Johan Gravdal

Change in performance of gait related physical tests with application of an orthotic solution in children with GMFCS level I or II and hemiplegia – an explorative study

Master's thesis in Physical Activity and Health
Supervisor: Karin Roeleveld
December 2022

Master's thesis

NTNU
Norwegian University of Science and Technology
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Children diagnosed with spastic hemiplegia usually experience gait restrictions and are less physical active and participate significantly less in sport than their peers.

- 16 participants
- AGE: 6 – 13 years
- GMFCS: Level 1: n=15, Level 2: n=1

Orthoses, such as AFO and FES, are commonly used to correct misalignment and help with loss of muscle function to improve gait.

Activities

Children's daily activities includes movements beyond gait on even ground, and children who frequently uses orthoses has reported to not wanting to use it in vigorous activity due to discomfort and being limited.

Movements typically represented in children's daily activity

- Walking (self-selected speed)
- Walking (maximum speed) — Significant decreased performance for FES users (p=0.013)
- Running speed
- Broad jump — Statistical trend of decreased performance for all (p=0.06)
- Sudden change of direction — Significant decreased performance for all (p=0.029), and a trend for AFO users (p=0.054)
- Transition from floor
- Transition from chair — Statistical trend of decreased performance for all (p=0.069)
- Walking in stairs

Conclusion

- Small decreasement in performance in some tests are seen with the use of orthosis
- There is no indication that the orthosis affected discomfort while performing the tests

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ABSTRACT

Background: Ankle foot orthosis (AFO) and functional electrical stimulation (FES) are commonly used orthoses for improving gait in children with spastic hemiplegia. However, children's daily activities include movements beyond gait on even ground, and few studies have examined the effect of the orthosis on the performance of such activities which are important for participation with typical developing (TD) peers.

Aim: The main aim is to see how the use of orthosis affects performance of different physical tests including movements typically represented in children's daily activities. We would also like to investigate if the use of orthosis affects discomfort while performing the physical tests.

Method: 16 participants, age 6 – 13 years, using an orthosis on regular basis (9 AFO, 7 FES) were recruited. They were diagnosed with spastic hemiplegia and had level I or II on the Gross Motor Function Classification System (GMFCS). Participants were instructed to perform eight different physical tests, including walking in self-selected speed and maximum speed, running, running with sudden change of direction, jumping, transition from floor and chair, and walking in stairs. Each participant conducted the tests twice, once with their orthosis and once without, in randomized order. Discomfort while performing the tests was reported in form of "Face Pain Scale" (FPS). To investigate the effect of the orthotic solutions, we conducted a paired t-test on the performance with and without the orthoses for AFO and FES users as a combined group and also separate groups.

Results: FES users decreased performance in "1 minute walk test" when wearing FES (p=0.013). There was also a significant decrease in performance for the combined groups in "10x5 meter shuttle run" with the use of the orthosis (p=0.029). A statistical trend of decreased performance was shown in "timed up and go" (p=0.069), and "broad jump" (p=0.06) for the combined groups with the use of the orthosis, and in "10x5 meter shuttle run" for AFO users separately (p=0.054).

Conclusion: From our results, there is no indication that AFO or FES improves performance of gait related physical tests in children with GMFCS level I or II. There seems to be a small decrease in performance in some tests, but likely of minor clinical importance. This does not exclude the possibility for individual improvements nor improvements in other ICF domains with the use of orthosis, for example to reduce energy expenditure.

SAMMENDRAG

Bakgrunn: Ankel - fotortoser (AFO) og “functional electrical stimulation” (FES) er ortoser som ofte blir tilpasset barn med spastisk hemiplegi for å forbedre gangen. Barns daglige aktiviteter består for øvrig av flere bevegelser enn kun gange på flatt underlag, og få studier har sett på effekten av ortosen på prestasjon i slike aktiviteter, som er viktige for deltakelse med normalt utviklende (TD) jevnaldrende.

Mål: Hovedmålet er å se hvordan bruken av ortose påvirker prestasjon i forskjellige fysiske tester som inkluderer bevegelser typisk representert i barns daglige aktiviteter. Vi ønsker også å undersøke om bruken av ortose påvirker ubehag under utførelse av de fysiske testene.

Metode: 16 deltakere, alder 6 – 13 år, som bruker ortose på daglig basis (9 AFO, 7 FES), ble rekruttert. De var diagnostisert med spastisk hemiplegi og hadde nivå I eller II på “Gross Motor Function Classification System“ (GMFCS). Deltakerne ble instruert til å utføre åtte forskjellige fysiske tester, inkludert gange i selvvalgt hastighet og maks ganghastighet, løping, løping med raske vendinger, hopping, forflytning fra gulv og fra stol, og gange i trapp. Hver deltaker utførte testene to ganger, én gang med ortosen og én gang uten, i randomisert rekkefølge. Ubehag under gjennomføring av testene ble rapportert i form av “Face Pain Scale” (FPS). For å undersøke effekten av ortoseløsningen, gjennomførte vi en paret t-test på prestasjon med og uten ortose for AFO- og FES-brukere som en kombinert gruppe og også som separerte grupper.

Resultater: FES-brukere hadde en statistisk signifikant redusert prestasjon i “1 minute walk test” (p=0.013) med bruk av FES. Det var også en signifikant reduksjon i prestasjon for kombinert gruppe i “10x5m shuttle run” (0=0.029) med bruk av ortose. En statistisk trend i redusert prestasjon ble vist i “timed up and go” (0.069) og “broad jump” (p=0.06) for kombinert gruppe med bruk av ortose, og i “10x5m shutte run” (p=0.054) for AFO-brukere separert.

Konklusjon: Fra våre resultater er det ingen indikasjon på at AFO eller FES forbedrer prestasjon i gangrelaterte fysiske tester for barn med GMFCS nivå I eller II. Det ser ut som det er en liten reduksjon i prestasjon i noen tester, men sannsynligvis av liten klinisk betydning. Dette ekskluderer ikke muligheten for individuelle forbedringer eller forbedringer i andre ICF-domener med bruk av ortose, for eksempel for å redusere energiforbruk.

Acknowledgements

A great thanks to Karin Roeleveld, my supervisor at the Norwegian University of Science and Technology's Department of Neuromedicine and Movement Science. I've learned a lot through this process and collaboration, and I am truly grateful for the guidance you've given. Also, a great thanks to Tobias Goihl and Siri Merete Brændvik for your comments and inputs in this thesis.

Thanks to Kristin Lie, for a good cooperation with the recruitment and data collection. Hope you'll find a relevant and inspirational job, whether it is in Trondheim or somewhere else.

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Thanks to Drevelin AS in Bergen, and especially Frøydis Jensen for welcoming me to do data collection there, helping me with recruitment of participants, as well as the carrying out of the tests.

Lastly, thanks to my wife, Solveig Gravdal, for listening and discussing the thesis and proofreading, even though I know you don't find it as interesting as I do.

Abbreviation

AFO = Ankle foot orthosis

CP = Cerebral palsy

CPO = Certified Prosthetist and Orthotist

FES = Functional Electrical Stimulation

GMFCS = Gross Motor Function Classification System

ICF = International Classification of Functioning, Disability and Health

NTNU = Norges Teknisk-Naturvitenskapelige Universitet (Norwegian University of Science and Technology)

REK = Regionale Komiteer for Medisinsk og Helsefaglig Forskningsetikk (Regional Committee for Medical and Health Research Ethics)

ROM = Range of Motion

TD = Typically developing

TOV = Trøndelag Ortopediske Verksted

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1 INTRODUCTION

1.1 BACKGROUND

Orthoses for lower extremities are commonly prescribed for children with neuromuscular deficits, such as cerebral palsy, to assist individuals with gait impairments (Lusardi & Bowers, 2013). The orthosis will either limit or assist movements and range of motion (ROM) in the ankle and foot joints (Morris, 2002) in order to improve gait. The ankle foot orthosis (AFO) encompasses the ankle, foot and leg segment (ISO, 2020), and controls the joint mechanically. It´s usually made out of plastic or composite material and can either be with or without a hinge. Functional electrical stimulation (FES) is another orthotic solution used for children with a mild gait impairment (El-Shamy & Abdelaal, 2016; Reed, 1997). In FES, a cuff is placed under the knee which stimulates the peroneus nerve that activates dorsiflexors so that the foot is lifted in the swing phase (Binder-Macleod & Lee, 1997) (see Table 2 for illustrations).

According to the yearly report from the Norwegian Cerebral Palsy registry (CPRN) and Cerebral Palsy follow up program (CPOP) (later merged to NorCP), approximately 60% of ambulatory children are fitted with orthoses in Norway, where AFO is the most commonly used (Andersen et al., 2019). Cerebral palsy (CP) is primarily a disorder of movement and posture (Sankar & Mundkur, 2005), and while as much as 70% of children with CP are able to walk, they all experience varying degrees of restrictions related to this function (Andersen et al., 2008). Spastic unilateral CP (hemiplegia) is the largest subtype of CP (Andersen et al., 2008) and common conditions that may cause gait deviations are spasticity, muscle contractures, weaknesses, bony deformities and impaired motor control (Khamis et al., 2018). The degree of gait related restriction is divided in a five-level clinical classification, Gross Motor Function Classification System (GMFCS), that describes the gross motor function in different settings, particularly sitting, standing and walking (Palisano et al., 1997). The less affected children, classified as level I, are mostly unrestricted and can accomplish most activities as their typically developing (TD) peers (Morris, 2002). However, with lower level of function in speed, balance and coordination (Palisano et al., 1997). For those with level II, some gross motor skills such as running and jumping might be even more limited, but they are still able to achieve daily activities without the need of any hand-held mobility device (Palisano et al., 1997). These limited functions can cause further limitations in activity and participation. Children with CP is found to be less physical active and participate significantly less in sport then their TD peers (Nooijen et al., 2014; Obeid et al., 2014; van Wely et al., 2012), and only 25% meet the public health recommended level of physical activity (Mitchell et al., 2015).

Few studies have looked into the direct effect of orthosis on activity and participation (Bjornson et al., 2016; Firouzeh et al., 2021). There are, however, correlations between energy efficiency during gait and activity limitation (Kerr et al., 2008; Maltais et al., 2005), and we know that improved gait and gross motor function have an impact on autonomy and participation (Bjornson et al., 2014). The aim of an orthosis when prescribed is usually to correct and align the foot segment (body structure) to enable the child to establish an efficient and symmetrical gait (body function), with the potential to enhance participation in activities and functional skills (Bjornson et al., 2014; Morris, 2002; Wingstrand et al., 2014). This is in the framework of International Classification of

Functioning, Disability and Health (ICF) (WHO, 2001) and is commonly used in clinical settings to provide an overview of how body structure and -function connects and impacts activity and participation (Rosenbaum, 2009).

The use of AFO for children with neuromuscular deficits like CP is found to improve gait parameters such as stride length, gait symmetry and single limb support, as well as increase speed and reduce oxygen consumption (Aboutorabi et al., 2017; Lintanf et al., 2018). However, it is argued that solving one problem with an orthosis can create another (Lusardi & Bowers, 2013). For example, orthoses with an aim in the body structure domain can restrict movements such as floor mobility, resulting in more challenging daily routines and imposing activity limitation (Autti-Rämö et al., 2006; Morris, 2002). Research on FES has found it to improve selective motor control, balance, walking speed and gait kinematic (Bailes, 2014; Zhu et al., 2022), and is reckoned to be a good alternative to AFO for those with hemiplegia (Prenton et al., 2016).

The use of AFO declines after the age of five (Wingstrand et al., 2014). User perception and self-report indicates that AFO is used at a low degree in vigorous activity by children with GMFCS I, due to discomfort and experienced stiffness of the orthosis causing limitations, according to two previous master thesis (Heggenhougen, 2021; Lie, 2022). This was, however, not the case for FES users (Lie, 2022). Although GMFCS includes walking in stairs, running, transitional movements and jumping in the description of classification of the lower levels, there is a lack of studies on the effect of orthosis in these types of movements (Firouzeh et al., 2021; Kane et al., 2016; Moll et al., 2017). Children with low level of GMFCS participate in daily activities that generally involves high-level gross motor skills. This includes running, jumping and skills acquiring sudden change of direction, which are important for their social participation (Clutterbuck et al., 2020). Measures involving more complex walking demands may be informative to clinicians (Kane et al., 2016).

1.2 Research aim

The main aim of this thesis is to investigate how the use of orthosis affects performance in different physical tests including movements typically represented in children's daily activities, for those commonly using an AFO or FES. We would also like to investigate if the use of orthosis affects discomfort while performing the physical tests, registered in form of Face Pain Scale (FPS).

1.3 Hypothesis

Based on former literature on orthosis use, we expected that AFO and FES will increase walking speed. However, in more dynamic tasks which involves more ankle movement the AFO might be restrictive. It is reasonable to think that FES is less restrictive in more dynamic movements, since it doesn't encompass the ankle mechanically. We expect AFO to cause some degree of discomfort while performing some of the tests, since this was reported as a reason for not wanting to use the orthosis in physical activity.

2 METHOD

2.1 PARTICIPANTS

Participants were recruited through the register of Trøndelag Orthopedic Workshops (Trøndelag Ortopediske Verksted, TOV) for Trøndelag and Ålesund, and through Drevelin Ortopedi AS in Bergen, and the physical tests were conducted at these three locations. Inclusion criteria were children with spastic hemiplegia. Ataxic and dyskinetic CP were exclusion criteria, since we wanted to ensure a homogeneous group with a closely related gait pattern. Diplegia was excluded since both gait pattern and orthosis design can differ from those with hemi-plegia, and the use of orthosis on both feet makes it uncertain whether is the one or the other that affects the results. The age span included was from 6 – 13 years, since this is when the use of orthosis starts to decline. Only children with a GMFCS-level of I or II were included, in order to be able to carry out all the physical tests without the need of any hand-held aid. They had to be able to understand and follow specific instructions in order to be included. The recruitment process lasted from August 2021 to March 2022.

2.2 SAMPLE SIZE

Calculation for sample size was done for a two-sided paired t-test for comparison of difference in performance with and without orthosis, measured in velocity. A mean difference of 10% in walking speed (0.1 m/s) is estimated to be of clinically relevance in walking (Schwartz et al., 2004). To detect a 10% increase in walking speed, with a power of 80% (using a two-sided paired t-test and a 5% significance level), thus reflecting a clinically significant improvement, 10 participants with the same type of orthosis are needed in each group. Taking correction for multiple variable testing and including participants with both GMFCS level I and II, 20 were considered sufficient.

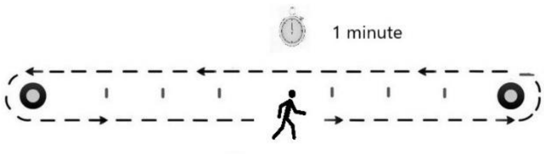
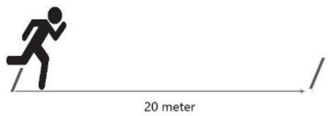
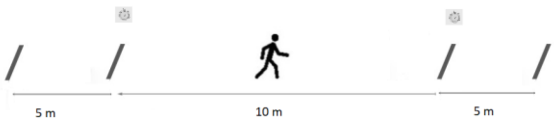
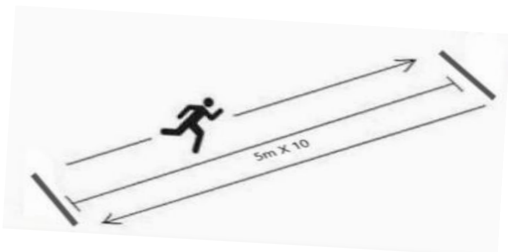
2.3 PROTOCOL AND PROCEDURE

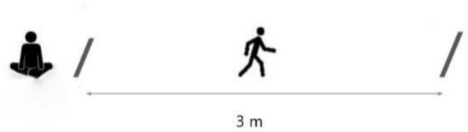
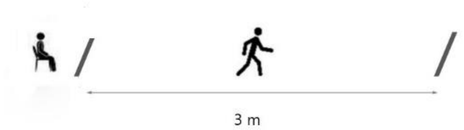
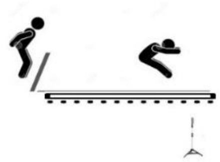
The study was approved by the Regional Committee for Medical and Health Research Ethics (REK #283727) and the university institute's privacy impact assessment. Data was stored on the NTNU server.

This study was part of a larger protocol contributing to two different master thesis projects at the Norwegian University of Science and Technology (NTNU). Only the protocol relevant to this study will be described.

Written consent was obtained from participant's parents or guardians, since all participants were under the age of 16. They were informed that they could withdraw from the study at any time without giving a reason.

TABLE 1: PHYSICAL TESTS INCLUDING MOVEMENTS TYPICALLY REPRESENTED IN CHILDRENS DAILY ACTIVITIES. FOR EACH OF THE EIGHT TESTS, THE TEST NAME AND ABBREVIATION, REFERENCE TO THE FULL PROTOCOL WITH VALIDATION, AND A SHORTER DESCRIPTION OF THE TEST WITH ILLUSTRATION IS GIVEN.

Test	Reference	Description
1 minute walk test *(1 min-wt)*	Wiedmann et al. (2021)	The participant was instructed to walk as fast as possible, without running, for 1 min. Distance (in meters) was marked and measured afterwards with a measuring wheel and used to determine maximum walking speed (m/s). 
20 meter run *(20m run)*	Fjørtoft et al. (2011)	The participant was instructed to run as fast as possible for 20 meters, a distance marked with tape. Time required to run the distance was measured (in seconds) and used to determine running speed (m/s). 
10 m walk test (self-selected speed) *(10MWT)*	Kane et al. (2016)	The participant was instructed to walk at a comfortable, self-selected speed between the same tape marks as the 20m run test. The time was measured when they crossed a tape mark after 5 meter acceleration and stopped when they crossed the tape mark 5 meter before the end. Time required to walk 10 m was measured and used to determine self-selected walking speed (m/s). 
10x5 meter shuttle run *(10x5m shuttle run)*	Fjørtoft et al. (2011)	The participant was instructed to complete 10 runs of 5m at a maximum speed. The participant had to cross a taped line with at least one foot. Each lap was counted out loud (by examiner), in order to keep track. Time required to perform the task was measured in seconds. 

Floor to stand test	Weingarten and Kaplan (2015)	The participant was asked to sit on the floor with legs crossed. On the count of three, the child would stand up, walk (not run) 3 meters crossing a tape mark, turn around and go back and sit back down. The clock was stopped when the participant was seated with legs crossed behind the mark, and the time required was registered in seconds. 
Timed Up and Go Test *(TUaG)*	Carey et al. (2016)	The participant was instructed to sit on a chair (without armrest). At "go", the participant would stand up, walk (not run) 3 meters crossing a tape mark, turn around and go back to sit back down on the chair. Time was measured in seconds. 
Broad jump	Fjørtoft et al. (2011)	The participant was instructed to stand with his or her feet parallel and shoulder width apart behind an exercise mat. When ready, the participant would swing their arms back and forth and jump as far as possible. The jump was filmed in order to see the landing and the meter stick, and the distance was measured in centimeters to the nearest 5-cm. 
Timed stair test	Dallmeijer et al. 2017	The participant started at the end of a staircase and asked to walk controlled up 5 steps (marked with tape) and down again, with help from handrail if needed. Time was measured in seconds. 

Eight different test that involved movements commonly represented in children's daily activities were chosen (see Table 1), including walking at self-selected speed, maximum walking speed, running, sudden change in direction, transition from both floor and chair, jumping and walking in stairs. The tasks were conducted in the same order as shown in Table 1. The children were taken through each task before conducting it, and if the instructions weren't followed, they were asked to perform the task one more time. They were only given one successful try on each test, except for broad jump, which was conducted twice, and where the best result was noted.

After every test the participants were asked to point out the amount of discomfort or pain they were feeling during the test in form of Face Pain Scale (FPS). FPS is a figurative scale, showing six different faces, illustrating discomfort or pain ranging from zero to five, where five is the highest degree of pain (illustrated in first row of Table 8 in results) (Hicks et al., 2001). Experienced discomfort or pain could either be from the orthosis or just from conducting the test.

The participants were frequently asked if they wanted a break or drink some water not to get exhausted. This was evaluated individually by the researcher so that it didn't get too time-consuming, nor let the children get demotivated to perform their best.

The participants were divided in equal numbers of who started with orthosis and who started without, and with equal numbers of FES and AFO users in each group.

2.4 DATA ANALYSIS

To investigate the effect of the orthotic solutions, we conducted a paired t-test on the performance with and without the orthoses for AFO and FES users as a combined group and also separate groups. Correction for multiple testing wasn't done since this study is explorative, but taken into consideration for result interpretation. 95% CI with p-values of the paired difference between the performance with and without orthosis is reported for the total group, and for the children using either AFO or FES separately. Both statistically significant results and statistical trends (close to statistically significant) are highlighted.

95% CI of the performance without orthosis is reported in results with comparison to data of TD peers obtained from other articles. Radar charts are also included, illustrating the participants performance with and without orthosis relative to TD peers. This was illustrated by setting mean performance of TD peers of each test as 100%, and the participants results as relative percentage.

Number of participants perceiving discomfort during each of the eight test is reported. Degree of discomfort or pain ranging from zero degree to five, illustrated with faces expressing different degrees of discomfort/pain.

3 RESULTS

3.1 PARTICIPANTS

Approximately 65 children who met the inclusion criteria were given information about the project, either by mail or at a clinic, whereby 16 ended up participating (eight in Trondheim, five in Bergen and three in Ålesund). Every participant had spastic hemiplegia. All but one participant was diagnosed with CP, which was diagnosed after the age of two, and therefore not technically a CP diagnosis. There were 11 boys and five girls, ranging from 6 to 13 years with a mean age of 10. years (SD = 2.12). All but one had GMFCS I, who had GMFCS II. Mean height was 147.4 cm (SD = 12.07) and mean weight was 40.5 kg (SD = 11.35). Equal number of participants had affected right and left side.

TABLE 2: PARTICIPANT CHARACTERISTICS

	ALL	**FES**		**AFO**	
Number of participants	16	7		9	
Type of orthosis		Alfess^{TM*} 3	Alfes** 4	Carbon fibre 2	Co-polymer 7
Age *(Mean ± SD)*	10.3 ± 2.12	10.86 ± 1.68		9.89 ± 2.42	
BMI *(Mean ± SD)*	18.3 ± 2.90	17.69 ± 2.96		18.82 ± 2.92	
Time since last botulinum toxin injection *(BoNT/botox)*		Median: 2 months (2 had never been treated with botox)		Median: 1 year (1 had never been treated with botox)	
Wearing orthosis at first attempt	7	3		4	
Wearing orthosis at second attempt	9	4		5	

* ONE UNIT WITH INCORPORATED ELECTRODES (ALFIMED AS)

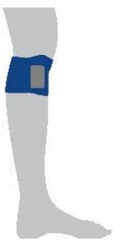
** SMALLER VERSION WITH DETACHABLE TEXTILE CUFF (ALFIMED/SHENZHEN XFT MEDICAL LIMITED, HAMBURG, GERMANY)

The children fitted with a new type of orthotic solution were given some weeks to accustom before conducting the tests. A few participants conducted the tests after having been fitted with a new AFO, but only if it was a type of AFO they were familiar with. They were also given some time to test it while walking and for adjustment to be made if needed. As the researcher is a certified prosthetist and orthotist (CPO), small adjustments were done when the participants expressed the need, but without interfering with other CPO's work and aim, or at someone else's workplaces. The participants were using their own orthosis, and choice, fit and function was not evaluated since we can assume that this was done by the CPO that did the initial fitting.

3.2 Orthosis description

Seven out of 16 had FES, more specifically ALFESS™ or ALFES Foot Drop System (Alfimed AS/Shenzhen XFT Medical Limited, Hamburg, Germany) (see Table 3 for description). Nine had custom made hinged AFO, where two were made of carbon fiber with unilateral NEUROSWING® mechanical ankle joint (Fior&Gentz, Lüneburg, Germany) and the rest were made with 2-3 mm copolymer plastic with bilateral Tamarack Flexure® ankle joint (Tamarack Habilitation Technologies, Inc, Minnesota, USA) (see Table 3 for illustration). One participant had an orthosis mounted on the shoe while performing the tasks the first time, but later received a FES orthosis. Since the first type of orthosis was unlike the others in the AFO group, and there was a need for more participants in the FES user group, this child participated a second time with FES. Only results from this try were included in the analysis.

TABLE 3: ORTHOSIS DESCRIPTION USED BY PARTICIPANTS, WITH ABBREVIATION AND ILLUSTRATION

Type of AFO	Abbreviation	Illustration	Description
Ankle foot orthosis	AFO		Hinged AFO made of 2-3 mm copolymer plastic with bilateral rubber Tamarack joint and plantar flexion stop.
		 Source: Fior&Gentz, Lüneberg, Germany www.Fior&gentz.de	Hinged AFO made of carbon fiber with unilateral metal joint from Fior&Gentz.
Functional electrical stimulation	FES		Microprocessor cuff with electrical stimulation of peroneus nerve from Alfimed. Both Alfess (one unit with incorporated electrodes) and Alfes (smaller version with detachable textile cuff) was used.

3.3 Test results

Results from the eight different tests including movements common in children's daily activities shows there is a significant decrease in gait speed in 1 min-wt with the use of FES compared to no orthosis (by 9.3 %, p=0.013) (see Figure 2 and 3, and Table 6). There is also a significant decrease in performance for the combined groups in 10x5m shuttle run with the use of orthosis (by 4.7 %, p=0.029) (see Figure 2 and 3, Table 4). A statistical trend for decreased performance is shown in TUaG (p=0.069) and broad jump (p=0.060) for the combined groups, and in 10x5m shuttle run for AFO users separately (p=0.054) (see Figure 2 and 3, Table 4 and 5).

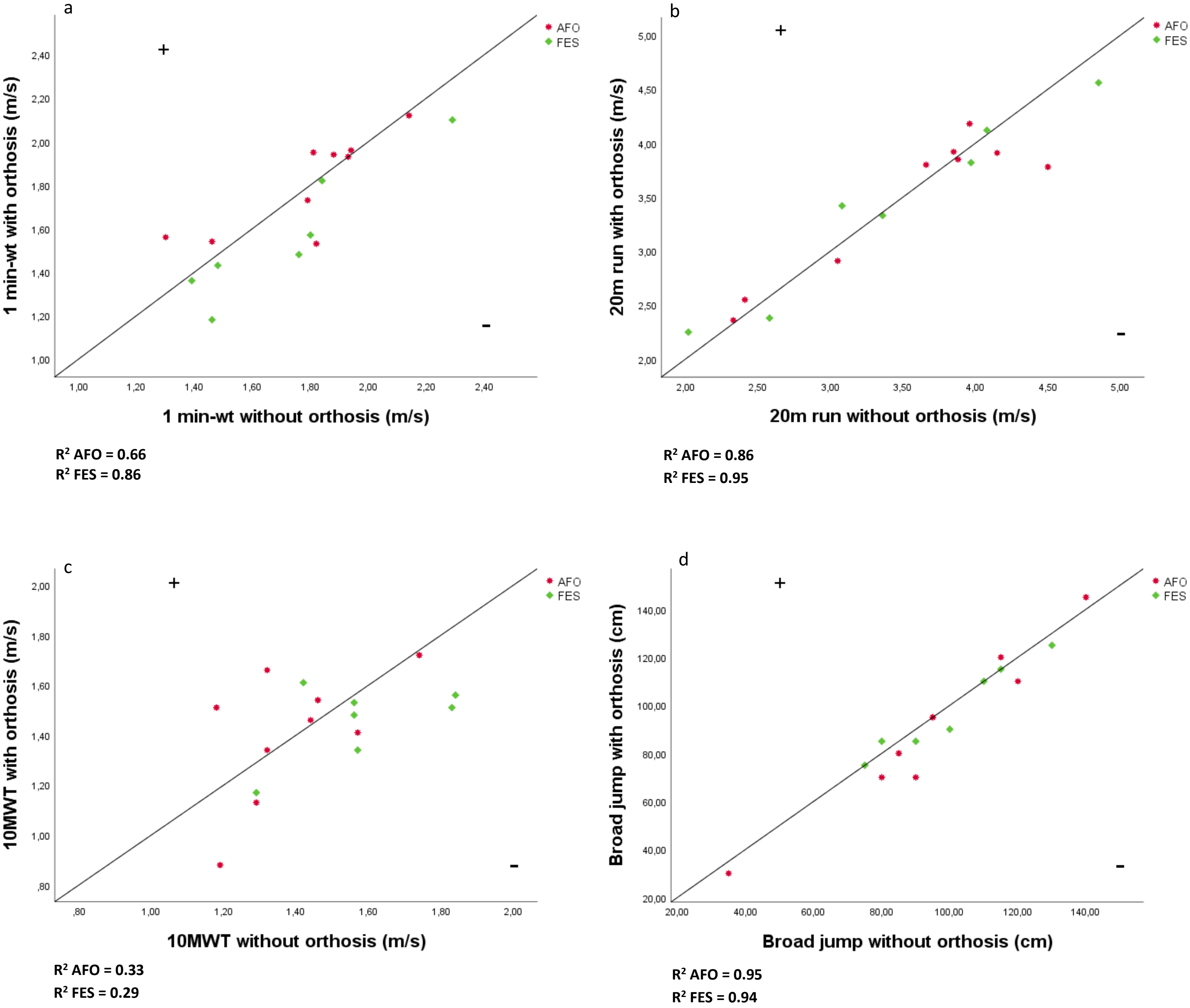
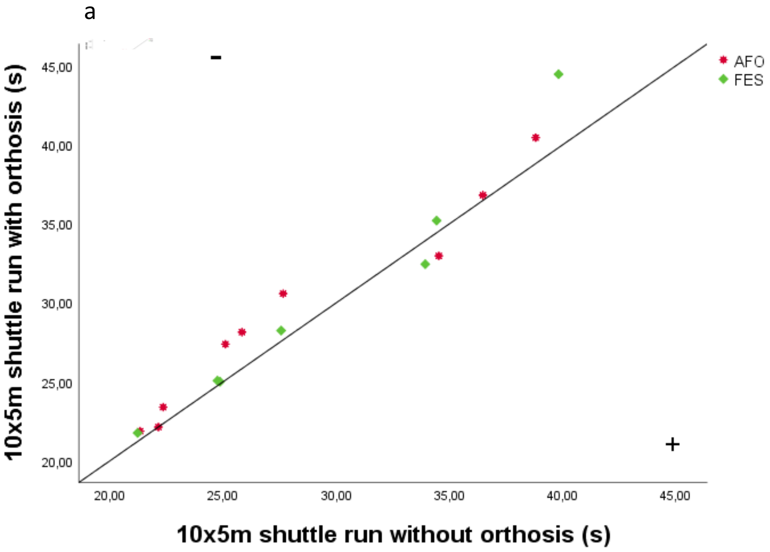
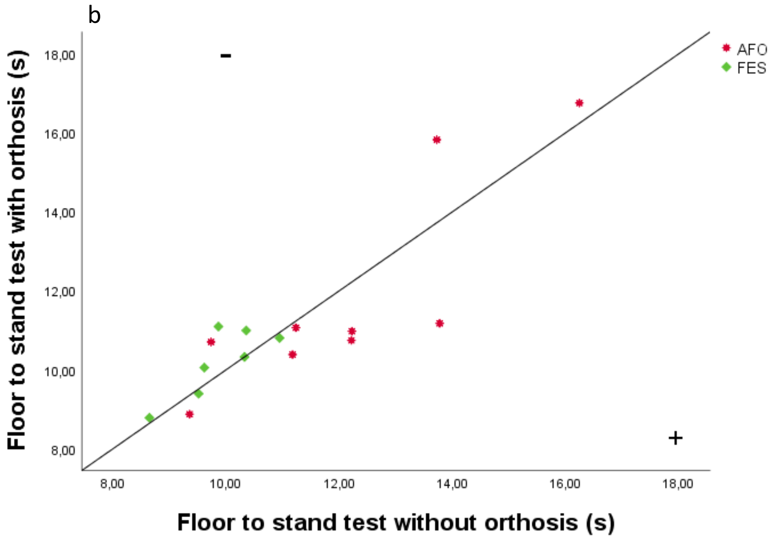


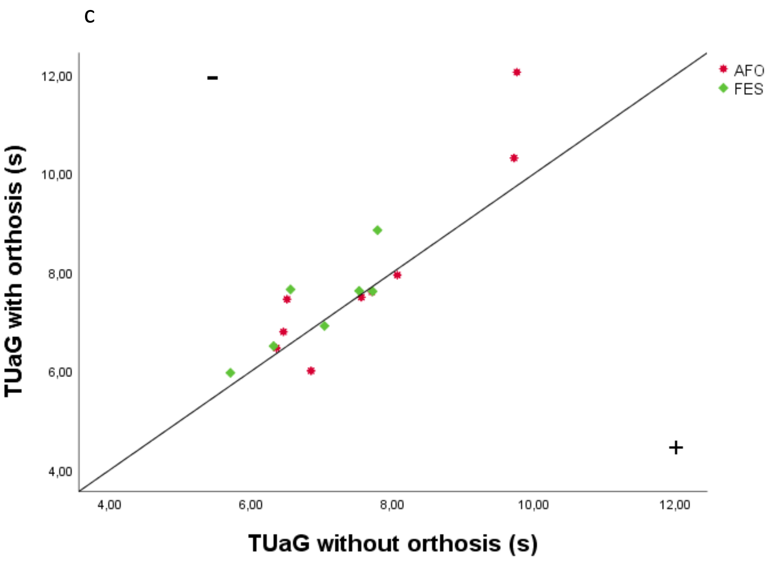
Figure 2a-d: Scatterplots with all the participants performance with and without orthosis in relation to each other. These four tests measure spatial movements, and larger numbers indicates better performance. Performance is improved when above the line of equality (black line as X=Y), indicated with a + sign. Explained variance (R^2) of the relation is inserted in the figure. Results if corresponding paired t-tests can be found in Table 4 - 6.



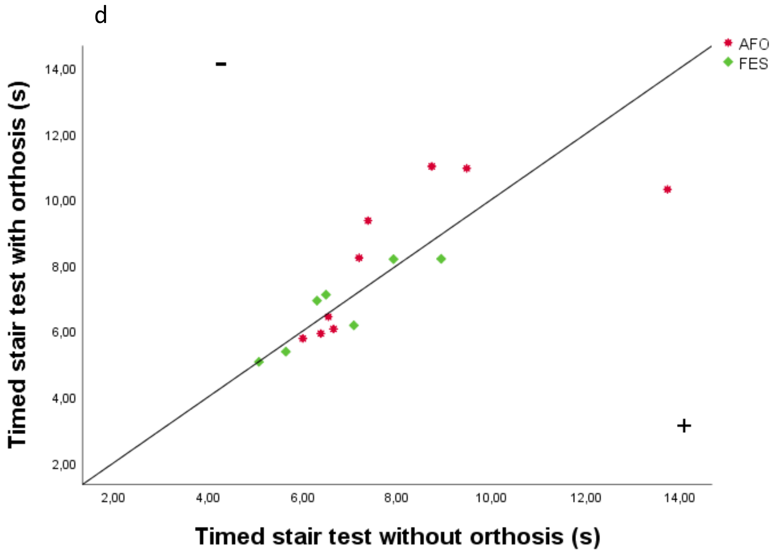
R^2 AFO = 0.96
R^2 FES = 0.96



R^2 AFO = 0.71
R^2 FES = 0.67



R^2 AFO = 0.85
R^2 FES = 0.70



R^2 AFO = 0.85
R^2 FES = 0.70

FIGURE 3A-D: SCATTERPLOTS WITH ALL THE PARTICIPANTS PERFORMANCE WITH AND WITHOUT ORTHOSIS IN RELATION TO EACH OTHER. THESE FOUR TESTS MEASURE TEMPORAL MOVEMENTS, AND LOWER NUMBERS INDICATES BETTER PERFORMANCE. PERFORMANCE IS IMPROVED WHEN BELOW THE LINE OF EQUALITY (BLACK LINE AS X=Y), INDICATED WITH A "+" SIGN. EXPLAINED VARIANCE (R^2) OF THE RELATION IS INSERTED IN THE FIGURE. RESULTS IF CORRESPONDING PAIRED T-TESTS CAN BE FOUND IN TABLE 4 - 6.

Figure 2a-d and 3a-d show a positive relation for the performance with and without orthosis, shown by plots falling close to the line of equality. The line of equality represents the null hypothesis, which is no difference in performance with and without orthosis (x=y). Most tests show no difference in performance with and without orthosis, as approximately equal numbers of participants fall on each side of the line of equality. For 1 min-wt, every FES users falls below the line, and all but two participants is above the line in 10x5m shuttle run, indicating a decrease in performance with orthosis. Both these results were statistically significant (see Table 4 – 6). Figure 2d and 3c shows a statistical trend of decreased performance with orthosis in broad jump and TUaG, respectively, as most participants falls on the negative side of the line (indicated with a "-"sign). Floor to stand test was the only test that had improvement with the use of orthosis for the combined groups (by 0.5%). Floor to stand test was the test where AFO users had the most improvement with the use of orthosis (by 2.9%). Coefficient of determination (R^2) is presented in each graph to show the strength of the relationship between the linear model and the depended variables.

TABLE 4: MEAN PERFORMANCE RESULTS WITH STANDARD DEVIATION (SD) FOR COMBINED GROUP ON EACH PHYSICAL TEST, WITH AND WITHOUT ORTHOSIS. CHANGES IN PERFORMANCE RESULTS IS NEGATIVE WHEN MEAN RESULTS ARE WEAKER WITH THE USE OF ORTHOSIS THAN WITHOUT. 95% CI OF MEAN DIFFERENCE AND P-VALUE ARE INCLUDED.

Test	**Mean performance with SD (with orthosis)**	**Mean performance with SD (no orthosis)**	**Changes in performance result with orthosis**	**95% CI of the difference with and without orthosis**	**P-value**
1 min-wt (m/s)	1.70 ± 0.28	1.76 ± 0.27	- 0.06	[-0.141 , 0.030]	0.186
20m run (m/s)	3.45 ± 0.73	3.48 ± 0.83	- 0.03	[-0.173 , 0.100]	0.574
10MWT (m/s)	1.43 ± 0.22	1.47 ± 0.21	- 0.04	[-0.156 , 0.064]	0.390
Broad jump (cm)	93.75 ± 27.29	97.19 ± 25.10	- 3.44	[-7.041 , 0.167]	0.060 **
10x5m shuttle run (s)	29.73 ± 6.87	28.79 ± 6.47	- 0.94	[-0.110 , 1.779]	0.029 *
Floor to stand test (s)	11.12 ± 2.16	11.18 ± 2.02	0.06	[-0.663 , 0.539]	0.829
TuAG (s)	7.70 ± 1.58	7.34 ± 1.15	- 0.36	[-0.032 , 0.742]	0.069 **
Timed stair test (s)	7.56 ± 1.99	7.47 ± 2.06	- 0.09	[-0.618 , 0.804]	0.784

** STATISTICALLY SIGNIFICANT*

*** STATISTICAL TREND*

TABLE 5: MEAN PERFORMANCE RESULTS WITH STANDARD DEVIATION (SD) FOR AFO USERS ON EACH PHYSICAL TEST, WITH AND WITHOUT ORTHOSIS. CHANGES IN PERFORMANCE RESULTS IS NEGATIVE WHEN MEAN RESULTS ARE WEAKER WITH THE USE OF ORTHOSIS THAN WITHOUT. 95% CI OF MEAN DIFFERENCE AND P-VALUE ARE INCLUDED.

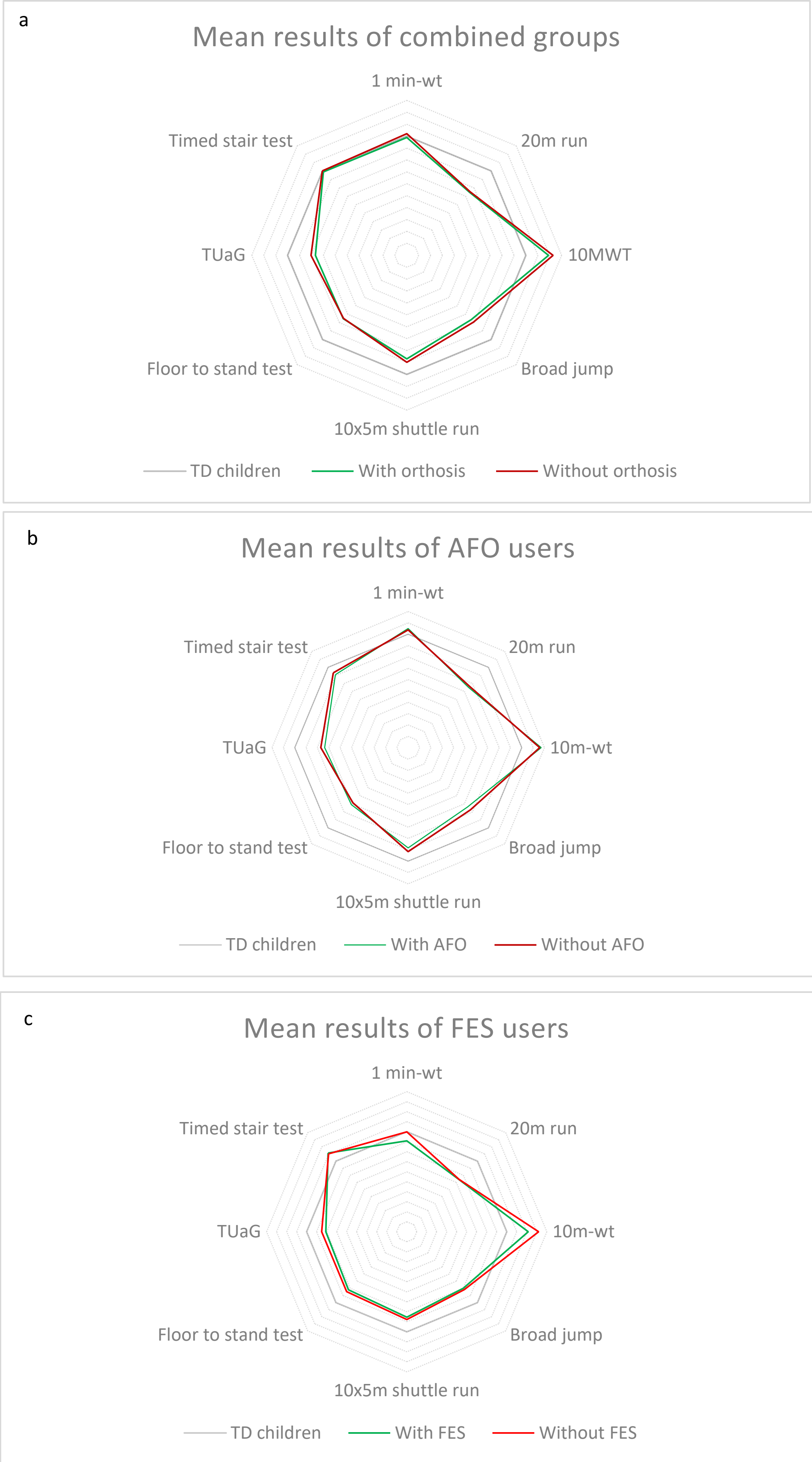
Test	Mean performance with SD (with orthosis)	Mean performance with SD (no orthosis)	Changes in performance results with AFO	95% CI of the difference with and without orthosis	P-value
1 min-wt (m/s)	1.81 ± 0.22	1.79 ± 0.26	0.02	[-0.095 , 0.137]	0.685
20m run (m/s)	3.47 ± 0.67	3.53 ± 0.76	- 0.06	[-0.280 , 0.162]	0.555
10MWT (m/s)	1.41 ± 0.26	1.39 ± 0.18	0.02	[-0.151 , 0.183]	0.835
Broad jump (cm)	90.56 ± 33.30	95 ± 29.58	- 4.44	[-10.66 , 1.766]	0.137
10x5m test (s)	29.29 ± 6.54	28.24 ± 6.66	- 1.05	[-0.021 , 2.132]	0.054 *
Floor to stand (s)	11.83 ± 2.63	12.18 ± 2.16	0.35	[-1.435 , 0.729]	0.473
TuAG (s)	8.01 ± 1.95	7.66 ± 1.32	- 0.35	[-0.328 , 1.035]	0.266
Timed stair test (s)	8.22 ± 2.23	8.01 ± 2.42	- 0.21	[-1.121 , 1.550]	0.721

* *STATISTICAL TREND*

TABLE 6: MEAN PERFORMANCE RESULTS WITH SD FOR FES USERS ON EACH PHYSICAL TEST, WITH AND WITHOUT ORTHOSIS. CHANGES IN PERFORMANCE RESULTS IS NEGATIVE WHEN MEAN RESULTS ARE WEAKER WITH THE USE OF ORTHOSIS THAN WITHOUT. 95% CI OF MEAN DIFFERENCE AND P-VALUE ARE INCLUDED.

Test	Mean performance with SD (with orthosis)	Mean performance with SD (no orthosis)	Changes in performance results with FES	95% CI of the difference with and without orthosis	P-value
1min-wt (m/s)	1.56 ± 0.31	1.72 ± 0.31	- 0.16	[-0.263 , -0.046]	0.013*
20m run (m/s)	3.41 ± 0.86	3.42 ± 0.96	- 0.01	[-0.221 , 0.204]	0.925
10MWT (m/s)	1.46 ± 0.15	1.58 ± 0.20	- 0.12	[-0.286 , 0.037]	0.109
Broad jump (cm)	97.86 ± 18.68	100.00 ± 19.79	- 2.14	[-6.656 , 2.370]	0.289
10x5m shuttle run(s)	30.30 ± 7.77	29.50 ± 6.67	- 0.80	[-0.921 , 2.524]	0.298
Floor to stand test (s)	10.20 ± 0.86	9.89 ± 0.74	- 0.31	[-0.147 , 0.773]	0.147
TuAG (s)	7.30 ± 0.94	6.94 ± 0.79	- 0.36	[-0.121 , 0.835]	0.117
Timed stair test (s)	6.71 ± 1.25	6.78 ± 1.33	0.07	[-0.629 , 0.503]	0.795

* STATISTICALLY SIGNIFICANT



FIGUR 4A-C: RADAR CHART OF MEAN PERFORMANCE WITH AND WITHOUT ORTHOSIS (GREEN LINE AND RED LINE, RESPECTIVELY) RELATIVE TO AVERAGE PERFORMANCE OF TYPICALLY DEVELOPING (TD) CHILDREN (GREY LINE). GREEN AND RED LINE FALLING ON GREY LINE INDICATES SAME PERFORMANCE AS TD CHILDREN.

Data of TD peers was obtained from other articles and compared to mean results from this study (see Figure 4a-c and Table 7). Figure 4a-c shows mean performance with and without orthosis relative to average performance of TD peers. This is to give an indication of how well the children with CP are able to participate with their healthy counterparts. We were not able to obtain data on TD children in timed stair test, as most test conditions were done with 10-14 steps instead of five. Normative data is therefore calculated as mean result from all participants, without orthosis. Mean performance results are generally lower for children with spastic hemiplegia. However, our study population did not perform statistically different from the average TD peers obtained from other articles, as mean difference of zero is a possible outcome in 95% CI (see table 7). The use of orthosis seems to not affect performance of physical tests including movements beyond walking on even ground in participation with TD peers.

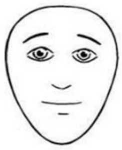
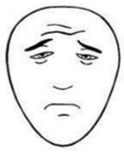
TABLE 7: PARTICIPANTS MEAN PERFORMANCE WITH STANDARD DEVIATION (SD) WITHOUT ORTHOSIS COMPARED TO THE AVERAGE OF TYPICALLY DEVELOPING (TD) PEERS FROM LITERATURE. SD FOR TD IS GIVEN WHERE THIS WAS POSSIBLE TO OBTAIN. EACH PHYSICAL TEST WITH MEASURE UNIT AND REFERANCE TO ARTICLE WHERE AVERAGE TD RESULT IS OBTAINED. 95% CI OF MEAN DIFFERENCE AND AGE OF TD IS INCLUDED.

Tests with reference to TD results	**Mean performance without orthosis**	**Average TD results from literature**	**Mean difference ***	**95% CI**	**Age of TD**
1 min-wt (m/s) *Wiedmann et al. (2021)*	1.76 ± 0.27	1.72 ± 0.29	0.04	[-0.57 , 0.64]	Mean: 7.6 ± 3.0 years Range: 3 – 12 years
20m run (m/s) *Fjørtoft et al. (2011)*	3.48 ± 0.83	4.62 ± 0.40	- 1.14	[-2.96 , 0.68]	Mean: 8.3 ± 2.21 year Range: 5 – 12 years
10MWT (m/s) *Kane et al. (2016)*	1.47 ± 0.21	1.2	0.27	[-0.18 , 0.73]	Mean: 7.8 ± 3.4 years
Broad jump (cm) *Fjørtoft et al. (2011)*	97.19 ± 25.10	122.54 ± 19.41	- 25.35	[-80.49 , 29.79]	Mean: 8.3 ± 2.21 year Range: 5 – 12 years
10x5m shuttle run (s) *Fjørtoft et al. (2011)*	28.79 ± 6.47	25.87 ± 2.03	- 2.92	[-11.30 , 17.14]	Mean: 10 ± 1.13 year Range: 8– 12 years
Floor to stand test (s) *Itzkowitz et al. (2016)*	11.18 ± 2.02	7.05	- 2.80	[-1.64 , 7.24]	Mean: 7.28 years Range: 5 – 13
TUaG (s) *Aboutorabi et al. (2017)*	7.34 ± 1.15	6.60 ± 1.1	- 1.44	[-1.07 , 3.96]	Mean: 8.3 ± 2.21 year Range: 5 – 12 years
Timed stair test (s)	7.47 ± 2.06	Not possible to obtain normative data			

** PARTICIPANTS MEAN PERFORMANCE WITHOUT ORTHOSIS COMPARED TO TD. NEGATIVE VALUE SHOWS DECREASED PERFORMANCE FOR PARTICIPANTS.*

The majority of the participants did not perceive discomfort in specific tests or between trials (with and without orthosis). We did not find any difference of expressed discomfort between AFO and FES users. They expressed slightly more discomfort with the use of orthosis, but in broad jump and TUaG, some also expressed more discomfort not wearing the orthosis. One participant expressed high degree of discomfort (4) from the AFO in all but one test.

TABLE 8: FACE PAIN SCALE (FPS). NUMBER OF PARTICIPANTS PERCEVING DISCOMFORT DURING EACH OF THE EIGHT TESTS AS INDICATED BY THE FPS.

							
		0	**1**	**2**	**3**	**4**	**5**
1 min-wt	W	12	2	2			
	WO	15	1				
20m run	W	13	2			1	
	WO	14	2				
10MWT	W	13	2			1	
	WO	15	1				
Broad jump	W	15				1	
	WO	14	1	1			
10x5m shuttle run	W	12	2	1		1	
	WO	14	1	1			
Floor to stand test	W	15				1	
	WO	16					
TUaG	W	15				1	
	WO	15	1				
Timed stairs test	W	15				1	
	WO	16					

W = WITH ORTHOSIS, WO = WITHOUT ORTHOSIS. PARTICIPANTS POINTING AT THE FACE MOST TO THE LEFT INDICATING THE LEAST DISCOMFORT (ZERO).

4 DISCUSSION

We wanted to examine how the use of orthoses affects performance of different physical tests including movements frequently used in children's daily activities. We expected an increase in walking speed for primary school children with hemiplegia with the use of AFO and FES (Aboutorabi et al., 2017; Zhu et al., 2022). We also expected a decrease in performance with AFO use in tests involving more dynamic movements, but not with FES use since the latter doesn't physically restrict ankle movement (Autti-Rämö et al., 2006; Heggenhougen, 2021; Lie, 2022; Morris, 2002). Result from this study showed a statistically significant decrease of maximum walking speed for FES users in 1 min-wt with the use of orthosis, which is somewhat surprising. The tests 10MWT and 1 min-wt were included even though they both are "walking on even terrain". This was done since we wanted to see if there were any differences between AFO and FES, also at the basic gait pattern, and walking speed is an important factor for the children when they are trying to keep up with their peers in play. Previous studies on FES' effect on gait speed are to some degree contradictory. A literature review done by Moll et al. (2017) included three articles where gait speed was examined with the use of FES for children with CP. Two found no effect (Orlin et al., 2005; Pool et al., 2015) and one described significant decrease (van der Linden et al., 2008). Van der Linden et al. (2008) included children with both hemiplegia and diplegia and did not describe the level of GMFCS. They also examined the effect of FES on other muscle groups, such as quadriceps, which makes it difficult to compare to our study.

We expected an increase in walking speed for AFO users, but results from our study showed no differences in neither self-selected walking speed nor maximum speed. Both literature reviews done by Aboutorabi et al. (2017) and Lintanf et al. (2018) found increased walking speed in children with hemiplegia with the use of hinged AFO. It seems, however, that most included studies examined self-selected walking speed, and few looked into maximum walking speed. The plantar flexors are important for propulsion at push-off and hence gait velocity (Winter, 1992). The reason why we did not see any change with the use of AFO might have been that most participants used a co-polymer AFO with plantar flexion stop, to prevent foot drop in swing phase. There might therefore be limited range of motion (ROM) for propulsion at push-off. Participants using a carbon-fiber orthosis with spring loaded mechanical joint might have a had a better effect at maximum gait speed, but with only two participants using this type of AFO, we did not see an indication for this. Our results on fast waking speed for FES users might also be due to the plantar flexors contribution in propulsion. The stimulus to the dorsiflexors might have been given to early when the user is just about to use the plantar flexors for propulsion. The ALFESS-system used in this study is based on XFT-2001EB, and gyro-recognition that will automatically recognize the foot's position, walking speed and changes in terrain (ALFESS™, 2021). In smart mode, the orthosis will calculate when to start the electrical stimulation and when to stop based on collected data from the patients first four steps (ALFESS™, 2021). It still gives a stimulus at the end of stand phase, but the timing might not be optimal. For tests such as timed stair test, TUaG, floor to stand test and 10x5m shuttle run, the distance might be too short for the FES to recognize the movement pattern before it is changed. Other types of FES that have a foot switch which is placed in the shoe to determine initial contact, might give a more precise stimulus for dorsiflexion at push-off in the gait cycle. None of the tests with transitional movements showed any change with the use of FES in this study.

Results from 10x5m shuttle run for all participants showed a statistically significant decrease in performance with the use of orthosis. Result from AFO users isolated showed a statistical trend in decreased performance with the use of orthosis, which was in accordance with the hypothesis. A statistical trend was also shown in TUaG and broad jump, where performance results decreased with the use of orthosis for all.

Discomfort is reported as a reason for not wanting to use the AFO in vigorous activity (Heggenhougen, 2021). We wanted to quantify the experienced discomfort and see if it was caused be the orthosis. A few participants expressed some degree of discomfort while performing some of the tests, but this was the case both with and without orthosis. We therefore found no reason that the use of orthosis affected discomfort or pain while performing the physical tests. There was, however, one participant expressing high degree of discomfort with the use of AFO on several of the tests, which was caused by the orthosis. We did not differentiate between AFO and FES in results of FPS (Table 8), as there were few pointing at second and third face (one and two, respectively), and we did not find any clear indication of which orthosis causing most discomfort. AFO can cause shear forces or pressure when doing dynamical movements, or when the orthosis is outgrown. FES can also cause discomfort when giving electrical stimuli, particularly when not expecting it. This can be the case when for example transitioning from floor and the gyroscope detects an angle of the shank that is equal to that of toe-off in stand phase. A loosely fitted FES can also cause electrical shock to the skin surface, and not to the deeper nerve.

Performance of the children with hemiplegia in this study are generally lower than average TD peers, which was expected. The data on TD children is obtained from former studies and is not a control group. The test conditions and mean age of TD peers differ slightly from this study, but it gives a generally guidance of how the participants performed compared to TD children. Timed stair test is usually done with 10 – 14 steps, but in order to execute the test in various locations (the participants house if needed), this study used five steps. It is therefore no data on TD children for this test. Better performance for participants in this study compared to average TD peers at 10MWT and 1 min-wt might be due to a longer acceleration-/deceleration distance, and higher age span, respectively.

4.1 Validity and reliability

The mean performance with the use of AFO was better in floor to stand test but worse in TUaG, which is somewhat contradictory, since it is reasonable to think that standing up from floor requires more ankle ROM than transitioning from a chair. It seems that most tests have a high reliability, indicated by a high R^2-value (see Figure 2 and Figure 3). The correlation and thus the explained variance between the performance with and without orthosis in 10MWT was somewhat low, and could indicate variance in orthosis effect or low reliability of the test.

1 min-wt was validated on children with bilateral spastic CP (diplegia) (McDowell et al., 2005). They state that if the study had recruited children with unilateral spastic CP or children not attending an orthopedic service, a ceiling effect would likely have been more noticeable. The 1 min-wt was the most time-consuming test and maybe also one of the more physical demanding one, except from 10x5m shuttle run. If, as McDowell et al. (2005) points out, this test reaches a ceiling effect, it might be reasonable to think that a ceiling effect is also the case why we didn't see any significant change in result in any other tests. Clutterbuck et al. (2020) argues that some of the outcome measures used on ambulant children with CP can reach a ceiling effect and might not identify limitations in high-level motor skills used in sport activities. This could also be the case for this study.

Kane et al (2016) claims that TUaG differentiates between GMFCS I-III and scores correlates with scores on both 10MWT and timed stair test. However, tests performed at fast speed and those involving obstacles and curbs may be more appropriate than TUaG and 10MWT for children with lower GMFCS (Kane et al., 2016).

Weinberg et al. (2010) argues that the floor to stand test might be a better measure than TUaG for the highly ambulatory children with CP since it is said to have a more face validity, meaning it tests what it is supposed to test, as the task frequently occurs in school setting. Zaino et al. (2004) discusses that Timed Up and Down Stairs test (with 14 steps) shows a wider range of scores across functional mobility levels, and might be better than TUaG to measure change across time or between intervention.

4.2 Strength and weaknesses

The tests were chosen with consideration of not being too demanding so that the children wouldn't be able to perform on the last test(s), or too time consuming so they would get demotivated. The tests were also chosen in order to be able to be carried out at several places, for example at their own homes if they couldn't travel to participate.

Sample size calculation were based on a homogenous sample of 20 participants. However, we ended up with 16. The results are best interpreted in divided groups based on orthosis type, since it is reasonable to think that the restriction of an orthosis is different from a hinged AFO and a FES, and therefore performance in the different tests. A copolymer AFO with rubber joint (Tamarack Habilitation Technologies, Inc, Minnesota, USA) will allow for more torsion than carbon fiber with a metal joint (Fior&Gentz, Lüneburg, Germany), so the two divided groups are also not completely homogenous.

This study examined the orthotic effect and not the therapeutic effect of FES, meaning the immediate effect and not the long-term effect when the orthosis is taken off after a period of use. A "carry-over effect" might be seen with use of FES-orthoses, meaning that some muscle activation is still present when the orthosis is taken off (Dunning et al., 2012). It is possible that the FES users have improved in some of the test from when they initially started using the orthosis, due to a therapeutic effect, and the effect between the two trails is not seen when performing without orthosis due to the carry-over effect. FES users performed better than AFO users without orthosis in six out of eight tests (see Table 5 and Table 6) This could also be due to more recent botox-injection for FES users, slightly higher mean age, or lower BMI (see Table 2 and 7).

We did not include ROM of lower extremity joints, description of gait pattern, details about trimlines and angles of the AFOs and orthotic aim. These are elements argued to be reported in guidelines of best practice when doing research on orthosis (Ridgewell et al., 2010). This could have been done to assure that the study is replicable. However, this was an explorative study and the participants were using their own orthosis in both trials. We did not test the effect of one orthotic solution up against another, but how the orthosis fitted for the participants affected performance in tests with movements typically represented in children's daily activity.

The data was considered to not having to be normalized to height, since we compared the results of performance of the same individuals, with and without orthosis. If we were too compared FES against AFO, we would have to normalize to height and using a repeated measures ANOVA with orthoses type as a factor. It might also have been better to normalize the data to the whole range of 95% percentile of TD data when doing comparison for participation. >95% could be defined as excellent, 50% as average (same as mean results for TD children) and <10% as poor performance. For further studies, we encourage to include a control group. The data used were from other articles, collected on TD children with approx. the same mean age and test conditions. On 1 min-wt, the age range was from 3 – 12 years of age, which is a lot considering there is an increase of gait speed with increasing age (Fritz & Lusardi, 2009).

5 Conclusion and future direction

With no difference with and without orthosis in most tests and statistical significant decrease in performance in 1 min-wt for FES users and 10x5m shuttle run for all, there were no results that reached what is seen to be clinically relevant (10%) (Schwartz et al., 2004). The 10% mark was set by Schwartz et al. (2004) as a minimum improvement for it to be worth undergoing surgery. The tests included in this study measured performance of different physical tests, and on most tests, we did not see any change. We do not know what the initially intended aim of the orthosis was for each participant. This was most likely set between the children/their parents, and the orthotist, physiotherapist and/or physician. If the aim was reduced energy consumption throughout the day or improve balance to prevent fall, it might still be clinically relevant to use the orthosis for this purpose. It is therefore important to establish the intended aim of the orthosis at the beginning, so there are no misconceptions of improvements that initially wasn't set. Aims targeting the activity- and participation domain are more difficult to evaluate if they are met, since there are several factors influencing. Decreased energy consumption can be a factor that increases participation, since the child isn't as fatigued throughout the day. But if they are to participate in sport, they might find the orthosis restrictive; not fitting in shoes, being too visual for others making them not wanting to participate or causing physical restrictions in some movements. The user must be informed that one orthosis might not have a positive effect in all activities or affect more than one level of ICF. This was also found to be the case for different interventions, both botox, orthosis and surgery (Novak et al., 2013). Secondly, it is important to be sure of positive effect on the desired outcome, either supported by scientific evidence or by relevant outcome measures and testing for each individual. There is still need for more high-quality research on orthoses (Aboutorabi et al., 2017; Figueiredo et al., 2008), and Khamis et al. (2018) encourages clinicians to evaluated effect and relevance of orthosis on a case to case basis. There might also be a need for different orthosis for various occasions. We know that the impact and importance of physical activity and participation with peers is key for children growing up, both for the psycho-social aspect and for motor development (Bjornson et al., 2014; Zeng et al., 2017), and there is need for more research on the direct effect of orthosis on daily activity and participation. For future research in laboratory settings, or in clinical settings, we suggest fewer, but more physical demanding outcome measures for the most active orthosis users, since some of the test might have reached a ceiling effect. Physical test may include obstacle and curbs, or different tests conducted at fast speed instead of self-selected.

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