





# Validation of the short physical performance battery via plantar pressure analysis using commercial smart insoles

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# Validation of the short physical performance battery via plantar pressure analysis using commercial smart insoles

Directed by Professor Jung Hyun Park

The Master's Thesis submitted to the Department of Medicine, the Graduate School of Yonsei University in partial fulfillment of the requirements for the degree of Master of Medical Science

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#### ABSTRACT

#### Validation of the short physical performance battery via plantar pressure analysis using commercial smart insoles

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(Directed by Professor Jung Hyun Park)

Background: The short physical performance battery (SPPB) is a test that measures the time it takes for the examinee to complete specific tasks independently and evaluates the risk of the subject falling based on their score. However, the standardized protocol of the SPPB using a stopwatch can lead to inaccuracies in test results due to human errors. The aim of this study is to utilize the smart insole equipped with a plantar pressure measurement function to conduct the SPPB assessment. We will then compare the results obtained using the smart insole with those obtained using a manual method with a stopwatch to validate its accuracy. Furthermore, we intend to propose the adoption of the smart insole as an efficient SPPB evaluation system.

Methods: This is a prospective, cross-sectional study conducted at the rehabilitation clinic of a tertiary-care hospital. Our study cohort consisted of inpatients and outpatients aged 50 years or older who were capable of independent walking (N = 40). We administered the SPPB concurrently using commercial smart insoles (SPPB-SI) and a manual method with a stopwatch (SPPB-M). The plantar pressure data collected from the smart insoles were employed to calculate the SPPB-SI scores. In addition to assessing the correlation between the SPPB-SI and SPPB-M, this study also explored the associations between the SPPB scores and various geriatric functional parameters. The statistical analysis method for this study involves assessing the agreement of the SPPB-SI and SPPB-M results using the



intraclass correlation coefficient test and the correlation analysis between the SPPB-SI and secondary variables is conducted using the Spearman correlation coefficient.

Results: A total of 40 participants with a mean age of  $72.98 \pm 9.27$ , mean total SPPB-SI score of  $7.72 \pm 2.50$ , and mean total SPPB-M score of  $7.95 \pm 2.63$  were included. The ICC between the total SPPB-SI and SPPB-M scores was  $0.831 \ (p < .001)$ , and that between component scores of the two measurements was  $0.896 \ (p < .001)$  for the balance test,  $0.901 \ (p < .001)$  for the gait speed test, and  $0.837 \ (p < .001)$  for the five chair stand test. The correlations with geriatric functional parameters remained consistent for both SPPB-SI and SPPB-M.

Conclusions: The use of commercial smart insoles for plantar pressure analysis in the SPPB highlights the potential of these devices as reliable tools for conducting SPPB assessments.

Key words : aged, frailty, plantar pressure, short physical functional performance battery, smart insole



#### Validation of the short physical performance battery via plantar pressure analysis using commercial smart insoles

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#### I. INTRODUCTION

The short physical performance battery (SPPB), first described in 1994 by Guralnik et al., is a clinical examination tool used to measure functional status and physical performance of the lower extremities.<sup>1</sup> It consists of three components: the balance, gait speed, and five chair stand tests.<sup>1</sup> Each test can be obtained from 0 to 4 points, and their total score ranges from 0 (worst) to 12 (best), with higher scores indicating better function.<sup>1</sup> The SPPB has primarily been utilized in the evaluation of older patients and has been identified as a diagnostic criterion for various geriatric syndromes in previous studies.<sup>2-4</sup>

In the standardized protocol of the SPPB, each component is measured manually using a stopwatch.<sup>5,6</sup> The score is calculated by an examiner who manually records the time taken for the completion of each test using a handheld stopwatch based on a predefined criterion.<sup>1</sup> However, this measurement method is prone to human error, potentially introducing variations in results due to differences in examiner skills and experience.<sup>7,8</sup> Currently, efforts are underway to address the limitations of the manual stopwatch approach by developing innovative devices that can provide more objective measurements for the SPPB.<sup>7,9</sup> Nevertheless, these devices are still in the research stage or are limited by space and cost. Consequently, further advancements are needed to improve the accuracy and accessibility of objective measurements in assessing physical performance with the SPPB.



Over the last decade, there has been a significant influx of wearable devices into our daily lives, designed for purposes such as fitness monitoring, disease detection, and healthcare promotion.<sup>10,11</sup> The market for these devices is continuously expanding, with new innovations emerging regularly. For these devices to seamlessly integrate into our routines, they must possess key attributes, including being lightweight, discreet, portable, user-friendly, cost-effective, and equipped with a prolonged battery life. Among the myriad wearable options available, smart insoles are gaining popularity as the preferred choice for everyday living. These innovative insoles meet the essential criteria, making them ideal for various applications. Furthermore, smart insoles serve as valuable complements to ubiquitous smartwatches and smartphones, which are typically positioned on the upper limbs or trunk.<sup>12</sup> By focusing on lower limb information, smart insoles contribute to the establishment of comprehensive body sensor networks.

In recent times, smart insoles capable of real-time measurement of plantar pressure during daily activities have entered the market, offering a compelling solution at reasonable prices.<sup>13-15</sup> Since the inception of smart insoles, numerous studies have explored their applications in the medical field. These studies encompass a wide range of areas, including but not limited to gait and posture stability analysis, prevention of foot wounds in individuals with diabetes, and assessment of fall risk in older adults by analyzing the distribution of plantar pressure.<sup>16-20</sup> Notably, several studies have reported high accuracies for gait and postural analysis based on real-time plantar pressure monitoring, leading to a gradual expansion of applications for smart insoles.<sup>21</sup>

Given the advantages of smart insoles—high accuracy, cost-effectiveness, low power consumption, and portability—it was expected that they could effectively conduct the SPPB. We anticipated a strong agreement between conventional manual stopwatch methods and newly introduced protocols with smart insoles. To validate this, we aimed to confirm SPPB results by measuring plantar pressure changes with commercial smart insoles and comparing them to examiner-recorded stopwatch data. Based on these findings, we propose integrating smart insoles as a novel system for SPPB measurements.



#### **II. MATERIALS AND METHODS**

#### 1. Study population

This study prospectively enrolled participants from both inpatient and outpatient rehabilitation clinics at the Gangnam Severance Hospital between January and May 2023. Eligible participants were as follows; 1) individuals aged 50 years or older; 2) those who were capable of walking independently, with or without a gait aid; and 3) those who possessed sufficient cognitive function to perform the required tests as per medical instructions. The exclusion criteria were as follows; 1) individuals who were unable to walk alone without someone's help; 2) those who had acute medical or surgical conditions; 3) those who had a terminal illness with a life expectancy of less than 6 months; and 4) those who are with cognitive impairments that prevented them from filling consent forms or following medical staff instructions.

#### 2. Ethical approval

The study protocol was approved by the Institutional Review Board and Ethics Committee of Gangnam Severance Hospital (No. 3-2022-0440). All participants provided written informed consent by themselves. The study protocol adheres to the ethical guidelines outlined in the 1975 Declaration of Helsinki.

#### 3. Commercial smart insoles

In this study, we utilized commercially available smart insoles I-SOL® (Gilon, Seongnam, Republic of Korea), to collect plantar pressure data. As illustrated in Figure 1, each insole was equipped with four circular force-sensitive resistor (FSR) sensors with a diameter of 14 mm each, and a triaxial accelerometer sensor (Bosch, Gerlingen, Germany). Additionally, the insoles contained a low-energy Bluetooth module (Nordic Semiconductor, Trondheim, Norway) and replaceable coin-type battery. The FSR sensors precisely detected changes in force at four specific key points which are hallux, medial forefoot,



lateral forefoot, and heel (Figure 2). The accelerometer sensors accurately captured the acceleration along the X-, Y-, and Z-axes. The data were collected at a frequency of 40 Hz using a Raspberry Pi 3 system.

The smart insole had a thickness of 6.0 mm at the front, 10.5 mm in the middle, and 10.0 mm at the back, with a total weight of 60 g. It was offered in a range of sizes, increasing in 5 mm increments, from 230 mm to 280 mm. Each participant had the opportunity to choose the size that best suited their feet.

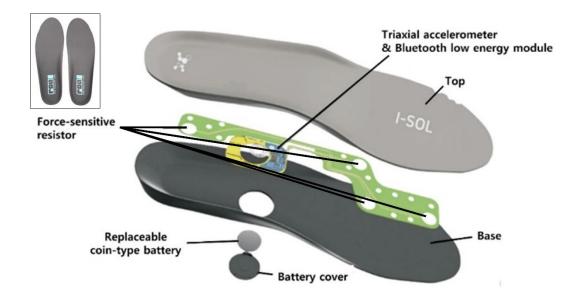
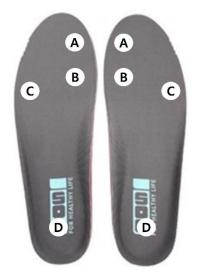


Figure 1. Smart insoles, I-SOL® (Gilon, Seongnam, Korea), and the layout of the smart insoles.





**Figure 2.** Positions of four force-sensitive resistor sensors in smart insoles. (A) Hallux, (B) medial forefoot, (C) lateral forefoot, and (C) heel.

4. SPPB measurement (the balance, gait speed, and five chair stand tests)

This study involved simultaneous administration of the SPPB measurement using smart insoles (SPPB-SI) and manual measurement of the SPPB using a manual method with a stopwatch (SPPB-M). Prior to the commencement of the study, the examiner underwent specific training to administer the SPPB by measuring the performance of five participants. The measurements consisted of three tests: the balance, gait speed, and five chair stand tests. For SPPB-SI, the participants performed each component of the SPPB while wearing the smart insoles. Concurrently, for the SPPB-M, an examiner administered the SPPB using a standardized protocol, relying on a stopwatch as described in a previous study.<sup>1</sup>

The balance test assessed the standing balance of the participants in three different positions: the side-by-side, semi-tandem, and tandem stances. In the semi-tandem stance, one foot's heel is placed on the toes of the other foot, while in the tandem stance, one foot's heel is positioned directly in front of the toes of the other foot. In each stance, participants were instructed to maintain the position for a maximum of 10 seconds, using their trunk



and arms for support if necessary. The examiner provided support by holding one of the participant's arms or a participant could lean against a wall while positioning his feet. The examiner would ask if they were ready, and once confirmed, the support was released, and the timing began. The semi-tandem stance was the first to be assessed, and if a participant couldn't maintain it for more than 10 seconds, the side-by-side position was tested instead. Timing was halted if participants moved their feet, sought support from the examiner, or when the full 10 seconds had passed. The tandem stance was assessed if the semi-tandem stance was successfully maintained for > 10 seconds. The duration of each position was recorded.

The gait speed test measured the participant's gait speed over a 4 meter distance, with or without the use of a gait aid. Participants were instructed to walk at their usual pace. The examiner recorded the time taken to complete the 4 meter distance or the maximum time if the distance was not fully covered. If possible, the test was performed twice and the faster time recorded was used for analysis.

In the five chair stand test, participants were given the instruction to rapidly stand up and sit down five times while crossing their arms. A chair with a straight back was employed for this purpose. The recorded measurement was the time taken to complete the entire task, which encompassed the duration from the initial seated position to the final standing position at the end of the fifth stand.

Furthermore, the scores of each component of the SPPB were calculated based on established cutoff points (Table 1).<sup>1</sup> A summary performance scale was generated by summing the scores from the three component tests to provide an overall assessment.



Tests	Time (seconds)	Score	Total
Balance test			4
Side-by-side stance	> 10	1	
Semi-tandem stance	> 10	1	
Tandem stance	> 10	2	
	3 - 10	1	
	< 3	0	
Gait speed test			4
	< 4.82	4	
	4.83 - 6.20	3	
	6.21 - 8.70	2	
	> 8.70	1	
	Unable to walk	0	
Five chair stand test			4
	< 11.19	4	
	11.20 - 13.69	3	
	13.70 - 16.69	2	
	16.70 - 60.00	1	
	> 60.00 or unable to perform	0	
Total			12

**Table 1.** Scoring systems of the short physical performance battery.



5. Interpretation of variations in measured plantar pressure

The plantar pressure obtained from the four FSR sensors was converted to kilopascal (kPa) units using the equations mentioned in a previous study as follows.<sup>13</sup>

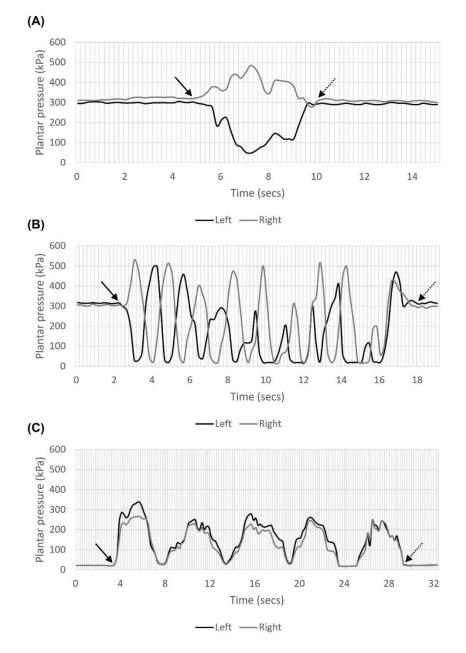
Pressure 
$$kPa = 10.7835 + 0.0587 \times FSR + 0.0004 \times FSR^2$$

We calculated the total plantar pressure of each feet by adding all pressure values. Based on this value, the change of the plantar pressure of each left and right over time was converted to a time-pressure graph. Examples of plantar pressure graphs for each SPPB component are shown in Figure 3.

Two independent interpreters who were blinded to the demographic and clinical parameters of the participants reviewed the graphs of a time-pressure curve on each side and determined the starting and ending points of the test based on the change in graph pattern (Figure 3). The starting point was the point at which the baseline pressure in a stable state rapidly changes upward or downward, and on the contrary, the ending point at which the pressure began to stabilize at the original baseline pressure level was the ending point. For the interpretation, 200 milliseconds vertical grids were introduced in the graphs to determine the time points. In cases where establishing these points was challenging, the interpreters engaged in discussions and reached a mutual agreement.

To assess the reliability between interpreters, two interpreters analyzed the plantar pressure graphs on the same day, and their results were compared. Additionally, to confirm the reliability within each interpreter, they re-analyzed plantar pressure graphs of all subjects at one-week intervals. In both analyses, the time elapsed between the starting and ending points was calculated, and the score of the SPPB was subsequently determined based on this data.





**Figure 3.** Examples of the plantar pressure graph for the short physical performance battery. (A) The balance, (B) gait speed, and (C) five chair stand tests. The solid black line represents the starting point, and the black dashed line indicates the endpoint.



#### 6. Covariables

Various functional geriatric parameters were estimated to assess the clinical relevance of the SPPB-SI results. For frailty status, we used the Korean version of the fatigue, resistance, ambulation, illnesses, and loss of weight scale (K-FRAIL, Appendix 1), which is derived from the original FRAIL scale and has been validated in diverse populations.<sup>22</sup> This straightforward screening tool consists of five self-reported items and can be administered within 2 - 3 minutes, without the need for any specialized equipment. Individuals indicating 1 - 2 positive items are categorized as prefrail, while those indicating 3 - 5 positive items are categorized as frail.<sup>23</sup>

Grip strength was measured using a handgrip dynamometer, with participants seated and their elbows resting on a table at a 90 degree bent angle. The maximum grip strength of both arms, measured twice for each arm, was used for analysis. In cases where only one arm was measured, the assessment was conducted on the dominant hand.

Functional capacities and activities of daily living were determined using the Korean version of the modified barthel index (K-MBI, Appendix 2).<sup>24</sup> The fall risk was assessed using the Korean version of berg balance scale (K-BBS, Appendix 3) which is a 14 item scale that quantitatively assesses balance and risk for falls in older community dwelling adults through direct observation of their performance.<sup>25</sup> Additionally, functional ambulatory category (FAC, Appendix 4) was used to determine the amount of physical support required for walking.<sup>26,27</sup> FAC categorizes walking ability based on the degree of physical support needed, ranging from 0 (non-functional ambulator) to 5 (independent ambulator on both level and non-level surfaces).<sup>27</sup> Cognitive function was evaluated using the Korean mini-mental state examination (K-MMSE, Appendix 5).<sup>28</sup>

Demographic information was also recorded for each participants, including age, sex, height, and weight.

#### 7. Statistical analysis

The sample size was calculated using tables based on Zou's formulas to evaluate the



intraclass correlation coefficient (ICC) between the SPPB-SI and SPPB-M.<sup>29</sup> With an ICC of 0.80 assumed as a priori, study power of 0.80 (1 -  $\beta$ ), and 95 % confidence interval half-width of less than 0.15, the study required 35 participants. To account for a possible 10 % dropout rate or exclusion during the testing process, our goal was to recruit 40 participants.

We employed the Pearson correlation coefficient and  $\kappa$  coefficient to establish the reliability between the time and scores recorded by the two interpreters for SPPB based on the plantar pressure graph, respectively. To visualize the concordance between the time measurements, we created a Bland-Altman plot, which illustrates the difference plotted against the average. Subsequently, we evaluated the ICCs of the total and component scores between the SPPB-SI and SPPB-M. Scatterplots with jitters and linear regressions were used to examine correlations between the total and component scores of both SPPB measurements. Furthermore, the Spearman's correlation coefficient was used to evaluate correlations between the SPPB-SI parameters and geriatric functional parameters. We also conducted a normality distribution test, specifically the Shapiro–Wilk test, to assess the distribution of the total SPPB-SI and -M scores.

The R statistical package version 4.1.2 (R Foundation for Statistical Computing, Vienna, Austria) was used to perform all data analyses. Statistical significance was set at p < .05.



#### **III. RESULTS**

A total of 40 individuals (24 women and 16 men) were included in this study. The basic characteristics of the participants are summarized in Table 2. All participants were able to walk independently, although four required a walking aid. Despite this, they were relatively fit, as indicated by a mean K-FRAIL score of  $1.55 \pm 1.13$ , mean K-BBS score of  $43.55 \pm 12.61$ , and mean FAC score of  $4.03 \pm 1.23$ . Of the total participants, 16 were able to perform their daily activities independently, with a K-MBI score of 100 points. The average K-MBI score was  $86.83 \pm 16.74$  points. Furthermore, participants scored an average of  $27.15 \pm 1.78$  points on the K-MMSE, indicating no limitations in their ability to direct and perform the test. There were no adverse events, including falls or any pain associated with participating in the tests.



Characteristics	Total ( $N = 40$ )
Gender, women	24 (60.0 %)
Age (years), mean (SD)	72.98 (9.27)
55–64	6 (15.0 %)
65–74	11 (27.5 %)
75–84	23 (57.5 %)
BMI (kg/m2), mean (SD)	23.51 (2.33)
K-FRAIL score, mean (SD)	1.55 (1.13)
Grip strength (kg), mean (SD)	19.95 (8.89)
K-MBI score, mean (SD)	86.83 (16.74)
K-BBS score, mean (SD)	43.55 (12.61)
FAC score, mean (SD)	4.03 (1.23)
K-MMSE score, mean (SD)	27.15 (1.78)
SPPB-SI score, mean (SD)	
Total score	7.72 (2.50)
Balance test score	3.76 (0.63)
Gait speed test score	2.08 (1.19)
Five chair stand test score	2.13 (1.34)
SPPB-M score	
Total score	7.95 (2.63)
Balance test score	3.68 (0.73)
Gait speed test score	2.18 (1.17)
Five chair stand test score	2.25 (1.26)

Table 2. Characteristics of the study participants.

Abbreviations: BMI, body mass index; FAC, functional ambulatory category; K-BBS, Korean version of berg balance scale; K-FRAIL, Korean version of the fatigue, resistance, ambulation, illness, and loss of weight scale; K-MBI, Korean version of the modified barthel index; K-MMSE, Korean mini-mental state examination; SD, standard deviation; SPPB-SI, short physical performance battery measured using smart insoles; SPPB-M, short physical performance battery measured using a manual method with a stopwatch.



The results of the intra- and inter-interpreter reliability of SPPB-SI time and scores are presented in Table 3. The time recordings of each SPPB-SI component, derived from the interpretation of the time-pressure graph, exhibited outstanding intra- and inter-reliability with Pearson correlation coefficients of 0.9 or higher. A Bland-Altman concordance analysis illustrated relatively small dispersion for both intra- and inter-interpreter reliability of time recordings (Figure 4, 5). All mean differences between two measurements demonstrated very good agreement, with the mean difference staying within 0.5. The component of SPPB-SI scores based on time recordings demonstrated excellent reliability with intra- and inter-interpreter coefficients of 0.8 or higher.

**Table 3.** Intra- and inter-interpreter reliability of the short physical performance battery measured through plantar pressure graph interpretation using smart insoles.

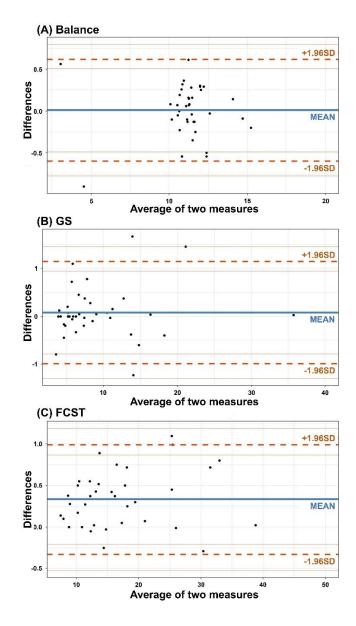
	Intra-interpreter reliability	Inter-interpreter reliability
SPPB-SI time		
Balance test time	$0.989^{*}$	0.957*
Gait speed test time	0.996*	0.993*
Five chair stand test time	0.999*	0.999*
SPPB-SI score		
Balance test score	$0.889^{*}$	$0.889^{*}$
Gait speed test score	$0.868^{*}$	$0.868^{*}$
Five chair stand test score	$0.899^{*}$	$0.865^{*}$

Score values were tested using the  $\kappa$  correlation coefficient, and time values were tested using the Pearson correlation coefficient.

Abbreviations: SPPB-SI, short physical performance battery measured using smart insoles.

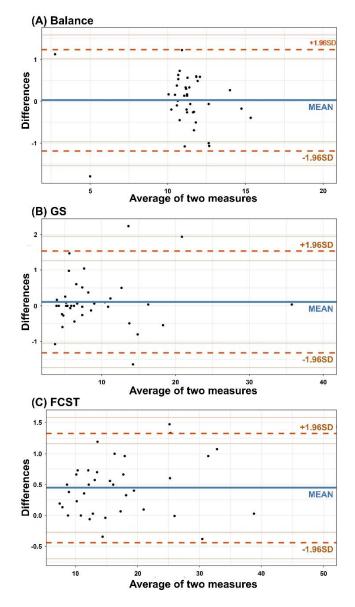
\**p* < .001





**Figure 4.** Bland-Altman plots for intra-interpreter reliability of the short physical performance battery times measured through plantar pressure graph interpretation using smart insoles. The solid horizontal line represents the mean difference, and the dotted lines represent the 95 % limits of agreement between the two measurements. (A) The balance (Balance), (B) gait speed (GS), and (C) five chair stand test (FCST).





**Figure 5.** Bland-Altman plots for inter-interpreter reliability of the short physical performance battery times measured through plantar pressure graph interpretation using smart insoles. The solid horizontal line represents the mean difference, and the dotted lines represent the 95 % limits of agreement between the two measurements. (A) The balance (Balance), (B) gait speed (GS), and (C) five chair stand test (FCST).



The mean total SPPB-SI and SPPB-M scores of the participants were  $7.72 \pm 2.50$  and  $7.95 \pm 2.63$ , respectively. The ICC between the average total SPPB-SI and SPPB-M scores was 0.831 (p < .001). The mean balance test scores for the SPPB-SI and SPPB-M were  $3.76 \pm 0.63$  and  $3.68 \pm 0.73$ , respectively, with an ICC of 0.896 (p < .001) between the two measurements. The mean gait speed test scores for the SPPB-SI and SPPB-M were  $2.08 \pm 1.19$  and  $2.18 \pm 1.17$ , respectively, with an ICC of 0.901 (p < .001) between the two measurements. The mean five chair stand test scores for SPPB-SI and SPPB-M were  $2.13 \pm 1.34$  and  $2.25 \pm 1.26$ , respectively, with an ICC of 0.837 (p < .001) between the two measurements. Correlations between the SPPB-SI and SPPB-M parameters using scatterplots with random jitters on the data points and a linear fitted line are displayed in Figure 6. Shaded areas represent the 95 % confidence intervals.

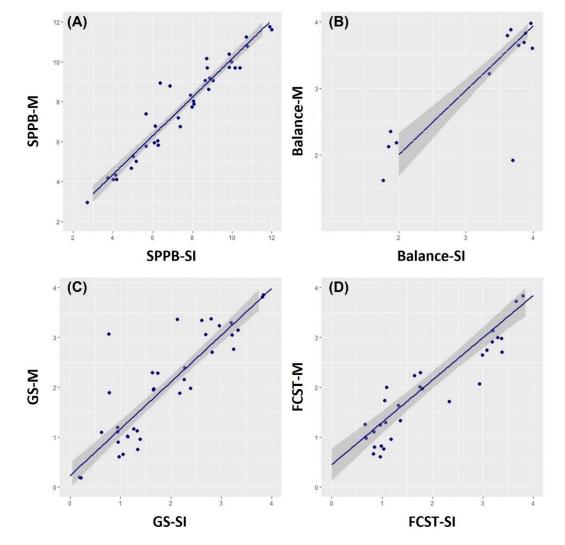
When considering a SPPB score of 9 or less as a vulnerable state, 28 and 27 individuals were classified as vulnerable by SPPB-SI and SPPB-M, respectively. The  $\kappa$  value for classifying vulnerability between the two measurements was 0.886 (p < .001).

Intraclass correlation coefficient between SPPB SI and SPPB-M *p* value SPPB score Total score 0.831 < 0.001 Balance test score 0.896 < 0.001 0.901 < 0.001 Gait speed test score Five chair stand test score 0.837 < 0.001

**Table 4.** Intraclass correlation coefficient between the short physical performance battery scores measured using smart insoles and a manual method with a stopwatch.

Abbreviations: SPPB, short physical performance battery; SPPB-SI, short physical performance battery measured using smart insoles; SPPB-M, short physical performance battery measured using a manual method with a stopwatch.





**Figure 6.** Scatterplots with jitters and linear fitted lines, including 95% confidence intervals, for scores of the short physical performance battery (SPPB) measured using a manual method with a stopwatch (M) and smart insoles (SI). (A) The total SPPB, (B) balance (Balance), (C) gait speed (GS), and (D) five chair stand scores.



To evaluate the content validity of SPPB-SI and SPPB-M, we analyzed the correlations between the SPPB parameters and commonly employed functional parameters in geriatric assessments. These measurements included K-FRAIL, grip strength, K-MBI, K-BBS, FAC, and K-MMSE scores. Correlations with these functional parameters remained consistent for both SPPB-SI and SPPB-M (Table 5).

	K-FRAIL	K-BBS	FAC	K-MBI	Grip strength	K-MMSE
SPPB-SI						
Total score	333	.686	.829	.743	.260	.303
	(.036)	(<.001)	(<.001)	(<.001)	(<.105)	(< .058)
BS	272	.360	.516	.432	.246	.091
	(.094)	(.025)	(.001)	(.006)	(.131)	(.584)
GS	349	.620	.775	.742	.276	.194
65	(.027)	(< .001)	(<.001)	(< .001)	(.085)	(.230)
FCST	165	.658	.737	.632	.201	.365
TCST	(.310)	(< .001)	(< .001)	(< .001)	(.215)	(.021)
SPPB-M						
Total score	355	.678	.836	.737	.233	.304
Total score	(.025)	(< .001)	(< .001)	(< .001)	(.148)	(.056)
BS	342	.424	.554	.471	.156	.094
5	(.031)	(.006)	.554 (< .001)	(.002)	(.338)	(.565)
<u> </u>	410	<0 <b>2</b>	001	7.40	200	100
GS	419	.682	.801	.749	.289	.199
	(.007)	(<.001)	(<.001)	(< .001)	(.071)	(.219)
FCST	220	.571	.697	.568	.157	.401
	(.172)	(<.001)	(<.001)	(<.001)	(.334)	(.010)

**Table 5.** Correlation between the short physical performance battery scores measured using smart insoles and a manual method with a stopwatch and geriatric functional parameters.

Data are presented as  $\rho$  (p-value).  $\rho$  and *p* value were obtained using the Spearman's test. Abbreviations: BS, balance test; FAC, functional ambulatory category; FCST, five chair stand test; K-BBS, Korean version of berg balance scale; K-FRAIL, Korean version of the fatigue, resistance, ambulation, illness, and loss of weight scale; K-MBI, Korean version of the modified barthel index; K-MMSE, Korean mini-mental state examination; GS, gait speed test; SPPB-SI, short physical performance battery measured using smart insoles; SPPB-M, short physical performance battery measured using a manual method with a stopwatch.



#### **IV. DISCUSSION**

This study showed a strong agreement between the total and component scores of the SPPB-SI and SPPB-M, as well as their respective counterparts in the study participants. Additionally, both SPPB-SI and SPPB-M scores were concordant with geriatric functional parameters. Moreover, we found a high degree of agreement between the measured test scores and times using a plantar pressure graph obtained from the smart insoles between interpreters. The significance of this study lies in being the first to validate the accuracy and propose the potential applicability of smart insoles in conducting the SPPB.

Several studies have previously explored the use of plantar pressure distribution obtained from smart insoles as a marker.<sup>21</sup> Specifically, a study performed in older patients has demonstrated that smart insoles can be utilized to predict fall risks and frailty.<sup>30-32</sup> More recent studies have expanded the application of plantar pressure analysis using smart insoles to include disease diagnosis. For instance, one study demonstrated the potential for early detection of Parkinson's disease using smart insoles, whereas another study suggested the use of smart insoles to predict and classify sarcopenia.<sup>19,33</sup> There are also ongoing efforts to utilize smart insoles for treatment purposes, which involve monitoring plantar pressure and inducing alterations in its distribution.<sup>34</sup>

While smart insoles have gained traction in the medical field, there has been a notable absence of analysis regarding their utilization for conducting the SPPB. As the society ages, evaluating the functional abilities of older individuals becomes increasingly important.<sup>35</sup> In this context, the SPPB is widely used and has proven to be an effective assessment tool.<sup>36</sup> In other words, the ability to more conveniently and correctly measure the SPPB in everyday life carries significant implications for an aging society. Thus, our study's successful demonstration of conducting the SPPB through plantar pressure analysis using smart insoles not only introduces the feasibility of this approach but also establishes a solid foundation for the effortless integration of the SPPB into diverse clinical settings and research initiatives.



Our results offer compelling evidence to support these assertions. The SPPB results, whether measured manually using a stopwatch or through smart insoles, demonstrated a significant level of consistency. Scores for each component of the SPPB also exhibited a comparable level of agreement. Conducting both tests simultaneously and given that smart insoles were inserted into the patient's shoes during the examination, the likelihood of influencing the results is minimal. Considering this, the substantial agreement between the two tests suggests that smart insoles can effectively replace the traditional stopwatch method.

Moreover, maintaining a consistent level of correlation with various geriatric functional assessment parameters adds further significance to the results of our study. Additionally, a high level of agreement was observed in the evaluation that identifies vulnerable status based on the total SPPB score. This not only confirms measurement accuracy but also suggests that smart insoles can serve as a viable alternative for assessing the clinical status of patients. The potential for such substitution is noteworthy, as it establishes a foundation for the continuous assessment of lower extremities function in elderly patients during their daily lives using smart insoles.

In this study, two independent interpreters were responsible for manually analyzing the plantar pressure graphs obtained from the smart insoles. While the results indicated a notably high level of reliability both within and between interpreters concerning the timing and scoring of SPPB, it's important to acknowledge that the analysis of plantar pressure graphs presents a significant challenge for future research. We believe that employing an automated algorithm, utilizing data from the plantar pressure fluctuation graphs, could offer a promising solution to this issue. In fact, there have been efforts to develop algorithms specifically designed for the analysis of plantar pressure parameters in distinct anatomical regions of the foot.<sup>37</sup> Furthermore, there have been reports of gait monitoring and fall detection systems incorporating automated algorithms for plantar pressure analysis, with some of these systems currently undergoing commercialization.<sup>38,39</sup> This advancement in smart insoles holds the potential to facilitate continuous monitoring of the functional status



and physical performance of the lower extremities in the daily lives of older individuals.

A noteworthy discovery in this study is that the agreement between the two measurement methods was higher for time measurements compared to scores of the SPPB. Paradoxically, this underscores the critical importance of precise time measurements. Although the test-retest reliability of the SPPB-M was acceptable and the minimal detectable change of it was reported as 1.7 points, which is larger than the gap between the two measurement methods in the study,<sup>40</sup> even slight variations in timing can lead to corresponding increases in score discrepancies. This highlights the need for the development of a new, more accurate, and consistently repeatable method, as opposed to relying on a stopwatch prone to potential human error.

This study had some limitations. First, the SPPB was performed by a single examiner. Although we acknowledge the possibility of human error in this test, we ensured accuracy by providing training with five participants and following standardized protocols during the assessment. Second, after converting the measured plantar pressure into a time-curve graph, the interpreter noted the corresponding time based on the changes observed in the graph. To address potential concerns, two independent interpreters evaluated the graph to ensure high inter- and intra-interpreter reliability. Third, we only used the results from FSR sensors except for the results from the accelerometer sensor. It is significant that the results of plantar pressure change alone confirmed a significant correlation, but further research and automated algorithm development will need to include acceleration sensor data. Finally, we included six participants aged < 65 years. This study sought to validate the accuracy of the SPPB using smart insoles by analyzing the results across various age groups, not restricting the study solely to elderly patients. In fact, when subjected to a normality distribution test, specifically the Shapiro-Wilk test, the distribution of both the total SPPB-SI and SPPB-M scores exhibited a normal distribution pattern. In simpler terms, this study design was significant because it demonstrated that the results of the two measurement methods were consistent across various score distributions of the SPPB.



#### V. CONCLUSION

The SPPB-SI, based on plantar pressure analysis using commercial smart insoles, demonstrated excellent agreement with the SPPB-M measured using a standardized protocol. These findings highlighted the potential of smart insoles as reliable SPPB inspection devices. In the future, the use of automated algorithms to analyze plantar pressure graphs may further validate this possibility.

#### 연세대학교 YONSEI UNIVERSITY

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#### APPENDICES

**Appendix 1.** The Korean version of the fatigue, resistance, ambulation, illnesses, and loss of weight scale (K-FRAIL).<sup>23</sup>

Domain	Question	Scoring
Fatigue (피로)	지난 한 달 동안 피곤하다고 느낀 적이 있습니까?	1 = 항상 그렇다 2 = 거의 대부분 그렇다 3 = 종종 그렇다 4 = 가끔씩 그렇다 5 = 전혀 그렇지 않다
Resistance (저항)	도움이 없이 혼자서 쉬지 않고 10 개의 계단을 오르는데 힘이 듭니까?	0 = 아니요 1 = 예
Ambulation (이동)	도움이 없이 300 미터를 혼자서 이동하는데 힘이 듭니까?	0 = 아니요 1 = 예
Illness (지병)	의사에게 다음 질병이 있다고 들은 적이 있습니까? (고혈압, 당뇨, 암, 만성 폐 질환, 심근 경색, 심 부전, 협심증, 천식, 관절염, 뇌경색, 신장 질환)	$0 = 0 \sim 4$ 7 $1 = 5 \sim 11$ 7 1
Loss of weight (체중 감소)	현재와 1년 전이 체중은 몇 kg 이었습니까?	0=5% 미만 감소 1=1년 간 5% 이상 감소

The scores for each domain are summed to calculate the total score. A total score of 0 indicates robustness, 1 to 2 suggests prefrailty, and 3 to 5 signifies frailty.



	1	2	3	4	5
	과제를	최대의	중등도의	최소의	완전히
항목	수행할 수	도움이	도움이	도움이나 감시가 필요한	독립적인
	없는 경우	필요한 경우	필요한 경우	감지가 걸표한 경우	경우
개인위생	0	1	3	4	5
목욕하기	0	1	3	4	5
식사하기	0	2	5	8	10
용변처리	0	2	5	8	10
계단 오르기	0	2	5	8	10
옷 입기	0	2	5	8	10
대변조절	0	2	5	8	10
소변조절	0	2	5	8	10
보행	0	3	8	12	15
의자 차*	0	1	3	4	5
의자/침대 이동	0	3	8	12	15
총점	0 / 100				

Appendix 2. The Korean version of the modified barthel ind	lex (K-MBI). <sup>24</sup>
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\*Assessment in case of inability to walk.



번호	내용	지시
1	앉은 상태에서 서기	서 보세요. 이때 지지하기 위해 두 손을 사용하지
		마십시오.
2	도움 없이 서 있기	붙잡지 말고 2분 동안 서 있어 보세요.
3	기대지 않고 스스로 앉기	두 팔에 의지하고 2분간 앉아 있으세요.
4	선 상태에서 앉기	앉아보세요.
5	이동하기	한쪽으로 이동할 수 있도록 의자를 배열해 놓는다.
		팔걸이가 있는 의자로 가도록 환자에게 이동을
		요구한다. 그리고 팔걸이가 없는 의자로 가도록
		환자에게 이동을 요구한다.
6	눈감고 서 있기	두 눈을 감고 10초 동안 서 있어 보세요.
7	양 발을 모으고 서 있기	양 발을 모으고 잡지 말고 서 보세요.
8	선 자세에서 팔을 펴고 뻗기	팔을 90 도로 올리세요. 손가락을 펴고 가능한 한
		앞쪽으로 멀리 뻗어보세요.
9	선 상태에서 바닥에서 물건	피검자의 발 앞에 있는 신발/슬리퍼를 집어보세요.
	잡아 올리기	
10	서서 양쪽 어깨를 넘어	
	뒤돌아보기	우측 어깨를 넘어 뒤를 돌아보세요.
11	360도 돌기	한 바퀴를 완전히 돌고 또 반대 방향으로 한 바퀴를
10		완전히 돌아보세요.
12	선 자세에서 발판에 양 발을	양 발을 발판에 각각 교대로 올려놓아 보세요. 4 번
12	교대로 놓기	반복해서 양 발을 교대로 발판에 올려놓아 보세요.
13	한 발을 다른 발 앞에 놓고	한 발을 다른 발 바로 앞에 놓는다. 피검자가 발을
	지지 없이 서 있기	다른 발의 바로 앞에 놓고 설 수 없다면, 설 수 있을
		만큼 발을 앞으로 더 내밀어 앞발의 뒤꿈치가 뒷발의
14		앞꿈치보다 앞으로 가게하고 서도록 한다.
14	한 발로 서 있기	잡지 말고 가능한 한 오래 한 발로 서 보세요.
총합	/ 56	

Appendix 3. The Korean version of berg balance scale (K-BBS).<sup>41</sup>



Category	Level	Description
0	Nonfunctional ambulator	A patient who is not able to walk at all or needs the help of 2 therapists
1	Ambulator, dependent on physical assistance [level II]	A patient who requires continuous manual contact to support body weight as well as to maintain balance or to assist coordination
2	Ambulator, dependent on physical assistance [level I]	A patient who requires intermittent or continuous light touch to assist balance or coordination
3	Ambulator, dependent on supervision	A patient who can ambulate on level surface without manual contact of another person but requires standby guarding of one person either for safety or for verbal cueing
4	Ambulator, independent, level surface only	A patient who can ambulate independently on level surface but requires supervision to negotiate (eg, stairs, inclines, nonlevel surfaces)
5	Ambulator, independent	A patient who can walk everywhere independently, including stairs

Appendix 4. The functional ambulatory category (FAC).<sup>26</sup>



하목	내용
1. 시간지남력	1. 년 (1)
	2. 월 (1)
	3. 일 (1)
	4. 요일 (1)
	5. 계절 (1)
2. 장소지남력	1. 나라 (1)
	2. 시/도 (1)
	3. 현재 장소명 (1)
	4. 몇층 (1)
	5. 무엇하는 곳 (1)
3. 기억 등록	1. 비행기 (1)
	2. 연필 (1)
	3. 소나무 (1)
4. 주의집중과 계산	$\begin{array}{ccc} 1.100 - 7(1) \\ 2. & -7(1) \end{array}$
	3. $-7(1)$
	$\begin{array}{ll} 4. & -7(1) \\ 5. & -7(1) \end{array}$
5. 기억회상	1. 비행기 (1)
	2. 연필 (1)
	3. 소나무 (1)
6. 언어	1. 이름대기 (2):(손목)시계 (1), 볼펜 (1)
	2. 명령시행 (3): "종이를 뒤집고 (1), 반으로 접은 다음 (1), 저에게
	주세요 (1)."
	3. 따라 말하기 (1):"백문이 불여일견"
	4. 읽고 그대로 하기 (1):"눈을 감으세요"
	5. 쓰기 (1):"오늘 기분이나 오늘 날씨에 대해서 써 보십시오."
7. 시각적 구성	보고 그리기 (1):"오각형"
	$\land$
	$\langle X \rangle$
	LX
총점	/ 30

Appendix 5. The Korean mini-mental state examination (K-MMSE).<sup>28</sup>

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ABSTRACT (IN KOREAN)

스마트 인솔 적용 족저압 분석을 통한 간편신체수행평가 시스템 검증

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배경: 간편신체수행평가 (short physical performance battery)는 대상자가 독립적으로 특정 작업을 수행하는 데 소요되는 시간을 측정하고, 그 시간에 따른 점수를 기반으로 대상자의 낙상 위험을 평가하는 툴이다. 표준화된 간편신체수행평가는 초시계를 이용하여 검사자가 직접 검사 시간을 측정하며, 이는 검사자 오류로 인한 평가 결과의 부정확성에 취약하다. 따라서, 본 기능이 탑재된 스마트 연구는 족저압 측정 인솔을 활용하여 간편신체수행평가를 시행하며, 그 결과와 검사자가 초시계를 이용하여 측정한 간편신체수행평가 결과를 서로 비교하여 그 정확도를 확인하고, 이를 통해 스마트 인솔을 효과적인 간편신체수행평가 시행 도구로서 제안하고자 하였다. 방법: 본 연구는 전향적 단편 연구로 50세 이상이며 독립적 보행이 가능한 황자 40명을 대상으로 하였다. 초시계와 스마트 인솔을 이용하여 간편신체수행평가를 검사하며, 그 결과값을 비교하였다. 또한, 스마트 인솔을 이용하여 구한 간편신체수행평가 결과값과 다양한 노인의 기능적 변수와의 연관성을 분석하였다. 본 연구의 통계적 분석 방법은 초시계와 스마트 인솔을 이용하여 측정한 간편신체수행평가 결과값에 대한 일치도 분석에는 급내상관계수 (intraclass correlation coefficient)를, 스마트 인솔을 이용하여 측정한 간편신체수행평가 결과값과 노인의 기능적 변수와의 상관성 분석에는 스피어만 상관 계수 (Spearman correlation coefficient)를 사용하였다.

결과: 총 40명이 본 연구에 참여하였으며, 그들은 평균 연령 72.98 ± 9.27세였으며, 평균 스마트 인솔 이용 총 간편신체수행평가 점수는 7.72 ± 2.50, 그리고 평균 초시계 이용 총 간편신체수행평가 점수는 7.95 ± 2.63 였다. 이 둘 간의 급내상관계수는 0.831 (*p* < .001) 이었고, 두 측정의 세부 항목 결과



간의 급내상관계수는 각각 균형검사는 0.896 (p < .001), 보행속도검사는 0.901 (p < .001), 그리고 의자에 앉았다 일어나기 검사는 0.837 (p<.001) 였다. 노인의 기능적 변수와의 스피어만 상관 관계는 스마트 인솔 이용 간편신체수행평가 결과값과 초시계 이용 간편신체수행평가 결과값에서 모두 일관되게 유지되었다.

결론: 스마트 인솔을 이용한 족저압 분석 기반 간편신체수행평가 수행 결과와 초시계를 이용한 간편신체수행평가 결과의 비교를 통해, 스마트 인솔이 간편신체기능평가를 수행할 수 있는 신뢰성 있는 도구로 활용할 수 있음을 입증하였다.

핵심되는 말 : 간편신체수행평가, 고령, 노쇠, 스마트 인솔, 족저압



### PUBLICATION LIST

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