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RESEARCH ARTICLE

RELIABILITY AND VALIDITY OF THE TURKISH VERSION OF THE COMPREHENSIVE LOWER LIMB AMPUTEE SOCKET SURVEY

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ABSTRACT

Purpose: The aim of this study was to translate the Comprehensive Lower Limb Amputee Socket Survey (CLASS) into Turkish and examine its reliability and validity in lower limb amputees.
Materials and Methods: This cross-sectional study included 97 lower limb amputees. Cronbach's alpha coefficient was used to evaluate internal consistency, and intraclass correlation coefficient was used to evaluate test-retest reliability. The retest of the CLASS was applied one week later. The satisfaction with the prosthesis subscale of the Trinity Amputation and Prosthesis Experience Scale (TAPES) was used to assess convergent validity.
Results: The mean age of the participants was 46.78±15.04 years and 71.1 % were male. Internal consistency was found to be high for all domains of the Turkish CLASS (Cronbach's alpha ranged from 0.81 to 0.90). Test-retest reliability was found to be high (intraclass correlation coefficient ranged from 0.82-0.95). A significant relationship was found between all domains of the CLASS and TAPES prosthesis satisfaction subscale (r=0.553 for stability domain, r=0.509 for suspension domain, r=0.482 for comfort domain, r= 0.444 for appearance domain, p<0.001).
Conclusion: The results of this study showed that the Turkish version of the CLASS is a reliable and valid tool for assessing user's perception about socket fit in lower limb prosthesis users.

Keywords: Prostheses, surveys, socket fit, amputee, reliability, validity

INTRODUCTION

In individuals with lower extremity amputation, walking ability is affected due to the loss of part of the locomotor system. Prosthetic rehabilitation is required to restore mobility and functional restoration (1, 2). In the rehabilitation process, prosthesis satisfaction plays an important role in the functional use of the prosthesis. Socket features must be suitable for fit, which is one of the most important factors affecting prosthesis satisfaction (3). The socket is very important as it is the part of the prosthesis that comes into contact with the user. The socket is the part where the prosthesis comes into contact with the residual limb and body weight is transferred to the prosthesis through the socket (4). Transmission of movements in the residual limb to other prosthetic elements is also achieved through the socket (5). Socket fit is the most considerable factor affecting rehabilitation for both clinicians and amputees (6, 7). In individuals with lower extremity

amputation, a safe and comfortable socket provides stable transfer of the load from the residual limb to the prosthesis, increasing functionality in daily living activities (8). If the socket is not a good fit, ulcers may occur on the residual limb due to localized pressure and shear stresses. These conditions complicate the use of prosthesis, and have a negative effect on mobility and daily activities (9).

The design, manufacture, and implementation of the socket is a time-consuming process for both the user and the prosthetist, and may require multiple service visits for individuals with amputations (8, 10). Socket-related evaluations are of great importance to ensure socket fit in the shortest time and most effectively. An initially well fitting socket can become incompatible over time due to volume changes in the residual limb, which can lead to skin-related discomfort and gait disturbances (11). Therefore, socket-related evaluations should be carried out at regular intervals. There are many techniques that for the biomechanical evaluation of socket fit (10, 12, 13). However, it is also necessary to evaluate the feedback of the prosthesis user about the socket. Patient-reported outcome measures are of great importance in ensuring patient-centred clinical management, evaluating the effectiveness of clinical interventions from the patient's perspective, and improving health care quality (14).

Various socket designs and suspension systems are currently available for individuals with lower extremity amputation (5, 15-17). User experiences should be evaluated to make it easier for clinicians to make decisions about prosthetic parts (18). There are various scales evaluating prosthesis satisfaction in Turkey (19, 20). However, since the socket is in contact with the residual limb and is the most important part for the comfort of the prosthesis, it should be evaluated in detail. The pressure distribution between the residual limb and the socket may vary during stair climbing and walking activities (21). Therefore, querying the socket-related parameters during different activities provides more accurate results. The Comprehensive Lower Limb Amputee Socket Survey (CLASS) is an easy and quick patient reported outcome measurement for the evaluation of the stability, suspension, comfort and appearance of the prosthetic socket during different activities (22). The purpose of the current study was to examine the reliability and validity of the Turkish version of CLASS.

MATERIAL AND METHODS

Study Design and Ethical Approval

This prospective cross-sectional screening study was conducted in a Prosthesis-Orthosis Service in Ankara between June 2021 and December 2022. The study was approved by Ethics Committee of Ankara Yıldırım Beyazıt University, in accordance with the Declaration of Helsinki (Decision Date: 14.06.2021, No: 68).

Translation and cultural adaptation

Translation was carried out in accordance with the Patient Reported Outcomes Measures principles of translation and cultural adaptation (23). Translation permission was received from the CLASS developers by the project manager in December 2020. After obtaining translation permission, the necessary Ethics Committee permission was obtained to start the study. Two forward translations were made by two native Turkish speaker translators living in Turkey who are experienced in translation in the field of health. The translators were informed about lower extremity prostheses, sockets and the purpose of the study. The forward translations were checked for inconsistencies, and discrepancies were resolved by consensus. Reconciliation decisions were reviewed by the project manager. Two back translations were then made by two native English speaker translators who are experienced in translation in the field of health. The back translations were compared with the original version and reviewed for inconsistencies, and again discrepancies were resolved by consensus. All the translations were compared with each other and with the original version. Conceptual equivalence between source and target language was achieved. In the original version of the CLASS, statements about stability, suspension, comfort, and appearance are written once, and the activities of sit, stand, walk, ascending and descending stairs are listed at the bottom (My socket is comfortable when I "…"). In the Turkish version, it was decided that it could not be understood because "…" is at the beginning of the sentence, and it was decided to repeat the phrase for each activity. (My socket is comfortable when I sit, My socket is comfortable when I stand etc.) The obtained translation was applied to 12 lower extremity prosthesis users who were Turkish native speakers and its comprehensibility was evaluated. All the prosthesis users stated that the questionnaire items were comprehensible and clear. The project manager

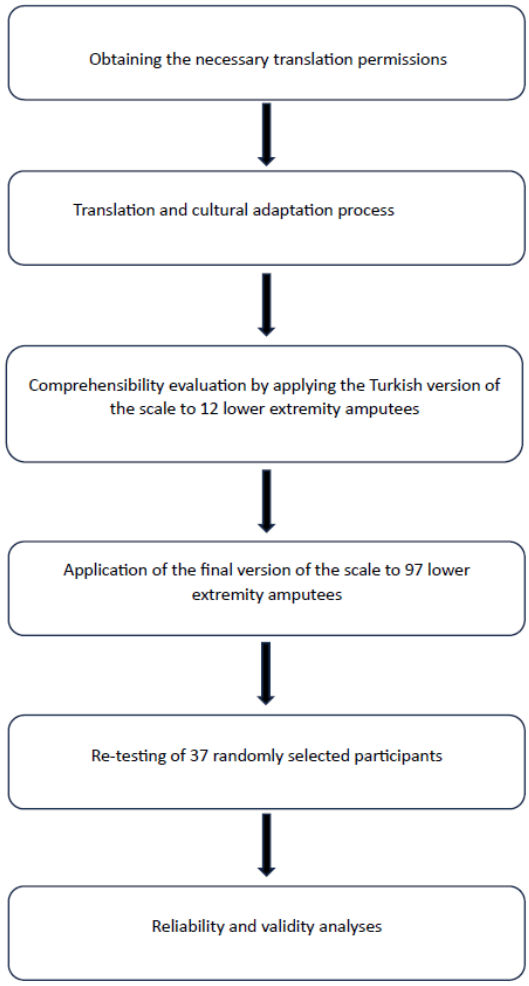

Figure 1. Flow Chart of the study

reviewed the results of the cognitive debriefing, and no changes were required at this stage. Proofreading was performed to correct minor errors before the translated questionnaire was used among the target population.

Participants

Criterion sampling method was used in the study. The study included individuals aged ≥18 years, who had unilateral lower extremity amputation, had been using their current prosthesis for at least 3 months, and were literate in Turkish. The informed consent was obtained from volunteers. After applying the Turkish version of CLASS, the retest was applied one week later to 37 randomly selected participants.

Outcome measures

The demographic and prosthesis-related information of the individuals was questioned and recorded. The CLASS and the satisfaction with the prosthesis subscale of the Trinity Amputation and Prosthetic Experience Scale (TAPES) were applied after questioning age, gender, level of amputation, reason for amputation, duration of prosthesis use, Medicare Functional Classification Level (24).

CLASS is an easy and quick self-report questionnaire that assesses the stability, suspension, comfort, and appearance of the prosthetic socket in lower extremity prosthesis users. It includes a total of 15 items; 12 items evaluating stability, suspension and comfort in sitting, standing, walking and stair climbing activities, and 3 items evaluating appearance during sitting, standing and wearing tight trousers. The questionnaire is scored using a 4-point Likert-type scale of 1= strongly disagree, 2= Disagree, 3= Agree, 4= Strongly agree. The percentage system equivalent of each subscale score and the total score were calculated. A high score indicates high socket satisfaction (22).

The TAPES satisfaction with the prosthesis subscale was used to assess criterion-based validity. This subscale includes 10 items scored with a 5-point Likert-type scale. A high score indicates high prosthesis satisfaction (20). The TAPES satisfaction with the prosthesis subscale was selected because prosthesis satisfaction is related to socket fit and this scale was previously used as a validation measure in the Persian version of CLASS (25).

Statistical Analysis

The obtained data were analyzed using IBM SPSS 25.0 for Windows software (SPSS Inc., Chicago, IL, USA). Internal consistency for homogeneity and test-retest reliability for reprodubility were analyzed. Internal consistency was assessed using the Cronbach's alpha coefficient, with values >0.80 considered as high internal consistency (26). The intraclass correlation coefficient (ICC) was used for test-retest reliability, with values >0.75 accepted as good reliability (27). Item-total correlation coefficient was used to evaluate the contribution of each item to the total subcale score (28). The item-total correlation coefficient is expected to be >0.25 (29). If more than 15% of the participants obtained the minimum score, the floor effect was considered to be present, and if more than 15% of the participants obtained the maximum score, the ceiling effect was considered to be present (30).

Convergent construct validity was evaluated by using the correlation between the TAPES satisfaction with the prosthesis subscale and the CLASS domains.

Table 1. Demographic and clinical features of the study population

		Mean	Standart deviation
Age (years)		46.78	15.04
Time since first prosthesis use (years)		17.25	15.06
Daily prosthesis use time (hours)		12.7	3.74
		n	**%**
Gender	Female	28	28.9
	Male	69	71.1
Cause of amputation	Trauma	63	64.9
	Vascular	14	14.4
	Congenital	6	6.2
	Other reasons	14	14.4
Amputation level	Transtibial	55	56.7
	Knee disarticulation	6	6.2
	Transfemoral	36	37.1
Activity level	K2	29	29.9
	K3	63	64.9
	K4	5	5.2

Spearman's correlation coefficient (r) was calculated to determine convergent construct validity. The correlation coefficients were considered as strong (r>0.76), good (0.51<r<0.75), moderate (0.26<r<0.50) and poor (r<0.25) correlation (31).

RESULTS

Evaluation was made of 97 lower extremity amputees. Of the individuals with transtibial amputation, 69.1% used the vacuum system, 7.3% the suction system, 16.4% the pin and lock system, and 7.3% other suspension systems. Of the individuals with knee disarticulation, 33.3% used the vacuum system, 33.3% the suction system, and 33.3% the soft insert mechanism. Of the individuals with transfemoral amputation, 19.4% used the vacuum system, 47.2% the suction system, and 33.3% the pin and lock system. The demographic characteristics of the participants and information about the amputations are presented in Table 1.

It was seen that the lowest score in the CLASS stability, suspension and comfort domains was obtained from the ascending or descending stairs item. In the Appearance domain, the lowest score was seen in the item related to wearing tight trousers. The item statistics are shown in Table 2.

The lowest score among the CLASS subscales was obtained from the appearance subscale. Cronbach's alpha was >0.80 in all the subscales, and the ICC was >0.80 in all the subscales. No floor effect was observed in any of the CLASS subscales, and the ceiling effect was observed only in the suspension subscale (Table 3).

The TAPES satisfaction with the prosthesis subscale was completed by 96.9% of the study participants. The total score of the TAPES satisfaction with the prosthesis subscale was mean 37.87±6.35 points (minimum:20, maximum:50). A statistically significant, positive correlation was found between the satisfaction with the prosthesis subscale and the CLASS stability subcale (r=0.553, p<0.001), suspension subscale (r=0.509, p<0.001), comfort subscale (r=0.482, p<0.001), and appearance subscale (r=0.444, p<0.001).

DISCUSSION

The aim of the current study was to translate the CLASS into Turkish, to adapt it cross-culturally, and to examine its psychometric properties for individuals with unilateral lower extremity amputation. The results of the current study demonstrated that the internal consistency and test-retest reliability Turkish

Table 2. Item statistics of domains of the CLASS

Items of the stability domain	Mean	Standart Deviation	Item-total correlation
Sit	3.11	0.71	0.656
Stand	3.11	0.69	0.794
Walk	3.03	0.68	0.782
Ascend or descent stairs	2.91	0.70	0.780
Items of the suspension domain			
Sit	3.20	0.67	0.661
Stand	3.18	0.66	0.800
Walk	3.07	0.73	0.859
Ascend or descent stairs	2.94	0.74	0.793
Items of the comfort domain			
Sit	3.03	0.74	0.575
Stand	3.14	0.59	0.764
Walk	3.06	0.65	0.779
Ascend or descent stairs	2.88	0.64	0.646
Items of the appearance domain			
Sit	2.75	0.82	0.731
Stand	2.98	0.74	0.709
Wear tight pants	2.45	0.90	0.578

version of CLASS was good. A moderate to good correlation was found between the Turkish CLASS domains and the TAPES satisfaction with the prosthesis subscale in the criterion-based validity analysis.

This study included unilateral lower extremity amputees with different demographic characteristics and clinical features. This increases the generalizability of the results of the study and shows that the psychometric properties of the Turkish CLASS are suitable for use in individuals with unilateral lower extremity amputations with different characteristics.

Various scales are used in Turkey to evaluate prosthesis satisfaction (19, 20). Although there are items related to socket fit in these scales, it is not possible to obtain a detailed assessment of the socket (3). Since the socket is the part where the prosthesis comes into contact with the user, it should be evaluated holistically during different activities. With the use of CLASS, the prosthesis users can better express their socket-related problems and it becomes easier for the prosthetist to resolve the problem. Since satisfaction with use is related to ambulation ability, and socket fit is an important factor affecting saticfaction with use, evaluation of socket fit is also important in terms of increasing functionality (3, 32).

It was determined that the lowest score in the comfort, suspension and stability subscales was obtained from the item related to stairs. The ascent and descent of stairs is an activity where intra-socket pressure is increased compared to walking on a flat surface (21). Therefore, low CLASS scores for ascending and descending stairs is an expected result. However, it has been shown that different interface systems have different effects on interface pressure when climbing and descending stairs (33). The evaluation of socket fit during different activities with CLASS can guide prosthesis prescribing. The score obtained from the Appearance subscale was found to be lower than the other subscale scores. In previous evaluations of prosthesis satisfaction in lower extremity amputees, the satisfaction scores regarding the appearance of the prosthesis have been reported to be low (3). The current study also showed that the satisfaction with socket appearance scores were the lowest of the socket-related parameters. This issue should be

Table 3. Reliability indicators of domains of the CLASS

Domains of the CLASS	Mean (SD)	Median	Range	Cronbach's Alpha	ICC (95% CI)	% with floor effect	% with ceiling effect
Stability	76.09 (15.09)	75	25-100	0.886	0.951 (0.907-0.974)	1	14.4
Suspension	77.57 (15.48)	75	25-100	0.900	0.871 (0.764-0.931)	1	18.6
Comfort	75.77 (13.68)	75	25-100	0.846	0.832 (0.700-0.910)	1	11.3
Appearance	68.29 (17.66)	66.66	25-100	0.815	0.825 (0.687-0.906)	4.1	8.2

SD: Standart Deviation, ICC: Intraclass Correlation Coefficient, CI: Confidence Interval

considered in new socket and prosthesis designs in order to increase user satisfaction.

The internal consistency of the CLASS subscales was found to be good. This result confirmed that the CLASS items were interrelated and consistent. The Cronbach's alpha coefficient ranged from 0.85 to 0.92 in the original version and 0.86-0.92 for the Persian version of the CLASS (22, 25). The value obtained in the current study is close to these values. The item-total score correlations show that the predictive utility of CLASS items is as strong as those of the original version (22). The test-retest reliability of the Turkish version of CLASS was found to be higher than the Persian version of CLASS for the stability and suspension subscales. For the comfort and appearance subscales, the ICC values were lower than those of the Persian version (25). The ICC value >0.80 obtained in all the subscales indicates high reproducibility.

No floor effect was found for any subscale in the Turkish version of CLASS, and the ceiling effect was seen only for the suspension subscale. Similarly in the Persian version of CLASS, there was no floor effect and the ceiling effect was found only in the suspension subscale (16.1%) (25). This could be attributed to the fact that the suspension systems used by the participants are up-to-date and advanced systems.

A moderate to good correlation was found between the TAPES satisfaction with the prosthesis subscale, which is also used in the Persian version for convergent validity, and the CLASS Turkish version. This result is similar to the results of Rouhani et al. The TAPES satisfaction with the prosthesis subscale is a general measure of prosthesis satisfaction (25). It contains items that may be related to the socket fit, such as the fit and comfort of the prosthesis, but since it does not provide a direct assessment of the socket, the moderate to good correlation is an expected result.

This study presents important results from examination of the reliability and validity of the Turkish CLASS. However, that the study was conducted in a single centre can be considered a limitation. The service where the study was conducted is located in the capital city of Turkey and is a preferred centre for prosthesis application by many individuals with lower extremity amputations residing in different cities. However, it is a private centre where high-tech prostheses are applied. It can be recommended that in future studies, the psychometric properties of the Turkish CLASS can be evaluated in amputees who apply to different centres. Additionally, it is a limitation that only certain psychometric properties were examined in the study. Further analyzes should be included in future studies.

Study Limitation

In this study, limitation that only certain psychometric properties were examined in the study. Further analyzes should be included in future studies..

CONCLUSION

The Turkish CLASS is a reliable and valid survey that can be used to evaluate socket fit in individuals using unilateral lower extremity prosthesis. The use of the Turkish version of CLASS may be useful for both evaluating the socket, which is the prosthesis component that lower extremity amputees have the most problems with, and for measuring the effectiveness of interventions.

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Conflict of interests: The authors hereby declare that there was no conflict of interest in conducting this research.

Ethical approval: The study was approved by the Ethics Committee of Ankara Yıldırım Beyazıt University, in accordance with the Declaration of Helsinki (Decision Date: 14.06.2021, No: 68).

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