OPEN

Comprehensive Validation of the German Version of the LIMB-Q

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Objective: Lower extremity trauma significantly impacts patients' lives, requiring a nuanced approach to evaluate outcomes beyond clinical measures. The LIMB-Q, a patient-reported outcome measure (PROM), assesses the multifaceted impacts of lower extremity trauma, including physical and emotional dimensions, from the patient's perspective. This study validates the German version of the LIMB-Q.

Methods: We relied on the translation of the LIMB-Q that had followed the International Society for Pharmacoeconomics and Outcomes Research best practice guidelines. Sixty patients who had undergone reconstructive surgery or amputation of the lower limb completed the LIMB-Q, Lower Extremity Functional Scale (LEFS), and Short Form Health Survey (SF-36). Internal consistency of the German LIMB-Q was determined by Cronbach's alpha, and reliability was assessed using the intraclass correlation coefficient. Construct validity was analyzed using Pearson correlation coefficients between the LIMB-Q, LEFS, and SF-36.

Results: Validation involved 60 patients. Internal consistency in a test-retest subset of 5 patients was good to excellent (α: 0.891 to 0.965). The intraclass correlation coefficient for these scales ranged from 0.821 to 1. The LIMB-Q domains significantly correlated with the corresponding domains of the SF-36 and LEFS, confirming excellent construct validity.

Conclusions: The German version of the LIMB-Q is conceptually equivalent to the original English version. It is a reliable and valid PROM for assessing physical and psychological impairments in patients who have undergone lower extremity reconstructive surgery or amputation.

Key Words: patient-reported outcome measurements, lower limb reconstruction, validation , LIMB-Q, PROMs, quality of life, QoL

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Lower extremity trauma, arising from accidents, military injuries, or medical conditions, profoundly affects patients' lives, often requiring extensive reconstruction or, in the most severe cases, amputation.[1] The physical and psychological aftermath of such trauma affects not only the patient's mobility and daily functioning but also their quality of life (QOL) and mental health.[2] Despite the prevalence of these conditions and their consequences, the assessment of patient outcomes has traditionally been limited to clinical measures that may not fully capture the patient's perspective and overall well-being.[3] Patient-reported outcome measures (PROMs) have emerged as essential tools in evaluating the effectiveness of medical treatments from the patient's viewpoint, highlighting the need for disease-specific instruments that address the unique challenges faced by individuals undergoing lower extremity reconstruction or amputation.[4] To this end, the LIMB-Q has been developed as a novel PROM specifically designed for lower extremity trauma patients.[5] The LIMB-Q aims to provide a comprehensive assessment of patients' perceptions of their symptoms, functional status, aesthetic concerns, psychological well-being, and the impact of medical information and surrounding factors on their lives. The LIMB-Q is structured to include multiple domains that reflect the multifaceted nature of recovery and adaptation to lower extremity trauma, encompassing both physical and emotional dimensions. Each domain has been carefully developed to ensure relevance and comprehensibility for patients, facilitating the collection of data that are both meaningful and actionable for clinicians and researchers.[6] The translation has previously been performed by combining World Health Organization and Professional Society for Health Economics and Outcomes Research guidelines. The process consisted of forward translations, a backward translation, expert panel meetings, cognitive debriefing interviews with patients, and several rounds of discussion and reconciliation with the creators of LIMB-Q. From the 2 forward translations, there was one primary discrepancy between the 2 translators that was discussed to determine the most conceptually accurate translation. From the backward translations, there were 63 items that required discussion and retranslation. Nine patients participated in the cognitive debriefing interviews, which led to three items being modified.[7] After the translation process, the validation of PROMs across different languages and cultures is crucial for ensuring their applicability and reliability in diverse healthcare settings. This process, known as cross-cultural adaptation, goes beyond mere translation; it involves careful consideration of linguistic nuances and cultural contexts that may influence patients' interpretation and responses to questionnaire items.[8] Validating PROMs in multiple languages not only facilitates international research collaboration but also ensures that healthcare providers can accurately assess and compare patient outcomes across different populations.[9] In the context of the LIMB-Q, a German validation is particularly valuable given the significant German-speaking population in Europe and the potential for its use in multinational studies focusing on lower extremity trauma and reconstruction. The primary objective of our study was to perform a comprehensive validation of the newly available German version of the LIMB-Q, ensuring its reliability, validity, and sensitivity to changes in a patient's condition. This process involved conducting a cross-cultural validation to confirm its applicability across different cultural contexts. Through

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this validation study, we aimed to establish the psychometric properties of the German version of the LIMB-Q and assess its potential for use in clinical practice and research. By rigorously validating this instrument, we lay the groundwork for its potential future establishment as a standard measure for assessing patient-reported outcomes in individuals who have experienced lower enhancing patient care and supporting the continuous improvement of treatment strategies in German-speaking countries.

MATERIAL AND METHODS

German LIMB-Q

The German (Switzerland) version of the LIMB-Q as recently published[10] was assessed. The LIMB-Q, authored by Drs. Lily Mundy, Anne Klassen, and Andrea Pusic, is the copyright of McMaster University, Johns Hopkins University, Duke University, and Brigham and Women's Hospital (Copyright©2024, McMaster University, Johns Hopkins University, Duke University, Brigham and Women's Hospital). The LIMB-Q has been provided under license from McMaster University and must not be copied, distributed, or used in any way without the prior written consent of McMaster University.

Patients and Data Sampling

We conducted a monocenter study at our Department of Plastic Surgery and Hand Surgery at the University Hospital of Zurich. Patients who had received either lower extremity reconstructive surgery or amputations were invited back to our outpatient clinic to participate. Approval was given by the Cantonal Ethics Committee of Zurich, Switzerland (ethical approval Nr.: 2022-00232). The inclusion criteria were defined as follows: Male and female patients aged 18 and older who had undergone reconstructive surgery or amputation on the lower extremity. Patients who were not able to fill in questionnaires due to insufficient knowledge of the German language were excluded. All patients gave written consent prior to study participation.

Participants received the following three questionnaires:

Lower Extremity Functional Scale (LEFS): Developed by Binkley et al. in 1999 at McMaster University, Canada. It is a 20-item questionnaire designed to assess the functional status of patients with lower extremity musculoskeletal conditions.[11]

Short form Health Survey 36 (SF-36): Originally developed by Ware and Sherbourne in 1992 as part of the Medical Outcomes Study in the United States. It is a 36-item questionnaire that measures eight domains of health-related QOL.[12]

LIMB-Q: Developed by Drs. Lily Mundy, Anne Klassen, and Andrea Pusic at McMaster University, Johns Hopkins University, Duke University, and Brigham and Women's Hospital in 2019. It is a comprehensive PROM specifically designed for patients with lower extremity trauma.[4]

The questionnaires were either completed at our outpatient clinic or at home via an online platform. Additionally we collected the following patient data: age, gender, body mass index (BMI), type of reconstruction, and type of trauma leading to the need for surgery.

Comprehensive Validation of the German LIMB-Q

To validate the translated version of the Limb-Q, we employed a comprehensive methodology that mirrors the validation process of the original instrument, while also addressing the unique challenges of cross-cultural adaptation. Cronbach's alpha was used to measure internal consistency of 13 of the domains. Domains specific to amputation only were not assessed because of the low number of patients with amputations included (4 patients only). Internal consistency based on Cronbach's alpha was classified as followed: excellent ($\alpha \geq 0.9$), good ($0.9 > \alpha \geq 0.8$), acceptable ($0.8 > \alpha \geq 0.7$), questionable ($0.7 > \alpha \geq 0.6$), or poor ($0.6 > \alpha \geq 0.5$). Test-retest reliability was assessed by calculating the intraclass correlation coefficient (ICC). Values above 0.70 were considered acceptable. To interpret the magnitude of the within-subjects variation of between the score on the 2 test occasions, we calculated the standard error of measurement (SEM) with the following formula: $SEM = SD_{12}\sqrt{1-ICC}$, where SD_{12} was the average standard deviation of the 2 ratings. To evaluate clinically important changes, we calculated the smallest real difference (SRD) with the following formula: $SRD = 1.96 \times SEM \times \sqrt{2}$.[13]

For comparison between the LIMB-Q, LEFS, and SF-36 the Pearson correlation coefficient was determined. Values of less than 0.40 were considered to be weak, values of 0.40 to 0.74 were considered to be moderate, values of 0.75 to 0.90 were considered to be strong, and values of greater than 0.90 were considered to be very strong. If the P value was <0.05, correlation was considered to be significant. In order to analyze construct validity, the following 10 hypotheses were raised. Considering all correlation coefficients for various domains of the SF-36 and the LIMB-Q as well as the overall score of the LEFS, significant correlation coefficients would occur for:

1. LIMB-Q "symptoms" and SF-36 "pain."
2. LIMB-Q "symptoms" and SF-36 "physical functioning."
3. LIMB-Q "function" and SF-36 "role limitations physical."
4. LIMB-Q "function" and SF-36 "physical functioning."
5. LIMB-Q "function" and SF-36 "social functioning."
6. LIMB-Q "psychological" and SF-36 "emotional well-being."
7. LIMB-Q Life Impact and SF-36 "social functioning."

On the other hand, we hypothesize a nonsignificant correlation for the following:

8. LIMB-Q "appearance" and LEFS.
9. LIMB-Q "appearance" and SF-36 "role limitations physical."
10. LIMB-Q "function" and SF-36 "emotional well-being."

Good construct validity was given if 75%–90% of the hypotheses were confirmed.

To analyze the impact of age, BMI, comorbidities and type of reconstruction on the LIMB-Q scales, we compared the Rasch score between the different patient groups.

For the statistical analysis International Business Machines Statistical Package for the Social Sciences (IBM SPSS), Version 22 (IBM Corporation, Armonk, NY) was used. Graphs were plotted in GraphPad Prism Version 7.04 (GraphPad, La Jolla, CA).

RESULTS

Patient Collective

A total of 60 patients completed the LIMB-Q questionnaire as well as the SF-36 and LEFS, comprising 11 women and 49 men. Among the study participants, 4 patients had undergone amputation at the lower limb level. All other patients received reconstructive limb savage surgery with free or pedicelled flaps. The mean age was 49 years, ranging from 18 to 79 years. These patients had undergone between 0 and 16 surgeries during their hospital stay for the affected limb. On average, 50 months had elapsed since the reconstructive surgery or amputation. The mean BMI of the patients was 25.5, which closely aligns with the average male BMI in Switzerland, as reported by the Federal Office of Public Health (Table 1). Each patient answered 20 items assessing the functional status related to lower extremity conditions within the LEFS, 36 questions across 8 health domains of the SF-36 and depending on they received reconstructive surgery with either 130 questions within 13 LIMB-Q scales or 156 questions within 15 LIMB-Q scales for patients with amputations. In total, patients after amputation surgery answered 212 questions while patients after reconstructive surgery answered a total of 186 questions.

Internal Consistency

The analysis of internal consistency, as shown in Table 2, revealed that Cronbach's alpha values for the scales ranged from 0.891

TABLE 1. Patient Demographics, LEFS Results, and Selected LIMB-Q Scale Results

	Min	Max	Mean	Std. Deviation
N = 60 (11 ♀)				
Age (yrs)	18	79	48.63	15.723
No. prior surgeries	0	16	4.40	3.310
Time since surgery (m)	0	151	50.50	38.968
BMI (kg/m²)	17	41	25.53	4.252
LEFS	9	80	59.83	15.924
LIMB-Q				
Life impact	26	100	69.60	21.573
Psych. impact	0	100	79.78	22.151
Function	0	100	66.62	20.933
Symptoms	0	100	68.13	16.555

to 0.965. The internal consistency for 12 scales exceeded 0.9, categorizing them as excellent. Two scales—specifically 'financial impact' and decision'—had alpha values above 0.8, which classified them as good.

Test-Retest Reliability

Based on 5 participants, they completed the LIMB-Q at 2 different occasions with an interval of 3–5 days (Table 2). The ICC was good for appearance reconstruction, sexual and health care professionals, and even excellent for the remaining scales. For the work scale, the ICC of 0.611 was identified. The answers within the different scores showed a variability (SEM) between 0 and 0.186. The SRD ranged from 0 to 1.34 for questions within the separate domains

Construct Validity

The correlations between the domains of the LIMB-Q and the corresponding domains of the SF-36 and LEFS were significant, as illustrated in Table 3. This finding confirmed all the hypotheses regarding the anticipated significant correlations between the assessed domains. Furthermore, we observed no significant correlation between the LIMB-Q domain concerning appearance and the LEFS, as well as the SF-36's role limitation due to physical health subscale. Similarly, no correlation was found between the LIMB-Q function domain and the SF-36's emotional well-being domain, aligning with our initial hypotheses. The construct validity of the LIMB-Q was therefore considered excellent, given the confirmation of all hypotheses.

DISCUSSION

When it comes to limb threatening lower extremity injuries, it has not yet been established if attempted limb salvage or amputation results in better function, satisfaction, or QOL for the patient.[14] Additionally, in limb reconstruction opinions about specific indications, like the selection of the flap or graft to be used, or the timing of definite reconstruction differ in many cases, and clear evidence is scarce.[15] A multitude of different outcome measurements is currently used in lower extremity reconstruction. So far, no consensus has been reached on what to measure and how.[3] The newly developed LIMB-Q aims to address this evaluation gap as a patient-reported outcome measure. The well-established translation process allowed the development of the German LIMB-Q, which is conceptually equivalent to the original English version. Cross-cultural differences in perception and reporting of health outcomes following lower extremity trauma between US and German populations are an important consideration in PROM validation.[8] While both cultures share many similarities as Western, industrialized nations, there may be subtle differences in how patients perceive and report their experiences.[9] For instance, cultural attitudes toward disability, expectations for recovery, and the impact on social and professional life may vary. German healthcare system's structure, with its universal coverage, might influence patient expectations and satisfaction differently compared to the US system.[16] Additionally, cultural norms regarding pain expression and the importance placed on mobility in daily life could affect how patients from each population respond to LIMB-Q items.[17] Our validation process aimed to capture these potential differences and ensure that the German version of LIMB-Q accurately reflects the experiences and priorities of German-speaking patients while maintaining comparability with the original version. This study provides a comprehensive validation of the German version of the LIMB-Q.

Internal consistency reflects the extent to which items within an instrument measure various aspects of the same characteristic or construct.[18] In all LIMB-Q scales, it was considered as good to excellent. Similar results have been demonstrated for the original English version of the LIMB-Q on 713 patients.[5] The reliability of the LIMB-Q was good to excellent for all scales. As healing and functional recovery after lower extremity trauma are a generally time consuming process of several months, readministering a PROM within 1 week should lead to the same results, provided it is reliable.[19] This could be demonstrated in our sample.

Criterion validity of the LIMB-Q could not be determined as it would require comparison with a gold standard reference questionnaire for patients with lower extremity reconstruction which does not exist. Instead, we assessed construct validity that proved to be good. In line

TABLE 2. Pearson Correlation Coefficient for Various LIMB-Q Domains and SF-36 Scores as Well as Lower Extremity Functioning Scale

	LIMB-Q Scales				
SF-36 Domain	**Appearance**	**Physical Function**	**Symptoms**	**Life Impact**	**Psychological**
Physical functioning	0.287*	0.706†	0.261*	0.598†	0.467†
Role limitations physical	0.131	0.438†	0.307*	0.518†	0.365†
Pain	0.444†	0.458†	0.446†	0.527†	0.481†
General health	0.273*	0.295*	0.262*	0.416†	0.304*
Emotional well-being	0.362†	0.216	0.192	0.380†	0.343†
Role limitations emotional	0.203	0.143	0.243	0.261*	0.261*
Vitality	0.279*	0.264*	0.219	0.459†	0.327*
Social functioning	0.379†	0.291*	0.378†	0.472†	0.505†
LEFS	0.123	0.666†	0.409†	0.498†	0.498†

*Correlation is significant at the 0.05 level (2-tailed).

†Correlation is significant at the 0.01 level (2-tailed).

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with the previous literature, we chose the SF-36 and LEFS to analyze convergent validity and divergent validity.[20] The SF-36 is a valid and reliable generic PROM that has been extensively studied in patients with lower extremity conditions.[21,22] The LIMB-Q domains on symptoms, function, and psychological correlated significantly with the corresponding SF-36 domains. In contrast, we found no correlation with the LIMB-Q domain on appearance. This is not surprising, as neither the SF-36 domains nor the LEFS includes questions on the appearance of the limb like the shape of the reconstructed limb or how different it looks. Considering that many young patients are affected by lower extremity trauma, this domain is of utmost importance and fundamental when assessing QOL in that patient population. Of course, trauma to the lower extremity will interfere with activities of daily living. The LEFS is a widely established and well-validated self-reported disability score that allows patients to rate difficulties and interferences with daily life due to an impaired function of the lower extremity.[23] Hence, it allowed us to specifically compare and correlate the LEFS score with the LIMB-Q domain on function. Indeed, we could confirm a significant correlation between both scores, which strengthens the validity of the LIMB-Q to assess limb function.

Severe lower limb injuries are significantly associated with considerable psychological distress. Data suggest that up to a third of patients suffering from severe lower extremity injuries may develop posttraumatic stress disorder.[24] While the functionality of a limb, to a certain degree, can be quantified, these measurements do not necessarily capture the full scope of patients' complaints and impairments. Thus, prioritizing both the mental and physical well-being of patients who have experienced limb-threatening injuries is essential for facilitating the best possible recovery from such traumatic events.[25] The LIMB-Q "Psychological" Scale demonstrates a correlation with the well-established, though not disease-specific, SF-36 "Emotional Well-Being" scale. By doing so, it addresses a critical gap, offering a more comprehensive understanding of the impact of lower extremity trauma on patients.

The LIMB-Q was developed with input from patients, ensuring that the concepts most important to those who have sustained lower extremity injuries were identified and utilized to create the scales.[4] Consequently, the LIMB-Q scales are capable of measuring outcomes that are common across all patients following lower extremity trauma, as well as outcomes specific to cohorts undergoing limb salvage and amputation. In the realm of lower extremity reconstruction, the most commonly used PROM is the LEFS. A significant correlation between several LIMB-Q scales and the LEFS was demonstrated in our cohort. Although the broad applicability of the LEFS is a strength, its generic nature means that it may not adequately capture specific deficits or issues related to particular lower extremity reconstruction or amputation cases. The LIMB-Q addresses this gap effectively.

This study has several limitations. Notably, it experienced attrition bias, as not all individuals who received reconstructive surgery to the lower limb in our department and were contacted were willing to be enrolled in the current form of follow-up assessments. This differential loss to follow-up could potentially introduce bias into the study's outcomes, as participants who returned for follow-up may systematically differ from those who did not. Additionally, 3 subscales of the LIMB-Q could not be assessed, specifically those intended for patients who have undergone lower limb amputation, because only 4 patients with amputations were included in this study. Therefore, no conclusions about the validity of these specific subscales can be drawn. The test-retest reliability was only assessed in a subset of 5 patients, which could theoretically introduce bias. However, this cohort presented a diverse group with an age range from 20 to 73 years, including both males and females, and patients with recent reconstructions as well as reconstructions that occurred over 2 years ago. This diversity leads us to believe that we assessed test-retest reliability on a representative subset.

CONCLUSIONS

The German version of the LIMB-Q Module is conceptually equivalent to the original English version and provides clinicians and researchers with a rigorously developed PROM for patients with lower extremity reconstruction or amputation. In comparison with existing PROMS for lower extremity impairment the LIMB-Q is unique in terms of the range of patients concerns and impairments which are covered by its 16 domains. Our study provides further evidence that the LIMB-Q is a valid PROM to capture QOL and disease-related symptoms after surgical treatment.

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