Transcultural validation of the SIGAM mobility grades in French: The SIGAM-Fr

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ABSTRACT

Background: The main French language scales evaluating functioning after lower-limb amputation have not undergone exhaustive psychometric validation.

Objective: A transcultural validation of the Special Interest Group in Amputee Medicine (SIGAM) mobility grades questionnaire, with 21 closed questions, as an administered questionnaire.

Methods: The questionnaire translation, back-translation and original-author validation was followed by a pretest with 5 patients to check comprehension. The psychometric properties of the scale were validated with 49 patients at the definitive prosthesis stage by an investigator via telephone. Criterion validity was evaluated by comparison with the Houghton Scale score and construct validity by correlation between the questionnaire scores and convergent dimensions (performing everyday activities and performing transfers on a numerical rating scale [NRS], 2-min walk test) and divergent dimensions (managing medication and stump skin care on an NRS). Internal consistency was assessed by the Kuder–Richardson Formula 20 (KR-20) coefficient and test–retest reproducibility by the Cohen kappa coefficient.

Results: The resulting questionnaire was validated by the original author after the back-translation. It showed good psychometric properties when administered by an investigator as a self-reporting questionnaire, excellent criterion validity (r = 0.89, P < 0.01), excellent reproducibility (kappa coefficient 0.87) and satisfactory construct validity. The KR-20 coefficient was 0.67.

Conclusion: The French version of the SIGAM mobility grades questionnaire (SIGAM–Fr) has satisfactory psychometric properties and can be administered in clinical practice.

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1. Introduction

Major amputation of the lower limb(s) is a health problem in many countries: in France, 4202 trans-femoral amputations and 3640 amputations at the knee or trans-tibia were performed in 2007 [1]. The estimated incidence of all-cause amputations is 1.4/10,000 people in Brazil and 3.4 and 1.7/10,000 people for men and women, respectively, in the United States [2]. The profile of patients undergoing lower-limb amputations has evolved, with amputations for vascular disease predominant [1], mainly in older frail patients, who require personalised program in terms of interventions and surveillance because of their potential comorbidities (mood status, cardiac impairment). Beyond these physical aspects, the participation of amputees in everyday life activities may be restricted depending on their psychological state, environmental factors, and prosthesis-related aspects.

The choice of the prosthesis depends on the patient’s objectives, especially the possibility of walking and its quality, which is a crucial element for autonomy and quality of life. The evaluation of walking ability is thus essential to achieve optimal management during rehabilitation.

We have many ways to evaluate deficiencies and limitations of activity resulting from amputation (locomotion problems, difficulties in performing transfers [e.g., from bed to wheelchair], etc.). Clinical tests used for evaluations include balance tests and
standardized walking tests (e.g., 2-min walk test, get-up-and-go test). These tests can be refined by instrumental evaluations (stabilometry, quantified gait analysis) that provide objective quantitative data resulting from specialised professional and technological resources, which are often time-consuming and expensive. Other evaluations involve questionnaires and scales. Such tools are subjective but are easy to administer in routine clinical practice, as a self-reporting or administered questionnaire. Certain generic questionnaires are available (e.g., Barthel index, Functional Independence Measure) but are of limited use because they are not specific to lower-limb amputees [3].

Questionnaires that are specific to functional limitations in amputees fitted with a prosthesis have shown good metrological qualities [3]. However, only 2 have been validated in French: the Houghton Scale and the Prosthetic Profile of Amputees. The Houghton Scale is an administered questionnaire in which walking ability carries considerable weight [4]. It can be used to evaluate the results of prosthetic fitting by considering use of the prosthesis, walking outside and stability of the patient on different surfaces. This scale has been validated in French, even though its criterion validity was moderate as compared with the Barthel index [5]. The Prosthetic Profile of the Amputee is a global questionnaire [6] that takes into account patients’ physical condition, satisfaction, use of the prosthesis, and interactions with the physical and social environment. This questionnaire features good validity and satisfactory reproducibility in French. It also includes a mobility index as a subscale, which aims to objectively analyse the functional capacities of patients with their prosthesis. However, it is time-consuming and difficult to use, which, despite its many advantages, limits its use in everyday clinical practice.

Because these questionnaires provide limited analysis or are too complex for everyday clinical practice, other tools are necessary. A transcultural validation of the Special Interest Group in Amputee Medicine (SIGAM) mobility grades questionnaire may be an alternative [3,7]. Indeed, this scale, proposed by the British Society of Rehabilitation Medicine, is a self-administered questionnaire comprising 21 closed questions (yes or no responses). It evaluates walking in terms of help from others, walking aids, walking distance and ability to walk on different surfaces and in different meteorological conditions (Appendix A). This questionnaire can be analysed simply by using a defined algorithm (Appendix A) that provides perfect reproducibility of analysis [7]. This questionnaire also shows good validity as compared with the Timed Walking Test [8] and the Rivermead Mobility Index [9] and good sensitivity to change. Therefore, the scale seems appropriate to obtain an objective clinical description of functional mobility in patients with lower-limb amputation. Given its ability to provide a simple, quick and comprehensive evaluation of functioning and walking for such patients, this detailed self-reporting questionnaire deserves to be translated into French [3]. The transcultural validation of a measurement instrument is a crucial process before its widespread use in international clinical trials [10]. The instrument’s first validation was in Dutch [11] and it has been used in British and Dutch research protocols [12] for evaluating activity limitations for lower-limb amputees.

The aim of this work was to undertake the transcultural translation of the SIGAM mobility grades questionnaire into French, then validate its psychometric properties by investigator administration of the questionnaire.

2. Methods

This was a single-centre prospective study approved by our institutional ethics committee and conformed to the principles outlined in the Declaration of Helsinki. The study was in 2 parts: transcultural translation and transcultural validation. Patients who helped validate the instrument gave their informed oral consent to be in the study.

2.1. Transcultural translation

We followed international recommendations for this type of work [13–16]. We requested permission to develop a French version of the SIGAM mobility grades questionnaire from the original author of the scale (Dr. N.H. Ryall) and asked him to take part in the instrument validation as an expert. Then, 2 bilingual native French-speaking translators translated the questionnaire into French. One of the translators is a physical medicine and rehabilitation physician and thus knew the concepts measured by the scale. The second does not work in the field of medicine, so the initial translations would not be affected by the medical culture, thus limiting the use of medical terms, which could be ambiguous or incomprehensible to patients. The committee of native French-speaking experts met to compare the 2 translations. Disagreements were resolved by discussion. Then, a bilingual native French-speaking translator, who had not taken part in the first translation and did not know the initial questionnaire, back-translated the questionnaire. This translator was neither a physician nor an expert in the field. The back-translation was presented to the original author of the questionnaire (Dr. N.H. Ryall) to determine whether it agreed with the original questionnaire from a conceptual point of view. Then the questionnaire was tested on a small sample of amputees patients (n = 5) to assess its feasibility.

2.2. Transcultural validation

2.2.1. Population and protocol

Patients included were consulting at the prosthesis-fitting centre at Dijon CHU following single-limb or double-limb trans-tibial or trans-femoral amputation. We excluded patients < 18 years old, with a prosthesis for < 6 months or recent modification of the prosthesis < 4 months (other than renewal of the socket), who were unable to complete the questionnaire because of cognitive disorders (Mini-Mental State Examination score < 23 [17,18]) or had language barriers.

2.2.2. Variables measured

For each patient, we recorded age, sex, level of amputation, reason for the amputation, score on the Hospital Anxiety and Depression Scale (HADS) [19,20], the Houghton Scale score [4] and self-evaluation of the following items by a Numerical Rating Scale (NRS) from 0 to 10: performing everyday activities, satisfaction with the prosthesis, performing transfers independently, care of the skin around the stump, managing medication and evaluating phantom pain. The SIGAM-Fr was administered by an investigator by telephone as a self-reporting questionnaire.

2.2.3. Psychometric validation

2.2.3.1. Criterion validity. We assessed the concurrent validity of the SIGAM-Fr score by its correlation with the score for the French version of the Houghton Scale, the reference scale in France, by Spearman’s correlation coefficient.

2.2.3.2. Construct validity. To assess construct validity, we evaluated convergent validity and divergent validity of the attributed grade. To assess convergent validity, we measured correlations between the SIGAM-Fr grades and values for variables that a priori reflected similar dimensions or concepts. For divergent validity, we examined correlations between the SIGAM-Fr grades and values for variables that a priori reflected dimensions or concepts that
differed from those evaluated by our questionnaire. Hence, we hypothesized that the SIGAM-Fr score would correlate closely with patient NRS scores for performing everyday activities (0: “inability to practice activities”; 10: “easy to practice activities”), performing transfers (0: “inability to perform transfers”; 10: “perfect performance of transfers”) and performing the 2-min walk test (data from previous consultations) and 2 would not correlate with NRS scores for managing medication (0: “unable to manage medications by self”; 10: “perfect management of medications by self”) and stump skin care (0: “no care of stump skin”; 10: “daily care of stump skin”). We used the NRS because of its ease of use and good understanding by patients. Furthermore, this method allowed us to cover areas not explored by other scales used for lower-limb amputees.

2.2.3.3. Reliability. We analysed the internal consistency of the questionnaire by the Kuder–Richardson Formula 20 (KR-20) because it deals with dichotomous variables (yes or no) [21] and examined its test–retest reproducibility by calculating the Cohen kappa coefficient [22]. Each patient completed the SIGAM-Fr twice at an interval of 2 weeks as an administered questionnaire during telephone interviews with an investigator. Patients were considered lost to follow-up after 3 unsuccessful attempts to contact them by telephone at day 14.

2.2.3.4. Evaluation of confounding factors. We chose several confounding factors that might modify the SIGAM-Fr score. We assessed the correlation between these factors and the SIGAM-Fr score by the Spearman’s correlation coefficient. Confounding factors were NRS scores for phantom pain (0: “permanent phantom pain”; 10: “no phantom pain”) and satisfaction with the prosthesis (0: “not satisfied at all with prosthesis”; 10: “perfect satisfaction with prosthesis”) and the HADS score.

Phantom pain, present in many patients, can have an important role in the mood of these patients. Moreover, phantom pain is commonly reduced by the use of the prosthesis. Because mood can modify patient’s walk, we considered it a confounding factor. Satisfaction with the prosthetic material, whether justified or not, determines the use of the prosthesis.

The HADS score is a validated score [19,20] that measures anxiety and depression. Mood can interfere with the patient’s motivation and induce an incorrect SIGAM-Fr score. The HADS score comprises 14 items scored from 0 to 3. Seven items explore anxiety with a threshold score of 12 and 7 explore depression with a threshold score of 8. The HADS is a self-reporting questionnaire that was administered by telephone by an investigator. To validate the use of the HADS score as an administered questionnaire, we evaluated its test–retest reproducibility at 2-week intervals by calculating the intra-class correlation coefficient (ICC) [23] for patients for whom the reproducibility of the SIGAM-Fr was evaluated as an administered questionnaire.

3. Statistical analysis

Statistica 7.0 (StatSoft) was used for all correlation calculations and Microsoft Excel for KR-20 coefficients. ICCs and Cohen kappa coefficients were calculated by use of SPSS 20.0 (SPSS Inc., Chicago, IL). Spearman’s correlation coefficients were classified in 5 categories: $r > 0.91$, excellent; $r: 0.90–0.71$, good; $r: 0.70–0.51$, moderate; $r: 0.50–0.31$, modest; $r: 0.31$, weak or nil [14]. The kappa coefficient was classified in 5 categories by agreement: $k > 0.81$, almost perfect; $k: 0.80–0.61$, strong; $k: 0.60–0.41$, moderate; $r: 0.40–0.21$, weak; $r: 0.21$, very weak [22]. $P < 0.05$ was considered statistically significant.

4. Results

4.1. Transcultural translation

The transcultural translation led to the French version of the SIGAM (SIGAM-Fr; see appendices). The author of the English version (Dr. N.H. Ryall) had no changes to the back-translation. The feasibility evaluated with 5 patients was satisfactory. The questionnaire took < 5 min to administer and patients had no difficulties understanding the questions.

4.2. Transcultural validation

In total, 50 patients (12 women) took part in the validation study (Fig. 1; mean age 61.5 ± 13 years, range 20–83 years); their characteristics are in Table 1. Trans-tibial amputations were the most frequent ($n = 34$ patients; 68%), and the reasons for amputation were mainly vascular. One native Italian-speaking patient was excluded because he could not complete the SIGAM-Fr questionnaire and did not understand the NRS because of minor cognitive disorders due to a
stroke. The results of the questionnaires used for validation are in Table 2.

4.2.1. Psychometric validation

4.2.1.1. Construct validity and criterion validity. We found good correlation between the SIGAM-Fr and Houghton Scale scores ($r = 0.89$, P < 0.01) (Table 3). Convergent validity ($n = 49$ patients) was moderate with the NRS score for everyday activities ($r = 0.58$, P < 0.01) and satisfaction with the prosthesis ($r = 0.51$, P < 0.01) and modest for performing transfers ($r = 0.31$, P = 0.03). The SIGAM-Fr score was not correlated with the 2-min walk test score ($n = 33$) (data not shown), but the correlation was moderate when considering only patients with a SIGAM-Fr score of at least D ($n = 10$), or able to walk more than 50 m ($r = 0.66$, P = 0.04). Divergent validity was satisfactory; all of our hypotheses were verified because of no significant correlation between the SIGAM-Fr and NRS scores for managing medicine and care of the stump.

4.2.1.2. Reliability. The internal consistency was < 0.7 (KR-20 coefficient 0.67). In total, 34 patients (mean age 61.8 ± 14.2 years) evaluated test-retest reliability. Two patients refused the retest and one was excluded because of a new skin lesion that disallowed fitting the prosthesis. The remaining patients were lost to follow-up. The Cohen kappa correlation coefficient was excellent, 0.87.

4.2.1.3. Confounding factors. The correlation between the SIGAM-Fr score and NRS score for phantom pain was moderate, whereas that between the SIGAM-Fr score and the HADS depression score and NRS score for satisfaction with the prosthesis was good ($r = 0.62$; $r = 0.51$, respectively, both $P < 0.01$). Four of 34 patients refused to evaluate the test-retest reliability of the HADS. The mean anxiety score when the test was administered by an investigator was $7 ± 4$ (ICC 0.65 [95% confidence interval 0.44; 0.82]). The mean HADS depression score at the initial test was $6 ± 5$ (ICC 0.95 [0.90; 0.98]).

5. Discussion

This work led to the translation, cultural adaptation and psychometric validation in French of an English language questionnaire allowing for functional assessment in patients with lower-limb amputation, the SIGAM-Fr.

The transcultural translation phase posed few difficulties, which can be explained by the spontaneous common choice of translation terms by both translators, such as “prothèse” for “false leg” and by using the simple vocabulary used in the original questionnaire, so the questionnaire was easy for patients to understand. The only difficulties concerned the construction of complex phrases (e.g., “Outdoors, do you just occasionally use a walking aid, such to increase your confidence in adverse weather conditions or on uneven ground?”). Indeed, the difficulty was in structuring the sentence so that all of the information could be understood and considered in the answer. The rest of the discussion concerned terminology such as “indoors”, “À l’extérieur” was finally chosen because it refers to the patient’s home and was thus easier, in our opinion, to understand.

We found very good criterion validity of the SIGAM-Fr when administered by an investigator, with significant correlation ($r = 0.89$) with the Houghton Scale score. The construct validity was satisfactory, as our hypotheses were verified. However, correlation with the 2-min walk test results was significant only if we excluded patients able to walk 50 m without stopping, which is probably explained by a floor effect of the 2-min walk test for distances < 50 m [24].

The SIGAM-Fr score was inversely correlated with the HADS depression and NRS phantom pain scores, so these factors may lead to a lower functional capacity. This is not surprising, since this result is consistent with the clinical observation that patients with a high level of depression and anxiety experience more difficulties in using their prosthesis [25].

Table 1

<table>
<thead>
<tr>
<th>Clinical and demographic characteristics of the 50 patients with lower-limb amputation taking part in the validation of the SIGAM-Fr.</th>
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<tbody>
<tr>
<td>Age (years), mean ± SD</td>
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<tr>
<td>Women</td>
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<td>Level of amputation</td>
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<tr>
<td>Trans-femoral</td>
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<td>Trans-tibial</td>
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<td>Bilateral</td>
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<td>Cause of amputation</td>
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<td>Vascular</td>
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<td>Traumatic</td>
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<td>Congenital</td>
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Data are no. (%) unless indicated.

Table 2

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<thead>
<tr>
<th>Results of questionnaires used for validating the SIGAM-Fr.</th>
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<tbody>
<tr>
<td>SIGAM-Fr score, no. (%)a</td>
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<td>Grade A</td>
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<td>Grade B</td>
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<td>Grade C</td>
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<td>Grade Ca</td>
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<td>Grade E</td>
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<td>Grade F</td>
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<tr>
<td>NRS score, mean ± SD</td>
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<tr>
<td>Performing everyday activities</td>
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<tr>
<td>Satisfaction with prostheses</td>
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<tr>
<td>Performing transfers</td>
</tr>
<tr>
<td>Managing medication</td>
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<tr>
<td>Phantom pain</td>
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<tr>
<td>Stump skin care</td>
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<tr>
<td>Houghton Scale, mean ± SD</td>
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<td>HADS, mean ± SD</td>
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<tr>
<td>Anxiety score</td>
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<tr>
<td>Depression score</td>
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<td>2-min walk test (m), mean ± SD</td>
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</tbody>
</table>

NRS: numerical rating scale; HADS: Hospital Anxiety and Depression Scale.

* See Appendix A for definitions of grades.
modify the SIGAM-Fr score and should be considered in its analysis. Moreover, these results suggest the importance of the psychological dimension in this population. Management of the psychological dimension could be helpful for improving the autonomy of these patients. We previously proposed appropriate care for patients with significant scores (HADS depression > 8 and anxiety > 12) [19,20]. The NRS phantom pain score was not correlated with the depression score (data not shown). One of the limits is that we evaluated phantom pain on an NRS, even though, for most of the patients, the pain occurred rarely but was paroxystic with high intensity peaks.

Internal consistency was < 0.7. However, the purpose of the questionnaire is to define several dimensions (purely aesthetic, walk ability, meteorological conditions, etc.), which are defined by several grades, so this point does not alter the quality of the scale.

One of the strengths of this work is the diversity of levels and causes of amputation captured, which reflects the real diversity of the population of lower-limb amputees. However, a large number of patients had amputations following trauma, as explained by the many young patients in our cohort and by recruitment bias: one of the physicians in the unit treats military patients who are more likely than the population at large to undergo trauma-related amputations.

The SIGAM-Fr scale is easy to use, as shown by the time taken to complete the questionnaire, < 5 min, so it is suitable for clinical practice. Moreover, the scale seems to reflect the functional abilities of patients, in terms of walking, with good psychometric properties because of an easy-to-use algorithm that provides a grade. This functional analysis is refined by a more specific analysis of the questionnaire, which, as well as the grade, provides the clinician with information on walking aids, nursing care or rehabilitation for the patient and the use of the prosthesis depending on the walking surface and weather conditions. This information can be important in the follow-up and specific rehabilitation for these patients.

This scale allows for 2 types of analysis: a quick analysis in the form of a score for each patient, which can be used in clinical practice to follow patients’ functional improvement and for research projects, and a more precise analysis that provides the clinician with a large number of additional elements for a clearer analysis of certain dimensions of walking, which can be used to refine rehabilitation protocols.

The first limitation of this work stems from the validation itself. Indeed, measurement bias may arise in administered questionnaires, and this risk is exacerbated when interviews are conducted by telephone: we could not be certain that patients were alone during the interviews or if they answered the questions without really understanding them and did not dare ask the investigator to repeat it. For this reason, we did not consider in the analysis the HADS data for the 4 patients for whom a third person helped with the answers. To have reproducible and comparable data, the same investigator interviewed all patients for both the test and retest. Only one patient was included by a different investigator. This situation is also a limitation and confirmation that inter-observer reliability should be tested before the widespread use of the questionnaire.

This work is the first part of a larger project. Indeed, further study by other associated teams will validate the reproducibility and the sensitivity to change of the SIGAM-Fr as a self-reporting questionnaire administered by an investigator. We will also continue the validation process for SIGAM-Fr as an self-administered questionnaire with sensitivity to change analysis. Moreover, the reliability of the algorithm by different assessors, following the same method used by Ryall et al. [7] would be of interest. This scale could thus be used for follow-up of lower-limb amputees as a self-reporting questionnaire administered by an investigator. Finally, this transcultural validation of the SIGAM-Fr could be suitable for widespread use in international clinical trials.

6. Conclusion

The French version of the SIGAM mobility grades questionnaire (SIGAM-Fr) shows good psychometric properties, with excellent reliability, excellent criterion validity and satisfactory construct validity. This scale could become an alternative to the Houghton Scale because of the analysis of domains not covered by this scale, allowing for a good follow-up of these patients and the choice of prosthetic material corresponding to their autonomy. Indeed, the SIGAM-Fr can be used to evaluate the restricted participation of amputees at different levels in a variety of conditions: at home, outside, on rough or level ground, and considering weather conditions and walking distance. In addition, this scale provides the clinician with information on the care received by the patient and the walking aids used. Finally, it considers the purely aesthetic use of the prosthesis, which is important and not covered in other questionnaires. The SIGAM-Fr is easy to use, taking < 5 min to administer by an investigator. This ease of use contrasts with the Prosthetic Profile of the Amputee, which, although comprehensive, is time-consuming for use in everyday clinical practice.

To achieve optimal use of this scale, other multicentre studies are under way and will allow its validation as a self-report questionnaire auto-administered and evaluation of its sensitivity to change.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.rehab.2015.02.003.

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