



Majority of female bariatric patients retain an obese identity 18–30 months after surgery

Tamara O. Perdue¹ · Ann Schreier² · Melvin Swanson² · Janice Neil² · Robert Carels³

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Abstract

Purpose When bariatric surgery is performed, a successful outcome is usually described as % total weight lost (EWL) or a change in BMI. These definitions fail to address the importance of post-operative psychosocial adjustment. Previous research has alluded to a ‘mind–body lag’ where the patient’s experienced body feels larger than their physically smaller post-operative body, perhaps as a result of amygdalae conditioning. The purpose of this study is to further investigate this psychological issue and assess its relationship to health locus of control, alexithymia, health quality of life and weight regain in bariatric surgery patients.

Methods Forty female bariatric surgery patients between 18 and 30 months post-op completed demographic data, survey instruments and anthropometric testing. Their evolving self-view, health locus of control, tendency toward alexithymic thought, and health quality of life were measured to identify significant relationships. Hermans’ Dialogical Self Theory was used to understand the conflicted self-view of the participants.

Results The majority of participants retained an obese view of self despite weight loss. Those who retained an ‘I-obese’ viewpoint were significantly more likely to see external situations and powerful others as controlling their weight, have difficulty identifying their feelings and score significantly lower in vitality, social functioning and mental health.

Conclusion Despite losing weight, the majority of participants retained an obese view of self that was significantly associated with a lessened health quality of life. Use of the Evolving Self-View (ESV) exploratory tool may allow early identification of post-operative patients with a prolonged ‘I-obese’ self-view and provide an opportunity for intervention.

Level of evidence Level III, cross-sectional case-control study.

Keywords Bariatric surgery · Body image · Weight loss · Post-operative care · Hermans’ dialogical self theory · Obesity

Tamara O. Perdue: doctoral student at ECU CON when this research was conducted.

✉ Tamara O. Perdue
perduet@ecu.edu

Ann Schreier
schreieran@ecu.edu

Melvin Swanson
swansonme@ecu.edu

Janice Neil
neilj@ecu.edu

Robert Carels
carelsr14@ecu.edu

Introduction

Bariatric surgery has increased in prevalence as a way to address the health issue of obesity and related metabolic disorders for patients with a body mass index (BMI) ≥ 40 kg/m² or a BMI ≥ 35 kg/m² accompanied by serious weight-related

¹ Brody School of Medicine, Metabolic Surgery Research Group, East Carolina University, 600 Moye Blvd, Greenville, NC 27834, USA

² College of Nursing, East Carolina University, Greenville, USA

³ Department of Psychology, East Carolina University, Greenville, USA

health conditions such as diabetes or heart disease [1]. When a patient with obesity decides to pursue bariatric surgery, a successful outcome is defined as rapid and sustained weight loss. In preparing pre-operatively for physical change, the patient may not be fully prepared for the psychological, emotional and social challenges that rapid weight loss presents [2]. Pre-surgical psychological testing is an established tool to screen for mental illness that may negatively affect adjustment [1]. There is another subtle psychological issue which is alluded to in the research literature, however; but remains largely unexplored in quantitative research.

Qualitative studies and case reports describe patients who have experienced rapid weight loss in a physical sense but remain a ‘fat person’ on the inside [3–7]. Previous researchers have defined this paradox as a ‘mind–body lag’ or ‘allocentric lock’ in which the patient’s body has physically become smaller but remains obese in the patient’s mind [6, 8]. Neuroscience research has found that the amygdalae play a role in processing allocentric (body as object in the physical world) sensory input to long-term memory and are influenced by survival instincts and emotions such as fear, anger and sadness. The societal stigma of obesity may result in negative emotions that are stored by the amygdalae, and repeatedly resurface in bariatric surgery patients despite weight loss [8, 9]. Psychology offers another view of how individuals with obesity become psychologically ‘stuck’ at their heavier weight through Hermans’ Dialogical Self Theory (DST).

Hermans states that as a person moves through space and time, they transition through a number of imaginative positions, or ‘I-positions’, some of which are extremely dominant [10]. A voice such as ‘I (am) obese’ may dominate a person’s life for many years. After bariatric surgery, their body changes, and the patient is forced to begin to see themselves in a new I-position, ‘I (am) ex-obese’ [3]. Some researchers have found that the ‘I am obese’ position remained dominant in most participants even after massive weight loss. The effect that the resulting psychological disquietude has on the recovery and subsequent weight management of the bariatric patient has not been quantitatively defined. Faccio et al. [3] used the framework of DST in her phenomenological study of pre- and post-operative bariatric surgery patients which serves as a sentinel study for this research project. The hypothesis for this research study is that women who have had bariatric surgery and have an ‘I-ex-obese position’ also have higher internal locus of control, higher health quality of life, lower alexithymia scores (resulting in better ability to identify and describe feelings) and less weight regain than women who have an ‘I-obese’ position.

Methods

Study design and sample selection

This study used a descriptive cross-sectional design and was approved by the University and Medical Center Institutional Review Board. The original sample consisted of 55 men and women. In that exploratory study [11], men and women were found to differ in significant ways. For purposes of further investigating the psychological transition in women, this study sample consisted of 40 female bariatric surgery patients who were between 18 and 30 months post-surgery. This post-operative time frame was selected in an attempt to investigate female patients who had already experienced the massive weight loss of the first post-operative year, but were still in the process of adjusting to life as a lighter weight person. There was not a pre-calculated sample size because of the exploratory nature of the ESV concept, and the unknown effect size. Patients were recruited in four ways: (1) records at a private bariatric surgery clinic with operating privileges at a MBSAQIP (Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program)-accredited hospital; (2) scheduled 24 month post-op visit; (3) monthly Bariatric Surgery Support Group; (4) Facebook page and the Patient Portal (automated phone system). Systematic random sampling and use of a phone script ensured that each participant was approached in a similar fashion. Each participant was scheduled for a 60-min interview appointment. Inclusion criteria consisted of female bariatric surgery patients, legal adults (21 years or older) who speak English, have a BMI ≥ 35 kg/m² and were seen at least twice in the first post-op year. Twenty-dollar gift card incentives were given to each participant at the conclusion of their interview.

Data collection

At the beginning of each 60-min interview, written informed consent was obtained from all individual participants included in the study. A Tanita scale was used to measure weight, BMI and body fat percentage. Height was recorded through self-report. During the face-to-face interview, a demographics form was completed and the participants were asked to complete six paper survey questionnaires, five of which have been used for past research focused on persons with obesity [2]: Multidimensional Health Locus of Control and Weight Locus of Control (MHLC and WLOC), Alexithymia (TAS-20), Body Shape Questionnaire (BSQ) and Health-Related Quality of Life (SF-36v2). The sixth questionnaire, Evolving Self-View After Bariatric Surgery (ESV) was developed for this

dissertation research. This paper will focus on the results from the ESV, MHLC, WLOC, TAS-20 and the SF36v2.

Survey instruments

Obesity identification was measured using questions developed by the researcher entitled ‘Evolving Self-View After Bariatric Surgery’ (ESV). The ESV identified the participant’s orientation as predominately ‘I-obese’ or ‘I-ex-obese’ using a 25-question tool based on the qualitative research of Faccio et al. [3]. A three-pronged statement from their research (p. 1713) generated three main concepts: thinking about oneself as if he/she was still the weight before surgery; behaving as if he/she were still the weight before surgery; and relating to others as if he/she were still the weight before surgery.

These three concepts were used to extrapolate 22 other statements that described situations and ways of thinking that fit within the three areas. The development of the ESV was an exploratory attempt to quantify the concept of ‘I-orientation’ or self-view following bariatric surgery as proposed by Faccio et al. [3]. The work of other qualitative researchers in the field of bariatric weight adjustment served as inspiration and background for the extrapolated statements and added content validity [3–6, 12–15]. To further establish content validity, three women who had bariatric surgery reviewed and commented on the ESV questions during their development. The ESV that contains 25 questions on a six-point Likert scale ranging from 1 (‘Strongly Disagree’) to 6 (‘Strongly Agree’) is written on the 7–8th grade level, and takes 5 min to complete.

Locus of Control (LOC) was assessed using the MHLC [16] (Cronbach’s $\alpha = 0.72$; 8th grade reading level) which has 18 questions using six-point Likert scale. The MHLC is scored on three scales: LOC Internal, LOC Chance, and LOC Powerful Others. The Powerful Others subscale in turn is divided into ‘Powerful Others (doctors)’ and ‘Powerful Others (others)’ which includes family, friends and religious figures. Each of the three subscales is scored on a scale from 6 to 36. MHLC authors state that the scores cannot be combined as a total score. Rather it is possible for an individual to be high or low on all three scales [17]. Weight Locus of Control was assessed using the WLOC instrument that uses a six-point Likert scale (5–6th grade reading level) [18, 19]. Alexithymia was assessed using the Toronto Alexithymia Survey (TAS-20) which has 20 questions on a five-point Likert scale (Cronbach’s $\alpha = 0.81$; 5–6th grade reading level). The TAS-20 has three subscales: Difficulty Identifying Feelings, Difficulty Describing Feelings and Externally Oriented Thinking [20, 21]. Health-Related Quality of Life was measured using the SF-36v2 survey which has eight domains, or subscales (Cronbach’s $\alpha > 0.70$ on all items; 5–6th grade reading

level; three- and five-point Likert scales). The SF-36v2 is one of the most commonly used tools for health studies and assesses both physical and mental health across age and disease groups with *t* scores based on a normative group with standard score of 50 and $SD = 10$ [22]. Higher scores on the subscales indicate higher levels of health.

Data analysis

Demographic data and instrument responses were analyzed using SPSS v22. The SPSS Two-Step Cluster Analysis procedure is an exploratory tool designed to reveal natural groupings (or clusters) of cases within a dataset that would otherwise not be apparent. The clustering algorithm works with continuous variables, categorical variables, or any combination of the two variable types. Users can select to have the procedure automatically determine clusters or they can specify the number of clusters. The output of the analysis includes the number of cases in each cluster and the importance of each variable in developing the separate clusters. The first step of the two-step procedure is formation of pre-clusters. Pre-clusters are clusters of the original cases that are used in place of the raw data in the hierarchical clustering. As a case is read, the algorithm decides, based on a distance measure, if the current case should be merged with a previously formed pre-cluster or start a new procedure. When pre-clustering is complete, all cases in the same pre-cluster are treated as a single entity. In the second step, the two-step procedure uses the standard hierarchical clustering algorithm on the pre-clusters to determine the number of clusters.

To determine whether the 25 ESV items could identify two separate groups of women in the original study sample, the ESV items were entered as continuous variables to the two-step procedure and the two cluster option was selected. The log-linear distance criterion and Schwartz’s Bayesian criterion were default selections for the distance criterion and clustering criterion, respectively. The output of the procedure identified two clusters and six items with the highest cluster prediction importance (Table 3). One of the clusters included 28 women and was labeled ‘I-obese’, while the second cluster included 12 women and was labeled ‘I-ex-obese’.

Results

This female sample was almost evenly divided between Caucasian and African-American participants, with roughly two-thirds reporting that they were married. Almost two-thirds of the sample reported at least some college or a college degree, and incomes were evenly distributed between \$26,000 and \$100,000. The mean age was 48 ($SD 9.97$)

Table 1 Demographic characteristics of female participants ($N=40$)

Characteristic	<i>n</i>	%
Age at time of survey (years)		
24–35	3	8
36–45	14	35
46–55	14	35
56–65	7	18
66–68	2	5
Race		
African-American	19	48
Caucasian	21	53
Marital status		
Divorced	4	10
Married	26	65
Single	10	25
Highest level of education completed		
Less than HS diploma or GED	3	8
HS diploma or GED	2	5
Some college	10	25
Assoc degree	8	20
Four-year college degree	8	20
Some graduate school	5	13
Masters degree	3	8
Doctoral degree	1	3
Household income ^a		
\$25,000 or less	3	8
\$26,000–50,000	8	20
\$51,000–75,000	10	25
\$76,000–100,000	10	25
\$100,000 or more	8	20

Totals of percentages are not 100 for every characteristic because of rounding

^aTotal reported ($N=39$)

Table 2 Female participant characteristics ($N=40$)

Characteristic	<i>M</i>	<i>SD</i>
Age at time of survey (years)	48.00	9.97
Months post-op time of survey	22.47	3.44
Pre-op weight	271.20	41.55
Today's weight	171.01	35.11
Pre-op BMI	45.07	7.40
Today's BMI ^a	28.31	6.14
Percent total weight loss	36.94	8.97
Weight age 18 ^b	168.67	45.80
BMI age 18 ^c	28.41	7.35

^aFor this item, $n=37$ since some participants refused BMI

^bWeight at age 18 is a recalled weight

^cBMI calculation based on adult height

and the mean number of months post-op was 22 (SD 3.44) (Tables 1, 2).

ESV mean scores ranged from < 1.50 to ≥ 3.00 for the sample. Mean scores for 'I-obese' participants clustered at the higher end of the scale and mean scores for 'I-ex-obese' clustered at the lower end of the scale (Table 3). Six of the 25 ESV items (Table 4) were strong predictors of 'I-position' membership and are listed in descending order of strength of prediction. The significant items on the ESV fell into two of the three stem concept areas: relating to physical feelings of how the participant moves and acts in the physical world, and how the participant interacts with others. The 40 female participants clustered into either 'I-obese' or 'I-ex-obese' categories. Overall, there were more women in the 'I-obese' category ($n=28$, 70%) than 'I-ex-obese' ($n=12$, 30%). All mean scores for 'I-obese' and 'I-ex-obese' groups differed significantly for the six items. This remainder of this paper focuses on the use of the ESV score as a distinguishing variable.

Results for the MHLC and WLOC scales showed higher mean scores in the participants who identified as 'I-obese' on the ESV continuum, than those who identified as 'I-ex-obese'. This held true for all three subscales of the MHLC and on the WLOC. An independent samples *t* test was conducted to explore the impact of the 'I-position' on the MHLC scores and WLOC. The locus of control scores of 'I-obese' participants was significantly higher for two of the subscales (Table 5): Powerful Others and Weight Locus of Control.

Results for the TAS-20 scale showed that participants who identified as 'I-obese' on the ESV continuum had higher mean scores for the TAS-20 Total score, the Difficulty Identifying Feelings subscale and the Difficulty Describing Feelings subscales, indicating more alexithymia. An independent samples *t* test was conducted to explore the impact of the 'I-position' on the TAS-20 scores. The scores were significantly higher for 'I-obese' participants on the Difficulty Identifying Feelings subscale (Table 5).

Results for the SF36v2 (Health-Related Quality of Life or HRQOL) show that participants who identified as 'I-obese' on the ESV continuum had lower mean scores on seven out of eight domain subscales, as well as the Mental Health Summary scale. Lower scores indicate a lower level of health. An independent sample's *t* test was conducted to explore the impact of the 'I-position' on the SF36v2 scores. The scores were significantly lower for 'I-obese' participants on the Vitality (VT) scale, Mental Health (MH) scale, and the Mental Health Component Summary. In addition, there were two scales that were lower with moderate significance and moderate effect sizes (Table 5). These scales were General Health (GH) scale and Social Functioning (SF) scale.

There were four weight measures included in this analysis: pre-operative weight, lowest weight achieved, recalled

Table 3 Evolving self-view items' mean scores and SD

	<i>M</i>	<i>SD</i>
1. Today, I think about myself as if I were still the weight I was before surgery	2.65	1.56
2. I have difficulty recognizing myself in a mirror or reflection in a window	2.48	1.22
3. I have difficulty recognizing my lighter weight self in photographs or videos	2.43	1.17
4. Who I am on the outside is not the same as who I am on the inside	2.95	1.50
5. I feel sad about losing my previous, fatter self	1.18	0.39
6. When I look at myself in a mirror, the person I see is not really who I am	1.90	1.13
7. My thinner self battles with my fatter self	2.58	1.37
8. My body is the center of my attention even though I have lost weight	3.18	1.50
9. Today, I behave as if I were the same weight that I was before surgery	2.03	1.07
10. It is hard to get used to shopping for clothes for my new lower weight	2.65	1.67
11. I still turn sideways to pass through doors, turnstiles, or crowded areas as if I were my fatter self	2.15	1.39
12. I prefer to eat alone where no one can see me	1.53	0.85
13. I don't like to try new activities for health and recreation even though I am thinner	1.53	0.68
14. My thinner body fits into the world like my fatter body used to	3.08	1.76
15. In my mind, I can still 'feel' my fatter self when I move	2.33	1.29
16. I have difficulty acting like a thinner person acts	2.43	1.15
17. Today, I relate to others as if I were the same weight that I was before surgery	3.18	1.48
18. People compliment me on my appearance but I have trouble believing them	2.48	1.26
19. Losing weight has not made it easier to interact with others	2.33	1.40
20. Conversations about weight make me uncomfortable	1.90	1.13
21. When I get to know people, I feel that I need to share my weight loss story	3.15	1.56
22. I prefer to be with new friends, rather than old friends who knew me before my weight loss	1.55	0.64
23. I feel less powerful in my thinner body	1.60	0.74
24. People still think of me as being a fat person	1.93	1.05
25. Being a thinner person is harder than I thought it would be	1.83	0.96

Table 4 Differences between the six most important evolving self-view items that identified the I-obese and I-ex-obese clusters

ESV item number ^d	I-obese ^a		I-ex-obese ^b		η^2
	<i>M</i> ^c	<i>SD</i>	<i>M</i> ^c	<i>SD</i>	
17. Today, I relate to others as if I were the same weight that I was before surgery	3.68	1.28	2.00	1.23	0.28
15. In my mind, I can still 'feel' my fatter self when I move	2.75	1.29	1.33	0.49	0.26
22. I prefer to be with new friends, rather than old friends who knew me before my weight loss	1.75	0.64	1.08	0.29	0.24
9. Today, I behave as if I were the same weight that I was before surgery	2.36	1.06	1.25	0.62	0.23
18. People compliment me on my appearance but I have trouble believing them	2.86	1.18	1.58	1.00	0.22
23. I feel less powerful in my thinner body	1.82	0.77	1.08	0.29	0.21

All the mean scores between the I-obese and I-ex-obese groups were statistically significant, $p < .01$

η^2 is the proportion of variance in the dependent variables by the independent variable. Conventional estimates for small, medium and large effects would be the values of η^2

Items listed in order of importance in the cluster formation

^a $n = 28$

^b $n = 12$

^cHigher mean scores indicate more agreement with item

^dEqual to 0.01, 0.06, and 0.14, respectively

Table 5 Differences between I-obese and I-ex-obese women on study measures ($N=40$)

Measures	I-obese ^a		I-ex-obese ^b		<i>t</i> (38)	<i>p</i>	η^2
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>			
Health locus of control							
LOC internal	27.04	3.54	27.17	3.79	0.11	0.92	<0.001
LOC chance	15.96	4.46	13.42	4.66	1.63	0.11	0.065
LOC powerful others	19.32	3.24	16.50	5.30	2.07	0.045	0.101
Weight locus of control	7.82	2.60	5.58	1.51	2.78	0.008	0.169
Alexithymia							
Difficulty identifying feelings	12.21	3.98	8.42	2.91	2.98	0.005	0.189
Difficulty describing feelings	9.50	3.51	7.75	3.31	1.47	0.150	0.053
Externally oriented thinking	16.61	3.65	17.25	4.65	0.47	0.640	0.006
SF36v2							
Physical functioning	53.64	5.53	53.57	10.96	0.03	0.990	<0.001
Role physical	54.08	5.03	54.35	5.34	0.15	0.880	0.001
Bodily pain	51.01	9.23	54.54	9.78	1.09	0.280	0.030
General health	57.11	6.18	61.11	4.57	2.01	0.051	0.096
Vitality	54.40	6.78	61.02	8.29	2.64	0.012	0.155
Social functioning	53.22	7.84	57.34	0	1.80	0.079	0.079
Role emotional	50.08	9.22	53.56	4.95	1.23	0.230	0.038
Mental health	52.27	8.10	60.46	2.81	3.39	0.002	0.233
Physical health summary	54.66	6.82	54.53	7.90	0.06	0.960	<0.001
Mental health summary	51.48	10.17	59.22	2.96	2.57	0.014	0.148

^a $n = 28$ ^b $n = 12$

weight at age 18 and percent of pre-op weight lost. On the first three measures, the participants who identified as ‘I-obese’ on the ESV continuum had mean weights that were higher than their ‘I-ex-obese’ counterparts. In addition, the ‘I-ex-obese’ individuals showed a slightly greater percent of pre-op weight lost. In independent samples *t* test, however, these differences were not found to be significant.

Discussion

This research may provide further insight into the fact that obesity is a multifactorial disease with biological, environmental and psychological roots [2]. A more traditional focus on weight loss as the primary measure of surgical success fails to emphasize this fact. Significant relationships between the correlation of the ESV results (obesity identity) with other psychosocial and emotional indicators may help us understand how bariatric patients see themselves. First, the participants in this study whose obesity identity remained ‘I-obese’ had a significantly higher external orientation toward their views of their health and weight than participants who had transitioned to see themselves as ‘I-ex-obese’. In particular, ‘I-obese’ individuals were oriented to the influence of powerful others as forces instrumental in their ability to stay healthy and maintain their weight

(MHLC and WLOC). The subscale of ‘Powerful Others’ on the MHLC refers not only to health providers, but also family, friends and religious figures. Physicians, nurses, nutritionists, psychologists and other health providers that are assisting ‘I-obese’ individuals to maintain their weight and adjust post-operatively should recognize that programs must provide positive external reinforcement, include these significant others, and not count on all patients being motivated within themselves to maintain the prescribed diet and exercise programs. The results of the TAS-20 revealed that those participants who are higher on the ‘I-obese’ continuum are significantly more likely to have the alexithymic trait of ‘difficulty in describing feelings’. Researchers have described this as ‘meta-cognition’, or the participant’s ability to see their situation from a removed, external position. Without this ability, it is difficult for patients to be self-aware and mindful about behavioral decisions such as eating and exercise.

In addition, the participants who identified as higher on the ‘I-obese’ continuum experienced significant negative impact on their vitality (feeling full of life and having energy), their mental health (feeling calm, peaceful and happy) and their overall mental health component measurement as measured on the SF36v2. These findings are similar to the results from a systematic review which found that post-operative physical HRQOL improved more

readily than psychological HRQOL in bariatric patients [2]. General health (see themselves as healthy, less likely to get sick and trending toward good health) and social functioning (ability to spend time in normal social activity) were negatively affected to a lesser degree. These findings support the mixed results of other studies that assess the impact of bariatric surgery and diminished post-op weight on quality of life and life satisfaction [23–27]. This research seems to indicate that the patient's position on the 'I-obese' continuum may assist in identifying those patients that do not experience the expected increase in health quality of life after bariatric surgery.

This research was limited by the fact that all the participants are patients of the same surgeon in a private practice office in the Southeastern US and, therefore, may not be representative of all bariatric patients. In addition, this research is not longitudinal and, therefore, does not account for changes in attitudes or psychological adjustment over time. When assessing the issue of weight regain, the time frame may not have been extended far enough to capture the weight regain after the 24–30-month period. The data collected in this research depends mostly on self-report and thus may be prone to bias and recall issues. Another limitation of this study is that there was no control group of patients with severe obesity or normal weight patients to establish what constitutes baseline mental health for these groups. Further, the sample in this study was small and the results on the ESV are preliminary. Future research with more diverse and larger samples is needed to further develop an ESV instrument. With further studies, validity (construct, content and face validity), internal consistency and factor analysis can be established.

Post-operative weight loss maintenance for bariatric surgery patients is variable and dependent on type of procedure that is used, patient selection and time frame. Courcoulas et al. [28] recommend improved pre-op patient selection and education, along with enhanced post-operative support to positively affect weight maintenance. This research expands upon Courcoulas et al.'s [28] recommendations for standardized survey instruments to triangulate and define personality traits and psychological positions that may significantly affect adjustment and post-op weight loss. The ESV may meet this call by serving as a 'diagnostic umbrella' under which psychological and health quality of life measures fall. Mental health counseling and support should be a prescribed part of the post-operative care for bariatric surgery patients who remain fixed on the 'I-obese' end of the identity continuum. For future research, a longitudinal study is recommended to implement the ESV at later post-operative periods in an effort to identify the attenuation or strengthening of these personality traits and ongoing weight maintenance. Validation of the role of negative emotions and fear/survival instincts

as moderated by the amygdala could be validated through qualitative and quantitative research on early weight stigma experiences. An increased emphasis on basic post-operative psychological counseling is recommended to address the adjustment concerns of bariatric surgery patients.

Conclusion

Despite losing weight, the majority of participants retained an obese view of self that was significantly associated with a lessened health quality of life. Use of the developing ESV exploratory tool may allow early identification of post-operative patients with a prolonged 'I-obese' self-view and provide an opportunity for intervention. The females in this study who still identified as obese were more externally influenced by 'Powerful Others', and were more likely to experience difficulty in describing and identifying feelings (Alexithymia). Those women still identify as 'I-obese' also reported lower vitality, social functioning and mental health than those who identified themselves as 'I-ex-obese'. While these data are preliminary, further examination of the psychological adjustment of women who received bariatric surgery is warranted even when successful goals of weight loss are achieved.

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Compliance with ethical standards

Conflict of interest The authors (Drs. Perdue, Schreier, Swanson, Neil and Carels) declare that they have no conflict of interest in the research and writing of this manuscript.

Human and animal rights statement All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendment or comparable ethical standards.

Informed consent Written informed consent was administered to all participants.

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