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The Sex Effects Scale: Pilot Validation in a Healthy Population

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ABSTRACT ~ Objective: Sexual dysfunction is frequently associated with depression and is often exacerbated by antidepressant treatment. The true prevalence of antidepressant induced dysfunction during a major depressive episode is generally underreported, due to reliance on spontaneous self-report data and the reluctance of physicians to use standardized rating scales. The aim of this study is to validate the Sex Effects scale (SexFX) in a healthy population, addressing internal and inter-rater reliability, test-retest reliability, as well as convergent and divergent validity. **Materials and Methods:** The SexFX is a 13-item scale that assesses severity of sexual dysfunction across the domains of desire, arousal, and orgasm based on the frequency of behaviour. Healthy participants ($N = 53$) had the SexFX and Changes in Sexual Functioning Questionnaire (CSFQ) administered at two timepoints, two weeks apart. **Results:** The Cronbach's α was 0.91 and 0.93 for the male and female scales, respectively, and inter-rater reliability was very high with ICCs of 0.99 for both the male and female scales. Concurrent validity with the CSFQ was adequate. **Conclusion:** The SexFX demonstrated satisfactory psychometric properties, providing the results necessary to proceed with further validation trials. *Psychopharmacology Bulletin. 2010;43(3):15-25.*

INTRODUCTION

Sexual dysfunction is estimated to occur in more than 50% of patients with major depressive disorder (MDD).¹⁻² Antidepressant treatment often compounds this problem, causing treatment-emergent sexual side effects in male and female patients receiving pharmacotherapy.³⁻⁵ The extent to which an antidepressant medication induces dysfunction varies with dose and across drug classes.

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Both selective serotonin reuptake inhibitors (SSRIs) and serotonin nor-epinephrine reuptake inhibitors (SNRIs) can cause significant impairment in libido, arousal or orgasm.⁶ Antidepressants that act on other receptors including dopamine (bupropion) and melatonin (agomelatine) are less likely to be associated with sexual dysfunction.⁷⁻¹⁰

The management of sexual dysfunction is a neglected aspect of pharmacotherapy despite being rated as 'extremely important', 'very important' or 'important' by 85% of MDD patients receiving an antidepressant.¹¹ Consequently, since sexual dysfunction in depression is a leading cause of treatment discontinuation or non-adherence during short and long-term treatment with an antidepressant,¹²⁻¹⁵ it should be systematically evaluated during the appropriate phase of antidepressant treatment.

One large review of antidepressant trials, demonstrated only 8% of trials used a specific instrument to assess sexual adverse events,¹⁶ and in a separate study patients were twice as likely to report sexual side effects upon direct questioning compared to reliance on spontaneous self-report (69% vs. 35%).¹⁷ This supports the use of validated scales that are brief and easy to administer during drug development as well as in clinical practice in order to more effectively identify and manage sexual side effects.

Many sexual function scales exist that qualitatively address subjective aspects of sexual dysfunction. Although the gold standard sexual function scales such as the Derogatis Sexual Function Inventory¹⁸ and Female Sexual Function Index¹⁹ have been used extensively in clinical research, the use of scales specifically designed for depressed populations is preferable in MDD samples. Several scales have been created and validated for MDD: the Arizona Sexual Experience scale (ASEX),²⁰ the Psychotropic Related Sexual Dysfunction Questionnaire (PRSexDQ or SalSex),²¹⁻²² and the most-frequently used measure in depression research, the Changes in Sexual Functioning Questionnaire (CSFQ).²³⁻²⁴ The Sex Effects Scale (SexFX) was developed as a brief 13-item gender-specific, clinician-administered instrument to assess treatment-emergent sexual dysfunction in depression. Where other scales primarily measure the subjective quality of sexual experience, the SexFX primarily measures the frequency of sexual experiences in the domains of desire, arousal and orgasm, yet also includes a subjective evaluation of the intensity of sexual satisfaction in a global satisfaction domain. This makes the scale particularly useful in evaluating the side effects of pharmacotherapy, by providing a quantitative behavioural index of sexual dysfunction.

The clinical validity of the SexFX has been previously established in depressed populations comparing sexual side effects associated with different antidepressants.^{10,25} The purpose of this study is to assess the

psychometric properties of the SexFX in a healthy population. The parameters that will be assessed include internal consistency reliability, test-retest and inter-rater reliability, as well as concurrent and divergent validity.

MATERIALS AND METHODS

Subjects

A community sample of 53 healthy subjects (24 female and 29 male) between the ages of 18 and 65 were recruited from posted advertisements. Participants were included if they were fluent in written and spoken English, and were also able and willing to provide informed consent to participate in the study. Exclusion criteria included any current psychiatric illness or psychotropic medication, history of significant psychiatric illness, or any significant medical condition. Approval was obtained for this study from the University Health Network Research Ethics Board and written informed consent was obtained from each subject prior to study enrolment.

Measures

Sexual function in the preceding 2 weeks was assessed using the 13-item clinician-administered Sex FX Scale, male and female versions (Appendix 1). The first 11 items address 3 domains—desire (items 1–4), arousal (items 5–8) and orgasm (items 9–11) (e.g. Desire item 1: “How often in the past two weeks have you experienced a desire for sexual activity?”). The desire domain is the same for both male and female questionnaires. Slight differences exist in the wording of questions for both arousal and orgasm domains. Responses are rated according to the frequency of activity in the past 2 weeks (0, 1–2, 3–4, 5–9, ≥ 10). A frequency of ‘0’ times is given a score of 0, a frequency of 1–2 times a score of 1, and so forth up to a frequency of ≥ 10 times, which is given a score of 4. However, some items are scored in reverse (items 5, 8, 10 and 11). The summation of items 1 to 11 produces a total Sex FX Scale score, where higher scores reflect better functioning. Items 12 and 13 provide a subjective measure of global satisfaction of sexual function (e.g. “How would you describe satisfaction with your sexual functioning”) on a 0–10 point scale, where 0 is the worst and 10 is the best. The summation of these two items provides a global satisfaction index (GSI). The scale takes approximately 5–10 minutes to administer.

The Changes in Sexual Functioning Questionnaire 14-item (CSFQ-14)²⁴ was used to assess the concurrent validity of the SexFX. The CSFQ-14

measures sexual function by use of a 5-point Likert scale. It is designed to assess sexual function across the domains of desire, arousal and orgasm. A higher score on this scale also reflects better sexual functioning. The scale takes approximately 5–10 minutes to administer.

The Centre for Epidemiological Studies-Depression Scale (CES-D)²⁶ was used to screen for depressive symptoms. The CES-D consists of 20 questions and takes 2–5 minutes to administer. The questions are answered on a 4-point frequency scale (“Less than 1 day” to “Most or all [5–7] days”) for symptoms that have occurred within the past week. Total scores range from 0 to 60, with a standard cut-point of ≥ 16 to indicate depression.

Study Procedures

The SexFX and CFSQ were administered by two independent raters (Rater A and Rater B) at each of the two visits separated by two weeks. Subjects were screened for depressive symptomatology using the CES-D at both visits and excluded if they scored ≥ 16 at either visit.

18

Kennedy, Rizvi,
Fulton, et al.

Statistical Analyses

Statistical analyses were performed using Statistical Packages for the Social Sciences (SPSS), version 16.0. All analyses were performed separately for males and females. Internal consistency reliability for items 1–11 on the SexFX was assessed using Cronbach's α and the average inter-item correlation (AIC). Inter-rater reliability was assessed using an intra-class correlation (ICC) and test-retest reliability (Time 1 and Time 2) was assessed using Pearson's correlation coefficients or Spearman's Rho coefficients for individual items, the three subscales, and GSI. Concurrent validity was assessed using correlations between the total scores and subscales of the SexFX and CFSQ-14. Divergent validity of the SexFX with the CES-D was also assessed using Pearson's correlation coefficients or Spearman's Rho for the total scores.

RESULTS

Sample

Of the 53 healthy controls who formed the full analysis set (FAS), 9 men and 3 women did not return for a second visit. Demographic and clinical characteristics are shown in Table 1. Tests for normality for the male and female samples revealed a non-normal distribution for the

SEX EFFECTS SCALE VALIDATION

male data, where scores were skewed to the higher end. Consequently, non-parametric correlations (Spearman's Rho) were used to assess test-retest reliability and validity. Overall, men reported significantly higher total scores on the SexFX compared to women, which was accounted for by higher scores on "desire" and "arousal" domains (Figure 1).

TABLE 1

PARTICIPANT CHARACTERISTICS

	MALES	FEMALES
Enrolled		
Visit 1	29	24
Visit 2	20	21
Age (SD) (years)	39.1 (13.3)	31.0 (11.3)
% Caucasian		
Visit 1	59	63
Visit 2	45	62
CES-D Score		
Visit 1	6.7 (5.1)	8.1 (5.7)
Visit 2	6.6 (5.6)	8.8 (8.0)

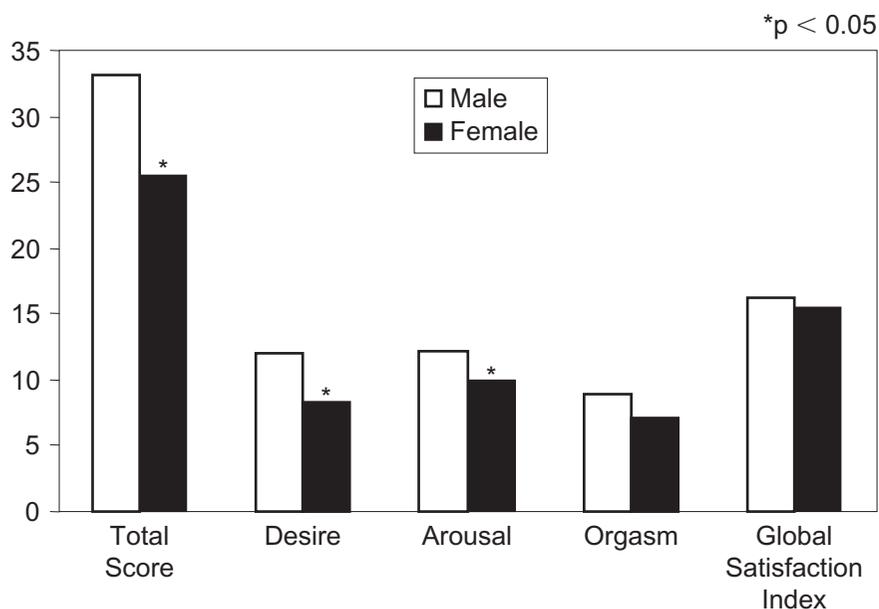
SD = standard deviation

19

Kennedy, Rizvi,
Fulton, et al.

FIGURE 1

SEAFX COMPARISON OF DOMAIN AND TOTAL SCORES IN MEN AND WOMEN



Reliability

Internal Consistency Reliability

Cronbach's α was 0.91 and 0.93 for the male and female scales, respectively. The average inter-item correlations were in the moderate range: 0.47 for males and 0.49 for females. Domains of desire, orgasm and the GSI demonstrated greater internal consistency reliability than the arousal domain (Table 2).

Test-Retest Reliability

Correlations for total scores between the first and second visit were 0.72 and 0.83 ($p < 0.001$), for men and women, respectively (Table 2). Correlation coefficients across the subscales were moderate to high (≥ 0.60) and significant at the $p < 0.05$ level.

Inter-Rater Reliability

Scores between 'Rater A' and 'Rater B' were compared across all items using ICCs. Inter-rater reliability was very high with ICCs of 0.99 for both the male and female scales.

Validity

Concurrent Validity

Table 3 shows the correlations among the 3 subscales of the CSFQ-14 and the 4 subscales of the SexFX. Scales measuring similar constructs significantly correlated between both measures. For women, desire, arousal, orgasm and global satisfaction on the SexFX were moderately to highly correlated with the desire, arousal, and orgasm subscales on the CSFQ ($r = 0.70, 0.67, \text{ and } 0.59$, respectively, all $p < 0.05$). Although also significant, correlations between the male and female scales were lower for men.

TABLE 2

SEAFX INTERNAL CONSISTENCY AND TEST-RETEST RELIABILITY

	CHRONBACH ALPHA (α)		TEST-RETEST	
	MALE	FEMALE	MALE (RS)	FEMALE (R)
Desire	0.94	0.95	0.60*	0.78**
Arousal	0.51	0.64	0.75**	0.75**
Orgasm	0.87	0.86	0.76**	0.86**
Total Scale (Items 1–11)	0.91	0.93	0.72**	0.83**
Global Satisfaction	0.80	0.79	0.67**	0.66**

(r) = Pearson correlations; (rs) = Spearman's rho
* $p < 0.01$ ** $p \leq 0.001$

TABLE 3

SEXFX CONCURRENT VALIDITY CORRELATIONS WITH THE CSFQ

a) Correlations across desire, arousal and orgasm domains

SexFX Domains

	MALE	FEMALE	CSFQ-14 DOMAINS
Desire	0.59*	0.73**	Desire
Arousal	0.49*	0.67**	Arousal
Orgasm	0.48*	0.59*	Orgasm

b) Correlations of the SexFX global satisfaction index with CSFQ domains

SexFX GSI

	MALE	FEMALE	CSFQ-14 DOMAINS
	0.28	0.38	Desire
	0.44*	0.68**	Arousal
	0.56*	0.62**	Orgasm

* $p < 0.01$ ** $p \leq 0.001$

Divergent Validity

Overall, the SexFX demonstrated high divergent validity against the CES-D. The correlations for the SexFX subscales and total score ranged from -0.03 to -0.25 for the female questionnaire and -0.01 to -0.28 for the male questionnaire. None of the correlations for either scale against the CES-D were statistically significant.

DISCUSSION

The results of this study provide preliminary support for the SexFx scale as a reliable and valid tool for assessing sexual function in non-clinical samples. Overall, the SexFX demonstrated satisfactory psychometric properties, including internal consistency, test-retest and inter-rater reliability. Defining the question structure in terms of specific frequency may allow for greater objectivity than sexual function measures that primarily assess the subjective perception of sexual experience, particularly when evaluating the degree of antidepressant side effects. Nevertheless, quality of sexual experience is an important aspect of functioning, and the additional global satisfaction index addresses this facet. Several aspects of the analyses should be highlighted.

Internal Consistency Reliability

Inter-item correlations reflect the multi-dimensional nature of a scale.²⁷ The closer correlations are to 1.0, the more unidimensional the scale. However, perfect correlations are also indicative of redundancy in

items. As expected, the SexFX scale demonstrated moderate inter-item correlations, which supports the multi-factorial nature of sexual function (desire, arousal, orgasm).

The SexFX scale demonstrated high internal consistency reliability, comparable to other commonly used scales such as the CSFQ-14,²⁴ the ASEX²⁰ and SaSex.²¹ However the arousal subscale did not perform as well as the other scales, particularly in men. This suggests arousal may be a more variable aspect of sexual function in a healthy population. As a result, the current study may have been underpowered to detect consistent findings in a highly variable construct.

Test-retest reliability was, again, higher in women than men. Correlations were adequate with the exception of the desire domain in men (0.60) and the GSI for men and women. The correlations of the GSI across two weeks were just below 0.70 for both men and women; however, it is unclear whether this instability was due to environmental factors or sample size. Consequently, further validation is required to confirm this finding.

22

Kennedy, Rizvi,
Fulton, et al.

Validity

The concurrent validity of the SexFX compared to the CSFQ-14 was higher in women than men. This may be due, in part, to the skewed distribution of male data. For divergent validity outcomes, the lack of correlation between the SexFX and depressive symptoms, as defined by the CES-D, was expected given the size of a healthy population. This is consistent with findings from other validation studies of sexual function scales in healthy groups.^{20,28}

In a previous trial using the SexFX scale to assess sexual function, scores particularly for desire, are lower in depressed individuals compared to the healthy controls.²⁹ Since the statistical significance of these differences is unknown, further analyses regarding the differences between depressed and healthy populations are necessary to develop appropriate cut-off scores and further develop the reliability and validity of the SexFX scale.

Several study limitations may have affected the outcomes of the analyses. The sample size did not provide significant power to examine the influence of ethnicity and age on scores. Considering the variability of sexual function with age, having appropriate numbers of participants in various age groups would be prudent. In the current study, the different ages of the participants may have biased the results. Consequently, additional validation studies in a larger healthy participant sample with an age distribution upon which age-related norms can be generated is necessary. The use of female raters only may have

also affected the outcome of the interviews, particularly for male participants. Future studies should be aimed at assessing the effect of rater sex on individual response. In conclusion, this pilot validation in a healthy sample provides evidence to proceed with further validation studies of the SexFX in a larger healthy population. ❖

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APPENDIX I. SEX EFFECTS SCALE

A. Female Version

DIRECTIONS: Both sexual interest and activity can be affected by depression. Some of the medications used to treat depression can also alter sexual interest and activity. I am going to ask you a few questions about different aspects of your sexual life.

During the past two weeks, how often did you:

DESIRE	0	1-2	3-4	5-9	≥10						
1. Experience a desire for sexual activity	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>						
2. Fantasize about sexual activity	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>						
3. Have an interest in initiating sexual activity	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>						
4. Have the ability to feel sexually excited ("turned on")	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>						
AROUSAL	0	1-2	3-4	5-9	≥10						
5. Have difficulty with vaginal lubrication	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>						
6. Become aroused without being touched	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>						
7. Engage in sexual activity (intercourse or masturbation)	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>						
8. Have difficulty staying lubricated during sexual activity	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>						
ORGASM	0	1-2	3-4	5-9	≥10						
9. Experience an orgasm	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>						
10. Take longer than you would like to have an orgasm	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>						
11. Fail to have an orgasm during sexual activity	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>						
SATISFACTION OVERALL: If you have to give a number between 0 (worst case) and 10 (best case) how would you describe:											
12. Satisfaction with your sexual functioning:	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>	7 <input type="checkbox"/>	8 <input type="checkbox"/>	9 <input type="checkbox"/>	10 <input type="checkbox"/>
13. Enjoyment of your sexual romantic life:	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>	7 <input type="checkbox"/>	8 <input type="checkbox"/>	9 <input type="checkbox"/>	10 <input type="checkbox"/>

B. Male Version

DIRECTIONS: Both sexual interest and activity can be affected by depression. Some of the medications used to treat depression can also alter sexual interest and activity. I am going to ask you a few questions about different aspects of your sexual life.

During the past two weeks, how often did you:

DESIRE	0	1-2	3-4	5-9	≥10
1. Experience a desire for sexual activity	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
2. Fantasize about sexual activity	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
3. Have an interest in initiating sexual activity	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
4. Have the ability to feel sexually excited ("turned on")	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>

AROUSAL	0	1-2	3-4	5-9	≥10
5. Have difficulty getting an erection	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
6. Have an erection without being touched	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
7. Engage in sexual activity (intercourse or masturbation)	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
8. Have difficulty staying erect during sexual activity	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>

ORGASM	0	1-2	3-4	5-9	≥10
9. Experience an orgasm	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
10. Take longer than you would like to ejaculate	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
11. Fail to ejaculate during sexual activity	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>

SATISFACTION OVERALL: If you have to give a number between 0 (worst case) and 10 (best case) how would you describe:											
12. Satisfaction with your sexual functioning:	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>	7 <input type="checkbox"/>	8 <input type="checkbox"/>	9 <input type="checkbox"/>	10 <input type="checkbox"/>
13. Enjoyment of your sexual romantic life:	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>	7 <input type="checkbox"/>	8 <input type="checkbox"/>	9 <input type="checkbox"/>	10 <input type="checkbox"/>

24

Kennedy, Rizvi,
Fulton, et al.

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SEX EFFECTS SCALE VALIDATION

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