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Sexual Functioning and Sex Hormones in Men Who Underwent Bariatric Surgery

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Abstract

Importance—The relationship between obesity and impairments in male sexual functioning is well documented. Relatively few studies have investigated changes in sexual functioning and sex hormones in men who achieve significant weight loss with bariatric surgery.

Objective—To assess changes in sexual functioning, sex hormones, and relevant psychosocial constructs in men who underwent bariatric surgery.

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Study concept and design: Sarwer, Wadden, Rosen, Mitchell, Courcoulas

Acquisition of data: Spitzer, Lancaster, Gourash

Analysis and interpretation of data: Sarwer, Christian

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Design, Setting and Participants—A prospective cohort study of 32 men from the Longitudinal Assessment of Bariatric Surgery-2 (LABS) investigation who underwent a Roux-en-Y gastric bypass (median BMI [25th percentile, 75th percentile] 45.1 [42.0, 52.2]) and completed assessments between 2006 and 2012.

Intervention—Bariatric surgery was performed by a LABS-certified surgeon.

Main Outcomes and Measures—Sexual functioning was assessed by the International Index of Erectile Functioning (IIEF). Hormones were assessed by blood assay. Quality of life (QoL), body image, depressive symptoms and marital adjustment were assessed by questionnaire.

Results—Men lost, on average, (95% confidence interval) 33.3% (36.1%, 30.5%) of initial body weight at postoperative Year 1, 33.6% (36.8%, 30.5%) at Year 2, 31.0% (34.1%, 27.9%) at Year 3, and 29.4% (32.7%, 26.2%) at Year 4. Participants experienced significant increases in total testosterone ($P<0.001$) and sex hormone binding globulin (SHBG) ($P<0.001$) through postoperative Year 4. While men reported improvements in sexual functioning after surgery, these changes did not significantly differ from baseline, with the exception of overall satisfaction at postoperative Year 3 ($P=0.008$). Participants reported significant improvements in physical domains of health-related quality of life (HRQoL), all domains of weight-related QoL, and body image, but not in the mental health domains of HRQoL or relationship satisfaction.

Conclusions and Relevance—Men who lost approximately one-third of their body weight following Roux-en-Y gastric bypass experienced significant increases in total testosterone and SHBG. They did not, however, report significant improvements in sexual functioning, relationship satisfaction or mental health domains of HRQoL. This pattern of results differs from that of women who have undergone bariatric surgery, who reported almost uniform improvements in sexual functioning and psychosocial status.

Trial Registration—<http://www.clinicaltrials.gov> ID# NCT00670098 <https://register.clinicaltrials.gov/prs/app/action/SelectProtocol?sid=S0001JXP&selectaction=View&uid=U0000XTL&ts=4&cx=-2bwzz2>

Keywords

Sexual Functioning; Sex Hormones; Quality of Life; Obesity; Bariatric Surgery

Introduction

Obesity, and extreme obesity in particular, is associated with significant medical and psychosocial comorbidity.¹⁻² A large number of studies have found a relationship between extreme obesity and impairments in quality of life, as well as greater depressive symptoms and increased body image dissatisfaction.³⁻⁷ Individuals with obesity often report untoward changes in sexual functioning and decreased sexual satisfaction.^{6,8-13} In a recent study of individuals with extreme obesity who presented for bariatric surgery, 51% of women and 36% of men reported a sexual dysfunction.¹³ The presence of dysfunctional sexual behavior was associated with lower levels of quality of life and impairment in other areas of psychosocial functioning for women. In contrast, the impact of sexual dysfunction on the psychosocial functioning of men was less pronounced or uniform.¹³ Obesity has been

associated with untoward changes in several sex hormones in women and men, which also may adversely impact sexual functioning.^{13–17}

Weight loss following lifestyle modification or bariatric surgery has been associated with significant improvements in sexual functioning^{18–21} and sex hormones.^{16, 21–23} For example, we recently found that women who underwent bariatric surgery, and experienced a mean weight loss of 33.5% (95% CI, 31.5%–35.6%) at postoperative year 2, reported significant improvements in overall sexual functioning and specific domains of functioning, including desire, arousal, lubrication, and satisfaction.²⁴ These women also reported significant improvements in body image, depressive symptoms, and most domains of quality of life, and they experienced improvements in total testosterone, estradiol, follicular stimulating hormone, sex hormone binding globulin and DHEA-S.

As women represent the vast majority of individuals who present for bariatric surgery, there has been less opportunity to study changes in sexual functioning and sex hormones in men who undergo bariatric surgery. For example, in a study of 10 men who underwent Roux-en-Y gastric bypass, Reis and colleagues found marginally significant improvements in self-reported sexual functioning two years after surgery, improvements in total testosterone, follicle stimulating hormone and prolactin were more robust.²¹ This study, however, was limited by its small sample size. Further, it did not include an assessment of psychosocial factors, such as quality of life, body image and romantic relationship satisfaction, that could influence sexual behavior. The present study was undertaken to address this gap in the literature. We hypothesized that men would experience improvements in sexual functioning, sex hormones and psychosocial variables of interest, with a pattern of results similar to that seen with women.²⁵

Method

Study Design

This study used data collected from the Longitudinal Assessment of Bariatric Surgery (LABS) consortium. The LABS study design is detailed elsewhere.^{26–28} LABS-2 is investigating the long-term effects of bariatric surgery on patients' weight, as well as physical and mental health status. The present study is considered an ancillary study of LABS-2 as it extends lines of investigation to other, more specific questions, including our previous reports on baseline sexual functioning¹³ and changes in female sexual functioning two years after surgery.²⁵

Thirty-two men undergoing Roux-en-Y gastric bypass and participating in the LABS-2 study from two of the ten LABS sites (the Neuropsychiatric Research Institute [NRI] and the University of Pittsburgh Medical Center [UPMC]) were studied. Data were collected between 2006 and 2012. Participants were assessed prior to surgery and annually thereafter. Year 2 was the primary point of interest since most bariatric surgery patients reach maximum weight loss by this time.²⁹ We also report three and four year outcomes. The trial was approved by the Institutional Review Boards at NRI, UPMC, and the University of Pennsylvania. Informed consent was received from all participants.

Participants

Men met the inclusion criteria of the LABS-2 study (at least 18 years old and seeking a first bariatric surgical procedure) and also met all medical and mental health criteria for bariatric surgery. Men who were non-ambulatory, those with significant or uncontrolled medical conditions (including recent history of stroke, untreated or uncontrolled hypertension, history of renal or hepatic disease), and those with untreated or uncontrolled psychiatric conditions were excluded. Men had to report involvement in a relationship that provided them with opportunity for sexual activity with a partner. Participants received a \$40.00 gift card (to a local department or bookstore) following completion of each assessment and to enhance retention.

Interventions

Bariatric surgery. Surgery was performed by a LABS-certified surgeon. Thirty-two men underwent Roux-en-Y gastric bypass performed using standard techniques.

Measures

Participants completed the following assessments:

International Index of Erectile Function (IIEF). The IIEF is a widely-used, 15-item scale that assesses five domains of male sexual functioning: erectile function (range: 0–30); orgasmic function (0–10); sexual desire (2–10); intercourse satisfaction (0–15); and overall satisfaction (2–10). Lower scores indicate less satisfaction and greater dysfunction.^{30–31}

The Short Form Health Survey-36 item version (SF-36). The SF-36 was used to assess health-related quality of life (HRQoL). Eight subscales assess separate domains of health and related functioning. Items on the physical functioning, physical role functioning, pain, and general health subscales were used to calculate the physical health summary score. Items on vitality, social functioning, emotional role functioning and mental health subscales were used to calculate the mental health summary score. Higher scores indicate more positive health-related quality of life.³²

Impact of Weight on Quality of Life-Lite (IWQOL-Lite). The IWQOL-Lite assessed weight-related quality of life.^{33–34} The measure contains 31 items, with each item beginning with the phrase “Because of my weight,” which assess five domains: work; physical function; public distress; sex life; and self-esteem. Responses are combined to calculate a total score that ranges from 0 to 100; higher scores indicate a better quality of life.

Body Image Quality of Life Inventory (BIQLI). The BIQLI is a 19-item measure of the positive and negative impact of body image on various qualities of life.³⁵ Respondents’ feelings are assessed in regard to beliefs about the self and life in general, emotional states, same and other-sex relationships, eating and exercise, grooming activities, and sexual experiences, as well as family and work/school contexts. Participants respond to items using a 7-point scale ranging from –3 (“Very Negative Effect”) to +3 (“Very Positive Effect”); 0 is labeled “No Effect.” Higher scores suggest more positive body image quality of life.

Body Shape Questionnaire (BSQ). The Body Shape Questionnaire assessed dissatisfaction with body shape.³⁶ The 38 items on the measure are rated on a scale of 1 (“Never”) to 6 (“Always”) based on how the respondent has been feeling over the last 4 weeks. Higher scores indicate greater dissatisfaction.

Dyadic Adjustment Scale (DAS). Relationship satisfaction was assessed by Dyadic Adjustment Survey.³⁷ The measure addresses four domains that measure the quality of marriage or similar dyads: dyadic consensus, dyadic satisfaction, dyadic cohesion, and affectional expression. Items can be summed to a total score; higher scores indicate higher levels of satisfaction.

Beck Depression Inventory-II (BDI-II). The BDI-II assessed depressive symptoms.³⁸ Scores range from 0 to 63, with higher scores indicating greater symptoms.

Sex Hormones

A 20 ml blood sample was obtained from each participant. Samples were cooled on ice and centrifuged within 15 min of drawing. Plasma was removed from the vacutainer within 15 min after centrifugation, placed into polypropylene tubes, and bulk-shipped to the Clinical Translational Research Center at the University of Pennsylvania for analysis. We assessed total testosterone, free testosterone, luteinizing hormone (LH), and sex hormone binding globulin (SHBG). Total testosterone and SHBG were analyzed using standard enzyme-linked immuno assay (ELISA) (IBL Hamburg) assay kits. Luteinizing hormone was analyzed by means of Chemiluminescent (Roche Elecsys) laboratory assays. Free testosterone was analyzed using RIA assay kits (Siemens Los Angeles).

Statistical Analysis

Descriptive statistics were used to summarize the baseline characteristics of participants. Frequencies and percentages were used for categorical data; median values and inter-quartile ranges were calculated for continuous data.

An intercept and time point-only normal mixed model with a heterogeneous compound symmetry covariance matrix was used to report changes in sexual functioning scores, sex hormone levels, psychosocial measures, and weight. For each assessment, pairwise comparisons were made between baseline and each follow-up time point; P values and confidence limits were adjusted for the multiple comparisons using simulation. The reported modeling values and changes were used to account for missing data at each time point. (The observed mean values and standard deviations of each assessment are reported in the eTables 1 and 2 in the Supplemental Tables. The observed values were similar to the modeled values.)

Analyses were conducted using SAS version 9.2 (SAS Institute Inc). All reported P values are 2 sided; $P < .05$ was considered to be statistically significant.

Results

Forty one men provided informed consent. Six were found to be ineligible; 3 were not in a relationship that provided regular access to a sexual partner, two did not undergo surgery and one had a BMI that did not meet the inclusion criteria for the study. Three men underwent a laparoscopic adjustable gastric banding procedure and were excluded from these analyses. Of the thirty-two men who underwent a Roux-en-Y gastric bypass procedure, 1 died before the 1 year assessment. The other 31 participants completed at least 1 follow-up assessment. Follow-up data were collected at all 4 time points for 28 participants, at 3 time points for 1 participants, and at 2 time points for 2 participants. (Figure 1) Participants were considered as having provided data if any of the following were completed: physical measurements, blood samples or at least 1 self-assessment measure.

Demographic Characteristics

Baseline demographic and descriptive characteristics, reported previously,¹³ are presented in Table 1. Men had a median body mass index of 45.1 kg/m². All were white and all but one reported at least a high school diploma or GED.

Weight Loss

The average (95% confidence interval) percent reduction in initial weight at postoperative Year 1 was 33.3% (36.1%, 30.5%), which increased at postoperative Year 2 to 33.6% (36.8%, 30.5%). At postoperative Years 3 and 4, total percent weight loss was 31.0% (34.1%, 27.9%) and 29.4% (32.7%, 26.2%), respectively.

Sexual Functioning and Sex Hormones

Men reported improvements on all subscales of the IIEF at postoperative Years 2, 3 and 4 as compared to baseline; however, with one exception, these changes did not reach statistical significance. At postoperative Year 3, overall satisfaction was significantly different from baseline. By Year 4, this change was no longer significant (Table 3).

Men experienced statistically significant increases in total testosterone ($P < .001$), free testosterone ($P = 0.045$), LH ($P = .024$) and SHBG ($P < .001$) at postoperative Year 1. The change in free testosterone did not remain significantly different from baseline after year 1; the change in LH remained significantly greater at postoperative Year 2 ($P = .024$) but not at postoperative Year 3 or 4. The increases from baseline for total testosterone ($P < .001$) and SHBG ($P < .001$) were significant at all postoperative assessments (Table 2).

We also were interested in the use of erectile dysfunction (ED) medications and their potential impact on changes in sexual functioning. The use of these medications was less common than anticipated. Four men reported taking (ED) medications during the course of the study. One participant reported taking ED medication at baseline, 2 participants reported taking ED medication at one follow-up visit; and 1 participant reported taking ED medication at baseline and multiple follow-up visits. The small numbers of individuals using these medications precluded formal analysis.

Psychosocial Variables

Results of the psychosocial variables of interest are found in Table 4. Participants reported statistically significant improvements in all of the physical domains of HRQoL (Physical Component Summary Score, Physical Functioning, Role Physical, Pain, and General Health) as well as the Vitality subscale from the mental health domain of the SF-36 at postoperative Years 1, 2, 3 and 4. They did not report significant changes in the Mental Component Summary Score or other mental domain subscales, except on the Social Functioning. At postoperative Years 2, 3 and 4, men reported significantly higher Social Functioning from baseline. Men also reported significant improvements in weight-related quality of life and body image. Relationship satisfaction did not change significantly from baseline at any postoperative assessment point. Depressive symptoms decreased after surgery, but the change from baseline did not reach statistical significance until Years 3 and 4.

Discussion

The present study provides new information on changes in sexual functioning, sex hormones and associated domains of psychosocial functioning in men who underwent bariatric surgery. The sample of men lost approximately 30% of their weight two years after surgery, the primary endpoint, and experienced modest weight regain in years 3 and 4. These substantial weight losses were accompanied by significant increases in total as well as free testosterone, LH and SHBG at postoperative Year 1. However, only the increases in total testosterone and SHBG remained significantly improved from preoperative levels at postoperative Year 4. Contrary to expectations, men did not report significant improvements in sexual functioning on the primary measure, the IIEF. They did report significant improvements in the physical domains of HRQoL (as assessed by the SF-36), weight-related quality of life (including the Sex Life subscale), and body image. However, they did not report uniform changes in the mental health components of quality of life or satisfaction with their romantic relationships. Statistically significant changes in depressive symptoms were only seen at postoperative Year 3.

We recently found statistically significant improvements in self-reported sexual functioning in women who had lost a comparable amount of weight one and two years after bariatric surgery.²⁵ Changes in self-reported sexual functioning for men one and two years after surgery, and as compared to baseline, were in the anticipated direction. Men reported increased sexual desire, improved erectile functioning and ejaculation, and greater satisfaction with intercourse and all sexual activity. However, the differences from baseline did not reach statistical significance.

Results of studies of changes in self-reported sexual behavior in men who have undergone bariatric surgery have been inconsistent. In a retrospective study of laparoscopic adjustable gastric banding patients, which also used the IIEF, Ranasinghe and colleagues similarly did not find statistically significant improvements in male sexual functioning.³⁹ Our observations, as well as those by Ranasinghe and colleagues, are in contrast to studies by Reis et al²¹ and Mora et al⁴⁰ which also used the IIEF and found statistically significant improvements in overall sexual functioning in the first two years after bariatric surgery. Review of the current results and those of Mora and colleagues suggests that we appeared

to have larger variability in our self-reported sexual functioning, which may have prevented some of our changes from reaching statistical significance. The relatively small sample size also may have left us underpowered to detect statistically significant differences. Dallal and colleagues found statistically significant improvements in the sexual functioning, as assessed by the Brief Male Sexual Function Inventory, in 97 men who had undergone bariatric surgery.⁹ While the main LABS study has 156 men enrolled at NRI and UPMC, we were only able to recruit 32 into this study. This was an artifact of the nature of the recruitment for this ancillary study, which began after recruitment for the main study. Very few men who were asked to enroll in this study declined.

Men who underwent bariatric surgery had significant increases in all sex hormones of interest at postoperative Year 1. These short-term results largely replicate those of Mora and colleagues.⁴⁰ Changes in total testosterone and SHBG remained statistically significant from baseline through postoperative Year 4, suggesting that these improvements are durable over time. Free testosterone and LH also improved from baseline but did not remain statistically significant at postoperative Year 4. Mora and colleagues similarly found no changes in LH, but did observe statistically significant improvements in free testosterone one year after a comparable weight loss.⁴⁰

Men also reported significant improvements in many, but not all, domains of psychosocial functioning following bariatric surgery. Improvements in HRQoL (predominantly the physical components assessed by the SF-36), weight-related quality of life, and body image were reported one year after surgery and remained significantly improved from baseline three years later. This is a novel contribution to the literature, as few studies have documented improvements in the psychosocial functioning of men who have undergone bariatric surgery. Men did not report statistically significant improvements on several of the “mental” domains of quality of life, assessed by the SF-36, nor did they report improvements in the domains of relationship satisfaction assessed by the DAS. This is in contrast to our study of women, which found statistically significant improvements in all domains of HRQoL and most domains of relationship satisfaction (with the exception of the Cohesion subscale of the DAS).

Despite the study’s novel contributions to the literature, the study has limitations. The small sample size is one. In addition, the sample was exclusively white and almost entirely non-Hispanic. The lack of minority representation limits our ability to comment on changes in sexual functioning, sex hormones, and psychosocial functioning in other individuals. This is an unfortunate circumstance for most of the bariatric surgical research conducted in the United States, where persons from racial and ethnic minorities present for surgery at lower rates compared to whites. We also were interested in exploring whether those individuals who had a sexual dysfunction diagnosis as baseline (primarily erectile dysfunction) reported resolution with weight loss. Unfortunately, the presence of missing data at selected assessment points, the use of ED medications in some men, and the changes in sex hormones, made the results of this analysis largely impossible to interpret. Finally, it also is possible that the use of financial incentives to promote the completion of study visits could have biased the results in some manner. This is a well established practice in

many areas of clinical research and without conclusive evidence that it promotes biased responding to paper and pencil assessments.

In conclusion, this study provides new information on changes in sexual functioning, sex hormones and psychosocial functioning in men who have undergone bariatric surgery. While men reported improvements in sexual functioning, these changes did not reach statistical significance. Relevant sex hormones increased significantly at postoperative Year 1 and changes in total testosterone and SHBG remained significant 4 years after surgery. Improvements in physical and weight-related quality of life, as well as body image, followed the same pattern. These results contrast with our recent investigation of women who had undergone bariatric surgery and reported consistent improvements in sexual functioning, quality of life, body image, depressive symptoms and relationship satisfaction. The psychosocial benefits that accompany the more substantial weight losses seen with bariatric surgery may be less broad and encompassing for men than for women.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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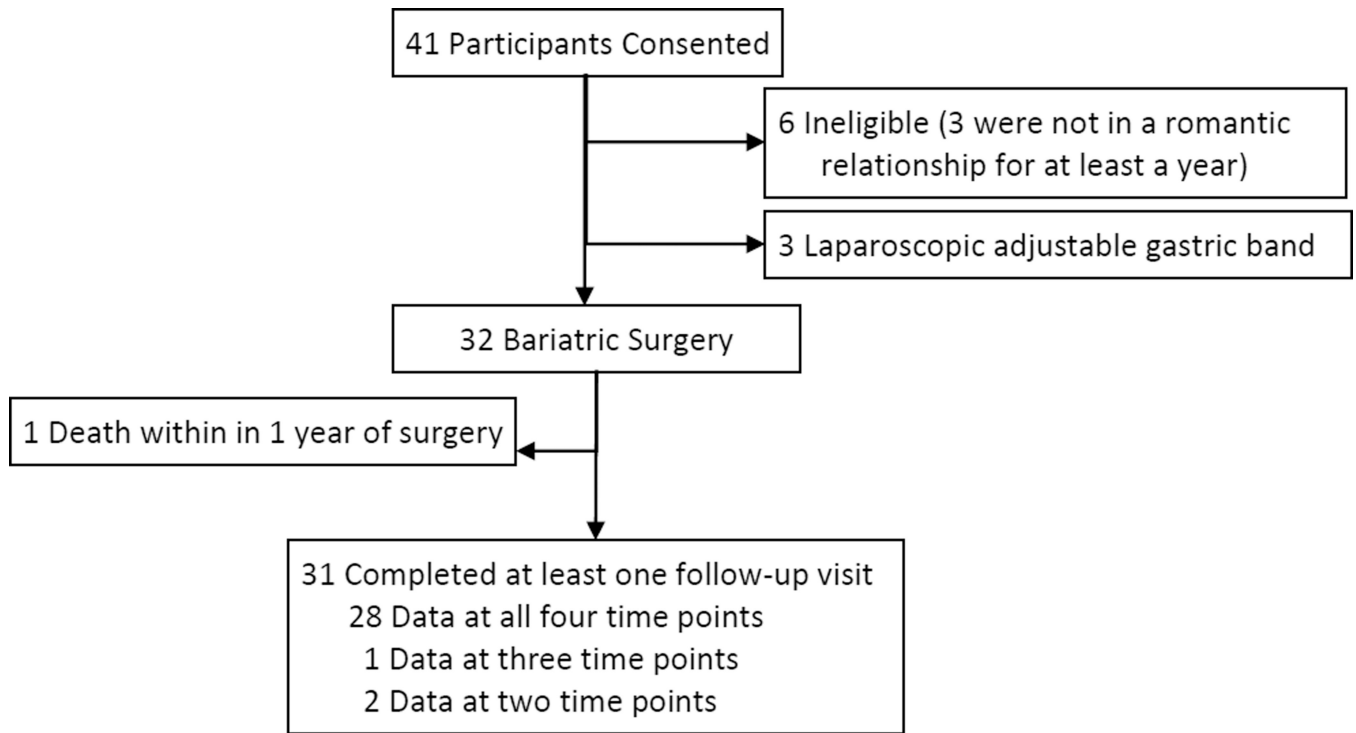


Figure 1.
Recruitment and retention of study participants

Table 1

Baseline characteristics of participating men

Number of men	32
Age (years)	
Median (Q1, Q3)	48 (39, 55)
Range	24 – 64
Race -n (%)	
White	32 (100)
Black	0 (0.0)
Other	0 (0.0)
Ethnicity -n (%)	
Hispanic	1 (3)
Non-Hispanic	31 (97)
Highest education level^a -n (%)	
Some high school	1 (3)
High school diploma or GED	3 (10)
Some college	9 (29)
Other post high school education	11 (35)
College diploma	4 (13)
Graduate or professional degree	3 (10)
Body mass index (kg/m²)	
Median (Q1, Q3)	45.1 (42.0, 52.2)
Range	37.3 – 64.6
Weight (kg)	
Median (Q1, Q3)	149.3 (130.7, 170.0)
Range	111.4 – 228.2
Waist circumference^a (cm)	
Median (Q1, Q3)	145.4 (136.5, 155.5)
Range	122.4 – 183.0

^aMissing data: 1 education; 1 waist circumference

Q1 = 25th percentile; Q3=75th percentile

Table 2

Percent weight loss at each time point

	n	Model-Based Estimates Mean (95% CI)	
Year 1	30	33.3	(36.1, 30.5)
Year 2	28	33.6	(36.8, 30.5)
Year 3	30	31.0	(34.1, 27.9)
Year 4	30	29.4	(32.7, 26.2)

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Table 3

Change in International Index of Erectile Function (IIEF) and Sex Hormone Levels

	Model Based Estimates, Mean (SD)					Model Based Mean Change (95% CI)					P-Value			
	Baseline	Year 1	Year 2	Year 3	Year 4	Year 1 from Baseline	Year 2 from Baseline	Year 3 from Baseline	Year 4 from Baseline	Year 1 vs Baseline	Year 2 vs Baseline	Year 3 vs Baseline	Year 4 vs Baseline	
IIEF Scores														
Erectile function	19.9 (11.6)	21.3 (10.4)	24.4 (8.5)	23.1 (10.2)	23.1 (9.4)	1.4 (-4.0, 6.8)	4.5 (-0.6, 9.6)	3.2 (-2.0, 8.4)	3.1 (-2.3, 8.6)	0.910	0.099	0.357	0.395	
Orgasmic function	7.1 (3.9)	7.2 (4.0)	8.7 (2.7)	8.1 (3.3)	7.6 (3.8)	0.1 (-2.1, 2.4)	1.6 (-0.3, 3.5)	1.0 (-0.9, 3.0)	0.6 (-1.7, 2.8)	>0.99	0.113	0.490	0.926	
Sexual desire	6.4 (2.5)	7.6 (2.2)	7.5 (1.9)	7.1 (2.2)	7.5 (2.3)	1.2 (-0.0, 2.4)	1.1 (-0.0, 2.2)	0.7 (-0.5, 1.8)	1.1 (-0.2, 2.3)	0.058	0.057	0.423	0.118	
Intercourse satisfaction	7.3 (5.6)	8.5 (5.2)	9.0 (4.9)	9.0 (5.0)	8.7 (5.0)	1.2 (-1.6, 3.9)	1.7 (-0.9, 4.4)	1.7 (-0.9, 4.3)	1.4 (-1.3, 4.1)	0.672	0.308	0.281	0.531	
Overall satisfaction	6.1 (2.8)	7.0 (2.6)	7.2 (2.8)	7.6 (2.4)	6.8 (2.5)	0.9 (-0.4, 2.2)	1.1 (-0.3, 2.4)	1.5 (0.3, 2.7)	0.7 (-0.6, 2.0)	0.266	0.171	0.008	0.499	
Sex Hormone Levels														
Total testosterone, ng/dL	317.1 (112.1)	495.5 (185.8)	508.7 (149.7)	470.0 (137.7)	432.8 (108.5)	178.4 (99.1, 257.8)	191.6 (121.0, 262.2)	152.9 (84.3, 221.6)	115.7 (52.9, 178.6)	<.001	<.001	<.001	<.001	
Free testosterone, pg/mL	7.7 (2.5)	10.1 (5.4)	8.5 (2.6)	8.5 (3.1)	8.0 (2.4)	2.4 (0.0, 4.7)	0.8 (-0.5, 2.1)	0.7 (-0.8, 2.3)	0.3 (-1.1, 1.7)	0.045	0.361	0.582	0.963	
LH, mIU/mL	3.8 (3.2)	6.3 (7.7)	7.8 (10.4)	6.8 (10.8)	6.5 (8.3)	2.5 (0.3, 4.8)	4.0 (0.5, 7.5)	3.0 (-0.7, 6.7)	2.6 (-0.1, 5.4)	0.024	0.024	0.136	0.063	
SHBG, nmol/L	21.6 (8.1)	60.3 (22.3)	64.1 (19.4)	66.6 (14.4)	60.6 (16.0)	38.7 (30.0, 47.4)	42.5 (34.7, 50.3)	45.0 (39.2, 50.9)	39.0 (32.0, 46.1)	<.001	<.001	<.001	<.001	

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Table 4

Change in Psychosocial Measures

	Model Based Estimates, Mean (SD)					Model Based Mean Change (95% CI)					P-Value			
	Baseline	Year 1	Year 2	Year 3	Year 4	Year 1 from Baseline	Year 2 from Baseline	Year 3 from Baseline	Year 4 from Baseline	Year 1 vs Baseline	Year 2 vs Baseline	Year 3 vs Baseline	Year 4 vs Baseline	
SF-36														
Physical component summary	35.1 (9.9)	51.9 (6.5)	51.2 (6.8)	50.9 (6.7)	47.2 (7.7)	16.9 (12.9, 20.9)	16.1 (11.9, 20.3)	15.8 (11.8, 19.8)	12.1 (7.8, 16.5)	<.001	<.001	<.001	<.001	
Mental component summary	51.3 (9.4)	48.0 (14.6)	51.8 (10.2)	51.5 (9.1)	51.9 (7.4)	-3.3 (-9.7, 3.1)	0.5 (-4.6, 5.6)	0.1 (-4.4, 4.7)	0.6 (-3.7, 4.9)	0.511	0.998	>0.99	0.992	
Physical functioning	37.0 (10.9)	52.2 (5.2)	52.5 (5.3)	51.5 (7.3)	51.5 (5.6)	15.2 (10.3, 20.0)	15.5 (10.6, 20.4)	14.5 (9.4, 19.6)	14.4 (9.5, 19.4)	<.001	<.001	<.001	<.001	
Role-physical	39.5 (10.9)	50.1 (10.0)	52.8 (7.3)	51.4 (8.2)	47.3 (11.0)	10.6 (5.1, 16.2)	13.3 (8.2, 18.4)	11.9 (6.8, 17.0)	7.8 (1.7, 13.9)	<.001	<.001	<.001	0.008	
Pain	39.0 (9.6)	47.7 (12.9)	48.4 (10.5)	48.3 (8.9)	44.2 (9.0)	8.7 (3.4, 13.9)	9.3 (4.7, 14.0)	9.2 (5.2, 13.3)	5.2 (0.9, 9.5)	<.001	<.001	<.001	0.011	
General health	40.6 (10.4)	54.0 (10.0)	51.0 (9.1)	52.0 (8.2)	49.2 (8.2)	13.4 (9.2, 17.6)	10.4 (6.2, 14.5)	11.4 (7.5, 15.2)	8.6 (4.6, 12.6)	<.001	<.001	<.001	<.001	
Vitality	40.4 (9.4)	52.3 (10.0)	51.6 (8.8)	52.8 (7.3)	50.5 (7.2)	12.0 (7.0, 17.0)	11.3 (6.4, 16.2)	12.4 (8.2, 16.7)	10.1 (5.7, 14.6)	<.001	<.001	<.001	<.001	
Social functioning	45.3 (11.2)	49.2 (13.0)	52.2 (9.9)	51.8 (9.5)	51.1 (8.1)	3.9 (-3.0, 10.9)	6.9 (0.7, 13.1)	6.5 (0.7, 12.3)	5.8 (0.2, 11.5)	0.416	0.025	0.024	0.042	
Role-emotional	49.6 (9.5)	48.2 (11.7)	53.4 (6.8)	50.2 (9.9)	51.3 (9.8)	-1.4 (-7.3, 4.6)	3.8 (-0.9, 8.5)	0.7 (-4.7, 6.0)	1.7 (-3.9, 7.3)	0.942	0.141	0.995	0.871	
Mental health	49.0 (8.1)	48.3 (14.6)	50.7 (9.9)	51.2 (9.0)	50.7 (6.5)	-0.8 (-6.6, 5.1)	1.6 (-2.7, 6.0)	2.1 (-1.7, 5.9)	1.6 (-1.7, 5.0)	0.993	0.778	0.456	0.587	
IWQOL - Lite														
Total IWQOL	49.9 (20.0)	91.7 (11.2)	93.5 (11.2)	91.7 (9.3)	90.4 (11.2)	41.8 (34.8, 48.9)	43.6 (36.4, 50.8)	41.8 (34.8, 48.9)	40.5 (33.3, 47.7)	<.001	<.001	<.001	<.001	
Work	65.5 (18.5)	94.4 (11.4)	96.4 (14.8)	94.0 (10.1)	93.1 (12.9)	28.9 (21.5, 36.3)	30.9 (22.8, 38.9)	28.5 (21.3, 35.8)	27.6 (19.7, 35.6)	<.001	<.001	<.001	<.001	
Physical function	38.0 (21.1)	92.0 (8.3)	94.0 (8.0)	90.1 (9.3)	88.8 (11.2)	54.0 (46.0, 62.0)	56.0 (47.9, 64.1)	52.0 (44.0, 60.0)	50.7 (42.5, 59.0)	<.001	<.001	<.001	<.001	
Public distress	56.1 (28.9)	94.0 (14.1)	96.6 (10.5)	96.6 (6.8)	95.2 (9.7)	37.9 (28.1, 47.7)	40.5 (30.4, 50.7)	40.5 (29.9, 51.0)	39.1 (28.9, 49.3)	<.001	<.001	<.001	<.001	
Sex life	60.0 (37.1)	93.7 (12.7)	92.6 (17.6)	92.7 (13.3)	91.4 (15.0)	33.7 (20.1, 47.2)	32.5 (19.0, 46.1)	32.7 (19.2, 46.2)	31.4 (17.8, 45.0)	<.001	<.001	<.001	<.001	
Self-esteem	49.3 (30.1)	86.7 (19.2)	89.7 (21.0)	88.9 (15.1)	87.3 (17.5)	37.4 (26.5, 48.3)	40.4 (29.0, 51.7)	39.6 (28.8, 50.4)	38.0 (26.9, 49.1)	<.001	<.001	<.001	<.001	
BIQOL	-0.3 (1.3)	0.7 (1.4)	0.8 (1.4)	1.0 (1.3)	0.7 (1.1)	1.0 (0.3, 1.7)	1.1 (0.4, 1.9)	1.3 (0.6, 2.0)	1.1 (0.4, 1.7)	0.003	<.001	<.001	<.001	
BSQ	85.4 (33.3)	55.8 (20.7)	57.5 (23.2)	54.2 (21.1)	54.6 (21.1)	-29.6 (-42.3, -17.0)	-28.0 (-40.9, -15.0)	-31.2 (-43.8, -18.6)	-30.8 (-43.9, -17.7)	<.001	<.001	<.001	<.001	
DAS														
Overall	109.8 (17.3)	106.6 (21.2)	106.6 (23.3)	111.5 (18.8)	108.2 (18.0)	-3.2 (-10.8, 4.4)	-3.2 (-11.5, 5.2)	1.7 (-4.9, 8.3)	-1.6 (-8.4, 5.1)	0.706	0.773	0.926	0.945	
Consensus	46.1 (6.4)	45.0 (7.8)	44.4 (10.5)	47.5 (6.5)	46.1 (6.4)	-1.1 (-4.5, 2.3)	-1.6 (-6.1, 2.8)	1.4 (-1.5, 4.3)	0.0 (-3.0, 3.1)	0.853	0.795	0.598	>0.99	
Satisfaction	38.1 (6.3)	37.5 (7.1)	36.1 (10.0)	38.3 (7.0)	37.4 (8.2)	-0.6 (-3.0, 1.8)	-2.0 (-5.5, 1.5)	0.2 (-2.1, 2.5)	-0.7 (-3.6, 2.1)	0.944	0.434	0.998	0.923	
Cohesion	15.5 (4.1)	15.6 (4.5)	15.5 (5.0)	15.8 (5.4)	14.1 (6.3)	0.1 (-2.0, 2.1)	-0.1 (-2.4, 2.2)	0.3 (-2.0, 2.6)	-1.5 (-4.3, 1.4)	>0.99	>0.99	0.994	0.547	

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	Model Based Estimates, Mean (SD)					Model Based Mean Change (95% CI)				P-Value			
	Baseline	Year 1	Year 2	Year 3	Year 4	Year 1 from Baseline	Year 2 from Baseline	Year 3 from Baseline	Year 4 from Baseline	Year 1 vs Baseline	Year 2 vs Baseline	Year 3 vs Baseline	Year 4 vs Baseline
Affectional expression	8.3 (2.5)	8.4 (2.3)	8.3 (2.4)	8.7 (2.4)	8.6 (2.3)	0.1 (-1.2, 1.3)	-0.1 (-1.4, 1.2)	0.3 (-0.9, 1.6)	0.2 (-1.0, 1.4)	>0.99	>0.99	0.902	0.983
BDI-I	6.5 (5.9)	4.1 (5.7)	4.0 (7.1)	2.1 (3.6)	4.1 (5.1)	-2.4 (-5.1, 0.3)	-2.5 (-5.8, 0.9)	-4.4 (-6.9, -2.0)	-2.5 (-5.2, 0.3)	0.103	0.203	<.001	0.085