

# Validation of the Fatigue Severity Scale in Danish patients with systemic lupus erythematosus

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## ABSTRACT

**INTRODUCTION:** Fatigue is a symptom of systemic lupus erythematosus (SLE), which has a substantial effect on the patients' quality of life and is a parameter that is difficult to quantify. The Fatigue Severity Scale (FSS) is a validated and reliable tool for quantifying fatigue. However, no Danish translation has yet been developed or validated. The aim of this study was to translate the FSS from English into Danish and subsequently to test and describe its validity and reliability in Danish SLE patients.

**MATERIAL AND METHODS:** The FSS was translated from English into Danish and then back-translated. The translation agreed upon by medical professionals was tested for construct validity in an unselected group of SLE patients. The final version was tested for content validity, internal consistency and test-retest reliability in a second unselected group of SLE patients using the Danish version of the Short-Form Health Survey (SF-36). All patients included were outpatients with SLE of low to moderate disease activity, and low to moderate organ damage.

**RESULTS:** Correlations were found between the Danish FSS and the main component scores of the SF-36. We found a high Cronbach's alpha as well as acceptable results of the intraclass correlation coefficient and the Bland-Altman plot.

**CONCLUSION:** The Danish FSS translation is a valid and reliable measure of fatigue in the Danish SLE patients included in this study.

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**TRIAL REGISTRATION:** not relevant.

Systemic lupus erythematosus (SLE) is a chronic autoimmune systemic disease characterised by a wide variety of clinical manifestations and an unpredictable course with flares and remissions [1]. Fatigue is a symptom often associated with inflammatory diseases and is caused by multiple factors, including disease activity, medical treatment and comorbid conditions such as depression and fibromyalgia [2]. Fatigue has a high prevalence among SLE patients (67-90%) and can be one of the most dominating symptoms, limiting the daily activity of many patients [2, 3]. The patients' self-assessed health-

related quality of life as measured by e.g. the Medical Outcomes Study Short Form-36 Health Survey (SF-36) is affected negatively by fatigue [2].

Fatigue is difficult to quantify; although frequent, it is subjective and heterogeneous; however, several methods have been developed for quantification, and an international ad hoc committee has recommended the use of validated instruments [4]. For English-speaking SLE patients, the Fatigue Severity Scale (FSS) has been validated and found reliable [5]. The FSS consists of a form with nine items concerning fatigue symptoms; each item is rated from one to seven. A higher score indicates a higher level of fatigue. The FSS has been translated and validated in several languages including Swedish – however, to our knowledge, not yet in Danish [6-8].

Fatigue correlates poorly with disease activity as measured by the Systemic Lupus Erythematosus Disease Activity Index (SLEDAI) [9, 10], but well with the SF-36, a survey for self-reporting mental and physical health regardless of disease type widely used in autoimmune diseases [11]. Based on internationally developed and validated questions in eight different domains or subscales (physical functioning, vitality, bodily pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning, and mental health), a quantitative measurement of the patient's health is made. The SF-36 can be summarized in two main domains, a Physical Component Summary (PCS) and a Mental Component Summary (MCS) as well as a total score. The scale spans from 0 to 100, higher scores representing better health.

The goal of this study was to translate the FSS into Danish and subsequently to test and describe the validity and reliability of the FSS in a sample of Danish SLE outpatients.

## MATERIAL AND METHODS

### Translation

The original FSS was translated into Danish by two physicians knowledgeable in both English and Danish. Subsequently, a back-translation into English was performed by two Danes knowledgeable in English. The translations were discussed with a medical expert on SLE and a Danish consensus version was agreed upon. The original

## ORIGINAL ARTICLE

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 TABLE 1

Patient characteristics for the cohort group.

Patient sex, men/women, n	8/43
Patient age, mean (range), yrs	49.1 (19-80)
Patient age at diagnosis, mean (range), yrs	36.6 (13-79)
Disease duration, mean (range), yrs	12.5 (0.0-41.8)
SLICC, mean (range)	2.1 (0-11)
SLEDAI, mean (range)	3.6 (0-12)

SLEDAI = Systemic Lupus Erythematosus Disease Activity Index.

SLICC = Systemic Lupus International Collaborating Clinics/American College of Rheumatology Damage Index.

 TABLE 2

The Danish translation of the Fatigue Severity Scale (FSS).

FSS	Translation
1 My motivation is lower, when I am fatigued	Min motivation er lavere, når jeg er træt
2 Exercise brings on my fatigue	Motion gør mig træt
3 I am easily fatigued	Jeg bliver let træt
4 Fatigue interferes with my physical functioning	Træthed begrænser min fysiske formåen
5 Fatigue causes frequent problems for me	Træthed skaber tit problemer for mig
6 My fatigue prevents sustained physical functioning	Træthed forhindrer længerevarende fysisk aktivitet
7 Fatigue interferes with carrying out certain duties and responsibilities	Træthed påvirker min evne til at udføre visse pligter og ansvar
8 Fatigue is among my 3 most disabling symptoms	Træthed er af mine 3 mest funktionsindskrænkende symptomer
9 Fatigue interferes with my work, family, or social life	Træthed påvirker mit arbejde, familieliv og fritid

English FSS questionnaire was compared with the Danish translation and the two were deemed to be linguistically and conceptually in correlation with one another.

### Patients

The initial study to assess content validity included five Danish SLE outpatients evaluated at the Department of Rheumatology, Glostrup Hospital, Denmark. The patients evaluated the comprehensibility of the initial Danish FSS translation during qualitative interviews. A few linguistic changes were made and the final edition of the Danish FSS was subsequently developed.

The evaluation of construct validity, reliability and validity was performed with 60 SLE patients from a population-based cohort followed at Odense University Hospital, Denmark [12]. A Danish FSS questionnaire (FSS-1) was handed out along with a SF-36 questionnaire for immediate completion in an ambulatory setting where also Systemic Lupus International Collaborating Clinics/American College of Rheumatology Damage Index (SLICC) [9] and SLEDAI scores were obtained by a

rheumatologist. Before leaving, an envelope with an additional Danish FSS questionnaire (FSS-2) was given to the patient who then completed it at home and returned it by mail within one week.

All patients included were diagnosed with SLE by experienced rheumatologists and fulfilled four or more classification criteria from the American College of Rheumatology [13]. All patients had low to moderate disease activity and low to moderate disease damage as assessed with the SLEDAI and the SLICC by a rheumatologist.

Informed consent was obtained from all participating patients.

### Statistical methods

Testing for content validity of the Danish FSS questionnaire was done through qualitative interviews on the first Danish translation and the Danish FSS was finalised based on this.

Reliability was tested by internal consistency using Cronbach's alpha, where a value over 0.70 is satisfactory, while a value above 0.90 is regarded as clinically applicable [14, 15]. Test-retest reliability was done by analysing the Danish FSS questionnaires completed by patients on two occasions (FSS-1 and FSS-2) using the intraclass correlation coefficient (ICC), where a value above 0.70 is an acceptable level of reliability [15]. A Bland-Altman plot (difference plot of spread by test-retest) [14] was made as well.

Testing for construct validity was done using Spearman's rank correlation coefficient ( $r_s$ ) to describe correlations between the Danish FSS and the SF-36 main components, the SLICC and the SLEDAI scores. A value of  $r_s \leq 0.25$  signifies little or no correlation, 0.26-0.49 low correlation, 0.50-0.69 moderate correlation, 0.70-0.89 high correlation, while a value of 0.90-1.0 signifies very high correlation.

Statistical analysis was done using SPSS (Statistical Package for the Social Sciences) version 19.0.

It was hypothesized that the translated FSS would display correlation with both SF-36 subscales, but not with the SLEDAI, the SLICC, age or disease duration.

*Trial registration:* not relevant.

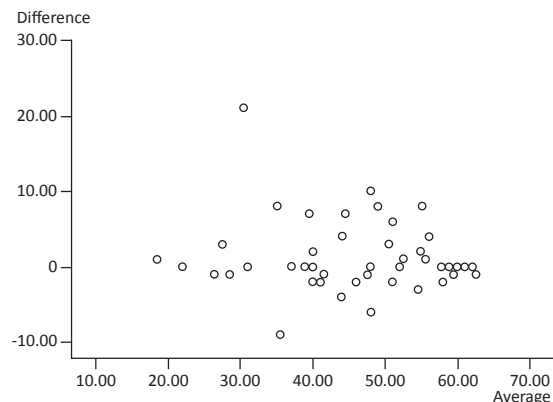
### RESULTS

In total, 65 patients participated, five in our content validity-group and 60 in the validation group (see **Table 1**). Answer percentage in our cohort group was high, 85%. Nine patients were excluded due to lack of completed questions in the FSS (1 and 2) or the SF-36. Thus, in total 51 answers from our cohort group were complete and useable.

Content validity was ensured by qualitative inter-


**FIGURE 1**

Test-retest reliability (Bland-Altman plot) of the Danish Fatigue Severity Scale (FSS) translation (FSS-1 and FSS-2).



views consistently agreeing on validity (data not presented here). A few sentences were rephrased and a final Danish FSS was complete (**Table 2**).

Internal consistency reliability using Cronbach's alpha was 0.96, and corrected item-to-total correlation was 0.92. Test-retest reliability using ICC was 0.92, while the Bland-Altman plot (**Figure 1**) showed a bias of 1.12 (95% confidence interval: -0.16-2.40).

A significant correlation was found between the FSS-1 and the SF-36 main component scores PCS and MCS (Spearman's rank correlation coefficient,  $r_s = -0.65$  and  $-0.47$ , both  $p < 0.01$ ). A correlation of FSS-1 was found with the SLEDAI ( $r_s = 0.344$ ,  $p = 0.014$ ), while none was found with the SLICC, age and disease duration (**Table 3**).

## DISCUSSION

This study reports how the FSS was translated from English into Danish, and subsequently tested for reliability and validity with Danish SLE patients. Reliability was proven by a high Cronbach's alpha, acceptable results of the ICC and the Bland-Altman plot. These findings allow for multiple testing with the Danish translation of the FSS in Danish SLE patients.

There was a high level of correlation between the Danish FSS translation (FSS-1) and the Danish SF-36 main component scores PCS and MCS, which confirms the construct validity and thus indicates that fatigue affects both the physical and mental ability of SLE patients. Correlations between the FSS and the SF-36 subscales have also been demonstrated by others [8, 16]. Thus, our findings demonstrate good convergent and divergent validity.

A significant, but low correlation was found between the FSS and the SLEDAI, signifying that fatigue


**TABLE 3**

Correlations between the Danish FSS-1 and SF-36 (PCS, MCS), SLICC, SLEDAI, age and disease duration (n = 51).

Danish FSS-1	$r_s$	p-value
SLICC	0.252	0.074
SLEDAI	0.344	0.014
SF-36, PCS	-0.652	< 0.01
SF-36, MCS	-0.474	< 0.01
Patient age	0.060	0.68
Disease duration	0.018	0.90

FSS-1 = Fatigue Severity Scale 1;  $r_s$  = Spearman's rank correlation coefficient; SF-36, MCS = Medical Outcomes Study Short Form-36 Health Survey, Mental Component Summary; SF-36, PCS = Medical Outcomes Study Short Form-36 Health Survey, Physical Component Summary; SLEDAI = Systemic Lupus Erythematosus Disease Activity Index; SLICC = Systemic Lupus International Collaborating Clinics/American College of Rheumatology Damage Index.

somewhat correlates with disease activity in our patients. A Swedish study found a low correlation between the FSS and another disease activity measure, Systemic Lupus Activity Measure [9], but no association with the SLEDAI [8]. Others have also reported correlation between the FFS and the SLE activity scores [16, 17]. However, the literature regarding the relationship between disease activity and fatigue is divergent [2], and our finding is indicative of this. It is generally agreed upon that the FSS is not a measure of disease activity [10]; however, it seems plausible that both dimensions are affected by the patients' present SLE manifestations. A reason may be that variables associated with disease activity, such as depression and sleep quality, affect fatigue through an indirect causal pathway [2].

No correlation was found between the Danish FSS translation and the SLICC or disease duration, which is in line with other published studies [8, 16]. We did not find a correlation between the FSS and age – this correlation has been reported by some [18], but not by others [8, 16]. Our findings indicate that the FSS can be used in all adult age groups regardless of disease duration. However, we have not evaluated the FSS in a prospective study; therefore the ability to measure changes in fatigue over time, which is of relevance in daily clinical practice, needs further investigation.

A strength of our study is the cohort of well-defined outpatients included. A limitation is the relatively small sample size. Another limitation is the lack of measurements for factors known to contribute to fatigue, such as fibromyalgia and depression.

As the clinical picture of SLE is highly variable, European League Against Rheumatism (EULAR) recommends the use of assessed quality of life in routine clinical practice because this facilitates collection of relevant data that otherwise may be overlooked [19]. The Danish

Fatigue, a symptom of systemic lupus erythematosus, has a substantial effect on patient quality of life.



FSS presented here is valid for use in clinical practice. Until now, evaluation of fatigue is done based on the patient's history or VAS, while administration of questionnaires is yet withheld from routine practice due to concerns of feasibility [19]. Patient-reported assessments, like the FSS, may contribute to the necessary evaluation of overall health in SLE patients during daily clinical practice as well as clinical trials in the future [20].

## CONCLUSION

Our findings indicate that the Danish translation of the FSS is a reliable and valid measure of fatigue in patients with SLE with low to moderate disease activity and low to moderate organ damage. This self-reported dimension is important in the clinical surveillance of SLE patients because it offers the patient an opportunity to quantify and report a highly prevalent symptom of great importance to the patient's quality of life.

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