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ABSTRACT

Background. Functional electrical stimulation (FES) can be used for compensation of foot-drop for post-stroke individuals by preprogrammed fixed stimulation; however, this stimulation seems no more effective than mechanical ankle foot orthoses.

Objective. We evaluated the metrological quality of inertial sensors for movement reconstruction as compared with the gold-standard motion capturing system, to couple FES with inertial sensors to improve dorsiflexion on the paretic side, by using an adaptive stimulation taking into account individuals' performance post-stroke.

Methods. Adults with ischemic or hemorrhagic stroke presenting foot-drop and able to walk 10 m, were included from May 2016 to June 2017. Those with passive ankle dorsiflexion < 0° with the knee stretched were excluded. Synchronous gait was analyzed with the VICON© system as the gold standard and inertial measurement units (IMUs) worn by participants. The main outcome was the dorsiflexion angle at the heel strike and midswing phase obtained from IMUs and the VICON system. Secondary outcomes were stride length, walking speed, maximal ankle dorsiflexion velocity, and fatigue detection.

Results. We included 26 participants (18 males; mean age 58 [range 45-84] years). During heel strike, the dorsiflexion angle measurements demonstrated a root mean square error (RMSE) of 5.5°; a mean average error (MAE) of 3.9°; Bland-Altman bias of -0.1° with limits of agreement -10.9° to +10.7° and good intraclass correlation coefficient (ICC) at 0.87 between the 2 techniques. During the midswing phase, the RMSE was 5.6; MAE 3.7°; Bland-Altman bias -0.9° with limits of agreement -11.7° to +9.8° and ICC 0.88. Good agreement was demonstrated for secondary outcomes and fatigue detection.

Conclusions. IMU-based reconstruction algorithms were effective in measuring ankle dorsiflexion with small biases and good ICCs in adults with ischemic or hemorrhagic stroke presenting foot-drop. The precision obtained is sufficient to observe the fatigue influence on the dorsiflexion and therefore to use IMUs to adapt FES.

Key words: inertial measurement unit; kinematic parameters; foot drop; stroke; functional electrostimulation

Introduction

Stroke is the leading cause of acquired disability in adults in high-resource countries (1,2). Most people with stroke (60-80%) will at least temporarily lose the ability to walk without help (3). There is a large variation in the modifications of angular movement, such as ankle dorsiflexion, in hemiplegic individuals, demonstrated by gait analysis.

The term "foot drop" refers to an inability to perform complete ankle dorsiflexion, resulting in poor foot clearance when walking, which decreases walking speed and increases the risk of falls. This deficiency of dorsiflexion may be related to insufficient voluntary control of flexor muscles, lack of selectivity of the latter or hyper-activation of the antagonistic muscles, which leads to abnormal gait. Among people with hemiplegia post stroke, 20% to 50% are affected by foot drop problems due to stroke (4–6). Classic rehabilitation of foot drop syndrome involves improving ankle dorsiflexion by voluntary contractions or electrostimulation and by controlling spasticity. The use of an ankle-foot orthosis (AFO) is the most classic palliative approach when rehabilitation does not obtain adequate ankle dorsiflexion to walk.

Neuroprostheses, with functional electrical stimulation (FES) of the peroneal nerve, anterior tibialis and lungus fibularis during the swing phase, are used to treat foot drop syndrome. The effectiveness of FES to correct foot drop and improve walking speed has been clearly demonstrated (7,8). However, FES seems non-superior to the AFO for walking speed. FES has some advantages as compared with AFO: it is able to induce a physiological muscular contraction and to respect the degrees of articular freedom, which is often impeded by an orthosis, thus suggesting a possible therapeutic effect (9). In the 2 main studies comparing FES and AFO, participants preferred the FES system to AFO, especially during the more complex activities of movement, such as walking over obstacles, half turns or climbing stairs (7,8). Moreover, AFOs can be uncomfortable, bulky, and, if poorly fitted, produce areas of pressure and tissue breakdown. Finally, the FES system parameters do not change as the individual walks. One of the areas for improving the FES could be adaptive stimulation triggered by changes in different gait parameters and fatigue detection, for example, less intense stimulation to reduce muscle fatigue from overstimulation when ankle dorsiflexion is sufficient and increasing stimulation when ankle dorsiflexion is insufficient.

Conventionally, stimulation is triggered by the detection of gait cycle events, such as the heel strike from a switch placed under the heel (e.g., the ODSTOCK Medical Ltd system©) or inclination of the tibia during swing phase (WalkAide system©). Upon detection of these events, the stimulator delivers a pre-programmed stimulation sequence (using fixed parameters) (6,7,9–11). These current detection systems cannot provide an adapted stimulation according to the individual's performance or the type of movement performed.

Inertial measurement units (IMUs) are wearable devices for gait analysis including 3-axis accelerometers, 3-axis gyroscopes and 3-axis magnetometer sensors. Because of their small size and weight, IMUs have been used in gait analysis of healthy individuals (12–15) and individuals with orthopedic disorders (16) or neurological disorders (17–21). Previous studies of healthy individuals have demonstrated errors in ankle dorsiflexion of about 5° (22,23).

The technical feasibility of continuously monitoring the progress of the gait cycle from IMUs has been previously validated (24), and the use of an IMU to trigger FES has been shown to be as effective as a heel contactor. Azevedo et al. (24) provided information from an IMU on the optimal timing of stimulation, but information is lacking on which gait parameters can be reliably obtained for individuals using a FES and then used to adjust the intensity of the stimulation.

The main aim of this study was to evaluate the metrological qualities of the data-processing algorithms derived from IMUs against an external optical-motion capturing system for a post-stroke population. We hypothesized that the kinematic and gait parameters obtained from IMUs present an accurate estimate of the individuals' gait patterns that render their use feasible to adjust functional electrostimulation. The 2 main outcomes were ankle dorsiflexion during heel strikes and midswing phases. Secondary outcomes were fatigue detection, stride length, speed, and maximum ankle dorsiflexion velocity at heel strike.

Materials and methods

Participants

This was a monocentric and prospective pilot study. The inclusion criteria were adults 20 to 75 years old with a supra-tentorial ischemic or hemorrhagic stroke, regardless of the delay post-stroke, who could walk 10 m without human aid, with or without a walking stick, and had a foot drop syndrome requiring the use of technical assistance to overcome this deficiency. We excluded individuals who presented a fixed equine with passive dorsal flexion of the ankle < 0°, with the knee stretched. All participants provided written informed consent for inclusion before study participation. The protocol was approved by a national ethics committee and the local ethics committee of the University Hospital Nimes, France (no. 2015-A00572-47).

Equipment

Equipment for data collection

Participants were equipped with 4 IMUs (Fox HikoB© Villeurbanne, France, L45 x W36 x H17 mm, weight: 22g) featuring a 3-axis accelerometer, a 3-axis magnetometer and a 3-axis gyrometer respectively mounted on the feet and shanks (Fig. 1). This inertial sensor is a generic low-cost inertial sensor based on the basic Micro Electro Mechanical Systems accelerometer, gyrometer and magnetometer and a low-power processor. Each IMU was strapped on a rigid support together with 4 reflective markers tracked by an optical motion capture system (OMCS, Vicon© Bonita MX), with cameras installed along a Gaitrite© (CIR System Inc.) walkway system.

Equipment to correct foot drop

Two stimulating skin electrodes (electrical stimulation Odstock ODFS III©) were positioned facing the peroneus and common fibular nerve and facing the anterior tibialis muscle to induce dorsiflexion. Stimulation was triggered by the detection of a gait cycle event from a switch placed under the heel. Suitable stimulation intensity parameters were chosen for each participant to ensure comfort and a maximum range of motion elicited by the stimulation.

Clinical evaluation and measurement

A clinical evaluation was done before gait analyses. Passive ankle dorsiflexion on the paretic side with stretched and flexed knee was measured with a goniometer. Muscle strength and spasticity on lower limbs, autonomy abilities and postural performance were assessed by using the Medical Research Council (MRC) scale, the Ashworth Scale, the Barthel scale and the Postural Assessment Scale for Stroke (PASS), respectively.

The walking path was 10 m long: participants walked 5 m, made a first half turn, walked 5 m and then made a second half turn. After a familiarization period, participants walked 3 passages at a comfortable speed under FES, to compensate for technical problems (e.g., sensor fault or wireless synchronization). If 3 passages were available, one passage was used at random. Participants were asked to remain static for < 1 min before walking, with an assumption on the alignment of body segments. The 0° corresponds to the relative angle between the foot and the tibia at this time.

The following parameters were measured at each step with the VICON and IMUs (25): dorsiflexion at heel strike, dorsiflexion at midswing phase, stride length, speed, maximum ankle velocity as the maximum angular speed between heel strike and foot flat events. Heel strike, foot flat and toe off was determined by using the Gaitrite© system. Midswing phase was determined by the mid time between toe off and heel strike.

To detect fatigue, we measured the mean ankle dorsiflexion in the midswing phase on the paretic side at the beginning and end of a 6 min walk test (6MWT). The mean dorsiflexion angle was computed in 2 distinctive periods, between 15 sec and 30 sec and between 5 min 30 sec and 5 min 45 sec.

Data analysis

Raw inertial measures were angular speed, acceleration and magnetic field. Angular speed and acceleration were integrated to obtain rotational angle and linear speed. Magnetic field was estimated by a magnetometer in the IMUs and heading was given. To limit drift and errors of data from accelerometers and gyroscopes, a previously described filter was used (26,27). Further information on the Martin and Salaun algorithm, the quaternion notation, and geometrical calibration used are available in a previous article (25).

Statistical analysis

Statistical analyses involved using the "footstep as the statistical individual", presuming independence between each measurement. The root mean square error (RMSE) and mean absolute error (MAE) were compared between IMUs and the VICON system for the main outcomes (ankle dorsiflexion during heel strikes and midswing phases) and secondary outcomes (stride length, speed, maximum ankle dorsiflexion velocity at heel strike). The agreement in measures between IMUs and the VICON system was evaluated graphically by the Bland-Altman method (28) and the intraclass correlation coefficient (ICC). Bland-Altman diagrams were used to provide a reliable measure of agreement and present the mean of the difference (bias) as well as the 95% confidence interval (CI) of the bias (limits of agreement). The ICC for absolute agreement (29) was used to calculate the ratio of the intraclass variation in the parameter to the between-class variation due to repeated measurements. The ICC values were classified as poor (0–0.5), moderate (0.5–0.74), good (0.75–0.9) and excellent (0.9–1.0) absolute agreement (30,31).

To illustrate fatigue by using the mean ankle dorsiflexion at the beginning (15 to 30 sec) and at the end (5 min 30 sec to 5 min 45 sec) during the 6MWT, a paired Wilcoxon test was performed separately for each method (IMUs and VICON). The percentage differences between the IMUs and VICON system were compared by paired Wilcoxon test. The RMSE was calculated by using the differences before/after the 6MWT for the IMUs and VICON system. Statistical analysis involved using SAS v9.4 (SAS Inst., Cary, NC, USA).

Results

We recruited 29 people (mean [SD] age 58.5 [10.4] years; 9 females) with ischemic (n=19) or hemorrhagic stroke (n=10) from the Physical Medicine and Rehabilitation Department at Le Grau du Roi Hospital, Nîmes University Hospital, France, from May 2016 to June 2017. The age of 2 participants (84 and 76 years old) was older than the protocol (20 to 75 years old), but they did not significantly differ from the other participants in characteristics or parameters and therefore were included in the study. Of the 29 individuals initially included, 3 (10%) did not perform any test. Therefore, 26 participants were included in the final descriptive analysis.

No adverse events occurred during the study. For participant characteristics see Table 1 (and the online Table). Initial clinical evaluation demonstrated an initial median passive dorsiflexion ankle of 10° (interquartile range [IQR] 5–20) when the knee was flexed and 0° (IQR 0–10) with a straightened leg. Median maximum voluntary contraction was 3.5/5 (range 1–5) for hip flexion, 2.5/5 (range 0–4) for ankle dorsiflexion, and 4/5 (range 3–5) for knee extension. Spasticity levels ranged from 0 to 3, with no participants showing severe spasticity (4 or 5/5).

The median Bartel score was 82.5 (range 55–100). In all, 13 participants (50%) were able to walk independently on flat ground but required help with stairs, unstable ground or a slope; 8 (31%) were independent regardless of location and 5 (19%) required verbal help from someone. The median PASS score was 31 (range 25–35).

Results for the two main outcomes, ankle dorsiflexion during stance and midswing phases, are shown in Table 2. Low mean errors between IMUs and VICON were observed, RMSE < 6.1° and MAE < 4.3°, but with a large dispersion of error (95% CI ±12°). Good agreement of the IMUs compared to the reference system was observed for the main outcomes by the Bland-Altman method and for the ICC. Bland-Altman graphics for dorsiflexion during stance and midswing are in Figure 2.

Results for secondary outcomes (stride length, speed, maximum ankle dorsiflexion velocity) shown in Table 3, were similar to main outcomes with overall good agreement.

Fatigue detection was illustrated by a paired Wilcoxon test of the means of the dorsiflexion of ankle at the beginning (30 sec) and the end (345 sec) of a 6MWT: $p = 0.005$ for IMUs and $p = 0.004$ for the VICON system. We found no difference between the 2 methods to illustrate fatigue at the end of the 6MWT ($p = 0.1909$) (online Figure*)*. The correlation between the 2 methods was good, with ICC = 0.76 (95% CI 0.41–0.92). The RMSE of the difference at the beginning/end of the 6MWT between the VICON system and IMUs was 2.82°.

Discussion

The IMU-based algorithms developed in this study are a promising tool for assessing kinematic and spatio-temporal gait parameters of post-stroke individuals. Results demonstrated low errors and good agreement between IMUs and the optical motion capturing system to estimate ankle dorsiflexion on heel strikes (initial contacts) and during midswing phases and for other spatio-temporal gait parameters during straight walking. Furthermore, the IMU accuracy was sufficient to illustrate fatigue that occurred during a 6MWT, so their use is feasible to adjust functional electrostimulation. To our knowledge, this is the first clinical study to compare IMUs and a 3-D optical motion capture system to determine kinematic parameters (ankle dorsiflexion) and other spatiotemporal gait parameters on paretic and healthy sides in post-stroke individuals. Additionally, our cohort is large as compared with that in previous experimental study designs (16,18).

A number of technical problems were encountered during evaluations: synchronization difficulties between the systems; loss of detection or breakdown of VICON© reflective markers; and artefacts caused by the presence of a cane between the reflective markers and VICON© cameras. IMUs and reflective markers were attached on the same rigid mounts to guarantee the ability to compare measurements. These rigid mounts were fixed on body segments by using approximated anatomical landmarks, which resulted in an accessible methodology and allowed individuals to fix the future FES-IMU system themselves (with just a strap), within an ecological situation at home. Using IMUs to measure gait parameters in ecological situations may elicit other sources of error and cause artefacts when they are fixed on soft tissue. Future coupled IMUs and FES could address this problem by using more rigid attachments to the leg.

To exploit raw inertial measures of the IMU devices, computed integrations are needed: angular speed to rotational angle, acceleration to linear speed, and magnetic field to heading. Multiple factors can cause integration drift: sensor physical rotation, constant induced, function of time and temperature. Algorithms are needed to reduce this drift. In the present study, Martin and Salaun's algorithm was used (27). The advantages of this algorithm are increased reliability, a model that is not very demanding in terms of calculations, and considering all sensor characteristics. Because the accuracy of the spatio-temporal parameters showed very good results in straight walking, Martin and Salaun's algorithm is a promising algorithm for gait parameter extraction. A potential limitation is that only straight walking was assessed and results could be different in non-straight conditions (half turns).

A statistical limitation of the present study is that the number of participants needed was not estimated to reduce limits of agreement. Because this was a pilot study, no previous data are available on the use of IMU Fox Hikob as FES in comparison to the VICON system in people with foot drop to analyze dorsiflexion angles, so statistical justification of sample size estimations is difficult. Considering the small samples of previous experimental protocols in other types of FES in people with foot drop [e.g., Seel et al. (19), 4 participants], we aimed to provide a larger estimation of gait analysis parameters with a larger sample size.

Previous studies compared other IMU devices to the gold-standard VICON, in both healthy individuals and in other pathological conditions. However, different algorithms to process IMU signals were used and different clinical variables analyzed. In contrast to high computational loads required by extended Kalman filter (EKF) use, the algorithm we tested was chosen to be later implementable on a low-cost and low-power IMU. The algorithm used in Martin et al. (27) had similar accuracy as that of EKF, but using only an 8-bit micro-controller. Despite these differences in study design, similar mean errors were demonstrated. For example, small RMSEs found in the post-stroke participants in our study were similar to the RMSE of foot angles demonstrated in previous studies in healthy individuals, about 5° (30,31). Seel et al. demonstrated even smaller errors, comparing data provided by an IMU with a 3-D optical motion capturing system to analyze the movement of a trans-femoral amputee: RMSE of knee flexion/extension angles were < 1° on the prosthesis and about 3° on the human leg. For the ankle dorsiflexion, the 2 deviations were approximately 1° (16). However, unlike other authors, this study used an additional pre-clinical evaluation step to motion-calibrate the sensor in relation to specific anatomical landmarks, perhaps reducing the errors. We did not use this step in our study because it is time-consuming and is less relevant to a "real life" scenario of a future system (FES+IMU) placement by the individual. We used an easier, more practical calibration of the IMUs, with participants asked to remain static for < 1 min before walking, with an assumption on the alignment of body segments. Furthermore, despite the replicable good mean errors we reported, one limitation of our results is the large dispersion in error. Future considerations for research need to include over how many consecutive steps the errors should be calculated. A one-off error of more than 5° may not be clinically relevant but if calculated over several consecutive steps might impede the correction adaptive stimulation of the IMU system. We recommend that in a future FES system coupled with IMUs, adaptive stimulation should only occur if the decrease in performance is confirmed over several steps (e.g., 3, but to be determined in future research). Such a procedure will allow the aberrant data due to an excessive measurement error to be suppressed and improve the clinical application of these devices.

In addition to adapting FES to the walking performance, the metrological qualities of the IMUs allows for considering adapting FES according to the type of displacement performed (half-turn, obstacles, stairs etc.). IMUs are already used as a tool for analyzing spatio-temporal parameters in clinical practice, and our study opens perspectives for their use as a tool for analyzing kinematic parameters.

The present study was a necessary preliminary step before further research comparing current FES systems (with pre-programmed stimulation) and a FES system coupled with IMUs and the algorithm tested in this study providing an adaptive stimulation. Stimulation could be adapted to the type of movement performed: different intensity or duration of stimulation when the individual passes an obstacle or climbs stairs. Indeed, by varying the parameters of the electrical pulse, the results measured or felt by the individual may be different. By improving the stimulation parameters, the FES could benefit individuals more than a simple ankle foot orthosis. Studies comparing neuroprostheses and ankle foot orthosis evaluated gait speed as the outcome, whereas other main outcomes may be more clinically pertinent such as a functional ambulation task (9) or fatigue. As shown in the present study, fatigue detection was illustrated by IMUs after a 6MWT, with a small error rate as compared with the VICON system. Further exploration of the data is needed to determine when the change in fatigue occurs. Using this in future studies, it may be interesting to evaluate a FES system that will adapt stimulation intensity to the fatigue detected by an IMU or reduce fatigue with appropriate stimulation parameters. Moreover, the individual's performance and perception during different activities of daily living or walking stairs, slopes and irregular grounds should be also considered.

Conclusion

The data-treatment algorithms from IMUs were able to accurately capture kinematic and spatio-temporal gait parameters as compared with the reference optical motion capturing system for post-stroke individuals with foot drop syndrome. We found low mean errors between IMUs and the VICON system to measure ankle dorsiflexion, but with large dispersion. The precision obtained was sufficient to detect fatigue and to use a coupling of this IMU with an adaptive FES system in future studies, with an aim of improving foot drop correction in post-stroke hemiplegic individuals.

Conflict of interest. None declared

Legends

Figure 1. Equipment for data collection: the red markers of the inertial measurement units (IMUs) on the feet and shank, and the white reflective markers of the VICON system can be seen. The cable is the functional electrical stimulation (FES) system.

Figure 2. Bland-Altman graphics. For dorsiflexion during heel strike for non-paretic side (A), paretic side (B). For dorsiflexion during midswing for non-paretic side (C), paretic side (D). Vertical axis represents the difference (VICON-IMU) and the horizontal axis is the mean (VICON-IMU/2).

Online Figure. Comparison of the mean ankle angle dorsiflexion between IMU and VICON at the beginning (30 sec) and end (345 sec) of a 6 minute walk test (fatigue detection).

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FIGURES

Figure 1:

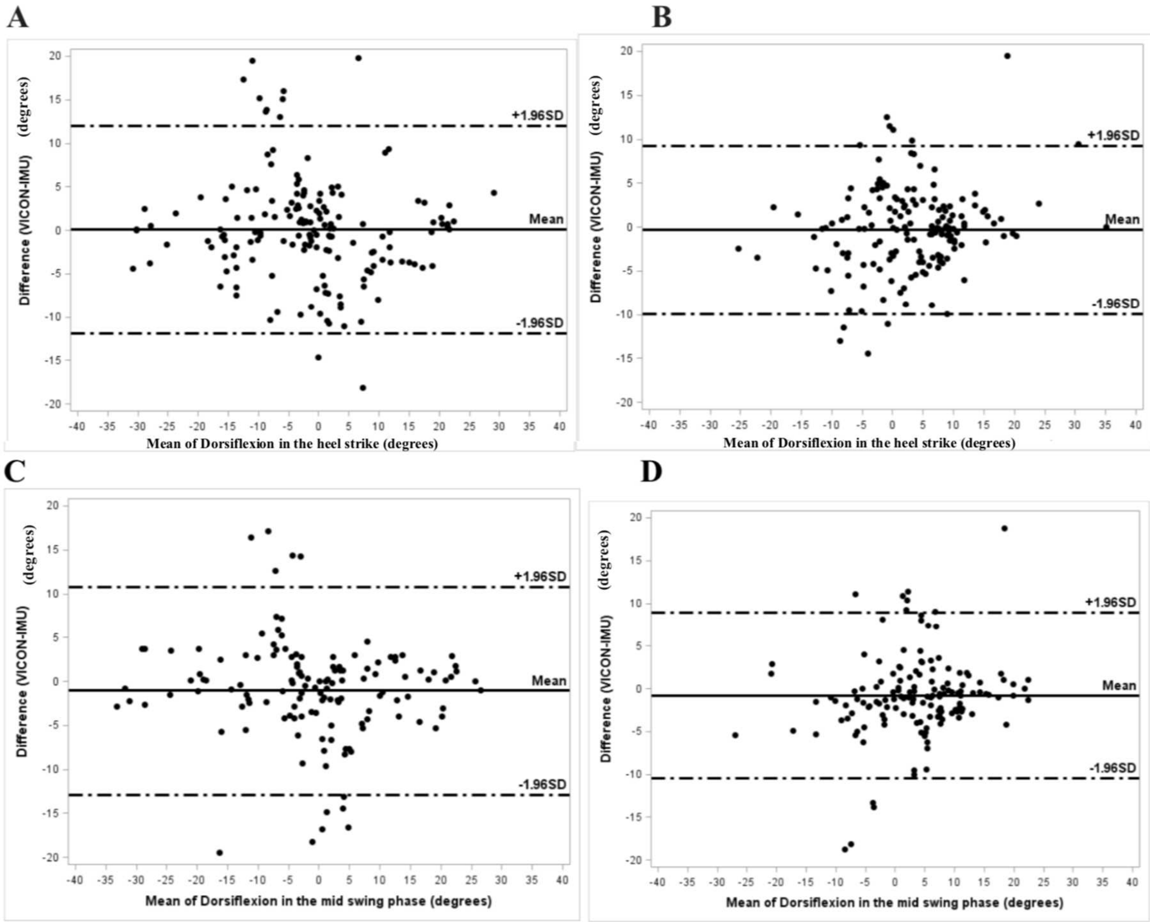
A
Difference (VICON-IMU) (degrees)
+1.96SD
Mean
-1.96SD
Mean of Dorsiflexion in the heel strike (degrees)
B
Difference (VICON-IMU) (degrees)
+1.96SD
Mean
-1.96SD
Mean of Dorsiflexion in the heel strike (degrees)
C
Difference (VICON-IMU) (degrees)
+1.96SD
Mean
-1.96SD
Mean of Dorsiflexion in the mid swing phase (degrees)
D
Difference (VICON-IMU) (degrees)
+1.96SD
Mean
-1.96SD
Mean of Dorsiflexion in the mid swing phase (degrees)

Figure 2:

TABLES

Table 1. Participant characteristics.

Sex	
Female	8 (31)
Male	18 (69)
Side of the injured brain	
Right	15 (58)
Left	11 (42)
Type of stroke	
Hemorraghic	9 (35)
Ischemic	17 (65)
Technical assistance	
None	3 (11)
Canadian stick	15 (58)
Simple stick	6 (23)
Tripod stick	2 (8)
Ankle foot orthosis	
ASTEP	7 (27)
LIBERTE	9 (35)
Other model	2 (8)
Orthopedic shoes	8 (31)

Data are n (%).

Table 2. Results for main outcomes.

		IMU	VICON	RMSE (°)	MAE (°)	Bland-Altman VICON-IMU		ICC [95% CI]
		Mean (SD)	**Mean (SD)**			**Bias**	**SD**	
Dorsiflexion on heel strike (degrees)	All data	0.8 (10.9)	0.6 (10.9)	5.5	3.9	-0.1	5.5	**0.87** [0.84–0.89]
	Paretic side	3.2 (8.8)	2.9 (9.6)	4.9	3.6	-0.3	4.9	**0.86** [0.81–0.89]
	Non-paretic side	-1.7 (12.3)	-1.6 (11.7)	6.1	4.3	0.1	6.1	**0.87** [0.83–0.9]
Dorsiflexion in the midswing phase (degrees)	All data	1.7 (11.2)	0.8 (11.3)	5.6	3.7	-0.9	5.5	**0.88** [0.85–0.9]
	Paretic side	3.8 (8.5)	3 (9.4)	5	3.4	-0.8	4.9	**0.85** [0.80–0.89]
	Non-paretic side	-0.4 (13.1)	-1.5 (12.6)	6.1	4.1	-1.1	6	**0.89** [0.85–0.92]

IMU, inertial measurement unit; ICC, intraclass correlation coefficient; SD, standard deviation; MAE, mean average error; RMSE, root mean square error

Table 3. Results for secondary outcomes.

		IMU	VICON	Bland-Altman VICON-IMU		
		Mean (SD)	**Mean (SD)**	**Bias**	**SD**	**ICC** [95% CI]
Stride length (m)	All data	0.6 (0.2)	0.6 (0.2)	0	0.1	**0.86** [0.82–0.89]
	Paretic side	0.6 (0.2)	0.6 (0.2)	0	0.1	**0.83** [0.76–0.88]
	Non-paretic side	0.6 (0.2)	0.6 (0.2)	0	0.1	**0.88** [0.83–0.91]
Speed (m/s)	All data	0.2 (0.2)	0.3 (0.1)	0	0	**0.92** [0.90–0.94]
	Paretic side	0.3 (0.2)	0.3 (0.1)	0	0	**0.91** [0.87–0.94]
	Non-paretic side	0.3 (0.2)	0.3 (0.1)	0	0	**0.93** [0.90–0.95]
Maximum ankle dorsiflexion velocity (degree/sec)	All data	94.6 (93.3)	94.18 (93.52)	0.1	3.4	**1**
	Paretic side	73.6 (78.4)	72.6 (77.9)	0.2	3.5	**1**
	Non-paretic side	115.7 (102.2)	115.6 (105.6)	-0.1	3.4	**1**

IMU, inertial measurement unit; ICC, intraclass correlation coefficient; SD, standard deviation.