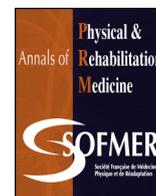Available online at

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Original article

Transcultural adaptation and validation of a French version of the Prosthetic Limb Users Survey of Mobility 12-item Short-Form (PLUS-M/FC-12) in active amputees

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ABSTRACT

Background: The PLUS-M 12-item Short-Form is a self-questionnaire that assesses the perceived capacity of lower limb amputees (LLAs) to perform a number of daily-life activities. Its psychometric properties are excellent (intraclass correlation coefficient [ICC] > 0.9, fast administration and scoring, normative data available), and it can be used in clinical practice or for research purposes.
Objective: We aimed to develop a French version of this questionnaire and to assess its psychometric properties.
Methods: We followed international recommendations for translation and cross-cultural validation of questionnaires. In total, 52 LLAs (age 53 ± 16, 40 males, 28/12/12 transtibial/Gritti-Stokes/transfemoral, 20/28/4 ischemic/traumatic/other) participated. Criterion and construct validities were assessed with the Pearson correlation coefficient (PCC) between the PLUS-M 12-item Short-Form and other constructs (Prosthetic-Profile-of-the-Amputee-Locomotor Capabilities Index, Activities-specific Balance Confidence scale, 2-min walking test and Timed Up and Go test), internal consistency with the Cronbach α and reliability with the ICC in 46 individuals who completed the questionnaire twice in a 7-day interval.
Results: The mean (SD) PLUS-M 12-item Short-Form *T*-score was 56.1 (7.8; range 40.3 to 71.4). Construct and criterion validity, internal consistency and reliability ranged from low to excellent ($r = 0.43$ to 0.84, $P < 10^{-2}$ to 0.002; Cronbach $\alpha = 0.90$, ICC = 0.89 [0.81–0.94]). We found no floor or ceiling effect.
Conclusions: The French version of the PLUS-M 12-item Short-Form has good to excellent psychometric properties, comparable to those of the original version. Its use could definitely be proposed for both clinical and research purposes, once its validation is completed by assessing other psychometric qualities, especially sensitivity to change.

1. Introduction

Major lower limb amputation (LLA), defined by any level of amputation above the foot, leads to restricted mobility, which is a key component of health-related quality of life (HRQoL) in lower limb amputees (LLAs) [1–5]. The objectives and outcome of LLA rehabilitation vary between basic prosthesis use and household ambulation to the resumption of high-energy physical activities.

Researchers and rehabilitation specialists search to improve the treatments available, to extend degrees of freedom and to increase the number of tasks that can be accomplished by LLAs while wearing a prosthesis [6,7].

Assessment of mobility by use of self-reporting instruments is central to selecting, optimizing, and evaluating the effectiveness of prosthetic interventions for people with LLA [8,9]. A wide range of measures specific or non-specific to LLA used for measuring the mobility of LLAs are available [8,10]. Nevertheless, only a small proportion are used regularly in clinical practice. Various issues concerning their feasibility, interpretability, sensitivity to change, and psychometric testing interfere with their use [8,10,11].

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Among self-reporting questionnaires, the Prosthetic-Profile-of-the-Amputee-Locomotor Capabilities Index (PPA-LCI) [12], the Houghton scale [13], and the Special Interest Group in Amputee Medicine (SIGAM-Fr) [14] exist in French.

The PPA-LCI contains 14 items reflecting perceived potential or not to perform different tasks. The index has excellent internal consistency (Cronbach α = 0.95) and reliability (intraclass correlation coefficient [ICC] = 0.98), and good construct validity but a high ceiling effect [12,15].

The Houghton scale can distinguish between "successful household ambulation" and "successful rehabilitation" by evaluating walking indoors and outdoors, depending on the terrain, the use of mobility aids (including wheelchair) and the time of prosthesis use. The scale has excellent reliability (ICC = 0.96) and responsiveness to change, moderate internal consistency (Cronbach α = 0.70) and construct validity, so it is useful for a simple rapid evaluation of locomotion [15,16] and for assessing post-intervention change [10]. As Deathe et al. declared, both these instruments can be useful during initial rehabilitation stages [10], but their usefulness in long-term follow-up is limited.

The SIGAM-Fr evaluates participation restriction at various levels and under various conditions and leads to a classification of 6 clinically meaningful "mobility grades". The scale has very good criterion validity (tested by the Houghton Scale, r = 0.89, $P < 0.01$) and satisfactory construct validity as well as moderate internal consistency (KR-20 coefficient = 0.67) and excellent test–retest reliability (Cohen kappa = 0.87) [14]. Easy to use, it is recommended also in an outpatient setting. Nevertheless, it does not exclusively assess functional mobility with a prosthesis because it accounts for wheelchair use and the aesthetic aspect, and its sensitivity to detect mobility improvement outside its scope of questions is reported as limited [10].

The Prosthetic Limb Users Survey of Mobility (PLUS-M) [1] includes 44 items that were defined by using data from a large number of LLAs. The scoring was developed with item response theory [17]. Two PLUS-M instruments (12 and 7 items) have been developed [8,18]. The PLUS-M 12-item Short-Form is a self-administered questionnaire that assesses the LLA's perceived capacity to perform various activities that vary in difficulty by using their main prosthesis. The answers reflect the difficulty with which the person estimates that he/she could perform the activity, on a 5-point scale ranging from "unable to do" to "without any difficulty". The higher the score, the higher the level of mobility.

The PLUS-M has been subject of a thorough validation procedure, and its psychometric properties are good to excellent. The score showed strong correlation with scores on the Prosthesis Evaluation Questionnaire-Mobility Scale (PEQ-MS), Activities-specific Balance Confidence scale (ABC) and Patient-Reported Outcomes Measurement Information System Physical Function (PROMIS-PF) (r = 0.78, 0.81 and 0.81, respectively, $P < 0.001$). It was found moderately correlated with scores on the Amputee Mobility Predictor (AMP) and Timed Up and Go (TUG) tests (r = 0.54, 0.56, $P < 0.001$) [8]. Reproducibility was excellent (ICC > 0.9) [1]. The minimal detectable change (MDC) has been calculated (4.5), and normative data (T-scores) are available, allowing for comparisons between an individual's score to those reported for the development sample or its subgroups (by level/cause of amputation, sex, age). Duration of administration and scoring do not exceed 5 min [1,18]. The survey does not measure falls or activities performed with physical assistance or with wheelchairs [1]. Thus, its use in clinical practice is encouraged because it appears clinically meaningful, appropriate for individual care, and rapid and easy to administer and interpret and could help secondarily in the formulation of recommendations [1,8,18].

We considered that a French self-questionnaire evaluating the perceived mobility of LLAs exclusively while using their prosthesis, that is easy to use and helpful in clinical practice and especially targeted to experienced prosthesis users is lacking. Our objective was the transcultural translation of the PLUS-M 12-item Short-Form into French and assessment of its psychometric properties after applying it in a population of individuals with unilateral, major LLA. We expected results permitting its use in clinical practice for LLA rehabilitation and for research purposes.

2. Methods

2.1. Study design

We conducted a multi-site international prospective study. The study plan, conforming to the principles outlined in the Declaration of Helsinki, was approved by the ethics committee of the canton of Vaud, Switzerland (Comité d'éthique du canton de Vaud, protocol no.: 2017-01382) and the internal ethics board of the Institut Régional de Réadaptation (IRR), France.

2.2. Setting

Three tertiary care centres of physical and rehabilitation medicine (PRM) participated in the study, 2 in French language-speaking counties in Switzerland [Orthopedic Hospital, Centre Hospitalier Universitaire Vaudois (CHUV), Clinique Romande de Réadaptation (CRR)] and one in France (IRR). The 3 centres provide inpatient and outpatient rehabilitation services for LLAs by experienced interdisciplinary teams as well as long-term follow-up. One of the authors was responsible for conducting the study, collecting and storing data in each centre (November 2017 to February 2018).

2.3. Transcultural translation

Permission to proceed was obtained, and translation was conducted in consultation with the developers. We initially followed the "informal translation" process as recommended on http://www.plus-m.org/. We considered the already available but not validated Canadian-French version of the PLUS-M [19] that was not fully adapted for the French-speaking population in Europe. A double native French and English bilingual person independently established a European-French version by editing the Canadian-French one, after the developers provided information on the scoring forms and item definition guides, including item-by-item descriptions of the intention behind each item, phrase, and term. A version considered ready for verification was obtained. Another English-speaking bilingual person performed an independent review, found no discrepancies between the versions, and proposed only a few minor modifications. A first European-French version of the PLUS-M was formatted.

Afterward, we completed the process following international recommendations for cross-cultural translation and adaptation of questionnaires [20,21]. A committee of 4 French-speaking bilingual experts revised this last version with Professor Brian Hafner, the original author of the questionnaire. Then, a bilingual English native-speaking person, with bilateral LLA, who did not know the original questionnaire, performed a back translation of the 12 items included in the PLUS-M 12-item Short-Form. Another independent bilingual person then compared the 2 English versions in terms of semantic and conceptual equivalence and found no significant discrepancies. The translation led to the creation of the "PLUS-M Formulaire Court en 12 items" (PLUS-M/FC-12).

2.4. Transcultural validation

2.4.1. Population studied

Patients were invited in an ambulatory setting, by telephone, and by written invitation briefly describing the study's goals and procedure. All patients had previously received multidisciplinary rehabilitation with prosthesis fitting and/or follow-up at participating PRM centres. Inclusion criteria were French-speaking, unilateral major LLA for at least 1 year, use of their main prosthesis during indoor and outdoor activities, and ability to answer the questionnaires. We excluded people with documented cognitive impairment, bilateral LLA, and prosthesis use for aesthetic purposes or limited in household activities. Investigator and participants gave their signed informed consent during the visit.

2.4.2. Variables measured

Data collected for every participant included demographic and general variables (age, sex, level, cause and time since amputation, type of prosthetic equipment), scores of 2 physical performance tests (TUG and 2-min walking test [2MWT]) [22,23] and the 3 self-administered questionnaires: PPA-LCI, ABC [24,25] and PLUS-M/FC-12. We asked participants to complete the questionnaires during the medical visit but also gave them the choice to complete them at home and send them to us by mail. We asked participants to complete the PLUS-M/FC-12 a second time 7 days later and mail it to us.

2.4.3. Psychometric validation

2.4.3.1. Face validity and usefulness. At the end of the visit, the investigator conducted an individual interview with participants on the content of the PLUS-M/FC-12 and its form.

2.4.3.2. Criterion validity. The PPA-LCI assesses perceived mobility skills and we considered its item content the closest to the activities described in the PLUS-M/FC-12. To test the criterion validity of the PLUS-M/FC-12, we calculated the Pearson correlation coefficient (PCC) between the T-scores for the PLUS-M/FC-12 and the PPA-LCI scores. Given the PPA-LCI's ceiling effect and the fact that items refer to similar but less demanding tasks, we did not expect an excellent correlation.

2.4.3.3. Construct validity. We hypothesized that T-scores for the PLUS-M/FC-12 would be correlated with scores of instruments that measure various aspects related to mobility (convergent validity). For that purpose, we used the TUG, 2MWT, and ABC. The TUG is a widely used test assessing ambulatory skills and recommended mostly to measure household ambulation [10]. We performed it as described in Schoppen et al. [22]. The 2MWT is a valid method for assessing walking endurance in LLA individuals and is recommended as more appropriate to measure "community" ambulation [10]. In the 3 PRM centres, it was performed as follows: participants were asked to walk back and forth on a 25-m distance at their most rapid but safe speed. Participants were allowed to use any walking aid they used in their everyday life. The ABC is a self-reporting scale that provides information regarding fear of falling when performing various tasks requiring different degrees of mobility, and its use is also recommended in LLAs [24,26,27]. We expected gradual correlations of the PLUS-M/FC-12 scores with the aforementioned instrument scores, the strongest with the ABC and lowest with the TUG.

2.4.3.4. Internal consistency. We calculated the Cronbach α coefficient.

2.4.3.5. Test–retest reliability. We calculated the ICC between 2 completions at a 1-week interval. If we did not receive the second PLUS-M/FC-12 after 21 days and 3 attempts to contact participants, we considered the participants lost to follow-up. We still analyzed all the medical data collected until then, so as not to compromise the value of the study as a whole.

2.4.3.6. Floor and ceiling effect. A percentage of 15% or more of participants with the lowest or highest T-score would reveal a significant floor or ceiling effect, respectively [28].

2.5. Sample size

The reproducibility of the original version has been evaluated as excellent, with ICC > 0.9 [3]. With an ICC > 0.9, we needed 50 participants to reject the hypothesis that the actual ICC is < 0.6, which corresponds to the lower limit for a "good" reproducibility.

2.6. Statistical analysis

We used the Kruskal-Wallis one-way ANOVA and Pearson chi-square test to compare demographic data and score results for each centre. PCCs were classified in 5 categories: $r \geq 0.91$, very high; 0.90–0.71, high; 0.70–0.51, moderate; 0.50–0.31, low; < 0.31, negligible [29]. The ICC was classified as < 0.40, poor; 0.40–0.59, fair; 0.60–0.74, good; 0.75–1.00, excellent [30]. $P < 0.05$ was considered statistically significant. Number Cruncher Statistical System (NCSS) v9 [31] was used for all correlation calculations.

3. Results

3.1. Transcultural translation

Table 1 summarizes the differences between the European-French and the Canadian-French versions of the PLUS-M 12-item Short-Form. For example, for the last item, we preferred to describe the word "hills" as "walking upslope and downslope" (*montées et descentes de pentes*) instead of *collines*, as in the Canadian-French version, which is not widely used in Europe. Before its final acceptance, we administered the PLUS-M/FC-12 to 5 people with LLA who reported full comprehension of its items and ease in completing it.

3.2. Transcultural validation

In total, 52 participants (mean [SD] age 53 [16] years, 40 [77%] males, 28/12/12 transtibial/Gritti-Stokes/transfemoral, 20/28/4 ischemic/traumatic/other) were included: 39 in Switzerland (25 at CHUV, 14 at CRR) and 13 in France (IRR). Detailed demographic data are in Table 2. Comparison of homogeneity of samples from the 3 centres revealed no significant differences. Table 3 shows the prosthetic equipment of participants.

Seven of the participants decided to only perform the physical tests during the visit and complete the questionnaires at home. Overall, 50/52 participants completed the PLUS-M/FC-12; one decided to complete only the PLUS-M/FC-12 and not the remaining questionnaires. Three participants skipped a question at first administration of the PLUS-M/FC-12 and 3 others at the second administration. We used the algorithm recommended by the developers to calculate their T-scores. Table 4 details the scores for the tools used for statistical assessments and compares results between centres.

3.3. Psychometric validation

3.3.1. Criterion validity

Data for 49 participants were available. Correlation with the PPA-LCI score was moderately high but still significant ($r = 0.56, P < 10^{-4}$).

Table 1

English version of the Prosthetic Limb Users Survey of Mobility and differences between the 2 French versions: European-French and Canadian-French. Differences are in italics.

Items	Original English version	Canadian-French version	European-French version
Item 1	Are you able to walk a short distance in your home?	Êtes-vous capable de monter et descendre *les bordures de trottoirs* ?	Êtes-vous capable de monter et de descendre *d'un trottoir* ?
Item 3	Are you able to walk across a parking lot?	Êtes-vous capable de traverser un *stationnement* ?	Êtes-vous capable de traverser un *parking* ?
Item 4	Are you able to walk over gravel surfaces?	Êtes-vous capable de marcher *sur des surfaces en gravier* ?	Êtes-vous capable de marcher *sur du gravier* ?
Item 6	Are you able to walk while carrying a shopping basket in one hand?	Êtes-vous capable de marcher tout en portant un panier *d'épicerie à la main* ?	Êtes-vous capable de marcher tout en portant un panier *de courses d'une main* ?
Item 7	Are you able to keep walking when people bump into you?	Êtes-vous capable de continuer à marcher si quelqu'un vous bouscule ?	Êtes-vous capable de continuer à marcher si quelqu'un vous bouscule *accidentellement* ?
Item 9	Are you able to keep up with others when walking?	Êtes-vous capable de *tenir le rythme des autres* qui marchent avec vous ?	Êtes-vous capable de marcher *aussi vite que les personnes* qui marchent avec vous ?
Item 10	Are you able to walk across a slippery floor?	Êtes-vous capable de marcher sur un *plancher* glissant ?	Êtes-vous capable de marcher sur un *sol* glissant ?
Item 11	Are you able to walk down a steep gravel driveway?	Êtes-vous capable de *marcher en descendant une pente abrupte en gravier* ?	Êtes-vous capable de *descendre un chemin de gravier escarpé* ?
Item 12	Are you able to hike about 2 miles on uneven surfaces, including hills?	Êtes-vous capable *faire une randonnée d'environ 3 km sur des surfaces inégales, incluant des collines* ?	Êtes-vous capable *de marcher environ 3 km sur des surfaces inégales, incluant des montées et descentes de pentes* ?

Table 2

Baseline characteristics of participants overall and by centre.

Characteristics	Overall (*n* = 52)	By centre			*P*-value
		CHUV (*n* = 25)	IRR (*n* = 13)	CRR (*n* = 14)	
Age (years), mean (SD) [min–max]	53.2 (16.0) [26–89]	55 (15) [26–81]	51 (14) [27–66]	53 (20) [27–89]	0.625
Sex, male	40 (77)	18 (72)	9(69)	13(93)	0.249
Time since amputation (years), mean (SD) [min–max]	9.9 (10.4) [1–43]	8 (9) [1–43]	14 (12) [2–36]	10 (10) [1–36]	0.235
Level of amputation					0.097
Transtibial	28 (54)	13 (52)	8(62)	7 (50)	
Transfemoral	12 (23)	3 (12)	5 (38)	4 (29)	
Gritti-Stokes	12 (23)	9 (36)	0 (0)	3 (21)	
Cause of amputation					0.528
Traumatic	28 (54)	13 (52)	7 (54)	8 (57)	
Ischemic	20 (38)	11 (44)	4 (31)	5(36)	
Tumor	3 (6)	0 (0)	2 (15)	1 (7)	
Infection	1 (2)	1 (4)	0 (0)	0 (0)	

Data are *n* (%) unless indicated. CHUV: Orthopedic Hospital, Centre Hospitalier Universitaire Vaudois; CRR: Clinique Romande de Réadaptation; IRR: Institut Régional de Réadaptation.

3.3.2. Construct validity

Data for 49 participants were available. Correlation was strongest with the ABC score ($r = 0.84$, $P < 10^{-6}$). Correlation with the 2MWT score was moderate but significant ($r = 0.53$, $P < 10^{-4}$) and with the TUG was low ($r = -0.43$, $P < 10^{-2}$).

3.3.3. Internal consistency

The calculated Cronbach's α was 0.90, indicating excellent internal consistency.

Table 3

Basic prosthetic equipment features of participants.

Prosthetic equipment features	
Prosthetic foot (*n* = 52)	
Class I	1 (2)
Class II	21 (40)
Class III	27 (52)
Class IV	3 (6)
Prosthetic knee (*n* = 24)	
Microprocessor controlled – C-leg	11 (46)
Microprocessor controlled – Rheo knee	4 (17)
Mechanical – free knee motion	6 (25)
Mechanical – blocked in extension	3 (13)

Data are *n* (%) of participants.

3.3.4. Test–retest reliability

The ICC calculated for the 46 individuals who completed the PLUS-M/FC-12 twice was excellent, 0.89 [95% confidence interval 0.81–0.94].

3.3.5. Face validity and usefulness

Overall, individuals reported a good understanding of the items and elevated relevance of the tasks assessed. Some patients made remarks. Among them, we noted difficulty to answer all questions having in mind just one prosthesis, format that misses considering variables such as physical fitness or perceived physical effort, inability to perform requested tasks because of factors limiting prosthesis use (e.g., skin issues), and lack of an item evaluating the use of public transportation.

3.3.6. Floor and ceiling effect

We found no significant floor or ceiling effect. No participants had the lowest *T*-score and only 4 (8%) had the highest *T*-score.

4. Discussion

We translated and cross-culturally adapted the original English version of the PLUS-M 12-item Short-Form in the European-French language and tested its psychometric properties.

Table 4

Scores for tests and questionnaires (criterion and construct validity) and first and second administration of "PLUS-M Formulaire Court en 12 items" (PLUS-M/FC-12) (T-scores) overall and by centre.

Tests and questionnaires	Overall ($n = 52$)	By centre			P-value
		CHUV ($n = 25$)	IRR ($n = 13$)	CRR ($n = 14$)	
2MWT (m)	148 (45)	133 (50)	152 (32)	170 (37)	0.041
	[48–226]	[48–226]	[115–210]	[65–225]	
TUG (s)	11 (6)	11 (7)	13 (4)	10 (6)	0.135
	[6–32]	[6–32]	[7–19]	[6–27]	
ABC (/100)	82 (17)	76 (18)	89 (12)	84 (16)	0.067
	[44–100]	[44–100]	[60–100]	[52–100]	
PPA-LCI (/42)	40 (4)	39 (5)	41 (1)	40 (3)	0.577
	[20–42]	[20–42]	[37–42]	[34–42]	
PLUS-M/FC-12 T T-score 1	56 (8)	53 (6)	61 (9)	58 (7)	0.030
	[40–71]	[40–65]	[48–71]	[48–71]	
PLUS-M/FC-12 T T-score 2	55 (7)	53 (7)	58 (6)	55 (7)	0.115
	[39–67]	[39–63]	[50–67]	[45–67]	

Data are mean (SD) [min–max]. CHUV: Orthopedic Hospital, Centre Hospitalier Universitaire Vaudois; CRR: Clinique Romande de Réadaptation; IRR: Institut Régional de Réadaptation; 2MWT: 2-min walking test; TUG: Timed Up and Go; ABC: Activities-specific Balance Confidence; PPA-LCI: Prosthetic-Profile-of-the-Amputee-Locomotor Capabilities Index.

Minimal difficulties in the choice of the better-adapted translation of some terms were discussed. To assess criterion and construct validity, we used the ABC, PPA-LCI, 2MWT, and TUG because they are all recommended tools for use in LLAs [10,11,26], they are easy to use and widely used, and they measure various features related to mobility. The mean scores in our study showed that globally our sample presented a high level of mobility, with good walking ability and confidence in their balance while performing activities. According to the PLUS-M Short-Form User Guide, a *T*-score of 50 is equivalent to the mean score reported by unilateral LLAs included in the development study, and 50% of individuals with unilateral LLA are expected to have a *T*-score of 50 or higher [18]. Our study sample's mean *T*-score of 56.1 corresponds at a level of mobility that more than 70% of LLAs would consider superior to their level and therefore shows that the participants were skilled ambulators.

Correlation with PPA-LCI scores was, as expected, moderately strong ($r = 0.56$), for good criterion validity. The high known ceiling effect of the PPA-LCI played a role in this result. In fact, 28 of participants achieved the highest possible score on the PPA-LCI (42/42). Because the PPA-LCI's use is recommended mostly in an initial rehabilitation stage [10] and participants' mean time since amputation was nearly 10 years, the not excellent correlation is reasonable. Of note, the original's instrument validation study [8] found a strong ability of the PLUS-M 12-item Short-Form to detect differences in functional mobility. Significant differences were found between mean *T*-scores for subgroups classified according to K-level classification [32]. The above result may reflect this feature.

PLUS-M/FC-12 showed excellent correlation with ABC scores, a result similar to the development study ($r = 0.84$ vs 0.81). This result is consistent with evidence that balance is the aspect of physical capacity with strongest correlation with walking ability after LLA [33]. The fairly strong correlation with the 2MWT score and the low correlation with the TUG score are not surprising. The 2MWT measures do not correspond to real life conditions [10]. The high ceiling effect of the TUG explains this correlation result. More precisely, 33 participants had a score ≤ 10 s in the TUG test. We consider that our hypothesis for gradual correlation between scores of the PLUS-M/FC-12 and the instruments compared is fulfilled: the PLUS-M/FC-12 correlation was lower with the TUG score and progressively higher with 2MWT and ABC scores.

We consider the PLUS-M/FC-12 suitable for use in a clinical outpatient setting in active unilateral LLAs who are experienced in the use of a prosthesis because of the excellent internal consistency and reproducibility of its items, as evidenced by the Cronbach α and ICC (0.90 and 0.89, respectively), in our sample, and the rapidity and simplicity of use. Additionally, participants globally found the instrument interesting and useful. Their remarks on the instrument demonstrate the multitude of factors affecting the mobility of such individuals. From these remarks, we could eventually propose the addition/replacement of an item concerning the use of public transportation and/or an open question, asking respondents to describe difficulties in another activity that they find particularly important.

The PLUS-M 12-item Short-Form already exists in a large number of languages [34]. To our knowledge, our study is the first to be published that validates a translated version. The multisite character with participants having received interdisciplinary rehabilitation services from 3 different teams reinforces the reliability of our results. Additionally, most participants completed the questionnaires during a guided medical visit, so the risk of measurement bias with questionnaires administered at home or by telephone was minimized.

5. Study limitations

The first limitation is the particularity of our translation procedure in that no initial translation was made because we used the already available Canadian-French version to format a European-French one. Otherwise, we followed an initially informal translation procedure as described by the developers and then proceeded with a back translation and second verification to solidify the result and conform to international guidelines.

Most (54%) participants had a traumatic origin of amputation. This feature does not replicate the real epidemiologic data in which traumatic causes represent $< 10\%$ of major LLA cases. There is a dual explanation for this. First, the exclusion criteria, and particularly the cognitive impairment and prosthesis use limited to household activities, concerning mostly older dysvascular amputees. Second, we recognize some recruitment bias. The CRR is a trauma-oriented rehabilitation centre, and the CHUV and IRR preferentially receive patients aged 18 to 65 years. Consequently, our sample would include an increased proportion of amputees due to traumatic reasons. We first recruited patients completing our criteria during a consultation period between November 2017 and February 2018.

We did not perform a cognitive screening of the candidates before inclusion in the study. However, participants' full medical history is registered in each centre. Hence, we believe that

documented cognitive impairment as an exclusion criterion was sufficient to guarantee the adequacy of their answers.

The use of the PLUS-M instruments is suggested for experienced prosthesis users (use $\geq$ 6 months) [18], and we also suggest using the PLUS-M/FC-12 with caution in patients with amputation dates < 1 year, because it was not tested in such a population. Moreover, the objectives of inpatient rehabilitation do not necessarily include a high level of prosthesis use and all activities described in the PLUS-M/FC-12 items.

The PLUS-M/FC-12 and the version with 7 items (PLUS-M/FC-7) were uploaded and are available at http://www.plus-m.org/translations.html. Translation of the user's guide in French is in progress. Further validation testing of the PLUS-M/FC-12 is necessary before suggesting it for administration in all LLAs. We propose a longitudinal evaluation with a large-scale administration including item response theory testing, comparison between different K-levels and subgroups of LLAs (by etiology/level of amputation) and assessment of sensitivity to change after intervention. Future studies should include international teams working on further testing of the instrument, to develop an international consensus on normative data and even an international classification of mobility levels according to its scores.

6. Conclusions

The PLUS-M/FC-12 is a valid instrument to evaluate perceived mobility in French-speaking, active people with unilateral LLA who are experienced prosthesis users. It covers a broad spectrum of activities, is adapted for high-level ambulators and is suitable for administration in ambulatory clinical practice. It helps the rehabilitation team distinguish and prioritize patients' needs in prosthetic adaptations and therapies. Added to the Houghton, PPA-LCI and SIGAM-Fr scales, it completes the variety of instruments measuring the mobility of French-speaking LLAs by responding to the need for a tool targeted to be used in a long-term outpatient rehabilitation setting. Its validation should be completed by assessment of other psychometric qualities and especially its sensitivity to change. The use of this short-form questionnaire for both clinical and research purposes could then be definitely proposed, especially in active amputees.

Disclosure of interest

The authors declare that they have no competing interest.

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