

Sensing the path to mobility

*Advancing gait
rehabilitation with
sensor technology*

DONDERS
SERIES

Carmen Ensink

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Proefschrift

ter verkrijging van de graad van doctor
aan de Radboud Universiteit Nijmegen
op gezag van de rector magnificus prof. dr. J.M. Sanders,
volgens besluit van het college voor promoties
in het openbaar te verdedigen op

woensdag 15 januari 2025
om 12.30 uur precies

door

Carmen Joanne Ensink
geboren op 15 januari 1993
te Hengelo

The printing of this thesis was financially supported by the Sint Maartenskliniek.

Cover design

Christel Hovestad-Jansen

Design/lay-out and print

Promotie In Zicht | www.promotie-inzicht.nl

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Promotor

Prof. dr. N.L.W. Keijsers

Copromotor

Dr. K. Smulders (Sint Maartenskliniek)

Manuscriptcommissie

Prof. dr. R.G.J. Meulenbroek

Prof. dr. ir. P.H. Veltink (Universiteit Twente)

Dr. N.M. de Vries

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Chapter 1



General introduction

General Introduction

Walking is an essential activity in our daily life, as indicated by the almost 9500 steps taken by healthy adults on average each day [1]. We walk to get from one place to another or as a recreational activity. Moreover, many daily life activities involve walking, such as household work, doing groceries, or walking the dog. Walking is also positively correlated with general physical health [2]. However, approximately 20-30% of the Dutch population aged 55 and older have limited walking ability. This percentage increases up to 60% in people over 80 years [3-5]. The ability to walk depends on good physical function. People with restricted gait function have lower physical activity levels, reflected in an average daily step count of only 5048 [6].

Adequate assessment of an individual's walking ability and limitations is important to determine the severity of gait impairments, identify appropriate treatment plans, and evaluate treatment effectiveness [7,8]. The assessment of walking ability often revolves around analyzing the gait capacity: how well an individual performs under optimal conditions [9]. Gait capacity comprises the ability to generate a stepping pattern, while maintaining balance and adjusting gait to meet environmental challenges and task requirements [10]. Nowadays, numerous technologies are available to objectively quantify walking activity and assess gait characteristics to describe the gait capacity, with wearable sensors gaining increasing interest [11,12]. Advanced gait analysis systems such as the Gait Real-time Analysis Interactive Lab (Motek Medical, Amsterdam) and C-Mill (Motek Medical, Amsterdam) can also be used for gait rehabilitation programs.

Treatment of walking impairments generally involves physiotherapy, with the therapist providing feedback on certain gait characteristics. For example, therapists may aim to increase stride length or encourage an adjustment in the gait pattern, such as lifting the foot higher. Wearable sensors have the potential to analyze these gait characteristics in real time. This opens up the possibility of providing feedback during self-guided gait exercises, potentially enhancing exercise effectiveness [13]. However, the accuracy of gait characteristic estimation by wearable sensors relies heavily on the algorithms applied to the captured data [14]. Therefore, the overarching aim of this thesis is to develop and evaluate algorithms for analyzing signals from wearable inertial measurement units (IMUs) to assess and provide feedback on various gait characteristics in people with walking impairments. While various diseases can cause walking impairments [15], this thesis focuses on describing gait patterns in two common diseases: people with stroke (*Box 1*) and lower-extremity osteoarthritis (*Box 2*).

Evaluation of walking

Many neurological and musculoskeletal diseases can affect the ability to generate a normal gait pattern, resulting in gait characteristics that deviate from the typical gait pattern's characteristics. For example, people with hip osteoarthritis generally make shorter strides [15], and many people with stroke show reduced ability to lift their paretic foot [16]. The gait pattern is a sequence of repetitive movements of both legs in interaction with the trunk and the arms. Each repetition of this pattern is called a gait cycle and can be described by temporal (e.g. gait cycle duration and stance time), spatial (e.g. stride length and step width), kinematic (e.g. range of motion and maximal knee angle), and kinetic characteristics (e.g. propulsive force, maximal vertical ground reaction force). Figure 1 shows the gait cycle of the right leg, including examples of these gait characteristics. The longstanding practice of describing gait characteristics, segmenting the gait cycle in different phases, and defining instants is called gait analysis.

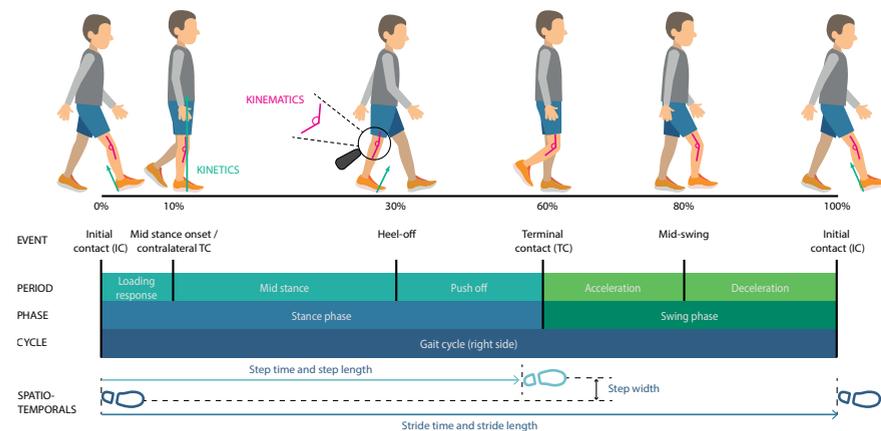


Figure 1. Gait cycle of the right leg.

A brief history of gait analysis technology

Gait analysis is a long-standing practice and has witnessed substantial developments in the field [17,18]. One of the most basic methods to assess gait capacity concerns the evaluation of spatiotemporal gait characteristics. This can be achieved by measuring the distance covered within a fixed timeframe or by measuring the time needed to cover a predetermined distance, both providing an average gait speed. Additionally, adding step count enables the derivation of cadence and the average step length. To date, this is still one of the most commonly used methods to gain an overall

measure of an individual's gait capacity. However, it is important to note that this method only provides average characteristics to describe the gait pattern instead of a stride-by-stride evaluation.

A noteworthy pioneer in the early phases of gait analysis technology for a more detailed assessment of the gait pattern was Gaston Carlet [17]. Carlet developed a shoe with pressure transducers, which resulted in the first record of the characteristic double bump shape of the ground reaction force in normal human gait as early as 1872 [18]. Only a few years later, in 1878, Muybridge [19] and Marey [20] were among the first to describe human movement by using a series of cameras to take multiple pictures. Further advancements in human gait analysis were made by Eberhart and Inman, who used interrupted light to analyze human motion [21,22]. Their innovative methodology involved capturing photographs of subjects walking in front of a camera with small light bulbs at the hip, knee, ankle, and foot. To create a visual record, a slotted disk was rotated in front of the camera to generate a sequence of white dots at constant time intervals. These dots were then connected to determine joint angles, which could be measured manually. To this day, their work forms the fundament of the technique behind the widely-used marker-based optical motion capture systems.

Nowadays, marker-based optical motion capture systems in combination with force plates and electromyography are used for detailed gait analysis. The optical motion capture system tracks the position of optical markers strategically placed on the body, while force plates measure ground reaction forces and electromyography captures muscle activation patterns. Integration of these technologies into clinical practice has enhanced consensus among clinicians regarding diagnostic reasoning, clinical decision-making, and treatment plans for individuals with walking impairments [23,24]. Although instrumented gait analysis is proven to be of great value, it remains a costly assessment requiring specialized laboratory facilities and trained personnel for operation. Additionally, the configuration and number of cameras in optical motion capture systems determine the measurement volume, restricting the available walking space. Therefore, researchers have explored alternative technologies aimed at facilitating quick and easy measurement setups without the need for dedicated laboratory environments [1,25,26].

A promising breakthrough in this field comes from IMUs. Currently, commercially available IMUs consist of tri-axial accelerometers (measuring acceleration) and gyroscopes (measuring angular velocity), often in combination with magnetometers (measuring the earth's magnetic field). Early versions of IMUs needed a fairly large battery pack and had limited data storage capacity. However, substantial

advancements in both hardware and software resulted in small and lightweight IMUs with increased battery life and storage capacity to record data for multiple hours [27]. These improvements have made IMUs minimally invasive for research participants [28].

The development of IMUs originates from the single-axis accelerometer measuring acceleration. The measured acceleration consists of two components: the change in velocity along the sensor axis and the gravitational force. As gravity consistently acts in the same direction, the measured magnitude of the gravity component depends on the orientation of the accelerometer, while the change in velocity magnitude is attributed to the accelerometer's motion. By combining three accelerometers into a tri-axial accelerometer, an estimate of its orientation relative to gravity can be made. However, during movement, this estimate is flawed and can not distinguish between different orientations around the direction of gravity. To this end, gyroscopes are added to calculate the sensor's orientation change by integrating the measured angular velocity [29]. To enhance the sensor orientation estimation in the transverse plane, around the gravitational direction, magnetometers have been integrated, measuring the earth's magnetic field (Figure 2) [29]. Once the IMU's orientation is determined, the gravitational component can be subtracted from the measured acceleration, leaving only the acceleration attributed to the sensor movement. This

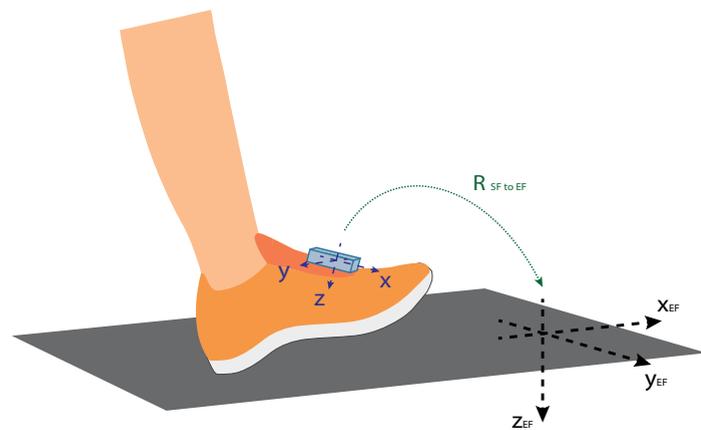


Figure 2. IMU sensor frame (SF) can be transformed using the estimated orientation (R) to align with the earth frame (EF). In the earth frame, the x-axis points to the magnetic north, the z-axis aligns with the gravitational direction, and the y-axis is perpendicular to the plane formed between the x- and z-axes. Once the IMU is oriented in the earth frame, the gravitational component can be subtracted from the measured acceleration to assess the linear acceleration of the IMU.

marks a crucial difference between optical motion capture systems and IMUs. While optical motion capture systems measure the 3D position of markers in space, IMUs deduce the positional change through double integration of the measured acceleration.

Using inertial measurement units for gait analysis

Deriving temporal, spatial, and kinematic gait characteristics from IMU signals relies heavily on the IMU's position on a specific body segment and subsequent processing steps during data analysis. Each body segment has its own distinct movement pattern during a gait cycle. As such, the signal of the recorded IMU data (acceleration, angular velocity, magnetic field) depends on the location of the IMU on the body (e.g. the foot, shank, or lower back). For example, Figure 3 illustrates the difference in the angular velocity signals between an IMU placed at the foot and the lower back.

Gait event detection and estimation of temporal gait characteristics

Previous research has shown that placing IMUs on the feet yields the most accurate identification of gait events (e.g. initial and terminal contact with the walking surface) in healthy participants [14,30,31]. While it is common to place IMUs on the lower back and the shanks, IMUs attached to the feet are closest to the impact source when walking. This results in more prominent signal features in the gyroscope and accelerometer data, with minimal delay, that correspond to gait event instances compared to data recorded by an IMU placed, for example, at the trunk.

For data captured from IMUs on the feet, a large variety of datatype and signal feature combinations have previously been used to identify gait events. Initial contact has been identified by the detection of peaks in either the angular velocity around the flexion-extension axis [30–33] or vertical acceleration [31,34]. Similarly, terminal contact has been identified through peak detection in the anterior-posterior component [31], vertical component [34], and magnitude [30] of the acceleration, as well as peak detection in the angular velocity around the flexion-extension axis [31–33]. While some studies attempted to identify the most accurate combination of IMU location and identification method both in healthy [14,31] and pathological gait [30,31], there is no clear evidence for a single best approach. In this thesis and based on the results from pilot data, I used the instant of crossing zero in angular velocity around the flexion-extension axis to identify initial contact and peak vertical acceleration to identify terminal contact. Regardless of the method used, once initial contact and terminal contact events for both feet are accurately identified, temporal gait characteristics such as stride time (between subsequent initial contact events), swing time (terminal to initial contact), and stance time (initial to terminal contact) can be calculated (see also Figure 1 for gait phase definitions). For example, the gait

cycle duration equals the time elapsed between two consecutive initial contact events.

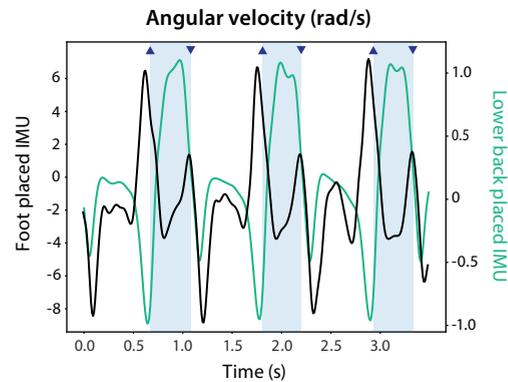


Figure 3. Angular velocity captured by IMUs on the foot (black, left y-axis) and lower back (green, right y-axis) in healthy gait. Shaded areas are swing phases that start at terminal contact (triangle pointing up) and end at initial contact (triangle pointing down).

Estimation of spatial gait characteristics

To calculate spatially dependent gait characteristics, the acceleration in the earth frame has to be integrated twice to estimate the change in position relative to the initial position. From the estimated change in position in combination with the identified gait events, spatially dependent gait characteristics can be derived for each gait cycle. Attaching IMUs to the feet enables the deduction of spatial gait characteristics from the IMU's positional change while obtaining these characteristics from IMUs attached to a more proximal segment requires the application of biomechanical models [35,36]. Although previous research with these models showed promising results in the estimates of spatial gait characteristics [36], applying a model inherently introduces assumptions and uncertainties [35]. Therefore, feet-placed IMUs might be more accurate in estimating spatial gait characteristics.

Another benefit of IMUs placed at the feet concerns the correction of sensor drift. Sensor drift, stemming from signal noise, is a concern when integrating the acceleration data. This integration of noise results in a gradual increase in error over time. Typically, the sensor drift is corrected by forcing the velocity to be zero when you are certain that the sensor is stationary. When sensors are attached to the feet, this correction can be done during the flat foot phase of walking [37]. By applying this correction in each flat foot phase, the impact of sensor drift on position determination is minimized. Sensors attached to more proximal segments often lack such a clear static period.

Therefore, a zero velocity correction cannot be applied for each gait cycle during walking, resulting in the accumulation of sensor drift over time and a corresponding increase in error with each gait cycle.

Once the position and gait events are known, the difference in position between certain gait events can be used to determine spatial and spatially dependent gait characteristics. For instance, the difference in position between two successive initial contact events is equal to the stride length. Dividing this stride length by the elapsed time between these initial contact events yields the stride velocity.

Although the algorithms for gait event identification and calculations of gait characteristics from IMU data show promising results in the assessment of healthy gait, their performance is challenged in pathological gait [38–40]. This stems from deviating cyclic patterns in pathological gait compared to the assumed cyclic pattern of healthy people for which the algorithms were designed. For example, impaired dorsiflexion of the foot will likely result in less prominent angular velocity peaks around the transverse axis captured by an IMU attached to the foot, commonly used to identify initial contact [41]. As a result, recognition of the angular velocity peaks, and thus initial contact, by an algorithm can be more challenging and remains inadequately addressed in impaired gait to date.

Estimation of kinematic gait characteristics

To determine joint kinematics, a setup is required in which an IMU is attached to each body segment around a joint (Figure 4) [42–44]. After determining the orientation of both sensors in the global coordinate system, the orientation of the IMU attached to one segment (e.g. the foot) can then be expressed in the coordinate system of the IMU attached to the other segment (e.g. the lower leg) to estimate the joint (e.g. ankle) angles [42–44].

Given that an IMU must be attached to each segment around a joint to calculate joint angles, the setup requires a larger number of sensors compared to the minimal setup to determine spatiotemporal gait characteristics. Moreover, an additional calibration is often needed to obtain reliable joint angle estimates [42,44]. This calibration involves defining the IMU's local coordinate system in relation to the segment's coordinate system. One common method involves recording data from movements in a single plane, such as ankle flexion-extension [44]. Cross-talk of this movement on, for instance, the rotation axis of the sensor is corrected in the actual measurement through this calibration and will only be attributed to the flexion-extension movement. Alternatively, sensor-to-segment alignment can be achieved by placing the IMUs so that their local coordinate systems align with the anatomical coordinate

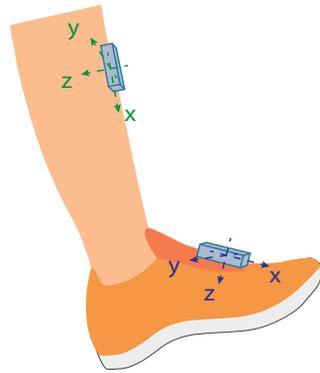


Figure 4. To calculate joint angles from IMUs, in this example the ankle joint angle, it is necessary to express the orientation of both IMUs in the global frame to be able to compare their orientations. Subsequently, the orientation of the IMU attached to one segment (e.g. the foot) can be expressed in the coordinate system of the IMU attached to the other segment (e.g. the lower leg) by applying a rotation. This rotation is the estimate of the joint (e.g. ankle) angles.

system. This approach eliminates the necessity for posture and movement calibration, and it has been successfully applied to the foot and shank [45,46].

IMU's to provide feedback on gait

With the possibility to analyze gait characteristics in real time, IMUs have the potential to provide real-time feedback on the performance of these characteristics [13]. This creates opportunities for extending therapeutical guidance beyond the clinical setting, potentially enhancing the effectiveness of self-guided training exercises. For example, in people after a stroke, foot orientation at initial contact is an important aspect of gait rehabilitation (see *Box 1*). This foot orientation at initial contact, is defined as the angle between the foot and the walking surface, referred to as the foot strike angle. A drop foot leads to toe-first contact rather than heel-first, increasing the risk of stumbling and falls [47,48]. By attaching an IMU to the foot, the orientation of the foot can be estimated and provided as feedback, with the idea to improve the foot strike angle and prevent stumbling. While it is known that task-specific extrinsic feedback (for example by a physiotherapist) effectively enhances ankle power [49] and ankle angle at initial contact [13], limited knowledge exists regarding the effect of using IMUs to provide feedback for training purposes on gait characteristics [13,50].

Outline of this thesis

The aim of this thesis is to develop and evaluate IMU-based algorithms to assess and provide feedback on gait characteristics in people with gait impairments. Chapters 2, 3, and 4 focus on the development of valid algorithms to analyze different gait characteristics, while chapters 5 and 6 study their clinical relevance. Chapter 7 evaluates the impact of feedback on the gait pattern.

In *Chapter 2*, I describe the development and accuracy of an IMU-based algorithm to extract spatiotemporal gait characteristics of straight-ahead walking. To ensure that the algorithm is applicable across diverse gait patterns, and irregular validation is conducted in healthy people during regular and irregular walking as well as in people with stroke. The research question of this study is: what is the accuracy of an IMU-based algorithm to estimate spatiotemporal gait characteristics from IMU data in regular and irregular gait?

In *Chapter 3*, the algorithm validated in Chapter 2 is applied to evaluate the effect of including accelerating and decelerating steps around a turn on spatiotemporal gait characteristics. To obtain a substantial number of strides to estimate gait characteristics, a walking trajectory of 5 to 10 meter is commonly used to walk back and forth with 180-degree turns at each end. Understanding the effect of accelerating and decelerating strides on average and the variability of gait characteristics is essential for isolating the steady-state portion of gait. This study has two main research questions: 1) what is the effect of stride selection methods on the means and variability of spatiotemporal gait parameters in tests including turns? and 2) how many strides preceding and following 180-degree turns should be excluded for analysis of steady-state gait?

After focusing on spatiotemporal gait characteristics in previous studies, *Chapter 4* concentrates on kinetic (forward propulsion) and kinematic (foot strike angle) gait characteristics. In people with stroke, improving the foot strike angle and forward propulsion are common goals in gait rehabilitation. The ability to assess these characteristics would be of great additional value for the applicability of IMUs in clinical practice. Therefore, the goal of Chapter 4 is twofold: first, I analyze if the foot strike angle can be measured with an IMU. Secondly, as IMUs do not measure force, I will study if a suitable indicator for forward propulsion can be identified from IMU data. The research questions of this study are: 1) what is the accuracy of the IMU-derived foot strike angle compared to optical motion capture in people with stroke? and 2) are there IMU-based parameters indicative for forward propulsion in people with stroke?

In *Chapter 5*, I use the validated algorithm from Chapter 2 to quantify the gait characteristics of people with knee osteoarthritis with and without an indication for knee replacement surgery. It is conceivable that people who are considered candidates for surgery have poorer levels of mobility than those who are not considered appropriate candidates for surgery. In this study, we compared mobility metrics assessed with wearable sensors between people with and without an indication for knee joint replacement surgery, to explore if differences between groups existed. The research question of this study is: which gait characteristics discriminate between individuals who are and are not deemed appropriate candidates for knee joint replacement surgery?

In *Chapter 6* I translate the System Usability Scale [51] to Dutch, to be able to evaluate the usability of a feedback system that I will develop in Chapter 7. Worldwide, the System Usability Scale is the most common questionnaire to evaluate system usability [52]. Since it is a prerequisite to administer questionnaires in the user's native language, I translate the System Usability Scale to Dutch and validate its applicability for healthcare technologies by assessing internal consistency, test-retest reliability and construct validity. After translating the questionnaire, the research question for the validation phase of this study is what is the internal consistency, test-retest reliability and construct validity of the Dutch version of the System Usability Scale for healthcare innovations with a focus on rehabilitation technologies?

In *Chapter 7*, I study if people in the chronic phase after a stroke are able to adjust their gait pattern when real-time feedback on the foot strike angle and propulsive force is provided. Additionally, I examine how people after a stroke perceive the usability of the feedback system for training purposes using the Dutch version of the System Usability Scale. The research questions addressed are: 1) can people with stroke adjust their foot strike angle and forward propulsion based on real-time feedback? and 2) how do participants perceive the usability of the system providing this feedback?

Finally, a summary of the presented studies followed by a general discussion of the results and avenues for future research will be given in *Chapter 8*.

Box 1: Gait patterns after stroke

Worldwide, stroke is the leading cause of acquired physical disability in adults, with an incidence rate of approximately 90 per 100.000 people, rising to around 1200 per 100.000 people aged over 75 years old [53]. A stroke manifests as an acute neurological deficit with symptoms lasting for at least 24 hours, caused by a vascular injury within the central nervous system [53]. This vascular injury stemming from either infarction or hemorrhage, induces brain ischemia. Depending on the specific brain region, patients show different symptoms that vary in severity.

A stroke often causes damage to the descending motor pathways, resulting in loss of motor selectivity and muscle force, particularly prominent around the ankle region. Around 20% of people after a stroke suffer from weakness of the ankle dorsiflexors, commonly referred to as 'drop foot' [16]. This weakness can result in a midfoot or even toe landing instead of the typical heel strike in healthy gait (Figure 5).

In combination with a reduced ability to flex the knee and hip, the foot drags across the walking surface during the swing phase. To prevent this, patients often use an energetically inefficient compensatory mechanism around the hip called 'circumduction'. Hip circumduction is characterized by abducting the paretic hip and lifting the pelvis on the paretic side. Furthermore, patients with a drop foot generally have concomitant weakness in ankle plantarflexors, causing diminished forward propulsion during push-off [54]. Together, these factors contribute to reduced gait speed, unstable gait, and altered gait pattern compared to healthy gait [47].

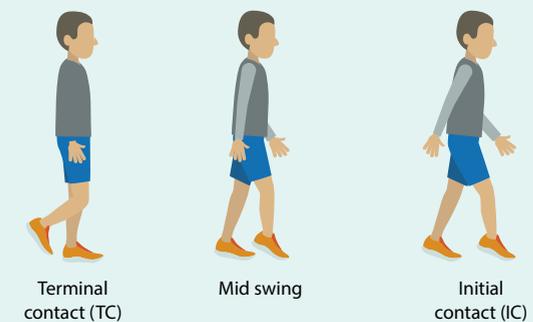


Figure 5. Swing phase of the right leg with a drop foot.

Box 2: Gait with lower-extremity osteoarthritis

Osteoarthritis predominantly affects weight-bearing joints, such as the hip or knee in approximately 10-18% of people older than 60 years worldwide [55,56]. Joints affected by osteoarthritis show degeneration of the articular cartilage, subchondral bone, ligaments, capsulesynovium and periarticular muscles. While the underlying etiology of osteoarthritis is complex, pain, stiffness, and instability are common shared symptoms among people [56]. Generally, pain is the most disabling symptom, leading to substantial limitations in mobility and difficulties with activities of daily life [56,57]. This is also underlined by several studies reporting altered gait characteristics in people with osteoarthritis, such as decreased gait speed, shorter strides, and reduced range of motion of the affected joint compared to those without osteoarthritis [15,58].

To date, there is no curative treatment for osteoarthritis. Therefore conservative treatment modalities focusing on pain relieve and slowing the progression of osteoarthritis based on physiotherapy, pain management, and lifestyle modifications are the first step [56]. When the effects of conservative treatment have worn off, joint replacement surgery may be considered [56].

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Chapter 2



Validation of an algorithm to assess regular and irregular gait using inertial sensors in healthy and stroke individuals

C.J. Ensink
K. Smulders
J.J.E Warnar
N.L.W. Keijsers

PeerJ. 2023. Dec;11:e 16641

Abstract

Studies using inertial measurement units (IMUs) for gait assessment have shown promising results regarding accuracy of gait event detection and spatiotemporal parameters. However, performance of such algorithms is challenged in irregular walking patterns, such as in individuals with gait deficits. Based on the literature, we developed an algorithm to detect initial contact (IC) and terminal contact (TC) and calculate spatiotemporal gait parameters. We evaluated the validity of this algorithm for regular and irregular gait patterns against a 3D optical motion capture system (OMCS).

Methods

Twenty healthy participants (aged 59 ± 12 years) and 10 people in the chronic phase after stroke (aged 61 ± 11 years) were equipped with 4 IMUs on both feet, sternum and lower back (MTw Awinda, Xsens) and 26 reflective markers. Participants walked on an instrumented treadmill for 2 minutes (i) twice with their preferred stride lengths and (ii) once with irregular stride lengths ($\pm 20\%$ deviation) induced by light projected stepping stones. Accuracy of the algorithm was evaluated on stride-by-stride agreement of IC, TC, stride time, length and velocity with OMCS. Bland-Altman-like plots were made for the spatiotemporal parameters, while differences in detection of IC and TC time instances were shown in histogram plots. Performance of the algorithm was compared between regular and irregular gait with a linear mixed model. This was done by comparing the performance in healthy participants in the regular vs irregular walking condition, and by comparing the agreement in healthy participants with stroke participants in the regular walking condition.

Results

For each condition at least 1500 strides were included for analysis. Compared to OMCS, IMU-based IC detection in both groups and condition was on average 9–17 (SD ranging from 7 to 35) ms, while IMU-based TC was on average 15–24 (SD ranging from 12 to 35) ms earlier. When comparing regular and irregular gait in healthy participants, the difference between methods was 2.5 ms higher for IC, 3.4 ms lower for TC, 0.3 cm lower for stride length, and 0.4 cm/s higher for stride velocity in the irregular walking condition. No difference was found on stride time. When comparing the differences between methods between healthy and stroke participants, the difference between methods was 7.6 ms lower for IC, 3.8 cm lower for stride length, and 3.4 cm/s lower for stride velocity in stroke participants. No differences were found on differences between methods on TC detection and stride time between stroke and healthy participants.

Conclusions

Small irrelevant differences were found on gait event detection and spatiotemporal parameters due to irregular walking by imposing irregular stride lengths or pathological (stroke) gait. Furthermore, IMUs seem equally good compared to OMCS to assess gait variability based on stride time, but less accurate based on stride length.

Introduction

Gait analysis is a valuable tool for diagnosis and treatment evaluation of gait impairments in clinical settings. Traditionally, optical motion capture systems (OMCS) and force plates are used for gait analysis. However, a major downside of these expensive systems is the requirement of a lab with specialized staff, limiting the accessibility of gait analysis in clinical practice. Moreover, these dedicated labs often provide optimal controlled conditions for gait assessment, limiting ecological validity [1]. A promising alternative for gait analysis is the use of inertial measurement units (IMUs). These compact wearable sensors enable gait analysis not restricted to the lab setting, at a lower cost, and easier to operate.

In the past decades, many research groups have developed algorithms for gait assessment based on IMU data. An overview of different algorithms is given in a reviewing article by Diaz et al. [2] and a performance comparison of seventeen common algorithms is made in the review by Panebianco et al. [3]. These gait algorithms are developed to identify gait events and subsequently calculate spatiotemporal gait parameters. Despite the increasing number of studies in this field, several limitations hinder further uptake in clinical settings.

The first obstacle to using IMU-based gait parameters in the clinic stems from a scarcity of validation studies testing IMU-based algorithms in people with irregular walking patterns. The validity of gait algorithms has predominantly been tested for regular gait in healthy participants [3]. However, individuals with gait deficits often walk with irregular patterns (e.g. due to neurological diseases) [3–5]. It is known that data from IMUs is less predictable in irregular gait patterns, compromising the performance of many of the developed algorithms [6,7]. For example, Hundza et al. found a mean error of 2 cm in stride length estimation in healthy controls, which increased to 11 cm in people with Parkinson's disease [6].

A second limitation of published algorithms is that they are typically designed and optimized for specific locations of the IMUs on the body, e.g. shank, ankle or shoe. As signal features of IMUs depend on the body location, the applicability of these algorithms to placement on other body parts can be limited. Most common set-ups are (combinations of) one IMU on the lower back, one sensor on each shank, or on both feet [3]. In general, IMUs placed closer to the source of impact (lower legs or feet with the walking surface) have the most prominent signal features [3,8]. Moreover, Jasiewicz et al. found that feet-based algorithms outperform shank-based algorithms regarding the accuracy of gait event detection in pathological gait [9]. They concluded that the irregular and less smooth movement of the shank during pathological gait

was likely due to increased instability, which in turn caused more disturbances in the sensor signal [9]. Unfortunately, the number of studies evaluating the validity of gait algorithms processing data from IMUs on the feet in pathological gait is limited [2,3]. Finally, almost all validated gait algorithms are undisclosed. So far, most gait algorithms are only schematically described in published articles [4–7,9–15]. Without code sharing, replication, validation, and use of these algorithms in the clinic remains challenging.

Based on previous literature [5,10,16,17], we developed an algorithm for gait assessment using IMUs on both feet and the trunk (lumbar level). We evaluated the validity of this algorithm against an OMCS for regular and irregular walking patterns. We operationalized irregular walking patterns in two ways: first, by using stepping targets on an instrumented treadmill in healthy participants, cueing walking with constant and varying step lengths. Secondly, we evaluated the algorithms in people with stroke. Based on results previously reported in the literature we based our algorithm on [5,10,16,17], we expected a similar and small constant error of less than 5 cm between the gait algorithm and OMCS in regular and irregular walking in healthy participants and in regular walking in people with stroke. However, a larger variability of the error in the stroke population compared to the healthy population, was expected based on previous literature in pathological gait [18]. Participants were tested on a treadmill to collect a large number of steps for each participant. Healthy participants performed overground walking to ensure consistent results for this condition. We also developed the gait algorithm in an open-source programming language (Python), making the data and code freely available for further use.

Materials and methods

Participants

Healthy participants aged between 40 and 90 years old, who were able to walk for at least two minutes without assistance were recruited from the community between April 2021 and February 2022. We included five participants per age category, 40–49, 50–59, 60–69 and 70+ years, resulting in a total of N=20 healthy participants (Table 1). Exclusion criteria were any diseases affecting gait or balance, such as osteoarthritis, neurological or neuromuscular disease or deformities of the lower extremities, and BMI > 30 kg/m².

Stroke participants were able to walk for at least two minutes without assistance, participated in a walking therapy group due to their stroke, were above 18 years, and had to understand verbal instructions. Exclusion criteria were any other diseases affecting gait or balance, hemispatial neglect, and a BMI > 30 kg/m². A total of N=10

stroke patients from the gait rehabilitation program of the Sint Maartenskliniek were included in this study. Clinical data of the stroke participants were derived from the electronic patient record. Participant characteristics can be found in Table 1, the Chi-square and Mann-Whitney U tests revealed no significant differences ($p \geq 0.05$) between the groups based on gender, age, height or weight.

Table 1. Participant characteristics.

	Healthy participants	Stroke population
N	20	10
Gender (male/female)	10/10	7/3
Age (mean ± SD years)	59 ± 12	61 ± 11
Height (mean ± SD cm)	174 ± 7.2	176 ± 7.5
Weight (mean ± SD kg)	75 ± 8.0	81 ± 9.1
Affected side (left/right)	-	4/6
Stroke type (ischemic/hemorrhagic)	-	7/3
FAC score (min-max)	-	3-5

FAC: Functional Ambulation Categories.

The study protocol was in line with the Declaration of Helsinki and was granted an exemption of the Dutch medical scientific research act (WMO) by 'METC Oost-Nederland' (identification number: 2021-8191). Prior to study participation, written informed consent was provided by all participants.

Materials

Participants were equipped with 4 IMUs (MTw Awinda, Xsens, Enschede) at the dorsal side of both feet, sternum, and lower back (L4/5) and 26 reflective markers for the OMCS according to the VICON plug-and-gait lower body model [19]. Xsens MT Manager software suite version 2019.2 was used for data capture of the IMUs. All treadmill walking conditions were performed on the GRAIL (Gait Real-time Interactive Analysis Lab, (Motek Forcelink, Amsterdam, the Netherlands)); an instrumented treadmill with an ten-camera OMCS (VICON, Oxford, United Kingdom). All overground walking conditions were performed in the overground gait lab, with a ten-camera OMCS (VICON, Oxford, United Kingdom). The IMU system and OMCS recorded at 100 Hz and were synchronized by a high-low pulse with OMCS as master.

Measurement protocol

During treadmill walking, healthy and stroke participants wore a harness attached to the ceiling for safety precautions. All participants walked on the treadmill at a

self-selected speed before data collection for approximately four minutes for familiarization purposes. Subsequently, they walked on the instrumented treadmill in two conditions: regular and irregular treadmill walking.

In the regular treadmill walking condition, participants walked for 2 minutes at a self-paced, comfortable walking speed. Self-paced walking allowed participants to adjust the speed of the treadmill by walking more at the front of the belt (increase in speed) or at the back of the belt (decrease in speed). The participants with stroke performed the regular walking task in self-paced mode if possible, but in fixed speed mode if their walking capacity was insufficient to regulate the treadmill's speed. After the regular walking condition, all participants performed the irregular walking condition, consisting of a precision stepping task at the average walking speed during the regular walking condition. Rectangular stepping stones (30x15 cm) were projected on the treadmill, functioning as step targets. The stepping stones were projected at stride lengths randomly varying between 80-120% (80, 90, 100, 110, 120) of the preferred stride length of the individual participant. Participants were instructed to walk without holding the handrail bars if possible but were allowed to do so if needed. Participants were allowed to rest between walking conditions. For each of the measurements, data collection was started once participants indicated they had reached a comfortable walking speed. Data were recorded for a duration of two minutes and stopped before participants were decelerating, ensuring no accelerating and decelerating phases were included in the dataset for further analysis.

The healthy participants performed an additional overground walking task. They were asked to walk ten times back and forth through the measurement volume of the overground gait lab (approximately 5 meters) at a comfortable walking speed.

Data processing

All data processing and analysis described in this paragraph and in 'Data analysis' are included in the algorithm code available at: https://github.com/SintMaartenskliniek/IMU_GaitAnalysis (Release 'Validation study', tag 'v1.1.0').

IMU data captured by MT Manager software (2019.2) included angular velocity and acceleration in the sensor frame, acceleration in the earth frame, and orientation in quaternion and Euler angle format. OMCS data was captured by VICON Nexus software (version 2.4). All further data processing and analyses were performed in Python 3.10.

Prior to any data analysis, a second-order low-pass Butterworth filter was applied to the angular velocity (15 Hz cut-off frequency) and acceleration data (17 Hz cut-off

frequency) of the IMUs, according to Sabatini et al. [5]. OMCS data was filtered with a second-order low-pass Butterworth filter (15 Hz cut-off frequency).

Data analysis

Figure 1 shows a typical gait cycle and corresponding mediolateral gyroscope and vertical accelerometer signals of the IMUs on the feet, and the velocity of the heel and toe markers of the OMCS. A gait cycle consists of a stance phase, initiated by an initial contact event (IC), and a swing phase, starting at a terminal contact event (TC). Accurate identification of IC and TC events is crucial for correctly calculating spatiotemporal gait parameters. They also define the time period for further integration of the IMU signals to determine spatial parameters.

Another important gait event for the IMU-based gait algorithm is the instant of mid-swing, which is used to identify the IC and TC. Based on Sabatini et al., mid-swing events were identified as the maximum in the clockwise direction of the angular velocity around the mediolateral axis (i.e. the axis of rotation for flexion-extension movements) [5]. To this end, `scipy.signal.find_peaks` function with peak distance at 0.7 seconds, prominence at 1 rad/s was used. Based on Behboodi et al. [10], IC events were identified at the first instance of zero-crossing, positive to negative, after mid-swing in the angular velocity around the mediolateral axis. Peaks between mid-swing events in the vertical acceleration based on Mercer et al. were used to identify TC events (`scipy.signal.find_peaks` function with no further specifications) [17,20]. In case multiple peaks were found, the peak at the instance with the largest angular velocity in the anti-clockwise direction was identified as the actual TC event; the others were deemed as an artefact. Finally, foot flat was identified based on Behboodi et al. [10]. The start of foot flat was defined as the instant of TC on the contralateral side. The end of foot flat (i.e. heel-off) was identified at the instant of mid-swing on the contralateral side [10]. Based on the instants of the gait cycle, stance phase (initial contact to terminal contact), swing phase (terminal contact to initial contact) and foot flat phase (start of foot flat to end of foot flat) were identified.

After gait event detection, spatial parameters were calculated. The tri-axial velocity of the foot was estimated by numerical integration of the accelerometer (earth frame) signal according to equation 1 over the duration of the trial (120 s). However, this involves some signal drift. To reduce this signal drift, a sigmoid curve, based on a p-chip interpolation (`scipy.interpolate.pchip_interpolate` function) was subtracted from the signal (zero-velocity updates) [13]. The p-chip interpolation function was defined between each period of foot flat (equation 2). Hereafter, zero-velocity updates were applied at each foot flat (equation 3) [21–23].

$$\text{velocity}_{\text{raw}}(t) = \text{acceleration}(t) * T_s + \text{velocity}(t-1) \quad (1)$$

for each instant t , with $T_s = 1/\text{sample frequency}$

$$\text{velocity}_{\text{de-drifted}}(t) = \text{velocity}_{\text{raw}}(t) - \text{sigmoid curve of drift estimation}(t) \quad (2)$$

$$\text{velocity}(t) = \text{velocity}_{\text{de-drifted}}(t) - \text{velocity}_{\text{de-drifted at foot flat}} \quad (3)$$

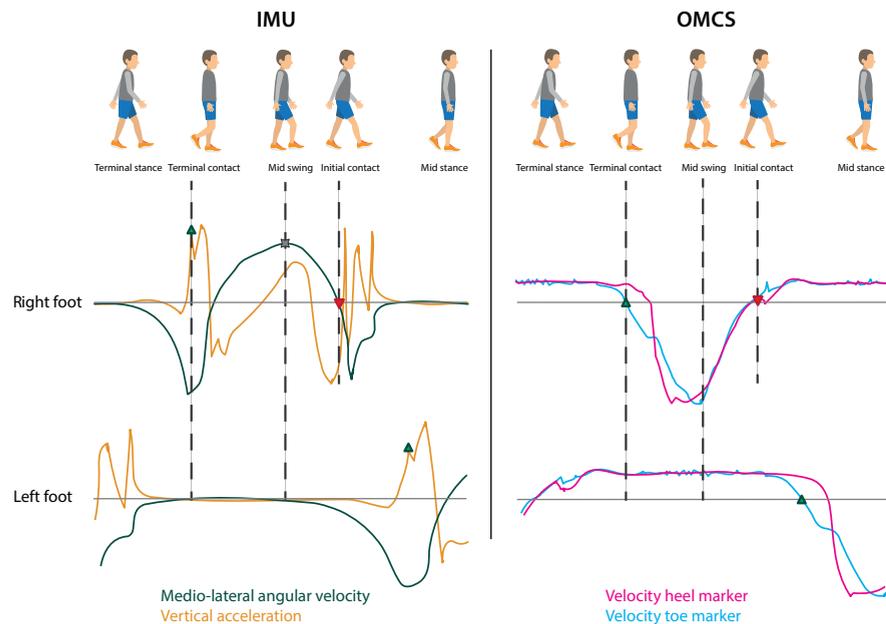


Figure 1. Typical gait cycle with corresponding IMU and OMCS data. Upper graph is of the right foot and the lower graph is of the left foot as presented in the gait cycle on the top of the figure. The left graphs show the angular velocity around medio-lateral axis (flexion-extension movement, green) and vertical acceleration (earth frame, orange) of the IMUs attached to the feet. The right graphs show the velocity of the toe marker (blue) and velocity of the heel marker (pink) of the OMCS. Terminal contact (green triangle pointing up) was determined at the peak acceleration before mid-swing (IMU) and zero-crossing of the velocity of the toe marker (OMCS). Mid-swing (cross) was identified at peak angular velocity (IMU). Initial contact (red triangle pointing down) was identified at the zero-crossing of the angular velocity after mid-swing (IMU) and zero-crossing of the velocity of the heel marker (OMCS). Foot flat was identified between terminal contact and mid-swing of the contralateral foot (for both IMU and OMCS).

Note that the initial velocity at the start of the measurement ($t = 0$) was set at zero. Since the measurements started while participants were walking and the leg could be in the swing phase, this could result in an inaccurate velocity estimation until the first foot flat phase was reached.

Numerical integration of the velocity over the duration of the trial (120 s) results in tri-axial position estimation over the duration of the trial:

$$\text{position}(t) = \text{velocity}(t) * T_s + \text{position}(t-1) \quad (4)$$

for each instant t , with $T_s = 1/\text{sample frequency}$

Note that the initial position at the start of the measurement ($t = 0$) was set at zero. Stride time was defined as the time between two consecutive IC events:

$$\text{stride time}_n = \text{time at IC}_n - \text{time at IC}_{n-1} \quad (5)$$

Stride length was defined as the distance traveled by the foot during the stride time (IC till following IC) in the horizontal plane:

$$\text{stride length}_n = \sqrt{(\text{position } X_{\text{IC}_n} - \text{position } X_{\text{IC}_{n-1}})^2 + (\text{position } Y_{\text{IC}_n} - \text{position } Y_{\text{IC}_{n-1}})^2} \quad (6)$$

Stride velocity was calculated as the stride length divided by the stride time:

$$\text{stride velocity}_n = \text{stride length}_n / \text{stride time}_n \quad (7)$$

Gait event detection in the OMCS data was performed according to the validated velocity based method of Zeni et al. [24]. This method defines TC at the instant that the velocity vector in anterior-posterior direction of the toe marker crosses zero in the anterior direction. IC is defined at the instant that the velocity vector in the anterior-posterior direction of the heel marker crosses zero in the posterior direction. For treadmill walking, the position of the toe and heel markers in the global coordinate system were used whereas the position of toe and heel markers were calculated relative to the pelvis for overground walking. Stride time and stride velocity were calculated according to the same definitions as used for the sensor algorithm (equations 5 and 7). Stride length for OMCS data during treadmill walking was calculated as the average velocity of the ankle on the contralateral side during flat foot (equations 8 and 9), multiplied by the stride time and added to the difference in position between IC and the following IC along the Y-axis, which is the axis in line with the walking direction (equation 10). In overground walking the stride length was calculated as the difference in position between two consecutive IC events of the heel marker (equation 11).

$$\text{swing time}_n = \text{IC}_n - \text{TC}_{n-1} \quad (8)$$

$$\text{velocity}_{\text{treadmill}_n}^{\text{contralateral foot}} = \frac{(\text{position } Y_{\text{TC} + 0.1 * \text{swing time}}^{\text{contralateral foot}} - \text{position } Y_{\text{TC} + 0.6 * \text{swing time}}^{\text{contralateral foot}})}{(0.5 * \text{swing time})} \quad (9)$$

$$\text{stride length}_n \text{ OMCS treadmill walking} = (\text{position } Y_{\text{IC}_n} - \text{position } Y_{\text{IC}_{n-1}}) + \text{velocity}_{\text{treadmill}_n}^{\text{contralateral foot}} * \text{stride time}_n \quad (10)$$

$$\text{stride length}_n \text{ OMCS overground walking} = (\text{position } Y_{\text{IC}_n} - \text{position } Y_{\text{IC}_{n-1}}) \quad (11)$$

Post-hoc analysis

Two methods are frequently used in literature to identify gait events: the OMCS-based method used in this study and a method based on force plate data [3,10,13,16]. The benefit of OMCS-based gait event detection is that multiple strides per stretch in the overground lab can be analyzed against only one stride per stretch on force plates. To maximize the number of strides for analysis in the overground lab and be consistent in the methods used, the IMU-based algorithm was validated against OMCS in both settings. Nevertheless, during treadmill walking trials, force data was collected by the embedded force plates of the GRAIL. We checked the magnitude of the difference, including limits of agreement (LoA) at 1.96 standard deviation (SD), in gait event detection between the OMCS-based method and force plate data as ground truth.

Statistical analysis

Groups were compared on gender distribution by the Chi-square test, and on age, height and weight by the Mann-Whitney-U test. The validity of the gait algorithm was evaluated on a stride-by-stride basis, quantifying the agreement of the instant of IC and TC, stride time, stride length, and stride velocity, with OMCS-derived outcomes as reference [24]. For stride time and length variability, we calculated the coefficient of variation (CoV) for each participant, defined as the SD over all strides divided by the mean of all strides within a participant. Differences between sensor and OMCS-derived timing of IC and TC were visualized in histograms. For stride time, stride length and stride velocity, we created Bland-Altman-like plots to reflect the agreement between the IMU-based and OMCS-based analysis. Because the difference between methods for stride length and velocity showed a downward trend with increasing means of the value (non-uniformity), evaluated using linear regression models, we did not calculate the limits of agreement. To evaluate variance within and between subjects, we constructed Bland-Altman-like plots based on the mean over strides within a participant, as well as based on all separate strides (except for CoV measures which can only be calculated per participant).

To evaluate the algorithm's performance in irregular walking, we compared differences between methods for regular with irregular conditions in healthy controls and for regular with irregular conditions in stroke participants using a linear mixed model with the difference between methods for each gait parameters as dependent measure, condition as fixed effect and participant ID as random effect. We also tested differences between methods comparing healthy versus stroke participants during regular walking. For this comparison, we constructed linear mixed models with the difference between methods of each gait parameter as dependent variable, group (healthy vs stroke) as fixed effect and participant ID as random effect. For CoV measures, we compared regular vs irregular walking in healthy participants using a paired t-test and compared healthy and stroke participants during regular walking using an unpaired t-test.

The significance level was set at alpha 0.05. Differences between overground and treadmill walking in the differences between methods were described by mean differences and SD. All statistical analysis was done in RStudio (R version 2022.02.0), using the lme4 package (version 1.1-29).

Results

Treadmill walking

All participants performed all regular and irregular walking conditions except for one individual with stroke (participant ID: STR_03), whose walking capacity was insufficient to perform the target stepping task. Therefore, only a fixed-speed trial representing regular walking from this participant was included for further analysis. One other stroke participant (participant ID: STR_09) had to perform the regular walking task at a fixed treadmill speed. All other participants performed the regular walking condition in self-paced mode. Stride time varied between 0.71 and 2.58 s, stride length between 0.26 and 1.83 m, and stride velocity between 0.14 and 1.73 m/s across all participants and conditions (Table 2).

Gait event detection

Detection of IC when collapsing groups and conditions was on average 9-17 ms later based on IMU compared to OMCS (Figure 2, panels A, E). TC was on average 15-24 ms earlier for the IMU-based method (Figure 2, panels B, F). For both gait events, the variance of difference between methods (SD for each individual) was limited in healthy participants, and more apparent in stroke participants (Figure 2, panels C, D and G, H).

Table 2. Median and IQR of IMU-based and OMCS-based parameters.

	Healthy participants (n=20)				Stroke participants (n=10)			
	Regular walking		Irregular walking		Regular walking		Irregular walking	
	IMU	OMCS	IMU	OMCS	IMU	OMCS	IMU	OMCS
Stride time (s) median (IQR)	1.05 (0.09)	1.05 (0.09)	1.07 (0.13)	1.07 (0.13)	1.42 (0.36)	1.42 (0.36)	1.36 (0.28)	1.36 (0.29)
CoV stride time (%) median (IQR)	1.80 (0.66)	1.80 (0.62)	6.15 (1.65)	6.11 (1.45)	4.65 (3.91)	4.65 (3.91)	6.49 (3.42)	5.79 (3.91)
Stride length (m) median (IQR)	1.32 (0.13)	1.35 (0.13)	1.31 (0.10)	1.34 (0.13)	0.78 (0.38)	0.78 (0.38)	0.76 (0.32)	0.76 (0.31)
CoV stride length (%) median (IQR)	4.55 (1.98)	4.74 (2.58)	6.62 (0.75)	7.25 (0.77)	8.54 (3.85)	8.54 (3.85)	8.57 (3.60)	8.51 (3.85)
Stride velocity (m/s) median (IQR)	1.26 (0.12)	1.29 (0.13)	1.23 (0.13)	1.26 (0.16)	0.62 (0.27)	0.62 (0.28)	0.62 (0.39)	0.61 (0.39)
CoV stride velocity (%) median (IQR)	5.26 (2.62)	5.48 (3.11)	5.13 (0.99)	5.51 (0.98)	8.93 (2.46)	8.93 (2.46)	7.75 (2.64)	7.61 (2.46)

Median and IQR were calculated over the mean per trial for each parameter, CoV was calculated as the median and IQR over the CoV per trial for each parameter.

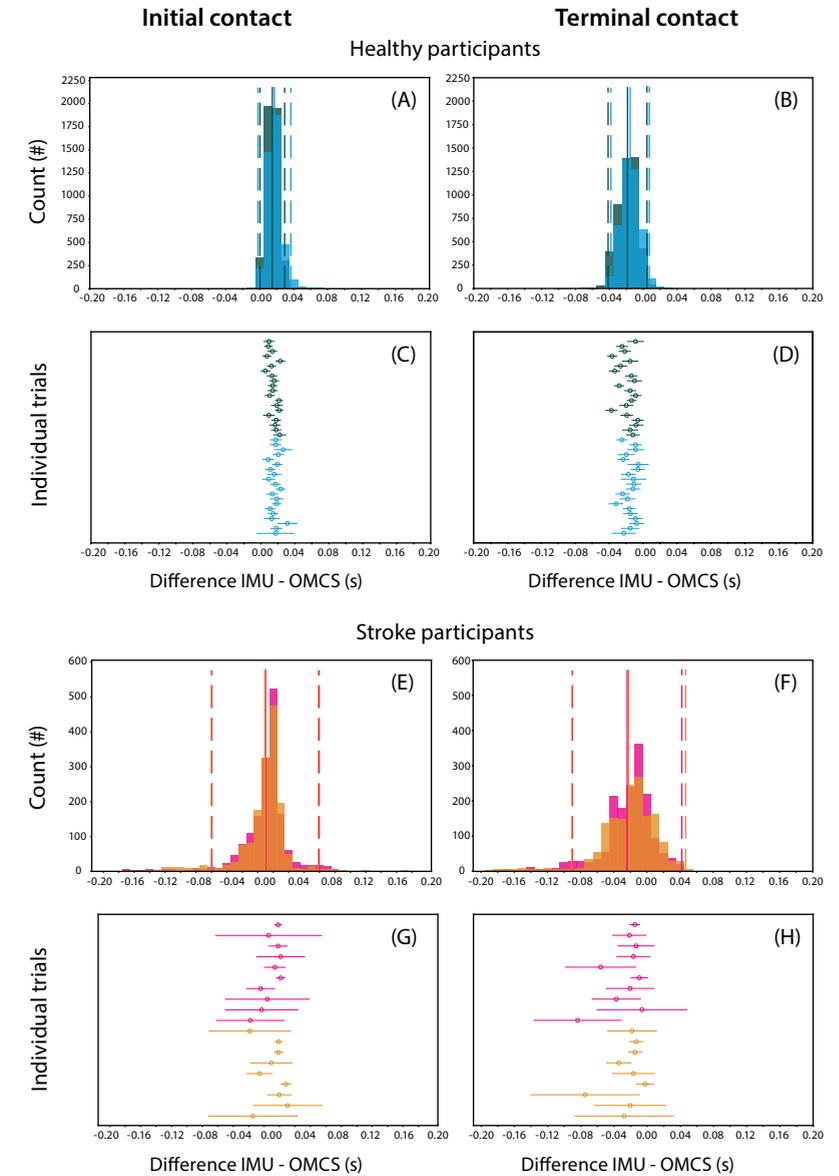


Figure 2. Differences in IC (left panels) and TC (right panels) between IMU-based and OMCS-based algorithms in regular (green) and irregular (blue) walking conditions in healthy participants (top panels, A-D) and in regular (pink) and irregular (orange) walking conditions in stroke participants (bottom panels, E-H). Histograms are on a stride-by-stride basis for all participants. Solid vertical lines indicate mean difference and dashed vertical lines indicate the 1.96*SD. The 'Individual trials' plots show the mean difference and SD for each trial.

When comparing regular with irregular walking in healthy participants, the difference between methods for IC was 2.5 (95%CI: 2.2, 2.8) ms smaller in the regular condition ($t = 15.76$, $p < 0.001$, Table 3). The difference between methods for TC was 3.4 (95%CI: 3.0, 3.8) ms smaller in the irregular compared to regular condition ($t = 18.06$, $p < 0.001$, Table 3). The second operationalization of the effect of irregular walking, comparing stroke with healthy participants, showed that the difference between methods for IC was 7.6 (95%CI: -14.0, -1.1) ms smaller for stroke than healthy participants ($t = -2.30$, $p = 0.029$, Table 3), while TC did not differ significantly between groups (95%CI: -21.2, 3.5, $t = -1.41$, $p = 0.169$, Table 3). The third operationalization of the effect of irregular walking, comparing regular with irregular walking conditions in stroke participants, showed that the difference between methods for IC was 2.6 ms (95%CI: -4.9, -0.3) lower for the irregular than regular condition ($t = -2.17$, $p = 0.030$, Table 3). The difference between methods for TC was 2.2 ms (95%CI: -4.2, -0.1, $t = -2.05$, $p = 0.040$, Table 3).

Spatiotemporal parameters

Figure 3 shows the Bland-Altman-like plots for the spatiotemporal gait parameters averaged per subject (left panels) and on a stride-by stride basis (middle and right panels). The stride time difference between methods did not vary as a function of the value of the method itself in both healthy and stroke participants. Differences between methods for stride time were on average 0 ms, with low between-subject variance for all conditions in healthy participants (SD = 0.01 s) and 0.04 s during regular walking and 0.05 s during irregular walking in stroke participants (Table 4).

In healthy participants, the difference between methods on stride time was not different between regular and irregular walking ($t = 0.153$, $p = 0.878$, Table 3), and not different between healthy participants and stroke participants during regular walking ($t = -0.111$, $p = 0.912$, Table 3). Also, no differences between methods were found between the regular and irregular walking condition on stride time in stroke participants ($t = 0.618$, $p = 0.537$, Table 3). Differences between methods for CoV of stride time did not significantly differ between regular and irregular walking in healthy participants ($t = 1.189$, $p = 0.249$, Table 5 and Figure 4), or between healthy and stroke participants during regular walking ($t = -1.909$, $p = 0.089$, Table 5 and Figure 4), or between regular and irregular walking conditions in stroke participants ($t = -1.038$, $p = 0.330$, Table 5). However, a larger mean CoV of stride time and stride length in the irregular trials, suggests that the proposed method to induce irregularity seemed to work.

Table 3. Statistical output of linear mixed regression models to compare irregular vs regular walking in healthy participants and in stroke participants, and comparison stroke vs healthy participants in regular walking.

		Intercept	95%CI		Coefficient	95%CI		t-value*	p-value*
			Lower	Upper		Lower	Upper		
Healthy, irregular vs regular walking	IC detection	1.502	1.293	1.712	0.248	0.217	0.279	15.762	0.000
	TC detection	-1.879	-2.223	-1.534	0.339	0.302	0.376	18.057	0.000
	Stride time	0.000	-0.000	0.000	0.000	-0.000	0.000	0.153	0.878
	Stride length	-0.034	-0.049	-0.019	0.003	0.002	0.004	4.500	0.000
	Stride velocity	-0.033	-0.046	-0.019	0.004	0.002	0.005	5.951	0.000
Stroke vs healthy, regular walking	IC detection	1.499	1.129	1.870	-0.755	-1.400	-0.111	-2.297	0.029
	TC detection	-1.878	-2.590	-1.166	-0.890	-2.124	0.345	-1.413	0.169
	Stride time	0.000	-0.001	0.001	-0.000	-0.001	0.001	-0.111	0.912
	Stride length	-0.034	-0.047	-0.022	0.038	0.016	0.060	3.422	0.002
	Stride velocity	-0.032	-0.044	-0.021	0.034	0.014	0.054	3.313	0.003
Stroke, irregular vs regular walking	IC detection	0.876	-0.080	1.833	-0.256	-0.487	-0.025	-2.173	0.030
	TC detection	-2.746	-4.325	-1.166	-0.217	-0.424	-0.010	-2.050	0.040
	Stride time	-0.000	-0.002	0.002	0.001	-0.002	0.004	0.618	0.537
	Stride length	0.003	-0.004	0.011	0.001	-0.002	0.005	0.652	0.515
	Stride velocity	0.001	-0.006	0.007	0.002	-0.001	0.004	0.429	0.153

Linear mixed models were used to evaluate the performance of the algorithm in irregular walking compared to regular walking. In the comparison healthy irregular vs healthy regular walking, and in the comparison stroke irregular vs stroke regular walking, the regular walking trials were used as the reference with the difference between methods for each gait parameter as dependent measure, condition as fixed effect and participant ID as random effect. In the comparison stroke vs healthy in regular walking, the walking trials of the healthy participants were used as the reference with the difference between methods of each gait parameter as dependent variable, group (healthy vs stroke) as fixed effect and participant ID as random effect. IC: Initial contact, TC: Terminal contact. *Relate to the coefficient (not the intercept).

In both conditions, stride length in healthy participants was 0.03 m (SD regular: 0.04 m, SD irregular: 0.05 m) smaller when based on IMUs compared to OMCS (Table 4 and Figure 3). In stroke participants, the stride length difference between methods was 0.00 m (SD regular: 0.06 m, SD irregular: 0.04 m, Table 4 and Figure 3). Comparing regular vs irregular walking in healthy participants, resulted in larger differences between methods for the regular walking condition (0.003 m, $t = 4.500$, $p < 0.001$, Table 3). The difference between methods for stride length during regular walking

Table 4. Mean and SD of the difference between methods (IMU vs OMCS) during treadmill walking on a stride-by-stride basis.

	Healthy participants (n=20)		Stroke participants (n=10)	
	Regular walking	Irregular walking	Regular walking	Irregular walking
N strides (total)	4577	4200	1671	1586
IC detection (ms)	15 [7]	17 [10]	10 [35]	9 [35]
TC detection (ms)	-19 [12]	-15 [12]	-24 [34]	-22 [35]
Stride time (s)	-0.00 [0.01]	0.00 [0.01]	-0.00 [0.04]	0.00 [0.05]
Stride length (m)	-0.03 [0.04]	-0.03 [0.05]	0.00 [0.06]	0.00 [0.04]
Stride velocity (m/s)	-0.03 [0.04]	-0.03 [0.04]	-0.00 [0.03]	0.00 [0.03]

Differences were calculated as 'IMU-based parameter - OMCS-based parameter' and displayed as mean [SD]. IC: initial contact, TC: terminal contact.

was closer to zero for stroke patients compared to healthy participants (0.038 m, $t = 3.422$, $p = 0.002$, Table 3). The difference between methods for CoV of stride length was larger in irregular walking compared to regular walking (-0.44%, $t = -4.198$, $p < 0.001$, Table 5). Differences between methods for CoV of stride length in stroke participants (0.7% higher in IMU vs OMCS) was not different from healthy participants during regular walking (0.2% lower in IMU vs OMCS; $t = -1.186$, $p = 0.266$, Table 5). There were also no differences found between methods for CoV of stride length in irregular walking compared to regular walking in stroke participants ($t = -1.165$, $p = 0.278$, Table 5).

Stride velocity in healthy participants was 0.03 m/s (SD = 0.04) lower when based on IMUs compared to OMCS (Table 4). In stroke participants, stride velocity difference between methods was 0.00 m/s (SD = 0.03, Table 4). Comparing regular vs irregular walking in healthy participants, resulted in smaller differences in regular walking (0.004 m/s, $t = 5.951$, $p < 0.001$, Table 3). Differences between methods were larger for healthy participants compared to stroke participants during regular walking (0.034 m/s, $t = 3.313$, $p = 0.003$, Table 3).

Details of the statistical output can be found in Table 3 and Table 5. A table including the mean differences and SDs for each subject, for each walking condition can be found in the supplementary materials.

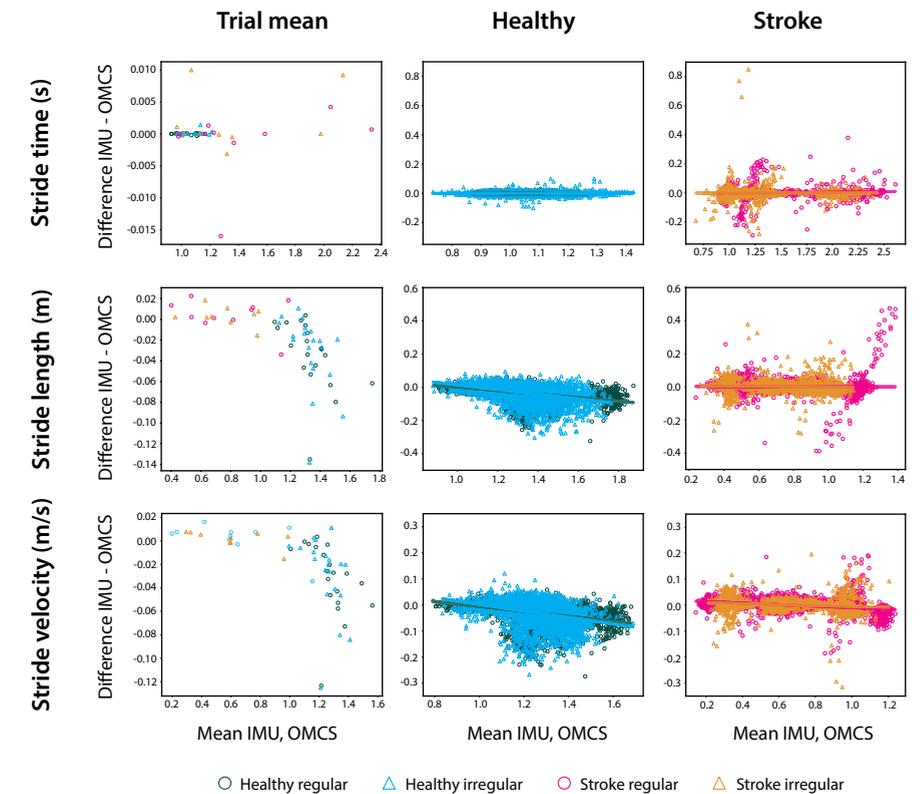


Figure 3. Bland-Altman analyses of the mean spatiotemporal parameters per condition in healthy regular (green ○), healthy irregular (blue Δ), stroke regular (pink ○) and stroke irregular (orange Δ) walking conditions. Middle panels are the Bland-Altman analyses in the healthy population in regular (green) and irregular (blue) walking on a stride-by-stride basis. Right panels are the Bland-Altman analyses in the stroke population in regular (pink) and irregular (orange) walking on a stride-by-stride basis. Note that the y-axis for means per trial is on a different scale as the plots on a stride-by-stride basis.

Table 5. Statistical output of t-tests to compare difference between methods for variance (CoV) in stride time and stride length.

		Mean difference	95%CI		t-value	p-value
			Lower	Upper		
Healthy, irregular vs regular walking	Stride time	0.046	-0.035	0.127	1.189	0.249
	Stride length	-0.439	-0.657	-0.220	-4.198	0.000
Stroke vs healthy, regular walking	Stride time	0.994	-2.172	0.184	-1.909	0.089
	Stride length	1.052	-3.055	0.951	-1.186	0.266
Stroke, irregular vs regular walking	Stride time	-0.513	-1.654	0.627	-1.038	0.330
	Stride length	-0.903	-2.691	0.885	-1.165	0.278

Paired samples t-tests were used to evaluate the performance of the algorithm in irregular walking compared to regular walking within healthy participants and within stroke participants. In these comparisons the regular walking trials were used as the reference. Unpaired t-tests (Welch two sample) were used to evaluate the performance of the algorithm in stroke participants compared to healthy participants in regular walking. In this comparison the walking trials of the healthy participants were used as the reference.

Overground walking

Spatiotemporal parameters per subject ranged between 0.94 and 1.28 (median = 1.01) s for stride time, 1.18 and 1.64 (median = 1.40) m for stride length and 1.05 and 1.70 (median = 1.36) m/s for stride velocity. Table 6 shows differences in gait event detection and spatiotemporal parameters between IMU-based and OMCS-based analysis during overground walking.

Post-hoc analysis

OMCS detected IC 0.03 s [LoA: -0.01; 0.07] and TC 0.01 s [LoA: -0.03; 0.05] after the force plates. See supplementary materials for full details of this analysis and histograms (Figure S1) of the mean differences.

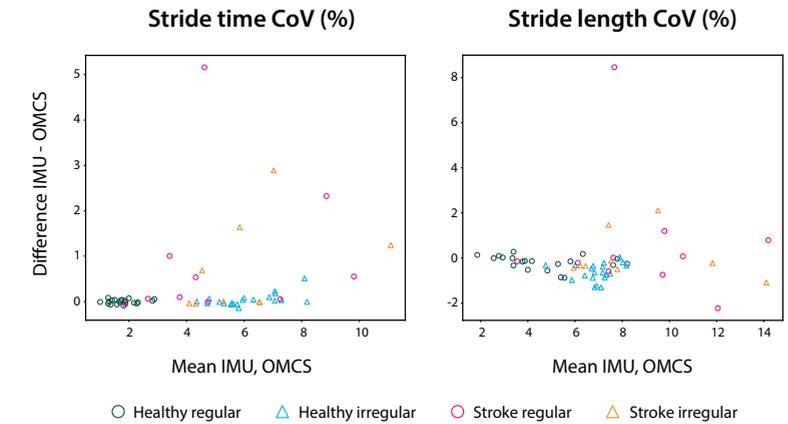


Figure 4. Bland-Altman analyses of the variability of spatiotemporal parameters per trial in healthy regular (green ○), healthy irregular (blue Δ), stroke regular (pink ○) and stroke irregular (orange Δ) walking conditions.

Table 6. Mean differences and SD between IMU-based and OMCS-based parameters during overground walking.

Healthy participants (n=20)	Overground walking
N strides (total)	1426
IC detection (ms)	-6 [19]
TC detection (ms)	-40 [17]
Stride time (s)	0.00 [0.03]
Stride length (m)	-0.08 [0.05]
Stride velocity (m/s)	-0.08 [0.07]

Differences were calculated as IMU-based parameter – OMCS-based parameter' and displayed as mean [SD].

Discussion

The aim of this study was to evaluate the developed algorithm for gait assessment using IMUs on both feet and the trunk, for regular as well as irregular walking patterns. We found high accuracy of gait event detection, stride time, and stride time variability during regular and irregular walking in healthy participants compared to OMCS. In healthy participants, mean stride length and stride velocity were slightly underestimated with 3 cm and 3 cm/s, respectively. However, the accuracy was much worse in several healthy participants, with errors increasing up to 13 cm and 13 cm/s, respectively. The algorithm's accuracy did not substantially worsen for irregular walking compared to regular walking in healthy participants. Likewise, the irregular walking pattern that was observed in stroke participants resulted in similarly high accuracy of the algorithm.

The accuracy of our IMU-based algorithm on stride time in healthy participants was 0 ± 10 ms, which was comparable to previous research evaluating accuracy during regular walking with errors of 9 ± 22 ms [25]. Regarding spatial parameters, previous validation studies with sensors on the feet have reported an average underestimation of stride length between 2 and 12 cm in healthy participants [6,25,26]. In the study by Morris et al., an average underestimation of 10 cm with their IMU-based algorithm was reported, which increased to 18 cm with increasing stride length. This trend of increasing underestimation with increasing stride length, and thus increasing gait speed, was also seen in the current study. At gait speeds above 1.2-1.3 m/s, the underestimation of stride length increased to maximally 13 cm in one subject. Although this error is still smaller than as reported in Morris et al. [25], increasing errors with increasing gait speeds is a significant concern when applying foot-mounted IMU algorithms for the assessment of healthy gait. Caution should also be warranted when comparing groups with different gait speeds. When verifying these results for the overground trials, a slightly larger but still acceptable error of 8 cm compared to 10 cm reported in previous literature was found [25].

In artificially induced irregular walking in healthy participants by irregularly spaced stepping targets, the algorithm's accuracy was similar to regular walking. The higher mean CoVs of stride time and stride length in the irregular walking condition compared to the regular walking condition indicated that the irregular walking manipulation was successful. In contrast, the irregular walking condition in stroke participants slightly increased the CoV of stride time, but did not impact the CoV of stride length. No differences in the accuracy of stride time estimation were found between the irregular and regular walking conditions (0 ms) in both groups. Although significant, the differences in accuracy between irregular and regular walking were

only 0.3 cm for stride length and 0.3 cm/s for stride velocity in healthy participants. Therefore, we concluded that temporal and spatial parameters were assessed with the same accuracy in irregular walking compared to regular walking.

To be able to use the gait algorithm in clinical populations, evaluation of the algorithm's performance in irregular walking patterns due to pathology was an important aim of this study. In the stroke population, the mean error of the estimated stride length compared to OMCS was 0 cm and 0 cm/s for stride velocity. In previous research, the calculated error for stride length in people with irregular gait due to Parkinson's disease was also lower than in healthy participants [25] (Parkinson's disease group 8.5 cm vs. healthy peers 10 cm).

The higher accuracy in people with stroke compared to healthy participants was not in line with our hypothesis. One factor underlying a higher accuracy of spatial parameters in stroke participants might be the slower walking speed in this group compared to the healthy group. As stride length was calculated by double integration of the acceleration data, relatively small errors in event detection or timing of zero-velocity updates can cause inflated errors in spatial parameters. Consequently, lower walking speeds resulting in lower acceleration peaks are less affected by errors in gait event detection compared to faster walking speeds with higher acceleration. However, IC and TC event detection were highly accurate in healthy participants with low between-strides variance, at least partly contradicting this explanation. Therefore, a small error in the timing of zero-velocity updates seems most likely, as we did not validate the detection of the foot flat phase (TC to mid-swing of the contralateral leg). Additionally, between foot flat phases, a drift compensation based on a sigmoid curve is performed. This drift compensation might overestimate the actually measured drift, this results in subtracting too much of the acceleration leading to an underestimation of stride length and velocity. Exploring other drift compensation techniques might further improve the accuracy of the algorithm.

In addition to mean values of gait parameters, variability between the strides of an individual (CoV) is of clinical interest [27,28]. Variability of stride time could be accurately assessed with IMUs in both healthy participants and stroke patients. In contrast, lower accuracy was found in spatially dependent CoV parameters with the IMUs.

This study has some limitations meriting attention. First, all participants walked at their preferred gait speed, resulting in a different range of gait speeds between both groups. Therefore, we cannot distinguish the effect of walking slower from the effect of walking more irregularly. This could be evaluated by having healthy participants

walk at lower than comfortable speeds and people with stroke walk at higher gait speeds. A downside of this approach is that it might lead to unnatural gait patterns, reducing the ecological validity of the results. Additionally, we observed that even after a familiarization period of the self-paced mode, some participants had difficulty maintaining a constant comfortable walking speed during the regular walking condition. This most likely resulted in a higher CoV in stride length, time, and velocity in the regular walking condition than reported in the literature [29]. Secondly, we only focused on a limited number of spatiotemporal parameters among many of the potential gait characteristics reported in the literature [30,31]. The selected spatiotemporal gait parameters are the most crucial in the algorithm to assess spatiotemporal gait parameters. Additional parameters such as step time and double support time are typically derived from the identified gait events and parameters included in this study. Nonetheless, it could be valuable to analyze the accuracy and errors of other spatiotemporal gait parameters when these are used for research or clinical purposes. Thirdly, we designed our protocol to have equal walking duration for all participants and in each condition. Because participants walked with different walking speeds, stride length and time, different number of strides between subjects were recorded. It might be beneficial for future studies to standardize the number of measured strides. Lastly, verification that the IMU-based algorithm could also be used in overground walking was only performed in healthy participants. This was done to decrease the burden on stroke patients, as we had no reason to suspect different results for this analysis in stroke participants, but we cannot provide proof for this assumption.

Conclusions

Overall, the accuracy of the proposed IMU-based algorithm was high for temporal gait parameters in regular and irregular walking patterns in healthy and people with stroke, while there was room for improvement for spatially dependent parameters. Although *general* accuracy in irregular gait was as good as in regular walking, stride length and velocity errors in individual cases were substantial and beyond clinically relevant differences. Therefore, the IMU-based algorithm performs satisfactory for walking speeds up until 1.2 m/s. Caution should be applied when considering individual outcomes, groups walking at high gait speed, and when comparing groups with different walking speeds. Further development of algorithms is needed for these purposes.

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Supplementary materials

Post-hoc analysis: IMU-based and OMCS-based gait event detection against force plate-based gait event detection

Introduction

Two methods are frequently used in literature to identify gait events; one being the OMCS-based method as used in this study, the other is based on force plate data [1–4]. The benefit of OMCS-based gait event detection, is that multiple strides per stretch in the overground lab can be analyzed, against only one stride per stretch on force plates.

To maximize the amount of strides for analysis in the overground lab, and be consistent in the used methods, the IMU-based algorithm was validated against OMCS in both settings. Nevertheless, during all treadmill walking trials force data was collected by the embedded force plates of the GRAIL. To check the magnitude of the difference including limits of agreement (LoA) at 1.96 standard deviation in gait event detection between the OMCS-based method used in this study and force plate data as ground truth, post-hoc analysis was performed.

Methods

All code for this post-hoc analysis is included in the scripts available from: https://github.com/SintMaartenskliniek/IMU_GaitAnalysis (Release 'Validation study, tag v1.1.0'). Force plate data from all GRAIL trails was filtered by a fourth order, zero shift Butterworth filter with cut-off frequency 20 Hz and down sampled to 100 Hz. Gait event detection was done based on a 10 Newton threshold. IC events were identified at the first instance the vertical force exceeded the threshold for at least 0.4 seconds, while TC events were identified at the first instance the vertical force was less than the threshold for at least 0.4 seconds.

Not all gait events could be identified based on the force plate data (participants did not always place their right foot on the right force plate and their left foot on the left force plate). Therefore, it was assumed that if a gait event was detected by both force plates and OMCS or IMU-based algorithms, they would be within a 0.2 second time window. Gait events within this window were then compared on instance of detection by histograms of the difference.

Results

OMCS detected IC 0.03 s [LoA: -0.01; 0.07] and TC 0.01 s [LoA: -0.03; 0.05] after the force plates. IMU-based analysis detected IC 0.02 s [LoA: -0.06; 0.10] and TC 0.03 s [LoA: -0.01; 0.07] after the force plates. Histograms of the difference between these methods are shown in Supplementary Figure 1.

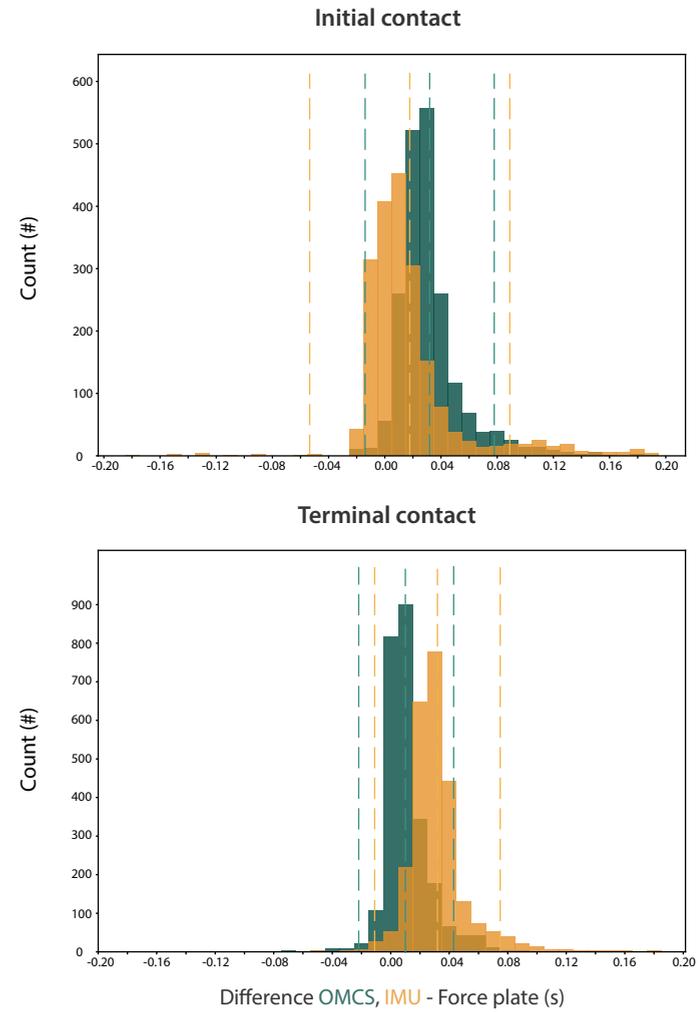


Figure S1. Differences in IC (top panel) and TC (bottom panel) detection with IMU-based (orange) and OMCS-based (green) algorithms and force plate based gait event detection. Histograms are on a stride-by-stride basis for all participants. Solid vertical lines indicate mean difference and dashed vertical lines indicate the $1.96*SD$.

Table S1. Mean difference (mean) with standard deviation (SD) for each subject, for all walking trials.

Trial ID	Regular walking						Irregular walking						
	Stride time (s)		Stride length (m)		Stride velocity (m/s)		Stride time (s)		Stride length (m)		Stride velocity (m/s)		
	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD	
STR_01_SP	0.00	0.01	0.01	0.03	0.01	0.02	STR_01_SS	0.00	0.02	0.01	0.02	0.01	0.01
STR_02_SP	0.00	0.08	0.02	0.14	0.01	0.06	STR_02_SS	0.00	0.03	0.01	0.07	0.00	0.06
STR_03_FS	0.00	0.07	0.01	0.04	0.01	0.01	STR_04_SS	0.00	0.04	0.02	0.05	0.01	0.02
STR_04_SP	0.00	0.04	0.02	0.06	0.01	0.02	STR_05_SS	0.00	0.01	0.00	0.02	0.00	0.01
STR_05_SP	0.00	0.01	0.00	0.02	0.00	0.02	STR_06_SS	0.00	0.01	0.00	0.02	0.00	0.01
STR_06_SP	0.00	0.01	0.00	0.02	0.00	0.02	STR_07_SS	-0.06	0.01	0.01	0.02	0.01	0.01
STR_07_SP	0.00	0.01	0.01	0.02	0.01	0.02	STR_08_SS	0.01	0.10	0.00	0.04	0.00	0.03
STR_08_SP	0.00	0.03	0.00	0.02	0.00	0.02	STR_09_SS	0.00	0.07	0.00	0.06	0.01	0.05
STR_09_FS	-0.01	0.08	0.00	0.06	0.01	0.04	STR_10_SS	0.09	0.01	-0.02	0.02	-0.02	0.01
STR_10_SP	0.00	0.01	-0.03	0.02	-0.03	0.02	HC_01_SS	0.05	0.01	-0.08	0.05	-0.08	0.04
HC_01_SP	0.07	0.01	-0.05	0.03	-0.05	0.03	HC_03_SS	0.00	0.01	0.01	0.02	0.01	0.02
HC_03_SP	0.00	0.01	0.00	0.02	0.00	0.02	HC_04_SS	0.05	0.01	-0.04	0.02	-0.04	0.02
HC_04_SP	0.09	0.01	-0.05	0.02	-0.05	0.02	HC_05_SS	0.00	0.01	0.00	0.02	0.00	0.02
HC_05_SP	0.08	0.01	0.00	0.02	0.00	0.02	HC_06_SS	0.00	0.01	0.00	0.03	0.00	0.02
HC_06_SP	0.04	0.01	-0.02	0.02	-0.02	0.02	HC_07_SS	0.00	0.01	-0.01	0.03	-0.01	0.03
HC_07_SP	0.05	0.01	0.00	0.01	0.00	0.01	HC_08_SS	0.05	0.01	0.00	0.02	0.00	0.01
HC_08_SP	0.00	0.01	-0.05	0.03	-0.05	0.03				-0.05	0.04	-0.05	0.04

Table S1. Continued.

Trial ID	Regular walking						Irregular walking						
	Stride time (s)		Stride length (m)		Stride velocity (m/s)		Stride time (s)		Stride length (m)		Stride velocity (m/s)		
	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD	
HC_09_SP	0.00	0.01	-0.14	0.04	-0.12	0.04	HC_09_SS	0.00	0.01	-0.14	0.06	-0.13	0.05
HC_10_SP	-0.05	0.01	0.00	0.02	0.00	0.01	HC_10_SS	0.00	0.01	-0.01	0.02	-0.01	0.02
HC_11_SP	0.05	0.01	-0.08	0.03	-0.07	0.02	HC_11_SS	-0.05	0.01	-0.09	0.05	-0.08	0.04
HC_12_SP	0.05	0.01	-0.01	0.01	-0.01	0.01	HC_12_SS	0.00	0.01	-0.01	0.03	-0.01	0.02
HC_13_SP	0.10	0.01	-0.03	0.02	-0.03	0.01	HC_13_SS	0.00	0.01	-0.03	0.03	-0.02	0.02
HC_14_SP	0.00	0.01	-0.01	0.02	-0.01	0.02	HC_14_SS	0.00	0.01	-0.02	0.03	-0.02	0.03
HC_15_SP	0.05	0.01	-0.06	0.05	-0.06	0.04	HC_15_SS	-0.05	0.01	-0.05	0.06	-0.05	0.05
HC_16_SP	0.08	0.01	-0.03	0.02	-0.04	0.02	HC_16_SS	0.09	0.01	-0.02	0.03	-0.02	0.02
HC_18_SP	-0.04	0.01	-0.03	0.02	-0.03	0.02	HC_18_SS	0.04	0.01	-0.02	0.02	-0.02	0.02
HC_19_SP	0.00	0.01	-0.03	0.02	-0.03	0.02	HC_19_SS	0.05	0.01	-0.02	0.01	-0.02	0.01
HC_20_SP	-0.04	0.01	-0.03	0.03	-0.03	0.03	HC_20_SS	0.05	0.01	-0.03	0.03	-0.03	0.03
HC_21_SP	-0.05	0.01	-0.01	0.01	-0.01	0.01	HC_21_SS	0.00	0.03	0.00	0.03	0.00	0.03
HC_22_SP	-0.09	0.01	-0.06	0.04	-0.06	0.04	HC_22_SS	-0.05	0.01	-0.02	0.04	-0.02	0.03

Mean differences were calculated as 'IMU-based parameter – OMCS-based parameter' and displayed under 'mean', while 'SD' notes the standard deviation of this difference. Trial ID's starting with 'STR' are from stroke patients and 'HC' are from healthy controls. In regular walking, trial IDs containing 'SP' are at self-paced comfortable walking speed, while trial IDs containing 'FS' are at fixed-speed comfortable walking speed. In irregular walking, trial ID's contain 'SS' indicating irregular walking induced by stepping stones.

Chapter 3



The influence of stride selection on gait parameters collected with inertial sensors

C.J. Ensink
K. Smulders
J.J.E Warnar
N.L.W. Keijsers

Sensors. 2023. Feb;23:2002

Abstract

Different methods exist to select strides that represent preferred, steady-state gait. The aim of this study was to identify the effect of different stride-selection methods on spatiotemporal gait parameters to analyze steady-state gait.

A total of 191 patients with hip or knee osteoarthritis (aged 38–85) wearing inertial sensors walked back and forth over 10 m for two minutes. After the removal of strides in turns, five stride-selection methods were compared: (*ALL*) include all strides, others removed (*REFERENCE*) two strides around turns, (*ONE*) one stride around turns, (*LENGTH*) strides <63% of median stride length, and (*SPEED*) strides that fall outside the 95% confidence interval of gait speed over the strides included in *REFERENCE*. Means and SDs of gait parameters were compared for each trial against the most conservative definition (*REFERENCE*).

ONE and *SPEED* definitions resulted in similar means and SDs compared to *REFERENCE*, while *ALL* and *LENGTH* definitions resulted in substantially higher SDs of all gait parameters. An in-depth analysis of individual strides showed that the first two strides after and last two strides before a turn were significantly different from steady-state walking.

Therefore, it is suggested to exclude the first two strides around turns to assess steady-state gait.

Introduction

Gait is one of the most fundamental activities of daily life. Unsurprisingly, gait impairments negatively impact independent living and the quality of life of individuals [1]. Gait capacity is commonly described by the means and variability of spatiotemporal gait parameters during steady-state walking. While the mean gait speed is widely accepted as an indicator of overall gait capacity, the variability of spatiotemporal gait parameters is associated with dynamic balance [2,3]. However, to adequately quantify the measures of variability, a substantially higher number of steps needs to be analyzed than is typically recorded in overground gait labs using optical motion analysis [4]. Inertial measurement units (IMUs) can be used to record a multitude of steps per trial, with the additional advantage that they can be used outside the lab, in more ecologically valid settings and in real life [3,5]. However, as testing space in the clinic can be limited, gait assessments typically include back-and-forth walking, including turns. The acceleration and deceleration phases associated with these turns can substantially influence the mean and variability of spatiotemporal gait parameters [4]. Therefore, to characterize straight-ahead gait, only the strides in the steady-state portion of gait should be included for analysis, thus discarding the strides made in turns and during acceleration and deceleration phases. Although the validity of gait event detection and estimation of spatiotemporal gait parameters using IMUs has received ample attention [6–9], these studies did not evaluate how choices regarding the exclusion of strides in turns and periods of acceleration and deceleration affect spatiotemporal gait parameters during steady-state gait.

Stride-selection methods presented in the literature are based on two main methods. Either a fixed number of strides are excluded around turns or after starting [10], or strides are identified based on a certain relative threshold, e.g., minimum stride length [11]. As yet, it is unclear to what extent different methods to select strides affect the calculated means and variance of spatiotemporal gait parameters. Therefore, the aim of this study was to compare methods to select strides representative of steady-state, straight-ahead gait. Our first research question was: what is the effect of stride-selection methods on the means and variability of spatiotemporal gait parameters in tests including turns? The second research question was: how much do strides preceding and directly following the turns deviate from the steady-state portion of the walking trajectory? We analyzed these strides in more depth to understand the effect of acceleration and deceleration phases on the observed difference between selection methods. For this study, people with osteoarthritis (OA) of the lower limb joints or joint replacement after OA were included. OA of the lower limb joints is a well-known cause of impaired gait capacity [12,13]. People with OA, for example, walk with a lower gait speed compared to their healthy

peers [13], but without the more severe impairments, such as freezing of gait or drop foot related to neurological diseases.

Materials and methods

Subjects

Participants were recruited from the outpatient clinic of the orthopedic department of the Sint Maartenskliniek between October 2020 and October 2021. They were invited to participate if they had visited the clinic for end-stage knee, hip or ankle OA confirmed by an orthopedic surgeon, or after total knee or hip arthroplasty (TKA or THA) due to OA. Participants had to be at least 18 years old. People were excluded if they had gait or balance problems caused by anything other than OA. Informed consent was obtained from each participant prior to testing. A total of 191 people participated in this study, and eight people participated twice; before and after joint replacement surgery. This resulted in a total of 199 measurements that were analyzed.

Gait Assessment

Participants were equipped with four IMUs (Xsens Awinda, Enschede, the Netherlands) placed on both feet (dorsum side of the foot), the upper part of the sternum, and the lumbar level (L4/L5) of the trunk. Subsequently, participants walked back and forth over 10 m in a broad hallway in the clinic, performing 180° turns after each 10 m stretch (Figure 1). They were instructed to walk for two minutes at a self-selected, comfortable pace and to turn beyond the 10 m mark (line). No specific instructions were given on how to turn (e.g., pivot turn or taking multiple steps). Measurements were captured with MTManager software suite (version 2019.2) at 100 Hz. The planning, conduct and reporting of this study was in line with the Declaration of Helsinki. The study protocol was approved by the institutional review board.

Stride Identification

The identification of initial contact [7] and terminal contact [14], as well as calculating the resulting stride-by-stride spatiotemporal parameters [9] and detection of turns [15] was performed using previously validated algorithms [7,9,14,15]. First, the raw data of the IMUs attached to the feet were filtered by a second-order low-pass Butterworth filter (15 Hz cut-off frequency for angular velocity, and 17 Hz cut-off frequency for acceleration) [7]. Next, mid-swing was identified at the local maximum (clockwise direction) of the filtered angular velocity around the mediolateral axis (flexion–extension movement), directly followed by the zero-crossing (negative slope) corresponding to initial contact [7] (Figure 2). Terminal contact was identified at the peak in the filtered, vertical free acceleration of the IMUs on the feet before

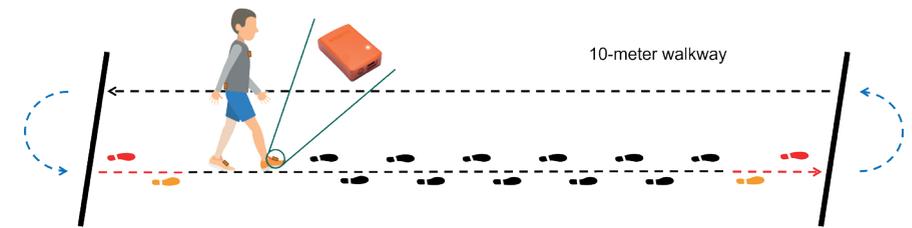


Figure 1. Set-up for 2 min walking test. Participants were instructed to turn after the 10 m marks (thick, black lines), but no specific instructions on how to turn were given (e.g., pivot turn or taking multiple steps). Orange and red indicate the first and second foot strike after a turn (blue) and the last and second to last foot strike before the turn start, respectively.

the identified mid-swing [14]. In case multiple peaks were identified, the peak with the smallest angular velocity was considered the true terminal contact. To identify turns, the angular velocity of the IMU on the lumbar level was rotated to the earth frame, after which the maxima were detected around the absolute vertical axis [15] (Figure 3). The start of a turn was defined as the last instant that the absolute angular velocity around the vertical axis was $<5^\circ/\text{s}$. The finish of each turn was defined as the last instant at which the absolute angular velocity was $>5^\circ/\text{s}$ [15]. Linear velocity was calculated by integrating the free acceleration of the IMUs on the feet. To eliminate drift in the linear velocity and resulting position estimation, zero velocity updates were performed during mid-stance [16–18]. Position estimation was performed by integrating the zero-velocity updated linear velocity. All resulting spatiotemporal parameters were calculated on a stride-by-stride basis. The stride time was calculated as the time between two consecutive initial contacts. The gait speed was calculated as the average velocity between two consecutive initial contacts. The stride length was calculated as the absolute difference in position between a terminal contact and the following initial contact.

Five definitions to include strides representative for steady-state gait were compared. Before applying any definition, all strides made within turns were removed. Definitions are the following:

1. *ALL*: Include all strides;
2. *REFERENCE*: Remove first 2 strides after, and last 2 strides before turn [10];
3. *ONE*: Remove first stride after, and last stride before turn;
4. *LENGTH*: Filter out strides $<63\%$ of median stride length [11];
5. *SPEED*: Calculate mean and 95% confidence interval (95% CI) of gait speed over the strides included in *REFERENCE*, then include all strides within this 95% CI.

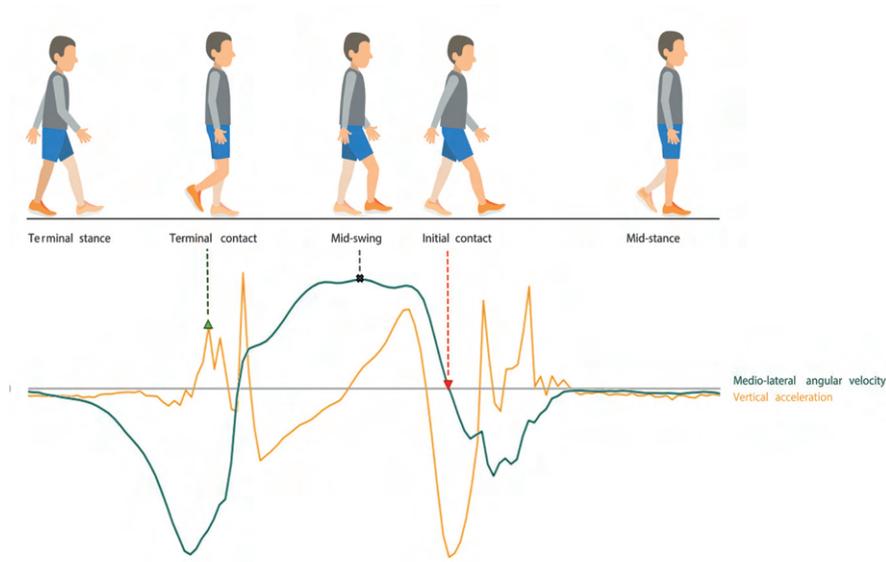


Figure 2. Stride identification was performed based on the filtered mediolateral angular velocity (green graph) and vertical free-acceleration (orange graph) signal features of the foot sensors. Terminal contact was determined at the local peak in vertical acceleration (green triangle pointing up), mid-swing at the peak in medio-lateral angular velocity (cross), and initial contact at zero-crossing of the medio-lateral angular velocity (red triangle pointing down).

Statistical Analysis

For each definition, the means and standard deviation (SD) of gait speed, stride length and stride time over strides were calculated for each trial using Python's numpy (v1.22.0) package. Definitions were compared against the most conservative definition, *REFERENCE*, using mean differences and their 99% confidence interval (99% CI). For the in-depth analysis, the first four strides after and before a turn were compared with the middle section of the walking trajectory using mean differences and their 99% CI. The middle section of the walking trajectory consists of the fifth stride after the turn, up to and including the fifth stride before the next turn. To explore if age and gait speed differences between participants affected the acceleration and deceleration phases, the research sample was split into tertiles based on age (youngest 33%, middle 33% and oldest 33%) and gait speed achieved in the middle section of the walking trajectory speed (fastest 33%, middle 33% and slowest 33%) (Appendix B). Statistical analysis was performed by shared control mean difference statistical tests (ordered groups ANOVA) of Python's dabest (v0.3.1) package [19].

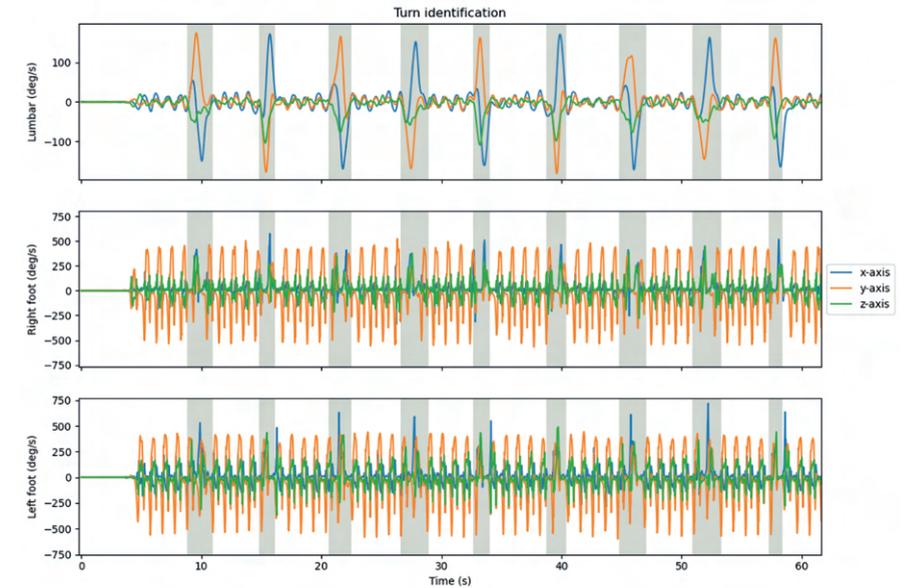


Figure 3. Turns (grey areas) were identified at the local maxima of the absolute angular velocity (rotated to the earth frame) around the vertical axis (green z-axis) of the lumbar sensor (top graph) [11]. The start of a turn was defined as the last instant that the absolute angular velocity around the vertical axis was <5 °/s. The finish of each turn was defined as the last instant at which the absolute angular velocity was >5 °/s [11].

Results

Subject Characteristics

Participants were aged between 38 and 85 years (mean \pm SD: 63.1 ± 9.0), and 110 were female and 81 male. In total, 93 measurements were performed in end-stage OA, and 106 were after joint-replacement surgery. See Table 1 for all participant characteristics.

Spatiotemporal Gait Parameters

Comparison between Selection Definitions

The average number of selected strides per trial ranged from 108 (*REFERENCE*) to 160 (*ALL*), while the average amount of turns per trial was 10 (range 1 to 19). Means and SDs of gait speed, stride length and stride time for definition *REFERENCE*, and the mean differences and associated 99% CI of each definition with *REFERENCE* are shown in Figure 4. Mean gait speed did not differ from *REFERENCE* for any definition. The SDs of gait speed of all definitions were different compared to *REFERENCE*, ranging

Table 1. Participant characteristics.

Participant Characteristics	
N total ¹	191
Male/female (N)	81/110
Age (mean ± SD years)	63.1 ± 9.0
End-stage OA/post surgery (N) ¹	93/106
Hip/Knee/Ankle OA (N)	71/117/3
Height (mean ± SD cm)	173.8 ± 9.7
Weight (mean ± SD kg)	85.4 ± 15.8

¹ Eight participants had two measurements (pre- and post-surgery). OA: osteoarthritis.

from -0.00 (99% CI: $-0.01, -0.00$) m/s for *SPEED* to 0.04 (99% CI: $0.04, 0.05$) m/s for *ALL*. Stride length did not differ from *REFERENCE* for any definition. The SD of stride length differed from *REFERENCE* for all definitions except *SPEED*, ranging from 0.00 (99% CI: $0.00, 0.01$) m for *ONE* to 0.03 (99% CI: $0.03, 0.04$) m for *ALL*. Definitions *ALL* and *LENGTH* resulted in a significantly higher stride time of 0.02 (99% CI: $0.00, 0.04$) s than *REFERENCE*. The stride time derived from *ONE* and *SPEED* did not significantly differ from *REFERENCE*. The SDs of stride time of all definitions were different compared to *REFERENCE*, ranging from 0.00 (99% CI: $0.00, 0.01$) s for *SPEED* to 0.06 (99% CI: $0.05, 0.07$) s for *ALL*. Table A1 of Appendix A includes all means and SDs of gait speed, stride length, stride time and the number of strides included per definition, as well as their differences with *REFERENCE*.

In-Depth Analysis of Strides around Turns vs. Middle Section

Figure 5 shows the average gait speed, stride length and stride time over all subjects of the first 4 strides after a turn and the last 4 strides before a turn. When comparing the 99% CIs, substantially decreased values for gait speed in the first two strides following the turn were found compared to the middle portion of walking. This was the result of higher stride times and—although to a lesser extent—lower stride length. The subsequent third stride showed some overlap with the middle part. In the strides before a turn, a similar, but reversed, trend was seen but with smaller mean differences, and overlap with steady-state gait was already visible for the second stride before the turn. Mean differences of SDs showed strikingly similar patterns. Table A2 of the Appendix A includes all means and SDs of gait speed, stride length and stride time for each of the four strides around a turn and the strides in the middle section of the walking trajectory, as well as their differences with the strides in the middle section of the walking trajectory. No differences in mean and SD of the gait speed between the three age groups and between the three speed groups were found (Appendix B).

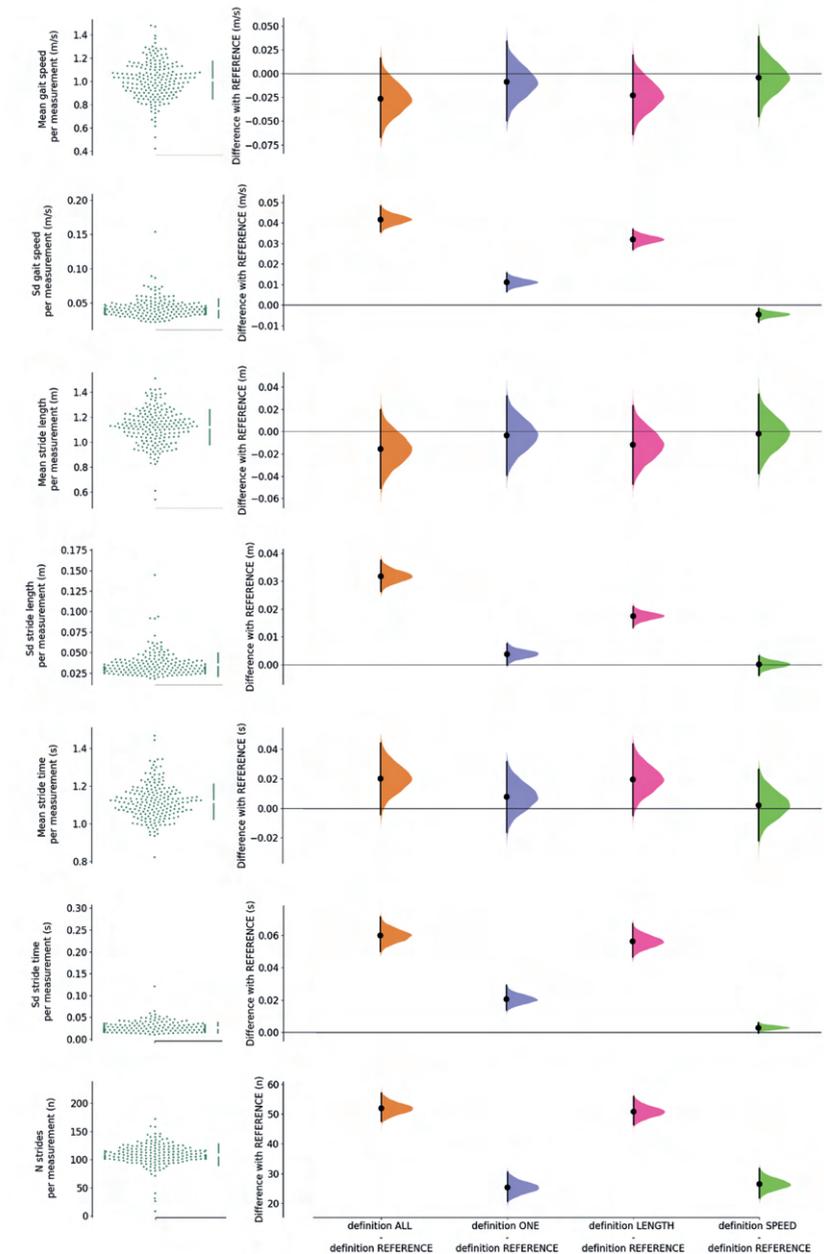


Figure 4. Scatterplot of means and SD of gait speed, stride length and stride time for definition *REFERENCE*, and the mean difference plots for each definition with *REFERENCE*, including the average number ± SD of selected strides per trial for each definition (N).

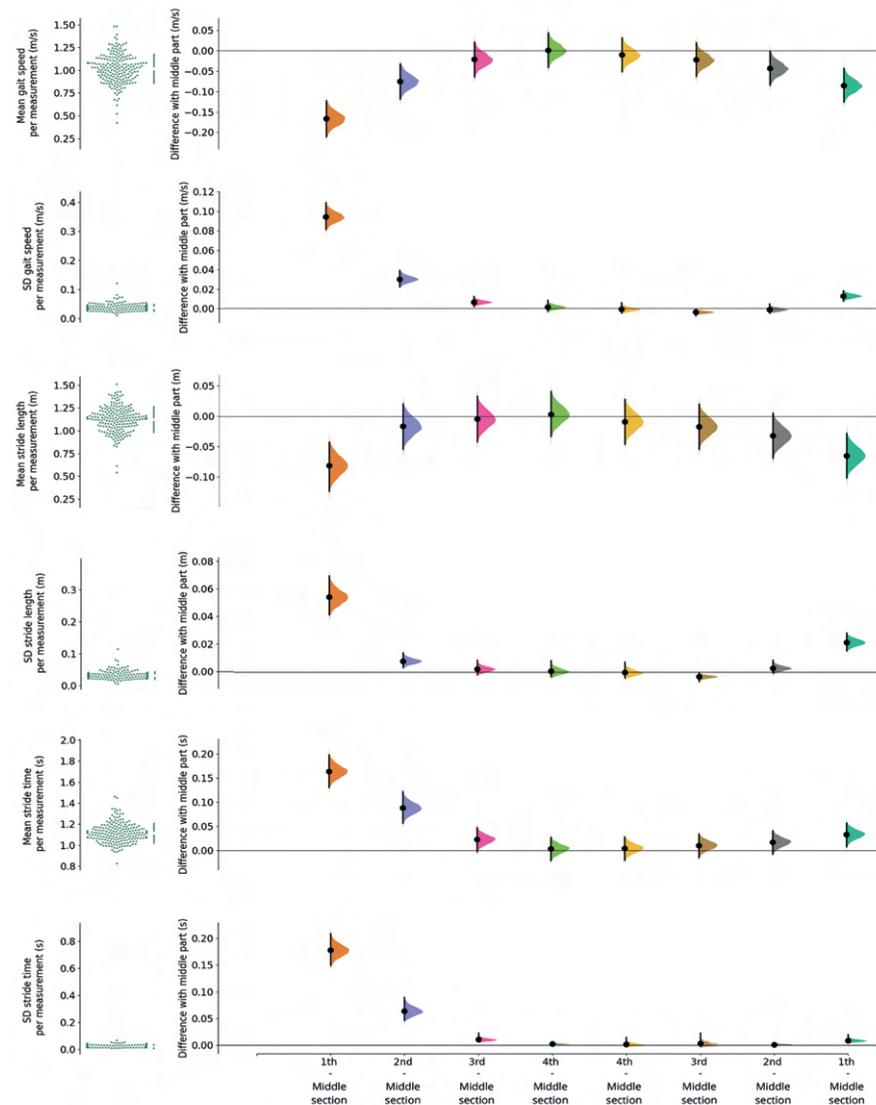


Figure 5. Subplots of the means and SDs of the strides in the middle section of the walking trajectory, and the mean differences and associated 99% CI of the first 4 strides around a turn. The first 4 strides after a turn show increasing speed and stride length with decreasing stride time. The last 4 strides before a turn show decreasing speed and stride length with increasing stride time. The difference between these strides with the mean gait speed, stride length and stride time of the middle section of the walkway are plotted in the lower subplots.

Discussion

Unsurprisingly, our definition analysis showed that excluding strides based on different methods affected the means and variance of the spatiotemporal gait parameters. Excluding only the first and last stride around each turn (*ONE*), or through speed-based outlier analysis (*SPEED*), yielded highly similar means and variance of spatiotemporal gait parameters compared to the more conservative method, excluding two strides around each turn (*REFERENCE*). Including all strides in the straight-ahead portion of gait (*ALL*) or all strides that are at least 63% of the median stride length (*LENGTH*) seemed too lenient, including too much of the acceleration and deceleration phases. The in-depth analysis indicated that the first two strides after and last two strides before a turn were different from the steady-state walking period. Furthermore, strides after the turn (e.g., acceleration phase) had a more significant effect on the calculated spatiotemporal parameters compared to the strides before the turn (deceleration phase).

The absolute differences between the means of the spatiotemporal gait parameters of the five methods were very limited. The maximum mean deviation was 0.03 m/s in gait speed, 2 cm in stride length, and 20 ms in stride time (*ALL*). Nonetheless, the first stride after the turn was on average 0.17 m/s slower compared to the middle section, while the second stride before and the first stride after a turn were also considerably slower: 0.08 m/s. This suggests that these deviating strides had a limited effect on the mean, likely due to the relatively high number of strides in the middle section ($n = 108$ strides) compared to the number of first and second strides around turns ($n = 10$ turns). Importantly, it should be noted that the effect of including strides around the turn may be different when using other, mainly shorter, walking trajectories than our 10 m walkway.

In contrast to the means, marked differences between selection methods were observed for the variance of the gait parameters. To illustrate, including all strides in the analysis doubled the SD of gait speed from 0.04 m/s to 0.08 m/s. Although the *ONE* and *SPEED* methods resulted in almost similar SD values (for example -0.01 m/s mean difference for gait speed), the 99% CI of the mean difference was still above 0, suggesting a consistent effect on the variance. Researchers and clinicians interested in the variability measures of gait should therefore proceed with extra caution in their decision making regarding the inclusion of strides for the analysis of gait.

The *SPEED* and *LENGTH* methods in our analysis could be seen as a form of outlier analysis. As definition *LENGTH* included almost all strides in the straight-ahead portion, *LENGTH* revealed similar results to *ALL* and seemed too lenient. The *SPEED*

definition resulted in very similar outcomes as *ONE* and *REFERENCE*, but with a higher number of strides per trial included. A potential downside of these outlier analyses is that strides during the steady-state gait are excluded. This can be the case in patients with high variability in their gait pattern, for example, due to freezing of the gait in Parkinson's disease. Due to the high variability, an inappropriate number of strides might get identified as outliers and as such get discarded by these methods, even though these strides might be highly interesting, and exclusion could be problematic. Additional data analysis on a group with a higher variability in their gait pattern is recommended to determine the effect of the different methods on the variance of spatiotemporal gait parameters.

Our in-depth analysis of the four strides before and after each turn showed differences in the first two strides around each turn compared to the middle section of the trajectory. Furthermore, the acceleration phase after a turn seems to affect the spatiotemporal gait parameters more than the deceleration phase before a turn. It should be noted that the ability to accelerate during gait initiation or decelerate to accommodate turning can be impacted by gait impairments due to age-related deficits. Muir et al. reported that adults over 80 years old needed more steps to reach their steady gait speed compared to the younger adults.[10]. Besides age-related gait difficulties, a number of factors can impact the ability to accelerate during gait initiation, or deceleration before a turn, including pain or motor problems stemming from neurological or musculoskeletal diseases. Almost without exception, such impairments result in lower gait speed. To test if age-related or other factors impacting gait speed confounded our results, we compared subgroups regarding age and gait speed. This supplementary analysis did not provide evidence that age or factors affecting gait speed impacted the ability to accelerate or decelerate (Appendix B). Nonetheless, as our sample size was restricted to individuals with OA, we cannot rule out that these findings do not translate to people with more severe gait impairments, such as in people after stroke or with Parkinson's disease.

As mentioned above, the influence of excluding more or less strides around turns is also dependent on how many strides are collected as part of the steady-state gait (i.e., the included strides). This number depends on the length of the walkway, the total testing time, and gait speed of an individual. To illustrate, excluding two strides at both ends (*REFERENCE*) of a ten-meter walkway will leave approximately six meters for steady-state gait. As the stride length in this study was 1.12 m on average, this would result in the inclusion of five strides per leg on average per stretch of the trajectory. In settings where shorter walkways are used, assessors could estimate in advance how many stretches would be needed to obtain the number of strides necessary for their specific research or clinical purpose.

This study includes some limitations that merit attention. First, the study population was restricted to people with OA in the lower extremities. Even though a large data set of 199 measurements was used, caution should be exercised when translating these results to other groups with gait impairments, as also laid out above. Secondly, various components of the algorithm for gait analysis were validated in previous studies [7,9,14,15], but a validity study for the entire algorithm for this set-up is still in progress (with promising results). Thirdly, only basic spatiotemporal gait parameters were analyzed. The effect of stride selection on other kinematic or non-linear dynamic measures warrants investigation in future studies.

In conclusion, our analyses suggest that the first two strides during the acceleration and last two strides during the deceleration phases around turns should not be included. Nevertheless, the specific aims of the gait assessment and available test conditions should guide the decision on which selection method to use to select strides representative of the preferred, steady-state gait.

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Supplementary materials

Appendix A

Table A1. Mean [99% CI] across subjects and the average within subject SD [99% CI] for gait speed, stride length, stride time and number of strides for each definition.

	Mean Reference	Mean All	Mean difference All-reference	Mean One	Mean difference One-reference	Mean Length	Mean difference Length-reference	Mean Speed	Mean difference Speed-reference
Mean gait speed (m/s)	1.01 [0.98;1.04]	0.99 [0.96;1.02]	-0.03 [-0.07;0.02]	1.00 [0.97;1.03]	-0.01 [-0.05;0.03]	0.99 [0.96;1.02]	-0.02 [-0.06;0.02]	1.01 [0.98;1.04]	-0.00 [-0.05;0.04]
SD gait speed (m/s)	0.04 [0.04;0.04]	0.08 [0.08;0.09]	0.04 [0.04;0.05]	0.05 [0.05;0.06]	0.01 [0.01;0.02]	0.07 [0.07;0.08]	0.03 [0.03;0.04]	0.04 [0.04;0.04]	-0.00 [-0.01;-0.00]
Mean stride length (m)	1.12 [1.1;1.15]	1.11 [1.08;1.13]	-0.02 [-0.05;0.02]	1.12 [1.09;1.14]	-0.00 [-0.04;0.03]	1.11 [1.08;1.14]	-0.01 [-0.05;0.02]	1.12 [1.09;1.15]	-0.00 [-0.04;0.03]
SD stride length (m)	0.04 [0.03;0.04]	0.07 [0.06;0.07]	0.03 [0.03;0.04]	0.04 [0.04;0.04]	0.00 [-0.00;0.01]	0.05 [0.05;0.06]	0.02 [0.01;0.02]	0.04 [0.03;0.04]	0.00 [-0.00;0.00]
Mean stride time (s)	1.12 [1.1;1.13]	1.14 [1.12;1.16]	0.02 [-0.00;0.04]	1.13 [1.11;1.14]	0.01 [-0.02;0.03]	1.14 [1.12;1.15]	0.02 [-0.00;0.04]	1.12 [1.1;1.14]	0.00 [-0.02;0.03]
SD stride time (s)	0.03 [0.02;0.03]	0.09 [0.08;0.1]	0.06 [0.05;0.07]	0.05 [0.04;0.05]	0.02 [0.01;0.03]	0.08 [0.07;0.09]	0.06 [0.05;0.07]	0.03 [0.03;0.03]	0.00 [-0.00;0.00]
Mean strides (N)	108 [105;112]	160 [157;164]	51 [48;57]	134 [130;137]	25 [21;31]	159 [156;163]	51 [47;56]	135 [132;138]	27 [22;32]

Table A2. Mean [99% CI] of gait speed, stride length, and stride time of the first four strides after and before a turn, and the middle section of the walking trajectory. Included are the difference (diff) of these strides with the middle section.

	Middle Section	Strides after Turn									Stride Before Turn							
	Mean	Mean 1 th	Mean Diff. 1 th - Middle Section	Mean 2 nd	Mean Diff. 2 nd - Middle Section	Mean 3 rd	Mean Diff. 3 rd - Middle Section	Mean 4 th	Mean Diff. 4 th - Middle Section	Mean 4 th	Mean Diff. 4 th - Middle Section	Mean 3 rd	Mean Diff. 3 rd - Middle Section	Mean 2 nd	Mean Diff. 2 nd - Middle Section	Mean 1 th	Mean Diff. 1 th - Middle Section	
Mean gait speed (m/s)	1.02 [0.99;1.05]	0.85 [0.82;0.88]	-0.17 [-0.21;-0.12]	0.94 [0.91;0.97]	-0.08 [-0.12;-0.03]	0.99 [0.96;1.03]	-0.02 [-0.06;0.02]	1.02 [0.99;1.05]	0.00 [-0.04;0.04]	1.01 [0.98;1.04]	-0.01 [-0.05;0.03]	0.99 [0.96;1.02]	-0.02 [-0.06;0.02]	0.97 [0.94;1.0]	-0.04 [-0.08;-0.00]	0.93 [0.9;0.96]	-0.09 [-0.13;-0.04]	
SD gait speed (m/s)	0.04 [0.03;0.04]	0.13 [0.12;0.14]	0.09 [0.08;0.11]	0.07 [0.06;0.08]	0.03 [0.02;0.04]	0.04 [0.04;0.05]	0.01 [0.00;0.01]	0.04 [0.03;0.04]	0.00 [-0.00;0.01]	0.04 [0.03;0.04]	-0.00 [-0.00;0.01]	0.03 [0.03;0.04]	-0.00 [-0.01;-0.00]	0.04 [0.03;0.04]	-0.00 [-0.00;0.00]	0.05 [0.04;0.05]	0.01 [0.01;0.02]	
Mean stride length (m)	1.12 [1.10;1.15]	1.04 [1.01;1.08]	-0.08 [-0.12;-0.04]	1.11 [1.08;1.14]	-0.02 [-0.05;0.02]	1.12 [1.09;1.15]	-0.00 [-0.04;0.03]	1.13 [1.1;1.16]	0.00 [-0.03;0.04]	1.12 [1.09;1.14]	-0.02 [-0.05;0.03]	1.11 [1.08;1.13]	-0.02 [-0.05;0.02]	1.09 [1.07;1.12]	-0.03 [-0.07;0.01]	1.06 [1.03;1.09]	-0.06 [-0.10;-0.03]	
SD stride length (m)	0.03 [0.03;0.03]	0.09 [0.07;0.1]	0.05 [0.04;0.07]	0.04 [0.04;0.04]	0.01 [0.00;0.01]	0.03 [0.03;0.04]	0.00 [-0.00;0.01]	0.03 [0.03;0.04]	0.00 [-0.00;0.01]	0.03 [0.03;0.04]	-0.00 [-0.00;0.01]	0.03 [0.03;0.03]	-0.00 [-0.01;-0.00]	0.03 [0.03;0.04]	0.00 [-0.00;0.01]	0.05 [0.05;0.06]	0.02 [0.02;0.03]	
Mean stride time (s)	1.12 [1.1;1.13]	1.28 [1.25;1.31]	0.16 [0.13;0.20]	1.20 [1.18;1.23]	0.09 [0.06;0.12]	1.14 [1.12;1.16]	0.02 [-0.00;0.04]	1.12 [1.1;1.14]	0.00 [-0.02;0.03]	1.12 [1.1;1.14]	0.00 [-0.02;0.03]	1.13 [1.11;1.14]	0.01 [-0.01;0.03]	1.13 [1.12;1.15]	0.02 [-0.01;0.04]	1.15 [1.13;1.17]	0.03 [0.01;0.06]	
SD stride time (s)	0.02 [0.02;0.02]	0.20 [0.17;0.23]	0.18 [0.15;0.21]	0.09 [0.06;0.11]	0.06 [0.05;0.09]	0.03 [0.03;0.04]	0.01 [0.01;0.02]	0.02 [0.02;0.03]	0.00 [-0.00;0.01]	0.02 [0.02;0.03]	0.00 [-0.00;0.01]	0.02 [0.01;0.03]	0.00 [-0.00;0.02]	0.02 [0.02;0.03]	0.00 [-0.00;0.00]	0.03 [0.02;0.04]	0.01 [0.00;0.02]	

Appendix B. Analysis for Impact of Age and Gait Ability

Appendix B1. Methods

To explore if stride-selection definitions should be different depending on age or difficulty, we analyzed the acceleration and deceleration phases for different age and gait speed groups. We split the research sample into tertiles based on age and on gait speed, as achieved in the middle section of the walking trajectory. The first four strides after a turn and last four strides before a turn were compared to the middle section of the walking trajectory using mean differences and their 99% CI. The middle section of the walking trajectory consisted of the fifth stride after the turn, up to and including the fifth stride before the next turn. In each subgroup, we performed shared control mean difference statistical tests (ordered groups ANOVA) of Python's dabest (v0.3.1) package [19].

Appendix B2. Results

The results of the mean and SD of gait speed for the different age groups for the first strides after a turn, and the last strides before turning are presented in Figures A1 and A2. Results of the mean and SD of gait speed for the different speed groups are presented in Figures A3 and A4. The mean differences between the first strides after and last stride before a turn and the middle section were very similar between age groups and speed groups. This was true for the mean of gait speed as well as the SD of gait speed. Similar results were found for the stride time and stride length.

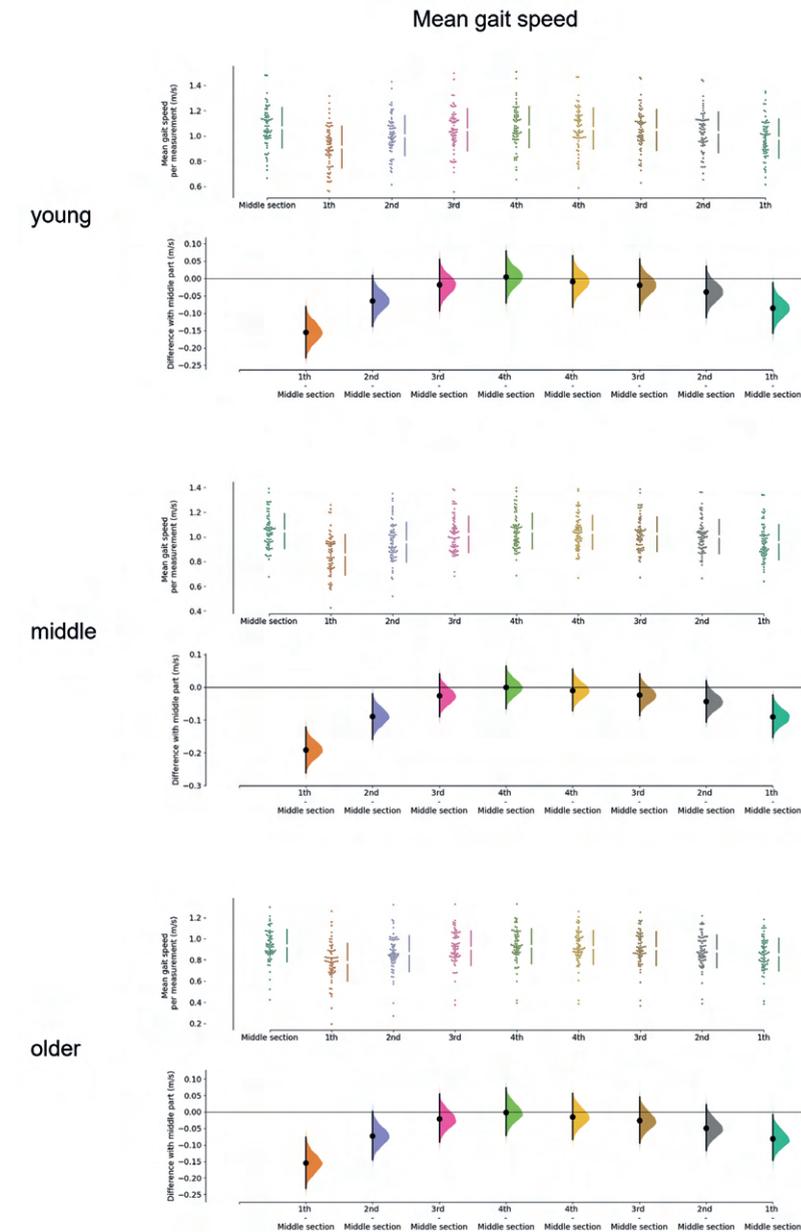


Figure A1. Mean gait speed of the different participants during the walking trajectory, and the mean differences and associated 99% CI of the first and last 4 strides around a turn. The top subplot includes data of the young age group, the middle subplot, the middle age group, and the bottom subplot, the older age group.

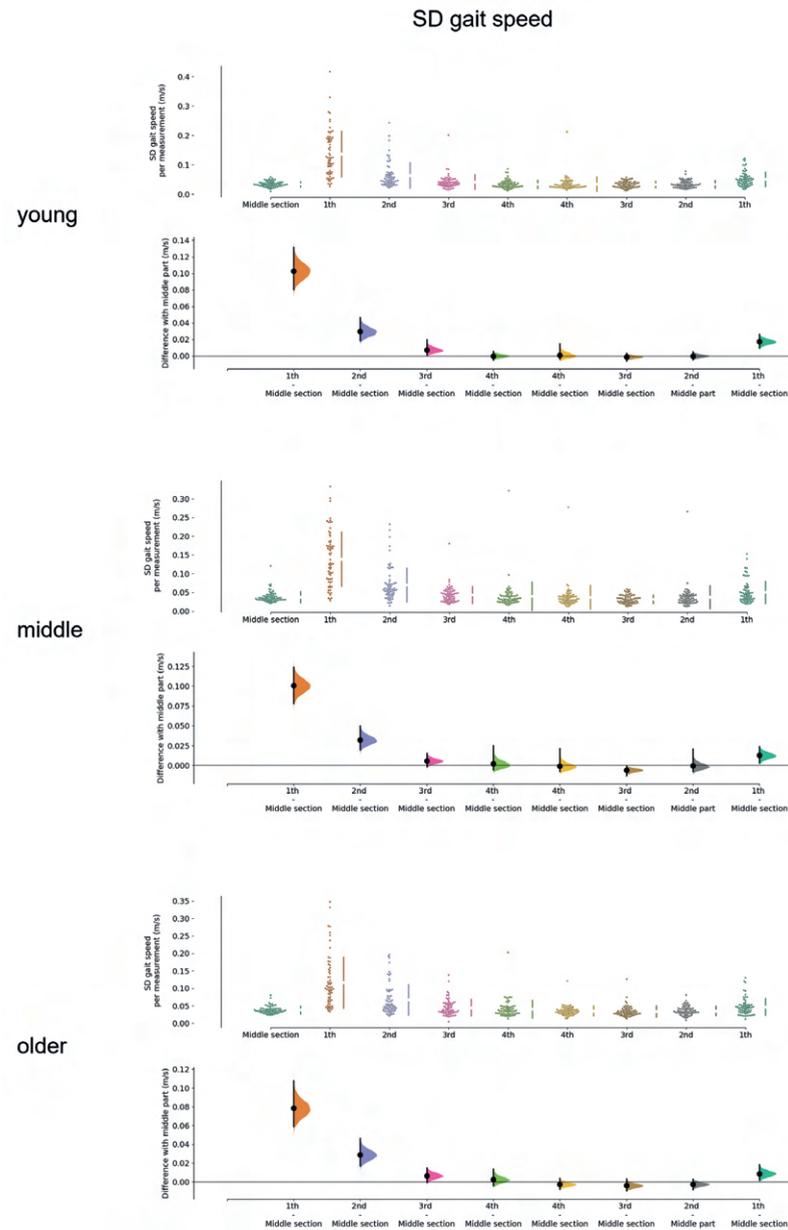


Figure A2. SD of the different participants during the walking trajectory, and the mean differences and associated 99% CI of the first and last 4 strides around a turn. The top subplot includes data of the young age group, the middle subplot, the middle age group, and the bottom subplot, the older age group.

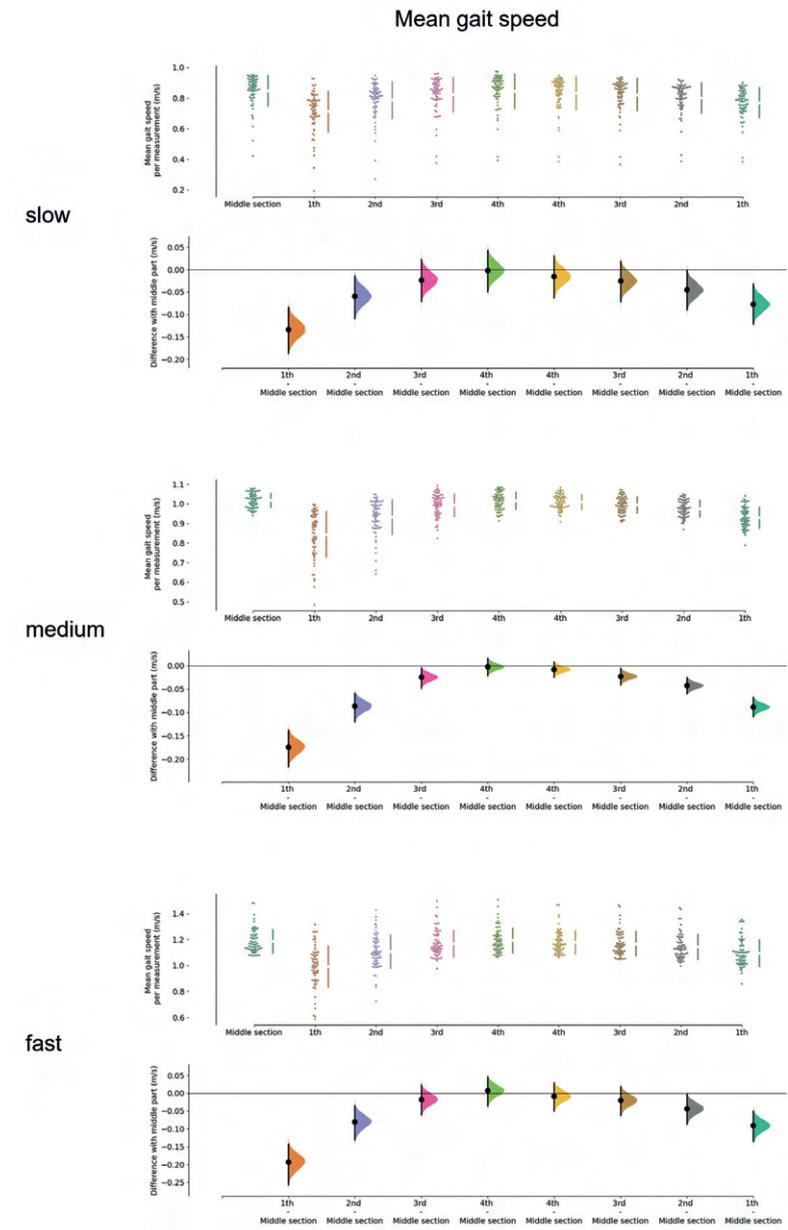


Figure A3. Mean gait speed of the different participants during the walking trajectory, and the mean differences and associated 99% CI of the first and last 4 strides around a turn. The top subplot includes data of the slow gait speed group, the middle subplot of the medium gait speed group and the bottom subplot of the fast gait speed group.

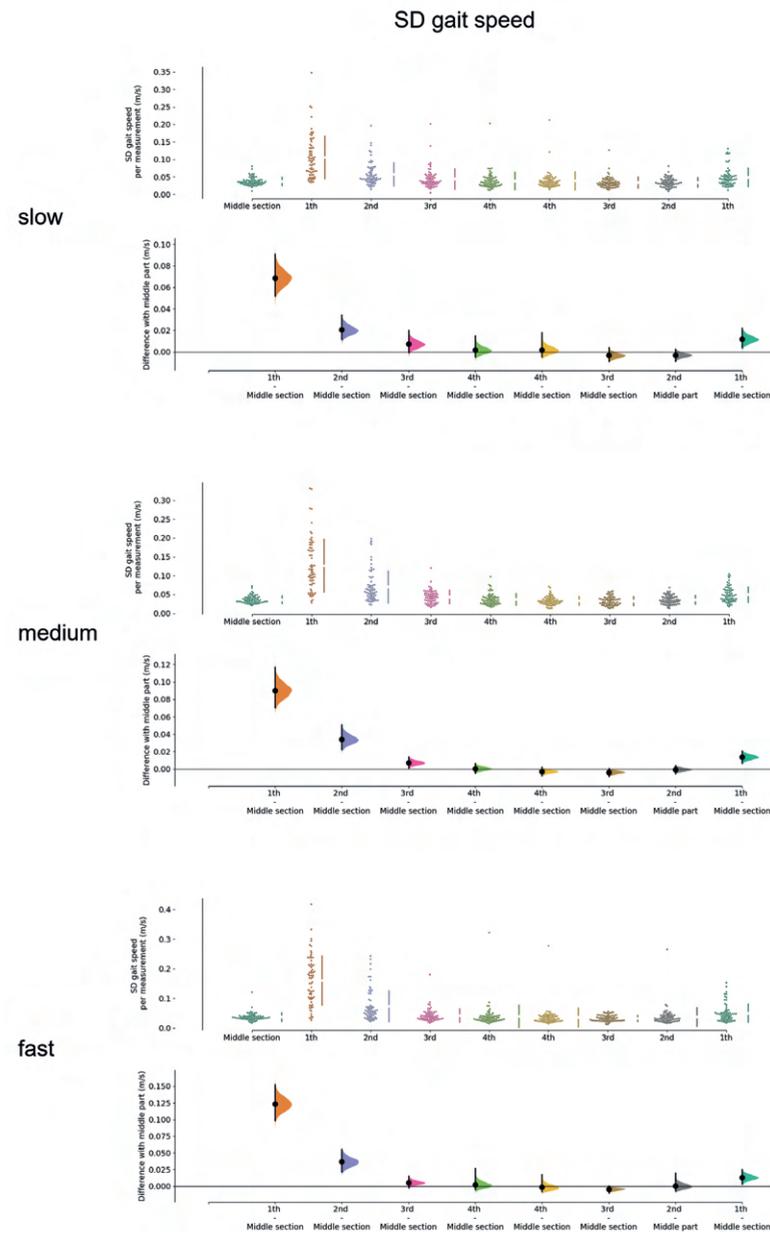


Figure A4. SD of the different participants during the walking trajectory, and the mean differences and associated 99% CI of the first and last 4 strides around a turn. The top subplot includes data of the slow gait speed group, the middle subplot of the medium gait speed group and the bottom subplot of the fast gait speed group.

Chapter 4



Assessment of foot strike angle and forward propulsion with wearable sensors in people with stroke

C.J. Ensink
C.J. Hofstad
T. Theunissen
N.L.W. Keijsers

Sensors. 2024. Jan;24:710

Abstract

Effective retraining of foot elevation and forward propulsion is a critical aspect of gait rehabilitation therapy after stroke, but valuable feedback to enhance these functions is often absent during home-based training.

To enable feedback at home, this study assesses the validity of an inertial measurement unit (IMU) to measure the foot strike angle (FSA), and explores eight different kinematic parameters as potential indicators for forward propulsion. Twelve people with stroke performed walking trials while equipped with five IMUs and markers for optical motion analysis (the gold standard). The validity of the IMU-based FSA was assessed via Bland–Altman analysis, ICC, and the repeatability coefficient. Eight different kinematic parameters were compared to the forward propulsion via Pearson correlation. Analyses were performed on a stride-by-stride level and within-subject level.

On a stride-by-stride level, the mean difference between the IMU-based FSA and OMCS-based FSA was 1.4 (95% confidence: -3.0; 5.9) degrees, with ICC = 0.97, and a repeatability coefficient of 5.3 degrees. The mean difference for the within-subject analysis was 1.5 (95% confidence: -1.0; 3.9) degrees, with a mean repeatability coefficient of 3.1 (SD: 2.0) degrees. Pearson's *r* value for all the studied parameters with forward propulsion were below 0.75 for the within-subject analysis, while on a stride-by-stride level the foot angle upon terminal contact and maximum foot angular velocity could be indicative for the peak forward propulsion.

In conclusion, the FSA can accurately be assessed with an IMU on the foot in people with stroke during regular walking. However, no suitable kinematic indicator for forward propulsion was identified based on foot and shank movement that could be used for feedback in people with stroke.

Introduction

Stroke survivors commonly face challenges related to impaired balance and gait, often attributed to diminished foot elevation and inadequate forward propulsion [1]. These challenges significantly increase the risk of falls and result in decreased gait speed [2,3], negatively impacting daily activities and overall quality of life [4]. Therefore, effectively retraining foot elevation and forward propulsion is a critical aspect of gait rehabilitation therapy [5]. During in-clinic therapy, therapists provide valuable feedback to patients to enhance these functions to further improve their gait pattern. Given that stroke survivors commonly experience not only motor impairments but also sensory deficits [6], this feedback is of utmost importance for successful rehabilitation. However, once patients are discharged from clinical care, they no longer receive feedback on their gait pattern during home-based training.

One potential solution is to integrate inertial measurement units (IMUs) for real-time feedback within home-based training. Since reduced foot elevation and insufficient forward propulsion are major factors contributing to gait problems in stroke [7,8], outcome parameters for feedback assessed with IMUs should be related to these impairments. Reduced foot elevation often results from weakness in the ankle dorsiflexors and is often characterized by toe landing rather than heel strike [7]. Therefore, the ankle angle or foot strike pattern (forefoot, midfoot, or rearfoot) could be used to train foot elevation. Previous research has demonstrated that IMUs can accurately estimate lower limb kinematics and spatiotemporal parameters [9–12]. Although the insights offered by lower limb joint angles are valuable [7,8], at least two sensors are needed to measure the angles of one joint, one on the proximal and one on the distal segment [11]. On the other hand, previous research on running kinematics revealed that a single IMU on the foot was able to distinguish between foot strike patterns (forefoot, midfoot, and rearfoot) [13,14]. Therefore, IMUs have the potential to offer valuable feedback to people with stroke on the foot strike angle (FSA), the angle formed between the foot and the walking surface upon initial contact (IC).

Besides feedback on the FSA, feedback on forward propulsion could also be useful for stroke survivors during exercise performance at home. However, IMUs cannot measure force directly, making the quantification of forward propulsion challenging through this modality [15]. Therefore, it is interesting to study if there are indicative gait characteristics for forward propulsion that can be measured with an IMU. It is generally thought that increasing forward propulsion leads to a higher gait speed with larger strides, resulting in altered kinematics of the foot and lower leg such as an increased angular velocity of the foot and a larger shank-to-vertical angle upon terminal contact (TC) [7,8,12,16–18]. Therefore, changes in foot and shank kinematics

might be indicative of the generated forward propulsion. Pieper et al. [12] found support for this idea via a strong correlation between peak shank acceleration and peak forward propulsion in healthy individuals, both at individual and group levels. Although Pieper et al. mimicked pathological gait patterns by imposing unilateral movement constraints on the ankle and knee joint, it is unknown if the correlation holds true in pathological gait (e.g., stroke survivors).

The present study has two objectives: (1) to validate the accuracy of the IMU-derived FSA in individuals with stroke against the gold-standard optical motion capture system (OMCS), and (2) to identify IMU-derived parameters that are indicative of forward propulsion in individuals with stroke. We hypothesized that the FSA could be measured with high accuracy (a deviation from the gold standard of <5 degrees), based on previous work regarding the shank angle, which reached a mean difference of 0.7 degrees with a repeatability coefficient of 4.2 degrees compared to that of the OMCS [10]. Regarding the second aim, we anticipated that several foot and shank kinematic variables during the gait cycle would exhibit a moderate correlation (Pearson correlation coefficients ranging from 0.5 to 0.75) with forward propulsion. Based on the general belief expressed in the literature that decreased forward propulsion leads to altered gait kinematics, decreased gait speed, and shorter stride lengths [7,8,12,16–19], we measured the foot and shank angle upon TC, the maximum angular velocity and angular acceleration during the stance phase (IC to TC) of both the foot and shank, the maximum shank linear acceleration, and the stride length with the gold standard (OMCS), and evaluated these parameters as indicators for the actual forward propulsion. These parameters were chosen based on the previously found promising results for the shank linear acceleration [12], gait speed [12,18], stride length [17,18], and peak angular velocity of the lower limb segments [18,19], and their potential to be derived from only a single IMU. Finally, the same metrics were calculated with the IMU system to verify that the IMU system reaches similar correlations between these metrics and the forward propulsion.

Materials and methods

Participants

Twelve participants were recruited between January 2023 and June 2023 from physiotherapy practices in and around Nijmegen, as well as from social media groups for stroke survivors. Participants were eligible when they had experienced a stroke at least 6 months prior, were at least 18 years old, had unilateral motor deficits, and could walk for at least 5 min without assistive devices. Individuals were excluded if they lacked a sufficient cognitive ability to understand basic instructions, had a

history of orthopedic or neurologic disorders (excluding stroke) that could affect gait or balance, had undergone surgery to correct drop foot, or were unable to perform any ankle flexion–extension. All participants gave their written informed consent prior to participation.

The study protocol was in line with the Declaration of Helsinki and was granted an exemption by the Dutch Medical Scientific Research Act (WMO) from ‘METC Oost-Nederland’ (identification number: 2021-13295).

Materials

Participants were equipped with five IMUs (MTw Awinda, Movella, Enschede, The Netherlands) attached to the dorsal side of both feet, the anterior aspect of their shanks, and the lower back (L4/5), along with 20 reflective markers for the OMCS. Reflective markers were placed according to the VICON plug-and-gait lower body model [20]. MT Manager software suite version 2019.2 was used for the data capture of the IMUs. Participants walked on the GRAIL (Gait Real-time Interactive Analysis Lab, (Motek Medical, Amsterdam, The Netherlands)), an instrumented treadmill with an eight-camera OMCS (VICON, Oxford, UK), embedded force plates (Motek Medical, Amsterdam, The Netherlands), and a wide (180°) circular screen in front of the treadmill, creating a virtual environment. The IMU and OMCS both recorded at a sample frequency of 100 Hz, while the force plates operated at 1000 Hz. All systems were time-synchronized by a high-low pulse, with the OMCS serving as master.

Measurements

After a familiarization period, participants performed five walking trials on the GRAIL. The first and last trials involved self-paced regular walking, where participants had control over the speed of the treadmill by positioning themselves at the front (to accelerate) or at the back (to decelerate) of the belt [21]. Data were captured for two minutes starting when participants indicated that they were at a comfortable walking speed. Trials two to four introduced variability in the FSA and anterior–posterior propulsion by providing feedback on either their FSA, propulsion, or both simultaneously. Feedback was provided visually via a vertical slide bar on the GRAIL’s screen, with the slide moving upwards to the green end or downwards to the red end based on the participant’s performance. The second and third trials were randomized across subjects with feedback on either the FSA (based on OMCS data) or propulsion (based on the force plate data). During the fourth trial, participants received feedback on both parameters. At the start of each feedback trial, participants walked 10 strides without feedback. The GRAIL system calculated their regular FSA and propulsion, followed by 2 min of walking with feedback, during which data were captured. All measurements and visual feedback were embedded in a custom-built GRAIL application.

Data Processing

IMU data captured by MT Manager software (2019.2) included angular velocity and acceleration data in the sensor frame, acceleration in the earth frame, and orientation in a quaternion and Euler angle format. OMCS data were captured by VICON Nexus software (version 2.4). All further data processing and analyses were performed in Python 3.10.

A second-order low-pass Butterworth filter was applied to the angular velocity (cut-off frequency of 15 Hz) and acceleration data (cut-off frequency of 17 Hz) of the IMUs [22,23]. OMCS data were similarly filtered using a second-order low-pass Butterworth filter with a 15 Hz cut-off frequency. Force plate data were filtered using a fourth-order low-pass Butterworth filter with a 20 Hz cut-off frequency [24].

All of the code for data processing and analysis is available at the following link: <https://github.com/SintMaartenskliniek/MovingReality> (Release: "Validation study", tag: "v1.0.0", date: 6 January 2024).

Data Analysis

Each trial had a data recording time of 120 s. Data recording started 10 s after initiating the trial to exclude the initial acceleration phase to reach the comfortable walking speed. Data recording was stopped before the participant began decelerating to end the trial.

For the OMCS data, gait events were determined based on the validated method of Zeni et al. [24]. This method identifies IC as the instant when the velocity vector in the anterior–posterior direction of the heel marker crosses zero in the posterior direction. TC corresponds to the instant where the velocity vector in the anterior–posterior direction of the toe marker crosses zero in the anterior direction. For IMU data, IC events were identified at the instant of the first zero-crossing of the angular velocity around the mediolateral axis after mid-swing (maximum angular velocity around the mediolateral axis) [23]. TC events were identified at the peak vertical acceleration between mid-swing events (maximum angular velocity around the mediolateral axis) [23]. The foot flat phase, when the foot was flat on the walking surface, was identified between TC and the mid-swing of the contralateral side.

The OMCS global coordinate system was defined with the z-axis aligned to the vertical direction, the y-axis aligned to the walking direction, and the x-axis perpendicular to this plane. The IMUs used in this study also provide acceleration in the global frame. The IMU global frame is defined such that the x-axis is pointing to the magnetic north, the z-axis is aligned with the gravity direction, and the y-axis

is perpendicular to this plane. Figure 1 shows a schematic illustration of the experimental setup.

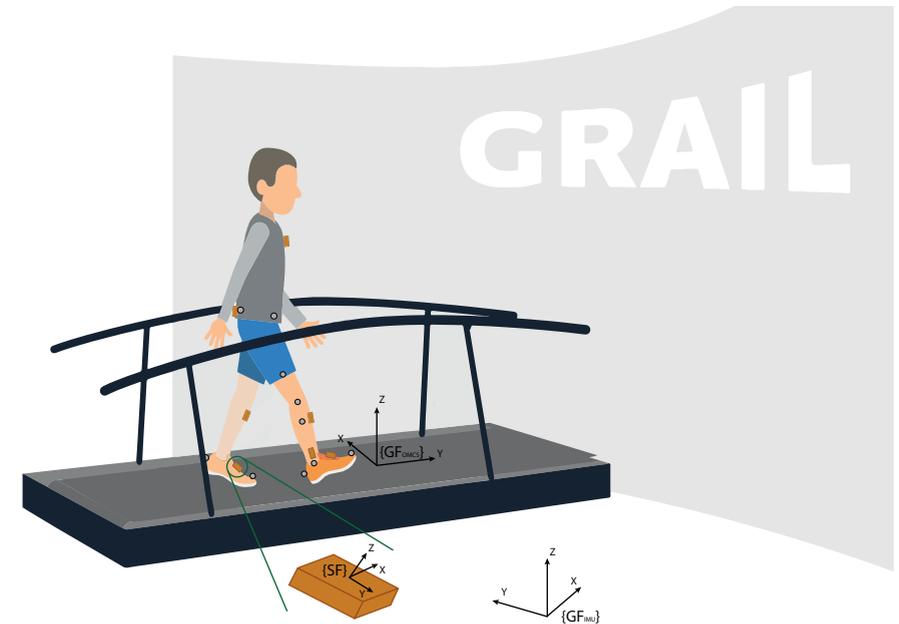


Figure 1. Schematic representation of the measurement setup. Note the grey optical markers at the toe and heel of the feet, defining the foot segment, as well as the markers at the knee and ankle, defining the shank segment. $\{SF\}$ represents the local sensor frame of the IMU, $\{GF_{OMCS}\}$ represents the global frame of the OMCS system, and $\{GF_{IMU}\}$ represents the global frame of the IMU system.

The foot segment was defined between the position of the toe and heel markers from the OMCS data (Equation (1)), after which the foot angle during the gait cycle was calculated in accordance with Equation (2). During the foot flat phase, the foot angle was considered to be zero degrees. Therefore, the foot angle was adjusted by subtracting the mean foot angle measured during the mid-stance of the first 10 strides (Equation (2)). Subsequently, the foot angle was converted from radians into degrees in accordance with Equation (3).

$$\text{Foot segment}_{OMCS} = \text{position}_{TOE MARKER} - \text{position}_{HEEL MARKER}, \quad (1)$$

$$\text{Foot angle}_{\text{OMCS}} = \tan^{-1} \left(\frac{\text{foot segment}_{\text{OMCS}} \text{ vertical component}}{\text{foot segment}_{\text{OMCS}} \text{ walking direction component}} \right) \quad (2)$$

$$\text{Foot angle}_{\text{OMCS}} = (\text{foot angle}_{\text{OMCS}} - \text{mean}(\text{foot angle}_{\text{OMCS}} \text{ mid-stance of stride 1 to 10})) \times 180/\pi, \quad (3)$$

Finally, the foot strike angle was determined for each IC event based on the OMCS event algorithm (Equation (4)):

$$\text{Foot strike angle}_{\text{OMCS, IMU}} = \text{foot angle}_{\text{OMCS, IMU}} \text{ at IC}, \quad (4)$$

For IMU data, the Euler angles directly retrieved from the sensor were used as the estimated foot angles, with the Euler pitch angle corresponding to the foot angle of interest. Importantly, we assumed that the sensor axes were aligned with the axes of the foot segment. The foot angle as measured with the IMU is tilted due to attachment to the dorsal side of the foot (see Figure 2). This was corrected by subtracting the mean foot angle measured during the foot flat phase of the first 10 strides in accordance with Equation (5), considering the foot angle during the foot flat phase to be zero degrees. Finally, the foot strike angle was determined as the foot angle upon IC, for each IC event based on the IMU event algorithm (Equation (4)).

$$\text{Foot angle}_{\text{IMU}} = (\text{foot angle}_{\text{IMU}} - \text{mean}(\text{foot angle}_{\text{IMU}} \text{ foot flat of stride 1 to 10})), \quad (5)$$



Figure 2. The measured IMU-based foot angle (foot angle + α) corrected with the mean foot angle (α) during the foot flat phase of the first 10 strides, to consider the foot angle during the foot flat phase to be zero degrees.

For our second aim, the parameter of interest was forward propulsion. In the literature, two main approaches have been used to quantify this parameter. First, forward propulsion has been defined as the area under the curve (AUC) of the measured anterior–posterior ground reaction force (GRF) during each push-off [25]. This involves the numerical integration of the GRF in the anterior–posterior direction from the breaking-to-propulsion transition until TC is observed with bodyweight

normalization (Equation (6) and Figure 3) [25]. Second, forward propulsion has been defined as the maximum value of the anterior–posterior GRF during each push-off (Equation (7)).

$$\text{Forward propulsion}_{\text{AUC}} = \int_{\text{BPT}}^{\text{TC}} \text{GRF}_{\text{AP direction}} dt,$$

$$\text{with } dt = 1/\text{sample frequency, TC} = \text{terminal contact,} \quad (6)$$

BPT = breaking-to-propulsion transition, GRF = ground reaction force,
and AP = anterior-posterior;

$$\text{Forward propulsion}_{\text{peak}} = \text{maximum}(\text{GRF}_{\text{AP direction}}),$$

$$\text{with GRF}_{\text{AP direction}} \text{ for each breaking-to-propulsion transition} \quad (7)$$

until terminal contact

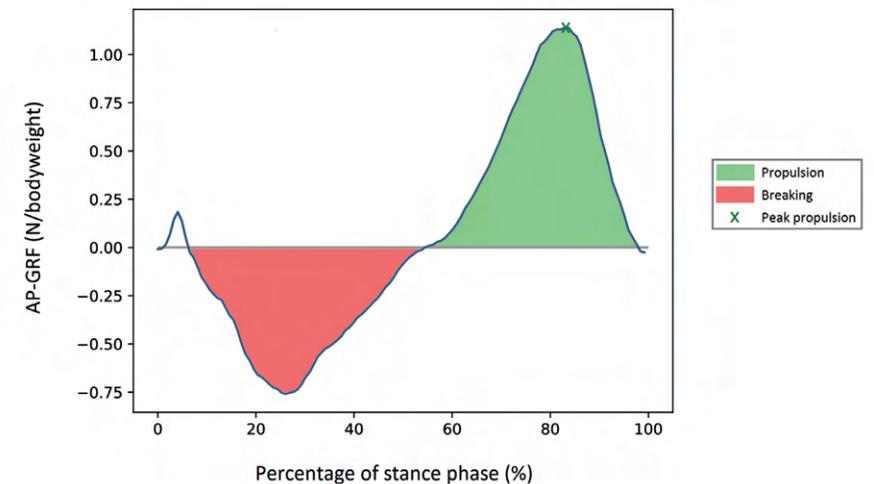


Figure 3. Forward propulsion measured by the area under the curve from the breaking-to-propulsion transition until TC, indicated with green. Peak forward propulsion, indicated with x, was defined as the maximum value from the breaking-to-propulsion transition until TC.

Eight parameters were identified as possible indicators for forward propulsion: the foot and shank angle upon TC, the maximum angular velocity and angular acceleration during the stance phase (IC to TC) of both the foot and shank, maximum shank linear acceleration, and the stride length. The calculation of the foot angle over time is described above for both systems. For each gait cycle, the foot angle upon TC was calculated. For OMCS data, the shank angle over time was calculated in accordance

with Equations (8) and (9), while the IMU-based shank angle was directly derived from the Euler angle of the sensor output. Again, the shank angle upon TC for both systems was calculated for each gait cycle.

$$\text{Shank segment}_{\text{OMCS}} = \text{position}_{\text{KNEE MARKER}} - \text{position}_{\text{ANKLE MARKER}}, \quad (8)$$

$$\text{Forward propulsion}_{\text{peak}} = \text{maximum}(\text{GRF}_{\text{AP direction}}),$$

$$\text{with GRF}_{\text{AP direction}} \text{ for each breaking-to-propulsion transition} \\ \text{until terminal contact} \quad (9)$$

$$\text{Shank angle}_{\text{OMCS}} = \tan^{-1}\left(\frac{\text{shank segment}_{\text{OMCS vertical component}}}{\text{shank segment}_{\text{OMCS walking direction component}}}\right)$$

The foot and shank angular velocity were calculated as the first derivative of the foot and shank angle for the OMCS, respectively. For the IMU-based foot and shank angular velocity, the angular velocity directly measured from the gyroscope was used. The foot and shank angular acceleration were subsequently calculated as the derivative of the foot and shank angular velocity for both measurement systems. Finally, the maximum value of each of the parameters for each gait cycle was taken. The linear acceleration of the shank was calculated as the square root of the squared acceleration in the global frame in the horizontal plane (Equation (10)) for both systems. For the OMCS, the acceleration along the x- and y-axis was calculated with the second derivative of the x- and y-positions of the shank segment defined in Equation (8). For the IMUs, the acceleration in the global frame was directly retrieved from the IMU data. For the shank's linear acceleration, again, the maximum value during each stance phase was computed.

$$\text{Shank linear acceleration} = \sqrt{(\text{acceleration}_{\text{x-axis}})^2 + (\text{acceleration}_{\text{y-axis}})^2} \quad (10)$$

Statistical Analysis

Participant characteristics were reported using descriptive statistics. The normality of the data was tested using the Shapiro–Wilk test, and results were reported accordingly. To assess the reliability and agreement of the IMU-derived FSA compared to those of the gold standard, intraclass correlation and Bland–Altman analysis were performed for all strides of all participants, as well as for each participant individually. The latter, referred to as within-subject analysis, was performed to evaluate whether or not the parameters could be used as feedback for individualized home-based training. To determine if a potential parameter was a suitable indicator for forward propulsion, the Pearson correlation coefficients between the potential parameters (foot angle at TC, shank angle at TC, maximum foot angular velocity, maximum shank

angular velocity, maximum foot angular acceleration, maximum shank angular acceleration, maximum shank linear acceleration, and stride length), the AUC and peak forward propulsion were calculated. This analysis was performed for both the OMCS and IMU system. This dual approach allowed us to evaluate the potential of these parameters to serve as indicators for forward propulsion (AUC and peak) based on the gold-standard method OMCS, and to confirm the IMU's ability to serve the same purpose. Both ICC and Pearson correlation values were interpreted as weak (<0.5), moderate (0.5–0.75), good (0.75–0.9), and excellent (>0.9) reliability and correlation [26]. A parameter was considered a possible indicator for forward propulsion if the significant ($p < 0.05$) Pearson correlation value was at least good ($r > 0.75$).

Results

Participant Characteristics

All 12 participants (7 male/5 female) were previously enrolled in a gait rehabilitation training program post-stroke. Their mean age was 61 years (SD: 9.5) with a median time since stroke onset of 25 months (6 to 210 months). Eight participants experienced an ischemic stroke, two experienced a hemorrhagic stroke, and from two participants the type of stroke was unknown. The average comfortable gait speed was 1.0 (SD: 0.3) m/s. Participant characteristics are presented in Table 1.

Table 1. Participant characteristics.

Participant Characteristics	
N	12
Gender (male/female)	7/5
Age (mean ± SD years)	61.0 ± 9.5
Height (mean ± SD cm)	176.4 ± 8.5
Weight (mean ± SD kg)	85.0 ± 14.7
Affected side (left/right)	6/6
Stroke type (ischemic/hemorrhagic/unknown)	8/2/2
Time since stroke onset (median (IQR) months)	24.5 (11; 76.5)
Gait speed (mean ± SD m/s)	1.0 ± 0.3

Foot Strike Angle Validation

In total, 11,985 strides from all trials and all participants were included for stride-by-stride validity analysis. Excellent reliability of the IMU-based FSA compared to the

OMCS-based FSA was found via the ICC (ICC (3,1) = 0.97, 95%CI: [0.96; 0.97]). Figure 4 shows the Bland–Altman analysis of the FSA measured on a stride-by-stride basis. Differences between the IMU-based FSA and OMCS-based FSA were on average 1.4 degrees, with 95% limits of agreement ranging from –3.0 to 5.9 degrees. The repeatability coefficient was 5.3 degrees.

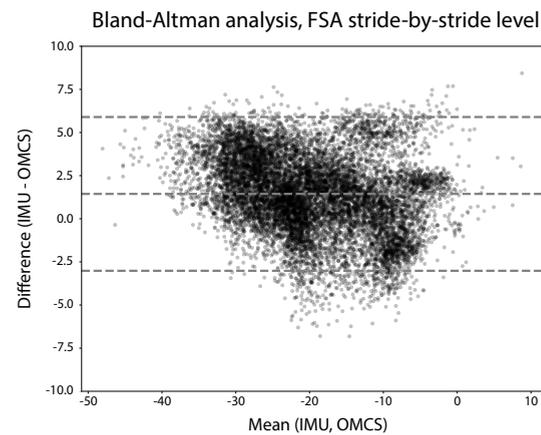


Figure 4. Bland–Altman analysis of the FSA (degrees) of all strides of all participants. The difference between measures is calculated as IMU-based FSA—OMCS-based FSA.

For the within-subject analysis, the step count per subject ranged from 630 to 1283 steps. Differences between the IMU-based and OMCS-based FSA were on average 1.5 degrees, with 95% limits of agreement ranging from –1.0 to 3.9 degrees (Figure 5). The mean repeatability coefficient for the within-subject analysis was 3.1 (SD: 2.0) degrees. Figure A1 in Appendix A shows the Bland–Altman analysis of the FSA on a stride-by-stride level for each participant.

Indicative Parameter for Forward Propulsion

Out of the 11,985 strides recorded in total, 7591 strides were suitable for a further analysis of propulsive force, as they involved only one foot on a single force plate. For each individual, between 1693 and 931 strides were included in this analysis (median 665 strides).

All IMU-based indicators for forward propulsion demonstrated only weak to moderate Pearson correlation coefficients with the AUC forward propulsion on a stride-by-stride level (see Table 2). The equivalent OMCS-based parameters revealed similar weak to moderate Pearson correlation coefficients. The mean and SD of the Pearson

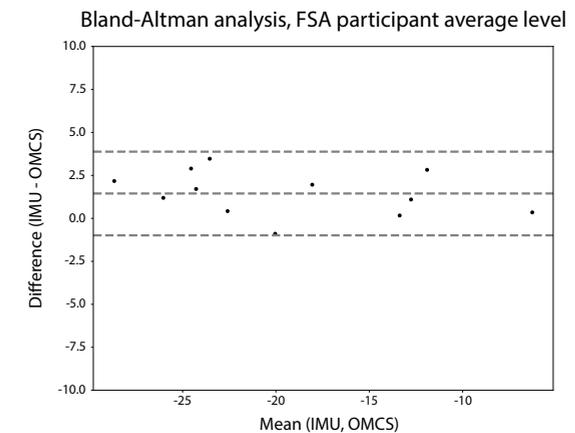


Figure 5. Bland–Altman analysis of the mean FSA (degrees) per participant. The difference between measures is calculated as mean IMU-based FSA—mean OMCS-based FSA.

correlation between the indicators for forward propulsion and the measured AUC forward propulsion for the within-subject analysis are presented in Table 3. The mean Pearson correlations ranged between 0.06 and 0.63 with relatively high SD values, indicating large differences between subjects. Appendix A, Figure A2, includes correlation graphs of each of the parameters with the AUC forward propulsion.

Table 2. Pearson correlation between different gait characteristics and the AUC forward propulsion for the stride-by-stride analysis.

Parameter	IMU-Based	OMCS-Based
	Pearson r	Pearson r
Foot angle upon TC	0.43 *	0.52 *
Max foot angular velocity	0.23 *	0.32 *
Max foot angular acceleration	–0.01	0.18 *
Shank angle upon TC	0.26 *	0.42 *
Max shank angular velocity	–0.13 *	0.12 *
Max shank angular acceleration	0.23 *	0.21 *
Shank linear acceleration	0.17 *	–0.01
Stride length	0.26 *	0.50 *

All parameters are separately evaluated based on OMCS data and IMU data. * indicates significant correlations ($p < 0.05$).

Table 3. Mean and standard deviation of the within-subject analysis for the Pearson correlation between the different gait characteristics and the AUC forward propulsion.

Parameter	IMU-Based	OMCS-Based
	Pearson r Mean \pm SD	Pearson r Mean \pm SD
Foot angle upon TC	0.44 \pm 0.26	0.49 \pm 0.31
Max foot angular velocity	0.19 \pm 0.37	0.39 \pm 0.31
Max foot angular acceleration	0.04 \pm 0.26	0.19 \pm 0.42
Shank angle upon TC	0.32 \pm 0.37	0.63 \pm 0.22
Max shank angular velocity	0.01 \pm 0.34	0.09 \pm 0.37
Max shank angular acceleration	0.17 \pm 0.24	0.19 \pm 0.42
Shank linear acceleration	0.28 \pm 0.17	0.06 \pm 0.20
Stride length	0.20 \pm 0.26	0.49 \pm 0.20

All parameters are separately evaluated based on OMCS data and IMU data.

All IMU-based indicators for the peak forward propulsion demonstrated only weak to moderate Pearson correlation coefficients in the stride-by-stride analysis, except for stride length ($r = 0.76$) (see Table 4). The equivalent OMCS-based parameters revealed higher Pearson correlation coefficients of up to $r = 0.77$ for the maximum foot angular velocity and $r = 0.76$ for the foot angle upon TC. The mean and SD of the Pearson correlation between the indicators for forward propulsion and the measured peak forward propulsion for the within-subject analysis are presented in Table 5. While the mean Pearson correlation for the within-subject analysis did not exceed 'moderate' correlation values, the relatively high SD values between 0.19 and 0.49 indicate large differences between subjects. Appendix A, Figure A3, includes correlation graphs of each of the parameters with the peak forward propulsion.

Table 4. Pearson correlation between different gait characteristics and the peak forward propulsion for the stride-by-stride analysis.

Parameter	IMU-Based	OMCS-Based
	Pearson r	Pearson r
Foot angle upon TC	0.61 *	0.77 *
Max foot angular velocity	0.63 *	0.78 *
Max foot angular acceleration	0.05 *	0.64 *
Shank angle upon TC	0.21 *	0.68 *
Max shank angular velocity	-0.14 *	0.53 *
Max shank angular acceleration	0.46 *	0.60 *
Shank linear acceleration	0.38 *	0.35 *
Stride length	0.76 *	0.74 *

All parameters are separately evaluated based on OMCS data and IMU data. * indicates significant correlations ($p < 0.05$).

Table 5. Mean and standard deviation of the within-subject analysis for the Pearson correlation between the different gait characteristics and the peak forward propulsion.

Parameter	IMU-Based	OMCS-Based
	Pearson r Mean \pm SD	Pearson r Mean \pm SD
Foot angle upon TC	0.47 \pm 0.26	0.56 \pm 0.37
Max foot angular velocity	0.50 \pm 0.22	0.59 \pm 0.26
Max foot angular acceleration	0.22 \pm 0.17	0.28 \pm 0.36
Shank angle upon TC	0.15 \pm 0.45	0.55 \pm 0.33
Max shank angular velocity	-0.05 \pm 0.31	0.16 \pm 0.49
Max shank angular acceleration	0.14 \pm 0.31	0.28 \pm 0.36
Shank linear acceleration	0.25 \pm 0.23	0.18 \pm 0.18
Stride length	0.20 \pm 0.26	0.49 \pm 0.20

All parameters are separately evaluated based on OMCS data and IMU data.

Discussion

The present study aimed to evaluate the accuracy of the IMU-derived FSA and to identify IMU-derived indicators for forward propulsion in individuals with stroke. The results show high accuracy for the IMU-derived FSA compared to that of the gold standard. Regarding the second aim, weak to moderate correlations between eight potential indicators and the measured forward propulsion were found.

The stride-by-stride evaluation revealed a mean difference of 1.4 degrees with a standard deviation of 2.3 degrees for the IMU-derived FSA, coupled with an excellent intraclass correlation (>0.9) when compared to that of the gold standard, indicating an acceptable level of accuracy. Previous research on the assessment of FSA with IMUs was performed in healthy participants during running. Although running is inherently different from walking, our results surpassed the accuracy even when analyzed on a stride-by-stride basis (3.9 ± 5.3 degrees) [14]. Furthermore, the results of this study are in line with the accuracy of estimated shank angles in walking, both of which are based on the same principle of estimating segment orientation from a single IMU [10]. When the FSA was averaged across all strides within each participant, every participant had a difference of less than 5 degrees compared to that under the gold standard (see Figure 5). More importantly, while the repeatability coefficient on a stride-by-stride basis was just above 5 degrees (5.3), a mean repeatability coefficient of only 3.1 degrees was found when analyzed within subjects. Given that the repeatability within subjects is well within the set limit of 5 degrees and only slightly exceeds it in the stride-by-stride analysis, we conclude that the FSA could accurately be assessed with an IMU in people with stroke.

For the second aim, potential indicators for forward propulsion, defined as either the AUC or the peak anterior–posterior GRF, were evaluated. Based on the previous literature [7,8,12,16–19], seven kinematic parameters of the shank and foot, as well as stride length, were evaluated by calculating the correlation coefficient with the generated forward propulsion. The stride-by-stride analysis for AUC forward propulsion yielded weak to moderate correlations (see Table 2). When considering peak forward propulsion, previous research has shown that shank linear acceleration could serve as a good to excellent indicator [12]. Unfortunately, our study did not replicate this correlation for either the OMCS- ($r = 0.35$) or IMU-derived ($r = 0.38$) shank linear acceleration parameter (see Table 4). However, maximum foot angular velocity, foot angle upon TC, and stride length marginally exceeded the threshold for a good correlation, suggesting their potential as indicators for peak forward propulsion, aligning with the review of Roelker et al. [18]. Unfortunately, only the IMU-based equivalent correlation coefficient for stride length reached the level of a good

correlation, whereas the maximum foot angular velocity and foot angle at TC had only a moderate correlation. The absence of strong correlations between any of the parameters with forward propulsion on a stride-by-stride basis might be attributed to heterogeneity in gait patterns within our study population. While all participants were chronic stroke patients with affected gait, there were notable differences in gait speed and gait pattern, including varying degrees of stiff knee gait and compensatory strategies such as hip circumduction. This altered gait in stroke patients could also explain the disparity between our study and the research of Pieper and colleagues [12], which involved healthy participants tested during regular walking and walking with simulated pathological gait. Based on the current study, we conclude that none of the proposed IMU-derived indicators could serve as a valid indicator for forward propulsion.

Since a general application of sensors is to integrate them in real-time home-based training settings [27,28], the individual participant correlation between the potential indicators and forward propulsion was also evaluated. Averaged across subjects, this within-subject analysis yielded moderate correlations for the AUC and peak forward propulsion. Again, the correlation coefficients of the OMCS-based parameters were lower than their IMU-based equivalent parameters. Importantly, substantial inter-individual variability in the various potential indicative parameters for both AUC and peak forward propulsion was found, as indicated by the high SDs across participants (see Tables 3 and 5). Nevertheless, none of the explored parameters reached the minimum requirement of a ‘good’ correlation ($r > 0.75$) for a substantial number of individuals. Therefore, we do not consider any of the studied parameters as appropriate to provide feedback on forward propulsion to improve the gait pattern.

This study has some limitations. Firstly, the evaluation of straight-ahead treadmill walking, though common in research protocols, does not fully capture the complexity of real-life walking scenarios involving curved paths, uphill, downhill terrain, and uneven surfaces. Gait kinetics and kinematics can notably differ under these diverse conditions compared to those under straight-ahead walking [29]. Therefore, the ecological validity of our findings, both in terms of the validity of the FSA and indicators of forward propulsion in real-world walking scenarios, warrants further investigation. Secondly, the discrepancy found in correlations of the forward propulsion with possibly indicative parameters between OMCS-derived and IMU-derived parameters suggests that there is a difference between the parameters when obtained with the OMCS and IMU. Enhancing the validity of the IMU-based parameters would be valuable and could result in correlation values similar to the OMCS-based equivalents with forward propulsion. This would mean that maximum foot angular velocity and foot angle upon TC could be used to assess an individual's

peak forward propulsion based on multiple strides. Thirdly, our study population consisted of twelve participants based on the recommendation as a rule of thumb for pilot studies [30]. While this was a convenient sample to test the usability of a feedback system for the first time, this limited number of participants might not include all different variations of gait patterns. Future research could explore the effect of differences in gait patterns on the correlation of certain gait characteristics with forward propulsion. Lastly, our choice to evaluate relatively simple parameters as indicators for forward propulsion was driven by the potential application of a real-time feedback system for home-based rehabilitation. Prioritizing computational efficiency and usability, the number of required IMUs was limited to one or a maximum of two attached to the affected leg. Furthermore, other parameters that could be derived from the sensors, such as the timing of the selected parameters in the gait cycle, could also be valuable to estimate the forward propulsion. According to the literature [12,17], there was no reason to believe that the timing of the selected parameters was an indicator for forward propulsion. Nevertheless, the potential of these parameters and their combination should be explored in future studies. However, we acknowledge that individuals with stroke use diverse gait strategies, including dominant hip strategies and swing initiation alterations or step length modifications. Therefore, a more sophisticated, potentially multimodal analysis of a combination of different parameters and a fusion of data from various body segments, such as the pelvis, thigh, shank, and foot, may offer a better indicator for forward propulsion [15,31]. While the use of multiple IMUs might be feasible for in-clinic rehabilitation, implementing a multi-sensor setup in the home situation in these patients is often unfeasible.

Conclusions

The findings in the current study offer valuable insights that can contribute to the development of feedback systems aimed at improving the gait pattern of stroke survivors. This study demonstrated that the FSA can be accurately assessed with an IMU on the foot during straight-ahead walking. Our proposed foot and shank movement parameters were not suitable to provide patients with feedback regarding forward propulsion.

Acknowledgments

We would like to thank our research intern Dries Cavelaars for his contribution to the data acquisition and Bart Nienhuis for all of his technical support.

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Supplementary materials

Appendix A

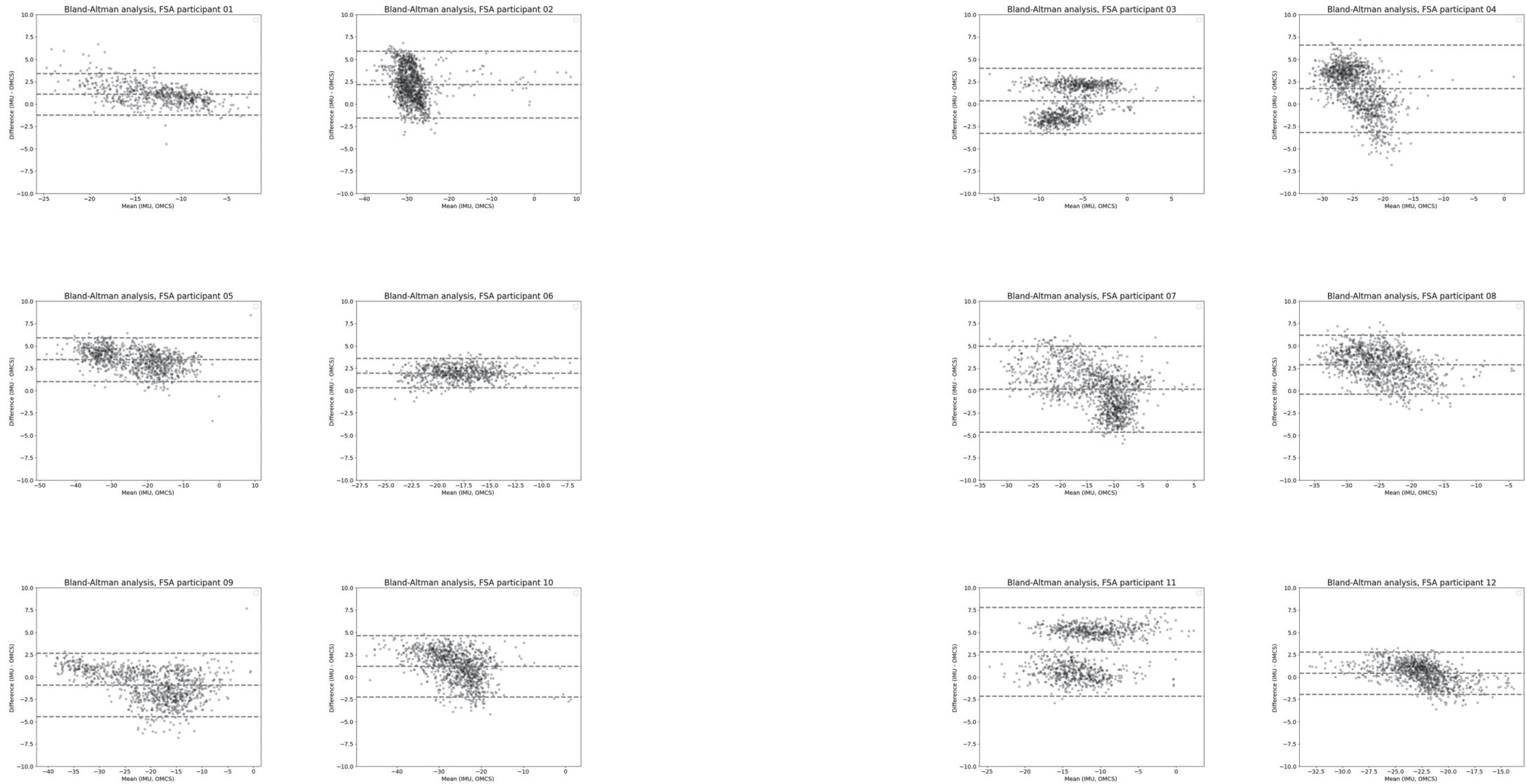


Figure A1. Bland–Altman analysis of the FSA (degrees) on a stride-by-stride level for each participant. The difference between measures is calculated as IMU-based FSA—OMCS-based FSA.

Figure A1. Continued.

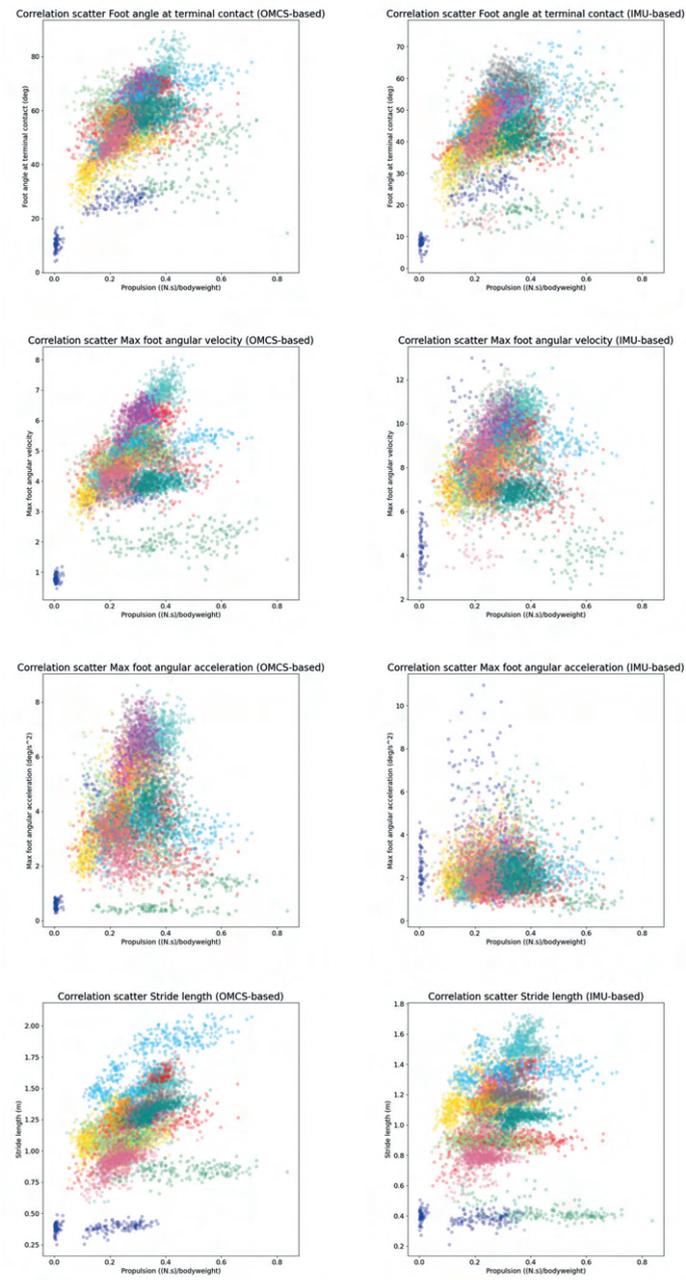


Figure A2. Correlation graphs of the potential indicators and the forward propulsion (area under the curve). Each color represents a different participant.

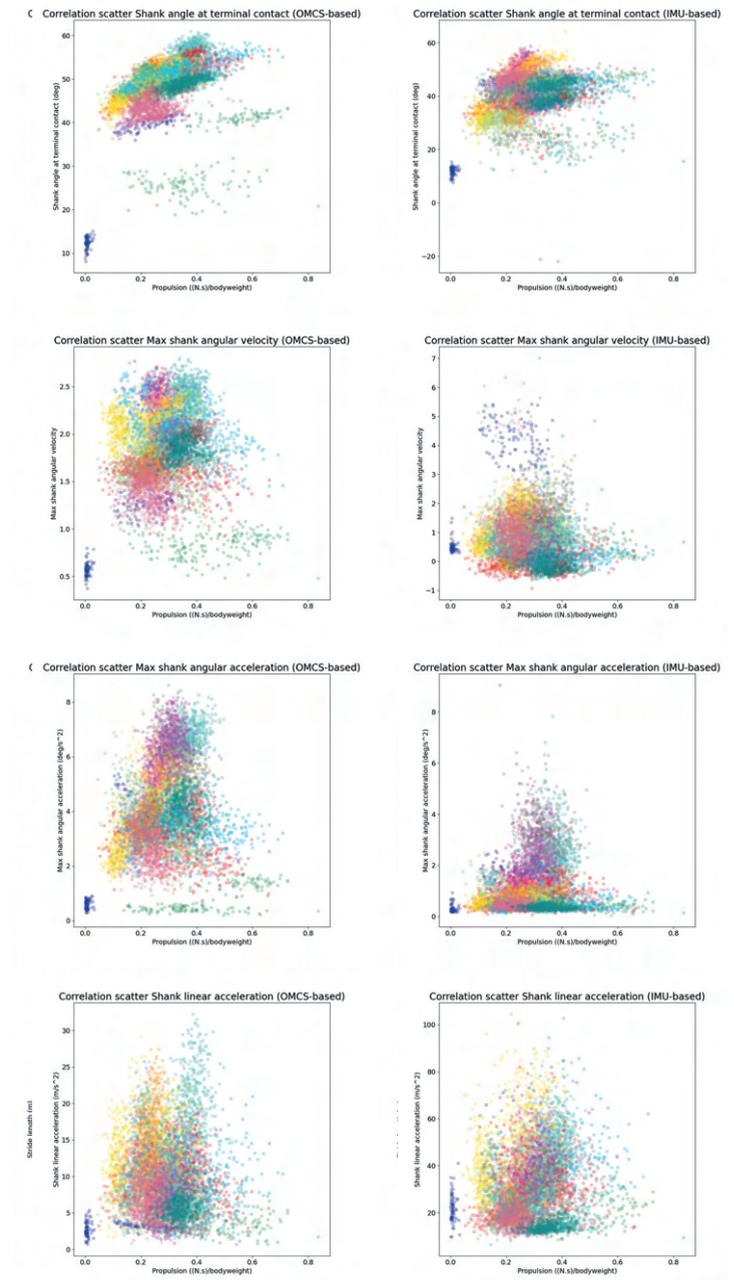


Figure A2. Continued.

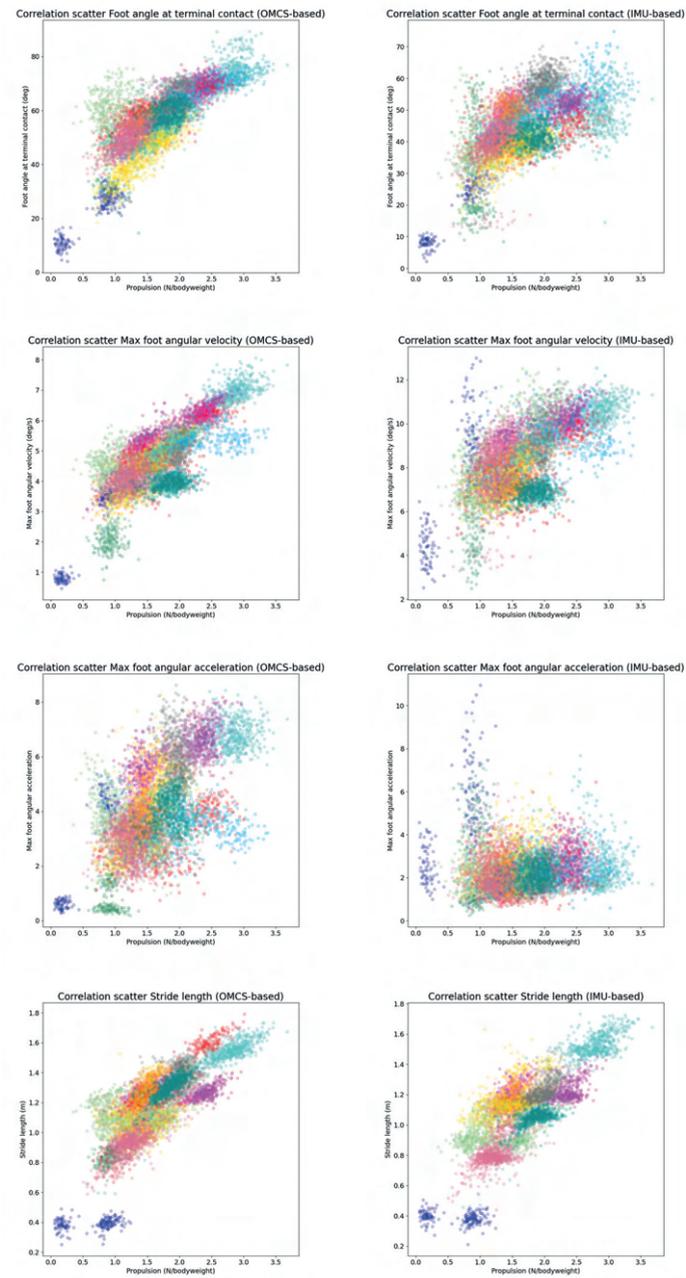


Figure A3. Correlation graphs of the potential indicators and the forward propulsion (peak). Each color represents a different participant.

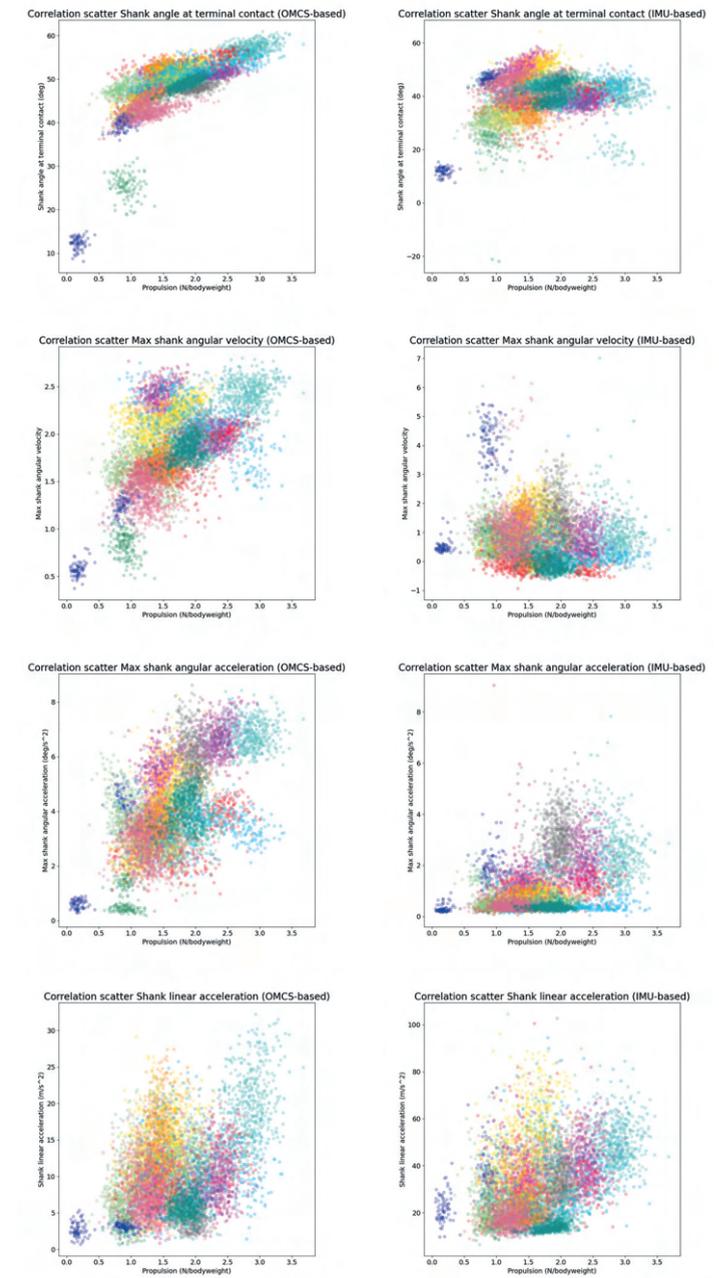


Figure A3. Continued.

Chapter 5



Mobility characteristics in individuals with and without an indication for knee arthroplasty: An explorative analysis

F.J. Bruning
C.J. Ensink
K.C. Defoort
J.M.H. Smolders
I.E. van der Horst-Bruinsma
C.H.M. van den Ende
K. Smulders

Abstract

Objective

It is conceivable that people who are considered candidates for total knee arthroplasty (TKA) due to knee osteoarthritis (OA) have poorer walking capacity than people who are not considered to benefit from TKA. This study explored the discriminative ability of mobility metrics between individuals with a TKA indication and individuals with no TKA indication.

Methods

Objective measurements of mobility with the use of inertial sensors were collected on the same day as the decision-making regarding TKA eligibility. Inertial sensors on both feet, lower back and trunk were used to collect gait data during short mobility tests. Subsequently, participants walked up and down a 10-meter walkway for two minutes, and performed sit-to-stand tasks. Based on the decision made with the orthopedic surgeon, individuals were assigned to the TKA indication (N = 58) group or no TKA indication (N = 73) group. Mobility metrics were compared between the two groups.

Results

OA severity was slightly higher in the TKA group compared to the no TKA group, indicated by the Kellgren–Lawrence score. No differences were found between groups on other group characteristics. Gait speed in the indication TKA group was 0.08 m/s (95%CI:[-0.15, -0.01]) lower than in the no TKA indication group. Other mobility metrics were not significantly different between the groups.

Conclusions

Unlike expected, the difference in objective mobility metrics between patients who were considered to receive a TKA and those who were not, were very small. Only gait speed was slightly higher (0.08 m/s) in the group without the TKA indication, but the other metrics were not different between the groups. Therefore, it is conceivable that the decision regarding TKA indication was based on other parameters than mobility factors.

Introduction

Individuals with severe knee osteoarthritis (OA) can experience substantial limitations in daily life mobility such as during walking, turning, and rising from a chair [1]. Knee joint replacement surgery (total knee arthroplasty; TKA) is recommended when joint pain, refractory to conservative treatment, restricts daily activities substantially [2]. For people with knee OA, limited walking capacity is a key symptom to consider TKA [3-5]. Moreover, people with knee OA rate improvement in walking as a main criterion to consider TKA successful [6]. This patient perspective on the importance of walking echoes findings that show that walking metrics (e.g. gait speed) are markers of physical health status [7-10]. Hence, this suggests that for patients, quality of mobility is an important factor in the decision-making process regarding TKA.

In clinical practice, evaluation of mobility relies on self-reports rather than on objective assessment of walking. Previous work has shown that self-reported mobility correlates only weakly with objectively assessed mobility metrics [11-13]. More specifically, self-reports are more strongly associated with pain scores than with performance-based mobility measures [11, 14, 15]. Thus, relying on self-reported walking limitations often results in over- or underestimation of walking performance. This can contribute to ambivalent information and as such complicate decision-making for TKA.

It is conceivable that people who are considered candidates for TKA have poorer levels of mobility than those who are not considered appropriate candidates for TKA. This study aimed to explore the discriminative ability of a set of mobility metrics assessed with wearable sensors in people with advanced knee OA. More specifically, we assessed a group of people after they visited the orthopedic surgeon to discuss suitability to undergo TKA and compared mobility metrics of individuals who were deemed appropriate candidates for TKA to those who were not deemed candidates for TKA.

Methods

Participants

In this cross-sectional study, we used mobility metrics from an existing data set of the Sint Maartenskliniek, collected between 2020 and 2022 for the development of a mobility tool at the orthopedic outpatient department. The data set was established by inviting individuals with knee or hip OA and individuals following knee or hip arthroplasty, to participate in short mobility tests directly following consultation at the orthopedic outpatient clinic. Additional criteria to participate in the mobility

tests included age between 18-90 years old and the ability to walk for at least 2 minutes without a walking aid. For the purpose of this study, we only analyzed data from individuals with knee OA (e.g. excluding individuals who came for hip OA or postoperative consultations), and excluded individuals with neurological or neuromuscular disease affecting gait. No sample size calculation was performed, because we used an existing data set in this study.

During the consultation at the orthopedic outpatient clinic, the patient and orthopedic surgeon discussed appropriateness of TKA. The outcome of the consultation was reported in the electronic patient record. From the electronic patient record, we first identified all participants within the data set who underwent TKA. In addition, we screened all electronic patient records of participants who did not undergo TKA, to identify the people who were deemed candidates for TKA by the orthopedic surgeon but did not undergo surgery due to a variety of practical reasons (e.g. patient did not wish to undergo surgery at that time). In all participants, the judgment of the orthopedic surgeon was used to assign individuals to either the no TKA indication group or the TKA indication group.

This study was registered before data analysis at Open Science Framework (<https://osf.io/fdvrs>).

Procedure and data collection

Characteristics of the study population (sex, age, body mass, height, number of other lower extremity joint arthroplasties) were extracted from the patient's electronic health record. In case of missing characteristics in the electronic health record, a member of the research team asked the participant to provide this information prior to the mobility tests. As part of standard clinical practice, anterior-posterior radiographic images of the knee were taken prior to the consultation with the orthopedic surgeon. On these images, radiographic severity of knee OA was scored using the Kellgren-Lawrence grading system, with 0 = none, until 4 = severe [16]. The images were independently scored by one researcher from our group and a resident from the orthopedic department of the Sint Maartenskliniek. In case of a difference in grading, consensus was reached by scoring the images together.

For mobility assessment, participants were equipped with four inertial sensors (MTw Awinda, Movella, Enschede, the Netherlands). Sensors were placed on the dorsum of each foot, at the sacrolumbar level of the lower back, and sternum (Figure 1, panel A), consistent with the set-up in a validation study from our group [17]. MT Manager 2019.2 was used to capture sensor data with a sample frequency of 100 Hz. Subsequently, participants performed two mobility tasks. First, they walked up and

down a 10-meter walkway for two minutes, making 180 degree turns at both ends (Figure 1, panel A). Participants were instructed to walk at their comfortable walking speed, wearing their own shoes. Secondly, participants were asked to perform a sit-to-stand task without using the armrests of the chair, as part of an additional short walk test (which was not further analyzed). This test was repeated three times (Figure 1, panel B).

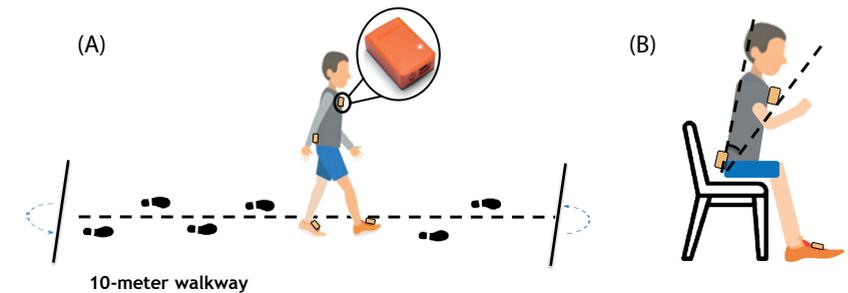


Figure 1. Placement of inertial measurement units (orange rectangles) on both feet, lower back and sternum during 2 minute walking over a 10-meter walkway (A) and sit-to-stand task (B).

Data processing

An algorithm validated by our group [17] was used to derive mobility parameters from the raw data collected with the inertial sensors during the two-minute walk.

Gait speed, stride time, step time asymmetry, and trunk range of motion in the coronal plane were derived from the steady-state parts of the two-minute walk (excluding acceleration and deceleration phases before and after turns) [18]. For turning, the maximal turn velocity during each 180 degrees turn was calculated from the lumbar sensor. All metrics were calculated per stride or per turn, and averaged per participant. Using the algorithm of Pham et al. (2018) [19], the trunk flexion range of motion during sit-to-stand transfers (lean angle) was calculated. For all participants, the median lean angle of three sit-to-stand tasks was used as outcome.

Step time asymmetry was calculated according to Equation 1. In this measure, 50% indicates perfect symmetry, >50% indicates higher step time of the most affected leg than least affected leg, and <50% indicates higher step time for the least affected leg than most affected leg.

$$\text{Step time asymmetry} = \frac{\text{step time}_{\text{most affected leg}}}{\text{step time}_{\text{most affected leg}} + \text{step time}_{\text{least affected leg}}} * 100\% \quad (1)$$

Data processing was conducted with Python in Pycharm Community Edition 2021.3.2. Scripts are publicly available at <https://osf.io/fdvrs>.

Statistical Analysis

Mean differences between groups (TKA indication – no TKA indication) and 95%-confidence intervals (95%CI) were calculated for all anthropometric, clinical, and mobility parameters to compare the no TKA indication and TKA indication groups. Prior to analysis of the mobility parameters, age, sex, height, body mass, Kellgren-Lawrence grade, and number of other lower extremity joint arthroplasties (e.g. knee, hip or ankle replacement or arthrodesis surgery) were identified as potential confounders for the between-group comparison. To account for a potential confounding effect on differences on mobility metrics, a multiple regression analysis was conducted with the mobility metrics as dependent variable, group (no TKA indication vs. TKA indication) as independent factor, and covariates mentioned above. Effect sizes were calculated for all mobility metrics using Cohen's *d*, interpreting *d* between 0.2 and 0.5 as small effect, between 0.5 and 0.8 as moderate effect, and >0.8 as large effect. Fisher's exact test was used to determine differences between groups for number of other arthroplasties and Kellgren-Lawrence grade. A post-hoc analysis was performed with a Kruskal-Wallis test to assess differences in gait speed across Kellgren-Lawrence grades in the study population. Due to low numbers of Kellgren-Lawrence grades 0 to 2, these grades were merged into one group. Statistical analysis of the data was conducted in RStudio (2022.02.0) using the R stats package version 4.1.2. Scripts for data processing are publicly available from: <https://osf.io/fdvrs>.

Results

Study population

Characteristics of the study population are summarized in Table 1. Data of 131 individuals were analyzed, of which 73 had a TKA indication, and 58 did not have a TKA indication. We did not observe significant differences between the no TKA indication and TKA indication groups for age, body mass, height and body mass index (BMI). The number of other lower extremity joint arthroplasties was not significantly different between the groups. There was a significant difference between groups for Kellgren-Lawrence grades, which was predominantly grade 4 in the TKA indication group.

Table 7. Characteristics of the study groups.

Characteristics	No TKA indication (N=73)	TKA indication (N=58)	
Female, N (%)	43 (59%)	32 (55%)	-
Age (years), mean (SD)	64.2 (8.7)	64.2 (9.4)	-0.01 [-3.14, 3.12]
Body mass (kg), mean (SD)	86.4 (14.5)	87.7 (16.3)	1.31 [-4.03, 6.66]
Height (m), mean (SD)	1.73 (0.09)	1.74 (0.09)	0.01 [-0.02, 0.04]
BMI (kg/m ²), mean (SD)	28.6 (4.1)	28.8 (4.6)	0.20 [-1.31, 1.72]
Number of other lower extremity joint arthroplasties, N (%)			<i>p-value between- group comparison (Fisher's exact test)</i> 0.53
0	52 (71.2%)	36 (62.1%)	
1	19 (26.0%)	19 (32.8%)	
2	2 (2.7%)	2 (3.4%)	
3	0 (0%)	1 (1.7%)	
Kellgren-Lawrence grade, N (%)			< 0.001
0	0 (0%)	0 (0%)	
1	2 (2.7%)	0 (0%)	
2	13 (17.8%)	1 (1.7%)	
3	27 (37.0%)	6 (10.3%)	
4	29 (39.7%)	51 (87.9%)	
N/A	2 (2.7%)	-	

TKA: Total knee arthroplasty, BMI: Body Mass Index

Mobility characteristics

Mobility metrics are summarized in Table 2 and visualized in Figure 2. Individuals in the indication TKA group walked at a 0.08 m/s (95%CI: -0.15, -0.01) lower gait speed than individuals in the no indication for TKA group. Correcting for covariates did not change this difference. We found no significant differences on other mobility metrics. A post-hoc analysis showed no significant differences on gait speed between severities of radiographic knee OA ($X^2(2) = 4.11, p = 0.13$).

Table 8. Mobility metrics for individuals with an indication for TKA and no indication for TKA.

Mobility outcome	No TKA indication (N=73)	TKA indication (N=58)	Mean difference [95%CI]	Corrected mean difference [95% CI]	Effect size (Cohen's d)
Gait speed (m/s)	1.17 (0.20)	1.09 (0.20)	-0.08 [-0.15, -0.01]	-0.08 [-0.15, -0.01]	0.42
Stride time (s)	1.12 (0.09)	1.15 (0.10)	0.03 [0.00, 0.06]	0.03 [-0.01, 0.07]	-0.31
Step time asymmetry (%)	49.9 (1.05)	50.0 (1.00)	0.03 [-0.32, 0.39]	-0.16 [-0.57, 0.26]	-0.03
Trunk coronal RoM (deg)	13.8 (6.6)	16.1 (8.33)	2.05 [0.23, 5.59]	2.05 [-1.02, 5.12]	-0.39
Peak turn velocity (deg/s)	187 (45.0)	175 (45.1)	-12.8 [-28.5, 2.87]	-14.0 [-31.4, 3.48]	0.28
Lean angle (deg)	53.2 (15.3)	56.8 (13.8)	3.53 [-1.78, 8.84]	5.73 [-0.49, 11.94]	-0.24

Metrics for the groups are shown as mean (SD). [95%CI]: 95% Confidence interval. RoM: Range of motion.

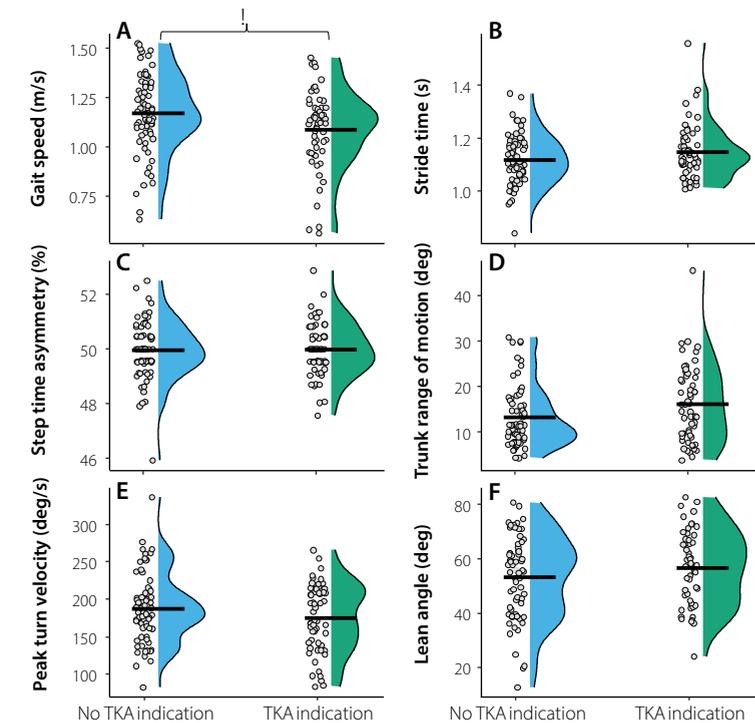


Figure 2. Raincloud plots comparing mobility metrics of the no TKA indication and TKA indication groups. Grey dots represent individuals within each group. Panel A: Gait speed (m/s), B: Stride time (s), C: Step time symmetry (%), D: Trunk range of motion (deg), E: Peak turn velocity (deg/s), F: Lean angle (deg). Peak turn velocity. Black horizontal line shows the mean of the group. * indicates statistical significant difference between the groups.

Discussion

The aim of this study was to explore differences in mobility metrics between knee OA individuals who were and were not deemed appropriate candidates for TKA. The results showed on average a lower gait speed in the group with a TKA indication than in the group without, but no differences between groups on other mobility metrics.

The difference in gait speed between groups was significant but small, as reflected in the effect size of 0.42. Moreover, the absolute mean difference of 0.08 m/s can be considered low when compared to minimal clinically important difference, which ranges between 0.10–0.20 m/s in people with gait impairments [20]. Previous studies evaluating gait speed in subgroups of individuals with knee OA are scarce. In one

study [21], individuals scheduled for TKA walked at a 0.33 m/s lower gait speed than individuals with moderate knee OA (not TKA candidates). However, direct comparison with this study is difficult as the group characteristics, in particular the radiographic OA severity, between our and their study differs substantially.

We noted substantial heterogeneity within groups on all mobility metrics. To illustrate, gait speed ranged from 0.5 to 1.5 m/s across the whole study population. For reference, walking speeds below 0.8 m/s are considered to be indicative of difficulties walking outdoors, whereas a gait speed above 1.2 m/s can be considered as normal, not limiting the activities of daily life [22]. The reference value of gait speed in healthy individuals in the same age range as our study population is ~1.4 m/s with a standard deviation between 0.13-0.14 [23], compared to a standard deviation of 0.2 m/s in our study population. Taken together, the range in gait speed suggests that in both our study groups, people with unimpaired to severely impaired walking capacity were present.

Besides stride characteristics, we were interested in metrics reflecting potential compensation strategies, to reduce pain and loading on the affected knee. Such compensation strategies can surface as changes in trunk motion or asymmetries in the stepping pattern [24-26]. Lateral lean of the trunk towards the unaffected leg has been associated with reduced moments around the knee, and, although less convincingly, with lower pain levels [24, 27]. More lateral trunk lean, as well as more trunk motion in the frontal plane, has been observed in people with knee OA when compared to healthy individuals [24, 28]. However, no differences in trunk range of motion during walking in the coronal plane were found between individuals with and without a TKA indication in this study. It should be noted that this range of motion is independent of the absolute lateral trunk lean angle. For example, a person with a range of motion of 10 degrees can have an absolute lateral lean angle of 5 degrees to the left to 5 degrees to the right, or from perfectly upright to 10 degrees to the right. Therefore, we cannot rule out the possibility that individuals with an indication for TKA walked with more absolute lateral trunk lean than those without a TKA indication, while demonstrating similar lateral trunk range of motion. Compensation in terms of asymmetry between left-right step characteristics was also not observed in our study sample, with near-perfect symmetry values for step time. Although asymmetry in individuals with knee OA has been reported in studies evaluating knee kinematics and kinetics [29, 30], our findings are in line with a recent meta-analysis concluding that step time asymmetry was not higher in individuals with knee OA than in healthy individuals [31]. This can suggest that unloading of the affected knee, evident in kinetic or kinematic measures, does not translate to adaptations in temporal stepping or trunk motion characteristics.

Turning and sit-to-stand transfers were included in our study as important components of mobility, which are known to be impaired in people with knee OA [31, 32]. In line with most metrics in this study, no differences were found between people with and without a TKA indication on either turning or sit-to-stand metrics. Compared to reported mean turning peak velocities of healthy subjects in other studies using very similar methodologies, both groups had on average low peak turn velocities [33-35]. This confirms the potential value of evaluating turning in people with knee OA, although the group comparison did not show specific sensitivity of this parameter to discriminate between subgroups of knee OA.

Multiple factors play a role in the decision-making process regarding a TKA indication. Likely, this contributed to the limited differences in mobility metrics between people with and without an indication for TKA. Globally, the guidelines for TKA appropriateness vary, and substantial heterogeneity in patients' characteristics and disease severity when undergoing TKA has been observed [36, 37]. This study involved only surgeons of one Dutch hospital, adhering to the Dutch orthopedic guidelines for TKA indication [36]. Indication criteria according to the Netherlands Orthopaedic Association include radiographic knee OA severity (Kellgren-Lawrence ≥ 2), and the impact of knee pain on quality of life and participation (work or social) [36]. Based on radiographic severity, the TKA indication group was notably homogeneous with almost 90% of the people classified as Kellgren-Lawrence grade 4. Still, the level of impact of knee OA severity on an individual's daily life can vary substantially. Moreover, the expectation of the surgeon regarding the likelihood that TKA can improve an individual's quality of life is an important factor in the decision-making process. These different factors in the comprehensive decision-making process likely increased the variance within groups, and contributed to small differences between groups.

This study has a number of limitations which should be considered when interpreting the results. First, we excluded participants who were unable to walk for at least two minutes without assistive devices. Assuming that people unable to walk would be more likely to be in the group with TKA indication, exclusion of this group may have led to underestimation of the group differences between the groups.

Another limitation is the absence of pain scores or other patient-related outcome measures in this study. Based on the guidelines that indicate to refer a patient to an orthopedic surgeon only after conservative treatments have failed [38], it could be expected that all participants in this study had considerable levels of pain or discomfort. However, in clinical practice inadequate referrals, and underutilization of conservative treatment modalities are seen [39]. As such, pain scores may have been helpful to better understand the differences between the groups in our study. Finally,

we did not perform a sample size calculation for this study, as we used an existing data set. The available sample size in this study may have limited us in detecting significant differences in parameters with small between-group differences (i.e. type II error).

In summary, the differences in mobility metrics between patients who were considered candidates for TKA and those who were not were limited, with only a small difference in gait speed. Lack of difference between groups can be explained by the heterogeneity within groups, which can be explained by the multiple factors involved in determining TKA indication. Future research is needed to better understand the value of objective mobility assessment in enhancing TKA decision-making.

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Chapter 6



Translation and validation of the System Usability Scale into a Dutch version: D-SUS

C.J. Ensink
N.L.W. Keijsers
B.E. Groen

Disability and Rehabilitation. 2022. Dec;46:395-400

Abstract

Background

The System Usability Scale (SUS) is the most commonly used questionnaire to assess usability of healthcare innovations but is not available in Dutch (D-SUS). This study aims to translate the SUS to Dutch and to determine its internal consistency, test-retest reliability and construct validity in healthcare innovations focused on rehabilitation technologies.

Methods

Translation of the SUS was performed according to the WHO recommendations. Fifty-four participants filled out the D-SUS and Dutch Quebec User Evaluation of Satisfaction with assistive Technology (D-QUEST) twice. Internal consistency was assessed by Cronbach's alpha. Test-retest reliability was evaluated by Gwet's agreement coefficient (Gwet's AC2) on item scale, and Pearson correlation coefficient (PCC) for the overall D-SUS scores. Construct validity was assessed with the PCC between the D-SUS and D-QUEST overall scores. (Netherlands Trial Register, ID: NL9169)

Results

After translation, Cronbach's alpha was 0.74. Gwet's AC2 was 0.68 and the PCC between the first and second overall D-SUS scores was 0.75. No significant difference in D-SUS score between the two measurements was found. Repeatability coefficient was 18.4. The PCC between the D-SUS and D-QUEST overall scores was 0.49

Conclusions

The D-SUS is a valid and reliable tool for usability assessment of healthcare innovations, specifically rehabilitation technologies.

Introduction

Development of new healthcare innovations including rehabilitation technologies occurs at fast speed, but their implementation in modern hospitals and rehabilitation centers is often not successful. Successful implementation of new healthcare innovations in clinical practice is more likely when users are positive about their usability [1]. Furthermore, the likeliness that the intended users are positive about the usability of such systems increases when they are involved in the process of prototyping, testing and evaluating the innovations during the development (e.g. interactive design thinking approach) [2]. Therefore, evaluation of system usability of healthcare innovations by their intended users is important during all developmental phases until implementation.

System usability includes system effectiveness, system efficiency, and user satisfaction (ISO 9241-11). Questionnaires are commonly used to assess the different aspects of system usability, as they are quick and easy to perform. Previous research has shown that it is important to use questionnaires in the language of the target population's native language [3,4]. For healthcare innovations the System Usability Scale (SUS) [1,2] and Quebec User Evaluation of Satisfaction with assistive Technology (QUEST) [5] are the most commonly used usability questionnaires worldwide. A Dutch version of the QUEST (D-QUEST) is available to evaluate satisfaction with an assistive device and related services. The D-QUEST consists of 12 items, which are scored on a 5-point Likert scale from 'totally unsatisfied' to 'totally satisfied'. The first eight items are about the device itself, the remaining four items about the delivery process. In case a respondent is not satisfied, they are asked to provide a reason. The D-QUEST shows an acceptable level of internal consistency (Cronbach's alpha=0.88) and content validity (Spearman's rho=0.78) for assistive devices [6]. The D-QUEST is designed for users with several months of experience with a certain device [7] and is therefore less feasible in the development phase. Furthermore, the D-QUEST is not suitable for eHealth applications, since statements regarding size and weight are not applicable to software.

The SUS was developed as a fast and complete measure of subjective perception of system usability within the development and evaluation phase [1]. The SUS is the international standard for measuring usability of different technologies such as websites, mobile applications, eHealth applications, and hardware installation kits [8, 9, 10]. The scale consists of 10 items, which can be filled out within 10 minutes. All items are scored on a 5-point Likert scale from 'strongly disagree' to 'strongly agree'. Scores per item are converted to the overall SUS score, which ranges from 0 to 100, representing the overall system usability [8]. Overall scores from 0 to 50 indicate 'not

acceptable', 51 to 67 indicate marginal level of usability, and 68 to 100 indicate 'acceptable' levels of usability [9]. So far, translations of the SUS have been made into Arabic [11], Chinese [12], Danish [13], Indonesian [14], Malay [15], Polish [16], and Portuguese [17], but there is no official Dutch translation yet [8]. Hence, a Dutch version of the SUS is recommended for evaluation during the development of rehabilitation technologies and healthcare innovations in the Netherlands. In addition, validation of the SUS in healthcare innovations is limited to an eHealth application for mental health [13]. So far, validation of the SUS in rehabilitation technologies with different types of users is lacking. In contrast to many application in which the SUS has been used, most rehabilitation technologies have patients as well as therapists as users. Neurological patients often need assistance from therapist filling out a questionnaire especially when not formulated in their native language. These limitations withhold the use of the SUS in all stages of the development of rehabilitation technologies.

The primary aim of this research was to translate the original English version of the SUS into Dutch (D-SUS). The secondary aim was to determine the internal consistency, test-retest reliability and construct validity of the D-SUS in healthcare innovations with focus on rehabilitation technologies in the Netherlands. Patients and therapists were included as users. It was hypothesized that the D-SUS has acceptable internal consistency and good test-retest reliability as has been found in other language versions of the SUS [17, 23]. Furthermore, a moderate correlation was expected with the D-QUEST.

Materials and methods

Healthcare innovations cover a very wide range of technological (rehabilitation) systems each with a unique purpose. Therefore, users of a wide variety of healthcare innovations focused on rehabilitation technologies were included in this study. Participants were users of gait training devices (GRAIL, C-Mill, ZeroG®), wearable exoskeleton (ReWalk™), and eHealth applications (Garmin Connect, Polar Flow).

The study protocol was submitted at the medical ethical board 'CMO regio Arnhem-Nijmegen' (identification: 2020-6848) and was granted an exemption of the Dutch medical scientific research act (WMO). The study was registered at the Netherlands Trial Register (identification: NL9169). Permission to translate the original version of the SUS to Dutch was given by the original author prior to the start of this study.

The study consist of two phases: The translation phase (Phase I) and the validation phase (Phase II). For an overview see figure 1.

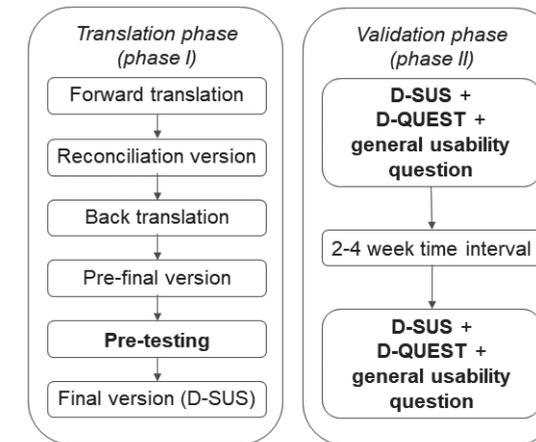


Figure 1. Flowchart of phase I: Translation phase, and phase II: Validation phase of this study.

Phase I: Translation phase

Phase I includes the translation of the original English version of the SUS into Dutch following the WHO recommendation for translating questionnaires [18]. It consists of the following steps:

- (1) Forward translation:
 - a. Forward translations: the original version was translated into Dutch by two independent native Dutch speakers.
 - b. Reconciliation version: the two translated versions were compared by the forward translators and combined into one reconciliation version.
- (2) Back-translation: the reconciliation version was translated back into English by a native English speaker without any prior knowledge of the original version of the SUS.
- (3) Pre-final version: based on dissimilarities between the back-translation and original SUS, adjustments were made to the reconciliation version, resulting in a pre-final version of the D-SUS. In case of major changes of concepts and sentence structures, steps 2 and 3 were repeated.
- (4) Pre-testing: the pre-final version was tested in a small sample size (n=10) on understandability (face validity) of the questions by asking participants to think aloud. This gave an idea about the interpretation of the items [19]. This information was used to adjust the pre-final version into the final version. In case major

changes of concepts and/or sentence structures after pre-testing were needed, steps 2, 3 and 4 were carried out again. Participants in this step of the translation phase had to be either a patient or therapist aged 18 years or older, have Dutch as a native language, and must have at least one rehabilitation session experience with the GRAIL.

- (5) Final version: proofread the final version of the D-SUS for minor errors such as typos.

Phase II: Validation phase

Phase II includes assessment of the internal consistency, test-retest reliability and construct validity of the D-SUS in healthcare innovations, with focus on rehabilitation technologies. To be eligible to participate in this study, one had to be at least 18 years old, have good understanding of the Dutch language, and have at least four different sessions of use of either gait training devices (GRAIL, C-Mill, ZeroG®), wearable exoskeleton (ReWalk™), or eHealth applications (Garmin Connect, Polar Flow) either as a patient or as a therapist.

Participants received the D-SUS, D-QUEST, and the general usability question (“How would you rate the application on a scale from 0 to 10?”) via CastorEDC in their email twice, the second measurement being after a wash-out period of 2 to 4 weeks after the first measurement. The Garmin Connect and Polar Flow users did not receive the D-QUEST, since this questionnaire is not suitable for eHealth applications.

The score contributions of each item and the overall D-SUS score were calculated as recommended by the original author [1]. The internal consistency by Cronbach’s alpha was determined for the first measurement. Cronbach’s alpha ranges between 0 and 1, and is considered ‘excellent’ (>0.9), ‘good’ (>0.8), ‘acceptable’ (>0.7), ‘questionable’ (>0.6), ‘poor’ (>0.5) and ‘unacceptable’ (<0.5) [20].

Test-retest reliability was assessed by several tests. Gwet’s agreement coefficient with second-order chance correction (AC2) was calculated for each item of the D-SUS. Gwet’s AC2 was interpreted as: ‘poor’ (<0.0), ‘slight’ (≤0.2), ‘fair’ (≤0.4), ‘moderate’ (≤0.6), ‘substantial’ (≤0.8), and ‘almost perfect’ (>0.8) agreement, based on the Landis and Koch scale for Kappa statistics since no equivalent scale for Gwet’s AC2 exists [21]. For the test-retest reliability of the overall D-SUS score, the Pearson correlation coefficient (PCC) was determined. The PCC values range between -1 and 1, and absolute values are considered as ‘weak’ (PCC < 0.4), ‘moderate’ (PCC < 0.7), ‘strong’ (PCC ≥ 0.7), and ‘perfect’ (PCC = 1) correlation [22]. In addition, Bland-Altman analysis was performed. Differences in mean overall D-SUS scores between the first and second measurement were tested with a dependent t-test in case the data is normally distributed (tested with Shapiro-Wilk test for normality), otherwise it’s non-

parametric equivalent will be used (Wilcoxon signed-rank test). As an indication for measurement errors, the repeatability coefficient and limits of agreement were calculated. Furthermore, the percentage of agreement was determined by comparing the agreement in qualitative score (usable/not-usable) of both D-SUS evaluation moments. The cut-off point for usable/not-usable is set at an overall score of 68-points on the D-SUS as defined by the original author of the SUS [8].

Construct validity [23] of the D-SUS was assessed by the PCC between the overall D-SUS score and the overall D-QUEST score. The overall D-QUEST score was calculated as the normalized sum score of the product evaluating part of the questionnaire, disregarding the part evaluating the delivery process. The D-QUEST is not suitable for eHealth applications, therefore users could not fill out the D-QUEST and were not taken into account for analysis of construct validity. Additionally, the correlation between the overall D-SUS score and the general usability question was assessed by the PCC.

Results

Phase I: Translation phase

In the back translation of the reconciliation version of the D-SUS there were two major differences compared to the original SUS. The first difference was “technical person” from the original SUS, which has a literal translation in Dutch that seems inappropriate for usability testing in healthcare innovations. The translation for “expert” was used for the Dutch pre-final version. The other difference with the original SUS came from the word “cumbersome”. This word has no appropriate translation in Dutch. We considered the Dutch word “lastig” as the most appropriate translation for the pre-final version of the D-SUS.

The characteristics of the 10 participants (7 patients / 3 therapists) of the pre-testing of the pre-final version, who scored the items while thinking aloud, are shown in table 1. The literal translation of “inconsistencies” (“inconsistenties”) resulted in misunderstanding of item 6, which was solved by using “tegenstrijdigheden” instead. The use of the “tegenstrijdigheden” translation as alternative of the literal translation of “inconsistencies” was discussed with a native English speaker and considered to be appropriate.

Items 3, 4 and 7, appeared to be difficult to understand for most users due to unnecessary long sentence structures. Dutch is a much more direct language than English, and participants got confused with use of extra verbs that do not add to

the conceptual meaning of a question. For example, the original version of item 3 is “I thought the system was easy to use”, the literal translation in the pre-final version was “Ik denk dat het systeem gemakkelijk te gebruiken was”. In Dutch, the same conceptual meaning is achieved by the shorter final version: “Ik vond het systeem gemakkelijk te gebruiken”. The final version of the D-SUS is shown in table 2.

It also became evident that the role of the user affects the understanding of the different items. For example, therapists named the technical staff of the hospital as the expert of the system, whereas the patients named their therapist as the expert of the system (item 4, including adaptation of “technical person” to “expert”).

Table 1. Participant characteristics of phase I: translation phase.

Gender (n)	Male	7
	Female	3
Age (years)	Mean ± sd	54 ± 12
Level of education (n)	Secondary education	2
	Vocational education and training	1
	Higher education	7
Role (n)	Therapist	3
	Patient	7

Phase II: Validation phase

For the validation phase, 60 participants were included (30 patients, 20 therapists, 10 eHealth users). Five participants were lost-to-follow up between the first and second measurement, one participant only filled out half of the D-SUS at the first measurement and one participant did not complete the D-QUEST at the second measurement. This resulted in 54 datasets used to test the internal consistency, test-retest reliability and construct validity. Characteristics of the 54 participants are shown in table 3.

Cronbach’s alpha as a measure of internal consistency was 0.74 [95% CI: 0.62, 0.83]. Gwet’s AC2 as a measure for test-retest reliability was 0.68 [95% CI: 0.65, 0.72], $p < 0.05$. The PCC between the first and second overall D-SUS scores was 0.75, $p < 0.05$. The Bland-Altman plot of the first and second overall D-SUS scores is shown in figure 2, including the repeatability coefficient (18.4) and limits of agreement ([-17, 20]). A paired samples t-test showed no significant difference between the first and second overall D-SUS score ($p = 0.29$). The percentage of agreement in qualitative score

Table 2. Original English items of the System Usability Scale and the final version of the translated Dutch version.

	Original SUS item	Translated Dutch version
1	I think that I would like to use this system frequently.	Ik denk dat ik dit systeem vaak zou willen gebruiken.
2	I found the system unnecessarily complex.	Ik vond het systeem onnodig ingewikkeld.
3	I thought the system was easy to use.	Ik vond het systeem gemakkelijk te gebruiken.
4	I think that I would need the support of a technical person to be able to use this system.	Ik denk dat ik de hulp van een expert nodig heb om dit systeem te kunnen gebruiken.
5	I found the various functions in this system were well integrated.	Ik vond de verschillende functies van dit systeem goed geïntegreerd.
6	I thought there was too much inconsistency in this system.	Ik denk dat er te veel tegenstrijdigheden in dit systeem zaten.
7	I would imagine that most people would learn to use this system very quickly.	Ik kan me voorstellen dat de meeste mensen heel snel leren om dit systeem te gebruiken.
8	I found the system very cumbersome to use.	Ik vond het systeem heel lastig om te gebruiken.
9	I felt very confident using the system.	Ik voelde me zelfverzekerd tijdens het gebruik van het systeem.
10	I needed to learn a lot of things before I could get going with this system.	Ik moest veel dingen leren voordat ik met het systeem aan de slag kon gaan.

(usable/not-usable) between the D-SUS measurement moments was 78%. Regarding the construct validity of the D-SUS, the PCC between the overall D-SUS score and the overall D-QUEST score was 0.49 (figure 3) and the PCC between the overall D-SUS score and the general usability question was 0.28.

Table 3. Participant characteristics of phase II: validation phase. The total number of analyzed datasets is 54 (of which 53 were complete).

Gender (n (%))	Male	25 (46%)
	Female	29 (54%)
Age (years)	Mean \pm sd	45 \pm 16
System users (n (%))	GRAIL	15 (28%)
	C-Mill	10 (19%)
	ZeroG®	11 (20%)
	ReWalk™	8 (15%)
	Garmin Connect/Polar Flow	10 (19%)
Role (n (%))	Therapist	19 (35%)
	Patient	25 (46%)
	eHealth user	10 (19%)

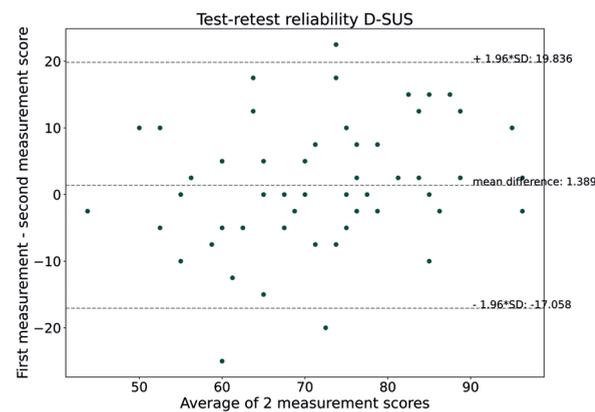


Figure 2. Bland-Altman plot of the first and second overall D-SUS scores for test-retest reliability.

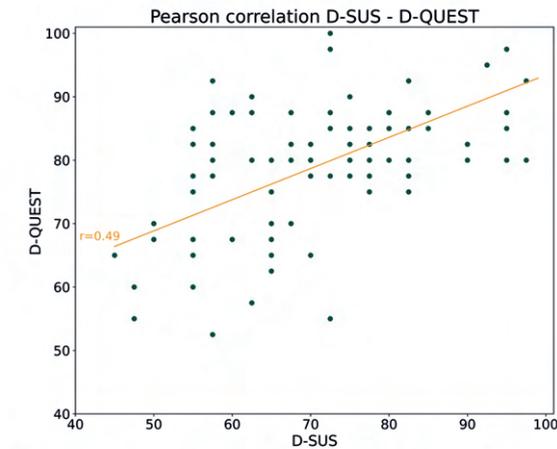


Figure 3. Pearson correlation between overall D-SUS score and normalized, sum D-QUEST score for construct validity.

Discussion

In this study a Dutch version of the SUS was translated from the original English version and validated for rehabilitation technologies and eHealth applications. The translation phase indicated that the different items were easy to understand. However, the role of the user (therapist or patient) influenced the interpretation of the different items. The D-SUS had acceptable internal consistency, high test-retest reliability, and acceptable agreement on qualitative score (usable/not-usable) on group level. On an individual level fairly high repeatability coefficients were found on the overall D-SUS scores. A moderate correlation between the D-SUS and D-QUEST and a weak correlation between D-SUS and the general usability question was found.

From the translation phase of this study it became evident that the ten items of the D-SUS were easy to understand. However, unsurprisingly, differences in interpretation were found between therapists and patients. Generally, therapists mainly took into account what they have to learn about the system, whereas patients also considered their physical abilities to use a certain rehabilitation technology. Therefore, we recommend to assess the usability in patients and therapists during all stages in the development of rehabilitation technologies, which are used by therapists and patients. Furthermore, it is important to use questionnaires in the language of the target population's native language [3,4]. Therefore, assessment of the usability in both groups in their native language will potentially increase the use of the SUS. This

might in turn promote the usability and the implementation of rehabilitation technology in clinical practice.

Internal consistency of the D-SUS, as measured with Cronbach's alpha was slightly smaller compared to previous translation studies (0.79-0.84 [10]), but was still exceeding the minimum acceptable value of 0.7 [20].

The D-SUS had a good test-retest reliability on a group level indicated by the strong PCC of 0.75 and lack of significant difference between the two measurements. In addition, on an individual level participants agreed with themselves on qualitative score (usable/not usable) in 78% of the cases, which is in line with previous research [17]. However, the overall D-SUS scores showed a fairly high repeatability coefficient (18.4). Unfortunately, no repeatability coefficients have been reported in the literature before. The high repeatability coefficient could be explained by filling errors when positive/negative statements are alternated as found in previous literature [17, 24]. However, no clear evidence was found in this study to indicate so, as Gwet's AC2 was 'substantial' at 0.68. Another possible explanation is that a participant's views upon rehabilitation technology could be affected by physical and emotional mood state and physical ability [25]. These could vary between measurements and might differ, for example, due to just finishing a difficult therapy session or before the start of one. A limitation of this study is that we did not standardize the timing of the evaluation relative to the therapy session, which could have reduced the effect of physical and emotional mood. As it was an inclusion criterium that participants were familiar with the system for which they filled out the questionnaires, differences in D-SUS scores between measurements due to learning effects were minimized. Hence, the agreement on qualitative score of the D-SUS indicates that the D-SUS can be used in a relatively small population to identify whether or not a rehabilitation technology is usable or not. However, a larger population is needed to indicate if the usability of a rehabilitation technology has been improved or is better in comparison to another system.

For construct validity, moderate and weak PCC's were found between the D-SUS, D-QUEST, and the general usability question, indicating that they are measuring usability on different, but related constructs. The D-SUS asks to score the items on level of agreement, whereas the D-QUEST asks to score on level of satisfaction. This is an important difference, as one could, for example, agree on 'I found the system unnecessarily complex' for a very unnecessarily complex system, but on the same time be very satisfied with using the system. Additionally, not all items of the D-QUEST are relevant to training devices (GRAIL, C-Mill) or even applicable to eHealth applications [5]. A weak correlation was measured between the D-SUS and the

general usability question. Similar to the D-QUEST, it is most likely that participants rate a system primarily based on the subdomain user satisfaction rather than the complete concept of system usability when asked to rate a system on a scale from 0 to 10. Moreover, the weak correlation indicates that one single question is not interchangeable with the more extensive D-SUS.

In conclusion, the translated version is considered equivalent to the original version in terms of internal consistency, and has proven to be a valid and reliable tool to assess usability of healthcare innovations, and specifically rehabilitation technologies, in the Dutch adult population. Use of the D-SUS allows for a quick and easy evaluation of usability during all stages of development, promoting usability and successful implementation in clinical practice. One should, however, be careful with relying on individual D-SUS scores to evaluate an improvement in usability.

Acknowledgements

The authors would like to thank Hennie Rijken for his efforts in recruiting participants from the gait expertise center of the Sint Maartenskliniek and Jolanda Alingh for her contribution in the translation phase. This project has received funding from the Interreg 2 Seas programme 2019-2023 co-funded by the European Regional Development Fund (2S05-038).

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Chapter 7



Effect of feedback on foot strike angle and forward propulsion in people with stroke

C.J. Ensink
C.J. Hofstad
R. van Ee
N.L.W. Keijsers

Submitted

Abstract

Background

Effective retraining of foot elevation and forward propulsion is essential in stroke survivors' gait rehabilitation. However, home-based training often lacks valuable feedback. eHealth solutions based on inertial measurement units (IMUs) could offer real-time feedback on fundamental gait characteristics. This study aimed to investigate the effect of providing real-time feedback through an eHealth solution on foot strike angle (FSA) and forward propulsion in people with stroke.

Methods

Twelve stroke survivors completed five walking trials on an instrumented treadmill: A) regular walking (1), B) feedback on FSA, C) feedback on propulsion, D) feedback on both FSA and propulsion, and E) regular walking (2). Visual feedback was presented through a green-to-red vertical slide bar on a screen in front of the participants. Linear mixed models evaluated the impact of feedback on FSA and propulsion, considering the sequence of feedback delivery, and potential learning or fatigue effects over the trials. Post-hoc pairwise comparisons were performed to assess the effect of different feedback types.

Results

Linear mixed models revealed a main effect on FSA and propulsion by feedback on FSA and propulsion, respectively. FSA significantly increased from 16.6° in the initial regular walking trial to 24.0° during FSA feedback and 23.6° during combined FSA and propulsion feedback trials ($p < 0.001$). Forward propulsion significantly improved by one third in the feedback on propulsion and combined feedback on both FSA and propulsion conditions compared to the first regular walking trial ($p < 0.001$).

Conclusions

The positive effect of real-time feedback on FSA and forward propulsion highlight the potential of eHealth solutions in tailoring rehabilitation strategies in stroke survivors.

Introduction

Stroke survivors have a significantly increased risk of falls and often face mobility problems due to impaired balance and gait [1]. Most common gait impairments in people with stroke are reduced foot elevation during the swing phase and insufficient forward propulsion during push-off [2], [3]. Reduced foot elevation is often caused by weakness of the ankle dorsiflexors and frequently referred to as a 'drop foot'. It is characterized by a negative Foot Strike Angle (FSA), meaning that people with drop foot make initial contact with the toe, rather than the heel of the foot [2]. As a result, drop foot often prevents a proper loading response, causing problems in weight acceptance and balance. Furthermore, stroke survivors suffering from drop foot frequently use compensatory strategies such as hip circumduction to prevent foot drag [2]. Additionally, inadequate forward propulsion is the result of reduced push-off force, caused by weakness of the ankle plantar flexors [3]. Insufficient forward propulsion prevents stroke survivors from generating strides with typical length and speed.

In the subacute phase after stroke, effective rehabilitation training is critical to restore the ability to lift the foot and generate proper forward propulsion [4]. Furthermore, studies indicate that individuals with chronic stroke possess a propulsive reserve in the paretic limb, which can be enhanced through task-specific training [5], [6]. Similarly, a randomized controlled trial showed that dorsiflexion-assisted gait training in the chronic phase of stroke resulted in an improved foot strike angle, with participants making initial contact with their heel rather than their flat foot or toe [7]. Traditionally, therapists provide stroke survivors with valuable feedback to improve their gait pattern during in-clinic therapy. After discharge from the clinic, a challenge arises for stroke survivors as they need to continue their training to enhance their ongoing recovery. However, the critical feedback provided by therapists during in-clinic therapy becomes less accessible, potentially hindering the continuity and effectiveness of the rehabilitation process [8].

Recent advancements in eHealth solutions have shown great promise in extending therapeutic guidance beyond the clinical setting and integrating into the daily lives of patients [9]. With the integration of wearable devices such as inertial measurement units (IMUs), the potential arises to design portable eHealth systems independent of laboratory environments. Moreover, an eHealth solution based on IMUs could provide patients with real-time feedback on crucial gait patterns such as foot elevation and forward propulsion [10], [11]. This real-time feedback could empower patients to make immediate adjustments to their gait patterns. This offers a compelling solution to bridge the gap between traditional in-clinic therapy and

self-guided home-based gait training. However, there is currently limited research available that focused on assessing the impact of real-time feedback through eHealth solutions on the gait patterns of stroke survivors [12].

The successful implementation of any eHealth solution in rehabilitation therapy, either in-clinic or at home, depends not only on its effectiveness but also highly on its perceived usability by end-users [13], [14]. Involving end-users during the development phase of eHealth solutions is critical as it increases the usability and the chances of actual implementation. Therefore, the aim of this study is twofold: 1) to investigate the direct effect of providing real-time feedback by an eHealth solution on the FSA and forward propulsion in stroke survivors, and 2) to study how stroke survivors perceive the usability of real-time feedback that can be used by eHealth solutions at home.

Methods

Participants

Twelve participants were included from physiotherapy clinics in the Nijmegen region, along with online Facebook communities for stroke survivors. Inclusion criteria were a stroke incidence of at least 6 months prior, age of 18 years or older, unilateral motor impairments, and the capability to walk unassisted for at least 5 minutes. Exclusion criteria were insufficient cognitive ability to understand basic instructions, a history of orthopedic or other neurologic disorders affecting gait or balance, prior surgery to correct drop foot, or an inability to perform ankle flexion-extension movements. All participants provided their written informed consent before participation.

The study protocol was in line with the Declaration of Helsinki and was granted an exemption of the Dutch Medical Scientific Research Act (WMO) from 'METC Oost-Nederland' (identification number: 2021-13295).

For reference values of the FSA and forward propulsion of unaffected gait, data recorded in a previous study of 20 healthy participants were analyzed [15]. Participants had to be between 40 and 90 years old and had to be able to walk for at least two minutes without assistance to be included in the study. Exclusion criteria were any diseases affecting gait and balance and a BMI > 30 kg/m².

Materials

The entire measurement protocol was performed on the GRAIL (Gait Real-time Interactive Analysis Lab, (Motek Medical, Amsterdam, the Netherlands)). The GRAIL is

an instrumented treadmill with embedded force plates (Motek Medical, Amsterdam, the Netherlands), an eight-camera optical motion capture system (OMCS) (VICON, Oxford, United Kingdom), and a wide (180°) screen positioned in front of the treadmill replicating a virtual environment. Prior to engaging in any walking trials, participants were securely fastened in a non-weight-bearing harness to prevent possible falls.

Participants were equipped with 20 reflective markers for the OMCS, following the VICON plug-and-gait lower body model [16], along with 5 IMUs (Xsens MTwAwind, Movella, Enschede) attached to the dorsal side of both feet, frontal shanks, and lower back (L4/5) [17]. Data was recorded at a sample frequency of 100 Hz for the OMCS, while the force plates recorded at 1000 Hz. All systems were time synchronized by a high-low pulse, with the OMCS serving as master. OMCS and force plate data of the healthy controls were previously collected using the same methods as in the current study [15]. Data of the IMUs were not used in the current study.

Usability of the real-time feedback solution was measured using the Dutch version of the System Usability Scale (SUS) [14].

Measurements

After an initial period of familiarization with walking on GRAIL, participants performed a series of five walking trials. In the first trial participants were able to control the speed of the treadmill by walking at the front of the belt (accelerating) or at the back of the belt (decelerating); the self-paced walking mode. During this self-paced trial, data recording started after participants indicated they were at comfortable walking speed, and stopped after capturing 120 seconds of data. The researcher would end the trial by decelerating the treadmill until standing still.

During the second to fifth trial, participants walked at a fixed speed and were provided with feedback on their gait pattern. The fixed speed was set at the average comfortable walking speed of the first trial. In trials two and three participants received feedback on either the FSA or the generated forward propulsion by a custom made GRAIL application. The order of the feedback was randomized across subjects. The fourth trial entailed participants receiving feedback on both parameters. Each feedback trial started with participants performing ten strides without feedback, in which the regular FSA and forward propulsion was computed based on the marker data and force plate data, respectively. See the data analysis section below for a detailed description. After the ten initial strides, feedback was provided. The feedback was provided visually through a green to red vertical slide bar on the GRAIL's screen in front of the subject. Increasing the FSA or forward propulsion led to a disk moving towards the green end (top of the slide bar), whereas decreasing the FSA or forward

propulsion led to the disk moving towards the red end of the bar (bottom of the slide bar). The fifth walking trial was a self-paced trial similar to the first trial. All walking trials lasted for at least 120 seconds.

After completing all five walking trials, participants were released from the harness, and all markers and IMUs were removed. Subsequently, participants filled out the SUS questionnaire. They were instructed to focus their evaluation exclusively on the eHealth solution for real-time feedback with the IMUs used for data capture.

The data of the healthy controls was previously collected during a self-paced walking trial [15]. To this end, a protocol similar to the measurement protocol for the first self-paced trial of the current study was used.

Data processing

All code for data processing and analysis is available from: <https://github.com/Sint-Maartenskliniek/MovingReality> (Release: “Effect study”).

Data was collected through VICON Nexus software (version 2.4). All subsequent data processing and analyses were performed in Python 3.10. Upon further analysis, OMCS data was filtered by a second-order low-pass Butterworth filter, with a 15 Hz cut-off frequency.

Data analysis

The foot angle was defined as the angle between the foot segment and the walking surface (Figure 1 and [17]), which was calculated according to equations 1 and 2 [14].

$$\text{Foot segment} = \text{position}_{\text{toe marker}} - \text{position}_{\text{heel marker}} \quad (1)$$

$$\text{Foot angle} = \tan^{-1} \left(\frac{\text{foot segment}_{\text{vertical component}}}{\text{foot segment}_{\text{walking direction component}}} \right) \quad (2)$$

The foot angle was considered as zero-degrees during foot flat phase by subtracting the mean foot angle measured in the first 10 mid-stance periods and subsequently converted from radians to degrees according to equation 3.

$$\text{Foot angle} = (\text{foot angle} - \text{mean}(\text{foot angle}_{\text{mid-stance of stride 1 to 10}})) * 180 / \pi \quad (3)$$

Finally, the FSA was determined as the foot angle at each initial contact (IC) according to equation 4.

$$\text{Foot strike angle} = \text{foot angle}_{\text{at IC}} \quad (4)$$



Figure 1. The foot strike angle.

Forward propulsion is generally characterized by either the peak or impulse (time integral) of the anterior-posterior ground reaction force (GRF), both normalized for bodyweight. In this study, we used the impulse as it is independent of walking speed in contrast to the peak GRF [18]. This impulse was calculated by the time integral of the bodyweight-normalized anterior-posterior GRF from the breaking-to-propulsion transition till terminal contact (TC) (equation 5 and Figure 2) [17], [18].

$$\text{Forward propulsion} = \int_{\text{BPT}}^{\text{TC}} \text{GRF}_{\text{AP direction}} dt \quad (5)$$

with $dt = 1/\text{sample frequency}$, BPT = breaking-to-propulsion, TC = terminal contact, AP = anterior-posterior.

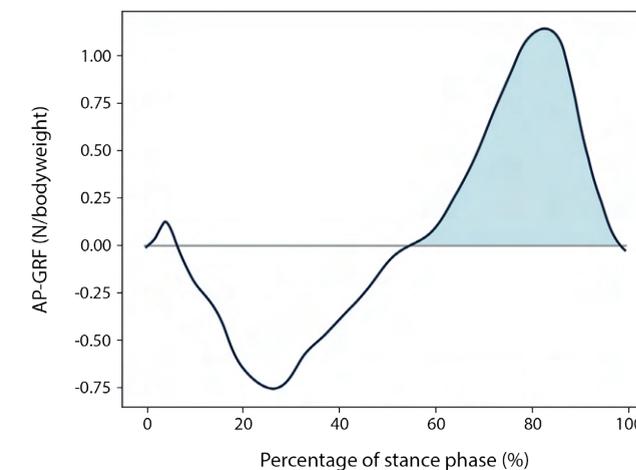


Figure 2. Forward propulsion characterized by the bodyweight normalized anterior-posterior ground reaction force from the breaking-to-propulsion transition till terminal contact.

Statistical analysis

For each trial, the mean FSA and forward propulsion were calculated over the first 100 steps of a trial after setting the reference values in the first 10 steps. Differences in FSA and forward propulsion between healthy individuals and people with stroke were tested with an unpaired samples t-test.

Linear mixed models were used to determine the effect of feedback type on the FSA and propulsion. Fixed effects were feedback type and the order in which the different types of feedback were given. Random effects of and for the intercept and slope were included to take learning and fatigue effects into account, as well as participant ID. Post-hoc pairwise comparisons were performed to estimate the effect of the different types of feedback. Effects were significant in case the adjusted p value for multiple comparisons was <0.05 . All statistical analysis was performed in R4.1.2 (R core Team, 2021, Vienna, Austria), with its lme4 for model definition and grafify for post-hoc comparisons packages.

The individual SUS scores were visualized by a histogram plot and the median and interquartile range were calculated. The SUS scores were compared to the minimum score of 68 points for the feedback system to be labelled as 'usable' or 'not usable' [19]. In addition, the achieved difference on the FSA and forward propulsion were correlated (Pearson correlation) to the SUS score, to explore if the ability to improve the FSA or forward propulsion were related to the SUS score. To this end, the difference between the first regular walking trial and the trial with feedback in FSA and forward propulsion was calculated.

Results

Participant characteristics

Prior to this study, all 12 participants (7 male / 5 female) with a mean age of 61 (SD: 9) years had participated in a post-stroke gait rehabilitation training program. Participants experienced either an ischemic stroke (n=8) hemorrhagic stroke (n=2), or unknown cause (n=2). The median time since stroke onset was 24.5 (range: 6-210) months. The average comfortable gait speed was 1.0 (SD: 0.3) m/s. Table 1 shows the participant characteristics. All participants were able to perform all trials, but due to poor marker visibility during the FSA feedback trial for participant PP006, this trial had to be excluded from further analysis.

Participant characteristics of the 20 healthy individuals included in the previous study are also shown in Table 1 [15]. Healthy participants had a smaller body weight and a higher gait speed ($p<0.05$) compared to the stroke participants.

Table 1. Participant characteristics.

	Stroke participants	Healthy controls
N	12	20
Gender (male / female)	7 / 5	10 / 10
Age (mean \pm SD years)	61.0 \pm 9.5	59 \pm 12
Height (mean \pm SD cm)	176.4 \pm 8.5	174 \pm 7.2
Weight (mean \pm SD kg)*	85.0 \pm 14.7	75.0 \pm 8.0
Affected side (left / right)	6 / 6	-
Stroke type (ischemic / hemorrhagic / unknown)	8 / 2 / 2	-
Time since stroke onset (median (IQR) months)	24.5 \pm (11; 76.5)	-
Comfortable gait speed (mean \pm SD m/s)*	1.0 \pm 0.3	1.3 \pm 0.1

*Weight and gait speed were significantly ($p<0.05$) different between the stroke participants and healthy controls.

Effect of feedback on the FSA

For each stroke participant the mean and standard deviation of the FSA for each trial is shown in Table 2 and Figure 3. The FSA in healthy participants (29.0 \pm 8.7 degrees), was significantly different ($p<0.01$) from the FSA of the first regular walking trial in people with stroke (15.6 \pm 7.3 degrees).

Table III shows the output of the linear mixed model, revealing: 1) a significant main effect of feedback type, meaning that the type of feedback has an effect on the FSA, 2) no interaction effect between the order in which feedback was given (first feedback on FSA or propulsion) and feedback type, and 3) a main group effect, meaning that there was a different intercept between the group that received first feedback on propulsion compared to the group that first received feedback on the FSA, independent of the trial. Post-hoc pairwise comparison revealed a significant increase in FSA for all trails compared to the first regular trial ($p<0.05$). No significant difference was found between the FSA feedback trial and the trial with feedback on both the FSA and forward propulsion. Table 4 shows the output of the post-hoc pairwise comparison.

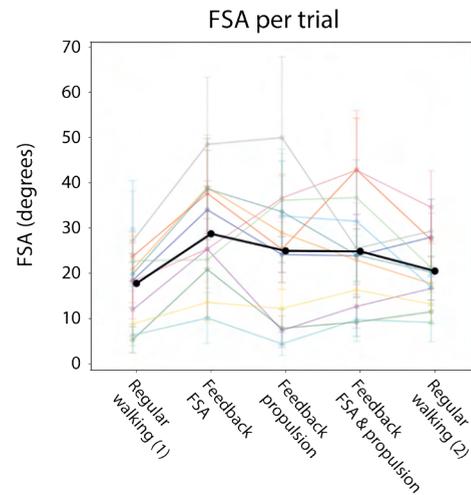


Figure 3. Mean and standard deviation of the FSA per participant in each of the trials. Mean of the FSA across subjects is shown in black.

Table 2. Mean±SD of the FSA (degrees) measured in each trial for each participant.

Participant ID	Regular walking (first time)	Feedback on FSA	Feedback on propulsion	Feedback on FSA and propulsion	Regular walking (second time)
PP001	9.9±2.6	16.2±3.4	13.0±4.2	14.0±3.0	16.2±2.6
PP002	25.9±11.0	37.0±3.2	32.9±1.2	34.0±1.5	33.3±4.6
PP003	6.0±2.1	8.1±3.4	6.7±3.5	8.2±2.8	8.2±3.0
PP004	25.4±4.6	29.9±2.9	27.4±2.2	31.6±2.3	29.3±2.5
PP005	9.5±4.1	25.1±9.8	17.8±4.5	23.1±7.4	31.1±3.1
PP006	21.1±3.4	-	19.1±2.3	19.4±2.5	18.6±4.5
PP007	10.5±3.8	19.1±8.6	8.6±3.1	16.9±6.6	19.4±3.2
PP008	20.5±5.4	27.5±3.7	27.5±3.5	28.6±3.3	27.4±4.0
PP009	10.1±4.9	29.5±5.1	16.1±5.3	20.4±7.5	16.0±5.4
PP010	21.9±3.5	27.2±5.0	30.0±3.2	33.9±5.2	28.0±2.5
PP011	7.5±3.7	14.5±3.2	12.6±3.6	16.3±3.2	11.4±4.5
PP012	18.5±2.5	24.2±3.7	20.1±2.2	26.4±3.4	21.2±1.4
Mean (from linear mixed model) ± SE	16.6±1.88	24.0±1.92	20.3±1.88	23.6±1.88	22.3±1.88

Mean±SD of the FSA. Marker visibility in the trial with feedback on the FSA of participant PP006 was very poor and therefore discarded for further analysis. The 'Mean±SE' row shows the mean and standard error for each trial calculated by the linear mixed model.

Table 3. Statistics of the model fit of the linear mixed model for the FSA.

Fixed effects	Estimate	2.5%	97.5%	t-value	df	p-value
Intercept	10.578	6.226	14.930	4.764	17.851	0.000
Feedback on FSA	9.415	6.438	12.391	6.199	46.978	0.000
Feedback on propulsion	4.050	1.074	7.027	2.667	46.978	0.010
Feedback on FSA and propulsion	7.613	4.636	10.589	5.013	46.978	0.000
Regular walking (second time)	7.959	4.983	10.936	5.241	46.978	0.000
Group first feedback on propulsion	11.969	5.227	18.711	3.480	17.851	0.003
Feedback on FSA : Group first feedback on propulsion	-3.876	-8.689	0.938	-1.578	47.088	0.121
Feedback on propulsion : Group first feedback on propulsion	-0.682	-5.293	3.930	-0.290	46.978	0.773
Feedback on FSA and propulsion : Group first feedback on propulsion	-1.081	-5.693	3.530	-0.460	46.978	0.648
Regular walking (second time) : Group first feedback on propulsion	-4.418	-9.030	0.193	-1.878	46.978	0.067

Effect of feedback on the propulsion

Table 5 and Figure 4 shows the mean and standard deviation of the bodyweight normalized forward propulsion for each stroke participant for each trial. The forward propulsion in healthy participants (0.32 ± 0.058 N/kg·s) was significantly larger than the forward propulsion in people with stroke measured during the first regular walking trial (0.24 ± 0.066 N/kg·s).

Table 4. Post-hoc pairwise comparison of the FSA estimates from the linear mixed model.

Comparison	Estimate	SE	df	t-ratio	p-value
Regular walking (first time) - Feedback on FSA	-7.477	1.35	56.8	-5.545	<0.001
Regular walking (first time) - Feedback on propulsion	-3.709	1.29	56.6	-2.873	0.014
Regular walking (first time) - Feedback on FSA and propulsion	-7.072	1.29	56.6	-5.477	<0.001
Regular walking (first time) - Regular walking (second time)	-5.750	1.29	56.6	-4.453	<0.001
Feedback on FSA - Feedback on propulsion	3.767	1.35	56.8	2.794	0.014
Feedback on FSA - Feedback on FSA and propulsion	0.405	1.35	56.8	0.300	0.765
Feedback on FSA - Regular walking (second time)	1.727	1.35	56.8	1.280	0.257
Feedback on propulsion - Feedback on FSA and propulsion	-3.363	1.29	56.6	-2.604	0.020
Feedback on propulsion - Regular walking (second time)	-2.041	1.29	56.6	-1.580	0.171
Feedback on FSA and propulsion - Regular walking (second time)	1.322	1.29	56.6	1.024	0.345

Degrees-of-freedom method: Kenward-Roger, p value adjustment: fdr method for 10 tests.

The linear mixed model revealed (See Table 6): 1) a significant main effect of feedback type, meaning that the type of feedback has an effect on the forward propulsion, 2) no interaction effect between the order in which feedback was given (first feedback on propulsion or FSA), and 3) no main group effect, meaning that the group that received first feedback on propulsion had a similar propulsion compared to the group that first received feedback on the FSA, independent of the trial. Post-hoc pairwise comparison revealed a significant increase in forward propulsion for all trials compared to the first regular trial ($p < 0.05$), except for the FSA feedback trial. No significant difference was found between the forward propulsion feedback trial and the trial with feedback on both the FSA and forward propulsion. Table 7 shows the output of the post-hoc pairwise comparison.

Table 5. Mean \pm SD of the bodyweight normalized propulsion (N/kg·s) measured in each trial for each participant.

Participant ID	Regular walking (first time)	Feedback on FSA	Feedback on propulsion	Feedback on FSA and propulsion	Regular walking (second time)
PP001	0.26 \pm 0.11	0.47 \pm 0.13	0.48 \pm 0.14	0.48 \pm 0.12	0.37 \pm 0.13
PP002	0.35 \pm 0.06	0.34 \pm 0.02	0.42 \pm 0.04	0.39 \pm 0.03	0.38 \pm 0.03
PP003	0.10 \pm 0.09	0.12 \pm 0.07	0.15 \pm 0.11	0.14 \pm 0.12	0.19 \pm 0.14
PP004	0.26 \pm 0.03	0.27 \pm 0.04	0.31 \pm 0.05	0.31 \pm 0.04	0.29 \pm 0.03
PP005	0.19 \pm 0.06	0.31 \pm 0.12	0.29 \pm 0.09	0.35 \pm 0.11	0.38 \pm 0.04
PP006	0.25 \pm 0.02	-	0.22 \pm 0.02	0.22 \pm 0.02	0.25 \pm 0.02
PP007	0.19 \pm 0.07	0.22 \pm 0.10	0.25 \pm 0.07	0.21 \pm 0.09	0.25 \pm 0.08
PP008	0.29 \pm 0.04	0.29 \pm 0.03	0.36 \pm 0.05	0.37 \pm 0.05	0.32 \pm 0.04
PP009	0.24 \pm 0.06	0.23 \pm 0.12	0.26 \pm 0.05	0.27 \pm 0.10	0.27 \pm 0.08
PP010	0.22 \pm 0.05	0.23 \pm 0.07	0.46 \pm 0.10	0.40 \pm 0.09	0.28 \pm 0.07
PP011	0.21 \pm 0.04	0.23 \pm 0.04	0.24 \pm 0.06	0.24 \pm 0.04	0.24 \pm 0.05
PP012	0.32 \pm 0.03	0.30 \pm 0.03	0.40 \pm 0.05	0.38 \pm 0.04	0.33 \pm 0.03
Mean (from linear mixed model) \pm SE	0.245 \pm 0.025	0.266 \pm 0.026	0.326 \pm 0.025	0.318 \pm 0.025	0.299 \pm 0.025

Mean \pm SD of the time integrated, bodyweight normalized forward propulsion. The 'Mean \pm SE' row shows the mean and standard error for each trial calculated by the linear mixed model.

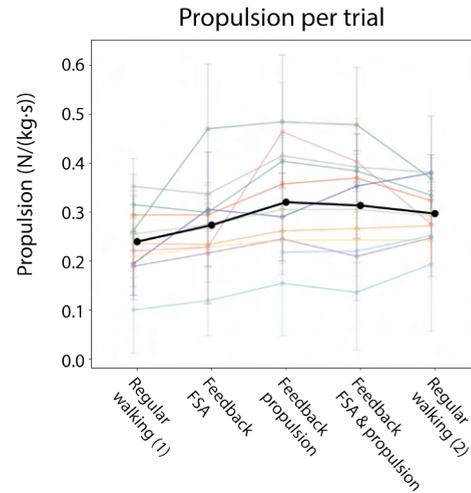


Figure 4. Mean and standard deviation of the forward propulsion per participant in the trial with and without feedback. Mean of the forward propulsion across subjects is shown in black.

Table 6. Statistics of the model fit of the linear mixed model for the propulsion.

Fixed effects	Estimate	2.5%	97.5%	t-value	df	p-value
Intercept	0.212	0.154	0.270	7.164	18.171	0.000
Feedback on propulsion	0.079	0.038	0.119	3.802	46.973	0.000
Feedback on FSA	0.055	0.014	0.05	2.640	46.973	0.011
Feedback on FSA and propulsion	0.082	0.041	0.122	3.939	46.973	0.000
Regular walking (second time)	0.078	0.037	0.118	3.745	46.973	0.000
Group first feedback on propulsion	0.066	-0.024	0.156	1.433	18.171	0.169
Feedback on propulsion : Group first feedback on propulsion	0.005	-0.058	0.067	0.144	46.973	0.886
Feedback on FSA : Group first feedback on propulsion	-0.068	-0.134	-0.003	-2.036	47.089	0.047
Feedback on FSA and propulsion : Group first feedback on propulsion	-0.018	-0.081	0.044	-0.575	46.973	0.568
Regular walking (second time) : Group first feedback on propulsion	-0.048	-0.111	0.015	-1.506	46.973	0.139

Table 7. Posthoc pairwise comparison of the forward propulsion estimates from the linear mixed model.

Comparison	Estimate	SE	df	t-ratio	p-value
Regular walking (first time) - Feedback on propulsion	-0.081	0.018	56.6	-4.603	<0.001
Regular walking (first time) - Feedback on FSA	-0.021	0.018	56.8	-1.119	0.318
Regular walking (first time) - Feedback on FSA and propulsion	-0.07	0.018	56.6	-4.109	<0.001
Regular walking (first time) - Regular walking (second time)	-0.053	0.018	56.6	-3.032	<0.001
Feedback on propulsion - Feedback on FSA	0.060	0.018	56.8	3.288	<0.001
Feedback on propulsion - Feedback on FSA and propulsion	0.009	0.018	56.6	0.494	0.623
Feedback on propulsion - Regular walking (second time)	0.028	0.018	56.6	1.570	0.174
Feedback on FSA - Feedback on FSA and propulsion	-0.052	0.018	56.8	-2.815	0.013
Feedback on FSA - Regular walking (second time)	-0.033	0.018	56.8	-1.785	0.133
Feedback on FSA and propulsion - Regular walking (second time)	0.019	0.018	56.6	1.076	0.318

Degrees-of-freedom method: Kenward-Roger, p value adjustment: fdr method for 10 tests.

Perceived usability of the feedback

Figure 5 shows the individual SUS scores of all participants. The SUS scores for the real-time feedback method, had a median score of 84 (range: 65 – 100). Eleven out of twelve participants scored the SUS with at least 68 points, meaning that they found the feedback method usable in its current state. The Pearson correlation between the SUS scores and the achieved improvement on the FSA and forward propulsion was -0.18 and 0.39, respectively.

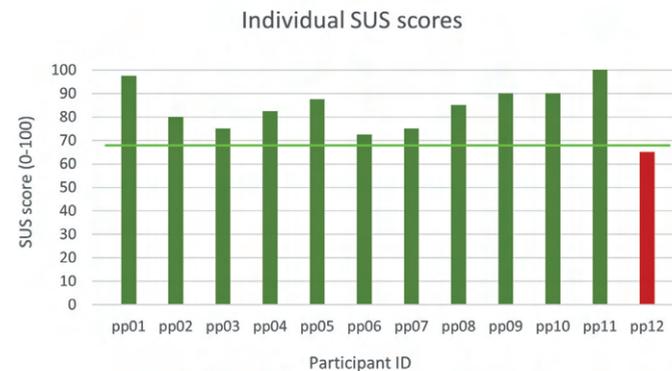


Figure 5. Individual SUS scores. Scores above the minimum value of 68 points (horizontal line) to be labelled as 'usable' were marked green, scores below 68 points ('not usable') were marked red.

Discussion

This study aimed to investigate the effect of real-time feedback on the FSA and forward propulsion in individuals with stroke, while also assessing the usability of a real-time feedback system. Feedback improved the FSA and propulsion, and participants found the feedback system usable.

The included individuals with chronic stroke had a significantly lower FSA compared to the healthy controls indicating an impaired foot elevation during the loading response phase. The FSA of 16 degrees observed in the current study, aligns with individuals with stroke who are prescribed an ankle foot orthosis [7], [20], [21]. Although unilateral motor impairments affecting gait was an inclusion criterium, the walking ability varied among participants as indicated by the comfortable gait speed ranging between 0.4 and 1.6 m/s. When feedback on the FSA was provided, an average improvement of 7.5 degrees in FSA was seen, resulting in a FSA comparable with the healthy controls. Similar improvements in FSA were seen when feedback was provided on both FSA and propulsion. Moreover, the improvements in FSA were in line with interventions such as an ankle foot orthosis and electrical functional stimulation [20], [21]. It is important to acknowledge the considerable variability in the FSA during regular walking among participants and the heterogeneity in the magnitude of improvement when provided with feedback. Nevertheless, nine of the 12 participants were able to substantially (>5 degrees) improve the FSA in the walking trials with real-time feedback on the FSA. Furthermore, the magnitude of improvement during the feedback trial appeared unrelated to the FSA during regular walking. This suggests that people with various severity of reduced FSA could benefit from eHealth solutions providing feedback on this gait characteristic.

In line with previous research, the generated forward propulsion was significantly lower in the individuals with chronic stroke compared to the healthy controls [5], [6]. We found a substantial improvement of approximately one-third with feedback on the forward propulsion, bringing it to a level similar to the healthy control group. Out of the twelve participants, seven showed considerable improvement (> 0.05 N/(kg·s)), while four showed a slight increase. These findings align with previous research by Santucci et al [12], who found that the peak forward propulsion increased with 0.05 N/kg during walking trials with audio-visual feedback on the forward propulsion. Furthermore, in the study of Genthe et al. [9], the results revealed that a short-term training effect was already present with larger peak forward propulsion after an 18-minute training session compared to the baseline measurement before walking with feedback. Similarly, in our study, there was an increased forward propulsion in the second regular walking trial without feedback compared to the first regular walking trial without feedback. The consistent results emphasize the positive impact of feedback on forward propulsion. However, it is important to note that one participant was not able to increase forward propulsion with feedback. While no factors such as walking speed or time since stroke could explain this outlier, individual factors or possibly fatigue might influence the response to feedback, necessitating further exploration into patient-specific characteristics.

Surprisingly, even when feedback was directed towards the forward propulsion, participants still demonstrated an improvement in the FSA, and, to a lesser extent, vice versa. This suggests a nuanced interplay between gait characteristics, implying that interventions targeting specific gait parameters might also induce other positive changes in the gait pattern after stroke [22], [23]. Although most participants improved both the FSA and propulsion in the trial with feedback on both parameters, they found this condition challenging. The difficulty seems to stem from the need to divide attention between two intricate gait characteristics, further complicated by the similarity in the provided feedback (both a moving disk along the vertical sliding bar). Previous research by Day [24], Spencer [25], and Powers [26], address the importance of the modality and frequency of feedback in gait training. The results of this study underscore the importance of optimizing the design and presentation of feedback to enhance the user experience, particularly when addressing multiple parameters simultaneously. While the SUS scores did not explicitly suggest this design improvement, the statements in the SUS prompted participants to mention it while completing the questionnaire. Although participants felt fairly confident using the system, the SUS revealed that they expected needing assistance from someone with technical skills to get the eHealth solution up and running. Hence, eHealth solutions intended for use beyond the clinical setting must be exceptionally robust and user-friendly, enabling patients to don and doff the system independently.

To provide feedback during overground walking in the patient's own environment, the feedback should be based on wearable IMUs rather than the highly advanced and costly GRAIL system used in this study. However, our aim was to investigate the effect of feedback on the gait pattern in people with stroke. Therefore, we choose to provide accurate feedback on the certainly true FSA and forward propulsion. While the FSA has been validly measured with IMUs, there is no usable method for forward propulsion with these devices in people with stroke [17]. Future research should focus on identification of suitable parameters to assess propulsion and other relevant gait parameter characteristics. Furthermore, feedback modalities in terms of visual, auditory or haptic cues have not been investigated and warrant further attention in people with not only motor- but also possible sensory deficits [27].

Despite the promising findings, this study has inherent limitations. The inclusion criteria focused on patients with gait problems with some remaining ability to actively dorsiflex the ankle. As a result, some participants had no substantial limitations in the FSA and/or forward propulsion. Even though all participants benefited from the feedback, this could potentially limit the generalizability of the results to a broader stroke survivor population. However, it was necessary to include individuals with 'some reserve function' to study the potential of eHealth solutions as a training tool. Individuals with no remaining function have to rely on other solutions, such as an ankle foot orthoses or implanted peroneal functional electrical stimulator [1]. Furthermore, the study only assessed the immediate effect and short-term aftereffects of feedback. Since the FSA and forward propulsion improved significantly in the short term between the first and last trials without feedback, future research should explore the long-term impact of continued training for a more comprehensive understanding of the intervention's efficacy.

Conclusion

In conclusion, this study provides valuable insights into the immediate effects of real-time automated visual feedback on gait parameters in chronic stroke survivors. The observed positive impact of real-time feedback on the FSA and the generated forward propulsion in combination with good usability scores from almost every participant underscore the potential of eHealth solutions in personalized gait rehabilitation.

Acknowledgements

We thank our research intern Dries Cavelaars for his help in the data acquisition, Bart Nienhuis for designing the custom built feedback application, and our participants for their enthusiastic participation in this study.

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Chapter 8



Summary and general discussion

Summary and general discussion

The general aim of this thesis was to develop and evaluate IMU-based algorithms to assess and provide feedback on gait characteristics in people with gait impairments. This chapter starts with a summary of the main findings followed by a general discussion with directions for future research.

Summary

The aim of *Chapter 2* was to develop and validate an IMU-based algorithm to measure spatiotemporal gait characteristics in normal and affected gait patterns. To this end, both healthy participants and people with stroke performed walking tests while equipped with IMUs and simultaneously measured with the gold standard for movement analysis: optical motion capture. The IMU-based algorithm demonstrated comparable or better performance in slower, impaired gait compared to faster, unaffected, gait patterns. At a group level, the difference between the IMU-based and gold standard stride time was 0.00 ± 0.01 s for healthy participants and 0.00 ± 0.04 s for stroke participants. For healthy participants, the IMU-based algorithm underestimated the stride length with 0.03 ± 0.04 m, while 0.00 ± 0.03 m difference was found in the stroke population. However, while the accuracy of the spatiotemporal gait characteristics was good in both healthy individuals and those affected by stroke on a group level, the error increased at higher gait speeds. In walking speeds up to 1.2 m/s, the accuracy of the spatiotemporal gait characteristics was good for both participant groups. While the comfortable walking speed of the stroke participants was up to 1.2 m/s, the comfortable walking speed of the healthy participants reached up to 1.65 m/s. At these higher gait speeds, errors in spatial gait characteristics increased up to 13 cm, while temporal gait characteristics remained consistently excellent.

In *Chapter 3*, the effect of accelerating and decelerating strides around turns on the assessment of gait characteristics was examined. By including only strides in the analysis of gait characteristics that are not influenced by the acceleration and deceleration around turns, a fairer interpretation of the gait capacity and a better comparison between settings is ensured. While accelerating and decelerating strides had only a very limited effect on the mean spatiotemporal gait characteristics, the variance of the gait characteristics was substantially influenced by these strides. To illustrate, including the accelerating and decelerating strides deviated only 0.03 m/s from the mean steady-state gait speed of 1.01 m/s, while including these strides doubled the variance from 0.04 m/s to 0.08 m/s compared to the steady-state portion. In depth analysis of strides around turns showed that the first two strides around each turn differed significantly from the steady-state portion. Therefore,

discarding these two strides around each 180-degree turn is advised for analysis of steady-state gait. The ability to select strides representative for steady-state gait also opens up the possibility to measure gait capacity over shorter, more feasible, walking trajectories, which can be walked back and forth multiple times.

In *Chapter 4*, I extended and validated the IMU-based algorithm of Chapter 2 to estimate the foot strike angle and forward propulsion. Assessment of the foot strike angle and forward propulsion allows for a more comprehensive understanding of the gait pattern, which is especially relevant in patients with drop foot after a stroke and limited ability to generate push-off force. While the orientation of an IMU could be used to provide an estimate of the foot strike angle, IMUs cannot measure force. Therefore, based on previously found promising results, eight parameters were evaluated as indicators for forward propulsion: the stride length, the maximum angular velocity, and angular acceleration during the stance phase of both the foot and shank, the maximum shank linear acceleration, and the foot and shank angle upon terminal contact. While the foot strike angle could be accurately assessed by an IMU (1.4 ± 2.3 degrees), the propulsion was found not to be adequately represented by any of the studied parameters, suggesting the need for a more sophisticated approach.

In *Chapter 5*, differences in gait, turn, and sit-to-stand characteristics, between individuals with knee osteoarthritis who were and were not candidates for knee joint replacement surgery were explored. The IMU-based algorithm developed in Chapter 2 was used to obtain gait speed, stride time, and step time from the steady-state portion of gait (Chapter 3). Additionally, we calculated the trunk movements in the coronal plane during walking, the peak turn velocity, and lean angle during sit-to-stand transfers [1]. Individuals who were candidates for knee joint replacement surgery had a slight, but significant, lower gait speed compared to the individuals without an indication for surgical treatment. None of the other studied parameters showed differences between these groups. However, substantial within-group heterogeneity was observed in both groups. Therefore, an individualized approach with follow-up over time might be more helpful than a single measurement in the decision-making process for surgical intervention.

Good system usability increases the likelihood of actual adoption of a system by the intended user [2]. Therefore, a usability assessment of the IMU-based gait analysis and feedback system holds valuable information on the requirements for implementation. The international standard to assess the usability of a system is the System Usability Scale (SUS) [3]. In *Chapter 6* I translated the System Usability Scale to Dutch (D-SUS), since it is important to use a questionnaire in the target population's

native language [4,5]. In addition, the applicability of the D-SUS to medical technologies was validated. During the translation phase, participants filled out the pre-final version of the D-SUS while thinking aloud. This revealed misunderstanding of three items due to long sentence structures, caused by additional verbs that are not commonly used in the (more direct) Dutch language. These three items were reformulated by a shorter version with the same conceptual meaning. In this phase, it became also evident that the role of the user affects their understanding of different items. For example, patients name their therapists as system experts, while therapists identify the technical staff of the hospital as system experts. In the validation phase of the study, users of different rehabilitation systems and eHealth applications filled out the final version of the D-SUS twice. The results indicate that the Dutch version of the SUS can be used on a group level, with acceptable internal consistency and good test-retest reliability. However, some caution is warranted with the interpretation of individual scores due to a relatively high repeatability coefficient. The final, validated, translation of the D-SUS facilitates testing the usability of IMUs to assess and provide feedback on gait characteristics among native Dutch speakers.

In *Chapter 7*, the effect of real-time feedback on the foot-strike angle and propulsive force in people with stroke was investigated. Feedback on the foot-strike angle was effective, stimulating patients to enhance their foot-strike angle by 7.5 degrees on average. However, responses to feedback on the propulsive force varied, with some individuals successfully increasing the forward propulsion by 33% while others struggled to do so. Notably, participants reported positive experiences with the feedback system and expressed willingness to undergo further gait training using this technology.

General discussion

Movement analysis with IMUs is quick and easy to perform. In combination with appropriate processing algorithms, IMUs can provide a comprehensive, objective assessment of a patient's walking capacity [6–9]. Furthermore, IMUs can facilitate real-time assessment in daily life, enabling targeted feedback to train specific aspects of the gait pattern [10–12]. The findings in the studies of this thesis led to several points for discussion regarding the potential of IMU-based gait analysis. Additionally, I will discuss some future perspectives on IMU-based gait assessment and the potential to provide feedback on gait patterns.

Gait assessment with IMUs

Gait assessment and, particularly the assessment of spatiotemporal gait characteristics, has a long-standing history. Nowadays, several measurement systems are available for gait assessment, such as optical motion capture, video-based assessment, pressure-sensitive walkways, and wearable sensors. Important aspects of these systems are their validity, reliability, and responsiveness for each of the gait characteristics they claim to measure. In this thesis, I developed and validated an IMU-based algorithm to estimate spatiotemporal gait characteristics (Chapter 2) and the foot strike angle (Chapter 4).

Chapter 2 of this thesis showed that temporal gait characteristics can be measured validly in both healthy participants and in people with affected gait patterns due to stroke. In both groups, the gait events and resulting temporal gait characteristics were measured with high validity, with errors in the order of the measurement error. This is in line with results from previous studies in healthy [9] and pathological gait [6]. However, in affected gait patterns, accurate gait event detection was not consistently achieved (Chapter 2). For example, in individuals with a shuffling gait pattern, where there is no distinct swing phase and continuous contact of the foot with the ground, the IMU signal-to-noise ratio decreases while the number of peaks increases. Consequently, the algorithm erroneously identified gait events at signal peaks within the forward motion of the foot. A potential remedy for this issue is to exclude the period of forward motion as the possible instant of a gait event for this type of gait. Similarly, in people with a pronounced drop foot, the algorithm encountered challenges in identifying initial contact events. The absence of a heel strike during initial contact caused deviations in the angular velocity signal used for gait event detection. However, the subsequent foot orientation changes after initial toe contact and could be used to identify a flat foot stance phase. Therefore, using the first integration of the angular velocity as an estimate of the foot orientation might be more accurate than the angular velocity or acceleration in this type of gait pattern and should be further explored in future research.

Chapter 2 also demonstrated that spatial gait characteristics can be measured validly in both normal and pathological gait patterns on a group level. Nonetheless, our results suggested that the accuracy of the estimation of spatial gait characteristics depends on gait speed. At gait speeds over 1.2 m/s, an underestimation of up to 13 cm/s by the IMU-based algorithm was found. These higher gait speeds were associated with stride lengths over 1.3 m, which were also underestimated up to 13 cm. While this error is in line with previous studies reporting differences of 7 to 18 cm in stride length from the gold standard [6–8], it is larger than the clinically relevant change of 7.2 to 11.1 cm reported in the literature [13,14]. This measurement error is an issue of concern when describing or comparing groups of individuals who walk at high gait speed or when monitoring individuals over time to measure treatment effects. Therefore, IMU-based algorithms for the assessment of spatial gait characteristics still need further improvements.

In the following paragraphs, I will discuss potential improvements to the algorithm. First, I will propose improvements within its current one-size-fits-all design, such as improvements in the drift compensation process. Secondly, I will discuss disease-specific or gait pattern-specific adjustments to further refine the algorithm's performance.

Drift compensation process and accuracy of spatial gait characteristics

One aspect of the algorithm that might be improved to achieve higher accuracy in spatial metrics is the drift compensation process. IMU signals inherently include noise, which leads to sensor drift. As the signal noise is integrated into the measured acceleration, the error accumulates. This causes the estimated velocity and position to deviate from their true values over time. Sensor drift can be minimized through zero velocity updates, where the velocity is forcibly set to zero during periods when it is certain to be zero [15]. Zero velocity updates are sometimes combined with an additional correction of the estimated drift between two subsequent zero velocity update periods [16,17]. Both types of drift compensation processes rely on specific assumptions and choices, which will be discussed in the following paragraphs. The algorithm in this thesis used such a combined approach.

A crucial decision in the zero velocity updates concerns the timing of these updates, which can significantly affect the final gait characteristics. Zero velocity updates are often taken over the entire period or at a specific instant within the stance phase [16,18]. During the development of the algorithm in Chapter 2 of this thesis, I assumed that the foot velocity is zero throughout the foot flat period (midstance to heel off [19], see also Figure 1 in Chapter 1). While there was no direct indication that this assumption was invalid, the observed underestimation in stride length of up to 13 cm

at high speed (>1.2 m/s) suggests that there may have been movement during the assumed stationary phase. An alternative approach is to apply the zero velocity updates at a single instant during the foot flat phase. However, this method might not fully compensate for drift, since new drift begins to accumulate immediately after the zero velocity update. As a result, this approach might result in an overestimation of the spatially dependent gait characteristics.

The second part of the drift compensation process involves estimating and compensating for the drift that occurs during two subsequent zero velocity updates (e.g., during the swing). The estimation of this drift is based on the assumption that, during the flat foot phases (e.g. zero velocity update periods), the foot remains at the same vertical position with minimal movement (e.g. flat on even ground) [16,17]. Therefore, any measured change is assumed to be due to signal drift. Two common, but contrasting, assumptions for estimating drift between two foot flat periods are: 1) drift increases linearly between two foot flat periods [16], and 2) drift increases non-linearly between two foot flat periods, with less drift just after the first foot flat period compared to just before the subsequent foot flat period [17]. The algorithm used in this thesis operates based on the second assumption. The underestimation of spatial gait characteristics at high gait speeds found in Chapter 2 suggests that this approach may have led to an overestimation and overcompensation of drift between the zero velocity updates.

Although a previous review has described various methods currently used for drift compensation [15], evaluation of the effect of these methods on spatial gait characteristics is lacking. Assuming that the underestimation of spatial gait characteristics in Chapter 2 was the result of inadequate drift compensation, the accuracy most likely depends on the stride length. Therefore, I recommend studying the effect of drift compensation methods on the accuracy of the spatial gait characteristics. To this end, I propose to study the effect of the timing of the zero velocity updates and drift estimation methods while participants walk with various stride lengths and at various gait speeds. This could result in a single best combination of a zero velocity update timing and a drift estimation method, but this could also show that different combinations are most appropriate for different gait speeds or stride lengths.

Gait pattern-specific algorithms

The current algorithm was developed as a one-size-fits-all, general algorithm. The main advantage of this approach is its potential applicability to everyone, irrespective of any condition affecting the gait pattern. Most of the general algorithms are based on the assumption that a typical cyclical pattern is present in any of the signals. For the algorithm developed in this thesis the typical cyclical pattern is assumed in the

mediolateral angular velocity and vertical acceleration signals (see Figure 1 in Chapter 2). However, in individuals with a gait impairment, this assumed cyclical pattern might not always be present. For example, in people with stroke who experience severe drop foot, the movement of the foot during the swing phase results in a deviating cyclical pattern of the angular velocity. Due to the foot not being lifted during the swing phase, the positive peak during this phase and the following negative peak due to a normal heel strike are not present. Instead, due to the orientation of the foot, initial contact will be made with the toe (see Figure 5 in Chapter 1), followed by placing the heel on the ground, resulting in a (small) positive peak around the initial contact event.

An alternative approach is to develop disease or gait pattern-specific algorithms. Disease-specific algorithms operate on the assumption that individuals with the same disease exhibit similar gait patterns, which likely differ from people with unimpaired gait or other pathological conditions. For example, in previous research the shank of children with cerebral palsy was expected not to move solely in the sagittal plane during the stepping motion, based on the typical gait patterns seen in this disease [19]. Therefore, the combined angular velocity around all three axes was used to identify gait events in this study [19]. Similarly, in people with Parkinson's disease with a shuffling gait pattern, it is likely that the angular movements of the lower limbs are limited. A previous study in this population showed promising results on algorithms to identify gait events based on the shank acceleration [18]. However, different types of gait impairments might be present within a specific disease. This is certainly the case for people with stroke, who can exhibit stiff knee gait, drop foot, and a range of compensation strategies [20]. These different gait impairments result in different movement patterns, which are captured by the IMUs by deviating cyclical patterns (see also Chapter 1). Even though the algorithm developed in this thesis was designed as a one-size-fits-all general algorithm, a certain cyclical pattern is assumed to be present to some extent in the IMU data. The variability in gait patterns within the stroke population resulted in a variety of signal patterns that are more or less similar to this assumed cyclical pattern. This might explain the relatively wide-spread performance by the algorithm within the stroke group in Chapter 2. Therefore, the variability in gait patterns within diseases suggests that algorithms could be better optimized for specific gait patterns that might be observed across different diseases.

A gait pattern-specific approach requires a gait pattern recognition detection step, combined with a pattern-specific gait event detection method and spatial gait parameter calculation. For example, in people with a drop foot, the peak of the mediolateral angular velocity from foot mounted IMUs is minimal or absent while this peak angular velocity is highly accurate for detecting gait events in healthy

individuals [9]. This absence in people with a drop foot results in inaccurate or no detection of initial foot contact, as noted in Chapter 2 of this thesis. By incorporating a pattern recognition step in the algorithm, this deviating signal pattern can be distinguished from the typical signal pattern. After recognizing this deviating signal pattern, other signal features or peaks in other signals (e.g., vertical acceleration) could be used for a more accurate detection in this specific gait pattern. Ideally, the pattern recognition step should not require operator input. This can be achieved by comparing the signal with an existing set of known gait signals followed by appropriate analysis steps to identify gait events and calculate spatial gait parameters. Artificial intelligence methods have demonstrated their potential in automating this process, enhancing the accuracy and efficiency of gait pattern recognition and event detection.

Artificial intelligence

The application of artificial intelligence is rapidly expanding and becoming increasingly accessible in today's technological landscape [21,22]. Using artificial intelligence for example in a pattern recognition step before estimating gait characteristics from IMU data might improve the algorithm's performance. Especially in recognizing pathological gait, where IMU data may deviate significantly from the typical signal pattern that is seen in normal gait, and adjusting the following step to identify signal features is a promising application of artificial intelligence [23]. However, algorithms based on artificial intelligence require training with existing data with known gait characteristics as an input to achieve a high performance (e.g. supervised learning). Given the goal of accurately estimating gait characteristics across a wide range of gait patterns, substantial amounts of data are needed to train such algorithms effectively. This underscores the importance of data sharing among research groups to build robust datasets that encompass diverse gait patterns [22]. The data collected in the studies of this thesis are publicly available and contribute to this necessary large dataset of variable gait patterns. This collaborative effort facilitates the development of more accurate and adaptable algorithms, ultimately advancing the field of gait analysis and enhancing patient care.

Steady-state gait

When describing someone's gait capacity by means and variability of gait characteristics, we are often interested in the steady-state portion of gait. Walking back and forth along a trajectory includes 180-degree turns and acceleration and deceleration phases around these turns. Including the strides in these accelerating and decelerating periods in the gait analysis can result in lower gait speeds and greater variability than someone's actual comfortable walking speed and variability during steady-state gait. Therefore, we identified which strides around turns were accelerating or

decelerating strides in Chapter 3 of this thesis. By excluding these strides, only the steady-state portion of gait are used to assess someone's gait capacity. Including only the steady-state portions also facilitates the comparison of results from different test settings (e.g. between test sites or over multiple measurements over time). This enabled us to combine data from different previous studies to increase the study sample size and reuse available gait data in Chapter 5. Regarding the assessment of gait to support decision-making for treatment, it might be needed to measure people multiple times over time to identify changes in mobility. For example, in people with knee osteoarthritis, tracking their walking abilities and limitations over time might be helpful in discussing whether or not to consider a surgical intervention. This underscores the importance of adequate comparisons between tests.

For analysis of steady-state gait to be feasible in clinical practice, one of the considerations is the length of the walking trajectory that can be used for assessment. Long walkways allow for more steady-state strides to be analyzed per stretch, but the available space is often limited in clinical settings. Chapter 3 revealed that when walking back and forth, two strides around each turn should be discarded for the analysis of steady-state gait. These discarded strides cover a distance of approximately four meters; two meters at each end of the walkway. For the 10 meter walkway used in Chapter 3, this left six meters, resulting in an average of five steady-state strides per stretch. Previous research in healthy older adults showed that a minimum of 12 strides during steady-state gait is necessary to assess gait variability [24], while 15 strides suffice for people with neurological diseases [25]. This implies that on a walkway of 10 meters, the minimum number of required strides can be obtained by walking the walkway three times back and forth. When reducing the length of the walkway even further to only seven meters, walking back and forth five or six times should suffice. This method enhances the practicality of gait analysis in clinical practice by reducing the space needed while still providing reliable data on spatiotemporal gait parameters. This, in contrast to for example, the 30 meter walkway required for the traditional 2- and 6-minute walk tests [26,27]. However, a study confirming that both the mean and variability of gait characteristics during steady-state gait obtained from this shortened walkway and the 30 meter walkway are similar, is recommended.

Future applications of IMUs

Monitoring changes in patients' mobility over time, such as by physiotherapists, and potentially at home instead of in a hospital, could improve the screening process and treatment plans. For example, in Chapter 5, we found substantial within-group heterogeneity while examining the gait characteristics of knee osteoarthritis patients with and without an indication for surgical intervention. Although a single measurement

did not clearly distinguish between these groups based on gait characteristics, I expect that an individualized approach with multiple follow-up measurements over time could be more effective in identifying when a patient is a suitable candidate for surgical intervention. To this end, a study monitoring the mobility of patients with osteoarthritis could provide a better understanding of the progression of mobility problems. Integrating pain scores and comorbidities in this monitoring could further enhance the insights gained.

Conducting measurements in ecologically valid settings offers valuable insights into individuals' actual behavior in their own environments (performance) compared to their abilities under optimal conditions in a clinical setting (capacity). Capturing real-world walking metrics requires further development and research on the performance of algorithms [28]. Given that people do various activities beyond walking, such as cycling and driving, future research should focus on accurately distinguishing between walking and other activities. While previous research found promising results in identifying walking versus "non walking" activities [28,29], it remains unclear which specific non-walking activities participants performed in these studies and how these activities affect the identification of walking periods. For example, identifying walking is easier if participants were only walking or sitting during the measurements compared to participants who were walking, cycling, and driving a mobility scooter. Moreover, considering the diversity of walking surfaces in real-world settings (e.g. carpet vs. pavement, flat vs. incline), studying the effect of these surfaces on the estimated gait characteristics would provide valuable insights. Once walking periods are accurately identified, the current algorithm should be able to extract gait characteristics from real-world data effectively.

Gait analysis using IMUs holds promise not only for clinical practice but also to evaluate new interventions aimed at enhancing gait capacity and performance. This is particularly important because research has shown that patient-reported outcome measures (PROMS) exhibit a stronger correlation with pain and satisfaction compared to physical function in patients undergoing total knee arthroplasty [30,31]. Furthermore, while PROMS tend to reach a ceiling effect just three months after surgery [32], objectively measured gait characteristics begin to show improvement during this period [33,34]. Therefore, IMU-based gait analysis seems to offer additional informative value over PROMS for evaluating rehabilitation programs. In addition, IMUs could offer an objective evaluation of the effectiveness of different gait rehabilitation programs, such as those for stroke patients. However, before the algorithm developed in this thesis can be used for this purpose, further research on the test-retest reliability, responsiveness, and interrater reliability is necessary. To achieve this, a study could be designed with multiple measurements and multiple

assessors. The study could include three measurements before an intervention (e.g. total knee arthroplasty), with two assessments by the same assessor and one by a different assessor to evaluate the test-retest and interrater reliability, respectively. Subsequently, post-intervention measurements should be conducted and compared to the pre-intervention measurements to assess the responsiveness. Performing multiple measurements post-intervention would also allow for monitoring progress in rehabilitation.

Feedback

In addition to gait assessment, IMUs offer the potential to provide real-time feedback on gait characteristics during training [10–12]. The possibility to provide feedback on gait characteristics based on IMUs could expand training possibilities beyond traditional clinical setting and rehabilitation periods [12]. Given the growing pressure on healthcare systems due to rising patient numbers, shortage of qualified personnel, and escalating healthcare costs [35,36], the prospect of continuing rehabilitation exercises at home independently and without direct medical supervision is a promising development. Four key requirements for an effective feedback system have been mentioned in the literature [37–39]:

- 1) feedback should be given on a parameter relevant to the patient,
- 2) the parameter should be measured accurately,
- 3) the patient should be capable to adjust the parameter (e.g., a casted ankle joint cannot be moved regardless of the amount of feedback), and
- 4) the system should be user-friendly in measuring and providing feedback [37–39].

IMUs can be used to assess a wide range of gait characteristics that can be used as a feedback parameter [10,11,38,40]. For example, adjusting the foot progression angle in people with knee osteoarthritis could decrease knee load [41], while in people with stroke, the foot strike angle and propulsion is often an important rehabilitation goal [12]. To meet the first two key requirements for a suitable feedback system in people with stroke, Chapter 4 of this thesis validated the foot strike angle, demonstrating a high level of accuracy with an error of less than 2°. In addition, several parameters indicative for forward propulsion were explored. Previous research has shown the potential of a single pelvis IMU to estimate the 3D components of the ground reaction force during overground gait, indicating that the forward propulsion could be determined [42]. However, the relatively complex calibration procedures required for this approach hinder its usability for patients. Unfortunately, none of the explored IMU-foot based gait characteristics in Chapter 4 showed a strong correlation with forward propulsion. Therefore, future research should investigate more sophisticated approaches to measure the forward propulsion with IMUs while prioritizing ease of use for patients.

Chapter 7 of this thesis aimed to investigate the third and fourth key requirements of a suitable feedback system. While almost all participants with stroke were able to adjust their gait pattern based on visual feedback on the foot strike angle, the ability to increase their forward propulsion varied significantly among participants. The study in Chapter 7 was essential to identify the capabilities of chronic stroke patients to adjust relevant gait characteristics based on feedback and to explore their openness to use IMUs for training purposes. However, the feedback provided was still based on optical marker data and force plates. A crucial next step in the development of an IMU-based feedback system is to conduct a study on the ability to provide real-time feedback based on IMU data. This approach has been demonstrated in studies on the foot progression angle and postural balance in elderly [40], highlighting the potential for IMUs to deliver effective real-time feedback.

Regarding the fourth requirement, the user friendliness, Chapter 7 indicated that people with stroke were open to use an IMU-based feedback system for training purposes. In addition, other studies also expressed cautious optimism about IMU-based gait training and feedback systems [12,37]. However, limited research has been performed on how patients prefer to train in their own environment, the type of feedback (e.g. visual, auditory, haptic) that would be suitable for that context, and how patients perceive the interaction with the hardware and software of IMU-based feedback training without any human supervision [12,39,43]. Future research should also focus on the timing of feedback, such as whether it should be provided at initial contact or during the following foot flat phase. Furthermore, exploring the amount and type of feedback participants prefer to receive is crucial. This includes determining whether users prefer both positive and negative feedback or only feedback on steps with a gait pattern that could be improved.

General conclusions

The studies in this thesis led to a publicly available algorithm that can be used to derive spatiotemporal gait characteristics and the foot strike angle, using IMUs on the feet and trunk in people with and without gait impairments. The algorithm demonstrated excellent accuracy when group data were collected during steady-state walking in standardized settings. However, improvements are needed for estimating spatial gait characteristics at higher gait speeds and temporal gait characteristics for people with irregular gait patterns.

When comparing groups with- and without an indication for surgical treatment for osteoarthritis, only limited differences between the groups, and large heterogeneity within both groups, were found on mobility characteristics. These results underscore that the decision for surgical treatment is based on multiple factors, but that

objectively measuring gait characteristics could be a factor to be considered in the shared decision making process.

When provided with feedback on their measured foot strike angle and forward propulsion, people with stroke were able to significantly improve these gait characteristics. Furthermore, the D-SUS indicated that participants found the feedback to be a usable training tool to improve certain gait characteristics. Nonetheless, there are still some hurdles to overcome for the implementation of an IMU-based feedback solution, such as identifying the most suitable feedback modality and determining the appropriate timing for feedback delivery.

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Nederlandse samenvatting

Nederlandse samenvatting

Lopen is een essentiële activiteit die een onmiskenbare rol speelt in ons dagelijks leven. Wanneer iemands loopvaardigheid beperkt is, heeft dit een significante impact op hun functioneren en welzijn. Het is dan ook van groot belang om de loopvaardigheid nauwkeurig in kaart te brengen. Dit vormt de basis voor het opstellen van een passend behandelplan en het evalueren van de effectiviteit van de behandeling. Dit proefschrift richtte zich op het ontwikkelen en evalueren van algoritmes, die met behulp van draagbare bewegingssensoren, de loopvaardigheid van mensen met loopoefeningen objectief kunnen meten. Daarnaast onderzocht ik of het mogelijk is om mensen met een beroerte het looppatroon aan te laten aanpassen, door hen real-time feedback te geven op basis van bewegingssensoren.

In *hoofdstuk 1* geef ik de relevante achtergrond informatie voor dit proefschrift. Ik bespreek in dit hoofdstuk onder andere wat we aan het looppatroon kunnen meten en hoe we dit kunnen doen. Zo kan je het lopen beschrijven in temporele- en spatiele maten (bijvoorbeeld de stapduur en stapgrootte) en met behulp van kinematica en kinetica (bijvoorbeeld de enkelhoek en afzetkracht). In de manier waarop we het lopen kunnen meten speelt technologie een steeds belangrijker rol, waarbij er steeds meer interesse is voor het gebruik van draagbare sensoren.

Op basis van algoritmes uit de wetenschappelijke literatuur, heb ik een algoritme ontwikkeld om temporele en spatiele loopparameters te bepalen met behulp van bewegingssensoren. In *hoofdstuk 2* valideerde ik dit algoritme in gezonde deelnemers en mensen in de chronische fase na een beroerte, terwijl zij op een geïnstrumenteerde loopband liepen met regelmatige of onregelmatige stappen. De temporele en spatiele loopparameters die bepaald werden door het algoritme voor de bewegingssensoren werden vergeleken met de gouden standaard voor bewegingsanalyse (optical motion capture). Het algoritme voor bewegingssensoren resulteerde in vergelijkbare of betere waarden in temporele en spatiele loopparameters tijdens het lopen met onregelmatige stappen dan met de regelmatige stappen. Hoewel de nauwkeurigheid van de temporele en spatiele loopparameters op groepsniveau goed was, zowel bij gezonde personen als bij mensen met een beroerte, werden de spatiele loopparameters vaak onderschat bij hogere loopsnelheden. Deze onderschatting was met name aanwezig in de groep gezonde deelnemers, omdat zij sneller liepen (tot 1.65 m/s) dan de deelnemers met een beroerte (tot 1.2 m/s).

Gezien de beperkte ruimte waarin looptesten soms worden afgenomen, lopen mensen vaak over een korte afstand waarbij ze zich op beide uiteinden omdraaien om het traject meerdere keren op en neer te lopen. In *hoofdstuk 3* heb ik onderzocht

hoe versnellende en vertragende stappen rondom een draai van invloed zijn op het gemiddelde en de variabiliteit van temporele en spatiele loopparameters. Door deze stappen niet mee te nemen in de analyse, kan het comfortabele looppatroon nauwkeuriger worden beschreven. Hoewel versnellende en vertragende stappen maar een klein effect hadden op het gemiddelde van de temporele en spatiele loopparameters, verdubbelde de variabiliteit van deze parameters wanneer deze stappen werden meegenomen. Een verdiepende analyse van de stappen rondom de draai toonde aan dat de eerste en laatste twee stappen significant verschilden van de stappen tijdens het comfortabele lopen. Daarom wordt geadviseerd om de twee stappen voor en na een draai uit te sluiten wanneer men het comfortabele looppatroon wil beschrijven. Door deze selectie toe te passen, kunnen looptesten voor het bepalen van temporele en spatiele loopparameters tijdens comfortabel lopen worden uitgevoerd op locaties waar alleen een beperkte loopafstand beschikbaar is.

In *hoofdstuk 4* is het algoritme voor bewegingssensoren van hoofdstuk 2 uitgebreid om twee relevante loopparameters te meten die beperkt kunnen zijn bij mensen na een beroerte. De eerste parameter is de voethoek, gedefinieerd als de hoek die de voet met de grond maakt bij het neerzetten. Deze parameter is met name relevant voor patiënten met een afhanginge voet (dropfoot). De tweede parameter is de voorwaartse propulsie, gedefinieerd als de voorwaartse kracht tijdens de afzet, die relevant is voor mensen die moeite hebben met het genereren van voorwaartse kracht. Hoewel de oriëntatie van een bewegingssensor gebruikt kan worden om de voethoek te meten, is dit type sensor niet in staat om kracht te meten. Daarom zijn acht verschillende parameters geëvalueerd als indicatoren voor de voorwaartse propulsie: schredelengte, maximale hoeksnelheid en hoekversnelling tijdens de stand fase van zowel de voet als het onderbeen, de maximale lineaire versnelling van het onderbeen, en de hoek van de voet en het onderbeen bij eind-contact. Hoewel de voethoek nauwkeurig kon worden beoordeeld door de bewegingssensor (1.4 ± 2.3 graden), was geen van de onderzochte parameters indicatief voor de voorwaartse propulsie, wat suggereert dat een meer geavanceerde benadering hiervoor nodig is.

In *hoofdstuk 5* werden verschillen in loop-, draai- en zit-tot-sta-parameters onderzocht tussen mensen met knieartrose die wel en geen kandidaat waren voor een knieprothese. Het algoritme voor bewegingssensoren (hoofdstuk 2) werd gebruikt om looptijd, schredetijd en staptijd te verkrijgen uit het comfortabele gedeelte van het lopen (hoofdstuk 3). Daarnaast hebben we de rompbewegingen tijdens het lopen bepaald en gekeken naar de mate waarin men tijdens de zit-tot-sta beweging voorover leunt. De groep mensen die kandidaat waren voor een knieprothese hadden een kleine, maar significant, lagere loopsnelheid in vergelijking met de groep mensen

zonder indicatie voor een knieprothese. Geen van de andere parameters vertoonde verschillen tussen deze groepen, mede door de heterogeniteit in beide groepen.

Het is cruciaal om de bruikbaarheid van het loopanalyse- en feedbacksysteem op basis van sensoren te testen, aangezien een goede bruikbaarheid de kans vergroot dat het systeem daadwerkelijk wordt gebruikt door de beoogde gebruiker. Daarom is het belangrijk om waardevolle informatie over de bruikbaarheid van het systeem al in een vroeg stadium te verkrijgen voor de verdere ontwikkeling van het systeem. De internationale standaard voor het beoordelen van de bruikbaarheid van een systeem is de System Usability Scale (SUS). In *hoofdstuk 6* is de SUS vertaald naar het Nederlands (D-SUS), omdat een vragenlijst in de moedertaal veel voordelen heeft. Bovendien werd in hoofdstuk 6 de toepasbaarheid van de D-SUS op medische technologieën gevalideerd. De Nederlandse versie van de SUS kan op groepsniveau worden gebruikt, maar enige voorzichtigheid is geboden bij de interpretatie van individuele scores. Op basis van de bevindingen kon worden geconcludeerd dat de D-SUS geschikt is om snel en gemakkelijk de bruikbaarheid van loopanalyse- en feedbacksysteem te testen onder Nederlandstalige deelnemers.

In *hoofdstuk 7* werd het effect van real-time feedback op de voethoek en voorwaartse propulsie bij mensen na een beroerte onderzocht. De feedback over de voethoek stimuleerde mensen om hun voethoek gemiddeld met 7.5 ± 1.4 graden te verbeteren. Deelnemers waren echter minder consistent in het verbeteren van de voorwaartse propulsie op basis van feedback. Terwijl sommige deelnemers erin slaagden de voorwaartse propulsie met een derde te verhogen, lieten anderen nauwelijks verbetering zien. Bovendien reageerden de deelnemers positief op de bruikbaarheid van het feedbacksysteem en waren ze bereid om het lopen verder te trainen met behulp van deze technologie.

De gezamenlijke resultaten van dit proefschrift heb ik besproken in *hoofdstuk 8*. In dit hoofdstuk worden de gemaakte keuzes en hun gevolgen binnen het ontwikkelde algoritme voor sensoren besproken. Daarnaast worden mogelijke richtingen voor vervolg toepassingen voor het meten van lopen met sensoren gegeven. Tot slot worden de overwegingen besproken die nog moeten worden onderzocht met betrekking tot een feedback systeem met sensoren ter verbetering van de loopvaardigheid.



Dankwoord

Dankwoord

Wauw, daar ligt echt een heel boekje, en mijn naam staat op de kaft. Hoewel ik er rete-trots op ben dat ie nu af is, voelt het toch een beetje raar dat mijn naam daar zo alleen op de voorkant staat. Onderzoek, en zeker een heel promotietraject, doe je namelijk helemaal niet alleen. Ik ben dan ook blij dat ik in dit hoofdstuk de ruimte heb om een paar mensen in het zonnetje te zetten en te bedanken voor hun aandeel aan dit proefschrift en mijn promotie.

Op de eerste plaats mijn kleine -maar grootse- promotieteam: Noël en Katrijn! Mijn promotietraject ging niet helemaal 'volgens het boekje', maar met jullie fijne begeleiding is er wel een heel mooi boekje uit voort gekomen. Noël, ik kan je pragmatische instelling en onophoudelijke nieuwsgierigheid enorm waarderen. Bij het eerste onderzoek dat we samen deden wilde ik het liefst eerst alle theorie die er te vinden was uitgezocht hebben, jij zei: 'ga maar gewoon een pilot testje doen'. Volgens mij keek ik je een beetje vreemd aan, maar een half uur testen leerde me meer dan een hele dag lezen. Daarnaast leerde je mij dat ik van een onderzoek mag verwachten dat ik er een antwoord op mijn vraag mee vindt, maar dat het nog vaker tot veel meer nieuwe vragen leidt. Inmiddels schijnt het traditie te worden dat jouw promovendi iets over jouw gevoel voor humor te zeggen in hun dankwoord, dan kan ik natuurlijk niet achter blijven: ik heb me er prima mee vermaakt de afgelopen jaren! Katrijn, bij het schrijven van mijn algemene discussie vroeg je me gekscherend 'Wat heb ik je nou geleerd?!', toen de kapstok per ongeluk al weer twee kantjes lang was geworden... Oeps. Maar, ik heb enorm veel van je geleerd; van je kritische houding als het gaat om het neerzetten van een goede onderzoeksvraag en of dat wat je in dat onderzoek doet die vraag wel echt gaat beantwoorden, maar ook om altijd zo naar andere onderzoeken te blijven kijken. Hoewel de afgelopen jaren mijn vermoeden bevestigd hebben dat wetenschappelijk schrijven niet mijn grootste talent en hobby is, heb ik gelukkig ook van je geleerd korte kapstokken te maken, waardoor dat schrijven toch steeds net een beetje makkelijker werd. Ik startte bij de Maartenskliniek met de instelling dat ik nog niet wist of ik wel wilde promoveren, ik wilde vooral werken aan coole dingen die mensen zouden helpen en ik wilde ontdekken of onderzoek doen wel bij mij past. Bedankt dat jullie mij de vrijheid lieten om aan verschillende gave projecten te werken, jullie betrokkenheid, en alles wat jullie mij geleerd hebben de afgelopen jaren. Ik wacht echter wel nog steeds op een cursus Segway-rijden, de leverdatum van die dingen komt (gepaard met de nieuwbouw) inmiddels steeds dichterbij toch?

Brenda, je was al betrokken sinds mijn sollicitatie bij de Maartenskliniek omdat het idee was dat ik van alles in het MOTION project zou gaan doen. Aangezien het maken

van het kinderformaat exoskelet enige vertraging heeft opgelopen is het mij, buiten het vertalen van de SUS, nooit helemaal gelukt om toffe onderzoeken binnen dit project te doen. Toch wil ik je hier wel even speciaal noemen, jouw betrokkenheid en interesse is bewonderingswaardig. Regelmatig hoorde ik je weer over de gang rennen want 'sjips ik moet opschieten, ben al laat', maar vervolgens vond je ook altijd tijd om via de waterkoker met een kop thee in de hand even te vragen hoe het weekend was. Bedankt voor de fijne samenwerking, zowel voor een fraai hoofdstuk in dit boekje als ook daarnaast. Er komt geen 'buurvrouw Gerda' stukje meer uit mijn pen of toetsenbord zonder dat ik ook even aan jou denk.

Jolien, zonder jou hadden de eerste studies in mijn boekje er waarschijnlijk heel anders uit gezien. Bedankt voor al je harde werk, geduld, enthousiasme en spontane bijklets-koffietjes met een stukje chocolade tussendoor. Cheriël, bedankt voor alle gezellige uurtjes in het lab, alles wat je me geleerd hebt over het begeleiden van studenten, en al je vragen bij de moeilijke technische dingen. Samen met de passie en het enthousiasme van Theo en René heb ik enorm genoten van alles wat we in het Movin(g) Reality project hebben gedaan. Bart, bedankt voor al je GRAIL-hulp, met name de feedback applicatie die je hebt gemaakt was geweldig. Frank, spontaan hebben we nog een leuk stuk samen gemaakt dat een mooie plek in mijn boekje heeft gekregen. Bedankt, ik ben blij dat jij het meeste schrijfwerk hebt gedaan en je mij lekker met de analyse scrips liet prutsen. Lise, ons TrunkyXL project is helaas niet terug te vinden in dit boekje, maar bedankt voor alle gezellige uurtjes in het lab! Ik vraag me nog steeds af of we meer pilot- en testtijd of daadwerkelijke meeturen hebben gemaakt, maar het maakt me eigenlijk niet uit, ik heb er enorm van genoten. Vraag me alleen niet meer voor de camera, vloggen blijkt echt meer jouw ding dan het mijne. Ieder van jullie heeft mij op zijn eigen manier geïnspireerd om van deze projecten een succes te maken. Ik prijs me gelukkig met de samenwerking die ik met jullie allemaal heb gehad, dank jullie wel!

Hard werken gaat het beste in een fijne werksfeer. Hiervoor wil ik in het bijzonder mijn kamergenootjes van de afgelopen jaren bedanken, aangezien ik nogal eens van kamer gewisseld ben, zijn er dat er veel, maar jullie mogen je hier allemaal aangesproken voelen. Naast hard werken was er ook altijd tijd voor samen lachen, samen klagen, samen successen vieren, en samen tiny habits uitvoeren. Collega's van de reva-research en later het team motorisch functioneren, jullie zijn niet alleen toppers bij research content meetings en journal clubs, maar ook de beste in verkleedpartijtjes, Jos-borrels en afsluitende patattafels. Collega's van de afdeling research en het LEC, fijn dat jullie altijd klaar staan om mee te denken, de leuke sfeer op de afdeling, het onderzoek weer even in perspectief van de praktijk plaatsen, en jullie hulp met het werven van studiedeelnemers. Bedankt voor de fijne tijd allemaal.

Wat alle onderzoeken in dit boekje ook gemeen hebben, is dat zich voor elk van de studies er in razend tempo deelnemers hadden aangemeld. Zelfs in coronatijd. Lieve deelnemers, bedankt voor alles. Bedankt voor jullie inzet en hulp om deze onderzoeken tot een goed einde te brengen, het delen van jullie verhalen, inzichten, relativeringsvermogen, positiviteit en geduld. Bedankt dat jullie mij niet alleen als onderzoeker, maar ook als mens lieten groeien. Zonder jullie was dit allemaal niet gelukt!

Als laatste wil ik mijn privé-team achter dit succes ook even in het zonnetje zetten. Lieve vrienden en familie, en in het bijzonder lieve pap, mam, Coen en Laura, soms was het lastig uitleggen waar ik nou mee bezig was de afgelopen jaren. Ik hoop dat vandaag het allemaal een beetje duidelijker heeft gemaakt. Bedankt voor alles: voor de feedback op mijn sollicitatiebrief voor deze werkplek, jullie vertrouwen dat ik het tot een goed einde zou schoppen, elke keer weer jullie oprechte interesse -ook als ik het niet goed uit kon leggen-, de keren dat ik weer eens laat thuis was en mijn benen onder de tafel kon steken, en de keren dat de NS mij niet meer thuis bracht en jullie me weer ergens op hebben gehaald. Coen en Laura, fijn dat jullie vandaag bij de verdediging het extra steuntje in mijn rug zijn als mijn "nimfjes", ik ben super trots om samen met jullie hier te mogen staan. Werken en het doen van onderzoek is leuk, maar tijd om te ontspannen, te relativeren en even te resetten vind ik minstens zo belangrijk. Gelukkig heb ik hele fijne mensen om me heen om dit samen mee te doen door te meppen tegen squashballetjes, het maken van fietstochtjes, hardloopprondjes, en wandelingen -soms met hond of gepaard met zoektocht naar kabouters-, de bezoeken aan de Efteling, fanatiek gespeelde spelletjes, en alles daar tussenin. Bedankt lieve vrienden en familie, jullie zijn goud waard!



Curriculum vitae

Curriculum vitae

Carmen Ensink was born on January 15th 1993 in Hengelo. After graduating from secondary school in 2011 at the Twickel College in Hengelo, she started the bachelor Technical Medicine at the University of Twente in 2012. In 2016, she obtained her bachelor degree and started the master Human Movement Sciences at the University of Maastricht in the same year. During her masters she became interested in the field of rehabilitation. Carmen performed her graduation internship at Adelante Zorggroep, where she investigated the effect of task oriented strength training on the arm and hand function in children with cerebral palsy. After her graduation in 2017, Carmen performed an additional internship at the Roessingh Research and Development on the effect of a soft robotic glove on the hand function of people with stroke. She started in 2018 as a junior researcher at the OCON (Orthopedische kliniek Oost-Nederland), aiming to identify movement patterns in the rehabilitation period after anterior cruciate ligament reconstruction surgery with wearable sensors. In 2019 she started with the PhD project leading to this thesis aiming at measuring and providing feedback on gait characteristics with wearable sensors at the Sint Maartenskliniek. Currently, Carmen is working as an 'Impact manager research' for the DEMPACT consortium at Alzheimer Nederland.



List of publications

List of publications

This thesis

Ensink, C., Smulders, K., Warnar, J., & Keijsers, N. (2023). Validation of an algorithm to assess regular and irregular gait using inertial sensors in healthy and stroke individuals. *PeerJ*, 11, e16641. doi: <https://doi.org/10.7717/peerj.16641>

Ensink, C. J., Smulders, K., Warnar, J. J., & Keijsers, N. L. W. (2023). The Influence of Stride Selection on Gait Parameters Collected with Inertial Sensors. *Sensors*, 23(4), 2002. doi: <https://doi.org/10.3390/s23042002>

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Other publications

C.J. Ensink, L. Wilders, N.L.W. Keijsers. Validity and feasibility of trunk stability training in virtual reality. In *Proceedings of XR4REHAB Conference 2023 – Scale up for impact!*

C.J. Ensink, J.E. Warnar, K. Smulders, N.L.W. Keijsers. The influence of methods for stride selection on gait parameters collected with wearable sensors. *ISPGR World Congress 2022*

C.J. Ensink, J.E. Warnar, K. Smulders, N.L.W. Keijsers. Validation of an algorithm to assess irregular gait based on inertial sensors. *ISPGR World Congress 2022*

Carmen Ensink, Brenda Groen, Noël Keijsers. Translation and validation of the System Usability Scale to a Dutch version. *CareTech symposium 2022*

Theo Theunissen, **Carmen Ensink**, René Bakker, and Noël Keijsers. Movin(g) Reality: Rehabilitation after a CVA with Augmented Reality. In *Proceedings of the European Conference on Pattern Languages of Programs 2020*, EuroPLoP '20, New York, NY, USA, 2020. Association for Computing Machinery. doi: <https://doi.org/10.1145/3424771.3424819>

Desirée Struijk-Vlaswinkel, Fanny Schils, Noël Keijsers, Lise Wilders, **Carmen Ensink**, Gert-Jan Brok, Kiki Coppelmans, Colin Rosen, Hanneke van Duinhoven. Trunky XL everybody a six-pack! In *Proceedings of the Virtual EuroVR Conference 2020*. doi: 10.32040/2242-122X.2020.T38

Noël Keijsers, Cheriël Hofstad, René van Ee, Bart van Oosteren, **Carmen Ensink**, Theo Theunissen, David van Dommelen, Jille Treffers. Movin(g) Reality. In *Proceedings of the Virtual EuroVR Conference 2020*. doi: 10.32040/2242-122X.2020.T38



PhD Portfolio

PhD Portfolio

Name PhD student: Carmen J. Ensink

Department: Research, Sint Maartenskliniek

Graduate School: Donders Graduate School

Training Activities	Year
Research content meetings	2019-2023
Journal club	2019-2023
eBROK course and re-registration	2019, 2023
Workshop 'Schrijven voor patiënten'	2020
R basics	2020
Webinar "Epidemiological research in the real world"	2020
ISPGR online symposium	2020, 2021
Webinar MedTech "Translationeel Onderzoek"	2021
Webinar "Balance"	2021
Dutch Congress of Rehabilitation Medicine	2021
ICMS annual and mid-summer events	2021-2023
Movement Analysis Club UTwente	2022-2023
Webinar "Medical Device Regulation"	2022
Workshop "Boost your writing skills"	2022
Donders Graduate School – Scientific Integrity Course	2022
Donders Graduate School – Introduction Day	2022
ISPGR World congress	2022
SMALLL Congress	2022
Adobe Masterclass "InDesign, Illustrator & Photoshop"	2023
Donders Graduate School – Graduate School Day	2023
Workshop "Presenteren"	2023

Teaching Activities	Year
Supervision pre-master student	2019
Supervision HBO student	2019
Supervision Bachelor student	2021
Meet the PhD	2021, 2022
Supervision Master student	2022



Research data management

Research data management

This research followed the applicable laws and ethical guidelines. Research Data Management was conducted according to the FAIR principles. The paragraphs below specify how this was achieved.

Ethics and privacy

This thesis is based on the results of human studies, which were conducted in accordance with the principles of the Declaration of Helsinki. All studies met the requirements for exemption from the medical ethics committee reviewed by the medical ethics committee on Research Involving Human Subjects region Arnhem-Nijmegen (chapter 2 - dossier number: 2021-8191, chapters 4 and 7 - dossier number: 2021-13295, and chapter 6 - dossier number: 2020-6848), or the institutional board of the Sint Maartenskliniek (chapters 3 and 5 - dossier number: RJK/we). Written informed consent was given by all participants for the collection, processing, and sharing of their data for future research. The privacy of the participants was warranted by the use of pseudonymization.

Funding

The studies described in chapters 2, 3, and 5 are part of the MOTOR project, which is co-funded by Stichting ReumaNederland, Smith and Nephew and the PPP Allowance made available by Health Holland, Top Sector Life Sciences & Health. The studies described in chapters 4, and 7 are funded by Interreg North-West Europe as part of the VR4REHAB open innovation network and ZonMw as part of the Topspecialistische Zorg & Onderzoek (10070022010004). The study described in chapter 6 is part of the MOTION project, which is funded by Interreg - 2SeasMersZeeën.

Data collection and storage

Data for chapters 2, 4, and 7 were collected through Vicon (Vicon Motion Systems Ltd., Oxford, UK) and MTManager (Movella, Enschede, The Netherlands), then transferred to Spyder (Spyder IDE, available from: <https://www.spyder-ide.org>), and subsequently to RStudio (RStudio, Boston, USA). Data for chapters 3 and 5 were collected through MTManager and transferred to Spyder. For chapter 5 this data was subsequently transferred to RStudio. Data for chapter 6 was collected through electronic Case Report Forms (eCRF) using Castor EDC (Castor, Amsterdam, The Netherlands) and transferred to Spyder.

Pseudonymized data were stored and analyzed on the department server, accessible only to project members working at the Sint Maartenskliniek. These secure storage options ensure the availability, integrity and confidentiality of the data. Paper (hardcopy) data are stored in file cabinets within the department.

Data sharing

The datasets of chapters 2, 4, and 7 are suitable for reuse, and published along with their respective research articles (DOI chapter 2: <https://doi.org/10.5281/zenodo.8198714>, DOI chapter 4 and 7: <https://dx.doi.org/10.21227/dn2j-5e57>). Data were made reusable by adding sufficient documentation and by using the preferred and sustainable data formats. All data used for these chapters including all analysis scripts are also publicly available at the GitHub page of the Sint Maartenskliniek (<https://github.com/Sint-Maartenskliniek>). The metadata of the dataset used in chapters 3 and 5 is published at Open Science Framework (<https://osf.io/fdvr5>). Requests for access of this data will be checked by a data access committee formed by the department. The data of chapter 6 are not suitable for reuse and will be archived for at least 15 years after termination of the study.



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for Cognitive Neuroscience**

Donders Graduate School for Cognitive Neuroscience

For a successful research Institute, it is vital to train the next generation of young scientists. To achieve this goal, the Donders Institute for Brain, Cognition and Behavior established the Donders Graduate School for Cognitive Neuroscience (DGCN), which was officially recognized as a national graduate school in 2009. The Graduate School covers training at both Master's and PhD level and provides an excellent educational context fully aligned with the research program of the Donders Institute.

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