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## The reliability test of a smart insole for gait analysis in stroke patients

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### Abstract

**Background:** This study analyzed the reliability of smart guides for gait analysis in patients with stroke.

**Design:** Cross-sectional study.

**Methods:** The participants of the study were 30 patients with stroke who could walk more than 10 m and had an MMSE-K test score of  $\geq 24$ . Prior to the experiment, the subjects or their guardians entered their demographic characteristics including gender, age, height, weight into the prepared computer. The experiment was conducted in a quiet, comfortable, and independent location, and the patient was reminded of the equipment description, precautions, and safety rules for walking. A smart insole was inserted into the shoes of the patients and the shoes were put on before the patients walked three times on the 5-m gait analysis system mat installed in the laboratory.

**Results:** The reliability of the equipment was compared with that of the gait analysis system, and the results of this study are as follows: among the gait analysis items, velocity had an ICC=0.982, the cadence had an ICC=0.905, the swing phase on the side of the gait cycle had an ICC=0.893, the swing phase on the side of the gait had an ICC=0.839, that on the non-affected side had an ICC=0.939, single support on the affected side had an ICC=0.812, and support on the non-affected side had an ICC=0.767.

**Conclusion:** The results of this study indicate no sta-

tistical difference between the smart insole and the gait analysis system. Therefore, it is believed that real-time gait analysis through smart insole measurement could help patients in rehabilitation.

**Key words:** Gait, Reliability, Stroke, Smart insole.

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## I . Introduction

Stroke occurs when a blood vessel is blocked by thrombosis or when there is vascular rupture, which limits the supply of oxygen and nutrients to the brain, resulting in brain damage (Kim et al., 2020). Stroke is now a major disease affecting human life and health (Wang et al., 2018). Stroke affects approximately 795,000 people (Benjamin et al., 2017) each year, and despite many advances in prevention and treatment, stroke is becoming more frequent and unpredictable (Mayo et al., 2002). Patients with stroke tend to use the unaffected side more frequently than the paralyzed side in the long term, resulting in asymmetry (Moon et al., 2016) in both lower limbs and weakening of the upper and lower limbs of the affected side (Campbell et al., 2010). Patients with stroke have problems with gait, such as arm swing and amplitude reduction (Pistacchi et al., 2017) a, reduction in nervous subsystem integration capability, increased cadence (Mirelman et al., 2019), decreased active postural control (Perry, 1992), and decreased stride, which lead to problems including body asymmetry among (Ramakrishnan et al., 2019, Lim et al., 2020). The weakened muscles of the paralyzed upper and lower extremities cause approximately 61%–80% of the body's weight to be skewed to the lower extremities (Sackley et al., 1996), resulting in asymmetric balance, gait, weight-bearing, and abnormal movements, especially in patients with stroke (Dickstein et al., 1984). Gait velocity is a powerful measure of life expectancy and a guide for rehabilitation, and a typical gait speed test is the 10-m walk test (Middleton, 2015). It is important to determine the simultaneous efficacy of each test to enable it to be used in comparison with or interchangeably with other tests for gait speed. The gait analysis system has proved reliable for measuring spatiotemporal gait parameters and providing estimates of the level of gait (Bilney, 2003). The gait analysis system is a portable ‘carpet’ gait path with built-in pressure sensors throughout its length. Subjects can walk on the carpet without wires or markers, and data such as gait velocity, cadence, gait length, single and double support duration, and stride throughout the gait cycle can be quickly and easily obtained (Bilney et al., 2003; Webster et al., 2005; Dusing et al., 2007; Kressig et al., 2006). In particular, spatiotemporal variable measurements are often used during gait measurements to monitor progress, and plan interventions and discharge from stroke groups. Spatiotemporal measurements require improved portable equipment that is not inconvenient for patients and is not resistant. Spatial and temporal measurements of gait patterns are performed to identify and diagnose gait deviations, determine appropriate treatment, and monitor patient progress (Bilney et al., 2003). Various evaluation tools are used to evaluate balance and gait. Researchers use an image-based three-dimensional (3D) motion capture system that requires a large space and is preferred by researchers because of its expertise and accuracy, despite the difficulty in carrying it around (Tao et al., 2012). Clinicians and therapists must be able to align the balance of patients with stroke with the goals of the tests and evaluations required for walking analysis. The choice of reliable and validated evaluation tools is critical. In patients with early stroke undergoing rehabilitation, precise gait measurements are essential, especially in those with a slower gait or more severe disorders (Balasubramanian et al., 2009). Recently, the popularity of wearable sensors has increased in pedestrian analysis and these sensors have become more popular among clinicians (Benson et al., 2018). The main advantage of wearable sensors is that they can collect biomechanical data at a relatively low cost and in many environments (Kavanagh et al., 2008; Kobsar et al., 2014; Mannini et al., 2016). Advances in gait analysis technology have focused on methods that enable continuous gait monitoring without interruption in real-world environments outside the laboratory, such as wearable sensors (Chen et al., 2016).

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However, these wearable sensors are attached to the body, which requires an individual's willingness and can cause problems with discomfort and adhesion. Considering that gait aids such as walkers and rollers are routinely prescribed to patients who need them during rehabilitation and who are restricted from moving, a valid gait analysis system is needed to continuously capture gait parameters without interfering with the users (Werner et al., 2019). Therefore, we want to assist with the rehabilitation and goal-setting of patients by comparing smart guidance and gait analysis systems with objective clinical measuring equipment and by introducing equipment that is convenient to carry, free of restrictions on location, and can be monitored in real time.

## II. Method

### 1. Subjects

This study used a cross-sectional design. Participants' gait parameters such as gait velocity, cadence, swing phase, stance phase, single support, and double support were measured when walking through a smart insole gait analysis system. Forty-four patients who were diagnosed with stroke and received inpatient and outpatient treatment were recruited. These patients met the inclusion criteria for study selection at Hospital B in Seongnam-si, Gyeonggi-do, and agreed to participate in the study. The inclusion criteria were as follows: diagnosis of stroke, an MMES-K score of 24 or more, normal mental status, being able to perform a 10-m walk test, and knowledge of and agreement to the purpose of this study. The exclusion criteria were as follows: visual and auditory defects, inability to follow the instructions of the therapist, somatic sensory impairments affecting balancing abilities, and damage that could affect gait. Prior to the experiment, patients who participated in the study were informed of the purpose and requirements of the study and that they could withdraw their consent to participate, and signed a consent form for participation. This study was approved by the Institutional Bioethics Committee of Bundang Jesaeng Hospital (approval number: DMC202008004-HE001) and was registered (KCT0005558) in the Clinical Research Information Service of the Republic of Korea. The objectives and procedures to be performed in the study were fully understood by the subjects, and all subjects provided informed consent. Therefore, this study was based on the ethical principles of the Declaration of Helsinki.

### 2. Procedure of the study

Prior to the experiment, the subjects or their guardians entered their demographic characteristics including gender, age, height, weight into the prepared computer. The experiment was conducted in a quiet, comfortable, and independent location, and the patient was reminded of the equipment description, precautions, and safety rules for walking. A smart insole was inserted into the shoes of the patients and the shoes were put on before the patients walked three times on the 5-m gait analysis system mat installed in the laboratory. There was no restriction on shoes, and acceleration and deceleration were measured at the beginning and end of the gait path (Cleland et al., 2019). The physical therapists walked next to the patients outside the walking mat to ensure the safety of the patient (Kuys et al., 2011). Software developers continuously monitored the smart insoles and gait analysis systems to help cope with equipment errors. During the experiment, the test was immediately stopped if the patients showed fatigue, complained of pain, and change

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information.

### 3. Outcome measurement

#### 1) Gait analysis

In this study, pedestrian capability was analyzed using the Gait Analysis System (GAITRite, CIR System Inc, USA, 2008) to collect data on gait analysis for subjects (McDonough et al., 2001; Van & Besser, 2004). The GAITRite is an electronic walking mat that is 5 m long, 61 cm wide, and 0.6 cm high. A total of 16,128 sensors, each measuring 1 cm in diameter, were arranged vertically along the gait mat every 1.27 cm to collect information. Measurements included velocity, cadence, swing phase, stance phase, and requirement of single support or double support. All within-gait correlations (intermediate-class correlations [ICC]=0.96) of the comfortable velocity of the gait analysis system were highly correlated between 0.96 (Van Uden et al., 2004), and the measurement of gait characteristics using video motion analysis (ICC=0.94) (McDonough et al., 2001). In this study, information was collected by walking on a gait analysis system with the subject wearing a smart insole, standing 2 m behind the gait mat, and walking on the gait mat following the examiner's verbal signal.

#### 2) Smart insole

In this study, we used Pedisol (R-C-SP0-Pedisol250, Spina Systems Co., Ltd., South Korea, 2019), a smart insole used to collect data on the gait analysis of patients. Pedisol has 40 pressure sensors mounted in the sole of the shoe which gather information through force sensing resistor (FSR) sensors when walking, and the collected information is transmitted to a mobile phone, personal computer (PC), or tablet via Bluetooth 3.0 communication. The data transfer cycle lasted for 100 ms and weighed 214 g on a 250-mm scale. The experiment required the subject to stand in front of the gait mat and walk at the most comfortable velocity following the examiner's verbal signal to the outside of the mat. Measurements included velocity, cadence, swing phase, stance phase, single support, and double support.

### 4. Data analysis

All analyses in this study were performed using SPSS (version 21.0; IBM, Armonk, NY, USA). For descriptive statistics, the frequency, average and standard deviation were reported. Continuous variables of the study subjects were tested for normality using a Shapiro-Wilk test, and the ICCs were used to assess reliability between the two measurements for each item. Internal consistency was based on the value of Cronbach's alpha.

## III. Results

Regarding the general characteristics of the participants, sex, age, height, weight, and leg length were evaluated <Table 1>.

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Table 1. General characteristics (N=30)

		Person	%
Sex (Male/Female)	Male	16	53.33%
	Female	14	46.67%
Age (years)	50 >	10	33.33%
	50-59	12	40.00%
	60 <	8	26.67%
	60 >	10	33.33%
Weight (kg)	60-69	6	20.00%
	70-79	8	26.67%
	80 <	6	20.00%
	150 >	1	3.33%
Height (cm)	150-159	9	30.00%
	160-169	10	33.33%
	170 <	10	33.33%
	Affected (Rt./Lt.)	Right	17
	Left	13	43.33%
Diagnostic name	Cerebral hemorrhage	5	16.67%
	Cerebral infarction	25	83.33%
Onset	1 year >	15	50.00%
	1-2 years	4	13.33%
	2-3 years	2	6.67%
	3-4 years	1	3.33%
	4-5 years	1	3.33%
	5 years <	7	23.33%

Gait analysis was performed using a gait analysis system and a smart insole for the analysis of each participant's velocity, cadence, affected side swing phase, non-affected side swing phase, affected side stance phase, non-affected side stance phase, affected side single support, non-affected side single support, affected side double support, and non-affected side double support <Table 2>.

The average velocity was 77.05 for the gait analysis system and 0.98 for the smart insole (ICC, 73.39). The mean cadence was 93.72 for the gait analysis system and 83.00 for the smart insole (ICC, 0.91). The mean in terms of the affected side swing phase was 33.40 for the gait analysis system, and 33.51 for the smart insole (ICC, 0.89). Regarding the non-affected side swing phase, the average was 28.82 for the gait analysis system and 28.23 for the smart insole (ICC, 0.94). The mean of the affected side stance phase was 66.60 for the gait analysis system and 0.89 for the smart insole (ICC, 66.49). The mean of the non-affected side stance phase was 71.18 for the gait analysis system and 71.77 for the smart insole (ICC, 0.94). The mean of the affected side single support was 28.85 for the gait analysis system and 22.24 for the smart insole (ICC, 0.81). The mean of the non-affected side single support was 33.38 using the gait analysis system and 26.50 using the smart insole (ICC, 0.77). The mean of the affected side double support system was 37.60 for the gait analysis system and 36.76 for the smart insole (ICC, 0.76). The average for the emergency side double support device was 37.53 for the gait analysis system and 36.30 for the smart insole (ICC, 0.77).

Table 2. Reliability of gait variables (N=30)

	Gait analysis		ICC	95% Confidence interval	
	Gait analysis system	Smart insole		Lower	Upper
Velocity ( <i>cm/s</i> )	77.05±32.29 <sup>a</sup>	73.39±25.53	0.98	11.38	18.7
Cadence ( <i>steps/min</i> )	93.72±18.83	83.00±16.78	0.91	1.5	19.93
Affected side swing phase (%GC)	33.40±4.69	33.51±5.20	0.89	2.45	2.67
Non-affected side swing phase (%GC)	28.82±6.63	28.23±5.10	0.94	2.47	3.65
Affected side stance phase (%GC)	66.60±4.69	66.49±5.21	0.89	2.45	2.67
Non-affected side stance phase (%GC)	71.18±6.62	71.77±5.10	0.94	2.47	3.64
Affected side single support (%GC)	28.85±6.63	22.24±3.74	0.81	3.83	9.39
Non-affected side single support (%GC)	33.38±4.73	26.50±6.49	0.77	3.95	9.82
Affected side double support (%GC)	37.60±8.89	36.76±7.69	0.76	3.45	5.14
Non-affected side double support (%GC)	37.53±9.01	36.30±6.85	0.77	2.91	5.36

<sup>a</sup>Mean ± standard deviation, %GC=%gait cycle.

## IV. Discussion

Patients with stroke develop central nervous system problems (Duncan et al., 2002; Verheyden et al., 2006), loss of motion, and abnormal weight distribution (Kelley et al., 2009), and often have physical symmetry problems (Bohannon, 1988). These problems lead to restrictions in social activities and a decrease in independence (Perry et al., 1995), causing problems in daily life in the community (Antipova et al., 2019). Identifying and solving problems in patients with stroke is an important goal of rehabilitation (Michael et al., 2005; Patterson et al., 2008).

The use of equipment is limited by the environment because the assessment requires a dedicated space that does not interfere with the equipment (Bamberg et al., 2008). The recent emergence of small wearable devices linked to mobile phones, tablets, and personal computers (PCs) has enabled pedestrian evaluation, and these devices are still being studied to evaluate the possibility of further development (Sprager et al., 2015). This study was conducted to explore the reliability of smart insoles for gait analysis in 30 patients with stroke. To compare the resulting values of gait analysis in patients with stroke, we used a gait analysis system with Pedisol (Spina Systems Co., Ltd., R-C-SP0-Pedisol250, 2019, Korea) and a smart insole. We performed measurements in participants walking repeatedly (three times) over a 10-m distance with the gait analysis system (GAITRite, CIR system Inc, USA, 2008) installed on hard ground and wearing a smart insole.

In this study, the reliability test for velocity and cadence showed a confidence level (ICC) of 0.982 and 0.905, respectively. In a previous study, Cleland et al. (2019) placed a 1-m gap between the gait analysis system and the 10-m walk test and measured the velocity at a comfortable and again at a fast gait. The ICC for the fast gait velocity was 0.94 and that for the comfortable velocity was 0.77. In our study, the ICC was 0.982, as measured at a faster velocity than the velocity chosen by the individual. Kuys et al. (2011) had a distance of 2 m before and after in the gait analysis of patients with stroke using a gait analysis system, and in the study of confidence between the two groups, the ICC

of velocity was 0.89 and the ICC of cadence was 0.92, and the ICC was measured at a slower rate than the target (0.69 m/s). Bilney et al. (2003) had a distance of 3 m before and after in the gait analysis of normal participants using the gait analysis system and examined the reliability between slow, normal, and fast velocity, with three repeated measurements, which showed that the ICC for slow, normal, and fast gait velocity was 0.99, and the ICC for cadence was 0.99. In this study, we found an ICC of 0.893 for the affected side swing phase, 0.940 for the non-affected side swing phase, 0.893 for the affected side stance phase, and 0.993 for the non-affected side stance phase. Werner et al. (2019) conducted a reliability check between the smart walker and the gait analysis system, with a distance of 1 m at the beginning and end of the swing phase, and found an ICC of 0.72. The ICC of the stance phase was 0.83. and the gait velocity was measured at a fast velocity. In this study, the ICC for the affected side single support was 0.812, the ICC for the non-affected side single support was 0.767, the ICC for the affected side 3 was 0.758, and the ICC for the non-affected side double support was 0.773. Latorre et al (2019) performed a one-minute walk test on patients with stroke and those without stroke using a Kinect v2 camera and a 10-meter walk test to analyze gait at a velocity of 0.970, and found an ICC of 0.939 for cadence, and double support time of 0.904. To avoid errors during measurement, it was conducted at a deserted velocity and the participants walked at a comfortable velocity of their choice. Gait analysis of patients with stroke was conducted through a 10-m walk test. At the start of the gait, the participant was instructed to move the leg on the affected side first (Delafontaine et al., 2019), with measurements showing positive intraparty correlation at velocity, cadence, swing phase, stance phase, single support, and double support. Based on the evidence that the gait velocity of the participants can be constant on the gait mat at a distance of 1–3 m before and after considering acceleration and deceleration (Wang et al., 2012). This study minimizes errors in measurement by placing the participant 2 m from the starting point in the gait analysis. The gait measurement is believed to have high correlation at low velocity, self-contained velocity, and especially at high velocity (Cleland et al., 2019), the latter of which has also been equally rapid in this study, positively affecting the intra-level correlation between the velocity and cadence between the two measurements. The reliability of single and dual supports was relatively lower than that of other items, resulting in foot drop (Campbell et al., 2010), and causing gait problems due to pressure on the soleus and Achilles tendons (Park et al., 2019) in patients with stroke. These problems may have been limited (Braun et al., 2015) by data input to the smart insole for individuals built on pressure sensors, such as accurate footprint recognition error problems, reduced stability (Törnborn et al., 2017) during walking, and the use of gait aids. Smart insoles are measured (Seo et al., 2020) by placing them in the shoes, and the pressure generated while walking is attached to the front of the footpad so that data are collected through the sensor of the insole (Abdul Razak et al., 2012). Considering the various foot sizes of stroke patients, smart insoles measuring from 220 mm to 280 mm in thickness were prepared. However, the front of the feet did not make contact with the smart insoles during gait for those patients wearing 5-mm shoes, such as 225 mm, 235 mm, and 245 mm. If these problems are not solved, the data may differ from barefoot measurements (Braun et al., 2015). Due to the high heel area of the smart insole, the problem of not fitting into the patients' shoes, and the lack of flexibility of the insole during walking, we were not able to exclude hard and foreign feelings. As the participants walked three times on the gait mat, the time before the information of the smart insole was sent to the tablet or PC and converted was longer than the time taken with the gait analysis system; the patients thus had to wait before walking again. Objective evaluation of the functional state of the patient after stroke is essential, but stroke evaluation measures are limited. After moving to a designated place to evaluate patients with stroke at a

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hospital, there is a situation where evaluations are made or a new hall is needed to install the evaluation equipment. Gait analysis is possible using a smart insole, regardless of the time and place, because there are no time or space constraints at home or in hospital, and gait can be measured and used for education (Seo et al., 2020). The limitations of this study are that due to the nature of hospitals, fewer patients were hospitalized and outpatients were selected according to the criteria; thus, it is difficult to generalize the findings regarding gait analysis to all patients with stroke. We consider that a more accurate measurement would have been made if a gait analysis study had first been conducted on a patient with stroke, then on a group of participants without stroke, to correct trial errors and problems sufficiently before performing the measurements on a participant with stroke. This study tested the reliability of smart devices for gait analysis in patients with stroke and showed a positive ICC in both measured temporal gait variables. In future studies, more diverse patients with stroke are required. In addition, modifications of the pressure information transmission and information processing methods are required to adapt to the gait characteristics of patients with stroke. If the methods are improved and more flexible materials are used, the systems will be more suitable for gait analysis in patients with stroke. Continuous development and research is needed for gait analysis of all patients with stroke in line with the increasingly simplified and convenient types of wearable equipment.

## V. Conclusion

This study was conducted to test the reliability of a smart insole for the gait analysis of stroke patients. The study found that the smart insole for gait analysis in stroke patients was comparable to the gait analysis system for velocity, cadence, swing phase, stance phase, single support, and double support. The values for these were ICC=0.982 for velocity, ICC=0.905 for gait, and ICC=0.893 for damage. A value of 73 is shown. Therefore, the smart insole used in this study may be suitable clinical gait analysis equipment for future patients with stroke.

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