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Faculteit Geneeskunde en Levenswetenschappen

master in de revalidatiewetenschappen en de kinesitherapie

Masterthesis

Effect of ankle foot orthoses on the gait pattern in persons with stroke

Ode Van Ussel
Phaedra Vandebosch

Eerste deel van het scriptie ingediend tot het behalen van de graad van master in de revalidatiewetenschappen en de kinesitherapie

PROMOTOR :
Prof. dr. Peter FEYS

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BEGELEIDER :
Dhr. Bert LAERMANS
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2017
2018

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University Hasselt - Diepenbeek

Faculty medicine and life science

Master rehabilitation science and physiotherapy

Master thesis part 1:
Systematic review

Effect of ankle foot orthoses on the gait pattern in persons with stroke.

Highlights:

- The most commonly used software system to measure spatiotemporal and kinematic parameters in patients with stroke is the Vicon Nexus Camera Motion analysis system.
- Gait is detected at a self-selected walking speed via markers on a walkway or treadmill and analyzed in a three-dimensional perspective.
- The parameters that are most sensitive to change when wearing an AFO are: cadence, walking speed, step length, swing duration, positive- and negative ankle power, ankle ROM, knee ROM, ankle moments and knee moments.

Students: Phaedra Vandenbosch and Ode Van Ussel

Promotor: Prof. Peter Feys

Co-promotors: Prof. Dr. Pieter Meyns and Dr. Bart Dingenen

Orthomed: Mr. Rafael Baeten and Mr. Bert Laermans

Context

This literature review is situated in the subdomain of the neurorehabilitation, specifically applied on stroke patients. The study is a collaboration of the department physiotherapy and rehabilitation science at the University of Hasselt in Belgium on the one hand and the company Orthomed on the other hand. More specifically, it is conducted by two master students in the physiotherapy and rehabilitation science that worked independently for the systematic review under the supervision and guidance of promotor Prof. Dr. Peter Feys and copromotors, Prof. Dr. Pieter Meyns and Dr. Bart Dingenen with Rafaël Baeten and Bert Laermans of Orthomed. In collaboration with Orthomed, promotor and copromotors the research protocol was composed. The two students worked together on the literature study and both students participated in all parts of this systematic review.

Orthomed is a progressive company for orthopedic aids in Belgium that since 2016 exists of three collaborating firms. The expertise of Orthomed are orthopedics, prostheses, wheelchairs / mobility, stoma care and home appliances. They tend to give the best qualitative products and services to different departments to strive for the best care and quality of life for the patients.
(http://www.orthomed.be/index.html)

This study is set up because of the growing need for orthopedic aids in stroke patients. For the Netherlands there was in 2007 an estimation of 226.000 stroke patients reported by the KNGF guidelines and on top of that there is a prediction of 45.000 persons diagnosed with stroke every year. (Koninklijk Nederlands Genootschap voor Fysiotherapie, 2014). Two out of three of these patients have gait impairments (Jorgensen, Nakayama, Raaschou, & Olsen, 1995).

Therefore, this study aims to verify the most commonly used protocol to investigate the changes in different spatiotemporal, kinematic and kinetic parameters and their sensitivity to change when an ankle foot orthosis is used.

PART 1: Literature study

PART 2: Research protocol

PART 1: Literature study

1. Abstract

Background: Dorsiflexor weakness and plantarflexor spasticity is common in stroke patients and indicates a drop foot syndrome. A solution for this problem can be an ankle foot orthosis (AFO).

Method: Databases Pubmed and Web of Science are searched with the following MeSH terms (Medical Subject Headings): “Foot orthoses” [Mesh] AND “Walking” [Mesh] AND “Stroke” [Mesh] AND “Adult” [Mesh] NOT “Musculoskeletal diseases” [Mesh].

Results: The Vicon Nexus Camera Motion analyze system is most commonly used to measure spatiotemporal, kinematic and kinetic parameters in stroke patients. Gait is detected through reflective markers and analyzed in a three-dimensional (3D) perspective. The parameters that are most sensitive to change are: cadence, walking speed, step length, swing duration, positive- and negative ankle power, ankle dorsiflexion ROM, ankle plantar flexion ROM, knee flexion ROM, dorsiflexion moment and knee flexion moment.

Discussion and conclusion: For the quality assessment two articles scored below 50% of the maximal score of the checklist. Eleven articles scored between 50% and 75%. The last article scored more than 82% of the maximal score.

Aim: Investigating the effect of an AFO on the walking pattern of patients with neurologic disorders and more specific a muscle weakness of the dorsiflexors of the ankle.

Research questions: Primary: Which differences are measurable between walking without an AFO, with a dynamic AFO and with a static AFO in spatiotemporal, kinematic and kinetic parameters. Secondary: Is there a difference in user satisfaction between the static and the dynamic AFO.

Important keywords: Foot orthoses, Stroke, Walking.

2. Introduction

According to the revised definition of stroke in 2013, a distinction is made between the ischemic cause and the hemorrhage cause. The ischemic stroke is defined as “An episode of neurological dysfunction caused by focal cerebral, spinal or retinal infarction.” The hemorrhage stroke is defined as “Rapidly developing clinical signs of neurological dysfunction attributable to a focal collection of blood within the brain parenchyma or ventricular system that is not caused by trauma.” This is cited out of (Sacco et al., 2013).

Stroke exists of a wide and various spectrum of symptoms. Problems in language, sensation, cognition and motoric function can occur. These deficits are commonly accompanied with unilateral numbness, loss of vision in one eye, aphasia, sudden imbalance or ataxia. Moreover, damage of the corticospinal tract causes motor deficits and therefore weakness of the contralateral side. This weakness can be replaced by spasticity and hyperreflexia, so that at six to eight weeks post-stroke there can be a combination of spasticity and weakness in the lower extremity. The extensor muscles in the affected limb are most effected by spasticity. During gait this leads to enhanced circumduction, exorotation and a drop foot. (Grossman, S.C., & Porth, C.M. Porth’s Pathophysiology: Concepts of Altered Health States (ninth edition) (2014))

According to the KNGF guidelines there is an estimation of 45.000 people per year diagnosed with stroke in the Netherlands. The current prevalence is predicted on 226.000 people, which dates from the year 2007. (Koninklijk Nederlands Genootschap voor Fysiotherapie, 2014) A study of Jorgensen et al. (Jorgensen et al., 1995) concluded that two out of three stroke patients have an impaired gait function in the acute phase. After rehabilitation (usually 11 weeks) 64% of the survivors regain their independent walking ability, 14% can walk with an aid and 22% will not regain their walking ability. Often the walking aid Ankle Foot Orthosis (AFO) is prescribed in a patient with neuromuscular disabilities to improve the gait pattern. One of these disabilities is the ‘drop foot’, which refers to the inability or difficulty to move the ankle to dorsiflexion (moving the foot upward, against gravity, while standing or sitting). (Zollo et al., 2015)

Different types of AFOs are designed to improve the walking ability in which every AFO has different characteristics. For instance, there are solid AFOs made from polypropylene with a rigid structure, whereas other more flexible dynamic AFOs consist of carbon fiber, glass fiber and Kevlar. (Zollo et al., 2015) The articles of Kobayashi et al. (Kobayashi et al., 2016; Kobayashi, Orendurff, Singer, Gao, & Foreman, 2017) demonstrate that when given a more rigid AFO, the ankle will be more dorsiflexed and therefore it will force the knee to go to a more flexed position during stance, with the exception for initial contact. Another characteristic is the placement of the leaf, which can be a posterior ankle foot orthosis (PAFO) with straps anterior or an anterior ankle foot orthosis (AAFO) with straps posterior (C. C. Chen et al., 2010). Both AFO types were made to stabilize the ankle, though the AAFO is thought to be stronger and able to resist higher mechanical forces. It also takes less time to consume (Rao & Aruin,

2006). Other types of AFOs are an AFO-oil damper and an AFO in combination with functional electrical stimulation (FES), etc. (Schiemanck et al., 2015; Yamamoto, Ibayashi, Fuchi, & Yasui, 2015).

Due to the different symptoms in stroke patients, difficulties in gait can occur. One of these difficulties is an increased energy cost related with walking. The energy cost to lift the paretic leg during swing is increased, whereas the knee flexion is decreased in hemiplegic persons. This can lead to compensations such as hip hiking or circumduction during swing. Moreover, a larger step width is reported which can lead to balance limitation and compensations. Other differences for spatiotemporal parameters may be step length, cadence, etc. For kinematic parameters there can be changes in joint angles. Additionally, for kinetic parameters there are differences in forces and joint moments. (G. Chen, Patten, Kothari, & Zajac, 2005).

To determine the changes of an AFO on the gait pattern a clinical gait analysis can be used to retrieve information about spatiotemporal, kinematic and kinetic parameters. The gold standard for measuring movement is the three-dimensional (3D) motion analysis system. (Armand, Decoulon, & Bonnefoy-Mazure, 2016; Galna et al., 2014). Even though the 3D motion analysis system is the gold standard there is little use in the clinical settings. This can be explained by the high purchase price of the systems and the time that is necessary to set up the system. (Schurr, Marshall, Resch, & Saliba, 2017). Still, there is variation in systems and protocols used to perform the 3D analysis. For measuring the gait pattern various surfaces are used like the walkway that often difference from a carpeted walkway to a walkway with pressure mat and a Bertec split-belt instrumented treadmill, etc. (C. C. Chen et al., 2010; Chern, Chang, Lung, Wu, & Tang, 2013; Kobayashi et al., 2017). Another difference between studies can be found in the system used to analyze the gait pattern for example the Vicon motion system, ELITE system, a real-time motion capture system, etc. (C. C. Chen et al., 2010; Fatone & Hansen, 2007; Gatti et al., 2012).

The first aim of this systematic review is to report which dimensions, systems, protocols and outcome parameters are frequently used to determine changes in the gait pattern of stroke patients when wearing an AFO. Being unaware of a standard protocol to perform a gait analysis in stroke patients, leads this study search towards articles using gait analysis for measuring spatiotemporal, kinematic and kinetic parameters in stroke patients. When performing a gait analysis, different spatiotemporal, kinematic and kinetic parameters are measured. Not all parameters may be equally sensitive to change when wearing an AFO. Therefore, the secondary aim of this study is to report multiple spatiotemporal, kinematic and kinetic parameters and their sensitivity to change when stroke patients walk with an AFO.

First a **PICO** was set up as followed:

Patients: Stroke patients
Intervention: AFO
Comparison: without or with another AFO
Outcome: Spatiotemporal, kinematic and/or kinetic outcome parameters

3.1 Research questions

Primary research question/aim: which systems, dimensions and protocols are commonly used to evaluate spatiotemporal, kinematic and kinetic outcome parameters during gait analysis in stroke patients?

Secondary research question/aim: which spatiotemporal, kinematic and kinetic parameters are assessable and which of these parameters are most sensitive to change by means of gait analysis when an AFO is used in stroke patients?

3.2 Literature search

The combination of MeSH-terms and keywords used are displayed in table 1. Databases Pubmed and Web of Science were searched between October 2017 and April 2018. On Pubmed following Mesh-terms were used: Foot Orthosis, Walking, Stroke, Adult and Musculoskeletal diseases. These terms were combined with 'AND' and 'NOT' to become the final search strategy: "Foot orthosis" [Mesh] AND "Walking" [Mesh] AND "Stroke" [Mesh] AND "Adult" [Mesh] NOT "Musculoskeletal diseases" [Mesh]. On Web of Science we used the same terms and combined them with 'topic'.
No filters were applied in any of the search strategies. After these 41 articles were found, one article was corresponding between the two databases. The articles were listed in table 2 and screened for in- and exclusion, which is also displayed in figure 1.

3.3 Selection criteria

The following inclusion and exclusion criteria were set up. Inclusion criteria were: patient related: acute or chronic stroke patients. Intervention related: AFO. Outcome related: spatiotemporal, kinematic and/ or kinetic parameters during unperturbed gait. Spatiotemporal parameters include parameters like: cadence, stride and stance duration, single support, walking speed, stride length, step length, etc. Kinematic parameters are movements of the joints and consist of angles. Kinetic parameters include forces that act on the body or are generated by the body. This contains power and moments of the relative joints.

Exclusion criteria were: patient related: healthy persons as only participants, musculoskeletal diseases, multiple diseases and a sample size less than five. Comparison related: knee ankle foot orthosis (KAFO), powered orthosis, FES or foot drop stimulator (only excluded for the secondary research question). Outcome related: gait speed as only spatiotemporal, kinematic or kinetic outcome parameter. Systematic reviews and meta-analyses.

3.4 Quality assessment

A quality check-up was performed for each included article using the Strobe-statement checklists for cohort, case-control and cross-sectional studies (combined). (https://www.strobe-statement.org/index.php?id=available-checklists). These checklists can be found in the appendix. The same checklist was used for each type of observational study to allow comparison between articles with different design. One randomized controlled trial was included (Nikamp et al., 2017), for which the CONSORT 2010 checklist for randomized trials was utilized.

For the interpretation of the checklist a three-point scale is used:

- 2: clearly described
- 1: doubtful
- 0: not mentioned
- Inapplicable questions were not included in the total score

After assigning the points a percentage of this total score is calculated. This information can be found in table 3.

Furthermore, a SWOT-analysis was conducted for defining strengths and weaknesses of the included articles. This information can be found in table 4.

3.5 Data extraction

The information concerning characteristics of the population is represented in table 5. Table 6 represents an extensive elaboration of the methodologic instruments, which can give insight into the primary research question. Table 7 contains information concerning the different gait parameters and their changes during interventions. More specifically, it contains information regarding the secondary research question. For the secondary research question, all spatiotemporal, kinematic and kinetic parameters were included. Other parameters such as energy expenditure, user satisfaction, obstacle avoidance, EMG measurements (co-activation index, tibialis anterior activation index, push-off index, premature calf activation index) and weight baring symmetry during stance were excluded. The article of Schiemanck et al. (Schiemanck et al., 2015) was excluded for the secondary research question because there was only information about the outcome parameters when walking with an AFO and no comparison without or with another AFO. Therefore, no statements can be made about the changes in parameters when wearing an AFO. Additionally, the article of van Swigchem et al. (van Swigchem, Roerdink, Weerdesteyn, Geurts, & Daffertshofer, 2014) was excluded for the secondary research question because all measurements were done while avoiding obstacles. Therefore, the inclusion criteria ‘spatiotemporal, kinematic and/ or kinetic parameters during unperturbed gait’ was not met.

4. Results

4.1 Study selection

The output of the search strategy comes down to a total of 41 articles, which were screened on title/abstract and full text as described in table 2. Of these 41 articles, 14 met the in- and exclusion criteria. For the primary research question all 14 articles were included and for the secondary research question 12 articles were included. Reasons to exclude two articles for the secondary research question are twofold. First, it only contains information about spatiotemporal, kinematic or kinetic parameters when walking with FES (Schiemanck et al., 2015). Second, it only contains information about spatiotemporal, kinematic or kinetic parameters during obstacle avoidance (van Swigchem et al., 2014). Following the above, a specific search has been conducted for patient homogeneity between the different articles, which is registered in table 5.

In the 14 studies a total of 185 hemiplegic patients and 49 control subjects were included. The sample size ranged from five to 39 participants. The age of the participants ranged from 23 to 77 years old with an average age of 55 years old. However, not all studies reported the ages of their participants. Time since stroke was for 10 out of 14 articles more than six months, whereas acute stroke was reported in two of the 14 articles. The other two articles had both acute and chronic stroke patients. Only three articles mentioned both types of stroke (ischemic and hemorrhagic) (C. C. Chen et al., 2010; Nikamp et al., 2017; Schiemanck et al., 2015). The study of Pohl et al. (Pohl & Mehrholz, 2006), included hemiparetic patients due to stroke or traumatic brain injury. All studies allowed walking with an assistive device if necessary. They could walk at a self-selected walking speed, except in one study, where two subjects were excluded because their walking speed (without AFO) was two standard deviations above the average speed (Zissimopoulos, Fatone, & Gard, 2014). Generally, there were more men included than women. One study even included no women and only eight men (Kobayashi et al., 2016).

4.2 Quality assessment

Strobe-statement checklists for cohort, case-control and cross-sectional studies (combined) were used to check the quality of the studies. The results of this assessment are displayed in table 3.

4.3 Results data-extraction

4.3.1 Primary research question

To measure the gait pattern, markers were used in 12 studies in which 11 of these studies used retro-reflective or reflective markers (C. C. Chen et al., 2010; Fatone & Hansen, 2007; Gatti et al., 2012; Kobayashi et al., 2016; Kobayashi et al., 2017; Nikamp et al., 2017; Schiemanck et al., 2015; Singer, Kobayashi, Lincoln, Orendurff, & Foreman, 2014; Yamamoto et al., 2015; Zissimopoulos, Fatone, & Gard, 2015; Zollo et al., 2015). Van Swigchem et al. (van Swigchem et al., 2014) did not mention which kind of markers were used. Three of these twelve studies used them according to the modified Cleveland clinic marker set (Kobayashi et al., 2017; Singer et al., 2014). The markers were placed on eight segments: two on the feet, two on the shanks, two on the thighs, one on the pelvis and one HAT (head, arm, trunk). If necessary, the markers were placed on the AFO. The Helen Hayes full-body marker set (standard marker set) was used to lighten the anatomical landmarks in two studies (Fatone & Hansen,

2007; Zissimopoulos et al., 2015). These markers are placed bilateral on the shod foot proximal to the third metatarsal phalangeal joint, on the lateral malleoli, anterior on the shanks and thighs, femoral lateral epicondyles, between the processes styloid of the wrist, also on the SIAS (spina iliaca anterior superior) and the SIPS (spina iliaca posterior superior). Gatti et al. (Gatti et al., 2012) used the retroreflective markers by Davis et al. (Davis, Ounpuu, Tyburski, & Gage, 1991). The precise number of markers in the other studies can be found in table 6, no standard method for placement of these markers was mentioned.

A walkway was used in seven studies. In four of these seven studies, a 10-meter walkway was implemented. Zissimopoulos et al. (Zissimopoulos et al., 2015) placed medio-lateral targets on the floor with tape. Chern et al. (Chern et al., 2013) put a pressure mat in the middle of his 10-meter walkway and Fatone et al. (Fatone & Hansen, 2007) used a walkway with six embedded force plates (named the flush) in the floor. Only Gatti et al. (Gatti et al., 2012) used a 10-meter walkway in the gait lab without any special aspects. Chern et al. (C. C. Chen et al., 2010) used a carpeted walkway but did not mention the distance. Zollo et al. (Zollo et al., 2015) was the only one using a three-meter walkway and Schiemanck et al (Schiemanck et al., 2015) a 15-meter walkway.

A treadmill was implemented in four of the fourteen studies. A Bertec split-belt fully instrumented treadmill was used in the studies of Kobayaski et al. and Singer et al. (Kobayashi et al., 2016; Kobayashi et al., 2017; Singer et al., 2014). Van Swigchem et al. (van Swigchem et al., 2014) used a treadmill with maximum speed between two or three km/h and they had obstacles placed in front of the patient with an electromagnet.

Six force plates (6 AMTI) were used to examine the different kinetic parameters in the study of Yamamoto et al. (Yamamoto et al., 2015). Self-selected walking speed was applied in every included article (C. C. Chen et al., 2010; Chern et al., 2013; Fatone & Hansen, 2007; Gatti et al., 2012; Kobayashi et al., 2016; Kobayashi et al., 2017; Nikamp et al., 2017; Pohl & Mehrholz, 2006; Schiemanck et al., 2015; Singer et al., 2014; van Swigchem et al., 2014; Zissimopoulos et al., 2015; Zollo et al., 2015).

Different software systems were wielded to analyze the data of the different outcome parameters. Eight studies (C. C. Chen et al., 2010; Kobayashi et al., 2016; Kobayashi et al., 2017; Nikamp et al., 2017; Schiemanck et al., 2015; Singer et al., 2014; van Swigchem et al., 2014; Yamamoto et al., 2015) used a Vicon Nexus ten-camera or six-camera motion analysis system. A real-time motion capture system was utilized in three studies (Fatone & Hansen, 2007; Gatti et al., 2012; Zissimopoulos et al., 2015). It exists of eight digital or infrared cameras (Gatti et al 2012). Zollo et al. (Zollo et al., 2015) used the stereo-photogrammetric system with eight infrared cameras and two digital cameras. Pohl et al. (Pohl & Mehrholz, 2006) did not mention which system and cameras they utilized, only that they used software developed at Klinik Bavaria. Data was analyzed in a three-dimensional perspective for all studies except for (Pohl & Mehrholz, 2006). Even though four studies did not explicitly mention whether data was 2D or 3D, it was suspected that it was a 3D analysis system after investigation of the used equipment (Gatti et al., 2012; Pohl & Mehrholz, 2006; Zissimopoulos et al., 2015; Zollo et al., 2015). Only in the study of

Pohl et al. (Pohl & Mehrholz, 2006) it was not clear which dimension was used because equipment was not mentioned.

Safety harnesses were used to secure the participants during gait (Kobayashi et al., 2016; Kobayashi et al., 2017; Singer et al., 2014). The participants had either a familiarization period of three weeks (Schiemanck et al., 2015; Yamamoto et al., 2015), or time to practice before measurement to get used to the AFO, duration of practice was not mentioned (C. C. Chen et al., 2010; Gatti et al., 2012; Kobayashi et al., 2017).

4.3.2 Secondary research question

An overview of the results can be found in table 7.

Spatiotemporal parameters

The spatiotemporal parameters that are most sensitive to change when wearing an AFO are gait speed, step length and cadence. More than halve of the studies that investigated these parameters found significant changes.

Six out of fourteen articles found results for gait speed, no significant results were found in three of this six articles (C. C. Chen et al., 2010; Fatone & Hansen, 2007; Nikamp et al., 2017). Two articles showed a significant increase in walking speed when wearing different AFO types (such as the AFO with oil damper and the AAFO) when compared with barefoot conditions (Gatti et al., 2012; Yamamoto et al., 2015). Chern et al. (Chern et al., 2013), reported a significant difference but it was not clear if the gait speed was increased or decreased.

Step length is reported in seven of the fourteen studies. Three of these studies reported no significant changes in the step length (C. C. Chen et al., 2010; Nikamp et al., 2017; Zollo et al., 2015). One article reported no significant difference for the paretic leg however in the non-paretic leg there is a significant increase found by Yammamoto et al. (Yamamoto et al., 2015). In another study they found a significant difference but no information was found in the article about which side (paretic or non-paretic) improved or deteriorated (Chern et al., 2013). In the articles of Fatone et al. and Gatti et al. (Fatone & Hansen, 2007; Gatti et al., 2012), a significant larger step length was found in the non-paretic leg when wearing an AFO.

Cadence was investigated in three out of fourteen articles. One study showed a significant increased cadence when wearing an AFO (Nikamp et al., 2017). Another article reported no significant differences (Zollo et al., 2015). And the last article reported a change in cadence when wearing an AFO but they did not report if the cadence increases or decreases (Chern et al., 2013).

A total of three articles discussed the stride duration. Of these three articles there was only one with a significant increase (Nikamp et al., 2017), the other studies found no significant changes (C. C. Chen et al., 2010; Zollo et al., 2015)

Only one study investigated the effect of an AFO on the stride length, they found no significant differences (Nikamp et al., 2017).

Results for step width were discussed in three of the fourteen studies whereof two articles reported no significant differences (Nikamp et al., 2017; Zissimopoulos et al., 2015). The last study found a significant decrease in step width when stroke subjects walked with an AFO (Fatone & Hansen, 2007).

No significant differences were reported for stance duration (Nikamp et al., 2017). Also, Yammamoto et al. (Yamamoto et al., 2015) noted no significant differences in loading response time.
For single support duration there was one article reporting a significant increase but the second article reported no significant difference. (Nikamp et al., 2017; Yamamoto et al., 2015)
According to the article of Nikamp et al. (Nikamp et al., 2017), there were no significant changes for the double limb support. However the second article found a significant lower percentage of double support in the hemiplegic leg while wearing an AFO (Zollo et al., 2015). And the last article of Pohl et al. (Pohl & Mehrholz, 2006), found a significant reduction of double stance duration when wearing an AFO.
For swing duration two out of fourteen articles reported results. Nikamp et al. (Nikamp et al., 2017), noted no significant changes. Yet the article of Yammamoto et al. (Yamamoto et al., 2015), found a significant decrease in pre-swing time.
Another study investigated the percentage of swing and reported an increase for the affected side compared with healthy controls (Zollo et al., 2015).
The parameter mediolateral foot-placement showed no significant changes when using different AFO types (Zissimopoulos et al., 2015).
The article of Nikamp et al. (Nikamp et al., 2017) found a significant decrease in foot progression when wearing an AFO.

Kinematic parameters

Range of motion (ROM) of the ankle and knee are the most sensitive kinematic parameters to change during gait in stroke patients while wearing an AFO.

Two articles reported results of center of pressure (CoP) sway, Fatone et al. (Fatone & Hansen, 2007), found that when participants walked with an AFO the CoP moves posterior of the ankle in contrast to an anterior displacement without an AFO. Also, the displacement with AFO is eliminated whereas without AFO the CoP moves twice during mid-stance. The second article found that an AFO caused a better alignment of the CoP with the axis of the foot and caused a lateral shift of the CoP (Chern et al., 2013). Pohl et al. (Pohl & Mehrholz, 2006), described an increased weight bearing symmetry when wearing an AFO.
The ROS (roll over shape) arc radius and length both improved significantly in the hemiplegic leg when wearing an AFO (Fatone & Hansen, 2007).

Nine of the fourteen included studies investigated the ankle ROM, of these nine articles eight found a significant difference. A significant decrease in plantar flexion is found during initial contact, and swing (C. C. Chen et al., 2010; Fatone & Hansen, 2007; Nikamp et al., 2017; Zissimopoulos et al., 2015). During stance and initial contact, a significant increased dorsiflexion was seen when walking with an AFO (C. C. Chen et al., 2010; Kobayashi et al., 2016; Kobayashi et al., 2017; Yamamoto et al., 2015; Zollo et al., 2015). However during stance Fatone et al. (Fatone & Hansen, 2007) found no significant differences for the ankle dorsiflexion angle. The article of Yamamoto et al.(Yamamoto et al., 2015), found a significant decrease in peak plantar flexion during stance and swing phase but when looking at

the article of Singer et al. (Singer et al., 2014), no significant change was reported. The peak dorsiflexion was significantly increased during stance and swing phase (Yamamoto et al., 2015).
Chen et al. (C. C. Chen et al., 2010) found a significant decrease in the maximal eversion during stance and maximal inversion during swing.

Changes in the ROM of the ankle joint are found. Because of the AFO-moment there is a decreased plantar flexion detected during late stance which can limit the push-off (Kobayashi et al., 2017), but also during initial contact the plantar flexion angle declines with the use of an AFO and a slight increase for dorsiflexion is detected even during swing phase (Fatone & Hansen, 2007). Also Chen et al. (C. C. Chen et al., 2010), found a significant decrease of plantar flexion to neutral not only during initial contact but also during swing phase. Yet during stance they detected a significantly increased dorsiflexion. Yamamoto et al. (Yamamoto et al., 2015), found that dorsiflexion was increased during the swing-phase after three weeks of AFO-OD use and that plantar flexion during swing significantly decreased when using AFO-OD(Yamamoto et al., 2015)(Yamamoto et al., 2015)(Yamamoto et al., 2015)(Yamamoto et al., 2015)(Yamamoto et al., 2015)(Yamamoto et al., 2015)(Yamamoto et al., 2015)(Yamamoto et al., 2015). Adduction angle in the ankle changed, it declined significantly during initial contact when wearing an AFO. No significant differences were seen for inversion during initial contact, yet there was a significant decrease of maximal eversion during swing phase with an AFO (C. C. Chen et al., 2010). During pre-swing, peak plantar flexion significantly diminished and during terminal stance it significantly raised when wearing the AFO-OD (Yamamoto et al., 2015). Peak dorsiflexion in stance-phase significantly increased when wearing an AFO-OD (Yamamoto et al., 2015).

For the knee ROM six out of nine studies found significant differences during gait with an AFO.
The knee flexion and peak knee flexion increased significantly during initial contact and swing (Gatti et al., 2012; Kobayashi et al., 2016; Kobayashi et al., 2017; Singer et al., 2014; Zollo et al., 2015). Kobayashi et al. (Kobayashi et al., 2016), found a significant decrease in the knee extension when walking with an AFO. No differences for knee angles were found by Yamamoto et al. (Yamamoto et al., 2015).
Changes in peak knee flexion angle are found, it diminished significantly during swing phase at the affected side when using the dynamic AFO, no effects were found between affected and non-affected side for flexion ROM during the stance phase (Zollo et al., 2015).

Four studies investigated the hip and pelvic ROM during gait with an AFO, two of these studies found significant changes. Chen et al. (C. C. Chen et al., 2010), found a significant decrease for the hip adduction angle when walking with an AFO. Hip flexion increased significantly during initial contact (Nikamp et al., 2017). Yamamoto et al. and Zissimopoulos et al. (Yamamoto et al., 2015; Zissimopoulos et al., 2015), found no significant results for the hip angles.
For the pelvis a significant decrease in pelvic tilt was seen by Zollo et al. (Zollo et al., 2015) in contrast to this result Nikamp et al. (Nikamp et al., 2017), found no significant changes for the ROM in the pelvis. No effect of an AFO is seen in obliquity, circumduction, abduction/adduction ROM of the hip during swing phase (Zissimopoulos et al., 2015; Zollo et al., 2015). But there is a significant increased flexion of the hip detected during initial contact, no differences in angles were found for the pelvis (Nikamp et

al., 2017). Except for Zollo et al. (Zollo et al., 2015), who found that pelvic ROM during stance significantly decreased while wearing the dynamic AFO and significantly increased during swing. Peak flexion at swing phase decreased significantly for the dynamic AFO (Zollo et al., 2015).

Kinetic parameters

The kinetic parameters that were most sensitive for change are the ankle moments with significant differences in three out of four studies, the knee moments with two out of four studies and the positive- and negative ankle power (with one out of one study).

The positive ankle power decreased during late stance when wearing an AFO and the peak negative ankle power increased during mid stance when wearing an AFO (Yamamoto et al., 2015).
A significant increased dorsiflexion moment was seen during initial contact and the first ankle rocker (Kobayashi et al., 2016; Kobayashi et al., 2017; Singer et al., 2014). Due to the AFO-moment a decreased plantar flexion is seen during stance and push-off.
For the knee kinetics a significant decreased knee flexion moment was seen by Kobayashi et al. (Kobayashi et al., 2016) and a significant decreased peak knee extension moment was seen by Singer et al. (Singer et al., 2014). Nikamp et al. (Nikamp et al., 2017) found no significant results.
Some changes were found in the internal and external moments of the different joints. At the ankle joint there was a greater dorsiflexion moment detected during initial contact because of the higher plantar flexion resistance of the AFO (Kobayashi et al., 2017). This dorsiflexion moment also increased the heel rocker (Kobayashi et al., 2017; Singer et al., 2014). The knee peak flexion moment significantly decreased (Kobayashi et al., 2016) because of the increasing plantar flexion stiffness that causes the knee to go to flexion and then causes an internal moment to extension (Singer et al., 2014). The knee flexion angle is higher with AFO than without one (Gatti et al., 2012). The AFO dorsiflexion moment also affects the ankle position, significantly more dorsiflexion is seen during initial contact and swing phase (Kobayashi et al., 2017), nothing is seen during stance phase (Nikamp et al., 2017). For the gait symmetry, one article found a significant decrease of the deceleration forces but no significant difference was found for the acceleration forces (Pohl & Mehrholz, 2006).

5.1 Quality of included articles

The strobe-statement (combined) checklist was used for 13 of 14 included articles (C. C. Chen et al., 2010; Chern et al., 2013; Fatone & Hansen, 2007; Gatti et al., 2012; Kobayashi et al., 2016; Kobayashi et al., 2017; Pohl & Mehrholz, 2006; Schiemanck et al., 2015; Singer et al., 2014; van Swigchem et al., 2014; Yamamoto et al., 2015; Zissimopoulos et al., 2015; Zollo et al., 2015). For Nikamp et al. (Nikamp et al., 2017) we used the consort RCT checklist.

Only two articles scored below 50% of the maximum score (Fatone & Hansen, 2007; Singer et al., 2014), 11 of the 14 studies scored within 50% and 75% of the maximal score (C. C. Chen et al., 2010; Chern et al., 2013; Gatti et al., 2012; Kobayashi et al., 2016; Kobayashi et al., 2017; Nikamp et al., 2017; Pohl & Mehrholz, 2006; Schiemanck et al., 2015; Yamamoto et al., 2015; Zissimopoulos et al., 2015; Zollo et al., 2015) and one article obtained a score of 82% (van Swigchem et al., 2014).

Following key points were notable when looking at the checklists. A common issue with the assessed quality of the included studies is the description of setting, location, and relevant dates (periods of recruitment, exposure, follow-up and data collection), 11 studies described the setting but not location or dates of their interventions (C. C. Chen et al., 2010; Chern et al., 2013; Fatone & Hansen, 2007; Gatti et al., 2012; Kobayashi et al., 2016; Kobayashi et al., 2017; Pohl & Mehrholz, 2006; Schiemanck et al., 2015; Singer et al., 2014; Yamamoto et al., 2015; Zollo et al., 2015). In eight articles there is no information about the source and method of the selection of patients (C. C. Chen et al., 2010; Chern et al., 2013; Fatone & Hansen, 2007; Kobayashi et al., 2016; Kobayashi et al., 2017; Pohl & Mehrholz, 2006; Singer et al., 2014; Yamamoto et al., 2015). The determination and how the sample size was arrived at a certain number is not described in any of the studies (C. C. Chen et al., 2010; Chern et al., 2013; Fatone & Hansen, 2007; Gatti et al., 2012; Kobayashi et al., 2016; Kobayashi et al., 2017; Nikamp et al., 2017; Pohl & Mehrholz, 2006; Schiemanck et al., 2015; Singer et al., 2014; van Swigchem et al., 2014; Yamamoto et al., 2015; Zissimopoulos et al., 2015; Zollo et al., 2015). The lack of explaining how missing data was addressed was seen in 12 articles, it is possible that there was no missing data but also this was not mentioned (C. C. Chen et al., 2010; Chern et al., 2013; Fatone & Hansen, 2007; Gatti et al., 2012; Kobayashi et al., 2016; Kobayashi et al., 2017; Schiemanck et al., 2015; Singer et al., 2014; Yamamoto et al., 2015; Zollo et al., 2015).

Other performed analyses (for example, of subgroups and interactions of sensitivity analysis) were not reported in six studies (C. C. Chen et al., 2010; Fatone & Hansen, 2007; Gatti et al., 2012; Kobayashi et al., 2017; Pohl & Mehrholz, 2006; Singer et al., 2014), it was doubtful in six other studies (Chern et al., 2013; Kobayashi et al., 2016; Schiemanck et al., 2015; Yamamoto et al., 2015; Zissimopoulos et al., 2015; Zollo et al., 2015) and it was performed in one study (van Swigchem et al., 2014). Only the RCT of Nikamp et al. (Nikamp et al., 2017) used a flowchart in their article. 12 studies used a cross sectional study design, these articles report the number of included patients at the beginning of the study but did not mention any information about drop-outs. It is not clear if all included patients are analyzed and used for interpretation of the results (C. C. Chen et al., 2010; Chern et al., 2013; Fatone & Hansen, 2007; Gatti et al., 2012; Kobayashi et al., 2016; Kobayashi et al., 2017; Nikamp et al., 2017; Pohl & Mehrholz, 2006; Singer et al., 2014; van Swigchem et al., 2014; Zissimopoulos et al., 2015; Zollo et al., 2015).

5.2 Weaknesses of the included articles

In table 4 there is an overview of strengths and weaknesses of all studies.

Considerable weaknesses were the following:

- Multiple studies did not give any information about the recruitment of their patients, however most studies gave information about their participants such as their age, time since stroke, gender, etc. For this reason, a selection bias can be overlooked.
- Another weakness in nearly all studies was a small sample size, which ranged from five to 39 participants. Only one of the articles included more than 30 test subjects (39 subjects and 20 of them were controls) (van Swigchem et al., 2014).
- Blinding of participants and assessor to the intervention was not possible because the studies compared walking with and without AFO on the same test subjects.
- Only four of the fourteen studies used a standard footwear during measurements (Chern et al., 2013; Fatone & Hansen, 2007; Gatti et al., 2012; Pohl & Mehrholz, 2006). The other studies used the footwear of the participant (Nikamp et al., 2017; Schiemanck et al., 2015; van Swigchem et al., 2014; Yamamoto et al., 2015; Zissimopoulos et al., 2015), Chen et al. (C. C. Chen et al., 2010) measured without footwear or did not give any information about the footwear (Kobayashi et al., 2016; Kobayashi et al., 2017; Singer et al., 2014; Zollo et al., 2015).
- All studies were done over a short period of time therefore we do not have any information about the effects of the AFO for long term use.
- Only three studies gave information about the familiarization period. Two studies allowed familiarization with the AFO (Gatti et al., 2012; Pohl & Mehrholz, 2006) and two did not allow familiarization with AFO (Nikamp et al., 2017)
- Only four studies used a control group, for shtis study the results of the control group were not included so this limitation did not influence the results. (C. C. Chen et al., 2010; Fatone & Hansen, 2007; van Swigchem et al., 2014; Zissimopoulos et al., 2015)
- Four of the fourteen studies used a treadmill to perform gait analysis at a self-selected walking speed, the use of a treadmill could affect the self-selected walking speed because the patients cannot walk naturally (Kobayashi et al., 2016; Kobayashi et al., 2017; Singer et al., 2014; van Swigchem et al., 2014))
- One study did not use a standard AFO for measurements, all participants used their own AFOs this can influence the results.
- The article of Schiemanck et al. (Schiemanck et al., 2015) had a selection bias, all patients needed to undergo an operation before participating in the study. This suggests that all patients were very motivated to participate in the study
- Five studies did not report any strengths and weaknesses of their study in the discussion section (Chern et al., 2013; Fatone & Hansen, 2007; Kobayashi et al., 2016; Kobayashi et al., 2017; Zollo et al., 2015)

5.3 Discussion of results

The most common used techniques are as followed: a gait analysis in a 3D perspective was used in all studies(C. C. Chen et al., 2010; Chern et al., 2013; Fatone & Hansen, 2007; Gatti et al., 2012; Kobayashi et al., 2016; Kobayashi et al., 2017; Nikamp et al., 2017; Pohl & Mehrholz, 2006; Schiemanck et al., 2015; Singer et al., 2014; van Swigchem et al., 2014; Yamamoto et al., 2015; Zissimopoulos et al., 2015; Zollo et al., 2015) and the use of markers was mentioned in 12 out of 14 studies (C. C. Chen et al., 2010; Fatone & Hansen, 2007; Gatti et al., 2012; Kobayashi et al., 2016; Kobayashi et al., 2017; Nikamp et al., 2017; Schiemanck et al., 2015; Singer et al., 2014; van Swigchem et al., 2014; Yamamoto et al., 2015; Zissimopoulos et al., 2015; Zollo et al., 2015), most commonly used markers were the reflective markers. A 10-meter walkway was implemented in four out of seven studies (Chern et al., 2013; Fatone & Hansen, 2007; Gatti et al., 2012; Zissimopoulos et al., 2015) that used a walkway, a three-meter walkway and 15-meter walkway were used less frequently. Four out of fourteen studies chose a treadmill to perform the gait analysis and used a maximal walking speed of two to three km/hour (Kobayashi et al., 2016; Kobayashi et al., 2017; Singer et al., 2014; van Swigchem et al., 2014). In all studies these trials were completed at a self-selected walking speed. Only one study used force plates to quantify gait outcome between interventions (barefoot, only shoes, AAFO and PAFO)(Yamamoto et al., 2015). Finally, the most used system was the Vicon Nexus ten-camera or six-camera motion system to capture the gait pattern. Other used systems are for example a real-time motion capture system and a stereo-photogrammetric system. These are the used methods in the included articles, there is however no strong evidence that these are the best manners to capture the gait pattern.
A consideration in the used methods was that when walking on a treadmill there is a loss of the natural gait pattern, this can have an influence on the outcomes. Also, Nikamp et al. (Nikamp et al., 2017) found that when measuring with a 3D system the gait speed will decrease, this can be explained by the fact that participants are more careful when this equipment is used.

For the secondary outcome parameter there is a variety in the used parameters, some are used more frequently than others. This makes it difficult to reach a clear conclusion about which parameters are most sensitive to change. Parameters that are most likely to significantly change are:

- Cadence (with two out of three studies)
- Walking speed (with four out of six studies)
- Step length (with four out of seven studies)
- double support (with one out of two studies)
- Positive- and negative ankle power (with one out of one study).
- Ankle moments (with three out of four studies).
- Knee moments (with two out of four studies).
- Ankle ROM (with eight out of nine study).
- Knee ROM (with six out of eight studies).

Also, other non-discussed outcome parameters can be influenced by an AFO. For example, the AFO-OD showed according to Yamamoto et al. (Yamamoto et al., 2015) a more erected trunk after 3weeks. Another important improvement of the AFO can be the self-confidence. The article of Zissimopoulos et

al. (Zissimopoulos et al., 2014) showed that the balance confidence was related to the walking speed and that both improved when wearing an AFO.

An influencing factor is that the included studies used different AFOs. A difference can be the material the AFO is made of, such as rigid or elastic material, different grades of resistance or different structures (like PAFO or AAFO), this has different effects on the ROM, power, ... in the joints. Self-selected walking speed was allowed in every article, this means that walking speed could be different for each participant in each study. This can possibly cause a misjudgment in the results.

Also, most studies are cross-sectional studies and were measured ones, maybe other changes can be seen in long term studies.

The timing of the AFO use, acute of chronic phase of stroke, may influence the gait parameters because patients have not yet developed compensatory strategies (Nikamp et al., 2017). In de article of Zissimopoulos et al. (Zissimopoulos et al., 2015) hypothesized that the circumduction (compensation for better foot clearance) would reduce when wearing an AFO however there was no reduction in hip hiking, circumduction of abduction/adduction of the hip. This can be a reason for early AFO use to avoid the development of compensation strategies.

5.4 Strengths and weaknesses of the systematic review

The databases Pubmed and Web of science were used to complete the literature search, a limited amount of qualitative studies were found about 3D gait measurement in patients with stroke, this affects the quality of the systematic review. 13 cross-over trials and one randomized controlled trial are included in this systematic review. More RCTs could have increased the level of evidence of this systematic review.

Long-term effects remain largely unexamined therefore parallel-group randomized controlled trials are necessary to examine long-term effects in the future.

Another limitation is the limited research about several parameters such as ankle positive and negative power, duration of different gait phases, step width, … these parameters are mentioned in less than three included studies.

The firmness of the conclusions of the systematic review depends on the completeness of the data that is found. One article was not included because the full-text was not available. However, authors were contacted and multiple databases were searched for. Risk of publication bias will therefore be small.

Strengths of the systematic review are that the same participants were measured in a cross-over trial this makes it an effective design to measure immediate differences, it is efficient to measure biomechanics in a single day and to minimize drop-out. Another strength is the large number of outcome parameters that were investigated in the included articles.

5.5 Recommendations for future studies

Following suggestions are made to improve the research on gait pattern with AFOs in stroke patients.

5.5.1 Participants

A first recommendation is a larger sample size, only one of the included articles had a sample size of more than 30 participants (van Swigchem et al., 2014). This limits the generalisation of the study results.

A weakness in these studies is that the patients cannot be blinded because they had to wear an AFO, therefore in future research we recommend blinding of the assessors.
Chronic stroke participants were included in most of the articles, these are often patients that have already developed compensations with or without the use of an AFO. An interesting research field can be the investigation of acute stroke patients and the effect of early AFO use to prevent or reduce the development of compensations.

5.5.2 Study design and method

When we look at the study designs only one of the included articles was a RCT (Nikamp et al., 2017), more RCTs can increase the level of evidence of the studies.
There is a need for a standard 3D gait analysis protocol, some items were similar such as the use of markers and a 3D perspective but other important items differed between articles like the parameters that were measured and the walking surface. The most frequently used walkway in the included articles was the 10meter walkway and walking on a treadmill.
Little information can be found about the validity, reproducibility, sensitivity and reliability of the 3D gait analysis for stroke patients. The Vicon is considered the golden standard for three-dimensional motion analysis yet there are very little articles investigating the use of this systems in stroke patients (Galna et al., 2014). Future research can contribute to more complete information in this research domain.

5.5.3 Outcome parameters

Limited measurements of hip and pelvis kinematics are performed in current studies. It is possible that a change in these parameters could be obtained when wearing an AFO. However, when investigating research in children with cerebral palsy there are also limited hip parameters found with significant changes (Kerkum et al., 2015). Also, the spatiotemporal parameters (stride length, stance duration, single support duration, percentage of double support, mediolateral foot-placement and foot-progression) and the kinematic parameters (peak positive ankle power, peak negative ankle power, pressure sway, weight bearing symmetry and ROS arc radius) are described in only one or two of the included articles. More investigation of the sensitivity to change of these parameters in future research can provide a better overview of their sensitivity to change.

6. Conclusion

This systematic review indicates that the most commonly used software system to measure spatiotemporal and kinematic parameters in patients with stroke is the Vicon Nexus Camera Motion analysis system. Gait is detected through markers and analyzed in a three-dimensional way. Given the volume of space that can be measured in a lab setting participants must walk on a treadmill or on a walkway of ten meters at their self-selected walking speed. Force plates are sometimes implemented to measure kinetic parameters of the relative joints.
The parameters that are most sensitive to change when wearing an AFO are: cadence, walking speed, step length, swing duration, positive- and negative ankle power, ankle ROM, knee ROM, ankle moments and knee moments.

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7. Appendix systematic review

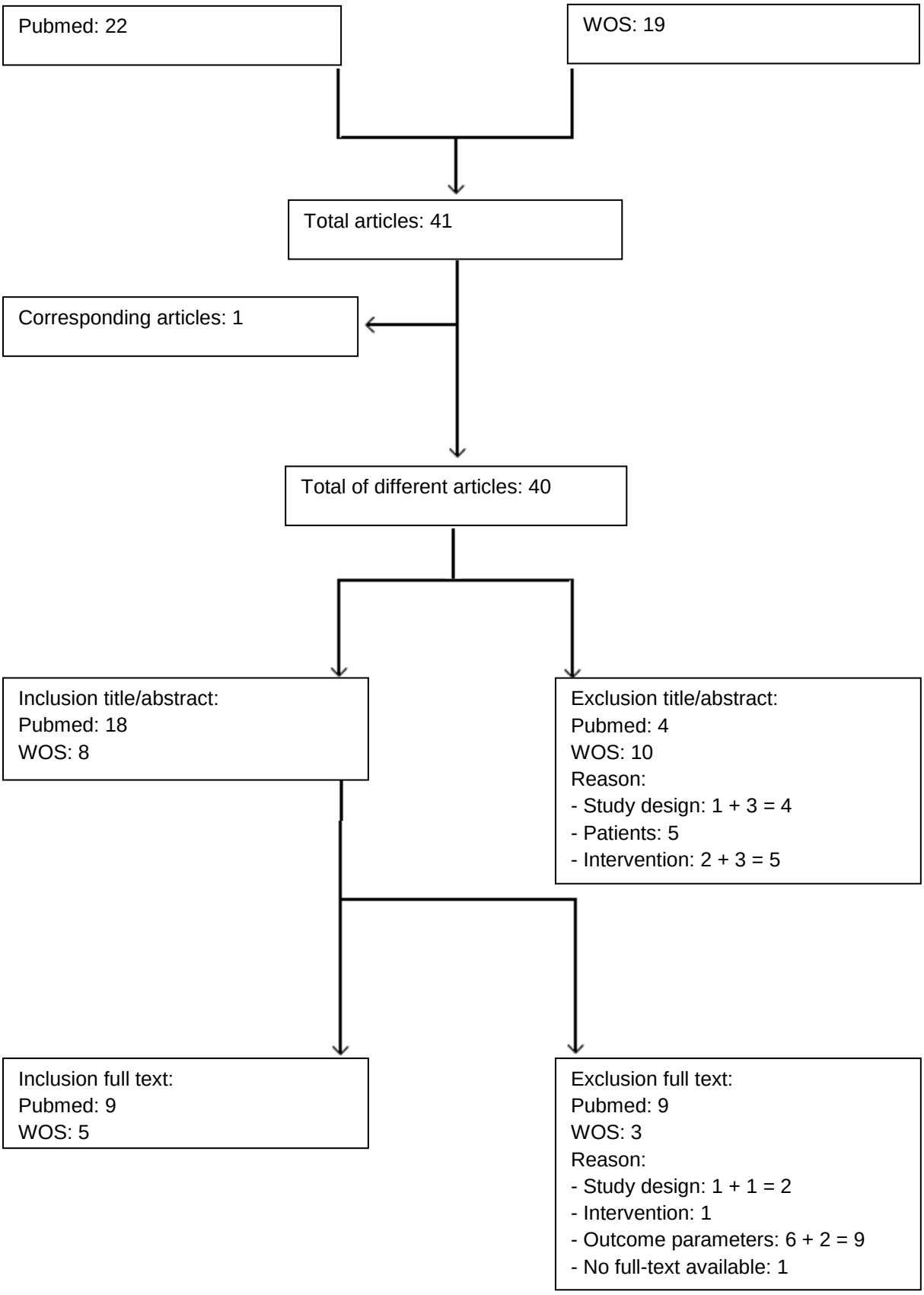

Figure 1: Flowchart

Table 1
Mesh-terms

Pubmed

No	Terms	Number of articles October 2017	Number of articles April 2018
General terms			
#1	Foot orthoses	586	640
#2	Walking	44062	45726
#3	#1 AND #2	212	237
#4	Nervous system diseases	2515992	2282345
#5	#1 AND #2 AND #3	84	90
Disease			
#6	Stroke	108903	112290
#7	#1 AND #6	34	37
#8	#1 AND #2 AND #6	23	25
#9	#1 AND #2 AND #4 AND #6	23	25
Adult/Children			
#10	Adult	6381347	6492968
#11	#8 AND #10	20	22
#12	Children	1735604	1758780
#13	#11 NOT 12	20	22
Exclusion			

#14	Musculoskeletal diseases	982326	9949996
#15	#11 NOT #14	20	22
3D			
#16	Three-dimensional analysis	0	0
#17	Three-dimensional gait analysis	0	0
#18	#15 AND #16	0	0
#19	#15 AND #17	0	0

Web of science

No	**Terms**	**Number of articles October 2017**	**Number of articles April 2018**
General terms			
#1	Foot orthoses	1702	1751
#2	Walking	160504	164064
#3	#1 AND #2	771	796
#4	Nervous system diseases	98775	100634
#5	#1 AND #2 AND 3	1	1
Disease			
#6	Stroke	283468	289347
#7	#1 AND #6	146	155
#8	#1 AND #2 AND #6	108	116
#9	#1 AND #2 AND #4 AND #6	1	1
Adult/Children			

#10	Adult	1279128	1304583
#11	#8 AND #10	18	19
#12	Children	59	61
#13	#11 NOT 12	18	19
Exclusion			
#14	Musculoskeletal diseases	11591	11898
#15	#11 AND 14	18	19
3D			
#16	Three-dimensional analysis	121128	121128
#17	Three-dimensional gait analysis	1846	1846
#18	#15 AND #16	4	4
#19	#15 AND #17	0	0

Table 2
In- and exclusion

Source: Pubmed

No.	Auteur	Year	Title	In- or exclusion: Title/abstract	In- or exclusion: Full-text
#1	Kobayashi T, Orendurff MS, Singer ML, Gao F, Foreman KB.	2017 april	Contribution of ankle-foot orthosis moment in regulating ankle and knee motions during gait in individuals post-stroke.	Included	Included
#2	Nikamp CDM[1], Hobbelink MSH[2], van der Palen J[3], Hermens HJ[4], Rietman JS[5], Buurke JH[4].	2017 june	A randomized controlled trial on providing ankle-foot orthoses in patients with (sub-)acute stroke: Short-term kinematic and spatiotemporal effects and effects of timing.	Included	Included
#3	Prenton S1, Hollands KL, Kenney LP.	2016 Oct 5	Functional electrical stimulation versus ankle foot orthoses for foot-drop: A meta-analysis of orthotic effects.	Excluded: Meta- analyses	/
#4	Kobayashi T1, Orendurff MS2, Singer ML3, Gao F4, Daly WK2, Foreman KB3.	2016 Jun	Reduction of genu recurvatum through adjustment of plantar flexion resistance of an articulated ankle-foot orthosis in individuals post-stroke.	Included	Included
#5	Jones PS1, Pomeroy VM2, Wang J3, Schlaug G3, Tulasi Marrapu S1, Geva S1, Rowe PJ4, Chandler E2, Kerr A4, Baron JC1,5; SWIFT-Cast investigators.	2016 Feb	Does stroke location predict walk speed response to gait rehabilitation? Does stroke location predict walk speed response to gait rehabilitation?	Excluded: No spatiotemporal, kinematic or kinetic outcome parameters	/
#6	Schiemanck S1, Berenpas F2, van Swigchem R3, van den Munckhof P4, de Vries J5, Beelen A1, Nollet F1, Geurts AC2.	2015	Effects of implantable peroneal nerve stimulation on gait quality, energy expenditure, participation and user satisfaction in patients with post-stroke drop foot using an ankle-foot orthosis.	Included	Included: For first research question Excluded: For second research question (FES)
#7	Farmani F1, Mohseni Bandpei MA2, Bahramizadeh M3, Aminian G3, Nikoo MR4, Sadeghi-Goghari M5.	2016 Oct	The effect of different shoes on functional mobility and energy expenditure in post-stroke hemiplegic patients using ankle-foot orthosis.	Included	Excluded: No spatiotemporal, kinematic or kinetic outcome parameters

#8	Maeshima S1, Okazaki H2, Okamoto S2, Mizuno S2, Asano N2, Maeda H2, Masaki M2, Matsuo H2, Tsunoda T2, Sonoda S2.	2015 Jun	A comparison of knee-ankle-foot orthoses with either metal struts or an adjustable posterior strut in hemiplegic stroke patients.	Excluded: KAFO	/
#9	Bethoux F1, Rogers HL2, Nolan KJ3, Abrams GM4, Annaswamy T5, Brandstater M6, Browne B7, Burnfield JM8, Feng W9, Freed MJ10, Geis C11, Greenberg J12, Gudesblatt M13, Ikramuddin F14, Jayaraman A15, Kautz SA16, Lutsep HL17, Madhavan S18, Meilahn J19, Pease WS20, Rao N21, Seetharama S22, Sethi P23, Turk MA24, Wallis RA25, Kufta C2.	2015 Nov-Dec	Long-Term Follow-up to a Randomized Controlled Trial Comparing Peroneal Nerve Functional Electrical Stimulation to an Ankle Foot Orthosis for Patients with Chronic Stroke.	Included	Excluded: No spatiotemporal, kinematic or kinetic outcome parameters
#10	Singer ML1, Kobayashi T2, Lincoln LS3, Orendurff MS3, Foreman KB1.	2014 Nov	The effect of ankle-foot orthosis plantarflexion stiffness on ankle and knee joint kinematics and kinetics during first and second rockers of gait in individuals with stroke	Included	Included
#11	Hyun CW1, Kim BR2, Han EY3, Kim SM4.	2015 Mar	Use of an ankle-foot orthosis improves aerobic capacity in subacute hemiparetic stroke patients.	Included	Excluded: Gait speed as only spatiotemporal, kinematic of kinetic outcome parameter
#12	Chen CL1, Teng YL1, Lou SZ1, Chang HY2, Chen FF1, Yeung KT3.	2014 Nov	Effects of an anterior ankle-foot orthosis on walking mobility in stroke patients: get up and go and stair walking.	Included	Excluded: TUG as only outcome parameter
#13	Zissimopoulos A1, Fatone S2, Gard S2.	2015 Oct	Effects of ankle-foot orthoses on mediolateral foot-placement ability during post-stroke gait.	Included	Included
#14	Naito Y1, Kimura Y, Hashimoto T, Mori M, Takemoto Y.	2014 Mar	[Quantification of gait using insole type foot pressure monitor: clinical application for chronic hemiplegia].	Excluded: Insoles No AFO	/
#15	van Swigchem R1, Roerdink M, Weerdesteyn V, Geurts AC, Daffertshofer A.	2014 May	The capacity to restore steady gait after a step modification is reduced in people with post-stroke foot drop using an ankle-foot orthosis.	Included	Included

#16	Yamamoto S1, Ibayashi S2, Fuchi M2, Yasui T3.	2015 Apr	Immediate-term effects of use of an ankle-foot orthosis with an oil damper on the gait of stroke patients when walking without the device.	Included	Included
#17	Lan Y1, Xu GQ, Huang DF, Mao YR, Chen SZ, Pei Z, Zeng JS.	2013 Oct	Association between improved trunk stability and walking capacity using ankle-foot orthosis in hemiparetic patients with stroke: evidence from three-dimensional gait analysis.	Included	Excluded: No full-text available
#18	Chern JS, Chang HS, Lung CW, Wu CY, Tang SF.	2013	Static ankle-foot orthosis improves static balance and gait functions in hemiplegic patients after stroke.	Included	Included
#19	Zissimopoulos A1, Fatone S, Gard S.	2014 Apr	The effect of ankle-foot orthoses on self-reported balance confidence in persons with chronic post-stroke hemiplegia.	Included	Excluded: Gait speed as only spatiotemporal, kinematic of kinetic outcome parameter
#20	Kluding PM1, Dunning K, O'Dell MW, Wu SS, Ginosian J, Feld J, McBride K.	2013 Jun	Foot drop stimulation versus ankle foot orthosis after stroke: 30-week outcomes.	Included	Excluded: Gait speed as only spatiotemporal, kinematic of kinetic outcome parameter
#21	Everaert DG1, Stein RB, Abrams GM, Dromerick AW, Francisco GE, Hafner BJ, Huskey TN, Munin MC, Nolan KJ, Kufta CV.	2013 Sep	Effect of a foot-drop stimulator and ankle-foot orthosis on walking performance after stroke: a multicenter randomized controlled trial.	Included	Excluded: Gait speed as only spatiotemporal, kinematic of kinetic outcome parameter
#22	Yamamoto S1, Tomokiyo N, Yasui T, Kawaguchi T.	2013 Jun	Effects of plantar flexion resistive moment generated by an ankle-foot orthosis with an oil damper on the gait of stroke patients: a pilot study.	Included	Excluded: sample size < 5

Source: Web of science

No.	Auteur	Year	Title	In- or exclusion: title/ abstract	In- or exclusion: Full-text
#1	Delafontaine, Arnaud; Gagey, Olivier; Colnaghi, Silvia; et al.	APR 28 2017	Rigid ankle foot orthosis Deteriorates Mediolateral Balance control and vertical braking during gait initiation	Excluded: No stroke patients	/

#2	Mizuno, S (Mizuno, Shiho)[1]; Sonoda, S (Sonoda, Shigeru)[2]; Takeda, K (Takeda, Kotaro)[3]; Maeshima, S (Maeshima, Shinichiro)[2]	2017	Effect of muscle tone on ankle kinetics during gait with ankle-foot orthoses in persons with stroke	Included	Excluded: No 2D of 3D gait analysis Instrumented AFO
#3	Farmani, Farzad; Bandpei, Mohammad Ali Mohseni; Bahramizadeh, Mahmood; et al.	OCT 2016	The effect of different shoes on functional mobility and energy expenditure in post-stroke hemiplegic patients using ankle-foot orthosis	Included → same as Pubmed article #7	Excluded: No spatiotemporal, kinematic or kinetic outcome parameters
#4	Chantraine, Frederic; Schreiber, Celine; Kolanowski, Elisabeth; et al.	JUL 2016	Control of Stroke-Related Genu Recurvatum With Prolonged Timing of Dorsiflexor Functional Electrical Stimulation: A Case Study	Excluded: FES (exclusion for secondary research question) Sample size < 5	/
#5	Nolan, Karen J.; Yarossi, Mathew; Mclaughlin, Patrick	AUG 2015	Changes in center of pressure displacement with the use of a foot drop stimulator in individuals with stroke	Included	Excluded: Only foot drop stimulator
#6	Dunning, Kari; O'Dell, Michael W.; Kluding, Patricia; et al.	AUG 2015	Peroneal Stimulation for Foot Drop After Stroke a Systematic Review	Excluded: Systematic review	/
#7	Ferrarin, M ; Rabuffetti,] ; Bacchini, M ; Casiraghi, A ; Castagna,A; Pizzi, A; Montesano, A.	APR 2015	Does gait analysis change clinical decision-making in post-stroke patients? Results from a pragmatic prospective observational study	Excluded: No AFO Children < 18	/
#8	Zollo, L.; Zaccheddu, N.; Ciancio, A. L.; et al.	APR 2015	Comparative analysis and quantitative evaluation of ankle-foot orthoses for foot drop in chronic hemiparetic patients	Included	Included
#9	Menotti, Federica; Laudani, Luca; Damiani, Antonello; et al.	SEP 2014	Comparison of walking energy cost between an anterior and a posterior ankle-foot orthosis in people with foot drop	Included	Excluded: Sample size with stroke < 5
#10	Vistamehr, Arian; Kautz, Steven A.; Neptune, Richard R.	MAY 2014	The influence of solid ankle-foot-orthoses on forward propulsion and dynamic balance in healthy adults during walking	Excluded: No stroke patients	/
#11	Tyson, S. F.; Sadeghi-Demneh, E.; Nester, C. J.	OCT 2013	A systematic review and meta-analysis of the effect of an ankle-foot orthosis on gait	Excluded: Systematic review	/

			biomechanics after stroke.		
#12	Arvin, Mina; Kamyab, Mojtaba; Moradi, Vahideh; et al.	APR 2013	Influence of modified solid ankle-foot orthosis to be used with and without shoe on dynamic balance and gait characteristics in asymptomatic people	Excluded: No stroke patients	/
#13	Andres Gatti, Marcelo; Freixes, Orestes; Anibal Fernandez, Sergio; et al.	OCT 11 2012	Effects of ankle foot orthosis in stiff knee gait in adults with hemiplegia	Included	Included
#14	Phillips, Margaret F.; Robertson, Zoe; Killen, Brian; et al.	JUN 2012	A pilot study of a crossover trail with randomized use of ankle-foot orthoses for people with charcot-marie-tooth disease	Excluded: No stroke patients	/
#15	Keenan, Mary Ann	SEP 2011	The Management of Spastic Equinovarus Deformity Following Stroke and Head Injury	Excluded: Information about the operation	/
#16	Chen, Chih-Chi; Hong, Wei-Hsien; Wang, Chin-Man; et al.	DEC 2010	Kinematic features of rear-foot motion using anterior and posterior ankle-foot orthosis in stroke patients with hemiplegic gait	Included	Included
#17	Tyson, Sarah F.; Kent, Ruth M.	2009	Orthotic devices after stroke and other non-progressive brain lesions	Excluded: Literature review Upper and lower limb	/
#18	Fatone, Stefania; Hansen, Andrew H.	2007	Effect of ankle-foot orthosis on roll-over shape in adults with hemiplegia	Included	Included
#19	Pohl, M; Mehrholz, J.	APR 2006	Immediate effect of an individual designed functional ankle-foot orthosis in stance and gait in hemiparetic patients	Included	Included

Table 3

Percentage of maximal score in the checklists

Article	% of maximal score
(Chen et al., 2010)	59%
(Chern, Chang, Lung, Wu, & Tang, 2013)	63%
(Fatone & Hansen, 2007)	43%
(Gatti et al., 2012)	61%
(Kobayashi et al., 2016)	52%
(Kobayashi, Orendurff, Singer, Gao, & Foreman, 2017)	55%
(Nikamp et al., 2017)	57%
(Pohl & Mehrholz, 2006)	64%
(Schiemanck et al., 2015)	73%
(Singer, Kobayashi, Lincoln, Orendurff, & Foreman, 2014)	45%
(van Swigchem, Roerdink, Weerdesteyn, Geurts, & Daffertshofer, 2014)	82%
(Yamamoto, Ibayashi, Fuchi, & Yasui, 2015)	62%
(Zissimopoulos, Fatone, & Gard, 2015)	66%
(Zollo et al., 2015)	59%

Table 4
SWOT- analysis

Author/Date/Title	Strengths of the study	Weaknesses of the study
Chen, Chih-Chi; Hong, Wei-Hsien; Wang, Chin-Man; et al. December 2010 Kinematic features of rear-foot motion using anterior and posterior ankle-foot orthosis in stroke patients with hemiplegic gait	- Walking trials in random order - Control group - Clear explanation of producing the AFO's and the differences between the AFO's	- No information about recruitment of patients - No information about the distance of the walkway - Small study population - Inclusion of both patients who already had an AFO and patients who did not. - Healthy subjects did not walk as fast as the stroke patients - Analyzed only posterior leaf-spring → cannot generalize for all posterior AFO's - No blinding of patients and assessor
Chern JS, Chang HS, Lung CW, Wu CY, Tang SF. 2013 Static ankle-foot orthosis improves static balance and gait functions in hemiplegic patients after stroke.	- Walking trials in random order - Standard footwear - Blinded occupational therapists	- No information about recruitment of patients - Small sample size - No blinding of patients and assessor - Inclusion and exclusion criteria not mentioned - Shoes have concealed the efficacy of the AFO for balance during stand - No discussion of strengths and limitations of the study
Fatone, Stefania; Hansen, Andrew H. 2007 Effect of ankle-foot orthosis on roll-over shape in adults with hemiplegia	- Standardized footwear - Control group - Measurement of pelvic movements	- Small study population - Interventions not clearly described - No discussion of strengths and limitation in the study - No information about recruitment of patients - No blinding of patients and assessor
Andres Gatti, Marcelo; Freixes, Orestes; Anibal Fernandez, Sergio; et al. October 2012 Effects of ankle foot orthosis in stiff knee gait in adults with hemiplegia	- Standard footwear - Walking trials in random order	- No information about recruitment of patients - Inclusion patients who already had an AFO and patient who didn't. - Small sample size - No blinding of patients and assessor
Kobayashi T1, Orendurff MS2, Singer ML3, Gao F4, Daly WK2, Foreman KB3 2016 Jun Reduction of genu recurvatum through adjustment of plantarflexion resistance of an articulated ankle-foot orthosis in individuals post-stroke.	- Gait trials were in random order - AFO characteristics (initial angle + heel height) were the same during all gait trials	- Small study population - Interventions not clearly described - Few outcome parameters - No information about recruitment of patients - No limitations mentioned in the discussion - No control groups - No blinding of patients - A treadmill can have a negative influence on the gait - No information about standard footwear
Kobayashi T, Orendurff MS, Singer ML, Gao F, Foreman KB.	- Use of standardized reflective markers - Use of a clear systematic protocol	- No information about recruitment of patients - Small study population

2017 april Contribution of ankle-foot orthosis moment in regulating ankle and knee motions during gait in individuals post-stroke.		- No information about the baseline characteristics of the outcome parameters - No limitations mentioned in discussion - A treadmill can have a negative influence on the gait - No control groups - No blinding of subjects and assessors - No information about standard footwear
Nikamp CDM[1], Hobbelink MSH[2], van der Palen J[3], Hermens HJ[4], Rietman JS[5], Buurke JH[4]. 2017 june A randomized controlled trial on providing ankle-foot orthoses in patients with (sub-)acute stroke: Short-term kinematic and spatiotemporal effects and effects of timing.	- Walking random with and without AFO, - Markers are not replaced between the 2 conditions. - Patients short after stroke who have not walked with an AFO - Measurement of frontal plane and pelvic movements - Baseline comparison of the characteristics of the participants and outcome parameters - Used block randomization	- No standardized footwear - Only short-term results - No blinding of patients and assessor - Small sample size - Not all included subjects were included in the data-analyses - Doubtful if it is clinically relevant
Pohl, M; Mehrholz, J. 2006 Apr Immediate effect of an individual designed functional ankle-foot orthosis in stance and gait in hemiparetic patients	- Standard footwear - Gait trials in random order - Information about recruitment of patients	- Small sample size - No blinding of patients and assessor - Only short-term results - Gait speed and stride length were not measured
Schiemanck S1, Berenpas F2, van Swigchem R3, van den Munckhof P4, de Vries J5, Beelen A1, Nollet F1, Geurts AC2 2015 Effects of implantable peroneal nerve stimulation on gait quality, energy expenditure, participation and user satisfaction in patients with post-stroke drop foot using an ankle-foot orthosis.	- Source of recruitment of patients is given - Multiple measurements at different times - Always used the same AFO and same shoes during the different measurements. - Use of a timeline.	- No standard AFO - No standard footwear - No control groups - Small sample size - Selection bias - Patients were young and had a high balance capacity this limits the generalization - No blinding of patients
Singer ML1, Kobayashi T2, Lincoln LS3, Orendurff MS3, Foreman KB1 2014 Nov The effect of ankle-foot orthosis plantarflexion stiffness on ankle and knee joint kinematics and kinetics during first and second rockers of gait in individuals with stroke	- The sequence of spring stiffness was randomized for each gait trial	- Small sample size - Massiveness of the AFO - Walking on a treadmill can limit the self-selected walking speed - No control group - No information about recruitment of patients - A treadmill can have a negative influence on the gait - No blinding of patients and assessor - No information about standard footwear
van Swigchem R1, Roerdink M, Weerdesteyn V, Geurts AC, Daffertshofer A. 2014 May The capacity to restore steady gait after a step modification is reduced in people with poststroke foot drop using an	- Random release of the objects (different in timing in a trial and between trials) - Control group	- No standard footwear - No information about recruitment of patients - A treadmill can have a negative influence on the gait - No blinding of patients and assessor - No self-selected speed but close to the self-selected speed

ankle-foot orthosis.		
Yamamoto S1, Ibayashi S2, Fuchi M2, Yasui T3. 2015 Apr Immediate-term effects of use of an ankle-foot orthosis with an oil damper on the gait of stroke patients when walking without the device.		- No standard footwear - Small sample size - No information about recruitment of patients - No control groups - Variation in profile of participants. - No blinding of patients and assessor
Zissimopoulos A1, Fatone S2, Gard S2. 2015 Oct Effects of ankle-foot orthoses on mediolateral foot-placement ability during post-stroke gait.	- Gait trials in random order - Control group	- No standard AFOs - Small sample size - No blinding of patients and assessor
Zollo, L.; Zaccheddu, N.; Ciancio, A. L.; et al. April 2015 Comparative analysis and quantitative evaluation of ankle-foot orthosis for foot drop in chronic hemiparetic patients	- Gait trials in random order	- No information about recruitment of patients - No discussion of strengths and limitations of the study - Small sample size - No information about footwear - No blinding of patients and assessor - No information about standard footwear

Table 5
Subject Characteristics

Author	Title	Quantity	Gender	Age	Characteristics of stroke	Country	Prior AFO use	Allowed walking with an assistive device	Allowed time to adapt to AFO
Chen, Chih-Chi; Hong, Wei-Hsien; Wang, Chin-Man; et al. December 2010	Kinematic features of rear-foot motion using anterior and posterior ankle-foot orthosis in stroke patients with hemiplegic gait	14 subjects 11 controls	Stroke: Male: 9 Female:5 Control: Male: 5 Female: 6	Stroke: Mean: 56 years Control: Mean: 55 years	- Time since stroke ranged from 2 months to 5 years and 6 months - Brunnstrom Stage of involved lower limb: 3-5 - MAS ankle: 1+ to 3 - No assistive device	Not mentioned	Yes: 8 No: 6	Not mentioned	Not mentioned
Chern JS, Chang HS, Lung CW, Wu CY, Tang SF. 2013	Static ankle-foot orthosis improves static balance and gait functions in hemiplegic patients after stroke.	15 subjects	Male: 11 Female: 4	38-71 years	- Residual hemiparesis 11 right/ 4 left - Time since stroke ranged from 1- 20 months - BBS (static): 12-24 - BBS (dynamic): 16-30 - MAS (ankle dorsiflexor): 0-2 - MAS (ankle plantar flexor): 0-3 - Brunnstrom Stage lower limb: 3-4	Not mentioned	Not mentioned	Not mentioned	Not mentioned
Fatone, Stefania; Hansen, Andrew H. 2007	Effect of ankle-foot orthosis on roll-over shape in adults with hemiplegia	13 subjects 12 controls	Stroke: Male: 7 Female: 6 Control: Male: 8 Female: 4	Stroke: Mean: 51 years Control: Mean: 57 years	- Years since stroke: 8 years - 3 right/ 10 left hemiparesis	Not mentioned	Not mentioned	Not mentioned	Not mentioned
Andres Gatti,	Effects of ankle foot orthosis in stiff knee	10 subjects	Male: 7 Female: 3	> 18 years	- Chronic post-stroke hemiplegia	Not mentioned	No: 2 Partially: 6	Not mentioned	Yes

Marcelo; Freixes, Orestes; Anibal Fernandez, Sergio; et al. October 2012	gait in adults with hemiplegia			Mean: 46 years	- > 18 years old - MAS: 1-3 - Lower limb strength: 4 (moderate + mild paresis) - Walk at least 10-meter		Constantly: 2		
Kobayashi T1, Orendurff MS2, Singer ML3, Gao F4, Daly WK2, Foreman KB3 2016 Jun	Reduction of genu recurvatum through adjustment of plantarflexion resistance of an articulated ankle-foot orthosis in individuals post-stroke.	8 subjects	Male: 8 Female: 0	Mean 52 years	- Unilateral limb Involvement - 3 right/ 3 left - 7 years post-stroke	Not mentioned	Not mentioned	Not mentioned	Not mentioned, only time to adapt to walking on the treadmill
Kobayashi T, Orendurff MS, Singer ML, Gao F, Foreman KB. 2017 april	Contribution of ankle-foot orthosis moment in regulating ankle and knee motions during gait in individuals post-stroke.	10 subjects	Male: 8 Female: 2	56 years	- > 6 months post-stroke - Unilateral limb problems - 6 right/ 4 left hemiparesis - Safely walk on treadmill without walking aid + with AFO	Not mentioned	Not mentioned	Walk safely on the treadmill without a walking aid	Not mentioned, only time to adapt to walking on the treadmill
Nikamp CDM[1], Hobbelink MSH[2], van der Palen J[3], Hermens HJ[4], Rietman JS[5], Buurke JH[4].	A randomized controlled trial on providing ankle-foot orthoses in patients with (sub-)acute stroke: Short-term kinematic and spatiotemporal effects and effects of timing.	33 subjects → 20 included	Male: 10 Female: 10	>18 years	- 0-6 weeks post-stroke → (sub-)acute - Indication for AFO - 12 left/ 8 right hemiparesis	Netherlands (rehabilitation center Enschede)	Flexible: 18 rigid:2	Permitted	No

2017 june

Pohl, M; Mehrholz, J. April 2006	Immediate effect of an individual designed functional ankle-foot orthosis in stance and gait in hemiparetic patients	28 subjects	Male: 20 Female: 8	23-77 years Mean: 52 years	- Time since stroke ranged from 1-6 months - Use of AFO less than 1 week - Stand without assistant device for 20 sec and walk 15-meter with or without walking aids. - FAC: 2-5 - MAS: < 2 - 10 right/18 left hemiparesis	Not mentioned	Use of AFO <1	Yes	Yes
Schiemanck S1, Berenpas F2, van Swigchem R3, van den Munckhof P4, de Vries J5, Beelen A1, Nollet F1, Geurts AC2. 2015	Effects of implantable peroneal nerve stimulation on gait quality, energy expenditure, participation and user satisfaction in patients with post-stroke drop foot using an ankle-foot orthosis.	10 subjects and 8 patients were used for analysis (one had peroneal neuropathy after surgery and the other patient was not present at 28% of the consultations.	Male: 5 Female: 5	18-65 years Mean: 47 years	- > 6 months - MAS (ankle plantar flexor): < 3 - Independent walking for 10 minutes without walking aids. - Response to surface-based peroneal nerve stimulation. - 6 left/ 4 right hemiparesis - BBS (median range): six	Nijmegen (rehabilitation of the Radboud University Medical Center) an Amsterdam (Academic Medical center).	Not mentioned	Not mentioned	Not mentioned, only time to adapt to the system.
Singer ML1, Kobayashi - T2, Lincoln LS3, rendurff MS3, Foreman KB1	The effect of ankle-foot orthosis plantar flexion stiffness on ankle and knee joint kinematics and kinetics during first and second rockers	5 subjects	Male: 3 Female: 2	Mean: 62 years	- 6 years post-stroke - Walking on treadmill with AFO, without walking aids	Not mentioned	Not mentioned	Not mentioned	Not mentioned

2014 Nov	of gait in individuals with stroke									
van Swigchem R1, Roerdink M, Weerdesteyn V, Geurts AC, Daffertshofer A. 2014 May	The capacity to restore steady gait after a step modification is reduced in people with post stroke foot drop using an ankle-foot orthosis.	19 subjects 20 controls	Stroke: Male: 15 Female: 4 Control: Male: 17 Female: 3	Stroke: 55 years Control: 54 years	- - -	> 6 months Polypropyleen (17) Spring (two)	Not mentioned	Had their own AFO. (Not mentioned which AFO	Not mentioned	Not mentioned
Yamamoto S1, Ibayashi S2, Fuchi M2, Yasui T3. 2015 Apr	Immediate-term effects of use of an ankle-foot orthosis with an oil damper on the gait of stroke patients when walking without the device.	8 subjects	Male: 5 Female: 3	55 years	- - - -	Chronic phase post-stroke Hemiparesis Allocated according to walking speed (A-H) Everybody seek 1-3 sessions per week for 20 minutes	Not mentioned	PAFO: 3 MAFO: 1 None: 4	Not mentioned	Not mentioned
Zissimopoulos A1, Fatone S2, Gard S2 2015 Oct	Effects of ankle-foot orthoses on mediolateral foot-placement ability during post-stroke gait.	15 subjects 6 controls	Stroke: Male: 8 Female: 5 Control: not mentioned	Stroke: 55 years Control: not mentioned	- - -	At least 1-year post-stroke > 18 years Everyone uses a non-rigid polymer AFO	Not mentioned	PLS: 3 Artic. DF assist: 1 Artic. PF assist stop and DF assist: 2 Artic. PF stop: 7	Not mentioned	Not mentioned
Zollo, L.; Zaccheddu, N.; Ciancio, A. L.; et al. April 2015	Comparative analysis and quantitative evaluation of ankle-foot orthosis for foot drop in chronic hemiparetic patients	10 subjects	Male: 7 Female: 3	Mean: 64 years	- - - -	Foot drop syndrome > 6 months stroke Walk without assistance, with or without support MMSS: >22	Not mentioned	Not mentioned	Yes	Not mentioned

Table 6
Methodological design

Authors + date	Title	Protocol	Dimension (2D/3D)	Walking surface	Analysis system	Model of AFO:
Chen, Chih-Chi; Hong, Wei-Hsien; Wang, Chin-Man; et al. December 2010	Kinematic features of rear-foot motion using anterior and posterior ankle-foot orthosis in stroke patients with hemiplegic gait	- Self-selected speed - three trails - Barefoot - Time to practice with AFO Randomized order of trails with 5 minutes of rest between the trails	3D	Carpeted walkway	Vicon motion analysis system - 8 infrared cameras - 7 retroreflective markers	- Anterior AFO ● Thermoplastic material - Posterior AFO ● Polypropylene
Chern JS, Chang HS, Lung CW, Wu CY, Tang SF. 2013	Static ankle-foot orthosis improves static balance and gait functions in hemiplegic patients after stroke.	Gait +CoP roll-over patterns at a self-selected walking pace. Stability limits during voluntary weight shifting (AP + ML direction) Every task was measured under 4 conditions: 1. Barefoot 2. Wearing shoes 3. Shoes + AAFO's 4. Shoes + PAFO's	3D data processor (pressure mat)	10-meter walkway with pressure mat in the middle.	Customized written program (RS scan pressure measurement system). Foot switches for cycle calculation	Low-temperature thermoplastic AAFO's and PAFO's were custom-molded.
Fatone, Stefania; Hansen, Andrew H. 2007	Effect of ankle-foot orthosis on roll-over shape in adults with hemiplegia	Measurement: - Subjects with hemiplegia with AFO - Subjects with hemiplegia without AFO - Subjects without hemiplegia	3D	10-meter walkway (flush in the floor) with 6 force plates	Use of a real-time motion capture system: - 8 cameras, - Reflective markers placed on the subjects (Helen Hayes marker set)	- Thermoplastic articulated AFO ● 90° plantar flexion stop ● Free dorsiflexion ● Full-length foot plate ● Dorsal strap Made from polypropyleen + Tamarack Flexure Joints

		→ Standardized shoes (extra-depth leather shoes) → Self-selected walking speed - The subjects had 2 weeks of accommodation before the data collection.				
Andres Gatti, Marcelo; Freixes, Orestes; Anibal Fernandez, Sergio; et al. October 2012	Effects of ankle foot orthosis in stiff knee gait in adults with hemiplegia	Measurement: - Each condition was performed six times. - Three sets with orthosis + shoes and three barefoot - Self-selected speed - Time to practice with AFO	3D	10m walkway in the gait lab	Motion capture system ELITE was used. - 8 infrared cameras - Retroreflective markers by Davis et al. (1991)	Customized polypropylene AFO - Dorsal strap → proper foot alignment Standardized footwear (zero difference in the sole)
Kobayashi T1, Orendurff MS2, Singer ML3, Gao F4, Daly WK2, Foreman KB3 2016 Jun	Reduction of genu recurvatum through adjustment of plantar flexion resistance of an articulated ankle-foot orthosis in individuals post-stroke.	- Self-selected walking speed - Safety harness.	3D motion analysis laboratory.	Bertec split-belt instrumented treadmill	Data → Vicon 10 camera motion analysis system. Visual3D C-Motion for post-processing the data. - Reflective marker (Modified Cleveland Clinic Marker set, 8 segments)	Articulated AFO with adjustable plantar flexion resistance (4 different spring rates) in randomized order.
Kobayashi T, Orendurff MS, Singer ML, Gao F, Foreman KB. 2017 april	Contribution of ankle-foot orthosis moment in regulating ankle and knee motions during gait in individuals post-stroke.	Gait analysis: - Safety harness - Self-selected walking speed - 5 successful steps - Time to practice with AFO	Vicon 3D motion analysis system + visual3D → post-processing the data.	Bertec instrumented treadmill (200Hz)	Vicon Nexus 10-camera motion analysis system + Visual3D C-Motion - Retroreflective markers placed on head, trunk and limbs, according to	Articulated AFO, made with a steel spring with different rates to resist different plantarflexion forces. No resistance for dorsiflexion. 4 different spring levels

					the modified Cleveland clinic marker set.	were used presented by S1, S2, S3 and S4
Nikamp CDM[1], Hobbelink MSH[2], van der Palen J[3], Hermens HJ[4], Rietman JS[5], Buurke JH[4]. 2017 june	A randomized controlled trial on providing ankle-foot orthoses in patients with (sub-)acute stroke: Short-term kinematic and spatiotemporal effects and effects of timing.	Walking with and without AFO in one trail with a random order: Group 1: AFO-provision at the start of the study Group 2: AFO-provision, 8 weeks after the start of the study. - Self-selected walking speed	3D	Not mentioned	6-camera Vicon MX 12 + motion-analysis system with reflective markers Data processing via the lower-body Plug-In-Gait model from Vicon and custom in-house software from MATLAB.	3 commonly used off-the shelf, non-articulated, posterior leaf, polyrthylene or polypropylene AFO's
Pohl, M; Mehrholz, J. April 2006	Immediate effect of an individual designed functional ankle-foot orthosis in stance and gait in hemiparetic patients	Measurement: - All subjects practiced walking with and without AFO before data collection - Use of standardized shoes - No walking aids allowed - Five double step measurements were recorded - Self-adapted walking speed	Not mentioned	Platform walkway with 2 force plates	Software developed at Klinik Bavaria → camera not mentioned	- Semi-rigid AFO ● Soft and hard cast material ● Biomechanically like thermoplastic models ● AFO: double-stopped in a range of 80°-90°. ● Does not surround the metatarsophalangeal joints which allows them to roll-off over the front foot.
Schiemanck S1, Berenpas F2, van Swigchem R3, van den Munckhof P4, de Vries J5, Beelen A1, Nollet F1, Geurts AC2. 2015	Effects of implantable peroneal nerve stimulation on gait quality, energy expenditure, participation and user satisfaction in patients with post-	5 walking trials for each walking aid (AFO and FES). - Self-selected walking speed. - Familiarization period (3 weeks)	3D	15m walkway	Vicon Motion system 16 reflective markers	AFO of the participant and FES system (ACTi-Gait)

	stroke drop foot using an ankle-foot orthosis.						
Singer ML1, Kobayashi - T2, Lincoln LS3, rendurff MS3, Foreman KB1 2014 Nov	The effect of ankle-foot orthosis plantar flexion stiffness on ankle and knee joint kinematics and kinetics during first and second rockers of gait in individuals with stroke	- Self-selected walking speed - 2 different trials with 2 different spring conditions. - Wearing a harness.		3-dimensional motion analysis laboratory.	Bertec split-belt fully instrumented treadmill	Vicon 10-camera motion analysis system. Data post-processed with a Visual3D C-Motion. Data was synchronized with a Vicon Nexus. Reflective markers via the modified Cleveland Clinic Marker Set defining 8 segments.	Stiffness-adjustable experimental ankle-foot orthosis
van Swigchem R1, Roerdink M, Weerdesteyn V, Geurts AC, Daffertshofer A. 2014 May	The capacity to restore steady gait after a step modification is reduced in people with post-stroke foot drop using an ankle-foot orthosis.	- Preferred walking speed		3- dimensional motion analysis system (Vicon Motion Systems, Vicon-UK, Oxford, United Kingdom)	Treadmill (2 or 3 Km/h. Electromagnet held an obstacle prior to the participants	The position of the marker was analyzed with a 6- camera, 3-dimensional motion analysis system (Vicon Motion Systems, Vicon-UK, Oxford, United Kingdom). Bilateral hip excursions in sagittal plane were measured with goniometers (Biometrics SG150, Biometrics Ltd, Newport, United Kingdom (sampling rate 1.000 Hz)) that were placed on to the lateral side of the trunk + leg.	AFO: - Polypropyleen - Splint
Yamamoto S1, Ibayashi S2, Fuchi M2, Yasui T3. 2015 Apr	Immediate-term effects of use of an ankle-foot orthosis with an oil damper on the gait of stroke patients when walking without the device.	Everyone wore their own shoes. Familiarization period 3 conditions: 1. Gait without AFO use 2. Gait without the AFO-OD after 3 weeks		Three-dimensional motion analysis system	Force plates (6 AMTI)	10 Vicon MX cameras) and 6 force plates. Sampling frequency of 100Hz. 16 reflective markers.	AFO-OD

		3. Gait with AFO-OD after 3 weeks of use.				
Zissimopoulos A1, Fatone S2, Gard S2 2015 Oct	Effects of ankle-foot orthoses on mediolateral foot-placement ability during post-stroke gait	Clinical gait analysis: 2 conditions: with AFO/ without AFO Self-selected walking speed.	3D	10-m walkway, Target ML foot placement → tape lines on the floor	Kinematic data collected with a 120 Hz eight-camera digital Realtime motion capture system. Retro-reflective markers placed on anatomical landmarks → Helen Hayes full-body marker set (standard marker set). Data were processed with commercial software. Marked data is smoothed with fourth-order bidirectional Butterworth filter with cut-off frequency of 6 Hz.	Non-rigid polymer AFO: - 3 with posterior leaf spring - 1 with articulated dorsiflexion assist - 2 with articulated plantar flexion and dorsiflexion assist - 7 with articulated plantar flexion stop
Zollo, L.; Zaccheddu, N.; Ciancio, A. L.; et al. April 2015	Comparative analysis and quantitative evaluation of ankle-foot orthosis for foot drop in chronic hemiparetic patients	Biomechanical gait analysis: - Five walking trials without orthosis - Five walking trials with the Codivilla-spring - Five walking trials with the toe-off - Self-selected speed - Ambulation aids allowed.	3D	3m walkway	Stereo-photogrammetric system with 8 infrared cameras and 2 digital cameras. 20 passives and retroreflecting markers. 8 miniaturized probes with active EMG electrodes (via the Davis protocol)	- Solid orthosis or Codivilla-spring ● Posterior leaf ● Made of polypropylene - Dynamic orthosis or Toe-Off ● Anterior leaf ● Made of carbon fiber, fiberglass and Kevlar -

Table 7
Outcome parameters

Author	Title	Spatiotemporal parameters	Kinematic parameters	Kinetic parameters	Other parameters
Chen, Chih-Chi; Hong, Wei-Hsien; Wang, Chin-Man; et al. December 2010	Kinematic features of rear-foot motion using anterior and posterior ankle-foot orthosis in stroke patients with hemiplegic gait	- No significant differences for self-selected speed, comfortable walking speed, step length and cycle time between the anterior AFO, posterior AFO and barefoot conditions	<u>Angle</u> Ankle - PAFO significantly decreases the plantar flexion to neutral during, initial contact and swing. - PAFO increases significantly for dorsiflexion during stance. - Adduction angle during initial contact decreases significantly for both AAFO and PAFO in comparison without AFO. - No significant results were found for maximal adduction during stance phase and maximal abduction during swing phase - No significant differences for inversion during initial contact - Significant decrease of maximal eversion to neutral during stance with an AAFO compared with no AFO - Significant decrease in maximal inversion during swing for both AFOs compared with no AFO		
Chern JS, Chang HS, Lung CW, Wu CY, Tang SF. 2013	Static ankle-foot orthosis improves static balance and gait functions in hemiplegic patients after stroke.	- Significant differences with PAFO and AAFO for walking speed, cadence and step length			- PAFO caused a better alignment of the CoP with the axis of the foot - AAFO caused a lateral shift of the CoP.
Fatone, Stefania; Hansen, Andrew H.	Effect of ankle-foot orthosis on roll-over shape in adults with hemiplegia	- Significantly lower walking speed in hemiplegic persons	<u>Angles</u> Ankle		- The ROS arc radius and length increased significantly in the

2007			compared with healthy controls - Walking speed with and without orthoses was not significantly different - Significant increase of step length in the non-hemiplegic leg when wearing an AFO - Significant decrease in step width when walking with an AFO. The step width is still significantly lower in hemiplegic persons than in control subjects.	- Plantar flexion angle decreases significantly to neutral during initial contact with AFO compared with no AFO - Significant decrease in plantar flexion angle to slight dorsiflexion during mid-swing - Significant decrease in dorsiflexion during initial contact in hemiplegic persons compared with control persons - No significant difference found for dorsiflexion angle during mid-swing in hemiplegic persons compared with control subjects		involved limb, also it significantly altered the sagittal plane locomotion of the first COP point, this moves posterior to the center of the ankle. - The Arc length and radius were not significantly different between control subjects and subjects with an AFO - When an AFO was used the COP point moves posterior of the ankle joint compared to subjects without an AFO, here the COP point moves to anterior of the ankle joint - Without AFO the COP progression changes twice during mid stance, with the use of an AFO this change was eliminated.
Andres Gatti, Marcelo; Freixes, Orestes; Anibal Fernandez, Sergio; et al. October 2012	Effects of ankle foot orthosis in stiff knee gait in adults with hemiplegia	- With AFO a significantly higher gait speed - With AFO a significantly larger step length in the non-paretic leg		<u>Angles</u> Knee - Peak knee flexion angle was significantly different for both with and without AFO		
Kobayashi T1, Orendurff MS2, Singer ML3, Gao F4, Daly WK2, Foreman KB3 2016 Jun	Reduction of genu recurvatum through adjustment of plantar flexion resistance of an articulated ankle-foot orthosis in individuals post-stroke.			<u>Angle</u> Ankle - Significant increase in peak dorsiflexion (in conditions S3 and S4) Knee - Significant decrease in peak knee extension angle (in conditions S2, S3 and S4)	<u>Moments</u> Ankle - Peak dorsiflexion moment increased significant (in condition S4) Knee - Peak knee flexion moment decreased significant (in conditions S3 and S4)	

Kobayashi T, Orendurff MS, Singer ML, Gao F, Foreman KB. 2017 april	Contribution of ankle-foot orthosis moment in regulating ankle and knee motions during gait in individuals post-stroke.			<u>Angles</u> Ankle - The AFO dorsiflexion moment influenced the ankle position, more ankle dorsiflexion is seen. (Significant for conditions S3 and S4) Knee - The AFO dorsiflexion moment influenced the knee position, more knee flexion is seen. (Significant for conditions S3 and S4)	<u>Moments</u> Ankle - The higher the plantar flexion stiffness the greater the dorsiflexion moment during initial contact. (Significant for conditions S3 and S4), greatest during early stance and decreases during swing phase. - A higher AFO dorsiflexion moment increases the heel rocker. - Due to the AFO moment there is a decreased plantar flexion in late stance this can limit the push-off phase.
Nikamp CDM[1], Hobbelink MSH[2], van der Palen J[3], Hermens HJ[4], Rietman JS[5], Buurke JH[4]. 2017 june	A randomized controlled trial on providing ankle-foot orthoses in patients with (sub-)acute stroke: Short-term kinematic and spatiotemporal effects and effects of timing.	- Significant increase for cadence, stride duration and single support. - No significant results for walking speed, stride length, step length, step width, stance duration, first double support, second double support and swing duration.		<u>Angles</u> Ankle - The dorsiflexion increases significant during initial contact - No significant difference of dorsiflexion during stance - The dorsiflexion increases significant during swing phase Foot - Significant decrease of foot-progression during initial contact after AFO provision Knee - Significant increased knee flexion was solely seen during initial contact Hip - Significant increased hip flexion was solely seen during initial contact Pelvis	

				- No significant changes were seen in pelvis angles	
Pohl, M; Mehrholz, J. April 2006	Immediate effect of an individual designed functional ankle-foot orthosis in stance and gait in hemiparetic patients	-	Double stance duration reduces significantly with an AFO		- Gait symmetry significantly differenced with and without the AFO for deceleration forces - No significant differences in other gait symmetry parameters (acceleration forces)
Schiemanck S1, Berenpas F2, van Swigchem R3, van den Munckhof P4, de Vries J5, Beelen A1, Nollet F1, Geurts AC2. 2015	Effects of implantable peroneal nerve stimulation on gait quality, energy expenditure, participation and user satisfaction in patients with post-stroke drop foot using an ankle-foot orthosis. → excluded for secondary research question				
Singer ML1, Kobayashi -T2, Lincoln LS3, rendurff MS3, Foreman KB1 2014 Nov	The effect of ankle-foot orthosis plantar flexion stiffness on ankle and knee joint kinematics and kinetics during first and second rockers of gait in individuals with stroke			<u>Angles</u> Ankle - Decreased peak plantar flexion angle (in condition S2) Knee - There is only a slight increase in peak knee flexion in 2 of 5 subjects	<u>Moments</u> Ankle - Increased dorsiflexion moment during first rocker Knee - Increased peak knee extension moment
van Swigchem R1, Roerdink M, Weerdesteyn V, Geurts AC, Daffertshofer A. 2014 May	The capacity to restore steady gait after a step modification is reduced in people with post-stroke foot drop using an ankle-foot orthosis. → Excluded for secondary research question				
Yamamoto S1, Ibayashi S2, Fuchi M2, Yasui T3.	Immediate-term effects of use of an ankle-foot orthosis with an oil damper on the gait	-	Significant increased walking speed with AFO-OD (after 3 weeks	<u>Angles</u> Ankle	<u>Power</u> Ankle

2015 Apr	of stroke patients when walking without the device.	of AFO-OD use) compared with no AFO (before AFO-OD use) and no AFO (after 3 weeks of AFO-OD use) - No significant differences in results for loading response time - No significant differences in results for single stance time - Significant decrease for pre-swing time before and after 3 weeks AFO-OD use. Also, significant decreased for the AFO-OD (after 3 weeks of AFO-OD use) compared to no AFO (before AFO-OD use) and no AFO (after 3 weeks of AFO-OD use) - Non-paretic step length increases significantly for AFO-OD compared without AFO (before 3 weeks of use) and without AFO (after 3 weeks of use) - No significant differences in results for paretic step length	- Significant increased dorsiflexion at initial contact for AFO-OD (after 3 weeks of AFO-OD use) compared with no AFO (before AFO-OD use) and no AFO (after 3 weeks of AFO-OD use) - Significantly increased peak plantar flexion during loading response for AFO-OD (after 3 weeks of AFO-OD use) compared with no AFO (before AFO-OD use) - Significant increased peak dorsiflexion during stance for the AFO-OD (after 3 weeks of AFO-OD use) compared with no AFO (before AFO-OD use) and no AFO (after 3 weeks of AFO-OD use) - Significant decreased peak plantar flexion during pre-swing for the AFO-OD (after 3 weeks of AFO-OD use) compared with no AFO (before AFO-OD use) - Significant decreased plantar flexion during swing for the AFO-OD (after 3 weeks of AFO-OD use) compared with no AFO (before AFO-OD use) and no AFO (after 3 weeks of AFO-OD use) - Significant increased dorsiflexion during swing for AFO-OD (after 3 weeks of AFO-OD use) compared with no AFO (before AFO-OD use) and AFO (after 3 weeks of AFO-OD use)	- Negative power during mid stance when patients were walking without AFO at the beginning of the study → this increased after 3 weeks - In late stance there was a little peak positive power before using the AFO → this was high without using after 3 weeks of intervention with an AFO. → Yet is was deceased when using the AFO

				Knee - No significant effects are found for none of the examined parameters: angle at initial contact, peak flexion in loading response, peak extension in stance, peak flexion in swing. Hip: - No significant effects are found for none of the examined parameters: Flexion at initial contact, Peak extension in stance.	
Zissimopoulos A1, Fatone S2, Gard S2 2015 Oct	Effects of ankle-foot orthoses on mediolateral foot-placement ability during post-stroke gait.	- No significant difference in step width		<u>Angles</u> Ankle - Significant decreased plantar flexion during mid swing Hip - AFOs have no effect on peak pelvic obliquity, circumduction or hip abduction/adduction ROM during swing of the affected limb	Mediolateral foot-placement (ML) - AFOs had no effect on ML foot placement.
Zollo, L.; Zaccheddu, N.; Ciancio, A. L.; et al. April 2015	Comparative analysis and quantitative evaluation of ankle-foot orthosis for foot drop in chronic hemiparetic patients	- No significant difference was measured for following parameters: Cadence, stride time, step length. - Percentage of the swing phase significantly increased for the affected side for all three conditions compared to healthy controls - Percentage double support phase is significantly lower for the affected side for all three conditions compared to healthy controls		<u>Angles</u> Ankle - The ankle angle during initial contact is significantly lower in de paretic leg than in the non-paretic leg in the condition with shoes - The ankle angle during initial contact increased significantly to dorsiflexion in the paretic leg when wearing a solid AFO compared with shoes. - Both AFOs decreased significantly for the	

dorsi-plantar flexion ROM during stance compared with shoes
- In both AFO conditions the paretic leg was significantly lower in dorsi-plantar flexion ROM during stance compared with the non-paretic leg
- In both AFOs conditions the paretic leg was significantly lower for dorsi-plantar flexion ROM during swing compared with the non-paretic leg
- In the conditions with shoes and with solid AFO the paretic leg was significantly lower for dorsiflexion peak during swing compared to the non-paretic leg. The dynamic AFO is significantly lower than with shoes.

Knee
- Peak flexion angle significantly decreases during swing phase for the affected side in all 3 conditions. For the dynamic AFO in comparison with solid AFO and in comparison, with shoes.
- No significant results were found for flexion ROM between affected and non-affected side during stance phase.

Hip
- Significant decrease in all 3 conditions for flexion-extension ROM for the non-affected side

			during stance. No significant results are found during swing-phase. - Peak flexion during swing phase is significantly between affected and non-affected limb with dynamic AFO and with shoes. - No significant results were found for adduction and abduction during swing phase. - Pelvic tilt ROM during stance significantly decreased while wearing the dynamic AFO. - Pelvic tilt ROM during swing significantly increased in comparison of the non-affected side.

Checklists

1. **Kinematic features of rear-foot motion using anterior and posterior ankle-foot orthosis in stroke patients with hemiplegic gait**

	Item No	Recommendation	Yes/No	Score
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Yes	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Yes	2
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Yes	2
Objectives	3	State specific objectives, including any prespecified hypotheses	Yes	2
Methods				
Study design	4	Present key elements of study design early in the paper	Yes	2
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Doubtful	1
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls ***Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants**	No	0
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	/	/
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Yes	2
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	No	0
Bias	9	Describe any efforts to address potential sources of bias	Yes	2
Study size	10	Explain how the study size was arrived at	No	0
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	No	0
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Yes	2
		(*b*) Describe any methods used to examine subgroups and interactions	Yes	2
		(*c*) Explain how missing data were addressed	No	0
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed ***Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy**	Doubtful	1
		(*e*) Describe any sensitivity analyses	Doubtful	1

Results				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analyses	Doubtful	1
		(b) Give reasons for non-participation at each stage	NA	/
		(c) Consider use of a flow diagram	No	0
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Yes	2
		(b) Indicate number of participants with missing data for each variable of interest	No	0
		(c) *Cohort study*—Summarize follow-up time (eg, average and total amount)	/	/
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	/	/
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	/	/
		***Cross-sectional study*—Report numbers of outcome events or summary measures**	Yes	2
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Yes	2
		(*b*) Report category boundaries when continuous variables were categorized	NA	/
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA	/

Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	No	0
Discussion				
Key results	18	Summarize key results with reference to study objectives	Yes	2
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Yes	2
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Yes	2
Generalizability	21	Discuss the generalizability (external validity) of the study results	No	0
Other information				
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	No	0
Total score: 34/58 → 59%				

2. **Static ankle-foot orthosis improves static balance and gait functions in hemiplegic patients after stroke**

	Item No	Recommendation	Yes/No	Score
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Yes	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Yes	2
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Yes	2
Objectives	3	State specific objectives, including any prespecified hypotheses	Yes	2
Methods				
Study design	4	Present key elements of study design early in the paper	Yes	2
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Doubtful	1
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls ***Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants**	No	0
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	/	/
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Yes	2
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	No	0
Bias	9	Describe any efforts to address potential sources of bias	Yes	2
Study size	10	Explain how the study size was arrived at	No	0
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	No	0
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Yes	2
		(*b*) Describe any methods used to examine subgroups and interactions	Yes	2
		(*c*) Explain how missing data were addressed	No	0
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed ***Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy**	No	0
		(*e*) Describe any sensitivity analyses	Doubtful	1
Results				

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analyses	Doubtful	1
		(b) Give reasons for non-participation at each stage	NA	/
		(c) Consider use of a flow diagram	No	0
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Yes	2
		(b) Indicate number of participants with missing data for each variable of interest	No	0
		(c) *Cohort study*—Summarize follow-up time (eg, average and total amount)	/	/
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	/	/
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	/	/
		***Cross-sectional study*—Report numbers of outcome events or summary measures**	Doubtful	1
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Yes	2
		(*b*) Report category boundaries when continuous variables were categorized	NA	1
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA	1
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Doubtful	1
Discussion				
Key results	18	Summarize key results with reference to study objectives	Yes	2
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Yes	2
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Yes	2
Generalizability	21	Discuss the generalizability (external validity) of the study results	Yes	2
Other information				
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Yes	2
Total score: 39/62 → 63%				

3. Effect of ankle-foot orthosis on roll-over shape in adults with hemiplegia

	Item No	**Recommendation**	**Yes/No**	**Score**
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Yes	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	No	0
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Yes	2
Objectives	3	State specific objectives, including any prespecified hypotheses	Yes	2
Methods				
Study design	4	Present key elements of study design early in the paper	No	0
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Doubtful	1
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up ***Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls** *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	No	0
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed ***Case-control study*—For matched studies, give matching criteria and the number of controls per case**	NA	/
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	No	0

Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	No	0
Bias	9	Describe any efforts to address potential sources of bias	Yes	2
Study size	10	Explain how the study size was arrived at	No	0
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Doubtful	1
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Yes	2
		(*b*) Describe any methods used to examine subgroups and interactions	Yes	2
		(*c*) Explain how missing data were addressed	No	0
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed ***Case-control study*—If applicable, explain how matching of cases and controls was addressed** *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	No	0
		(*e*) Describe any sensitivity analyses	Doubtful	1

Results				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analyses	Doubtful	1
		(b) Give reasons for non-participation at each stage	NA	/
		(c) Consider use of a flow diagram	No	0
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Yes	2
		(b) Indicate number of participants with missing data for each variable of interest	No	0
		(c) *Cohort study*—Summarize follow-up time (eg, average and total amount)	/	/
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	/	/
		***Case-control study*—Report numbers in each exposure category, or summary measures of exposure**	Yes	2
		Cross-sectional study—Report numbers of outcome events or summary measures	/	/
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Doubtful	1
		(*b*) Report category boundaries when continuous variables were categorized	NA	/
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA	/
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	No	0
Discussion				
Key results	18	Summarize key results with reference to study objectives	Yes	2
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	No	0
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Yes	2
Generalizability	21	Discuss the generalizability (external validity) of the study results	No	0
Other information				
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	No	0
Total score: 25/58 → 43%				

4. Effects of ankle foot orthosis in stiff knee gait in adults with hemiplegia (Gatti et al., 2012)

	Item No	**Recommendation**	**Yes/No**	**Score**
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Yes	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Yes	2
Introduction				

Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Yes	2
Objectives	3	State specific objectives, including any prespecified hypotheses	Yes	2
Methods				
Study design	4	Present key elements of study design early in the paper	No	0
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Doubtful	1
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls ***Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants**	No	0
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	/	/
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Yes	2
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	No	0
Bias	9	Describe any efforts to address potential sources of bias	Yes	2
Study size	10	Explain how the study size was arrived at	No	0
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Yes	2
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Yes	2
		(*b*) Describe any methods used to examine subgroups and interactions	Yes	2
		(*c*) Explain how missing data were addressed	No	0
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed ***Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy**	NA	/
		(*e*) Describe any sensitivity analyses	Doubtful	1

Results				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analyses	Doubtful	1
		(b) Give reasons for non-participation at each stage	NA	/
		(c) Consider use of a flow diagram	No	0
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Yes	2
		(b) Indicate number of participants with missing data for each variable of interest	No	0
		(c) *Cohort study*—Summarize follow-up time (eg, average and total amount)	/	/
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	/	/
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	/	/
		***Cross-sectional study*—Report numbers of outcome events or summary measures**	Yes	2
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Doubtful	1
		(*b*) Report category boundaries when continuous variables were categorized	NA	/
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA	/
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	No	0
Discussion				
Key results	18	Summarize key results with reference to study objectives	Yes	2
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Yes	2
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Yes	2
Generalizability	21	Discuss the generalizability (external validity) of the study results	Yes	2

Other information				
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	No	0
Total score: 34/56 → 61%				

5. <u>Reduction of genu recurvatum through adjustment of plantarflexion resistance of an articulated ankle-foot orthosis in individuals post-stroke</u>

	Item No	Recommendation	Yes/No	Score
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Yes	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Yes	2
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Yes	2
Objectives	3	State specific objectives, including any prespecified hypotheses	Yes	2
Methods				
Study design	4	Present key elements of study design early in the paper	No	0
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Doubtful	1
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls ***Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants**	No	0
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	/	/
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	No	0
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*Yes*	*2*
Bias	9	Describe any efforts to address potential sources of bias	Yes	2
Study size	10	Explain how the study size was arrived at	No	0
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Yes	2
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Yes	2
		(*b*) Describe any methods used to examine subgroups and interactions	Yes	2
		(*c*) Explain how missing data were addressed	Doubtful	1
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed ***Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy**	NA	/
		(*e*) Describe any sensitivity analyses	Doubtful	1

Results				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analyses	Doubtful	1
		(b) Give reasons for non-participation at each stage	NA	/
		(c) Consider use of a flow diagram	No	0
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	No	0
		(b) Indicate number of participants with missing data for each variable of interest	No	0
		(c) *Cohort study*—Summarize follow-up time (eg, average and total amount)	/	/
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	/	/

		Case-control study—Report numbers in each exposure category, or summary measures of exposure	/	/
		***Cross-sectional study*—Report numbers of outcome events or summary measures**	*Yes*	*2*
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Yes	2
		(*b*) Report category boundaries when continuous variables were categorized	NA	1
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA	1
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Doubtful	1
Discussion				
Key results	18	Summarize key results with reference to study objectives	Yes	2
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	No	0
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	No	0
Generalizability	21	Discuss the generalizability (external validity) of the study results	No	0
Other information				
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	No	0
Total score: 31/60 → 52%				

6. Contribution of ankle-foot orthosis moment in regular ankle and knee motions during gait in individuals post-stroke

	Item No	**Recommendation**	**Yes/No**	**Score**
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Yes	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Yes	2
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Yes	2
Objectives	3	State specific objectives, including any prespecified hypotheses	Yes	2
Methods				
Study design	4	Present key elements of study design early in the paper	No	0
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Doubtful	1
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls ***Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants**	Doubtful	1
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	/	/
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	No	0
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Yes	2
Bias	9	Describe any efforts to address potential sources of bias	Yes	2
Study size	10	Explain how the study size was arrived at	No	0
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Yes	2
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Yes	2
		(*b*) Describe any methods used to examine subgroups and interactions	Yes	2

		(*c*) Explain how missing data were addressed	No	0
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed ***Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy**	NA	/
		(*e*) Describe any sensitivity analyses	Doubtful	1

Results				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analyses	Yes	2
		(b) Give reasons for non-participation at each stage	NA	/
		(c) Consider use of a flow diagram	No	0
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	No	0
		(b) Indicate number of participants with missing data for each variable of interest	No	0
		(c) *Cohort study*—Summarize follow-up time (eg, average and total amount)	/	/
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	/	/
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	/	/
		***Cross-sectional study*—Report numbers of outcome events or summary measures**	Yes	2
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Yes	2
		(*b*) Report category boundaries when continuous variables were categorized	NA	/
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA	/
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	No	0
Discussion				
Key results	18	Summarize key results with reference to study objectives	Yes	2
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	No	0
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Yes	2
Generalizability	21	Discuss the generalizability (external validity) of the study results	No	0
Other information				
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	No	0
Total score: 31/56 → 55%				

7. A randomised controlled trail on providing ankle-foot orthosis in patients with (sub) acute stroke: Short term kinematic and spatiotemporal effects and effects of timing

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No	Score
Title and abstract				
	1a	Identification as a randomised trial in the title	Yes page 1	2
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	No page 1	0
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Yes page 1 + 2	2
	2b	Specific objectives or hypotheses	Yes page 1 + 2	2
Methods				

Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Yes page 2	2
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	No	0
Participants	4a	Eligibility criteria for participants	Yes page 2	2
	4b	Settings and locations where the data were collected	No	0
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Yes 2 + 3	2
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Yes page 3	2
	6b	Any changes to trial outcomes after the trial commenced, with reasons	No	0
Sample size	7a	How sample size was determined	No	0
	7b	When applicable, explanation of any interim analyses and stopping guidelines	No	0
Randomization:				
Sequence generation	8a	Method used to generate the random allocation sequence	Yes page 2	2
	8b	Type of randomization; details of any restriction (such as blocking and block size)	Yes page 2	2
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Yes page 2	2
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	No	0
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	NA → not possible	/
	11b	If relevant, description of the similarity of interventions	NA	/
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Yes page 3	2
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Yes page 3	2
Results				
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Yes page 3	2
	13b	For each group, losses and exclusions after randomization, together with reasons	Yes page 4	2
Recruitment	14a	Dates defining the periods of recruitment and follow-up	No	0
	14b	Why the trial ended or was stopped	NA	/
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Yes page 4	2
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Doubtful	1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Yes page 3 + 5	2
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	No	0
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	No	0
Harms	19	All-important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	No	0
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Yes page 6	2
Generalizability	21	Generalizability (external validity, applicability) of the trial findings	No	0
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Yes page 6	2

Other information				
Registration	23	Registration number and name of trial registry	No	0
Protocol	24	Where the full trial protocol can be accessed, if available	No	0
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Yes	2
Total score: 39/68 → 57%				

8. Immediate effect of an individual designed functional ankle-foot orthosis in stance and gait in hemiparetic patients

	Item No	**Recommendation**	**Yes/No**	**Score**
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Yes	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Yes	2
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Yes	2
Objectives	3	State specific objectives, including any prespecified hypotheses	Yes	2
Methods				
Study design	4	Present key elements of study design early in the paper	Yes	2
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Doubtful	1
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls ***Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants**	Doubtful	1
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	/	/
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Yes	2
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	No	0
Bias	9	Describe any efforts to address potential sources of bias	Yes	2
Study size	10	Explain how the study size was arrived at	No	0
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Doubtful	1
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Yes	2
		(*b*) Describe any methods used to examine subgroups and interactions	Yes	2
		(*c*) Explain how missing data were addressed	No	0
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed ***Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy**	NA	/
		(*e*) Describe any sensitivity analyses	Doubtful	1

Results				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analyses	Doubtful	1
		(b) Give reasons for non-participation at each stage	NA	/
		(c) Consider use of a flow diagram	No	0
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Yes	2
		(b) Indicate number of participants with missing data for each variable of interest	No	0
		(c) *Cohort study*—Summarize follow-up time (eg, average and total amount)	/	/

Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	/	/
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	/	/
		***Cross-sectional study*—Report numbers of outcome events or summary measures**	Yes	2
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Doubtful	1
		(*b*) Report category boundaries when continuous variables were categorized	NA	/
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA	/
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	No	0
Discussion				
Key results	18	Summarize key results with reference to study objectives	Yes	2
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Yes	2
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Yes	2
Generalizability	21	Discuss the generalizability (external validity) of the study results	Yes	2
Other information				
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	No	0
Total score 36/56 → 64%				

9. Effects of implantable peroneal nerve stimulation on gait quality, energy expenditure, participation and user satisfaction in patients with post-stroke drop foot using an ankle-foot orthosis.

	Item No	**Recommendation**	**Yes/No**	**Score**
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Yes	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Yes	2
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Yes	2
Objectives	3	State specific objectives, including any prespecified hypotheses	No	0
Methods				
Study design	4	Present key elements of study design early in the paper	No	0
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Doubtful	1
Participants	6	**(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up** *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	Yes	2
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	NA	/
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Yes	2
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Yes	2
Bias	9	Describe any efforts to address potential sources of bias	Yes	2
Study size	10	Explain how the study size was arrived at	No	0
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Yes	2

Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Yes	2
		(*b*) Describe any methods used to examine subgroups and interactions	Yes	2
		(*c*) Explain how missing data were addressed	No	0
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	No	0
		(*e*) Describe any sensitivity analyses	Doubtful	1

Results				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analyses	Yes	2
		(b) Give reasons for non-participation at each stage	Yes	2
		(c) Consider use of a flow diagram	No	0
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Yes	2
		(b) Indicate number of participants with missing data for each variable of interest	Yes	2
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	Doubtful	1
Outcome data	15*	***Cohort study*—Report numbers of outcome events or summary measures over time**	Yes	2
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	/	/
		Cross-sectional study—Report numbers of outcome events or summary measures	/	/
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Yes	2
		(*b*) Report category boundaries when continuous variables were categorized	Yes	2
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	No	0
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Doubtful	1
Discussion				
Key results	18	Summarise key results with reference to study objectives	Yes	2
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Yes	2
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Yes	2
Generalizability	21	Discuss the generalizability (external validity) of the study results	Yes	2
Other information				
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	No	2
Total score: 48/66 → 73%				

10. **<u>The effect of ankle-foot orthosis plantarflexion stiffness on ankle and knee joint kinematics and kinetics during first and second rockers of gait in individuals with stroke</u>**

	Item No	**Recommendation**	**Yes/No**	**Score**
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Yes	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Yes	2
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Yes	2
Objectives	3	State specific objectives, including any prespecified hypotheses	Yes	2
Methods				
Study design	4	Present key elements of study design early in the paper	Yes	2

Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Doubtful	1
Participants	6	**(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up** *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	No	0
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	NA	/
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Yes	2
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	No	0
Bias	9	Describe any efforts to address potential sources of bias	Yes	2
Study size	10	Explain how the study size was arrived at	No	0
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	No	0
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	No	0
		(*b*) Describe any methods used to examine subgroups and interactions	Yes	2
		(*c*) Explain how missing data were addressed	No	0
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	Doubtful	1
		(*e*) Describe any sensitivity analyses	Doubtful	1

Results				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analyses	Doubtful	1
		(b) Give reasons for non-participation at each stage	NA	/
		(c) Consider use of a flow diagram	No	0
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	No	0
		(b) Indicate number of participants with missing data for each variable of interest	No	0
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	NA	/
Outcome data	15*	***Cohort study*—Report numbers of outcome events or summary measures over time**	NA	/
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	/	/
		Cross-sectional study—Report numbers of outcome events or summary measures	/	/
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	No	0
		(*b*) Report category boundaries when continuous variables were categorized	NA	1
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA	1
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	No	0
Discussion				
Key results	18	Summarise key results with reference to study objectives	Yes	2
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Yes	2
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Doubtful	1
Generalizability	21	Discuss the generalizability (external validity) of the study results	No	0
Other information				

Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	No	0
Total score: 27/60 → 45%				

11. <u>The capacity to restore steady gait after a step modification is reduced in people with poststroke foot drop using an ankle-foot orthosis.</u>

	Item No	Recommendation	Yes/No	Score
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Yes	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Yes	2
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Yes	2
Objectives	3	State specific objectives, including any prespecified hypotheses	Yes	2
Methods				
Study design	4	Present key elements of study design early in the paper	Yes	2
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Yes	2
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls ***Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants**	Yes	2
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	/	/
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Yes	2
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*Yes*	*2*
Bias	9	Describe any efforts to address potential sources of bias	No	0
Study size	10	Explain how the study size was arrived at	No	0
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Yes	2
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Yes	2
		(*b*) Describe any methods used to examine subgroups and interactions	Yes	2
		(*c*) Explain how missing data were addressed	No	0
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed ***Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy**	Yes	2
		(*e*) Describe any sensitivity analyses	Doubtful	1

Results				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Yes	2
		(b) Give reasons for non-participation at each stage	Yes	2
		(c) Consider use of a flow diagram	No	0
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Doubtful	1
		(b) Indicate number of participants with missing data for each variable of interest	Yes	2
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	/	/
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	/	/

		Case-control study—Report numbers in each exposure category, or summary measures of exposure	/	/
		***Cross-sectional study*—Report numbers of outcome events or summary measures**	*Doubtful*	*1*
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Yes	2
		(*b*) Report category boundaries when continuous variables were categorized	NA	/
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA	/
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Yes	2
Discussion				
Key results	18	Summarize key results with reference to study objectives	Yes	2
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Yes	2
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Yes	2
Generalizability	21	Discuss the generalizability (external validity) of the study results	Yes	2
Other information				
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Yes	2
Total score: 49/60 → 82%				

12. <u>Immediate-term effects of use of an ankle-foot orthosis with an oil damper on the gait of strokepatients when walking without the device.</u>

	Item No	**Recommendation**	**Yes/No**	**Score**
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Yes	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Yes	2
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Yes	2
Objectives	3	State specific objectives, including any prespecified hypotheses	Yes	2
Methods				
Study design	4	Present key elements of study design early in the paper	Yes	2
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Doubtful	1
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls ***Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants**	No	0
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	/	/
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Yes	2
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	No	0
Bias	9	Describe any efforts to address potential sources of bias	No	0
Study size	10	Explain how the study size was arrived at	No	0
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Yes	2
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Yes	2
		(*b*) Describe any methods used to examine subgroups and interactions	Yes	2

		(*c*) Explain how missing data were addressed	No	0
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed ***Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy**	No	0
		(*e*) Describe any sensitivity analyses	Doubtful	1

Results				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analyzed	Doubtful	1
		(b) Give reasons for non-participation at each stage	No	0
		(c) Consider use of a flow diagram	No	0
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Yes	2
		(b) Indicate number of participants with missing data for each variable of interest	No	0
		(c) *Cohort study*—Summarize follow-up time (eg, average and total amount)	/	/
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	/	/
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	/	/
		***Cross-sectional study*—Report numbers of outcome events or summary measures**	Doubtful	1
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Yes	2
		(*b*) Report category boundaries when continuous variables were categorized	NA	/
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA	/
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Doubtful	1
Discussion				
Key results	18	Summarize key results with reference to study objectives	Yes	2
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Yes	2
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Yes	2
Generalizability	21	Discuss the generalizability (external validity) of the study results	Yes	2
Other information				
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Yes	2
Total score: 37/60 → 62%				

13. <u>Effects of ankle-foot orthoses on mediolateral foot-placement ability during post-stroke gait.</u>

	Item No	**Recommendation**	**Yes/No**	**Score**
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Yes	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Yes	2
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Yes	2
Objectives	3	State specific objectives, including any prespecified hypotheses	Yes	2
Methods				
Study design	4	Present key elements of study design early in the paper	Yes	2
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Yes	2
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls	Yes	2

		***Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants**		
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	/	/
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	No	0
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Yes	0
Bias	9	Describe any efforts to address potential sources of bias	Yes	2
Study size	10	Explain how the study size was arrived at	No	0
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	No	0
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Yes	2
		(*b*) Describe any methods used to examine subgroups and interactions	Yes	2
		(*c*) Explain how missing data were addressed	No	0
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed ***Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy**	Doubtful	1
		(e) Describe any sensitivity analyses	Doubtful	1

Results				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analyzed	Doubtful	1
		(b) Give reasons for non-participation at each stage	NA	/
		(c) Consider use of a flow diagram	No	0
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Yes	2
		(b) Indicate number of participants with missing data for each variable of interest	No	0
		(c) *Cohort study*—Summarize follow-up time (eg, average and total amount)	/	/
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	/	/
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	/	/
		***Cross-sectional study*—Report numbers of outcome events or summary measures**	Doubtful	1
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Yes	2
		(*b*) Report category boundaries when continuous variables were categorized	NA	1
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA	1
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Doubtful	1
Discussion				
Key results	18	Summarize key results with reference to study objectives	Yes	2
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Yes	2
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Yes	2
Generalizability	21	Discuss the generalizability (external validity) of the study results	Yes	2
Other information				
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Yes	2
Total score: 41/62 → 66%				

14. Comparative analysis and quantitative evaluation of ankle-foot orthosis for foot drop in chronic hemiparetic patients

	Item No	Recommendation	Yes/No	Score
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Yes	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Yes	2
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Yes	2
Objectives	3	State specific objectives, including any prespecified hypotheses	Yes	2
Methods				
Study design	4	Present key elements of study design early in the paper	Yes	2
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Doubtful	1
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls ***Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants**	Yes	2
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	/	/
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	No	0
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	No	0
Bias	9	Describe any efforts to address potential sources of bias	Yes	2
Study size	10	Explain how the study size was arrived at	No	0
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	No	0
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Yes	2
		(*b*) Describe any methods used to examine subgroups and interactions	Yes	2
		(*c*) Explain how missing data were addressed	No	0
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed ***Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy**	Yes	2
		(*e*) Describe any sensitivity analyses	Doubtful	1

Results				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Doubtful	1
		(b) Give reasons for non-participation at each stage	NA	/
		(c) Consider use of a flow diagram	No	0
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Yes	2
		(b) Indicate number of participants with missing data for each variable of interest	No	0
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	/	/
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	/	/
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	/	/
		***Cross-sectional study*—Report numbers of outcome events or summary measures**	Doubtful	1
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Yes	2
		(*b*) Report category boundaries when continuous variables were categorized	NA	/
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA	/

Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Doubtful	1
Discussion				
Key results	18	Summarise key results with reference to study objectives	Yes	2
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	No	0
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	No	0
Generalizability	21	Discuss the generalizability (external validity) of the study results	Yes	2
Other information				
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Yes	2
Total score: 34/58 → 59%				

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PART 2: Research protocol

Introduction

Annually 45.000 people are diagnosed with stroke in the Netherlands, it can appear at every age, though it is more likely in older people (Koninklijk Nederlands Genootschap voor Fysiotherapie, 2014). According to the definition a distinction of two types can be made, ischemic or hemorrhage. (Sacco et al., 2013), defined the two as followed, ischemic is “An episode of neurological dysfunction caused by focal cerebral, spinal, or retinal infarction.” And the hemorrhage stroke is “Rapidly developing clinical signs of neurological dysfunction attributable to a focal collection of blood within the brain parenchyma or ventricular system that is not caused by trauma.” This disease causes a lot of changes in physical functioning of the people. A common deficit in persons with stroke is a drop foot. It is the inability to lift their foot against gravity (Zollo et al., 2015), often due to spasticity of the plantar flexors, weakness of the dorsiflexors or a combination of the two. This can lead to changes in spatiotemporal, kinematic and kinetic parameters during gait. (G. Chen, Patten, Kothari, & Zajac, 2005). This is confirmed by the systematic review that was conducted for master thesis part one, there was seen that when addressing the foot drop syndrome an ankle foot orthosis (AFO) is often prescribed and that AFOs can affect the gait pattern by altering the spatiotemporal, kinematic and kinetic parameters.

There are different types of AFOs, which type of AFO that is used, depends on the characteristics of the participant. A distinction between rigid, semi-rigid and non-rigid can be made. Rigid, static or solid AFOs are often made of thermoplastic or thermoformable materials, the change of dorsiflexion angle during gait is strongly limited (Daryabor, Arazpour, & Aminian, 2018). Semi-rigid AFOs do not surround the metatarsophalangeal joint, which implies better roll-off over the front foot (Pohl & Mehrholz, 2006). The articulated, dynamic or non-rigid AFO has a variety of hinges and flexion stops, it is adjustable in plantar flexion resistance, these different resistors will change the dorsiflexion angle in the ankle during gait (Daryabor et al., 2018). In the study of (Zollo et al., 2015) was found that both types of AFOs, solid and dynamic ones showed equal effects on reducing the ROM of the dorsi-plantar-flexion angle in the ankle and therefore both AFOs were effective in changing the foot drop syndrome. They saw no differences between the AFOs for the spatiotemporal parameters and both orthoses ensured balance between the two limbs, yet because of the small sample size future research is necessary to confirm these statistical significant results.

Three-dimensional gait analysis is the gold standard for measuring the gait pattern (Armand, Decoulon, & Bonnefoy-Mazure, 2016; Galna et al., 2014). In ‘master thesis part 1’ the primary aim was to determine which systems are used to analyze gait and to determine which system was most appropriate to measure spatiotemporal, kinematic and kinetic parameters. In the included literature of “master thesis part one” was found that the Vicon Nexus camera motion analyzing system and the Realtime motion capture system are commonly used to measure gait. (C. C. Chen et al., 2010; Fatone & Hansen, 2007; Gatti et al., 2012; Kobayashi et al., 2016; Kobayashi, Orendurff, Singer, Gao, & Foreman, 2017; Nikamp et al., 2017; Schiemanck et al., 2015; Singer, Kobayashi, Lincoln, Orendurff, & Foreman, 2014; van

Swigchem, Roerdink, Weerdesteyn, Geurts, & Daffertshofer, 2014; Yamamoto, Ibayashi, Fuchi, & Yasui, 2015; Zissimopoulos, Fatone, & Gard, 2015). These systems measured gait in a three-dimensional perspective and are sometimes combined with a force plate system. The parameters that can be measured with these systems and which are sensitive to change are: cadence, walking speed, step length, swing duration, positive and negative ankle power, ankle ROM, knee ROM, ankle moments and knee moments. Reflective markers are used to analyze the gait, these can be set up via the modified Cleveland clinic marker set, it exists of eight segments: two on the feet, two on the shanks, two on the thighs, one on the pelvis and one HAT(head, arm, trunk), the markers are placed on the AFO (Kobayashi et al., 2017; Singer et al., 2014). Another possibility is a standard marker set by Helen Hayes full-body marker set, markers are bilateral placed on the shod foot proximal to the third metatarsal phalangeal joint, on the lateral malleoli, anterior on the shanks and thighs, femoral lateral epicondyles, between the processes styloid of the wrist, also on the SIAS (spina iliaca anterior superior) and the SIPS (spina iliaca posterior superior) (Fatone & Hansen, 2007; Zissimopoulos et al., 2015). Usually a walkway or a treadmill is used during gait analysis. The distance of the walkway differs, the most common distance is ten meters (Chern, Chang, Lung, Wu, & Tang, 2013; Fatone & Hansen, 2007; Gatti et al., 2012; Zissimopoulos et al., 2015). Participants walk at a self-selected walking speed, commonly an average speed of two to three Km/h.

The suitability and usability of an AFO is based on its benefits and discomforts. The patients' feedback is necessary for deciding which orthosis is most optimal. Assessing satisfaction is done in some papers and collected by the systematic review of (Bettoni et al., 2016). Characteristics that seem related with user satisfaction are age, gender and health status (Cleary & McNeil, 1988). For Orthomed this can be an interesting outcome parameter to optimize their products and services.

In 'master thesis part 2' an observational cross-over trial will be set up to investigate which parameters will change when using the camera system (PRO.vision) presented by Orthomed, this is their request. The PRO.vision can measure gait in a two- or three-dimensional perspective, it contains two cameras and 5 markers. Outcome measurements of thee system include spatiotemporal and kinematic parameters. An AFO can change the gait pattern in a positive way but when it is too difficult to use and the patient does not feel comfortable, you can question its usefulness. It is important to know the patients' user-satisfaction, this can be quantified by different questionnaires. Possible options are the OPUS-questionnaire, Quebec User Evaluation of Satisfaction with assistive Technology and The Activities-specific Balance Confidence (ABC) scale (Bettoni et al., 2016; Zissimopoulos, Fatone, & Gard, 2014).

Aim of the study

This master thesis is a collaboration of Hasselt University under supervision and guidance of promotor Prof. Dr. P. Feys, copromotors Prof. Dr. P. Meyns and Dr. B. Dingenen and Orthomed under supervision of Rafael Beaten and Bert Laermans.

The study contributes the effect of an AFO on the walking pattern of stroke patients with a drop foot. In this research we want to compare walking without AFO, with a dynamic AFO and with a static AFO. Secondary we want to investigate the user satisfaction in the clients between the two different AFOs.

Research question

- Primary research question: Which differences are measurable between the conditions walking without an AFO, with a dynamic AFO and with a static AFO in spatiotemporal, kinematic and kinetic parameters in patients with stroke?

- Secondary research question: Is there a difference in user satisfaction between the static and the dynamic AFO?

Hypotheses

- Primary research question:

  1. A first expectation is that there will be more dorsiflexion of the ankle or a more neutral position of the ankle during the swing phase and push off, greater walking speed, more knee flexion during mid-stance, an increased step length and a decreased cadence for the conditions with AFO than without AFO.

  2. A second hypothesis is that the walking trial with the dynamic AFO and the static AFO will deliver similar results on previously mentioned parameters in the first hypothesis. And that both AFOs will have better results than walking without an AFO.

- Secondary research question:

  1. The next hypothesis is that the dynamic AFO will deliver a higher satisfaction rate than the rigid AFO, perhaps the elastic material can provide a more pleasant feeling and can cause more comfort for the patient.

Method

Design

Observational cross-sectional study

Participants

15 patients with a drop foot due to stroke, above 18 years old will be recruited between August 2018 and October 2018 from the database of Orthomed.

Contact details Orthomed:

Genk: Henry Fordlaan 43, 3600 Genk
info@orthomed.be
+32 (0)89-30 72 39
Hasselt (Demolder): Het Dorlik 12, 3500 Hasselt
info@demolder.eu
+32 (0)11-28 64 90
Website: http://www.orthomed.be/index.html

In- and exclusion criteria

Inclusion criteria:

- Unilateral stroke, left or right due to ischemic or hemorrhagic
- Chronic stroke: > 6 months post-stroke
- Participants > 18 years old
- Foot drop syndrome due to stroke
- Manual muscle test of the ankle dorsiflexion between F0 and F3.
- Able to walk 20 meters independently without other walking devices than the AFO
- Ability to walk at a walking speed of two to three km/hour for 20 meters
- Able to understand simple Dutch or English verbal instructions
- Already using any type of non-electrically controlled AFO for indefinite time.

Exclusion criteria:

- Other disabilities that could affect the gait pattern (cardiac, metabolic and/ or pulmonary diseases, diabetes, psychiatric disorders, chronic deformities of the lower limb, musculoskeletal diseases, other pathologies involving locomotion, foot anomalies like equinovarus...)
- Other neurological symptoms that could affect the gait pattern like pusher or neglect
- Increased muscle tone in ankle plantar flexors, knee extensors or hip flexors: score on the Modified Ashworth scale > 2 in each muscle group

Patient recruitment

Patients that met the in- and exclusion criteria will be selected out of the database of Orthomed

Medical ethics

A request for approval of this study will be send to the commission for medical ethics at the Medical Research Ethics Committees United (MEC-U) and commission for medical ethics of the hospital of eastern Limburg (ZOL). Patients will receive an informed consent that needs to be signed to be included in the study. Patients can leave the study at any time.

Intervention/ Measurements

Before the intervention, participants will be asked to make an appointment with Orthomed for measurements to fabricate the personalized AFO. The AFOs are fabricated and paid by Orthomed.

Primary research question

For the measurement of the gait pattern the PRO.vision system will be used, this system can be used for dynamic motion analysis in 2D as well as 3D perspective.

PRO.vision information:

Streifeneder

ortho.production GmbH

Moosfeldstrasse 10

82275 Emmering

Germany

T +49 8141 6106-0

F +49 8141 6106-50

export@streifeneder.de

https://www.streifeneder.com/op/products/ortho.lab-motion-analysis-tools-software/pro.vision-3d-motion-analysis-system

www.streifeneder.com/op

The PRO.vision system for 3D dynamic motion analysis consists of two cameras and five markers. The markers are placed on the participant as followed:

- Sagittal plane
    - In the middle of the shoulder so that it moves minimally when the shoulder is moved
    - On the trochanter major
    - On the knee axis
    - On the line of the ankle joint two centimeters vertically on the surface
    - On the fifth metatarsus at the same height as marker four
- Frontal plane
    - Upper edge of sternum
    - Left spina iliaca anterior superior
    - Right spina iliaca anterior superior
    - In the middle of the patella
    - In the middle of the calf, ten centimeters above the instep

Participants were asked to walk back and forth on a 10-meter walk-way at a comfortable speed until one full strike is registered by the system. Because this registration takes place in the first trial we allowed familiarization of the AFO, so that there is minimal diversity in experience with the AFO. Familiarization is executed though a five-minute warm up with and without the AFO, this method is used in the article of Pohl & Mehrholz et al. During the warm up period the participants can also familiarize to the setting (Pohl & Mehrholz, 2006).

During the measurements the participants will start five meters before the walkway and are instructed to only decelerate after the last mark so that the walking speed is not influenced.
The PRO.vision is aimed in the middle of the walkway at the sagittal and frontal plane and so that the participant is filling the whole screen. Participants will be instructed to walk with the arm held against the body until all markers are recognized by the system during one full stride. These measurements are executed for three conditions: wearing only their own shoes, wearing a personalized static AFO and wearing a personalized dynamic AFO.

Attention points for surroundings and placement of the PRO.vision:

- Avoid reflective objects in the surroundings
- Do not place the camera system towards sunlight or other light sources (for example table lamps)
- Displays, monitors, screens, ... should not be visible in the video
- There must be a stable background light. No flickering lights, this can decrease the quality of the video
- Check if the markers are glowing bright enough, if not change the batteries.

Secondary research question

For the measurement of the patients satisfactory the Client Satisfaction with Device in the Orthotics and Prosthetics Users' Survey (CDS-OPUS) and The Activities-specific Balance Confidence (ABC) Scale are selected. The CDS-OPUS questionnaire has been approved in the article of (Bettoni et al., 2016) and gives information about the satisfaction of the device and about the satisfaction with the service of the clinical staff. The ABC-scale was used in the article of (Zissimopoulos et al., 2014). This questionnaire asks the participants about their percentage of confidence to not lose their balance during functional activities.

A familiarization period of three weeks is used for the participants to get them accustomed to the AFO. Than the participants are called by the assessors to fill out the questionnaire.

Outcome parameters

For the selection of the outcome parameters for the primary research question we refer to the first part of this master thesis where we investigated the sensitivity of different parameters to change while wearing an AFO during gait. The following parameters were concluded to be the most sensitive to change:

- Primary outcome parameters
    - Spatiotemporal parameters
        - Gait speed
        - Cadence
        - Single support
        - Step length
        - Swing duration

        - Kinematic
            - Ankle ROM
            - Knee ROM

- Secondary outcome parameters
    - User satisfaction
        - CDS-OPUS questionnaire
        - ABC-scale

Data analysis

For the data analysis a mixed model is used because the three conditions (comparison of wearing only their own shoes, wearing a personalized static AFO and wearing a personalized dynamic AFO) are measured in every participant, this makes the results dependent. The fixed effects are the outcome parameters (gait speed, cadence, single support, step length, swing duration, ankle ROM and knee ROM) and the three conditions (comparison of wearing only their own shoes, wearing a personalized static AFO and wearing a personalized dynamic AFO). The random effect are the different participants. The statistical analysis will be performed in JMP 2.0 with an alfa level of 0.05.

Time planning

1. Protocol submitted at the committee (MEC-U and ZOL) in July 2018
2. Approval of the committee for study protocol by August 2018
3. Recruitment of patients by September 2018
4. Data acquisition by November 2018
5. Data analysis by February 2018
6. Written master thesis by June 2018

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Appendix

Questionnaire 1: Client Satisfaction with Device in the Orthotics and Prosthetics Users' Survey (CDS-OPUS)

Questionnaire 2: The Activities-specific Balance Confidence (ABC) Scale

20694

Client ID

OPUS: Satisfaction With Device and Services

Please mark the response that most closely reflects your opinion.

	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree	Don't Know / Not Applicable
1. My prosthesis / orthosis fits well	○	○	○	○	○	○
2. The weight of my prosthesis / orthosis is manageable	○	○	○	○	○	○
3. My prosthesis / orthosis is comfortable throughout the day	○	○	○	○	○	○
4. It is easy to put on my prosthesis / orthosis	○	○	○	○	○	○
5. My prosthesis / orthosis looks good	○	○	○	○	○	○
6. My prosthesis / orthosis is durable	○	○	○	○	○	○
7. My clothes are free of wear and tear from my prosthesis / orthosis	○	○	○	○	○	○
8. My skin is free of abrasions and irritations	○	○	○	○	○	○
9. My prosthesis / orthosis is pain free to wear	○	○	○	○	○	○
10. I can afford the out-of-pocket expenses to purchase and maintain my prosthesis / orthosis	○	○	○	○	○	○
11. I can afford to repair or replace my prosthesis / orthosis as soon as needed	○	○	○	○	○	○
12. I received an appointment with a prosthetist / orthotist within a reasonable amount of time	○	○	○	○	○	○
13. I was shown the proper level of courtesy and respect by the staff	○	○	○	○	○	○
14. I waited a reasonable amount of time to be seen	○	○	○	○	○	○
15. Clinic staff fully informed me about equipment choices	○	○	○	○	○	○
16. The prosthetist / orthotist gave me the opportunity to express my concerns regarding my equipment	○	○	○	○	○	○
17. The prosthetist / orthotist was responsive to my concerns and questions	○	○	○	○	○	○
18. I am satisfied with the training I received in the use and maintenance of my prosthesis / orthosis	○	○	○	○	○	○
19. The prosthetist / orthotist discussed problems I might encounter with my equipment	○	○	○	○	○	○
20. The staff coordinated their services with my therapists and doctors	○	○	○	○	○	○
21. I was a partner in decision-making with clinic staff regarding my care and equipment	○	○	○	○	○	○

Patient Name: _____ Date: _____

The Activities-specific Balance Confidence (ABC) Scale*

Instructions to Participants: For each of the following activities, please indicate your level of confidence in doing the activity without losing your balance or becoming unsteady from choosing one of the percentage points on the scale from 0% to 100% If you do not currently do the activity in question, try and imagine how confident you would be if you had to do the activity. If you normally use a walking aid to do the activity or hold onto someone, rate your confidence as if you were using these supports.

0%	10	20	30	40	50	60	70	80	90	100%
No Confidence										Completely Confident

How confident are you that you will not lose your balance or become unsteady when you…

1. …walk around the house? _____%
2. …walk up or down stairs? _____%
3. …bend over and pick up a slipper from the front of a closet floor? _____%
4. …reach for a small can off a shelf at eye level? _____%
5. …stand on your tip toes and reach for something above your head? _____%
6. …stand on a chair and reach for something? _____%
7. …sweep the floor? _____%
8. …walk outside the house to a car parked in the driveway? _____%
9. …get into or out of a car? _____%
10. …walk across a parking lot to the mall? _____%
11. …walk up or down a ramp? _____%
12. …walk in a crowded mall where people rapidly walk past you? _____%
13. …are bumped into by people as you walk through the mall? _____%
14. …step onto or off of an escalator while you are holding onto a railing? _____%
15. …step onto or off an escalator while holding onto parcels such that you cannot hold onto the railing? _____%
16. …walk outside on icy sidewalks? _____%

*Powell LE & Myers AM. The Activities-specific Balance Confidence (ABC) Scale. Journal of Gerontology Med Sci 1995; 50(1):M28-34.

Total ABC Score: _____

Scoring: _____ / 16 = _____% of self confidence
Total ABC Score

MEDICARE PATIENTS ONLY
100% - _____% Function = _____% Impairment

Patient Signature: _____ Date: _____

Therapist Signature: _____ Date: _____

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BEOORDELING VAN DE WETENSCHAPPELIJKE STAGE-DEEL 1

Wetenschappelijke stage deel 1 (Masterproef deel 1- MP1) van de Master of Science in de revalidatiewetenschappen en de kinesitherapie bestaat uit **twee delen**:

1) De literatuurstudie volgens een welomschreven methodiek.
2) Het opstellen van het onderzoeksprotocol ter voorbereiding van masterproef deel 2.

Omschrijving van de **evaluatie**:

1) 80% van het eindcijfer wordt door de promotor in samenspraak met de copromotor gegeven op grond het product en van het proces dat de student doorliep om de MP1 te realiseren, met name het zelfstandig uitvoeren van de literatuurstudie en het zelfstandig opstellen van het onderzoeksprotocol, alsook de kwaliteit van academisch schrijven.
2) 20% van het eindcijfer wordt door de interne jury gegeven op grond van het ingeleverde product en de mondelinge presentatie waarin de student zijn/haar proces toelicht.

In de beoordeling dient onderscheid gemaakt te worden tussen studenten die, in samenspraak met de promotor, een nieuw onderzoek uitwerkten en studenten die instapten in een lopend onderzoek of zich baseren op voorgaande masterproeven of onderzoeksprojecten. Van deze laatste worden bijkomende inspanningen verwacht zoals bv. het bijsturen van de eerder geformuleerde onderzoeksvraag, de kritische reflectie over het onderzoeksdesign, het uitvoeren van een pilotexperiment.

Beoordelingskader:

Beoordelingskader: criteria op 20	
18-20	Excellente modelmasterproef
16-17	Uitmuntende masterproef
14-15	Zeer goede masterproef die zich onderscheidt van de andere masterproeven
12-13	Goede masterproef
10-11	Voldoende masterproef die op een aantal vlakken zwak scoort
8-9	Onvoldoende masterproef die niet aan de minimumnormen voldoet
6-7	Ernstig onvoldoende masterproef of een masterproef die slechts één van beide bevat
≤ 5	Ernstig onvoldoende en onvolledige masterproef

ZELFEVALUATIERAPPORT

Onderstaand zelfevaluatierapport is een hulpmiddel om je wetenschappelijke stage -deel 1 zelfstandig te organiseren. Bepaal zelf je deadlines, evalueer en reflecteer over je werkwijze en over de diepgang van je werk. Check de deadlines regelmatig. Toets ze eventueel af bij je (co)promotor. Succes!

Prof. M. Vanvuchelen, coördinerende verantwoordelijke wetenschappelijke stages

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KNOWLEDGE IN ACTION

ZELFEVALUATIERAPPORT **WETENSCHAPPELIJKE STAGE - DEEL 1** **RWK**

Naam & Voornaam STUDENT: …Phaedra Vandebosch

Naam & Voornaam (CO)PROMOTOR & PROMOTOR: Pieter Meyns, Bart Dingenen, Peter Feys

TITEL masterproef (Nederlandstalig of Engels): Effect of ankle foot orthoses on the gait pattern in persons with stroke.

LITERATUURSTUDIE	Gestelde deadline	Behaald op	Reflectie
De belangrijkste concepten en conceptuele kaders van het onderzoekdomein uitdiepen en verwerken	Eind oktober	Eind oktober	Behaald
De belangrijkste informatie opzoeken als inleiding op de onderzoeksvraag van de literatuurstudie	Eind oktober	Eind oktober	Behaald
De opzoekbare onderzoeksvraag identificeren en helder formuleren in functie van de literatuurstudie	Eind oktober	Midden December	Niet behaald
De zoekstrategie op systematische wijze uitvoeren in relevante databanken	Midden december	Begin Januari	Niet behaald
De kwaliteitsbeoordeling van de artikels diepgaand uitvoeren	Eind januari	Begin februari	Niet behaald
De data-extractie grondig uitvoeren	Begin februari	Begin februari	Behaald
De bevindingen ïntegreren tot een synthese	Eind mei	Begin juni	Niet behaald

ONDERZOEKSPROTOCOL	Gestelde deadline	Behaald op	Reflectie
De onderzoeksvraag in functie van het onderzoeksprotocol identificeren	Eind mei	Begin Juni	Niet behaald
Het onderzoeksdesign bepalen en/of kritisch reflecteren over bestaande onderzoeksdesign	Eind mei	Begin Juni	Niet behaald
De methodesectie (participanten, interventie, uitkomstmaten, data-analyse) uitwerken	Eind mei	Begin Juni	Niet behaald

ACADEMISCHE SCHRIJVEN	Gestelde deadline	Behaald op	Reflectie
Het abstract tot he point schrijven	Begin Juni	Begin Juni	Behaald
De inleiding van de literatuurstudie logisch opbouwen	Begin Februari	Eind februari	Niet behaald
De methodesectie van de literatuurstudie transparant weergegeven	Eind februari	Eind februari	Behaald
De resultatensectie afstemmen op de onderzoeksvragen	Eind april	Begin maart	Niet behaald
In de discussiesectie de bekomen resultaten in een wetenschappelijke tekst integreren en synthetiseren	Midden mei	Eind mei	Niet behaald
Het onderzoeksprotocol deskundig technisch uitschrijven	Eind mei	Begin Juni	Niet behaald
Referenties correct en volledig weergeven	Begin januari	Tot begin juni	Er werd tussenduur aan de referenties gewerkt

ZELFSTUREND EN WETENSCHAPPELIJK DENLEN EN HANDELEN	Aanvangsfase	Tussentijdse fase	Eindfase
Een realistische planning opmaken, deadlines stellen en opvolgen	Oktober	Januari	Goed
Initiatief en verantwoordelijkheid opnemen ten aanzien van de realisatie van de wetenschappelijke stage	Oktober	Januari	Goed

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Kritisch wetenschappelijk denken	Oktober	Januari	Goed
De contacten met de promotor voorbereiden en efficiënt benutten	Oktober	Januari	Goed
De richtlijnen van de wetenschappelijke stage autonoom opvolgen en toepassen	Oktober	Januari	Goed
De communicatie met de medestudent helder en transparant voeren	Oktober	Januari	Goed
De communicatie met de promotor/copromotor helder en transparant voeren	Oktober	Januari	Goed
Andere verdiensten:	/	/	/

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Omschrijving van de **evaluatie**:

1) 80% van het eindcijfer wordt door de promotor in samenspraak met de copromotor gegeven op grond het product en van het proces dat de student doorliep om de MP1 te realiseren, met name het zelfstandig uitvoeren van de literatuurstudie en het zelfstandig opstellen van het onderzoeksprotocol, alsook de kwaliteit van academisch schrijven.
2) 20% van het eindcijfer wordt door de interne jury gegeven op grond van het ingeleverde product en de mondelinge presentatie waarin de student zijn/haar proces toelicht.

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ZELFEVALUATIERAPPORT **WETENSCHAPPELIJKE STAGE - DEEL 1** **RWK**

Naam & Voornaam STUDENT: Ode Van Ussel

Naam & Voornaam (CO)PROMOTOR & PROMOTOR: Pieter Meyns, Bart Dingenen, Peter Feys

TITEL masterproef (Nederlandstalig of Engels): Effect of ankle foot orthoses on the gait pattern in persons with stroke.

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Een realistische planning opmaken, deadlines stellen en opvolgen	Voldoende	Goed	Zeer goed
Initiatief en verantwoordelijkheid opnemen ten aanzien van de realisatie van de wetenschappelijke stage	Zeer goed	Goed	Zeer goed

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De richtlijnen van de wetenschappelijke stage autonoom opvolgen en toepassen	Voldoende	Goed	Goed
De communicatie met de medestudent helder en transparant voeren	Goed	Goed	Goed
De communicatie met de promotor/copromotor helder en transparant voeren	Goed	Goed	Goed
Andere verdiensten:			

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VOORTGANGSFORMULIER WETENSCHAPPELIJKE STAGE DEEL 1

DATUM	INHOUD OVERLEG	HANDTEKENINGEN
31/10/2017	Algemeen overleg en kennismaking Promotor.	Promotor: Copromotor: Student(e): Student(e):
10/11/2017	- Kennismaking copromotors en Orthomed - onderzoeksvraag uitdiepen. - Eerste resultaten - Plan van aanpak	Promotor: Copromotor: Student(e): Student(e):
30/11/2017	- In- en exclusie criteria - Gescreende artikels - Onderzoeksvraag	Promotor: Copromotor: Student(e): Student(e):
22/01/2017	- Algemene vragen geselecteerde artikels - Checklist - Vorderingen bespreken.	Promotor: Copromotor: Student(e): Student(e):
25/04/2018	- Feedback op geschreven document - Vragen ivm geschreven doc. overlopen - Specificeren primaire onderzoeksvraag uitkomsten. - Bespreking inhoud protocol.	Promotor: Copromotor: Student(e): Student(e):
27/04/2018	- Feedback op geschreven document - Vragen ivm geschreven delen overlopen - Bespreking inhoud protocol	Promotor: Copromotor: Student(e): Student(e):
09/05/2018	- Feedback op geschreven document - Vragen ivm geschreven delen overlopen	Promotor: Copromotor: Student(e): Student(e):
30/05/2018	- Bespreking protocol met inzichten Orthomed.	Promotor: Copromotor: Student(e): Student(e):
		Promotor: Copromotor: Student(e): Student(e):
		Promotor: Copromotor: Student(e): Student(e):