Measuring mobility in persons with a lower-limb amputation

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Measuring mobility in persons with a lower-limb amputation

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Promotor:	Prof. dr. J.H.B. Geertzen
Copromotores:	Dr. L.D. Roorda Dr. G.M. Rommers
Beoordelingscommissie:	Prof. dr. H.J. Stam Prof. dr. J.W. Groothoff Prof. dr. G.G Vanderstraeten

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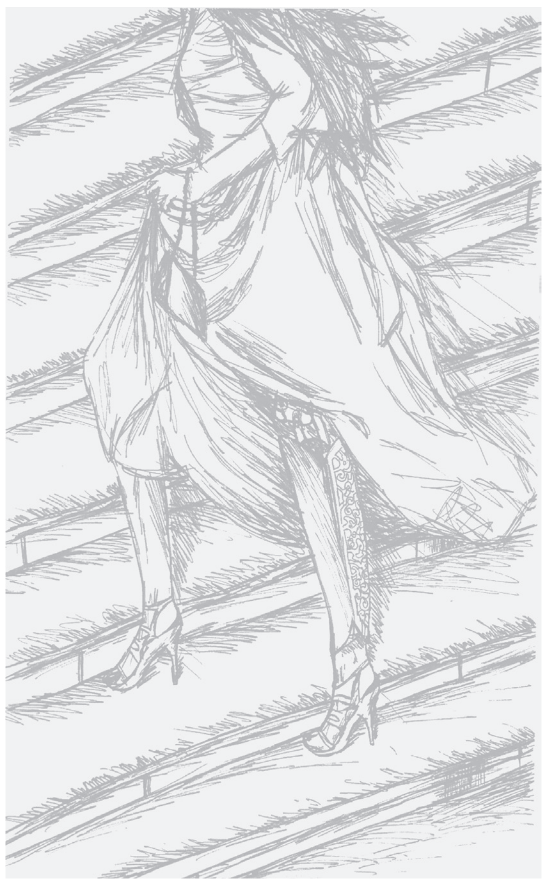
Chapter 1

General introduction



Background of the thesis

There are about 20 lower-limb amputations (LLAs) per 100000 inhabitants annually in the Netherlands.[1] This includes major LLAs (transtibial and higher) and minor LLAs (foot amputations, toe amputations). They are both mainly performed as a result of vascular disease and/or diabetes mellitus.[2] Persons with minor LLAs are mostly treated with shoe adaptations or (semi-) orthopedic shoes. In the Netherlands, these treatments are mostly accomplished via close cooperation between a physiatrist and an orthopedic shoe technician in a combined appointment.[3]

Persons with a major LLA are mostly treated in a multi-disciplinary rehabilitation team. Such rehabilitation treatment is initiated and coordinated by a physiatrist when treated in a rehabilitation center, or by an elderly care physician when treated in a nursing home.[4] Many different kinds of therapists can be involved in the rehabilitation treatment: physiotherapists, occupational therapists, nurses, psychologists, social workers, orthopedic engineers and so on.[2] As such, biomedical, psychosocial and engineering interventions come together to restore impaired body functions and structures.[5]

After a LLA, a main goal of rehabilitation is to restore mobility.[6] Therefore, a mobility outcome measurement was chosen as an indicator of quality of care by the Netherlands Society of Physical and Rehabilitation Medicine (VRA) and the Dutch Society of Rehabilitation Centers (RN). They chose The SIGAM/WAP mobility scale,[7] despite this scale only measures the walking aspect of mobility. In the ICF model (see figure 1), mobility is a component of "activity", and a mobility limitation can be defined as difficulty with walking and moving around (ICF codes d450-d469) and changing or maintaining body position (ICF codes d410-d429).[8]

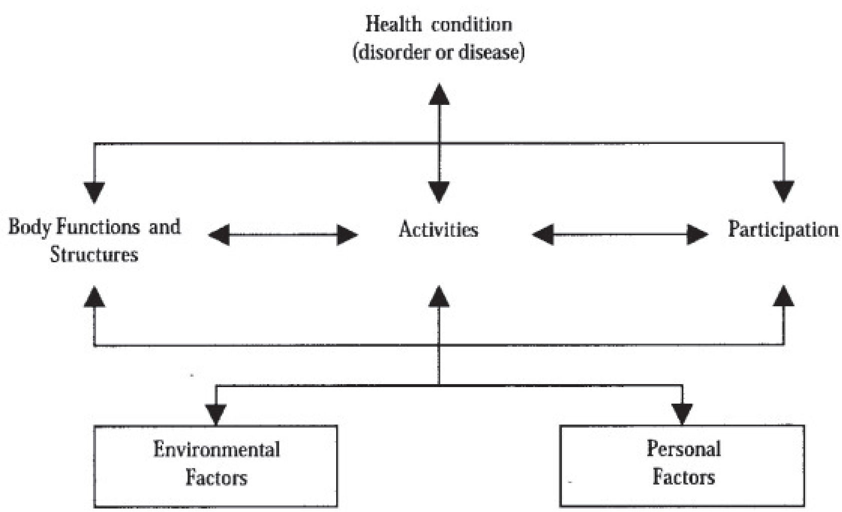


Figure 1: the ICF model

Mobility is regarded by persons with a LLA as the most relevant ability for their quality of life.[9] Indeed, if we ask a patient who will undergo a LLA what the goal of rehabilitation treatment is, he or she will probably answer 'to participate as before with a prosthesis', even though about half of them will not be prescribed with a prosthesis following their LLA. Mobility rehabilitation with a prosthesis initially focuses on being able to rise and sit down, followed by standing (for longer periods), walking and climbing stairs.

Many instruments have been developed to measure mobility limitations in persons with a LLA, but no golden standard exists and psychometric properties are mostly unknown.[10-12] Instruments that provide a detailed measurement of aspects of mobility, such as rising and sitting down, walking and climbing stairs, are either non-existent or have not yet been validated in persons with a LLA. Research methodologists often argue that rather than developing new measurement instruments, existing ones should be rigorously tested and improved, if necessary.[13] Recently, quality criteria were proposed for these measurement instruments:[14]
(1) *content validity*, i.e. the extent to which the concepts of interest are comprehensively represented by the items in the questionnaire. To rate the content validity, the conceptual framework must have been clearly described, as well as the item selection and item reduction, and the interpretability (items should be short and simple).
(2) *internal consistency*, i.e. the extent to which items in a questionnaire (sub)scale are correlated (homogeneous), thus measuring the same concept.
(3) *criterion validity*, i.e. the extent to which scores on a particular instrument relate to a golden standard. However, there is no golden standard in mobility scales in persons with a LLA.
(4) *construct validity*, i.e. the degree to which the scores on a measurement instrument are consistent with theoretically derived hypotheses (e.g. with regard to internal relations, relationships to scores of other instruments, or differences in scores between relevant groups), based on the assumption that the instrument validly measures the construct being measured.
(5) *reproducibility*, i.e. the degree to which repeated measurements in stable persons (test-retest) provide similar answers. Reproducibility includes reliability and agreement.[15] Reliability refers to how well individuals can be distinguished from each other; whereas, agreement indicates how close the repeated measurements are to the original measurements.
(6) *responsiveness* i.e. the ability of a questionnaire to detect clinically important changes over time.
(7) *floor or ceiling effects*, i.e. more than 15 % of respondents achieve the lowest or highest possible score.[14]
(8) *interpretability*, i.e. the degree to which one can assign qualitative meaning to quantitative scores. This can be derived by presenting norm values or scores of relevant subgroups of patients.

Nowadays, scales with a good fit with an Item response Theory (IRT) model are recommended.[16, 17] Important advantages of a fit with the IRT model are the possibility of (hierarchical) item ordering in one scale, the independency of the amount and the characteristics of the sample, and the possibility of computerized adaptive testing (CAT). In CAT, the computer tries to locate the patient's position on the hierarchical scale with just a few questions. This system enlarges the feasibility of assessment by individual measurement: per patient, items are selected based on previous responses, tailored to individual level. This results in precise and comprehensive measurement with just a few items. As far as we know, only three instruments assessing mobility limitations in persons with a LLA have been studied for a fit with an IRT model: the SIGAM mobility grades,[18] the Prosthesis Evaluation Questionnaire (PEQ) mobility scale section[19] and the Locomotor Capabilities Index (LCI).[20] The SIGAM mobility grades exclusively assesses walking aspects of mobility, whereas the LCI and PEQ provide only superficial information about mobility, due to the limited number of questions concerning the mobility items.

For a detailed measurement of mobility in persons with a lower-extremity disorder, Roorda ea. developed the Questionnaire Rising and Sitting Down, the Walking Questionnaire, and the Climbing stairs Questionnaire.[21-23] The author showed a good fit with non-parametric IRT models. Moreover, he showed good content validity, good internal consistency, and, on initial examination, no floor or ceiling effects. With such good clinimetric properties of this questionnaire, and such relevant items regarding mobility in persons with a LLA, it is interesting to study if this questionnaire is appropriate to assess the mobility limitations specifically in persons with a LLA.

Aims of the thesis

The aims of this research were:

1) to assess the construct validity and the reproducibility of the Questionnaire Rising and Sitting Down, the Walking Questionnaire, and the Climbing stairs Questionnaire in persons with a LLA.
2) to assess the mobility limitations in rising and sitting down and in climbing stairs in prosthesis-wearing persons with a LLA, and their relationship with several personal and clinical variables.

The outline of this thesis is as follows:

The first part of this thesis (chapters 2-4) describes the psychometric testing of the Questionnaire Rising and Sitting Down, the Walking Questionnaire, and the Climbing stairs Questionnaire in persons with a LLA after rehabilitation treatment. Chapter 2 describes the testing of the construct validity and the reproducibility (both reliability and agreement) of the Questionnaire Rising and Sitting Down in persons with a LLA. Chapter 3 reports on the construct validity and test-retest reliability of the Walking Questionnaire in persons with a LLA. Chapter 4 describes the testing of the construct validity and test-retest reliability of the Climbing Stairs Questionnaire in persons with a LLA.

In the second part of this thesis (chapters 5-6), the outcome on 2 aspects of mobility limitations in persons with a LLA are described: rising and sitting down, and climbing stairs. Chapter 5 focuses on a detailed description of limitations in rising and sitting down and their relationship with personal and clinical variables. Chapter 6 describes in detail the necessity and ability to climb stairs in better-performing persons with a LLA and the relationship between the ability to climb stairs with personal and clinical variables. In chapter 7, the main findings of this thesis are discussed, and recommendations for further using the questionnaires and implications for clinical practice are given.

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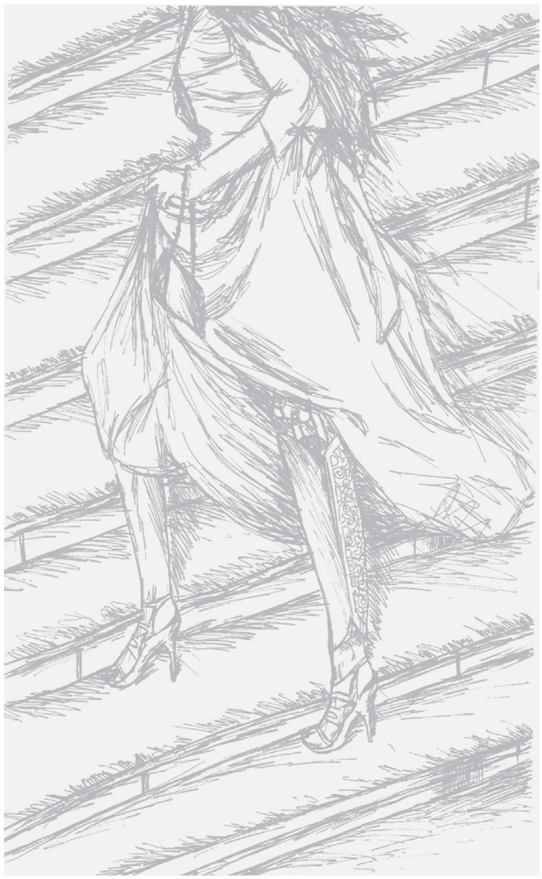
Chapter 2

Construct validity and test-retest reliability of the Questionnaire Rising and Sitting Down in lower-limb amputees

De Laat FA[1,2,3], Rommers GM[3], Geertzen JH[3], Roorda LD[4]



[1] *Rehabilitation Center Leijpark, Libra Zorggroep, Tilburg, The Netherlands;*

[2] *Rehabilitation Center Tolbrug, Jeroen Bosch Hospital, 's Hertogenbosch, The Netherlands;*

[3] *Department of Rehabilitation Medicine, University Medical Center of Groningen, Groningen, The Netherlands;*

[4] *Department of Rehabilitation Research, Reade, Center of Rehabilitation and Rheumatology, Amsterdam, The Netherlands.*

Arch Phys Med Rehabil 2011; 92: 1305-10

ABSTRACT
Objective: To investigate the construct validity and test-retest reliability of the Questionnaire Rising and Sitting Down (QR&S), a patient-reported measure of activity limitations in rising and sitting down, in lower-limb amputees.

Design: Cross-sectional study.

Setting: Outpatient department of a rehabilitation center.

Participants: Lower-limb amputees (N=171; mean age ± SD, 65±12y; 71% men; 83% vascular cause) participated in the study, 33 of whom also participated in the reliability study.

Interventions: Not applicable.

Main Outcome Measures: Construct validity was investigated by testing 8 hypotheses: limitations in rising and sitting down according to the QR&S would be: (1) greater in lower-limb amputees who are older, (2) independent of level of amputation, (3) greater in lower-limb amputees with a bilateral amputation, and (4) greater in lower-limb amputees who had rehabilitation treatment in a nursing home. Furthermore, limitations in rising and sitting down will be positively related to activity limitations according to (5) the Locomotor Capabilities Index (LCI), (6) the questions about rising and sitting down in the LCI, (7) the Climbing Stairs Questionnaire, and (8) the Walking Questionnaire. Construct validity was quantified with an independent *t* test and Pearson correlation coefficient. Test-retest reliability was assessed with a 3-week interval and quantified with the intraclass correlation coefficient (ICC), standard error of measurement, and smallest detectable difference (SDD).

Results: Construct validity (7 of 8 null hypotheses not rejected) and test-retest reliability were good (ICC= .84; 95% confidence interval, .65-.93; standard error of the measurement= 6.7%; SDD= 18.6%).

Conclusions: The QR&S has good construct validity and good test-retest reliability in lower-limb amputees.

Key Words: Amputation; Disability evaluation; Questionnaires; Rehabilitation.

List of Abbreviations

CI	confidence interval
GRCQ	Global Rating of Change Questionnaire
ICC	intraclass correlation coefficient
LCI	Locomotor Capabilities Index
QR&S	Questionnaire Rising and Sitting Down
SDD	smallest detectable difference

An important goal in the rehabilitation of lower-limb amputees is that they learn to walk with a prosthesis and regain functional independency. For mobility in walking, lower-limb amputees have to be able to rise,[1] stand and maintain balance,[2] initiate gait,[3] walk, terminate gait,[4] and to sit down. Therefore, rising and sitting down are important aspects of mobility in lower-limb amputees, and the assessment of limitations in rising and sitting down is of great value in prosthetic training.

Studies focusing on limitations in rising and sitting down in lower-limb amputees are scarce. Moreover, these studies often use performance-based measurements to assess the limitations,[5-8] and therefore, they do not provide information about the patient's perspective of limitations in rising and sitting down. Furthermore, these performance-based measurements are often part of a test battery, and as a consequence, these studies do not report in detail on limitations in rising and sitting down. The only study that specifically addressed standing up from a chair in transfemoral amputees is a biomechanical study,[9] but it provided no detailed information about the patient's perspective of limitations in rising and sitting down.

Therefore, when the aim is to assess the patient's perception of limitations in rising and sitting down, a self-report questionnaire is more appropriate than a performance test.[10] Questions about these limitations in lower-limb amputees are mostly included in a more comprehensive questionnaire, for instance the Locomotor Capabilities Index (LCI)[11, 12] or the Prosthesis Evaluation Questionnaire, [13] and therefore only assess global limitations in transfers. As far as we know, the only questionnaire that provides a detailed assessment of limitations in rising and sitting down is the Questionnaire Rising and Sitting Down (QR&S).[14, 15]

The QR&S is a patient-reported questionnaire that measures activity limitations in rising and sitting down. It contains 39 items formulated in behavioral terms (eg, I have [some] difficulty getting up from a high-seated chair) with dichotomous response options (yes box marked/yes box not marked). The sum score is based on the 1-parameter logistic model and standardized (range, 0-100) with higher scores indicating less limitation. The selection of items to be included in the QR&S was based on an extensive literature review, and the first draft version was subjected to the opinions of experts. The improved version was then tested in 759 patients with lower-extremity disorders (including 230 lower-limb amputees) living at home.[15] It was found to be unidimensional and had a good fit with the 1-parameter logistic model, good intratest reliability, and good content validity.[15] Its construct validity, indicating that the instrument validly measures the construct "limitations in rising and sitting down," has only been assessed in patients with complex regional pain syndrome type 1, which yielded satisfactory results.[16] However, the construct validity and test-retest reliability of the QR&S, indicating the reproducibility of the measurements over time, has not yet been studied in lower-limb amputees.

In the present study, our objectives were therefore to assess (1) the construct validity and (2) the test-retest reliability of the QR&S in lower-limb amputees.

METHODS

Participants

Participants were recruited between 1998 and 2008 in the Outpatient Department of the Rehabilitation Center Tolbrug, 's Hertogenbosch, in The Netherlands.

The first group consisted of lower-limb amputees at the end of their outpatient rehabilitation treatment in this center (rehabilitation center group). These lower-limb amputees were assessed just before the start of their follow-up in the outpatient department. The second group consisted of lower-limb amputees directly after discharge from inpatient or outpatient rehabilitation treatment in nursing homes in the region of Tolbrug, 's Hertogenbosch (nursing home group). These lower-limb amputees were assessed at the start of their follow-up at the outpatient department of the rehabilitation center. The 2 groups together encompassed all lower-limb amputees undergoing rehabilitation treatment in this region. Only lower-limb amputees who were wearing a prosthesis after their rehabilitation treatment were selected. For the test-retest reliability study, a subgroup of lower-limb amputees who had finished their rehabilitation treatment between June 2003 and November 2004 was recruited from the rehabilitation center group. All participants provided informed consent.

Procedure

The rehabilitation center group received the first questionnaire from the therapists on their penultimate day of treatment. They were asked to fill in the questionnaire at home and to bring it with them on the last day of treatment. The nursing home group received the questionnaire during their first appointment in the rehabilitation center. They were asked to fill in the questionnaire at home, and to return the completed questionnaire by mail. The first questionnaire consisted of the QR&S, LCI,[12, 17] Climbing Stairs Questionnaire 15 items,[18] and Walking Questionnaire 35 items.[19]

For the test-retest reliability study, patients received a second questionnaire by mail 3 weeks later. This period was considered to be long enough to ensure that the participants would not remember their first responses (recall bias). They were asked to fill in the second questionnaire at home and return it by mail. Patients who returned questionnaires with missing data were contacted by telephone by an independent physician and asked to provide the missing data. This second questionnaire consisted of the QR&S and a self-constructed Global Rating of Change Questionnaire (GRCQ). The GRCQ was used to exclude patients whose limitations had changed significantly in the 3-week period after treatment. Patient instructions and items of the GRCQ can be found in Appendix 1. Participants were considered to be stable with respect to their limitations in rising and sitting down if they rated themselves between 6 and 10 on the GRCQ.

Measurements

Data on sociodemographic characteristics, diagnosis, and prosthesis prescription were extracted from medical records.

To assess construct validity, we selected the following patient-reported measurement instruments with a good conceptual framework[20, 21] measuring mobility or aspects of mobility: the LCI,[11, 12, 17] the Climbing Stairs Questionnaire,[18] and the Walking Questionnaire.[19]

The LCI[11, 12, 17] is a patient-reported assessment of a range of locomotor activities. It consists of 14 items with 4 response options: unable (score 0), able if someone helps me (score 1), able if someone is near me (score 2), or able alone (score 3). The sum scores range from 0 to 42, with higher scores indicating more locomotor capabilities (or less limitation). There are 3 items concerning rising and sitting down: get up from a chair, pick up an object from the floor when you are standing up with your prosthesis, and get up from the floor. The LCI has good construct validity and test-retest reliability.[11, 22]

The Climbing Stairs Questionnaire[18] is a patient-reported questionnaire that measures activity limitations in climbing stairs. It consists of 15 items with dichotomous response options. The sum score is calculated by adding the scores of the 15 items. This sum score is subsequently standardized (range, 0-100), with higher scores indicating less limitation in climbing stairs. Patients can mark a 16th item if they do not climb stairs at all, due to their health, and these patients are given the minimum score. The Climbing Stairs Questionnaire showed to have: (1) good fit with the monotonicity model[18] (or scalability), indicating that the items form a scale; (2) good fit with the double monotonicity model,[18] indicating invariant (hierarchical) item ordering; (3) good intratest reliability, indicating good repeatability of the sum score; (4) good robustness, indicating both stability of scalability and invariant item-ordering in sub-groups of patients; and (5) some differential item functioning (4 items for amputees compared with nonamputees). Furthermore the Climbing Stairs Questionnaire has good construct validity and test-retest reliability in lower-limb amputees.[23]

The Walking Questionnaire[19] is a patient-reported questionnaire that measures activity limitations when walking inside and outside the house. It contains 35 items with dichotomous response options (yes box marked/yes box not marked). The sum score is calculated by adding the scores for the 35 items. Subsequently, the sum score is standardized (range, 0-100), with higher scores indicating less limitation in walking. Patients can mark a 36th item if they do not walk inside the house at all, and these patients are given the minimum scores. Patients can mark a 37th item if they do not walk outside the house at all due to their health, and these patients are treated as if they had marked the yes box for all the items concerning walking outside the house. The Walking Questionnaire was tested in 981 patients with lower- extremity disorders, (including 239 lower-limb amputees) who were living at home. It had: (1) good fit with the monotonicity model, (2) good fit with the double monotonicity model, (3) good intratest reliability, (4) good robustness, and (5) some differential item functioning (6 items for amputees compared with nonamputees).[19]

The study protocol was approved by the Research Ethics Committee of the Jeroen Bosch Hospital, 's Hertogenbosch.

Analysis

Construct validity. Construct validity indicates the degree to which the scores on a measurement instrument are consistent with theoretically derived hypotheses (eg, with regard to internal relationships, relationships with the scores of other instruments, or differences in scores between relevant groups), based on the assumption that the instrument validly measures the construct to be measured. Construct validity is considered to be good if at least 75% of the hypotheses are not rejected in a study group of at least 50 participants.[24] There are, as far as we know, no available scales that specifically assess rising and sitting down in lower-limb amputees. Therefore, before examining our data, we formulated 8 hypotheses based on the available literature concerning the relationship between transfers of general mobility limitations and patient-related factors in lower-limb amputees, or based on clinical experience. We hypothesized that limitations in rising and sitting down according to the QR&S would be:

1. Greater in lower-limb amputees who are older.[22, 25, 26]
2. Equal in lower level of amputation (transtibial or Syme amputation) and higher level of amputation (transfemoral or knee disarticulation).[13, 27, 28]
3. Greater in lower-limb amputees with a bilateral amputation than in lower-limb amputees with a unilateral amputation.[25, 29]
4. Greater in lower-limb amputees who had rehabilitation treatment in a nursing home than in lower-limb amputees who had this treatment in an outpatient department of a rehabilitation center.[29]
5. Greater in lower-limb amputees who have more limitations in locomotor capabilities, according to the LCI.[22, 27]
6. Greater in lower-limb amputees who have more limitations in the 3 items concerning rising and sitting down in the LCI.[22, 27]
7. Greater in lower-limb amputees who have more limitations in climbing stairs, according to the Climbing Stairs Questionnaire.[18, 23]
8. Greater in lower-limb amputees who have more limitations in walking, according to the Walking Questionnaire.[19]

Hypotheses addressing relationships (hypotheses 1, 5, 6, 7, and 8) were quantified with Pearson correlation coefficient, and hypotheses addressing the presence or absence of differences were quantified with the independent *t* test (hypotheses 2, 3, and 4; 2-tailed $P<.05$).

Test-retest reliability. Test-retest reliability refers to the reproducibility of measurements with the same instrument over time. To assess the reproducibility of the QR&S, we used the QR&S data from the first and second questionnaires of the patients who rated themselves stable on the GRCQ. Reproducibility includes reliability and agreement.[30] Reliability refers to how well individuals can be distinguished from each other; whereas, agreement indicates how close the repeated measurements are to the original measurements. The most frequently used reliability parameter is the intraclass correlation coefficient (ICC), which is calculated as the ratio of the variance between participants and the total variance. To estimate the test-retest reliability of the QR&S, we calculated the ICC with 95% confidence interval (CI), using a 2-way random model. Patients and measures were considered to be random effects. An ICC of at least .70 was considered to be satisfactory for group comparisons, whereas an ICC of at least .90 was considered to be satisfactory for individual comparisons.[24] Agreement was quantified by the standard error of measurement, the square root of the within-subject variance, which indicates how close the scores for repeated measurements are. The smallest detectable difference (SDD) can be derived from the SEM, where SEM is defined as the standard error of measurement: $SDD=1.96\times\sqrt{2}\times SEM$.[31] The SDD is the smallest difference in measurement that can be interpreted as a real difference between 2 measurements in an individual. Standard errors of measurement and SDDs are expressed in the units of the measurement scale. To our knowledge, there are no generally accepted criteria for satisfactory standard error of measurement and SDD values for group or individual comparisons. To visualize the agreement, we represented the data graphically in a Bland-Altman plot.[32] All statistics were calculated with SPSS 15.0 for Windows.[a]

RESULTS

Patient Characteristics

Of the 175 lower-limb amputees who fulfilled the selection criteria, 171 were willing to participate in the construct validity study. The lower-limb amputees who were unwilling to participate were: 2 with a transtibial amputation, 1 with a knee disarticulation, and 1 with a transfemoral amputation, all from the rehabilitation center group. The characteristics of the 171 lower-limb amputees are presented in table 1.

For the test-retest reliability study, 35 of the 171 lower-limb amputees who participated in the construct validity study met the additional selection criteria. Of these 35 lower-limb amputees 2 were unwilling to fill in the second questionnaire: 1 with a transtibial amputation and 1 with a transfemoral amputation. The resulting data therefore concerned 33 lower-limb amputees, only 22 of whom considered their condition to be stable with regard to their limitations in rising and sitting down.

Table 1: Patient Characteristics

	Characteristic	Data
Age (y)		
	Mean years ± SD	65±11
	Range (minimum to maxinum)	37-92
Sex		
	Women	50 (29)
	Men	121 (71)
Setting		
	Rehabilitation center	154 (90)
	Nursing home	17 (10)
Amputation etiology		
	Vascular	142 (83)
	Infection	13 (8)
	Traumatic	13 (8)
	Oncologic	3 (2)
Amputation level		
	Hip disarticulation	3 (2)
	Transfemoral	54 (32)
	Knee disarticulation	8 (5)
	Transtibial	93 (54)
	Syme	1 (1)
	Amputation unilateral	159 (93)
	Transfemoral and transtibial	2 (1)
	Transtibial and transtibial	7 (4)
	Syme and transtibial	3 (2)
	Amputation bilateral	12 (7)

* NOTE. N=171. Values are expressed as n (%) unless noted otherwise

Construct Validity

The results of the 8 hypotheses that we tested are presented in table 2. Only hypothesis 3 (bilateral vs unilateral amputation) was rejected.

Table 2. Construct Validity of the Questionnaire Rising and Sitting Down in Lower-Limb Amputees

Hypothesis*	n	Pearson correlation coefficient	p†	Standardized mean ± SD Sum Score	p‡
1. Age	171	-.17	.03		
2. Amputation - level§	159				
Higher (transfemoral or knee disarticulation)	65			44±17	.23
Lower (transtibial or Syme amputation)	94			48±16	
3. Amputation side	171				
Bilateral	12			41±16	.23
Unilateral	159			47±16	
4. Setting	171				
Nursing home	17			37±19	.01
Rehabilitation center	154			47±16	
5. Locomotor capabilities	164	.40	<.001		
6. Rising and sitting down items of LCI	170	.29	<.001		
7. Limitations in climbing stairs	171	.42	<.001		
8. Limitations in walking	171	.55	<.001		

Abbreviations: LLA, lower-limb amputee; LCI, Locomotor Capabilities Index.
* Eight hypotheses were tested. Limitations in rising and sitting down, according to the Questionnaire Rising and Sitting Down, will be:
1. greater in LLAs who are older;
2. equal in higher level of amputation or lower level of amputation;
3. greater in bilateral LLAs than in unilateral LLAs;
4. greater in LLAs who had their rehabilitation treatment in a nursing home than in LLAs who had this treatment in a rehabilitation center;
5. greater in LLAs who have more limitations in locomotor capabilities according to the LCI;
6. greater in LLAs who have more limitations in rising and sitting down according to the 3 corresponding questions of the LCI;
7. have more limitations in climbing stairs according to the Climbing Stairs Questionnaire;
8. have more limitations in walking according to the Walking Questionnaire.

† significance (2-tailed P) of Pearson correlation coefficient
‡ significance (2-tailed P) of independent t test
§ LLAs with unilateral amputation only

Test-Retest Reliability

Mean ± SD scores for the first and second QR&S were 42±13 and 39±19, respectively. The 3-week test-retest reliability of the QR&S was good, with an ICC of .83 (95% CI, .65-.93). The agreement of the QR&S was good with a standard error of measurement of 6.7% and an SDD of 18.6%. Agreement is presented graphically in a Bland-Altman plot (fig 1). Although overall agreement between measurements was acceptable, we found large differences for 2 lower-limb amputees in the lower range of the mean sum score.

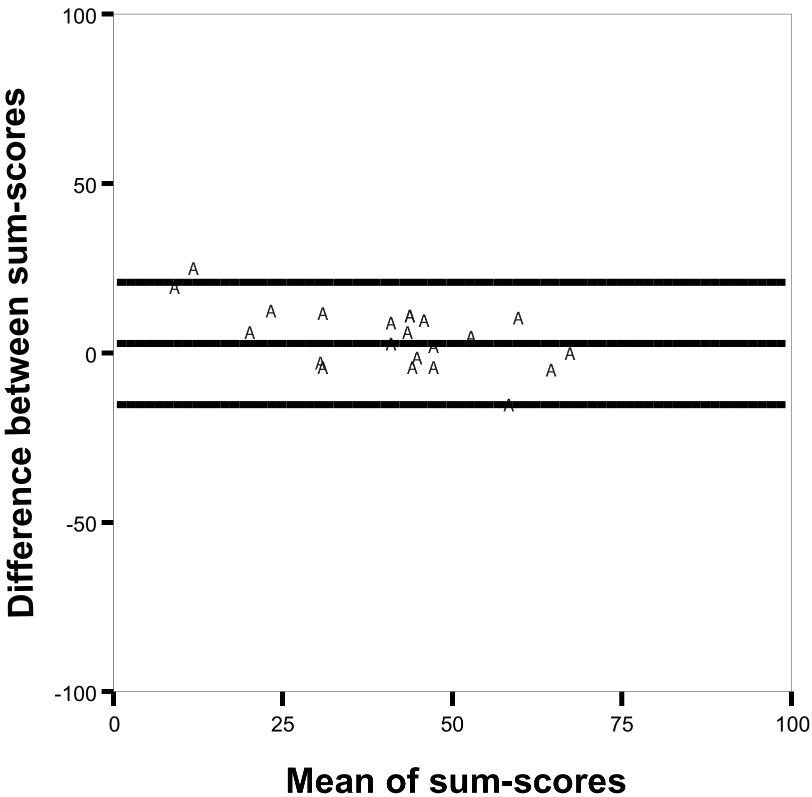


Fig.1 Bland-Altman plot with the difference between the sum scores of the first and second assessment of the Questionnaire Rising and Sitting down against the mean difference of the first and second assessment with 95% limits of agreement.

DISCUSSION

The objective of this study was to assess the construct validity and test-retest reliability of the QR&S in lower-limb amputees. As far as we know, this is the only patient-reported questionnaire that assesses items related to rising and sitting down. The results of our study showed that the QR&S has good construct validity and good test-retest reliability for group comparisons in lower-limb amputees.

Of the 175 lower-limb amputees who fulfilled the selection criteria, only 4 were unwilling to participate in the study. With regard to the cause and level of amputation, our study was similar to lower-limb amputees in general in The Netherlands.[33, 34]

With regard to the construct validity assessment, it was difficult to formulate hypotheses a priori, because there is hardly any literature that specifically reports on the relationship between patient-reported perceptions of limitations in rising and sitting down and clinical factors in lower-limb amputees. We found no relationship between limitations in rising and sitting down, according to the QR&S, and unilateral versus bilateral amputation (hypothesis 3), possibly due to the small number of bilateral amputees (n=12) who participated and the fact that we selected only lower-limb amputees who wore a prosthesis. Therefore, the bilateral amputees may have had fewer activity limitations.

The test-retest reliability of the QR&S was good. The SDD resulting from the found test-retest agreement was 18.6%, indicating that to detect a true difference, the difference between the 2 measurements has to be at least 19 (on a scale from 0-100). This value is quite high, but for application in a group of lower-limb amputees (eg, for research purposes), smaller differences can be detected, because then the SDD has to be divided by $\sqrt{n}$.[24, 30] Thus, for example, in a group of 25 lower-limb amputees, a difference of only 3.7 can be considered as a true difference in limitations in rising and sitting down.

Study Limitations

One limitation of our study is that the nonresponse rate of the lower-limb amputees treated in nursing homes is unknown, because only those lower-limb amputees who had a first follow-up appointment at the outpatient department of the rehabilitation center after their rehabilitation treatment in a nursing home were invited to participate. Nevertheless, all the lower-limb amputees who kept this appointment were willing to participate. Possibly, those who were unwilling to attend the follow-up appointment in the rehabilitation center were the worst performers in the nursing home group. So the difference between the 2 groups might have been even greater.

Another limitation of our study is that the lower-limb amputees were selected at the end of their multidisciplinary rehabilitation treatment, when only 22 of the 33 participants of the reliability study considered their condition to be stable with regard to their limitations in rising and sitting down. The reason for this was not investigated in the present study. For nonstable participants, the reason could be that the socket was fitting less well because of atrophy of the stump in the meantime, which can continue for up to 2 years after amputation.[35] In future studies, the reliability of the QR&S should therefore be reassessed in lower-limb amputees without stump atrophy who have experience in wearing their prosthesis. Furthermore, recent standards recommend at least 50 participants for a test-retest reliability study .[24] Therefore, we recommend that future research should replicate our study in a much larger sample.

Finally, we used only patient-reported measurement instruments to assess the construct validity of the QR&S, because the results of a performance test are not necessarily strongly related to perceived limitations.[36] However, we recommend that the construct validity of the QR&S should be further assessed with data from biomechanic and performance-based studies of lower-limb amputees.

CONCLUSIONS

The QR&S provides a detailed assessment of patient-reported limitations in rising and sitting down, and it has good construct validity and good test-retest reliability in lower-limb amputees directly after their multidisciplinary rehabilitation treatment. Based on the results of the reliability study, the QR&S can be recommended for group comparisons of lower-limb amputees, but not for individual comparisons.

APPENDIX 1:

How do you rate your ability to rise and sit down now, compared with the first time you filled in the questionnaire?

(1) Extremely good.
(2) Very much better.
(3) Much better.
(4) Better.
(5) Somewhat better.
(6) Slightly better.
(7) Almost the same, marginally better.
(8) No change.
(9) Almost the same, marginally worse.
(10) Slightly worse.
(11) Somewhat worse.
(12) Worse.
(13) Much worse.
(14) Very much worse.
(15) Extremely bad.

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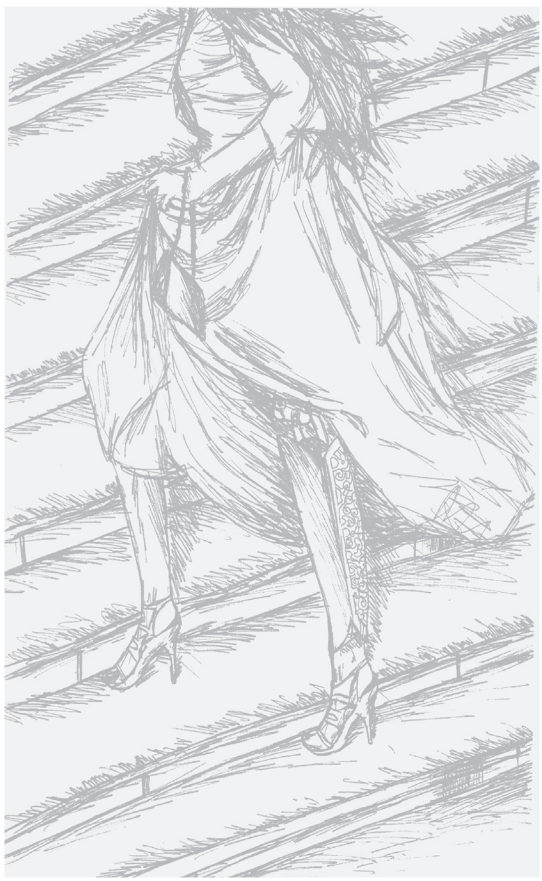
Supplier

a. SPSS Inc, 233 S Wacker Dr, 11th Fl, Chicago, IL 60606.

Chapter 3

Construct validity and test-retest reliability of the Walking Questionnaire in people with a lower limb amputation

De Laat FA[1,2,3], Rommers GM[3], Geertzen JH[3], Roorda LD[4]



[1] Rehabilitation Center Leijpark, Libra Zorggroep, Tilburg, The Netherlands;

[2] Rehabilitation Center Tolbrug, Jeroen Bosch Hospital, 's Hertogenbosch, The Netherlands;

[3] Department of Rehabilitation Medicine, University Medical Center of Groningen, Groningen The Netherlands;

[4] Department of Rehabilitation Research, Reade, Center of Rehabilitation and Rheumatology, Amsterdam, The Netherlands.

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ABSTRACT

Objective: To investigate the construct validity and test-retest reliability of the Walking Questionnaire, a patient-reported measure of activity limitations in walking in people with a lower limb amputation.

Design: Cross-sectional study.

Setting: Outpatient department of a rehabilitation center.

Participants: People with a lower limb amputation (N=172; mean age ± SD, 65±12 y; 71% men; 82% vascular cause) participated in the study, 33 of whom also participated in the reliability study.

Interventions: Not applicable.

Main Outcome Measures: Construct validity was investigated by testing 11 hypotheses: Limitations in walking according to the Walking Questionnaire will be greater in people with a lower limb amputation who (1) are older, (2) have a bilateral amputation, (3) have a higher level of amputation, (4) underwent their rehabilitation treatment in a nursing home, (5) walk less (in terms of time), and (6) walk shorter distances. Furthermore, limitations in walking will be positively related to activity limitations according to the (7) the Locomotor Capabilities Index, (8) 'distance walked' question on the Prosthetic Profile of the Amputee Questionnaire, (9) Questionnaire Rising and Sitting Down, (10) Climbing Stairs Questionnaire and (11) Special Interest Group on Amputation Medicine / Dutch Working Group on Amputations and Prosthetics mobility scale. Construct validity was quantified by using the Mann-Whitney *U* test and Spearman correlation coefficient. Test-retest reliability was assessed with a 3-week interval and quantified using the intraclass correlation coefficient.

Results: Construct validity (10 of 11 hypotheses not rejected) and test-retest reliability were good (intraclass correlation coefficient = .73; 95% confidence interval, .43-.88).

Conclusions: The Walking Questionnaire has good construct validity and test-retest reliability in people with a lower limb amputation.

Key Words: Amputation; Disability evaluation; Questionnaires; Rehabilitation.

List of Abbreviations

CI	confidence interval
GRCQ	Global Rating of Change Questionnaire
ICC	intraclass correlation coefficient
LCI	Locomotor Capabilities Index
PPA	Prosthetic Profile of the Amputee
SIGAM	Special Interest Group on Amputation Medicine
SIGAM/WAP	Special Interest Group on Amputation Medicine / Dutch Working Group on Amputations and Prosthetics

A main goal of rehabilitation after lower-limb amputation is to restore mobility.[1] Mobility is regarded by people with a lower limb amputation as the most relevant ability for their quality of life.[2] An important aspect of mobility is the ability to walk. With an adequate prosthesis and rehabilitation treatment many people with a lower limb amputation are able to improve their ability to walk. This is associated with increased activities of daily living[3] and successful job reintegration.[4]

Many mobility scales have been used to measure limitation in walking,[5] but no criterion standard exists.[5-7] Most scales are based on patient-reported or physician-reported categories of ambulation,[8-11] observation of performance,[12, 13] or generic instruments applied to people with a lower limb amputation.[14, 15] For assessing perceived limitations in mobility in a patient's home environment, the Locomotor Capabilities Index (LCI)[16-18] is often used. However, the LCI has a high ceiling effect,[19] and only 6 of the 14 questions concern walking.

A patient-reported questionnaire that provides a detailed measurement of limitations in walking inside and outside the house is the Walking Questionnaire.[20] It contains 35 items formulated in behavioral terms with dichotomous response options ("yes" box marked/"yes" box not marked). These items operationalize aspects of walking such as velocity, uncertainty, adaptations, and use of walking aids (eg, I do walk outside, but I walk unsteadily over obstacles). The sum score is calculated by adding the scores for the 35 items. This sum score is subsequently standardized (range, 0-100), with higher scores indicating less limitation in walking. Patients can mark a 36th item if they do not walk inside the house at all. These patients are then given the minimum score. Patients can also mark a 37th item if they do not walk outside the house at all because of their health. These patients are treated as if they had marked the "yes" box for all items concerning walking outside the house. The Walking Questionnaire was tested in 981 home-dwelling patients with lower extremity disorders (including 239 people with a lower limb amputation). It has (1) good fit with the monotonicity model (or scalability), indicating that the items form a scale; (2) good fit with the double monotonicity model, indicating invariant (hierarchical) item ordering; (3) good intratest reliability, indicating good repeatability of the sum score; (4) good robustness, indicating both stability of scalability and invariant item ordering in subgroups of patients; and (5) some differential item functioning (6 items in amputees, compared with nonamputees), indicating that measurements should be interpreted cautiously when comparisons are made between amputees and nonamputees. Its construct validity and test-retest reliability have not yet been investigated in people with a lower limb amputation.

Therefore, the main objective of this study was to assess the construct validity of the Walking Questionnaire in people with a lower limb amputation. The secondary objective was to assess the test-retest reliability of the Walking Questionnaire in people with a lower limb amputation.

METHODS

Participants

Participants were recruited between 1998 and 2008 in the outpatient department of Rehabilitation Center Tolbrug, 's Hertogenbosch, in The Netherlands. Inclusion criteria were as follows: patients were 18 years or older; they were wearing a prosthesis at the end of their rehabilitation treatment after a recent lower-limb amputation; and they were able to understand and fill in the questionnaires. A first group of patients consisted of people with a lower limb amputation from the rehabilitation center (rehabilitation center group). These people with a lower limb amputation were assessed before the start of their follow-up in the outpatient department. A second group consisted of people with a lower limb amputation directly after discharge from their inpatient or outpatient rehabilitation treatment in nursing homes in the region of Tolbrug, 's Hertogenbosch (nursing home group). These people with a lower limb amputation were assessed at the start of their follow-up at the outpatient department of the rehabilitation center. The 2 groups together encompassed all people with a lower limb amputation undergoing rehabilitation treatment in this region. For the test-retest reliability study, a subgroup of people with a lower limb amputation, who had finished their rehabilitation treatment between June 2003 and November 2004, was recruited from the rehabilitation center group.

The study protocol was approved by the Research Ethics Committee of the Jeroen Bosch Hospital, 's Hertogenbosch. All participants gave informed consent.

Procedure

To assess construct validity, all participants received an initial questionnaire consisting of the Walking Questionnaire,[20] a rating scale to measure time walked, a rating scale to measure distance walked, the LCI,[18, 21] the "distance walked" question of the Prosthetic Profile of the Amputee (PPA) Questionnaire,[18] the Questionnaire Rising and Sitting Down,[22] and the Climbing Stairs Questionnaire.[23] The subgroup in the reliability study also received the Special Interest Group on Amputation Medicine / Dutch Working Group on Amputations and Prosthetics (SIGAM/WAP) mobility scale.[9] The rehabilitation center group received this initial questionnaire from their therapists on the second-to-last day of treatment. They were asked to complete the questionnaire at home and bring it with them on the last day of treatment. The nursing home group received the questionnaire during their first follow-up appointment in the rehabilitation center. They were asked to complete the questionnaire at home, and return it by mail.

To assess test-retest reliability, the previously described subgroup received a second questionnaire consisting of the Walking Questionnaire and 2 self-constructed Global Rating of Change Questionnaires (GRCQs). Study participants received the questionnaire 3 weeks after the initial questionnaire was administered, as this period was considered to be long enough to ensure that the participants would not remember their first responses (recall bias). The GRCQs were used to exclude patients whose limitations in walking had changed significantly in the 3-week period after discharge from treatment. Patient instructions and the items of the GRCQs can be found in appendix 1. Participants were considered to be stable with respect to their limitations in walking if they gave themselves a rating of between 6 and 10 on both GRCQs. Patients were asked to fill in the second questionnaire at home and to return it by mail. People with a lower limb amputation who returned questionnaires with missing data were contacted by telephone by an independent physician and asked to provide the missing data.

Measurements

Data on age, sex, and diagnosis were extracted from each patient's medical record.

To assess the time and distance walked, we used self-developed rating scales (appendix 2). Patients were instructed to rate the maximum time and distance they walk (without stopping) in their daily lives. In addition to these rating scales, patient-reported measurement instruments with a good conceptual framework[19, 24] measuring mobility or aspects of mobility in people with a lower limb amputation were selected. These were the LCI,[18, 21] the "distance walked" question of the PPA Questionnaire,[18] the Questionnaire Rising and Sitting Down,[22] the Climbing Stairs Questionnaire,[23] and the SIGAM/WAP mobility scale.[9]

The LCI[18, 21] is a patient-reported assessment covering a range of locomotor activities, such as rising from a chair or the floor, walking on a variety of surfaces, and climbing stairs and curbs. The LCI is a part of the larger PPA, a questionnaire measuring prosthetic use and factors potentially related to prosthetic use. The LCI consists of 14 items with 4 response options: unable (score 0), able if someone helps me (score 1), able if someone is near me (score 2), or able alone (score 3). The sum scores range from 0 to 42, with higher scores indicating better locomotor capabilities. The construct validity and the test-retest reliability of the LCI have been reported to be good.[16, 17]

The "distance walked" question of the PPA Questionnaire[18] has 6 response options ranging from "I do not walk with my prosthesis" (score 0) to "I am not limited in walking" (score 6). This "distance walked" question has been reported to have moderate to substantial reliability.[17]

The Questionnaire Rising and Sitting Down[22, 25] is a patient-reported questionnaire measuring activity limitations in rising and sitting down. It contains 39 items with dichotomous response options ("yes" box marked/"yes" box not marked). The sum score is based on the 1-parameter logistic model[22] and is standardized (range, 0-100), with higher scores indicating less limitation. The Questionnaire Rising and Sitting Down is a unidimensional scale. It has good fit with the 1-parameter logistic model, good intratest reliability, and good content validity.[22] Furthermore, the Questionnaire Rising and Sitting Down has good construct validity and test-retest reliability in people with a lower limb amputation.[26]

The Climbing Stairs Questionnaire[23] is a patient-reported questionnaire that measures activity limitations in climbing stairs. It consists of 15 items with dichotomous response options. The sum score is calculated by adding the scores of the 15 items. This sum score is subsequently standardized (range, 0-100), with higher scores indicating less limitation in climbing stairs. Patients can mark a 16th item if they do not climb stairs at all, because of health reasons, whereby they are given the minimum score. The Climbing Stairs Questionnaire has been shown to have good scalability, hierarchical item ordering, and good intratest reliability. Furthermore, the Climbing Stairs Questionnaire has good construct validity and test-retest reliability in people with a lower limb amputation.[27]

The SIGAM/WAP scale[9, 10] is used to measure levels of mobility in lower limb amputees. It is a physician-reported or patient-reported questionnaire designed to measure ambulation, using walking aids if necessary. It contains 21 items with dichotomous response options ("yes" box marked/"yes" box not marked). An algorithm has been designed to distinguish between 6 different mobility grades. The Special Interest Group on Amputation Medicine (SIGAM) scale has proven to be a feasible (questions are simple, easy to assess, and not overly time-consuming), reliable, and valid measure.[10] The Dutch version of the SIGAM scale is called the SIGAM/WAP and has been showed to have good intertest reliability.[9]

Analysis

Construct validity. Construct validity indicates the degree to which the scores on a measurement instrument are consistent with theoretically derived hypotheses (eg, with regard to internal relations, relationships to scores of other instruments, or differences in scores between relevant groups), based on the assumption that the instrument validly measures the construct being measured. Construct validity is considered to be good if at least 75% of the hypotheses are not rejected in a study group of at least 50 participants.[28] Based on the available literature regarding the relationship between limitations in walking after rehabilitation and sociodemographic factors in people with a lower limb amputation, 11 hypotheses were formulated before analyzing the study data. We hypothesized that limitations in walking, according to the Walking Questionnaire, would be greater in people with a lower limb amputation who (1) are older[7, 16, 29]; (2) have a bilateral amputation as opposed to a unilateral amputation[7, 30]; (3) have a higher level of amputation (transfemoral or knee disarticulation) as opposed to a lower level of amputation (transtibial or Syme amputation)[7, 16]; (4) had undergone rehabilitation treatment in a nursing home as opposed to having received their treatment in an outpatient department of a rehabilitation center[30]; (5) walk shorter distances, according to their rating of distance walked; (6) walk less (in terms of time), according to their rating of time walked; (7) have more limitations in locomotor capabilities, according to the LCI[16]; (8) have more limitations in walking distance, according to the "distance walked" question of the PPA[17]; (9) have more limitations in rising and sitting down, according to the Questionnaire Rising and Sitting Down[22, 26]; (10) have more limitations in climbing stairs, according to the Climbing Stairs Questionnaire[23, 27]; and (11) have more limitations in walking mobility, according to the SIGAM/WAP mobility scale.[9, 10]

Hypotheses addressing relationships (hypotheses 1, 5-11) were quantified using Spearman correlation coefficients, and hypotheses addressing the presence or absence of differences (hypotheses 2-4) were quantified using the Mann-Whitney *U* test (2-tailed $P<.05$)

Test-retest reliability. Test-retest reliability refers to the reproducibility of measurements using the same instrument over time. To assess the reproducibility of the Walking Questionnaire, we used Walking Questionnaire data from the first and second questionnaires of the participants who had rated themselves as being stable on the GRCQ. To estimate the test-retest reliability of the Walking Questionnaire, we calculated the intraclass correlation coefficient (ICC) with 95% confidence interval (CI), using a 2-way mixed model. Patients were considered to be random effects, while the measurement effect was considered to be a fixed effect. An ICC of at least .70 was considered to be satisfactory for group comparisons, whereas an ICC of at least .90 was considered to be satisfactory for individual comparisons.[28] To visualize the agreement, we represented the data graphically in a Bland-Altman plot.[31] All statistics were calculated using SPSS 15.0 for Windows.[a]

RESULTS

Patient Characteristics

The inclusion criteria were met by 175 people with a lower limb amputation, of whom 172 were willing to participate in the construct validity study. Two people with a transtibial amputation and 1 person with a knee disarticulation, all from the rehabilitation center group, were unwilling to participate. Characteristics of the 172 people with a lower limb amputation are listed in table 1. Only 12 of the 172 participants had bilateral lower limb amputation.

Of the 172 people with a lower limb amputation who participated in the construct validity study, 35 met the additional selection criteria for the test-retest reliability study. Of these 35 people with a lower limb amputation, 2 were unwilling to fill in the second questionnaire; 1 had a transtibial amputation and 1 had a transfemoral amputation. The resulting data therefore concerned 33 people with a lower limb amputation, only 22 of whom considered themselves to be stable with regard to their limitation in walking.

Table 1. Patient Characteristics (N=172)

	characteristics	values
Age (y)		65±11 (37-92)
Sex		
	Women	50 (29)
	Men	122 (71)
Amputation etiology		
	Vascular	143 (83)
	Infection	13 (8)
	Traumatic	13 (8)
	Oncologic	3 (2)
Amputation level unilateral total		160 (93)
	Hip disarticulation	3 (2)
	Transfemoral	55 (32)
	Knee disarticulation	8 (5)
	Transtibial	93 (54)
	Syme	1 (1)
Amputation level bilateral total		12 (7)
	Transfemoral and transtibial	2 (1)
	Transtibial and transtibial	7 (4)
	Syme and transtibial	3 (2)
Setting		
	Rehabilitation center	155 (90)
	Nursing home	17 (10)

NOTE. Values are mean ± SD (range) or n (%).

Construct Validity

Results of the hypotheses that we tested are listed in table 2. Hypothesis 2 (bilateral vs unilateral amputation) was rejected, but the other 10 hypotheses were not. Despite the small number of patients (34), we also found a relationship between limitations in walking as measured by the Walking Questionnaire, and limitations in walking mobility as assessed with the SIGAM/WAP mobility scale.

Table 2. Construct Validity of the Walking Questionnaire in People With a Lower Limb Amputation

	Hypothesis*	n	Spearman Correlation Coefficient	P†	Standardized median (IQR) sum score	P‡
1.	Age	172	-.18	<.05		
2.	Amputation	172				.30
	Bilateral	12			33 (19 - 68)	
	Unilateral	160			47 (25 -72)	
3.	Amputation - level§	160				<.05
	Higher (transfemoral or knee disarticulation)	66			40 (22 - 67)	
	Lower (transtibial or Syme amputation)	94			58 (32 - 77)	
4.	Setting	172				<.001
	Nursing home	17			19 (3 - 40)	
	Rehabilitation center	155			50 (31 - 75)	
5.	Time walked rating scale	172	-.47	<.001		
6.	Distance walked rating scale	172	-.39	<.001		
7.	Locomotor capabilities according to the LCI	164	.50	<.001		
8.	distance walked according to the PPA	172	.46	<.001		
9.	Limitation in rising & sitting down	171	.57	<.001		
10.	Limitation in climbing stairs	172	.60	<.001		
11.	SIGAM/WAP score	34	.37	<.05		

Abbreviation: IQR, interquartile range; PPA, Prosthetic Profile of the Amputee; LCI, Locomotor Capabilities Index.

* Eleven hypotheses were tested. Limitations in walking, according to the Walking Questionnaire, will be greater in people with a lower limb amputation who:

1. are older;
2. have a bilateral amputation than in people with a unilateral lower limb amputation;
3. have a higher level of amputation than in people with a lower level of amputation;
4. had undergone rehabilitation treatment in a nursing home compared with people with lower limb amputation who had received their treatment in a rehabilitation center;
5. walk less (in terms of time), according to their rating scale of time walked;
6. walk shorter distances, according to their rating scale of distance walked;
7. have more limitations in locomotor capabilities, according to the LCI;
8. walk shorter distances, according to the PPA 'distance walked' question;
9. have more limitations in rising and sitting down, according to the Questionnaire Rising and Sitting Down;
10. have more limitations in climbing stairs, according to the Climbing Stairs Questionnaire;
11. have more limitations in walking mobility, according to the SIGAM/WAP mobility scale;

† significance (2-tailed P value) of Spearman correlation coefficient

‡ significance (2-tailed P value) of Mann-Whitney U test (dichotomous variables)

§ people with unilateral lower limb amputation only

Test-Retest Reliability

Mean scores ± SD for the first and second Walking Questionnaire assessments were 52±30 and 55±29, respectively. The 3-week test-retest reliability of the Walking Questionnaire was good, with an ICC of .73 (95% CI, .43-.88). Agreement is shown graphically in the Bland-Altman plot (fig 1). Although overall agreement between measurements was acceptable, we found a large difference for 1 lower limb amputee.

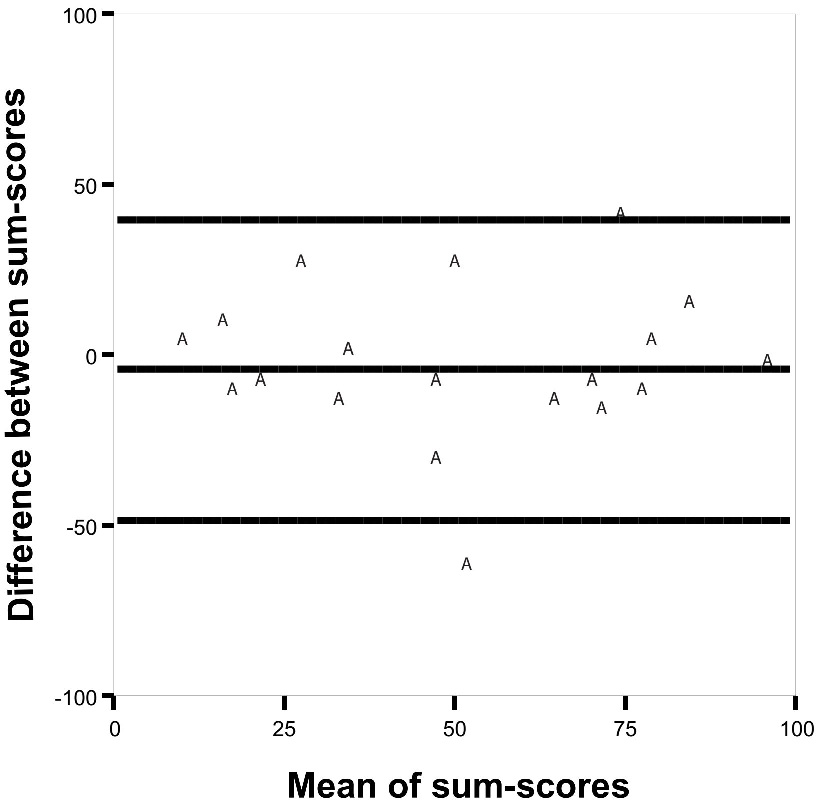

Figure 1. Bland-Altman plot with difference between sum-scores of the first and second assessment of the Walking Questionnaire against the mean of sum-scores. The dashed horizontal lines show the mean difference and the 95% limits of agreement.

DISCUSSION

The objective of this study was to assess the construct validity and test-retest reliability of the Walking Questionnaire in people with a lower limb amputation. We showed that the Walking Questionnaire has good construct validity and good test-retest reliability for group comparisons in people with a lower limb amputation. There are several other questionnaires assessing walking in people with a lower limb amputation, with good clinimetric properties[8-13, 15-18]; however, unlike the Walking Questionnaire, they do not provide detailed measurements of perceived limitations in walking.

The number of dropouts in our study was low. Only 3 of the 175 people with a lower limb amputation who fulfilled the selection criteria were unwilling to participate in the validity study. Furthermore, only 2 of the 35 people with a lower limb amputation were unwilling to participate in the reliability study. In addition, with respect to mean age and cause and level of amputation, our sample of people with a lower limb amputation was similar to other cohorts of people with a lower limb amputation in The Netherlands.[32, 33]

The construct validity of the Walking Questionnaire in people with a lower limb amputation was good, since only 1 of our 11 hypotheses was rejected. We found no relation between limitation in walking, according to the Walking Questionnaire, and unilateral versus bilateral amputation (hypothesis 2). This was probably because of the small number of bilateral amputees (n=12) in the study and the selection criteria that required the people with a lower limb amputation to wear a prosthesis. Therefore, the selected bilateral amputees may have had fewer activity limitations. The SIGAM/WAP was not available at the start of the study. Hence, data were only available for a subgroup of the participants. This was gathered by an independent physician just after the SIGAM/WAP was made available in The Netherlands.

The test-retest reliability of the Walking Questionnaire in people with a lower limb amputation was good. The test-retest reliability of the Walking Questionnaire has also been studied in patients with complex regional pain syndrome type 1. These patients showed a slightly higher ICC (.78.- .84) when compared with the patients in our study (.73), which may have been attributable to the shorter test-retest interval (1 wk) used in that study.[34]

Study Limitations

One limitation of our study is that the nonresponse rate of the people with a lower limb amputation treated in nursing homes was unknown. Only people with a lower limb amputation who had a first follow-up appointment at the outpatient rehabilitation center, after their rehabilitation treatment in a nursing home, were invited to participate in the study. Nevertheless, all the people with a lower limb amputation who attended this appointment were willing to participate.

Another limitation of our study is that we had only 12 people with a bilateral lower limb amputation in our study. Therefore, we were not able to distinguish between people with a unilateral or bilateral lower limb amputation, although people with a bilateral lower limb amputation would probably experience more limitations in walking because of using 2 prostheses.

A third limitation of our study is that the people with a lower limb amputation were selected at the end of their multidisciplinary rehabilitation treatment. At that stage, only 22 of the 33 participants in the reliability study considered their condition as being stable with respect to limitations in walking. The reasons for this were not investigated in the present study. For participants who reported their limitations in walking as being unstable, we suggest that one of the main reasons could be that atrophy of the stump could lead to an ill-fitting socket. Stump atrophy can continue for up to 2 years after amputation.[35] Furthermore, recent standards recommend that at least 50 participants be included in a test-retest reliability study.[28] Therefore, we recommend that future research should replicate our study in a much larger sample, composed of experienced prosthesis users who are unlikely to experience further stump atrophy.

Finally, we only used patient-reported measurement instruments to assess the construct validity of the Walking Questionnaire. We chose this strategy because performance tests are not necessarily strongly related to perceived limitations.[36, 37] However, we recommend that the construct validity of the Walking Questionnaire should be further assessed with data from biomechanical and performance-based measures of people with a lower limb amputation. Such measures could include the ability to stand on 1 leg,[7] timed walk tests,[12, 38] or examination of the relationship between the Walking Questionnaire and ambulatory activity monitors.[37, 39]

CONCLUSIONS

The Walking Questionnaire provides a detailed assessment of patient-reported limitations in walking. It has good construct validity and test-retest reliability in people with a lower limb amputation directly after their multidisciplinary rehabilitation treatment. Based on the results of our reliability study, the Walking Questionnaire is suitable for group comparisons but not for individual comparisons.

APPENDIX 1: THE GLOBAL RATING OF CHANGE QUESTIONNAIRES

(1) How do you rate your ability to walk inside your house now, compared with the first time you filled in the questionnaire?
(2) How do you rate your ability to walk outside your house now, compared with the first time you filled in the questionnaire?

Response options:

		YES
1.	extremely good	☐
2.	very much better	☐
3.	much better	☐
4.	better	☐
5.	somewhat better	☐
6.	slightly better	
7.	almost the same; marginally better	☐
8.	no change	☐
9.	almost the same; marginally worse	☐
10.	slightly worse	
11.	somewhat worse	☐
12.	worse	☐
13.	much worse	☐
14.	very much worse	☐
15.	extremely bad	☐

APPENDIX 2: RATING SCALES OF TIME AND DISTANCE WALKED

What is the maximum time in succession that you actually walk in your daily life?

		YES
1.	I walk 2 hours or more	☐
2.	I walk 1 hour	☐
3.	I walk 30 minutes	☐
4.	I walk 15 minutes	☐
5.	I walk 7 or 8 minutes	☐
6.	I walk 4 minutes	☐

7. I walk 2 minutes ☐
8. I walk 1 minute ☐
9. I walk half a minute ☐

What is the maximum distance in succession that you actually walk in your daily life?

	YES
1. I walk 8 kilometers or more	☐
2. I walk 4 kilometers	☐
3. I walk 2 kilometers	☐
4. I walk 1 kilometer	☐
5. I walk 500 meters	☐
6. I walk 250 meters	☐
7. I walk 125 meters	☐
8. I walk 50 meters	☐
9. I walk 25 meters	☐
10. I walk 12 meters	☐
11. I walk 6 meters	☐
12. I walk a couple of meters	☐

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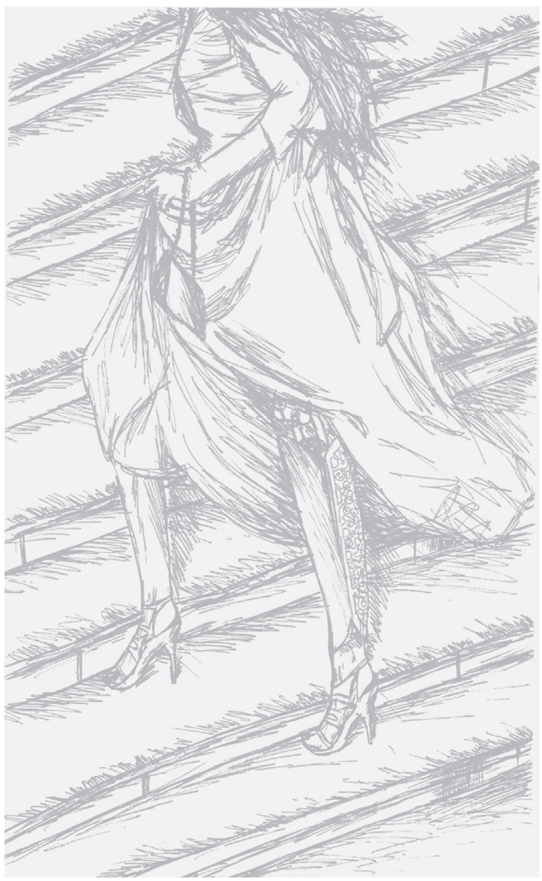
Supplier

a. SPSS Inc, 233 S Wacker Dr, 11th Fl, Chicago, IL 60606.

Chapter 4

Construct validity and test-retest reliability of the Climbing Stairs Questionnaire in lower-limb amputees

De Laat FA[1,2,3], Rommers GM[3], Geertzen JH[3], Roorda LD[4]



[1] Rehabilitation Center Leijpark, Libra Zorggroep, Tilburg, The Netherlands;

[2] Rehabilitation Center Tolbrug, Jeroen Bosch Hospital, 's Hertogenbosch, The Netherlands;

[3] Department of Rehabilitation Medicine and Graduate School for Medical Sciences, University Medical Center of Groningen, Groningen, The Netherlands;

[4] Department of Rehabilitation Medicine and Psychology, Jan van Breemen Institute, Amsterdam, The Netherlands.

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ABSTRACT
Objective: To investigate the construct validity and test-retest reliability of the Climbing Stairs Questionnaire, a patient-reported measure of activity limitations in climbing stairs, in lower limb amputees.

Design: A cross-sectional study.

Setting: Outpatient department of a rehabilitation center.

Participants: Lower-limb amputees (N=172; mean ± SD age, 65±12 y; 71% men; 82% vascular cause) participated in the study; 33 participated in the reliability study.

Interventions: Not applicable.

Main Outcome Measure(s): Construct validity was investigated by testing 10 hypotheses: limitations in climbing stairs according to the Climbing Stairs Questionnaire will be greater in lower-limb amputees who: (1) are older, (2) have a vascular cause of amputation, (3) have a bilateral amputation, (4) have a higher level of amputation, (5) have more comorbid conditions, (6) had their rehabilitation treatment in a nursing home, and (7) climb fewer flights of stairs. Furthermore, limitations in climbing stairs will be related positively to activity limitations according to: (8) the Locomotor Capabilities Index, (9) the Questionnaire Rising and Sitting down, and (10) the Walking Questionnaire. Construct validity was quantified by using the Mann-Whitney *U* test, Kruskal-Wallis test, and Spearman correlation coefficient. Test-retest reliability was assessed with a 3-week interval and quantified using the intraclass correlation coefficient (ICC).

Results: Construct validity (8 of 10 null hypotheses not rejected) and test-retest reliability were good (ICC= .79, 95% confidence interval, .57-.90).

Conclusion: The Climbing Stairs Questionnaire has good construct validity and test-retest reliability in lower-limb amputees.

Key Words: Amputation; Questionnaires; Rehabilitation.

List of Abbreviations

CI	confidence interval
FCI	Functional Comorbidity Index
GRCQ	Global Rating of Change Questionnaire
ICC	intraclass correlation coefficient
LCI	Locomotor Capabilities Index

Climbing stairs is 1 of the most demanding tasks for maintaining mobility.[1] In addition, it is an important issue for lower-limb amputees, as reported by themselves.[2] In the Netherlands, the use of stairs was investigated in elderly lower-limb amputees. It was found that 6 months after rehabilitation treatment, only 15 of 36 (42%) were able to use stairs, whereas 92% were able to make a transfer and move around inside the house and 64% were able to walk outside the house.[3] Nowadays, there is growing interest in more task- and context-specific training in amputees, such as climbing stairs.[4] However, although many lower-limb amputees consider climbing stairs to be an important issue and many of them are unable to do so, the limitations that lower-limb amputees experience in climbing stairs have not yet been studied in great detail.[1]

Performance tests and questionnaires are used most frequently to assess limitations in climbing stairs. In a clinimetric review of existing measures of stair negotiation, no validated scales were found.[5] Subsequently, several studies focusing on stair negotiation have been published. In a study of patients after total hip replacement, a performance test was used to assess stair negotiation: the Timed Stair Test.[6] Other studies focused on lower-limb amputees with microprocessor-controlled prosthetic knee mechanisms. In these studies, other performance tests were used to assess stair negotiation: the Stair Assessment Index[7] and Montreal Rehabilitation Performance Profile.[8] However, to our knowledge, the clinimetric properties of these performance tests have not yet been studied.

To assess patient-reported perception of limitations in climbing stairs, a questionnaire seems to be more appropriate than a performance test.[9] To our knowledge, the only questionnaire that provides detailed measurement of limitations in climbing stairs is the Climbing Stairs Questionnaire.[10] The Climbing Stairs Questionnaire is a patient-reported questionnaire that measures activity limitations in climbing stairs. It consists of 15 items formulated in behavioural terms (eg, I go up the stairs but it takes longer) with dichotomous response options (Yes box marked/Yes box not marked). The sum score is calculated by adding scores for the 15 items. This sum score subsequently is standardized (range, 0-100), with higher scores indicating less limitation in climbing stairs. Patients can mark a 16th item if they do not climb stairs at all,because of their health, and these patients are given the minimum score. Item selection for the Climbing Stairs Questionnaire was based on an extensive literature review, and the first draft version was subjected to the opinions of experts. The final scale was tested in 759 patients with lower-extremity disorders (including 192 lower-limb amputees) living at home. It had (1) good fit with the monotonicity model[10] (or scalability), indicating that the items form a scale; (2) good fit with the double monotonicity model,[10] indicating invariant (hierarchical) item ordering; (3) good intratest reliability, indicating good repeatability of the sum score; (4) good robustness, indicating both stability of scalability and invariant item ordering in subgroups of patients; and (5) some differential item functioning (4 items in amputees compared with nonamputees). However, the construct validity of the Climbing Stairs Questionnaire, indicating that the instrument validly measures the construct "limitations in climbing stairs," has not yet been investigated. Furthermore, test-retest reliability of the Climbing Stairs Questionnaire, indicating the reproducibility of measurements over time, has been investigated in only a small study with 21 patients with complex regional pain syndrome type 1, which yielded satisfactory results.[11]

Therefore, the main objective of this study was to assess the construct validity of the Climbing Stairs Questionnaire in lower-limb amputees. The secondary objective was to assess test-retest reliability of the Climbing Stairs Questionnaire in lower-limb amputees.

METHODS

Participants

Participants were recruited between 1998 and 2008 in the outpatient department of Rehabilitation Center "Tolbrug, 's Hertogenbosch" in the Netherlands. A first group consisted of lower-limb amputees at the end of their outpatient rehabilitation treatment in this center (rehabilitation center group). These lower-limb amputees were assessed just before the start of their follow-up in the outpatient department. A second group consisted of lower-limb amputees directly after discharge from inpatient or outpatient rehabilitation treatment in nursing homes in the region of "Tolbrug, 's Hertogenbosch" (nursing home group). These lower-limb amputees were assessed at the start of their follow-up at the outpatient department of the rehabilitation center. The 2 groups together encompass all lower-limb amputees undergoing rehabilitation treatment in this region. Only lower-limb amputees who were wearing a prosthesis after their rehabilitation treatment were selected. For the test-retest reliability study, a subgroup of lower-limb amputees who finished their rehabilitation treatment between June 2003 and November 2004 was recruited from the rehabilitation center group.

Procedure

The rehabilitation center group received the first questionnaire from the therapists on the penultimate day of treatment. Patients were asked to fill in the questionnaire at home and bring it with them on the last day of treatment. The nursing home group received the questionnaire during their first appointment in the rehabilitation center. They were asked to fill in the questionnaire at home, and return the completed questionnaire by mail. The first questionnaire consisted of the Climbing Stairs Questionnaire, a rating of the number of stair flights climbed, the LCI,[12-14] the Questionnaire Rising and Sitting down,[15, 16] and the Walking Questionnaire.[17]

For the test-retest reliability study, patients received a second questionnaire by mail 3 weeks later. They were asked to fill in the second questionnaire at home and return it by mail. Lower-limb amputees who returned questionnaires with missing data were contacted by telephone by an independent physician and asked to provide the missing data. This second questionnaire consisted of the Climbing Stairs Questionnaire and a self-constructed GRCQ. In the GRCQ, patients were asked: :"How do you rate your ability to climb stairs now compared with the first time you filled in the questionnaire?" The 15 response options were: extremely good; very much better; much better; better; somewhat better; slightly better; almost the same, marginally better; no change; almost the same, marginally worse; slightly worse; somewhat worse; worse; much worse; very much worse; and extremely bad. Participants were considered to be stable with respect to their limitations in climbing stairs if they rated themselves on the GRCQ as: slightly better; almost the same, marginally better; no change; almost the same, marginally worse; or slightly worse.

Measurements

Sociodemographic characteristics, diagnosis, prosthesis prescription, and information about comorbid conditions were extracted from the medical records. Comorbidity was assessed by using the FCI,[18] a physician-reported assessment of the number of comorbid conditions. The FCI consists of a list of 18 items addressing several diagnoses, the presence of which (yes/no) is scored. The sum score is calculated by adding the scores for the 18 items (range, 0-18), with higher scores indicating more comorbid conditions. The construct validity of the FCI has been studied, and physical functioning decreased with an increase in FCI score.[18] To obtain the most reliable FCI score, we used a method described earlier[19]: 2 investigators (F.A.d.L. and an independent physician) scored the presence of all 18 diagnoses independently, and, in case of disagreement, each score was discussed until consensus was achieved.

To assess the number of flights of stairs climbed, we used a rating scale with 8 response options: 0, ½, 1, 2, 3, 4, 5, or 6 flights of stairs. Patients were instructed to rate the maximum number of flights of stairs that they actually climbed in their daily life, with no reference to a specific time frame. Item scores were subdivided into 3 categories (0,1, and ≥ 2 flights) because these were considered to be the clinically most relevant categories.

To test construct validity, we selected, in addition to the rating scale assessing the number of the number of flights of stairs climbed, patient-reported measurement instruments with a good conceptual framework[20, 21] measuring mobility or aspects of mobility. The following instruments were selected: the LCI,[12-14] Questionnaire Rising and Sitting down,[15, 16] and Walking Questionnaire.[17]

The LCI[12-14] is a patient-reported assessment of a range of locomotor activities, such as rising from a chair or the floor, walking on a variety of surfaces, and climbing stairs and curbs. It consists of 14 items with 4 response options: unable (score 0), able if someone helps me (score 1), able if someone is near me (score 2), or able alone (score 3). The sum scores range from 0 to 42, with higher scores indicating more locomotor capabilities (or less limitation). The construct validity and the test-retest reliability of the LCI have been reported to be good.[13]

The Questionnaire Rising and Sitting down[15, 16] is a patient-reported questionnaire that measures activity limitations in rising and sitting down. It contains 39 items with dichotomous response options (Yes box marked/Yes box not marked). The sum score is based on the 1-parameter logistic model[15] and standardized (range, 0-100), with higher scores indicating less limitation in rising and sitting down. Item selection for the Questionnaire Rising and Sitting down was based on an extensive literature review, and the first draft version was subjected to opinions of experts.[15] An improved scale was tested in 759 patients with lower-extremity disorders (including 230 lower-limb amputees) living at home.[16] The Questionnaire Rising and Sitting down is a unidimensional scale, and it has good fit with the 1-parameter logistic model, good intratest reliability and good content validity.[16] The construct validity of the Questionnaire Rising and Sitting down has not yet been studied.

The Walking Questionnaire[17] is a patient-reported questionnaire, that measures activity limitations in walking inside and outside the house. It contains 35 items with dichotomous response options (Yes box marked/Yes box not marked). The sum score is calculated by adding scores for the 35 items. Subsequently, the sum score is standardized (range, 0-100), with higher scores indicating less limitation in walking. Patients can mark a 36th item if they do not walk inside the house at all, and these patients are given the minimum scores. Patients can mark a 37th item if they do not walk outside the house at all because of their health, and these patients are treated as if they had marked the box Yes for all items concerning walking outside the house. The Walking Questionnaire was tested in 981 patients with lower-extremity disorders (including 239 lower-limb amputees) living at home. It had (1) good fit with the monotonicity model, (2) good fit with the double monotonicity model, (3) good intratest reliability, (4) good robustness, and (5) some differential item functioning (6 items in amputees compared with nonamputees).

The study protocol was approved by the Research Ethics Committee of the Jeroen Bosch Hospital, 's Hertogenbosch.

Analysis

Construct validity. Construct validity indicates the degree to which the scores on a measurement instrument are consistent with theoretically derived hypotheses (eg, with regard to internal relations, relations with scores of other instruments, or differences in scores between relevant groups) based on the assumption that the instrument validly measures the construct to be measured. With so few available scales for lower-limb amputees in climbing stairs, before examining our data, we formulated 10 hypotheses based on the available literature or, in case of total absence of literature, clinical experience. We used literature addressing the relation between general mobility limitations and sociodemographic factors in lower-limb amputees after rehabilitation. We hypothesized that limitations in climbing stairs according to the Climbing Stairs Questionnaire would be greater in lower-limb amputees who (1) are older,[22-24] (2) have a vascular cause of amputation than in lower-limb amputees with a nonvascular cause of amputation,[22, 25] (3)have a bilateral amputation than in lower-limb amputees with a unilateral amputation,[22, 26] (4) have a higher level of amputation (transfemoral or knee disarticulation) than in lower-limb amputees with a lower level of amputation (transtibial or Syme amputation),[22, 23] (5) have more comorbid conditions according to the FCI,[24, 25] (6) had rehabilitation treatment in a nursing home than in lower-limb amputees who had this treatment in an outpatient department of a rehabilitation center,[26] (7) climb fewer flights of stairs according to their rating of the number of flights climbed, (8) have more limitations in locomotor capabilities according to the LCI,[23] (9) have more limitations in rising and sitting down according to the Questionnaire Rising and Sitting down,[15, 16] and (10) have more limitations in walking according to the Walking Questionnaire.[17]

Hypotheses addressing relations (hypotheses 1, 5, 8, 9, and 10) were quantified by using the Spearman correlation coefficient, and hypotheses addressing the presence or absence of differences were quantified by using the Mann-Whitney *U* test (hypotheses 2, 3, 4, and 6) or Kruskal-Wallis test (hypothesis 7; 2-tailed $P<.05$).

Test-retest reliability. Test-retest reliability refers to the reproducibility of measurements using the same instrument over time. To assess the reproducibility of the Climbing Stairs Questionnaire, we used Climbing Stairs Questionnaire data from the first and second questionnaires of participants who rated themselves stable on the GRCQ. Reproducibility includes reliability and agreement.[27] Reliability refers to how well individuals can be distinguished from each other, whereas agreement addresses how close the repeated measurements are to the original measurements. The most frequently used reliability parameter is the ICC. To estimate the test-retest reliability of the Climbing Stairs Questionnaire, we calculated the ICC with 95% CI by using a 2-way mixed model. Patients were considered to be random effects, whereas the measure effect was a fixed effect. An ICC of .70 is considered to be satisfactory for group comparisons, and ICC of .90 to .95 was satisfactory for individual comparisons.[28] To visualize the agreement, we represented the data graphically in a Bland-Altman plot.[29] All statistics were calculated by using the SPSS 15.0 for Windows program.[a]

RESULTS

Patient Characteristics

A total of 175 lower-limb amputees fulfilled the selection criteria, and 172 were willing to participate in the construct validity study. Two lower-limb amputees with a transtibial amputation and 1 lower-limb amputee with a knee disarticulation, all from the rehabilitation center group, informed us that they were unwilling to participate. Characteristics of the 172 lower-limb amputees are listed in table 1.

Of 172 lower-limb amputees who participated in the construct validity study, 35 met the additional selection criteria for the test-retest reliability study. Two of these 35 lower-limb amputees were unwilling to fill in the second questionnaire: 1 had a transtibial amputation and 1 had a transfemoral amputation. Data therefore were available for 33 lower-limb amputees, only 24 of whom considered themselves to be stable with respect to their limitations in climbing stairs.

Table 1: Patient Characteristics

Age (y)			
	Mean (SD)		65±11
	Range		37-92
Sex			
	Women		50 (29)
	Men		122 (71)
Setting			
	Rehabilitation center		155 (90)
	Nursing home		17 (10)
Amputation etiology, n (%)			
	Vascular		143 (83)
	Infection		13 (8)
	Traumatic		13 (8)
	Oncologic		3 (2)
Amputation level, n (%)			
	Hip disarticulation	3 (2)	
	Transfemoral	55 (32)	
	Knee disarticulation	8 (5)	
	Transtibial	93 (54)	
	Syme	1 (1)	
	Amputation unilateral		160 (93)
	Transfemoral and transtibial	2 (1)	
	Transtibial and transtibial	7 (4)	
	Syme and transtibial	3 (2)	
	Amputation bilateral		12 (7)

NOTE. N=172. Values expressed as n (%) unless noted otherwise.

Construct Validity

Results of hypotheses that we tested are listed in table 2. Hypotheses 3 (bilateral vs unilateral amputation) and 4 (higher, ie, transfemoral or knee disarticulation, vs lower, ie, transtibial or Syme level of amputation) were rejected, but the other 8 hypotheses were not rejected.

Table 2. Construct validity of the Climbing Stairs Questionnaire in lower-limb amputees

Hypothesis*	n	Spearman correlation coefficient	p†	Standardized median (IQR) sum score	p‡
1. Age	172	-.26	<.001		
2. Amputation - etiology	172				
Vascular	143			31 (0 - 56)	<.05
Non-vascular	29			44 (28 - 69)	
3. Amputation - side	172				
Bilateral	12			9 (0 - 31)	.090
Unilateral	160			38 (8 - 56)	
4. Amputation - level§	160				
Higher (transfemoral or knee disarticulation)	66			31 (0 - 58)	.256
Lower (transtibial or Syme amputation)	94			44 (19 - 56)	
5. Comorbid conditions	170	-.19	<.05		
6. Setting	172				
Nursing home	17			0 (0 - 34)	<.001
rehabilitation center	155			38 (19 - 63)	
7. No. of stair flights climbed	171				
0	61			0 (0 - 22)	<.001
1	56			44 (31 - 56)	
≥2	54			50 (31 - 69)	
8. Locomotor capabilities	164	.52	<.001		
9. Limitations in rising & sitting down	171	.42	<.001		
10. Limitations in walking	172	.60	<.001		

Abbreviation: IQR, interquartile range; LLA lower-limb amputee

* Ten hypotheses were tested. Limitations in climbing stairs, according to the Climbing Stairs Questionnaire, will be more in LLAs who:

1. are older;
2. have a vascular cause of amputation than in LLAs with a nonvascular cause of amputation;
3. have a bilateral amputation than in LLAs with a unilateral amputation:
4. have a higher level of amputation than in LLAs with a lower level of amputation;
5. have more comorbid conditions according to the FCI;
6. had rehabilitation treatment in a nursing home compared with LLAs who had this treatment in a rehabilitation center;
7. climb fewer flights of stairs according to their rating of the number of stair flights climbed;
8. have more limitations in locomotor capabilities according to the LCI;
9. have more limitations in rising and sitting down according to the Questionnaire Rising and Sitting down;
10. have more limitations in walking according to the Walking Questionnaire.

† significance (2-tailed *P*) of Spearman correlation coefficient

‡ significance (2-tailed *P*) of Mann-Whitney *U* test (dichotomous variables) or Kruskal-Wallis Test (trichotomous variables).

§ LLAs with unilateral amputation only

Test-Retest Reliability

Mean ± SD scores for the first and second Climbing Stairs Questionnaires were 61±36 and 73±32, respectively. The 3-week test-retest reliability of the Climbing Stairs Questionnaire was good, with an ICC of .79 (95% CI .57-.90). Agreement is shown graphically in the Bland-Altman plot (fig 1). Although overall agreement between measurements was acceptable, we found large differences for 2 lower-limb amputees in the mid range of the mean sum score.

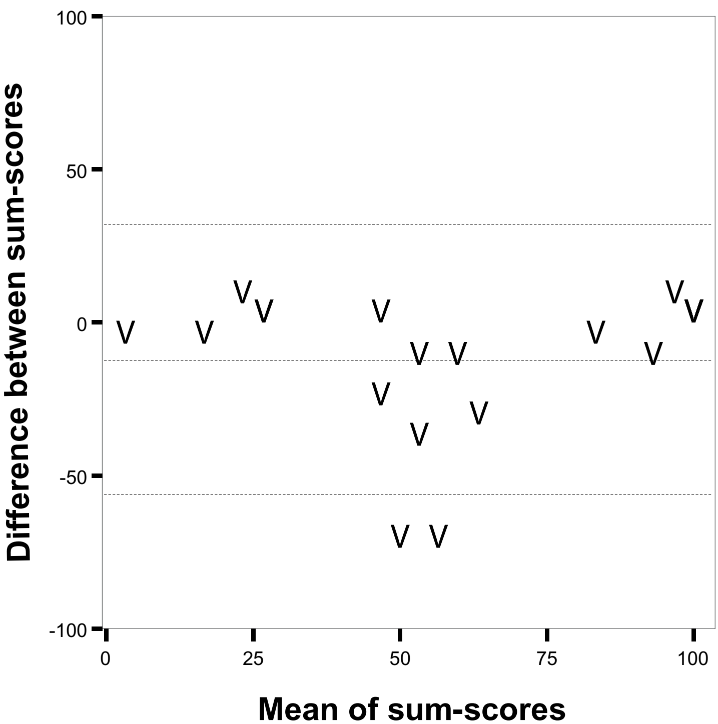

Figure 1. Bland-Altman plot of the reliability study with difference between sum scores of the first and second assessment of the Climbing Stairs Questionnaire against the mean of sum scores. Dashed horizontal lines show the mean difference and the 95% limits of agreement.

DISCUSSION

The objective of this study was to assess the construct validity and test-retest reliability of the Climbing Stairs Questionnaire in lower-limb amputees. In general, it is recommended that it is preferable to investigate the clinimetric properties of an existing measurement and not develop a new one.[30] In this study, we showed that the Climbing Stairs Questionnaire has good construct validity and good test-retest reliability for group comparisons in lower-limb amputees.

Only 3 of 175 lower-limb amputees who fulfilled the selection criteria were unwilling to participate in this study, whereas 2 of 35lower-limb amputees were unwilling to participate in the reliability study. In addition, with respect to cause and level of amputation, our sample of lower-limb amputees was similar to other samples of lower-limb amputees in the Netherlands.[31, 32]

The construct validity of the Climbing Stairs Questionnaire in lower-limb amputees was good, because only 2 of our 10 hypotheses were rejected. We found no relations between limitations in climbing stairs according to the Climbing Stairs Questionnaire and unilateral versus bilateral amputation (hypothesis 3). This probably is caused by the small number of bilateral amputees (n=12) in the study and the selection criterion stating that lower-limb amputees must wear a prosthesis. Therefore, the selected bilateral amputees may have fewer activity limitations. Furthermore, we found no relations between limitations in climbing stairs and level of amputation (hypothesis 4). The only other study addressing the relation between limitations in climbing stairs (according to the Climbing Stairs Questionnaire) and level of amputation (comparing lower-limb amputees with hip disarticulation and hemipelvectomy) also reported no difference in limitations in climbing stairs between the 2 groups compared.[33] This might indicate that patients with different levels of amputation were selected for rehabilitation treatment on the basis of their anticipated activity limitations.

Test-retest reliability of the Climbing Stairs Questionnaire in lower-limb amputees was good. Test-retest reliability of the Climbing Stairs Questionnaire has also been studied in patients with complex regional pain syndrome type 1,[11] and, in that study, ICC equaled .87, which is slightly higher than the ICC of .79 in our study. This slightly higher ICC may be explained by the shorter test-retest interval of 1 week in that study, compared with the present 3-week interval in our study. In the literature, there is discussion about the optimal test-retest interval. A relatively short interval (eg, 1 wk) may result in recall bias, whereas a relatively long interval (eg, 3 wk) may result in a change in the construct being measured. In our study, we combined the 3-week interval (to prevent recall bias) with a global rating of change scale (to prevent the selection of "changing" patients).

Study Limitations

However, our study has limitations. The response rate of lower-limb amputees treated in nursing homes is unclear. Only lower-limb amputees who had a first follow-up appointment at the outpatient department of the rehabilitation center after their rehabilitation treatment in a nursing home were asked to participate in the study; therefore, nonresponse in this group is unknown. However, all lower-limb amputees who kept this appointment were willing to participate. We assume that lower-limb amputees who were not willing to attend the follow-up in the rehabilitation center, are the worst performers in the nursing home group, and the difference between the rehabilitation group and the nursing home group might have been even greater if we missed former nursing home patients. Another limitation of our study is that we selected only lower-limb amputees after their multidisciplinary rehabilitation treatment, which may have resulted in a sample of lower-limb amputees with fewer limitations. However, selecting patients at the beginning of their rehabilitation treatment might have resulted in an increase in the number of patients who could not yet climb stairs at all. To test construct validity, we selected patient-reported measurement instruments. Arecently published study reported a relation between self-reported difficulty in climbing stairs and certain patient characteristics, such as arthritis, depression, and fear of falling, in nondisabled elderly people.[34] Further testing of the construct validity of the Climbing Stairs Questionnaire with specific stair-climbing performance tests in amputees (eg, muscle strength in the legs,[35] the Timed Stair Test,[6] or Stair Assessment Index[7]) therefore is recommended, although results of a performance test are not necessarily related to perceived limitations.[36]

Finally, it is remarkable that only 24 of 33 participants in the reliability study considered themselves to be stable with respect to their limitations in climbing stairs. We did not investigate the reasons for this in the present study. For nonstable participants, the reason could be that the socket was fitting less well, because of atrophy of the stump in the meantime. Stump atrophy can continue for up to 2 years after amputation.[37] It also could be that lower-limb amputees consider climbing stairs a heavy and frightening activity and give up climbing stairs when rehabilitation treatment has stopped and they are no longer trained and encouraged to climb stairs. We recommend that future studies repeat the reliability testing of the Climbing Stairs Questionnaire in experienced prosthetic users, to address this issue.

CONCLUSIONS

The Climbing Stairs Questionnaire provides a detailed assessment of patient-reported limitations in climbing stairs and has good construct validity and test-retest reliability in lower-limb amputees directly after their multidisciplinary rehabilitation treatment. Based on results of the reliability study, the Climbing Stairs Questionnaire can be recommended for group comparisons, but not for individual comparisons.

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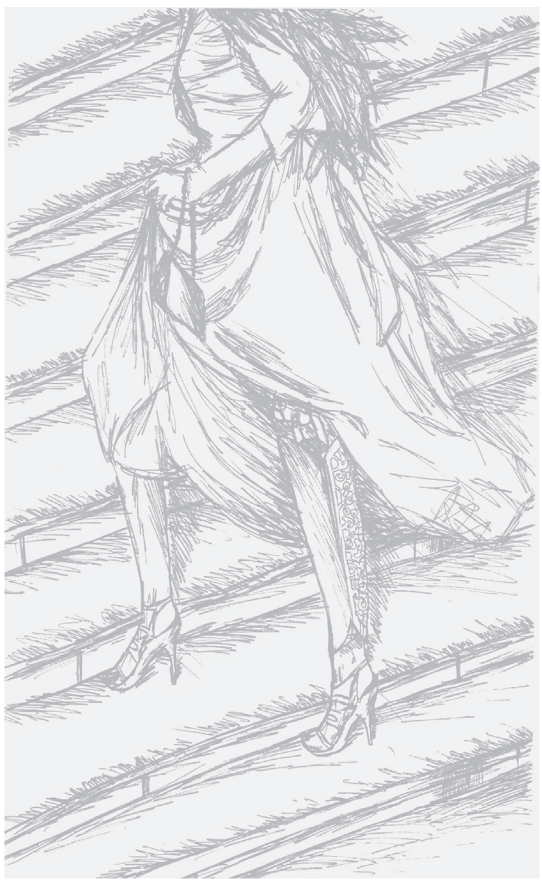
Supplier

a. SPSS Inc, 233 S Wacker Dr, 11th Fl, Chicago, IL 60606.

Chapter 5

Rising and sitting down after rehabilitation for a lower-limb amputation

De Laat FA[1,2,3,] Dijkstra PU[3], Rommers GM[3], Geertzen JH[3], Roorda LD[4]



[1] Rehabilitation Center Leijpark, Libra Rehabilitation Medicine and audiology, Tilburg, The Netherlands;

[2] Rehabilitation Center Tolbrug, Jeroen Bosch Hospital, 's Hertogenbosch, The Netherlands;

[3] Department of Rehabilitation Medicine, University Medical Center of Groningen, Groningen The Netherlands;

[4] Amsterdam Rehabilitation Medicine Research Center | Reade, Amsterdam, The Netherlands.

Submitted

ABSTRACT
Objective: To study the perceived independence in rising and perceived limitations in rising and sitting down in persons after a lower-limb amputation (LLA) and the relationship of these perceptions with personal and clinical characteristics.

Design: Cross-sectional study.

Setting: Outpatient department of a rehabilitation center.

Participants: Persons with a LLA (N=172; mean age 65 ± 12y; 73% men).

Interventions: Not applicable.

Main Outcome Measure(s): Perceived independence in rising was assessed with the Locomotor Capabilities Index. Limitations in rising and sitting down were assessed with the Questionnaire Rising and Sitting down (range 0-100, with higher scores indicating less limitation). Multivariate logistic and linear regression analyses were respectively used to investigate the associations between independence and limitations in rising and sitting down, and personal and clinical characteristics.

Results: Of the participants, 91% and 47% perceived independence in rising from a chair and rising from the floor, respectively. Older-aged and women perceived less independence in rising. Participants perceived marked limitations in rising and sitting down (mean score was 46 ± 16), with those rehabilitated in a nursing home perceiving more limitations.

Conclusion: After a LLA, most persons are able to rise independently from a chair, but many perceive a decreased independence in other forms of rising, especially older participants and women. Persons with a LLA, especially those rehabilitated in a nursing home, perceive considerable limitations in rising and sitting down.

Key Words: mobility; questionnaires; amputation; activities of daily living

LIST OF ABBREVIATIONS

LCI	Locomotor Capabilities Index
LLA	lower-limb amputation
QR&S	Questionnaire Rising and Sitting down

Although rising and sitting down are prerequisites for regaining mobility after a lower-limb amputation (LLA), studies focusing on limitations in rising and sitting down in persons with a LLA are scarce. Questions about rising and sitting down in persons with a LLA are only included in more comprehensive questionnaires,[1, 2] and only superficially assess the limitations in rising and sitting down.

Important aspects of rising and sitting down in persons with a LLA are the perceived independence in rising and the perceived limitations in rising and sitting down. If a person does not perceive independence during rising, he or she may become dependent on an adapted chair, may not be able to rise without help, or might have to move to a nursing home because transfers and walking become impossible. If a person perceives many limitations in rising and sitting down, he or she will seek help within the healthcare system or avoid rising and sitting down, which will lead to diminished mobility.

Little is known about factors that may influence rising and sitting down in persons with a LLA. Persons with a LLA of older age or those who were rehabilitated in a nursing home perceive more limitations in rising and sitting down than younger people and those rehabilitated in a rehabilitation centre.[3] We are not aware of studies assessing other clinical characteristics such as the components of the prosthesis in relation to limitations in rising and sitting down.

The first objective of this study was to describe the perceived independence in rising and the perceived limitations in rising and sitting down in persons with a LLA at the end of rehabilitation treatment. The second objective was to analyze the relationship between independence and limitations in rising and sitting down, and personal and clinical characteristics.

METHODS

Participants and procedure

Participants were persons with a LLA recruited at the end of their rehabilitation treatment in the rehabilitation center, or at their first follow-up appointment after rehabilitation treatment in nursing homes in the same region. More details regarding the recruitment of the participants and the distribution of the questionnaires have been described elsewhere.[3]

The study protocol was approved by the Research Ethics Committee of the Jeroen Bosch Hospital, 's Hertogenbosch. All participants gave informed consent.

Measurements

Ability to rise independently. To measure the perceived independence in rising, we used 3 questions of the Dutch version of the Locomotor Capability Index (LCI)[1, 4] specifically addressing this concept (appendix). The construct validity and the test-retest reliability of each of the 3 questions has been found to be good.[1]

Limitations in rising and sitting down. To measure the perceived limitations in rising and sitting down, we used the Questionnaire Rising and Sitting down (QR&S).[5] The sum score is standardized (range, 0 to 100), with higher scores indicating less limitation. The QR&S shows good construct validity and test-retest reliability in persons with a LLA.[3]

Personal and clinical characteristics. Data on personal (age, sex) and clinical variables (amputation cause and level, type of prosthetic knee and foot, and comorbidities) were extracted from medical records. The assessment of comorbidity has been described previously.[6]

Data analysis

For the statistical analysis, rising was dichotomized into independent ("able alone") *versus* not independent; age was centered at 65 to make the results clinically interpretable. Other variables were dichotomized (table 1).

With the ability to rise independently in all 3 questioned circumstances as the outcome, the personal and clinical characteristics were univariately tested for their association, using nonparametric statistics. Associated variables ($p < .1$) were subsequently entered into a logistic regression as predictors. With limitations in rising and sitting down as the outcome, associations were tested using parametric and non-parametric statistics as appropriate. Associated variables ($p < .1$) were subsequently entered into a linear regression. Through backward stepwise elimination, the non-contributing variables ($p \geq .1$) were excluded.

RESULTS

Participants

A total of 172 persons with a LLA participated in the study. Three persons with a LLA were unwilling to participate. The age (mean ± SD) of the participants was 65 ± 12 years (table 1). Data regarding the comorbidity and the ability to rise independently were available for all but 2 participants, while data for the QR&S was available for all but 1 participant.

Table 1: Demographics and results of the univariate analysis of characteristics in rising and sitting down in persons with a lower-limb amputation

		n (%)	Independence in rising: n (%)	Limitations in rising and sitting down: Mean ± SD sum score
Personal characteristics				
-Age			*p<.001**	*p=.025‡, r=-.171*
		172 (100)	*72/170* (42)	46±16
-Sex			*p=.035*	*p=.954**
	women	50 (29)	15/50 (30)	46±15
	men	122 (71)	57/120 (48)	46±17
Clinical characteristics				
- Amputation cause			*p=.052†*	*p=.262**
	vascular	143 (83)	55/141 (39)	47±16
	non-vascular	29 (17)	17/29 (59)	43±17
- Amputation level			*p=.270†*	*p=.231**
	higher (HD, TF or KD)	66 (38)	25/65 (38)	45±17
	lower (TT or Syme)	94 (55)	44/93 (47)	48±16
	bilateral§	12 (7)	3/12 (25) §	41±16§
-FCI			*p=.002†*	*p=.971**
	0-3	103 (61)	52/103 (50)	46±18
	≥4	67 (39)	18/66 (27)	46±13
- Setting			*p=.007†*	*p=.026‖*
	nursing home	17 (10)	2/17(12)	37±19
	rehabilitation center	155 (90)	70/153(46)	47±16
- Prosthetic knee			*p=.002†*	*p=.482**
	knee lock	26 (39)	4/26 (15)	46±13
	other	41 (61)	21/40 (53)	43±19
- Prosthetic foot			*p=.181†*	*p=.096**
	single-axis	82 (48)	30/81 (37)	44±17
	other	90 (52)	42/89 (47)	48±15

Abbreviations: FCI, Functional Comorbidity Index; HD, hip disarticulation; TF, transfemoral amputation; KD, knee disarticulation; TT, transtibial amputation.
*Significance (2-tailed p) of independent t-test
† Significance (2-tailed p) of Pearson chi-square test
‡ Significance (2-tailed p) of Pearson correlation coefficient
§ not univariately analyzed because of the small number of patients
‖ Significance (2-tailed) of Mann-Whitney U test

Ability to rise independently

One hundred fifty six (91%) of the participants were able to get up from a chair independently, 117 (68%, 1 missing) to pick up an object from the floor when standing up with their prosthesis, and 80 (47%, 1 missing) were able to get up from the floor. In total, 72 (42%, 2 missing) participants were able to rise independently in all 3 circumstances. The results of the univariate analysis are shown in table 1. Multivariate logistic regression analysis showed that older participants and women perceived less independence in rising (table 2).

Table 2. Results of the multivariate logistic and linear regression analyses to predict outcome in rising and sitting down in persons with a lower-limb amputation

Independence in rising (logistic regression)					Nagelkerke R^2
Predictors	!!	S.E.	OR (95% CI)	p-value	.33
Age centered 65 years*	-0.10	.02	.90 (.87; .94)	<.001	
Sex (men / women)†	1.31	.45	3.69 (1.53; 8.92)	.004	
Constant	-1.25	.39	.29	.001	
Limitations in rising and sitting down (linear regression)					R^2
Predictors	!!	S.E.	(95% CI)	p-value	.23
Age centered 65 years‡	-0.18	.11	(-0.40; .03)	.093	
Nursing home (yes / no) §	-8.65	4.20	(-16.94; -0.36)	.041	
Constant	47.18	1.29	(44.64; 49.72)	<.001	

Clinical interpretation:
*Every year older than 65 further reduces the ability to rise independently. The odds of a patient who is 75 years of age of rising independently is $(e^{-0.09})^{10} \approx 0.90^{10} \approx 0.35$ times less than that of someone who is 65 years of age.
† The odds of women rising independently is 3.7 times lower than men.
‡ Every year older than 65 further reduces the mean outcome in rising and sitting down. This mean outcome (range, 0-100 with higher scores indicating less limitation) for a patient who is 75 years of age is 0.18 x 10 = 1.8 lower than for someone who is 65 years of age.
§ The mean outcome of the limitations in rising and sitting down is 8.65 lower in persons treated in a nursing home than in persons treated in a rehabilitation center.

Limitations in rising and sitting down

On the QR&S, participants scored 46 ± 16 (mean ± SD), indicating marked limitations. The results of the univariate analysis are shown in table 1. Multivariate linear regression analysis showed that participants rehabilitated in a nursing home perceived more limitations in rising and sitting down (table 2).

DISCUSSION

In this study, we showed that persons with a LLA perceived being good in rising independently from a chair, but being less independent when getting up from the floor. They perceive marked limitations in rising and sitting down. Older-aged and women perceived being more often dependent in rising, whereas those rehabilitated in a nursing home perceived more limitations in rising and sitting down.

The study population was the total number of persons with a LLA from the region ʻs Hertogenbosch. The study population is representative regarding cause and level of amputation in the whole of The Netherlands.[7]

The ability to rise independently in the original Canadian study of the LCI was as follows: 92% could get up from a chair, 76% could pick up an object from the floor when standing up with their prosthesis, and 63% could get up from the floor independently.[8] This is similar to our results. These results and the results of the multivariate analysis show that getting up from the floor independently may need more attention in task- and context specific rehabilitation treatment, especially in older-aged and women.

The QR&S has been previously studied in hip disarticulation and hemipelvectomy amputees with a mean score of 54.[9] This higher score is probably due to a lower mean age (56) as well as recruitment source (rehabilitation center versus an orthopedic workshop with a very high percentage of tumors as cause of amputation).

Study Limitations

Our main study limitation is that we assessed only easily obtainable personal and clinical variables. We did not assess other variables which might influence rising and sitting down, such as muscle force or foot positioning.[10] In future studies, these variables need attention in the assessment of rising and sitting down in persons with a LLA.

CONCLUSIONS

A considerable number of persons with a LLA reported a decreased ability in rising and sitting down, especially women, those of advanced age or those rehabilitated in a nursing home. Therefore, these sub-groups with a LLA require special attention when being trained in rising and sitting down.

Appendix: questions in the Locomotor Capabilities Index concerning standing up

	0	1	2	3
Get up from a chair	!!	!!	!!	!!
Pick up an object from the floor when you are standing up with your prosthesis	!!	!!	!!	!!
Get up from the floor (e.g. if you fell)	!!	!!	!!	!!

note: 0 = unable; 1 = able if someone helps me; 2 = able if someone is near me; 3 = able alone.

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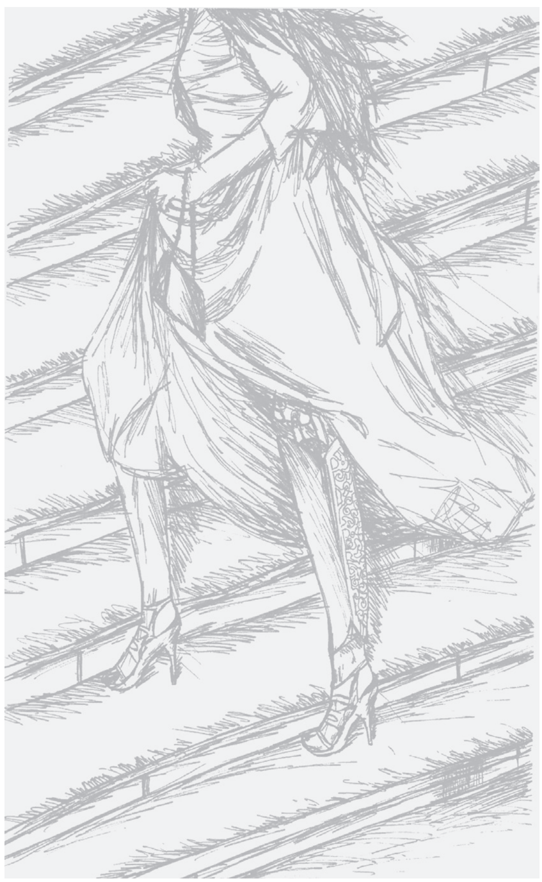
Chapter 6

Climbing stairs after rehabilitation for a lower-limb amputation

De Laat FA[1,2,3,] Rommers GM[3], Dijkstra PU[3], Geertzen JH[3], Roorda LD[4]



[1] Rehabilitation Center Leijpark, Libra Zorggroep, Tilburg The Netherlands;

[2] Rehabilitation Center Tolbrug, Jeroen Bosch Hospital, 's Hertogenbosch The Netherlands;

[3] Department of Rehabilitation Medicine, University Medical Center of Groningen, Groningen The Netherlands;

[4] Amsterdam Rehabilitation Medicine Research Center | Reade, Amsterdam, The Netherlands.

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ABSTRACT

Objective: To study the necessity and the ability to climb stairs in persons after a lower-limb amputation (LLA) and the relationship of this ability with personal and clinical variables.

Design: Cross-sectional study.

Setting: Outpatient department of a rehabilitation center

Participants: Persons with a LLA (N=155; mean age 64.1 ± 11.2y; 73% men).

Interventions: Not applicable.

Main Outcome Measure(s): The necessity to climb stairs was assessed with the Prosthetic Profile of the Amputee. Several indicators of the ability to climb stairs were assessed: (1) independence in climbing stairs with a handrail and (2) without a handrail, according to the Locomotor Capabilities Index; (3) numbers of floors actually climbed, according to a rating scale; and, (4) limitations in climbing stairs, according to the Climbing Stairs Questionnaire (range 0-100, with higher scores indicating less limitations). Multivariate logistic regression analysis was used to investigate the associations between the ability to climb stairs with personal and clinical variables.

Results: Of the participants, 47% had to climb stairs. The ability to climb stairs was as follows: (1) 62% independently climbed stairs with a handrail and (2) 21% without a handrail; (3) 32% didn't climb any stairs, 34% climbed ½ or 1 floor, and 34% climbed 2 floors or more; (4) the median sum score (interquartile range) of the Climbing Stairs Questionnaire was 38 (19; 63), indicating marked limitations. Older participants and women were less able to climb stairs with and without a handrail.

Conclusion: A considerable number of persons with a LLA have to climb stairs in their home environment. Many of them, especially older participants and women, are particularly hampered in their ability to climb stairs.

Key Words: mobility; questionnaires; amputation

List of Abbreviations

FCI	Functional Comorbidity Index
ICF	International Classification of Functioning, Disability and Health
LCI	Locomotor Capabilities Index
LLA	lower-limb amputation
PPA	Prosthetic Profile of the Amputee

Persons with a lower-limb amputation (LLA) report that climbing stairs is an important issue,[1] but this issue has not yet been studied in great detail.[2] Furthermore, climbing stairs has only been investigated in persons with a LLA as a superficial, secondary outcome.[3,4,5] Based on these studies, between 42-80% of persons with a LLA are able to climb stairs independently.

In daily clinical practice, climbing stairs in persons with a LLA could be very important. This is particularly so if there is a necessity for the person to climb stairs within, or in order to enter, their house. However, even if this is not the case, climbing stairs may still be of great importance in order to access other places which have not been adapted for the mobility-impaired person. Important aspects of the ability to climb stairs are safety, independency during stair climbing, the number of flights of stairs the person can negotiate, and whether limitations are perceived. If a person lives alone and is not able to climb stairs independently, or only able to climb a small number of flights of stairs, either the home environment would need to be adapted, the person would need to move to another house, or would need admission to a long-stay care facility. Generally, if a person does not perceive any limitations, he or she would not seek help within the healthcare system.

There are many factors that may influence the ability of persons with a LLA to climb stairs. When amputation is caused by vascular problems, the ability to climb stairs decreases.[6] The use of an auto-adaptive prosthetic knee[7, 8] improves the ability to climb stairs when compared with a standard prosthetic knee. Patients using different prosthetic feet have shown no preference during climbing stairs.[9, 10] However, these studies only investigated young persons with trauma as the cause of LLA, and hence these results cannot be generalized to an elderly population where cause of amputation varies. Persons with a LLA of older age or with more comorbidities were less able to climb stairs.[6] Most persons with a LLA who underwent rehabilitation in a nursing home were unable to climb stairs after completing their program.[6] Based on these results, the ability to climb stairs seems to be a more relevant issue in persons with a LLA undergoing rehabilitation treatment outside a nursing home, that is, in inpatient or outpatient rehabilitation center settings.

The first objective of this study was to describe in detail the necessity and ability to climb stairs in persons with a LLA at the end of outpatient treatment in a rehabilitation center. The second objective was to analyze the relationships between the ability to climb stairs and personal and clinical variables.

METHODS

Participants

Participants were recruited between 1998 and 2008 in the outpatient department of Rehabilitation Center Tolbrug, 's Hertogenbosch, in the Netherlands. Patients were at the end of their outpatient rehabilitation treatment because of a recent LLA (in some cases this had been preceded by inpatient rehabilitation). They had to meet the following inclusion criteria: aged ≥ 18 years; currently wearing a prosthesis; and be able to understand and fill in questionnaires. The study protocol was approved by the Research Ethics Committee of the Jeroen Bosch Hospital, 's Hertogenbosch. All participants gave informed consent.

Procedure

Data on personal (age, sex) and clinical variables (amputation cause and level, type of prosthetic knee and foot, and comorbidities) were extracted from medical records. The number of comorbid conditions was assessed by physicians using the Functional Comorbidity Index (FCI).[11] The FCI consists of a list of 18 items addressing several diagnoses, the presence of which (yes/no) is scored. The sum score is calculated by counting the items scored with 'yes'. A study examining the construct validity of the FCI has shown that physical functioning decreases with an increase in the FCI score (r = -.47).[11] To obtain the most reliable FCI score, we used a method described previously.[12] Two investigators (F.A.d.L. and an independent physician) scored the presence of all 18 diagnoses independently, and, in case of disagreement, each score was discussed until consensus was reached.

The participants received a questionnaire about climbing stairs from the therapists on the penultimate day of treatment. This questionnaire comprised, among other things, questions about the necessity and the ability to climb stairs. Participants were asked to fill in the questionnaire at home and bring it with them on the last day of treatment. Participants who returned questionnaires with missing data were contacted by telephone by an independent physician and were subsequently asked to provide the missing data.

Measurements

Necessity to climb stairs

To measure the necessity to climb stairs, we used the Dutch version of the Prosthetic Profile of the Amputee (PPA).[5] The PPA is a patient-reported outcome measure assessing factors related to prosthetic use in persons with a LLA. Three questions of the PPA, specifically addressing the necessity to climb stairs in the house and in entering or leaving the house, and their interference with daily activities, were used (appendix 1). The test-retest reliability of these three items is moderate to substantial (Cohen's Kappa = .45 - .73).[13]

Ability to climb stairs

Ability to climb stairs independently with and without a handrail. To measure the perceived independence in climbing stairs, we used the Locomotor Capabilities Index (LCI).[5, 13, 14] The LCI forms a part of the PPA. Four questions of the LCI specifically address independence in stair climbing: "Go up the stairs with a handrail", "Go down the stairs with a handrail", "Go up a few steps (stairs) without a handrail", and, "Go down a few steps (stairs) without a handrail". These items have 4 response options: "able alone", "able if someone is near me", "able if someone helps me", or, "unable". The construct validity and the test-retest reliability of each item of the LCI is good.[13, 15]

Number of stairs climbed. To measure the number of floors climbed, we used a simple rating scale with 8 response options: 0, ½, 1, 2, 3, 4, 5, or 6 floors. Participants were instructed to rate the maximum number of floors that they climbed in daily life, with no reference to a specific time-frame or type of stair.

Limitations in climbing stairs. To measure the perceived limitations in climbing stairs, we used the original Dutch version of the Climbing Stairs Questionnaire.[16] It consists of 15 items with dichotomous response options. The sum score is calculated by adding scores for the 15 items. This sum score is subsequently standardized (range 0-100, with higher scores indicating less limitation in climbing stairs). Patients can mark a 16th item if they do not climb stairs at all because of their health, and these patients are given a score of 0.The items of the Climbing Stairs Questionnaire form a reliable and hierarchical scale.[16] Items and hierarchy in persons with a LLA[16] are shown in appendix 2. The questionnaire has been tested in persons with a LLA and exhibited good construct validity (8 of 10 hypotheses not rejected) and test-retest reliability (intraclass correlation coefficient = .79).[6]

Data analysis

We described the necessity and ability to climb stairs, and personal and clinical characteristics of the participants with the mean ± SD for continuous variables, the median (interquartile range) for ordinal variables, and counts (percentages) for dichotomous and categorical variables. Regarding the ability to climb stairs, persons who need to climb stairs were compared to persons who do not, by using the Mann Whitney U-test.

For the univariate and multivariate analyses, the indicators of the ability to climb stairs and some clinical variables were dichotomized, as shown in appendix 3. This was because the residuals were not normally distributed so linear regression analysis was not possible. Age was centered at 65 to make the results more clinically interpretable.

The personal and clinical variables were univariately tested for the indicators of the ability to climb stairs by using the Pearson chi-square, the Kruskal-Wallis test and the Mann-Whitney U-test. Variables with significant relationships ($p<.1$) were subsequently entered into a logistic regression as predictors; the indicators of the ability to climb stairs as the outcomes (dependent variables). Through backward stepwise elimination, the non-contributing variables ($p\geq.1$) were excluded. All statistics were calculated using SPSS 18.0 for Windows.[a]

RESULTS

Patient characteristics

A total of 158 persons with a LLA fulfilled the inclusion criteria, and 155 were willing to participate. Two persons with a transtibial amputation and 1 with a knee disarticulation amputation were unwilling to participate. The age (mean ± SD) of the participants was 64.1 ± 11.2 years. The characteristics of the 155 participants are presented in table 1. Data regarding the number of floors climbed and FCI data were not available for 1 and 2 participants, respectively.

Table 1: Patient characteristics, outcome and univariate analysis of variables in climbing stairs in persons with a lower-limb amputation

		n (%)	Independence in climbing stairs with a handrail: n (%)	Independence in climbing stairs without a handrail: n (%)	Numbers of stairs climbed: median outcome (IQR)	Limitations in climbing stairs: median sumscore (IQR)
Age			*p=.001**	*p=.031**	*p<.001†*	*p=.041†*
	<50	22 (14)	19 (86)	8 (36)	2 (1½; 4)	53 (31; 69)
	50-59	38 (25)	28 (73)	11 (29)	2 (1; 2)	44 (25; 63)
	60-69	49 (32)	31 (63)	9 (18)	1 (0; 2)	38 (19; 56)
	≥70	46 (30)	18 (39)	4 (9)	0 (0; 1)	28 (0; 58)
Sex			*p<.001**	*p=.002**	*p<.001‡*	*p=.892‡*
	women	42 (27)	15 (36)	2 (5)	0 (0; 1)	44 (0; 69)
	men	113 (73)	81 (72)	30 (27)	1 (½; 2)	38 (19; 56)
Amputation cause			*p=.421**	*p=.130**	*p=.304‡*	*p=.140‡*
	vascular	126 (81)	76 (60)	23 (18)	1 (0; 2)	38 (13; 56)
	non-vascular	29 (19)	20 (69)	9 (31)	1 (0; 2)	44 (28; 69)
Amputation level			*p=.567**	*p=.228**	*p=.140‡*	*p=.632‡*
	higher (TF or KD)	57 (37)	34 (60)	9 (16)	1 (0; 2)	31 (16; 63)
	lower (TT or Syme)	87 (57)	56 (64)	21 (24)	1 (0; 2)	44 (19; 63)
	bilateral§	11 (7)				
FCI			*p=.075**	*p=.014**	*p=.001‡*	*p=.066‡*
	0-3	93 (61)	62 (67)	25 (27)	1 (½; 2)	44 (22; 63)
	≥4	60 (39)	33 (55)	7 (12)	0.5 (0; 1)	31 (0; 56)
Prosthetic knee			*p=.584**	*p=.325**	*p=.038‡*	*p=.108‡*
	knee lock	21 (36)	11 (52)	2 (10)	0 (0; 1)	31 (0; 53)
	other	37 (64)	23 (62)	7 (19)	1 (0; 2)	44 (19; 69)
Prosthetic foot			*p=.001**	*p=.074**	*p=.003‡*	*p=.007‡*
	single-axis	69 (45)	33 (48)	11 (16)	1 (0; 1)	31 (0; 53)
	other	86 (55)	63 (73)	21 (240	1 (0; 2)	44 (25; 63)

Abbreviations: FCI, Functional Comorbidity Index; IQR, interquartile range; TF, transfemoral amputation; KD, knee disarticulation; TT, transtibial amputation.

*Significance (2-tailed p) of Pearson chi-square test

† Significance (2-tailed p) of Kruskal-Wallis test

‡ Significance (2-tailed p) of Mann-Whitney U test

§ not analyzed because of the small number of patients

Necessity to climb stairs

Of the participants in our study, 44% had to climb stairs within their house and 6% had to climb stairs to enter or leave their house. In total, 47% had to climb stairs within <u>or</u> to enter or leave their house. The necessity to climb stairs in persons with a LLA was related to a better ability to climb stairs on all outcome variables (p<.001). In 36% of the participants who had to climb stairs, this interfered with their daily activities. This interference was related to a worse ability to climb stairs (p≤.05), except for independence of climbing stairs without a handrail.

Ability to climb stairs

Ability to climb stairs <u>with</u> a handrail. Of the participants, 62% were able to climb up and down stairs independently.

Ability to climb stairs <u>without</u> a handrail. Of the participants, 21% were able to climb up and down a few steps (stairs) independently.

Number of stairs climbed. Of the participants, 32% did not climb stairs, 5% climbed ½ a floor, 29% climbed 1 floor and 34% climbed 2 floors.

Limitations in climbing stairs. The median (interquartile range) sum score for the Climbing Stairs Questionnaire was 38 (19, 63).

Relationship between the ability to climb stairs, and personal and clinical variables

Ability to climb stairs independently <u>with</u> a handrail. Univariate analysis showed a relationship (p≤.05) between this ability and age, sex and type of prosthetic foot (table 1). The multivariate logistic regression analysis showed a decrease in independence in climbing stairs <u>with</u> a handrail in older participants, women and participants fitted with a single-axis foot (table 2).

Table 2. Multivariate logistic regression analysis to predict outcome in climbing stairs in persons with a lower-limb amputation

Independence in climbing stairs with a handrail (yes =1, no=0)					R*R
Predictors	‼	S.E.	OR (95% CI)	p-value	.400
Age centered 65 years*	-0.09	.02	.91 (.87; .96)	<.001	
Sex (men =1, women=0)†	2.25	.52	9.51 (3.46; 26.14)	<.001	
Prosthetic foot (single-axis versus other)	-0.99	.43	.37 (.16; .86)	.020	
Constant	-0.53	.44	.59(.25; 1.39)	.229	
Independence in climbing stairs without a handrail (yes =1, no=0)					
Predictors	‼	S.E.	OR (95% CI)	p-value	.227
Age centered 65 years	-0.07	.02	.94 (.90; .97)	.001	
Sex (men =1, women=0)	2.23	.78	9.25 (1.99; 42.91)	.004	
Constant	-3.33	.76	.04 (.01; .16)	<.001	
Floors actually climbed (≥ ½=1, <½=0)					
Predictors	‼	S.E.	OR (95% CI)	p-value	.348
Age centered 65 years	-0.08	.02	.92 (.88; .96)	<.001	
Sex (men =1, women=0))	1.61	.52	5.03 (1.98; 12.73)	.001	
Prosthetic foot (single-axis versus other)	-0.90	.42	.41 (.18; .92)	.032	
Functional Comorbidity Index (0-3 =1, ≥4=0)	0.73	0.42	2.08 (0.92; 4.74)	.081	
Constant	-0.29	.45	.74 (.31; 1.79)	.514	
Limitations in climbing stairs (no=1, yes =0)					.096
Predictors	‼	S.E.	OR (95% CI)	p-value	
Functional Comorbidity Index (0-3 =1, ≥4=0)	1.28	.65	3.6 (1.0 to 12.9)	.050	
Constant	-1.18	.57	.31 (.10 to .94)	.039	

Abbreviations:R*R, Nagelkerke R*R
Legend:
*Every year older than 65 further reduces the ability to climb stairs with a handrail independently.
The odds of a patient who is 75 years of age of climbing stairs with a handrail independently is $(e^{-0.09})^{10} \approx 0.91^{10} \approx 0.41$ times less than that of someone who is 65 years of age.
†The odds of women climbing stairs with a handrail independently is 9.5 times lower than men.

Ability to climb stairs independently <u>without</u> a handrail. Univariate analysis showed a relationship ($p \leq .05$) between this ability and age, sex and comorbidity (table 1). The multivariate logistic regression analysis showed a decrease in independence in climbing stairs <u>without</u> a handrail in older participants and women (table 2).

Number of stairs climbed. Univariate analysis showed a relationship ($p \leq .05$) between the perceived number of floors climbed, and age, sex, comorbidity, type of prosthetic knee and type of prosthetic foot (table 1). Multivariate analysis showed a decrease in the number of floors climbed in older participants, women and participants wearing a single-axis prosthetic foot (table 2).

Limitations in climbing stairs. Univariate analysis showed a relationship ($p \leq .05$) between perceived limitations in climbing stairs, and age and type of prosthetic foot (table 1). Multivariate analysis showed a relationship to comorbidity (table 2).

DISCUSSION

In this study, we showed that a considerable number of persons with a LLA have to climb stairs in their house, or to enter or leave their house, while their ability to do so is limited. Being female and being of advanced age were independently related to (most of the indicators of) the ability to climb stairs. There were no independent relationships between the ability to climb stairs, and amputation cause, amputation level, comorbidity or type of prosthetic knee.

The study population was the total number of persons with a LLA from the region 's Hertogenbosch (500000 inhabitants). We excluded persons with a LLA who underwent rehabilitation treatment in a nursing home, because in the Netherlands, most of these persons were unable to climb stairs after completing their program.[6] The study population is representative regarding the cause and level of amputation in The Netherlands.[17, 18]

The necessity to climb stairs in their home environment was present in 47% of the participants. In Canada, 54% of persons with a LLA climb stairs in their home.[4] The necessity to climb stairs at home in The Netherlands was previously assessed in 1995.[19] In that study, a group of noninstitutionalized elderly was investigated in Arnhem, a city similar to 's Hertogenbosch. The authors of that study reported that 55% of the participants lived in a house with stairs. The difference between their study and ours can be explained by the fact that the participants in our study, having more co-morbidities and a longer history of vascular problems, anticipated stair-climbing difficulties and adjusted their living situation accordingly.

The ability to climb stairs independently with and without a handrail (62% and 21%, respectively) are comparable with another Dutch study, where the results were 63% and 16%, respectively.[5] In the original Canadian study of the PPA, the results are better (82% independently with a handrail; 48% without a handrail)[4], probably because they included participants no earlier than 1 year post-rehabilitation treatment. It is possible that some of the participants, those with poorer health and being more disabled, had died. .

As far as we know, the actual number of floors climbed has not previously been studied in persons with a LLA. Our results show that a considerable number of persons with a LLA are able to climb only a limited number of floors.

Limitations in climbing stairs has been previously studied in hip disarticulation and hemipelvectomy amputees.[20] The scores for the Climbing Stairs Questionnaire for these 2 groups were 54 and 66, respectively. These values are higher than those in our study, even in our participants who had a lower amputation level. Our population was of course different to the study on hip disarticulation and hemipelvectomy amputees, also in terms of age and recruitment location (rehabilitation center versus an orthopedic workshop with a very high percentage of tumors as cause of amputation).

The relationship between the ability to climb stairs, and personal and clinical variables showed that women with a LLA reported remarkably less independence in climbing stairs and reported climbing less floors than men. As far as we know, this has not been previously reported. Therefore, our results need to be confirmed in future research. In one study, it was reported that women have less chance of being successfully fitted with a prosthesis,[21] however in a review study, examining outcomes of persons with a LLA, no gender differences were found.[22] In healthy, older women however, this phenomenon has been previously described[23, 24], but not exclusively.[25] Perhaps personal factors, like fear of falling, together with environmental factors (contextual factors) as explained in the ICF model[26] play a role. If so, more task- and context-specific training[27], and/or graded exposure training programs with stairs, during the prosthetic training period would be recommended in women with a LLA.

The relationship between wearing a single axis foot with less independency in climbing stairs and fewer stairs climbed was probably confounded by indication: a single axis foot is often prescribed in more disabled persons with a LLA.[28]

In an earlier study investigating the limitations in climbing stairs, a relationship relating to amputation cause was found.[6] In that study however, persons with a LLA who underwent rehabilitation in a nursing home, and who perform more poorly, were also included. In our study, there was no relationship between limitations in climbing stairs and amputation cause. The absence of this relationship in our study could be explained by a decrease in variability with respect to amputation cause (e.g. fewer persons with severe vascular problems).

Study Limitations

Our study has some limitations. Firstly, our participants were only assessed at the end of their rehabilitation treatment. Therefore, we don't know if they will change (e.g. decrease) their stair-climbing behavior after cessation of their rehabilitation treatment, when they are no longer training and/or being encouraged to climb stairs. As such, we recommend that longitudinal studies, following stair-climbing ability over time, need to be conducted.

Secondly, we included only those persons with a LLA who were wearing a prosthesis and the end of their treatment in a rehabilitation center. In this way, we excluded more severely disabled persons with a LLA, persons who can also experience difficulty when faced with stairs. In such cases, alternative stair handling methods have been described.[29]

Thirdly, the focus of the study was on stairs in and around the participants' homes. Stairs encountered in the community however, can also present barriers to independence.

Fourthly, we dichotomized most of the dependent and independent variables because the residuals were not normally distributed. The variables concerning ability in climbing stairs were dichotomized in 'independence' versus 'other'. The personal and clinical variables were dichotomized based on literature or clinical experience, but were not evidence based.

Finally, we did not investigate personal factors such as fear of falling or self-efficacy, i.e. a person's confidence in his or her ability to complete a task. These could be issues warranting further investigation in difficult tasks like climbing stairs. Also, other variables like physical fitness could be related to the ability to climb stairs, even though physical tests are not necessarily strongly related to perceived limitations.[30, 31] We recommend that future studies assessing stair climbing should therefore also take into consideration cognitive and physical parameters of persons with a LLA, as well as performance measures such as using a step activity monitor.

CONCLUSIONS

A considerable number of persons with a LLA have to climb stairs in their home environment after amputation and ensuing rehabilitation treatment. They report a decreased ability to climb stairs, especially so amongst women and persons of advanced age. Therefore, these sub-groups with a LLA require special attention when being trained in climbing stairs.

Appendix 1

1. Do you have to use stairs inside your house?
NO → go to question 3.
YES, with a handrail
YES, without a handrail

2. Does this interfere with your daily activities?
NO
YES

3. Must you use stairs to enter and leave your house?
NO
YES, with a handrail
YES, without a handrail

From: Prosthetic Profile of the Amputee, questions no 26, 28 and 29.

Appendix 2

Hierarchy of the items of the Climbing Stairs Questionnaire in persons with a lower-limb amputation.

I go down stairs and (almost) always hold on to the handrail (item 10)
I go up stairs and (almost) always hold on to the handrail (item 4)
I go up stairs but in a different way e.g. I draw one foot next to the other on every step (item 2)
I go up stairs but it takes me longer (item 1)
I go down stairs but it takes me longer (item 7)
I go down stairs but in a different way, e.g. I place one foot next to the other on every step or I go down"backwards" (item 8)
I do go up and down stairs but less frequently (item 13)
I go down stairs but with (some) difficulty (item 9)
I go up stairs but with (some) difficulty (item 3)

I do go up and down stairs but I try to avoid them (item 14)
I do go up and down stairs but I climb less flights / floors (item 15)
I go up stairs and (almost) always use an aid, e.g. a walking stick or a crutch (item 5)
I go down stairs and (almost) always use an aid, e.g. a walking stick or a crutch (item 11)
I go up stairs and am (almost) always helped by someone (item 6)
I go down stairs and am (almost) always helped by someone (item 12)

I do not climb any stairs at all due to my health status (item 16)

Note: hierarchy of the Climbing Stairs Questionnaire from minor limitations to severe limitations in climbing stairs. The original item numbers are in brackets. The scores are dichotomized into slight (score 43-100) *versus* severe limitations (score 0-43),visualized by the horizontal line. A score of ≤ 43 will, given the hierarchical order of the items, in general, correspond to a "YES" answer to the items 14-15-5-11-6-12, indicating limitations such as avoidance of stairs, or requiring help. In this way, independence in climbing stairs is at risk. A score of > 43 corresponds to a "YES" answer to the other items, indicating independence in climbing stairs but while holding on to the banister or climbing stairs in a different way.[16]

From: Roorda LD, Roebroeck ME, van Tilburg T, Lankhorst GJ, Bouter LM. Measuring activity limitations in climbing stairs: development of a hierarchical scale for patients with lower-extremity disorders living at home. Arch Phys Med Rehabil 2004;85:967-71.

Appendix 3. Dichotomization of the indicators of the ability to climb stairs and clinical variables in persons with a lower-limb amputation

Ability to climb stairs			
Ability to climb stairs <u>with</u> a handrail	independent	*versus*	with supervision / with help / unable
Ability to climb stairs <u>without</u> a handrail	independent	*versus*	with supervision / with help / unable
Floors climbed	½-1-2-3-4-5-6	*versus*	0
Limitation in climbing stairs	44-100 (none - slight)	*versus*	0-43 (more - severe)
Clinical variables			
Functional Comorbidity Index	≤3	*versus*	≥4
Prosthetic knee mechanism	polycentric knee, swing phase controlled knee, other	*versus*	mechanical knee lock
Prosthetic foot mechanism	SACH foot, dynamic-elastic response foot	*versus*	single axis foot

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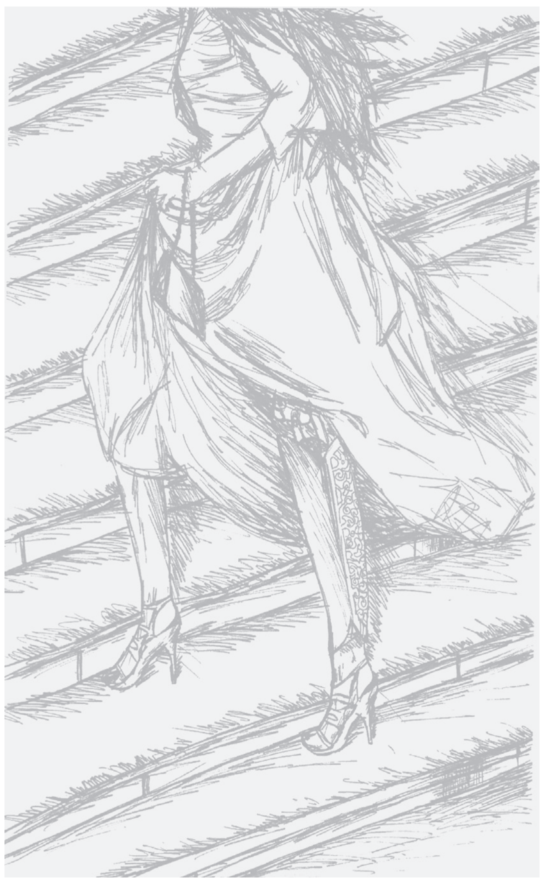
Supplier

a. SPSS Inc, 233 S Wacker Dr, 11th Fl, Chicago, IL 60606.

Chapter 7

General discussion



The main purpose of the research underlying this thesis was to test mobility questionnaires in persons with a lower-limb amputation (LLA), and describe the outcome of some aspects of mobility. Mobility is defined in the ICF-model as the ability to move by changing body position or by moving from one place to another.[1] For good mobility, one has to be able to rise and sit down first, and then be able to stand. Thereafter, walking and finally climbing stairs becomes the challenge.

If we ask a patient who will undergo a LLA what the goal of rehabilitation treatment is, he or she will probably answer 'to regain mobility by using a prosthesis'. Indeed, mobility was the primary concern, using goal attainment scaling (GAS), in a study population undergoing prosthetic training.[2] After prosthetic training, persons with a LLA rate 'walking in a comfortable way' as the most important function of the prosthesis. Furthermore, the fit of the residual limb is regarded as the most important characteristic of the prosthesis.[3, 4] Moreover, mobility is regarded by persons with a LLA as being the most relevant ability for their quality of life.[5]

Given that mobility is regarded as such an important factor for persons with a LLA, measuring mobility is of great value. This can be performed, in general, by using questionnaires (perception), physical tests such as the Timed Up and Go test or the 10 meter walk test (capacity), or activity monitors (performance).[6] However, the agreement between perception, capacity and performance is poor.[7, 8]

In daily clinical practice, patients will seek help within the health care system if they perceive limitations in mobility, not due to poor capacity or performance. Therefore, it is interesting to measure perceived limitations in mobility. Unfortunately, there is no gold standard for measuring mobility in persons with a LLA.[9-11] Moreover, several manufacturers of prosthetic components use their own mobility classification system.[12] For measuring limitations in rising and sitting down, and for climbing stairs, there are no instruments at all.

As stated in the introduction section of this thesis, a measurement instrument has to meet several quality criteria. In daily clinical practice, the instrument also has to be feasible: easy to administer, not too time consuming and simple. Moreover, we want such an instrument to be as sensitive as possible, in order to discriminate between patient groups or for evaluating treatment effects.[13] In assessing perceived mobility, this would often result in a questionnaire with a large number of items, providing a significant respondent burden. A possible solution to this is a questionnaire with a number of items which forms a hierarchy. This hierarchy can be tested with an item response theory (IRT) model.[14] Because not all items of a hierarchical questionnaire are relevant for every patient, progress through such a questionnaire may be achieved by using start-and-stop rules[15, 16] or "adaptive or dynamic" instead of "static" questions.[17] The use of computer adaptive tests (CATs), based on IRT, promises to reduce respondent burden and enhance measurement precision.[18] A CAT uses information from questions already answered (item responses) in order to select the next most appropriate question. By asking the most appropriate questions for each patient, a CAT makes it possible to present fewer items and achieve greater measurement precision across the entire range of a construct.

To date, 3 instruments assessing mobility limitations in persons with a LLA have been studied regarding a fit with a IRT model: the "Special Interest Group on Amputation

Medicine" (SIGAM) mobility grades,[19] the Locomotor Capabilities Index (LCI),[20] and the Prosthesis Evaluation Questionnaire mobility scale section (PEQ-MS).[21] A disadvantage of the SIGAM mobility grades is that it only assesses walking aspects of mobility. The fit of the SIGAM mobility grades with a IRT model was assessed using a Rash analysis.[19] Only the 2 middle mobility grades (category C and D) had acceptable fit values, and in these categories they did not differentiate for walking aids. As stated by the authors, the SIGAM mobility grades are useful as a classification instrument, but are not suitable to be used for a more detailed assessment of walking. The LCI showed a good fit using a Rash analysis in 10 out of 14 items,[20] as did the PEQ-MS with a 5-level response format.[21] However, both the LCI and PEQ-MS only give superficial information about mobility due to the limited number of questions concerning this concept.

In summary, shortcomings exist in the currently used instruments assessing mobility in persons with a LLA. Therefore, the purpose of the research underlying this thesis was twofold:

1) to test 3 general mobility questionnaires, with good clinimetric properties and fitting with an IRT model, in persons with a LLA in order to determine if these questionnaires are appropriate to assess perceived mobility limitations specifically in this population. To achieve this, we utilised The Questionnaire Rising and Sitting Down, the Walking Questionnaire and the Climbing Stairs Questionnaire.[22-25]

2) to describe the perceived outcome of rising and sitting down, and climbing stairs, in persons with a LLA.

In this section, some aspects of the instrument testing procedure will be discussed. Then, the outcomes in rising and sitting down and climbing stairs are discussed. Lastly, recommendations will be made for further research using outcome measures in persons with a LLA and the implications for clinical practice will be discussed.

Instrument testing

Study population.

To test an instrument, it is essential to define the study population. In this thesis, the study population was comprised of persons with a LLA, using a prosthesis and recruited after rehabilitation treatment in rehabilitation center Tolbrug, 's Hertogenbosch. Moreover, persons with a LLA who underwent rehabilitation in the nursing homes surrounding the rehabilitation center were included during the first follow-up consultation in the outpatient department of the rehabilitation center. As such, all persons with a LLA who underwent rehabilitation in the region of the rehabilitation center defined the study population. To increase response rates, participants received a certificate after their rehabilitation treatment and the completion of the questionnaire in the rehabilitation center, indicating a 'good' level of standing and walking. Eventually, a high response rate (>95%) was achieved. Unfortunately, it is not known if there were more persons with a LLA who underwent treatment in a nursing home who did not receive a follow-up appointment in the outpatient department of the rehabilitation center. Despite this, the study sample was similar to other Dutch studies with regard to personal and clinical variables.[26, 27]

Comorbidity of the study population.
There is growing interest in measuring the comorbidity of a study population.[28] There are qualitative methods, searching for a specific diagnosis, and quantitative methods, calculating the number of diagnoses, sometimes including severity. Comorbidity is measured to describe the study population or as a predictor of study outcome,[28] also in studies of persons with a LLA.[29] There are several instruments for scoring comorbidity, of which the Cumulative Illness Rating Scale (CIRS)[30] and the Charlson Index[31] are the mostly commonly used. These indices, however, have been developed primarily to predict mortality. As such, a-symptomatic diagnoses are included, such as hypertension, and disabling diseases like arthritis are excluded. Therefore, the Functional Comorbidity Index (FCI),[32] a comorbidity index with physical function as the outcome of interest, was used in this study. The FCI proved to have a good conceptual framework.[32] Validity of the FCI was tested in 2 databases, consisting of a total of 37,000 patients, with the physical function subscale of the SF-36 as the dependent variable. The FCI showed a stronger relation to physical function than the Charlson Index[32] (R^2= 0.29 and 0.18, respectively). Moreover, the FCI is easy to administer, as only summation regarding the presence or absence for 18 diseases is required (weighting of diseases is not necessary). Severity ratings would probably provide better adjustment, however the documentation of this in the medical records varies greatly, or is often missing. The preliminary results of comorbidity in persons with a LLA showed that the time required to assess the FCI from the medical records was less than 4 minutes per patient. Furthermore, the presence of comorbidity was high, especially in persons with vascular disease as cause of amputation.[33] Table 1 presents the diagnoses/items of the FCI along with the number of participants having these diagnoses in the whole study population. In total, 60 persons with a LLA (35.3%) had at least 1 of the following 3 cardiac diseases: angina pectoris, congestive heart failure or myocardial infarct.

Table 1. Items of the FCI and characteristics of the study population (in sequence of the original developers)

	number	(%)
arthritis (rheumatoid and osteoarthritis)	37	21.8
osteoporosis	10	5.9
asthma	4	2.4
chronic obstructive pulmonary disease / emphysema	22	12.9
angina pectoris	26	15.3
congestive heart failure	27	15.9
myocardial infarct	32	18.8
neurological disease (e.g. multiple sclerosis, Parkinson's)	10	5.9
stroke	23	13.5
diabetes	69	40.6
peripheral vascular disease	145	84.3
gastrointestinal ulcer	26	15.3
depression	11	6.5
anxiety or panic disorders	11	6.5
visual impairment	16	9.4
hearing impairment	8	4.7
lumbago / degenerative disc disease	38	22.4
obesity, BMI > 30	21	12.2

* NOTE. N=170.

Validity testing

Validity is the degree to which an instrument truly measures the construct(s) it purports to measure.[34] In general, 3 different types of validity can be distinguished: content validity, criterion validity and construct validity. These concepts are defined in the general introduction. The Questionnaire Rising and Sitting Down, the Walking Questionnaire and the Climbing Stairs Questionnaire have shown good content validity.[22-25] In situations in which there is no golden standard (criterion validity), as is the case with mobility scales in persons with a LLA, construct validation should be used to provide evidence of validity. To assess the construct validity, hypotheses have to be formulated and tested. Therefore, before examining the data, hypotheses were formulated based on either the available literature concerning the relationship between mobility limitations and patient-related factors in persons with a LLA, or on clinical experience. Answers to a number of the hypotheses were found in a review article from Sansam,[35] however, many of the investigated factors showed non-consistent findings. Moreover, the authors only studied walking, as opposed to other aspects of mobility such as rising and sitting down or climbing stairs. We gathered data on personal (age, sex) and clinical variables (amputation cause and level, type of prosthetic knee and foot, and comorbidities) from medical records.

Construct validity is considered to be good if at least 75% of the hypotheses are not rejected in a study group of at least 50 participants, however larger samples (e.g. over

100 participants) are preferred.[36] The 3 questionnaires tested in this study met this criterion. With respect to the hypotheses, there was no relationship between limitation in mobility and unilateral versus bilateral amputation. This was probably due to the small number of persons with a bilateral amputation (n=12) in the study population, and the selection criteria which required these persons to wear a prosthesis (bias by indication). Remarkably, level of amputation was only related to perceived limitation in walking. Probably, when rising and sitting down, and when climbing stairs, the "sound" leg is mainly used to perform these activities,[37] although biomechanical studies of these activities are scarce. Cause of amputation was only related to limitation in climbing stairs, probably because of the general consequences of vascular disease. In walking, cause of amputation has shown varying results as a predictive factor[35], therefore, this was not selected as a hypothesis. Indeed, we did not find a relationship between cause of amputation and limitation in walking, as measured by the Walking Questionnaire.

Reproducibility testing

Reproducibility is the degree to which repeated measurements in stable persons (test-retest) provide similar answers.[34] Reproducibility includes reliability and agreement.[38] Reliability refers to how well individuals can be distinguished from each other, whereas agreement indicates how close the repeated measurements are to the original measurements. The ICC was used as the reliability parameter, which is calculated as the ratio of the variance between participants and the total variance. An ICC of at least .70 was considered to be satisfactory for group comparisons, whereas an ICC of at least .90 was considered to be satisfactory for individual comparisons.[36] We showed that the 3 questionnaires are suitable for group comparisons (ICC's between 0.73 and 0.83), but not for individual comparisons. Related to other mobility scales for persons with a LLA, the results are comparable with the PEQ-MS[39] and the LCI.[40] However, recent standards recommend at least 50 participants for a test-retest reliability study.[36] As we included only 22 participants who had rated themselves as being stable with regard to their limitations in mobility, we therefore recommend that future research should replicate our study in a larger sample.

For the Questionnaire Rising and Sitting Down, we were able to calculate agreement as the outcome was normally distributed. Agreement was quantified by the standard error of measurement (SEM), the square root of the within-subject variance, which indicates how close the scores for repeated measurements are. The smallest detectable difference (SDD) can be derived from the SEM: $SDD=1.96\times\sqrt{2}\times SEM$.[41] The SDD is the smallest difference in measurement that can be interpreted as a real difference between 2 measurements in an individual. The agreement of the Questionnaire Rising and Sitting Down was good with an SEM of 6.7% and an SDD of 18.6%, indicating that to detect a true difference, the difference between the 2 measurements has to be at least 19 (on a scale from 0-100). This value is quite high, however, for application in a group of persons with a LLA (e.g. for research purposes) smaller differences can be detected, because the SDD has to be divided by $\sqrt{n}$.[36, 38] Thus, for example, in a group of 100 persons with a LLA, a difference of only 2 can be considered as being a true difference in limitations in rising and sitting down. To our knowledge, there are no other mobility scales for persons with a LLA reporting a SDD.

Remarkably, only $^2/_3$ of the participants in our reliability study (n=33) considered their condition to be stable with regard to their limitations in mobility in the 3-week period directly after completion of their outpatient rehabilitation treatment. Obviously, other factors are involved in perceived mobility, such as stump atrophy,[42] or perhaps persons with a LLA avoid strenuous activities like climbing stairs once they are no longer training and being encouraged. Therefore, longitudinal testing of the instrument in this population and follow-up treatment after the initial rehabilitation treatment are recommended.

Other clinimetric properties and testing

With respect to floor or ceiling effects, we found a floor effect of 20% for the Climbing Stairs Questionnaire in persons with a LLA after treatment in a rehabilitation center. After training in a nursing home, persons with a LLA were mostly unable to climb stairs, so this questionnaire is not recommended for this population in this setting. The Questionnaire Rising and Sitting Down and the Walking Questionnaire showed no floor or ceiling effects.

Regarding the quality criteria for measurement instruments as outlined in the general introduction, we now have adequate answers about the construct validity, the reproducibility and floor or ceiling effects. The content validity and internal consistency have been previously established.[22-25] The interpretability and sensitivity to change will be discussed in the outcome and study limitations sections of this chapter, respectively.

Outcome in rising and sitting down and climbing stairs and advice for therapy

Rising and sitting down

Rising and sitting down are prerequisites for regaining mobility after a LLA. In a study population of persons with a transtibial amputation, due to vascular disease, rising maneuvers were performed 43 times a day, on average.[7] Although rising maneuvers can hardly be avoided, literature about the perceived abilities in rising and sitting down in persons with a LLA is surprisingly scarce. We showed that 91% of the persons with a LLA perceived independence in rising, however only half of them were able to rise from the floor independently. Univariate analysis showed a relationship between perceived independence in rising, and age, gender, number of comorbidities, rehabilitation setting and type of prosthetic knee. Multivariate logistic regression analysis showed a decrease in independence in rising in older participants and women. The odds of women rising independently were 3.7 times lower than men. These results show that, alongside just learning to walk, more attention must be paid to task- and context-specific rehabilitation treatment like rising and getting up from the floor, especially in the older aged and women. In this way, both muscle force and balance would be trained, as well as the regaining of self-confidence through repetition.[43] The entire study population perceived many limitations in rising and sitting down, with a mean score of 46 (range, 0-100). Those rehabilitated in a nursing home perceived more limitations in rising and sitting down, independently of any other variables. They had a mean score of 37. The limitations in rising and sitting down, according to the original developers of the Questionnaire Rising and Sitting Down, are most pronounced when rising from or sitting down in a car seat, followed by a low chair.[25] Therefore, especially these types of seats create limitations in rising and sitting down. If, therefore, training is not possible in persons with a LLA who are rehabilitated in a nursing home, seat adaptations have to be made or caregivers have to be instructed during the rehabilitation process in order to diminish these limitations.

Climbing stairs

Persons with a LLA report that climbing stairs is an important issue.[4] Literature about perceived independence and limitations in climbing stairs in persons with a LLA is scarce. Not only these parameters were assessed, also the need to climb stairs was assessed. In our study region, the north-east of Brabant, 47% of our study participants had to climb stairs within or to enter or leave their house. Therefore, climbing stairs is an important ability to train during rehabilitation treatment. Remarkably, 62% of our participants were able to climb up and down the stairs independently with a handrail, whereas only 21% were able to do so without a handrail. Multivariate logistic regression analysis showed a decrease in independence in the older aged and women, for both situations. For women, the odds of climbing stairs with or without a handrail independently were more than 9 times lower than for men. We are not aware of any literature describing such a large gender difference in a task in persons with a LLA. In a study with persons aged 75 years and older, women showed less self-confidence than men in climbing stairs. Furthermore, they used a handrail more often than men.[44] Older women with a LLA possibly live alone more often than men, could experience less support with difficult tasks such as climbing stairs. Therefore, they could have less self-confidence and a greater fear of falling, resulting in a decrease in perceived independence in climbing stairs. Also other tasks demanding self-confidence, like driving a car, are relearned less often by women than men after a LLA.[45] To improve self-confidence, more task- and context-specific training[43] and/or graded exposure with stairs (while using a handrail) are recommended as soon as possible during prosthetic training. The perceived limitations in climbing stairs were considerable, with a median sum score for the Climbing Stairs Questionnaire of 38 (range, 0-100). Multivariate logistic regression analysis showed a relationship between perceived limitations in climbing stairs and the number of comorbidities, according to the FCI, however univariate factor analysis of the separate comorbidities only showed a relationship with COPD. Obviously, muscle force, as well as endurance and motor learning, are necessary when climbing stairs, in contrast to strategies for rising or walking.

Limitations of the study and recommendations for further research using the mobility questionnaires in persons with a LLA

Instrument testing

In the domain of construct validity testing, cross-cultural validity testing is an aspect for translated instruments alongside hypothesis testing.[46] We used the original Dutch version of the questionnaires, so cross-cultural testing was not necessary. However, to disseminate these questionnaires worldwide, an English version is essential. Therefore, to facilitate future research outside the Netherlands, we translated the original Dutch version into English, using a triple forward, double backward translation. The result of the most recent layout with both versions is shown in the appendix.

In the domain of the responsiveness, the sensitivity to change of the questionnaires was not tested in our cross-sectional study, as it was not possible to measure this phenomenon. Evaluating the sensitivity to change of a measurement instrument in the same study in which the instrument is used as an outcome measure makes it impossible to draw any firm conclusions about responsiveness.[34] For future studies, we recommend responsiveness studies with the same approach as our validation study: testing hypotheses about expected mean differences, formulated a priori, in a study population that is known to change, for example by prosthetic training or due to change of (a part of) the prosthesis. These hypotheses would then need to be compared with changes in other variables, for example other test instruments or a well-formulated global rating of change scale.[34]

In the domain of testing the interpretability of the outcome, response shift can occur[34]. Response shift is a change in the meaning of one's self-evaluation of a target construct, as a result of: (a) a change in the respondent's internal standards of measurement (i.e. scale recalibration), (b) a change in the respondent's values (i.e. the importance of component domains constituting the target construct), or (c) a redefinition of the target construct (i.e. reconceptualization).[34] In this study, response shift was not assessed. Response shift often occurs after a health crisis (such as amputation) or long-term disability. In our questionnaires, questions about task difficulty or duration could result in response shift, especially recalibration. Response shift has never been studied after a LLA, but it would be interesting to assess the contribution of response shift in patient-reported outcome after a LLA. This can be done by using the"then-test":[34] the patient is asked to fill in a (mobility) questionnaire; after a length of time (in which response shift would be expected), he/she is asked to do so again for his/her situation at the time of initial completion of the questionnaire. If there are any differences, this can be related to response shift. Another option to detect response shift is to combine perceived activity level with a physical test (capacity) and assess the changes in both instruments.

Outcome in rising and sitting down and climbing stairs

In the ICF model[1], activities such as (limitations in) rising and sitting down, or climbing stairs, are influenced by all domains of the ICF model (general introduction, figure 1): health condition (disorder or disease), body functions and structures, participation and contextual factors (environmental factors and personal factors). In this study, health condition was assessed by describing level and cause of amputation and by using the FCI.

Body function and structures, such as balance,[29] stump characteristics (including contractures),[47] muscle power, and physical fitness[48] were not assessed, so the influence of these variables remains unclear. Biomechanical analysis of sit-to-stand transfer[49] and during stair climbing[50] in healthy persons has shown considerably higher moments in the hip and knee compared with walking on level ground. Biomechanical analysis in persons with a LLA is scarce. In persons with a (mainly) non-vascular transfemoral LLA, it has been found that standing up is performed with minimal loading of the prosthetic leg.[37, 51] Also in persons with a transtibial amputation, the loading of the prosthetic limb has been found to be strongly diminished.[52] Biomechanical analysis of climbing stairs in persons with a traumatic LLA has shown a reduction in moments of the prosthetic limb, due to adaptations in motor strategies.[53] We are not aware of studies relating body

functions and structures to (perceived limitations in) rising and sitting down or climbing stairs. In this study, there was no relationship between level or cause of amputation and rising and sitting down or in climbing stairs after a LLA. It could be that this is a real phenomenon, or that response shift may have occurred (see section above).
Participation can be tested using a step activity monitor. The relationship between participation and activities in persons with a LLA remains unclear. In one study, there was no relationship between the LCI and the number of steps in persons with a LLA due to vascular causes.[7]
Personal factors such as fear of falling[29] or self-efficacy, i.e. a person's confidence in his or her ability to complete a task, could play a role in difficult tasks like climbing stairs. Investigation of these factors was beyond the scope of this study but is an interesting topic for future research.
In summary, the relationship between (limitations in) activities in persons with a LLA and the other domains of the ICF model are unknown and warrant further investigation.

Implications for clinical practice

Instrument development

As stated in the introduction section of this chapter, the use of computer adaptive tests (CATs) is a following step to improving the feasibility of the questionnaires. Moreover, a CAT has better clinimetric properties than a short version of a questionnaire.[18] The Questionnaire Rising and Sitting Down is most promising for a CAT, because rising and sitting down is necessary for all persons with a LLA, including those who were rehabilitated in a nursing home. Moreover, the Questionnaire Rising and Sitting Down showed no floor or ceiling effects, had residuals which were normally distributed, a known smallest detectable difference, and preliminary results of this questionnaire in other cohorts show good responsiveness (Roorda, personal communication). To design a CAT, data, including personal and clinical characteristics, from 1000 to 2000 participants are needed. This is approximately the total number of major LLA in the Netherlands in 1 year.[27] With help of all the members of the Workgroup Amputation and Prosthetics (WAP), a workgroup of the Netherlands Society of Physical and Rehabilitation Medicine (VRA), it must be possible to create a CAT within 2 years. In this period, a national digital medical record system in rehabilitation medicine will be implemented. This is, therefore, an excellent opportunity to create a database with personal and clinical characteristics (including comorbidities) of persons with a LLA, with outcome parameters such as the CAT of the Questionnaire Rising and Sitting Down. When the WAP is able to define who, when and how the outcome parameters need to be assessed, such information can then be built into the digital medical record system, easily enabling a Dutch database of mobility in persons with a LLA!

Outcome in rising and sitting down and climbing stairs

As stated before, rising and sitting down has to be trained as soon as possible during rehabilitation treatment after a LLA, even when a lower-limb prosthesis has not yet been prescribed. If training is not possible, seat adaptations have to be implemented or caregivers have to be instructed during the rehabilitation process. Climbing stairs has to be trained as soon as a (interim) lower-limb prosthesis is delivered. Especially in women, who perceive less independence in climbing stairs, graded exposure training with stairs (while using a handrail) is recommended as soon as possible.

Final considerations

The aims of measurement in rehabilitation medicine can be divided into: screening tools, monitoring tools, assessing patient-centered care, decisional aids, facilitating multidisciplinary team communication and evaluating quality of care.[54] The Questionnaire Rising and Sitting Down, the Walking Questionnaire and the Climbing Stairs Questionnaire can be used as screening and monitoring tools, as well as decisional aids (e.g. showing necessity for seat adaptations or instruction of care-givers caring for patients perceiving limitations in rising and sitting down).

During the last decade, the Rehabilitation Activities Profile (RAP)[55] has been introduced in Rehabilitation Medicine in the Netherlands to facilitate multidisciplinary team communication and achieve an interdisciplinary team approach. This tool includes the conclusions of team meetings, consisting of a primary problem, a primary goal and discipline-specific treatment goals regarding the patient and proxies at the ICF activities and participation level.[55] Goal Attainment Scaling (GAS) is useful as a patient-centered care tool. GAS is an individualized evaluative outcome measurement tool that rates the extent to which goals are attained. It can be used to evaluate change in a patient´s and his or her family's functioning during rehabilitation. In the last decade there has been growing interest in its use and application in the field of prosthetics as the demand for tools responsive to clinically important changes increases.[2] Outcome measurement using GAS can be applied for all common diagnoses in rehabilitation. GAS offers the attractive possibility to measure what one intends to measure, because the content of the scales is tailored to the individual circumstances of a patient. GAS can be used in addition to standardized instruments, as the use of standardized measures only might result in many individual rehabilitation goals being missed.[56] Moreover, measurement of goal attainment provides information about the clinical relevance of the individual's outcome in addition to a change score as measured by standardized measures.

Evaluating quality of care is still controversial. In the Netherlands, the "Health Care Transparency Program" has been adapted into the "Insight in Rehabilitation" project for the rehabilitation sector. In this project, 3 key indicators are distinguished: structural indicators, referring to a health care organization's facilities; process indicators, referring to management procedures during treatment; and outcome indicators, referring to the desired benefits of health-care efforts. It is assumed that good outcomes are the product of well organized and managed health care. For persons with a LLA, in which mobility is rated as an important function after a LLA, a mobility scale has been proposed as the outcome indicator. However, it is doubtful if persons with a LLA will benefit by having only a mobility score with no practical consequences. Benefit will be attained if the scores over a given period could be collated and discussed in the individual's treatment team.[57]

In summary, during the daily practice of rehabilitation treatment of persons with a LLA, measurement of mobility should not be limited to questionnaires, but should be combined with other assessments such as a patient-centered care tool like GAS and tools evaluating quality of care.

Answering the questions

The Questionnaire Rising and Sitting Down, the Walking Questionnaire and the Climbing Stairs Questionnaire have good construct validity and good test-retest reliability in persons with a LLA after their multidisciplinary rehabilitation treatment. Based on the results of the reliability studies, these questionnaires can be recommended for group comparisons of persons with a LLA, but not for individual comparisons.

Most persons with a LLA are able to rise from a chair independently, while half of them are able to rise from the floor independently. Multivariate logistic regression analysis showed a decrease in independence in rising in older participants and women. Perceived limitations in rising and sitting down are considerable in persons with a LLA, with those rehabilitated in a nursing home perceiving more limitations in rising and sitting down, independently of other variables. Climbing stairs was necessary for 47% of our study population. However, although 62% were able to climb up and down stairs independently <u>with</u> a handrail, only 21% were able to do so <u>without</u> a handrail. Multivariate logistic regression analysis showed for both situations a decrease in independence in older participants and women. The perceived limitations in climbing stairs were considerable, with a median sum score for the Climbing Stairs Questionnaire of 38 (range 0-100). Multivariate analysis showed a relationship between perceived limitations in climbing stairs and the number of comorbidities in our study population.

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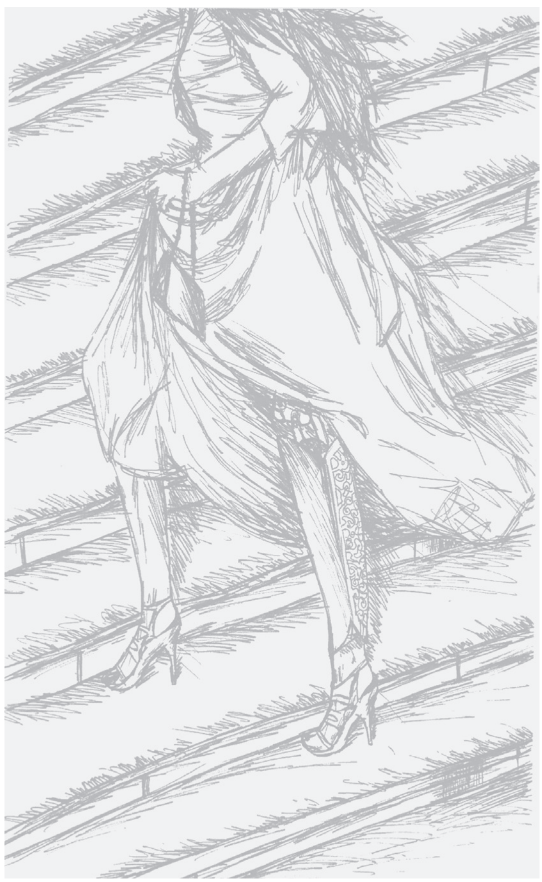
Appendix 1

Dutch version of the Questionnaires



Vragenlijst Traplopen

Vragenlijst Lopen

Vragenlijst Opstaan en Gaan Zitten

December 2012

Vragenlijst Traplopen (versie 5.0 - dicho)
Vragenlijst Lopen (versie 5.0 - dicho)
Vragenlijst Opstaan en Gaan Zitten (versie 5.0 - dicho)

Dr. Leo D. Roorda
Dr. Marij E. Roebroeck
Prof. dr. Theo G. van Tilburg
Prof. dr. Gustaaf J. Lankhorst

Amsterdam Rehabilitation Research Center | Reade
Postbus 58271
1040 HG Amsterdam
T 020 589 6281
F 020 489 6704
E l.roorda@reade.nl
W www.reade.nl

ALGEMEEN

1. Welke datum is het vandaag?

dag **maand** **jaar**

2. Wat is uw geboortedatum?

dag **maand** **jaar**

Kruis de uitspraak aan die ***op u van toepassing*** *is.*

3. Wat is uw geslacht?
   - ☐ vrouw
   - ☐ man

TRAPLOPEN

Wilt u hieronder aangeven of u trappen loopt? Bij traplopen kunt u denken aan traplopen bij u thuis maar ook aan traplopen elders (bijvoorbeeld in huis van familie of vrienden, of in winkels).

*Kruis de uitspraak aan die **op u van toepassing** is.*

Loopt u trappen?

☐ ik loop helemaal geen trappen door mijn gezondheidstoestand

☐ ik loop helemaal geen trappen omdat ik geen trappen tegenkom in mijn dagelijks leven

☐ ik loop helemaal geen trappen omdat ……………………………………………………

*Als u één van de hokjes hierboven hebt aangekruist (en dus helemaal **geen** trappen loopt) ga dan verder met de uitspraken over* **LOPEN IN HUIS** *op pagina 117.*

☐ ik loop wel trappen

*Als u het hokje hierboven hebt aangekruist (en dus **wel** trappen loopt) ga dan verder op deze pagina.*

De volgende uitspraken gaan over veranderingen die - door uw gezondheidstoestand - kunnen optreden bij het traplopen.

	JA	NEE
*Kruis **JA** aan als de uitspraak* - ***op u van toepassing is** en ook* - ***samenhangt met uw gezondheidstoestand***	☒	☐
*Kruis in alle overige gevallen **NEE** aan*	☐	☒

Trappen **op**lopen	**JA**	**NEE**
- ik loop de trap **op** maar doe er langer over	☐	☐
- ik loop de trap **op** maar op een andere manier (bijvoorbeeld ik trek iedere keer een been bij)	☐	☐
- ik loop de trap **op** maar met (enige) moeite	☐	☐
- ik loop de trap op en houd me daarbij (bijna) altijd vast aan de leuning	☐	☐
- ik loop de trap **op** en gebruik daarbij (bijna) altijd een hulpmiddel (bijvoorbeeld een stok of een kruk)	☐	☐
- ik loop de trap **op** en word daarbij (bijna) altijd door iemand geholpen	☐	☐
Trappen **af**lopen		
- ik loop de trap **af** maar doe er langer over	☐	☐
- ik loop de trap **af** maar op een andere manier (bijvoorbeeld ik plaats iedere keer een been bij of ik ga “achteruit” de trap af)	☐	☐
- ik loop de trap **af** maar met (enige) moeite	☐	☐
- ik loop de trap **af** en houd me daarbij (bijna) altijd vast aan de leuning	☐	☐
- ik loop de trap **af** en gebruik daarbij (bijna) altijd een hulpmiddel (bijvoorbeeld een stok of een kruk)	☐	☐
- ik loop de trap **af** en word daarbij (bijna) altijd door iemand geholpen	☐	☐
Trappen **op- en af**lopen		
- ik loop wel trappen **op en af** maar minder vaak	☐	☐
- ik loop wel trappen **op en af** maar ik vermijd ze	☐	☐
- ik loop wel trappen **op en af** maar minder trappen / verdiepingen	☐	☐

LOPEN IN HUIS

Wilt u hieronder aangeven of u in huis loopt?

*Kruis de uitspraak aan die **op u van toepassing** is.*

Loopt u in huis?

☐ ik loop helemaal niet in huis door mijn gezondheidstoestand

☐ ik loop helemaal niet in huis omdat ……………………………………………………

> *Als u één van de hokjes hierboven hebt aangekruist (en dus helemaal **niet** in huis loopt) ga dan verder met de uitspraken over* **BED EN TOILET** *op pagina 121.*

☐ ik loop wel in huis

> *Als u het hokje hierboven hebt aangekruist (en dus **wel** in huis loopt) ga dan verder op deze pagina.*

De volgende uitspraken gaan over veranderingen die - door uw gezondheidstoestand - kunnen optreden in het lopen in huis.

	JA	NEE
*Kruis **JA** aan als de uitspraak* - ***op u van toepassing is** en ook* - ***samenhangt met uw gezondheidstoestand***	☒	☐
*Kruis in alle overige gevallen **NEE** aan*	☐	☒

Algemeen	JA	NEE
- ik loop in één kamer en niet in andere kamers (bijvoorbeeld ik loop alleen maar in de huiskamer of in de slaapkamer)	☐	☐
- ik loop in huis maar ik kom daarbij niet in alle kamers	☐	☐
- ik loop in huis maar kortere afstanden	☐	☐
- ik loop in huis maar kortere perioden	☐	☐
- ik loop in huis maar langzamer	☐	☐
- ik loop in huis maar minder vaak	☐	☐
- ik loop in huis maar ik sta vaker even stil	☐	☐
- ik loop in huis maar op een andere manier (bijvoorbeeld ik loop mank, waggel, strompel of loop met een stijf been)	☐	☐
- ik loop in huis maar met (enige) moeite	☐	☐
- ik loop in huis maar ik loop onzeker	☐	☐
- ik loop in huis en houd me daarbij (bijna) altijd ergens aan vast (bijvoorbeeld aan de tafel, aan een meubel of aan de muur)	☐	☐
Hindernissen		
- ik loop in huis maar ik loop langzamer over "hindernissen" (bijvoorbeeld drempels of opstapjes)	☐	☐
- ik loop in huis maar ik loop minder vaak over "hindernissen"	☐	☐
- ik loop in huis maar ik loop op een andere manier over "hindernissen" (bijvoorbeeld ik trek iedere keer een been bij)	☐	☐
- ik loop in huis maar met (enige) moeite over "hindernissen"	☐	☐
- ik loop in huis maar ik loop onzeker over "hindernissen"	☐	☐

BUITEN LOPEN

Wilt u hieronder aangeven of u buiten loopt?

*Kruis de uitspraak aan die **op u van toepassing** is.*

Loopt u buiten?

☐ ik loop helemaal niet buiten door mijn gezondheidstoestand

☐ ik loop helemaal niet buiten omdat ……………………………………………………

*Als u één van de hokjes hierboven hebt aangekruist (en dus helemaal **niet** buiten loopt)*

ga dan verder met de uitspraken over **BED EN TOILET** *op pagina 121.*

☐ ik loop wel buiten

*Als u het hokje hierboven hebt aangekruist (en dus **wel** buiten loopt)*
ga dan verder op deze pagina.

De volgende uitspraken gaan over veranderingen die - door uw gezondheidstoestand - kunnen optreden in het buiten lopen.

	JA	**NEE**
*Kruis **JA** aan als de uitspraak* - ***op u van toepassing is** en ook* - ***samenhangt met uw gezondheidstoestand***	☒	☐
*Kruis in alle overige gevallen **NEE** aan*	☐	☒

Algemeen	**JA**	**NEE**
- ik loop wel buiten maar kortere afstanden	☐	☐
- ik loop wel buiten maar kortere perioden	☐	☐
- ik loop wel buiten maar langzamer	☐	☐
- ik loop wel buiten maar minder vaak	☐	☐
- ik loop wel buiten maar ik sta vaker even stil	☐	☐
- ik loop wel buiten maar op een andere manier (bijvoorbeeld ik loop mank, waggel, strompel of loop met een stijf been)	☐	☐
- ik loop wel buiten maar met (enige) moeite	☐	☐
- ik loop wel buiten maar ik loop onzeker	☐	☐
- ik loop langzamer	☐	☐
Hulpmiddelen		
- ik loop buiten (bijna) altijd met een hulpmiddel (bijvoorbeeld met een stok, een kruk, een rollator of een looprekje)	☐	☐
- ik loop buiten de langere afstanden (bijna) altijd met een hulpmiddel	☐	☐
- ik gebruik (bijna) altijd een hulpmiddel om andere mensen bij te benen (bijvoorbeeld met een stok, een kruk, een rollator of een looprekje)	☐	☐
Hindernissen		
- ik loop wel buiten maar ik loop langzamer over "hindernissen" (bijvoorbeeld opstapjes, stoepranden, slechte bestrating of oneffen ondergronden)	☐	☐
- ik loop wel buiten maar ik loop minder vaak over "hindernissen"	☐	☐
- ik loop wel buiten maar ik loop op een andere manier over "hindernissen" (bijvoorbeeld ik trek iedere keer een been bij)	☐	☐
- ik loop wel buiten maar met (enige) moeite over "hindernissen"	☐	☐
- ik loop wel buiten maar ik loop onzeker over "hindernissen"	☐	☐
Kruispunten		
- ik steek kruispunten over maar ik doe er langer over	☐	☐
- ik steek kruispunten over maar met (enige) moeite	☐	☐

BED EN TOILET

Wilt u hieronder aangeven van wat voor soort toilet en bed u meestal gebruik maakt?

Kruis de uitspraak aan die ***op u van toepassing*** *is.*

1. Maakt u (meestal) gebruik van een gewoon of van een verhoogd toilet?

☐ ik maak (meestal) gebruik van een gewoon toilet

☐ ik maak (meestal) gebruik van een verhoogd toilet

☐ anders, namelijk …..……….…..…….…..……….……………………………………...

2. Maakt u (meestal) gebruik van een toilet met of zonder armsteunen / beugels?

☐ ik maak (meestal) gebruik van een toilet **zonder** armsteunen / beugels

☐ ik maak (meestal) gebruik van een toilet **met** armsteunen / beugels

☐ anders, namelijk …..……….…..…….…..……….……………………………………...

3. Maakt u (meestal) gebruik van een gewoon of van een verhoogd bed?

☐ ik maak (meestal) gebruik van een gewoon bed

☐ ik maak (meestal) gebruik van een verhoogd / senioren bed

☐ anders, namelijk …..……….…..…….…..……….……………………………………...

De volgende uitspraken gaan over veranderingen die - door uw gezondheidstoestand - kunnen optreden in het in het opstaan en gaan zitten.

	JA	NEE
*Kruis **JA** aan als de uitspraak* - ***op u van toepassing is*** *en ook* - ***samenhangt met uw gezondheidstoestand***	☒	☐
*Kruis in alle overige gevallen **NEE** aan*	☐	☒

OPSTAAN

Hoge stoel	JA	NEE
- ik doe er langer over om van een hoge stoel overeind te komen (bijvoorbeeld een eetkamerstoel, een keukenstoel of een bureaustoel)	☐	☐
- ik kom met (enige) moeite van een hoge stoel overeind	☐	☐
- ik gebruik altijd mijn armen als ik van een hoge stoel overeind kom (bijvoorbeeld ik trek me op aan de tafel, ik zet me af op de armleuning of ik zet me af op de zitting)	☐	☐
Lage stoel of bank		
- ik doe er langer over om van een lage stoel of bank overeind te komen (bijvoorbeeld een "luie" stoel of een diepe bank)	☐	☐
- ik moet altijd eerst een eindje naar voren schuiven voordat ik van een lage stoel of bank overeind kom	☐	☐
- ik kom met (enige) moeite van een lage stoel of bank overeind	☐	☐
- ik gebruik altijd mijn armen als ik van een lage stoel of bank overeind kom (bijvoorbeeld ik trek me op aan de tafel, ik zet me af op de armleuning of ik zet me af op de zitting)	☐	☐
Toilet		
- ik doe er langer over om van het toilet overeind te komen	☐	☐
- ik schuif altijd eerst een eindje naar voren voordat ik van het toilet overeind kom	☐	☐
- ik kom met (enige) moeite van het toilet overeind	☐	☐
- ik houd me altijd ergens aan vast om van het toilet overeind te komen (bijvoorbeeld aan de deurpost, aan het fonteintje, aan een handgreep of aan een armsteun)		
Bed		
- ik doe er langer over om van bed op te staan	☐	☐
- ik schuif altijd eerst naar de rand voordat ik van bed opsta	☐	☐
- ik sta met (enige) moeite op van het bed	☐	☐
- ik gebruik altijd mijn armen als ik van bed opsta (bijvoorbeeld ik houd me ergens aan vast of ik zet me met mijn handen af op het bed)	☐	☐
Auto		
- ik doe er langer over om uit een auto te stappen	☐	☐
- ik stap uit auto's maar ik doe dat op een andere manier (bijvoorbeeld ik zet eerst mijn beide benen op de grond en daarna sta ik op)	☐	☐
- ik stap met (enige) moeite uit een auto	☐	☐
- ik houd me altijd met twee handen ergens aan vast als ik uit een auto stap	☐	☐

GAAN ZITTEN

Hoge stoel	JA	NEE
- ik doe er langer over om op een hoge stoel te gaan zitten (bijvoorbeeld een eetkamerstoel, een keukenstoel of een bureaustoel)	☐	☐
- ik laat me het laatste stukje altijd ploffen als ik op een hoge stoel ga zitten	☐	☐
- ik ga met (enige) moeite op een hoge stoel zitten	☐	☐
- ik gebruik altijd mijn armen als ik op een hoge stoel ga zitten (bijvoorbeeld ik houd me vast aan de tafel, ik steun op de armleuning of ik steun op de zitting)	☐	☐
Lage stoel of bank		
- ik doe er langer over om op een lage stoel of bank te gaan zitten (bijvoorbeeld een "luie" stoel of een diepe bank)	☐	☐
- ik laat me het laatste stukje altijd ploffen als ik op een lage stoel of bank ga zitten	☐	☐
- ik ga met (enige) moeite op een lage stoel of bank zitten	☐	☐
- ik gebruik altijd mijn armen als ik op een lage stoel of bank ga zitten (bijvoorbeeld ik houd me vast aan de tafel, ik steun op de armleuning of ik steun op de zitting)	☐	☐
Toilet		
- ik doe er langer over om op het toilet te gaan zitten	☐	☐
- ik ga met (enige) moeite op het toilet zitten	☐	☐
- ik houd me altijd ergens aan vast als ik op het toilet ga zitten (bijvoorbeeld aan de aan een handgreep of aan een armsteun)	☐	☐
Bed		
- ik ga alleen maar op een "extra hoog" bed zitten en niet op een gewoon bed	☐	☐
- ik doe er langer over om op bed te gaan zitten	☐	☐
- ik ga met (enige) moeite op bed zitten	☐	☐
- ik gebruik altijd mijn armen als ik op bed ga zitten (bijvoorbeeld ik houd me ergens aan vast of ik steun met mijn handen op het bed)	☐	☐
Auto		
- ik doe er langer over om in een auto te gaan zitten	☐	☐
- ik ga in auto's zitten maar ik doe dat op een andere manier (bijvoorbeeld ik ga eerst zitten en daarna trek ik mijn benen naar binnen)	☐	☐
- ik laat me het laatste stukje altijd ploffen als ik in een auto ga zitten	☐	☐
- ik ga met (enige) moeite in een auto zitten	☐	☐
- ik houd me altijd met twee handen ergens aan vast als ik in een auto ga zitten	☐	☐

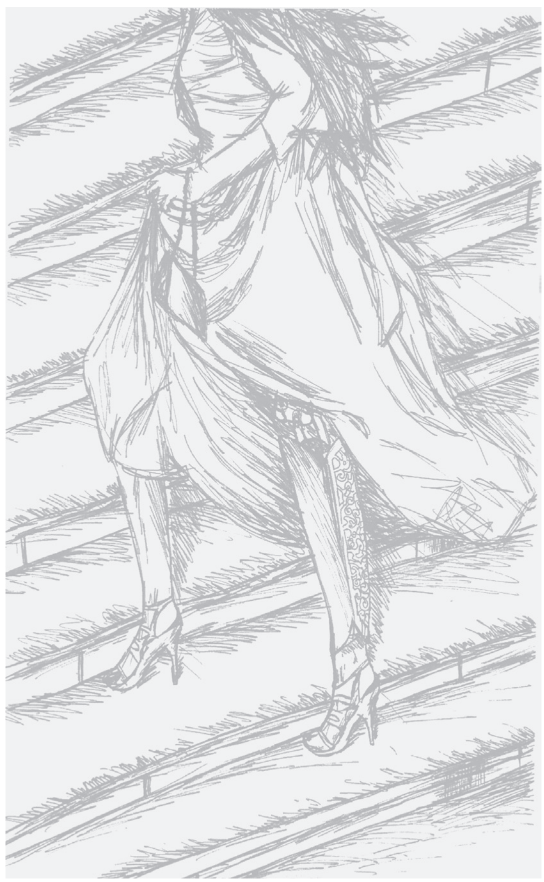
*Wilt u de hele vragenlijst nog een keer doorbladeren om te controleren of u **alle** uitspraken heeft aangekruist?*

*Als u nog **opmerkingen** heeft naar aanleiding van het invullen van deze vragenlijst, wilt u die dan hieronder noteren?*

Hartelijk dank voor het invullen van de vragenlijst!

Appendix 2

English version of the Questionnaires



Climbing Stairs Questionnaire

Walking Questionnaire

Rising and Sitting Down Questionnaire

□ □ □ □ □

Research participant

December 2012

Climbing Stairs Questionnaire (version 5.0 - dicho)
Walking Questionnaire (version 5.0 - dicho)
Rising and Sitting Down Questionnaire (version 5.0 - dicho)

Leo D. Roorda, MD, PT, PhD
Marij E. Roebroeck, PhD
Theo G. van Tilburg, PhD
Gustaaf J. Lankhorst, MD, PhD

Dr. Leo D. Roorda
Amsterdam Rehabilitation Research Center | Reade
PO Box 58271
1040 HG Amsterdam
The Netherlands
T +31 20 589 6281
F +31 20 489 6704
E l.roorda@reade.nl
W www.reade.nl

GENERAL

1. What is today's date?

day month year

2. What is your date of birth?

day month year

*Place a cross next to the statement that **applies to you**.*

3. What is your gender?

- ☐ female
- ☐ male

<u>GOING UP AND DOWN STAIRS</u>

Please indicate below whether you climb stairs. When climbing stairs you can think of climbing stairs at home, but also climbing stairs elsewhere (for instance in the home of family members or friends, or in shops).

*Place a cross next to the statement that **applies to you**.*

Do you climb stairs?

☐ I do not climb any stairs at all due to my health status

☐ I do not climb stairs at all because I do not encounter any stairs in my daily life

☐ I do not climb stairs at all because ....

> *If you placed a cross in one of the boxes above (thus indicating that you **do not** climb stairs at all) please proceed with the statements about **WALKING AT HOME** on page 133.*

☐ I do climb stairs

> *If you placed a cross in the box above (thus indicating that you **do** climb stairs) please proceed further on this page.*

The following statements about changes that, due to your health status, can occur when climbing stairs.

	YES	NO
*Place a cross next to **YES** if the statement* *- **applies to you** and also* *- **is related to your health status***	☒	☐
*In all other instances place a cross next to **NO***	☐	☒

Going **up** stairs	YES	NO
- I go **up** stairs but it takes me longer	☐	☐
- I go **up** stairs but in a different way (e.g. I draw one foot next to the other on every step)	☐	☐
- I go **up** stairs but with (some) difficulty	☐	☐
- I go **up** stairs and (almost) always hold on to the handrail	☐	☐
- I go **up** stairs and (almost) always use an aid (e.g. a walking stick or a crutch)	☐	☐
- I go **up** stairs and am (almost) always helped by someone	☐	☐
Going **down** stairs		
- I go **down** stairs but it takes me longer	☐	☐
- I go **down** stairs but in a different way (e.g. I place one foot next to the other on every step or I go down "backwards")	☐	☐
- I go **down** stairs but with (some) difficulty	☐	☐
- I go **down** stairs and (almost) always hold on to the handrail	☐	☐
- I go **down** stairs and (almost) always use an aid (e.g. a walking stick or a crutch)	☐	☐
- I go **down** stairs and am (almost) always helped by someone	☐	☐
Going **up and down** stairs		
- I do go **up and down** stairs but less frequently	☐	☐
- I do go **up and down** stairs but I try to avoid them	☐	☐
- I do go **up and down** stairs but I climb fewer flights / floors	☐	☐

<u>**WALKING AT HOME**</u>

Please indicate below whether you walk at home.

*Place a cross next to the statement that **applies to you**.*

Do you walk at home?

☐ I do not walk at all at home due to my health status

☐ I do not walk at all at home because ....

*If you placed a cross in one of the boxes above (thus indicating that you **do not** walk at home at all) please proceed with the statements about **BED AND TOILET** on page 137.*

☐ I do walk at home

*If you placed a cross in the box above (thus indicating that you **do** walk at home) please proceed further on this page.*

The following statements about changes that, due to your health status, can occur when walking at home.

	YES	NO
*Place a cross next to **YES** if the statement* - ***applies to you** and also* - ***is related to your health status***	☒	☐
*In all other instances place a cross next to **NO***	☐	☒

General	**YES**	**NO**
- I walk in one room but not in other rooms (e.g. I only walk in the living room or in the bedroom)	☐	☐
- I walk at home but I do not come into all rooms	☐	☐
- I walk at home but shorter distances	☐	☐
- I walk at home but for shorter periods	☐	☐
- I walk at home but more slowly	☐	☐
- I walk at home but less frequently	☐	☐
- I walk at home but I stand still (for a short moment) more often	☐	☐
- I walk at home but in a different way (e.g. I limp, waddle, stumble or walk with a stiff leg)	☐	☐
- I walk at home but with (some) difficulty	☐	☐
- I walk at home but I walk insecurely	☐	☐
- I walk at home but I (almost) always hold on to something (e.g. a table, a piece of furniture or the wall)	☐	☐
Obstacles		
- I walk at home but I walk more slowly over "obstacles" (e.g. thresholds or steps)	☐	☐
- I walk at home but I walk less often over "obstacles"	☐	☐
- I walk at home but I walk in a different way over "obstacles" (e.g. I draw one foot next to the other)	☐	☐
- I walk at home but with (some) difficulty over "obstacles"	☐	☐
- I walk at home but I walk insecurely over "obstacles"	☐	☐

WALKING OUTSIDE

Please indicate below whether you walk outside.

Place a cross next to the statement that ***applies to you****.*

Do you walk outside?

☐ I do not walk outside at all due to my health status

☐ I do not walk outside at all because ....

If you placed a cross in one of the boxes above (thus indicating that you ***do not*** *walk outside at all) please proceed with the statements about* ***BED AND TOILET*** *on page 137.*

☐ I do walk outside

If you placed a cross in the box above (thus indicating that you ***do*** *walk outside) please proceed further on this page.*

The following statements about changes that, due to your health status, can occur when walking outside.

	YES	NO
Place a cross next to ***YES*** *if the statement* *-* ***applies to you*** *and also* *-* ***is related to your health status***	☒	☐
In all other instances place a cross next to ***NO***	☐	☒

General	YES	NO
- I do walk outside but shorter distances	☐	☐
- I do walk outside but for shorter periods	☐	☐
- I do walk outside but more slowly	☐	☐
- I do walk outside but less frequently	☐	☐
- I do walk outside but I stand still (for a short moment) more often	☐	☐
- I do walk outside but in a different way (e.g. I limp, waddle, stumble or walk with a stiff leg)	☐	☐
- I do walk outside but with (some) difficulty	☐	☐
- I do walk outside but I walk insecurely	☐	☐
- I walk more slowly	☐	☐
Aids		
- I do walk outside (almost) always with an aid (e.g. a walking stick, a crutch, a wheeled walker or a walking frame)	☐	☐
- I (almost) always walk longer distances outside with an aid	☐	☐
- I (almost) always use an aid to keep up with other people (e.g. a walking stick, a crutch, a wheeled walker or a walking frame)	☐	☐
Obstacles		
- I do walk outside but I walk more slowly over "obstacles" (e.g. steps, curbs, badly-paved roads or uneven ground)	☐	☐
- I do walk outside but I walk less frequently over "obstacles"	☐	☐
- I do walk outside but I walk in a different way over "obstacles" (e.g. I draw one foot next to the other)	☐	☐
- I do walk outside but with (some) difficulty over "obstacles"	☐	☐
- I do walk outside but I walk insecurely over "obstacles"	☐	☐
Intersections		
- I cross intersections but it takes me longer	☐	☐
- I cross intersections but with (some) difficulty	☐	☐

<u>BED AND TOILET</u>

Please indicate below what type of toilet and bed you usually use.

*Place a cross next to the statement that **applies to you**.*

1. Do you (usually) use a normal or a raised toilet?
   - ☐ I (usually) use a normal toilet
   - ☐ I (usually) use a raised toilet
   - ☐ something else, namely ....

2. Do you (usually) use a toilet with or without armrests / handles?
   - ☐ I (usually) use a toilet **without** armrests / handles
   - ☐ I (usually) use a toilet **with** armrests / handles
   - ☐ something else, namely ....

3. Do you (usually) sleep in a normal bed or in a raised bed?
   - ☐ I (usually) sleep in a normal bed
   - ☐ I (usually) sleep in a raised / senior's bed
   - ☐ something else, namely ....

The following statements about changes that, due to your health status, can occur when rising and sitting down..

	YES	**NO**
*Place a cross next to **YES** if the statement* *- **applies to you** and also* ***- is related to your health status***	☒	☐
*In all other instances place a cross next to **NO***	☐	☒

RISING

Raised chair	**YES**	**NO**
- It takes me longer to get up from a raised chair (e.g. a dining chair, a kitchen chair or an office chair)	☐	☐
- I get up from a raised chair with (some) difficulty	☐	☐
- I always use my arms when I get up from a raised chair (e.g. I pull myself up by holding on to the table, I push myself up using the armrests or I push myself up off the seat)	☐	☐
Low chair or sofa		
- It takes me longer to get up from a low chair or sofa (e.g. an easy chair or a deep sofa)	☐	☐
- I always have to shift forward a little at first before I get up from a low chair or sofa	☐	☐
- I get up from a low chair or sofa with (some) difficulty	☐	☐
- I always use my arms when I get up from a low chair or sofa (e.g. I pull myself up by holding on to the table, I push myself up using the armrests or I push myself up off the seat)	☐	☐
Toilet		
- It takes me longer to get up from the toilet	☐	☐
- I always shift forward a little at first before I get up from the toilet.	☐	☐
- I get up from the toilet with (some) difficulty	☐	☐
- I always hold on to something to get up from the toilet (e.g. a door post, a washbasin, a handle or an arm support)	☐	☐
Bed		
- It takes me longer to get up from the bed	☐	☐
- I always shift to the edge of the bed first before I get up	☐	☐
- I get up from the bed with (some) difficulty	☐	☐
- I always use my arms when I get up from the bed (e.g. I hold on to something or I push myself up off the bed with my hands)	☐	☐
Car		
- It takes me longer to get out of a car.	☐	☐
- I get out of cars but I do that in a different way (e.g. I place both feet on the ground before I stand up)	☐	☐
- I get out of a car with (some) difficulty	☐	☐
- I always hold on to something with both hands when I get out of a car.	☐	☐

SITTING DOWN

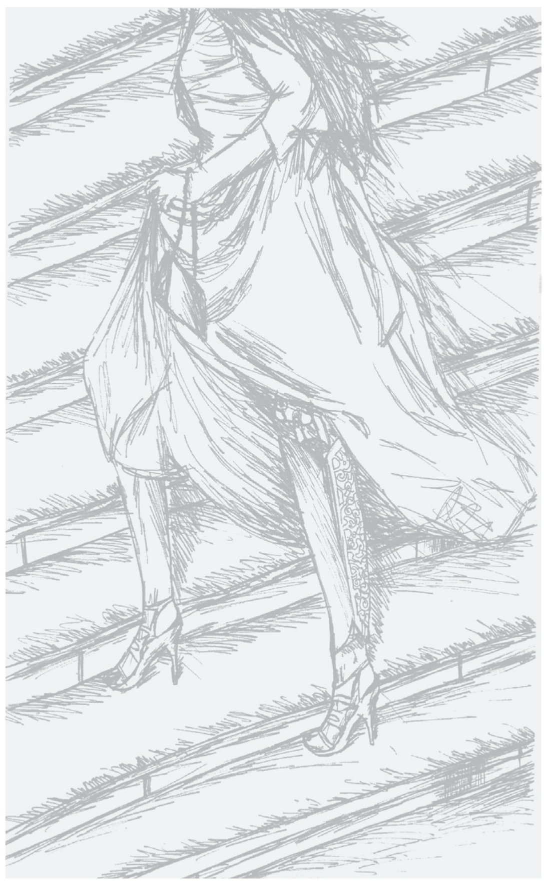
Raised chair	YES	NO
- It takes me longer to sit down on a raised chair (e.g. a dining chair, a kitchen chair or an office chair)	☐	☐
- When I sit down on a raised chair, I always flop down at the end	☐	☐
- I sit down on a raised chair with (some) difficulty	☐	☐
- I always use my arms when I sit down on a raised chair (e.g. I hold on to a table, I lean on the armrests or I lean on the seat)	☐	☐
Low chair or sofa		
- It takes me longer to sit down on a low chair or sofa (e.g. an easy chair or a deep sofa)	☐	☐
- When I sit down on a low chair or sofa, I always flop down at the end	☐	☐
- I sit down on a low chair or sofa with (some) difficulty	☐	☐
- I always use my arms when I sit down on a low chair or sofa (e.g. I hold on to a table, I lean on the armrests, or I lean on the seat)	☐	☐
Toilet		
- It takes me longer to sit down on the toilet	☐	☐
- I sit down on a toilet with (some) difficulty	☐	☐
- I always hold on to something when I sit down on the toilet (e.g. the door post, the washbasin, a handle or an arm support)	☐	☐
Bed		
- I only sit down on an "extra high" bed and not on an ordinary bed	☐	☐
- It takes me longer to sit down on the bed	☐	☐
- I sit down on a bed with (some) difficulty	☐	☐
- I always use my arms when I sit down on the bed (e.g. I hold on to something or I lean on the bed with my hands)	☐	☐
Car		
- It takes me longer to get into a car	☐	☐
- I get into cars but in a different way (e.g. I first sit down and then I pull my legs inside)	☐	☐
- When I get into a car I always flop down at the end.	☐	☐
- I get into a car with (some) difficulty	☐	☐
- I always hold on to something with both hands when I get into a car	☐	☐

Would you please go throughout the entire questionnaire to make sure you have placed a cross next to ***all*** *statements?*

Please indicate below if you have any ***comments*** *in relation to completing this questionnaire*

Thank you very much for completing this questionnaire!

Summary



Limitation in mobility is regarded as one of the most relevant disabilities regarding quality of life following lower limb amputation (LLA). With prosthetic devices and rehabilitation, many people with a LLA are able to restore their mobility.
There is no gold standard to assess perceived limitations in mobility for persons with a LLA. Furthermore, for transfers with a prosthesis (rising and sitting down) and for climbing stairs there are no assessment measures available at all. For ambulatory mobility, one has to be able to rise and sit down first, and then be able to stand. Thereafter, walking and finally climbing stairs become possible.
Nowadays, scales with a good fit with an Item Response Theory (IRT) model are recommended. Important advantages of a fit with an IRT model are the possibility of (hierarchical) item ordering in 1 scale, the independency of the amount and the characteristics of the sample, and the possibility of a computerized adaptive test (CAT). In a CAT, the computer tries to locate the patient's position on the hierarchical scale being tested with just a few questions.
To be able to conduct a more detailed assessment of activity limitations in rising and sitting down, walking in- and outdoors, and climbing stairs (perceived by patients at home), Roorda et al designed a questionnaire which was comprised of the Questionnaire Rising and Sitting Down, the Walking Questionnaire, and the Climbing stairs Questionnaire. The author showed a good fit with non-parametric IRT models in a large sample of home-dwelling persons with impairments of a lower-limb.
The main purpose of this thesis was to assess the construct validity and test-retest reliability of the Questionnaire Rising and Sitting Down, the Walking Questionnaire, and the Climbing stairs Questionnaire, in order to see if these questionnaires were appropriate to assess perceived mobility in persons with a LLA. If so, further exploration to create a CAT would then be possible. In addition, and because no data are available on the outcome of perceived mobility in rising and sitting down and climbing stairs in prosthesis-wearing persons with a LLA, these outcomes were measured.

In *chapter 2*, the construct validity and test-retest reliability of the Questionnaire Rising and Sitting Down in persons with a LLA was assessed. There was good construct validity (6 of 8 hypotheses not rejected) and good test-retest reliability for group, but not individual comparisons. Moreover agreement was calculated with the smallest detectable difference. This was 18.6%, indicating that to detect a true difference, the difference between the 2 measurements has to be at least 19 (on a scale from 0-100). For application in a group of persons with a LLA (e.g., for research purposes), smaller differences can be detected, because in such a situation the smallest detectable difference has to be divided by $\sqrt{n}$. Thus, for example, in a group of 100 persons with a lower LLA, a difference of only 2 can be considered as a true difference in limitations in rising and sitting down.

In *chapter 3*, the construct validity and the test-retest reliability of the Walking Questionnaire was assessed in persons with a LLA. To formulate hypotheses, time and distance walked were assessed, using self-developed rating scales. Furthermore, the 'walking distance' question of the Prosthetic Profile of the Amputee, and the SIGAM/WAP mobility scale were also assessed. Eventually, 11 hypotheses were formulated.

There was good construct validity (10 of 11 hypotheses not rejected) and good test-retest reliability for group, but not individual comparisons.

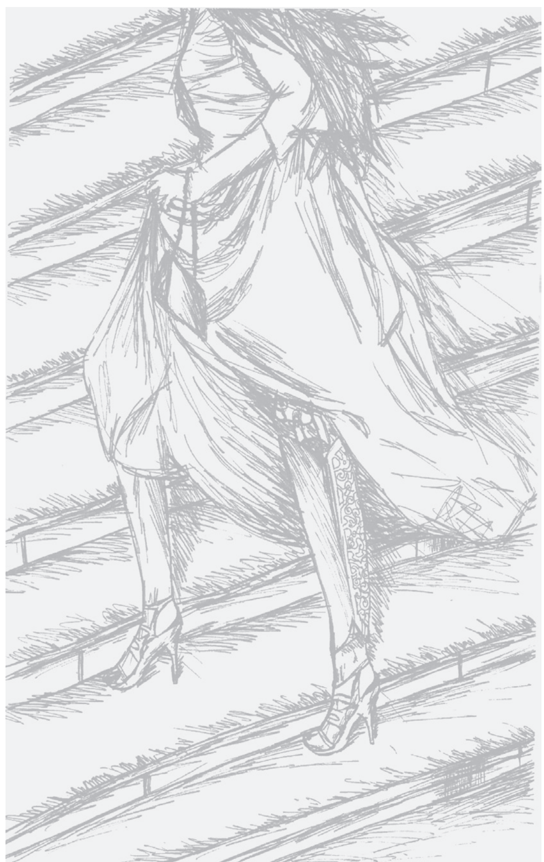
In *chapter 4*, the construct validity and the test-retest reliability of the Climbing Stairs Questionnaire was assessed in persons with a LLA. To formulate hypotheses, the number of floors climbed was assessed, using a self-developed rating scale. Additionally, the 'climbing stairs' questions of the Locomotor Capabilities Index were also used. Eventually, 10 hypotheses were formulated. There was good construct validity (8 of 10 hypotheses not rejected) and good test-retest reliability for group, but not individual comparisons.

The second part of this thesis focussed on outcome of some aspects of perceived mobility. In *chapter 5*, the outcomes of perceived independence in rising, and the perceived limitations in rising and sitting down in prosthesis-wearing persons with a LLA were described. To measure the perceived independence in rising, 3 questions of the Locomotor Capabilities Index were used. Perceived limitations in rising and sitting down were assessed with the Questionnaire Rising and Sitting Down. Of the persons with a LLA, 91% perceived independence in rising from a chair, but only half of them perceived that they were able to rise from the floor independently. Univariate analysis showed a relationship between perceived independence in rising, and age, gender, number of comorbidities, rehabilitation setting and type of prosthetic knee. Multivariate logistic regression analysis showed a decrease in independence in rising in older participants and women. The odds of women rising independently was 3.7 times lower than men. Persons with a LLA perceived many limitations in rising and sitting down, with a mean score of 46 (range, 0-100). Those rehabilitated in a nursing home perceived more limitations in rising and sitting down, independently of other variables, with a mean score of 37.

In *chapter 6*, the outcome of perceived necessity and ability to climb stairs in better-performing persons with a LLA was described. To measure the necessity to climb stairs, 3 questions of the Prosthetic Profile of the Amputee were used. These questions specifically address the necessity to climb stairs in one's house and in entering or leaving the house, and their interference with daily activities. The ability to climb stairs was measured with: perceived independence <u>with</u> and <u>without</u> a handrail according to the climbing stairs questions of the Locomotor Capabilities Index; the numbers of floors climbed according to a self-developed rating scale; and perceived limitations in climbing stairs according to the Climbing Stairs Questionnaire. Of the participants, 47% had to climb stairs within or to enter or leave their house, in 36% of them, this interfered with their daily activities. Remarkably, 62% was able to climb up and down stairs independently with a handrail, whereas only 21% were able to do so without a handrail. Multivariate logistic regression analysis showed a decrease in independence in older participants and women in both stair-climbing situations. For women, the odds of independently climbing stairs with or without a handrail was more than 9 times lower than for men. The number of floors climbed was low, with 32% of the participants not climbing any stairs, 5% climbing ½ a floor, 29% climbing 1 floor and 34% climbing 2 floors or more. The perceived limitations in climbing stairs were considerable, with a median sum score for the Climbing Stairs Questionnaire of 38 (range, 0-100). Multivariate logistic regression analysis only showed a relationship with the number of comorbidities.

In *chapter 7*, the discussion of the results of the conducted studies was described. Some comments were made about the study population, especially concerning the comorbidity of the participants. The procedure we followed for testing the construct validity and the test-retest reliability was explained and discussed for the Questionnaire Rising and Sitting down, the Walking Questionnaire, and the Climbing stairs Questionnaire in persons with a LLA. Other clinimetric properties were discussed. Thereafter, the outcome of rising and sitting down and climbing stairs in persons with a LLA was discussed, and advice regarding rising and sitting down and climbing stairs, based on these outcomes, was given. Recommendations for further testing and use of the questionnaires was made. Special attention was drawn to computer adaptive testing, which could be built into the digital medical record system; the Questionnaire Rising and Sitting Down is particularly suitable for this purpose. Finally, the questionnaires we used were compared with other measurement tools used in Rehabilitation Medicine and advice was given for compiling a comprehensive set of measurement tools.

Samenvatting



Na een beenamputatie is de revalidatie o.a. gericht op het herwinnen van de mobiliteit, gebruik makend van een prothese. Alhoewel er veel mobiliteitsschalen voor mensen met een beenamputatie zijn beschreven, is er geen gouden standaard. Voor het meten van transfers met een prothese (opstaan en gaan zitten) en voor traplopen zijn helemaal geen schalen beschreven. Voor goede mobiliteit is kunnen opstaan en gaan zitten een eerste vereiste, en daarna het kunnen blijven staan. Daarna is lopen en uiteindelijk traplopen gewenst.
Tegenwoordig worden schalen aanbevolen die een goede fit hebben met een Item response theorie (IRT) model. Belangrijke voordelen van een fit met een IRT model zijn de mogelijkheid van (hiërarchische) item volgorde in 1 schaal, de onafhankelijkheid van de uitkomst voor grootte en kenmerken van de steekproef, en de mogelijkheid van "geautomatiseerde zichzelf aanpassende schalen" (computererized adaptive testing, CAT). Bij CAT probeert de computer met slechts een paar vragen de locatie van de patiënt te vinden op de hiërarchische schaal.
Voor een meer gedetailleerde beoordeling van beperkingen in mobiliteit op het gebied van opstaan en gaan zitten, lopen en traplopen (zoals ervaren door thuiswonende patiënten), is door Roorda e.a. een vragenlijst ontworpen, bestaande uit de vragenlijst "opstaan en gaan zitten", de vragenlijst "lopen" en de vragenlijst "traplopen". De auteur toonde een goede fit aan met non-parametrische IRT modellen in een grote groep van thuiswonende mensen met een beperking aan het functioneren van een been.
Het belangrijkste doel van het proefschrift is het beoordelen van de construct validiteit en de test-hertest betrouwbaarheid van de vragenlijst "opstaan en gaan zitten", de vragenlijst "lopen" en de vragenlijst "traplopen" bij mensen met een beenamputatie. Als dat namelijk zo is, is verdere ontwikkeling van een CAT mogelijk. Bovendien, worden gegevens gepresenteerd omtrent ervaren mobiliteit in opstaan en gaan zitten, en in traplopen, bij mensen met een beenamputatie. Dit omdat er momenteel nog geen gedetailleerde gegevens zijn omtrent deze beperkingen bij onderhavige doelgroep.

In *hoofdstuk 2* werd de construct validiteit en test-hertest betrouwbaarheid van de vragenlijst "opstaan en gaan zitten" bij mensen met een beenamputatie beoordeeld. Er was goede construct validiteit (6 van de 8 hypothesen niet afgewezen) en goede test-hertest betrouwbaarheid voor groepsvergelijking maar niet voor individuele vergelijkingen. Bovendien werd de overeenkomst berekend met het kleinst waarneembare verschil. Dit was 18,6%, hetgeen wil zeggen dat, indien het verschil tussen 2 metingen ten minste 19 is (op een schaal van 0-100), er sprake is van een echt verschil. Echter, voor toepassing in een groep van mensen met een beenamputatie (bijvoorbeeld voor onderzoeksdoeleinden), kunnen kleinere verschillen worden opgespoord, omdat dan het kleinst waarneembare verschil moet worden gedeeld door $\sqrt{n}$. Zodoende zal in een groep van 100 mensen met een beenamputatie, een verschil van slechts 2 worden beschouwd als een echte verschil.

In *hoofdstuk 3* werd de construct validiteit en test-hertest betrouwbaarheid van de vragenlijst "lopen" bij mensen met een beenamputatie beoordeeld. Er werden zelf ontwikkelde schalen gebruikt die de tijd en de afstand die kon worden gelopen vastlegde. Daarmee konden hypothesen worden opgesteld betreffende de construct validiteit. Andere hypothesen werden getoetst aan de loopafstand conform deze vraag uit de Prosthetic Profile of the Amputee en aan de uitkomst van de SIGAM/WAP-schaal. Uiteindelijk werden er 11 hypothesen opgesteld. Er was goede construct validiteit (10 van de 11 hypothesen niet afgewezen) en goede test-hertest betrouwbaarheid voor groepsvergelijking maar niet voor individuele vergelijkingen.

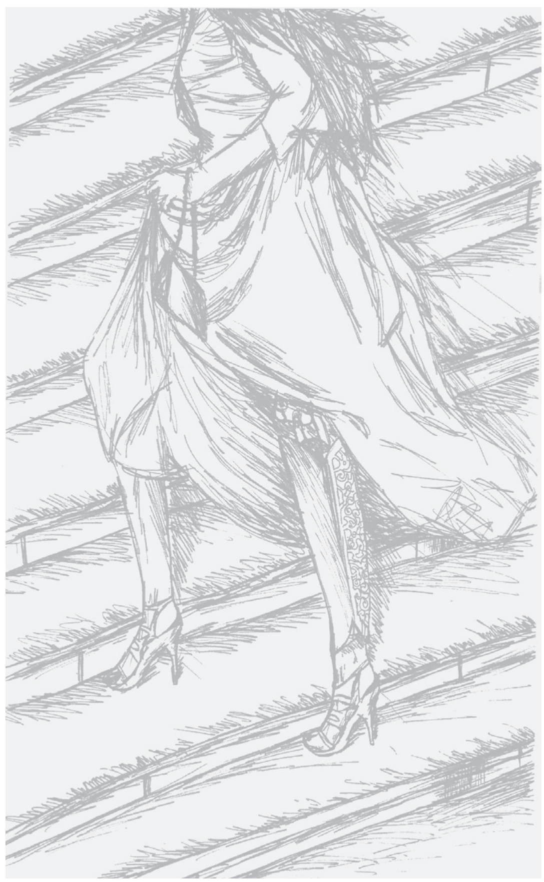
In *hoofdstuk 4* werd de construct validiteit en test-hertest betrouwbaarheid van de vragenlijst "traplopen" bij mensen met een beenamputatie beoordeeld. Er werden een zelf ontwikkelde schaal gebruikt die het aantal verdiepingen wat er kon worden gelopen vastlegde. Daarmee konden hypothesen worden opgesteld betreffende de construct validiteit. Andere hypothesen werden getoetst aan de traploop vragen uit de Locomotor Capabilities Index. Uiteindelijk werden 10 hypothesen opgesteld. Er was goede construct validiteit (8 van de 10 hypothesen niet afgewezen) en goede test-hertest betrouwbaarheid voor groepsvergelijking maar niet voor individuele vergelijkingen.

In het tweede deel van deze thesis is wordt ingegaan op de ervaren beperkingen in mobiliteit omtrent opstaan en gaan zitten en omtrent traplopen. Het resultaat van de ervaren onafhankelijkheid in opstaan en de ervaren beperkingen in opstaan en gaan zitten bij mensen met een beenamputatie en een prothese, wordt beschreven in *hoofdstuk 5*. Voor het meten van de ervaren onafhankelijkheid in opstaan zijn 3 vragen van de Locomotor Capabilities Index gebruikt, voor het meten van ervaren beperkingen in opstaan en gaan zitten is de vragenlijst"opstaan en gaan zitten"gebruikt. Van de mensen met een beenamputatie vond 91% dat zij zelfstandig konden opstaan uit een stoel, maar slechts de helft van hen vond dat zij in staat waren om zelfstandig op te staan van de grond. Univariate analyse toonde een relatie aan tussen ervaren onafhankelijkheid en leeftijd, geslacht, comorbiditeit, plaats waar revalidatie plaatsvond (revalidatiecentrum of verpleeghuis) en soort prothese knie. Multivariate logistische regressieanalyse toonde een afname van de onafhankelijkheid aan in opstaan bij ouderen en vrouwen. De odds van vrouwen om zelfstandig op te kunnen staan was 3.7 keer lager dan mannen. Mensen met een beenamputatie ervoeren veel beperkingen in opstaan en gaan zitten, met een gemiddelde score van 46 (bereik 0-100). Diegene die in een verpleeghuis hadden gerevalideerd ervoeren meer beperkingen in opstaan en gaan zitten, onafhankelijk van de andere variabelen. Ze hadden een gemiddelde score van 37.

Het resultaat van de ervaren noodzaak en de mogelijkheid om te traplopen bij de betere revalidanten met een beenamputatie wordt beschreven in *hoofdstuk 6*. Voor het meten van de noodzaak om te traplopen, werden 3 vragen uit de Prosthetic Profile of the Amputee gebruikt. Deze vragen gaan specifiek over de noodzaak tot traplopen in huis of om in of uit het huis te komen, en hun interferentie met dagelijkse activiteiten. Traplopen werd verdeeld in ervaren onafhankelijkheid in traplopen met en zonder leuning volgens de 4 desbetreffende vragen van de Locomotor Capabilities Index, het aantal verdiepingen dat er kon worden gelopen volgens een zelf ontwikkelde schaal en ervaren beperkingen in het traplopen volgens de vragenlijst "traplopen". Van de deelnemers moest 47% traplopen in huis en/of om in of uit huis te komen, bij 36% van hen, interfereerde dit met hun dagelijkse activiteiten. Bij 62% was er onafhankelijkheid in traplopen met leuning, echter slechts 21% was in staat om dit te doen zonder leuning. Multivariate logistische regressieanalyse toonde voor beide situaties een afname van de onafhankelijkheid aan bij ouderen en vrouwen. Bij vrouwen was de odds voor onafhankelijk traplopen met of zonder een leuning meer dan 9 keer lager dan bij mannen. Het aantal verdiepingen dat kon worden gelopen was laag: 32% van de deelnemers liep geen trap, 5% klom ½ trap, 29% klom 1 verdieping, en 34% klom 2 verdiepingen of meer. De ervaren beperkingen in het traplopen waren aanzienlijk, met een gemiddelde score op de vragenlijst "traplopen"van 38 (bereik 0-100). Bij multivariate logistische regressieanalyse liet alleen een relatie zien met comorbiditeit.

In *hoofdstuk 7* worden de resultaten van de uitgevoerde onderzoeken besproken. Enkele opmerkingen zijn gemaakt over de onderzoeksdeelnemers, met name de comorbiditeit van de deelnemers. Het testen van de construct validiteit en de test-hertest betrouwbaarheid is toegelicht en besproken voor de vragenlijst"opstaan en gaan zitten", de vragenlijst "lopen" en de vragenlijst "traplopen" bij mensen met een beenamputatie. Andere klinimetrische eigenschappen die bestudeerd kunnen worden, worden genoemd. Daarna worden de resultaten van het opstaan en gaan zitten en het traplopen bediscussieerd, en op basis daarvan adviezen gegeven omtrent deze items. Aanbevelingen voor het verder toetsen van de vragenlijsten worden gegeven. Speciale aandacht wordt gevraagd voor computer adaptieve testen (CAT), die in de digitale medisch dossier kunnen worden ingebouwd. Met name de vragenlijst "opstaan en gaan zitten"is geschikt voor deze toepassing. Ten slotte wordt het gebruik van meetinstrumenten, zoals de gebruikte vragenlijsten, vergeleken met andere meetinstrumenten in de revalidatiegeneeskunde en worden adviezen gegeven voor een set van meetinstrumenten.

Dankwoord



Dit hoofdstuk heeft het meeste tijd gekost namelijk 2 jaar! Gedurende het promotietraject heb ik hier steeds aan geschaafd en toegevoegd als ik weer hulp kreeg van deze of gene.

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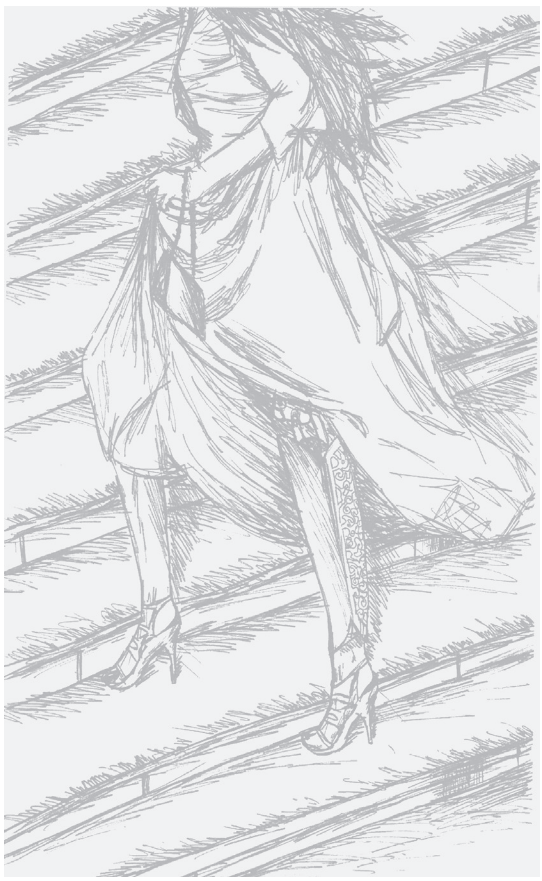
Curriculum Vitae



Fred A.J. de Laat was born in 1963 in Vught in the Netherlands. He attended between 1982 and 1990 the University of Nijmegen St Radboud studying medicine.

After his graduation, the author performed his replaced military service at Roessingh Research and Innovation (at the moment: Roessingh Research and Development). Thereafter he fulfilled between 1992 and 1996 his Specialty training in Physical Medicine and Rehabilitation at Rehabilitation Center Het Roessingh, Enschede, Twenteborg Hospital, Almelo, MST Hospital, Enschede and Rehabilitation Center Groot Klimmendaal, Arnhem, The Netherlands.

From 1996 until 2009, he worked as a physiatrist at Rehabilitation Center Tolbrug, Jeroen Bosch Hospital at 's Hertogenbosch, where he recruited the participants for his study. Since 2009, he is affiliated with Rehabilitation Center Leijpark, Libra Rehabilitation Medicine and Audiology, and has been drafting the manuscripts for his thesis. Currently, he is working as a physiatrist at TweeSteden Hospital and Rehabilitation Center Leijpark at Tilburg.

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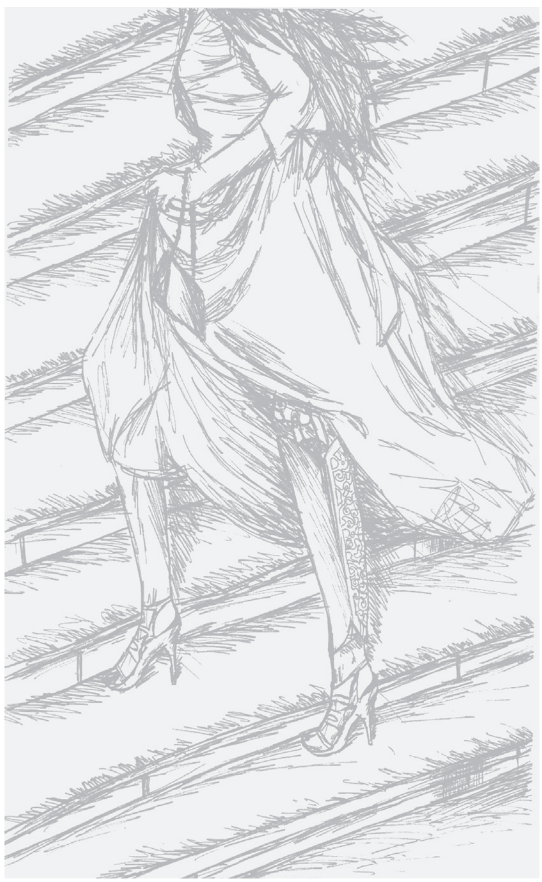

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EXPAND

Extremities, Pain and Disability

Missie: EXPAND draagt bij aan participatie en kwaliteit van leven van mensen met aandoeningen en amputaties van de extremiteiten of met pijn aan het bewegingsapparaat.

EXPAND omvat twee speerpunten: onderzoek naar aandoeningen aan en amputaties van extremiteiten met nadruk op stoornissen, activiteiten en participatie en onderzoek naar chronische pijn en arbeidsparticipatie. EXPAND draagt bij aan het UMCG-brede thema Healthy Ageing.

Research Department of Rehabilitation Medicine – Center for Rehabilitation UMCG

EXPAND

Extremities, Pain and Disability

Mission: EXPAND contributes to participation and quality of life of people with conditions and amputations of the extremities and musculoskeletal pain.

EXPAND focuses on two spearheads: research on the conditions and amputations of the extremities with emphasis on body functions and structures, activities and participations, and chronic pain and work participation. EXPAND contributes to Healthy Aging, the focus of the UMCG.