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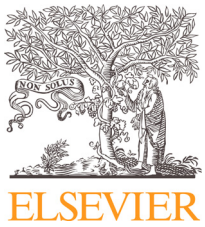
2022-05

Ketola , H , Kask , G , Barner-Rasmussen , I , Tukiainen , E , Blomqvist , C , Laitinen , M K , Kautiainen , H , Kiiski , J & Repo , J P 2022 , ' Measuring functional outcome in upper extremity soft-tissue sarcoma : Validation of the Toronto extremity salvage score and the QuickDASH patient-reported outcome instruments ' , Journal of Plastic, Reconstructive & Aesthetic Surgery , vol. 75 , no. 5 , pp. 1543-1550 . https://doi.org/10.1016/j.bjps.2021.11.081

http://hdl.handle.net/10138/346381
https://doi.org/10.1016/j.bjps.2021.11.081

Journal of Plastic, Reconstructive & Aesthetic Surgery 75 (2022) 1543–1550



JPRAS
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Measuring functional outcome in upper extremity soft-tissue sarcoma: Validation of the Toronto extremity salvage score and the QuickDASH patient-reported outcome instruments

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Received 14 March 2021; accepted 12 November 2021

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https://doi.org/10.1016/j.bjps.2021.11.081

KEYWORDS
Sarcoma;
Soft-tissue sarcoma;
Outcome measures;
Validation;
Patient reported outcome measures

summary Interest in functional outcome (FO) and health-related quality of life (HRQL) in extremity soft-tissue sarcoma (STS) patients has increased. The aim of this study was to validate two FO questionnaires for upper extremity STS patients: the Toronto Extremity Salvage Score (TESS) and short version of the Disability of Arm, Shoulder and Hand (QuickDASH), based on Finnish population data.

A multi-center study was conducted at two academic sarcoma centers. Surgically treated upper extremity STS patients were invited to participate. Patients completed the TESS and the QuickDASH with HRQL questionnaires the 15D and the QLQ-C30. The scores were analyzed and compared.

Fifty-five patients with a mean follow-up period of 4.7 years were included. Mean age was 63 years (standard deviation [SD] 14.6). The mean score for TESS was 88.5 (SD 15.1) and for QuickDASH 17.8 (SD 19.6). The QuickDASH had a statistically significantly better score coverage. A ceiling effect was noted, 27% and 20% for TESS and QuickDASH, respectively. The TESS and QuickDASH scores were strongly correlated (r= -0.89). The TESS score strongly correlated with the QLQ-C30 ($r = 0.79$) and the 15D score ($r = 0.70$). The QuickDASH score correlated strongly with the QLQ-C30 score (r=-0.71) and moderately with the 15D score (r= -0.56). The TESS score had a statistically significantly stronger correlation with the 15D score than QuickDASH ($p<0.005$).

Both the TESS and the QuickDASH provide reliable scores for assessing FO in upper extremity STS patients. The QuickDASH has a better coverage, whereas TESS showed a stronger correlation to HRQL scores.

Introduction

Soft-tissue sarcomas (STS) are rare mesenchymal malignant soft-tissue tumors, representing approximately 1% of all solid malignant tumors in adults.[1,2] STS can occur almost at any anatomical site, the most common sites being the limbs.[3] About 20% of STS present in upper extremities.[4] Age-adjusted incidence for STS in Finland is approximately 4.25 cases per 100,000 person-years with 243 new STS cases annually (ICD-10 codes C47-C49).[5]

Treatment of STS involves surgical excision with reconstructive surgery when required, frequently combined with radiotherapy, and in select cases with chemotherapy.[6-8] As no difference has been found between limb-salvage surgery and amputation in terms of survival or local recurrence, limb-salvage surgery is considered the gold standard of treatment for limb sarcoma.[9,10] Furthermore, limb-salvage surgery preserves more function than amputation.[10] The importance of FO in the treatment has been increasingly recognized.[6] Furthermore, evidence-based medical practice has increased interest in measuring FOs.[11]

Several methods have been described for assessing FO, including performance outcome measurements, clinician-reported outcome instruments, and patient-reported outcome (PRO) instruments.[12] In recent years, the use of PRO instruments as part of the clinical outcome assessment has increased.[13]

The Toronto Extremity Salvage Score (TESS) is the most widely adopted PRO instrument for outcome assessment after treatment of extremity STS.[12] No studies have yet focused on validating the TESS solely for upper extremity STS patients, as previous publications have used a mixed population of upper and lower extremity STS patients.[14], only the lower extremity patients.[15] or a combination of STS and bone sarcoma patients.[9]

Several other PRO instruments, such as the Disabilities of Arm, Shoulder and Hand (DASH) and its shorter version QuickDASH, are also used for upper extremity functional measurement.[16] The QuickDASH has previously been adapted to measure STS patients' postoperative clinical outcomes.[17] Thus far, the TESS has been the preferred option for a PRO instrument for upper extremity sarcoma patients.[18] Both PRO instruments have been translated and validated in Finnish.[19-23]

The aim of this study is to validate the Finnish translations of the TESS and the QuickDASH for upper extremity sarcoma patients by comparing them to physical scores of two health-related quality of life (HRQL) PRO instruments; and to evaluate how the TESS and the QuickDASH reflect HRQL aspect of these patients.

Methods

Study design

The protocol for this study was approved by the Ethics Committee of the Helsinki and Uusimaa Hospital District, Finland (permit no: 324/13/03/02/2014).

Patients were identified from hospital databases of two academic sarcoma centers, Helsinki University Hospital and

Tampere University Hospital. International Classification of Diseases, 10th revision (ICD-10, WHO) and applicable codes from the Nomesco Classification of Surgical Procedures (NCSP) (Finnish version) were used. The patients were recruited in a cross-sectional study out of all the patients operated on by the Helsinki and Tampere sarcoma teams and were still being on follow-up in 2017.

Inclusion criteria were as follows: limb sparing surgery, freedom from relapse and follow-up for at least 6 months, age at least 18 years, surgical treatment of upper extremity STS, and fluency in Finnish language. For this study, upper extremity STS was defined as a tumor located in the region measured from the scapula to the fingers.

Demographic, clinical, surgical, and oncological data were obtained retrospectively, whereas functional and HRQoL outcome data were collected prospectively.

The patients were invited to participate by mail, and the data was collected during follow-up visits or using a postal survey. The Finnish versions of TESS, the QuickDASH, the QLQ-C30 and the 15D were completed. Participation in the study was confirmed by filling in forms and providing a signed informed consent form.

Demographics, clinical, surgical, and oncological data were obtained retrospectively from patient records. Classification of tumor depth was based on the anatomical structures as follows: subcutaneous, intracompartmental (subfascial, contained in one anatomic compartment) and extracompartmental (exceeds the confines of the original compartment). Tumors were categorized by location as proximal (from the scapula to the elbow joint) or distal (distal of the elbow joint).

This study report was performed based on STROBE guidelines.[24] The study design and reporting of results adhered to the COnsensus-based Standards for the selection of health status Measurement INstruments (COSMIN) guidelines.[25]

PRO instruments

TESS

The TESS is a PRO instrument used to assess FO from the patient's point of view.[18] TESS has been translated and cross-culturally adapted into Finnish for both upper and lower extremities and tested in a pilot study in lower extremity patients as well validated for lower extremity STS patients.[15,19,20] It is extremity-specific and measures physical disability in daily activities. The TESS questionnaire has both upper and lower extremity versions. In this study, we used the upper extremity version of the TESS instrument. Twenty-nine items are rated on a scale from one to five, with five representing normal activity. The result ranges from 0 to 100, with 100 being the best score.

QuickDASH

The DASH is an upper-limb-specific PRO instrument that has been validated among patients with various hand and upper limb complaints.[16,26] The instrument was developed to assess patients' disability and performance. The DASH is one of the most widespread and best-tested PRO instruments to measure upper extremity function and has undergone a translation and cultural adaption as well as testing of its construct and structural validity in the Finnish version.[21-23] The QuickDASH is a shorter version of the original instrument.[27] The QuickDASH can be used instead of the DASH with similar precision.[28] The original DASH has 30 items, QuickDASH 11 items. These items are divided in two sections: function and symptoms (e.g. pain) and are measured on a scale from one to five, with one representing no symptoms or difficulty. The result ranges from 0 (no disability) to 100 (most severe disability).

EORTC QLQ-C30

The European organisation for Research and Treatment of Cancer (EORTC) QLQ-C30 questionnaire is a PRO instrument designed for assessing HRQL in cancer patients.[29] The questionnaire contains 30 questions. In this study, 22 of these questions were used to measure cancer-related functional impairment and complaints as well as impairment in perceived quality of life. These 22 items form nine multi-item scales representing different dimensions of HRQL: one global scale; five functional scales (physical, role, emotional, cognitive and social); and three symptom scales (fatigue, pain and nausea). We did not use the Nausea and vomiting, Dyspnea, Insomnia, Appetite loss, Constipation, Diarrhea, Financial difficulties as they would assumably not reflect level of physical function. Each item is scored on a scale from 0 to 100. High scores in global and functional scales indicate good QoL, but in symptom scales indicate more symptoms hence lower QoL. Questions are combined in scales according to predefined rules.

15D instrument

The 15D is a generic HRQL PRO instrument. The questionnaire covers 15 dimensions of health: mobility, vision, hearing, breathing, sleeping, eating, speech, excretion, usual activities, mental function, discomfort and symptoms, depression, distress, vitality and sexual activity. Each dimension has five levels, describing the patient's health state at that moment. A general HRQL score is calculated from the results of all 15 dimensions using a formula provided by the authors of the instrument. The index score varies between 0 representing the worst imaginable HRQL and 1 representing the best.[30]

Statistical analysis

The demographic and clinical data are presented as means with standard deviation (SD) and 95% confidence intervals (CIs) or as counts with percentages. The distribution of TESS and QuickDASH scores was assessed. To assess scale targeting (the extent to which the range of the variable measured by the instrument matches the range of that variable in the study population), floor and ceiling effects were examined. The ceiling effect describes a situation where a percentage of the subjects obtain the maximum score, or the best possible outcome. A floor effect is the opposite situation, i.e., subjects receive the minimum score, or the worst possible outcome. A floor or ceiling effect was considered confirmed if more than 15% of the patients received maximum or minimum scores, respectively.

Convergent validity refers to how closely the instrument is related to other variables and other measures of the same

Table 1 Correlation hypotheses and a summary of structural validity tests of TESS and QuickDASH in surgically treated upper limb STS patients.

	TESS	C/R	QuickDASH	C/R
QLQ-C30				
Global health status	Moderate	C	Moderate	C
Functional scales:				
Physical	Strong	C	Strong	C
Role	Strong	C	Strong	C
Emotional	Moderate	R	Moderate	R
Cognitive	Weak	C	Weak	C
Social	Weak	C	Weak	C
Symptom scales:				
Fatigue	Weak	R	Weak	R
Pain	Moderate	C	Moderate	C
15D	Strong	C	Strong	C
TESS	-		Strong	C
QuickDASH	Strong	C	-	

C= hypothesis confirmed, R=hypothesis rejected.

construct. Ideally, the instrument should correlate with similar measures and not correlate with dissimilar ones. Based on the COSMIN guidelines, correlation hypotheses for the tested instruments were created prior to analyzing the data (Table 1). Convergent validity can be considered adequate if >75% of the correlation hypotheses are confirmed.[31] The convergent validity was evaluated by examining the correlation between the TESS and the QuickDASH scores, the general HRQL 15D index score and the physical function, symptom and global health scales of QLQ-C30. The Spearman correlation coefficients between the instruments were calculated. To evaluate the measurement invariance the associations of TESS and QuickDASH scores with sex, age and body mass index (BMI) were examined. For age and BMI, the correlation was assessed using Spearman correlation coefficients. For the difference between men and women, an independent samples *t*-test was used. The strength of the Spearman correlation coefficients was interpreted as follows: 0.00–0.30 negligible, 0.30–0.50 weak, 0.50–0.70 moderate, 0.70–0.90 strong and 0.90–1.00 very strong correlation.[32]

Internal consistency was assessed using Cronbach α for both PRO instruments. An α value of 0.7 was used as a cut-off point, with values above it representing acceptable internal consistency.[33] The difference in score coverage between DASH and TESS was tested by comparing the mean TESS-score and inverted DASH-score with the paired *t*-test and the difference in variances by a likelihood-ratio (LR) test of equality of variances, allowing for unequal means and correlation between the two variables according to IBM instructions.[34] The inverted DASH-scale was calculated as 100-DASH, converting DASH into a similar scale as TESS with 100 representing the best possible value and 0 the worst.

Statistical analyses were conducted using STATA statistical software and IBM Statistical Package for the Social Sciences (SPSS) software program, version 25.0.

Table 2 Demographic and clinical characteristics among surgically treated upper limb STS patients ($n = 55$).

	$n = 55$
Female, n (%)	28 (50.9)
Male, n (%)	27 (49.1)
Age, years, mean (SD)	62.8 (14.6)
Tumor status (%)	
Primary	51 (92.7)
Recurrent	4 (7.3)
Tumor location, n (%)	
Proximal	36 (65.5)
Distal	19 (34.5)
Sarcoma subtype, n (%)	
Leiomyosarcoma	13 (23.6)
Undifferentiated pleomorphic sarcoma	12 (21.8)
Fibrosarcoma/myxofibrosarcoma	11 (20.0)
Liposarcoma	10 (18.2)
Malignant peripheral nerve sheath tumor	2 (3.6)
Other	7 (12.7)
Tumor size, mean (SD), cm	5.8 (5,3)
Tumor grade, n	
Low	26 (47.3)
High	29 (52.7)
Tumor depth, n	
Subcutaneous	25 (45.5)
Intracompartmental	12 (21.8)
Extracompartmental	18 (32.7)
Wound closure, n (%)	
Direct closure	26 (47.3)
Flap reconstruction	18 (32.7)
Skin graft	11 (20.0)
Chemotherapy, n (%)	10 (18.2)
Radiotherapy, n (%)	
Preoperative	2 (3.6)
Postoperative	17 (30.9)
Complications, n (%)	
None	49 (89.1)
Surgical complications	
Loss of skin graft	1 (1.8)
Wound infection, conservative treatment	1 (1.8)
Local revision	1 (1.8)
Pulmonary embolism	1 (1.8)
N/A	2 (3.6)
Follow-up after surgery, months, mean (SD)	56.9 (39.6)

Results

Sociodemographic and clinical details are presented in Table 2 Of 64 patients were invited to participate in the study, 55 patients (85%) participated, completing both the TESS and the QuickDASH questionnaires. Twenty of these patients were recruited in Tampere University Hospital and 35 in Helsinki University Hospital. Mean scores for the PROMs and HRQL instruments are presented in Table 3. The distribution of the TESS total scores was relatively strongly skewed towards higher scores (Figure 1), indicating lower disability. The mean difference in TESS and the inverted QuickDASH scores was 6.22 ($p<0.001$). The variance for QuickDASH was 383.084 and for the TESS 226.909. The dif-

Table 3 Mean scores of PROM and HRQL instruments among surgically treated upper limb STS patients ($n = 55$).

	N	Mean	Std. Deviation
QLQ-C30	55		
Physical functioning		81.6	20.5
Global health status		75.3	18.6
Role functioning		83.6	23.2
Emotional functioning		90.6	12.3
Cognitive functioning		92.1	11.0
Social functioning		95.5	10.4
Fatigue		18.6	16.7
Pain		17.6	22.6
15D	55	0.884	0.101
Mobility		0.886	0.195
Vision		0.911	0.162
Hearing		0.921	0.150
Breathing		0.898	0.183
Sleeping		0.852	0.169
Eating		0.981	0.811
Speech		0.973	0.086
Excretion		0.859	0.195
Usual activities		0.813	0.218
Mental function		0.896	0.164
Discomfort/symptoms		0.776	0.212
Depression		0.906	0.147
Distress		0.902	0.158
Vitality		0.861	0.161
Sexual activity		0.832	0.288
TESS score	55	88.5	15.1
QuickDASH score	55	17.8	19.6

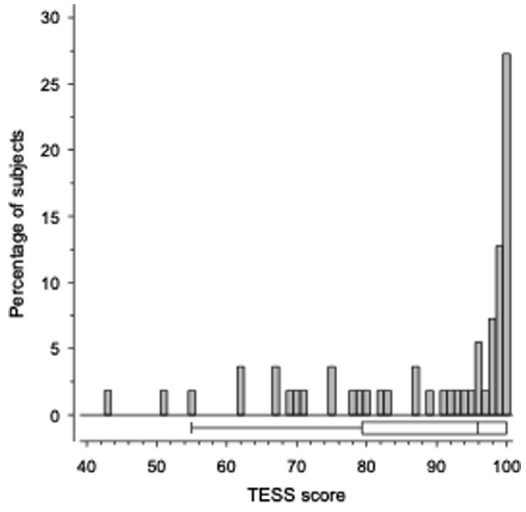

Figure 1 Distribution of TESS scores among surgically treated upper limb STS patients ($n = 55$).

ference in variance was statistically significant ($p<0.001$). This indicates that the QuickDASH had a better score coverage.

No floor effect for either PROM was detected, as no subjects scored the worst possible scores. A ceiling effect was present, with 27% and 20% achieving best possible score for TESS and QuickDASH, respectively.

Scores of the TESS and the QuickDASH were linearly correlated (Figure 3). The correlation of these two instruments was strong ($r= -0.89$, 95% CI -0.93 to -0.81). TESS showed strong correlation with the QLQ-C30 Physical Function scale ($r = 0.79$ 95% CI 0.67 to 0.87, $p<0.001$) as well as with the 15D ($r = 0.70$, 95% CI 0.53 to 0.81), and a moderate correlation with the QLQ-C30 global health scale ($r = 0.52$, 95% CI 0.29 to 0.69, $p<0.001$) (Table 4 and Figure 4). The QuickDASH had a strong correlation with the QLQ-C30 Physical Function scale ($r=-0.71$ 95% CI -0.82 to -0.55, $p<0.001$) and moderate correlation with the 15D ($r= -0.56$, 95% CI -0.72 to -0.35) (Table 4 and Figure 4). Both PRO instruments showed moderate correlation with QLQ-C30 pain and fatigue scales. The correlations of these two PRO instruments to the emotional, cognitive and social scales of QLQ-C30 and 15D were weak and not statistically significant. The correlation of the 15D mobility index was 0.463 ($p<0.001$) and -0.372 ($p = 0.005$) with the TESS and the QuickDASH, respectively.

Eight out of ten of correlation hypotheses were confirmed, confirming the convergent validity of both PRO instruments as adequate. A summary of the structural validation test results for DASH and TESS is shown in Table 1.

The difference between the correlations of TESS and the reverse DASH score with the QLQ-C30 Physical Function scale and the general 15D index were calculated. For the QLQ-C30 Physical Function scale, there was a difference of borderline statistically significance in correlation between TESS and QuickDASH, as difference in rho was 0.0800 (95% CI -0.0019 to 0.35, $p = 0.05$). A statistically significant difference was found between correlations with 15D as difference in rho was 0.14 (95% CI 0.073 to 0.38, $p<0.005$).

Cronbach α was 0.970 and 0.930 for TESS and QuickDASH, respectively, indicating an adequate internal consistency.

Spearman correlation coefficients for BMI and age with both instruments were calculated, and were found negligible (Table 5). The difference in TESS and QuickDASH scores between men and women was found to be insignificant ($p = 0.981$).

Discussion

The results of this study indicate that both the TESS and the QuickDASH provide reliable results for measuring FO of surgically treated upper extremity STS patients. The TESS had a higher cumulation of high scores than the QuickDASH, and the QuickDASH had statistically significantly better scale coverage. These findings may indicate that the QuickDASH might be more sensitive to measure the FO of the present patient group than the TESS. The scores of the TESS and the QuickDASH strongly correlated with each other. TESS has a statistically significantly stronger correlation with 15D general index than the QuickDASH, and a nonsignificantly stronger correlation with QLQ-C30 physical function scale. These findings would indicate that both instruments are able to detect FO, reflecting HRQL, the TESS slightly better than the QuickDASH. Both instruments seem to have a moderate correlation with QLQ-C30 pain and fatigue items, indicating better physical function correlating with less pain and fatigue. Both PRO instruments showed a statistically significant but weak correlation with the 15D mobility index. How-

Table 4 Spearman correlations of QLQ-C30 with TESS and QuickDASH among surgically treated upper limb STS patients ($n = 55$).

QLQ-C30	TESS[#] r (95% CI)	DASH[&] r (95% CI)
Global health status[#]	0.52 (0.29 to 0.69)***	−0.47 (−0.65 to −0.23)**
Functional scales[#]:		
Physical	0.79 (0.67 to 0.87)***	−0.71 (−0.82 to −0.55)***
Role	0.82 (0.71 to 0.89)***	−0.76 (−0.85 to −0.62)***
Emotional	0.32 (0.05 to 0.54)	−0.32 (−0.54 to −0.06)
Cognitive	0.42 (0.17 to 0.62)*	−0.36 (−0.57 to −0.10)
Social	0.34 (0.09 to 0.56)	−0.37 (−0.58 to −0.12)*
Symptom scales*:		
Fatigue	−0.57 (−0.73 to −0.36)***	0.60 (0.40 to 0.75)***
Pain	−0.65 (−0.78 to −0.46)***	0.69 (0.52 to 0.81)***

* $p<0.05$.
** $p<0.01$.
*** $p<0.001$; statistical significance calculated using Sidak adjusted probabilities.
[#] Higher values indicate better function.
[&] Lower values indicate better function* Lower values indicate less symptoms.

Table 5 Spearman correlations of PRO instruments with age and body mass index (BMI) among surgically treated upper limb STS patients ($n = 55$).

	Age	BMI
TESS	−0.17 ($p = 0.22$)	−0.09 ($p = 0.53$)
QuickDASH	0.03 ($p = 0.82$)	−0.01 ($p = 0.92$)

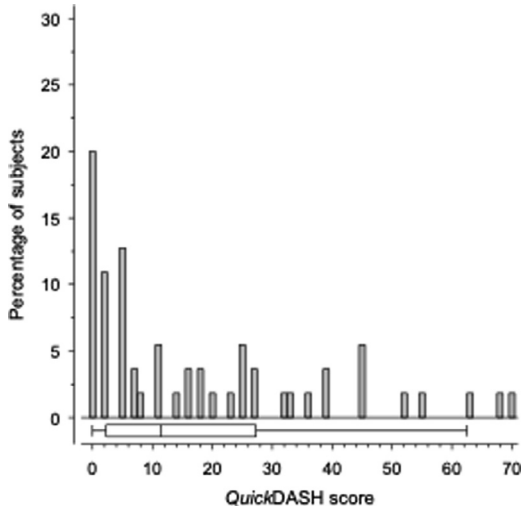

Figure 2 Distribution of QuickDASH scores among surgically treated upper limb STS patients ($n = 55$).

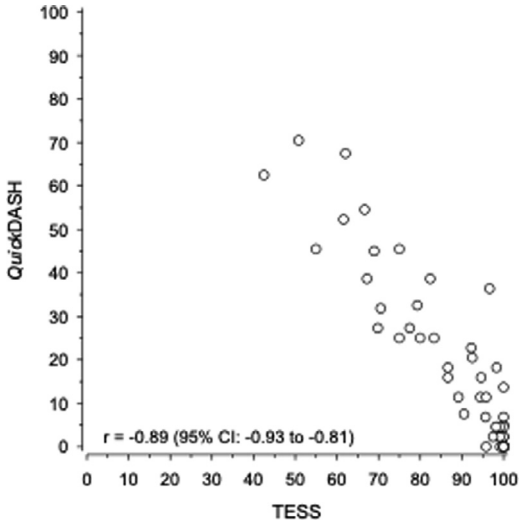

Figure 3 Spearman correlation of TESS and QuickDASH among surgically treated upper limb STS patients ($n = 55$).

ever, it is worth noting that the 15D measures functional restrictions as a whole, which puts more emphasis on lower extremities.

Figure 2

Convergent validity was assessed by calculating the correlation for the two PRO instruments TESS and the QuickDASH with each other and with the 15D and the QLQ-C30 instruments. Both exceeded the threshold of <75% of confirmed hypotheses indicating a strong convergent validity for the instruments.[31] Not only did the TESS and QuickDASH have correlating results with each other, both correlated also with 15D general index and QLQ-C30 global health and physical function scales. The strong correlation of TESS and QLQ-C30 results has been previously reported, as well as a correlation with other HRQL measures.[35] In recent studies assessing the construct validity of the QuickDASH, it was found to correlate with patients' capability and HRQL.[23,36] These findings supports our study findings, as the strongest correlations were noted with physical function, role and global health status items. As these are both PROMs that assess patient-reported physical outcome and function, it is logical that no correlation was found with social or cognitive scales.

Our mean TESS score of 88.5 is in line with previous studies of limb-salvage surgery results in the studies of limb sarcoma patients (mean TESS score 85).[37] and conservative reconstruction and radiotherapy for extremity STS patients (mean TESS score 98.2).[14] In this study, a ceiling effect was

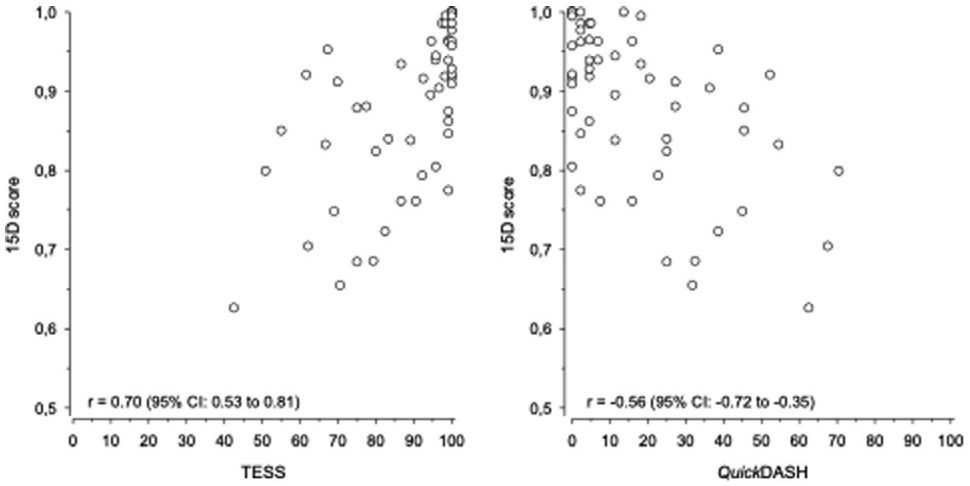

Figure 4 Spearman correlation of 15D with TESS and QuickDASH among surgically treated upper limb STS patients ($n = 55$).

noted for both PROMs. For the TESS, this has been noted in previous studies as well.[38] This may show a problem of construct or face validity; however, one potential explanation for the ceiling effect is that significant portion of the STS patients, even after treatment, does not suffer from impaired limb function.

The main strength of this study is a large multicenter patient sample focused exclusively on upper extremity STS patients. Recent validation study of the TESS studied populations of 98 bone and soft-tissue tumor patients.[38] TESS has also been validated in Japanese for patients with malignant musculoskeletal tumors in the upper extremities, with 53 patients.[39] The sample size and homogeneity of this study compares favorably with previous published scientific reports of validation of the TESS instrument.

The strength of this study was a multicenter study with relatively large sample of upper extremity STS patients. The study used the COSMIN checklist. According to this, the size of the patient group was sufficient for psychometric analyses with classical test theory and hypothesis testing.[25]

The findings of this study should be viewed in light of some limitations, including those inherent to its retrospective design. No data on preoperative FO was available due to the study design. This study was planned as a cross-sectional study, but future prospective study settings with at least two different time points could provide valuable data on the change in outcomes and responsiveness of the TESS and the QuickDASH in upper extremity soft-tissue sarcoma patients. This study focused on comparing the convergent validity of the TESS and the QuickDASH to physical scores of two HRQL instruments and how they reflect HRQL aspect in upper extremity soft-tissue sarcoma patients. Assessment of construct validity and scale attenuation have been conducted and provided in this study, but to receive full psychometric analyses of these questionnaires, further structural validity testing is recommended as well as testing of longitudinal validity of measurement error and responsiveness with different time points for obtaining the data.

Conclusion

This study can provide guidance in choosing suitable instruments for assessing postoperative function of upper limb STS patients. Both the TESS and the QuickDASH prove to have sufficient measurement properties to assess the FO of the upper limb STS patients. Despite the ceiling effects for TESS for QuickDASH, these instruments provide reliable information on postoperative FO and reflect accurately their HRQL after surgery.

Declaration of Competing Interest

The authors declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

Acknowledgements

The authors are grateful for financial support from the Musculoskeletal and Plastic Surgery Research Center Helsinki, Helsinki University Hospital and University of Helsinki, Finland. The authors thank Magnus Kjäldman for his contribution in the design of the study.

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