].

Severe ankle equinus increases the loading of the toes and forefoot. To prevent this, it is essential to promptly address the equinus gait to facilitate plantigrade walking and avoid the progression of the equinus deformity. The ankle-foot orthosis (AFO) is most frequently used in patients with cerebral palsy (CP) [6]. A meta-analysis has shown that walking with orthotics improves the equinus gait by 1,6° during the stance phase [7]. After three months of therapy, walking without orthotics improved the sole angle between 1° to 4° [8–10].

In clinical practice, various orthoses and wearing time strategies are recommended. To stretch the two-joint muscle gastrocnemius, the knee must be extended fully. This is achieved with knee-ankle-foot orthoses (KAFOs) or a night-time removable thigh shell attached to an AFO [11]. The AFO during the daytime extends the wearing time and is primarily prescribed to improve foot alignment and gait pattern [6].

It has been shown that using AFOs during the daytime enhances Gross Motor Function Measure scores more effectively than using them both during the day and at night [12].

Despite various available orthotic options, the optimal duration for

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https://doi.org/10.1016/j.gaitpost.2025.01.034
Received 11 September 2024; Received in revised form 24 January 2025; Accepted 28 January 2025
Available online 30 January 2025

wearing these orthoses remains uncertain. Tardieu et al. [13] evaluated the efficacy of orthotic management on soleus muscle contracture at rest in a small number of children with CP. They found no progression following stretching the muscle for at least 6 hours/day [13]. This was further supported by Maas et al. [11] investigating night-time bracing. They found no improvement with the wearing time of 3.2 hours (SD +/- 1.9 hours), below the recommended duration [11].

The assessment of wearing time is an additional issue that must be considered. Neither the recommended nor the parent-reported wearing time of a KAFO corresponds with the objectively measured wearing time using temperature sensors [14].

The aims of the study are: firstly, to report the compliance with orthotic bracing and secondly, to report the effect of wearing time on improving clinical and gait parameters.

We hypothesise that the expected compliance of wearing an AFO is with less than 50 % of patients wearing the orthotics shorter than the prescribed time. Secondly, the peak ankle dorsiflexion improves during stance following a wearing time of more than 6 hours/day.

2. Method

2.1. Participants

A single-centre prospective, no-blinded clinical study was conducted between June 2018 and November 2020 in the Orthopaedic Children's Hospital, Aschau. The study was approved by the Medical Ethics Committee of the Technical University of Munich (4/18S). Children and adolescents with equinus deformity due to SCP presenting at the hospital outpatient department were requested to participate in this study. A written consent was obtained from the participants' parents before their inclusion.

Inclusion criteria were GMFC I and II, participants between ages 5 and 15 years, and a dynamic or fixed equinus deformity to be treated with orthotic bracing for the next three months.

Exclusion criteria include previous bone or muscle surgeries on the affected limb within the past year, Botulinum toxin injections in the lower extremity within the last six months, leg length discrepancy exceeding 2 cm (due to compensatory equinus) [15], and knee flexion contracture exceeding 10°. Participants with intellectual disability that prevented them from following instructions were also excluded from the study.

2.2. Intervention

A modular 2-component, custom-made AFO was used to treat the equinus deformity (Fig. 1). All the participants were fitted with an orthotic of similar design and material (Baise and Pohlig, Pohlig GmbH®) [16] to eliminate the differences in the material and construction-dependent stretching properties. The custom-made AFO was fabricated following surface laser-scanning (using Freeform Software) of the leg and foot to improve the accuracy of the fitting, and it was constructed using prepreg carbon technology.

The modular custom-made orthotic comprises two parts: a lower leg shell with dorsal support, extending from calf to knee and secured by a ventral Velcro strap and a circular foot shell with a dorsal flap-door to allow for the slipping-in of the foot. The bilateral ankle joints (F1734; Ottobock GmbH & Co. KG, Duderstadt, Germany) connect the two components, with modular parts that allow precise adjustment of the circular foot section via a screw-like mechanism. This adjustment corrects intra-articular misalignment in the subtalar joint to a neutral position, effectively addressing flatfoot or clubfoot deformities. Plantarflexion is limited to 0°, while dorsiflexion is adjustable between 5° and 10°, based on knee flexion during walking and calf muscle tension during clinical testing, to minimize pressure and friction from the orthosis during movement. Additional gas springs are applied to the foot to allow for improvement in the released ROM of the orthosis through

Fig. 1. Ankle-foot-orthosis with an adaptable circular foot shell (medial view).

pressure overnight. Over time, the spring is gradually replaced with a stronger one. When the resistance is low, the joint is simply set further into dorsiflexion (DF) using an adjusting screw at the joint, which is easier to manage. During the day, the screw is removed.

According to Tardieu et al.'s recommendation, participants were instructed to wear the orthotic while sleeping for 6 hours at night. If passive ankle dorsiflexion was less than 5° from neutral or a dynamic equnius was present, the orthotic wearing time was extended up to 23 hours, as recommended by routine hospital practice. The same orthosis with identical joints is used both day and night. For daytime use, the orthotic footwear is chosen from two manufacturers based on patient preference, featuring a standard sole construction. If knee flexion occurs during walking or standing, it is counteracted with a negative heel, while the orthosis-shaft alignment determines the ankle joint position. For nighttime use, the foot orthotics support correction of the subtalar joint to a neutral position achieved during the day. A toe off ankle-foot orthosis aided weak dorsiflexors during the swing phase of walking. Participants with a positive Silfverskjold test wore an additional thigh shell while sleeping to maintain knee extension and stretch the gastrocnemius muscle.

2.3. Measurements

All the participants in the study underwent an initial assessment at the time of recruitment and were re-evaluated at the end of three months of treatment with the AFO. These evaluations included an instrumented three-dimensional gait analysis using an 8-camera Vicon Motion Systems Ltd. (Oxford, UK) system and two force plates from AMTI

Table 1
Summary of prescribed Ankle-Foot Orthoses and their wear, including additional orthotics.

	participants (n = 32)
Day and night use	**11/32**
• with full knee extension[a]	6/12
Only night use	**21/32**
• with full knee extension[a]	9/21
Orthotics during the day with:	10/21
• insoles	5/21
• foot orthoses	6/21
• ankle-foot orthosis for drop foot	

[a] with an additional thigh shell adapted to the AFO to maintain the knee in full extension during the night

(Watertown, MA, USA) integrated into a 13-meter-long walkway. The force plates captured ground reaction forces during walking. Reflective markers were placed on the children's bodies according to a modified Plug-In gait Model [17]. During the assessments, participants were instructed to walk barefoot at their self-selected pace along the walkway until five valid strikes on the force plates were recorded. No orthosis was worn during the analysis. Marker data were collected at a rate of 200 Hz, while force plate data were recorded at 1000 Hz. Following the measurements, passive dorsiflexion and other clinical parameters were assessed using a goniometer as part of the routine clinical examination.

2.4. Wearing time

To assess the actual wearing time of AFOs and understand their impact, a temperature sensor data logger (orthotimer®, Rollerwerk Medical Engineering & Consulting, Balingen, Germany) was embedded in the lower leg shell, positioned close to the calf muscle. The sensor monitored temperature fluctuations without hindrance, minimising pressure points and discomfort. The sensor was integrated into the more severely affected leg's orthosis for bilateral involvement. In instances of an adaptable thigh shell, an extra temperature data logger was placed near the hamstring muscle belly. All participants were informed about the sensor integration.

Temperature data was recorded at 15-minute intervals over three months and stored in an integrated memory. The internal memory automatically retains data from the last 100 days, ensuring coverage of at least the preceding three months during data readout at follow-up.

2.5. Study protocol

The participants were examined by an experienced pediatric orthopaedic surgeon during their outpatient clinical examination. This was called timepoint T1 when the participants were recruited for the study if they fulfilled the inclusion criteria. The most suitable orthotic concept was prescribed following the doctor's examination, which included the daytime and nighttime wear durations and the use of an additional thigh shell for the stretching of the gastrocnemius. The participants and their parents were instructed to seek immediate assistance from the orthopaedic technician in case of any difficulties with the orthosis. The participants were scheduled for a follow-up appointment in three months (T2) following the orthotic fitting. The exact timing of this appointment could vary slightly depending on the doctors' availability and the children's school holidays.

2.6. Data processing and statistics

The study's primary outcome was the peak ankle dorsiflexion in the stance phase of gait to detect the change in the equinus deformity after bracing.

Secondary outcomes included parameters associated with equinus gait. Noteworthy examples encompassed the peak plantar flexion moment [Nm/kg] in the first half of the stance phase and manual measurement of passive ankle dorsiflexion. The gait and clinical parameters are presented in Tables 2 and 3. Only temperature values ranging between 30.0 and 38.5°C were utilised to determine the actual wearing time of the orthosis. Wear was confirmed by a minimum of three consecutive values (45 minutes) falling within this temperature range. The daily average wearing time was calculated as the ratio of identified wearing time to the total monitoring days (T1 to T2). The daytime wear was defined as periods between 8 a.m. and 6 p.m. To examine the impact of wearing time on peak ankle dorsiflexion during stance and its effects on clinical and gait parameters, the cohort is divided into two distinct groups: individuals who adhere to the recommended 6 hours or more per day (referred to as the compliant group) and those who wear the orthosis for less than 6 hours per day (considered the non-compliant group), functioning as a control group. The

Table 2
Mean values (standard deviation) of anthropometrics, spatiotemporal data, and parameters of the clinical exam, as well as ANOVA and post hoc test results. Significant results are marked in bold.

Parameter	Mean (standard deviation)				ANOVA			Post hoc *t*-test			
	C – pre	C – post	NC – pre	NC – post	group	intervention	interaction	C – NC (pre)	C – NC (post)	C (pre-post)	NC (pre-post)
Anthropometrics											
Age (years)	9.9 (2.9)	10.2 (2.9)	11.2 (3.0)	11.6 (2.9)	0.222	**0.000**	0.721	0.240	0.207	**0.020**	**0.009**
Bodyweight (kg)	37.1 (14.0)	38.3 (13.7)	43.8 (16.4)	45.4 (16.3)	0.206	**0.001**	0.549	0.225	0.190	**0.002**	**0.028**
Body height (cm)	140.0 (14.7)	142.0 (13.8)	148.0 (17.9)	150.0 (17.3)	0.172	**0.000**	0.885	0.183	0.162	**0.001**	**0.000**
BMI	18.2 (3.9)	18.5 (3.8)	19.2 (4.0)	19.5 (3.7)	0.464	0.078	0.734	0.502	0.432	0.173	0.225
Shank length (cm)	33.0 (4.2)	33.2 (4.1)	35.5 (5.1)	35.9 (5.2)	0.116	0.046	0.446	0.133	0.103	0.393	**0.049**
Shank length discrepancy (cm)	−0.3 (0.7)	0.1 (0.5)	−0.1 (0.7)	−0.3 (0.8)	0.575	0.487	0.036	0.497	0.102	**0.031**	0.365
Clinical exam											
Dorsiflexion strength [0–5]	3 (1)	3 (1)	3 (1)	3 (1)	0.81	0.827	0.663	0.708	0.940	0.714	0.817
Plantarflexion strength [0–5]	3 (1)	3 (1)	3 (1)	3 (1)	0.724	0.444	0.932	0.709	0.671	0.786	0.702
Dorsiflexion (knees extended) [°]	1 (4)	5 (7)	−1 (7)	1 (6)	0.137	0.007	0.386	0.371	0.102	**0.041**	0.089
Dorsiflexion (knees flexed) [°]	6 (5)	10 (7)	3 (6)	5 (5)	0.012	0.013	0.494	0.059	**0.020**	0.083	**0.048**
Knee extension [°]	−1 (2)	0 (2)	−1 (5)	0 (5)	0.833	0.086	0.453	0.982	0.681	0.184	0.814
Popliteal angle [°]	10 (15)	12 (15)	17 (17)	17 (19)	0.285	0.661	0.759	0.247	0.387	0.718	0.937

C = compliant group (n = 16); NC = non-compliant group (n = 16); pre = measurement at baseline; post = follow up after three months of bracing; popliteal angle was measured with the contralateral limb in maximum hip and knee flexion, significance level was set to α = 0.05

Table 3
Mean values (standard deviation) of primary outcome and parameters from 3DGA, ANOVA, and posthoc test results. Significant results are marked in bold.

Parameter	Mean (standard deviation)				ANOVA			Post hoc *t*-test			
Primary outcome	C – pre	C – post	NC – pre	NC – post	group	intervention	interaction	C – NC (pre)	C – NC (post)	C (pre-post)	NC (pre-post)
peak ankle dorsiflexion stance [°]	6.5 (6.8)	10.0 (6.8)	6.9 (6.5)	6.0 (5.0)	0.399	0.142	**0.015**	0.845	0.069	**0.004**	0.515
Kinematic											
sole angle at initial contact [°]	−0.7 (6.4)	−3.4 (7.7)	−1.5 (7.6)	−1.67 (6.5)	0.863	**0.012**	**0.024**	0.728	0.499	**0.010**	0.766
peak ankle dorsiflexion swing [°]	−0.2 (4.7)	2.2 (4.6)	−1.4 (6.3)	−1.3 (5.9)	0.207	0.054	0.073	0.565	0.071	**0.019**	0.918
Kinetic											
peak plantarflexion moment first half of stance [Nm/kg]	1.0 (0.3)	0.8 (0.2)	1.0 (0.3)	1.0 (0.3)	0.156	0.100	**0.003**	0.836	0.010	**0.008**	0.210
peak plantarflexion moment second half of stance [Nm/kg]	1.2 (0.3)	1.1 (0.3)	1.1 (0.2)	1.2 (0.2)	1.000	0.447	0.249	0.782	0.769	0.807	0.116
peak plantarflexion power at push-off [W/kg]	2.3 (0.9)	2.5 (0.8)	2.4 (0.6)	2.5 (0.5)	0.89	0.059	0.987	0.892	0.892	0.192	0.178
Spatiotemporal											
Velocity (non-dim.)	0.41 (0.07)	0.43 (0.05)	0.40 (0.06)	0.42 (0.05)	0.397	0.033	0.757	0.428	0.412	0.238	0.059
Step length (non-dim.)	70.8 (7.5)	71.6 (7.3)	68.3 (10.1)	70.7 (8.8)	0.572	0.070	0.363	0.447	0.762	0.544	0.045

C = compliant group (n = 16); NC = non-compliant group (n = 16); pre = measurement at baseline; post = follow up after three months of bracing, significance level was set to α = 0.05

designation of "Non-compliance" is treated as an approximation to receiving no therapy.

A two-factor ANOVA model with repeated measures in time was used to evaluate the intervention between the two groups. Post-hoc t-tests were performed to detect significant intervention and interaction effects. Statistical analyses were performed using MatLab 6.2 (The Mathworks Inc., Natick, USA), and the significance level was set at $\alpha = 0.05$.

As a reference value for a clinically significant change in peak ankle dorsiflexion in the stance phase of walking, the minimal clinically detectable difference (MCDD) for this parameter is calculated since the minimal clinically important difference is unknown. To find this threshold, the MCDD is calculated as MCDD = 1.96 * SEM *$\sqrt{2}$, where SEM is the standard error of the peak ankle dorsiflexion in stance [17]. This results in an MCDD of 2.9°.

3. Results

3.1. Participants

Forty-one participants were enrolled in the study. Reasons for dropout after initial measurement T1 were the need for additional treatment (n = 1), being unavailable for the final measurement (n = 5) and temperature sensor defects (n = 3). Therefore, complete gait, clinical and temperature data at T1 and T2 were available for 32 participants. Their mean age at T1 was 10 years 7 months (SD 3 years), of which 21 were males and 11 were females. Unilateral involvement was seen in 17 participants. GMFCS: level I was seen in 18 participants, and 14 were level II.

Of the 32 participants, 11 used AFO day and night. Table 4 reports the individual clinical data and orthotic setup, this demonstrated that three patients (7, 14 and 30) had neither passive ankle dorsiflexion below 5° nor dynamic equinus. Daytime usage was associated with improved gait performance. Two patients (21 and 31) did not receive daytime care due to school routine conflicts, as agreed by the physician and parents. Among these 11 participants using an AFO day and night, 6/12 were prescribed an additional thigh shell. The remaining 21 participants exclusively used the AFO during the night. 9/21 also utilised an additional thigh shell. Those who exclusively used the AFO during the night were provided additional orthotic devices for daytime use, as outlined in Tables 1 and 4.

The duration between T1 and T2 averaged 99 ± 13 days. Participants wore the AFOs for an average of 6.6 ± 4.3 hours/day (24 hours), ranging from 0.5 to 21.6 hours/day. Fig. 2 displays the individual mean values for each participant for both the AFOs and, if prescribed, the thigh shell.

Forty-seven percent (15 participants) wore the AFO for over 6 hours/day. Considering only days when the orthosis was worn, the mean daily wearing time increased to 7.9 ± 3.8 hours/day (1.3–21.6 hours). In Fig. 2, days with AFO usage are represented as percentages above bars relative to the entire measurement period. Fourteen participants (Number 18–32 in Figs. 2 and 3) were prescribed an additional thigh shell. The average wearing time was 4.1 ± 2.5 hours/day, ranging from 1.2 to 9.2 hours/day. Considering actual days worn, the mean increased to 5.9 ± 2.2 hours/day, with a range of 2.9–9.9 hours/day.

Eleven participants were advised to wear the AFO during the day to extend overall wearing time (indicated by blue frames in Fig. 3). Only two participants (26 and 30) wore the AFO for over 6 hours during the daytime.

The outcomes of the mixed ANOVA are presented in Tables 2 and 3. The results indicate that in the compliant group (n = 16) with more than six hours of wearing time per day as average over the 3-month period, there is a significant improvement in the primary outcome, peak ankle dorsiflexion in the stance phase, after three months. There are also significant improvements in the sole angle at initial contact, peak ankle

Table 4
Clinical description of the patients and the orthotics that have been prescribed. The involvement was either bilateral (B) or unilateral (U). The foot deformity were clubfeet (CB), normal feet (NF) and flatfeet (FF).

No	Involvement	Foot deformity	GMFCS	Age	Sex	Body height [cm]	Body weight [kg]	BMI	Passive DF (0° knee)	Active DF (GA)	Spasticity [0 – 4 MAS]	Night/ Day & Night	Thigh Shell	Day orthotics	Gas spring	Increased Body Height [cm]	Increased Body Weight [kg]
1	U	FF	1	9	M	139.0	39.5	20	10	2.1	2	Night	0	Insoles	1	1.2	1.5
2	B	FF	1	10	M	130.0	27.9	17	0	5.9	1	Night	0	Insoles	1	1.8	0.8
3	U	FF	1	11	M	152.2	54.7	24	0	9.3	0	Night	0	Insoles	0	1.3	3.2
4	U	NF	2	14	M	158.0	58.3	23	0	12.5	2	Night	0	AFODF	1	2.0	1.3
5	B	FF	2	13	M	146.0	47.0	22	0	9.7	2	Night	0	Insoles	0	2.0	2.2
6	B	FF	1	12	M	158.0	37.0	15	10	13.4	1	Night	0	Insoles	0	0.5	2.1
7	B	FF	2	9	M	133.5	26.9	15	0	−0.2	1	Day & Night	0	AFO	0	2.5	0.5
8	U	CF	1	14	F	164.5	63.1	23	0	13.3	1	Night	0	AFODF	1	0.0	−2.3
9	B	FF	1	7	F	130.0	28.2	17	5	11.0	1	Night	0	DAFO	0	2.5	0.9
10	U	FF	1	14	F	158.0	63.0	25	0	19.2	2	Night	0	Insoles	0	1.5	−1.9
11	U	FF	2	10	F	136.0	28.5	15	0	−4.7	2	Day & Night	0	AFO	0	0.5	1.7
12	U	FF	2	8	F	137.5	40.0	21	0	−6.3	1	Day & Night	0	AFO	0	3.5	1.4
13	B	FF	2	13	F	163.5	62.5	23	0	6.2	1	Night	0	Insoles	1	0.0	−0.1
14	U	CF	2	10	M	145.0	31.0	15	0	7.7	2	Day & Night	0	AFO	1	−0.5	2.6
15	B	NF	2	15	M	177.0	54.3	17	0	12.2	2	Night	0	0	1	1.0	0.5
16	U	FF	1	13	M	145.0	43.0	20	5	−0.4	1	Night	0	DAFO	0	4.0	1.4
17	U	FF	1	11	M	142.5	30.3	15	−15	−4.4	1	Day & Night	0	AFO	0	−0.2	−0.4
18	U	CF	1	5	M	119.0	24.4	17	10	18.5	1	Night	1	DAFODF	0	1.0	0.8
19	B	FF	2	8	M	134.4	36.0	20	5	8.9	0	Night	1	Insoles	0	1.6	1.2
20	U	NF	1	8	F	134.0	26.1	15	5	6.4	1	Night	1	AFODF	1	1.0	0.9
21	U	CF	2	14	M	156.3	59.6	24	−5	7.8	2	Night	1	AFODF	1	−0.8	2.2
22	B	FF	1	8	M	135.5	31.8	17	0	1.8	2	Night	1	Insoles	1	1.0	0.6
23	B	FF	2	10	M	135.5	29.4	16	−10	3.0	1	Day & Night	1	AFO	0	2.5	2.6
24	U	NF	1	15	F	160.0	57.4	22	0	14.7	1	Night	1	AFODF	1	0.5	−1.0
25	B	NF	2	14	M	169.5	64.2	22	−5	6.5	1	Day & Night	1	AFO	1	1.0	0.8
26	U	FF	1	12	M	149.0	31.0	14	−5	6.8	2	Day & Night	1	AFO	0	1.5	1.8
27	B	FF	1	8	F	140.5	31.1	16	−5	−0.6	2	Day & Night	1	AFO	0	2.5	1.0
28	U	FF	1	6	M	115.0	19.2	15	10	1.8	1	Night	1	DAFO	0	3.0	2.0
29	B	NF	2	13	F	161.0	37.3	14	−10	3.9	2	Day & Night	1	AFO	1	−1.0	0.3
30	B	NF	2	6	M	123.0	23.8	16	0	0.9	2	Day & Night	1	AFO	0	3.5	2.0
31	U	FF	1	12	M	163.0	70.1	26	−5	0.0	1	Night	1	Insoles	1	2.5	4.4
32	B	FF	2	6	F	107.5	17.8	15	0	0.5	1	Night	1	DAFO	0	3.5	0.7

MAS = Modified Ashworth Scale; AFO = ankle-foot orthosis; AFODF = ankle-foot orthosis for drop foot; DAFO = Dynamic ankle-foot orthosis; GA = Gait analysis, DF = Dorsiflexion, DAFODF DAFO and AFODF

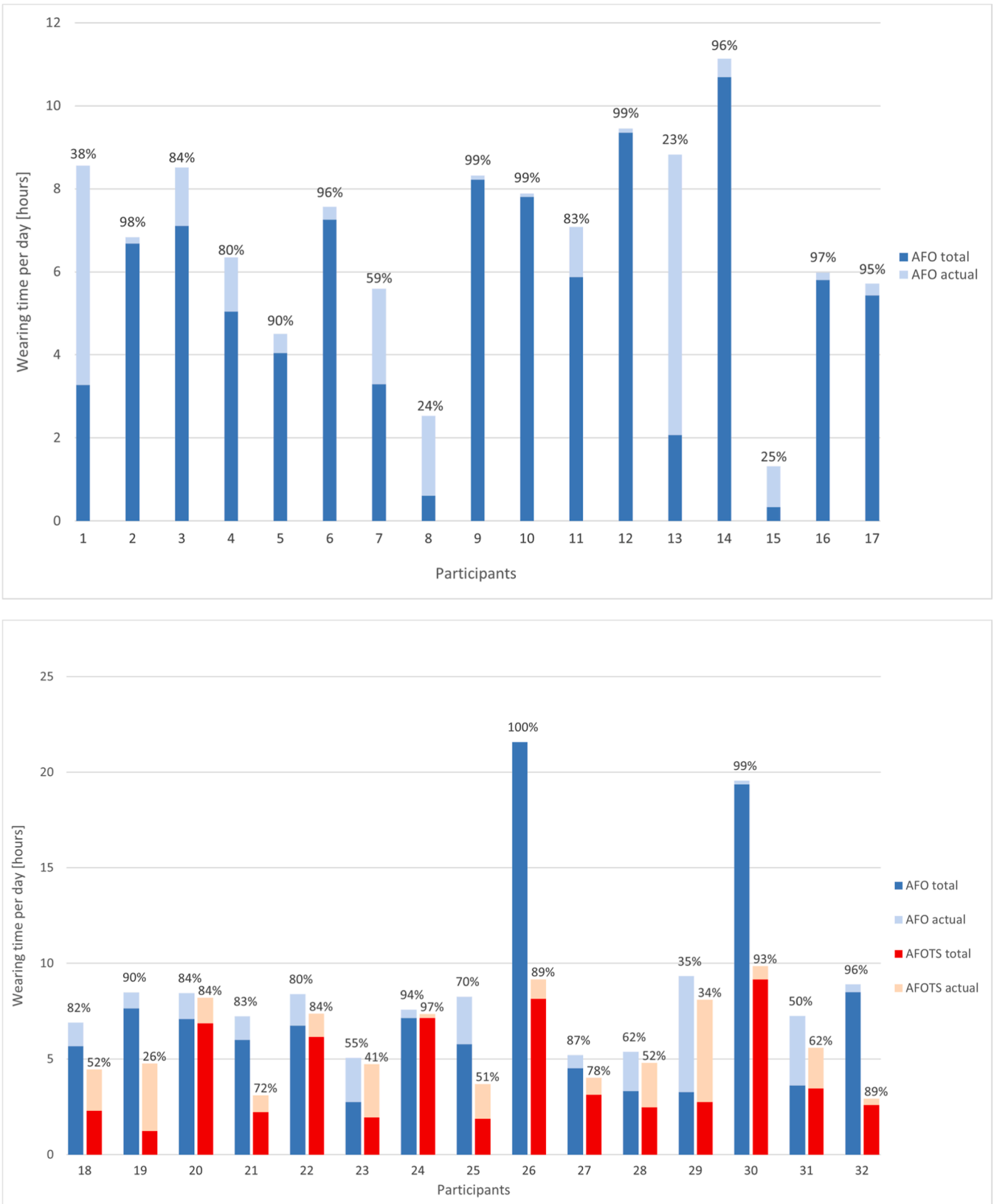

Fig. 2. Mean wearing time of orthoses. Blue bars: mean wearing time (hours per day) related to measurement period for AFO for participants 1 until 32. Red bars: mean wearing time (hours per day) related to measurement period for additional thigh shell for participants 18 until 32. Light bars: mean wearing time (hours per day) related to days of wearing (actual wearing time). Percentages above the bar: Number of days of actual wearing days in relation to the measurement period; AFO=ankle foot orthosis; AFOTS=ankle foot orthosis with thigh shell.

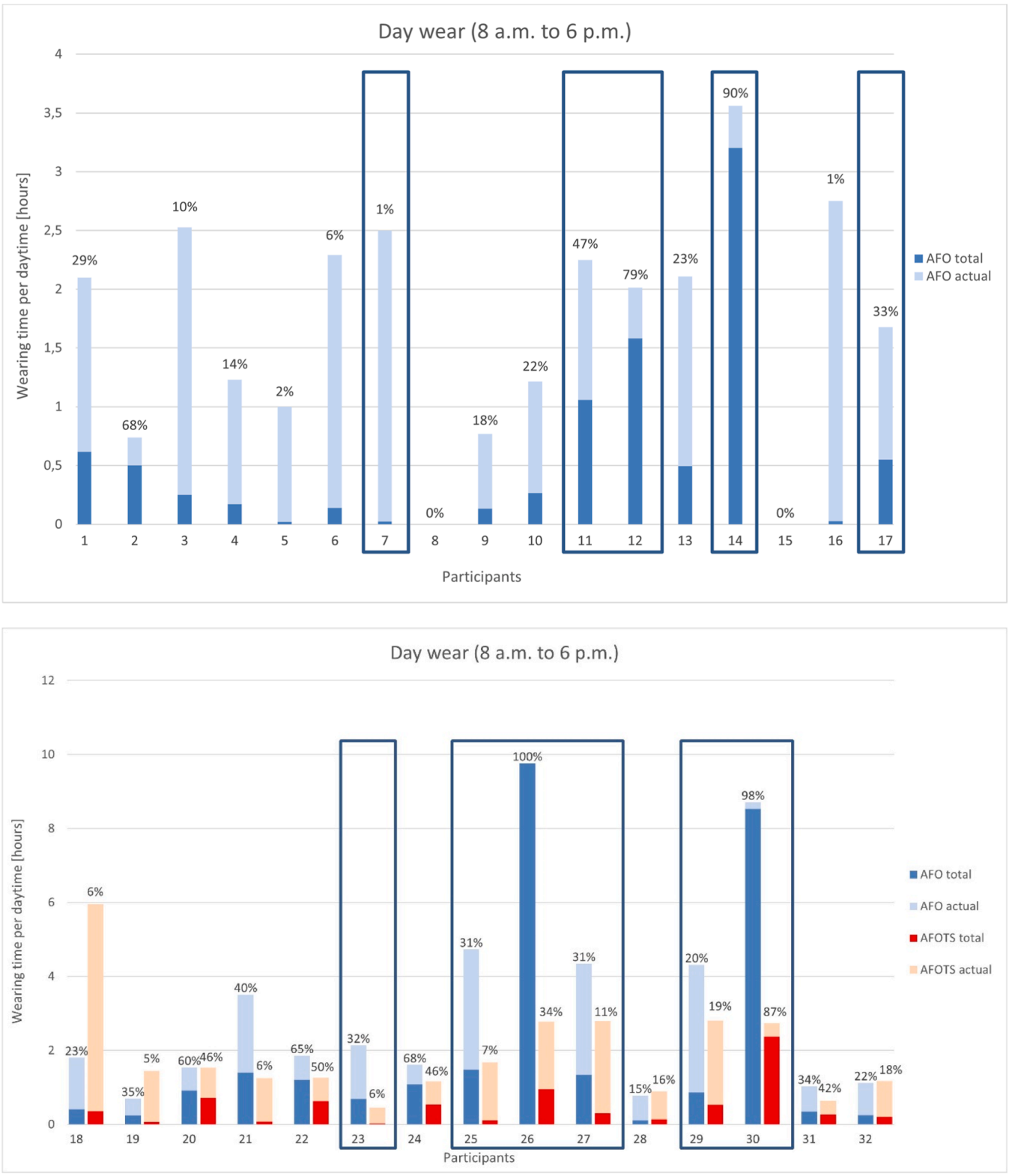

Fig. 3. Mean day wearing time of orthoses. Blue bars: mean wearing time (hours per day) related to measurement period for AFO for participants 1 until 32. Red bars: mean wearing time (hours per day) related to measurement period for additional thigh shell for participants 18 until 32. Light bars: mean wearing time (hours per day) related to days of wearing (actual wearing time). Percentages above the bar: Number of days of actual wearing days in relation to the measurement period Blue frames: Participants with prescribed daytime use. AFO=ankle foot orthosis; AFOTS=ankle foot orthosis with thigh shell.

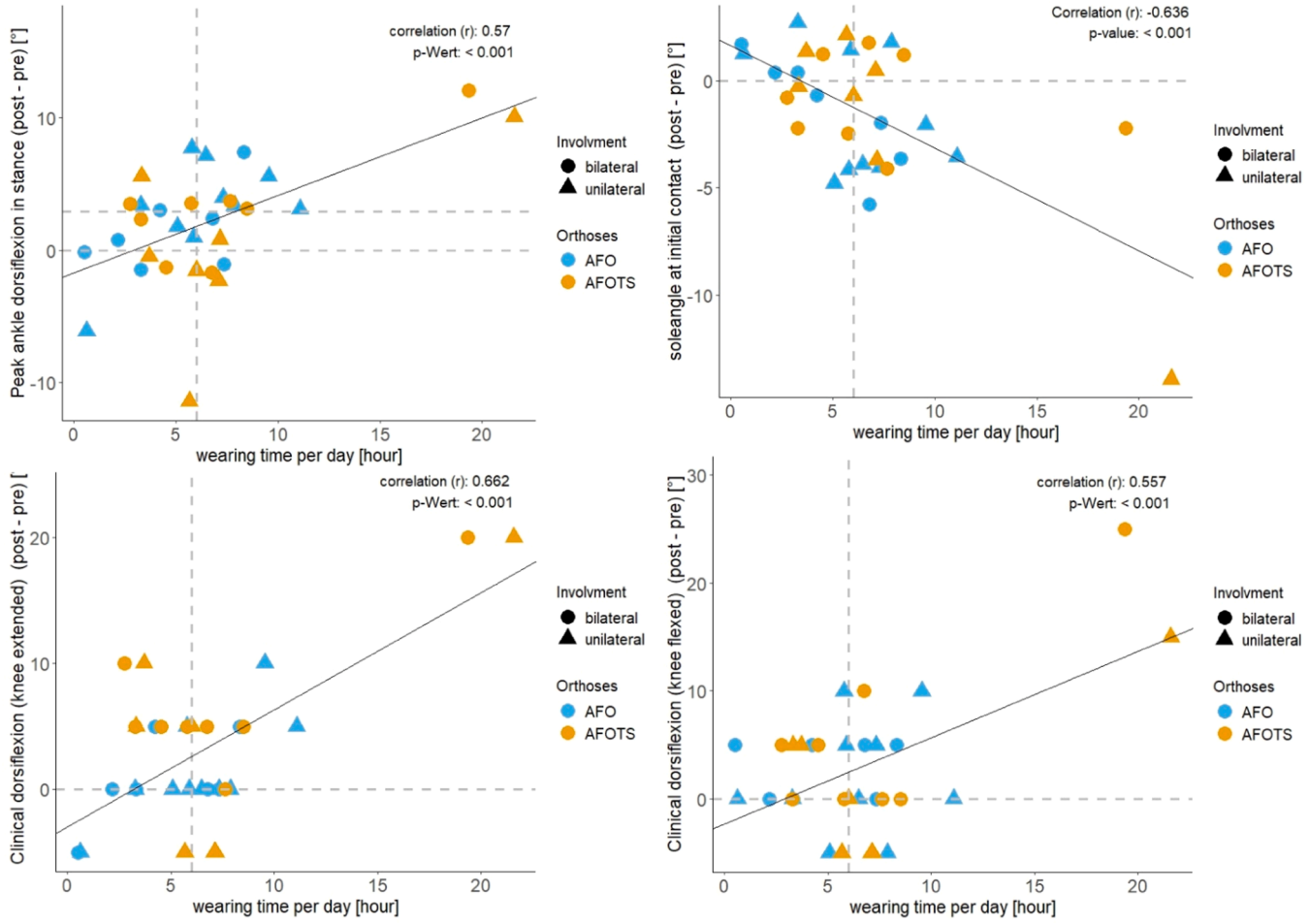

Fig. 4. Longitudinal relationship between wearing time per day of the ankle-foot-orthosis and changes in equinus related parameters. Scatter plots illustrating the examined longitudinal relationships are presented for peak dorsiflexion in stance, sole angle at initial contact (the angle between the surface and the sole), and clinical dorsiflexion with knees extended and flexed. Values are depicted as changes from their preceding values in each 3-month period. Each symbol corresponds to an individual participant, with blue symbols indicating those with ankle foot orthosis (AFO) and red symbols representing participants with an additional thigh shell during the night (AFOTS). For bilateral involvement, the more severely affected side is presented. The vertical line is positioned at 6 hours per day, while the dashed horizontal line is set at 0°, denoting no change in the parameters. The dashed-dotted horizontal line, representing peak ankle dorsiflexion in stance, indicates the Minimal Detectable Difference (MDD) at 2.9°. Regression lines are plotted as solid lines for all participants. AFO=only ankle foot orthosis; AFOTS=ankle foot orthosis with thigh shell.

dorsiflexion in swing, and peak plantarflexion moment in the first half of the stance. In the non-compliant group (n = 16), there are no significant changes between before and after treatment.

When measured with knee extension, the clinical parameters reveal a notable enhancement in passive dorsiflexion within the compliant group. An improvement in the dorsiflexion measured at 90 degrees of knee flexion was observed in the non-compliant group. The correlation between the daily wearing time of AFO and changes in gait- and clinical-related parameters is depicted in Fig. 4. The intersection point of the regression line at the recommended 6 hours per day suggests a value of 1.8°; this is lower than the MCDD of 2.9°. To attain the MCDD, wearing the AFO for approximately 7.8 hours per day is recommended, as the regression line indicates. The zero point, denoting no difference between post and pre-assessments and identified by the intersection with the regression line, produces distinct values for various parameters: peak ankle dorsiflexion occurs following orthotic wearing time of 2.9 hours/day, sole angle at initial contact at 3.5 hours/day, ankle dorsiflexion at 90° knee flexion at 2.8 hours/day and ankle dorsiflexion at 0° knee flexion at 3.2 hours/ day.

4. Discussion

Our first hypothesis, that compliance is less than 50 % of patients wearing the orthotics shorter than prescribed by the physician, can be confirmed. The second hypothesis can also be confirmed that a minimum of more than 6 hours/day significantly improves 3.3° (SD=4.0°). The improvement in the concomitant group reaches the MCDD of 2.9°.

Examining the correlation in greater detail between the duration of wearing time and the improvement in peak ankle dorsiflexion, it is clearly evident that a longer wearing time may result in a more favourable outcome. However, according to the regression line, a 7.8 hours/day wearing time is required to achieve the clinically relevant improvement (MCDD) of 2.9°, while wearing the device for 6 hours per day resulted in an improvement of 1.8°.

The advancements observed in this study align with those found in other research investigating the impact of a 3-month orthotic bracing period. Hösl et al. [8] demonstrated an average improvement of 2° in ankle dorsiflexion during stance [8]. Similarly, Maas et al. [11] reported a 1.7° improvement in the angle between the longitudinal axis of the leg and foot sole at the midstance of gait [11]. However, these authors did not measure the wearing time. As the effectiveness of the orthosis strongly depends on the duration of wear, their results should be

interpreted with caution.

Unfortunately, just under half of the participants achieve the commonly prescribed 6 hours/day in the literature. Similar findings were reported by Schwarze et al. [18], where the wearing time was significantly below the recommended duration. Nearly one-third of participants wore the orthosis for less than four hours on average per day. This is even shorter than the typical sleep duration in children, suggesting that in some cases, the orthosis was removed shortly after bedtime, possibly due to discomfort, sweating, itching, cramps, stiffness, or the KAFO rubbing against the opposite leg. Participants extending daytime orthosis usage showed limited acceptance, with only two surpassing 6 hours. Assessing daytime wear between 8 a.m. and 6 p.m., when most activity occurs, proved challenging due to diverse daily rhythms in the 5–15 age group. Bar charts in Fig. 3 indicate some wore the orthosis for an extended time during the defined period despite no recommendation. Participants may have rested while wearing the orthosis during the day.

The thigh shell's average wearing time is 4.1 ± 2.5 hours/day, lower than the AFO. This indicates lower tolerance for the thigh shell, leaving the question of its effect on the gastrocnemius muscle unanswered. Maas et al. [11] also reported similar findings regarding the wearing time of KAFO, with an average duration of 3.2 ± 1.9 hours/day [11]. Only one participant wore the KAFO for 6 hours per prescribed night. They identified some reasons for the low acceptance in the analysis of orthosis acceptance questionnaires, with the main factors being pain due to muscle stretching and pressure sores. Additional reasons included a hot or sweaty leg, itching, cramps, stiffness, or the KAFO hitting or rubbing against their contralateral leg.

However, AFO decreases muscle thickness when the gastrocnemius is not stretched, making muscle fascicles shorter [8]. The question of whether it is advisable to allow more movement in knee flexion to reduce discomfort but potentially increase the wearing time has already been mentioned by Maas et al. [11] and remains unanswered [11].

4.1. Limitations

Our study did not collect information regarding the acceptance of orthoses to gain insight into the reasons for the low wearing time. However, it is reasonable to assume that similar results would have emerged in a survey, as reported by Maas et al. [11].

The Minimal Clinically Important Difference (MCID) denotes the slightest change in a clinical outcome measure that holds significance and meaning from the patient's perspective. Unfortunately, the MCID for orthotic treatment in equinus deformity has not been established. Consequently, we attempted to calculate the Minimal Clinically Detectable Difference (MCDD) and employed it as a reference parameter for a meaningfully relevant change.

During the study period, the participants' body height increased on average by 2 cm; despite this, no deterioration of the equinus deformity was observed.

Physiotherapy prescription was not changed during the intervention period and was identical for all patients. While this approach ensured consistency in the prescribed treatments across all participants, variations in its delivery might have occurred, as different physiotherapists provided the therapy to different patients. This variation could introduce subtle differences in the treatment experience due to individual physiotherapists' expertise, techniques, and patient interactions.

It is challenging to create a control group, as children with cerebral palsy and equinus deformity are typically treated conservatively with orthotics and physiotherapy. Since these children are in a growth phase, a period of three months without therapy could potentially lead to a prolonged worsening of equinus. Therefore, this study compared the effect of consistent orthotic treatment with that of a group who wore the orthoses infrequently.

5. Conclusion

Our results show that only 47 % of the participants achieved the desired wearing time of six hours/day. Additionally, there is low compliance with the thigh shell and daytime orthosis usage.

However, wearing time does impact equinus deformity, highlighting the necessity of identifying factors influencing wearing behaviour to derive measures for extending wearing time.

Funding

This research was supported by rege e.V, a German support association for the rehabilitation and health of spastic paralysed and movement-impaired children and adolescents. The sponsor had no involvement in this work.

CRediT authorship contribution statement

Chakravarthy U. Dussa: Writing – review & editing, Resources. **Daniela Lewens:** Writing – review & editing, Resources. **Leonhard Döderlein:** Writing – review & editing, Conceptualization. **Matthias Hösl:** Writing – review & editing, Funding acquisition, Conceptualization. **Harald Boehm:** Writing – review & editing, Supervision, Methodology, Formal analysis, Conceptualization. **Claudia Oestreich:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Formal analysis, Conceptualization. **Renate Oberhoffer-Fritz:** Writing – review & editing, Methodology.

Conflict of interest

None of the authors have financial or personal relationships with others or organisations that inappropriately influence this work.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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