2014•2015
FACULTEIT GENEESKUNDE EN LEVENSWETENSCHAPPEN
master in de revalidatiewetenschappen en de kinesitherapie

Masterproef

The influence of ankle-foot orthoses (AFO's) on the ambulation during the Six-Minute Walk Test (6MWT) in chronic stroke patients

Promotor :
Prof. dr. Peter FEYS

Copromotor :
Mevrouw Vendula DOLEZALOVA

Copromotor :
Mevrouw ELS HOUBEN

Leni Meuws

Proefschrift ingediend tot het behalen van de graad van master in de revalidatiewetenschappen en de kinesitherapie

universiteit hasselt
KNOWLEDGE IN ACTION

Universiteit Hasselt | Campus Hasselt | Martelarenlaan 42 | BE-3500 Hasselt
Universiteit Hasselt | Campus Diepenbeek | Agoralaan Gebouw D | BE-3590 Diepenbeek

universiteit hasselt
KNOWLEDGE IN ACTION

2014•2015
FACULTEIT GENEESKUNDE EN LEVENSWETENSCHAPPEN
master in de revalidatiewetenschappen en de kinesitherapie

Masterproef

The influence of ankle-foot orthoses (AFO's) on the ambulation during the Six-Minute Walk Test (6MWT) in chronic stroke patients

Promotor :
Prof. dr. Peter FEYS

Copromotor :
Mevrouw Vendula DOLEZALOVA

Copromotor :
Mevrouw ELS HOUBEN

Leni Meuws

Proefschrift ingediend tot het behalen van de graad van master in de revalidatiewetenschappen en de kinesitherapie

universiteit hasselt
KNOWLEDGE IN ACTION

ACKNOWLEDGEMENTS

First of all, I would like to express my sincere gratitude to a few people for their great support and contributions to this master thesis.

At first, I would like to thank my promotor, Prof. Dr. Peter Feys and co-promotor Msc. Els Houben for the opportunity to participate in this particular master thesis. I would like to thank them for providing me their always valuable guidance, support and advice throughout this entire learning process. Thanks to them I had the opportunity to gain a lot of knowledge regarding to the gait pattern, the use of an ankle-foot-orthosis (AFO) and the great experience of scientific research in stroke patients.

Secondly, I would like to thank Msc. Vendula Doležalová who did her internship at the Study Centre for Rehabilitation Research (REVAL) at that time. She guided my fellow master students and me throughout the study preparations, execution and statistical analysis, for which my sincere gratitude.

I also would like to thank master students Lotte Schaekers and Dorine Tanscik, they were part of this study group and helped with the data collection.

Furthermore, I am grateful to the participants in this study, who have willingly put their time and effort into this study. Without their voluntary participation, this master thesis would not be possible.

In addition, I would like to thank the Rehabilitation Department of ZOL (Ziekenhuis Oost-Limburg) in Lanaken and the Study Centre for Rehabilitation Research (REVAL) for the opportunity to utilize their infrastructure and resources to accomplish this study.

At last, I would like to thank my family, partner and closest friends for their support and encouragement during the entire process of this master thesis.

Beringen, 21st of February 2015 L.M.

SITUATING

This master thesis is situated in the faculty 'Medicine and Health Sciences' of the University of Hasselt and it concerns the field of neurological rehabilitation. It is part of an ongoing study performed by multiple students, targeting the use of ankle-foot orthoses (AFO's) in stroke patients. The research group was set up by a collaboration between the Rehabilitation Department of ZOL (Ziekenhuis Oost-Limburg) in Lanaken and the University of Hasselt.

Problems concerning gait and walking capacity are among the most important impairments in people after stroke. To minimize fatigue, prevent falls and associated injuries, walking has to be efficient and safe (Neumann, 2002). An ankle-foot orthosis (AFO) is often prescribed to alter the gait pattern in a positive way and to improve walking capacity (Nolan et al., 2009). However there is a widely spread use of AFO's in the population with stroke, the specific effects of an AFO on functional and prolonged walking are not well known. Therefore, the purpose of this master thesis is to investigate alternations in the gait pattern before and after the Six-Minute-Walk Test (6MWT) while comparing two different types of AFO with no AFO and to identify the pacing pattern changes during this 6MWT.

In the Rehabilitation Department of ZOL (Ziekenhuis Oost-Limburg) in Lanaken, the use of an AFO is greatly encouraged. Msc. E. Houben is a physiotherapist in this setting and co-promotor of this study. Over the last eight years, she has been participating in a weekly, multi-disciplinary (physician, physical therapist and orthotic technician), ankle-foot orthosis consult. From her clinical experience, she noted major effects of the AFO and wanted to see them reflected in objectively measurable research. In conjunction with prof. dr. P. Feys, the promotor of this study, a collaboration was set up in the academic year (AY) 2012-13. Prof. dr. P. Feys leads the neurological rehabilitation educational program of the University of Hasselt and is also a researcher at the Study Centre for Rehabilitation Research (REVAL). Together, we determined the research question: 'The influence of ankle-foot orthoses (AFO's) on the ambulation during the Six-Minute Walk Test (6MWT) in chronic stroke patients.' An important aspect of ambulation we want to focus on is endurance, by which we mean walking a longer period of time without declining in gait velocity. We hypothesized that walking could be prolonged by wearing an AFO without having a negative impact on the fatigue and other stroke-related symptoms.

This research consist of two literature searches combined as one observational pilot study with three major objectives. During AY 2012-13, master student D. Tancsik performed a literature search based on the effects of an AFO on the spatio-temporal parameters in stroke patients as a first important aim of this study. Furthermore, together with the promotor and co-promotor, she prepared a first version of the research protocol for this pilot study. Last AY, 2013-14, as a second important objective of this pilot study, master student L. Schaekers and I studied the literature regarding the effects of an AFO on the dynamic balance and walking capacity in stroke patients. At the same time (AY 2013-14) we completed the protocol together with our promotor, co-promotor and international student V. Doležalová. The research protocol was approved in June 2013 by the committee of Medical Ethics of

ZOL (Ziekenhuis Oost-Limburg) and by the University of Hasselt. Thereafter, the pilot study was carried out where the spatio-temporal parameters, dynamic balance and functional walking were investigated in stroke patients when wearing a standard prefabricated AFO (Maramed), an individualised AFO (Y-Tech) or not wearing an AFO. This pilot study was guided by E. Houben and V. Doležalová (intern REVAL) and performed at the Rehabilitation Department of ZOL (Ziekenhuis Oost-Limburg) in Lanaken. Chronic stroke patients were recruited from the outpatient rehabilitation unit of the Rehabilitation Department of ZOL by E. Houben. The data collection was guided by V. Doležalová and performed by ourselves, except for some descriptive outcome measures. The reflex testing, Functional Ambulation Categories, Fugl-Meyer Sensory Assessment, Tardieu Scale and Modified Ashworth Scale, were collected by a specialised doctor and experienced physical therapist to minimize measurement error. Later in AY 2013-14, D. Tancsik and L. Schaekers wrote their master thesis on two of the three major objectives of this study, namely the spatio-temporal parameters and functional balance. This master thesis is the last part of this collaboration and concerns the third major objective, i.e. walking capacity. The statistical analysis was performed with guidance of V. Doležalová and P. Feys. The interpretation of the results was established with the supervision of the promotor and co-promotor.

The influence of ankle-foot orthoses (AFO's) on the ambulation during the Six-Minute Walk Test (6MWT) in chronic stroke patients.

Opgesteld volgens de richtlijnen van *International Journal of Rehabilitation Research*
http://edmgr.ovid.com/ijrr/accounts/ifauth.htm

ABSTRACT

Objectives: To determine the influence of ankle-foot orthoses (AFO's) on the ambulation capacity and gait pattern during the Six-Minute Walk Test (6MWT) in chronic stroke patients.
Design: Observational study
Methods: Chronic stroke patients (n=15) from an outpatient rehabilitation service have participated. Thirteen participants completed 6MWT in three different conditions: Without an AFO, wearing a prefabricated AFO (Maramed) or an individualized AFO (Y-Tech). Heart rate (bpm) and covered distance (m) per minute were tracked. Spatio-temporal parameters were recorded before and after the 6MWT by use of the GAITRite® system. A Visual Analogue Scale (VAS) concerning fatigue was filled out. Participants were divided into a with assistive device subgroup (AD-group; TUG ≥20s) or a without assistive device subgroup (Without AD-group; TUG <20s).
Results: Significant effects in motor and sensory descriptive tests were found between the subgroups, whereas the general patient characteristics were homogenous. Significant improvements ($p < 0,05$) in total distance covered (m) were found in favour of the Y-Tech, in both the total group and the AD-group. Only small and inconsistent results were found concerning heart rate and spatio-temporal parameters.
Conclusions: An individualised AFO (Y-Tech) can increase the covered distance during the 6MWT and thereby improve functional ambulation in stroke patients (more than a standardized Maramed). Stroke patients with relatively higher degree of functionality, benefit less from an AFO when concerning ambulation during a longer period of time. According to this study, there are only small and inconsistent effects of a longer walking effort on the spatio-temporal parameters of the gait pattern.

Keywords
Ankle-foot orthosis (AFO), 6-Minute Walk Test (6MWT), stroke, ambulation, gait pattern, heart rate, spatio-temporal parameters

INTRODUCTION

Walking capacity is a crucial aspect of daily life functioning. It is a key element of ambulation. Walking serves an individual's basic need to move from place to place. Walking needs to be efficient and safe to minimize fatigue, prevent falls and associated injuries (Neumann, 2002). Ambulation is the sensory-motor skill that underlies basic activities of daily living (BADL; e.g. feeding, dressing, hygiene) and instrumental activities of daily living (IADL; e.g. shopping and cooking) (O'sullivan, 2007). To attain participation at home and in the community, we need the ability to walk independently with sufficient endurance (Bohannon et al., 1991; Lin et al., 2006). Unfortunately, stroke survivors often have difficulties with walking capacity which includes walking velocity and endurance (Bohannon et al., 1988; Perry et al., 1995).

Stroke is a neurological dysfunction with an acute onset which can be caused by sudden haemorrhages or ischemia in the brain (Wang et al., 2005). According to Feigin et al.,2003, stroke is the second leading cause of death worldwide and one of the most striking causes of long-term disabilities (Abe et al., 2009; Feigin et al., 2003). Approximately 30-40% of stroke patients have significant disabilities. Possible consequences of stroke are impairments of sensory, motor, cognitive, perceptual and language functions (O'Sullivan, 2007; Tyson & Rogerson, 2009). Motor deficits are characterized by paralysis or weakness. Although there are many disabling symptoms, the recovery of mobility, in particular walking, has been identified as the most important goal stated by patients after stroke (Bohannon et al., 1988). As part of this restoration of function, there are a lot of factors that play a part in the limitation of walking and have a significant restrictive role in the activities of daily living in stroke patients. As mentioned earlier, one of them is walking capacity, in particular walking endurance (Cakar et al., 2010; Lin et al., 2006).

Walking can be defined as 'an activity in which the body advances at a slow to moderate pace by moving the feet in a coordinated fashion' (MeSH). Walking distance and gait velocity are the two most essential key indicators of walking capacity (Bohannon et al., 1991). According to Robinett & Vondran, 1988, we have to be able to cover a distance of minimum 13 meters and maximum 480 meters to access services in the community (e.g. post office, medical buildings and stores) (Robinett & Vondran, 1988). They also state that an average pedestrian crossing requires a gait velocity of approximately 1,38m/s to reach the opposite side in a safe manner. Therefore, we can state that 'being able to walk' itself, is not enough to be independent in our society. Physical therapists must take into account that walking a longer distance and walking at an adequate gait velocity are essential to safely participate and to reintegrate in community life.

Considering the importance of regaining the ability to walk after stroke, it is crucial that physical therapists use accurate outcome measures with positive psychometric properties (Fulk et al., 2008). Walking capacity can be measured with the Six-Minute Walk Test (6MWT), 25-Foot Walk (25ftW), 10-Meter Walk Test (10mWT) and the 5-Meter Walk Test (5mWT). In this particular study, we have used the 6MWT because it is a widely used clinical test in the stroke population and has adequate to

excellent psychometric properties. Fulk et al., 2008, reported a high degree of reliability and a high correlation with other measures of walking ability that are commonly used. Test-retest reliability has been reported as excellent (Fulk et al., 2008). Furthermore, when encompassing walking endurance besides walking speed, the 6MWT is a more appropriate measurement. It includes walking endurance more than the tests with a shorter distance or tests with a shorter duration.

In order to improve the rehabilitation of gait, many walking aids and devices, such as an ankle-foot orthosis (AFO), can be used. An AFO is an apparatus used to support, align, prevent or improve the function of the ankle joint (MeSH). An AFO provides medio-lateral stability in the stance phase, facilitates toe clearance in the swing phase, promotes heel strike, supports dorsiflexion, stops excessive plantar flexion and corrects the ankle joint (Abe et al., 2009; Erel et al., 2011; Park et al., 2009; Simons et al., 2009; Tyson & Thornton, 2001; de Wit et al., 2004). There are many different types of AFO, which can be divided into static versus dynamic, anterior versus posterior or custom-made versus prefabricated AFO's. By using an AFO in stroke patients, many of the important walking components can be positively influenced.

From previous studies it can be concluded that an AFO has positive effects on spatio-temporal parameters (e.g increased gait velocity, cadence, step – and stride length, single support time, symmetry and a decrease in double support time) (Abe et al., 2009; Esquenazi et al., 2009; Park et al., 2009; Rao et al., 2008; Schaekers & Tancsik, 2014). However it is unknown how clinically meaningful these changes are for daily life functional walking capacity. In other words, it is unknown if stroke patients can functionally benefit from an AFO. Previous studies reported inconsistent findings regarding the effects on the functional walking capacity when wearing an AFO. They showed that the use of an AFO could reduce the energy expenditure and increase gait velocity (Danielsson & Sunnerhagen, 2004). Whether an AFO has an effect on walking capacity or not, depends on the compositions of the orthosis (Gok et al., 2003). Moreover, only ten articles were found which states that research concerning this particular interest, is greatly limited. Six articles included the 10-Meter Walk Test (10mWT) as an outcome measure. Three out of these six articles applied comfortable walking speed (Simons et al., 2009; de Wit et al., 2004; Wang et al., 2005) as an instruction, the other half maximal walking speed (Hesse et al., 1996; Hesse et al., 1999; Mojica et al., 1988). All studies except one applying maximal walking speed reported significant improvements in favour of the AFO. Three out of ten articles concerning walking capacity used the 6MWT. Two studies investigated the effects on total distance covered during the 6MWT. Both articles found significant effects in total distance covered in benefit of the AFO (Hung et al., 2011; Nolan et al., 2009). Additionally, Nolan et al., 2009 divided their population in three groups based on the ambulation index (AI). In group 1 (the fast patients, walked 25ft. in ≤ 10sec), there were no differences between not wearing and wearing an AFO. In group 2 (the moderate patients, walked 25ft. in ≤ 20sec), borderline significance (p=0,069) was found in benefit of the AFO. Only in group 3 (the slow patients, walked 25ft. in > 20sec), they found significant increases in covered distance in favour of the AFO. Based on Nolan et al., 2009, we can conclude that slower patients benefit more from the use of an AFO while walking long distances compared to moderate and faster walking patients (Nolan et al., 2009). This conclusion cannot be

confirmed by the other two articles because no subgroups were made (Franceschini et al., 2003; Hung et al., 2011). Contrary to Nolan et al., 2009, Franceschini et al., 2003 did not report the total distance covered, but found significant improvements in self-selected speed and energy cost of walking when patients were wearing an AFO. Nolan et al., 2009 also reported a significant increase in the mean velocity when wearing an AFO compared to not wearing an AFO. In the study of Erel et al., 2011, patients walked 100m with a heart rate monitor to measure the Physical Cost Index (PCI). The PCI is the walking heart rate minus resting heart rate divided by the walking speed ($[HR_{Walking}-HR_{Rest}]$/ walking speed) (Erel et al., 2011). Significant decreases in the PCI were found when patients walked with an AFO compared to not wearing an AFO. Because of their disturbed gait pattern, stroke patients have an increased muscular effort and therefore a higher energy expenditure (Erel et al., 2011). It is important to measure the energy cost of stroke patients while walking a longer distance to estimate their limitations in daily life. With a combination of the 6MWT and the PCI, an estimation can be made of the patients' capacity and fatigue. For practical reasons, the choice was made to keep track of the resting heart rate and the heart rate during the 6MWT in our study, not the PCI.

All of the above previous research leads to the following starting points for this study. There is a need for knowledge about the specific effects of an AFO on walking capacity when considering the varying severity of stroke patients. Therefore a distinction between more severely impaired patients and less impaired patients was made. Another important issue is that worn shoes could have an impact on the effects of an AFO, that is why we used a standardised shoe throughout all testing. Only one article compared different types of AFO, the remaining articles all compared not wearing an AFO with wearing an AFO and in most of them different types of AFO were used in the AFO condition. As a consequence of the different futures of various AFO types, it is not possible to draw clear conclusions, which is why there was decided to use three conditions, one control condition without AFO, one with a standardised prefabricated AFO (Maramed) and one condition with an individualised AFO (Y-Tech). Furthermore, no study has investigated the differences in spatio-temporal parameters before and after a 6MWT with and without an AFO. That part of the study is entirely unique and is not comparable to preceding studies.

The research questions that are of interest in this study are: (1) Does an individualised AFO (Y-Tech) have a positive effect on the walking capacity (gait velocity, walking distance, heart rate, fatigue) in chronic stroke patients compared to not wearing an AFO? (2) Is this effect (Y-Tech) different from a standardised prefabricated AFO (Maramed)? (3) Does an individualised AFO (Y-tech) have an effect on the spatio-temporal parameters post 6MWT compared to the pre parameters in chronic stroke patients and this in comparison to not wearing an AFO? (4) Is this effect (Y-tech) different from a standardised prefabricated AFO (Maramed)? (5) All prior questions regarding the differences between two subgroups that were categorised according to the need of an assistive device during a longer period of walking.

MATERIALS AND METHODS

Participants

Participants were recruited from the outpatient services of the Rehabilitation Department of ZOL (Ziekenhuis Oost-Limburg) in Lanaken. Thirteen participants were included by the co-promotor of this study, Msc. E. Houben, in collaboration with medical responsible Dr. Hallet. Only patients who have been in the outpatient rehabilitation service over the last year, were included. They were included according to the following inclusion criteria: (a) diagnosis of hemi-paresis caused by a cerebrovascular accident (CVA), (b) chronic phase stroke patients (> 3 months post-stroke), (c) patients have the ability to walk safely with and without an AFO, (d) patients have the ability to understand simple instructions and (e) patients are familiar with wearing an AFO (Y-Tech) since at least one month. Participants were excluded when (a) bilateral assistive devices were needed while walking or when (b) a history of orthopaedic problems (related to the lower extremities) that would interfere with gait performance, was present.
The study is approved by the Committee of Medical Ethics of the hospital (ZOL) and the university of Hasselt. All the participants included in this research procedure have read, signed and approved the informed consent.

Intervention and devices

In this study two different types of devices were used: a Maramed and a Y-Tech (see figure 1a and figure 1b). The Maramed is a prefabricated AFO. This type of orthosis is made of polypropylene and is fabricated in a neutral dorsi-flexed position. The Maramed has a thin and limited width of material behind the ankle, which leads to a restricted amount of stability of the ankle. Three different sizes (small, medium, large) were available in this study. The hybrid Y-Tech is an individualised AFO from the company V!GO©. This AFO consists of a polypropylene sheet (4-5mm) with integrated thermoplastic carbon reinforcement and a strap to fixate the foot in the AFO. It can be adapted according to the individual needs of the patient. Each participant included in this study already owned an individualised Y-Tech. These apparatus were used in combination with standardized sport shoes.

Figure 1a: Maramed

Figure 1b: Y-Tech

Research design and procedure

All the tests needed for this master thesis were performed in the Rehabilitation Department of ZOL (Ziekenhuis Oost-Limburg) in Lanaken. Fifteen patients were tested in three days each over a three-week period (see figure 2). In our experiment, all the individuals received the same interventions. There were three testing conditions: condition 1 without an AFO, condition 2 with a standardized AFO (Maramed) and condition 3 with an individualized AFO (Y-tech). All three conditions were randomized for all tests (GAITRite® measurements and balance testing on day 2 and Six-Minute Walk Test (6MWT) on day 3). All the patients received standard instructions, dependent on the test or item to be taken. During the recovery periods, the AFO was removed or changed in another condition, with the assistance of the examiner.

On day one, a preparatory session (session 1) took place where the patients were familiarized with the Maramed orthosis. Descriptive outcome measures such as patient characteristics and descriptive tests were collected and each experimental clinical test was demonstrated and practiced once. All descriptive tests were performed without an orthosis and with standardized sport shoes, which were also fitted on day one. The descriptive outcome measures and tests used were (a) passive ankle dorsiflexion, (b) the Tardieu Scale (TS), (c) the Modified Ashworth Scale (MAS), (d) the motor part of the Brunnstrom Fugl- Meyer of the Lower Extremities (BFM-LE), the sensory part of the Brunnstrom Fugl-Meyer of the LE, (f) the Sensory Extinction Test, (g) the Motricity Index, (h) the Berg Balance Scale and (i) Functional Ambulation Categories (FAC). Additionally, the Timed Up and Go (TUG) was performed three times and an average was calculated. These scores were used as an objective criterion to divide the total patient group into two subgroups. When patients completed the test in less than 20 seconds, they were placed in the “without assistance device group” (without AD-group). When they performed the test in 20 seconds or more, they were assigned to the “with assistive device group” (AD-group). All the patients in the AD-group had to use a walking cane during the tests of day two and day three. The main reason for this subdivision was the hypothesis that stroke patients with an assistive device can possibly benefit less or even more from an AFO (than persons without assistive device). Other reasons were to guarantee the participants’ safety at all times and to obtain a clearer and more standardised estimation of the patient group.

On the second day of testing, the spatio-temporal changes and functional balance capabilities were studied. The protocol and results of the testing of session 2 will not be discussed in further detail for the reason that it is not the main interest of this master thesis. These results were discussed in the master thesis of D. Tancsik and L. Schaekers in AY 2013-14.

On the third day, the spatio-temporal changes as well as the walking capacity were measured. Patients performed the 6MWT three times, once in each condition. The 6MWT was performed in a quiet hallway to minimize the possibility of distractions during the test. A distance of 25 meters was marked with small stripes of tape every 5 meters and at the turning points at each end of the walkway. Participants were instructed to walk as far as possible, safely, and at their self-selected comfortable pace throughout the six minutes. According to the TUG criteria of session one, participants in the AD-

group were imposed to use a standardised walking cane. Participants in the without AD-group were not allowed to use a walking aid. A new randomisation was executed before the start of the tests. Before and after each test, participants walked once over the GAITRite® carpet (to detect spatio-temporal changes) at the same pace as they complete the 6MWT. The GAITRite® was positioned in a room where there was enough space to allow a dynamic start over the instrumented section of the carpet. The participant started two meters before the carpet. This extra walking space was foreseen so that patients walked at a constant walking speed. This space was marked with a white tape. The patients were positioned with their toes just prior to the tape, and instructed to walk across the mat and then to fluently continue walking to the starting line of the 6MWT. After the 6MWT, patients were instructed to continue walking fluently over the GAITRite® carpet one more time at the same pace as they completed the 6MWT. Hereafter, patients filled out the Visual Analogue Scale (VAS) to acquire a better understanding of the subjective fatigue during the different conditions. Their heart rate was monitored constantly with a finger pulse oximeter. The resting heart rate was determined exactly before starting the 6MWT and was tracked every minute of the 6MWT. Just after ending the 6MWT, the heart rate was noted again and the time needed to return to the resting heart rate was observed, as well as the heart rate after two minutes of rest. Between each testing condition a standardized recovery period of 15 minutes took place. During this recovery period, the participant sat in a chair with armrests and had the opportunity to drink some water. According to the randomisation, the AFO was removed or changed in another condition, with the assistance of one examiner.

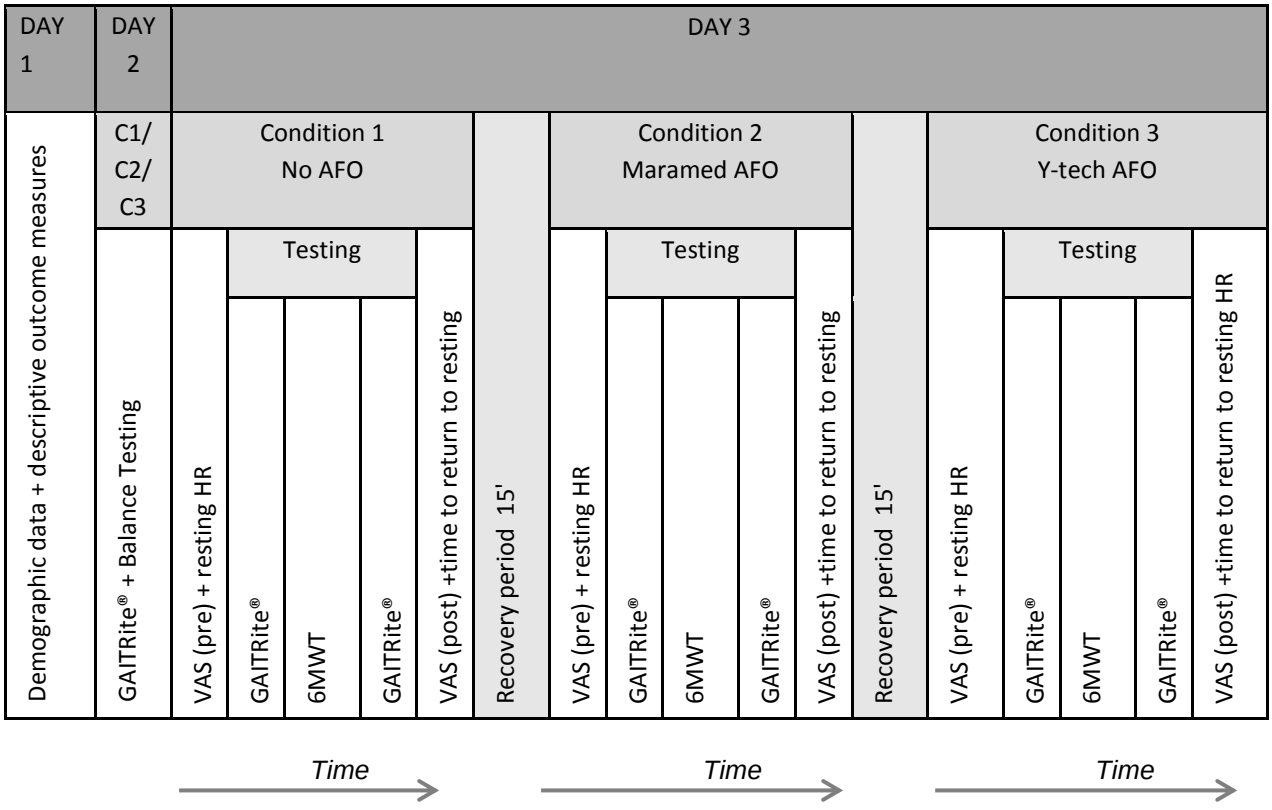


Figure 2: Study design

Outcome measures

The following patient characteristics were collected: gender (male/female), weight (kg), height (cm), BMI (kg/m^2), birth date, stroke onset (months), location of stroke (right/left hemisphere, brain trunk, cerebellum, other), type of stroke (infarction/haemorrhagic), lateralisation of stroke (right/ left), time of wearing AFO before study (months), AFO size (small, medium, large) and shoe size.

The severity of motor and sensory dysfunction were evaluated by following tests:
The active and passive range of motion (ROM) in the affected ankle were measured with a goniometer in both lying and sitting position. Kim et al., 2011 reported a low to moderate inter-rater reliability and moderate to high intra-rater reliability in ankle joint dorsi-flexion using a standard goniometer in asymptomatic individuals (Kim et al., 2011).
The degree of spasticity was measured with the Modified Ashworth Scale (MAS) and Tardieu Scale (TS). The MAS is a 5-point ordinal scale (0-4 points). This test evaluates stiffness in the lower extremity with the use of a passive movement. Neumann, 2002 reported a good intra-rater reliability [ICC 0.84] and a good inter-rater reliability [ICC 0.83] (Neumann, 2002). Li et al., 2013 showed a fair inter- and intra-rater reliability [ICC 0.48 and 0.48] for the plantar flexors in stroke patients (Li et al., 2013).
The TS is a 6-point ordinal scale (0-5 points). These measurements took place at three velocities; V1: as slow as possible (slower than the natural drop of the limb segment under gravity), V2: speed of the limb segment falling under gravity and V3: as fast as possible (faster than the rate of the natural drop of the limb segment under gravity). All these tests were taken in supine position. Li et al., 2013 showed a quit good inter- and intra-rater reliability [ICC 0.82 and 0.79] for the ankle flexors in stroke patients (Li et al., 2013).
Reflex activity, synergies, coordination and sensation of the lower extremities were measured by the Brunnstrom Fugl- Meyer of the Lower Extremities (BFM-LE). The BFM-LE is a 3-point ordinal scale (0-2 points). The tests of the lower extremity include: reflex activity of the m. triceps surae/quadriceps femoris, random movement in the flexion/extension synergy, possibility to combine the flexion/extension synergy, full dissociation of synergies is possible, normal reflex activity, coordination and sensation. Sanford et al., 1993 reported a reliability of [ICC 0.96] in acute stroke patients (Sanford et al., 1993).
The Sensory Extinction test is a 2-point nominal scale. This test was used to identify neglect for light tough on the patient's thighs. This test was taken after the sensory part of the FMA-LE and it can only be examined if sensation in the lower extremities is present.
In order to evaluate the maximal isometric strength or minimal active amplitude of the lower extremities, the Motricity Index (MI) was used. The Motricity Index (MI) is a 6-point ordinal scale (0, 11, 19, 22, 26 and 33 points). When there is a total score of the leg part (99 points), one point can be added (total points 100). Fayazi et al., 2012 reported a high test-retest reliability [ICC 0.93] with one-week interval (Fayazi et al., 2012). Only the lower limb part was used in this study.

Additionally, the Berg Balance Scale (BBS), Timed Up and Go (TUG), Brunel Balance Assessment (BBA) and Functional Ambulation Categories (FAC) were used to describe the participants' activity level.

The BBS is a 14-items test to evaluate balance. Each item is scored using a 5-point ordinal scale (0-4 points). A score of 4 indicates: independent function. A score of 0 indicates: unable to complete the task. In total there are 56 items to achieve. A score of < 45 represents a risk of falling. Blum & Korner-Bitensky, 2008, a systematic review reported an inter-rater reliability of [0.95-0.98], an intra-rater reliability of [0.97], a test- retest reliability of [0.98] and floor/ceiling effects (Blum & Korner-Bitensky, 2008). Pollock et al., 2011 reported a limited content validity (single-leg stance task and turning) (Pollock et al., 2011).

During the TUG, the patients had to rise from an armchair, walk three meters, turn, walk back to the starting point (chair) and sit down. The time needed to complete this trial was measured with a stopwatch (ratio scale). Ng & Hui-Chan, 2005 reported a good to excellent reliability [ICC range 0.69-0.99], test-retest [ICC 0.95] for chronic stroke patients (Ng & Hui-Chan, 2005). The concurrent validity with the BBS [ICC 0.81] and Barthel Index (BI) [ICC 0.78] had been reported in O'Sullivan, 2007 (O'Sullivan, 2007). This test predicts the fall risk in elderly subjects (Pollock et al., 2011). A score of <20 seconds represents that patients are independent for most transfers, a score of >30 stated that patients are dependent in most activities in daily life. The articles also stated an inter-rater reliability of [ICC: 0.99] and an intra-rater reliability of [ICC: 0.9]. In our protocol, the TUG was performed three times and an average was calculated. This average score was used for dividing the patients in two subgroups: With (>20sec) and without (≥ 20sec) assistive device according to a selected cut-off score of 20 seconds.

In the BBA, the patient had to complete a defined number of items which are hierarchically ordered, ranging from easy to difficult. The items range from: sit to stand, stepping to walking and lowering/ raising the base of support (BOS) by stepping on objects. The scoring utilizes a pass/ fail structure based on performance or time standards which dictates minimal detectable change on the scale (ordinal scale). When a patient fails one item, he or she automatically fails all the other items. At that moment, the test has to be stopped. Tyson & DeSouza, 2004 reported a high inter-test and test-retest reliability with 100% agreement [Kappa coefficient =1] in stroke patients. They also reported a good concurrent validity with the sitting Motor Assessment Scale [0.83], BBS [0.97] and the Rivermead Mobility Index [0.95] (Tyson and DeSouza, 2004).

The FAC is a 6-point ordinal scale (0-5 points). A score of 0 indicates: the patient cannot walk or needs assistance of two or more persons. A score of 5 indicates: the person can walk independent on a flat surface, uneven surfaces, inclinations and stairs. Viosca et al., 2005 reported a good inter-rater reliability [K = 0.74] (Viosca et al., 2005).

For the experimental part of this study, the GAITRite® system and 6MWT were used as primary outcome measures. A VAS was handled as a secondary outcome measure to evaluate the degree of fatigue during the different conditions. Additionally, a finger pulse oximeter was put on as a secondary outcome measure to keep track of the heart rate while testing.

During the 6MWT the patients' physical capacity was tested. They were instructed to walk as far as possible, safely, and at their self-selected, comfortable pace throughout the six minutes. Their scores on this test were based on the distance covered in these six minutes on a hard, flat surface along a 25 meters marked walkway. During the test, covered distance and heart rate were recorded every minute. The patient was allowed to rest if needed but had to stay upright. The use of an assistive device is obligated when patients had a score of ≥20 seconds on the descriptive TUG. Eng et al., 2004 and Flansbjer et al., 2005 reported an excellent test-retest reliability of the 6MWT for distance covered in meters [ICC 0.99] (Eng et al., 2004; Flansbjer et al., 2005). According to Kosak & Smith, 2005, the intra-rater reliability was adequate [ICC 0.74] and the inter-rater reliability was found to be good [ICC 0.78] (Kosak & Smith, 2005).

The GAITRite® system was used to detect changes in the spatio-temporal gait parameters. This system is a computer based instrumental walkway. It contains a carpet and a computer. The flexible roll-up carpet, available in various lengths, is embedded with sensors. The GAITRite® that we used is 5.37 meters long. The sensors are activated by mechanical pressure, when a subject walks across the carpet. The GAITRite® has also the ability to connect two cameras. This provides additional information about the gait pattern. We only handled one camera concerning practical reasons. We positioned the camera in between the frontal and sagittal plane of the patient walking across the carpet. The data arrived from the pressure sensors and video camera, were collected and stored by a connected computer. The computer software displayed automatically the spatio-temporal parameters and video material. The GAITRite® provided the following bilateral parameters: step length (cm), single support time (%GC) and double support time (%GC). The other parameters included: distance (cm), velocity (cm/sec) and cadence (steps/min). Bilney et al., 2003 showed a good test-retest reliability when patients were tested in three consecutive measurements on one day (Bilney et al., 2003). Van Uden & Besser, 2004 reported a high test-retest reliability of spatio-temporal parameters, over a one week period in healthy subjects (van Uden and Besser, 2004). They also described an [ICC: 0.92] at preferred walking speed, and an [ICC: 0.89] at fast walking speed. MCDonough et al., 2001 reported also a good reliability and validity for measuring spatio-temporal parameters. There was a concurrent validity with a paper pencil method [ICC: 0.95] and with a video-based analysis [ICC: 0.93] (McDonough et al., 2001).

A VAS was used to evaluate the participant his subjective experiences during walking. This instrument consists of a straight line with on the extreme ends opposite claims. The participant had to mark the point on the line that they feel that represented their perception of their current state. The VAS score was determined by measuring in millimetres from the left hand end of the line to the point that the participant had marked. For session 3, the question was: “How fatigued are you feeling now?”.

During the measurements of day 3, participants continuously wore a finger pulse oximeter. Iyriboz et al., 1991 reported a good correlation ($r=0.91$, $p<0.0001$) between pulse oximeter and ECG measurements in healthy subjects at rest and during exercise (Iyriboz et al., 1991). Before the 6MWT the resting heart rate of the patient was noted. Every minute of the test, the heart rate was monitored to check for alternations of the heart rhythm in response of the effort. Afterwards the time to return to the resting heart rate was determined.

Statistical analysis

Statistical analysis was carried out with STATISTICA 7. The results of the parameters in the three conditions were compared for the total group of subjects as well as for the two subgroups (AD-group and without AD-group), this with post-hoc analysis. Due to the small sample size, non-parametric statistics were used. Results of parameters in the three conditions were compared by means of the Wilcoxon Matched Pairs Tests and the Friedman ANOVA and Kendall's concordance. This analysis was performed for each of the experimental outcome measures. The level of significance was set at 0.05.

RESULTS

Results are represented in three tables. Table 1 shows an overview of the demographic data i.e. general patient characteristics (table 1a) and tests (table 1b), in both the total group and subgroups. Table 2 and 3 represent the results of the experimental outcome measures. Table 2 signifies the pacing pattern and is subdivided into table 2a, which shows the total distance and heart rate during the Six-Minute Walk Test (6MWT) and table 2b, which displays the covered distance per minute during the 6MWT. The spatio-temporal parameters and the scores of the Visual Analogue Scale (VAS) before and after the 6MWT can be found in table 3.

Fifteen subjects agreed to participate in this study. Two participants were not able to complete the 6MWT without an AFO, therefore data of only thirteen participants was available for analysis. These thirteen participants (eleven males and two females) with mean age of 61.38 years, mean weight of 83.58 kg, mean height of 1.73 m and mean stroke onset of 17.15months, completed the study. In the study sample there were seven participants with a stroke localized in the hemisphere, one localized in the cerebellum and five not otherwise specified (thalamus, combinations of hemisphere and cerebellum, combination of hemisphere, brainstem and thalamus). Ischemic stroke was the most common type with twelve cases, only one participant had a stroke of the haemorrhagic type. Stroke occurred the most on the left side of the brain (nine cases) compared to four participants with a right sided stroke. The mean time of wearing an AFO after their stroke was 6,77 months. The patient characteristics of the AD-group were comparable to those of the without AD-group. A detailed description of general patient characteristics is shown in table 1a.

Table 1a. Descriptive outcome measures, patient characteristics.

	Total group (n=13)	**Without AD (n=6)**	**With AD (n=7)**	**P-Value**
Age (years), mean ±SD	61,38 ± 7,74	61,17 ± 6,56	61,57 ± 9,16	ns
Gender (male/ female), n	(11/2)	(6/0)		ns
Weight (kg), mean ±SD	83,58 ± 16,36	81,50 ± 18,12	85,36 ± 15,95	ns
Height (m), mean ±SD	1,73 ± 0,08	1,74 ± 0,07	1,73 ± 0,09	ns
BMI (kg/m²), mean ±SD	27,70 ± 4,41	26,77 ± 3,93	28,50 ± 4,95	ns
Stroke onset (months), mean ±SD	17,15 ± 25,70	27,17 ± 36,73	8,57 ± 3,26	ns
Stroke location, n				
Left/ right hemisphere	7	3	4	ns
Cerebellum	1	0	1	ns
Other	5	3	2	ns
Stroke type (ischemic/ hemorrhagic), n	(12/1)	(6/0)	(7/1)	ns
Stroke lateralisation (left/ right), n	(4/9)	(2/4)	(2/5)	ns
AFO time (months), mean ±SD	6,77 ± 3,47	7,33 ± 3,45	6,29 ± 3,68	ns

Values are mean ± standard deviation (SD), or numbers (n) of participants, Stat. Sign. at p<0,05

Considering the descriptive tests, multiple significant differences were found when comparing the two subgroups (see table 1b). The range of motion (ROM) in the affected ankle was significantly different in three out of four starting positions, being overall the smallest in the AD-group. The active ROM in both groups was smaller compared to the passive ROM, as we would expect. No differences were found when comparing the Modified Ashworth Scale (MAS) and the TS (Tardieu Scale) between subgroups. The motor score of the Brunnstrom Fugl-Meyer (BFM) was significantly higher in the without AD-group compared to AD-group, which indicates that the participants in the without AD-group have a better motor recovery. In contrast to these results, the difference in the sensory part of the BFM was not significantly different and the AD-group had a slightly higher score. Also, no differences between subgroups were found in the sensory extinction test. The Motricity Index (MI) of the affected side showed significant results but only in the ankle part. The AD-group had significantly less strength in the ankle. No significant differences were found in the Berg Balance Scale (BBS). Further, significant results were found in the Functional Ambulation Categories (FAC) and the Timed Up and Go (TUG). Better scores were seen in the without AD-group. Overall, we can conclude that patients in the without AD-group showed better results in the descriptive tests compared to the AD-group.

Table 1b. Descriptive outcome measures, Tests (Motor and Sensory).

	Total group (n=13)	**Without AD (n=6)**	**With AD (n=7)**	**P-Value**
Ankle dorsi flexion(degrees), affected				
Sitting /a/	84,15 ± 14,81	93,67 ± 9,59	76,00 ± 13,93	p=0,024*
Sitting /p/	96,31 ± 9,57	99,17 ± 6,88	93,86 ± 11,34	ns
Supine /a/	75 ± 16,32	88,00 ± 5,97	63,86 ± 13,74	p=0,002*
Supine /p/	84,39 ± 10,59	90,67 ± 3,78	79,00 ± 11,79	p=0,041*
Tardieu Scale, affected (0-5)				
Ankle: V1	0,77 ± 0,60	0,5 ± 0,55	1,00 ± 0,58	ns
Ankle: V2	1,46 ± 1,56	1 ± 1,55	1,86 ± 1,57	ns
Ankle: V3	1,85 ± 1,35	1,50 ± 1,38	2,14 ± 1,35	ns
Modified Ashworth Scale (0-4)				
Affected side				
Ankle	1,69 ± 1,49	1,17 ± 1,47	2,14 ± 1,46	ns
Knee flexion	0,46 ± 0,88	0,17 ± 0,41	0,71 ± 1,11	ns
Knee extension	0,77 ± 1,17	0,67 ± 1,21	0,86 ± 1,21	ns
Unaffected side				
Ankle	0 ± 0	0 ± 0	0 ± 0	ns
Knee flexion	0 ± 0	0 ± 0	0 ± 0	ns
Knee extension	0 ± 0	0 ± 0	0 ± 0	ns
Brunnstrom Fugl-Meyer, motor score (LE) (0-34)	22,54 ± 4,24	25,00 ± 3,63	20,43 ± 3,69	p=0,047*
Brunnstrom Fugl-Meyer, sensory score (LE) (0-12)	10,31 ± 2,59	9,17 ± 3,37	11,29 ± 1,25	ns
Sensory Extinction Test, affected (Score 0/1)		(1/5)		ns
Motricity Index (0-100), affected				
Ankle	16,23 ± 8,56	21,17 ± 9,37	12,00 ± 5,29	p=0,049*
Knee	22,92 ± 4,77	23 ± 3,10	22,86 ± 6,12	ns
Hip	21,54 ± 4,82	23 ± 3,10	20,29 ± 5,88	ns
Total	60,69 ± 13,79	67,17 ± 13,96	55,14 ± 11,82	ns
Berg Balance Scale (0-56)	46,69 ± 4,42	48,83 ± 5,04	44,86 ± 3,08	ns
Functional Ambulation Categories (0-5)	3,54 ± 0,66	4 ± 0,63	3,14 ± 0,38	p=0,012*
Timed Up and Go (seconds)	22,82 ± 13,19	12,87 ± 3,05	31,34 ± 12,52	p=0,005*

*Values are mean ± standard deviation (SD), or numbers (n) of participants, (min.-max. scores), *: Stat. Sign. p<0,05,*

LE: Lower extremities

In table 2a, a comparison of the covered distance and average heart rate during the 6MWT was made between the three conditions, both in the total group and in the subgroups. When looking at the total distance covered in the total group, we found a significant difference in favour of the Y-Tech, compared to wearing no AFO and compared to the Maramed. The total distance covered during the 6MWT was significantly higher in the condition with Y-Tech. When performing post-hoc analysis in the subgroups, we can conclude that this overall significance in total group is caused by a significance in the AD-group. No significant differences were found within the without AD-group. Results are shown in figure 4.

Table 2a. Total distance (m) and heart rate (bpm) in three conditions during the Six-Minute Walk Test (6MWT).

					P-Value		
Variable	**Group**	**Without AFO**	**Maramed**	**Y-Tech**	**C1-C2**	**C1-C3**	**C2-C3**
Total distance (m)	Total	236,50 ± 121,61	240,54 ± 119,70	246,50 ± 120,22	ns	p=0,019*	p=0,028*
	Without AD	347,75 ± 67,10	350,67 ± 59,26	357,92 ± 66,19	ns	ns	ns
	With AD	141,14 ± 53,31	146,14 ± 56,64	151,00 ± 46,92	ns	p=0,06¥	p=0,046*
Average HR (bpm)	Total	89,83 ± 10,48	89,29 ± 11,27	90,55 ± 11,04	ns	ns	ns
Average HR in rest = 69,15	Without AD	91,56 ± 10,74	93,90 ± 11,97	93,53 ± 10,79	p=0,046*	ns	ns
	With AD	88,36 ± 10,85	85,33 ± 9,75	88,00 ± 11,41	p=0,018*	ns	p=0,018*

*Values are mean ± standard deviation (SD), Distance in meters (m), HR in beats/min., *: Stat. Sign. p<0,05, ¥: borderline stat. Sign., p>0,05 and p<0,1, AD: Assistive device, C1: Condition 1 (Without AFO), C2: Condition 2 (Maramed), C3: Condition 3 (Y-Tech)*

The distance covered per minute during the 6MWT within the three conditions is shown in table 2b. When comparing no AFO with the Y-Tech in the total group and in the AD-group, significant results or borderline significant results were found in every minute except for minute 2 and 5. When looking at the raw data, we can conclude that greater distances were covered with the Y-Tech compared to walking without AFO and the Maramed. An illustration of the distance covered per minute within the three conditions is shown in figure 3a.

Table 2b. Pacing pattern: Distance covered per minute in three conditions during Six-Minute Walk Test (6MWT).

		Minute 1 (m)	**Minute 2 (m)**	**Minute 3 (m)**	**Minute 4 (m)**	**Minute 5 (m)**	**Minute 6 (m)**
Without AFO	Total	40,39 ± 20,11	39,92 ± 20,68	39,31 ± 20,74	38,92 ± 20,23	38,62 ± 19,45	39,35 ± 20,95
	Without AD	59,25 ± 10,12	58,75 ± 11,27	58 ± 12,73	57,17 ± 11,92	56,17 ± 10,87	58,42 ± 12,11
	With AD	24,21 ± 7,90	23,79 ± 9,56	23,29 ± 8,73	23, 29 ± 9,03	23,57 ± 9,27	23,00 ± 9,07
Maramed	Total	41,54 ± 19,85	40,39 ± 21,06	39,65 ± 19,53	39,77 ± 19,16	39,92 ± 20,08	39,27 ± 20,60
	Without AD	59,92 ± 9,15	59,17 ± 11,14	57,42 ± 9,39	57,67 ± 9,75	58,50 ± 10,60	58,00 ± 10,66
	With AD	25,79 ± 9,54	24,29 ± 11,34	24,43 ± 10,15	24,43 ± 7,73	24,00 ± 8,50	23,21 ± 10,12
Y-Tech	Total	43,62 ± 21,46	40,77 ± 19,49	41,92 ± 19,78	41,54 ± 20,16	40,58 ± 20,28	41,15 ± 19,15
	Without AD	63,50 ± 11,81	58,58 ± 10,93	59,58 ± 11,12	59,17 ± 11,58	58,83 ± 12,53	58,25 ± 11,23
	With AD	26,57 ± 8,40	25,50 ± 8,43	26,79 ± 10,00	26,43 ± 11,13	24,93 ± 8,52	26,50 ± 9,24

Values are mean ± standard deviation (SD), distance in meters (m), AD: Assistive device

Significant differences in average heart rate were found when comparing no AFO with Maramed in the two subgroups and when comparing Maramed and Y-Tech within the AD-group (see table 2a). Significant increased heart rate was found in the without AD-group in the condition without AFO compared to the Maramed. Contrary to this result, the heart rate significantly decreased in the AD-group when comparing the Maramed with walking without an AFO. When comparing the Maramed with the Y-Tech within the AD-group, a significant increase in heart rate was found when wearing a Y-Tech. These significant differences in heart rate were very small and inconsistent. Further, the heart rate within conditions was examined. A significant result was found within the Maramed-condition, in the without AD-group. This means that there was a significant increase in heart rate when comparing the heart rate of minute six with the heart rate of minute one of the 6MWT. There was a mean increase of 7,67 beats per minute. Also, a borderline significance was found within the condition without an AFO, in the total group. Here, a mean increase of 1,92 beats per minute was found. Both of these results are not clinically relevant since they were very small and inconsistent. An illustration of the heart rate per minute during the 6MWT within the three conditions is shown in figure 3b.

Table 3 shows the comparison of spatio-temporal parameters and VAS before and after the 6MWT within the 3 conditions. There is no consistent trend when comparing the gait pattern before and after the 6MWT within these 3 conditions. A notable result was that within the condition without an AFO, there was a significant increase in the step length of the unaffected side after the 6MWT compared to before the 6MWT, both in total group and the subgroups. The same significant increase was seen within the condition with the Y-Tech in the total group and the without AD-group. The cadence of the total group in the condition without AFO was borderline significantly smaller after the 6MWT compared to before the 6MWT. This result was not seen within the conditions Maramed and Y-Tech. As expected, the VAS had an overall increase when comparing the scores after the 6MWT with the scores before the 6MWT within each condition. Significant increases were found within the condition without AFO, both in the total group and the without AD-group, in the condition with Maramed, in the total group and the AD-group and in the condition with Y-Tech in both the total group and the two subgroups. No significant increases were found when comparing the VAS scores between the three conditions. This VAS concerned the amount of fatigue during the 6MWT. In figure 3c, an illustration of the VAS per condition between the subgroups is visible.

Table 3. Gait pattern (spatio-temporal parameters) and Visual Analogue Scale (VAS) before and after the Six-Minute Walk Test (6MWT).

		Without AFO			Maramed			Y-Tech		
Spatio-temporal parameters and VAS		**Baseline value**	**Delta**	**P-Value**	**Baseline value**	**Delta**	**P-Value**	**Baseline value**	**Delta**	**P-Value**
Velocity (m/s)	Total	0,67 ± 0,38	0,003 ± 0,07	ns	0,72 ± 0,36	(-) 0,019 ± 0,09	ns	0,69 ± 0,34	0,035 ± 0,07	ns
	Without AD	1,00 ± 0,22	(-)0,005 ± 0,10	ns	1,04 ± 0,20	(-) 0,023 ± 0,13	ns	0,99 ± 0,22	0,07 ± 0,09	ns
	With AD	0,39 ± 0,19	0,009 ± 0,05	ns	0,45 ± 0,19	(-) 0,014 ± 0,03	ns	0,44 ± 0,17	0,010 ± 0,05	ns
Cadence (steps/min)	Total	81,37 ± 23,55	(-)3,277 ± 6,95	p=0,0912¥	82,90 ± 23,19	(-)2,223 ± 4,25	ns	80,72 ± 23,40	0,100 ± 4,70	ns
	Without AD	101,95 ± 14,57	(-) 3,367 ± 5,87	ns	103,65 ± 12,85	(-) 2,967 ± 5,00	ns	100,83 ± 16,11	(-) 0,417 ± 5,20	ns
	With AD	63,73 ± 12,06	(-) 3,200 ± 8,23	ns	65,11 ± 11,74	(-) 1,586 ± 3,78	ns	63,49 ± 11,28	0,542 ± 4,61	ns
Steplength affected side (cm)	Total	49,44 ± 10,73	0,549 ± 3,57	ns	51,44 ± 10,62	1,166 ± 6,80	ns	49,93 ± 10,67	1,122 ± 5,08	ns
	Without AD	58,18 ± 7,21	0,227 ± 4,05	ns	59,46 ± 0,96	(-) 2,47 ± 4,01	ns	57,87 ± 6,59	3,782 ± 4,93	ns
	With AD	42,39 ± 7,26	0,824 ± 3,41	ns	44,55 ± 8,09	4,285 ± 7,38	ns	43,12 ± 8,62	(-) 1,157 ± 4,27	ns
Steplength unaffected side (cm)	Total	42,44 ± 21,34	3,587 ± 6,31	p=0,0108*	46,82 ± 16,99	3,191 ± 6,98	ns	47,21 ± 14,35	3,064 ± 4,43	p=0,0331*
	Without AD	58,76 ± 6,83	1,889 ± 2,01	p=0,0278*	60,44 ± 7,90	1,966 ± 4,28	ns	58,57 ± 6,34	4,570 ± 3,35	p=0,0277*
	With AD	28,44 ± 19,42	5,044 ± 8,42	p=0,0630¥	35,15 ± 13,46	4,241 ± 8,90	ns	37,46 ± 11,75	1,773 ± 5,07	ns
Double Support Time affected side (%GC)	Total	40,74 ± 9,73	1,423 ± 5,15	ns	38,92 ± 8,50	0,654 ± 3,81	ns	38,57 ± 7,91	0,277 ± 2,47	ns
	Without AD	32,88 ± 3,88	0,833 ± 1,92	ns	32,48 ± 3,96	0,467 ± 2,49	ns	31,97 ± 3,16	(-) 0,733 ± 1,69	ns
	With AD	47,47 ± 7,89	1,929 ± 7,02	ns	44,44 ± 7,37	0,814 ± 4,88	ns	44,23 ± 5,98	1,143 ± 2,82	ns
Double support Time unaffected side (%GC)	Total	41,47 ± 10,12	0,415 ± 5,50	ns	38,68 ± 8,05	0,600 ± 3,51	ns	38,98 ± 7,96	0,062 ± 3,20	ns
	Without AD	33,25 ± 4,52	0,233 ± 3,12	ns	32,43 ± 3,85	0,450 ± 2,34	ns	32,47 ± 3,11	-) 0,900 ± 1,688	ns
	With AD	48,51 ± 7,91	0,571 ± 7,24	ns	44,03 ± 6,70	0,729 ± 4,48	ns	44,56 ± 6,33	0,886 ± 4,06	ns
VAS (0-10)	Total	2,82 ± 2,30	2,277 ± 2,12	p=0,0047*	2,76 ± 2,39	1,600 ± 2,13	p=0,0088*	2,60 ± 2,41	2,031 ± 2,09	p=0,00266*
	Without AD	3,93 ± 2,48	2,133 ± 1,23	p=0,0277*	3,933 ± 2,81	1,317 ± 1,64	p=0,0747¥	3,22 2,96	1,733 ± 1,08	p=0,0277*
	With AD	1,87 ± 1,78	2,400 ± 2,78	p=0,0630¥	1,76 ± 1,52	1,843 ± 2,78	p=0,0280*	2,07 ± 1,89	2,286 ± 2,75	p=0,0425*

*Baseline values and delta are mean ± standard deviation (SD), *: Stat. Sign. p<0,05, ¥: borderline stat. Sign. p>0,05 and p<0,1, AD: Assistive device, P-Value: before versus after 6MWT*

Figure 3. Line plots of (a) covered distance, (b) heart rate and (c) Visual Analogue Scale (VAS) during the Six-Minute Walk Test (6MWT) in three conditions.

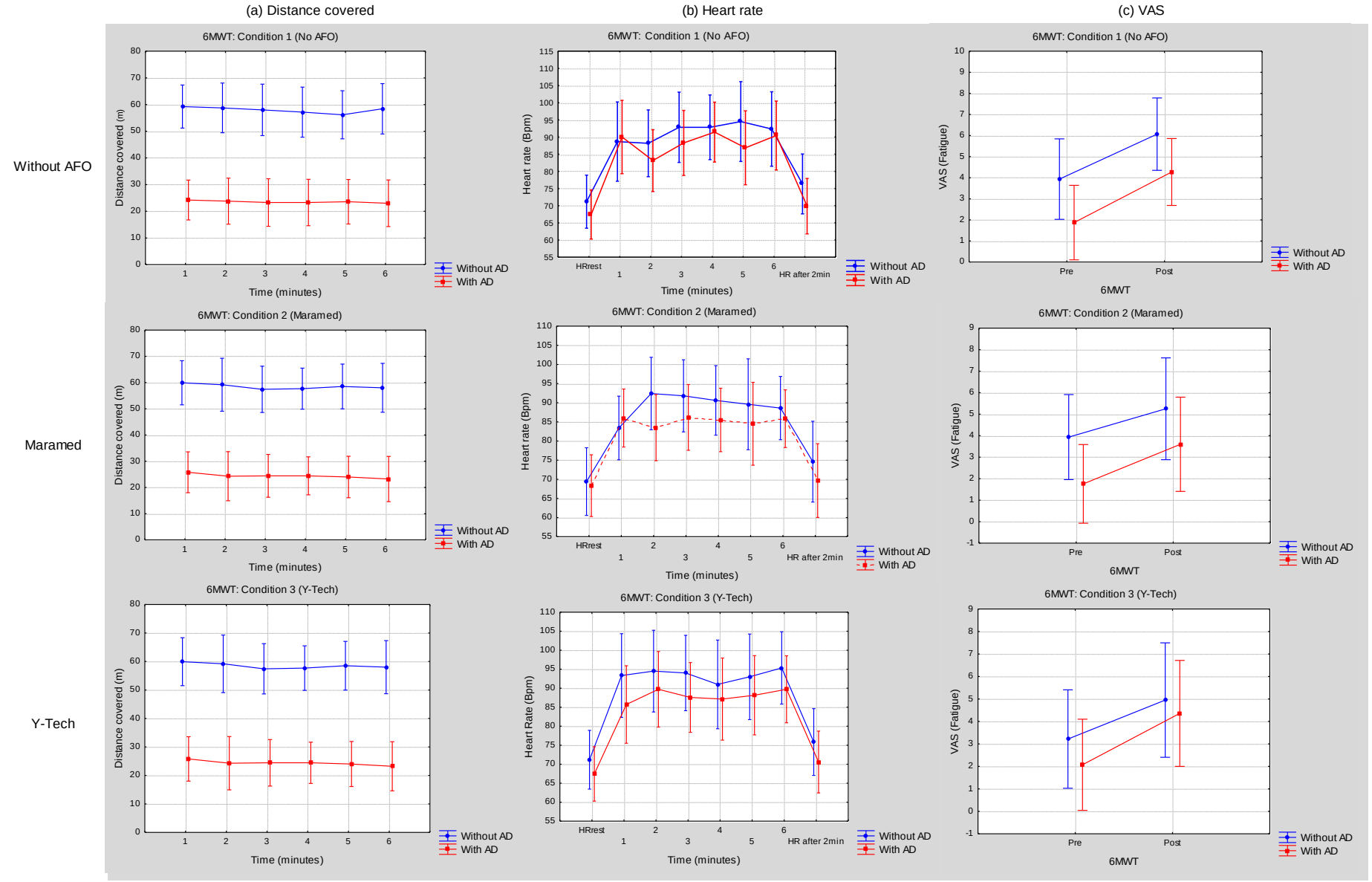
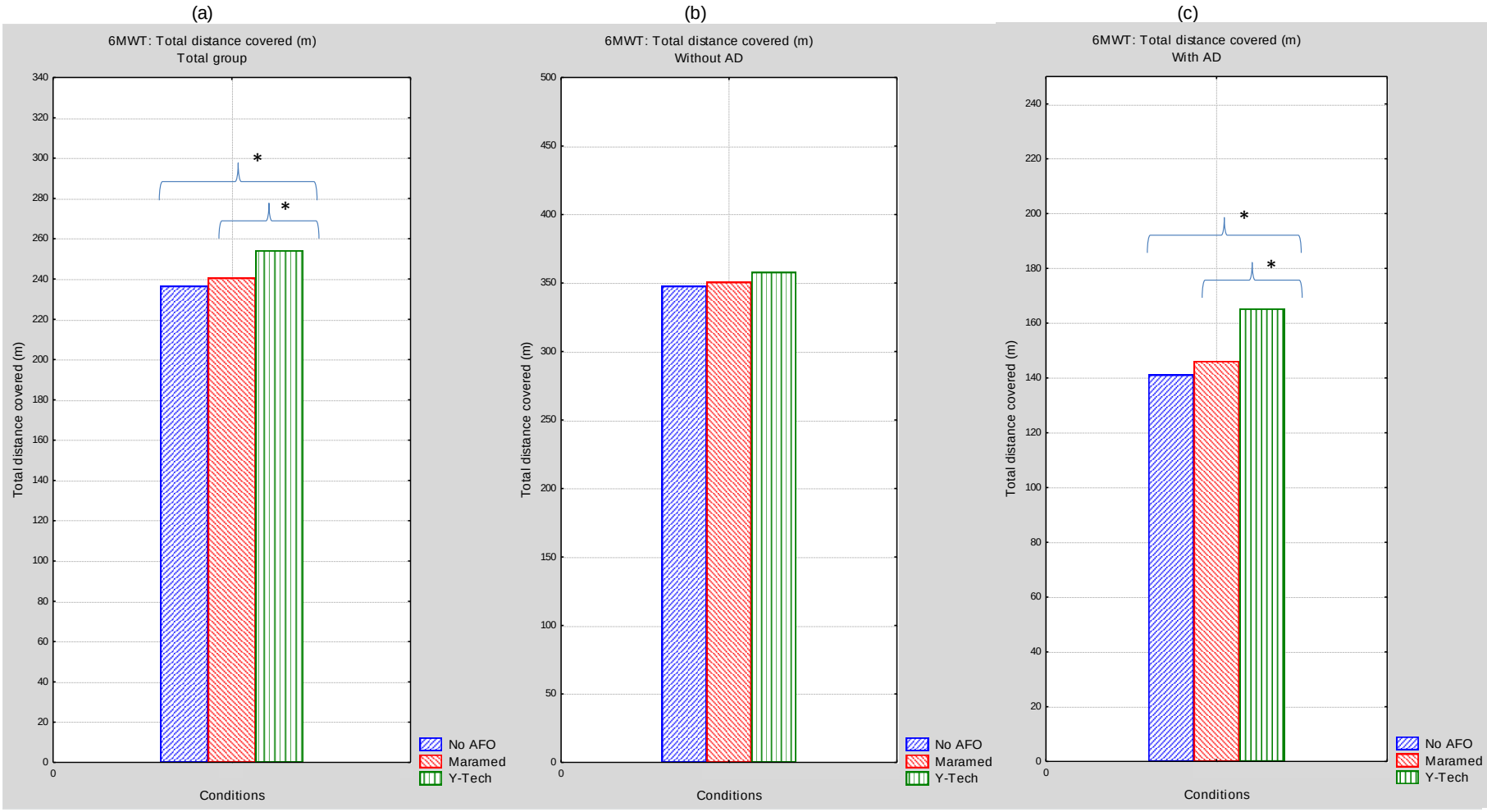


Figure 4. Results of the total distance covered (in meters) during the Six-Minute Walk Test (6MWT) in the total group (a), the without AD-group (b) and the AD-group (c).



DISCUSSION

The aim of this study was to explore the effects of two different ankle-foot orthoses (AFO's) on the ambulatory capacities and heart rate during the Six- Minute Walk Test (6MWT). We investigated the alternations in gait pattern before and after the 6MWT while comparing two different types of AFO compared to walking without an AFO and we identified the pacing pattern and heart rate during this 6MWT in each condition.

Previous studies have already well-established the beneficial effects of wearing an AFO on the gait pattern such as an increase in walking speed, cadence, step length and a decrease in double support time (Abe et al., 2009; Esquenazi et al., 2009; Park et al., 2009; Rao et al., 2008). Specifically a previous study, a master thesis (Schaekers & Tancsik, 2014), confirmed these results with the Y-Tech and Maramed, which were also applied in the present study, during a short distance walking at usual and fastest speed. The present study expanded previous research by investigating the effect of a longer walking effort (6MWT) on the spatio-temporal parameters in combination with the use of different types of AFO. We investigated the changes in gait pattern before and after the 6MWT and compared these possible alterations between the three conditions, i.e. without an AFO, with the Maramed and with the Y-Tech. We hypothesized that: (1) longer distances could be covered with an AFO with a smaller or similar increase in heart rate, while (2) the gait pattern would be more negatively affected when walking without an AFO, (3) especially in a more impaired group.

For the third part of this hypothesis, a subdivision into various groups had to be made. Therefore we used the criterion of walking with a cane or not, based on a time limit that had been set to complete the Timed Up and Go (TUG). First results showed that the TUG is an accurate criterion for subdividing our population, which was different at motor level, into two groups, i.e. the without AD-group (as the higher functioning participants) and the AD-group (as the lower functioning participants). This can be assumed because clear significant differences were found between the two subgroups in motor symptoms and capacity, i.e. significant differences in dorsiflexion of the affected ankle, the motor part of the Brunnstrom Fugl- Meyer of the Lower Extremities (BFM-LE), Motricity Index (MI) of the ankle, the Functional Ambulation Categories (FAC) and the TUG. Hereby, no significant differences were found in general patient characteristics, which means the subgroups were homogeneous on general aspects.

Secondly, we wanted to know if an AFO, specifically a Maramed or a Y-Tech, could increase the covered distance during the 6MWT and what effect it would have on the heart rate during the test. It had been hypothesized that these effects would be different depending on the ambulatory impairment level, i.e. the without AD-group and the AD-group in this study. The most important significant effects were found in total distance covered during the 6MWT and this in favour of the Y-Tech compared to no AFO and to the Maramed. This effect was present in the total group with post-hoc analysis revealing the difference to be present in the AD-group, not in the without AD-group. For this reason we can assume that people with lower physical abilities can benefit more from an AFO than people with a

higher degree of functionality. This confirms the results of the study of Nolan et al., 2009, which already concluded that subjects in the slower patient group benefit more from an AFO compared to people in the moderate and fast patient group (Nolan et al., 2009). In contrast to this study, they subdivided their study sample according to the Ambulation Index (AI), nevertheless their patient groups were comparable to the study sample of this study. Considering this result, we have to make an important remark. The clinically meaningfulness of this increase in covered distance can be discussed. The distance covered while wearing the Y-Tech was on average 10 meters further compared to not wearing an AFO (in both total group and the subgroups). For the total average scores of the different conditions, see table 2a. According to Perera et al., 2006, the smallest clinical meaningful change is 20meters (Perera et al., 2006). According to this data, the improvements reported with the Y-Tech in our study are not clinically meaningful. Here, there is also an important consideration, i.e. Perera et al., 2006 investigated the clinically meaningfulness of a change in 6MWT scores after a standard stroke rehabilitation program in stroke patients, not the immediate effect of an orthosis. Therefore the reported values may not be (completely) accurate and not to be generalized.

Furthermore, it was hypothesized that there would be a smaller increase in heart rate while walking with the AFO since walking with an AFO is more comfortable. Besides this, another hypothesis stated that there would be an equal increase in heart rate along with a greater distance covered, as this was the case with the Y-Tech. No consistent differences regarding the heart rate between the three conditions during the 6MWT were found.
Multiple hypotheses were considered to explain this lack of results. The most important hypothesis probably is the possible influence of the instructions of the 6MWT. Participants were instructed to walk as far as possible, safely, and at their self-selected, comfortable pace throughout the six minutes. It may be possible that the participants dosed their gait velocity too much since the instruction did not encourage to walk as fast as possible. Thereby it could be that the cardiovascular effort was limited and at most submaximal. This is also a potential explanation why the differences in covered distance are very small. Another possible explanation for the lack of results concerning the heart rate is that participants feel safer while walking at a slower pace. Therefore it could be possible that they did not reach a submaximal effort and their heart rate did not significantly increase. A third explanation could be that during their rehabilitation, stroke patients do not get enough challenge and do not focus enough on the achievement of increasing their gait velocity and repeatedly do not reach a submaximal exertion level. The last hypothesis is that the lack of increase in heart rate is due to muscle fatigue rather than physical exertion or cardiovascular endurance. All of these hypotheses influence each other and one is possibly the result of another.

Coming back to the main theory, as a second part, it was hypothesized that the gait pattern would be more negatively affected when walking six minutes without an AFO. Contrary to this, there were no differences in the gait pattern between the three conditions. Concerning the effects within the conditions, it was shown that there are few borderline significant changes on the gait pattern for the cadence and the step length of the unaffected side.

The cadence of the total group in the condition without AFO was borderline significantly smaller after the 6MWT compared to before the 6MWT. This result was not seen within the conditions Maramed and Y-Tech. This could be an indicator for a positive effect of wearing an AFO when walking a longer distance. When looking at the raw data, it can be noted that there is a smaller decline in the cadence after the 6MWT while walking with an AFO compared to walking without an AFO. However this result is not powerful enough and therefrom no conclusions can be made concerning the cadence.
When looking at the step length of the unaffected side, significant increases were found in the total group and without AD-group in the condition without an AFO and in the total group and without AD-group in the Y-Tech condition. Borderline significance was shown in the AD-group in the condition without an AFO. While the step length of the unaffected side increased, the gait velocity remained constant. These results concerning the step length of the unaffected side are not in line with the expectations. We would rather expect a decrease in step length of the affected side but not a compensatory increase of step length on the unaffected side. It is possible that due to the small sample size, some consistent effects on the gait pattern were missed out. Likewise it would be expected that these negative changes would be less in the conditions with the Maramed and Y-Tech in comparison with wearing no AFO but no significant effects on the gait pattern were found between the different conditions. Based on these results, we can assume that the impact of walking a longer distance on the gait pattern is very small at its best or even non-existent.
Because there is no previous research regarding to this research questions in the stroke population, we cannot compare our results with others.

A potential limitation of this study is that, due to the small sample size as well as due to our selection criteria, our participants and related results are not representative for the entire population. It is possible that our sample has a higher functionality level than the mean population of stroke patients because participants had to be able to walk the 6MWT without an AFO to complete the study, otherwise they were excluded. Another very important and possibly biasing limitation is that all our included subjects already wore an individualized AFO (Y-Tech) for an average period of 6,77 months prior to the study. The total distance covered was significantly greater in the Y-Tech condition compared to walking with the Maramed or no AFO. This result could have been caused by a longer familiarization time of the Y-Tech compared to the standardized AFO (Maramed). Furthermore, it could be useful to add kinematic analysis to observe the quality of the gait pattern since the GAITRite® system is only able to detect the quantitative spatio-temporal parameters. It is possible that there would have been a change in the quality of movement after performance of the 6MWT. Based on the results of this study, it could be useful to redo this experimental study design with a larger sample size, adding kinematic analysis and with other instructions of the 6MWT, i.e. to walk as fast as possible rather than to walk as far as possible, safely, and at their self-selected, comfortable pace. Additional research could focus on the long-term effects of different types of AFO's with a larger sample size. Ideally, testing should begin from the moment the AFO has been delivered to the patient so that habituation time can be standardized. Yet we need to be aware that it is very difficult to accomplish such research. In this study, it is possible that the effects of the Y-Tech were carried over to the extent

that the AFO remained effective without even wearing it, this because of the prolonged period of time while wearing the Y-Tech before the study.

In conclusion, it can be assumed that the TUG is an accurate indicator for subdividing a stroke population according to the ambulatory impairment level. An AFO, more specifically a Y-Tech, can increase the covered distance during the 6MWT and thereby improve the functional ambulation in stroke patients (more than a Maramed). Stroke patients with a relatively higher degree of functionality benefit less from an AFO when concerning ambulation during a longer period of time. Based on the results in our study, we can assume that the impact of walking a longer distance on the gait pattern is very small or non-existent.

REFERENCES

Abe H, Michimata A, Sugawara K, Sugaya N, Izumi S (2009). Improving gait stability in stroke hemiplegic patients with a plastic ankle-foot orthosis. Tohoku J Exp Med, 218(3):193-9.

Bilney B, Morris M, Webster K (2003). Concurrent related validity of the GAITRite walkway system for quantification of the spatial and temporal parameters of gait. Gait Posture, 17(1):68-74.

Blum L, Korner-Bitensky N (2008). Usefulness of the Berg Balance Scale in stroke rehabilitation: a systematic review. Phys Ther, 88(5):559-66.

Bohannon RW, Andrews AW, Smith MB (1988). Rehabilitation Goals of Patients with Hemiplegia. International Journal of Rehabilitation Research, 11(2):181-3.

Bohannon RW, Horton MG, Wikholm JB (1991). Importance of four variables of walking to patients with stroke. Int J Rehabil Res, 14(3):246-50.

Cakar E, Durmus O, Tekin L, Dincer U, Kiralp MZ 2010. The ankle-foot orthosis improves balance and reduces fall risk of chronic spastic hemiparetic patients. Eur J Phys Rehabil Med, 46, 364-368.

Danielsson A, Sunnerhagen KS (2004). Energy expenditure in stroke subjects walking with a carbon composite ankle foot orthosis. J Rehabil Med 2004, 36(4):165-8.

de Wit DC, Buurke JH, Nijlant JM, Ijzerman MJ, Hermens HJ (2004). The effect of an ankle-foot orthosis on walking ability in chronic stroke patients: a randomized controlled trial. Clin Rehabil, 18(5):550-7.

Eng JJ, Dawson AS, Chu KS (2004). Submaximal exercise in persons with stroke: test-retest reliability and concurrent validity with maximal oxygen consumption. Arch Phys Med Rehabil, 85(1):113-8.

Erel S, Uygur F, Engin S, I, Yakut Y (2011). The effects of dynamic ankle-foot orthoses in chronic stroke patients at three-month follow-up: a randomized controlled trial. Clin Rehabil, 25(6):515-23.

Esquenazi A, Ofluoglu D, Hirai B, Kim S (2009). The effect of an ankle-foot orthosis on temporal spatial parameters and asymmetry of gait in hemiparetic patients. PM R, 1(11):1014-8.

Fayazi M, Dehkordi SN, Dadgoo M, Salehi M (2012). Test-retest reliability of Motricity Index strength assessments for lower extremity in post stroke hemiparesis. Med J Islam Repub Iran, 26(1):27-30.

Feigin VL, Lawes CM, Bennett DA, Anderson CS (2003). Stroke epidemiology: a review of population-based studies of incidence, prevalence, and case-fatality in the late 20th century. The Lancet Neurology, 2(1):43-53.

Flansbjer UB, Holmback AM, Downham D, Patten C, Lexell J (2005). Reliability of gait performance tests in men and women with hemiparesis after stroke. J Rehabil Med, 37(2):75-82.

Franceschini M, Massucci M, Ferrari L, Agosti M, Paroli C (2003). Effects of an ankle-foot orthosis on spatiotemporal parameters and energy cost of hemiparetic gait. Clinical Rehabilitation, 17(4):368-72.

Fulk GD, Echternach JL, Nof L, O'Sullivan S (2008). Clinometric properties of the six-minute walk test in individuals undergoing rehabilitation poststroke. Physiother Theory Pract, 24(3):195-204.

Gok H, Kucukdeveci A, Altinkaynak H, Yavuzer G, Ergin S (2003). Effects of ankle-foot orthoses on hemiparetic gait. Clinical Rehabilitation, 17(2):137-9.

Hesse S, Luecke D, Jahnke MT, Mauritz KH (1996). Gait function in spastic hemiparetic patients walking barefoot, with firm shoes, and with ankle-foot orthosis. International Journal of Rehabilitation Research, 19(2):133-41.

Hesse S, Werner C, Matthias K, Stephen K, Berteanu M (1999). Non-velocity-related effects of a rigid double-stopped ankle-foot orthosis on gait and lower limb muscle activity of hemiparetic subjects with an equinovarus deformity. Stroke, 30(9):1855-61.

Hung JW, Chen PC, Yu MY, Hsieh YW (2011). Long-term effect of an anterior ankle-foot orthosis on functional walking ability of chronic stroke patients. Am J Phys Med Rehabil, 90(1):8-16.

Iyriboz Y, Powers S, Morrow J, Ayers D, Landry G (1991). Accuracy of pulse oximeters in estimating heart rate at rest and during exercise. Br J Sports Med, 25(3):162-4.

Kim PJ, PR, Mieras J, Thoms T, Freeman D, Page J (2011). Interrater and intrarater reliability in the measurement of ankle joint dorsiflexion is independent of examiner experience and technique used. Journal of the American Podiatric Medical Association, 101(5):407-14.

Kosak M, Smith T (2005). Comparison of the 2-, 6-, and 12-minute walk tests in patients with stroke. J Rehabil Res Dev, 42(1):103-7.

Li F, Wu Y, Li X (2013). Test-retest reliability and inter-rater reliability of the Modified Tardieu Scale and the Modified Ashworth Scale in hemiplegic patients with stroke. European Journal of Physical and Rehabilitation Medicine, 50(1):9-15.

Lin PY, Yang YR, Cheng SJ, Wang RY (2006). The relation between ankle impairments and gait velocity and symmetry in people with stroke. Arch Phys Med Rehabil, 87(4):562-8.

McDonough AL, Batavia M, Chen FC, Kwon S, Ziai J (2001). The validity and reliability of the GAITRite system's measurements: A preliminary evaluation. Arch Phys Med Rehabil, 82(3):419-25.

Mojica JAP, Nakamura R, Kobayashi T, Handa T, Morohashi I, Watanabe S (1988). Effect of Ankle-Foot Orthosis (Afo) on Body Sway and Walking Capacity of Hemiparetic Stroke Patients. Tohoku Journal of Experimental Medicine, 156(4):395-401.

Neumann DA (2002). *Kinesiology of the musculoskeletal system.* St. Louis, Missouri: Mosby.

Ng SS, Hui-Chan CW (2005). The timed up & go test: its reliability and association with lower-limb impairments and locomotor capacities in people with chronic stroke. Arch Phys Med Rehabil, 86(8):1641-7.

Nolan KJ, Savalia KK, Lequerica AH, Elovic EP (2009). Objective assessment of functional ambulation in adults with hemiplegia using ankle foot orthotics after stroke. PM R, 1(6):524-9.

O'Sullivan SB (2007). *Physical Rehabilitation.* Philadelphia: F.A. Davis Company.

Park JH, Chun MH, Ahn JS, Yu JY, Kang SH (2009). Comparison of gait analysis between anterior and posterior ankle foot orthosis in hemiplegic patients. Am J Phys Med Rehabil, 88(8):630-4.

Perera S, Mody SH, Woodman RC, Studenski SA (2006). Meaningful change and responsiveness in common physical performance measures in older adults. J Am Geriatr Soc, 54(5):743-9.

Perry J, Garrett M, Gronley JK, Mulroy SJ (1995). Classification of walking handicap in the stroke population. Stroke: 26(6):982-9.

Pollock C, Eng J, Garland S (2011). Clinical measurement of walking balance in people post stroke: a systematic review. Clin Rehabil, 25(8):693-708.

Rao N, Chaudhuri G, Hasso D, D'Souza K, Wening J, Carlson C (2008). Gait assessment during the initial fitting of an ankle foot orthosis in individuals with stroke. Disabil Rehabil Assist Technol, 3(4):201-7.

Robinett CS, Vondran MA (1988). Functional ambulation velocity and distance requirements in rural and urban communities. A clinical report. Phys Ther, 68(9):1371-3.

Sanford J, Moreland J, Swanson LR, Stratford PW, Gowland C (1993). Reliability of the Fugl-Meyer assessment for testing motor performance in patients following stroke. Phys Ther, 73(7):447-54.

Schaekers L, Tancsik D (2014). Masterproof part 2: What is the inlfuence of an ankle-foot orthosis (AFO) on the spatio-temporal gait parameters and functional balance in stroke patients?. University of Hasselt.

Simons CD, van Asseldonk EH, van der Kooij H, Geurts AC, Buurke JH (2009). Ankle-foot orthoses in stroke: effects on functional balance, weight-bearing asymmetry and the contribution of each lower limb to balance control. Clin Biomech, 24(9):769-75.

Tyson SF, DeSouza LH (2004). Development of the Brunel Balance Assessment: a new measure of balance disability post stroke. Clin Rehabil, 18(7):801-10.

Tyson SF, Rogerson L (2009). Assistive walking devices in nonambulant patients undergoing rehabilitation after stroke: the effects on functional mobility, walking impairments, and patients' opinion. Arch Phys Med Rehabil, 90(3):475-9.

Tyson SF, Thornton HA (2001). The effect of a hinged ankle foot orthosis on hemiplegic gait: objective measures and users' opinions. Clin Rehabil, 15(1):53-8.

van Uden CJ, Besser MP (2004). Test-retest reliability of temporal and spatial gait characteristics measured with an instrumented walkway system (GAITRite). BMC Musculoskelet Disord, 17;5:13.

Viosca E, Martinez JL, Almagro PL, Gracia A, Gonzalez C (2005). Proposal and validation of a new functional ambulation classification scale for clinical use. Arch Phys Med Rehabil, 86(6):1234-8.

Wang RY, Yen L, Lee CC, Lin PY, Wang MF, Yang YR (2005). Effects of an ankle-foot orthosis on balance performance in patients with hemiparesis of different durations. Clin Rehabil, 19(1):37-44.

Auteursrechtelijke overeenkomst

Ik/wij verlenen het wereldwijde auteursrecht voor de ingediende eindverhandeling:
The influence of ankle-foot orthoses (AFO's) on the ambulation during the Six-Minute Walk Test (6MWT) in chronic stroke patients

Richting: **master in de revalidatiewetenschappen en de kinesitherapie-revalidatiewetenschappen en kinesitherapie bij neurologische aandoeningen**
Jaar: **2015**

in alle mogelijke mediaformaten, - bestaande en in de toekomst te ontwikkelen - , aan de Universiteit Hasselt.

Niet tegenstaand deze toekenning van het auteursrecht aan de Universiteit Hasselt behoud ik als auteur het recht om de eindverhandeling, - in zijn geheel of gedeeltelijk -, vrij te reproduceren, (her)publiceren of distribueren zonder de toelating te moeten verkrijgen van de Universiteit Hasselt.

Ik bevestig dat de eindverhandeling mijn origineel werk is, en dat ik het recht heb om de rechten te verlenen die in deze overeenkomst worden beschreven. Ik verklaar tevens dat de eindverhandeling, naar mijn weten, het auteursrecht van anderen niet overtreedt.

Ik verklaar tevens dat ik voor het materiaal in de eindverhandeling dat beschermd wordt door het auteursrecht, de nodige toelatingen heb verkregen zodat ik deze ook aan de Universiteit Hasselt kan overdragen en dat dit duidelijk in de tekst en inhoud van de eindverhandeling werd genotificeerd.

Universiteit Hasselt zal mij als auteur(s) van de eindverhandeling identificeren en zal geen wijzigingen aanbrengen aan de eindverhandeling, uitgezonderd deze toegelaten door deze overeenkomst.

Voor akkoord,

Meuws, Leni