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ORIGINAL ARTICLE EXPERIMENTAL/SPECIAL TOPICS

The Body-QoL®: Measuring Patient Reported Outcomes in Body Contouring Surgery Patients

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Abstract
Background This study aimed to design a new patient-reported outcome (PRO) instrument to measure patient satisfaction after body-contouring procedures such as liposculpture, abdominoplasty, body-lift, thigh-lift, and arm-lift.
Methods Phase 1a involved an extensive literature review, 16 in-depth patient interviews, and expert focus groups with 5 plastic surgeons to develop a conceptual framework for the outcomes deemed important for body image and preliminary PRO instruments. In phase 1b, the preliminary instrument was tested with a second independent sample of 29 patients with whom simple interviews were additionally performed. In the second sample, scale reliability was calculated.
Results In phase 1a, the domains identified for the conceptual framework included clothing and body image, sexual and affective life, self-image and self-esteem, social relationships, and physical symptoms. In phase 1b, the scale internal consistency was 91.5 %.
Conclusions When psychometric evaluation is completed, the Body-Shape-Related Quality of Life instrument and its subscales will provide a reliable tool for plastic surgeons, researchers, and patients to use in measuring the impact and effectiveness of body-contouring procedures from the patient's perspective.
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This journal requires that authors assign a level of evidence to each submission to which Evidence-Based Medicine rankings are applicable. This excludes Review Articles, Book Reviews, and manuscripts that concern Basic Science, Animal Studies, Cadaver Studies, and Experimental Studies. For a full description of these Evidence-B

Keywords Body contouring surgery · Tummy tuck · Suction assisted Lipectomy · Patient reported outcomes · Quality of life · Massive weight loss

Since the development of evidence-based medicine (EBM) in the mid-1970s [1, 2], clinical medicine has experienced an explosion of knowledge generation with subsequent improvements in most fields of patient care [3]. Currently, properly designed cohort studies and randomized controlled trials stand as standards for gathering knowledge on the natural history of a disease and for determining the efficacy and effectiveness of new or existing treatments [4].

In body-contouring aesthetic plastic surgery, new techniques such Saldanha's lipoabdominoplasty [5], Lockwood's high lateral tension [6], Baroudi and Pollock's tension sutures [7], and upper and lower body-lift [8, 9] are challenging classic surgical paradigms. Also, new emerging technologies such as laser lipolysis [10] and vibration

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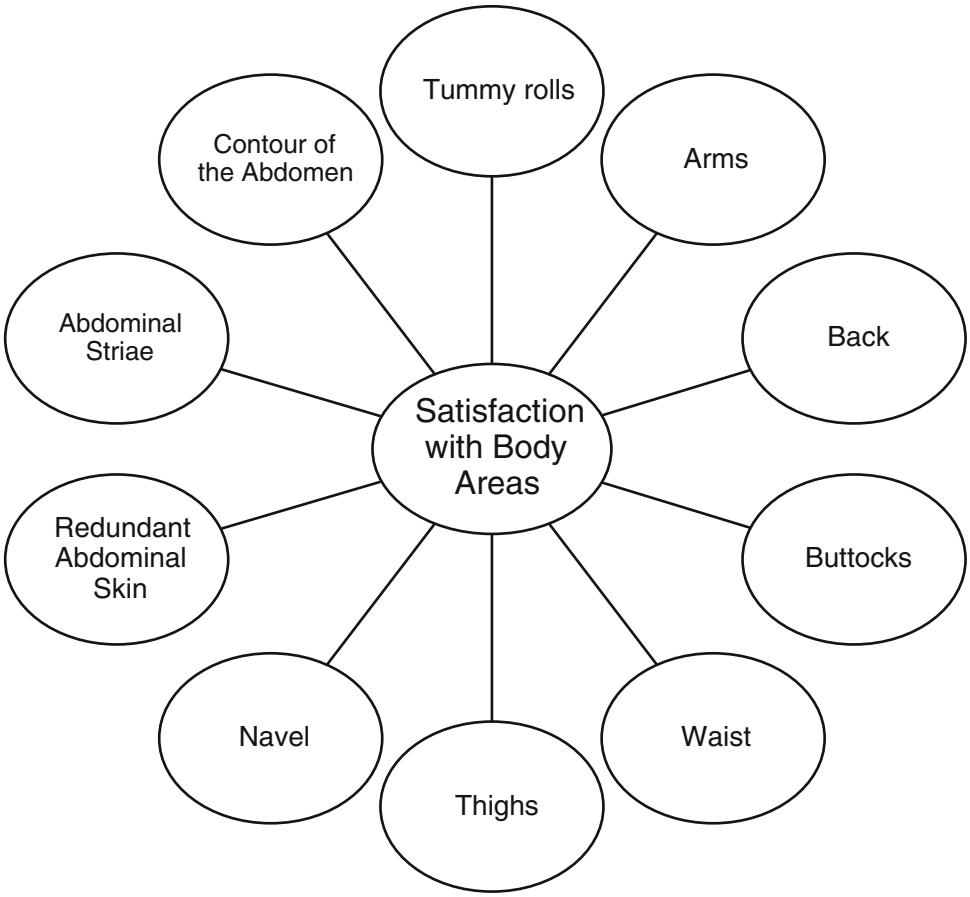

Fig. 1 Conceptual framework for satisfaction with body areas

amplification of sound energy at resonance (VASER) lipolysis [11], radiofrequency [12], and other devices claim to be superior in outcome, recovery, and complication rates compared with classic techniques.

Outcomes after cosmetic surgery usually are shown in journals and lectures as before and after pictures, and until very recently, no instruments had been developed to measure outcomes from the patient's perspective.

Outcomes research in plastic surgery evaluates the results of the surgery from the patient's perspective using a multidimensional scale. The research assesses not only the cosmetic outcome but also the improvement in physical, psychological, and social well-being after surgery. Measures of patient-reported outcomes are highly sophisticated questionnaires that quantify health-related quality of life (QoL) and other significant variables from the patient's perspective.

Pusic et al. [13] developed the Breast-Q instrument designed to measure QoL related to breast-reconstruction, breast-reduction, and breast-augmentation surgeries. Additionally, they have developed the preliminary FACE-Q instrument [14] designed to measure the results of blepharoplasty, face-lift, rhinoplasty, neck-lift, brow-lift, and chin implants. Our group translated the Breast-Q instrument into Spanish and validated it with a Spanish-speaking population [15]. The results for this population were found to be highly reliable.

Our study aimed to develop a new patient-reported instrument named the Body-Shape-Related Quality of Life (Body-QoL) separated into a set of subscales addressing each body-contouring procedure and each anatomic region such as the arms, back, buttocks, waist, thighs, and abdomen (Fig. 1).

These subscales were designed to measure a range of outcomes that we identified as important to body-contouring surgery patients and procedures.

To develop the content of the scales for body-contouring patients, the international guidelines for patient-reported outcomes (PROs) were followed [16, 17]. In general, a scientifically valid and reliable PRO instrument must be developed in three phases: phase 1a (conceptual framework formation), phase 1b (item generation, preliminary scale development, and pretesting), phase 2 (item reduction and psychometric evaluation), and phase 3 (final instrument testing) (Table 1). This report details the first phase of our study.

Table 1 Phases of patient-reported outcome instrument (PRO) measure development

Phase 1
1a
Construction of a conceptual framework that includes all dimensions of the phenomena to be measured. It is developed using a semistructured interview performed by a trained sociologist together with expert opinion and literature review.
1b
The preliminary instrument is tested with a sample of patients to clarify ambiguities in the wording of items, confirm appropriateness, and determine acceptability of the questionnaire and the total time required for its completion.
Phase 2
The questionnaire is applied with a large sample of patients to determine the best items for inclusion in the final instrument. In this phase, psychometric evaluation is performed, and the scale is minimized by filtering the questionnaire to develop a short instrument comprising the best items.
Phase 3
Psychometric evaluation of the final instrument is performed including test–retest reliability, targeting, validity, sensitivity, specificity, total item correlation, and the like. The objective is to determine the strengths and limitations of the instrument developed.

Methods

Phase 1a

The aim of phase 1a was to generate the conceptual framework for domains and item generation using a comprehensive literature review, field expert focus groups, and patient in-depth interviews.

Literature Review

We conducted literature searches for PRO instruments used in plastic surgery on Medline, the Mapi Research Trust [18] database, and specifically in the main plastic surgery journals [*Plastic and Reconstructive Surgery Journal* (PRS), *Journal of Plastic, Reconstructive & Aesthetic Surgery* (JPRAS), and *Aesthetic Plastic Surgery* (APS)]. The search terms we used included "body contouring," "patient-reported outcomes," "PRO," PROM," "liposuction," "lipolysis," "lipectomy," "massive weight loss," "tummy tuck," and "body-lift." Also, a directed search filtered by author for known authors working on PROM was conducted to identify any potentially relevant studies. The references for the studies identified were hand screened, and additional relevant studies were retrieved.

Table 2 Semistructured in-depth interview guide

Reasons for their surgery: influence/opinion/perceptions of partner, friends, family and/or society; motivation; and type of procedure chosen
Concepts of beauty: body appearance in general; details of the abdominal, arm, and thigh area that were altered; concerns of aging and overweight
Relationship between beauty and sexuality: psychological and sexual well-being and self-concept, mood, confidence with nude self-image, influence of body image in sexual life
Body self-image: image with clothes, self-esteem, body harmony, body shape
Social performance: work and normal activities, work impact, ability to participate in sports/fitness/activities, change in level of comfort, energy and vitality
Social relations: treatment of friends, colleagues, work partners, and family; discrimination at work

In-depth Interviews and Expert Focus Groups

Using a qualitative emergent design, we performed in-depth interviews with key informants. These key informants were patients scheduled for body-contouring surgery including abdominoplasty (tummy-tuck), liposuction, lipoabdominoplasty, thigh-lift, arm-lift, belt lipectomy, and lower body-lift.

Semistructured interviews were performed by a trained sociologist, who had a master of science in clinical epidemiology and extensive experience in qualitative research. During the interview, the patients were allowed to speak freely about their motivations for surgery, but they also were specifically questioned about concepts of beauty relating to body shape, sexuality, self-image, self-esteem, social relationships, and work relationships. (Table 2). Each interview lasted approximately 1 h. The patients were interviewed again 3 months after their surgery. In this interview, previous beliefs were compared with the current condition of the patients after surgery.

Sampling was performed to the point of redundancy as per qualitative research standards. When no further new data were acquired from patients, we stopped interviewing. A total of 16 patients were interviewed.

Five plastic surgeons with at least 5 years of experience were gathered in focus groups and asked about their beliefs regarding patients' motivation for surgery. The interviews were transcribed, and from the transcriptions, significant statements were gathered into common topic clusters. From the significant statements, items were developed. The items generated then were gathered into domains that emerged from the common topic clusters, leading to the construction of the preliminary scale.

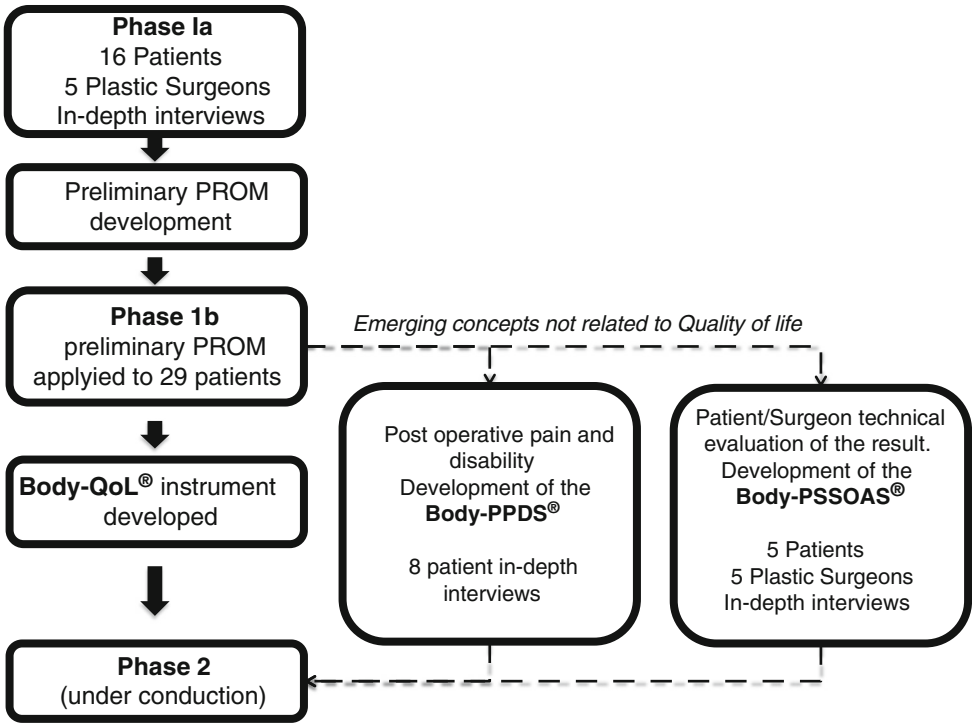

Fig. 2 Study flow diagram

Phase 1b

The preliminary scale developed during phase 1a was tested with a second sample of 29 patients different from the 16 patients interviewed previously. After completion of the questionnaire, a short interview was conducted with the patients. In this interview, they were asked about topics or domains possibly missing from the scale according to their perspective.

The patients also were asked about ambiguity of the questions, ease of reading, understanding, and response to each item. A flowchart diagram of the study is presented in Fig. 2.

Furthermore, the preliminary scale was shown to a group of plastic surgeons in an open discussion, during which they could add items that may have been omitted by the patients.

Preliminary scale reliability was measured, with the Cronbach alpha coefficient ranging from 0 to 1. A coefficient of 0.8 to 0.9 is considered as indicating good internal consistency, and a coefficient higher than 0.9 is considered as indicating excellent internal consistency (STATA 10.2; StataCorp., TX, USA).

Results

Literature Review

Three instruments specifically developed for plastic surgery were identified: the Breast-Q [13] and the Rhinoplasty Outcome Evaluation (ROE) [18], both of which have been fully developed, and the Face-Q [14], which currently is under development. Also, eight instruments not designed for plastic surgery but related to the domains identified in phase 1a, were identified: the Derriford Appearance Scale (DAS59 [18] and DAS24) [18], the Body Image Scale (BIS) [19], the Body Shape Questionnaire (BSQ) [20], Obesity and Weigh-Loss Quality-of-Life (OWLQOL), Weight-Related Symptoms (WRSM) [21], Impact of Weight on Quality of Life (IWQOL) [22–25], and Massive Weight Loss (MWL) [26]. Four systematic reviews [27, 28], one specifically regarding PROs for body-contouring surgery performed by Reavey et al. [29] and one narrative review [30], also were identified.

The aforementioned scales were fully reviewed, and from these, 261 items were isolated. The concepts underlying 141 of the items (54 %) were already included in the preliminary instrument developed during the phase 1a stage. Of the 120 concepts not covered by the initial Body-Qol instrument (46 %), only 1 was deemed relevant to our population of patients and was therefore added to our instrument.

Phase 1a

The basal characteristics of the patients are shown in Table 3. From the 16 interviews, 201 significant statements were identified and gathered into 5 domains and 93 items to form the preliminary instrument. The domains that emerged from the interviews were (A) clothing and

Table 3 Basal characteristics of the patients interviewed

Characteristics	Patients interviewed ($n = 16$)
Age (years)	
Mean ± standard deviation	40.3 ± 9.0
Interquartile range	32–47
Range	28–58
Gender	
Female	15
Male	1
Surgery type	
Abdominoplasty or lipo-abdominoplasty	7
Body liposculpture	3
Belt lipectomy	2
Thigh-lift	2
Body-lift	1
Arm-lift	1

physical appearance, (B) sexual and emotional life, (C) body image and self-esteem, (D) social relations, and (E) physical symptoms. In Fig. 3, a schematic of the QoL domains and the items for the Body-QoL are represented.

The items were organized using Likert 5-point scale statements, in which the patients expressed their agreement with the statement using a range from "fully agree" to "fully disagree." Table 4 presents an example of the domains and items.

Phase 1b

The preliminary instrument of 5 domains and 93 items was tested with an second sample of 29 patients different from the previous 16 patients. The characteristics of the patients are shown in Table 5.

The internal reliability of the instrument (Cronbach's alpha) was 91.5 % for the whole sample, reaching 92.8 % for the lipo-abdominoplasty patients and 97.5 % for the body-lift.

The median score was 35 of 65 points for domain A (clothing and physical appearance), 58.5 of 110 points for domain B (sexual and emotional life), 97 of 170 points for domain C (body image and self-esteem), 52 of 90 points for domain D (social relations), and 18 of 30 points for domain E (physical symptoms).

In the process of creating the scale, the concept of postoperative impairment and the patients' evaluation of the technical details of the surgery emerged. These concepts did not adjust to quality of life properly. Therefore, two new modules where created. The first module focused on patient pain, disability, and recovery after the surgery (PPDS), whereas the second module focused on patient and surgeon subjective/objective assessment of technical aspects of the surgery (PSSOAS) including scar length and width, symmetry, naturalness of the result, and the like.

For further development of the PPDS, eight additional in-depth patient interviews were undertaken identifying eight domains: (A) general symptoms, (B) inflammatory discomfort, (C) somatic pain, (D) neuropathic pain,

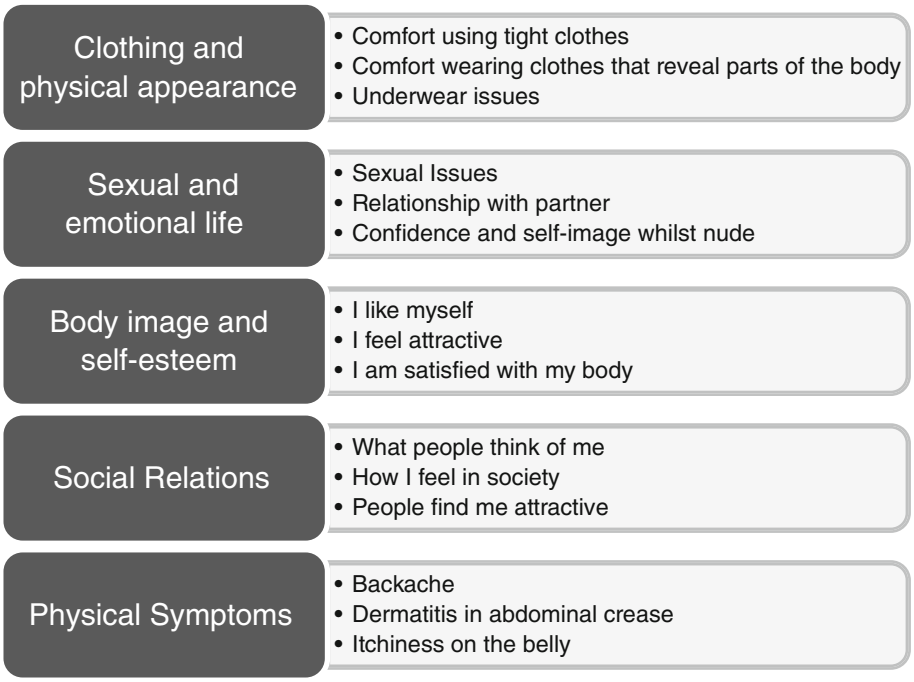

Fig. 3 Domain and item clustering of the Body-Shape-Related Quality of Life (Body-QoL) scale

Table 4 Example of domains and items from the preliminary Body-Shape-Related Quality of Life (Body-QoL) instrument

Domain and item	Fully agree	Somewhat agree	Indifferent	Somewhat disagree	Fully disagree
(A) Clothing and physical appearance					
I can dress in any clothes I want to wear					
I feel comfortable wearing tight clothing					
I like wearing tight clothing					
(B) Sexual and emotional life					
I like my partner to see me naked					
My partner finds me attractive when I am naked					
My partner finds me attractive					
(C) Body image and self-esteem					
I feel beautiful					
I have high self-esteem					
My body looks proportionate					
(D) Social relations					
I find myself at ease in social gatherings					
Other people find me beautiful					
I feel confident with my appearance at a social event					
(E) Physical symptoms					
I get a bad smell from my tummy folds when it's hot, as in the summer					
I always have to suck in my tummy when I walk					
My tummy gets wet					

Table 5 Basal characteristics of patients in phase 1b

Characteristics	Patients included ($n = 29$)
Age (years)	
Mean ± standard deviation	38.6 ± 11.1
Range	19–61
Gender	
Female	25
Male	4
Surgery type	
Abdominoplasty or lipo-abdominoplasty	22
Body liposculpture	2
Belt lipectomy or body-lift	5

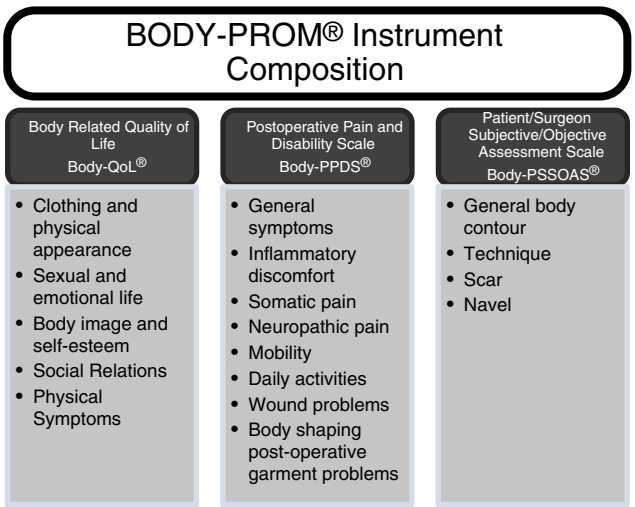

Fig. 4 The Body-PROM instrument is composed of three independent modules: module 1 (quality of life), module 2 (Postoperative Pain and Disability Scale), and module 3 (Patient/Surgeon Subjective/Objective Assessment Scale). Each of the subscales can be used independently and for different purposes

(E) mobility, (F) daily activities, (G) wound problems, and (H) body-shaping postoperative garment problems. The PPDS scale was tested with an independent sample of 58 patients and showed an internal consistency of 98.7 %.

Also, for further development of the PSSOAS, in-depth interviews with five additional patients and five surgeons were undertaken to create an instrument targeted to measure specific technical aspects of the surgery important to both surgeons and patients. The instrument is composed of four domains: (A) general body contour, (B) technique (e.g., cannula marks and localized fat), (C) scar, and (D) navel (shape, size, position, scar). The development of the PSSOAS instrument still is in phase 1b.

Discussion

We decided to name our preliminary instrument the Body-PROM. It encompasses the entire process of body contouring from the patients' perspective as a patient-reported outcome measure. The Body-PROM is composed of three modules: module 1 [Body-Shape-Related Quality of Life (Body-QoL)], module 2 [Postoperative Pain and Disability Scale (Body-PPDS)], and module 3 [Patient and Surgeon Subjective/Objective Assessment Scale (Body-PSSOAS)]. The individual modules may be used independently to address different aspects of the entire process, from the preoperative stage to the postoperative disability and outcome according to the perspective of both the patient and the surgeon. These three modules, schematically represented in Fig. 4, constitute the preliminary Body-PROM instrument.

The ability to measure patient satisfaction with surgical procedures is of increasing relevance [31, 32]. From an academic perspective, it allows us to quantify the outcomes of a given technique objectively and to draw comparisons between techniques [33–35]. From the clinical perspective, it allows for a better surgeon–patient relationship, presenting to the patients their improvements and making them active participants in their recovery process [36, 37].

In the first phase of our study, the interviews allowed us to gather valuable information for development of the preliminary scale.

The domains developed were consistent and coherent with prior knowledge and with previous publications [14, 38]. Also, we separated the core instruments into three modules focused respectively on body-image-related quality of life, postoperative pain, and technical result.

We separated the core instrument into three scales because we believe they will be useful for different types of phenomena. The QoL module will allow for comparison of improvement (or deterioration) that a single patient experiences after a procedure. It also will enable comparison between techniques, populations, centers, and regions, allowing for better determination of which patients experience the greatest improvement in their quality of life and are likely to be better candidates for surgery.

The PPDS module will allow comparison of the impact that recovery has on patients between different techniques. Every day, new technologies emerge that claim better recovery, less pain, and less ecchymosis. Most of these claims remain unproven, and the majority of new technologies are costly.

The PSSOAS module will provide a structured instrument to evaluate patients before and after pictures by both the patient and the surgeon. Interesting information will arise when the patient and surgeon disagree, and also when the PSSOAS evaluation is linked with the QoL improvement. Evaluation from patient (subjective) and observer (objective) perspectives has already been proposed by other authors for scar assessments [39].

We have made every effort to keep the scoring system simple. The Body-QoL instrument will allow for direct score comparison without score transformation to percentages or normalization, which would make the evaluation difficult for surgeons and difficult to use in daily clinical practice [40, 41].

In this stage, we are applying the core instrument (5 domains, 119 items) to our entire body-contouring population. Although young men or women seeking liposculpture for aesthetic purposes are a different population from massive weight loss (MWL) patients, at this stage, we decided to perform the full scale for all our patients and for all procedures and to break down the instrument based on the analysis. At the end of phase 2, we very likely will tailor different instruments for aesthetic body contouring and MWL body contouring, but we prefer to a priori keep the maximum sensitivity for our instrument and to reduce the items and separate the scales for different populations or surgical procedures based on statistical analysis and data.

The main limitation of our study is the length of the scale. Currently, completion of the scale takes approximately 10 min, and it can sometimes be difficult for patients to find time to answer the postoperative Body-QoL instrument. Another limitation results from the small number of males included in the study. This reflects the fact that in our setting, women are more concerned about their body image than men and subsequently seek body cosmetic surgery more often than men.

The time required to complete the instrument and the small number of males will be improved in the next phases of the study. After completion of phase 2, we will attempt a reduction of the scale to the least number of items possible, ideally, no more than 30 items.

For the implementation of phases 2 and 3, we developed a Website (http://www.bodyqol.com) that allows us to enter patient data, Body-QoL, and other clinical outcomes from any computer with an Internet connection, smartphone, or tablet. The Website acts as an online free database for body-contouring patients. This has been shown in other studies to improve questionnaire completion [42]. English and Spanish versions of the Body-QoL instrument are already available free online for clinicians and researchers, as well as for academic and nonprofit organizations. We welcome any researchers willing to collaborate in phases 2 and 3.

Once the three phases are concluded, the final Body-QoL instrument will allow for the identification of "normal values" for the population, measurement of patient satisfaction with body-contouring procedures, evaluation of the

impact that new technologies have on improving quality of life, and comparison between different techniques or devices used in body-contouring procedures [43–45]. Our next report will be given after the conclusion of study phases 2 and 3, which are currently being conducted.

Conclusions

Body-related quality of life, postoperative pain and disability, and technical results of the surgery after body-contouring procedures can be reliably measured from the patient's perspective. Body-image-related quality of life is a complex multidimensional phenomenon that encompasses body image, self-esteem, social relationship, sexuality, and physical symptoms. Impairment produced by surgical procedures affects multiple aspects of daily life, and pain is only one of the eight dimensions identified in our study.

Both patients and surgeons alike greatly value the results of the technical aspects of their surgery including body contour symmetry, muscular definition, naturalness of the result, absence of surgical stigmata, characteristics of the scar, and quality of the neo-umbilicus, all influencing the overall result.

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Conflict of interest The Body-PROM, Body-QoL, Body-PSSOAS, Body-PPDS, Lipo-PPDS and Tummy-PPDS are owned by Dr. Stefan Danilla, the developer of these instruments. The Body-PROM instruments and all modules and sub-scales (QoL, PPDS and PSSOAS) are free for use by academic and non-profit organizations. The authors declare that they have no other conflicts of interest to disclose.

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