

## Erectile Dysfunction/Andrology

**The Treatment Satisfaction Scale: A Multidimensional Instrument for the Assessment of Treatment Satisfaction for Erectile Dysfunction Patients and Their Partners**

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**Abstract**

**Background:** The development of the Treatment Satisfaction Scale (TSS) was previously reported (Kubin et al., 2004).

**Objective:** This article describes the psychometric validation process and psychometric properties (e.g., reliability, validity, and responsiveness) of TSS.

**Methods:** Initial patient and partner questionnaires were administered in a multi-national clinical trial. On the basis of exploratory analyses, iterative psychometric testing, and consideration of face validity and interpretability, the number of items was reduced, and six scales were constructed: “Satisfaction with Medication,” “Ease with Erection,” “Satisfaction with Erectile Function,” “Pleasure from Sexual Activity,” “Satisfaction with Orgasm,” and either “Sexual Confidence” (for patients) or “Confidence in Completion” (for partners).

**Results:** Multi-item scales had good internal consistency reliability and concurrent validity with the IIEF. All patient scales and most partner scales were valid in relation to clinical criteria, and all tested scales were responsive to change over time.

**Conclusion:** The TSS is brief, culturally valid, and the most comprehensive multidimensional measure of satisfaction with ED treatment for patients and their partners, and addresses some of the shortcomings of existing measures.

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**Keywords:** Erectile dysfunction; Psychometric validation; Treatment satisfaction

**1. Introduction**

Erectile dysfunction (ED) is a common disorder defined as a chronic inability to attain and/or maintain

penile erection sufficient for satisfactory sexual performance [1]. Although the earliest instruments such as the IIEF [2], developed to assess ED focused only on its functional aspects [3], newer instruments of satisfaction also assess perceptual life domains (e.g., feelings of well-being and satisfaction) from the patient's perspective. To some degree, these newer instruments also consider the importance of measuring the effects of ED on the partners of ED patients.

*Abbreviations:* ED, Erectile Dysfunction; QoL, Quality of Life; TSS, Treatment Satisfaction Scale.

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Satisfaction instruments that assess patient and partner satisfaction with treatment include the Sexual Life Quality Questionnaires (SLQQ) and the Erectile Dysfunction Inventory of Treatment Satisfaction Questionnaire (EDITS) [4,5]. Limitations of these instruments include the limited number of dimensions assessed (the SLQQ has two dimensions and the EDITS has only one) may obscure or omit important aspects of the patient's experience with ED and the effects of medication. For example, the existing instruments do not address concepts of sexual pleasure and confidence. Furthermore, the item generation and the evaluation of the content validity of the EDITS questionnaire were based on opinions of several ED experts rather than self-reports from patients themselves.

ED outcomes assessment instruments should be multidimensional and address the concepts of sexual dysfunction-related quality of life (QoL), sexual functioning, symptoms, and treatment satisfaction [6]. Moreover, as recent studies recognize that women also suffer when their partner has ED, [7–9] the inclusion of partner assessment is gaining importance.

To address the shortcomings of existing measures, the Treatment Satisfaction Scale (TSS) was developed [10]. Details on the conceptual model and development of the TSS have been previously reported [10]. This article describes the psychometric validation process and psychometric properties of the TSS, including its scale structure, validity, reliability, and responsiveness.

## 2. Material and methods

### 2.1. Development of initial versions of the TSS

Four TSS modules (“unmedicated” and “medicated” modules for patients and partners) were developed using accepted item generation and cross-cultural validation methodologies including in-depth interviews with patients and partners, simultaneous item generation in 5 languages, and forward and back translation to ensure cross-cultural validity, followed by a cognitive debriefing in 15 additional languages.

The initial versions of the “unmedicated” modules for patients and partners (for use when patients are not receiving treatment) included 12 core items that addressed various aspects of sexual satisfaction, pleasure, and confidence.

The initial versions of the “medicated” modules (for use when patients are receiving treatment for ED) included the 12 core items from the “unmedicated” modules, plus seven additional items for patients and six additional items for partners asking about satisfaction with various aspects of the patient's ED medication.

### 2.2. Trial, subjects, and measures

The initial versions of the TSS modules were administered in a randomized clinical trial including 317 patients and 70 partners from nine European countries. Table 1 provides a brief description of the trial and the timing of the self-administered assessments. The two assessments used for the TSS validation were the baseline assessment (immediately prior to the start of treatment) and the first assessment during the treatment phase of the trial (week 12). These assessments will be referred to as “baseline” and “follow-up.”

### 2.3. Phase I: item reduction and determination of scale structure

Items were examined for a number of undesirable characteristics: low completion rate, overly skewed response distributions, poor correlations with ED severity and the IIEF Erectile Function domain [3], and poor responsiveness to change. To investigate item

**Table 1**

Study design and sample characteristics

Study design	
Treatments	Flexdose Vardenafil or placebo
Duration of study	16 weeks
Countries/languages	Austria, Germany, Switzerland, France, Greece, Italy, Netherlands, Spain, UK
Timing of relevant self-administered assessments	
Patient and partner TSS (initial versions)	Unmedicated TSS at baseline, medicated TSS at week 12
International index of erectile function (IIEF)	Baseline, week 12
Global assessment question (GAQ)	Week 12
Baseline sample characteristics	
Patients	
<i>N</i>	317
Mean age, yr (range)	53.9 (21–75)
Married	83.28%
ED severity	
Severe	38.85%
Moderate	34.39%
Mild/moderate	19.43%
Mild	6.69%
No ED*	0.64%
Partners	
<i>N</i>	70

\* When screened, all patients had ED. At baseline a small number of patients had IIEF-EF scores which fell into the “No ED” category under the ED severity staging system that was used [15].

**Table 2**

Final Structure of TSS Modules

Scale name	Patient and partner TSS scales		
	Abbrev.	Summary of item content	Number of items
In both unmedicated and medicated modules:			
Ease with erection	EE	Ease of obtaining erection	1
Satisfaction with erectile function	SE	Satisfaction with onset of erection	3
		Satisfaction with duration of erection	
		Satisfaction with hardness of erection	
Pleasure	PL	Pleasure from sexual activity	1
Satisfaction with orgasm	SO	Satisfaction with orgasm	1
Sexual confidence (Patient TSS only)	SC	Confidence in initiating sex	2
		Confidence in completing sexual activity	
Confidence in completion (Partner TSS only)	CC	Confidence in partner completing sexual activity	1
In medicated modules only:			
Satisfaction with medication	SM	Confident medication would work	5
		Satisfied how long medication helped	
		Degree medication met expectations	
		Overall satisfaction with medication	
		Would continue with medication	

clustering and potential domain structure, principal components analyses (PCAs) using varimax rotation were run on the items at baseline and follow-up.

Prototype versions of scales were constructed and an iterative process of item deletion, scale refinement, and testing was followed. The effects of scale composition changes on psychometric properties were evaluated by conducting multi-trait/multi-item analyses [11] and reexamining internal consistency reliability, concurrent validity, and responsiveness after each change (Appendix A).

#### 2.4. Final TSS structure and scoring

Based on the initial analyses, six items were removed. Four of these items were unique and did not correlate with other items to form a dimension, demonstrated poor concurrent validity with external measures, and exhibited extremely skewed response distributions. Two additional items were deleted that cross-loaded onto multiple factors.

The final TSS content and scale structure for all four modules is presented in Table 2. The TSS Medicated modules consist of 13 items (patient version) and 12 items (partner version) in six dimensions: “Satisfaction with Medication (SM),” “Ease with Erection (EE),” “Satisfaction with Erectile Function (SE),” “Pleasure from Sexual Activity (PL),” “Satisfaction with Orgasm (SO),” and either “Sexual Confidence (SC)” (for patients) or “Confidence in Completion (CC)” (for partners). Whereas, the TSS Unmedicated modules contain eight or seven items, patient and partner respectively. This structure was chosen based on face validity and interpretability considerations in conjunction with the psychometric testing results.

All items in the final TSS are worded positively so that higher-coded response categories are associated with positive outcomes (e.g., greater satisfaction or pleasure). Item responses are scored on a five-point Likert scale. TSS scale scores were computed by taking the mean of each scale’s item responses and converting the result (using a linear transformation) to a 0 to 100 scale, with 0 being the worst possible score and 100 being the best.

### 2.5. Phase II: psychometric evaluation

#### 2.5.1. Floor and ceiling effects

Floor and ceiling effects (proportion of subjects with the lowest and highest possible scores) were examined for each scale at baseline

and follow-up. Floor and ceiling effects were deemed satisfactory if less than 20% of respondents endorsed the lowest or highest possible score. For the TSS, a floor effect would be acceptable since patients should improve over time under treatment.

#### 2.5.2. Internal structure

The internal validity of the final patient and partner TSS scale structures was examined using multi-trait/multi-item analysis [11] at baseline and follow-up. Item convergent validity was confirmed if a high percentage of item correlations were above 0.40 with their own scale (adjusted for overlap) [12]. To evaluate item discriminant validity, the correlation of each item with its own scale (adjusted for overlap) was compared to its correlation with each of the other TSS and IIEF scales; in a high percentage of comparisons, items should have higher correlations with their own scale than with other scales.

#### 2.5.3. Reliability

Cronbach’s  $\alpha$  was used to measure the internal consistency reliability of multi-item TSS scales. Cronbach’s  $\alpha$  above 0.70 is the accepted standard for internally consistent multi-item scales intended for group-level analyses [13,14].

#### 2.5.4. Concurrent validity

Concurrent validity was evaluated by examining baseline and follow-up correlations with conceptually related IIEF domains. Patient TSS scales were correlated with the IIEF Erectile Function (EF), Intercourse Satisfaction (IS), and Overall Satisfaction (OS) domains. These domains were selected for their relevance to erectile function and sexual satisfaction. Partner TSS scales were evaluated versus IIEF EF domain. This dimension was chosen to capture the impact of patient erectile function on partners’ sexual experience. Concurrent validity was confirmed if correlations with relevant domains were statistically significant and in the expected direction.

#### 2.5.5. Clinical validity

Clinical validity of the core patient and partner TSS scales was evaluated by testing for differences in mean scores by severity level. At baseline, patients were classified into five ED severity

categories (“Severe,” “Moderate,” “Moderate/Mild,” “Mild,” and “No ED”) using a standard classification scheme based on their IIEF EF domain score [15]. Because of the small number of patients in the “No ED” category at baseline, this category was combined with “Mild ED.” One-way ANOVAs were then used to test for statistically significant differences between mean scores of patients across the four different levels of clinical severity.

At follow-up, a Global Assessment Question (GAQ) asked patients whether their erections had improved. Their responses were used to classify them as either responders (improved) or non-responders (not improved). The clinical validity of the patient and partner SM scales was evaluated at follow-up using one-way ANOVA to test their ability to discriminate between responders and non-responders. Responders were expected to report significantly higher satisfaction with treatment.

### 2.5.6. Responsiveness (sensitivity and specificity)

The responsiveness to change (sensitivity and specificity) of the core TSS scales was evaluated using *t*-tests to compare the mean baseline to follow-up change scores of the two GAQ groups to zero. For the responder group, a large positive change was expected on all scales, whereas little or no change was expected for the non-responder group. The responsiveness of TSS was compared with the change on the IIEF domains, and all mean change scores were converted to standardized effect sizes (SES). Because the patient and partner SM scales were assessed only at follow-up, their responsiveness could not be evaluated in the present trial. Typically, an effect size of 0.20 is considered small, 0.40–0.50 is considered medium, and 0.80 or more is considered large and clinically meaningful [16].

## 3. Results

### 3.1. Data quality

The mean percentage of TSS items completed by each patient was 98.7% at the baseline and was 87.5% at follow-up. The mean percentage of TSS items completed by each partner was 95% at baseline and 85.7% at follow-up.

### 3.2. Floor and ceiling effects

Moderate floor effects were found at baseline and were prominent for patient SE (40.0%), SO (31.3%), EE (29.4%), and SC (21.2%), as well as partner CC (37.9%), SO (26.2%), SE (25.4%), and EE (16.4%). At follow-up, the floor effects were dramatically reduced (percentages reduced by half or better for most scales). Overall, ceiling effects did not appear to be a significant problem.

### 3.3. Internal structure

#### 3.3.1. Item convergent and discriminant validity

Evidence of item convergent and discriminant validity was found for all multi-item scales. At baseline and follow-up, 100% of items in the patient SE, SC, and SM and partner SE and SM had correlations  $\geq 0.40$  with their own scale (adjusted for overlap).

**Table 3**

Internal consistency reliability (Cronbach's  $\alpha$ )

	Unmedicated (Baseline)	Medicated (Follow-up)
<b>Patient TSS</b>		
Sat. with erectile function	0.82	0.96
Sexual confidence	0.70	0.87
Sat. with medication	na	0.96
<b>Partner TSS</b>		
Sat. with erectile function	0.88	0.92
Sat. with medication	na	0.94

Item discriminant validity of multi-item patient and partner TSS scales was supported. In over 98% of comparisons at baseline, patient SE and SC scale items were more highly correlated with their own scale (adjusted for overlap) than with other patient TSS and IIEF scales. The partner SE scale items were more highly correlated with their own scale (adjusted for overlap) than with other patient TSS and IIEF scales. At follow-up, this percentage was 99% and 95% for the patient and partner SM scale, respectively.

### 3.4. Reliability

All multi-item scales (SE, SC, and SM) satisfied the minimum recommended level of internal consistency reliability of 0.70 (Cronbach's  $\alpha$ ) at baseline and follow-up. Cronbach's  $\alpha$  could not be calculated for single item scales (EE, PL, SO, and CC) (Table 3).

### 3.5. Concurrent validity

The correlations of the patient TSS scales with the IIEF EF, IS, and OS domains were significant ( $p < 0.05$ ) and generally of at least moderate magnitude ( $r \geq 0.38$ ) in the trial at both baseline and follow-up. Correlations at follow-up were generally higher than at baseline. The strongest relationship appeared to be between the IIEF EF domain and the patient TSS SE scale ( $r = 0.61$  at baseline and 0.88 at follow-up).

All correlations between the partner TSS scales and the IIEF EF domain were significant ( $p < 0.05$ ). However, these correlations are weaker overall than those observed for the patient TSS scales. The partner SE, EE, and SM scales appear to have stronger and more consistent correlations with the IIEF EF domain ( $r \geq 0.41$  in all cases) than do the partner CC, PL, and SO scales. Correlations are much stronger at follow-up than at baseline (Table 4).

### 3.6. Clinical validity

All unmedicated patient TSS scales were able to discriminate between the four ED severity groups ( $p < 0.0001$ ) at baseline. Furthermore, mean scores

**Table 4**Concurrent validity correlations of patient and partner TSS scales with IIEF EF, IS and OS domains at baseline and follow-up (Pearson  $r$ )

IIEF domain	Unmedicated patient TSS (Baseline)						Medicated patient TSS (Follow-up)					
	SE	SC	PL	EE	SO	SM	SE	SC	PL	EE	SO	SM
Erectile function	0.61	0.41	0.41	0.56	0.43	na	0.88	0.81	0.74	0.70	0.72	0.82
Intercourse satisfaction	0.52	0.38	0.46	0.43	0.42	na	0.80	0.75	0.76	0.63	0.72	0.78
Overall satisfaction	0.52	0.52	0.57	0.40	0.54	na	0.83	0.78	0.81	0.63	0.80	0.78
	Unmedicated partner TSS (Baseline)						Medicated partner TSS (Follow-up)					
	SE	CC	PL	EE	SO	SM	SE	CC	PL	EE	SO	SM
Erectile function	0.50	0.29	0.32	0.52	0.40	na	0.83	0.60	0.57	0.70	0.54	0.77

on each unmedicated patient TSS scale increased as ED severity decreased.

The partner SE and EE scales were also able to discriminate between the four ED severity groups at baseline ( $p \leq 0.0003$ ). The overall pattern of increasing mean scores with decreasing ED severity is clearly discernible. Results for the partner CC, PL, and SO scales at baseline were mixed and inconclusive.

At follow-up, both the patient and partner SM scales were able to discriminate between groups of responders and non-responders ( $p < 0.0001$ ). Mean scores on both SM scales were consistently higher for the responder group than the non-responder group (Table 5).

### 3.7. Responsiveness (sensitivity and specificity)

All patient and partner TSS scales were responsive (sensitive to change) for the responder group. For all TSS scales, mean improvement from baseline to follow-up for the responder group was significantly different from zero, and SES was large (Fig. 1). Mean change scores for the non-responder group were generally not significantly different from zero; however, a significant negative change was found on the partner CC scale.

For comparison purposes, the responsiveness of the IIEF domains was also tested. Significant improvement on all IIEF domains was observed for the responder group. For the non-responder group, change was not significantly different from zero with the exception of significant negative change on the IIEF Sexual Desire scale.

## 4. Discussion

Scores on the TSS appeared to be reliable and related to measures of clinical severity of erectile functioning. TSS patient and partner scales demonstrated validity based on responder analysis and excellent responsiveness to change over time, with favorable effect size values relative to the IIEF. Of the scales in the TSS, the SE patient and partner scales appear to be the best for measuring change between untreated and treated states.

The moderate to high concurrent correlations between the patient and partner SE scale and the IIEF Erectile Function domain indicate that although there is a strong relationship between satisfaction with

**Table 5**

Clinical validity: One-way ANOVAs comparing baseline mean domain TSS scores by ED severity groups and GAQ groups at follow-up

Mean baseline TSS scores by ED Severity	$p$ -Value	Patient				$p$ -Value	Partner				
		Severe	Moderate	Moderate/Mild	Mild & No ED		Severe	Moderate	Moderate/Mild	Mild & No ED	
Domain											
Ease of erection	$p < 0.0001$	14.29	33.64	45.08	54.35	$p = 0.0003$	25.00	51.14	47.06	70.00	
Sat. with medication	$p < 0.0001$	4.38	19.08	28.53	36.59	$p < 0.0001$	8.71	30.68	31.86	41.67	
Pleasure	$p < 0.0001$	24.58	45.05	49.58	53.26	$p = 0.0274$	32.14	47.73	51.47	45.00	
Sat. with orgasm	$p < 0.0001$	16.81	32.94	43.03	52.17	$p = 0.0014$	20.24	48.81	42.65	60.00	
Sexual confidence	$p < 0.0001$	16.07	30.84	37.08	38.59	$p = 0.1000$	15.91	34.09	31.25	30.00	
Mean follow-up TSS scores by GAQ response	$p$ -Value	Responders		Non-Responders		$p$ -Value	Responders		Non-Responders		
Domain											
Sat. with medication	$p < 0.0001$	66.85		13.01		$p < 0.0001$	64.41		12.19		

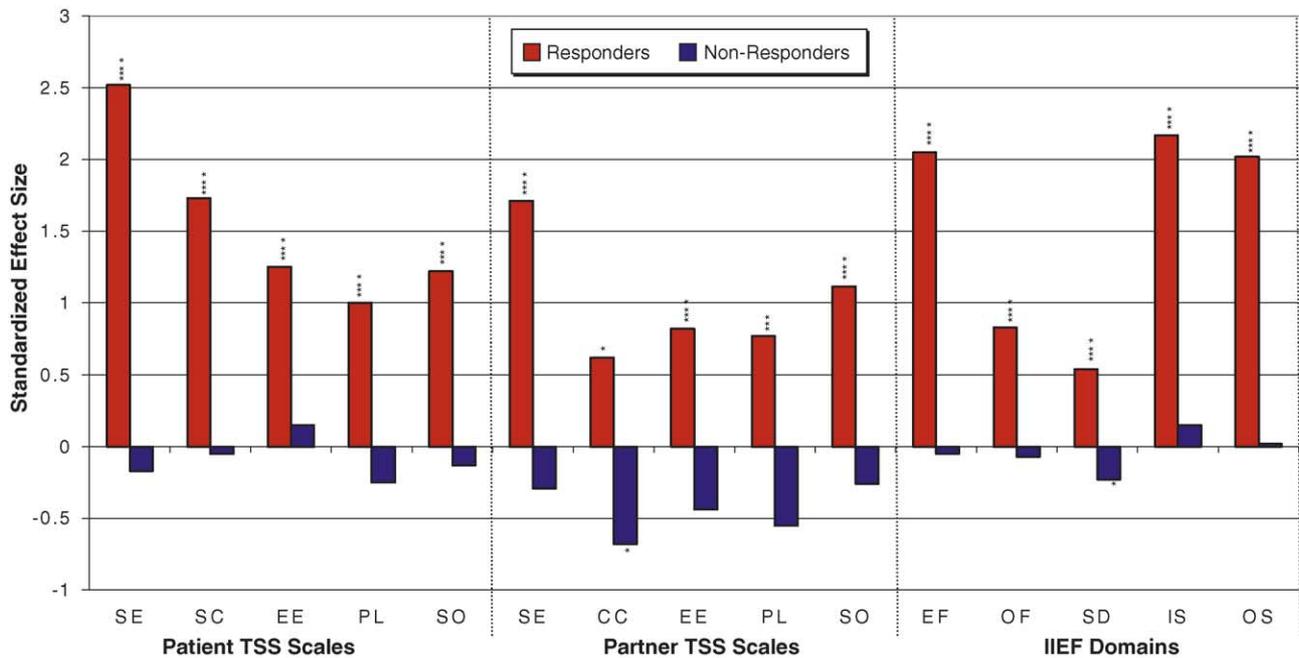


Fig. 1. SES of mean change on TSS and IIEF Scales for responders and non-responders. (KEY: SE = Satisfaction with Erectile Function, SC = Sexual Confidence, EE = Ease of Erection, PL = Pleasure, SO = Satisfaction with Orgasm, CC = Confidence in Completion, EF = Erectile Function, OF = Orgasmic Function, SD = Sexual Desire, IS = Intercourse Satisfaction, OS = Overall Satisfaction. Asterisks indicate mean group change is significantly different from zero: \*  $p < 0.05$ , \*\*  $p < 0.001$ , \*\*\*  $p < 0.0001$ ).

erectile function and erectile function itself, the two concepts are indeed distinct. Two patients (or two partners) may be equally satisfied at different levels of erectile function. An interesting question for future research is whether satisfaction with erectile function may be more important than the actual level of erectile function in influencing treatment-seeking behavior and satisfaction with care.

Excellent responsiveness was observed for all patient and partner TSS scales. The responsiveness of the patient TSS scales compares very favorably to the IIEF domains. Examining the standardized effect size results in Fig. 1, the patient SE scale appears to have better responsiveness than even the most responsive IIEF domains.

The moderate baseline floor effects observed on some TSS scales can be attributed to trial eligibility criteria that produced samples with more severe ED than might be found in the general ED clinical population.

Several factors may have contributed to the inconclusive clinical and concurrent validity results for the Partner Confidence in Completion, Pleasure, and Satisfaction with Orgasm scales. First, although these scales may adequately measure the concepts they purport to measure, many factors other than patients' erectile function may contribute to partners' scores on these scales [17]. Second, the baseline variability was

somewhat restricted due to trial eligibility criteria. Future studies including non-ED controls may provide greater variability for testing the validity of these scales. The superior follow-up concurrent correlations of these scales with erectile function suggest that results could have been more favorable if the ability of these scales to distinguish between ED severity groups at follow-up had been tested. Due to optional participation, the number of partners is smaller than the number of patients.

Scale responsiveness can be viewed as a longitudinal form of validity, and partner CC, PL, and SO scales were quite responsive to patient-reported improvement in erections at follow-up. This illustrates that improving patients' erectile function positively affects these scales for partners. Thus, these three scales are promising tools for studying the impact of patients' ED on their partners. Nonetheless, future studies in partners of ED patients will be needed to address the aforementioned questions.

Other areas of future research include investigating the validity and utility of the TSS in other forms of ED treatment such as topical and injected medications and psychotherapy. The TSS was designed for use in clinical trials, but may also be suited for other forms of group-level research. The high reliability of the SM and SE scales indicates their potential usefulness for monitoring patient progress over time in a clinical

setting. The moderate to high concurrent correlations between the patient and partner SE scale and the IIEF EF domain indicate that although there is a strong relationship between satisfaction with erectile function and level of functioning, the two concepts are indeed distinct.

Although the IIEF does include two scales measuring satisfaction and can measure change between untreated and treated states, it does not include scales measuring treatment satisfaction or ED's impact on partners. Besides the TSS, two existing questionnaires incorporate measurement of satisfaction with medication: the SLQQ and EDITS. The limited dimensionality of these two measures restricts their ability to measure the impact of ED and its treatment on important specific aspects of sexuality. While the EDITS includes a single scale capable of measuring change between treated and untreated states, the multidimensional approach of the TSS generates better face validity and interpretability than is achieved by combining various sexuality concepts into an overall "Sexual QOL" scale. Because the SLQQ [5] measures only satisfaction with treatment for ED, it cannot be used in a clinical trial to measure change between untreated

and treated states. Despite its multidimensionality, the TSS is very brief, with only seven to eight items in the patient and partner unmedicated modules and 12–13 items in the medicated modules. Moreover, the methodology used for developing the initial versions of the TSS incorporated important features such as in-depth patient and partner interviews and simultaneous item generation in multiple languages.

In summary, the TSS is a brief, practical, reliable, valid, and highly responsive multidimensional self-report instrument for measuring a range of sexuality concepts considered important by patients with ED and their partners, including satisfaction with medication, satisfaction with erectile functioning, ease of obtaining erection, sexual confidence, satisfaction with orgasm, and sexual pleasure. While other factors (e.g., sexual interaction) may indeed be important concepts to some patients or their partners, the TSS contains only those constructs deemed most important to patients and partners in the developmental process. Thus, we feel confident that the TSS captures the domains critical to satisfaction with ED treatment. To date, the TSS had been translated and cross-culturally validated into over 20 languages.

## Appendix A

### TSS items deleted from the initial versions and reasons for elimination

Item deleted	Reason
Patient	
If you ejaculated too early, did this interfere with your satisfaction with sexual activity? (unmedicated and medicated)	Not clustered with other items, low correlation with IIEF and other measures
If you ejaculated too late, did this interfere with your satisfaction with sexual activity? (unmedicated and medicated)	Not clustered with other items, low correlation with IIEF and other measures
How would you rate your level of sexual desire? (unmedicated and medicated)	Low loading, low correlation with IIEF, improved Cronbach $\alpha$ without it
To what extent did your condition allow you to have sex when you felt like it? (unmedicated)	May be misunderstood and interpreted differently from the unmedicated to medicated
To what extent did your treatment allow you to have sex when you felt like it? (medicated)	
How bothered were you by the need to have your sexual activity within a certain time period after taking this treatment? (medicated)	Unique, not clustered with other items
How much did side effects of this treatment disturb your enjoyment of your sexual activity? (medicated)	Unique, not clustered with other items



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