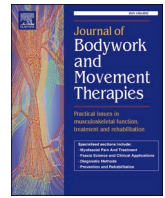




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## Validation of the Lower Extremity Motor Activity Log (LE-MAL) questionnaire with triaxial accelerometry-based activity monitors in chronic post-stroke hemiparesis

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## ABSTRACT

**Background:** Post-stroke hemiparesis commonly reduces mobility, limiting daily activities and participation. Objective monitoring, such as step counting, quantifies real-world ambulatory activity, while patient-reported outcome measures (PROMs) capture perceived functional performance. The Lower Extremity Motor Activity Log (LE-MAL), translated into Portuguese, assesses self-reported use of the more affected lower limb.

**Objective:** To examine the criterion-related validity of the LE-MAL by evaluating its association with step counts obtained from triaxial accelerometry activity monitors. **Methods:** In this cross-sectional validation study, 31 individuals with chronic post-stroke hemiparesis wore activity monitors for at least 10 h/day over three consecutive days. The LE-MAL was administered via structured interview. Criterion-related validity was assessed using Pearson's correlation coefficient. Agreement was further explored using the intraclass correlation coefficient (ICC; two-way mixed-effects model, consistency) and Bland–Altman analysis.

**Results:** The LE-MAL total score showed a positive, moderate correlation with the 3-day average step count ( $r = 0.52$ ,  $p < 0.01$ ). Agreement between LE-MAL scores and step counts was low (ICC<sub>single</sub> = 0.001, 95% CI –0.35 to 0.35;  $p = 0.497$ ), consistent with conceptual and metric differences between a PROM and an objective activity count. Bland–Altman analysis indicated a mean bias close to zero, wide 95% limits of agreement, and no evidence of proportional bias.

**Conclusion:** The LE-MAL demonstrates a positive, moderate association with objectively measured step counts, supporting its criterion-related validity as a PROM of perceived real-world use of the more affected lower limb. Used alongside activity monitoring, it may help clinicians interpret ambulatory behavior in individuals with chronic post-stroke hemiparesis.

### 1. Background

Hemiparesis is one of the most common disabilities following a stroke, characterized by loss of strength, muscular hyperactivity, and soft tissue contracture in the more affected hemibody (Lattouf et al., 2021). Despite these changes in body function, 52–85% of people with post-stroke hemiparesis regain their ability to walk, albeit with motor patterns different from those of individuals without disabilities. The main differences include reduced speed, step size, walking distance, and difficulty climbing ramps and stairs, impacting the mobility of individuals with post-stroke hemiparesis (Bohannon, 1987; Eng and Chu, 2002; Eng and Tang, 2007). Therefore, evaluating mobility is essential

after a stroke and is an important aspect that aids in the rehabilitation process (Wang et al., 2020).

Currently, small and lightweight wearable sensors, such as accelerometers, are rapidly revolutionizing mobility assessment in research settings. These sensors offer new opportunities for researchers to continuously record and quantify gait over time and can provide real-time feedback to patients and therapists. Their lightness and portability offer potential for research outside the laboratory and in natural environments (clinics, sports arenas, etc.) (Mohan et al., 2021). Triaxial accelerometry-based activity monitors are devices that combine acceleration, position, and time to capture steps through sensors and can be used for extended periods (Van Remoortel et al., 2012; Coleman and

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Smith, 1999; Mudge and Stott, 2008). Examples of commercially available activity monitors include the StepWatch Activity Monitor® (SAM), validated for individuals with post-stroke hemiparesis and proven to be reliable and accurate for measuring mobility in this population (Danks et al., 2014; Haeuber et al., 2004), and the Fitbit®, which has a strong correlation with the SAM when used in this population.

Despite this technological advancement and the reliable information these devices provide about mobility in natural settings, the cost may limit the clinical use of these instruments. Consequently, a variety of standardized scales are currently used to quantify mobility impairments post-stroke, but most aim to assess the capacity for performance and spatiotemporal parameters in controlled environments (Mohan et al., 2021). To measure the use of the affected lower limb in the individual's daily real-life environment and thus provide information about the function and spontaneous use of the lower limb after a stroke, the Lower Extremity Motor Activity Log (LE-MAL) questionnaire was developed (Dos Anjos et al., 2021). The LE-MAL differs from other clinical mobility measures by evaluating performance, i.e., task execution in a life context. Through a structured interview, the LE-MAL assesses the level of assistance, functional ability, and self-reported safety via subscales. The average of the subscale scores generates the total score.

In 2022, the LE-MAL was translated into Portuguese, and in the same study, Cristine de Faria et al. (2022) found no floor or ceiling effects. They identified inter-rater reliability between 0.80 and 0.86 for the total score and subscales, Cronbach's alpha coefficients for the LE-MAL and subscales ranged between 0.86 and 0.80, and there was a moderate significant correlation between the LE-MAL and the lower limb section of the Fugl-Meyer (Pearson correlation 0.55,  $p = 0.009$ ) (Cristine de Faria et al., 2022). However, criterion-related validity against objective, real-world ambulatory activity data (i.e., step counts collected in daily life) in individuals with chronic stroke has not yet been established. Since it is a recently developed instrument, it is necessary to evaluate its measurement properties, such as the criterion validity of the LE-MAL. Criterion validity refers to the extent to which scores of an instrument are consistent with an external criterion (Mokkink et al., 2019). In the present study, triaxial accelerometer-based activity monitors were used as an external criterion for real-world ambulatory activity, as these devices are widely accepted as accurate for step counting in people post-stroke. Importantly, step counts represent one objective dimension of mobility-related behavior and may not capture all contextual and perceived aspects of lower-limb use. Therefore, PROMs such as the LE-MAL are not intended to replace objective monitoring, but to complement it by capturing perceived functional use of the more affected lower limb in daily life. As the LE-MAL is a recently developed instrument, further evaluation of its measurement properties is warranted. Thus, this study aimed to examine the association between LE-MAL scores and step counts recorded by activity monitors in individuals with chronic post-stroke hemiparesis.

## 2. Method

### 2.1. Study design

This is a cross-sectional criterion validation study through the correlation between activity monitors and a self-reported mobility questionnaire. The hypothesis was that the instruments would demonstrate a positive correlation, ranging from moderate to very high.

### 2.2. Participants

Convenience sampling was employed to select individuals who met the inclusion criteria and expressed interest in participating in the study. Recruitment was conducted through community outreach efforts, utilizing flyers, posters, and electronic media. This study followed COSMIN recommendations for studies evaluating measurement properties. COSMIN suggests that a sample size of at least 30 participants is

generally sufficient for validity studies that estimate correlation coefficients, in order to achieve adequate methodological quality and reasonably precise estimates (Mokkink et al., 2019). Accordingly, we aimed to recruit at least 30 participants; a total of 31 individuals were included in the analyses. The inclusion criteria were: (1) diagnosis of chronic post-stroke hemiparesis (time since stroke  $\geq 6$  months), ischemic or hemorrhagic, (2) age 18 years or older, (3) ability to walk with or without assistive devices at least 8 m, 3 times a day, (4) a minimum score of 17 points on the Mini-Mental State Examination (MMSE) for cognitive dysfunction screening (Brucki et al., 2003), (5) no diagnosis of any other neurological, orthopedic, and/or respiratory dysfunctions unrelated to the stroke. Participant characterization is described in Table 1.

This study was approved by the Ethics Committee of the Federal University of São Carlos (CAAE: 45511321.7.0000.5504), and participants agreed to and signed the Informed Consent Form (ICF).

### 2.3. Instruments

The translated and adapted version of LE-MAL to Portuguese was used to evaluate how effectively the individual uses the affected lower limb in the real world (Cristine de Faria et al., 2022). Participants were asked in a standardized manner about the level of assistance needed to perform 14 tasks over the past week, the quality of their lower limb performance during these tasks, and how safe they felt performing each task without falling. The scales used to evaluate each of the 14 tasks are: Assistance, Functional Performance, and Confidence scale. Each scale contains 11 points, ranging from 0 to 10 (dos Anjos et al., 2021).

Additionally, activity monitors (StepWatch Activity Monitor® or Fitbit®) based on inertial sensors of acceleration, position, and time were used, which allow counting the steps of individuals with abnormal, slow gait, or with lower limb prostheses in a real environment (Hui et al., 2018). The Fitbit One is a small ( $48 \times 19 \times 10$  mm), lightweight (8 g) triaxial accelerometer that uses proprietary algorithms to count steps (Takacs et al., 2014; Klassen et al., 2016). A StepWatch activity monitor (Orthocare Innovations, Mountlake Terrace, WA, USA) was calibrated and attached to the lateral side of the ankle of the non-paretic leg with a strap or cuff. The sensitivity and cadence settings were adjusted for each participant so that the monitor recognized every step during fast, slow, and self-selected walking speeds (Mudge and Stott, 2008). A strong relationship (slope = 0.99; 95% confidence interval, 0.97–1.01) was found between the number of steps captured by the Fitbit One and the StepWatch Activity Monitor (Klassen et al., 2017).

### 2.4. Procedures

Individuals with post-stroke hemiparesis made multiple visits for data collection. During the first visit, they were informed about the research project, invited to participate, and asked to provide informed consent. After this moment, sociodemographic data were also collected. On the second visit, participants underwent an assessment of sensorimotor impairment and completed the LE-MAL questionnaire. The third visit took place at the participants' homes, where activity monitors were attached to their non-paretic ankles. Participants were instructed to wear the monitors for at least 10 h daily over three consecutive days, removing them only for bathing and sleeping. They were provided with a diary to record usage times and given the researcher's contact information for any questions. After the monitoring period, the researcher returned to collect the devices.

### 2.5. Statistical analysis

Descriptive statistics were calculated for participant characteristics, LE-MAL scores, and step counts. Criterion-related validity was primarily evaluated by examining the association between LE-MAL total score and the average number of steps recorded over the three monitoring days using Pearson's correlation coefficient. Correlation magnitude was

interpreted as very low (<0.26), low (0.26–0.49), moderate (0.50–0.69), high (0.70–0.89), or very high (0.90–1.00) (MUNRO, 2001).

To further explore agreement between the measures, an intraclass correlation coefficient (ICC) was computed using a two-way mixed-effects model with a consistency definition and 95% confidence intervals. In addition, Bland–Altman analysis was performed to evaluate mean bias and 95% limits of agreement and to visually inspect for proportional bias across the range of measurements. Statistical significance was set at  $\alpha = 0.05$ .

### 3. Results

Thirty-one individuals with chronic post-stroke hemiparesis participated in this study (Table 1). All participants used the activity monitors for three consecutive days, as instructed.

Table 2 presents the means (SD) of the scores obtained in the three scales of the LE-MAL: assistance, functional performance, and confidence, as well as the total score of the questionnaire and the minimum and maximum values obtained.

Pearson's correlation between the average number of steps recorded over the three days and the LE-MAL total score was positive and moderate ( $r = 0.52$ ) and statistically significant ( $p < 0.01$ ) (Fig. 1).

Agreement analyses indicated low ICC values between LE-MAL scores and step counts (two-way mixed, consistency: ICC\_single = 0.001, 95% CI –0.35 to 0.35;  $p = 0.497$ ; ICC\_average = 0.003, 95% CI –1.07 to 0.52;  $p = 0.497$ ). Bland–Altman analysis using standardized scores showed a mean bias close to zero, indicating no systematic difference between standardized LE-MAL scores and standardized step counts. The 95% limits of agreement were relatively wide, reflecting the conceptual and metric differences between a patient-reported outcome measure and an objective activity count. Visual inspection of the plot did not suggest proportional bias across the range of measurements.

### 4. Discussion

This study examined criterion-related validity of the LE-MAL by comparing self-reported perceived use of the more affected lower limb with objectively measured real-world ambulatory activity (step counts) obtained from activity monitors. As hypothesized, LE-MAL total score demonstrated a positive, moderate association with step counts. Importantly, while correlation reflects the degree to which higher LE-MAL scores are associated with higher levels of ambulatory activity, agreement analyses (ICC and Bland–Altman) address whether the two approaches yield interchangeable values. Given that LE-MAL is a PROM and step counts are objective activity counts expressed in different metrics and capturing partially distinct aspects of mobility-related behaviour, low agreement was expected and should not be interpreted as lack of validity.

The Bland–Altman analysis further supports the interpretation that LE-MAL scores and step counts capture related but non-interchangeable aspects of lower-limb use. Although a moderate association was observed, agreement was limited, as expected, because the LE-MAL reflects perceived functional use of the more affected lower limb, whereas step counts quantify overall ambulatory activity. The absence of systematic or proportional bias suggests that differences between methods were consistent across activity levels rather than driven by measurement error.

It is known that activity monitors are validated tools in the literature for measuring the mobility of individuals with hemiparesis. These studies demonstrate that both the SAM and, consequently, the Fitbit are accurate measures for counting the steps of individuals with hemiparesis in various contexts and walking speeds (Danks et al., 2014; Sandroff et al., 2014; Fulk et al., 2014; Klassen et al., 2017). Additionally, functional tests have also been validated for this population, with the Time

Up and GO (TUG) test being the most commonly used (de Morais Faria et al., 2015). However, these instruments are characterized as capacity tests, unlike perceived mobility questionnaires like the LE-MAL, which also include patient-reported outcome measures (PROM) for the use of lower limbs. This perception throughout rehabilitation is important because it requires individuals to become aware of the importance of physical activity and the consequences of sedentary behavior on their health condition, thereby encouraging lifestyle changes and engagement in treatment (Tieges et al., 2015).

The reliability and correlation of the LE-MAL with the Fugl-Meyer have already been tested (Cristine de Faria et al., 2022). However, the correlation presented in this study is closer to the outcome the questionnaire aims to measure, as it correlates self-reported mobility with objective mobility measured by the number of steps from activity monitors. Therefore, it is possible to assert that the LE-MAL is also capable of measuring the mobility of individuals with chronic hemiparesis post-stroke. It shows a positive and moderate correlation with these devices and can evaluate mobility in different contexts and daily activities in a real-world environment. Additionally, its application does not require financial investment in materials, prior training for the evaluator, or large spaces for its execution, unlike accelerometers and functional tests. From a clinical perspective, the LE-MAL may be used to complement objective monitoring by capturing perceived functional use of the more affected lower limb during daily tasks, supporting individualized goal setting, and identifying discrepancies between objectively recorded activity and perceived performance or confidence. This may inform clinical decision-making and patient-centered rehabilitation planning, particularly in settings where activity monitors are not readily available. Thus, the use of the LE-MAL can generate positive impacts on health in general, especially in public health, as it reduces the costs and time involved in the evaluation, being an easily accessible and manageable instrument.

### 5. Conclusion

LE-MAL total score demonstrated a positive, moderate association with objectively measured step counts. These findings support the criterion-related validity of the LE-MAL as a PROM assessing perceived real-world use of the more affected lower limb, complementing objective activity monitoring in individuals with chronic post-stroke hemiparesis.

#### Patient consent statement

The participants provided their written informed consent to participate in this study.

#### Informed consent

Written informed consent was obtained from the patient for publication of this research, including all clinical data and images. This study was approved by the Ethics Committee, and participants agreed to and signed the Informed Consent Form (ICF). The patient was informed that no identifying information would be disclosed and that all efforts would be made to ensure anonymity.

All copies of the signed consent forms are available for review by the Editor-in-Chief upon request.

#### Ethics statement

The studies involving human participants were reviewed and approved by the Ethics Committee of the Federal University of São Carlos (CAAE: 45511321.7.0000.5504).

**Permission to reproduce material from other sources**

Not applicable.

**Study registration**

Not applicable.

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**CRediT authorship contribution statement**

**Gabriela Cristina dos Reis:** Conceptualization, Data curation,

Formal analysis, Investigation, Methodology, Project administration, Writing – original draft, Writing – review & editing. **Nayara Kelly de Oliveira:** Conceptualization, Formal analysis, Methodology, Writing – original draft, Writing – review & editing. **Laura Hellen Cerqueira Gomes dos Santos:** Conceptualization, Formal analysis, Methodology, Writing – original draft. **Natalia Duarte Pereira:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Supervision, Writing – original draft, Writing – review & editing.

**Declaration of competing interest**

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

**Appendix**

**Table 1**  
Participant characteristics.

Characteristics (n = 31)	Mean (SD)	Range (min - max)
Age, years	59 (13.6)	(30 - 86)
Gender, men (%)	58	
Time since stroke, months	192 (60.7)	(6 - 264)
MMSE, score (0-30)	23.6 (3.8)	(17 - 30)
Fugl-Meyer, score (0 - 34)	24.5 (6.2)	(6 - 34)
Slight (n)	2	
Moderate (n)	10	
Marked (n)	17	
Severe (n)	2	

**Table 2**  
LE-MAL scores.

LE-MAL Scores (n = 31)	Mean (SD)	Range (min - max)
Scales		
Assistance	8.3 (1.5)	(3.73 - 10)
Functional Performance	6.5 (1.9)	(1.71 - 10)
Confidence	6.5 (2.0)	(1.86 - 10)
Total score	7.2 (1.7)	(3.48 - 10)

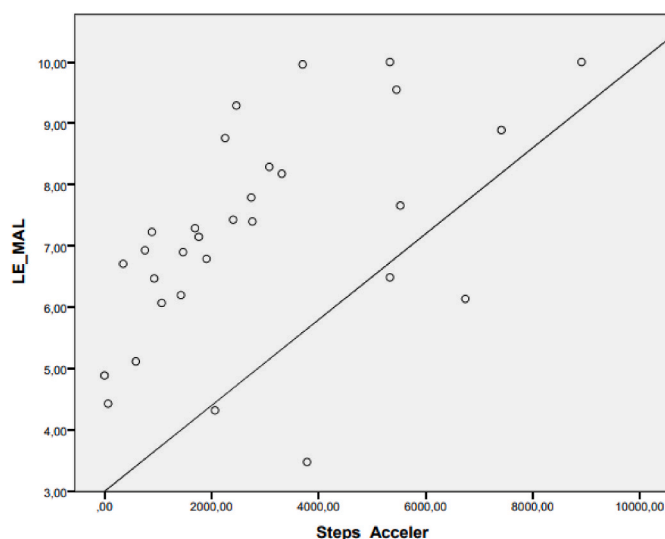


Fig. 1. Scatter plot showing the association between LE-MAL total score and average step counts over three days (Steps\_Acceler), with fitted regression line.

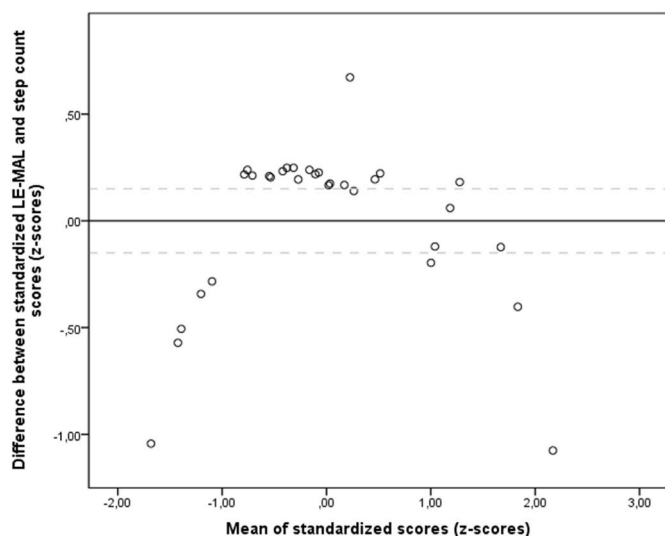


Fig. 2. Bland-Altman plot comparing standardized LE-MAL total scores and standardized step counts (z-scores). The solid line represents the mean difference (bias), and the dashed lines represent the 95% limits of agreement.

## Data availability

No datasets were generated or analyzed during the current study.

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