TIBAR

Therapist Inspired Balance Assisting Robot

TIBAR

'THERAPIST INSPIRED BALANCE ASSISTING ROBOT'

Juliet Haarman

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TIBAR

'THERAPIST INSPIRED BALANCE ASSISTING ROBOT'

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Chapter 1

General introduction

“It would be wonderful if patients could be enabled to make additional training hours in a self-administered, but safe way” - Physical therapist

Training intensity and training efficiency are important components when it comes to stroke rehabilitation. Patients benefit from a training environment where these components are taken into account by therapists. Due to limitations in the availability of physical therapists and the therewith entailed healthcare costs [1, 2], these components could not always be optimally incorporated in the current rehabilitation process. Patients might therefore benefit from a safe and self-administered training device that allows for additional training hours to be made, yet does not ask for the direct presence of a therapist during the training.

This thesis will describe the research that was performed in order to develop such a particular training device: TIBAR (Therapist Inspired Balance Assisting Robot). The training device specifically provides balance assistance during gait training. It only provides support to patients, however, when they are not able to keep themselves balanced. When no support is needed, patients must be able to move freely. This introduction starts with a general description of stroke and current rehabilitation methods. It continues with future perspectives, such as a description of existing robotic gait training devices and the requirements that should be set to develop the TIBAR. Lastly, the objectives and outline of this thesis will be presented.

1.1 Stroke

Stroke, or a CerebroVascular Accident (CVA) is the second leading cause of death for adults worldwide [3], with a prevalence of 1.7% in the Netherlands in 2015 [4]. A stroke is the consequence of either clogging of a blood vessel (Ischemic, 75%); rupture of a blood vessel in the brain (hemorrhagic/subarachnoid hemorrhagic, 20%); or caused by other factors (5%) [5]. Regardless of its origin, a stroke often results in brain damage. Risk of a stroke increases with increasing age and both prevalence and incidence are higher for men compared to women [4]. Due to demographic changes, the number of stroke subjects is increasing [1], with an expected increase of 35% by the year 2050 compared to 2006 [2].

Stroke survivors experience, due to the brain damage, a variety of disorders such as hemiparesis, sensory impairments and cognitive problems. This consequently affects their physical and cognitive abilities and they typically experience difficulties with walking over flat or complex terrain, balance, confidence, response times, attention, etcetera. As a result, fall risk increases and stroke survivors typically show an increased fall incidence rate of 2.2 - 7.7 times compared to healthy elderly subjects [6]. Both cognition and Activities of Daily Living (ADL's) are found to be a good predictor for falls, specifically since about 50% of the falls in older adults with chronic stroke occur at home during walking activities [7, 8]. Experiencing a fall often enhances the fear of falling. This in turn might lead to reduced physical activity, thereby reducing the quality of life (QOL). Additionally, reducing physical activity could lead to loss of bone mineral density and increase the risk of bone fractures [6]. In order to keep the QOL as high as possible, both physical and cognitive abilities must remain as high as possible on a functional level.

1.2 Rehabilitation after stroke

Improving physical and cognitive abilities is a major objective in stroke rehabilitation. Many aspects contribute to the process of increasing the functional ADL level of stroke survivors [9], such as the principles of motor (re-)learning that are mentioned in this section, and that are assumed to contribute to optimal training conditions. Motor learning is the process of improving skills associated with movement through practice, experience and memory, with long-lasting changes in the capability for responding. The applicability of these principles is associated with the ability level of patients. Therapist should therefore adapt their training to this level.

1.2.1 Level of independence and walking ability

The functional level of patients is often monitored by therapists with clinical scales. Many scales monitor only one single aspect of rehabilitation, such as balance (Berg Balance Scale / Dynamic Gait Index), motor impairment (Motricity Index) or cognition (Mini Mental State Examination / Fear of Falling). The Functional Ambulation Category (FAC), however, provides insight into several aspects of recovery simultaneously, as it represents walking independence and the amount of support that is needed to accomplish this [10, 11]. An increase in FAC score demonstrates an increase in the ability of patients to independently perform ADL's.

Fully functional and independent patients are represented by a FAC score of 4 and 5, whereas nonfunctional patients are represented by a FAC score of 0. The former patient groups are able to ambulate on both level (FAC 4 and 5) and non-level surfaces (FAC 5), whereas the latter group (FAC 0) is unable to ambulate and requires continuous support from more than one therapist. Dependent patients with FAC 1 require continuous manual support from a therapist to support body weight or assist coordination. Dependent patients with FAC 2 require intermittent support from a therapist, on level surfaces to assist balance. Patients classified with FAC 3 only require supervision and stand-by guarding of a therapist, rather than manual physical support.

An important step in the rehabilitation process of stroke survivors is therefore the transition from FAC 2 to FAC 3. This implicates that patients improve from being dependent on manual physical support towards a situation where they regain more ambulation independence and increase their potential to perform many ADL's independently.

1.2.2 Gait training of FAC 2 patients

Even though a large group of patients could be classified within the Functional Ambulation Category of 2, an individual training approach is required for each patient within this group due to cognitive abilities, contra indications or practical factors such as the occurrence of tasks in daily living. Each patient must receive training exercises that are adapted to their individual needs. Conventional gait therapy of FAC 2 patients typically focusses on ambulation over level surfaces, where intermittently manual balance assistance of

a physical therapist is given [12, 13]. The level of support is adaptable to the individual subject. Patients are allowed to move freely, but only receive support for balance recovery or coordination assistance when they are not able to keep themselves balanced [10]. This training method is found to be effective [11, 14]. Although therapists are already assumed to apply several principles of motor (re-)learning in their training sessions [15], therapeutic effectiveness might even be further increased when more principles of motor (re-)learning are incorporated into the training program, such that optimal training conditions arise.

1.2.2.1 Optimal training conditions: principles of motor (re-)learning

For optimal training conditions a number of principles are assumed to hold true regarding motor learning. They are explained in this section.

Error-based training

Essential in the process of motor (re-)learning is the principle of error-based training. This principle uses the process of trial and error and states that individuals do not improve on a task when they are not allowed to make mistakes [16]. Therapists apply this principle as they only provide support to the patient when the patient is not able to keep himself balanced. In order for therapists to provide patients with the correct information regarding their abilities and limitations, therapists should be able to distinguish between pelvic motions that occur during pathological gait, such as hemiplegia or hip-hiking, situations in which a patient is able to keep himself balanced and unsafe situations in which support is needed [17].

Active participation

Patient Empowerment is a key element that describes the active participation of patients during the training [18, 19]. In order to prevent patients from being passive [20], patients should be forced to explore their abilities: for instance by keeping the amount of movement freedom as large as possible. Domingo [21] found that allowing more pelvic variability during (robotic) training resulted in larger performance improvements after training. Specifically, as restricting certain degrees of freedom in the pelvic joint during gait training does not prevent these movements to be made during daily life. The training should be dedicated to the patient and not the other way around, such that the patient will be as active as possible [22].

Functional / Context specific learning

The main goal in training of stroke patients with FAC 2 is to create a level in which patients can safely and as independently as possible ambulate, such that they eventually are able to perform ADL's. ADL's are frequently tasks that are variable over time and require adaptation of the patient [23, 24]. Stroke survivors therefore benefit from a training program in which the focus lies on functional training such that they develop a coping strategy that is applicable in many situations [25–27]. Therapists should therefore not

solely focus on the walking task itself, but implement for instance complex terrains or double-tasks into the training sessions, similar to what is present in ADL's.

Feedback

In addition to the previously mentioned principle of motor (re-)learning and the ability to learn tasks, research shows that patients do not improve on a task when they do not receive feedback on their results [24, 28]. Therefore, feedback presentation is an important aspect that allows patients to interpret and correct for the errors that were made during the training [29–31]. Feedback can be presented in many ways to the patient: visually, auditory or sensory. Regardless of the type of feedback that is used, it is important that patients are able to link the information to their posture [30] in order to increase the effectiveness of the feedback [32, 33]. Therapists mainly provide sensory and auditory feedback to the patient. The former type being present in the form of balance assistance when patients are not able to keep themselves upright. The latter type in the form of verbal feedback that reports on the progress of a task.

Motivation

Motivation is an important aspect when it comes to (re-)learning tasks [34]. Specifically when it comes to repetitive or relatively simple tasks that could become monotonous to a patient. Motivation of patients is kept high when the training environment is engaging, thereby continuously creating new challenges. Therapists apply this principle by challenging patients to walk circuits during a training situation. Computer generated environments such as virtual reality have previously been shown to increase the motivation component of subjects during training [35]. Jaffe et al. [36] found that the use of augmented reality training led to better results during obstacle training than real training. However, the success of both virtual and augmented reality training environments is currently still dependent upon the knowledge of the target group. For stroke survivors it is important that the environment is simple, otherwise it will be too overwhelming for these patients that frequently cope with cognitive problems.

Training volume

Training volume is composed of several components, such as the duration of the training, the intensity and the amount of repetitions. In fact, training effectiveness increases when an optimal trade-off between these three parameters is found [37, 38]. For instance, Kwakkel [39] has stated that 'more is better', and found that functional recovery was higher when more training hours were made. However, Kwakkel [39] did not specify the level of effort of these patients to accomplish these results. The level of effort could be expressed with many parameters such as physiological or mental load. Several research groups (e.g. [40, 41]) have investigated the effect of training intensity on gait training outcome and found a relation between both parameters, indicating that this factor contributes to training outcome. During conventional training, training intensity should both comply with the individual needs and the motivation of the patient. Kwakkel [39] did not elaborate on the interval between two training sessions, but Krakauer [24] indicated that patients

learn best when tasks are presented in an alternating way, with rest intervals in-between. This method is called ‘contextual interference’ or ‘offline learning’ and it is assumed that during periods of rest, the brain continues to make neural connections that contribute to motor function relearning. This implies that patients benefit from rehabilitation training that takes place multiple times a week for shorter training durations, rather than one time per week for a longer duration [37].

1.3 Robotics in rehabilitation

Research has indicated that six months after a stroke, many stroke survivors are still classified as having FAC 2 [42]. It therefore remains important to continue gait training, even in the chronic phase of a stroke. However, the one-on-one contact between a therapist and a patient, and the constant need for supervision limits the training volume of patients. Moreover, as the number of patients is increasing [2] and will continue to increase in the future [1] it will be challenging to provide each stroke survivor with a suitable amount of training volume. A solution that enables patients to perform training at the optimal training volume is the use of (robotic) training devices that can be used in a self-administered way.

A wide variety of robotic devices has currently been developed. The design of the controller, the physical appearance and/or the intended patient group varies widely between these robotic devices. They can either be used overground or coupled to a treadmill (treadmill based). Overground devices have the advantage that they mimic a realistic training environment and are therefore context specific [42]. However, treadmill based devices require less physical space and allow for a training set-up in which many repetitions could easily be made. Physical appearance of these devices could be categorized as exoskeletons, end-effectors or overhead systems that mainly provide weight support. A first glance of the existing systems is presented below.

Patient groups with low walking ability (FAC 0/1) benefit from training that focuses on the entire gait cycle. Lokomat (Hocoma) [43], Lopes/Lopes II [17, 44] or Gait Master [45] are examples of devices that provide lower leg movement assistance. They allow many repetitions to be made such that gait patterns could be relearned. The FLOAT (Lutz Medical Engineering) and Zero-G (Aretech) focus on patients that benefit from a safe training system that allows fall prevention and body weight support. Both systems allow (multidirectional) movements to be trained overground and therefore mimic a context specific training situation. Kineassist (Kinea Design) additionally allows safe overground training, does not provide body weight support to the patient, but does allow posture correction. All three systems primarily focus on the safety of the patient, rather than provide balance assistance to a patient when an instable situation is detected. The treadmill-based ‘dynamic balance training device’ [46] and the overground system ‘E-go’ [47] are both systems that do focus on balance assistance. They focus on patients that require intermittent balance assistance. The passive constructions that are used in the ‘dynamic balance training device’ restrict the patient in utilizing the full walking area of the treadmill and thus primarily trains straight line walking. While the latter system neutralizes this aspect by using wheels to move with the patient overground, this particular system

does not aim to be used in a self-administered way, but aims to reduce the amount of therapists that is needed during a training session. The same research group has recently evolved the E-go into an actuated, admittance controlled device [48]. However, this system is currently only been used as a perturbation device rather than a device that assists in balance.

1.4 TIBAR: needs and requirements

All of the previously mentioned devices are intended to increase the efficiency of training, to lower the workload of therapists and the strain on healthcare costs. They allow therapy to be executed in a more individual way by the patient or with the need for fewer therapists. The developed devices have implemented many aspects of motor learning, but no training device is currently available that primarily focusses on intensive and self-administered training of FAC 2 patients where the focus lies on balance recovery. It was therefore aimed to develop a system (TIBAR) that has high potential to be used in a clinical setting: easy to use by the patient; low in costs such that every physical therapy practice can purchase it; and small in physical size such that it can easily be implemented in a clinical setting. It was aimed to implement the principles of motor (re-)learning into the development of the Therapist Inspired Balance Assisting Robot (TIBAR), such that optimal training conditions originate for the patient. Moreover, as it was shown that physical therapists naturally already have incorporated several of these principles into their gait training sessions, it was additionally aimed to translate the behavior of therapists into the TIBAR as accurately as possible. This enables patients to perform training sessions with the TIBAR, receive the same type of therapy as they are familiar with, without the actual assistance of a therapist. A storyboard with a scenario of the use of the TIBAR is presented in Figure 1. Here, a patient with limited balance control arrives at his physical therapy practice. He puts on his own safety gear and consequently steps on the treadmill. He connects himself to a balance support system that provides balance recovery when this is needed. Finally, he is able to start the training session and make additional training hours.

The patient should be able to move freely over the treadmill and only receive balance assistance by the system when this is needed. The system should allow challenging situations, like circuit walking, to be trained. Similar to conventional therapy, the system should not obstruct the movements of the user in any way: it should have low reflected inertia [49] and no noticeable physical presence, i.e. not obstruct the arm sway or the vision of the patient on the treadmill. Balance assisting events by the system should be experienced as comfortable by the patients and the system should not intimidate the patient. Furthermore, the system should be adaptable to a variety of physical characteristics and usage should not be limited by dexterity problems, hemiplegia or aspects such as hearing impairments [50].

Figure 1: Storyboard, describing the intended use of the TIBAR.

1.5 Thesis objectives

The objective of the research described in this thesis was to design and evaluate a training device that allows self-administered training of walking and balance. The device should as closely as possible mimic the behavior of therapists and comply with as many aspects of motor learning as possible. In order to accomplish this objective, research questions have been formulated:

- What is the best method of implementing optimal training conditions into a robotic training device?
- How should stroke related consequences such as hemiparesis be accounted for in a robotic training device?
- How can the behavior of physical therapists in terms of providing manual physical balance assistance best be implemented into a robotic training device?

1.5.1 Outline

Chapter 2 will focus on the aspects of active participation and error-based learning in robotic gait training devices. It is assumed that both active participation and the ability to make errors during gait training plays an important role in the improvement on functional outcome after training. Therefore, this chapter will investigate the effects of robotic gait training. It will compare functional recovery outcome measures of patients that have trained with devices that have incorporated these aspects ('patient-in-charge' devices) to devices that have not incorporated these aspects ('device-in-charge devices').

Chapter 3 aims to provide insight into the effects of motivation and feedback during training, in particular with computer generated environments such as an augmented reality training set-up. In contrast to virtual reality, fewer research has been performed on this type of training environment, whereas such an environment could also account

for a motivating training set-up. This chapter therefore aims to present insight into the abilities of an augmented training environment to learn a specific motor task.

Chapter 4 will present the effects of hemiplegia of stroke survivors on stepping responses. Stepping responses of the paretic and non-paretic leg after differently sized perturbations are investigated. It will present insight into the capabilities of these patients to deal with perturbations, such that this information can be implemented into the TIBAR.

Chapter 5 focusses on aspects such as functional training and adapting training sessions to individual needs. It was therefore aimed to map the behavior of therapists during a gait training session in terms of providing balance recovering assistance. This information could be transformed into the technical specifications of the TIBAR. This chapter therefore focusses on the timing of therapeutic balance assistance events and the characteristics of these events in terms of corrective forces.

Chapter 6 will present the development of the training system: TIBAR. It will describe the technical aspects of the system and it will evaluate the system with stroke survivors.

Lastly, **chapter 7** includes the general discussion of this thesis.

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Chapter 2

The effect of 'device-in-charge' versus
'patient-in-charge' support during robotic
gait training on walking ability and balance in
chronic stroke survivors:
A systematic review

Juliet A.M. Haarman, Jasper Reenalda, Jaap H. Buurke,
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Abstract

This review describes the effects of two control strategies – used in robotic gait-training devices for chronic stroke survivors – on gait speed, endurance and balance. Control strategies are classified as ‘patient-in-charge support’, where the device ‘empowers’ the patient, and ‘device-in-charge support’, where the device imposes a pre-defined movement trajectory on the patient. Studies were collected up to 24 June 2015 and were included if they presented robotic gait training in chronic stroke survivors and used outcome measures that were indexed by the International Classification of Functioning, Disability and Health. In total, 11 articles were included. Methodological quality was assessed using the PEDro scale. Outcome measures were walking speed, endurance and balance. Pooled mean differences between pre and post measurements were calculated. No differences were found between studies that used device-in-charge support and patient-in-charge support. Training effects were small for both groups of control strategies, and none were considered to be clinically relevant as defined by the Minimal Clinically Important Difference. However, an important confounder is the short training duration among all included studies. As control strategies in robotic gait training are rapidly evolving, future research should take the recommendations that are made in this review into account.

2.1 Introduction

One of the many important aspects in motor learning is believed to be the principle of error-based training [1, 2]. This principle holds that subjects do not improve on a task when they are not allowed to make errors. Subjects use their sensory system to detect movement errors and they consequently use this information to update their upcoming motor actions, thereby continually learning from their mistakes [3]. Physical therapists intuitively apply this principle during conventional gait training of, among others, stroke patients. They provide patients with more or less support, depending on the capabilities and needs of the patients. However, applying this principle demands high physical effort and awareness by the therapists due to the constant interaction between patient and therapist. In addition, the number of (chronic) stroke survivors is expected to grow rapidly due to a demographically changing human population [4]. With an increase of 35% stroke patients, predicted by the year 2050 [5], the workload of each individual physical therapist (and the resulting healthcare costs) will greatly increase in the near future. This puts great pressure on the ability of therapists to provide patients with sufficient training intensity. Kwakkel [6] indicated in a meta-analysis that rehabilitation therapy leads to better results when more hours were spent training by the patient (often regarded as the 'more is better' principle). Training frequency and physical effort by the patient are the two other factors that determine training intensity [7] and affect training outcome to a great extent.

Both (chronic) stroke survivors and therapists would benefit from having a good alternative to conventional gait-training. Gait-training in stroke rehabilitation is characterized by a high level of repeatability in terms of movements performed by the patient. The repetitive character of gait training makes this type of therapy in particular suitable for training through the use of robotic devices [8], thereby enabling patients to train with a sufficient level of training intensity. However, there is a large variability in robotic gait-training devices, for instance in terms of mechatronic design or because they are based on various control strategies. Several devices 'empower' the patients in their movements, thereby mimicking the working principle of physical therapists and the principle of error-based training. Other devices do not use these principles, and impose a pre-defined movement trajectory on the patient by use of guidance forces. As robotic gait training is a rapidly evolving field, this systematic review will investigate the reported effects of control strategy on clinical training effects.

Two categories are distinguished, based on the control strategy that is used in the robotic gait-training device: (1) devices that provide 'device-in-charge support'; and (2) devices that provide 'patient-in-charge support' to the patient. For patient-in-charge robotic support, the movement of the device is primarily controlled by the patient. This is commonly referred to as 'Patient Empowerment' [9]. Devices that apply patient-in-charge support mimic the way that physical therapists provide training to patients: they assist the patient during the training and let the patient be in charge of their movements as much as possible. This category is not only restricted to strategies such as 'Patient-Cooperative Control' [10] or 'Assist-As-Needed' [11], but includes all types of robotic devices in which the device reacts to the movements of the patient. Patient-in-charge support can be seen as the opposite of device-in-charge support, which imposes a pre-defined movement trajectory on the patient. No deviation from this trajectory is allowed by the device and

the robot fully controls the movements of the patient. Device-in-charge support does not use the principles of error-based training: patients are not challenged to learn from their mistakes as the robot continuously provides support to patients, regardless of their performance.

To date, it has not been possible to determine the clinical relevance of the various control strategies. Even though two papers [11, 12] have indicated that the control strategy could make a difference in determining which robotic device leads to the most optimal training effects, a descriptive approach is used in both papers to present the results, rather than to provide the reader with actual numbers that indicate clinical relevance. Moreover, both (sub)-acute and chronic stroke survivors are included in the descriptive analysis [12] which confounds the results. By solely including chronic stroke survivors, training effects will not be biased by natural recovery effects as it is believed that no spontaneous neurological recovery takes place after 6 months post-stroke [13]. Furthermore, upper and lower extremity training effects are assessed together, with no specific reference to lower extremity [12]. Since training goals and training methods are different for the upper and lower extremities, it might be more beneficial to separate these two.

This systematic review will focus on the clinical effects of two types of control strategies during robotic gait training: device-in-charge and patient-in-charge support. Results will be related to training effects after conventional physical therapy. A specific focus lies on walking ability and balance in chronic stroke survivors, as both aspects are prerequisites for community walking and other Activities of Daily Living (ADL). Outcome measures are the 10 meter walking test (10MWT), 6 minute walking test (6MWT) and Berg Balance Scale (BBS), as these are considered to be clinical tests that provide information about walking independence [14]. Clinically relevant training effects will be identified by comparing training results to the Minimal Clinically Important Differences (MCID) found in the literature. These values reflect changes in a clinical outcome measure that is meaningful to the patient [15].

2.2 Methods

2.2.1 Literature search

A systematic search of articles was conducted in NCBI PubMed, Center for International Rehabilitation Research Information and Exchange (CIRRIE), National Rehabilitation Information Center for Independence REHABDATA, PEDro and Cochrane Controlled Trials register up to 24 June 2015. Keywords included *stroke*, *CVA*, *cerebral vascular disorders*, *hemiplegic*, *training*, *therapy*, *treatment*, *robot*, *assistive device*, *assistive technology*, *training apparatus*, *interface*, *gait*, *balance*, *walking* and *locomotion*. A detailed description of our search strategy can be found as an online supplement. In addition to searching the databases, the reference lists of relevant publications (i.e. fitting the inclusion criteria or closely related to it) were checked for articles that satisfied the search criteria.

2.2.2 Study selection

Studies were included if they met the following criteria: (1) chronic stroke survivors (>6 months); (2) training with the intention to improve gait function by use of a robotic device that is specifically designed for this purpose; (3) focus on lower limb motor control; (4) use of functional outcome measures that measure human performance as classified by the International Classification of Functioning, Disability and Health; and (5) full length English publication in a peer-reviewed journal. No limitation was set on the year of publication. As robotic gait training with patient-in-charge support is a new research field, reports of both controlled and uncontrolled trials were included in this review. Studies were excluded if: (1) functional electrical stimulation was used complementary to the intervention; (2) the study was a case report and/or had fewer than five subjects within a subgroup; (3) the training consisted of one single session; or (4) the study was part of a larger trial in which the same subjects were used. The first round of article selection was based on title and abstract. In case of doubt, articles were included into the next round of selection. After full-text selection, results were compared by two reviewers (JAM Haarman and J Reenalda). In case of disagreement, a third reviewer (JS Rietman) was consulted.

2.2.3 Methodological quality judgment

The PEDro scale [16], comprising 11 items (Table 1) [17], was used to assess the methodological quality of the included studies. Studies were rated according to three subcategories: external validity (item 1), internal validity (items 2–9) and interpretability (items 10 and 11). Each item scored one point when it could be answered positively. The maximum total score was 11 points. Studies with 4 points or more were considered as having sufficient quality [18, 19] for further analysis. Methodological quality was assessed by two reviewers independently (JAM Haarman and J Reenalda) and compared afterwards. If no consensus was reached about the final score, a third reviewer (JS Rietman) was consulted.

Note that it was decided to include all items in the total score of the PEDro scale (max=11 points), instead of leaving the first item out as is usually the case. This was done in order to take all 11 aspects equally into account for the final score, especially as it is not possible with this type of research to comply with the blinding criteria (blinding of patients and blinding of therapist) as robotic devices are used and compared with conventional therapy (no use of robotic devices).

2.2.4 Data extraction

Data were extracted from the studies and categorized into: study design; patient characteristics; intervention; and outcome measures. A section of 'Robotics' was included to provide information about the training systems. Categories were formed within this section, on the basis of the type of control strategy that was used: (1) studies assessing robotics with device-in-charge support and (2) studies assessing patient-in-charge support. To relate the results to conventional therapy, a third category was formed in which conventional therapy was assessed. This third category included all patients from the included articles

that served as control subjects during the studies. Outcome measures that were chosen in this review are walking speed, as measured by the 10MWT, endurance, as measured by the 6MWT and balance, as measured by the BBS. These outcome measures are considered to be clinical tests that provide information about walking independence [14] and those activities that are important in performing ADL [20], the main focus point in conventional therapy [14, 21].

2.2.5 Data analysis

Studies assessing device-in-charge support were compared with studies assessing patient-in-charge robotic support for each outcome measure. Categorization of devices in one group or another was based on the classification that was defined in the Introduction section. In addition, results from the robotic treatment were compared with results from participants who acted as control groups in the included studies. Conventional therapy was often used as a control group in these studies. Mean differences were calculated for each individual study, by using the reported mean for pre- and post-measures. In addition, data were pooled for each control strategy and outcome measure, by using the sample size and mean values of each individual study. Inter-rater agreement after study selection was assessed by Cohen's kappa. MCID were presented in the literature for two outcome measures for a general population of stroke patients. The reported MCID value for the 10MWT was 0.18 m/s for stroke patients [22]. A value of 50 m [23] was reported for the 6MWT. No MCID value for stroke survivors on BBS was documented in the literature. The Minimal Detectable Change (MDC) for this outcome measures was reported as 4.66 points [24].

2.3 Results

2.3.1 Study selection

The systematic search strategy resulted in 389 articles. Based on title and abstract, 39 studies were included for full text reading. From these, 14 studies [[25]; [26–38] were found not to include chronic stroke patients. Five studies [39–43] were excluded because they did not use functional outcome measures as classified by the International Classification of Functioning, Disability and Health, and one study [44] was excluded because it was part of a larger trial already included in this review. Three studies [45–47] described training that consisted of just a single session and five studies [48–52] were case studies and/or used fewer than five subjects. Searching the references of relevant publications led to two [53, 54] additional articles. As a result, 13 articles matched the selection criteria [53–65]; eight studies assessed device-in-charge support, and five assessed patient-in-charge support. The flow diagram of the article retrieval process is presented in Figure 1. Inter-rater agreement after full-text selection was 'very good' (Cohen's $k=0.82$) [66]. Consensus was reached in all cases of disagreement.

Figure 1: Flow diagram of article retrieval.

2.3.2 Methodological quality judgement

Methodological quality scores ranged between 3 and 9 points. Details are presented in Table 1. Two studies [60, 61] were excluded from further analysis in this review because they had a quality score lower than 4. As a result, 11 studies were eligible for data extraction in the present review. Studies assessing robotics with device-in-charge support [53–59] had, on average, a quality score of 6.9 ± 1.4 points and studies assessing robotics with patient-in-charge support [62–65] had, on average, a quality score of 5.8 ± 2.4 points. The Mann–Whitney test indicated that this difference was non-significant ($p=0.25$). Inter-rater agreement assessing the methodological quality of the studies was ‘very good’ (Cohen’s $k=0.81$) [66]. Consensus was reached in all cases of disagreement.

2.3.3 Characteristics of included studies

2.3.3.1 Study details.

All studies had been conducted between 2005 and 2014. Seven studies were identified as randomized controlled trials (RCTs) [53–57, 64, 65], one study as a cross-over trial [58] and three studies were identified as effect studies without a control group [59, 62, 63]. The study by Wu et al. [64] was identified as an RCT as it compared two types of robotic training with patient-in-charge support, but it did not include a control group following conventional therapy. Details of the individual studies are presented in Table 2.

Table 1: Methodological quality of the studies. Y = yes (1 point), N = No (0 points), ? = Not clarified (0 points)

	1 = Westlake et al. (2009)	2 = Hornby et al. (2008)	3 = Kelley et al. (2013)	4 = Tanaka et al. (2012)	5 = Dias et al. (2007)	6 = Paurala et al. * (2005)	7 = De Luca et al. (2013)	8 = Ucar et al. (2014)	9 = Wu et al. (2011)	10 = Kubota et al. † (2013)	11 = Kawamoto et al. (2013)	12 = Stein et al. (2014)	13 = Wu et al. (2014)
1 Eligibility criteria were specified	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
2 Subjects were randomly allocated to groups	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
3 Allocation was concealed	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	?
4 The groups were similar at baseline regarding the most important prognostic indicators	Y	Y	Y	Y	Y	?	Y	Y	Y	?	Y	Y	Y
5 There was blinding of all subjects	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
6 There was blinding of all therapists who administered the therapy	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
7 There was blinding of all assessors who measured at least one key outcome	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
8 Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
9 All subjects for whom outcome measures were available received the treatment or control condition as allocated	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
10 The results of between-group statistical comparisons are reported for at least one key outcome	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
11 The study provides both point measures and measures of variability for at least one key outcome	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Total	8	7	9	7	6	6	5	3	3	4	4	9	6

* Only the control group and the gait training group were included in the analysis.

† Only the stroke patients were included in the analysis.

2.3.3.2 Patient characteristics

The number of subjects within the included studies ranged between 6 and 48. The cumulative number of subjects in the studies assessing device-in-charge support was 99, and in the studies assessing patient-in-charge was 64. The pooled mean age was 60.6 years in the device-in-charge group and 57.4 years in the patient-in-charge group. Time since stroke onset ranged between 1.4 and 7.4 years, with a pooled mean of 4.6 years (pooled mean of 3.9 years for the studies assessing device-in-charge support and a pooled mean of 5.7 years for the studies assessing patient-in-charge support). The baseline level indicated by walking speed varied among the individual studies between 0.18 m/s and 0.87 m/s, with a pooled mean of 0.51 m/s (pooled mean of 0.50 m/s for all studies assessing device-in-charge support and a pooled mean of 0.53 m/s for all studies assessing patient-in-charge support). Note that all pooled mean values are based on the mean values reported in the included studies. Training speed was based on individual baseline speeds and the progression that was made by each patient individually. Individual study details are presented in Table 2.

2.3.3.3 Robotics

Seven types of robotic devices were used across the 11 studies. Four devices used a control strategy with device-in-charge support: Lokomat, GaitMaster4, Gait Trainer and G-EO system. All four types of devices imposed a pre-programmed, high-stiffness, reference trajectory onto the lower legs of the subject [55, 56, 67–70]. This position-controlled pattern could either be imposed on the entire leg (exoskeleton; Lokomat) or only on the feet of the patient (end-effector; GaitMaster4, Gait Trainer, G-EO system). The level of guidance force does not depend on user input. Three devices used a control strategy with patient-in-charge support, in which the movement of the device is driven by the subject: Hybrid Assistive Limb (exoskeleton), Robotic Leg Orthosis (exoskeleton), Cable-Driven Robotic Gait Trainer (end-effector). The level of guidance force is variable within a training session and depends on user input.

Device-in-charge robotic support

Lokomat

Lokomat consists of a powered gait orthosis with linear actuators at the hip and knee joints, a treadmill and a Body Weight Support (BWS) system [71]. The device is attached to the patient at the location of the trunk, pelvis, upper and lower legs. Hip and knee joints of the Lokomat are aligned with the corresponding joints of the patient. Elastic straps are used to assist toe clearance. Lokomat is position controlled and imposes a pre-programmed reference trajectory to the lower legs of the patient, based on the walking pattern of a general group of healthy subjects [55]. No deviations from this reference trajectory are allowed by the device. The reference trajectory can be scaled to match patient characteristics such as step length.

Table 2: Characteristics of the included studies

Author(s)	Study Design	N	Age in years (mean ± SD)	Time poststroke in years (mean ± SD)	Baseline velocity (m/s)	Apparatus	Body Weight Support (Y/N)	Robotics Training (Y/N)	Interaction with human body	Study duration	Intervention Follow up	Outcome Measures Use of 10MWT, 6MWT and/or BBS	Use of other measures
Device-in-charge support													
Kelley et al. (2013)	RCT	E: 11 C: 9	E: 66.9 ± 8.5 C: 64.3 ± 10.9	E: 3.7 C: 1.4	E: 0.20 ± 0.10 C: 0.18 ± 0.12	Lokomat	E: Y C: N	E: Y C: N	Exoskeleton	150 min/wk for 8 wk Total = 20 h	3 months	10MWT, 6MWT	BI, FMA-L, SIS
		E: 27 C: 21	E: 57 ± 10 C: 57 ± 11	E: 4.1 ± 4.2 C: 6.1 ± 7.3	E: 0.59 ± 0.3 C: 0.6 ± 0.33	Lokomat	E: Y C: Y	E: Y C: Y	Exoskeleton	90 min/wk for 4 wk Total = 6 h	6 months	6MWT, BBS	FAI, SF36
Westlake et al. (2009)	RCT	E: 8 C: 8	E: 58.6 ± 16.9 C: 55.1 ± 13.6	E: 3.7 ± 2.2 C: 3.1 ± 1.7	E: 0.87 ± 0.55 C: 0.72 ± 0.37	Lokomat	E: Y C: Y	E: Y C: Y	Exoskeleton	90 min/wk for 4 wk Total = 6 h	–	6MWT, BBS SPPB, FMA-L, LLFDI	
Tanaka et al. (2012)	Cross-Over	E1: 7 E2: 5	E1: 63 ± 10 E2: 60 ± 8.5	E1: 4.6 ± 3.1 E2: 5.5 ± 5.6	E1: 0.75 ± 0.42 E2: 0.86 ± 0.16	Gait-Master4	E: N E: N	E: N E: N	End-Effector	40 min/wk for 6 wk Total = 4 h	1 month	10MWT	TUG
Dias et al. (2007)	RCT	E: 20 C: 20	E: 70.4 ± 7.4 C: 68.0 ± 10.7	E: 3.9 ± 5.3 C: 4.0 ± 2.5	E: 0.42 ± 0.25 C: 0.53 ± 0.33	Gait Trainer (GT1)	E: Y C: N	E: N C: N	End-Effector	216 min/wk for 5 wk Total = 18 h	3 months	10MWT, 6MWT	TMS, RMI, FMA-L, MI
Peurala et al. (2005)	RCT	E: 15 C: 15	E: 51.2 ± 7.9 C: 52.3 ± 6.8	E: 2.4 ± 2.6 C: 4.0 ± 5.8	E: 0.25 ± 0.28 C: 0.25 ± 0.39	Gait Trainer	E: Y C: N	E: N C: N	End-Effector	100 min/wk for 3 wk Total = 5 h	6 months	10MWT, 6MWT	MMAS, FIM
De Luca et al. (2013)	Before/After	E: 6	E: 56.6 ± 13.2	E: 5.1 ± 2.7	E: 0.41 ± 0.04	G-EO System	E: N	E: N	End-Effector	225 min/wk for 4 wks Total = 15 h	–	10MWT, 6MWT	TUG
Patient-in-charge support													
Kawanoto et al. (2013)	Before/After	E: 15	E: 61 ± 14.8	E: 3.9 ± 3.1	E: 0.41 ± 0.26	HAL (Hybrid Assistive Limb)	E: Y	E: N	Exoskeleton	50 min/wk for 8 wk Total = 6.6 h	–	10MWT, BBS	TUG
		E: 9	E: 56.8 ± 15.9	E: 6.4 ± 6.3	E: 0.39 ± 0.37	HAL (Hybrid Assistive Limb)	E: Y	E: N	Exoskeleton	40 min/wk for 8 wk Total = 5.3 h	–	10MWT, BB S	TUG
Stein et al. (2014)	RCT	E: 12 C: 12	E: 57.6 ± 10.7 C: 56.6 ± 15.1	E: 4.1 ± 3.2 C: 7.4 ± 12.8	E: 0.44 ± 0.45 C: 0.36 ± 0.47	RLO (Robotic Leg Orthosis)	E: N C: N	E: N C: N	Exoskeleton	150 min/wk for 6 wk Total = 15 h	1 month, 3 months	10MWT, BBS, 6MWT	FTSTS, TUG, CAFE40, Romberg
Wu et al. (2014)	RCT*	E1: 14 E2: 14	E1: 53.6 ± 8.9 E2: 57.4 ± 9.8	E1: 7.3 ± 5.6 E2: 7.1 ± 6.0	E1: 0.65 ± 0.38 E2: 0.72 ± 0.36	Cable-Driven Robotic Gait Trainer	E: Y	E: Y	End-Effector	135 min/wk for 6 wk Total = 13.5 h	2 wk	10MWT, BBS, 6MWT	MAS, ABC, SF-36

E = experimental group; C = control group. *Two experimental groups were compared to each other in this study.

GaitMaster₄

GaitMaster₄ is a footpad-type training device, each footpad having 2 Degrees-of-Freedom (DoF) [67]. Back and forth movements are allowed by use of a slider crank mechanism. A movable linear actuator at the end of the mechanism allows for up and down movements of the feet. Patients are therefore able to walk without the use of a treadmill. A double hinge mechanism is used between foot and footpad such that plantar and dorsal flexion of the foot is possible. GaitMaster₄ is position controlled: it uses a predefined reference trajectory, based on the movement trajectory of healthy subjects (pre-recorded with a motion capture system). In contrast to Lokomat, GaitMaster₄ only takes the foot trajectory into account and not the trajectory of the entire leg. This is done under the assumption that restrictions in the movement of the feet lead to restrictions (to some extent) in the movement of the rest of the legs (due to restrictions in the range of motion of human joints). Furthermore, the reference trajectory of GaitMaster₄ is adjustable to match specific (physical) patient characteristics. No BWS is used in this training set-up.

Gait Trainer

Gait Trainer is also a high-stiffness, position-controlled, footpad-type training device, based on a commercially available fitness trainer (Fast Track) [72]. Gait Trainer consists of two footplates that are positioned on two bars, two rockers and two cranks that provide propulsion. Crank propulsion and rocker dimensions are chosen such that they mimic foot movements during stance and swing without the use of a treadmill. To adapt the device to individual (physical) patient characteristics, such as stride length and phase, gear sizes can be varied. Gait Trainer additionally controls the center of mass of the patient. This is done by connecting the planetary gear system (with, among others, a vertical and horizontal crank) to the waist of the patient. The repetitive movements and circular motions of the footplates are thus (directly) used to constrain the movements of the center of mass of the subject. Note that the center of mass oscillates sinusoidally in the vertical and horizontal directions during normal gait, meaning that additional parts, such as transmission gears, are needed for the correct transmission of one subsystem to another. A BWS system is used to secure the subject in the training device.

G-EO

G-EO is similar to the above two devices: a footpad-type training device (end-effector), and also consists of two footplates, connected to a pivoting arm and two moving sledges [34]. Each footplate has 3 DoF and again, no treadmill is needed in this training set-up. The patient's center of mass is controlled in the vertical and horizontal directions, not as a direct consequence of the footpad motions as is the case with Gait Trainer, but its trajectory is programmable by the computer. G-EO is position controlled and uses reference trajectories of the feet and the center of mass of healthy subjects' data reported in the literature. The device has a BWS system (though not used in the study by De Luca et al. [59]).

Note that both the Gait Trainer and the G-EO system introduce a mode in which the patient can control the speed of the device when the active contribution of the patient is above a

selected threshold. However, this mode is only used in the study by Dias et al. [53] As only the speed of the device is adjustable and not the amount and the timing of the support, this device is categorized in the group of robotics providing device-in-charge support.

Patient-in-charge robotic support

Hybrid Assistive Limb

Hybrid Assistive Limb (HAL) is an exoskeleton that is attached to the pelvis and lower limbs of the subject [73]. The joints of the exoskeleton are aligned to the joints of the patient, and both hip and knee joints of the device are actuated (torque controlled). HAL is able to measure several bioelectric signals such as muscle activity (by skin surface electromyography (EMG) electrodes placed over muscles for hip and knee flexion and extension), ground reaction forces (from force pressure sensors in the shoes, to measure weight shift) and joint angles that are generated by the patient. In a complete voluntary mode, HAL uses the patient's EMG signals (which are believed to represent the patient's intentions) to assist the patient, so that the patient is able to execute the desired movements. HAL thus interactively provides motion assistance to the patient. The amount of assistive force is adjustable (in a configuration mode, before the start of a training session) to meet the individual needs of the patient and variable within a gait cycle (swing/stance phase). Torque signals are used as input signal to control for the desired output level of mechanical impedance; for instance, by keeping the impedance low when no support from HAL is needed in a specific phase. When patients have little muscle activity (meaning that the system is not able to identify user intentions based on EMG signals), ground reaction forces and joint angles are additionally used to support the movements of a patient. In that case, user intentions are inferred from comparison of ground reaction force and joint angles to a reference pattern recorded from healthy subjects. This mode is available for both legs and an entire training session, but can also be used for a specific interval or on one leg or one joint only. Both Kawamoto et al. [63] and Kubota et al. [62] used this mode for several patients in their study. HAL can be used overground without a treadmill. A movable BWS system is used to secure the patient while walking.

Robotic Leg Orthosis

Robotic Leg Orthosis (RLO) is an exoskeleton and is attached to the upper and lower leg of a patient so that sensing (angle and torque sensors) and actuation is possible at the knee [51]. A foot (force) sensor with ankle support is added to the orthosis to measure ground reaction forces and weight shift. Two small motors (one high-torque/low-speed motor and one low-torque/high-speed motor) are incorporated in the exoskeleton. Like HAL, this device can be used overground. Each individual user needs to configure the system to set up subject specific settings (i.e. set up the torque limits, range of motion limits and tuning parameters). After that, the system is ready to be used. The control algorithm combines this configuration information with real-time information of angle, torque and force to detect the movement intentions of the subject; for instance, is the knee flexed or extended, is the weight on the ball or the heel of the foot? Then, support is given to the leg (with high-torque/low-speed motor), with the amount of support depending on

the output of the control algorithm. Support is only given to the subject during stance phase, no actuation is provided to the leg during the swing phase, thereby not impeding the patient's movements (low-torque/highspeed motor is used to be able to monitor the movements, yet allow free-swinging of the leg). The patient is thus always in control of the system, as he or she has to initiate the movement. Moreover, configuration settings can be adjusted as the patient improves. No BWS system is used during training with this device.

Cable-Driven Robotic Gait Trainer

The Cable-Driven Robotic Gait Trainer (CaLT) is a training device that attaches four cables, driven by four motors, pulleys and cable spools to the ankles of the patient [74]. Each ankle is thus connected to two cables: one anterior cable that pulls on the ankle (assisting the movement, i.e. making the movement easier) and one posterior cable that pulls on the ankle (resisting the movement, i.e. making the movement harder). While walking on a treadmill, custom 3D position sensors at the ankle are used to record kinematics (rotational angular and linear position), and the measured data are used as input for the control algorithm. This algorithm compares the measured ankle trajectory with a reference (ankle) trajectory that is recorded in healthy subjects. The tolerance level of deviation between the desired (reference) and the measured path of the ankle is adjustable for each individual patient and training session. The control algorithm determines whether the patient needs assistance (anterior cable pulls on the ankle) or resistance (posterior cable pulls on the ankle) in its movements. Study results published by Wu et al. [74] suggest that the cable system is highly backdrivable, not impeding the movements of the patients at times that this is not desired. A BWS system is used during training with this device.

As mentioned previously, not all studies used BWS during the training, nor did all studies use a treadmill to assist the training. In total, eight studies used BWS [53–57, 62–64], and four studies used a treadmill [55–57, 64]. The level of BWS that was used was patient specific but often as low as possible (the highest reported value was 40%). The level of BWS was decreased as patients progressed through the various training sessions. Additional information about the robotic devices is listed in Table 2.

2.3.3.4 Intervention

Table 2 shows that training duration ranged between 3 and 8 weeks, with a total training time of 4–20 hours. The studies assessing device-in-charge support had, on average, a training duration of 10.6 hours, and the studies assessing patient-in-charge support had an average training duration of 10.1 hours. Seven of the studies included a follow-up measurement. Of these, three studies performed a short-term (2 months) follow-up measurement and five studies performed a long-term (>2 months) follow-up measurement. Both long-term and short-term follow-up measurements were performed in the study reported by Stein et al. [65]

2.3.3.5 Outcome measures

Nine studies used the 10MWT as the outcome measure; eight used the 6MWT and six studies used the BBS. A total of 18 additional outcome measures were used among the various studies and these are listed in Table 2.

Walking speed (10MWT)

The 10MWT was used as an outcome measure in five studies that assessed device-in-charge support (see Table 3). The pooled mean difference between pre and post training was 0.09 m/s (n=64 patients). Four studies (five experimental training groups) assessing patient-in-charge support used the 10MWT as the outcome measure, resulting in a pooled mean increase of 0.05 m/s (n=64 patients). The studies assessing conventional therapy demonstrated a pooled mean difference between pre and post measurement of 0.04 m/s (n=48 patients). Wide deviations are observed in the individual data within each subcategory, ranging from -0.07 m/s to +0.14 m/s. The greatest improvement was obtained by Tanaka et al. [58] with GaitMaster4, providing device-in-charge support (increase of 0.14 m/s). The second highest increases of 0.11 m/s were obtained by Dias et al. [53] with Gait Trainer (device-in-charge support) and Wu et al. [64] with CaLT-assistive-support (patient-in-charge support). The lowest improvement was obtained by Stein et al. [65] with RLO, providing patient-in-charge support (decrease of 0.07 m/s).

The pooled mean baseline level was found to be higher for the studies assessing patient-in-charge support, compared with the studies assessing either conventional therapy or therapy with device-in-charge support. None of the three categories indicated a pooled mean difference that represented a clinically relevant improvement as indicated by the MCID.

Endurance (6MWT)

The 6MWT was an outcome measure cited in six studies assessing device-in-charge support (see Table 4). The pooled mean difference was 17m for this category (n=86 patients). Two studies (involving three experimental training groups) assessing patient-in-charge support analyzed this outcome measure. Also, a pooled mean increase of 17m was observed in these studies (n=40 patients). Conventional therapy demonstrated a pooled mean increase of 22m (n=85 patients). The greatest improvement after training was obtained by Hornby et al. [56], in a conventional therapy group (increase of 34.0 m). This was followed by De Luca et al. [59] with GEO (device-in-charge support; increase of 33.2 m) and Stein et al. [65] with RLO (patient-in-charge support; increase of 27.5 m). The lowest improvement was also obtained in the conventional therapy group, reported by Westlake et al. [55] (decrease of 21.9 m).

Again, the baseline level for the studies assessing patient-in-charge support was found to be higher than for the other two categories. Individual study results did not demonstrate improvements that were indicated to be clinically relevant by the MCID.

Table 3: (Pooled) mean differences between pre and post measurements for gait speed (10MWT)

	Group size (N)	Pre training mean ($\pm$ std) (m/s)	Post training mean ($\pm$ std) (m/s)	Mean difference (m/s)
Device-in-charge support				
Kelley et al.	11	0.20 ($\pm$ 0.10)	0.20 ($\pm$ 0.10)	0.00
Tanaka et al.	12	0.84 (N.D.)	0.98 (N.D.)	0.14
Peurala et al.	15	0.25 ($\pm$ 0.28)	0.33 ($\pm$ 0.42)	0.08
De Luca et al.	6	0.39 ($\pm$ 0.37)	0.49 ($\pm$ 0.05)	0.10
Dias et al.	20	0.42 ($\pm$ 0.25)	0.53 (N.D.)	0.11
Pooled data	64	0.42	0.51	0.09
Patient-in-charge support				
Kubota et al.	9	0.39 ($\pm$ 0.37)	0.46 ($\pm$ 0.40)	0.07
Kawamoto et al.	15	0.41 ($\pm$ 0.26)	0.45 ($\pm$ 0.24)	0.04
Stein et al.	12	0.44 ($\pm$ 0.50)	0.36 ($\pm$ 0.47)	-0.07
Wu et al. - assistance group	14	0.65 ($\pm$ 0.38)	0.76 ($\pm$ 0.45)	0.11
Wu et al. - resistance group	14	0.72 ($\pm$ 0.36)	0.82 ($\pm$ 0.39)	0.10
Pooled data	64	0.53	0.58	0.05
Conventional Therapy				
Kelley et al.	9	0.18 ($\pm$ 0.12)	0.27 ($\pm$ 0.27)	0.09
Tanaka et al.	12	0.80 ($\pm$ 0.13)	0.77 (N.D.)	-0.03
Peurala et al.	15	0.25 ($\pm$ 0.39)	0.31 ($\pm$ 0.63)	0.06
Stein et al.	12	0.49 ($\pm$ 0.67)	0.52 ($\pm$ 1.10)	0.03
Pooled data	48	0.44	0.48	0.04

N.D. (No Data) This value was not presented in the paper.

Table 4: (Pooled) mean differences between pre and post measurements for endurance (6MWT)

	Group size (N)	Pre training mean ($\pm$ std) (m)	Post training mean ($\pm$ std) (m)	Mean difference (m)
Device-in-charge support				
Westlake et al.	8	267.3 ($\pm$ 187.2)	278.1 ($\pm$ 176.5)	10.8
Hornby et al.	27	170.0 ($\pm$ 86.0)	186.0 ($\pm$ 88.0)	16.0
Kelley et al.	11	53.9 ($\pm$ 30.5)	57.0 ($\pm$ 25.5)	3.1
Peurala et al.	14	152.3 ($\pm$ 89.6)	177.5 ($\pm$ 111.5)	25.2
De Luca et al.	6	196.0 ($\pm$ 53.8)	229.2 ($\pm$ 64.9)	33.2
Dias et al.	20	140.2 ($\pm$ 90.1)	159.1 (N.D.)	18.9
Pooled data	86	156.2	173.4	17.2
Patient-in-charge support				
Stein et al.	12	185.9 ($\pm$ 95.9)	213.4 ($\pm$ 108.2)	27.5
Wu et al. - assistance group	14	177.4 ($\pm$ 99.9)	197.5 ($\pm$ 109.5)	20.1
Wu et al. - resistance group	14	201.0 ($\pm$ 84.0)	207.0 ($\pm$ 80.0)	6.0
Pooled data	40	188.2	205.6	17.4
Conventional Therapy				
Westlake et al.	8	234.3 ($\pm$ 141.2)	212.4 ($\pm$ 113.5)	-21.9
Hornby et al.	21	170.0 ($\pm$ 86.0)	204.0 ($\pm$ 96.0)	34.0
Kelley et al.	9	48.8 ($\pm$ 21.0)	70.3 ($\pm$ 60.4)	21.5
Peurala et al.	15	111.8 ($\pm$ 57.3)	135.1 ($\pm$ 67.9)	23.3
Stein et al.	12	169.3 ($\pm$ 89.7)	194.8 ($\pm$ 83.2)	25.5
Dias et al.	20	141.5 ($\pm$ 102.2)	164.8 (N.D.)	23.3
Pooled data	85	146.1	167.9	21.8

N.D. (No Data) This value was not presented in the paper.

Table 5: (Pooled) mean differences between pre and post measurements for balance (BBS)

	Group size (N)	Pre training mean ($\pm$ std) (points)	Post training mean ($\pm$ std) (points)	Mean difference (points)
Device-in-charge support				
Westlake et al.	8	46.9 ($\pm$ 7.5)	48.3 ($\pm$ 6.8)	1.4
Hornby et al.	27	43.0 ($\pm$ 10.0)	44.0 ($\pm$ 10.0)	1.0
Dias et al.	20	36.9 ($\pm$ 6.5)	40.8 (N.D.)	3.9
Pooled data	55	41.3	43.4	2.1
Patient-in-charge support				
Kubota et al.	9	36.3 ($\pm$ 15.7)	41.7 ($\pm$ 8.8)	5.4
Kawamoto et al.	15	40.6 ($\pm$ 13.6)	45.4 ($\pm$ 8.0)	4.8
Stein et al.	12	46.1 ($\pm$ 11.7)	48.6 ($\pm$ 10.2)	2.5
Wu et al. - assistance group	14	43.6 ($\pm$ 9.0)	45.5 ($\pm$ 8.8)	1.9
Wu et al. - resistance group	14	44.1 ($\pm$ 8.8)	45.6 ($\pm$ 9.3)	1.5
Pooled data	64	42.5	45.6	3.1
Conventional Therapy				
Westlake et al.	8	47.0 ($\pm$ 7.0)	51.0 ($\pm$ 5.4)	4.0
Hornby et al.	21	42.0 ($\pm$ 10.0)	44.0 ($\pm$ 11.0)	2.0
Stein et al.	12	49.4 ($\pm$ 5.8)	49.2 ($\pm$ 5.8)	-0.2
Dias et al.	20	34.6 ($\pm$ 13.9)	38.0 (N.D.)	3.4
Pooled data	61	41.7	44.0	2.3

N.D. (No Data) This value was not presented in the paper.

Balance (BBS)

BBS was assessed in three studies that used device-in-charge support (see Table 5). The pooled mean difference between pre and post measurement was 2.1 points for these studies (n=55 patients). Five studies assessing patient-in-charge support measured this outcome measure. The pooled mean difference was found to be 3.1 points (n=64 patients). Conventional therapy demonstrated an increase of 2.3 points (n=61 patients). The greatest improvement after training was obtained by Kubota et al. [62] with HAL (patient-in-charge support, increase of 5.4 points). This was followed by Kawamoto et al. [63], also using HAL (patient-in-charge support, increase of 4.8 points). The lowest improvement was obtained by Stein et al.[65], in the conventional therapy group (decrease of 0.2 points).

Studies assessing device-in-charge support, patient-in-charge support and conventional therapy all demonstrated baseline levels that were of the same order of magnitude. Note, however, a score below 45 points indicates high fall risk. No MCID values were known for this outcome measure, but results of the individual studies could be compared with the MDC value. The two studies [62, 63] that used the HAL device demonstrated training effects larger than was indicated by the MDC value.

2.4 Discussion

The goal of this systematic review was to investigate the effects of ‘device-in-charge’ versus ‘patient-in-charge’ gait training on walking ability and balance in chronic stroke survivors. Devices were categorized based on the method they used to provide support to the patients: training by use of patient-in-charge support uses the principle of error-based training. Patients are challenged to learn from their mistakes as the robot only interferes with/supports the patient at times when that is needed. Otherwise, patients are in control of their own movements. This is opposite to device-in-charge support, which does not use this principle and provides the patients with continuous support throughout a training session. No preference for one type of control strategy over another was found in this review. In addition, training effects of individual robotic devices were compared with each other. Again, no preference for one device over another was found in the general sense. However, interesting observations regarding the training intensity and the effect of baseline levels were found that inform the conclusions in this review.

None of the studies indicates clinically relevant improvements, as indicated by the MCID (expect for HAL in terms of MDC for balance). The most important aspect affecting the interpretation of the results in this review is the short training duration in all the individual studies: training duration varied between 4 hours [58] and 20 hours [57]. Time post-stroke was, on average, 4.6 years for the included patients; thus it is questionable whether significant and relevant training effects would or could be observed after only short periods of training. Therefore, it is likely that training duration was too short [6], especially since the literature [7, 75, 76] indicates that physical effort, and its interaction with training duration and frequency, affects training outcome to a great extent. Physical effort describes the effort it takes for patients to execute and complete a training session. The articles included in this review only mention generally that treadmill speed was adapted to the progress of individual patients, but they do not provide details on the physical effort of patients, in terms of (for instance) oxygen uptake or Heart Rate Reserve (HRR) [75]. The ideal combination between physical effort, duration and frequency depends on the baseline characteristics of the patient and should be adapted when the patient improves [7, 77].

In addition, the baseline level of patients is of great importance in predicting training outcome. It is an indicator for the severity of the disorder and the ability of stroke survivors to recover. Patients in the studies assessing patient-in-charge support generally had higher baseline velocity (10MWT) and endurance (6MWT) levels than patients in the studies assessing device-in-charge support and conventional therapy. Yet all groups showed the same training effects (even though no clinical relevant results were observed). Physical effort in the form of the control strategy of the robotic device might have affected this: patients with lower baseline levels (indicating low walking ability) might have benefitted from device-in-charge support, as this requires less physical effort from the patient, whereas patients with a higher baseline level might have benefitted from patient-in-charge support, as this requires higher physical effort.

In terms of balance (BBS), no difference in baseline level was observed between the three categories. However, only studies using the HAL device demonstrated improvements that were larger than was indicated by the MDC values (even though this does not automatically

indicate a clinically significant improvement, and BBS still indicates a high fall risk in one study). The fact that devices within a category do not all use the same working principle might support this observation. For example, the CaLT uses a reference trajectory of healthy subjects and defines a band around this path in which the patient can move freely [74]. The HAL uses the patient's EMG signals, which are believed to represent the patient's movement intentions [73]. Both devices provide patient-in-charge support, but the way that assistance is provided varies widely. Furthermore, some evidence is found that the mechanical design of the devices affects training outcome in terms of independent walking [78–80]. A distinction is made between 'end effectors', that only control the trajectory of a specific end point of the legs (e.g. the position of the patient's feet), and 'exoskeletons', that control the trajectory of the entire lower leg. This review does not take this difference into account: end effectors in which the distal joints are exposed to a predefined trajectory are classified in the category of device-in-charge support: patients are not empowered and the working principle of physical therapists is not taken into account. However, the difference in the control of legs during the training might affect the way that balance is trained.

Many studies used BWS and/or a treadmill during the training sessions. Note that both are attributes of the device and the training setting rather than of the control strategy. Mehrholz et al. [81] reported on this topic and its training effects in terms of walking independence, and did not find evidence that training with BWS in stroke rehabilitation is more effective than training without BWS. Moreover, treadmill training (whether with or without BWS) was also not found to be more effective than training without a treadmill in terms of regaining walking independence.

Although individual results in this study do not seem to show a clear benefit of one type of training device over another, this does not mean that no differences in terms of training effects exist between them. The factors mentioned previously might have contributed to this, but other factors, such as the motivation of the patient, or the use of (bio-) feedback might also be of importance. Therefore, it would be useful if future research further categorizes the robotic devices, instead of using only two categories as is done currently. This would provide more information on the precise type of interaction of the device and the patient. It would eliminate the effects of the variability in control strategies and mechanical designs among the robotic devices within the current categories. In addition, measuring EMG might be a useful tool to classify the systems, as it provides more insight into the actual training that is provided by the robotic device (amount of assistance) and the amount of contribution that is required from the patient during the training session.

Moreover, it is very important to classify the baseline level of patients, not only to identify the severity of the impairment and the ability to recover, but also to determine the most suitable training session for patients in terms of physical effort, training duration and frequency. Pang et al. [82] indicated in a systematic review that stroke patients with moderate baseline characteristics and low cardiovascular risk should train at 40–50% of their HRR (progressing to 60–80% of their HRR) for 20–40 minutes and 3–5 times per week in order to improve their walking speed and endurance. Patients at higher risk should decrease their HRR to 30% [83]. Furthermore, it might be useful for such patients to include short 30-second bursts of rest during the training session [75]. These numbers must be interpreted as guidelines rather than prescriptive numbers, but they do indicate

that each training session must be adapted to the individual needs of a patient and the specific training environment: for instance, to determine a suitable treadmill speed during training. Moreover, these guidelines could additionally be used to classify the progress of patients.

2.4.1 Study limitations

Although this systematic review was conducted with care, there were some potential limitations. Even though the methodological quality was not statistically significantly different between the categories, the categories included both high and low-quality studies. In general, the methodological quality of the included studies was moderate. A low methodological quality indicates that the internal validity, external validity and interpretability of a study are low according to the PEDro scale.

No statistical tests could be performed on the data that were collected for this review, as no standard deviation for the paired difference could be calculated. This would require all the individual patient data from each study, which were not available. However, results from the data analysis in this review still provide insight into the effects of various control strategies: the analysis demonstrates the current status of research on this topic and enables the reader to appreciate the clinical relevance of the results. Furthermore, many studies that were included in this review only included a pre/post measurement with an experimental group but did not include a control group. The low number of RCTs was the reason that no meta-analysis could be performed in this review. Stronger conclusions could have been drawn if there had been more RCTs.

2.5 Conclusion

This systematic review investigated training effects in terms of walking ability and balance, after robotic gait training with 'device-in-charge support' and after 'patient-in-charge support', for chronic stroke survivors. This classification focuses on the effects of training with using devices that follow the principle of error-based training and thus 'empower' the patient (patient-in-charge support) in their movement during gait-training and training with devices that do not (device-in-charge support).

No differences were found between the two control strategies, in terms of training effects. All primary outcome measures demonstrated small differences that were not considered clinically relevant, as indicated by the MCID. In addition, training effects for individual robotic devices also did not indicate a preference for one type of device over the other. An important confounder affecting the results in this review was the short training duration among all included studies, specifically in relation to the long time post-stroke of the included patients. Also, the included studies did not objectify the physical effort of the patients during the training sessions. Future research should focus on these aspects: baseline levels of patients should be identified and the training (in terms of, among others, control strategy, training duration, frequency and intensity) should be adapted to that level in order to obtain training conditions that suit the patient.

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Chapter 3

Performance of a visuomotor walking task
in an augmented reality training setting

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Abstract

Visual cues can be used to train walking patterns. Here, we studied the performance and learning capacities of healthy subjects executing a high-precision visuomotor walking task, in an augmented reality training set-up. A beamer was used to project visual stepping targets on the walking surface of an instrumented treadmill. Two speeds were used to manipulate task difficulty. All participants ($n = 20$) had to change their step length to hit visual stepping targets with a specific part of their foot, while walking on a treadmill over seven consecutive training blocks, each block composed of 100 stepping targets. Distance between stepping targets was varied between short, medium and long steps. Training blocks could either be composed of random stepping targets (no fixed sequence was present in the distance between the stepping targets) or sequenced stepping targets (repeating fixed sequence was present). Random training blocks were used to measure non-specific learning and sequenced training blocks were used to measure sequence-specific learning. Primary outcome measures were performance (% of correct hits), and learning effects (increase in performance over the training blocks: both sequence-specific and non-specific). Secondary outcome measures were the performance and stepping-error in relation to the step length (distance between stepping target). Subjects were able to score 76% and 54% at first try for lower speed (2.3 km/h) and higher speed (3.3 km/h) trials, respectively. Performance scores did not increase over the course of the trials, nor did the subjects show the ability to learn a sequenced walking task. Subjects were better able to hit targets while increasing their step length, compared to shortening it. In conclusion, augmented reality training by use of the current set-up was intuitive for the user. Suboptimal feedback presentation might have limited the learning effects of the subjects.

3.1 Introduction

Gait training on a treadmill is often not experienced as an engaging activity, since subjects (both healthy and patients) usually do not have to pay much attention during steady walking [1]. A popular method to increase the motivation of the user is adding explicit goals (targets/games) to the training environment, using computer-generated environments. Two types of computer-generated environments can be distinguished: virtual reality and augmented reality. The first is already widely applied in training situations and the second is increasing in popularity. Virtual reality creates an artificial environment, where the visual representation is separated from the physical walking environment and the user solely interacts with the computer-generated world rather than with the real world. In training situations, this is often done by the use of a motion capture system that records body movements and displays these on a screen by using an animation [2]. Augmented reality integrates computer-generated elements within the real world. The visual representation is incorporated into the physical walking environment and the user interacts with the real world, which is overlaid with computer-generated elements. For example, by using beamers or other projection systems that project visual objects on an instrumented treadmill. Movements of the user directly interact with the game, without interference of a motion capture system or a screen in front of the user.

Visual feedback presented by both types of computer-generated environments (virtual reality as well as augmented reality) positively contributes to learning motor tasks [3, 4]. They can be used to manipulate training-context, thereby influencing context-specific learning and promoting transfer of learning to other situations [5, 6]. Van Diest et al. [7] investigated the use of virtual reality for balance improvements in elderly and found positive training results due to an increased motivational component compared to regular training. Choi et al. [8] used a virtual reality training set-up to show that visual feedback can be used to improve sequence learning. In particular, the results of the study implicate that by use of this training set-up, sequence learning can be integrated with a highly automatic task such as walking, even over a relatively small period of only 300 steps. In a virtual reality set-up, proprioceptive information needs to be remapped to what is seen on a screen. The results by Choi et al. therefore also showed a non-specific learning curve, as subjects increased on task performance throughout the course of the experiment. We hypothesize that augmented reality might be more intuitive to the user on this aspect, as the real world is already integrated in the training set-up. Several studies [9, 10] have demonstrated that augmented reality training can successfully be used for gait adaptability training in various patient groups. The results show that after a period of training in such an environment, subjects are better able to modulate their steps to the environment. However, contrary to the virtual reality environment, the effects of (sequenced) locomotor learning in an augmented reality training environment, have yet not been presented in literature. Performing such a study improves our knowledge on the performance and learning capacities (either non-specific or sequence specific) of subjects in relation to such a training set-up. This knowledge might ultimately lead to a better understanding of the different computer-generated environments, their applicability in training situations, and might thereby contribute to the improvement of training programs.

The goal of this paper is therefore to study locomotor performance and learning capacities

as a result of augmented reality training. Participants performed a visuomotor walking task, where they must change their step length to hit visual targets while walking on a treadmill in an augmented reality environment. The study design was derived from [11, 12], who have presented a method to identity training effects in motor learning tasks. Augmented reality training is expected to be intuitive to the user, therefore it was hypothesized that subjects are able to hit the visual targets at first try and that they show the ability to learn a sequenced walking task.

3.2 Materials and methods

Twenty participants (age 28.5 ± 7.2 years, 9M/11F) completed the training and all participants performed seven consecutive blocks of training to measure the performance and learning effects. This study was approved by the local Institutional Review Board. All methods conformed to the Declaration of Helsinki. All subjects gave written informed consent prior to participation.

3.2.1 Apparatus

The C-Mill (MotekForceLink, Amsterdam, The Netherlands) was used for the walking tasks. The C-Mill consists of an instrumented treadmill with an embedded force platform and a beamer that projects visual stepping targets (10x10 cm) on the walking surface (Figure 1A) and therefore represents an augmented reality training environment. Position of foot placement was defined as the center of pressure (CoP) at the end of mid-stance, meaning that at that time it was underneath the (marked) 5th metatarsal [13]. The supplied CueFors 2.0 Software provides spatiotemporal data with respect to the presented visual targets.

3.2.2 Procedure

Within the training set-up, two groups of ten participants were formed based on a (randomized) imposed walking speed. Speed was set at 2.3 ± 0.2 km/h for the low speed group and 3.3 ± 0.2 km/h for the high speed group, to manipulate task difficulty.

We measured the change in performance across seven consecutive training blocks (performed on the same day), each block consisting of 100 stepping targets (and thus 100 steps) (Figure 1B). Stepping targets were placed at short (80% of medium step length), medium (100%) or long (120%) stepping distances, in a random or sequenced order depending on the training block in the experiment. The medium step length was equal to $2/3$ of the subject's leg length. Width between the stepping targets was set in correspondence to the step width of each subject. The first random block (R1) was used to familiarize the subject to the task. In this block, distance between stepping targets was presented in a random manner, with no recurring pattern in the distance between the stepping targets. The second random block (R2) provided a measure of final baseline performance and again, a random order was used in the distance between the stepping targets to evoke a mixture of short, medium and long steps. In the subsequent third, fourth and fifth training

Figure 1: Visuomotor experiment set-ups. A) Augmented Reality set-up: stepping targets projected on the treadmill. B) Stepping tasks over seven consecutive training blocks. Each stepping task is composed of 100 stepping targets. Stepping targets can either be placed in a random order or in a sequenced order. C) Representation of the fixed sequence that is continuously presented throughout the 100 stepping targets of each Sequenced Training Block (S1 – S4). This fixed sequence is thus repeated 14.2x within each training block, to span a total of 100 stepping targets.

blocks (referred to by Figure 1B as S1-S3), participants were presented with a repeating step length sequence. This fixed sequence (short-long-medium-long-short-medium step length, see Figure 1C) was constantly repeated within a training block and over the three training blocks (S1 – S3), making these training blocks identical. The fixed sequence was thus repeated 14.2 times within a training block of 100 stepping targets. Participants were not explicitly informed about the structure of the sequences. The sixth training block was composed of random stepping targets (referred to as R3) where no fixed sequence was presented. In the last, seventh training block, participants were again presented with the fixed sequence of training block S1-S3. This training block measured the ability of subjects to recall the fixed sequence to which they were exposed before.

We instructed the participants to step in the middle of the visual stepping targets as accurately as possible, aiming with the marked 5th metatarsal on their feet.

Real-time visual feedback was provided to the subject during the experiment, by changing the color of target on a successful hit (green to white, indicating that white was a hit).

3.2.3 Data analysis

Primary outcome measures are performance (% correct hits in each block), and learning effects (amount of increase in performance over training blocks). A hit (positive score) was counted each time the distance between the center of the stepping target and foot placement was ≤ 5 cm in the anterior-posterior direction. Percentage of correct hits was calculated for each subject individually. Afterwards scores were averaged over all subjects within each training block separately, representing the performance.

Learning effects were divided in non-specific learning effect and sequence-specific learning effects. Non-specific learning represents the general increase in task performance throughout the course over the experiment. It was calculated as the difference between random training blocks R2 and R3 [11]. Both training blocks use a random target order. The difference in performance is therefore only due to a general increase in task performance. Sequence-specific learning represents the ability to learn a specific sequence pattern while performing a highly automatic walking task. It was calculated as the difference in performance between the sequenced training block S3 and the random training block R3 [11, 12]. It is presumed that the decline in performance between the two consecutive blocks is due to the lack of sequenced targets in random training block R3.

Secondary outcome measures are the performance (% correct hits) in relation to step length (short, medium, long steps) and the stepping error (distance from target) in relation to step length.

For short, medium and long steps, the distance between the foot position and the border of the stepping target (i.e., stepping error) was calculated. Stepping error was only calculated for steps in which no hit was encountered. Stepping error could either be positive (when subjects overshoot their target) or negative (when subjects undershoot their target).

Data was analyzed by using mixed models analysis (IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 19.0. Armonk, NY: IBM Corp.) to investigate training effects over the seven consecutive training blocks, to investigate effects of both speeds on

outcome measures and the interaction effects (training blocks*speed). If significant results were obtained, Dunn-Šidac [14] was used for post hoc pairwise analysis, in order to study non-specific and sequence-specific learning effect (i.e. compare performance scores on training block R2 and R3 and training block S3 and R3 respectively).

3.3 Results

All 20 subjects completed the experiment. Leg length and (medium) step length were $0.89 \text{ m} \pm 0.029 \text{ m}$ and $0.59 \text{ m} \pm 0.019 \text{ m}$ respectively. No statistical significant differences were found between the subjects of the lower and higher speed experiments regarding these demographic characteristics ($p > 0.15$). Cadence was kept constant for each training set-up over the seven training blocks and were $67.1 \pm 0.4 \text{ steps/min}$ for the lower speed, and $92.9 \pm 0.7 \text{ steps/min}$ for the higher speed.

3.3.1 Performance

Performance (training score) over the different training blocks is presented in Figure 2 for both speeds. Mixed model analysis indicated a significant effect of speed on performance ($F_{1,18} = 16.262$, $p = 0.001$), where training at higher speed elicits lower performance scores.

Furthermore, interaction effects were calculated (training blocks*speed) and were found non-significant ($F_{6,108} = 0.643$, $p = 0.695$). This demonstrates that the effect of training time (performance over the course of the different training blocks) on the change in performance was not different between the two speeds. This is also visible in the graphs: both speeds show consistent results. Specific details on this latter aspect are presented in the section below about learning effects.

Compared to performance in the virtual reality task used in Choi et al. (2016), subjects performed better in the augmented reality task, especially in the first two blocks (2, bars vs. dashed lines). The results suggest that the nature of the visual feedback plays an important role in guiding step length adjustments (see Discussion).

3.3.2 Learning effects

No deviations in performance were observed by the mixed model analysis over the different training blocks of the experiment, either at higher speed ($F_{6,54} = 0.440$, $p = 0.849$) or at lower speed ($F_{6,54} = 0.736$, $p = 0.623$). Therefore, neither non-specific learning effects, nor sequence specific learning effects were present after training in this current augmented reality training set-up, at both speeds.

Figure 3 presents the difference between training block R3 and R2, and between training block S3 and R3, thereby showing the lack in non-specific and sequence specific learning effects respectively at both speeds.

Figure 2: Performance (% of correct hits) over the seven consecutive training blocks after training at lower (dark grey) and higher (soft grey) speed. * Virtual reality results have been retrieved from Choi et al. 2016.

Figure 3: Learning effects presented at both speeds. Non-specific learning is calculated as R3-R2, sequence-specific learning as S3-R3. A positive value in the graph indicates a (although non-significant) learning effect.

3.3.3 Stepping error in response to step length variation

Mixed model analysis showed (at both speeds) significant different performance scores as a result of step length variation ($F_{2,18} = 7.636$, $p = 0.004$ for the low speed and $F_{2,18} = 9.982$, $p = 0.001$ for the higher speed). Post-hoc analysis identified that subjects were better able to hit the targets while increasing their step length, compared to shortening their step length (see Figure 4).

Additionally, stepping errors (Figure 5) were larger while subjects had to shorten their step length at the lower speed, compared to increasing their step length ($F_{2,18} = 26.081$, $p < 0.001$), but not at the higher speed ($F_{2,18} = 2.039$, $p = 0.159$). However, stepping error was found equally large at both training speeds ($F_{1,18} = 1.775$, $p = 0.199$). The positive value of the averaged stepping errors indicates that subjects tend to overshoot their target.

3.4 Discussion

The main purpose of this study was to investigate the performance and learning capacities of subjects performing an augmented reality visuomotor walking task. In accordance to our hypothesis, the results indicate that executing such a task is intuitive for participants when the targets are projected in an augmented reality setting. Proprioception and vision do not have to be remapped in such a situation: step adjustments can directly be targeted and no learning is required. Participants only have to focus on the task itself and do not have to perform a task, while remapping at the same time. Maximal training score after the first block of training was around 76% for the lower treadmill speed (2.3 km/h) and 54% for the higher treadmill speed (3.3 km/h), implicating that subjects had more difficulty to hit the targets correctly at the higher speed. Wezenberg et al. [15] and Peper et al. [16] indicate that both energy expenditure and attentional demands increase when subjects perform a visuomotor walking task, compared to regular walking without a stepping task. Peper et al. [17] confirm this observation by showing that comfortable walking speed decreased when subjects had to perform a visuomotor stepping task, compared to uncued walking. Preferred walking speed thus decreases when task difficulty increases. The decreased performance that was observed at the imposed higher walking speed in this study is therefore assumed to be the result of an increase in task difficulty: stepping time and speed dependent step-length preferences might be suboptimal at this training speed compared to the lower speed, thereby increasing task difficulty.

Performance scores indicate that, despite the intuitive character of augmented reality training, a certain room for improvement is still possible over the course of the trials, even at the lower walking speed. Task difficulty might again explain this observation. Although our results show relative high performance scores on initial try, several other studies illustrate the ability of subjects to reach performance scores of 100% while performing a visual stepping task on the C-Mill [18–20]. These studies used stepping targets that were large in size, whereas our stepping targets were small in size and needed to be hit with the 5th metatarsal of the foot, thereby greatly increasing the difficulty of the stepping task. Although the subjects in our study approached all stepping targets with (some part of) their foot, failing to hit the target with the specific, marked, area of the foot still

Figure 4: Performance (% of correct hits) of short, medium and long steps of the entire training, at lower (dark grey) and higher (soft grey) speed. * $p = 0.001$; ** $p = 0.005$; *** $p = 0.024$.

Figure 5: Stepping error (% of leg length) of short, medium and long steps of the entire training, at lower and higher speed. * $p = 0.017$; ** $p < 0.001$; *** $p = 0.002$.

resulted in a negative performance score, thereby explaining the difference in performance score between these studies and our study. Additionally and contrary to our hypothesis, augmented reality training did not elicit any learning effects. Feedback presentation might have played an important role in this as Lamoth et al. [21] showed that visual feedback is of major importance in a computer-generated training environment. Additionally, the principle of error-based learning [22] states that individuals do not improve on a task when they do not receive information about their mistakes. In particular in a high-precision task as the one that is performed in our study, subjects will not improve their performance scores when they are unaware of their incorrect foot placement. The influence of error-based feedback to motor task learning is further explained when observing the findings of virtual reality locomotor training by Choi et al. [8], who used a similar study design but did observe increased performance over the training blocks (non-specific learning curve) and, additionally, a sequence-specific learning curve. The aspect that proprioceptive information needs to be remapped to what is seen on a screen might explain (part) of the non-specific learning curve in this study. However, the location and timing of the feedback might additionally be of great importance.

Feedback is presented on a screen in the virtual reality set-up by Choi et al. [8], but under the feet of the subjects in the augmented reality set-up. Both Matthis et al. [23] and Patla et al. [24] found that individuals prefer obstacle appearances that are at least two step lengths ahead when walking on complex terrain, to have higher success rates. Individuals thus strongly focus on the next target, rather than to look closely to their current stepping location [25]. As the feedback in our study was presented at the end of mid-stance (when the COP was on the stepping target), the distance between the feedback location and the next target is larger, i.e. further from the central field of vision [23]. Chapman et al. [26, 27] confirm that subjects performing an accurate stepping task look away from the target around the moment of heel strike, i.e. before the end of mid-stance was reached. Even though no eye tracking methods have been performed that could confirm these assumptions, the location of feedback might have been suboptimal in our training set-up, thereby limiting the learning capacities of the subjects. It is therefore assumed that adapting the location of the visual feedback (closer to the central field of vision), or the method of providing feedback (auditory feedback), might be more suitable for use in the current augmented reality training set-up.

In accordance with previous observations by Patla et al. [28] and in the virtual reality training set-up by Choi et al. [8], we found that subjects experienced more difficulties in controlling shorter steps lengths compared to longer ones. Moreover, Patla et al. [28] showed that subjects who anticipate to a wrongly chosen intended stepping location have a preference to overshoot their target. It is then energetically more beneficial to lengthening the step when a misinterpretation about the intended position was made. Subjects then do not have to reduce the forward linear momentum of their body and they gain additional time to correctly locate their foot at the new position. We have observed these findings in our results for all step lengths, indicating the difficulty of participants to correctly control the step length distance. A smaller overshoot in stepping error was present during the execution of longer steps compared to shorter steps at lower walking speed: subjects more often undershoot the stepping target when it was positioned at a long stepping distance compared to a short stepping distance. No deviation in stepping error was present between short and long stepping targets at higher walking speed.

The difficulty of subjects to interpret step length distances might be explained in another study by Patla [29], which states that subjects prefer visual information about step length over proprioceptive information. In augmented reality training, both the stepping-target on the treadmill and the user move in opposite directions. This is in contrast to regular overground walking, in which only the subjects and not the stepping targets move. Reasonably, subjects might experience difficulties in interpreting relative distances between targets in the augmented reality training set-up, as the visual information might be disturbed in this situation. This aspect might, additionally to the suboptimal feedback presentation that was already mentioned, contribute to the lack of sequence learning that is observed in the augmented reality training set-up.

3.4.1 Study limitations

This study provides insight into the performance of subjects while executing a visuomotor walking task in an augmented reality training situation. The augmented reality training situation was composed of an instrumented treadmill with an embedded force platform, where the location of the foot (at the instant of the 5th metatarsal) was defined as the center of pressure (CoP) at the end of mid-stance. Although this assumption seems reasonable according to [13], tracking the COP as a measure for the location of the 5th metatarsal, rather than using a motion capture system, introduces a small inaccuracy in the results. Specifically for situations where single stance durations shortens. This inaccuracy is believed to be rather small, as the trends that are shown in 4 of this manuscript are still similar to the work by Choi et al. and Patla et al. [8, 28]. However, this inaccuracy could have led to a small decrease in the performance scores: there might have been several occasions where the COP was not yet located underneath the 5th metatarsal at the end of mid-stance, even though the 5th metatarsal was located on top of the target.

Furthermore, one must one keep in mind that any type of computer generated training environment (either augmented or virtual reality) could be presented to users by using other methods, e.g. using head mounted displays (HMD) instead of computer screens, or using more complicated visual graphics during augmented reality training. The method used in our study is an example of an augmented reality training environment and many other set-ups also fall within the category of augmented reality training environments. Results as stated in this study could therefore not be translated to other situations.

In addition, no records were collected in this study that classify the (subjective) perception of performance of the users themselves or their perception of the difficulty of the task. This would have allowed to further specify the consequences of the feedback presentation in the training set-up.

3.4.2 Future research

It was suggested in this study that feedback location might have had a large effect on the performance score and learning abilities of subjects. Therefore, future research should test the suggestion made in the discussion section of this paper that learning effects could

be obtained in augmented reality training when feedback was presented in a different manner, e.g. using auditory feedback.

In addition, in order to overcome the (believed small) inaccuracy in performance score that is introduced by the assumption that the location of the COP is underneath the 5th metatarsal at the end of mid-stance, stepping locations might be better expressed in terms of performed step lengths, rather than absolute foot placements. Specifically, as the COP location at the end of mid-stance is affected by cadence, walking speed and single support stance duration, the accuracy of the performance score might increase when performed step length is taken into account.

Furthermore, future work must extend the experiments to specific patient groups, as they might respond differently to the evaluated training situations. Van Ooijen et al. [10] already demonstrated improvements in training task after training with a similar augmented reality training set-up over a longer period of time. The lack of learning effects in healthy subjects that was found in this study might therefore not exclude learning effects in patient groups. It can be assumed based on the findings in this study and the intuitive character of augmented reality training, that such a training set-up is suitable for target groups (such as neurological patients) that specifically need to focus on the motor task itself and that should not be distracted by a complex environment or the performance of a dual task. Future work should point out whether conclusions hold for other groups of subjects.

In addition to this latter aspect, future work should investigate success rates at additional walking speeds. The highest speed that was used in this study (3.3 km/h) is a relatively low speed for healthy subjects, while walking on a treadmill. Although it was observed that the success rate of subjects is speed dependent, its exact relation is not yet clear. This relation might specifically be of importance while using an augmented reality training environment for patients.

3.5 Conclusion

This study demonstrates that although performing a high-precision stepping task in an augmented reality training environment was intuitive to the users, performance scores did not increase over the course of the trials. Subjects thus did not show non-specific learning effects, nor did the subjects show the ability to learn a sequenced walking task. Main reason for the lack of improvement seemed to be the suboptimal feedback presentation in the used training set-up in combination with the difficulty of the stepping task. Furthermore, subjects seemed to show difficulty in controlling step length variations while performing a stepping task.

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Chapter 4

Paretic versus non-paretic stepping
responses following pelvis perturbations in
walking chronic-stage stroke subjects

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Abstract

Background: The effects of a stroke, such as hemiparesis, can severely hamper the ability to walk and to maintain balance during gait. Providing support to stroke survivors through a robotic exoskeleton, either to provide training or daily-life support, requires an understanding of the balance impairments that result from a stroke. Here, we investigate the differences between the paretic and non-paretic leg in making recovery steps to restore balance following a disturbance during walking.

Methods: We perturbed ten chronic-stage stroke survivors during walking using medio-lateral perturbations of various amplitudes. Kinematic data as well as gluteus medius muscle activity levels during the first recovery step were recorded and analyzed.

Results: The results show that this group of subjects is able to modulate foot placement in response to the perturbations regardless of the leg being paretic or not. Modulation in gluteus medius activity with the various perturbations is in line with this observation. In general, the foot of the paretic leg was laterally placed further away from the center of mass than that of the non-paretic leg, while subjects spent more time standing on the non-paretic leg.

Conclusions: The findings suggest that, though stroke-related gait characteristics are present, the modulation with the various perturbations remains unaffected. This might be because all subjects were only mildly impaired, or because these stepping responses partly occur through involuntary pathways which remain unaffected by the complications after the stroke.

4.1 Background

Stroke survivors often experience problems with maintaining their balance. A variety of neurological deficits can hamper balance control during walking, such as hemiparesis, sensory impairments, as well as cognitive problems such as fear of falling. As a consequence, fall rates in stroke survivors are 2-8 times higher than those in healthy, age-matched subjects [1]. In general, especially balance control in the frontal plane is often considered challenging, requiring adequate foot placement to continue walking [2]. This might be an additional challenge when suffering from hemiparesis following a stroke, which could lead to differences in recovery steps made with the paretic and the non-paretic leg in response to a disturbance during walking. To reduce the fall risk of stroke survivors and make their rehabilitation more effective, it is required to characterize how balance control is affected by a stroke. Such knowledge might be used to provide limb-specific support in robot-assisted gait rehabilitation.

Stroke survivors typically show differences in gait characteristics between the paretic and non-paretic leg during unperturbed walking, for example as a result of decreased motor control in the paretic leg. In a study by Balasubramanian et al. subjects placed the paretic leg at an increased lateral distance from the pelvis compared to the non-paretic leg in mediolateral (ML) foot placement during unperturbed walking [3]. However, no differences in step width were found with regard to the leg used for stepping. It is therefore of importance to consider both legs individually, in a body referenced frame such as that of the center of mass (COM). Dean et al. studied the relation between gluteus medius muscle activity in the swing leg and both the ML position and velocity of the COM relative to the stance foot [4]. For low fall-risk subjects the results suggest a stronger activity modulation in the non-paretic swing leg than in the paretic swing leg, though it did not show how both legs respond to actual destabilizing conditions such as external perturbations.

Perturbations can be used to affect the body state, such as the position and velocity of the COM relative to the stance foot. This may lead to adjustments in foot placement location and timing to maintain balance. In Krasovsky et al. perturbations were applied by unexpectedly arresting the ankle of the leg at early swing [5]. Stroke survivors showed shorter step lengths and shorter swing times compared to healthy controls when stepping in response to perturbations applied to the non-paretic swing leg. Furthermore, in Hak et al. continuous ML support surface translations were used to assess if and how low-fall risk stroke survivors change their base of support (BoS) during walking through foot placement adjustments [6]. It was found that stroke survivors more strongly shortened their step length and step time, and increased their step width, as compared to healthy controls. However these studies did not compare the perturbation responses of the individual paretic and non-paretic limbs.

In healthy subjects, ML foot placement adjustments in response to ML perturbations relate to the ML COM velocity [7, 8]. This is reflected in a concept called the extrapolated center of mass (XCOM), which has been previously used to indicate fall risk in relation to foot placement [6, 9]. The XCOM can be derived from a linear inverted pendulum model [10, 11] and can be regarded as a point on the floor at a horizontal distance from the COM. This distance is directly proportional to the horizontal COM velocity through a proportionality constant ω_0^{-1} . If the inverted pendulum model would place its point-foot onto the XCOM,

the model will stop moving in an upright position. Placing the foot further away from the COM than the XCOM will cause the model to fall back in the direction from which it came. The further the model places its foot beyond the XCOM, the sooner the model is redirected in the opposite direction. Such movement is relevant to the ML direction of walking, where toppling over the leg is often not desired. Hence, investigating paretic and non-paretic foot placement in relation to the XCOM allows analysis from a simple model perspective.

The main purpose of this study is to characterize differences between the paretic and the non-paretic legs in walking chronic-stage stroke survivors in terms of ML stepping following ML pelvis perturbations. Rather than applying continuous disturbances, we will use transient perturbations directed inward and outward. We will also investigate how the steps are made in relation to the XCOM. Only low fall-risk subjects will be considered, to reduce the risk of actual falls in response to the perturbations.

4.2 Materials and method

4.2.1 Participants

Ten stroke survivors in the chronic stage (7 male, age: 52 ± 16 years, weight: 82.5 ± 13.6 kg, height: 1.75 ± 0.06 m, mean $\pm$ std) were recruited. All gave written informed consent before participation. All participants had a Functional Ambulatory Category score of 4, meaning that these subjects can walk independently on even surfaces, but might require assistance in more challenging situations such as uneven terrain [12]. Related clinical measures can be found in table 1. The experimental setup and protocol were approved by the local ethics committee, and was in accordance with the Declaration of Helsinki.

4.2.2 Apparatus

Subjects walked on an instrumented treadmill (custom Y-mill, Motekforce Link, Culemborg, the Netherlands), used to collect 3 degrees-of-freedom ground reaction forces and torques per foot. Subjects could be perturbed in the ML direction using a motor (SMH60, Moog, Nieuw-Vennep, the Netherlands) bolted to a support structure clamped to the treadmill's exterior frame. A brace (Distrac Wellcare, Hoegaarden, Belgium) worn by the subject could be connected to the motor through an aluminum horizontal rod and a vertical lever arm. The rod was connected to both the brace and the lever arm through ball joints, to allow freedom of movement in the anteroposterior (AP) direction. Given the motor range of motion, the maximum lateral excursion from the center of the treadmill was approximately 0.55 m in each direction. The motor was admittance controlled over Ethernet (User Datagram Protocol) at 1000 Hz, using xPC-target (The Mathworks, Natick, US). A schematic overview of the experimental setup can be found in Figure 1A. Additional details can be found in Vlutters et al. [8].

Figure 1: Experimental setup and single-subject perturbation profiles. (A) Schematic overview of the experimental setup. In the schematic the left leg is the stance leg. For the right stance leg the leftward and rightward arrow colors interchange. (B) Reference (dashed) and measured (solid) interaction force between motor and subject. (C) Reference (dashed) and measured (solid) motor impulse, obtained by integrating the interaction forces. (D) ML COM velocity relative to the walking surface. (E) EMG profile of the swing leg gluteus medius. Colors indicate the various perturbations. Lines represent within-subject averages of a single subject. Shaded areas indicate the within-subject standard deviation. The subject shown was the subject with the highest step frequency among subjects. The square on the time axis indicates the average time of heel strike after perturbation onset at toe-off (paretic and non-paretic pooled).

4.2.3 Data collection

Subject kinematic data were collected at 100 Hz using a 9 camera motion capture system (Visualeyez II, Phoenix Technologies Inc, Burnaby, Canada). Marker clusters, each consisting of 3 LEDs, were placed on the feet, lower legs, upper legs, pelvis, sternum and head. Additional single LEDs were placed on both lateral malleoli, and both lateral epicondyles of the femur. Gluteus medius EMG activity in both legs was recorded using a Bagnoli Desktop EMG system (Delsys, Natick, MA, USA) at 1000 Hz. Finally, subjects were filmed from the rear using a video camera to be able to detect any instances during which the subject grasped the handrails of the treadmill.

4.2.4 Protocol

Various bony landmarks were indicated using an LED based probe [13], prior to the experiment. These landmarks were the 1st and 5th metatarsal heads, calcaneus, medial and lateral malleoli, fibula head, medial and lateral epicondyles of the femur, greater trochanter of the femur, anterior and posterior superior iliac spines, xiphoid process, jugular notch, 7th cervical vertebra, occiput, head vertex and nasal sellion [14]. Subjects wore a safety harness at all times to prevent injury in case of a fall. The preferred walking speed was determined by gradually increasing the speed of the treadmill, until the subject felt comfortable. This was also used to have subjects familiarize with walking on the treadmill.

During the experiment subjects wore the brace around the pelvis and were instructed to walk at the center of the treadmill. First, a two minute baseline measurement at the preferred walking speed was recorded without applying perturbations. When no perturbations were applied the motors were admittance controlled such that the interaction force between the subject and the motor was as low as possible, see Figure 1B. In subsequent trials perturbations could be randomly applied at the instance of toe-off of either leg, such that subjects were required to use both the paretic and the non-paretic leg in the first recovery step. The toe-off instances were detected using the vertical ground reaction forces. Perturbations were 150 ms block pulses of magnitudes equal to 4, 7, and 10% of the subject's body weight. The direction could be inward (e.g. leftward for left stance) or outward (e.g. rightward for left stance). Though the motors cannot perfectly track the desired reference force, the delivered impulse is approximately as desired, see Figure 1C. Each perturbation condition was repeated 5 times, yielding 60 perturbations per subject. The perturbations were randomized over magnitude, direction, and onset instance (paretic or non-paretic toe-off). The minimum time between successive perturbations was also randomized, and varied between 6 and 12 seconds. Finally, Berg Balance Scale (BBS), Dynamic Gait Index (DGI), Mini-Mental Scale Examination (MMSE), Fall Efficacy Scale International (FES-I) and 10-meter-walking-test (10MWT) measures were collected within one week after the experiment.

4.2.5 Data processing

Data were processed using Matlab (R2013b, Mathworks, Natick, US). EMG data were de-trended, filtered with a 1st order 48-52 Hz Butterworth bandstop filter, then rectified, and filtered with a 1st order 20 Hz Butterworth low-pass filter. Marker data were filtered with a 4th order 20 Hz zero-phase Butterworth low-pass filter before reconstructing the global bony landmark positions from the probe measurements. Using the landmarks, the COM positions of the captured segments were estimated following Dumas et al. [14]. The total body COM was calculated as a weighted average of the segment COM positions, and was differentiated for a COM velocity. All other position and velocity data were expressed relative to those of the COM. Gait events of toe-off and heel strike were detected using landmarks of the feet [15]. Instances of perturbation onset were detected from the motor input signals. The recorded video data were visually inspected for perturbations during which subjects touched the hand-rails of the treadmill. Corresponding trials were removed from analysis.

For each subject, the position of the COM of both feet relative to the total-body COM, as well as the COM velocity, were extracted at the instances of heel strike and toe-off after the perturbation. The gait phase durations between these instants were also calculated. The EMG data of each individual muscle was scaled to the median of the maximum values occurring every gait cycle during the unperturbed walking condition. For each subject and in each condition, the scaled EMG time-averages between toe-off and heel strike were calculated, representing the averaged muscle activity level during the swing phase. All these data were sorted on perturbation magnitude, perturbation direction (inward or outward), and leg used for stepping (paretic or non-paretic). Since five right-sided and five left-sided paretic subjects participated in the study, all position, velocity, and EMG data resulting from the left side of the body were laterally mirrored for all subjects. All data in this paper is therefore presented as if the first recovery step was made with the right leg, for both the paretic and the non-paretic leg of all subjects. Next, for each subject all data were averaged over the repeated conditions to obtain repetition averages. These were in turn averaged for subject-averages and standard deviations. Finally, for each subject an XCOM proportionality constant was calculated following $\omega_0^{-1} = \sqrt{l/g}$ [7], in which l is the subject's leg length, and g the earth's gravitational constant. These were averaged across subjects for a subject-average proportionality constant.

4.2.5.1 Statistical analysis

Linear mixed models were used to determine the effect of all perturbations (fixed factor, with intercept), the effect of the leg used in the first recovery step (fixed factor, with intercept), and their interaction effect on the outcome measures. Outcome measures were the ML and AP distance between the leading foot and the COM, the ML and AP distance between both feet (step width and step length, respectively), the ML COM velocity at heel strike, the gait phase durations following the perturbations, and the EMG signal averages. To account for correlated repeated measures within the same subject, a random subject factor (intercept) was included in the model. The significance level was set to $\alpha = 0.05$, and a Dunn-Šidac correction was applied during post hoc analysis. In the post hoc comparison,

perturbation data were only compared to the unperturbed condition and not mutually. The Statistical Package for the Social Sciences version 19.0 (IBM Corporation, Armonk, NY, USA) was used for the statistical analysis.

4.3 Results

All subjects completed the experiment without falling. Subjects 1, 2, and 3 grabbed the handrails 4, 4, and 6 times respectively, mainly in response to the largest magnitude inward perturbations. The corresponding data were removed from analysis. Subject characteristics are presented in Table 1.

4.3.1 Foot placement location in ML and AP directions

Perturbations resulted in foot placement modulation. Here, we specifically focus on the location of the leading foot. Perturbations were applied such that each subject had to make the first recovery step with both the paretic- and the non-paretic leg. The locations of the feet relative to the COM at the instant of the first heel strike after the perturbation are presented in Figure 2. Note that because the data is presented relative to the COM, the stance foot data changes with the perturbations because the body is pushed away from it or towards it. Foot placement relative to the COM as a result of the different perturbations was not found to differ between the paretic and non-paretic leg, for both ML ($F_{6,117}=0.981$, $p=0.441$) and AP ($F_{6,117}=0.068$, $p=0.999$) distances between the COM and the leading foot. This indicates that no interaction effect was present between factors perturbation and leg used for stepping.

When considering the effects of the leg used in the stepping response, it is important to regard the foot location relative to the COM rather than relative to the trailing foot. In the frontal plane, the foot of the paretic leg is always laterally placed further away from the COM than the foot of the non-paretic leg ($F_{1,123}=26.956$, $p<0.001$). Instead, when considering step width, i.e. the ML the distance between the feet, no significant differences were found between the legs used in the first recovery step ($F_{1,123}=2.086$, $p=0.151$). For the AP distance between the COM and the leading foot no significant effects of factor leg were found ($F_{1,123}<0.001$, $p=0.999$). However the step length, i.e. the AP distance between the feet, was larger when stepping with the paretic leg compared to stepping with the non-paretic leg ($F_{1,123}=9.294$, $p=0.003$). The latter effects are therefore caused by the trailing leg, and are likely related to the time spent standing on that leg.

Mediolateral adjustments with the leading foot mostly occur in the direction of the perturbation. Especially for outward perturbations the foot appears to be placed further in the direction of the perturbation with increasing perturbation magnitude. Significant effects of factor perturbation were found for the ML distance between the COM and the leading foot ($F_{6,123}=7.215$, $p<0.001$), as well as for the AP distance between the COM and the leading foot ($F_{6,123}=24.799$, $p<0.001$). Post hoc analysis revealed that this AP distance decreased significantly for all outward perturbation compared to unperturbed walking ($p<0.002$), but did not change significantly for all inward perturbations ($p>0.160$).

Table 1: Subject Characteristics.

Patient ID	Gender	Age	Time post-stroke	Affected leg	Weight distr. stance	Weight distr. walking	BBS	DGI	MMSE	FES-I	10MWT	Treadmill speed during trials
(#)	(M/F)	(yrs)	(yrs)	(L/R)	(% nonPar/Par)	(% nonPar/Par)	(pnts)	(pnts)	(pnts)	(pnts)	(km/h)	(km/h)
1	M	66	10	R	54/46	58/42	51	-	28	16	-	0.4
2	M	30	7	R	48/52	56/44	55	22	30	30	4.5	1
3	F	70	9	R	51/49	59/41	55	22	26	17	1.9	0.7
4	M	63	10	L	54/46	53/46	55	22	27	19	4.6	2
5	M	38	5	R	40/60	50/50	48	21	28	29	3.3	1.6
6	M	67	7	L	55/45	57/43	53	-	30	22	-	2.2
7	M	64	4	L	56/44	54/46	56	-	26	16	-	5
8	M	45	3	R	46/54	43/57	56	23	27	34	4.7	2.2
9	F	29	8	L	54/46	61/39	56	22	28	17	3.7	2.2
10	F	46	29	L	61/39	58/42	56	24	30	17	4.7	2.4
Mean	-	52	9	-	52/48	55/45	54	22	28	22	3.9	2
(std)	-	16	7	-	6	5	3	1	2	7	1	1.3

Figure 2: Positions of the COM of the feet relative to the whole body COM. (A) Locations of the COM of both the leading and the trailing foot relative to the whole-body COM, at the instant of heel strike, for steps made with the paretic leg. (B) Same as in A, for steps made with the non-paretic leg. Triangles show subject averages and indicate the perturbation direction. Ellipses represent subject standard deviations. Colors indicate the perturbation magnitudes as a fraction of the subject's body weight.

4.3.2 Relation between ML foot placement and ML COM velocity

We investigated the mediolateral stepping location in relation to the ML COM velocity at the instant of heel strike, specifically in relation to the location of the XCOM at heel strike, see Figure 3. If the ML distance between the COM and the leading foot (y-axis) would increase with increasing mediolateral velocity (x-axis) at the same rate (ω_0^{-1}) as that of the pink XCOM line, then the foot would be placed at a fixed distance from the XCOM [7]. This would provide a simple explanation for lateral foot placement, based on a concept derived from a linear inverted pendulum model.

Factors perturbation and leg had a significant interaction effect on the ML COM velocity following the perturbations ($F_{6,114.068}=2.587$, $p=0.022$). As a result, steps made with the non-paretic leg show more variability in the COM velocity between the various perturbations, as compared to that of steps with the paretic leg. That is, for steps with the non-paretic leg outward perturbations lead to more positive COM velocities, whereas for inward perturbations it leads to smaller, or even a slightly negative COM velocity. Factor leg also provided a significant main effect on the ML COM velocity, with a higher velocity for steps made with the non-paretic leg ($F_{1,114.058}=7.011$, $p=0.009$). Furthermore, the various perturbations significantly affected the ML COM velocity at heel strike ($F_{6,114.068}=82.830$, $p<0.001$), increasing in the direction of the perturbation with increasing perturbation

magnitude (post hoc: step with paretic: $p \leq 0.027$ for all perturbations except for 0.04, 0.07 outward, step with non-paretic: $p \leq 0.007$ for all perturbations except for 0.04 outward). While at heel strike the ML distance between the COM and the leading foot showed modulation with the COM velocity, the average distances do not appear to modulate with the COM velocity in the same way as the XCOM does. That is, the ML distance of the foot relative to the COM does not relate to the ML COM velocity through a factor ω_0^{-1} . Instead, both the paretic and the non-paretic leg show an increase in foot-COM distance with increasing outward perturbation magnitude, but remain approximately the same with increasing inward perturbation magnitude. Therefore, for the presented results the XCOM alone is not a sufficient predictor of the lateral stepping location, though this might be different in a more homogeneous subject group.

Figure 3: Distance between the COM of the leading foot and the whole body COM against the COM velocity. (A) For recovery steps made with the paretic leg, at the instant of the first heel strike after the perturbation. (B) Same as in A, but for steps made with the non-paretic leg. Triangles show subject averages and indicate the perturbation direction. Ellipses represent subject standard deviations. Colors indicate the perturbation magnitudes. The pink dashed line indicates the position of the XCOM relative to the COM. This line has a slope of ω_0^{-1} and no intercept.

4.3.3 Gait phase durations

For all presented gait phase durations, modulation with the perturbations is invariant of the leg with which the step is made. No significant interaction effects were found between factors perturbation and leg on the duration of the swing phase in which the perturbation was applied ($F_{6,117}=0.163$, $p=0.986$), nor on the subsequent double support phase duration ($F_{6,115.993}=1.045$, $p=0.400$).

The most prominent gait phase duration modulation occurred in the swing phase during which the perturbation was applied. The duration of this swing was significantly affected by the perturbations ($F_{6,123}=26.035$, $p<0.001$), significantly increasing with increasing inward perturbation magnitude ($p \leq 0.045$), and decreasing with increasing outward magnitude ($p \leq 0.002$, except 0.04 outward), see Figure 4. In contrast, the subsequent double support durations were not significantly affected by factor perturbation ($F_{6,121.993}=1.864$, $p=0.092$).

The gait phase durations also reflect the differences between steps made with the paretic and the non-paretic leg. Subjects preferred to spend more time on the non-paretic leg than on the paretic leg during the single support phase, regardless of which perturbation was applied ($F_{1,123}=16.448$, $p<0.001$). Furthermore, the double support phase during which the weight is shifted from the paretic leg toward the non-paretic leg also last longer compared to the opposite shift ($F_{1,121.993}=23.365$, $p<0.001$).

Figure 4: Gait phase durations. (A) The single support duration during which the perturbations were applied, and the subsequent double support duration, for recovery steps made with the paretic leg. (B) Same as in A, but for recovery steps made with the non-paretic leg. Triangles show subject averages and indicate the perturbation direction. Vertical bars represent subject standard deviations. Colors indicate the perturbation magnitudes.

4.3.4 Gluteus medius activity

Subjects modulated the gluteus medius activity in the swing leg with the various perturbations, for both the paretic and non-paretic leg. Though more varied modulation appears to occur in the non-paretic leg over all perturbations, no interaction effects were found between factor leg and perturbation magnitude ($F_{6,88.978}$, $p=0.452$).

However, a significant effect of the perturbations was found on the gluteus medius activity levels ($F_{6,94.917}=18.993$, $p<0.001$), increasing on average. Especially for outward perturbations where the gluteus medius participates in foot placement adjustments through leg abduction, increased activity levels can be observed with increasing perturbation magnitude ($p<0.001$, except for 0.04 outward), see Figure 5. For inward perturbations the post hoc comparison provides no significant effects, though the non-paretic swing leg appears to show more EMG modulation than the paretic swing leg. Differences between both legs were not tested as activity levels of both legs were scaled to baseline values of each leg.

Figure 5: EMG responses. (A) For the paretic leg, modulation with the perturbation magnitude of the time-average EMG signals between toe-off (perturbation onset) and heel strike. (B) Same as in A, but for the non-paretic leg. Triangles show subject averages and indicate the perturbation direction. Vertical bars represent subject standard deviations. Colors indicate the perturbation magnitudes.

4.4 Discussion

We investigated the first recovery step following mediolateral pelvis perturbations in chronic-stage stroke survivors who walked at a self-selected speed. The transient perturbation were randomly applied at the instant of toe-off of the paretic and non-paretic leg, such that every subject had to make recovery steps with both legs. The aim was to evaluate and compare stepping responses regarding the use of the paretic and non-paretic leg. In accordance to our hypothesis, we found various differences in gait characteristics between steps made with the paretic and non-paretic leg. However, foot placement modulation in response to the various perturbations did not differ between the legs within the included group of stroke survivors.

4.4.1 Foot placement with respect to the COM

Our findings in perturbed walking support the analysis of foot placement measures with respect to the COM, similar as previously applied in unperturbed walking [3]. As in the work by Balasubramanian et al., in the current results the mediolateral distance between the feet is independent of the leg with which the step is made. However, this does not imply that there are no differences between both legs in terms of foot placement, as the paretic leading leg is placed at a consistent increased lateral distance from the body's COM. It has been suggested that this might be related to strength limitations in the paretic leg [3, 16], leading to the typical weight bearing asymmetry during stance [17]. These limitations could in turn lead to limited control over the COM motion with the paretic leg [18, 19], especially during the single support phase in which the paretic leg is the stance leg. This might also explain the larger variability in ML COM velocity following the perturbations applied during the paretic single support phase compared to those during the non-paretic single support phase. The results suggest that classical gait parameters such as step length and width might not fully capture balance and walking impairments in stroke survivors. Analysis of the feet locations relative to the COM might identify leg specific aspects of the impairment, and help specify gait-phase specific support in robotic gait training and rehabilitation.

4.4.2 Leg-independent step modulation in response to perturbations

The results imply that subjects attempt to execute similar stepping strategies with both legs, and that the modulation with the various perturbations is not hampered by the effects of the stroke. Though the paretic leg is laterally placed further away from the COM than the non-paretic leg when making a step, the way in which the foot placement location alters with the various perturbations does not statistically differ between both legs. Consequently, subjects do not modulate their stepping location worse with the paretic leg than with the non-paretic leg, in response to the various perturbations. Similar effects were observed in modulation of the gait phase duration following the perturbations. Although subjects spent more time standing on the non-paretic leg, they showed comparable changes in gait phase durations with both the paretic and the non-paretic legs in response to the different perturbations. One potential cause might be that the subjects were only mildly affected by the stroke, as classified by their clinical scales. Subjects with lesser scores on clinical outcome measures might have shown larger deviations. For instance, in a study by Dean et al. high fall risk subjects showed different stepping strategies compared to low fall risk subjects [4]. Another potential reason might be that the modulation is partly automatic. For example, Nashner et al. showed that balance perturbations during standing can trigger rapid postural adjustments that take precedence over voluntary movements [20]. It might be that these responses involve neural pathways that bypass the brain areas damaged by the stroke.

4.4.3 Gluteus medius activity modulation

It has previously been suggested that swing leg gluteus medius activation for ML foot placement might be based on sensory information from the stance leg [4, 21]. Our outward perturbations move the COM further away from the stance foot with increasing perturbation magnitude. Therefore, as in Dean et al., gluteus medius activity increased with increasing ML distance between the COM and the stance foot [4]. These effects occurred in both the paretic and the non-paretic swing legs, without significant interaction effects between factors leg and perturbation. These findings therefore match those for step location and step time modulation in this study, suggesting that modulation with the perturbations is not different between both legs in the current subject group.

With the current setup in stroke survivors, it is not possible to confirm whether this relation between the stance leg and the gluteus medius activity of the swing leg is a causal one. As stroke survivors often suffer from sensory impairments in the paretic leg [22], one would expect information from the stance leg to be less reliable if that leg is paretic. Consequently, if gluteus medius activity modulation would primarily depend on the state of the stance leg, one would expect the paretic swing leg to receive the best information. However, in Dean et al. the gluteus medius of the paretic swing leg showed poorer modulation with the state of the stance leg than that in the non-paretic swing leg [4]. It is therefore likely that effects of the stroke on the paretic leg dominate the relations in Dean et al., rather than how well information is conveyed from one leg to the other.

4.4.4 Absence of cross-stepping

In a similar study with healthy subjects, inward perturbations of sufficient magnitude lead to cross-steps [8]. These were not observed in the current study. Though the maximum perturbation magnitudes were not as high as in Vlutters et al. [8], subjects visually appeared to explicitly avoid crossing the legs. In case of larger magnitude inward perturbations, subjects tended to move the arms, or abduct the swing leg, possibly using angular momentum strategies [23] to recover from the perturbations. Similar leg abduction responses were reported in Dean et al. for unperturbed high fall-risk subjects [4]. Subjects might be reluctant to make cross-steps, as entangling the legs would hamper gait progression. These effects might be amplified by walking on a treadmill, as it requires the subjects to keep walking to prevent falling off the belt.

4.4.5 Analysis from a model perspective

Evaluating foot placement in relation to the XCOM as derived from a linear inverted pendulum model might aid in understanding why a subject places the foot at a certain location. It can be deduced how such a model would move depending on where its foot is placed relative to the XCOM. In general, subjects laterally placed their foot beyond the XCOM, further away from the COM than the XCOM itself. The foot was placed further beyond the XCOM for steps made with the paretic leg as compared to steps made with the non-paretic leg. Doing so in the model would make the COM fall back toward the

other leg, but at a higher rate for steps made with the paretic leg. This would require the subsequent step with the non-paretic leg to be of shorter duration, therefore spending less time standing on the paretic leg. This is in line with our findings, as well as with other studies in unperturbed walking [25].

Previous studies have investigated the XCOM as a linear predictor for a mediolateral stepping location in healthy subjects [7]. In Vlutters et al., the COM velocity related linearly to the mediolateral stepping location after the perturbation [8]. While the ML stepping location in our stroke subjects does modulate with COM velocity, and therefore with the XCOM, the data shows substantial variability. The strong linear trend observed in healthy subjects does therefore not hold here. This implies that the COM velocity holds some predictive power for a mediolateral stepping location in this group of stroke survivors, but not as apparent as in healthy subjects, or perhaps not through a linear relation.

4.4.6 Effects of walking speed

The subjects in this study were allowed to walk at a self-selected comfortable walking speed, resulting in a treadmill speed range from 0.4 to 5.0 km/h among subjects. This range leads to variability in spatio-temporal gait parameters such as step length, width, and frequency, which all alter with gait speed. However, our findings focus on the differences between the paretic and the non-paretic legs of the subject population as a whole. The effects of walking speed are likely to be equal for both legs within a single subject, allowing comparison between both legs throughout the subject population.

4.4.7 Limitations

The perturbation device was controlled such that the interaction force between the subject and the motor was as low as possible. The total reflected inertia from the motor to the pelvis is about 1 kg. In a study by Meuleman et al. it was concluded that up to 5.3 kg of inertia can be added to mediolateral pelvis movement without significantly affecting the gait [27]. Interaction with the motor is therefore not expected to affect the subjects' gait when no perturbation is applied. However, the rod used to connect the motor to the pelvis brace partly obstructed the right arm sway. Subjects were not able to fully swing their arm backward during the measurement trials, thereby possibly affecting the gait kinematics. Several subjects indicated that the rod was not a problem, or preferred walking with their arms in front of their body to hold the paretic hand. Little effects of this constraint on the lower limb responses are therefore expected.

It has previously been shown that self-selected overground walking speed as assessed by the 10MWT relates to the degree of walking impairment [28]. Based on this classification, all subjects in our study are within a group of community walkers, and are mildly affected. The subject data shows that the gait speed on the treadmill is often lower than that recorded in the 10MWT. Even though subjects were given a period of time to familiarize with the measurement set-up, subjects might adapt their gait while walking on a treadmill [29] due to being unfamiliar with the measurement setup, or due to fear of falling. However, in Zadavec et al. it was demonstrated that responses of healthy subjects to horizontal

pelvis perturbations show high degrees of similarity between overground and treadmill walking [30] Hence, despite the differences in treadmill and overground walking speed in our subjects, the responses to perturbations are expected to be similar in both scenarios given a walking speed.

Finally, the variety between subject characteristics such as the walking speed results in more variable data than what would be obtained with a more homogeneous subject group, or with more subjects. The variability in the data could affect the interpretation of the results, such as whether or not the XCOM provides predictive value for lateral foot placement in stroke survivors. Studying more consistent subject groups could reveal to what extent these relations hold for reactive stepping in response to perturbations.

4.5 Conclusions

The current work investigated paretic and non-paretic mediolateral stepping responses following ML pelvis perturbations in walking stroke survivors. Stepping responses were investigated for the first step taken after the perturbation. Following a perturbation, subjects preferred to spend more time standing on their non-paretic leg. Analysis in a body-referenced frame identified that the paretic leading leg was placed at a consistently increased ML distance from the body's COM. Despite these differences in gait characteristics, our results suggest that the modulation of the paretic and non-paretic leg with the various perturbations is not greatly hampered by the effects of the stroke. Foot placement and gluteus medius EMG activity imply that subjects attempted to execute similar stepping strategies with both legs. This might be explained because all subjects were classified as having low-fall risk, or because the responses might be partially involuntary, with the modulation not directly affected by the effects of stroke. Though modulation occurred in both legs, mediolateral foot placement in the presented group of stroke survivors could not be predicted using a linear predictor based on the COM velocity. If the subject is able to modulate steps using the paretic leg one might refrain from assisting leg swing during training using a robotic device or exoskeleton, and only provide support after foot contact in weight bearing.

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Chapter 5

Manual physical balance assistance of therapists
during gait training of stroke survivors:
Characteristics and predicting the timing

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Abstract

Background: During gait training, physical therapists continuously supervise stroke survivors and provide physical support to their pelvis when they judge that the patient is unable to keep his balance. This paper is the first in providing quantitative data about the corrective forces that therapists use during gait training. It is assumed that changes in the acceleration of a patient's COM are a good predictor for therapeutic balance assistance during the training sessions. Therefore, this paper provides a method that predicts the timing of therapeutic balance assistance, based on acceleration data of the sacrum.

Methods: Eight sub-acute stroke survivors and seven therapists were included in this study. Patients were asked to perform straight line walking as well as slalom walking in a conventional training setting. Acceleration of the sacrum was captured by an Inertial Magnetic Measurement Unit. Balance-assisting corrective forces applied by the therapist were collected from two force sensors positioned on both sides of the patient's hips. Measures to characterize the therapeutic balance assistance were the amount of force, duration, impulse and the anatomical plane in which the assistance took place. Based on the acceleration data of the sacrum, an algorithm was developed to predict therapeutic balance assistance. To validate the developed algorithm, the predicted events of balance assistance by the algorithm were compared with the actual provided therapeutic assistance.

Results: The algorithm was able to predict the actual therapeutic assistance with a Positive Predictive Value of 87% and a True Positive Rate of 81%. Assistance mainly took place over the medio-lateral axis and corrective forces of about 2% of the patient's body weight (15.9N (11), median (IQR)) were provided by therapists in this plane. Median duration of balance assistance was 1.1s (0.6) (median (IQR)) and median impulse was 9.4Ns (8.2) (median (IQR)). Although therapists were specifically instructed to aim for the force sensors on the iliac crest, a different contact location was reported in 22% of the corrections.

Conclusions: This paper presents insights into the behavior of therapists regarding their manual physical assistance during gait training. A quantitative dataset was presented, representing therapeutic balance-assisting force characteristics. Furthermore, an algorithm was developed that predicts events at which therapeutic balance assistance was provided. Prediction scores remain high when different therapists and patients were analyzed with the same algorithm settings. Both the quantitative dataset and the developed algorithm can serve as technical input in the development of (robot-controlled) balance supportive devices.

5.1 Introduction

Stroke survivors with a Functional Ambulation Category (FAC) of 2/3 often experience reduced balance control and difficulties with independent ambulation [1]. Physical therapists focus on improving these aspects in rehabilitation therapy, for instance by training tasks that specifically relate to Activities of Daily Living (ADL's) such as overground walking in and around the house [2, 3]. During these training sessions, therapists continuously need to supervise patients when they walk. When patients lose their balance, therapists provide manual physical balance assistance to the body in the form of small corrective forces. In any given situation, therapists consider patient-specific examination findings to determine if and when balance assistance is needed, such as a patient's specific muscle strength, isolated movement capacity, reaction or movement time deficits, co-morbid sensory loss, coordination deficits, as well as, fatigue status and fall history. Providing balance assistance not only allows patients to continue their training safely, it also lets them experience the boundaries of their abilities without actually falling. Such a process of experiencing trial-and-error in (re)learning motor tasks is commonly referred to as error-based training, a concept often applied in stroke rehabilitation [4]. The applicability of this concept was confirmed in observations during training sessions by the authors and by personal communication with therapists, who state that an optimal tradeoff between safety of the patient and physical manual balance assistance by the therapist is critical. When therapists provide assistance too soon, patients might not learn from their mistakes as imbalance is already corrected by the therapist before it is noticed by the patient. On the contrary, when therapists provide assistance too late, more corrective force is needed to stabilize the patient, thereby creating a possibly dangerous situation in which a therapist is not able to prevent the patient from falling. It has been shown that such (sensory) feedback is important in the learning process of patients [5, 6], especially when the patient is able to link this information to his/her body movements [7].

Even though gait training was found to be effective for stroke survivors in terms of regaining functional independence [8, 9], the one-on-one contact with the patient and the constant need for supervision makes this type of therapy time consuming, labor intensive and expensive in terms of healthcare costs. The burden on health care is expected to increase even further in the near future, limiting rehabilitation time and potentially its effectiveness for patients. Patients benefit from, among other aspects, a training environment where sufficient training hours at a suitable training intensity can be made [10]. A solution that might positively contribute to this aspect is the use of (robotic) devices that support balance [11, 12], with which patients can undertake additional training hours in a self-administered training environment. The intuitive and effective training method of therapists, and their complex integration of knowledge of the patient's abilities might be of great importance in the acceptance and effectiveness of such a device. Therefore, a first step in designing such a particular training device is to investigate this complex behavior and the possibilities to convert this information into a robotic device. Previous work by Galvez et al. was performed with a similar goal in mind [13]. The study intended to quantify and analyze the interaction forces between the physical therapist and the patient's hips and legs, while performing gait training that required continuous support by more than one therapist. However, no quantitative data is currently available that describes how a single therapist provides intermittent manual balance assistance to patients that are able

to walk for short distances, nor is data available that describes when therapists intuitively decide that patients need support.

Therapeutic balance-assisting forces could be provided at many locations on the body. Since no data is available on this, observations during training sessions by the authors and by personal communication with therapists have identified that the iliac crest is a preferred point of contact. Possibly as this allows accurate control of the center of mass (COM), an important parameter when it comes to balance. Additionally, a large number of existing fall detection systems [14–18] reflect that a relation exists between acceleration signals measured at the COM and the likelihood for falls. These fall detection systems measure accelerations of the COM and process this data by the use of specific algorithms in order to determine if and when the subject fell. The algorithms were validated by comparison of the detected falls from the recorded data with the actual falls of the subjects during the measurements. The studies all showed the ability to distinguish true falling events from other activities based on acceleration data, and a sensitivity > 80% and specificity of 100% was shown by Mathie et al. [17]. COM accelerations therefore seem to be highly related to falls. Other fall detection systems exist that use acceleration data of different body parts (i.e. trunk, thigh, head), but Kangas et al. [19] found that measurements from the waist and head were more useful for fall detection compared to the other body parts.

Predicting the intuitive and complex behavior of therapists in providing balance assistance logically depends on many more aspects than is the case in the predication of falls. Yet, given the relation between COM acceleration and falls as described above and the pelvis as the preferred place of therapists to provide balance assistance, we assume that a change in the acceleration of the patient's COM plays an important role in the decision of therapists to provide balance assistance. Although it might not capture all the moments in time at which balance assistance takes place, it is a first step in the development of the previously mentioned robotic training device. This paper therefore aims to develop an algorithm that predicts the timing of therapeutic balance assistance during overground walking, based on the accelerations of the patient's sacrum. Note that, in contrast to existing fall detection algorithms, the developed algorithm aims at detecting events of therapeutic balance assistance rather than to detect actual falls of the subjects. By comparing the predicted events of physical balance assistance with the actual therapeutic events, a measure is provided that validates the predictive abilities of the algorithm. Moreover, in order to provide insight into how therapists support patients during gait training, this paper will be the first to provide a step towards quantifying therapeutic balance-assisting forces. It will quantify balance assistance in terms of the anatomical planes in which force is provided, the duration of the force and the amount of force necessary to regain or retain the balance of the patient during overground walking. Aside from the general insight that this information gives into the behavior of therapist during gait training sessions, both the algorithm as well as the quantitative data can serve as a first step in setting up technical requirements for robotic balance gait training devices.

5.2 Method

5.2.1 Subjects

Eight male stroke survivors (age = 58 ± 6 years, height = 1.82 ± 0.06 m, mass = 84 ± 7.2 kg) were recruited for the overground walking task. Subjects were both recruited from Roessingh Rehabilitation Hospital in Enschede, The Netherlands, and physiotherapy practice PMI Rembrandt in Veenendaal, The Netherlands. Subjects were included if they met the following inclusion criteria: (1) Stroke survivor (either (sub-)acute or chronic); (2) Able to walk for a short distance (10 meters) without a walking aid, but with physical supervision of a therapist; (3) Able to understand and execute instructions of the walking tasks.

This study was approved by the local Medical Ethical Institutional Review Board and methods conformed to the Declaration of Helsinki. All subjects gave written informed consent prior to participation.

5.2.2 Equipment

Subjects were instrumented with two Force/Torque sensors and one inertial measurement unit (see Figure 1).

To capture the balance-assisting force characteristics of therapists, the two wired 6 Degree of Freedom Force/Torque sensors (Mini45 F/T sensor, ATI Automation Industrial, Apex, NC, USA) were fixated on the left and right side of a belt that was worn around the pelvis of the patient (Figure 1). Specifically, the sensors were positioned at the location of the iliac crest. Prior to the start of measurement trials, interviews were conducted with the patient's physical therapist and entire physical therapy treatment sessions were observed during which gait training sessions occurred. These sessions have revealed that the iliac crest is the preferred location to provide balance assistance to the patient. The belt with the sensors were oriented such that walking direction of the patient equaled the x axis of the sensor for each subject. The force sensors were connected to a power supply that was connected to a Data Acquisition (DAQ) card (National Instruments, Austin, TX, USA) in order to acquire the signals in Simulink (MathWorks, Natick, MA, USA).

A wireless inertial magnetic measurement unit (IMU) (MTw sensor, Xsens Technologies B.V., Enschede, the Netherlands), consisting of an accelerometer, gyroscope and magnetometer, was positioned at the sacrum to capture sacral motion throughout the measurement. The accelerometer signal (60 Hz) was specifically measured at the sacrum as this location closely resembles COM kinematics [20]. The IMU was mounted with adhesive skin tape to the lower back of the subject during overground walking training. Data recording was performed through MT Manager software (Xsens Technologies B.V., Enschede, the Netherlands).

To synchronize both measurement systems, a switch was manually pressed on one of the force sensors (leading to a peak in this data-signal), at the same time triggering the IMU

software to start recording. Force data was cut afterwards in MATLAB (MathWorks, Natick, MA, USA), based on this synchronization peak.

Figure 1: (Schematic) representation of the measurement systems on the body. Left: Measurement systems positioned at the body: Force/Torque sensors were (with a hip belt) positioned at both sides of the hips (black blocks). One IMU sensor (grey block) was positioned with adhesive skin tape to the sacrum of the subject. Right: Positioning of the Force/Torque sensor to the body.

5.2.3 Protocol

Measurements took place during a regular gait training session, and lasted no longer than 30 minutes for each patient. Patients were asked to arrive 15 minutes prior to the start of the measurement in order to mount the sensors correctly onto the body. Subjects walked at a self-selected walking speed and a physical therapist walked behind the patient to supervise and physically support the patient when necessary. Therapists were instructed to correct the balance of the patients at the location of the force sensors (at the iliac crest). Therapists did not have their hands on the patients at times other than when corrective forces were being applied.

Similar to conventional gait training sessions, subjects were asked to slalom (zigzag movement) around cones and walk in a straight line during the measurements, in order to represent training of ADL tasks. Patients that only needed few therapeutic balance-assisting force corrections were given an additional cognitive task (e.g. count down in increments of three) in order to provoke more postural instabilities during the measurements. Tasks were repeated in a random order until the end of the training time was reached, or until the patient was tired. Training took place on a level ground walkway of approximately 10m with a chair on both sides so that patients could rest in between the measurements (see Figure 2). As the force sensors were connected with wires, a trolley was used to guide the wires and transport the laptop alongside the patient.

When therapists provided corrective forces at a location other than the force sensors (e.g. at the shoulder or the trunk of the patient), no force characteristics could be captured

Figure 2: Schematic representation of the measurement set-up. Chairs were positioned 10 m from each other. In between the chairs were five cones, such that patients had to walk around them. Therapist walked behind the subject and only provided assistance when the patients was unstable.

by the force sensors. However, the moment in time of these balance-assisting events was still captured, as a timestamp was manually created in Simulink by one of the researchers that logged the time and the location of these events.

In order to obtain patient characteristics, Berg Balance Scale (BBS), Functional Ambulation Category (FAC), ten meter walking test (10MWT), Motricity Index (MI) and Dynamic Gait Index (DGI) were performed within one week after the measurement by the treating physical therapist of the patient.

5.2.4 Data analysis

5.2.4.1 Balance assisting force characteristics based on the force sensor data

Force data was filtered over all three axes with a 2nd order Butterworth, low-pass filter with a cutoff frequency of 5 Hz. Baseline offset was removed during a static condition prior to the start of each measurement and the resultant force $\sqrt{x^2 + y^2 + z^2}$ between the sensor that was mounted on the left and right side of the body was calculated over all axes separately. For all measurement trials, the start and stop time of each individual therapeutic balance-assisting event was manually selected. All measurements were checked and synchronized in correspondence with video recordings that were taken during the measurements. Subsequently, the maximal force and the duration of the therapeutic corrective forces were calculated for each event individually. Maximal force was presented as the absolute value, irrespective of the sign (positive or negative) of the correction applied.

5.2.4.2 Predicting the timing of therapeutic balance assistance based on acceleration data of the sacrum

Accelerometer data of the sacral IMU was processed in MATLAB, for each subject and measurement trial individually. The resultant acceleration signal of the X, Y and Z axes of the sensor was used for analysis, making the data independent of sensor orientation on the sacrum. The mean resultant value was subtracted from the data, such that gravitational acceleration was removed and free acceleration data remained. The periods in time where

a patient was not moving before the start and after the stop of each measurement were cut off, leaving only the actual movement data to be analyzed.

The algorithm that was built is based on the assumption that deviations in the sacral signal (for instance: relatively long periods in time where high accelerations in the signal are visible) represent the moments in time where therapeutic balance assistance takes place. Outlier detection was used to identify these time points. Interquartile ranges (IQR) and individual quartiles (e.g. Q1 - Q4) were calculated on the remaining dataset and were used to define the threshold for outlier detection of each subject and measurement trial individually [21]. Additionally, a moving average window (' δ ', seconds) was applied to calculate the average value of the data within a specified window width. A visual representation of the method used is presented in Figure 3. A threshold was set at $Q3 + \alpha \cdot IQR$ according to Tukey's method [21], where ' α ' was a factor that determined the height of the threshold. Each time an averaged value was above the defined threshold the data was marked as an outlier. The factor and the width of the moving average window were varied in order to retrospectively determine the most optimal set of parameters that lead to the best algorithm for outlier detection: ' α ' was varied between the constants 0.5 and 3.0 in steps of 0.1 and ' δ ' was varied between 0.5 and 3 seconds in steps of 0.01 seconds. All possible combinations between both parameters were used.

Figure 3: Visual representation of the algorithm. A moving average filter moves along the original signal (blue line), calculating an average value (red dot) of the data points within the window (red square). The red line represents the result of this. Each time the red line was above the pre-set threshold value, the moment in time was marked as an outlier.

The time points that were identified as actual events of therapeutic balance assistance (captured by both the force sensors as well as other locations on the body) were loaded into the acceleration dataset and compared with the outliers that were detected by the algorithm. Each outlier was classified as a True Positive (TP; both therapist and algorithm classify point in time as an event of balance assistance), False Negative (FN; therapist provides assistance, but algorithm does not find outlier) or False Positive (FP; therapist does not provide assistance, but algorithm finds outlier). Additionally, the Positive Predictive Value ($PPV = TP / (TP + FP) \cdot 100$) and True Positive Rate ($TPR = TP / (TP + FN) \cdot 100$) were calculated for each patient individually and on a group level, indicating the

ability of the algorithm to identify the events of balance assistance correctly.

Optimal settings were defined as the best combination of ' α ' and ' δ ', leading to the highest score of PPV and TPR at the same time. Optimal settings were determined by using the data of four, randomly selected subjects. The data of the remaining four subjects were used to validate these settings, and to test whether these settings still resulted in high PPV and TPR values for other subjects.

5.3 Results

Eight measurement sets were performed with the included patients. None of the subjects fell during the measurements. A total of seven different therapists provided physical balance assistance during the training sessions. Patient characteristics as well as scores on clinical measures are presented in Table 1.

5.3.1 Balance assisting force characteristics based on the force sensor data

Characteristics of the provided therapeutic correction forces are presented in Table 2. Median number of balance-assisting events during the total measurement set of each patient was 3 times (0.6) (median (IQR)). Median distance walked during this time span was 35m (21) (11.5 meters (18.3) walked per event of balance assistance, median (IQR)).

Corrective forces were mainly provided over the medio-lateral (ML) axis (frontal plane): Roughly 80% of the total force that was used is provided in this plane, representing 2% of the average body weight of the subjects. Around 10% ($\pm 0.2\%$ of the patient's body weight) of the total force was provided over both the anterior-posterior (AP) and superior-inferior (SI) axes. Seventy-eight percent of the total amount of events of balance assistance was located at the side of the pelvis (either on one or on both force sensors on the iliac crest). Other locations that were used, were the trunk and shoulder of the patient. The median duration of therapeutic assistance was typically 1.1s (0.6) and the median impulse per event over the ML-axis was typically 9.4Ns (8.2).

Typical examples of therapeutic balance-assisting force profiles are shown in Figure 4. Here, two hands have been used for the application of corrective force. The left hand exerts the largest amount of force on the body. The right hand of the therapist exerts a smaller amount of force on the body. It is used to provide stability to the pelvis of the subject and it helps the therapist in controlling the application and release of the corrective forces.

Table 1: Patient characteristics and measured walking speed during the trials.

Patient ID	Gender	Age	Weight	Therapist	ID	BBS	FAC	10MWT	MI	(MI leg)	DGI	Walking speed during trials
(#)	(M/F)	(yrs)	(kg)	(#)	(#)	(pnts)	(pnts)	(m/s)	(pnts)	(pnts)	(pnts)	(m/s)
1	M	60	81	1	1	41	3	0.17	51	42	12	0.22
2	M	56	91	1	1	38	3	0.46	42	28	10	0.38
3	M	64	76	2	2	32	3	0.31	81	42	14	0.31
4	M	54	80	3	3	46	4	0.85	107	53	-	0.54
5	M	58	82	4	4	47	4	0.47	62	34	13	0.33
6	M	68	85	5	5	34	3	0.27	77	48	-	0.28
7	M	58	79	6	6	44	2	0.4	132	57	16	0.2
8	M	49	98	7	7	46	4	0.4	153	83	12	0.3
Median	-	-	82	-	-	43	3	0.4	79	45	13	0.31
(IQR)	-	-	7	-	-	9	1	0.16	54	14	1.8	0.07

Table 2: Characteristics of therapeutic balance assistance during measurement trials.

Patient ID	# of balance assistance	Travelled distance (m)	Travelled distance / event (m)	Mean peak force / event (N)		Mean peak force / event (% body weight)		Mean peak force / event (N)	Mean peak force / event (% body weight)	Mean peak force / event (N)	Mean peak force / event (% body weight)	Mean Impulse (Ns)	Location of event / number of sensors hit		
				(ML-axis)	(N)	(% body weight)	(SI-axis)	(N)	(% body weight)	(AP-axis)	(N)	(Ns)	Both sensors	One Sensor	Other
1	6	28	4.7	12.3	1.5	0.3	2.2	0.3	1.2	0.2	0.7	2.5	4	1	1
2	3	42	14.0	13.6	1.5	0.2	1.9	0.2	1.3	0.1	1.0	6.3	1	1	1
3	3	28	9.0	28.9	3.8	0.7	5.1	0.7	2.2	0.3	1.0	13.9	0	1	2
4	1	21	21.0	-	-	-	-	-	-	-	-	-	0	0	1
5	1	63	63.0	-	-	-	-	-	-	-	-	-	0	0	1
6	7	42	6.0	18.1	2.1	0.2	1.4	0.2	2.2	0.3	1.7	12.5	7	0	0
7	3	15	5.0	6.5	0.8	0.2	1.8	0.2	4.0	0.5	1.2	4.2	1	2	0
8	3	100	33.0	25.5	2.6	0.1	1.1	0.1	2.4	0.2	1.9	13.1	0	3	0
Median (IQR)	3 (0.6)	35 (21)	11.7 (18.3)	15.9 (11)	1.8 (1.0)	0.2 (0.1)	1.9 (0.7)	0.2 (0.1)	2.2 (0.8)	0.3 (0.1)	1.1 (0.6)	9.4 (8.2)	13* (8*)	8* (-)	6* (-)

ML = medio-lateral, SI = superior-inferior, AP = anterior-posterior.

Missing data is indicated by an "-"; therapists did not provide assistance at the location of the force sensors in these cases. Characteristics of these events could therefore not be calculated.

* Total amount of hits per therapeutic balance assisting location.

Figure 4: Typical example of a force profile over time. Two hands were used during this event. Force profiles of both the left and right hand have been presented in the figure, as well as the resultant force between both hands. A positive value on the y-axis indicates a pushing force by the therapist. In this particular example, the subject is pushed towards the right.

5.3.2 Predicting the timing of therapeutic balance assistance based on acceleration data of the sacrum

Based on four randomly selected subjects (patient ID = 1, 4, 5 and 7), there were several combinations of window width ' δ ' and factor ' α ' that lead to similar PPV and TPR score. In all cases, ' δ ' was 2.5 seconds and ' α ' could be chosen as a constant value between 0.8 and 1.3, all leading to the same PPV and TPR values. With these algorithm settings, a PPV of 73% and a TPR of 80% was obtained on a group level. Individual PPV and TPR scores ranged between 67% and 100%.

The algorithm was validated by applying these settings (with ' α ' chosen as a constant of 1.0) to the remaining four subjects (patient ID = 2, 3, 6, 8). PPV and TPR values increased in this case to 87% and 81% respectively, on a group level. PPV and TPR scores of the individual subjects remained between 67% and 100%. Both the scores on an individual level as well as on a group level are presented in Table 3, for both groups.

Two typical examples of an acceleration signal over time are shown in which all balance-assisting events were correctly classified (Figure 5, left) or in which one of two events was not detected (Figure 5, right). Note that the events that were not detected, the therapeutic assistance force was applied at the shoulder.

Table 3: Left: Individual and group scores of subjects that were randomly selected to be in the development group of the algorithm (left) and the validation group of the algorithm (right). Scores are presented as the summed total of all measurements trials within a patient.

Patient ID (#)	TP (#)	FN (#)	FP (#)	PPV (%)	TPR (%)
1	4	2	1	80	67
4	1	0	0	100	100
5	1	0	0	100	100
7	2	1	1	67	67
Group total	8	3	2	73	80

Patient ID (#)	TP (#)	FN (#)	FP (#)	PPV (%)	TPR (%)
2	2	1	1	67	67
3	3	0	0	100	100
6	5	2	0	100	71
8	3	0	1	75	100
Group total	13	3	2	87	81

Figure 5: Typical examples of acceleration signals over time (blue). With the events of therapeutic assistance marked in green and the outliers detected by the algorithm marked with an asterisk. Note that the algorithm calculates average values of the data (by using the moving average filter) and compares them with the specified threshold. Therefore, several high peaks of the original sacral signal that are shown in blue are not detected by the algorithm as events of balance assistance, as they do not last long enough to result in averaged values that are high enough to exceed the threshold. Characteristics of the corrective forces are as follows: Left graph: Event #1 (TP) / #2 (TP) / #3 (TP), Peak Force 8.1 N / 6.5 N / 5.1 N, Location: Iliac Crest / Iliac Crest / Iliac Crest, Duration: 0.42 s / 1.3 s / 1.2 s. Right graph: Event #1 (FN) / #2 (TP), Peak Force: unknown / 48 N, Location: Shoulder / Iliac Crest, Duration: unknown / 0.57 s.

5.4 Discussion

This paper is the first to present insights into the behavior of therapists regarding manual physical balance assistance to stroke survivors during gait training in terms of force characteristics and prediction of the timing. We aimed to provide a quantitative dataset on the balance-assisting force characteristics and provide insight in the timing of these events, as such information is of importance in the technical development of (robotic) devices that support balance. As therapists integrate knowledge on many aspects of the patient, the results of this paper should be interpreted as a first step towards the analysis of this complex behavior. Regarding the timing of the balance-assisting events, we developed an algorithm that is able to predict therapeutic events, solely based on the acceleration signal of the patient's sacrum during a gait training session. Prediction scores remain high, even when different therapists and patients were analyzed with the same algorithm settings. Additionally, the results that were shown in the quantitative dataset imply that the therapists in this study in general use similar balance-assisting strategies while physically supporting the patients. For instance, correction forces were relatively low in all cases, corrective forces were mainly provided over the ML axis (80%) and the spread in duration was rather small. The quantitative results in this paper might best be interpreted as guide lines, rather than being fixed numbers, especially as this dataset is based on only eight subjects.

The complex clinical decision-making process of therapist in determining whether or not to apply a balance-assisting force, might explain PPV and TPR scores that are lower than 100%, indicating that the algorithm was not able to identify all therapeutic events correctly. Therapists integrate information such as the patient's muscle strength, reaction times, fatigue state and fall history in order to determine whether or not to provide balance assistance. Although the developed algorithm in our study already shows high prediction scores, a more elaborated or altered measurement set-up and algorithm might be needed to better approach the complex clinical decision-making process of therapists. Studies that focus on the prediction of falls, such as in the study by Li et al. [22] or Sim et al. [23] report PPV rates of 80% to 90%, and show that by adding more accelerometers or additional gyroscope sensors to the body (e.g. head or waist) the performance of the algorithm could be further increased. It was shown by, among others, Li et al. [22] and Bourke et al. [24] that performance of fall detection systems can be even further increased when adding gyroscope data to the algorithm, supplementary to acceleration data. This might specifically be beneficial when a large variety of ADL tasks need to be classified during gait training [25, 26] and an adequate distinction between the body movements is needed.

Although therapists aim to treat patients with the best possible care, there could have been situations in which the therapist was too careful and therapeutic balance assistance was provided at times when this was not actually needed. These situations could have led to FN scores at the side of the algorithm as no deviations would then be visible in the measured signal. This example indicates the complexity in interpreting FN and FP scores. For (robotic) devices, both FN as well as FP values should be as low as possible: missing a critical balance-assisting event at the side of the patient could lead to an actual fall when no safety harness is present, whereas the system might not measure up to the principles in

error-based training when assistance is provided too soon, thereby letting the patient not experience the boundaries of his abilities. By changing the algorithm settings (α and δ) that are presented in this study, one can adapt the error-based training component: allow more or less movement freedom, depending on the abilities of the patient. It should be emphasized that the present research and the developed algorithm serves as a first step towards this process. No (robotic) devices that focus on balance assistance are known that use a control mechanism that tries to mimic the complex behavior of therapist, whereas this might be of great importance in the acceptance and effectiveness of such a device. As a first step in this development, the developed algorithm and the used measurement set-up were kept as simple and intuitive as possible.

Even though the algorithm proves to have a good ability to predict therapeutic balance-assisting events correctly, it does not directly validate that sacral acceleration is wholly responsible for the therapist balance-assisting responses. In fact, a different contact location was reported in 22% of the corrections, even though therapists were specifically instructed to aim for the force sensors on the iliac crest. Beside the argument that this could be just common practice of therapists, the typical example of Figure 5 demonstrates that a different trigger (arm sway of the patient in order to restore balance) other than sacral accelerations, causes the therapist to apply corrective forces to the body. Although with the use of the present measurement setup it was attempted to capture a conventional gait training session as realistically as possible, restrictions in the used measurement set-up have limited the recording of the events that were not located on the force sensors. Consequently, these events were not taken into account in calculating median values. Yet, the used measurement set-up did not affect the number of balance-assisting events in any way, nor did it affect the timing of the events. Even though the use of force sensors logically deviates from a conventional clinical setting, none of the therapists indicated that they were forced to balance the patient at a location at which it was inconvenient for them. It was therefore expected that regarding the specific location of providing balance assistance, the measurement set-up did not significantly affect the behavior of the therapists. Logically, other methods could have been chosen to capture the corrective forces by therapists. For instance the use of force gloves that would allow the capturing of all therapeutic forces, regardless of the contact location on the body. However, most known force gloves [27, 28] are still in the development stage and/or have a limited amount of sensors on the glove, thereby introducing the risk that not all contact force between therapist and patient would be measured by the glove. Additionally, using these gloves would introduce the risk of having only one measurement from a specific body location, thereby restricting the ability to generalize the results. As the main goal of this manuscript was to provide first insights into the behavior of therapists, we have chosen to focus specifically on one location on the body at this stage of the research. Additionally, thickness of the force sensor prevents any contact between the therapist's hand and the patient's body: thereby ensuring that all force is captured by the force sensor.

Furthermore, in 38% of all balance-assisting events located at the iliac crest, the hands of the therapist hit only one sensor, even though two hands were used for the balance-assisting event in these cases. This affected the calculation of the resultant force. It caused an undershoot of the resultant force in some cases and overshoot in others. Yet, it is believed that the presented median corrective force is still a good representation of the average force profile that is used during a gait training session.

5.4.1 Limitations

Although this study was conducted with care, a couple of limitations can be identified. First of all, it should be noted that a certain inaccuracy exists in the time synchronization between both measurement systems. Both measurement systems were synchronized by pressing a switch (triggering the IMU software to start recording) against one of the force sensors (leading to a peak value in this data signal). Force data was cut afterwards in MATLAB, based on this synchronization peak. Even though it was intended by the researchers to shorten the duration of the peak value as much as possible, a small inaccuracy remained in the time synchronization between both systems. Secondly, a delay might exist between the instability of the subject and the timing of the balance-assisting event of the therapist, i.e. between a peak in the recorded acceleration data and a peak in the recorded force data. Both peaks do not occur exactly at the same time, mainly due to the reaction time of the therapist. Yet, it was assumed that the total time inaccuracy between both systems was no more than ± 0.5 seconds: When the actual balance-assisting event and the detected outlier were a maximum of ± 0.5 seconds apart, the outlier was classified as a TP.

Furthermore, the algorithm is based on data of four patients and four therapists, and is validated with data of the other four patients and three therapists. Positive Predictive Values and True Positive Rates remain high in the validation process, even though measurements of different subjects and patients were then included. This positively suggests that the algorithm is valid for a random group of therapists and/or patients, rather than being restricted to the measured group of subjects. However, it must be kept in mind that the optimal parameter settings (' α ' and ' δ ') that determined PPV and TPR scores, were in both cases obtained by using a group of (four) subjects with rather homogeneous patient characteristics. These setting might not be the most optimal settings when focusing on individual subjects, or even a single measurement trial. This is confirmed by the finding that for individual patients, PPV and TPR scores vary between 67% and 100%. Therefore, the present research only functions as a first step in the process of capturing the complex behavior of therapists.

5.4.2 Future work

The algorithm that was developed and the results of the balance-assisting force characteristics provide a good first impression of the requirements that can be set to (robotic) devices that support balance. Future work should first of all increase the number of subjects to further specify these requirements. A larger and more heterogeneous group of FAC 2/3 patients should be included for these measurements and the patients should perform additional tasks during the measurements: step over objects, 180 degree turns, variable step length, etcetera.

Furthermore, increasing the number of subjects, therapists and measurements would allow to specify inter-therapist variability. Although the quantitative results in this study imply that therapists in general use similar balance-assisting strategies, specific details on this matter might be of interest while developing robotic training devices, for instance in relation to specific walking tasks [13]. Although it must be kept in mind that force

characteristics might differ for each individual subject, training session and even for each intervention, increasing the number of subjects might enable the classification of balance-assisting events, thereby provide more insight into the aspect of inter-therapeutic variability.

In order to capture additional aspects of the complex behavior of therapists, it might be of interest to focus on verbal and sensory cues of therapists, to obtain characteristics of other body locations (such as shoulder or trunk), and to specify the directions of the balance assistance in relation to the gait cycle. For instance, it has now been observed from video analysis, in correspondence with the recorded data, that patients mainly fall sideways or to the back, and the therapist consequently pushes the patient upwards, to the front and over the medio-lateral axis. It might be of interest to study the ML balance assistance in relation to the gait cycle at the moment of intervening, and in relation to the affected side of the subject.

5.5 Conclusion

The goal of this study was to present a quantitative dataset on therapeutic balance assistance and predict the timing of these events. A threshold-based algorithm was developed that was able to predict timing of therapeutic balance assistance events with a Positive Predictive Value of 87% and a True Positive Rate of 81%. Quantitative data showed that patients on average received a balance-assisting corrective force every 11.5 meters and that instability mainly occurred in the frontal plane. They received force corrections by the therapists of around 2% of their total body weight, with a median duration of 1.1 s and a median impulse of 9.4 Ns. This study represents the first step in the analysis of complex behavior of physical therapists during gait training and this information can serve as input for the development of (robotic) devices that support balance.

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Chapter 6

TIBAR:
Therapist Inspired Balance Assisting Robot.
Development and evaluation of a balance
supporting robot for gait training

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Abstract

Background: Stroke survivors classified with a Functional Ambulation Category of 3 typically are able to ambulate on level surfaces but intermittently require balance assistance by physical therapists. Physical therapists focus on improving the balancing abilities of patients during conventional gait training by providing balance assistance to the patient's body. Although this method is found to be effective, patients benefit from an increased training volume. The use of a robotic training device that supports balance and that can be used in a self-administered way positively contributes to this need. This paper describes the development of the TIBAR (Therapist Inspired Balance Assisting Robot), a device that is inspired by the behavior of therapists in terms of providing support for balance recovery. Additionally, it will evaluate the behavior of the system in relation to conventional gait training.

Methods: The TIBAR is an admittance controlled system that is connected to the pelvis of the patient. It has low reflected inertia and the timing and amount of support is based on the patient's position of the center of mass in relation to a virtual circle that is created in the transversal plane around the body. Five stroke survivors, classified with a median FAC score of 3, were included in the study. Patients were asked to walk a circuit on a treadmill, while connected to the TIBAR. Balance assistance was solely provided by the TIBAR. Outcome measures to evaluate the system were (1) balance assisting characteristics in terms of peak force, duration, impulse and the plane in which the assistance took place; (2) timing of the balance assisting events in relation to timing of therapists; and (3) user acceptance.

Results: Balance assisting force characteristics of the TIBAR were comparable to therapeutic corrective forces, in terms of peak force (1% of body weight) and axis over which assistance took place (ML-axis). Duration and impulse of the assistance by the TIBAR was shorter (0.2 s and 0.7 Ns, respectively), but the number of balance assisting events was 17-29% higher when assistance was applied by the TIBAR compared to therapists. Subjects were able to move freely over the treadmill while performing a circuit training. User acceptance was rated as 'Good'.

Conclusions: This paper describes the development and evaluation of the first prototype of TIBAR. First results on the evaluation of this system show promising results that indicate the potential of the system. Future work should investigate the possibilities of extrapolating the results to other levels of stroke survivors and other patient groups.

6.1 Background

Stroke survivors that are classified with a Functional Ambulation Category (FAC) of 2/3 typically are able to ambulate on level surfaces, but intermittently require manual contact of a physical therapist to assist their balance during walking [1]. Patients are thus able to move freely, but will only receive balance assistance and thus experience support when they are not able to keep themselves upright [2]. Therapists integrate knowledge on patient specific abilities to determine if and when balance assistance is needed, such as muscle strength, fall history, fatigue, coordination characteristics and sensory loss. Previous work by Haarman et al. [3] identified that therapeutic balance assistance was often applied to the pelvic area and mainly over the medio-lateral (ML) axis during these training session. Pollock et al. [4] demonstrated that such a training set-up was found to be effective for stroke survivors; not only as it challenges patients to actively participate in the training [5], but also since it enables them to receive training in an error-based way [6, 7]. Error-based training uses the process of trial-and-error in (re)learning motor tasks such that patients learn the limitations of their balancing abilities. In order for therapists to provide patients with the correct information regarding their abilities and limitations, therapist should be able to distinguish between pelvic motions that occur during pathological gait, such as hemiplegia or hip-hiking, situations in which patients are able to keep themselves balanced and unsafe situations in which support is needed [8]. Even though therapeutic balance assistance typically has a peak force of only 2% of the patient's body weight [3], the need for continuous supervision and the one-on-one contact between patient and therapist make this type of therapy time consuming. As patients specifically benefit from a training environment where sufficient training hours at a suitable training intensity can be made [9], this possibly limits the rehabilitation effectiveness from patients. Moreover, as our population is aging [10] and consequently the number of patients is increasing [11], an even higher burden is put on the training volume of patients in the near future. A solution which increases the training volume of patients is the use of a robotic training device that can be used supplementary to conventional gait training sessions [12, 13] in a self-administered way. When such a device provides balance assistance to patients, similar as is done during conventional gait training, the device can provide patients with similar support as they experience during conventional gait training sessions. Using a robotic device would therefore increase the training volume while reducing the therapist load [14, 15].

A fair number of training devices have already been developed of which a small number is currently commercially available. Devices such as Lokomat (Hocoma) [14], Lopes/Lopes II [16, 17] or Gait Master [18] primarily focus on patient groups with low walking ability (FAC 0/1), thereby requiring constant support of one or two therapists during conventional therapy. The mere focus in these training sessions lies on relearning gait patterns. Similar to conventional therapy of patients with a FAC score > 1, we wish to allow more variability in pelvis movements [19]. Kineassist (Kinea Design) and FLOAT (Lutz Medical Engineering GmbH) are examples of training systems that allow such movements. Both systems move with a patient overground, allow challenging situations to be trained, at the same time allow as much active participation of the patient as possible. Both systems primarily focus on the safety of the patient, rather than focus on balance recovery when an instable situation is detected. Two systems which have incorporated balance recovery in their

design are a ‘dynamic balance training device’ [20] and the E-go [21]. Both systems provide horizontal forces to the patient’s pelvic area in order to keep him upright and are composed of passive constructions. The passive constructions that are used in the ‘dynamic balance training device’ restrict the patient in utilizing the full walking area of the treadmill and thus only train straight line walking. While the latter system neutralizes this aspect by using wheels to move with the patient overground, this particular system does not aim to be used in a self-administered way, but aims to reduce the amount of therapists that is needed during a training session. The same research group has recently evolved the E-go into an actuated, admittance controlled device [22]. However, this system is currently only being used as a perturbation device rather than a device that assists in balance.

All devices aim to lower the strain on therapists and have incorporated aspects of motor (re)learning in their controller design. However, no device is currently available that primarily aims to provide intensive training to stroke survivors with FAC 2/3, focused on balance recovery. We aimed to develop a system that has high potential for acceptance in a clinical setting, that is easy to use and small in physical size. Since the method itself that is applied by therapists does not ask for a substitution, we aimed to develop a device that mimics therapeutic behavior as much as possible. We therefore not only need to implement aspects such as error-based training or active participation of the patient, in addition we need to match the balance recovery force characteristics of therapists to those of the system, in terms of force, duration and impulse. Furthermore, the system should allow challenging situations to be trained, like circuit walking as this is part of conventional therapy [23, 24]. The system should match conventional gait training as much as possible in terms of the ability to train context specific and functionally [24–26], such that patients can transfer training effects into tasks of daily living. Similar to conventional therapy, the system should not obstruct the movements of the user in any way: it should have low reflected inertia [27] and no noticeable physical presence, i.e. not obstruct the arm sway or the vision of the patient on the treadmill. Last, balance assistance by the system should be experienced as comfortable by the patients and the system should not intimidate the patient.

This paper will describe the development and evaluation of a first prototype of this system: the TIBAR (Therapist Inspired Balance Assisting Robot). An experimental protocol is performed with the system in which five stroke survivors walked on a treadmill while connected to the TIBAR. In order to evaluate whether the system meets the requirements, we will provide details about the balance assisting characteristics that are provided by the system and we will evaluate whether the system is able to time its assistance similar to the timing of therapist. Furthermore, we will test the user acceptance of this system.

6.2 Method

6.2.1 Subjects

Five stroke survivors (age = 66 ± 13 years, height = 1.72 ± 0.07 m, mass = 78 ± 15 kg) were recruited for treadmill gait training. Subjects were recruited from physiotherapy practice PMI Rembrandt, Veenendaal, The Netherlands. Subjects were included if they met the

following inclusion criteria: (1) Stroke survivor (either (sub-)acute or chronic); (2) Able to walk for (short) distances on a treadmill without a walking aid, but with physical supervision of a therapist; (3) Able to understand and execute instructions of the walking tasks. This study was approved by the local Medical Ethical Institutional Review Board and methods conformed to the Declaration of Helsinki. All subjects gave written informed consent prior to participation.

6.2.2 Design description

The TIBAR (Figure 1) that was developed consisted of two hardware components: (1) a HapticMASTER (MOOG B.V., Nieuw Vennep, The Netherlands); and (2) a remote center mechanism. A controller design was developed to assess balance and determine the appropriate amount of balance assisting force that is needed for balance recovery.

6.2.2.1 HapticMASTER

The HapticMASTER (HM) is a commercially available, admittance controlled, haptic robot that can generate high forces and velocities [28]. It was used as a measurement device to assess balance and provide the subject with the appropriate amount of corrective force. Admittance controlled devices typically use the paradigm of ‘force in, displacement out’, thereby enabling production of high stiffness and a minimal friction component. The HM scores high on force, force depth, position resolution and haptic resolution [28], which makes the system extremely suitable for use in the TIBAR, in which the movements of the user should not be obstructed when no support is needed, but should be adequately corrected when this is needed. The HM has an end-effector with one load cell, positioned at the end of the horizontal robot arm that can measure 3 Degrees-of-Freedom (DoF).

6.2.2.2 Remote center mechanism

The remote center mechanism was used to connect the end-effector of the HM to the pelvis of the subject. This location was chosen, as previous work has indicated this location as the preferred contact point between therapist and patient [3]. The remote center mechanism allows movements of the total body’s COM over both the Anterior-Posterior (AP) and the Medio-Lateral (ML) axis to be directly translated into movements of the HM. Forces presented by the HM therefore directly affect the position of the body, see Figure 1.

Aluminum tubes are used to keep the mass as low as possible since this has to be carried by the subject. Total mass is 0.9 kg. The admittance control algorithm of the HM makes the end-effector of the machine behave like a zero-friction, floating mass of 3 kg. The total apparent mass that the system presents to the user consists of this virtual mass, plus the physical mass of the remote center mechanism (0.9 kg). The system therefore adds an apparent inertial mass (but not weight) of 3.9 kg to the patient’s pelvis. A study on the effects of inertia, showed that adding 5.3 kg of inertia to the pelvis in medial lateral direction had a negligible effect on gait kinematics [27].

Figure 1: TIBAR. Composed of the HapticMASTER (white horizontal beam), and the remote center mechanism (silver) that is attached to the end-effector of the HapticMASTER. The end-points of the remote center mechanism are attached to the pelvic belt that goes around the pelvis of the subject. Movements of the COM reflect movement in the HapticMASTER.

6.2.2.3 Controller design

Previous work by Haarman et al. [3] has led to important implications regarding the controller design of the TIBAR. Although the algorithm that controls the actions of the TIBAR is not a one-on-one copy of the algorithm that has been designed in this previous work, many of these implications have been incorporated into the controller design of the TIBAR. This work demonstrated for instance that timing of therapeutic balance assisting events could be predicted based on recorded data of the center of mass (COM) of the patient. It additionally indicated the need for only one sensor in predicting the timing of therapeutic behavior.

In the TIBAR, position data of the end-effector of the HM was real-time processed by D-Flow (software package by Motekforce Link, Amsterdam, The Netherlands) and represent the patient's COM movements. When patients move within their regular gait pattern, lateral movement trajectory of the COM spans about 4 cm during stance phase [29]. In order to prevent the TIBAR from intervening with the patients during their regular walking pattern, a virtual circle is created around the COM in the transversal plane, with a radius of 0.03m. Patients are able to move freely within this virtual circle, without being obstructed by the system. When patients move outside of the virtual circle, they experience corrective force in the form of spring stiffness, such that more force is provided when the COM moves further outside of the virtual circle. The stiffness of the spring is individually adjustable and is experimentally determined as approximately three times the weight of the subject per meter.

Similar to conventional treadmill gait training, patients must be able to span the entire treadmill width, therefore the position of the virtual circle was constantly updated (sample frequency = 300 Hz) such that it moved along with the COM over the treadmill. Since movements of the COM during regular gait show low accelerations [3], and are composed of low frequency components, the position of the virtual circle was updated with a low pass filter that did not interfere with the movements of the subject, according to formula (1.1)

$$p_{circle(i)} = \alpha \cdot p_{com(i)} + (1 - \alpha) \cdot p_{circle(i-1)} \quad (1.1)$$

With alpha being a dimensionless constant of the low-pass filter ($\alpha = 0.01$), defining the speed with which the virtual circle follows the COM over the treadmill. p_{circle} and p_{com} being the current or the previous position of the virtual circle and the COM, respectively.

Haarman et al. [3] additionally showed that the likelihood for therapeutic balance assisting events increased with increasing COM accelerations. The TIBAR is based on this information: when the COM moves at a high frequency, the position of the COM is moving faster than the low-pass filter can update the position of the virtual circle. As a result, the COM moves outside of the virtual circle and the patient experiences this as an balance assisting event by the system.

In critical situations where forces measured by the load cell of the HM exceed a threshold value, the low-pass filter stops updating the spring position and keeps it at a fixed position. It is then assumed that a subject is experiencing large perturbations. By keeping the spring at a fixed position, subjects gain more time to recover balance.

6.2.3 Protocol

Prior to the start of the measurement, subjects were positioned in a safety harness on the treadmill to determine comfortable walking speed under the supervision of their treating physical therapist. Subsequently, the TIBAR was connected to the patient by using the adjustable hip belt (Figure 2). Single trial time was 2-3 minutes, depending on the comfortable walking speed of the subject and was composed of regular (straight line) treadmill walking, and circuit walking: slalom and stepping over virtual obstacles that were projected with a beamer on the surface of the treadmill (C-Mill, Motekforce Link, Amsterdam, The Netherlands). This served, to provoke challenging situations and to test the ability of the system to span the entire treadmill-width. Physical support was primarily provided by the TIBAR. The therapist stood next to the subjects during the training sessions, but was instructed not to provide any physical support. Trials were repeated based on the fatigue level of the patient.

Patients in which tiredness levels were acceptable performed supplementary measurements that aimed to evaluate the timing of the balance assisting events of the TIBAR in comparison to the therapist. The TIBAR functioned during these measurements solely as a device to log COM data, rather than to provide the patient with assistance. Balance assistance was provided by the therapist and was manually logged by pressing a switch each time the therapist assisted the patient. Total experimental protocol lasted no longer than 30 minutes for each patient.

In order to obtain patient characteristics, Berg Balance Scale (BBS), Functional Ambulation Category (FAC), ten meter walking test (10MWT), Motricity Index (MI) and Dynamic Gait Index (DGI) were performed within one week after the measurement by the treating physical therapist of the patient.

Figure 2: Subject connected to the TIBAR on a treadmill. Subject is connected to a safety harness.

6.2.4 Data analysis

6.2.4.1 Balance assisting force characteristics

Position of both the COM and the virtual circle were continuously measured throughout the training session and forces exerted by the TIBAR were recorded. Data was processed afterwards in MATLAB (Mathworks, Natick, MA, USA). Each time the COM exceeded the virtual circle, balance assisting force characteristics were determined over both the ML as well as the AP axis separately. Measures to characterize the assistance of the system were the number of balance assisting events, the amount of peak force, the duration, the impulse and the axis over which the assistance took place.

6.2.4.2 Timing of balance assistance

Position data of the COM was continuously measured throughout the training sessions in which therapeutic balance assistance was provided to the patient and timing of these balance assisting events was manually logged. In order to investigate whether the timing of therapeutic assistance was similar to timing of assistance by the TIBAR, controller design of the TIBAR was implemented into MATLAB such that the location of the virtual circle could be reconstructed based on the recorded COM location. Balance assistance that would have been provided by the TIBAR could then be determined and compared to the actual therapeutic assistance that had taken place. Each balance assisting event was classified as True Positive (TP, both therapist and controller design classify point in time as an event of balance assistance), False Positive (FP, therapist has not provided assistance, but algorithm classifies point as an event of balance assistance) or False Negative event (FN, therapist provides balance assistance, but algorithm does not classify point as an event of balance assistance), similar to Haarman et al. [3]. Additionally, the Positive Predictive Value (PPV, $(TP/TP+FP) \cdot 100$) and True Positive Rate (TPR, $(TP/TP+FN) \cdot 100$) were calculated, indicating the ability of the algorithm to identify therapeutic events of balance assistance correctly.

6.2.4.3 User acceptance

The System Usability Scale (SUS) was used to measure user acceptance of the system by the patients. The SUS consists of 10 items, that could each be scored on a 5-point Likert scale ranging from 1 – strongly disagree to 5 – strongly agree. Scoring must be performed according to Brooke et al. [30]. A maximal score of 100 points can be obtained, where a higher scores indicates better usability of the system. A system that scores below 50 points can expect usability difficulties in the field, a SUS score between 50-70 points indicates OK usability, a SUS score above 70 indicates a good probability of acceptance and a SUS score above 85.5 indicates excellent usability [31, 32]. In addition, suggestions and comments that the participants mentioned during the trials were written down.

6.3 Results

All five subjects were able to complete the treadmill training without any falls. Patient characteristics as well as scores on clinical measures and walking speed during the measurement trials are presented in Table 1.

6.3.1 Balance assisting force characteristics

Figure 3 shows a typical example of balance assistance that is provided by the TIBAR. Here, the ML COM position and the ML borders of the virtual circle are presented over time. The regular gait pattern of the subject can easily be identified by the cyclic movement of the COM during the first half of the graph where the position of the COM stays within the virtual circle. When the COM moves outside of the virtual circle, the subject experiences a force until his COM position falls within the virtual circle again. The graph shows that the subject is quickly able to continue his training with his regular walking pattern. As the exerted force is the result of a spring stiffness, the force is applied gradually; with more force as the subject moves further outside the border of the virtual circle.

Balance assisting characteristics that were provided by the TIBAR are presented in Table 2. Median number of balance assisting events during the total measurement set of each patient was 8 times (5) (median (IQR)). Median distance walked during this time span was 55.5m (56). Therefore, a median of 13.9 (21.8) meter was walked per balance assisting event. Corrective forces were mainly provided over the ML axis: Roughly 60% (8.4N (5.4), median (IQR)) of the total force that was used is provided over this axis, representing about 1% of the average body weight of the subjects. Around 40% (5.3N, median) of the total force was provided over the AP axis. The median duration of an balance assisting event over the ML axis was typically 0.2s (0.1) and the median impulse per event over the ML-axis was typically 0.7Ns (1.2).

Figure 3: Representation of a typical measurement trial where assistance is provided by the TIBAR over the ML axis. COM trajectory over the ML axis is presented over time (black), together with the borders of the virtual circle of the system (red). The green bar indicates the balance assistance that is provided by the TIBAR.

Table 1: Patient characteristics and measured walking speed during the trials.

Patient ID	Gender	Age (yrs)	Weight (kg)	Therapist ID	BBS (pnts)	FAC (pnts)	10MWT (m/s)	MI (pnts)	MI (MI leg) (pnts)	DGI (pnts)	Walking speed during trials (m/s)
1	M	70	95	1	44	4	0.45	123	69	15	0.17
2	M	69	90	1	45	5	0.91	157	57	15	0.17
3	F	73	65	2	47	3	0.74	140	64	15	0.56
4	F	77	62	3	44	3	0.2	130	58	13	0.08
5	F	43	80	4	-	2	-	118	18	-	0.67
Median (IQR)	-	70 (4)	80 (25)	-	45 (2)	3 (1)	0.6 (0.4)	30 (17)	58 (7)	15 (1)	0.17 (0.39)

Table 2: Characteristics of balance assistance provided by the TIBAR during measurement trials.

Patient ID	Spring stiffness (N/m)	Total events of balance assistance (#)	Travelled distance (m)	Travelled distance / event (m)	Mean peak force / event (ML-axis) (N)	(% body weight)	Mean peak force / event (AP-axis) (N)	(% body weight)	Mean Duration (s)	Mean Impulse (Ns)
1	3000	4	55.5	13.9	4.1	0.4	-	-	0.15	0.4
2	3000	9	22.7	2.5	23.6	2.6	8.9	1	0.41	5.1
3	2000	4	97.2	24.3	9.7	1.5	2.8	0.4	0.28	1.7
4	1800	20	41.2	2.1	4.3	0.7	5.6	0.9	0.17	0.7
5	2500	8	304.7	38.1	8.4	1.1	4.9	0.6	0.17	0.6
Median	2500	8	55.5	13.9	8.4	1.1	5.3	0.8	0.2	0.7
(IQR)	1000	5	56	21.8	5.4	0.8	2.1	0.4	0.1	1.2

ML = medio-lateral, AP = anterior-posterior.
Missing data is indicated by an '-'; TIBAR did not provide assistance in this direction.

The workspace of the TIBAR is presented in Figure 4: it spans 1rad over the AP axis and 0.36m over the ML axis. The figure shows a typical example of the COM position over the course of a trial in this workspace. The graph shows that the subject is restricted in his movements over the AP axis by the workspace of TIBAR. Restrictions over the ML axis are solely due to the width of the treadmill.

Figure 4: Both the workspace (grey) and the COM position (blue) within this workspace is presented. Subject performed a circuit-walking task where he had to step around and step over projected objects on the treadmill.

6.3.2 Timing of balance assistance

Three out of five patients (patient ID # 1, 2 and 4) were able to complete the additional measurements in which balance assistance was provided by the therapist, rather than by the TIBAR. Balance assisting events that would have been provided by the TIBAR could then be reconstructed and compared to the actual therapeutic balance assistance that had taken place. Individual scores of each patient are presented in Table 3, where TP, FN and FP scores have been summed over all measurement trials of the patient. Patient specific PPV and TPR values have been calculated and presented in the table.

The ability of the TIBAR to predict therapeutic events of balance assistance correctly was defined by an average PPV and TPR score of respectively 70% and 100%. The average TPR score of 100% indicated that the TIBAR was able to capture all balance assisting events that were provided by the therapist. However, the average PPV score of 70% indicated that the TIBAR additionally identified events of balance assistance at moments when no actual assistance was provided by the therapist. A typical example of such a trial is presented in Figure 5. Here, both the actual therapeutic balance assistance, as well as the reconstructed TIBAR assistance is shown. The TIBAR was able to capture all four therapeutic events where balance assistance was provided, however, identified three additional events of balance assistance which were not provided by the therapist.

Table 3: Individual and group scores of the algorithm in the ability to predict therapeutic balance assistance. Scores are presented as the summed to measurements trials within a patient.

Patient ID	TP	FN	FP	PPV	TPR
(#)	(#)	(#)	(#)	(%)	(%)
1	5	0	2	71	100
2	7	0	2	78	100
4	6	0	4	60	100
Group total	18	0	8	70	100

Figure 5: Typical example of a trial where balance assistance was provided by the therapist (asterisk) over the ML axis. COM trajectory over the ML axis was recorded during these trials (black). This data was used to reconstruct borders of the virtual circle of the TIBAR (red), such that events of balance assistance could be calculated by the algorithm of the TIBAR (green). Comparing the actual therapeutic balance assistance with the events calculated by the system indicate the ability of the system to time its assistance in a similar manner as therapists. The TIBAR was able to capture all therapeutic events of balance assistance, however indicated three additional events.

6.3.3 User acceptance

SUS questions and scores are presented in Table 4. Overall SUS score is 77.0 points, which indicates a good probability that the system will be accepted. Subjects were rather unanimous in their scoring. Users strongly agreed with the negative statement of item number 4 about the technical support that is needed to use the system. Individual ratings were between 4 and 5 points. Patients were concerned that they were not able to control the system with one functional hand. However, subjects did find the system easy to use and not complex, referring to the fast donning/doffing times due to the use of an adjustable pelvic belt.

Two patients verbally commented that the sensation of the balance assistance by the TIBAR

Table 4: SUS questions and scoring.

Item (#)	Description	Mean Score	(SD)
1	I think that I would like to use this system frequently	4.40	0.55
2	I found the system unnecessarily complex	1.00	0.00
3	I thought the system was easy to use	4.40	0.55
4	I think that I would need the support of a technical person to be able to use this system	4.80	0.45
5	I found the various functions in this system were well integrated	4.60	0.89
6	I thought there was too much inconsistency in this system	1.00	0.00
7	I would imagine that most people would learn to use this system very quickly	4.40	0.89
8	I found the system very cumbersome to use	2.00	1.00
9	I felt very confident using the system	4.00	1.41
10	I needed to learn a lot of things before I could get going with this system	2.20	0.84
SUS (converted) total score		77.00	7.98

equaled the sensation of therapeutic assistance. Additionally, three patients verbally noted that they did not feel obstructed in their movement pattern by the system. Four subjects valued the fact that the system came from behind, thereby allowing arm swing (n=2) and free vision (n=4).

6.4 Discussion

The aim of this study was to develop and evaluate a first prototype of a robotic training system that can be used supplementary to conventional therapeutic sessions and that provides stroke survivors with similar freedom and support as they experience during conventional gait training. Therapists use the principle of error-based training [6, 7] during conventional gait training, in which the timing of providing balance assistance [33] and the degree to which pelvic movements are allowed [19] are crucial for both therapists and patients. Providing balance assisting corrective forces too soon might limit the possibility of patients to make movement errors, whereas providing balance assistance too late might create potentially dangerous situations. In order to determine whether the TIBAR complies on these aspects with conventional therapy, timing of balance assisting events and balance assisting force characteristics by the TIBAR could be compared to balance assisting force characteristics that were recorded during conventional therapy in Haarman et al. [3].

Results of the comparison on timing between therapists and the TIBAR confirmed that the system provides assistance at all moments in time when assistance was also provided by the therapist. However, in 29% of the balance assisting events that were provided by the TIBAR, no assistance was provided by the therapist. Even though the system seemed

to capture the timing of therapeutic balance assistance, patients might have experienced a restriction in their pelvic movements. Note that these numbers were obtained with only three patients and therefore represent an indication of the abilities of the system. When comparing the average number of balance assistance events by the TIBAR (one event of balance assistance each 14m) with the number recorded during conventional therapeutic gait training in Haarman et al. [3] (one event each 12m), an increase in events of 17% was found for the TIBAR compared to conventional training. It can be assumed that the group of included subjects in the current study was comparable to patients that received conventional therapy in our previous study [3]: both the inclusion criteria and the average patient characteristics were similar. This implicates that patients encounter the borders of the virtual circle faster when using the TIBAR compared to conventional therapy. The TIBAR might therefore have been too strict in defining instability for this specific group of stroke survivors. Virtual circle settings such as circle radius or dimensionless constant of the low-pass filter contribute to this aspect.

Virtual circle radius was currently based on the lateral COM displacement during the stance phase of the gait cycle [29], rather than the (larger) displacement that is reported in the present study throughout the entire gait cycle. This was specifically chosen as it was assumed that the low-pass filter was fast enough to update the virtual circle position throughout a gait cycle. However, as walking speed affects COM displacement to a great extent [34], the virtual circle radius still might have been chosen too tight, at least for subjects with a low walking speed. Decreasing the dimensionless constant of the low-pass filter can possibly decrease the number of balance assisting events by the system: the delay between the position of the virtual circle and the COM is then smaller, and patients are consequently less likely to encounter the borders of the virtual circle. The Positive Predictive Value of our controller is likely to increase in such a situation. However, it simultaneously might lower the True Positive Rate value as the likelihood for balance assisting events decreases when the update rate of the virtual border is increased.

Increasing the virtual circle radius might be another option that can reduce the number of unwanted balance assisting events [33]. However, when spring stiffness is unaltered in such a situation, the angle between the body and the ground might become too large. In particular, subjects have identified a decrease in comfort during previous experiments, when the angle between the body and the ground was too large at the time patients felt the correction force. Increasing the borders of the virtual circle might therefore require an increase in spring stiffness, in order to reduce the level of discomfort. Stiffness settings should be chosen such that balance assisting force characteristics mimic those from conventional therapy. In the present set-up, the average amount of peak force expressed in percentage body weight that was needed for assistance over the ML axis was similar to the force used in the conventional training set-up described in [3]. Evaluations on the user acceptance of the TIBAR revealed that patients very much enjoyed the sensation of the robotic support in its current settings. Several subjects noted that the sensation of the robotic balance assistance by the TIBAR equaled the sensation of the therapeutic assistance even though median duration and impulse of the balance assisting events were found to be lower in the robotic set-up compared to conventional therapy in Haarman et al. [3].

Adapting the settings of the virtual circle thus has both advantages and drawbacks. Optimal

parameter settings might differ between patient groups or even between patients that fall within the same subject group, due to differences in walking speed [34]. Additionally, observations during conventional gait training sessions have identified that patients with good balance abilities are allowed more challenging situations during their training, whereas patients with lesser balance require more assistance and assistance that is provided sooner in time. The primary goal of the TIBAR was to mimic the behavior of therapists as much as possible, such that a device could be developed that provides patients with the same type of therapy that they are familiar with, yet at the same time enabling them to increase their training volume. Therapists integrate knowledge of patient specific aspects to determine if and when assistance is needed. Although it might be challenging to incorporate this complex behavior into a robotic device, the TIBAR should allow for these individual patient needs. The algorithm that was presented in previous work of [3] did account for subject specific parameters and scored rather high on both PPV and TPR (87% and 86% respectively). The applicability of this specific algorithm in the TIBAR is however low. First of all, because the algorithm is acceleration-based, whereas the D-Flow software processes position data of the TIBAR. Differentiation of this signal to obtain acceleration data leads to delays in the data, which is unwanted when it comes to balance recovery. Second, the algorithm by [3] uses offline processing to determine subject specific parameters and thresholds, whereas the TIBAR requires real-time processing of the data.

Other research groups have identified algorithms that focus on pelvic support, such as in Koopman et al. [35] and Vallery et al. [36]. Even though these algorithms did not have the direct goal to mimic the behavior of therapists or compared their work to conventional gait training, they did focus on lateral pelvic support to allow balance recovery during the training. Both studies intend to allow as much pelvic motion as possible, since restricting certain degrees of freedom in the pelvic joint during gait training does not prevent these movements to be made during daily life [19]. Both algorithms have incorporated the principles of the extrapolated mass concept in their design in order to determine dynamic stability, based on the work by Hof [37]. This approach differs from the one that we have applied in the design of the TIBAR since we base the timing and amount of force of balance assistance on the behavior of therapists. The complex clinical decision-making process of therapist in determining whether or not to apply balance assistance complicates the ability to capture this behavior into an algorithm, especially since therapists do not solely base their assistance on COM movements. Yet, as literature has indicated that this method is effective [4], it seems beneficial to incorporate this technique as much as possible into a robotic device. The prototype of the TIBAR that has been presented in this paper should be seen as a first step into this process.

Similar to Bauby et al. [38] and Haarman et al. [3], our study additionally showed the ML axis to be the main plane over which corrective balance assistance was applied. Although balance in the sagittal plane was often found to be passively stable [38] the small number of balance assisting events that was provided in this plane during conventional gait training [3] was a reason to implement this type of support in the TIBAR. Results of the TIBAR show an increase in balance assistance over the AP axis compared to conventional therapy. These are likely to be the result of natural stride-to-stride velocity variations that occur during normal gait [39, 40], which are not accounted for during treadmill walking. Subjects encountered the limits of the TIBAR workspace due to these fluctuations

(visible in Figure 4), resulting in unwanted balance assistance. Additionally, subjects had the tendency to increase their walking speed on the appearance of an upcoming visual stepping target on the C-Mill, thereby showing high accelerations of their COM. This observation might explain the increased amount of force that was observed over the AP axis, since the force needed to reposition the subjects at the back-end of the treadmill was higher compared to the force needed for balance assistance.

6.4.1 Limitations

The TIBAR in its current form is a first prototype that was used to see the potential of such a system in an early stage of the development. This is important, since technical improvements can then accurately be fine-tuned to the input of the users (both therapists and patients). Although results already imply good potential of this system, it must be taken into account that evaluation have only been performed with a total of 5 subjects who were closely related in their patient characteristics. The abilities to extrapolate these results to stroke survivors with other characteristics should therefore be investigated.

Additionally, we have used a similar set of parameter settings in the controller design for all subjects. However, observations during conventional gait training sessions have identified that therapists adapt their level of support to the abilities of the patient. Current parameter setting might therefore be too strict or too loose for other levels of stroke patients. Future work should clarify whether other parameter settings are required for different levels of stroke survivors and other patient groups. The adaptive presence of the TIBAR easily allows for such changes to be made. Ultimately, one would identify several modes on the TIBAR, each mode corresponding to a specific level of support.

Furthermore, a therapist was located next to the treadmill during the measurement trials. The therapist did not physically contacted the subject, but verbally assisted the subject, thereby possibly increasing the feeling of safety on the side of the subject. Even though the current set-up still allowed to evaluate a device that reduces the physical workload of therapists, results might be altered (e.g. increase in number of balance assisting events) when no therapist is present next to the subject.

In addition to this latter aspect, the TIBAR in its current form is not suitable for use in a self-administered way. When subjects could control the device by themselves, this would enlarge the ability to increase training volume. Even though subjects were not asked to control the software of the device and received assistance during donning/doffing of the system, user acceptance analysis has identified that patients were not able to do so either. Self-administered control requires an interface that allows subjects to start a training session by themselves and the ability to control the device with only one functional hand, a restriction often observed in stroke survivors [41]. The pelvic belt that is used by the system is already controllable with one hand, but fastening of the safety harness was still too difficult in the present set-up. Future research should take these aspects into account.

6.5 Conclusion

The aim of this paper was to describe the development and the evaluation of the first prototype of TIBAR: a therapist inspired system that supports balance during gait training. Patients can increase their training volume with the device, whilst therapeutic load is decreased. Quantitative data showed that balance assisting force characteristics in terms of peak force and axis over which the assistance took place were comparable during therapeutic support and support provided by the TIBAR. For the current group of included patients, the timing of the balance assisting event provided by the TIBAR was similar to the timing of therapists. However, the number of balance assisting events by the TIBAR was 17-29% higher than the number of events that would have been provided by therapists to this group of patients. Median duration and impulse of the assistance by the TIBAR were both lower compared to therapeutic assistance. Patients indicated that they did not experience this decrease in contact time as a discomfort.

Overall user acceptance of the system was rated with 77 points on the System Usability Scale, indicating that the system has good potential for acceptance in a clinical setting. The system allows the COM to move over the treadmill, thereby indicating that challenging situations, such as circuit walking can be trained. The included patient group is rather homogeneous in terms of patient characteristics and therefore requires similar levels of support. It is assumed that by adapting parameter settings such as the virtual circle radius or the dimensionless constant of the low pass filter, the amount of support could be adapted to the level of the patient.

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Chapter 7

General discussion

The main objective of this thesis was to develop and evaluate a training device that allows self-administered training of walking and balance for stroke survivors: the Therapist Inspired Balance Assisting Robot (TIBAR). This device would enable patients to increase their training volume, without being dependent on the availability of therapists. Specifically, as our population is aging [1] and consequently the number of patients is increasing [2], an even higher burden is put on the training volume of patients in the near future, thereby limiting their rehabilitation effectiveness [3].

The TIBAR aimed to provide balance assistance to patients in a similar manner as is done by therapists during conventional gait training sessions. Therapists intuitively integrate knowledge on patient specific abilities to determine if and when balance assistance is needed, such as muscle strength, fall history, fatigue, coordination characteristics and sensory loss. This method was found to be effective in terms of functional recovery [4, 5], and integration of this method in a training device was therefore expected to be of great importance in the acceptance and effectiveness of such a device. The device therefore only provides balance assistance to patients when they are not able to keep themselves balanced. When no support is needed, patients are able to move freely. This strategy relates to aspects such as error-based training and active participation: both important contributors for optimal training conditions [6–8]. Other aspects of motor learning exist that contribute to optimal training conditions, such as a motivation, feedback and functional training. A selection of these optimal training conditions is naturally being applied during conventional gait training by physical therapists [9], but implementation of other conditions might make the training sessions even more effective. Therefore, it was not only aimed to translate the behavior of physical therapists during conventional gait training sessions, but also to apply the principles for optimal training conditions as accurately as possible within the TIBAR.

The chapters in this thesis relate to these aspects and aim to provide a method of optimally implementing them in the controller design of the TIBAR. Furthermore, effects of hemiplegia on walking and balance have been investigated in this thesis, and have resulted in additional implications regarding the controller design of the TIBAR. In addition to these software requirements, requirements have been set to the physical appearance of the TIBAR (hardware). These hardware requirements aim to create a self-administered training environment, for instance by taking dexterity problems due to hemiplegia into account. They additionally relate to factors such as allowing arm sway and free vision while training, in order to represent daily life situations [10, 11]. The TIBAR therefore has been designed such that its physical presence is located behind the patient. Furthermore, the TIBAR needs to be used on a treadmill. This enables training on a physically small area, yet allows many gait repetitions to be made. Games can be projected on the treadmill by use of a beamer, in order to provide the patients with a motivating environment where several tasks can be trained that represent Activities of Daily Living (ADL's), such as stepping over or stepping around objects.

While each individual chapter in this thesis provides insight into a specific topic, this general discussion will combine all information to discuss the ability of the TIBAR to implement these requirements and allow a self-administered training environment for hemiparetic patients. The discussion will evaluate the potential of the TIBAR to be used in a clinical setting and lastly, it will address focus points for further research.

7.1 Self-administered training

Prior to the start of the development of TIBAR a storyboard was presented that showed the intended use of the TIBAR (Figure 1). It showed a scenario to train patients with limited balance control without the need for constant stand-by presence of therapists during the entire training session. User evaluations in chapter 6 confirmed the potential of such a scenario and revealed that the system had good potential for use in a clinical setting. Subjects in particular enjoyed the ease of use of the system and its intuitive character, for instance in the connection between the TIBAR and the body of the patient by use of a pelvic-belt. The pelvic-belt allowed fast donning/doffing times and was designed such that the physical presence of the device was located behind the patient, thereby not intimidating the patient. While the prototype of the TIBAR was developed with self-administered control in mind, not all aspects that were shown in the scenario were already incorporated in the current prototype of the TIBAR or were tested in chapter 6.

Figure 1: Storyboard, describing the intended use of the TIBAR.

For instance, problems with dexterity are often reported as a consequence of a stroke [12–14]: Many patients only possess functionality in one hand and are therefore limited in the execution of tasks. In order for patients to individually control the TIBAR, patients should be able to put on their safety gear by themselves. Although the pelvic belt that is used to connect the patient's body to the TIBAR allows for this aspect, the safety harness ('MAGS suspension vest') that was currently used in the present test set-up of chapter 6 did not allow for self-administered use. In fact, no safety harnesses is currently available on the market that allows self-administered control with one functional hand. A novel safety harness has therefore been designed for use in the TIBAR (Figure 2), however, was not yet incorporated in the user evaluations in chapter 6 [15]. User evaluations that have been performed with this harness have positively criticized the intuitively and ease of use of this harness [15]. Only one fastener needed to be closed by patients in order to connect this harness properly to the body. This fastener is magnetic, thereby automatically fastening itself when both parts of the fastener approximate each other. Dexterity problems therefore not limit the usage of this harness. The shoulder straps of

the harness tighten themselves by their smart fastening mechanism, and do not require additional fasteners. Last, a zip at the back of the harness makes the harness compliant with different sized patients. Therapists then do not have to replace the entire harness for a different size, as is often the case with current harnesses.

Figure 2: Safety harness

7.1.1 Optimal training conditions: principles of motor (re)learning

When patients are positioned correctly within the TIBAR and start a training session, the level of the training should be adapted to the abilities of the patient and the training should comply with as many aspects of motor learning as possible. A selection of these principles has already been assumed to be incorporated in existing robotic gait training devices [16]. The systematic review described in chapter 2 provided further insight into these aspects, their implementation in robotic devices and their effects on functional recovery after training with these devices. A distinction was made in this chapter between devices that have incorporated the principle of error-based training and active participation in their controller design (patient-in-charge devices) and devices that did not incorporate these principles (device-in-charge devices). Based on research by many research groups regarding these principles on motor learning [8, 17, 18], it was expected that training with devices that allowed these principles throughout the training resulted in better functional training outcome compared to devices that did not train these principles. However, the results of chapter 2 did not confirm nor deny this hypothesis. In fact, this chapter revealed that other principles of motor learning contributed equally to the recovery of patients and in fact, could not be seen in isolation from one another.

Chapter 2 in particular focused on the confounding role of training volume, feedback and motivation in relation to training outcome. Training volume encloses aspects such as training duration, training repetition and training intensity. Total training duration in the studies that were described in Chapter 2 ranged from 4 to 20 hours. Kwakkel [19] stated that changes on functional recovery increase when the number of training hours increase. Based on this study, many of the included studies in chapter 2 did not provide a suitable training duration in order to be able to accomplish a reasonable functional improvement. However, the research by Kwakkel [19] did not elaborate on the amount of effort that should be put into the training throughout these training hours, nor did the majority of the included studies in chapter 2 objectively quantify the effort by the patients during the training sessions. Optimal training conditions originate when training intensity has been adapted to the abilities of the patient [20]. Training intensity is not only reflected by treadmill speed or the use of BWS, but also includes the amount of support that patients receive during the training. Patients who receive less support during a training session need to participate more actively in the training, thereby increasing the intensity of their training. The results of the systematic review in chapter 2 confirm that the amount of robotic support in relation to the abilities of the patient appear to be equally important as the training duration itself, indicating the need for individually adjustable training settings [21]. Therefore, similar as during conventional therapy, the TIBAR allows for an adaptable level of support: by adjusting patient specific settings in the TIBAR, patients with better skills can be offered less support than patients with fewer skills. Consequently, training intensity can be adapted to match patient specific needs. Although the TIBAR allows for patient specific settings, the system has not yet been tested regarding these individual settings. The future research section in this general discussion will provide additional insight into this matter.

Adapting the level of support to the abilities of patients, inseparably affects the motivation of patients. Motivation is the result of several components, such as difficulty and success rate of the task [22]. Physical therapists additionally comply to these factors during conventional gait training, by adapting the training environment to the level of the patient. For instance by use of circuit training during overground gait training sessions. Computer generated environments are often used to translate these motivating training set-ups to a treadmill [23]. This allows training of ADL related tasks on a relatively small area. Chapter 3 focused on this aspect and it evaluated the ability of subjects to perform a motor task in an augmented reality training environment. Based on this research, augmented reality training was assumed to be very intuitive to (healthy) subjects, as the included subjects in the study were able to hit virtually projected targets on initial try. Although this study did not directly relate the performance of subjects to their motivation while training, other studies have confirmed this component [24]. Additionally, the results in chapter 3 demonstrated the ability of an augmented reality environment to adapt the training environment to a specific patient group: patients that are cognitively impaired and/or need to focus on the motor task itself benefit from a training environment with less targets, tasks and external stimuli, compared to patients that prefer more challenging training environments [25, 26]. The inclusion of an augmented reality environment in the TIBAR seemed therefore beneficial for the motivational component of the training, compared to treadmill walking alone. It enables patients to train a variety of tasks where the difficulty of the task could be adapted to patient specific needs.

Chapter 3 emphasized that feedback presentation might have been suboptimal in the used training set-up, a statement that was substantiated by several research groups who state that visual feedback should be presented close to the field of vision [27–30]. Patla et al. [30] found that during treadmill walking, the field of vision lies two step lengths ahead of the subject. Feedback presentation on the treadmill of the TIBAR should therefore be approximately 1.1 meter ahead of the subject [31]. Additionally, aspects such as colorblindness should be taken into account while choosing the color of this feedback [32]. Verbal feedback about task performance of patients is often applied by physical therapists during overground conventional gait training. However, for a self-administered training set-up such as the TIBAR, auditory feedback might not be the most appropriate type of feedback: many patients experience hearing problems and the system might be located in a noisy, clinical environment [32]. An important aspect to take into account when choosing one type of feedback over another is interpretability of the feedback by patients. Patients should be able to link the feedback to their body movements [33–35].

7.1.2 Mimicking the behavior of therapists: balance assisting events

As stated previously, therapists combine patient specific information to determine if and when balance assistance is needed. When therapists judge that a patient is not able to keep himself balanced while walking, the therapist provides balance assistance. The ability to translate the intuitive and effective training method of therapists [4, 5] into a training device, might be of great importance in the acceptance and effectiveness of such a device. It was therefore aimed to translate the physical behavior of therapists during conventional gait training sessions as accurately as possible into the TIBAR. This has the advantage that training with this system might be intuitive to the users, and patients do not have to get used to a different training method. Potentially, this might increase the user acceptance of the system and consequently the training volume of patients.

Chapter 5 provides insight into therapeutic balance assistance in terms of force, duration and, among others, timing. Although the complex behavior of therapists is composed of many more aspects and could not solely be represented by this information, it provides a first step into the process of capturing therapeutic behavior and serves as information for the TIBAR's system requirements. An algorithm was developed to predict the timing of therapeutic balance assisting events based on sensory information. Although the number of included patients is limited, analysis showed that good predictive abilities were reached by using acceleration data recorded at the sacrum (Positive Predictive Value (PPV) and True Positive Rate (TPR) of respectively 86% and 85%). The use of only one sensor in the present algorithm positively affected the complexity, cost and ease of use of the TIBAR. While the results of the threshold-based algorithm confirm the potential in predicting therapeutic balance assistance based on only one sensor, a drawback of this simplified set-up is the fact that it does not capture more complex situations where therapists respond to different stimuli other than accelerations of the sacrum. A more elaborated or altered measurement set-up and algorithm might then be needed. Adding information from additional sensors, such as gyroscopes, could additionally account for this improvement, similar as was shown in Li et al [36] and in Bourke et al. [37].

The results in chapter 5 have led to important implications regarding the controller design

of the TIBAR in chapter 6, such as the predictive value of the center of mass (COM) in the determination of therapeutic balance assisting events, the need for only one sensor in predicting the timing of therapeutic behavior and the increase in therapeutic balance assisting events upon an increase in COM accelerations. Although these aspects have been incorporated into the controller design of the TIBAR in chapter 6, the algorithm that controls the actions of the TIBAR is not a one-on-one copy of the algorithm that has been designed in chapter 5. Two main reasons underlie this aspect. First, the D-Flow software that records data from the HapticMASTER processes the position of the COM of the body rather than its acceleration as is the case in chapter 5. Differentiation of the position data to acceleration data would result in a delay, which is unwanted when it comes to balance corrections. In fact, such a delay might lead to dangerous and unsafe situations. Second, the threshold-based algorithm of chapter 5 predicts the timing of therapeutic balance assisting events on prerecorded data. The threshold that determines whether or not an event would be classified as therapeutic balance assistance depends on the average acceleration activity within a dataset. Therefore, the algorithm in chapter 5 is, in its current form, not able to predict balance assisting events with real time data. In order to accomplish such a situation, the TIBAR would require a predetermined threshold value for each patient individually, based on a stable walking trial.

Despite the differences between both algorithms and again the limited number of included patients, the technical evaluation study in chapter 6 identified good predictability of therapeutic balance assisting events by the TIBAR. The system was able to capture all therapeutic balance assisting events correctly, but additionally showed that supplementary events of balance assistance were provided by the TIBAR in 17-29% of the cases. The algorithm settings of the TIBAR were therefore considered as being too strict in defining instability. Although the group of included patients was rather small and homogeneous regarding their patient characteristics, optimal training conditions arise when an individual training level is taken into account [21]. Therefore, predictability of therapeutic behavior might increase when algorithm settings are made patient specific. It is expected that algorithm settings within the TIBAR could easily be adapted to a variety of patients. Adapting the borders of the virtual circle and/or the dimensionless constant of the low pass filter would affect the movement freedom that is allowed within the TIBAR and consequently the number of events that are identified as being unstable.

Analysis in chapter 5 revealed that therapeutic balance assisting events were small in force (2% of body weight) and lasted for a short period (1 second). Resemblance between these therapeutic characteristics and the characteristics of balance assisting events by the TIBAR was high (chapter 6). Additionally, results on user acceptance evaluations confirmed the high level of comfort at the side of the user while receiving balance assistance by the TIBAR. However, the TIBAR currently does not account for natural stride-to-stride velocity variations during normal gait [38, 39], leading to a variable Anterior-Posterior (AP) position on the treadmill. As a result, patients frequently encountered the limits of the TIBAR workspace and the borders of the virtual circle over the AP axis, thereby negatively affecting the number of balance assisting events over this axis. As analysis showed that patients mainly became unstable over the Medio-Lateral (ML), rather than the AP axis, the virtual circle radius might be increased over this axis. Patients would then receive more movement freedom in the forward direction.

7.1.3 Effects of hemiplegia on balance assisting events

It was set in the requirements that training with the TIBAR should not be limited by effects of hemiplegia. Although several consequences of hemiplegia, such as limitations in hand function, have already been addressed in the general discussion, hemiplegia often also affects walking abilities. Therefore, the effects of hemiplegia in walking on the design of the TIBAR have been investigated in chapter 4. Here, several perturbation magnitudes were applied to both the paretic and the non-paretic leg of stroke survivors and stepping responses have been mapped. Results indicated that modulations to perturbation magnitudes were similar for both legs, even though stroke-related gait characteristics were present in the included group of patients. For instance, subjects had the tendency to keep their COM towards their non-paretic leg, regardless of the applied perturbation. When patients are in control of their movements, they prefer to keep their weight towards the non-paretic side of the body [40]. Although these results implicate that the TIBAR does not need to allow for different modulation strategies with both legs, its design might be improved when the asymmetrical medio-lateral COM movement-trajectory of patients is taken into account. Currently, the virtual circle within the controller design of the TIBAR (chapter 6) assumes equal changes of instability for both the paretic and non-paretic side of the body. However, an asymmetrical virtual circle around the COM might be more optimal for patients within the TIBAR. This would allow more movement freedom on the non-paretic side and less on the paretic side of the body. Again, asymmetry of the virtual circle is expected to be patient specific and dependent on the severity of the hemiplegia.

7.2 Future perspective

Although the number of patients that have been used for the development of the device might be limited, the prototype of the TIBAR that has been tested and the user acceptance evaluations that have been performed have indicated the potential of the device for use in a clinical setting. The TIBAR is small in physical size, thereby allowing placement in a variety of (semi-) clinical settings: from large rehabilitations centers to small physical therapy practices. This general discussion has indicated the strengths and limitations of the TIBAR with respect to self-administered use. Although the TIBAR already has implemented many aspects that contribute to optimal training conditions and the behavior of therapists, the aspect of patient specific training has not been optimally implemented in the TIBAR such that it allows for self-administered use.

Ultimately, different levels of support should be selectable within the TIBAR. Adaptations in the parameter settings of the controller design of the TIBAR should allow the amount of support to be adapted to the abilities of the patient. Settings have currently only been tested with a small, homogeneous group of stroke survivors regarding their patient characteristics. Future research should test parameters in relation to a heterogeneous group of patients. For instance, the radius of the virtual circle that is currently created around the COM in the transversal plane is based on literature, but individual needs might be better met when this setting is made patient specific. The TIBAR might then increase its ability to detect unstable situations correctly. Additionally, the difficulty level

of the augmented reality environment should be adaptable to the abilities of patients: suitable training tasks should be identified for patients with different characteristics, or eventually, for other patient populations. Feedback about the progress of patients should be presented to the therapist, such that the therapist is able to make adaptation to the level of the training task, to verbally discuss the progress with the patient and to monitor the motivation of the patient. Although the physical workload of therapists is thus positively affected by use of the TIBAR, the connection between patient and therapists remains.

Furthermore, the use of the HapticMASTER in the first prototype of the TIBAR makes the device still too expensive for use in a clinical setting such as a physical therapy practice. The use of the HapticMASTER in the first prototype of the TIBAR allowed for a set-up in which several algorithms and settings could easily be implemented and tested. In order to lower the costs, a critical look has to be given to the specifications of the HapticMASTER. The HapticMASTER scores high on force, force depth, position resolution and haptic resolution [41]. Even though a high response time and accuracy are needed within the TIBAR, force requirements that are needed for balance assistance are much lower than what is available in the HapticMASTER. Additionally, the HapticMASTER is able to actuate 3 degrees of freedom, but results in chapter 5 and 6 indicate that support over the AP axis is barely needed. It might therefore be beneficial for the costs of the device to omit this support axis in the TIBAR and solely focus on the ML axis. Furthermore, a large restriction of the HapticMASTER is its small workspace on the treadmill, in particular over the AP axis. A system that can move along with the patient over the length of the treadmill by use of a rail, yet provides ML balance assistance, might therefore be a good alternative.

“It would be wonderful if patients could be enabled to make additional training hours in a self-administered, but safe way” - Physical therapist

This thesis has shown the potential of a training device that allows self-administered but safe training. A prototype of such a system has been presented and steps for further research have been addressed. While transforming and developing this prototype into a device that is ready to be used in a (semi-) clinical setting, it is of high importance to keep both the therapists and patients involved throughout this process. After all, the success of a product depends on the acceptance by its end-users.

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Summary

Stroke survivors who are classified with a Functional Ambulation Category (FAC) of 2, typically are able to ambulate on level surfaces, but intermittently require manual contact of a physical therapist to assist their balance during walking. In order to execute Activities of Daily Living (ADL's), patients require a level of walking independence where no physical balance assistance is needed. Physical therapists use training to improve gait. During these training sessions, patients are able to move freely and only receive balance assistance (support) when they are not able to keep themselves upright. Providing balance assistance not only allows patients to continue their training safely, it also lets them experience the boundaries of their abilities without actually falling.

Even though gait training was found to be effective for stroke survivors in terms of regaining functional independence, the one-on-one contact with the patient and the constant need for supervision limits the training volume of patients. Patients benefit, among other aspects, from a training environment where sufficient training hours can be made at a suitable training intensity. Specifically, as our population is aging and consequently the number of patients is increasing, an even higher burden is put on the training volume of patients in the near future, thereby limiting their rehabilitation effectiveness. A solution that is expected to positively contribute to such a situation is the use of a robotic training device that supports balance, with which patients can undertake additional training hours in a self-administered training environment and that does not ask for the direct presence of a therapist during the training.

The development of such a device was described in this thesis: The TIBAR (Therapist Inspired Balance Assisting Robot). The TIBAR is a robotic device that provides balance assistance to patients at times when they are not able to keep themselves balanced. The device could be used in a self-administered way and must be used on a treadmill. An augmented reality environment could additionally be used on the treadmill to adapt the level of training exercises to the abilities of the patient. Research questions have been set in **chapter 1**, prior to the development of the TIBAR.

- What is the best method of implementing optimal training conditions into a robotic training device?
- How should stroke related consequences such as hemiparesis be accounted for in a robotic training device?
- How can the behavior of physical therapists in terms of providing balance assistance best be implemented into a robotic training device?

The research that has been performed in this thesis elaborates on these research questions and their implementation in the TIBAR. Research question 1 aims to implement optimal training conditions that are important in (re)learning motor tasks into the design of a robotic training device. Aspects of motor learning that are believed to be of importance are error-based training, active participation, functional/context specific training, feedback, motivation and training volume. **Chapter 2** focused on the implementation of the aspect of active participation and error-based learning in robotic gait training, two aspects in motor learning that are believed to be applied by physical therapists and are important in functional recovery. A systematic review was performed in this chapter that compared

robotic gait training studies with devices that did incorporate these aspects into their controller design ('patient-in-charge' devices) to studies with robotic devices that did not incorporate these aspects ('device-in-charge' devices). Effects on functional recovery after a period of training were mapped for both device categories. For patient-in-charge devices, the movement of the device is (primarily) controlled by the patient. These devices are believed to mimic the way that physical therapists provide training to patients: they assist the patient during the training and let the patient be in charge of their movements as much as possible. Patient-in-charge devices can be seen as the opposite of device-in-charge support, which imposes a pre-defined movement trajectory on the patient. No deviation from this trajectory is allowed by the device and the robot fully controls the movements of the patient. Results of the comparison between both categories showed no preference for one category over another in terms of functional recovery. An important confounder in these results is the effect of training volume. The training duration of the included studies was often too short to expect any functional recovery at the side of the patient. Moreover, the systematic review emphasized the finding that other aspects of motor learning contribute equally to the functional recovery of patients, such as motivation and feedback presentation. When these aspects are not combined optimally within a training device, functional recovery might be limited.

Chapter 3 additionally focused on these latter two aspects: motivation and feedback. This chapter focused on the ability of subjects to learn a visuo-motor walking task in an augmented reality training set-up. An augmented reality training environment is often used to increase the motivational component of a training. This might be of importance while performing training on a treadmill. It was chosen to use a treadmill within the TIBAR, since it was an important requirement of the TIBAR to develop a device that was small in physical size, such that it could easily be implemented in a clinical setting. Therefore, the use of a treadmill seemed ideal: it is small in physical size, yet enables training with many repetitions. However, gait training on a treadmill is often found monotonous and not experienced as an engaging activity. A popular method to increase the motivation of the user, specifically while training in a self-administered way, is by adding explicit goals (targets/games) to the training environment, such as in an augmented reality training set-up. Results identified the intuitive character of such a training environment and the ability of such an environment to adapt the level of the training to patient specific needs. This chapter additionally showed the importance of feedback presentation on the ability of subjects to learn a specific task. Feedback should be presented to patients within the field of vision and in such a way, that patients can link the information to their body movements.

Research question 2 is related to stroke related characteristics such as hemiparesis. It was set in the requirements that training with the TIBAR should not be limited by effects of hemiplegia. Therefore, the capabilities of these patients to deal with perturbations and their asymmetrical movements were taken into account in the development of the TIBAR. In **chapter 4**, several perturbation magnitudes and perturbation directions were applied to both the paretic and the non-paretic leg of stroke survivors and stepping responses were mapped. Although stroke related gait characteristics were present in the included group of patients, results indicated that modulations to perturbation magnitudes were similar for both legs. For instance, patients had the preference to keep their weight towards their non-paretic leg while stepping, but stepping modulations in response to

the perturbations did not differ between both legs. These results implicate that the TIBAR does not need to take different modulation strategies with both legs into account. However, the controller design of the TIBAR might be improved when the asymmetrical medio-lateral COM movement-trajectory of patients is taken into account.

The behavior of therapists during conventional therapy in terms of manual physical balance assistance appears to be effective for the functional recovery of stroke patients. Therefore, research question 3 focuses on the implementation of this behavior into the design of the TIBAR. **Chapter 5** elaborates on this aspect as it focused on mapping the intuitive and effective training method of therapists, in terms of physical manual contact between patient and therapist. Characteristics of therapeutic balance assistance were captured in terms of amount of force, duration and impulse. Results showed that corrective forces were mainly provided over the medio-lateral axis, that therapists used corrective forces of about 2% of the patients' body weight and that duration and impulse of the assistance was on average respectively 1.1s and 9.4 Ns. Predicting the intuitive and complex behavior of therapists in providing balance assistance logically depends on many aspects such as patient specific muscle strength, fall history and coordination characteristics. Still, it was attempted in this chapter to develop an algorithm that was able to predict the behavior of physical therapist in providing balance assistance with one sensor, such that this information could be transposed into the controller design of the TIBAR. By using the acceleration signal of a sacrum sensor, prediction rate was high, with a Positive Predictive Value and True Positive Rate of respectively 87% and 81%. Despite the fact that the number of included patients is limited in this chapter, the conclusions in chapter 5 contribute significantly to the knowledge on the behavior of therapists.

The information from these chapters has been combined to develop a first prototype of the TIBAR. A description of this device has been presented in **chapter 6**. In this prototype, the TIBAR is composed of the HapticMASTER; to assess balance and provide the subject with the appropriate amount of corrective force, and a remote center mechanism; to connect the HapticMASTER to the patient's body. The device has been tested with stroke survivors in a clinical setting and results have additionally been presented in this chapter. Results showed the ability of the system to provide balance assistance to patients with limited balance control. Technical validation of the TIBAR indicated the similarities between the behavior of therapists and the device, in terms of force characteristics and timing of the balance assisting events. User acceptance evaluations have indicated the good change for acceptance of such a device in a clinical setting. Patients enjoyed the sensation of the robotic balance assistance by the TIBAR, the quick donning/doffing time and the intuitive character of the device in terms of use. Although the number of included patients in this chapter is again limited, the results in this chapter illustrate the potential of the TIBAR as a balance assisting robot.

Finally, the ability of the TIBAR to execute self-administered training in a clinical setting was discussed in **chapter 7**. Here, it was shown that the current prototype of the TIBAR not only incorporated aspects such as the behavior of physical therapists, but also included principles of motor learning that contribute to optimal training conditions. However, several aspects have been identified that should be taken into account when further developing the TIBAR for self-administered clinical use. First of all, many stroke survivors experience dexterity problems, and therefore only have functionality in one hand. In order

for patients to individually control the TIBAR, patients should be able to put on safety gear by themselves. This chapter presented the development of a novel safety harness that can be controlled by these patients in a self-administered way. Second, this chapter emphasized the need to incorporate patient-specific parameters in the controller design of the TIBAR. Currently, the chosen parameter settings were similar for all stroke survivors that were included in the evaluation study. However, allowing individual parameter adjustments might make the training more effective as the level of support would then suit patient-specific needs. Last, the use of the HapticMASTER in the first prototype of the TIBAR might make the device still too expensive for use in a clinical setting. Therefore, a critical look has to be given to the specifications of the HapticMASTER, and the use of these specifications in the TIBAR.

Samenvatting

CVA patiënten die worden geclassificeerd met een 'Functional Ambulation Category (FAC)'-score van 2 worden gedefinieerd als patiënten die in staat zijn om te lopen op gelijke ondergrond, wanneer zij hier af en toe fysieke ondersteuning van een therapeut bij ontvangen. Revalidatie van deze patiënten heeft als doel om er onder andere voor te zorgen dat zij weer in staat zijn om zelfstandig dagelijkse activiteiten uit te kunnen voeren, zonder hierbij ondersteuning nodig te hebben van een therapeut. Conventionele looptherapie richt zich op dit aspect: Een patiënt wordt daarom zo vrij mogelijk gelaten tijdens de looptraining en krijgt alleen ondersteuning wanneer hij niet in staat is om zichzelf in balans te houden. Patiënten kunnen op deze manier in een veilige omgeving ontdekken wat hun grenzen zijn zonder daarbij te vallen.

Hoewel deze methode erg effectief is voor het revalidatieproces van patiënten, vergt het ook veel tijd en aandacht van therapeuten. Therapeuten moeten immers constant aanwezig zijn bij de training om patiënten waar nodig te assisteren in hun balans. Hierdoor komt het trainingvolume van patiënten onder druk te liggen. Door een toename in het aantal patiënten en de vergrijzing neemt deze druk, en daarbij de effectiviteit van revalidatietraining, nog verder toe. Een oplossing die kan bijdragen aan deze situatie is het gebruik van een robotisch trainingsapparaat dat balansondersteuning biedt aan deze groep patiënten. Wanneer het apparaat zelfstandig te gebruiken is door patiënten, niet direct de aanwezigheid vraagt van een therapeut en toch veilig is, dan kunnen patiënten zelfstandig aanvullende trainingsuren maken.

De ontwikkeling van een dergelijk apparaat wordt beschreven in dit proefschrift: de TIBAR (Therapist Inspired Balance Assisting Robot). De TIBAR is een robotisch apparaat dat balans ondersteuning geeft wanneer patiënten niet in staat zijn om zichzelf in balans te houden. Het kan door patiënten zelfstandig gebruikt worden en dient gebruikt te worden in combinatie met een loopband. Bovendien kan een augmented reality omgeving gebruikt worden op deze loopband om de training aan te passen aan het niveau van de patiënt. In **hoofdstuk 1** zijn onderzoeksvragen opgesteld die betrekking hebben op het ontwerp van de TIBAR:

- Wat is de beste methode om optimale trainingscondities te implementeren in een robotisch trainings apparaat?
- Op welke manier moeten CVA gerelateerde kenmerken, zoals hemiparese, worden geïmplementeerd in een robotisch trainings apparaat?
- Wat is de beste methode om het balans ondersteunende gedrag van therapeuten te implementeren in een robotisch trainings apparaat?

De hoofdstukken in dit proefschrift relateren aan deze onderzoeksvragen en beschrijven hoe deze aspecten tot het ontwerp van de TIBAR hebben geleid. Onderzoeksvraag 1 richt zich op het implementeren van optimale trainingscondities in een robotisch trainings apparaat, welke van belang zijn voor het leren van motorische taken. Dit zijn bijvoorbeeld principes als 'error-based learning', actieve participatie van de patiënt, motivatie, feedback en het leren van functionele taken. **Hoofdstuk 2** heeft zich gericht op de mogelijkheid tot implementatie van actieve patiënt participatie en 'error-based learning' tijdens robotische training. Deze twee aspecten worden niet alleen belangrijk geacht tijdens het aanleren

van motorische taken, maar therapeuten lijken ze ook toe te passen tijdens conventionele therapie. Een systematische review is daarom uitgevoerd waarin studies die zich richten op robotische looptraining met apparaten die deze principes toepassen ('patiënt-in-charge' apparaten) worden vergeleken met apparaten die deze principes niet toepassen ('device-in-charge' apparaten). Bij 'patiënt-in-charge' apparaten worden de bewegingen van het apparaat gestuurd door de patiënt. Hoewel de patiënt ondersteuning krijgt van het apparaat, is de patiënt zo veel mogelijk zelf in staat om te bepalen hoe hij wil bewegen. Deze methode lijkt daarom het meest op de werkwijze van therapeuten. 'Device-in-charge' apparaten werken tegenovergesteld aan deze apparaten, omdat ze de gebruiker een vooraf bepaald bewegingspatroon opleggen. Toch laten de resultaten van de systematische review geen voorkeur zien voor één van beide categorieën wat betreft functioneel herstel van de patiënt. Een belangrijke reden hiervoor is dat de geïnccludeerde studies weinig tot geen rekening houden met het effect van een ander aspect van motorisch leren: training volume. De trainingduur van de geïnccludeerde studies is namelijk vaak te laag om enig functioneel herstel te kunnen verwachten. Daarnaast toont de review aan dat motorische aspecten zoals motivatie en feedback net zo belangrijk zijn voor het functioneel herstel van patiënten als trainingsduur alleen. Wanneer deze aspecten niet optimaal worden gecombineerd in een trainingsapparaat dan kan het herstel van de patiënt worden belemmerd.

Ook **hoofdstuk 3** heeft zich gericht op deze twee laatste aspecten: motivatie en feedback. Het heeft zich gericht op de vaardigheid van patiënten om een visueel-motorische taak te leren in een augmented reality omgeving, een omgeving die gebruikt kan worden om de motivatie tijdens trainingen hoog te houden. Het gebruik van een dergelijke omgeving is vooral van belang bij het gebruik van een loopband, zoals het geval is bij de TIBAR. Er is gekozen voor het gebruik van een loopband omdat de fysieke afmeting van de TIBAR klein moest blijven. Wanneer de TIBAR weinig ruimte inneemt kan hij namelijk makkelijk geplaatst worden in een klinische omgeving, zoals een fysiotherapie praktijk. Daarom lijkt het gebruik van een loopband ideaal: deze zorgt er immers voor dat er op een klein oppervlakte toch veel stappen gezet kunnen worden door een patiënt. Een nadeel van het gebruik van een loopband is de eentonigheid en de lage mate van uitdaging die er in een dergelijke training te vinden is. Een populaire methode om de motivatie van patiënten tijdens een training op een loopband hoog te houden is het toevoegen van spellen in een augmented reality omgeving. Wanneer patiënten zelfstandig een training uitvoeren kan een dergelijke trainingsomgeving er in het bijzonder voor zorgen dat de motivatie hoog blijft. De resultaten van dit hoofdstuk tonen het intuïtieve karakter van de leeromgeving aan en de mogelijkheid om het niveau van de training aan te passen aan de capaciteiten van de patiënt. Daarnaast laat dit hoofdstuk zien dat het krijgen van feedback erg belangrijk is tijdens het aanleren van een taak. Feedback moet zodanig worden gepresenteerd aan patiënten dat zij het makkelijk kunnen zien en kunnen koppelen aan hun lichaamsbewegingen.

Onderzoeksvraag 2 heeft betrekking op doelgroep specifieke kenmerken, zoals hemiparese. Het richt zich op de mogelijkheid om de TIBAR complementair te maken met patiënt specifieke kenmerken ter gevolge van een halfzijdige verlamming. Trainen met de TIBAR mag namelijk niet gelimiteerd worden door effecten van hemiplegie. In **hoofdstuk 4** is daarom onderzocht of CVA patiënten verschil laten zien in stapresponsies met hun aangedane en hun niet-aangedane been, wanneer zij instabiel zijn. Er zijn daarom

verschillende verstoringen aangeboden aan een groep CVA patiënten. De verschillen in stapresponsies tussen beide benen zijn vergeleken. Deze patiënten toonden algemene CVA-gerelateerde verschillen in hun bewegingen, zoals de neiging om hun gewicht boven hun niet-aangedane been te houden. Toch was er geen verschil tussen de benen te zien in de modulatie ten gevolge van de verschillende verstoringen. Patiënten stapten dus met beide benen op eenzelfde manier uit. Deze resultaten impliceren dat de TIBAR geen verschillende modulatie strategieën in acht hoeft te nemen. Wel zou het gunstig kunnen zijn voor patiënten wanneer de ondersteuning die de TIBAR biedt rekening houdt met het typische asymmetrische looppatroon van patiënten.

Doordat het gedrag van therapeuten tijdens conventionele therapie effectief lijkt te zijn voor het herstel van de patiënt, was het een belangrijke eis om dit gedrag te implementeren in het ontwerp van de TIBAR. Onderzoeksvraag 3 beschrijft dit aspect, welke verder wordt uitgewerkt in **hoofdstuk 5**. Hoofdstuk 5 heeft zich gericht op de intuïtieve en effectieve trainingmethode van therapeuten tijdens conventionele therapie, in termen van het fysieke contact tussen patiënt en therapeut. Er is daarom geprobeerd om typische balans-ondersteuningskarakteristieken vast te leggen, zoals de locatie, kracht, duur, richting en impuls van een ondersteuning. Resultaten hebben laten zien dat krachten voornamelijk werden toegediend op de locatie van de iliac crest (bekkenrand), in de medio-laterale richting. Therapeuten gebruikten krachten van ongeveer 2% van het lichaamsgewicht van de patiënt, en de duur en impuls van een ingreep waren respectievelijk 1.1s en 9.4 NS. Het intuïtieve en complexe gedrag van therapeuten in het ondersteunen van balans hangt van veel patiënt specifieke aspecten af, zoals spiersterkte, val historie en coördinatie karakteristieken. Toch is er in dit hoofdstuk geprobeerd om een algoritme te ontwikkelen dat de timing van therapeutische balans ondersteuning kan voorspellen met een enkele sensor. Deze informatie kan dan gebruikt worden voor de aansturing van de TIBAR. Door gebruik te maken van een acceleratiesignaal van een sacrum sensor was het mogelijk om een algoritme te ontwikkelen dat therapeutische balansondersteuningen kon voorspellen met een 'Positive Predictive Rate' en 'True Positive Rate' van respectievelijk 87% en 81%. Ondanks dat het aantal geïnccludeerde patiënten in dit hoofdstuk gelimiteerd was leveren de conclusies uit dit hoofdstuk toch een belangrijke bron van informatie over het gedrag van therapeuten.

Resultaten uit bovenstaande hoofdstukken zijn gecombineerd en hebben bijgedragen aan de ontwikkeling van de TIBAR. Een beschrijving van een eerste prototype van dit systeem wordt gepresenteerd in **hoofdstuk 6**. Het prototype bestaat uit een HapticMASTER, welke wordt gebruikt om balans te analyseren en ondersteuningskrachten aan te bieden, en een 'remote center mechanism', om de krachten over te brengen van de HapticMASTER naar het lichaam van de patiënt. De TIBAR is geëvalueerd met CVA patiënten in een klinische omgeving en de resultaten hiervan zijn gepresenteerd in dit hoofdstuk. Deze resultaten laten zien dat de TIBAR in staat is patiënten met een gelimiteerde balanshandhaving te voorzien in balansondersteuning. Bovendien laat de technische analyse in dit hoofdstuk een grote gelijkens zien tussen de ondersteuning die geleverd wordt door de TIBAR en de ondersteuning die geleverd wordt door therapeuten. Gebruikersacceptatie testen tonen een grote kans van acceptatie aan van de TIBAR in een klinische omgeving. Patiënten ervaren de ondersteuning die geleverd werd door de TIBAR als prettig, ze waardeerden de snelle bevestiging van het apparaat aan het lichaam en het intuïtieve gebruik. Hoewel wederom het aantal geïnccludeerde patiënten gelimiteerd is in dit hoofdstuk, toont dit

onderzoek de potentie aan van de TIBAR als balans ondersteunende robot.

Tot slot is de mogelijkheid van patiënten tot zelfstandig gebruik van de TIBAR in een klinische omgeving bediscussieerd in **hoofdstuk 7**. Dit hoofdstuk laat zien dat niet alleen het gedrag van therapeuten, maar dat ook andere principes van motorisch leren die bijdragen aan optimale trainingscondities zijn geïntegreerd in het prototype van de TIBAR. Toch moeten een aantal aspecten in acht genomen worden bij de verdere ontwikkeling van de TIBAR voor zelfstandig gebruik in een klinische omgeving. Als eerste de bediening van het systeem met maar één functionele hand, een veelvoorkomend probleem onder CVA patiënten. Zelfstandig gebruik van het systeem vraagt namelijk ook om de mogelijkheid tot het zelfstandig aantrekken van een veiligheidsharnas. In dit hoofdstuk wordt daarom de ontwikkeling van een nieuw veiligheidsharnas gepresenteerd, welke op een zelfstandige manier, en met maar één functionele hand vastgemaakt kan worden. Als tweede legt dit hoofdstuk de nadruk op het includeren van patiënt-specifieke parameters in de aansturing van de TIBAR. Momenteel zijn parameters groep-specifiek. Toch zou training met een dergelijk systeem effectiever kunnen zijn wanneer de ondersteuning zich aanpast aan het individu dat met het systeem traint. Als laatste maakt het gebruik van de HapticMASTER in het eerste prototype van de TIBAR het systeem onnodig duur voor gebruik in een klinische omgeving. Hoewel het gebruik van de HapticMASTER een uitstekende manier was om de potentie van het systeem te testen, moet er kritisch gekeken worden naar de specificaties van de HapticMASTER en de specificaties die nodig zijn voor het functioneren van de TIBAR.

Dankwoord

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About the Author

Juliet Haarman was born in Raalte, the Netherlands, on December 14th 1988. After receiving her high school diploma (Gymnasium, Carmel College Salland) in 2007, she moved to Enschede to study Biomedical Engineering at the University of Twente. Her bachelor research project ('Joint impedance of the hip and knee joint in healthy elderly subjects'), was performed at the Department of Biomechanical Engineering, University of Twente. Immediately after, she continued the master programme and specialized in the field of 'Human Function Technology'. In 2012, she finished her master thesis ('design and validation of shin guards for professional soccer players'), performed at Roessingh Research and Development. She continued to work for RRD as a PhD student (2013-2017) where she was appointed on the project 'SAFE'. The results of this research are presented in this thesis. Currently she is employed as a researcher/project leader at Indes in Enschede.

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