

# Construct validity of the 2-minute walk test for patients with lower limb amputation using prosthesis

*Validade de construto do teste de caminhada de 2 minutos para pacientes com amputação de membro inferior protetizados*

*Validez de constructo de la prueba de marcha de 2 minutos para pacientes protésicos amputados de extremidad inferior*

Larissa Lavoura Balbi<sup>1</sup>, Milena Zavatini Secco<sup>2</sup>, Beatriz Bregantin Pinheiro<sup>3</sup>, Maira Stéfanie Castro Pereira<sup>4</sup>, Ana Regina Bavaresco Barros<sup>5</sup>, Marisa de Cássia Registro Fonseca<sup>6</sup>

**ABSTRACT** | Allied to functional assessment, walking tests have been reported to be reliable and valid for several populations, quantifying an individual's functional capacity and responding to changes during the rehabilitation process. This study aims to analyze the construct validity of the 2-minute walk test for patients with prosthetic lower limbs undergoing rehabilitation. A total of 51 patients aged over 18 years underwent the 2-minute walk test. These individuals had a clinical diagnosis of lower limb amputation at any level and had undergone rehabilitation at least six months at the time of assessment, which was correlated with the Functional Measure for Amputees (FMA) questionnaires and the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) aspects to obtain the Pearson Correlation Coefficient with a significance level of  $p < 0.05$ . Among the participants, 64.7% were male, with a mean age of 53.4 years, 59.92% had transtibial amputation and the main cause was trauma (54.90%). The average score for the questionnaires was 63.58 points for the Physical Capacity of the SF-36 and 37.14 points for question two of the FMA. The correlation of the distance walked in the 2-minute walk test showed a moderate correlation for the Physical Capacity of the SF-36 and a moderate correlation for question two of the FMA. The outcomes show a moderate correlation between the 2-minute walk test and the subjective function assessment tools used, showing that it is valid as an objective measure for the population studied.

**Keywords** | Amputation; International Classification of Functioning, Disability and Health; Gait; Prostheses and Implants.

**RESUMO** | Aliados da avaliação funcional, os testes de caminhada têm sido considerados confiáveis e válidos para várias populações, quantificando a capacidade funcional do indivíduo e respondendo a mudanças durante o processo de reabilitação. O objetivo deste artigo foi analisar a validade de construto do teste de caminhada de 2 minutos para pacientes com amputação de membro inferior protetizados, submetidos à reabilitação. Foi aplicado o teste de caminhada de 2 minutos em 51 pacientes maiores de 18 anos com diagnóstico clínico de amputação de membro inferior em qualquer nível e que tivessem sido submetidos à reabilitação há pelo menos seis meses no momento da avaliação, que foi correlacionada com os questionários Medida Funcional para Amputados (MFA) e os aspectos do *Medical Outcomes Study 36-Item Short-Form Health Survey* (SF-36), a fim de obter o coeficiente de correlação de Pearson com o nível de significância de  $p < 0,05$ . Entre os participantes do estudo, 64,7% eram do sexo masculino, com média de idade de 53,4 anos; 59,92% tinham amputação de nível transtibial e a principal causa foi trauma, com 54,9%. O escore médio para os questionários foi de 63,58 pontos para a capacidade física do SF-36, e 37,14 pontos para a segunda questão do MFA.

<sup>1</sup>Universidade de São Paulo (USP) - Ribeirão Preto (SP), Brazil. E-mail: larissabalbi@hotmail.com. ORCID-0000-0001-5977-2708

<sup>2</sup>Universidade de São Paulo (USP) - Ribeirão Preto (SP), Brazil. E-mail: milenazsecco@gmail.com. ORCID-0000-0002-7963-0616

<sup>3</sup>Universidade de São Paulo (USP) - Ribeirão Preto (SP), Brazil. E-mail: biabregantinp@gmail.com. ORCID-0000-0002-4089-1181

<sup>4</sup>Universidade de São Paulo (USP) - Ribeirão Preto (SP), Brazil. E-mail: mairacastro@usp.br. ORCID-0000-0002-0547-2395

<sup>5</sup>Universidade de São Paulo (USP) - Ribeirão Preto (SP), Brazil. E-mail: anaregina\_barros@hotmail.com. ORCID-0000-0002-5409-591X

<sup>6</sup>Universidade de São Paulo (USP) - Ribeirão Preto (SP), Brazil. E-mail: marisa@fmrp.usp.br. ORCID-0000-0001-8187-5834

A correlação da distância percorrida no teste de caminhada de 2 minutos mostrou moderada correlação com a capacidade física do SF-36 e com a segunda questão do MFA. Os achados mostram moderada correlação entre o teste de caminhada de 2 minutos e as ferramentas subjetivas de avaliação de função utilizadas, mostrando que é um instrumento válido como medida objetiva para a população estudada.

**Descritores** | Amputação; Classificação Internacional de Funcionalidade, Incapacidade e Saúde; Marcha; Próteses e Implantes.

**RESUMEN** | Se consideran las pruebas de marcha, utilizadas en la evaluación funcional, fiables y válidas en diversas poblaciones para cuantificar la capacidad funcional del paciente y responder los cambios durante su proceso de rehabilitación. El objetivo de este estudio fue analizar la validez de constructo de la prueba de marcha de 2 minutos en pacientes con amputación protésica de miembro inferior en rehabilitación. La prueba de marcha de 2 minutos se aplicó a 51 pacientes mayores de 18 años de edad, con diagnóstico clínico de amputación de miembro inferior a

cualquier nivel y que se habían sometido a rehabilitación al menos seis meses en el momento de la evaluación, lo que se correlacionó con los cuestionarios Medida Funcional para Amputados (MFA) y los ítems del *Medical Outcomes Study 36-Item Short-Form Health Survey* (Cuestionario de Salud, SF-36) para obtener el coeficiente de correlación de Pearson con un nivel de significancia de  $p < 0,05$ . El 64,7% de los participantes eran varones, con edad media de 53,4 años; el 59,92% tenía amputación transtibial, y la principal causa fue el traumatismo en el 54,9%. La puntuación media de los cuestionarios fue de 63,58 puntos para la capacidad física del SF-36; y para la pregunta dos del MFA, 37,14 puntos. La correlación de la distancia recorrida en la prueba de marcha de 2 minutos fue moderada para la capacidad física del SF-36 y para la pregunta dos del MFA. Los hallazgos muestran una correlación moderada entre la prueba de marcha de 2 minutos y las herramientas subjetivas de evaluación de la función utilizada, comprobando su validez como medida objetiva para la población estudiada.

**Palabras clave** | Amputación; Clasificación Internacional del Funcionamiento, de la Discapacidad y de la Salud; Marcha; Prótesis e Implantes.

## INTRODUCTION

Functional mobility is the main objective for people who have suffered lower limbs amputation, essential in domestic, community, and recreational activities. Therefore, it is a determinant of quality of life<sup>1</sup>.

Although evidence demonstrates the effectiveness of assessing the functional capacity of gait after prosthetics via computerized 3D analysis systems for diagnostic purposes or evolution measuring<sup>2</sup>, simpler measures which do not need high technology—such as performance tests or self-report questionnaires—can also be used for functional gait evaluation of people with amputation and prosthetized<sup>3</sup>.

Self-report instruments also help to measure health outcomes, such as mobility, providing information on personal experiences, perceptions, and opinions of individuals<sup>4,5</sup>. Moreover, their use in clinical practice provide us complementary information on the evolution and efficacy of the treatment<sup>6,7</sup>. Among the most used questionnaires, the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36)<sup>8</sup>—used to measure quality of life in its various physical and social domains—can be mentioned. Several tools have been validated and applied in the evaluation of the use of prostheses

in people with amputations, such as the Houghton Scale<sup>9</sup>, the Prosthetic Limb Users Survey of Mobility (PLUS-M™)<sup>10</sup>, and the Functional Measurement Questionnaire for Amputees (MFA)<sup>11</sup>, related to the activities of daily living of patients who use prosthesis<sup>12</sup>. The predictor of mobility for amputees was originally described by the Medicare functional classification level. This classification system consists of five levels, called “K levels,” ranging from zero to four. K0 refers to a person without the ability or potential to use a prosthesis and K4, a person able to exceed basic gait skills<sup>4,13</sup>.

Performance tests have also been reported as relevant for the evaluation of gait functionality after lower limb amputations<sup>3,14</sup>. The 2-minute walk test (2MWT)—which corresponds to a variation of the 6- and 12-minutes<sup>14</sup> walk test—has been increasingly used as a measure of evolution, combined with self-report questionnaires<sup>15</sup>. According to Brooks et al.<sup>16</sup>, the main advantage of the 2MWT is its shorter, easy applicability and, therefore, more appropriate for patients with disabilities. Moreover, 2MWT is responsive as a functional measure to the population with lower limb amputation in short-term evaluations, after three months of prosthetic fitting. The timed up and go (TUG) test was designed to assess the ability to perform basic mobility tasks such as sitting,

standing, walking, spinning, and to remain standing. The test was originally intended to assess the risk of fall in older people<sup>16</sup> and shows excellent inter- and intra-rater reliability in people with lower limb amputation<sup>17</sup>.

Performance tests on amputations can provide quantitative information on gait pattern, combined with the time-space parameters of gait<sup>3,13</sup>. Speed and distance—as valid and reliable measures of the individual's gait capacity<sup>15,18</sup>—also allow monitoring the evolution of a physical therapy treatment.

The 6-minute walk test proved to be valid for people with amputation, but the 2MWT can predict gait progression, allowing time savings for the patient and the therapist<sup>19</sup>. Furthermore, evolution measures should show the maintenance of long-term functional results, after the late and higher rehabilitation post-prosthetic fitting is completed.

This study aimed to assess whether the 2MWT test and the TUG could measure late functional mobility in people using prosthesis in the lower limb for at least six months. We verified the association of late functional mobility with the locomotor capacity index of the Functional Measurement for Amputees Questionnaire (LCI/FMA) and the subdomains of the Medical Outcomes Study Short-Form 36 Item Health Survey (SF-36) for patients with prosthetic lower limb amputation and subjected to rehabilitation by construct validity analysis. Our hypothesis was that the distance covered in two minutes and the timed up and go test would correlate moderately with the subdomains of the SF-36 and the ICL/FMA.

## METHODOLOGY

This is a cross-sectional study and conducted in the amputations outpatient clinic of a rehabilitation center of a tertiary reference hospital. The prostheses are made and/or assembled in outsourced orthopedic workshops. Then, they are delivered to patients in the outpatient clinic, after indication and dispensation by the Brazilian Unified Health System.

### Participants

The inclusion criteria—for patients attended at the outpatient rehabilitation center—were the following: individuals aged 18 years or older; all genders; showing clinical diagnosis of lower limb amputation, regardless

of the cause (it could be associated with diseases such as diabetes and hypertension); individuals cognitively able to answer the questionnaires and also physically able to perform the proposed tasks; and individuals who underwent rehabilitation in the pre- and post-prosthetic phases at least six months before the time of evaluation.

All participants were informed about the study and signed the informed consent form before answering the questionnaires and performing the proposed performance test.

### 2-minute walk test

The protocol design for this investigation was based on the studies by Brooks et al.<sup>18</sup> and Gremeaux et al.<sup>15</sup>, with an adaptation, so the participants could perform the test on a flat track of 30 meters at the external area of the rehabilitation center. The test was started with the individuals standing on the same marking for all evaluations. The time was recorded with a digital stopwatch and the distance measured in meters. The individuals were firstly familiarized with the test and then were instructed to walk as much as they could in two minutes, using auxiliary devices, if necessary.

### Test timed up and go

In the TUG test, participants were instructed to get up from a chair, walk three meters, turn 180°, return to the chair and sit<sup>16</sup>. This instrument was validated in a population of amputees with high intra- and inter-rater reliability, with 0.93 and 0.96 CI in unilateral transtibial and transfemoral populations, respectively<sup>17</sup>.

### Application of self-report questionnaires

Construct validity indicates whether the measure correlates with other instruments that evaluate the same construct<sup>20</sup>. Therefore, two questionnaires were used together with the 2-minute walk test: SF-36<sup>8</sup> and FMA<sup>11</sup>.

### Medical Outcomes Study 36-Item Short-Form Health Survey

The SF-36 is a generic measure of quality of life. The instrument consists of 36 questions related to eight domains: physical aspect; physical function; body pain; general health; emotional role; social function;

mental health; and vitality<sup>8</sup>. The first four subscales comprise the physical aspect score and the last four comprise the mental aspect score. The scores were calculated according to the scoring algorithms provided by Ware et al.<sup>21</sup> considering the variation of the score from 0 (worst health status) to 100 (better health status).

### Functional Measure for Amputees

The questionnaire has 14 questions related to the daily living activities of patients who use the prosthesis and covers questions related to the difficulties faced regarding the prosthesis. Only the second question, locomotor capacity index (LCI), was used because it generates a quantitative score ranging from 0 to 42 points, and the higher the score, the better the mobility<sup>11</sup>.

### Procedure

Information on age, gender, trauma mechanism, affected side, time of prosthesis use, and use of auxiliary gait device were collected from electronic medical records. The Mental State Mini-Examination Questionnaire<sup>22</sup> was applied for characterization based on educational levels, aiming to ensure that volunteers understood the questions inserted in each of the questionnaires—SF-36<sup>8</sup> and LCI/FMA<sup>11</sup>. The questionnaires were applied in the form of an interview conducted by a trained physical therapist, and, after the collections, all volunteers received complementary physical therapeutic guidance. Heart rate and blood pressure were measured using a sphygmomanometer and stethoscope before and after each test. The questionnaires were completed in the form of an interview before the 2MWT and TUG and, when necessary, the nursing team assisted the participant.

### Statistical analysis

De Vet et al.<sup>19</sup> suggest a sample from 30 to 50 volunteers for validity studies. Data normality was confirmed by the Kolmogorov-Smirnov test and construct validity was analyzed by Pearson correlation coefficient. This coefficient measures the degree of linear association between two variables, which can range from -1 to 1. Values close to -1 indicate maximum inverse correlation, and close to 1 indicate maximum direct correlation between analyzed variables<sup>20</sup>. The results were interpreted based on the classification described

by Dancey and Reidy<sup>23</sup>, which considers a correlation from 0.7 to 1 as strong; 0.4 to 0.6 as moderate; and  $\leq 0.3$  as weak. The significance level was set at  $p < 0.05$ . The Software SPSS version 20<sup>®</sup> was used

## RESULTS

Out of the 51 volunteers analyzed, most were male (64.7%), 70.4% of them studied for up to eight years, and 52.92% were retired. At the evaluation period, the mean age was 53.4 years old, while the mean age in the period that the participants were subjected by amputation was 47.58% (Table 1). Transtibial amputation was the most frequent (57.92%), as Figure 1 shows.

Table 1. Sample description

Characteristic	N (%)
Age	53.4 (SD 16.2)
Gender (male/female)	33/18 (64.7%/35.3%)
Schooling (%)	
Illiterate	3 (5.88%)
1 to 4 years of study	18 (35.2%)
5 to 8 years of study	18 (35.2%)
Over 8 years of study	6 (11.7%)
Could not inform	6 (11.7%)
Affected side (%) Unilateral/Bilateral	47/4 (92.2/7.8%)
Causes (%)	
Trauma	28 (54.9%)
Vascular	8 (16.67%)
Diabetes	8 (16.67%)
Oncology	5 (9.8%)
Congenital	1 (1.96%)
Knee type	
Physiological knee	34 (66.6)
Prosthetic knee	17 (33.3)
Occupation (%)	
Retired	27 (52.92%)
social security	13 (25.48%)
Active	11 (21.6%)

SD: standard deviation; N: sample number.

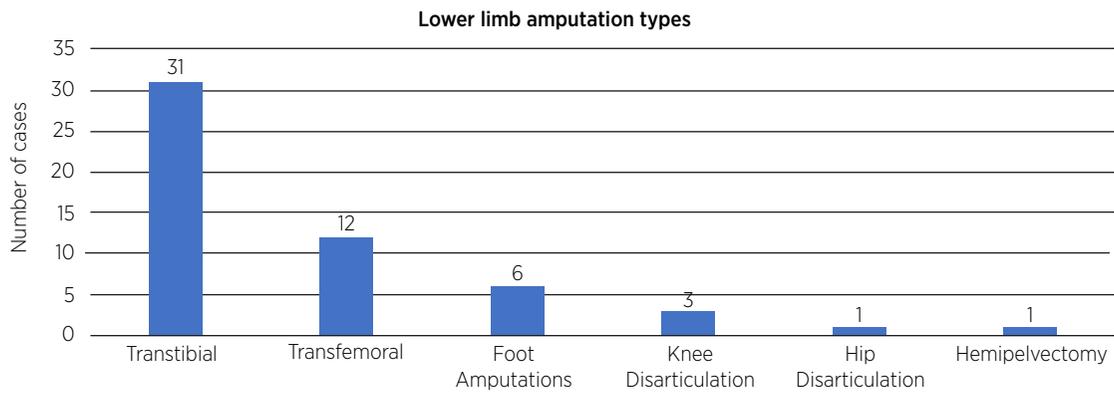


Figure 1. Distribution of the types of amputation in the sample (n=51)

Regarding the K levels of functionality, the sample was classified as K3/K4, corresponding to people with the ability to exceed the basic abilities of home ambulation.

Among the used questionnaires, the Mini Mental State Examination<sup>22</sup> showed an average of 26.5 points, indicating high cognitive performance. Regarding the second question of the FMA questionnaire<sup>11</sup>, the mean score was 37.1 points.

For the total sample evaluated, the 2MWT was moderately correlated with the functional capacity domain of the SF-36 ( $\rho=0.50$ ;  $p=0.01$ ) and the LCI/FMA ( $\rho=0.60$ ;  $p=0.01$ ) and obtained a strong correlation with the TUG ( $\rho=0.80$ ;  $p=0.01$ ), as shown in Table 2. The TUG was moderately correlated with the physical aspects of the SF-36 and had a strong correlation with the LCI/FMA ( $\rho=0.80$ ;  $p=0.01$ ).

Figure 2 shows the relation between average walking speed of individuals divided into subgroups according to the presence or not of the physiological knee.

Table 2. Measurement variables of performance tests and self-report questionnaires collected

	2MWT	TUG
Functional capacity	0.5**	-0.44*
Physical aspects	0.18	-0.47**
Pain	-0.16	-0.03
General health status	0.31*	-0.23
Vitality	0.22	-0.06
Social aspects	0.23	-0.12
Emotional aspects	0.12	-0.04
Mental health	0.31*	-0.04
Q2 FMA	0.6**	-0.7**
Timed up and go (TUG)	0.8**	1
2MWT	1	0.8**

FC SF-36: functional capacity domain of the SF-36 questionnaire; Q2 FMA: question 2 of the FMA questionnaire; (2MWT): 2-minute walk test.

\*\*Correlation is significant at the 0.01 level; \*Correlation is significant at the 0.05 level.

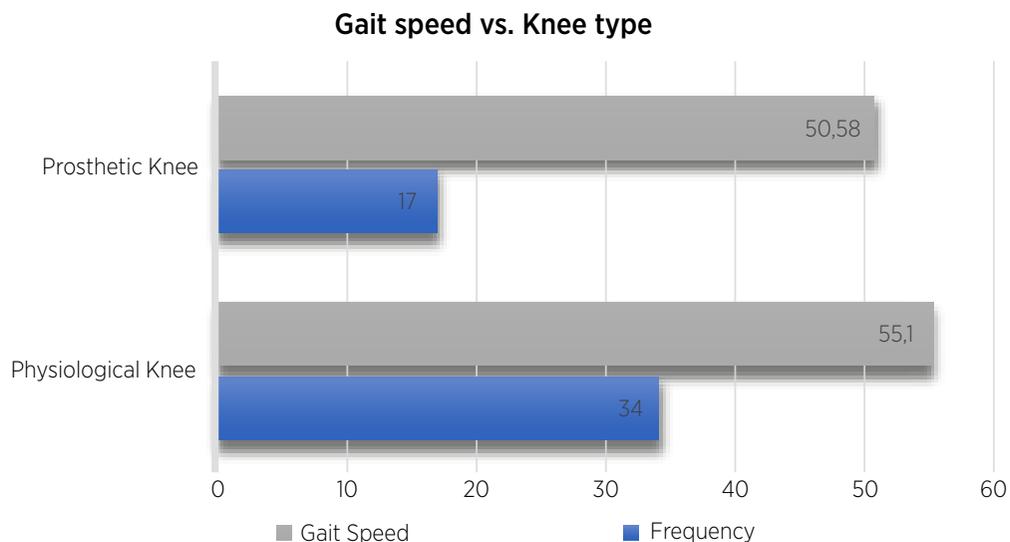


Figure 2. Average walking speed of the physiological or prosthetic knees subgroups

## DISCUSSION

The 2MWT was moderately correlated with the functional capacity domain of the SF-36, as found by Brooks et al.<sup>16</sup>, who describes the possibility of the tool better represent the physical limitation of the individual, and by Hafner et al.<sup>11</sup>, who reports the significance of this type of tool to verify how health condition and functional capacity impact the life of the affected individual. The 2MWT was moderately correlated with the second issue of FMA. The moderate correlation is explained by the individuality of each tool in collecting different information during the evaluation. The SF-36 tool is not specific for the population with lower limb amputation, but assesses the health condition from the individual's perspective, and the LCI/FMA brings information related to the use of the prosthesis, whereas the 2MWT assesses the individual's ability to walk for a certain time<sup>15</sup>. Therefore, the obtained data might be different, but complementary to each other, also providing information such as physical limitation and functional impact on the individual's life<sup>10</sup>.

TUG test has been recommended as an instrument for assessing mobility in amputees. For the total sample evaluated, this test showed a high negative correlation with 2MWT and LCI/FMA, because the shorter the distance covered in the 2MWT, the longer the time to perform the TUG test. The time using prosthesis—more than six months—was chosen because it is a strong predictor of later functional performance of gait with prosthesis. A longer period for physical and psychological adjustment, practice, and accommodation of prosthesis use may be related to outcomes in the study<sup>10</sup>.

The functional measurements of our sample also corroborate with the literature. In our study, the travelled distance in two minutes was 107.27 meters, lower than that established by Bohannon et al.<sup>24</sup> of 176.4 and 191.0 meters for healthy women and men, respectively, with the same mean age in the sample. The gait speed derived from walking tests is an indicator of gait ability with evidence supporting its reliability and validity. The mean speed reached at 2MWT for the total sample evaluated was 53.6m/min, below the mean reported in the literature for healthy individuals, of 83m/min<sup>15</sup>. However, our sample had a predominance of transtibial amputations, which remains above average when compared to findings by Brooks et al.<sup>16</sup> who indicate 43.5m/min for

transtibial amputations and 19.7m/min for transfemoral amputations, probably because our sample have more than six months of functional use of the prosthesis. Batten et al.<sup>25</sup> quantified gait speed in people with unilateral lower limbs amputation according to level K and confirmed that level K is also related to gait speed. It was found that people with lower limb amputation with higher K levels had faster gait speeds compared to those with lower levels. Different values for walking distances and average speeds obtained indirectly should be analyzed with caution and not generalized, since the evaluations may have been performed at separate times of the rehabilitation and protetization process. Based on the clinical and epidemiological variables, we observed that the sample was composed of male individuals, with a mean age above 50 years and few years of schooling. Regarding the etiology of amputation, a higher frequency was found due to traumatic causes, which goes against studies that indicate vascular diseases as responsible for about 75% of all lower limbs amputations<sup>15</sup>. This difference in the causes of amputations can be explained by the collection site, a tertiary-level hospital—regional reference in traumatology—with about 80% of cases related to motorcycle and automobile accidents.

Our study found some limitations during the collection process, making it difficult to recruit volunteers to participate in the study, such as inadequacies related to alignment and conservation conditions of prosthesis components, and lesions in the stumps, such as blisters and wounds, due to poorly adjusted prosthesis.

## CONCLUSION

The 2-minute walk test and the timed up and go test are valid as performance tests for later functional evaluation in people with lower limb amputation using prosthesis. The findings showed that these tests are practical, fast, easy to apply and low cost, besides being able to provide—together with the use of self-report questionnaires—complementary information that evidences the effect of the health condition and functional capacity in the life of the individual with lower limb amputation. Further studies of these tools and analyses of other measurement properties may provide more data on their applicability, guiding the process of rehabilitation and prosthetic fitting of the individual with lower limb amputation.

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